

A promise to learn – a commitment to act

Improving the Safety of Patients in England

**National Advisory Group on the
Safety of Patients in England**

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Executive Summary

Place the quality of patient care, especially patient safety, above all other aims.

Engage, empower, and hear patients and carers at all times.

*Foster whole-heartedly the growth and development of all staff,
including their ability and support to improve the processes in which they work.*

*Embrace transparency unequivocally and everywhere, in the service of accountability,
trust, and the growth of knowledge.*

At its core, the NHS remains a world-leading example of commitment to health and health care as a human right – the endeavour of a whole society to ensure that all people in their time of need are supported, cared for, and healed. It is a fine institution. But the events at Mid Staffordshire have triggered a need to re-examine what the NHS does and determine how it can improve further. The only conceivably worthy honour due to those harmed is to make changes that will save other people and other places from similar harm.

Our job has been to study the various accounts of Mid Staffordshire, as well as the recommendations of Robert Francis and others, to distil for Government and the NHS the lessons learned, and to specify the changes that are needed.

The following are some of the problems we have identified:

- Patient safety problems exist throughout the NHS as with every other health care system in the world.
- NHS staff are not to blame – in the vast majority of cases it is the systems, procedures, conditions, environment and constraints they face that lead to patient safety problems.
- Incorrect priorities do damage: other goals are important, but the central focus must always be on patients.
- In some instances, including Mid Staffordshire, clear warning signals abounded and were not heeded, especially the voices of patients and carers.
- When responsibility is diffused, it is not clearly owned: with too many in charge, no-one is.
- Improvement requires a system of support: the NHS needs a considered, resourced and driven agenda of capability-building in order to deliver continuous improvement.
- Fear is toxic to both safety and improvement.

To address these issues the system must:

- Recognise with clarity and courage the need for wide systemic change.
- Abandon blame as a tool and trust the goodwill and good intentions of the staff.
- Reassert the primacy of working with patients and carers to achieve health care goals.
- Use quantitative targets with caution. Such goals do have an important role *en route* to progress, but should never displace the primary goal of better care.

- Recognise that transparency is essential and expect and insist on it.
- Ensure that responsibility for functions related to safety and improvement are vested clearly and simply.
- Give the people of the NHS career-long help to learn, master and apply modern methods for quality control, quality improvement and quality planning.
- Make sure pride and joy in work, not fear, infuse the NHS.

The most important single change in the NHS in response to this report would be for it to become, more than ever before, a system devoted to continual learning and improvement of patient care, top to bottom and end to end.

We have made specific recommendations around this point, including the need for improve training and education, and for NHS England to support a network of safety improvement collaboratives to identify and spread safety improvement approaches across the NHS.

Our ten recommendations are as follows:

1. The NHS should continually and forever reduce patient harm by embracing wholeheartedly an ethic of learning.
2. All leaders concerned with NHS healthcare – political, regulatory, governance, executive, clinical and advocacy – should place quality of care in general, and patient safety in particular, at the top of their priorities for investment, inquiry, improvement, regular reporting, encouragement and support.
3. Patients and their carers should be present, powerful and involved at all levels of healthcare organisations from wards to the boards of Trusts.
4. Government, Health Education England and NHS England should assure that sufficient staff are available to meet the NHS's needs now and in the future. Healthcare organisations should ensure that staff are present in appropriate numbers to provide safe care at all times and are well-supported.
5. Mastery of quality and patient safety sciences and practices should be part of initial preparation and lifelong education of all health care professionals, including managers and executives.
6. The NHS should become a learning organisation. Its leaders should create and support the capability for learning, and therefore change, at scale, within the NHS.
7. Transparency should be complete, timely and unequivocal. All data on quality and safety, whether assembled by government, organisations, or professional societies, should be shared in a timely fashion with all parties who want it, including, in accessible form, with the public.
8. All organisations should seek out the patient and carer voice as an essential asset in monitoring the safety and quality of care.
9. Supervisory and regulatory systems should be simple and clear. They should avoid diffusion of responsibility. They should be respectful of the goodwill and sound intention of the vast majority of staff. All incentives should point in the same direction.
10. We support responsive regulation of organisations, with a hierarchy of responses. Recourse to criminal sanctions should be extremely rare, and should function primarily as a deterrent to wilful or reckless neglect or mistreatment.

The NHS in England can become the safest health care system in the world. That will require unified will, optimism, investment, and change. Everyone can and should help. And, it will require a culture firmly rooted in continual improvement. Rules, standards, regulations and enforcement have a place in the pursuit of quality, but they pale in potential compared to the power of pervasive and constant learning.

A promise to learn – a commitment to act:

Improving the safety of patients in England

We do not need to recite the details of the tragedy of Mid-Staffordshire in this report. Many people probably died from avoidable causes, and many more suffered unnecessary indignities and harm. The details are catalogued for posterity in Robert Francis's historic report; and the story is now indelibly part of the history of the NHS in England¹.

The only conceivably worthy honour due to those harmed is to make changes that will save other people and other places from similar harm. It would add tragedy to tragedy if the nation failed to learn from what happened, and to put those lessons to work. Without ever forgetting what has happened, **the point now is to move on.**

Beyond doubt the NHS can do that, perhaps better than any other health care system in the world. The wave of concern that led to commissioning this report ought not to obscure the enormous strengths of the NHS, its positive achievements, or its even greater promise.

In its core and concept, the NHS has been and remains a world-leading example of commitment to health and health care as a human right – the endeavour of a whole society to ensure that all people in their time of need are supported, cared for, and healed. The vast majority of those who serve in the NHS – clinicians, staff, managers, executives, and boards, contractors and partners – try every day to help to the very best of their abilities, and with deep and appropriate pride in their mission. This Advisory Group recommends important changes that we believe will lead to an even better and safer NHS, but we do not thereby suggest that the NHS has fundamentally lost its way. It is a fine institution that can and should now become much better.

Our job from March 2013 through to July 2013 has been to study the various available accounts of Mid Staffordshire, as well as the recommendations of Robert Francis and others, to distil for Government and the NHS the lessons learned, and to **specify the changes that are needed.**

In announcing our work, the Prime Minister boldly suggested that we might help the NHS achieve “zero harm.” We welcomed this ambitious call, but also agreed from the beginning that even the aims for improvement – what the NHS should strive to achieve and how quickly – would be subjects for our deliberations, and not set by others. We were formed as, and we remain, an independent Advisory Group, relying on our best thinking, not on outside instruction, for our findings.

We cannot and do not claim comprehensiveness in what we recommend. We knew that we would choose to remain silent on many of the Francis Report's 290 recommendations, and that we would not try to comment on everything important for the NHS to do next in the wake of Mid Staffordshire. Further, while we

¹ This report is focused on the NHS in England and where we say 'NHS' we are referring to the NHS in England. However, the lessons are applicable to other healthcare systems, both within the rest of the UK and worldwide.

wholeheartedly support changes in the configuration of services and detailed processes of care that will improve safety and quality, we do not in this report attempt to prescribe those changes. That is better left to commissioners and to the people who give care; they, not we, are the experts in care delivery.

We believe that the actions we propose are necessary, but they are not sufficient to secure a robust future for safety in the NHS. We are only one among many who will together help establish and maintain a better course. Indeed, several fine reports and studies overlapping our charge have appeared during the period of our work. Important among them is the recent Keogh Review, whose recommendations we endorse.

The problems

Motivating our recommendations are findings that we gathered from prior reports (those of Robert Francis and others), the statements of patients and other experts, the research evidence, and our own experience. Among the most important of these findings are the following:

1. **Patient safety problems exist throughout the NHS:** The Mid Staffordshire tragedy may be the most notorious recent lapse in care in the English NHS, but it is not unique. A few other trusts show signs that warrant prompt further scrutiny and, when appropriate, intervention, such as the Keogh review has recently ably modelled. More generally, like every other health care system in the world, the NHS experiences repeated defects in patient safety, and too many patients and carers suffer as a result. We feel strongly that, as for all healthcare systems, **the whole NHS should strengthen patient safety now and into the future.**
2. **NHS staff are not to blame:** Neither at Mid Staffordshire, nor more widely, is it scientifically justifiable to blame the staff of the NHS or label them as uncaring, unskilled, or culpable. A very few may be exceptions, but **the vast majority of staff wish to do a good job, to reduce suffering and to be proud of their work.** Good people can fail to meet patients' needs when their working conditions do not provide them with the conditions for success.
3. **Incorrect priorities do damage:** The Mid Staffordshire tragedy and wider quality defects in the NHS seem traceable in part to a loss of focus by at least some leaders on both excellent patient care and continual improvement as primary aims of the NHS (or to a misinterpretation by providers of the intent of leaders). In some organisations, in the place of **the prime directive, "the needs of the patient come first"**, goals of (a) hitting targets and (b) reducing costs have taken centre stage. Although other goals are also important, where the central focus on patients falters, signals to staff, both at the front line and in regulatory and supervisory bodies, can become contaminated. Listening to and responding to patients' needs then become, at best, secondary aims. Bad news becomes unwelcome and, over time, it is too often silenced. Under such conditions organisations can hit the target, but miss the point.
4. **Warning signals abounded and were not heeded:** Information on the deterioration of the quality of care at Mid-Staffordshire was abundant. It appeared in both narration (complaints from staff, carers and patients) and quantitative metrics (such as significantly high adjusted mortality rates compared with rates throughout England). **Loud and urgent signals were muffled and explained away.** Especially costly was the muffling of the voices of patients and carers who took the trouble to complain but whose complaints were too often ignored.
5. **Responsibility is diffused and therefore not clearly owned:** Responsibility for oversight and remedy for quality and safety concerns was, and is still to some extent, diffused in the NHS in England, with that responsibility divided among many agencies, and with unclear or at times non-existent lines of

coordination, communication, pattern-recognition and follow-up for action. **When so many are in charge, no one is.**

6. **Improvement requires a system of support:** The capability to measure and continually improve the quality of patient care needs to be taught and learned or it will not exist. The NHS needs a considered, resourced and driven agenda of capability-building in order to generate the capacity for continuous improvement. That investment in human development is absolutely necessary if, when alarms ring as they did in Mid Staffordshire, people with their hands on the steering wheel are to have the knowhow to diagnose and fix the problems. **The most important single change in the NHS in response to this report would be for it to become, more than ever before, a system devoted to continual learning and improvement of patient care, top to bottom and end to end.**
7. **Fear is toxic to both safety and improvement:** Fear impedes improvement in complex human systems. Time and again, we see the harvest of fear in the Mid Staffordshire story, a vicious cycle of over-riding goals, misallocation of resources, distracted attention, consequent failures and hazards, reproach for goals not met, more misallocation and growing opacity as dark rooms with no data came to look safer than ones with light. **"Better not to know" became the order of the day.** A symptom of this cycle is the gaming of data and goals; if the system is unable to *be* better, because its people lack the capacity or capability to improve, the aim becomes above all to *look* better, even when truth is the casualty.

Even while asserting unblinkingly what is amiss, it is important to notice and celebrate the strengths of the NHS. Big changes are needed, but **we do not believe that the NHS is unsound in its core.** On the contrary, its achievements are enormous and its performance in many dimensions has improved steadily over the past two decades.

We have the data. Waiting times are shorter than 15 years ago, cardiovascular care and outcomes are far better, cancer care is improving fast and healthcare-acquired infection rates have plummeted. Stroke care in London reached world-class levels. From the beginning of this century, the UK has seen unprecedented investments in training staff in quality improvement, in measuring service and outcomes and in fostering collaborative improvement projects among hundreds of hospitals and ambulatory practices. Those investments have paid off. NHS experts have pioneered patient-driven health care designs, in new models of "productive wards" and "productive operating theatres," and in patient safety research. Innovation is abundant; the barriers have been more to spread of effective new models than to their creation. Most impressive of all, perhaps, has been the consistent dedication to helping their patients among the vast majority of NHS clinicians – doctors, nurses, pharmacists, allied health professionals, mental health professionals and many more – as well as non-clinical staff.

Society, in general, and leaders and opinion formers, in particular, (including national and local media, national and local politicians of all parties, and commentators) have a crucial role to play in shaping a positive culture that, building on these strengths, can realise the full potential of the NHS. When people find themselves working in a culture that avoids a predisposition to blame, eschews naïve or mechanistic targets, and appreciates the pressures that can accumulate under resource constraints, they can avoid the fear, opacity, and denial that will almost inevitably lead to harm.

In pursuit of such a culture, as the leaders whom we encountered in our work know, a measured and balanced response, anchored in science and evidence, serves the nation well. Even while leaders speak out clearly and with courage, as they should, when things go wrong, it is helpful to avoid drama, accusation and overstatement either in the Mid Staffordshire case or in other cases of lapses in patient safety. No single person, party, or administration caused the problems that need to be solved, and everyone can help guide the

next steps if they work together. Likewise, the media's role in uncovering and highlighting genuine problems has been and will remain invaluable, but, at its best, the media is also a key resource for public education and the encouragement of improvement.

The solutions

This litany of problems is, of course, tough to read. However, these concerns are not unique to the NHS; they occur in all large health care systems. Recognising them is the first step toward the repair; knowing what is going wrong gives us the opportunity to set things right.

Set out below are the principles of action that have guided us in our choice of recommendations:

1. **Recognise with clarity and courage the need for wide systemic change:** All improvement begins with clear recognition and acknowledgement of the need to improve. Building a better, safer NHS will benefit from that recognition and involvement from everyone who has a contribution to make to health and care – not just the directly funded NHS, but also contractors and partners, large and small healthcare businesses, social enterprises and voluntary organisations, local authorities, privately funded carers, and, of course, patients, carers and communities. Everyone.
2. **Abandon blame as a tool.** Trust the goodwill and good intentions of the staff, and help them achieve what they already want to achieve: better care and the relief of human suffering. Misconduct can occur and it deserves censure. But, errors are not misconduct and do not warrant punishment:
3. **Reassert the primacy of working with patients and carers to set and achieve health care goals.** Patient safety is better served when patients and carers are as actively engaged in healthcare as they want to be:
4. **Use quantitative targets with caution.** Goals in the form of such targets can have an important role *en route* to progress, but should never displace the primary goal of better care. When the pursuit of targets becomes, for whatever reason, the overriding priority, the people who work in that system may focus too narrowly. Financial goals require special caution; they reflect proper stewardship and prudence, but are only a means to support the mission of the NHS: healing:
5. **Recognise that transparency is essential and expect and insist on it at all levels and with regard to all types of information** (other than personal data). The most valuable information of all is information on risks and on things that have gone wrong; and among the most valuable sources of information are the reports and voices of patients, carers and staff. Everyone, including staff, should be free to state openly their concerns about patient safety without reprisal, and there is no place for compromise agreements ("gagging clauses") that prevent staff discussing safety concerns:
6. **Ensure that responsibility for functions related to safety and improvement are vested clearly and simply** in a thoroughly comprehensible set of agencies, among whom full cooperation is, without exception, expected and achieved:
7. **Give the people of the NHS – top to bottom – career-long help to learn, master and apply modern methods for quality control, quality improvement and quality planning.** The NHS has an obligation to assure their growth and support:
8. **Make sure pride and joy in work, not fear, infuse the NHS.**

In sum, the recommendations below reflect our view that the quality of patient care should come before all other considerations in the leadership and conduct of the NHS, and that patient safety is the keystone dimension of quality. The pursuit of continually improving safety should permeate every action and level in the NHS.

The Francis Report recommended numerous types of new regulation. Regulation, especially using intelligent inspection by experts, does have an important role in setting out what is expected, monitoring the extent to which those expectations are met, and taking action when they are not met. Clear and prompt response to alarming signals, such as have now been investigated in the Keogh study of some hospitals with significantly high mortality rates, is crucial for quality control.

However, regulation alone cannot solve the problems highlighted by Mid Staffordshire. Neither quality assurance nor continual improvement can be achieved through regulation based purely on technically specific standards, particularly where a blunt assertion is made that any breach in them is unacceptable.

In the end, culture will trump rules, standards and control strategies every single time, and achieving a vastly safer NHS will depend far more on major cultural change than on a new regulatory regime.

As a universal healthcare system, free at the point of use, with common goals, structures and systems, the NHS is unique in the world, and can do what no other system can. It has the potential to be the safest healthcare system in the world. The best responses to the Francis Report, the best routes to badly needed improvements, will build on the strengths of the NHS, not ignore them or take them for granted. This will take time to bear fruit and require many years of effort, many messages and many deeds. There is no easy fix, but the prize is worth the price.

A note on the nature of quality and patient safety

To help readers understand the recommendations that follow, we need to describe our perspective on quality and how this relates to safety and the causes of harm.

Many modern industries define “quality” as “*the degree to which a system of production meets (or exceeds) the needs and desires of the people it serves*”. An effective quality management system includes *quality control* (to keep sound processes reliable on a daily basis), *quality improvement* (to decrease variation within and among NHS organisations so that the best becomes the norm) and *quality planning* (especially fostering innovative care models that can deliver better outcomes at lower cost).

Lord Darzi defined quality for the NHS as comprising three dimensions:

- Safety (avoiding harm from the care that is intended to help).
- Effectiveness (aligning care with science and ensuring efficiency).
- Patient-experience (including patient-centeredness, timeliness and equity).

All these dimensions count, but one among them – safety – emerges repeatedly as the most expected; patients, families and the public expect that the people and organisations that exist to help them will not hurt them. “*First do no harm*” is not just a slogan in health care; it is a central aim.

Yet, health care necessarily involves some risk. In seeking the benefits of modern medicine, patients may reasonably choose treatments that involve risk or cause side effects. People have chemotherapy knowing that

the effects are unpleasant. They accept the risk of the treatment in hope of cure or to prolong life. And, new treatments, even wondrous ones, always bring new threats to safety.

In addition to risks inherent in some treatments, there is also inescapable tension between the pursuit of safety and the pursuit of other healthcare priorities. If resources were infinite, many risks could be eliminated. But, resources are not infinite. Achieving a proper balance between risks and resources requires constant vigilance against reductions in resources – such as time, people or consumables – that raise risk to unnecessary and unacceptable levels. People at all levels of care and in all roles need to acknowledge this tension, so that dialogue remains clear, mature and open about how much risk to accept in pursuit of goals other than safety.

Even though hazards in care cannot be eliminated, harms to patients can be and should be reduced continually, everywhere and forever. The fight for safety is a never-ending struggle against entropy, engaged tirelessly and with focus against an enemy that continually emerges and re-emerges.

We distinguish three types of unnecessary risk of harm: risk of harm due to neglect or wilful misconduct; risk of harm due to failures in the system; and risk of harm from error. They are not the same. As Robert Francis has unequivocally shown, some harm is, indeed, due to neglect or to wilful misconduct. These rare sources of harm should be distinguished from the far more common kind: errors made by well-intentioned people or arising from failures in the system. Improving the reliability and safety of healthcare systems is a critical task for leaders. They need to differentiate carefully between error and neglect or wilful misconduct.

Error and neglect or wilful misconduct warrant different responses. Even apparently simple human errors almost always have multiple causes, many beyond the control of the individual who makes the mistake. Therefore, it makes no sense at all to punish a person who makes an error, still less to criminalise it. The same is true of system failures that derive from the same kind of multiple unintentional mistakes. Because human error is normal and, by definition, is unintended, well-intentioned people who make errors or are involved in systems that have failed around them need to be supported, not punished, so they will report their mistakes and the system defects they observe, such that all can learn from them. On the other hand, harm caused by neglect or wilful misconduct does warrant sanctions in health care, just as it does in other settings.

Recommendations

The recommendations that follow are grouped into nine categories:

- I. The Overarching Goal
- II. Leadership
- III. Patient and Public Involvement
- IV. Staff
- V. Training and Capacity-Building
- VI. Measurement and Transparency
- VII. Structures
- VIII. Enforcement
- IX. Moving Forward

In the first eight sections, we provide the key recommendations and a brief narrative. These are followed by our suggestions for specific actions by named actors. In the “Moving Forward” section, we offer some summary views and suggest the highest priority actions.

I. The overarching goal

Recommendation

1. The NHS should continually and forever reduce patient harm by embracing wholeheartedly an ethic of learning.

Patient safety should be the ever-present concern of every person working in or affecting NHS-funded care. The quality of patient care should come before all other considerations in the leadership and conduct of the NHS, and patient safety is the keystone dimension of quality.

Be in no doubt, we are herein advocating a monumental challenge, which will require unprecedented acts of will by the political and executive leadership of the NHS, deep thought and action by everyone in the NHS, patience and understanding from our patients, politicians and media organisations, and courage from everyone to soak up the inevitable failures and lapses along the way.

While “Zero Harm” is a bold and worthy aspiration, the scientifically correct goal is “continual reduction”. All in the NHS should understand that safety is a continually emerging property, and that the battle for safety is never “won”; rather, it is always in progress.

Quantitative targets and financial goals should not override protection of patients from harm. The Government, commissioners and health care providers should strive to strike a balance between minimising risk and allocating resources. Where scarcity of resources threatens to compromise safety, all NHS staff should raise concerns to their colleagues and superiors and be welcomed in so doing. This vigilance cannot come from regulation. It requires culture change and therefore countless, consistent and repeated messages and deeds over a period of years. It means living the values of the NHS Constitution. Goals and incentives should be clear, fully aligned, and focused on the interests of patients, with a high level of coherence across the system as a whole. The best way to reduce harm is for the NHS to embrace wholeheartedly a culture of learning.

Resource constraints will undoubtedly continue in the NHS. There are two ways to deal with this reality. One is by simply cutting budgets and thereby placing the burden on staff of caring with fewer resources. The other, better, way is through improvement – introducing new models of care and new partnerships among clinicians, patients and carers that can produce better care at lower cost. Only a culture of learning and improvement can follow that better way.

II. Leadership

Recommendation

2. All leaders concerned with NHS healthcare – political, regulatory, governance, executive, clinical and advocacy – should place quality of care in general, and patient safety in particular, at the top of their priorities for investment, inquiry, improvement, regular reporting, encouragement and support.

Leadership is about mobilising the attention, resources and practices of others towards particular goals, values or outcomes. The continual reduction of patient harm requires clarity and constancy of purpose among all leaders, from the front-line to the Prime Minister and across the whole system.

Leadership requires presence and visibility. Leaders need first-hand knowledge of the reality of the system at the front line, and they need to learn directly from and remain connected with those for whom they are responsible. Culture change and continual improvement come from what leaders do, through their commitment, encouragement, compassion and modelling of appropriate behaviours.

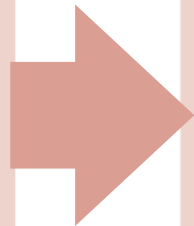
Society in general and opinion formers in particular, including national and local media, politicians of all parties, and commentators, have an opportunity to engage in and facilitate and mature, open and constructive conversation about improving safety in the NHS. This includes harnessing the goodwill of all NHS staff and avoiding generalised criticism of their intentions, motivations, skill or dedication.

Who	What
All staff and leaders of NHS-funded organisations	Every person working in NHS-funded care has a duty to identify and help to reduce risks to the safety of patients, and to acquire the skills necessary to do so in relation to their own job, team and adjacent teams. Leaders of health care provider organisations, managers, clinical leaders and Health Education England have a duty to provide the environment, resources and time to enable staff to acquire these skills.
All leaders and managers of NHS-funded organisations	All NHS leaders and managers should actively address poor teamwork and poor practices of individuals, using approaches founded on learning, support, listening and continual improvement, as well as effective appraisals, retraining and, where appropriate, revalidation.
NHS England	NHS England, through the NHS Leadership Academy, should designate a set of safety-leadership behaviours that can be used in leaders' hiring, in appraisals, in leadership development, and in promotion. The shift in leadership behaviour we think is required, and which could form the basis of a safety-leadership behaviour assessment, is provided in Box 1 .
Leadership bodies ² of NHS-funded organisations	All leadership bodies of NHS-funded health care providers should define strategic aims in patient safety, and should regularly review data and actions on quality, patient safety and continual improvement at their Board or leadership meetings.
Leadership bodies of NHS-funded organisations	Boards and leadership bodies should employ structures and processes to engage regularly and fully with patients and carers, to understand their perspectives on and contributions to patient safety.
Prime Minister and Government	Final responsibility for fostering a climate that supports learning and continual improvement in the NHS rests with the Prime Minister and the Government, who should so affirm repeatedly and forcefully.
Government and NHS organisations	The system should help patient representatives and community champions to become safety leaders, in part by offering them the opportunity to learn safety-leadership behaviours and skills.
Local Government Association	The Local Government Association should take lead responsibility for promoting better integration of the boundaries between health and social care in the interests of patient safety and encouraging local government to fulfil its scrutiny role effectively

¹ By Leadership Bodies we are referring to the variety of forms that different organisations use to run and lead themselves. These may be Boards, Committees or other structures.

Box 1**The shift in behaviour from leaders across the system that we need to see:****Leadership behaviours that increase risk and make healthcare less safe:**

- Blame staff (even when they haven't been given the conditions for success)
- Fail to focus on the patient (often signalling instead that targets and costs are 'centre stage')
- Make bad news unwelcome (too often silencing it)
- Not heed signals and warnings that things are amiss
- Muffle the voice of the patients, their carers and their families and largely ignore their complaints
- Fail to listen to staff
- Diffuse responsibility and disguise who is in charge
- Offer no systematic support for improvement capability
- Game data and goals
- Lead by rules and procedures alone in a disengaged way
- Apply sanctions to errors
- Create fearfulness amongst colleagues and staff
- Ignore the development of the next generation of leaders
- Treat all problems as though they can be "fixed" with existing technologies or writing clearer procedures

**Leadership behaviours that reduce risk and make healthcare more safe:**

- Abandon blame as a tool
- Constantly and consistently assert the primacy of safely meeting patients' and carers' needs
- Expect and insist upon transparency, welcoming warnings of problems
- Recognise that the most valuable information is about risks and things that have gone wrong
- Hear the patient voice, at every level, even when that voice is a whisper
- Seek out and listen to colleagues and staff
- Expect and achieve cooperation, without exception
- Give help to learn, master and apply modern improvement methods
- Use data accurately, even where uncomfortable, to support healthcare and continual improvement
- Lead by example, through commitment, encouragement, compassion and a learning approach
- Maintain a clear, mature and open dialogue about risk
- Infuse pride and joy in work
- Help develop the leadership pipeline by providing support and work experiences to enable others to improve their own leadership capability
- Recognise that some problems require technical action but that others are complex and may require many innovative solutions involving all who have a stake in the problem

III. Patient and public involvement

Recommendation

3. Patients and their carers should be present, powerful and involved at all levels of healthcare organisations from wards to the boards of Trusts.

The patient voice should be heard and heeded at all times.

Patient involvement means more than simply engaging people in a discussion about services. Involvement means having the patient voice heard at every level of the service, even when that voice is a whisper. Evidence shows that patient safety improves when patients are more involved in their care and have more control. Patient involvement is crucial to the delivery of appropriate, meaningful and safe healthcare and is essential at every stage of the care cycle: at the front line, at the interface between patient and clinician; at the organisational level; at the community level; and at the national level. The patient voice should also be heard during the commissioning of healthcare, during the training of healthcare personnel, and in the regulation of healthcare services.

The goal is not for patients and carers to be the passive recipients of increased engagement, but rather to achieve a pervasive culture that welcomes authentic patient partnership – in their own care and in the processes of designing and delivering care. This should include participation in decision-making, goal-setting, care design, quality improvement, and the measuring and monitoring of patient safety. Patients and their carers should be involved in specific actions to improve the safety of the healthcare system and help the NHS to move from asking, “What’s the matter?” to, “What matters to you?” This will require the system to learn and practice partnering with patients, and to help patients acquire the skills to do so.

Who	What
All NHS Organisations	Patients and their carers should be helped to establish effective relationships with their clinicians at every stage of their care, from GP surgery to hospital ward. (For example, there should be clear information about who is working on the ward and who will be each patient's primary nurse that day and night.)
All NHS Staff	Patients and their carers should always be given the opportunity to share their health concerns, histories, family situations, needs, preferences and hopes in order to help staff build effective partnerships during every stage of their care.
All NHS Organisations	Patients and (if the patient wishes) their carers should be involved as much as possible in their care planning. (For example, carers should be invited to and involved in ward rounds, multi-disciplinary meetings, Care Programme Approach meetings, discharge planning meetings and other significant clinical meetings.)
Commissioners and providers	NHS England, CCGs and provider organisations should ensure that a specific, named and recognised clinician, known to the patient, is responsible for the coordination of care for every patient at every phase of treatment regardless of setting.
All NHS organisations	Patients and their carers should always have access to and be given on request a clear, understandable and relevant summary of their health needs and preferences, which states how these needs will be met. This should include information about risks and alternatives and should allow them greater control of their healthcare.
Leaders of NHS organisations	It should always be clear who is responsible for patient safety concerns, and someone should be accessible to patients at every stage of treatment and 24 hours a day. When things do go wrong, incidents should be investigated appropriately and transparently, with the full involvement of the patient and their carers, who should be kept informed at every step of the way.
Leaders of NHS organisations	Patient feedback is instrumental to the measurement, maintenance and monitoring of safety; feedback should be collected as far as possible in real time and be responded to as quickly as possible.
Leaders of NHS organisations	Complaints provide vital information about the quality and safety of care and should be gathered and responded to in a timely way. The leaders of all healthcare organisations should continually improve their local complaint systems.
Government	We encourage further consideration of an independent national complaints management system that is easy to access and use, and that would also highlight and promote better practice and improvements in the NHS. We are aware that separate work is underway to look at the NHS complaints system, and we trust that appropriate recommendations will be implemented accordingly.
All NHS organisations	Patients and their carers should be represented throughout the governance structures of NHS-funded healthcare providers, for example by sitting on and actively participating in safety and quality committees. We encourage experimentation with full patient and carer membership on governing boards and on panels that hold boards to account. Patients and carers should be given appropriate support and training to take a full part in these structures, to understand safety science, and to contribute meaningfully.

Box 2: Actions for Patients and Carers

We seek to engage everyone in improving safety, as far as they can and wish to be involved. This includes patients and carers. Below are our suggested actions for them:

- Patients and carers should seek to establish relationships with healthcare staff and know their names. Patients and carers should seek to build constructive relationships with their caregivers and develop mutual respect, honesty and trust.
- Patients and carers should try to share their histories, family situations, needs and hopes to help staff build true and effective partnerships during their care. They should aim as far as possible, to become co-producers of their care.
- Patients should share their goals, participate in creating plans for their care, engage their families and bring carers or relatives to visit, particularly during ward rounds and other clinical meetings.
- Patients and their carers should alert those working in healthcare when care is not meeting their needs or when they see a practice that they feel is not safe.
- Patients should, when they wish, advise leaders and managers by offering their expert advice on how things are going, on ways to improve, and on how systems work best to meet the needs of patients. This may mean giving time to attend meetings, participating in sessions to learn how the health care system works, learning the “inside” language that they will encounter, and learning to speak effectively to “authority”.

IV. Staff

Recommendation

4. Government, Health Education England and NHS England should assure that sufficient staff are available to meet the NHS's needs now and in the future. Healthcare organisations should ensure that staff are present in appropriate numbers to provide safe care at all times and are well-supported.

Everyone in the NHS should be able to come to work every day knowing they will be treated with respect, supported to do their work and expand their skills, and be appreciated for what they do.

Boards and leaders of provider organisations should take responsibility for ensuring that clinical areas are adequately staffed in ways that take account of varying levels of patient acuity and dependency, and that are in accord with scientific evidence about adequate staffing.

People should work in well-structured teams.

Who	What
NICE	NICE should interrogate the available evidence for establishing what all types of NHS services require in terms of staff numbers and skill mix to assure safe, high quality care for patients.
All leaders of NHS-funded provider organisations	Staffing levels should be consistent with the scientific evidence on safe staffing, adjusted to patient acuity and the local context. (This includes, but is not limited to, nurse-to-patient staffing ratios, skill mixes between registered and unregistered staff, and doctor-to-bed ratios.) Boards and leaders of organisations should utilise evidence-based acuity tools and scientific principles to determine the staffing they require in order to safely meet their patients' needs. They should make their conclusions public and easily accessible to patients and carers and accountable to regulators.
HEE, Government and NHS England	Health Education England should assure that they have commissioned the required training places to meet future staffing requirements working with Government and NHS England to ensure appropriate planning and resources.
All leaders and managers of NHS-funded provider organisations	The leaders of all NHS-funded organisations should foster good teamwork in care. They should ask teams to set challenging and measurable team objectives; facilitate better communication and coordination within and among teams; and encourage teams to regularly take time out to review their performance and how it can be improved.
All leaders and managers of NHS-funded provider organisations	Leaders and managers should actively support staff by excellent human resource practices, promoting staff health and well-being, cultivating a positive organisational climate, involving staff in decision-making and innovation, providing staff with helpful feedback and recognising good performance, addressing systems problems, and making sure staff feel safe, supported, respected and valued at work.
All leaders and managers of NHS-funded provider organisations	NHS organisations, working with professional regulators, should create systems for supportively assessing the performance of all clinical staff, building on the introduction of medical revalidation.
All leaders and managers of NHS-funded provider organisations	Each organisation should be expected to listen to the voice of staff, such as through department and ward level cultural and teamwork safety surveys, to help monitor the safety and quality of care and variation among units. (However, surveys of culture have not been scientifically validated as a performance metric and should not be used for this purpose.) Staff should all be free to state openly their concerns about patient safety without reprisal. There is no place for compromise agreements ("gagging clauses") in such cases.

Box 3: Actions for Staff

Many of our recommendations focus on actions needed by leaders, agencies and organisations. However, only the actions of front line staff, such as these listed here, can realise safe compassionate patient care and improvements to the healthcare system:

- Place the needs of patients, families and carers at the centre of all your work, treating them with courtesy and respect, and intervene if you see others who do not.
- Be a quality inspector, never knowingly passing on a defect, error or risk to a colleague or patient, putting things right where you can, and reporting everything, especially where you need help to put it right.
- Be willing to acknowledge and be open when something has gone wrong and make timely apologies and reparation where appropriate.
- Appreciate that your responsibility is not only to your patients but also to help continuously improve the healthcare system in collaboration with others.
- Treat your colleagues with respect and courtesy and seek to create supportive teams with common goals.
- Commit to learning about patient safety as a core professional responsibility and develop your own ability to detect problems.
- Be willing to speak up to leaders when you believe that a lack of skills, knowledge or resources places patients at risk of harm, and be willing to listen to others when they identify these risks.
- Celebrate and take pride in improvements to patient care.

A NOTE ON STAFFING RATIOS:

Our primary recommendation on staffing patterns is that NICE undertake as soon as possible to develop and promulgate guidance based on science and data. Such guidance, we assume, would include methods by which organisations should monitor the status of patient acuity and staff workload in real time, and make adjustments accordingly to protect patients and staff against the dangers of inadequate staffing. We also assume, and hope, that innovations will develop and continue in technologies, job designs, and skill mix that will and should change ideal staffing ratios, so that this role for NICE ought to be ongoing.

That said, and while NICE does its job, we call managers' and senior leaders' attention to existing research on proper staffing, which includes, but is not limited, to conclusions about ratios. For example, recent work suggests that operating a general medical-surgical hospital ward with fewer than one registered nurse per eight patients, plus the nurse in charge, may increase safety risks substantially. This ratio is by no means to be interpreted as an ideal or sufficient standard; indeed, higher acuity doubtless requires more generous staffing. We cite this as only one example of scientifically grounded evidence on staffing that leaders have a duty to understand and consider when they take actions adapted to their local context.

V. Training and capacity building

Recommendations

5. **Mastery of quality and patient safety sciences and practices should be part of initial preparation and lifelong education of all health care professionals³, including managers and executives.**
6. **The NHS should become a learning organisation. Its leaders should create and support the capability for learning, and therefore change, at scale, within the NHS.**

The entire NHS should commit to lifelong learning about patient safety and quality of care through customised training for the entire workforce on such topics as safety science, quality improvement methods, approaches to compassionate care and teamwork.

The most powerful foundation for advancing patient safety in the NHS lies much more in its potential to be a learning organisation, than in the top down mechanistic imposition of rules, incentives and regulations. Collaborative learning through safety and quality improvement networks can be extremely effective and should be encouraged across the NHS. The best networks are those that are owned by their members, who determine priorities for their own learning.

³ Wherever this report refers to healthcare professionals we are explicitly including clinicians and non-clinicians alike who are involved in the healthcare system. This therefore includes managers, executives and relevant Governmental staff.

Who	What
Training and Education regulators, providers and HEE	The commissioners, regulators and providers of training and education for healthcare professionals (including clinicians, managers, Boards and relevant Governmental staff and leaders) should ensure that all healthcare professionals receive initial and ongoing education on the principles and practices of patient safety, on measurement of quality and patient safety, and on skills for engaging patients actively.
Education regulators, providers and HEE	Professional regulators (such as the GMC and NMC) should continue and build upon their good work to date with undergraduate and postgraduate education providers and Health Education England to ensure that medical and nursing undergraduates and postgraduates become thoroughly conversant with and skilful at approaches to patient safety and quality improvement.
NHS England and partners	NHS England working with partners (Royal Colleges, HEE, NHS Leadership Academy and others) should encourage and expand structured programmes to equip NHS leaders with an in-depth understanding of safety and improvement, and of managing the spread of innovations and good ideas within and among organisations.
All NHS organisations	NHS-funded health care providers should invest in building capability within their organisations to enable staff to contribute to improvement of the quality and safety of services to patients. Box 4 illustrates one sound view of the capability which should be expected from each level in an organisation. A properly resourced capability programme must be in place within 12 months.
NHS England and Government	NHS England should be given the resources to support and learn from existing collaborative safety improvement networks and to sponsor the development of new regional or sub-regional collaborative networks across the country, perhaps aligned to and working with the new Academic Health Science Networks.
All NHS organisations	Every NHS organisation should participate in one or more collaborative improvement networks as the norm.
NHS England	Improvement networks should include processes for monitoring and evaluation by the networks together with NHS England in order to understand what works and to assure that best processes are spread and scaled to benefit all patients in the system.
NHS England	NHS England should organise a national system of NHS Improvement Fellowships, to recognise the talent of staff with improvement capability and enable this to be available to other organisations.

Box 4

Suggested improvement skills required for each group in a provider organisation



Adapted from Kaiser Permanente

VI. Measurement and transparency

Recommendations

7. Transparency should be complete, timely and unequivocal. All non-personal data on quality and safety, whether assembled by government, organisations, or professional societies, should be shared in a timely fashion with all parties who want it, including, in accessible form, with the public.
8. All organisations should seek out the patient and carer voice as an essential asset in monitoring the safety and quality of care.

Patient safety cannot be improved without active interrogation of information that is generated primarily for learning, not punishment, and is for use primarily at the front line. Information should include: the perspective of patients and their families; measures of harm; measures of the reliability of critical safety processes; information on practices that encourage the monitoring of safety on a day to day basis; on the capacity to anticipate safety problems; and on the capacity to respond and learn from safety information. Data on staff attitudes, awareness and feedback are important resources to gain insights into staff concerns. However, it is counterproductive to use staff survey and attitude data as a performance management tool or to compare organisations.

Most health care organisations at present have very little capacity to analyse, monitor, or learn from safety and quality information. This gap is costly, and should be closed.

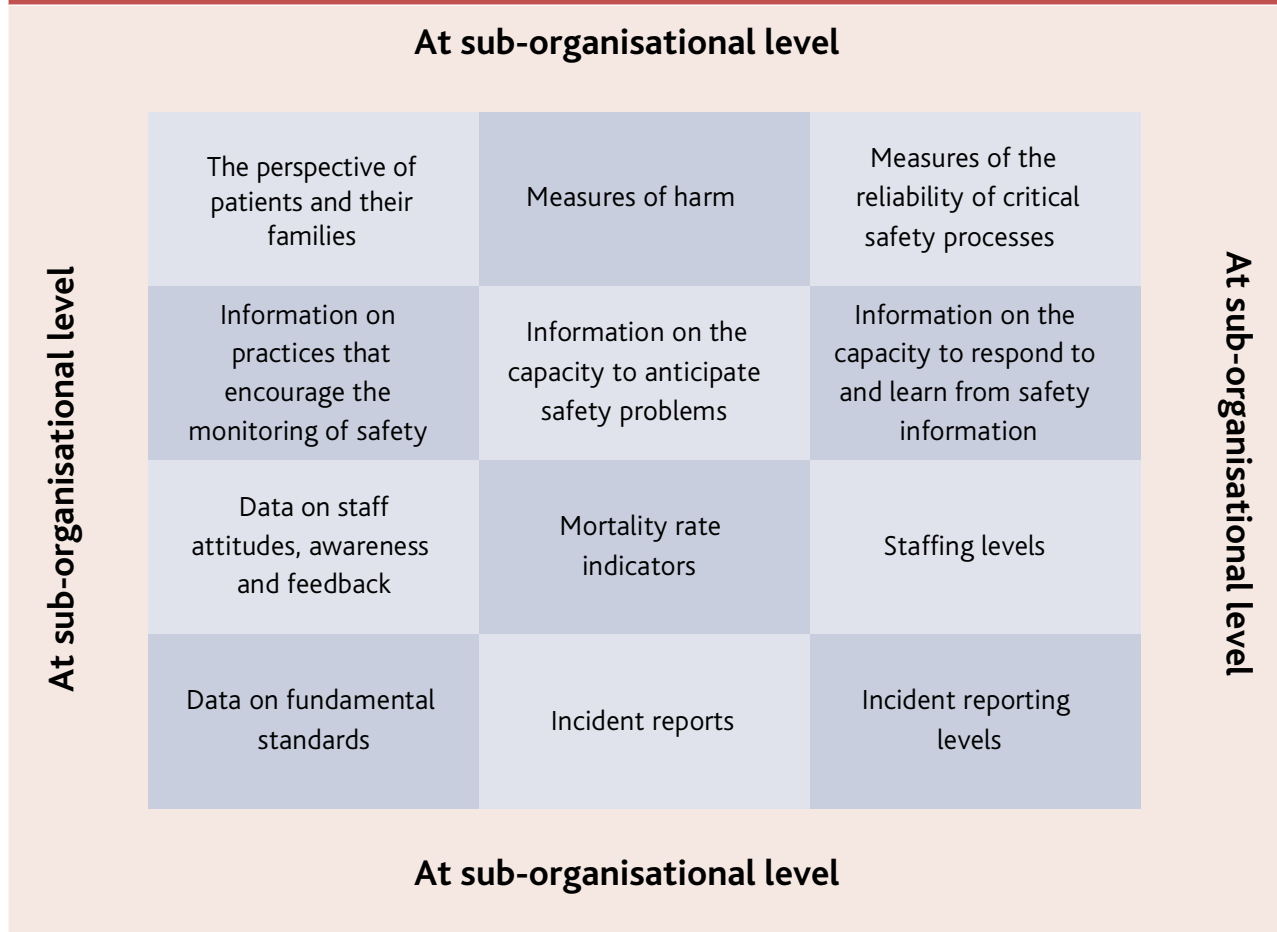
We believe that aggregated data may camouflage variation within organisations that would be revealed by intelligent fine-grained analysis at local level. Leaders need to seek out variation within their organisations (not just among organisations) if safety and quality are to be effectively monitored and improved.

There is no single measure of safety, but early warning signals can be valuable and should be maintained and heeded.

Who	What
All healthcare system organisations	Government, CQC, Monitor, TDA, HEE, NHS England, CCGs, professional regulators and all NHS Boards and chief executives should share all data on quality of care and patient safety that is collected with anyone who requests it, in a timely fashion, with due protection for individual patient confidentiality.
All healthcare system organisations	Government, CQC, Monitor, TDA, HEE, NHS England, CCGs, professional regulators and all NHS Boards and Chief Executives should include patient voice as an essential resource for monitoring and improving the safety and quality of care.
Commissioners	Commissioners should increase funding for NHS organisations to analyse and effectively use safety and quality information.
NHS-funded healthcare providers	Healthcare organisations should shift away from their reliance on external agencies as the guarantors of safety and quality and toward proactive assessment and accountability on their own part.
All NHS-funded healthcare providers	Providers should make use of peer review outside of formal systems – for example by partnering with other organisations – to facilitate learning.
All NHS organisations	Unless and until a better metric is developed, the NHS should use mortality rate indicators like the Hospital Standardised Mortality Rate or suitable alternatives as one of its ways to detect potentially severe performance defects worth investigating further. Mortality measurement should be used as a 'smoke detector' in a spirit of supportive and genuine inquiry, not used to generate league tables or similar comparisons.
All NHS organisations	Organisations should routinely collect, analyse and respond to local measures that serve as early warning signals of quality and safety problems such as the voice of the patients and the staff, staffing levels, the reliability of critical processes and other quality metrics. These can be 'smoke detectors' as much as mortality rates are, and they can signal problems earlier than mortality rates do.
All NHS-funded provider organisations	In addition to reporting aggregated data for the whole organisation, data on fundamental standards and other reportable measures, as required by CQC, should be reported by each ward, clinical department (and health care professional, where appropriate) within the Trust's Annual Quality Account. Leaders must understand the variation in their organisation, not just among organisations, in order to improve.

Box 5

Illustrating some of the suite of indicators that should be used by NHS organisations to assess safety improvement and variation. This data must be considered at ward/unit or other appropriate sub-organisational level in order to reveal the variation within an organisation.



VII. Structures and regulation

Recommendation

- 9. Supervisory and regulatory systems should be simple and clear. They should avoid diffusion of responsibility. They should be respectful of the goodwill and sound intention of the vast majority of staff. All incentives should point in the same direction.**

Delivering safe care is first and foremost the responsibility of providers, but having no regulation is not an option. Regulation should make clear the expectations that providers must meet, detect failings early, and take appropriate action when sub-standard care is found. The most effective regulation comes from a mixture of principles-based standards (developed by a process involving patients, carers and the public) and technical specifications where appropriate, supported by an inspection regime with true experts who are able to apply thoughtful judgement and the right actions in response.

The current NHS regulatory system is bewildering in its complexity and prone to both overlaps of remit and gaps between different agencies. It should be simplified.

The system needs to be agile, responsive and proportionate. This cannot be achieved through a series of prescriptive, technical standards that attempt to delineate between “acceptable” and “unacceptable” according to a tick-box or list. It can be achieved only through a well-resourced, highly coordinated, integrated and expert regulatory system employing intelligent and thoughtful inspection, able to apply both qualitative and quantitative judgement and take effective action when necessary. The same principles apply to oversight and performance management by commissioners and other supervisory bodies.

A high level of coherence is required across the system, with clear and fully aligned goals and incentives focused on the interests of patients at every level. All bodies involved in the oversight of health care providers need to actively avoid the creation of ‘priority thickets’ where providers become increasingly unclear about what they are doing and why, and where the goals they are supposed to achieve compete, conflict, or fail to cohere. Safety and quality stand the best chance when all of the drivers in the system – financial incentives, policies, regulatory strategies, use of competition, commissioning decisions, training, and organisational and professional norms – point in the same direction.

Who	What
CQC and NHS England	CQC should hold Boards responsible for ensuring that recommendations from patient safety alerts are implemented promptly. NHS England should complete the re-design and implementation of a patient safety alerting system for the health care system in England. CQC should assure that organisations respond effectively to these alerts except in the rare circumstances where organisations can demonstrate that implementation of an alert is not in the interests of specific patient groups.
CQC, Monitor and the TDA	The regulatory complexity that Robert Francis identified as contributing to the problems at Mid Staffordshire is severe and endures, and the Government should end that complexity. Further large-scale structural reform is not desirable at present; however, it is imperative that CQC, Monitor and the Trust Development Authority commit to seamless, full, unequivocal, visible and whole-hearted cooperation with each other and with all other organisational and professional regulators, agencies and commissioners.
Government	Government should continually review the extent of this cooperation, and, if cooperation fails, Government should act immediately and decisively.
Regulators, HEE, professional societies, commissioners	CQC, Monitor, TDA, professional regulators, HEE, professional societies, Royal Colleges, commissioners and others should streamline requests for information from providers so that they have to provide information only once and in unified formats. The same is true of inspections.
CQC	CQC should act as the coordinating hub for intelligence about quality and safety of care.
NHS England	NHS England should promptly coordinate the development of an explicit description of the systems of oversight and controls of quality and safety relevant to different types of provider organisations, identify any vulnerabilities in those systems, and, working with others, take action to correct them.
CQC	CQC should develop the “fundamental standards” recommended by Robert Francis, using a process involving patients, carers and the public. Where appropriate these should be specified as human rights standards or principles rather than in technical terms, with compliance to be determined through thoughtful judgement on the part of expert inspectors, informed by metrics. The actions to be taken in the event of breaches of fundamental standards should be consistent with the principles of responsive regulation – i.e. using a pyramid of enforcement, ranging from persuasion through to punishment.
Government	An in-depth, independent review of structures and the regulatory system should be completed by the end of 2017, once current proposed changes have been operational for three years (see Box 6).
Government	The Government should develop plans to allow for the permanent disqualification from relevant positions in the NHS of those at Director level or equivalent whose criminal liability is proven. This sanction is not to be used if someone is struggling in their current position or is facing intractable problems in achieving success. It is a sanction reserved for the worst conduct, and its availability as a sanction should act as a deterrent.
Government	The Government should ensure it is possible for healthcare support workers to receive training and development in order to meet clear codes of practice as is the case with medical, nursing and other professions.

Box 6

An independent review of NHS regulation should assess the weaknesses and strengths of the current system compared with various possible alternatives.

The independent review should assess the following:	The system should be compared with the following alternatives as a minimum:
• The extent to which the system is working	• Re-designation of CQC as a non-departmental public body accountable to Parliament rather than the Secretary of State
• Whether full and sincere cooperation and coordination have been achieved between the various agencies and bodies	• Merging regulators, or using an alternative model of non-government accreditation of healthcare organisations, perhaps modelled on the Joint Commission in the USA
• Whether the regulatory burden and cost is commensurate with the outcomes achieved	• Merging some or all of the organisational regulators so that responsibility for quality, patient safety, standards and outcomes are vested in one regulatory body and residual responsibilities are transferred to NHS England or other bodies (e.g. market and pricing responsibilities)
• Whether patients and those being regulated report that the system is effective and fair	• Consider if the current arrangements for public and community involvement and oversight of health and care, such as via HealthWatch and Health and Wellbeing Boards, are operating effectively and consider the case for revisiting earlier models like Community Health Councils

VIII. Enforcement

Recommendation

- 10. We support responsive regulation of organisations, with a hierarchy of responses. Recourse to criminal sanctions should be extremely rare, and should function primarily as a deterrent to wilful or reckless neglect or mistreatment.**

We considered very carefully the balance that must be achieved to support staff and organisations to learn from error and improve their practice with the need to assure accountability to the patient for egregious acts or omissions that cause death or serious harm. These two approaches are not mutually exclusive but unintended errors must be handled very differently from severe misconduct.

We believe that legal sanctions in the very rare cases where individuals or organisations are unequivocally guilty of wilful or reckless neglect or mistreatment of patients would provide deterrence whilst not impeding a vital open, transparent learning culture. Our proposals aim to place wilful or reckless neglect or mistreatment of all NHS patients on a par with the offence that currently applies to vulnerable people under the Mental Capacity Act.

We take full notice that a lack of regulation and sanctions was not the main problem in Mid Staffordshire. Indeed there already exists a series of robust sanctions and powers available to regulators such as CQC and the Health and Safety Executive. These should be used properly and the bodies with those powers resourced appropriately.

Ultimately, by far the greatest benefit to patient safety will be achieved by increasing the skills and the knowledge of the many rather than penalising the very few. We do not support the punishment of organisational leaders, Boards and chief executives, or others for poor performance that occurs for reasons beyond their control. We do recommend penalties for leaders who have acted wilfully, recklessly, or with a “couldn’t care less” attitude and whose behaviour causes avoidable death or serious harm, or who deliberately withhold information or provide misleading information.

Who	What
Government	The Government should create a new general offence of wilful or reckless neglect or mistreatment applicable both to organisations and individuals. Organisational sanctions might involve removal of the organisation's leaders and their disqualification from future leadership roles, public reprimand of the organisation and, <i>in extremis</i> , financial sanctions but only where that will not compromise patient care. Individual sanctions should be on a par with those in Section 44 of the Mental Health Capacity Act 2005.
Government	It is absolutely vital that any new legislation avoid criminalising unintended errors. An individual should not be convicted of this new offence unless it can be shown the failure was the fault of the individual alone and the individual was acting in a reckless or wilful manner. Liability should be proportionate to past conduct for both individuals and organisations.
Government	The Government should make it an offence for a healthcare organisation to withhold or obstruct the provision of relevant information to a commissioner, regulator, inspector, coroner or other person with a legitimate duty in relation to quality and safety of care.
Government	The application of any of the criminal sanctions referred should be based on the liability criteria set out in Box 7 .
Government and CQC	Where an incident qualifying as a Serious Incident (as defined by NHS England) occurs, CQC regulations should require that the patient or carers affected by the incident be notified and supported. We do not subscribe to an automatic 'duty of candour' where patients are told about every error or near miss, as this will lead to defensive documentation and large bureaucratic overhead that distracts from patient care. However, patients should be given all the information they ask for. Research should be commissioned to study how proactive disclosure of serious incidents, and the process of engaging with patients in relation to less serious incidents, can best be supported.
NHS-funded provider organisations and professional regulators	Employers need to improve their support of staff around implementing guidance on reporting of serious incidents and professional regulators should take appropriate action when required. Organisations should demonstrate that they have in place fully functional reporting systems for serious incidents, that staff know how to use them, that the systems are used, and that appropriate action is taken in response to incidents, including provision of appropriate support to the affected patients and their carers.
Government	We do not support the creation of a statutory duty for healthcare workers to report beliefs or suspicions about serious incidents to their employer, as this duty is adequately addressed in relevant professional codes of conduct and guidance.

Box 7

Applying criminal sanctions, or indeed any sanctions, can be appropriate only in the very rare cases of neglect or wilful misconduct. In addition, where sanctions are considered appropriate we believe that the criteria below must be assessed and be met before those sanctions are applied:

Culpability	The extent to which the neglect or mistreatment of a patient is 'wilful', i.e. intentional, reckless or reflects a reckless 'couldn't care less' attitude.
Substitution	Whether the act or omission is unacceptable and would not be undertaken by a reasonable person or organisation in similar circumstances.
Degree of control for individuals	Only intentional behaviours under people's control (reflecting a reasonable degree of wilfulness or recklessness) should be sanctioned and not unintended error.
Degree of control for organisations	Only failure to create a reasonable safe system of care, or failure to act within its own system of care, or failure to adequately control those systems, or a reckless disregard for the well-being of patients should be sanctioned, and not when the organisation has taken all reasonable steps to achieve compliance.
Severity	The extent to the individual or organisation knowingly or recklessly puts the patient at risk of death or severe harm.
Liability should be proportionate to past performance	The test would be the degree to which the implicated actions are part of a pattern of ongoing and persistent failures to engage with, improve or address safety. This pattern will be taken particularly seriously where previous regulatory actions or managerial or supervisory warnings have been ignored or neglected by those concerned.
Liability should be proportionate to the level of control	The test would be the degree to which an individual (staff and/or directors) have control over the systems within which the implicated actions take place.

Formal guidance should be developed in the use of these liability criteria factors

IX. Moving forward

Our aim was to develop a **small and cogent set of principles and actions** that, in our best judgment and on the basis of existing evidence, would help move the NHS as fast as possible toward better, safer care. In this, we have only partially succeeded. Our core recommendations are few, but the actions we suggest are more numerous than we initially intended. We were led there by the complexity of the NHS, itself, as a national endeavour. Many actors touch and shape the NHS. No one of them holds the keys to improvement. All have opportunities and duties to help, and the system can afford few bystanders.

Some of our recommendations have the hard edge of requirement and enforcement. For example:

- Providers should act on patient safety alerts, and regulators should ensure that they do.
- Transparency ought not to be optional.
- Staffing levels should be adequate, based on evidence.
- Sanctions should apply to reckless and wilful neglect or mistreatment of patients.

However, **our most important recommendations for the way forward envision the NHS as a learning organisation**, fully committed to the following:

- Placing the quality of patient care, especially patient safety, above all other aims.
- Engaging, empowering, and hearing patients and carers throughout the entire system and at all times.
- Fostering whole-heartedly the growth and development of all staff, including their ability and support to improve the processes in which they work.
- Embracing transparency unequivocally and everywhere, in the service of accountability, trust, and the growth of knowledge.

Every single actor in the landscape of the NHS should review these commitments and act on them. Especially important steps are the following:

For Government and NHS England Leaders:

1. State and restate the primacy of safety and quality as aims of the NHS: Assure prompt response to and investigation of early warning signals of serious problems, and, when needed, assure remedy.
2. Support investment in the improvement capability of the NHS.
3. Lead with a vision. Avoid the rhetoric of blame. Rely on pride, not fear.
4. Reduce the complexity of the regulatory system, and insist on total cooperation among regulators. If they do not cooperate, restructure them.

For NHS Organisation Leaders and Boards:

1. Listen to and involve patients and carers in every organisational process and at every step in their care.
2. Monitor the quality and safety of care constantly, including variation within the organisation.
3. Respond directly, openly, faithfully, and rapidly to safety alerts, early warning systems, and complaints from patients and staff. Welcome all of these.
4. Embrace complete transparency.
5. Train and support all staff all the time to improve the processes of care.
6. Join multi-organisational collaboratives – networks – in which teams can learn from and teach each other.
7. Use evidence-based tools to ensure adequate staffing levels.

For System Regulators:

1. Simplify, clarify, and align your requests and demands from the care system, to reduce waste and allow them to focus on the most important aims.
2. Cooperate fully and seamlessly with each other.

For Professional Regulators and Educators:

1. Assure the capacity and involvement of professionals as participants, teammates, and leaders in the continual improvement of the systems of care in which they work.
2. Embrace complete transparency.

For NHS Staff and Clinicians:

1. Participate actively in the improvement of systems of care.
2. Acquire the skills to do so.
3. Speak up when things go wrong.
4. Involve patients as active partners and co-producers in their own care.

For Patients and Carers:

1. As far as you are able, become active partners in your healthcare and always expect to be treated as such by those providing your healthcare.
2. Speak up about what you see – right and wrong. You have extraordinarily valuable information on the basis of which to make the NHS better.

The NHS in England can become the safest health care system in the world. That will require unified will, optimism, investment, and change. Everyone can and should help. And, it will require a culture firmly rooted in continual improvement. Rules, standards, regulations and enforcement have a place in the pursuit of quality, but they pale in potential compared to the power of pervasive and constant learning.

Annex A: A note on our methodology

The Committee assembled was dominated in a majority by scientists – experts in organisational theory, quality improvement, safety and systems – and with a healthy minority of people currently in management positions within the NHS in England, though not deeply enmeshed in the time and occurrences of the Mid Staffordshire story itself. We included four Americans and one Scot, because of their deep familiarity with safety at the level of large health care systems, and, most important of all, three patient-advocates, people who, connected by their experiences of poor or variable patient care, have become vocal and eloquent voices for making sure that the NHS is seen and led through the eyes of patients and carers. To assure enough access to details of the Mid Staffordshire story and its context, we appointed a few Senior Advisors, upon whom the Committee could call as needed for information and suggestions.

We agreed to serve if, and only if, neither government nor NHS management nor, for that matter, any particular stakeholder group had or sought authority to censor or predetermine our findings. We had the Francis report, and a gracious Robert Francis, himself, to draw upon, but were under no obligation to endorse that report, or to accept, reject, or even comment upon any or all of its recommendations. We had a free hand.

Our deadlines were short and our methods respectful both of all the prior work of Francis and others and of the constrained, albeit enthusiastic, time of our busy members, all of whom volunteered without remuneration for this service. Our support from a Secretariat generously provided by the NHS was superb and facilitative. Our meetings were mostly biweekly and mostly virtual, with our American and Scottish members connected by videoconferences.

The bulk of the analyses was conducted by seven working parties established at our first meeting, each chaired by a Committee member, on the following topics: (1) Aims for Improvement, (2) Structures, (3) Measurement and Transparency, (4) Training and Capacity-Building, (5) Patient and Public Involvement, (6) Enforcement, and (7) Leadership. We established and maintained additional subsidiary efforts on (8) Staff and (9) Assuring Implementation. Working parties met between Committee meetings, and produced draft sections and recommendations under strict timelines, reviewed and discussed at the full Committee meetings. Senior Advisors and others made comments by invitation at nearly all Committee meetings.

Our recommendations were based on our best knowledge of the available evidence and our considered judgement.

We agreed to try to limit our final recommendations to a very small number, and to stay riveted on action as the goal. The “customers” for our recommendations, we agreed, would be several, including, but not limited to: (1) the Government (2) the senior executives of NHS England, (3) the leaders and staff of NHS-funded organisations (4) other clinical and executive leaders in the NHS, and (5) the public at large.

Annex B: Letters

Letter to Senior Government Officials and Senior Executives in the Health Service

Thank you for the opportunity to advise you and your colleagues on next steps toward a better and safer NHS. It is a privilege to be allowed to assist an organization for which I have such great respect, and it has been a pleasure to work with the talented and committed Advisory Group that you allowed me to assemble.

The full Report represents the unanimous views of the Advisory Group. I wish here to take the liberty of adding some personal comments and reflections for your consideration.

You are stewards of a globally important treasure: the NHS. In its form and mission, guided by the unwavering charter of universal care, accessible to all, and free at the point of service, the NHS is a unique example for all to learn from and emulate. Faults are to be expected in any enterprise of such size and ambition, and, as you know, the nation's leaders have the dual duty to continually, unblinkingly recognize and reduce those faults and at the same time to maintain and build confidence in the grand vision of the NHS.

The Mid Staffordshire tragedy and its sequellae offer the chance to do both. Thanks to Robert Francis, the nation can see directly some important problems, worth solving, not just in Mid Staffordshire but throughout the NHS. Our Report describes some of those problems. Among them are a partial loss of focus on quality and safety as primary aims, inadequate openness to the voices of patients and carers, insufficient skills in safety and improvement, staffing inadequate for patients' needs, and very unhelpful complexity and lack of clarity and cooperation among regulatory agencies. You, as leaders, can help to remedy every one of those problems and the others that we name. I hope and strongly suspect that you will do so.

In trying to achieve remedy, your most certain and productive pathways will be built on the enormous strengths of the NHS – its people, their commitment, its charter, much of its track record, and the affection and wisdom of patients and carers. I hope that you will invest even more than ever before in learning, growth, development, ambition, and pride. This is the route that can make the NHS a “learning organization” in every sense of the term, and it can unleash momentum for improvement that no simple, top-down, control-oriented, requirement-driven culture ever can.

This is not to excuse or ignore the whole story, as Robert Francis and we understand it. Very occasionally at the root of harm do lie willful, reckless behaviors or neglect that cannot be tolerated, any more than reckless driving can be. There is an important role for responsive regulation by experts, enforcement, and consequences in such circumstances. It is equally important to be alert to early warning signs of possible serious quality and safety problems, and to investigate and act on them. Your recent advisors – Robert Francis, Sir Bruce Keogh, and we – do converge in our recommendations for clarity, timeliness, and reliability in taking action when such alarms sound.

But, as I think you know, this – acting on rare and outlying behaviors and on exceptional cases of poor performance – though necessary, will not create an overall far safer and better NHS; it cannot.

A culture of learning can . And the likelihood of such a culture's thriving in the NHS depends, more than on anything else, on how you, the senior leaders, behave, speak, and invest.

This report is longer than I had hoped it would be. We had no choice; the NHS is complex and actors are inescapably interdependent. As you will see, however, we offer one distillation that you may wish to keep in mind as you peruse the whole. These are four guiding principles that, I suggest, should inform every step you take in these matters – in what you think, say, and do:

- Place the quality and safety of patient care above all other aims for the NHS. (This, by the way, is your safest and best route to lower cost.)
- Engage, empower, and hear patients and carers throughout the entire system, and at all times
- Foster wholeheartedly the growth and development of all staff, especially with regard to their ability and opportunity to improve the processes within which they work.
- Insist upon, and model in your own work, thorough and unequivocal transparency, in the service of accountability, trust, and the growth of knowledge.

Time and again in our Group's deliberations, every member used the word "culture" to diagnose both the faults of and the possibilities for the NHS. I urge you to focus on the culture that you want to nurture: buoyant, curious, sharing, open-minded, and ambitious to do even better for patients, carers, communities, and staff pride and joy. If you read our recommendations carefully, and act on them, I believe that you will have set your compass right.

Don Berwick

Letter to the people of England

Your government and the leaders of the English National Health Service did me the honor earlier this year of asking me to assemble and chair an Advisory Group to recommend some important actions that leaders, clinicians, professional bodies, government agencies and others could take to improve the quality and safety of care in the NHS.

I took that assignment with hesitation and humility. I am an American, not English, and cannot claim the detailed knowledge and cultural sensibility that would lead to the best advice. But I was given a chance to recruit a wonderful group of people as the Advisory Group – most of whom have direct experience of your NHS while the rest admire it from afar – and who worked hard together to understand the problems and craft good suggestions. These included scholars whose careers have been devoted to studying safety and the conditions for excellence, clinicians and managers who know the NHS well, and, most important, patient representatives who could draw on their own experiences and their families', some tragic and hopefully never-to-be-repeated. This group gave me confidence that we would stay on the right track.

Of course, as you know, one of the main motivations for this assignment was the notorious "Mid Staffordshire" tragedy, in which serious problems in a hospital developed that led to avoidable patient deaths and injuries. That event spawned over two years of inquiry by Robert Francis, and, in early, 2013, the "Francis Report," with over 1700 pages and 290 recommendations. Your Government and NHS leaders turned to our Advisory Group for ideas on how to accelerate improvement of care in the wake of Mid Staffs. Ours was not the only group at all; lots of teams and leaders were tackling the same concerns while we did our work.

Our full report is now here for you and anyone else to see. It contains some technical material regarding regulation, improvement science, and management, but I hope that lay readers will find it comprehensible and sensible. Toward that end, I would like to share a few personal reflections for you possibly to ponder, as follows:

You will have read much in the public press that may alarm you about the patient care in the English NHS. After all, things did go quite wrong at Mid Staffs, and, like others, we believe that problems in care often occur throughout the NHS. In that, however, I assure you that the same can be said of every health care system in the world. Health care is complicated, and, even when the staff and clinicians are doing their very best (which is most of the time), errors occur and problems arise for patients that no one intends.

What you do have in the NHS is something that most other nations in the world don't have: a unified system of care that is completely capable of identifying its problems, admitting them, and acting to correct them. That is the process now underway; that is the process that led your leaders to convene our Advisory Group; and that is the process that can and, I believe, will help the English NHS to emerge over time as one of the safest health care systems in the world.

That is not easy. And it gets even harder if the staff of the NHS experience a culture of fear, blame, recrimination, and demoralization. I hope that you resist such general negativity, in yourself and anyone else, and instead clearly point the way with energy and optimism toward the care that you and I want, and that the vast majority of people who work in the NHS want to offer.

In the Mid Staffs story and elsewhere, there are occasional cases of people who willfully or recklessly did some harm. That, of course, cannot be tolerated, and occasionally strong measures of enforcement are needed. There are also clearly occasional organizations for which early warning signals suggest that serious problems may exist. In such cases, your government and NHS leaders can and should promptly investigate, reach conclusions, and act.

But enforcement, even though needed, is not really the route to an overall ever better NHS – the NHS you want. Instead, our report says, bet on “learning.” The English NHS is capable of vast and continual improvement of safety, quality, patient-centeredness, and even cost, if, and maybe only if, everyone involved engages in learning every day. The questions that come up in such a culture are ones like this:

- Whom do we serve, and what do they really want and need?
- How are we doing at meeting those needs?
- How do we know?
- What could we do differently that would do that better?
- Who knows something – a better model, maybe – that we could put to work here?

Imagine an NHS where everyone, all the time, was part of that journey, and has the respect and tools to improve. That’s what our Group recommends, in part, as you will see in this report.

We are recommending four main principles to guide everyone in trying to build an even better “learning NHS.” Here they are:

- Place the quality and safety of patient care above all other aims for the NHS. (This, by the way, is your safest and best route to lower cost.)
- Engage, empower, and hear patients and carers throughout the entire system, and at all times
- Foster wholeheartedly the growth and development of all staff, especially with regard to their ability and opportunity to improve the processes within which they work.
- Insist upon, and model in your own work, thorough and unequivocal transparency, in the service of accountability, trust, and the growth of knowledge.

In all of that you – patients, carers, and citizens – have a vital and exciting role to play. Your voice is key to the future. I hope that this report will give you more confidence in speaking up everywhere and all the time in a vital NHS, and will give those who care for you and want to help you the confidence and skills to invite you, hear you, and welcome you into authentic partnership.

Don Berwick

Letter to the clinicians, managers, and all staff of the NHS

First of all, thank you. For the nearly three decades that I have been able to observe and work with the NHS, nothing has impressed me more than you – the workforce of 1.3 million people who are trying to make real a vision of a vital, universal health care system, accessible to all, and free at the point of service. Your nation's commitment to health care as a human right and to healing as a shared mission is second to none in the world. And all of that is possible through you; only through you.

But, it gets rough sometime, doesn't it? Because you work in a publicly led and publicly funded system of care, you operate under a spotlight more intense than most professional communities ever do. And truth to tell, it doesn't always go so well. Every experienced clinician knows what it feels like to be involved in an error in care, despite one's very best efforts. And the abstract concept of a "system" that fails has concrete meaning in the life of every doctor, nurse, or therapist who couldn't find a crucial test result, became exhausted when staffing was inadequate to meet patients' needs, or watched a patient get an infection in a hospital.

When things go especially badly, as happened, for example, in Mid Staffordshire, and public and private sentiment heats up, it can feel especially rough. And, at its worst, problems like that can hurt morale, as people lose sight of how great the mission is and of how hard you are trying to do what's right.

I was asked by Government and your senior leaders to chair an Advisory Group to recommend what can be learned from recent instances of quality problems in the NHS, and how the system can more rapidly and certainly aim for improvements in patient care and safety. The Group comprised scholars with a special interest in health care quality, leaders familiar with the workings of the NHS, and, most important, patient representatives with personal experiences of both excellence and problems in care.

The resulting report represents our best effort at identifying changes that could help the English NHS become even more the effective, safe, and patient-centered system that you who work in the Service want it to be.

We have made numerous recommendations, some of which reflect the need to tighten surveillance of and response to serious problems in care, which need systemic fixes to help protect patients. As you well know, safety in any sector – aviation, roads, or health care – sometimes requires a commitment to reliability and adherence to proper standards. And some standards should be seriously enforced; the risks of not doing that are too great. In addition, when early warning signs from patients, carers, staff, or data suggest a possibility that serious problems exist in quality and safety, the Government and leaders of the NHS are duty-bound to investigate, reach sound conclusions, and take prompt action.

But, as you probably also know, real, sustainable, active improvement depends far more on learning and growth than on rules and regulations. And that is the balance we are suggesting that the NHS seek to strike – between the hard guardrails that keep things in proper order and the culture of continual learning that helps everyone to grow. A phrase that I believe I heard first in England captures that sense: "All Teach – All Learn." In such a culture, measurement is not a threat, it is a resource; ambition is not stressful, it is exciting; defects are seen as opportunities to learn; and curiosity abounds.

We are recommending four guiding principles, among others, to help the English NHS get better faster, and I urge you to think about these and ask how you can help incorporate them into your own daily work.

- Place the quality and safety of patient care above all other aims for the NHS. (This, by the way, is your safest and best route to lower cost.)
- Engage, empower, and hear patients and carers throughout the entire system, and at all times.

- Foster wholeheartedly the growth and development of all staff, especially with regard to their ability and opportunity to improve the processes within which they work.
- Insist upon, and model in your own work, thorough and unequivocal transparency, in the service of accountability, trust, and the growth of knowledge.

Our Group is urging leaders and the public at large to study, grasp, and act on these ideas, as well. We would hope to see the English NHS emerge as a vital “learning organization,” with you, who work in and for it, experiencing pride and joy in pursuing the great mission you have chosen: to heal.

Don Berwick

Annex C: List of Advisory Group Members

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Reading the signals

Maternity and neonatal services in East Kent – the Report of the Independent Investigation

October 2022

Dr Bill Kirkup CBE

HC 681

Return to an Address of the Honourable the House of Commons
dated 19 October 2022 for

Reading the signals

Maternity and neonatal services in East Kent – the Report of the Independent Investigation

Ordered by the House of Commons to be printed on 19 October 2022

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Open letter to the Secretary of State for Health and Social Care and Deputy Prime Minister and to the Chief Executive of the NHS

The death of a baby is a devastating loss for any family. As one bereaved mother put it, *“When your baby dies, it’s like someone has shut the curtains on life, and everything moves from colour to darkness.”* How much more difficult must it be if the death need not have happened? If similar deaths had occurred previously but had been ignored? If the circumstances of your baby’s death were not examined openly and honestly, leaving the inevitability of future recurrence hanging in the air?

The Panel investigating East Kent maternity services heard the harrowing accounts of far too many families to whom all of this had happened, and more. If it was hard for us to listen to, we could not imagine how much harder it was for those families to relive, although the effects on those who were giving us their accounts were often all too clear. The primary reason for this Report is to set out the truth of what happened, for their sake, and so that maternity services in East Kent can begin to meet the standards expected nationally, for the sake of those to come.

But this alone is not enough. It is too late to pretend that this is just another one-off, isolated failure, a freak event that *“will never happen again”*. Since the report of the Morecambe Bay Investigation in 2015, maternity services have been the subject of more significant policy initiatives than any other service. Yet, since then, there have been major service failures in Shrewsbury and Telford, in East Kent, and (it seems) in Nottingham. If we do not begin to tackle this differently, there will be more.

For that reason, this Report is somewhat different to the usual when it comes to recommendations. I have not sought to identify detailed changes of policy directed at specific areas of either practice or management. I do not think that making policy on the basis of extreme examples is necessarily the best approach; nor are those who carry out investigations necessarily the best to do it. More significantly, this approach has been tried by almost every investigation in the five decades since the Inquiry into Ely Hospital, Cardiff, in 1967–69, and it does not work. At least, it does not work in preventing the recurrence of remarkably similar sets of problems in other places.

This Report identifies four areas for action. The NHS could be much better at identifying poorly performing units, at giving care with compassion and kindness, at teamworking with a common purpose, and at responding to challenge with honesty. None of these are easy or necessarily straightforward, because longstanding issues become deeply embedded and difficult to change. Nor do I pretend to have the answers to how best they should be tackled: they require a broader-based approach by a wide range of experienced experts. But unless these difficult

areas are tackled, we will surely see the same failures arise somewhere else, sooner rather than later. This Report must be a catalyst for tackling these embedded, deep-rooted problems.

Above all, we must become serious about measuring outcomes in maternity services. There are obvious difficulties, given that pregnancy and childbirth are physiological in most cases and poor outcomes less common, but this must not become an excuse. Meaningful, risk-sensitive outcome measures can be found, as they have been in other specialties. They can be used, not to generate meaningless league tables, but to identify results that are genuine outliers. Only in this way can we hope to detect the next unit that begins to veer off the rails before widespread harm has been caused, and before it has had to be identified by families who have suffered unnecessarily. There is work under way in the NHS but it needs further support and direction and the approach must be mandatory, not optional. I am ready to discuss and explain further how this can best be done.

But if we are to break the cycle of endlessly repeating supposedly one-off catastrophic failures, all four areas must be addressed. There are very difficult and uncomfortable issues here, but we cannot in all conscience pretend that “it will not happen again” unless we are serious about tackling them.

My thanks are due to everyone who assisted with this Investigation, including NHS and Trust staff, and it would not have been possible without an incomparable Panel, Advisers and Secretariat. Most of all, however, thanks are due to the families, some of whom made the Investigation happen in the first place and all of whom helped us understand the reality, often at great personal cost to themselves. We owe it to them to listen and learn, not only for East Kent but for NHS services elsewhere.



Dr Bill Kirkup CBE

October 2022

Chapter 1: Missed opportunities at East Kent – our Investigation findings

Introduction

1.1 The Panel has examined the maternity services in two hospitals, the Queen Elizabeth The Queen Mother Hospital (QEQM) at Margate and the William Harvey Hospital (WHH) in Ashford, between 2009 and 2020, in accordance with our Terms of Reference. Responsibility for these services lay with East Kent Hospitals University NHS Foundation Trust (the Trust).

1.2 We have found a clear pattern. Over that period, those responsible for the services too often provided clinical care that was suboptimal and led to significant harm, failed to listen to the families involved, and acted in ways which made the experience of families unacceptably and distressingly poor.

1.3 The individual and collective behaviours of those providing the services were visible to senior managers and the Trust Board in a series of reports right through the period from 2009 to 2020, and lay at the root of the pattern of recurring harm. At any time during this period, these problems could have been acknowledged and tackled effectively. We identify here eight clear separate opportunities when that could and should have happened.

1.4 It is therefore only right that in our Report we indicate where, in our judgement, accountability lies for missing the opportunities to bring about real improvement in the clinical outcomes and in the wider experience of families in East Kent.

1.5 The consequences of not grasping these opportunities are stark. Our assessment of the clinical outcomes, set out in Chapter 2, shows that:

- Had care been given to the nationally recognised standards, the outcome could have been different in 97, or 48%, of the 202 cases assessed by the Panel, and the outcome could have been different in 45 of the 65 baby deaths, or 69% of these cases.
- The Panel has not been able to detect any discernible improvement in outcomes or suboptimal care, as evidenced by the cases assessed over the period from 2009 to 2020.

1.6 We have no doubt that these numbers are minimum estimates of the frequency of harm over the period. We made no attempt to review other records or to contact families who did not volunteer themselves. It was our judgement that we had enough evidence based on the existing 202 cases to identify the problems and their causes, and we did not wish to delay publication of our findings.

1.7 Nor was the harm restricted to physical damage. Chapter 3 sets out the equally disturbing effects of the repeated lack of kindness and compassion on the wider experience of families, both as care was given and later in the aftermath of injuries and deaths.

1.8 This chapter sets out what we have found in East Kent maternity services, and how the Trust failed to read the signals and missed the opportunities to put things right. We know that this will make for painful reading for families affected but also for the Trust, for regulators and for the wider NHS. But unless this is stated and acknowledged, history in East Kent and nationally suggests that there is a real danger that our Investigation will become yet another missed opportunity, not only in East Kent but elsewhere.

1.9 As well as setting out what happened, we identify here the underlying failures that led to the harm we found, as well as some key themes that must be addressed in the response to the failures in East Kent. This chapter also explains the missed signals and where accountability lies. The evidence behind our findings is laid out in Chapters 2 to 5; in Chapter 6, we draw out the lessons with recommendations both for East Kent and for national application.

Our findings

1.10 There is a crucial truth about maternity and neonatal services which distinguishes them from other services provided at hospitals. It is in the nature of childbirth that most mothers are healthy, and, thankfully, their babies will be too. But so much hangs on what happens in the minority of cases where things start to go wrong, because problems can very rapidly escalate to a devastatingly bad outcome.

1.11 We listened carefully to the families who have participated in our Investigation, and we listened equally carefully to staff at the Trust and in other relevant organisations. As a result, we identified problems at every level within the services:

- What happened to women and babies under the care of the maternity units within the two hospitals
- The Trust's response, including at Trust Board level, and whether the Trust sought to learn lessons
- The Trust's engagement with regulators, including the Care Quality Commission (CQC), and the actions and responses of the regulators, commissioners and the NHS, regionally and nationally.

Running through each one of these layers has been a failure to recognise and acknowledge the scale and nature of the problem.

1.12 We have found that the Trust wrongly took comfort from the fact that the great majority of births in East Kent ended with no damage to either mother or baby.

1.13 This failure reflects badly, not only on practice within East Kent maternity services, but on how statistics are used to manage maternity services across the country as a whole. We believe that it should be possible for individual trusts to monitor and assess whether they have a problem; that it should be possible for the NHS regionally and nationally to identify trusts whose safety performance makes them outliers; and that it should be possible for the regulators to differentiate the services provided more quickly and reliably. We set this out in our first key area for action, to be addressed below and in Chapter 6.

1.14 More immediately, the Trust should acknowledge the full extent and nature of the problems which have endured over the period. It has not yet done this in full. We have found that its failure to do so explains why the action that has been taken has not been sustained and has not had the impact needed.

What happened to women and babies

1.15 Chapter 2 gives details of our assessment as to whether the cases within our Investigation involved suboptimal care. We used the approach of the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI), now commonly referred to as CESDI scores.

1.16 In these cases, we have not found that a single clinical shortcoming explains the outcomes. Nor should the pattern of repeated poor outcomes be attributed to individual clinical error, although clearly a failure to learn in the aftermath of obvious safety incidents has contributed to this repetition.

1.17 Although there are shortcomings in the physical infrastructure at both hospitals, and there have been periods of staffing and resource shortages, we have not found that these played a causative role in what happened. While these factors require attention, and are rightly the subject of national consideration, they do not justify, explain or excuse the experience of the families using East Kent maternity services as revealed by our Investigation.

1.18 Similarly, the geography of East Kent, its coastal location, the demographics of its population and the distance between the two hospitals are factors, but they should not have been regarded as explaining or justifying the service provided. We have found evidence of these factors fuelling what is sometimes referred to as a “victim mentality”. Those who should have provided leadership have been tempted to regard themselves as victims of geography, recruitment difficulties and a neglected estate.

1.19 Rather, we have found that the origins of the harm we have identified and set out in this Report lie in failures of teamworking, professionalism, compassion and listening.

Failures of teamworking

1.20 Teamworking is crucial to modern healthcare. Poor teamworking may result from a lack of respect for other staff and a lack of mutual trust, with insufficient credence given to the views of others. Failure to work effectively together leads directly to poor care and jeopardises patient safety. In maternity services, it leads to staff failing to escalate clinical concerns promptly or appropriately. As a result, necessary assessments and interventions are either done by the wrong people with the wrong skillsets or are not done at all. In both cases, the risks to safety are obvious.

1.21 We found gross failures of teamworking across the Trust’s maternity services. There has been a series of problems between the midwives, obstetricians, paediatricians and other professionals involved in maternity and neonatal services in East Kent. Some staff have acted as if they were responsible for separate fiefdoms, cultivating a culture of tribalism. There have also been problems within obstetrics and within midwifery, with factionalism, lack of mutual trust, and disregard for other points of view.

1.22 We found clear instances where poor teamwork hindered the ability to recognise developing problems, and escalation and intervention were delayed. The dysfunctional working we have found between and within professional groups has been fundamental to the suboptimal care provided in both hospitals.

1.23 Poor teamworking was raised as a prominent feature by many of those we interviewed. Some obstetricians had *“challenging personalities ... big egos ... huge egos”*. Midwives showed *“cliquey behaviour”* and there was an in-group, *“the A-team”*. This behaviour was displayed *“in front of women”*. One clinician told us that *“many times we could have done better ... the culture in obstetrics and the relationship with midwifery were poor”*. An external assessor with wide experience of the NHS said that the Trust had *“the worst culture I’ve ever seen”*. Another, from a different organisation, had *“not encountered such behaviour anywhere else”*.

1.24 We have found divisions among the midwives which at times included bullying to such an extent that the maternity services were not safe. We also found that some obstetric consultants expected junior staff and locum doctors to manage clinical problems themselves, discouraged escalation, and on occasion refused to attend out of hours. This, too, put patient safety at significant risk. We have found that midwives and obstetricians did not always share common goals, and that this damaged the safety of patient care. One mother, who asked a paediatrician why her baby had died, was told that *“if you want to look for blame, you should be looking at the obstetricians not me”*.

Failures of professionalism

1.25 Professionalism means putting the needs of mothers and babies first, not the needs of staff. It means not being disrespectful and not disparaging other staff in front of women, who lose confidence in services as a result and may make poorly informed decisions about their care. It means not blaming women when something has gone wrong, and it means making decisions on who is best placed to care for an individual based on their clinical need, not on who belongs to which staff clique.

1.26 We found clear and repeated failures to uphold these principles. Staff were disrespectful to women and disparaging about the capabilities of colleagues in front of women and families. A family member heard a consultant describe the unit they were in as *“unsafe”* to a colleague in the corridor, which was hardly the way to raise any legitimate concerns they may have had.

1.27 Others sought to deflect responsibility when something had gone wrong. A staff member visited a mother the day after a significant problem with her baby had been missed at birth. The mother remembers that the staff member did not ask how her baby was, but said: *“[Y]ou do remember I was handing over, don’t you?”* Another woman, whose baby had died, was told: *“It’s God’s will; God only takes the babies that he wants to take.”*

1.28 In other cases, women themselves were blamed for their own misfortune. A woman admitted to hospital to stabilise her type 1 diabetes pointed out to antenatal ward staff that they were not adjusting her insulin correctly. She was told that *“we’re midwives not nurses and we don’t deal with diabetes ... it’s not our issue and you don’t fit in our box”*.

1.29 We heard that midwives who were not part of the favoured in-group at WHH were sometimes assigned to the highest-risk mothers and challenged to achieve delivery with no intervention. This was a downright dangerous practice.

Failures of compassion

1.30 Technical competence alone is not sufficient for good care, if it is delivered without compassion and kindness. Uncompassionate care can be devastating for the wellbeing and mental health of the recipients. It can cost women the care that they need and it can affect their peace of mind, sometimes in extremely fraught situations that involve the loss, or potential loss, of their baby’s or their own life or health.

1.31 We heard many examples of uncompassionate care that shocked us. A woman who asked for additional information on her condition during an antenatal check was dismissively told to look on Google. A mother who was anxious about her baby's clavicle, fractured during a difficult delivery, was told that *"collar bones break all the time because they are built to do that to get them out easier"*. Another, who asked why an additional attempt at forceps delivery was to be made, was brusquely told that it was *"in case of death"*. Women who pointed out that their spinal or epidural analgesia was not effective and they were in pain were ignored or disbelieved; one told us that *"they didn't listen ... they carried on, obviously, to cut me open. I could feel it all."*

1.32 The effects of many further examples of lack of compassion are considered in detail in Chapter 3.

Failures to listen

1.33 Good care must involve listening and responding appropriately. Women know what they are experiencing at that moment in a way that a clinical attendant cannot. Failing to listen – or, worse, telling someone that they must be wrong – is disrespectful and dangerous. A wise physician, William Osler, encouraged clinicians over 100 years ago to *"listen to the patient, [they are] telling you the diagnosis"*. Ignoring or discounting what a patient says means discarding clinical information that may make the difference between a good outcome and a disaster.

1.34 We have found that there have been repeated failures to listen to the families involved, as exemplified in Illustrative Case A.

Illustrative Case A

A's second pregnancy progressed normally to term, when she reported a loss of clear fluid and suspected that her waters had broken spontaneously. No fluid could be seen on examination, and she was sent home with a view to inducing labour a week later. After four days, however, she telephoned the hospital to say that she was experiencing contractions and her baby's movements had reduced markedly over the previous day. As her contractions were deemed not yet frequent enough to indicate established labour, she was asked to wait at home despite her concern over her baby's movements. When she attended the following day with more frequent contractions, her baby's heartbeat could not be found, and she gave birth to a stillborn baby.

1.35 In some cases, we have found that this failure to listen contributed to the clinical outcome. In others, it was part of a pattern of dismissing what was being said, which contributed significantly to the poor experience of the families within our Investigation, as Chapter 3 sets out. Aspects of the families' experiences have been extremely damaging and have had a significant effect on the outcome for them.

Failures after safety incidents

1.36 We found that the same patterns of dysfunctional teamworking and poor behaviour marred the response by staff after safety incidents, including those incidents that led to death or serious damage. Although some staff were caring and sympathetic, and this was recognised and welcomed by families, others were not. Sadly, but naturally, the poor responses are the ones that remain in families' memories. In a number of cases, the dysfunctional relationships between

the staff involved were all too visible to the families themselves. This was such a common feature that we have concluded that it was part of the culture at QEQM and WHH.

1.37 Time after time, we heard that staff not only failed to show compassion, they also denied responsibility for what had happened, or even that anything untoward had occurred. Similarly, we have found instances where the mother was blamed for what had happened.

1.38 Where things went wrong, clinical staff, managers and senior managers often failed to communicate openly with families about what had happened. Safety investigations were often conducted narrowly and defensively, if at all, and not in a way designed to achieve learning. The instinct was to minimise what had happened and to provide false reassurance, rather than to acknowledge errors openly and to learn from them. Where the nature of the safety incident made this impossible, a junior obstetrician or midwife was often found who could be blamed.

1.39 The following example (Illustrative Case B) illustrates a number of features we have found repeated many times, and the harm to wellbeing that can result from a failure to listen and to respond compassionately. It also shows that multiple failures may coexist in the same case.

Illustrative Case B

“We feel lucky that we have our daughter and grandson; other people weren’t as lucky as us. But we are where we are by a whole string of luck rather than by good planning and good care.” (B’s mother)

B was pregnant for the first time and chose care in her local Midwifery-Led Unit (MLU). She had a good relationship with the midwife she saw. The midwife told B how lucky she was to be fit and healthy, and B trusted her advice, although she had scans which showed excessive growth of her baby that was not investigated or followed up. At 39 weeks pregnant, B developed two significant complications of pregnancy: pre-eclampsia and obstetric cholestasis (a liver condition). A doctor recommended induction of labour and noted the risk of a postpartum haemorrhage and the need for tests of her disordered liver function and blood clotting. The blood-clotting results were lost until after her baby was born.

Despite the risk factors, B was monitored only intermittently in labour, and she received varying advice from different professionals about the likelihood of requiring a caesarean section, which unsettled her. Progress was slow, and the next day her cervix stopped dilating at 7cm. B’s baby was born by caesarean section, apparently uneventfully, although the need for extra stitching to control blood loss from the uterine incision was recorded.

Afterwards, B and her family were placed in a recovery room, where they remained alone for over two hours, undisturbed by staff who should have carried out postoperative checks. After this time, B’s family were alarmed by blood emerging from under the blanket and realised to their great distress that she was bleeding very heavily. They raised the alarm, and staff implemented the hospital’s protocol for massive postpartum haemorrhage.

B was taken to theatre while her mother and other family members were left with the new baby, waiting anxiously and tearfully for news in a four-bedded bay, separated from other mothers and babies only by curtains. After some time, their request to be moved to a side room was granted. In theatre, B was thought to be bleeding because of an atonic uterus – this is when the uterus has not contracted effectively after the birth –

and a device called a Bakri balloon was placed in the uterus and inflated to reduce the bleeding by compression. B was then transferred to the intensive care unit.

Meanwhile, the family remained with the baby, who now needed feeding. B's mother asked for assistance: *"I asked for milk, and this was the thing that was really quite upsetting at the time, the baby needing feeding, and I was told that 'we encourage breastfeeding here and if you want milk you have to go to ASDA, it's up the road'."* After she insisted, some milk was brought, but the irritation of staff was obvious, she said, and no advice was given on feeding under the circumstances. Some staff were subsequently helpful, but others made the family feel that they were being a nuisance.

During the night, family members saw the consultant obstetrician again, who explained that B was still bleeding and would need to return once again to theatre. The family recall the consultant saying, *"you're really lucky because I've phoned a friend' and this rings a bell, because I thought, oh no, we're going 50/50 next and then we're going to ask the audience. I couldn't believe [they were] saying it."*

The "friend" was a consultant gynaecological oncologist who carried out an exploratory operation. They found that there was an extensive collection of blood in the broad ligament (alongside the uterus). The bleeding was from a tear in the cervix extending into the upper vagina, which must have occurred at the time of either the caesarean section or the insertion of the Bakri balloon. The consultant tied off blood vessels in the pelvis, including the internal iliac artery, a major artery, and evacuated the blood. This stopped the bleeding, but B required extensive blood transfusion.

B's subsequent recovery was steady, but her mother remembers being severely reprimanded by midwives for taking the baby to the intensive care unit to bond with B, and the lack of contact and monitoring when B returned to the ward after several days. B felt that she would be just as well off at home, but was told that she shouldn't leave, because she was *"like a broken car that we've fixed up and if you leave you might just break down again"*. B realises that it was the doctor's way of trying to explain things, but she found it very insensitive and has not been able to forget what they said. *"In that moment, when I wasn't really being looked after, was I just going to break down, was I just going to die?"*

After they sent a letter of complaint, B and her mother were told that the unit was safe, with mortality rates below the national average, and that B's care would be reviewed because there was a good governance system for reviewing cases. B's family asked for the review to be shared with them but were told: *"It doesn't happen like that; the team sit round and read through the notes to check that the haemorrhage was managed correctly."* They also asked if the review would consider whether the haemorrhage could have been avoided and were told that it would not. Later, they found out that the case had not been recorded as a serious incident because the haemorrhage had been managed correctly and it was not an unexpected admission to intensive care. *"Nothing seemed to ring true"* to B and her mother.

B and her family found the lack of care and compassion to be the most distressing feature. *"The whole thing was 'you're lucky, you've got a baby, you're alive, you didn't die, your baby didn't die; you need to brush yourself down, get on with it and go on and have another baby'; it was really insensitive to the problems."*

B was advised to go and see the midwife to talk through her birthing story. She understood that this would be a therapeutic exercise that would help her understand what had happened. However, the midwife read her notes and said: *"I don't know why you're here, you're really lucky, you're alive, your baby's alive."* There was no recognition

of B's obvious guilt over feeling upset about what had happened when her baby had survived. She received only reinforcement that she should feel lucky to be alive. The impact on her mental wellbeing was not considered.

B had another appointment with her consultant. They told her that they fully expected to see her in a few months, because *"you've still got everything, you can still have a baby, we'll look after you"*. But the experience has left B terrified about becoming pregnant again. It appears that at no point was any explanation given that her continued bleeding had been due to surgical injury to her cervix and vagina.

"It just seemed that people would think that everything would be fine because I was alive and I would just move on and I shouldn't be sad or upset or mentally scarred from it, from a traumatic experience, and for me I was robbed from having my second baby. I've always wanted a second baby and I will never do that, ever, and no one appreciates that side to it."

This case illustrates clear problems of teamworking, professionalism, lack of compassion and failure to listen. B was made to feel ignored, marginalised and disparaged after the event. Also striking are the lack of frankness about what had happened and the failure to report and investigate a serious incident.

Failure in the Trust's response, including at Trust Board level

1.40 In specific instances where things have gone wrong, the Trust has found it easier to attribute the causes to individual clinical error, usually on the part of more junior staff, or to difficulties with locum medical staff. But we have found that these are symptoms of the problems, not the root causes. This has been combined with the disposition to minimise problems, so it is unsurprising that the Trust has given the appearance of covering up the scale and systematic nature of those problems.

1.41 The problems among the midwifery staff and the obstetric staff were known but not successfully addressed. The failure to confront these issues further damaged efforts to improve maternity services and exposed critical weaknesses in the Human Resources (HR) function. When bullying and divisive behaviours among midwives were challenged, the staff involved began a grievance procedure, following which, it appears to us, the Head of Midwifery was obliged to leave and not speak out. The bullying and divisive behaviours were not addressed.

1.42 One critical weakness was the lack of control that could be exercised in relation to consultants. We have found that experience in East Kent demonstrates the problems that occur when some consultants stubbornly refuse to change unacceptable behaviour. In these circumstances, the mechanisms that trusts are able to deploy to address such behaviour, either through professional regulation or HR processes, may prove frustratingly ineffective.

1.43 It seems to us that the Trust was disposed to replace staff in key managerial roles who identified and challenged poor behaviour. The staff who remained were those who either personified the poor culture or were prepared to live with it rather than question it.

1.44 We have found that the Trust Board itself missed several opportunities to properly identify the scale and nature of the problems and to put them right. These opportunities are described later in this chapter.

1.45 The Trust Board was faced with other challenges. Some of these concerned other hospital services, particularly the Accident and Emergency department, and the failure to meet targets. But those other challenges, though considerable, do not constitute a good enough reason for failing to put right the way in which maternity and neonatal services were operating.

1.46 The Trust Board did endorse a succession of action plans. It was said to us that “*if there is one thing East Kent can do it’s write an action plan*”. But these plans and the way in which the Trust Board engaged with them masked the true scale and nature of the problems. Instead, the plans supported an imagined world where there were fewer problems, and where the plans associated with newly appointed staff were deemed to be sufficient despite the previous recurring pattern of failure. Individuals were lauded only to fall out of favour, sometimes quite quickly.

1.47 The repeated turnover of staff at many levels, including Chief Executive, served to encourage this cycle; each time it was believed that this time things really would get better. Looking at cases to the end of 2020, we have not seen evidence to convince us that this cycle has ended.

1.48 Treating problems as limited one-off issues susceptible to being picked off by the latest action plan or new manager, rather than acknowledging their full extent and nature, has got in the way of confronting the issues head-on. Where issues have been brought into public focus by the efforts of families or through the media, too often the Trust has focused on reputation management, reducing liability through litigation and a “them and us” approach. Again, this has got in the way of patient safety and learning.

The actions of the regulators

1.49 We have reviewed how the Trust engaged with the regulators and others and how those organisations handled the signs of problems with maternity services in East Kent.

1.50 We have found that the Trust was faced with a bewildering array of regulatory and supervisory bodies, but the system as a whole failed to identify the shortcomings early enough and clearly enough to ensure that real improvement followed.

1.51 In practice, there was no shortage of regulatory and other bodies holding relevant information. The list includes:

- General Medical Council (GMC)
- Nursing and Midwifery Council (NMC)
- Local Supervising Authority (LSA; previously performing the role of supervision of midwives)
- Royal College of Obstetricians and Gynaecologists (RCOG)
- Royal College of Midwives (RCM)
- NHS England (NHSE)/NHS Improvement (NHSI) (merged from April 2019 as NHSE&I; NHSE again from July 2022)
- Care Quality Commission (CQC)
- Healthcare Safety Investigation Branch (HSIB)
- Clinical Commissioning Groups (CCGs)
- Local Maternity System/Local Maternity and Neonatal System (LMS/LMNS)

1.52 Looked at individually, a case can be made that the distinctive role of each organisation should have added positively to identifying and addressing the problems. However, standing back from that detail, it is hard to avoid the impression that, in practice, the plethora of regulators and others served to deflect the Trust into managing those relationships and away from its own responsibility.

1.53 The task of regulators was made more difficult by the extent to which problems were denied; this denial ran right through the Trust, from clinical staff to Trust Board level. Even five years on, the Panel has been told that “*we were not as bad as people were saying we were [in 2015/16]*” and that “*it only takes one case [baby Harry Richford] to trigger an investigation*”. A critical RCOG report in 2016 (see paragraphs 1.97–1.102) was based on “*hearsay and uncorroborated comments*”. Legitimate challenge by the CQC was “*always met with anger and defensiveness*”.

1.54 There are inherent tensions in the roles of regulators and professional bodies, both individually and collectively. The RCM, for example, combines three functions: that of promoting quality maternity services and professional standards; that of advising and commissioning legal representation for individual members subject to disciplinary and professional processes; and that of a representative body for its membership. We found that these functions became entangled when the RCM was involved in problems relating to midwife behaviour in East Kent, and it was not possible to tell in what capacity it was operating at any one time, fuelling the perception that these problems were too difficult for the Trust to resolve.

1.55 The actions of the regulators and others are set out in Chapter 5.

1.56 We have found that NHSE&I did seek to help bring about improvements in the Trust. We have heard that a Quality Surveillance Group was established at least as early as April 2014. This followed identification of concerns by the CCGs (see paragraphs 1.75–1.81). As with the other regulators, we have found that the intervention of NHSE&I and its predecessors failed to secure the necessary improvements in the services provided.

Missed opportunities

Illustrative Case C

1.57 A young mother (C) arrived at the hospital having had a healthy pregnancy. She had been told by a community midwife that the slowing down of her baby’s movements was not a reason for concern. Following a scan late on in the pregnancy, C was further reassured that there were no underlying problems with her baby.

1.58 When C went into labour late in the evening, she was told to wait until her contractions were stronger and more frequent before travelling to the hospital. She felt discouraged and waited until the following afternoon, despite the altered movements of her baby. On arrival, she vomited in the corridor, often a sign of a rapidly progressing labour. The first midwife on the scene could not tell how dilated C’s cervix was and brought in another midwife.

1.59 The standard method for checking a baby’s heartbeat is by using what is known as a doppler. The staff present followed this practice but detected C’s heartbeat instead. The midwife left for a break and another one was brought in from the labour ward. The new midwife spotted that the baby’s own heartbeat was not recovering quickly enough after the contractions. The first midwife was called back and, following discussions, C was taken to the labour ward.

1.60 C wanted to push but had been told not to do so. But now she was told to push and the baby was delivered with forceps without additional pain relief. C remembers seeing her baby in the resuscitation cot in the corner of the room. She felt euphoric at having given birth but also concerned by what she saw. She assumed that her baby would be resuscitated and that she would be able to hold the baby at any moment. She remembers being told that her baby was breathing before then seeing her baby being taken away to the neonatal intensive care unit.

1.61 C was left in the room with her family – her parents and partner. No member of staff stayed with them or joined them, and they were not told what was happening. C remembers that she was bleeding profusely and that her father left the room in order to ask whether somebody could attend, only to be told that *“they are all in the staffroom having a cup of tea to recover from the shock”*.

1.62 When the consultant obstetrician arrived, C remembers being told that her baby was being cooled on a life support machine, because of the effects of a lack of oxygen. She was also told that the baby had too much acid in her blood as a result of distress in labour. And then the awful news. Her baby might not survive, or might survive with brain damage.

1.63 For a time, as any parent would, C and her partner were hopeful that their baby would indeed recover. C was expressing milk for her newborn child, who was well grown and had appeared healthy.

1.64 In the coming days, C and her partner would see the effects of their baby’s organs shutting down. They stayed up all night with their baby not knowing when the baby’s last breath would be. The baby passed away in C’s arms the following afternoon.

1.65 Some months later the family had a meeting with the Head of Midwifery and with the head of the MLU. They remembered being told that *“many many mistakes had been made”*; their baby’s death could have been prevented had delivery been only a matter of hours earlier. In response to a question, C was told that ten babies had died since her baby.

1.66 As well as the Trust admitting negligence, C recalls being told that if the family wanted to take any legal action the hospital would be supportive. C and her partner considered carefully what to do and came to their decision. They would pursue the case in order to highlight the issue higher up in the NHS, with the aim of preventing similar outcomes in the future.

1.67 Concern about the death of baby Harry Richford in November 2017 precipitated our Independent Investigation. But this is not Harry Richford; it is baby Amber Bennington, who was born seven years earlier, in August 2010, and who died nine days later.

1.68 There are similarities between the two cases. One is that the Panel has found that in both cases different clinical management would have been expected to have made a difference to the outcome.

1.69 Another similarity is that both families have wanted their experience to be considered in order that the services be improved. The fact that it took the experience of Sarah and Tom Richford, seven years after the experience of Lucy and David Bennington, to bring East Kent maternity services into national focus suggests that the issues are deep and entrenched, and that the Trust has not been ready to look for signs of problems.

1.70 It is clear that concerns have arisen throughout the period since 2009 when the Trust was constituted, and that numerous opportunities have been missed to rectify the situation that had developed. It is likely that the sooner this was tackled, the more straightforward it

would have been, before problematic attitudes and behaviour, and dysfunctional teamworking, became embedded. Yet each of these opportunities was missed in one way or another, and the consequences continued. The most significant are set out here.

Missed Opportunity 1: Internal review and report, 2010

1.71 On 24 September 2010, Dr Neil Martin, the Trust's Medical Director, gave a presentation to the Board on a recent serious untoward incident within maternity services. He also reported that the Trust's internal monitoring process had highlighted an increase in the number of babies showing symptoms of hypoxic ischaemic encephalopathy (HIE), a type of brain damage that occurs when babies do not receive enough oxygen and/or blood circulation to the brain. An internal review was being undertaken and external midwifery support had immediately been put in place at WHH due to a concern about a decrease in the skill mix at the unit.

1.72 The review examined the antepartum management of 91 babies who had an unexplained admission to the neonatal intensive care and special care baby units within East Kent between January and September 2010. In 40% of the cases examined, the review highlighted the presence of suboptimal care, and in a third of those cases the suboptimal care was considered possibly, probably or likely to be a factor that was relevant to the outcome. Of the 91 cases reviewed, there were 16 perinatal deaths; significant or major suboptimal care was noted in 4 of those cases. Six babies were identified as likely to have what the report described as "long-term handicap"; significant suboptimal care was identified in three of those cases.

1.73 More broadly, the review report raised significant concerns about midwifery and obstetric management, midwifery staffing and skill mix, and resuscitation of babies showing signs of a shortage of oxygen. The review identified a number of themes, many of which are recurring issues in the inspections that took place and in the reports and findings published between 2010 and 2020. The main themes were poor identification of fetal growth restriction, failure to diagnose labour leading to inadequate fetal monitoring, incorrect intermittent fetal monitoring, poor practice of continuous fetal monitoring with failure to correctly identify pathological traces and escalate concerns, and failure to follow guidelines.

1.74 The outcome of the review was to move the standalone midwifery units at Canterbury and Dover and to locate them alongside the obstetric units at Margate and Ashford. Recommendations were made to remind staff to practise within guidelines, to improve diagnosis of labour in low-risk settings, to improve standards in fetal monitoring, to review clinical guidance and resuscitation arrangements where meconium is present, to review the process by which medical staff of all grades learn from adverse events, and to review the process of escalating concerns about the progress of labour to more senior staff on call. We could find no evidence that these recommendations were followed up.

Missed Opportunity 2: Clinical Commissioning Group reporting to NHS England from spring 2013

1.75 The CCGs were created and commenced oversight from 1 April 2013. From the very outset, East Kent CCGs raised concerns about the Trust, including concerns about maternity services; they included these concerns in monthly written reports to NHSE. For example, in the June 2013 Quality Report to NHSE, the CCGs noted:

There is concern about the number of Serious Incidents (SIs) relating to maternity services at the Trust. Prior to April 2013 there were five SIs relating to maternity still open and in April 2013, two more were logged.¹

1.76 These concerns were repeated in the August 2013 Quality Report to NHSE:

The quality group and the Kent and Medway Quality Surveillance Group have both expressed concerns in relation to the number of serious incidents and the severity and trends within serious incidents related to maternity services within East Kent. Site visits have already taken place to both maternity units and further work with the trust and members of the quality surveillance group will now be taking place to further explore these issues.²

1.77 The Panel heard that the CCGs were “met with anger and defensiveness by the Trust, always, no matter whether it was a financial challenge or clinical challenge” – “you took a deep breath to have the conversations before you picked up the phone or you met with them”.

1.78 Another interviewee said:

The Trust thought they were exemplars of best practice and there was a real arrogance back in 2013 ... they would say it in public meetings, “we are the best acute trust in the country, we are innovative, we are clinically excellent, we are the safest place to be” ... they would narrate it ... over and over to try and make it become fact ... you then had NHSE saying, “yeah we haven’t really got any specific issue” ... and then you had us [CCGs] ... shouting, “... they’re not financially stable, their leadership is falling apart ... they’re not a cohesive leadership team ... they’re not safe from a clinical and patient safety perspective ... there are many gaps, and then they’ve got big cultural issues, huge cultural issues ...”

1.79 These differences between the Trust and the CCGs were recognised by a member of the Trust Board and the Executive, who spoke of their astonishment at the level of antagonism in the room when attending their first Quality Surveillance Meeting with the CCGs.

1.80 The CCGs found it difficult to gain recognition of their concerns within NHSE. It is not clear whether this was because the CCGs were able to bring fresh eyes to bear on the situation, or whether there had been rapid deterioration, but the existence of problems identified in 2010 makes rapid deterioration an unlikely explanation.

1.81 Having failed to gain traction with NHSE, the CCGs approached the CQC, and the Panel heard that it was this engagement that contributed to the CQC inspection in 2014. In the meantime, however, both the Trust and NHSE failed to accept that the CCGs had grounds for concern – another missed opportunity to recognise and address what was happening.

Missed Opportunity 3: Care Quality Commission report and governance issues, 2014

1.82 The CQC inspected the Trust over six visits in March 2014 and published its findings on 13 August 2014. The overall rating for the Trust was “Inadequate”, with findings that the Trust was “Inadequate” in the domains of providing safe care and being well led, and a finding of “Requires Improvement” for effective and responsive services. Again, there are significant similarities between some of the CQC findings and those in previous and subsequent reviews.

1.83 Key findings from the CQC included the divide between senior management and frontline staff, governance and assurance processes that did not reflect reality, very poor staff engagement, poor reporting and investigation of safety incidents, and limited use of clinical audit. The CQC noted an unusually high number of staff raising concerns about safety directly with its inspectors.

1.84 Maternity services were given a less stringent rating: “Requires Improvement”. Unfortunately, this implied that problems in maternity care were not as bad as elsewhere, not only downplaying the very significant problems that had existed for several years, but also deflecting attention to those areas seen as higher priorities.

1.85 The reaction of the Trust was again one of defensiveness and disbelief, and we found that there was a very tense and difficult relationship between the Trust and regulators throughout. One former member of the Board and Executive told us that a decision had been taken by the Trust to “*fight the regulators*”. We heard that the Trust reacted very badly to the CQC report, sending back hundreds of minor challenges, including grammatical and spelling issues, rather than addressing its substance. Despite issues being flagged as poor by the CQC during its inspections and reported back to the Trust each day, there was still disbelief when the report came in. Six months were spent quibbling over it, and when action plans were drawn up, they were of poor quality and not effectively followed up. This was another significant missed opportunity.

Missed Opportunity 4: Bullying and inappropriate behaviour within the Trust and maternity services, 2014/15

1.86 Bullying and harassment have been prevalent features in the Trust’s maternity services over a prolonged period, as reported by many staff with whom we spoke. Staff surveys confirmed that staff felt disengaged, and reports of bullying and harassment were numerous. Some interviewees were explicit that the effects of this behaviour put the safety of care at risk.

1.87 This issue came to a head in 2014/15, initially when the Trust’s Chief Nurse received an anonymous letter:

I work on maternity at the William Harvey. I’m ashamed to say that I feel intimidated at work. I have been made to look stupid in front of patients and other staff at work. I feel completely unsupported by our most senior staff. At times I dread going to work with certain people ... Management and those with authority are not approachable, there is a blame culture, a just get on with it and shut up attitude, slog your guts out and still get grief. It’s ok if your face fits, we operate a one rule for one, and another rule for everyone else on maternity ... you need to know that at times the unit is [an] awful place to be.

1.88 In response to this and to other evidence of staff unhappiness, the new Head of Midwifery undertook a review, working alongside the Trust’s HR department. In all, 110 staff were interviewed. There were consistent reports from over half of these staff of abrupt and sarcastic senior staff, junior staff being shouted at and humiliated in front of others, staff feeling intimidated and undermined in front of patients, alleged racism, and a daunting and frightening work environment.

1.89 The Head of Midwifery decided, with HR, that some senior midwives who were repeatedly identified as central to the issues should be relocated or suspended pending further action. A collective letter of grievance with 49 signatories was subsequently submitted via the RCM, alleging failures of process in the review. It is notable that this letter admitted that the unit was “*dysfunctional*”.

1.90 We heard that, as a result, the Trust withdrew support from the review process and from the Head of Midwifery. Consequently, she resigned from her post in August 2015. She requested advice from the RCM on whistleblowing about the culture of bullying and intimidation prevalent in the unit and was advised against disclosure in the interests of patient safety because of the

risk this posed to her future career prospects. It is notable that the RCM was already aware of the dysfunctional behaviours at the Trust.

1.91 The Panel heard of no further efforts to address the bullying behaviour, which, we heard, persisted. This was another significant missed opportunity.

Missed Opportunity 5: *The Report of the Morecambe Bay Investigation, 2015*

1.92 The report into the serious failings in Morecambe Bay maternity services was published in early 2015. It identified, among other issues, failings of poor working relationships and dysfunctional teamworking, failures of risk assessment and planning, and failure to investigate properly and learn from safety incidents. All of these features were already evident in East Kent maternity services.

1.93 In May 2015, the Head of Midwifery at the East Kent Trust had already noted the similarity of issues and lessons identified within the Morecambe Bay report and sought to raise similar issues of concern with the Trust leadership. She was not heeded.

1.94 When we interviewed staff in 2021/22, some told us that they still believed the comparison to be misplaced. The Trust had commissioned a report later in 2015 specifically addressing this question; it found that the East Kent Trust “*was not another Morecambe Bay*”.

1.95 Given what the Trust knew about its own services at this point, this is an extraordinary conclusion; we can only suppose that it reflects the pattern of false assurance and defensiveness that characterised much of the Trust’s behaviour.

1.96 The Morecambe Bay report included a message for other trusts in 2015:

It is vital that the lessons, now plain to see, are learnt and acted upon, not least by other Trusts, which must not believe that “it could not happen here”. If those lessons are not acted upon, we are destined sooner or later to add again to the roll of names [of dishonoured trusts].³

Missed Opportunity 6: *Report of the Royal College of Obstetricians and Gynaecologists, 2016*

1.97 In 2015, concerned about accumulated evidence on the working culture in maternity services, the Medical Director, Dr Paul Stevens, commissioned a review by the RCOG. He specifically identified for review the poor relationship between obstetricians and midwives, compliance with clinical standards, poor governance and response to safety incidents, supervision of trainees, consultant accessibility and responsiveness, and consultant presence on the delivery suite.

1.98 The RCOG review reported in February 2016 and made serious criticisms of the maternity services in East Kent. Among other things, the report was critical of the lack of engagement of obstetricians in drawing up guidelines, which were of poor quality as a result. Safety incident investigations were inadequate and failed to identify areas where obstetric practice could be improved. Some consultant obstetricians at QEQM consistently failed to attend labour ward rounds, review women in labour, or draw up care plans; they also refused to attend when asked to when on call out of hours. Although these consultants were clearly contravening their duties to the Trust and to their profession, the RCOG review found that “*this unacceptable practice has continued not to be addressed despite repeated incident reporting with the result that this unit has developed a culture of failing to challenge these poorly performing consultants*”.⁴

1.99 As a result of these appalling patterns of behaviour, trainees were under pressure to cope with clinical issues they were not competent to deal with unsupported, and midwives felt that there was no point in escalating emerging urgent clinical concerns. In addition, both groups of staff had given up reporting concerns about unacceptable behaviour, as no action was taken. Educational supervision of trainees was inconsistent, posts were often filled by locums, and morale was poor.

1.100 In keeping with the familiar pattern of defensiveness, the Trust told the RCOG that it would not respond to the report in light of an anticipated CQC inspection. When this occurred, the RCOG report was not shared with the CQC. Within the Trust, the RCOG review report was not widely distributed and was dismissively described as *“a load of rubbish”* by some senior obstetricians. A meeting of the Trust Quality Committee heard that *“initial information from the recent [RCOG] Maternity Review report is clear – the Trust does not have an unsafe maternity service but there is improvement work to do around how the service is run in some areas”*.

1.101 There was, however, sufficient pressure that maternity services were recognised as presenting an “extreme” risk, with potential harm to both pregnant women and neonates, in the Corporate Risk Register in June 2016. The resulting action plan, heavily process-oriented, was subsequently merged with a general improvement plan in response to the national Maternity Transformation Programme, diluting it and losing some of the specific elements prompted by the RCOG report. Fewer than a quarter of the action points had been completed when the risk was removed from the Register in 2019.

1.102 Most obviously, at no time was there an explicit plan documented or actioned to address the identified failure of some consultants to fulfil their professional duties. We heard that it was a *“difficult area”*, that *“quiet words”* were had, that two consultants had moved on or retired, and that another had a modified job plan that excluded overnight labour ward cover. While we recognise the constraints, and will comment elsewhere on them, the failure to tackle this explicitly or visibly has left echoes in the unit that still persist. This was another significant missed opportunity.

Missed Opportunity 7: The death of baby Harry Richford

1.103 Baby Harry Richford died on 9 November 2017 in the neonatal unit at WHH in Ashford, seven days after he was delivered at QEQM in Margate. The cause of death was recorded as hypoxic ischaemic encephalopathy (HIE).

1.104 Many of the same red flags that had shown themselves in the litany of previous inspections, reviews and reports appear again in baby Harry’s case. Not only does this apply to the clinical care given to his mother, Sarah Richford, it is also evident in the way that the whole family were treated after his death. The patient safety issues echoed the problems that had been highlighted first in the Trust’s internal review of 2010 and most recently again in the RCOG report, published 18 months before Sarah attended QEQM.

1.105 Sarah witnessed conflict and disagreement between the obstetric and midwifery teams about the way that oxytocin was being used to augment her labour. Midwives were concerned about changes to the continuous heart trace of the baby, but the obstetric team disagreed.

1.106 Obstetric cover on the labour ward was provided by a locum specialist registrar, whose knowledge and experience had not been assessed by a Trust consultant. When there was disagreement over Sarah’s care plan, neither the locum registrar nor the midwifery team escalated this to the consultant on call, contrary to guidelines. Sarah was not reviewed by an obstetric consultant during either the 1pm or 6pm assessment rounds, contrary to unit protocols.

1.107 There were further features of concern over the baby's condition coming up to delivery, and the locum registrar undertook to expedite delivery, either by forceps delivery or, if this was not possible, by a caesarean section. It appears that the locum registrar discussed this by telephone with the consultant on call, who agreed with the plan but did not attend, although it was likely to present challenges to an inexperienced obstetrician.

1.108 After an unsuccessful attempted forceps delivery, a caesarean section was undertaken. Unsurprisingly, in view of the descent of the baby's head, this proved very difficult; several attempts were made to dislodge the head from the pelvis, including by applying pressure vaginally. The consultant on call was contacted by telephone and offered advice but was still not in attendance.

1.109 There were major difficulties in resuscitating baby Harry after delivery, including delay in establishing an airway, together with delay in escalating concerns to a consultant paediatrician on call.

1.110 In keeping with the familiar pattern of downplaying problems and seeking to avoid external scrutiny, the Trust classified baby Harry's death as "expected" on the basis that he was admitted to the neonatal unit at WHH with severe HIE, and therefore death was not an unexpected outcome. For that reason, the Trust initially refused to refer baby Harry's death to the coroner for investigation. There were errors in the data sent to the national audit, Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK).

1.111 Baby Harry's family faced great difficulty in finding out what had gone wrong, although they were sure that something had, and they began to distrust any information they received from the Trust. The weeks, months and years that followed baby Harry's death involved sustained efforts by his family to seek understanding and truth about what had happened during his delivery. Their efforts included referring the case to HSIB and to the CQC for investigation and pressing to have a full inquest into the circumstances of his death.

1.112 This pattern of behaviour by the Trust, clearly evident in this case, recurred in many others that we examined. It included denying that anything had gone amiss, minimising adverse features, finding reasons to treat deaths and other catastrophic outcomes as expected, and omitting key details in accounts given to families as well as to official bodies. Although we did not find evidence that there was a conscious conspiracy, the effect of these behaviours was to cover up the truth.

1.113 Even had none of the previous failings been known – and they were – baby Harry's death should surely have been a catalyst for immediate change. In fact, it required public remonstrance by a coroner over two years later, precipitated by the persistence, diligence and courage of baby Harry's family, to reveal an organisation that did not accept its own failings, considered itself above scrutiny or accountability, and consistently rejected the opportunity to learn when things went wrong.

Missed Opportunity 8: Engagement with the Healthcare Safety Investigation Branch from 2018

1.114 HSIB was established in 2017 in response to widespread concern that the NHS was not learning consistently from safety incidents. Its brief is to carry out independent investigations into safety incidents, focusing on systems and processes, to identify learning. In light of previous issues, most obviously at Morecambe Bay, HSIB was given a special brief to look at all maternity incidents that fulfilled certain harm criteria. In 2018, it became evident that East Kent

maternity services were an outlier because of the rate of occurrence of safety incidents resulting in serious harm.

1.115 From the outset, HSIB experienced difficulties in its dealings with the Trust, including problems obtaining information, staff attendance at interviews, and support for the process from the Trust's senior leadership team. HSIB found this to contrast sharply with the response of other trusts in the region, which generally welcomed the opportunity to have "fresh eyes" on any problems. The East Kent Trust, on the other hand, challenged HSIB's right to carry out investigations and its credentials to act as what the Trust saw as another regulator.

1.116 HSIB's concerns increased over the course of 2018, particularly over failures to escalate clinical concerns, unsupported junior obstetric staff, the use and supervision of locum doctors, management of reduced fetal movement, neonatal resuscitation, and fetal monitoring and its interpretation. In light of its "*grave concerns*", HSIB sought a meeting with the Trust's senior leadership team, which took place in June 2019.

1.117 The accounts of that meeting that we heard from more than one source left us shocked, given the extent of the problems at the Trust that by then had been evident for almost ten years. The HSIB team was not made welcome but was left waiting in a corridor for an extended period. Senior executives greeted them in an "*incredibly aggressive*" manner, saying "*I don't know why you are here*" and telling HSIB that its recommendations were "*not needed*". The tone of the meeting was one of defensiveness and aggression, and there was a "*heated discussion*" about a maternal death.

1.118 Although relationships between the Trust and HSIB became more cordial, we heard that the Trust did not achieve the same level of acceptance and learning evident in other trusts that HSIB deals with. This is the most recent in this long series of missed opportunities.

Where accountability lies

1.119 This section has highlighted our findings and set out the series of missed opportunities that has characterised the whole period since the establishment of the Trust in 2009. Any one of these was a chance to rectify a situation that had clearly gone very wrong and was continuing to deteriorate. Had any of these opportunities been grasped, there would undoubtedly have been benefits in terms of death, disability and other harm avoided, and in terms of the mental wellbeing of many families who were disregarded, belittled and blamed.

1.120 We do not blame, or identify, those who have made honest clinical errors. Clinicians should not have to live in fear of clinical error and its aftermath; it is an inescapable accompaniment to practice everywhere. The fundamental point is to recognise and report error, so that it can be investigated and learned from. The route to improved maternity services would be fatally undermined if individuals, be they midwives or consultants, were deterred from reporting, or from entering practice, by the fear that honest clinical errors would result in public or professional vilification.

1.121 We have found that repeated problems were systemic, particularly reflecting problems of attitude, behaviour and teamworking, and they reflect a persistent failure to look and learn. They concerned both hospitals and continued throughout the period we have investigated. They included poor professional behaviour among clinicians, particularly a failure to work as a cohesive team with a common purpose.

1.122 Each of these problems has been visible to the senior management of the Trust. In these circumstances, while it is right that this report should be clear about those systemic issues and how they have been evident through the organisation, we have concluded that accountability lies with the successive Trust Boards and the successive Chief Executives and Chairs. They had the information that there were serious failings, and they were in a position to act; but they ignored the warning signs and strenuously challenged repeated attempts to point out problems. This encouraged the belief that all was well, or at least near enough to be acceptable. They were wrong.

Key areas for action

1.123 It is a privilege to have been asked to investigate maternity and neonatal services in East Kent. But, in doing so, we are faced with a reality of national as well as local significance.

1.124 This Investigation is simply the latest to focus on failings in an individual NHS trust. The list is now a long one, going back at least as far as the 1960s. As the Health Foundation has pointed out, most people think of the inquiry into failures of care at Ely Hospital in Cardiff in 1967 as the first NHS inquiry.

1.125 The period since then has been punctuated by reviews into local circumstances: for example, the *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*, published in 2013. With maternity services alone, the spotlight has been shone on Morecambe Bay in 2015, on Shrewsbury and Telford in 2021/22, East Kent, with this Investigation commissioned in 2020, and now Nottingham.

1.126 The pattern is now sadly familiar: detailed investigation, lengthy reports, earnest and well-intentioned recommendations – all part of a collective conviction that this must be the last such moment of failure, with the lessons leading to improvement, not just locally but nationally. Experience shows that the aspirations are not matched by sustained improvement. Significant harm then follows, with almost always patients and families the first to raise the alarm.

1.127 In investigating East Kent maternity services and their missed opportunities, we have become all too aware that a conventional report, with multiple recommendations, overlapping with recommendations from other inquiries, other periods and other sources, is unlikely to break free of this pattern.

1.128 For this reason, we have set ourselves the objective of identifying a more limited number of key themes and recommendations, and of not confusing the already difficult – if not impossible – task of making sense of those that already exist.

1.129 Within this approach, we want to tackle head-on the fundamental issue affecting maternity services that this succession of reviews creates. The frequency with which supposedly one-off outliers keep cropping up despite previous investigations and reports makes it, in our view, unsafe to suppose that East Kent is the last one that will be identified. The answer cannot be to hope that individual reviews and multiple recommendations prevent recurrences elsewhere. If that approach were the right one, it would have worked by now. It hasn't.

1.130 We have identified four key areas for action that we believe must be addressed.

Key Action Area 1: Monitoring safety performance – finding signals among noise

1.131 We have come to the view that something more reliable needs to be put in place, not only in East Kent but also elsewhere and nationally, to give early warning of problems before they cause significant harm. The aim must be for every trust to have the right mechanism in place to monitor the safety of its maternity and neonatal services, in real time; for the NHS to monitor the safety performance of every trust; and for neither the NHS nor trusts to be dependent on families themselves identifying the problems only after significant harm has been done over a period of years.

1.132 We are clear that such a mechanism can be developed in order to spot the relevant signals. In Chapter 6, we recommend how this should be done. This is not a toolkit, because it must be nationally standardised, and it is not optional. It will be based on:

- Better outcome measures that are meaningful, reliable, risk adjusted and timely
- Trends and comparators, both for individual units and for national overview
- Identification of significant signals among random noise, using techniques that account properly for variation while avoiding spurious ranking into “league tables”.

1.133 In essence, it is clear that in East Kent the Trust too often treated the concerns expressed by families as “noise” when they were in fact an accurate signal of real problems. One example is how the family of baby Harry Richford was treated, particularly when they sought answers to legitimate questions. But that is not the only such example. The accounts we have heard from families show persuasively that the Trust’s mindset was too often to be defensive and to minimise problems; and that this mindset was itself a barrier to learning.

1.134 The Trust also took false reassurance from national statistics that appeared to suggest that the number of baby deaths was no higher than in other trusts, underlining the shortcomings of available information. This was very clear from the accounts we have heard from the Trust’s staff. For example, a senior clinician accepted that the Richford case was tragic and avoidable but added that, *“however, when you look at the figures it was only in 2017 that [East Kent] were slightly outside average Trust behaviour”*.

1.135 Chapter 5 describes how the Trust sought to monitor its performance. By contrast, we have identified a more reliable approach that would utilise the available statistics in the way suggested in Chapter 6, for the use of clinical teams, trusts, regulators and the public, as well as listening to what women and their families say – treating that too as a likely signal, not as noise.

Key Action Area 2: Standards of clinical behaviour – technical care is not enough

1.136 The frequent instances we have found of a distressing and harmful lack of professionalism and compassion are of great concern to us. Of course, we are aware that the majority of clinical staff do not behave like this; but, equally, it would be wrong to imagine that these behaviours are confined to East Kent’s maternity services.

1.137 This is not a finding of technical incompetence. But the experience shared vividly with us by families and often confirmed by staff accounts has demonstrated that technical competence is not enough. In any clinical situation, not least the stressful circumstances of giving birth, there is an equal need for staff to behave professionally and to show empathy. The evidence of staff

not showing kindness or compassion and not listening or being honest has been both harrowing and compelling.

1.138 Part of a professional approach is explaining what is happening or has happened honestly and openly – at the time, whenever possible, and certainly afterwards. But what we have found is that, too often, the response has been based on personal and institutional defensiveness, on blame shifting and punishment.

1.139 We have found a worrying recurring tendency among midwives and doctors to disregard the views of women and other family members. In fact, in a significant number of cases, the Panel has found compelling evidence that women and their partners were simply not listened to when they expressed concern about their treatment in the days and hours leading up to the birth of their babies, when they questioned their care, and when they challenged the decisions that were made. Too often, their well-founded concerns were dismissed or ignored altogether.

1.140 A particular area of concern was the telephone advice given to mothers to stay at home if they were not adjudged to be in established labour. It is foolhardy to disregard the woman's voice, especially if she has experience of previous labour, and we saw evidence of distressing births before the mother's arrival in the maternity unit as a result. But it is dangerous when the caller has also reported other problems such as altered movements by the baby, and we saw examples of babies lost as a consequence of such advice.

1.141 We have also found a pattern of particularly stubborn and entrenched poor behaviours by some obstetric consultants, particularly at QEOM. We are clear that this has been damaging, not just to team relationships but also to the safety of women and their babies.

1.142 Some consultants did not attend when requested, although they were on call, and they did not attend scheduled labour ward rounds. They discouraged both junior staff and midwives from calling them at night, leading most staff to conclude that they just had to get on with it without the advice or presence of consultants when those consultants were on call. These concerns were known to the Trust, having been clearly identified in the RCOG report of 2016 and confirmed subsequently by the Trust itself in an audit conducted in April and May 2016. The RCOG did not immediately offer to be involved in how these problems might be resolved, and was rebuffed by the Trust on offering to revisit six months later.

1.143 We note that, in seeking to overcome the reluctance of some consultants to attend when on call, the Trust's actions were weaker than when dealing with midwives. This difference was evident to staff, who put it to us in these terms: *"Nurses would potentially be disciplined ... doctors would be asked to reflect on what happened."*

1.144 It is apparent to us that this reflects a much wider difficulty. Any trust seeking to address problematic behaviour by consultants will face significant constraints. Employers effectively have no sanctions short of dismissal against a consultant who defies them, and experience suggests that if employers do act, or if a consultant claims constructive dismissal, the employers are very likely to lose at an employment tribunal. In such situations, external support for trusts is often unhelpful, while defence organisations mobilise their full resources in support of their member. When the GMC was belatedly informed of the unacceptable consultant behaviour in East Kent, it decided that no fitness to practise proceedings were required, and confirmed to us later that it was not able to address *"lower-level behavioural issues, or cultural issues, or attitudinal issues"*. Without wishing to detract from the importance of employment protection, it cannot be right that behaviour which seriously threatens patient safety cannot be robustly addressed.

1.145 There is a pressing need to understand better the gross lapses of professionalism, compassion and willingness to listen that these events illustrate, including their prevalence, the underlying causes, and – most importantly – how they can be changed. Unless we address the balance between the technical aspects and the human kindness needed to care for people compassionately, effectively and safely, the problems evident in East Kent will recur elsewhere.

Key Action Area 3: Flawed teamworking – pulling in different directions

1.146 We have found that teamworking in East Kent maternity services was dysfunctional. This was clear in the accounts we have heard from families and was consistently supported by the evidence of the staff interviews and available records. Many staff described “toxic”, “stressful” working environments. Arguments between staff were played out in front of families just at the time when truly effective teamwork was required and just when families needed to see that teamwork at work.

1.147 Fundamentally, there were poor relationships both within and between professional groups. There were factions and divisions within midwifery. There was poor working in obstetrics, with a division between consultants and junior staff that left unsupported staff to deal with complex situations beyond their experience. The failure of obstetric staff and midwives to trust and, in some cases, respect each other added a further significant threat to patient safety.

1.148 In sometimes suggesting that the relationships between midwives and obstetricians and neonatologists were satisfactory, staff revealed the limitations in their concept of teamworking. This was, at most, a concept of each discipline doing its own job to an acceptable standard, but within rigidly demarcated and sometimes conflicting roles. In part, this resulted from an inflexible interpretation of a wider maternity debate, positioning midwives as the defenders of women against intervention and obstetricians as the inflictors of over-medicalised models of care.

1.149 This is no basis for effective teamworking in maternity services. Midwives and obstetricians each bring a unique set of skills and experience to maternity care. They should contribute to maternity care as equal and valued partners. But it is inconceivable that they might have objectives that differ. There is not a separate role to promote “normal” birth or to reduce caesarean sections, or to be the “guardians of normality”, any more than there is a separate role to promote safety. A team that does not share a common purpose is not a team.

1.150 We have not found any systematic policy in East Kent maternity services of inappropriately favouring either unassisted birth or assisted vaginal birth in circumstances where this would place women and babies at risk. Those we interviewed were careful to say that there was no such policy. We have found, however, that the way in which “normal birth” was spoken about and set out in material for mothers created an expectation that it was an ideal that staff and women should strive to achieve. On some occasions, this pressure of expectation seemed to contribute to staff decisions not to escalate concerns or to intervene, decisions that were otherwise inexplicable.

1.151 One particular example is the Vaginal Birth After Caesarean (VBAC) Clinic, which started at QEQM in 2005 and was operational across the Trust by 2007. The inherent expectation of the clinic was clearly the promotion of VBAC, and it certainly operated in that way. While VBAC is a welcome and appropriate plan for some women, the benefits must be weighed against the risks, particularly of uterine rupture, taking into account any adverse factors. There were clear examples of women who were at high risk from VBAC where we could find no evidence that these risks were discussed, or that a decision which placed a woman at high risk was communicated to her or flagged to inform her future care. Such decisions need to be taken carefully, free from inherent prejudice about the “best” method of delivery.

1.152 We believe that insufficient attention has been given nationally to the language that is used around “normality” and to the presentation of information, or to the expectations that both can create among both maternity staff and mothers. Language and information that are helpful in the majority of cases can have disastrous consequences when labour does not progress physiologically. We are aware that some recent steps have been taken to improve this, but these are insufficient in our view to remove the risk of misunderstanding and misinterpretation.

1.153 Trainees in all disciplines contribute significantly to the work of maternity teams, providing care while gaining experience. For this to be effective, they need to feel supported, both by their peers and by senior staff, and they also need to take part in supervised learning. We found that clinicians in training did not feel supported; they felt isolated, exposed and vulnerable, and they sometimes worked unsupervised in complex situations beyond their experience. This applied equally to midwives and obstetricians, as well as to paediatricians in some cases.

1.154 We found that bullying and harassment were frequently reported, working relationships with other disciplines did not feel comfortable, and more senior staff could be undermining and unhelpful. There were shortages of junior medical staff and posts often had to be filled by locums, further impeding the development of teamworking. New staff were made to feel unwelcome, were excluded from cliques, and were given challenging cases and expected to manage them without support.

1.155 In part, this can be related to national changes in the training of junior medical staff brought about by the need to reduce working hours and compress training. While both of these have welcome consequences, principally in reducing fatigue and unjustifiably extended training, they also have unwelcome consequences. Shift working reduces continuity of care and increases the likelihood of information loss or error at handovers. The loss of the former “firm” system, in which junior medical staff were part of a stable clinical unit headed by one or more consultants, has reduced the feeling of belonging for staff, as well as the opportunity for staff to develop trust and knowledge of colleagues’ capabilities. It is important that we find ways to counter these unwelcome features and improve the sense of belonging among staff.

1.156 A more longstanding difficulty is the separation of early training into different clinical disciplines, when staff’s future ability to work in teams in a mutually supportive way will be crucial. Staff who work together should train together from the outset, at least in part, and not just in rehearsing emergency drills (which is the most common form of joint training claimed).

1.157 We believe that there is a pressing need to understand the effects of the dynamics of training and education, and how changes made for good reasons have had unintended consequences. More generally, we believe that it is time to think about a better concept of teamwork for maternity services – one that establishes a common purpose across, as well as within, each professional discipline.

Key Action Area 4: Organisational behaviour – looking good while doing badly

1.158 Throughout the period we have investigated, it was clear that the Trust prioritised reputation management to the detriment of being open and straightforward with families, with regulators and with others.

1.159 With families, this was evident in the way in which their concerns were dismissed. Where there were complaints, too often the Trust’s instinct was to manage those complaints rather than to consider what was being said as feedback and learning.

1.160 With regulators and others, we have found that too much effort was consumed in seeking to challenge and undermine any scrutiny. For example, it is revealing that when the CQC report became available in 2014, the Trust *“went through every line, every word of [it] and came up with hundreds of challenges to the report, grammatical, spelling ... rather than actually going to the essence of the report and seeing ‘what do we do’”,* as a member of staff put it to us.

1.161 Unfortunately, these problems are far from restricted to East Kent. Indeed, reputation management could be said to be the default response of any organisation that is challenged publicly. When the end result is that patient safety is being damaged, unrecognised and uncorrected, however, it is especially problematic. At present, the benefits of inappropriate and aggressive reputation management outweigh the meagre risks to an organisation of behaving in this way. This balance must be addressed.

1.162 We have found at Chief Executive, Chair and other levels a pattern of hiring and firing, initiated by NHSE. The practice may never have been an explicit policy, but it has become institutionalised. In response to difficult problems, pressure is placed on a trust’s Chair to replace the Chief Executive, and/or to stand down themselves.

1.163 There may be organisations in which the frequent and short-term appointment of key staff proves effective. It is clear that this approach was not just ineffective in East Kent, but wholly counterproductive. These decisions appear to us to have been made separately from any question of accountability: the effect was simply to rotate in a new face and rotate out the previous incumbent elsewhere.

1.164 In practice, the appointments that were made led the Trust, and NHSE, to believe that things were changing when in fact the underlying shortcomings remained. This approach also led to the term of the then Chief Executive being cut short in 2017, when some of our interviewees suggested that improvements were beginning to be made.

1.165 We are conscious of the damage caused by the succession of appointments as Chief Executive, Chair and Head of Midwifery, but also in other posts. Enthusiasm for the newly appointed individuals created unrealistic expectations that only fuelled criticism when those expectations were not met; this was described to us as a flawed model based on *“heroic leadership”*. NHSE and the Trust have not yet been able to break free of this unproductive cycle.

1.166 The problems of organisational behaviour that place reputation management above honesty and openness are both pervasive and extremely damaging to public confidence in health services. A legal duty of truthfulness placed on public bodies has been proposed as one of the responses to the Hillsborough disaster. It seems that NHS regulation alone is unable to curtail the denial, deflection and concealment that all too often become subsequently clear, and more stringent measures are overdue.

Conclusion

1.167 The Independent Investigation into East Kent Maternity Services has been a challenge to carry out, and at times difficult, but the Panel has never once doubted that it has been so very much more challenging, difficult and personally demanding for the families without whom it would not have been possible.

1.168 We have set out in this chapter the stark findings of deep problems at every level in the Trust, from labour ward clinicians to the Board and external relationships. We have summarised the shocking consequences for the lives of women, babies and families, their health and their wellbeing. We have identified the significant missed opportunities stretching back to 2010 to prevent the continuing toll. We have introduced the four areas for action that we believe are essential to correct the underlying problems in East Kent and elsewhere, and to prevent recurrence. These are considered further in Chapter 6, with a route to taking action in each area.

1.169 Our lasting gratitude goes to the families who put aside for a while the cares they should not have had to bear, to help us to understand the events, and to make the Investigation happen in the first place. We all owe them our undertaking to make things better. It is essential that the findings of this Report are heard, and the necessary actions heeded, around the NHS as in East Kent.

Chapter 2: The Panel's assessment of the clinical care provided

This chapter explains that, had care been given to nationally recognised standards, the outcome could have been different in 97 of the 202 cases the Panel assessed (48%), and it could have been different in 45 of the 65 cases of baby deaths (69.2%).

In the 25 cases involving injury to babies, 17 involved brain damage. This included hypoxic ischaemic encephalopathy (HIE, a type of brain damage that occurs when babies do not receive enough oxygen and/or blood circulation to the brain) and/or cerebral palsy attributable to perinatal hypoxia (insufficient oxygen). Had care been given to nationally recognised standards, the outcome could have been different in 12 of these 17 cases (70.6%).

In the 32 cases involving maternal injuries or deaths, the Panel's findings are that in 23 (71.9%), had care been given to nationally recognised standards, the outcome could have been different.

The Panel has not been able to detect any discernible improvement in outcomes as evidenced by cases over the period within our assessment (2009 to 2020). Our assessment has also indicated that the outcomes and patterns of suboptimal care concerned both the Queen Elizabeth The Queen Mother Hospital at Margate (QEQM) and the William Harvey Hospital in Ashford (WHH).

Introduction

2.1 We have conducted a review of each of the 202 cases where the families involved asked to participate in this Independent Investigation, and where their care by the maternity and neonatal services of East Kent Hospitals University NHS Foundation Trust (the Trust) fell within the scope of the Investigation's Terms of Reference. This chapter describes the review undertaken, our sources of evidence and its results.

2.2 We have reviewed 202 cases, identified using our Terms of Reference and via families who had approached us to participate in the Investigation. In focusing on reviewing what happened in these participating cases, we have had the benefit of richer sources of evidence than we would have had by looking at, for example, clinical records in isolation. Specifically, our review draws upon the following three sources of evidence:

- **Family listening sessions:** In the great majority of the participating cases (189 out of 202), the family was prepared to relive their often traumatic experience for the benefit of this Investigation. In a minority of cases (13), the family wanted their experience to be heard without going through the distressing process of retelling what had happened. In these cases, the Panel focused on the information available in the clinical notes. We wish to place on record our thanks to each and every family, regardless of the decision they took on this point. The family listening sessions have provided a wealth

of evidence, expressed in a compelling way and creating a clear and vivid picture of what happened. In many cases the family listening sessions have included the husband or partner. Where they were present for the birth, their account as witnesses to what happened has proved to be invaluable, often including details which go beyond those available from other sources. In addition, the accounts of husbands and partners are testament to their own personal experiences as events unfolded; they are considered further in Chapter 3.

- **The clinical records:** We have had full access to the records we needed to conduct our review of the 202 cases. We would like to thank the team in the Trust who have made this possible in a full and timely fashion. In every case where the participating families have themselves been given documents, they have been ready and generous in making these available to the Investigation.
- **Interviews with clinical staff and others:** Chapter 4 sets out what we heard more generally from the staff at the Trust, past and present, and from others whose role has shed light on the maternity and neonatal services provided. In conducting our clinical review, we were able to invite to case-specific interviews the staff involved, including midwives, doctors and managers, where we judged that it would be helpful to do so. We are pleased to report that in every such case the person involved agreed to participate. This too has provided a very rich vein of evidence, largely confirming what the families witnessed and were able to recall in their accounts. Some of those interviewed provided additional documents which have helped to complete the picture.

2.3 Drawing upon these sources of evidence, this chapter explains how the clinical review was conducted. It also sets out its results, both in terms of the grading of suboptimal care (using the standardised scoring system developed for the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI)) and the associated harm in each case (adapted from the NHS National Reporting and Learning System (NRLS) definitions of degrees of harm). A fuller description of our process of clinical assessment is given in Appendix B.

2.4 Alongside the clinical review, the Investigation has witnessed the wider range of harm which followed from the experience of the participating families. That wider experience, described in Chapter 3, is no less significant than the clinical outcomes.

Clinical review and grading of cases

2.5 The Investigation spans the period from 2009 – when the Trust achieved foundation status, so acquiring a new degree of autonomy and financial independence – to the end of 2020. A number of women came forward whose pregnancies fell outside the timeline set out in the Terms of Reference or whose approach to the Investigation came after we had completed this phase of our work. The Panel considered information about these cases, for background, but they do not feature within the grading of cases.

2.6 Figure 1 does not show the total number of births in the Trust or indicate where the births relate to suboptimal care or a poor outcome. It does show how the participating cases span the period covered by the Investigation.

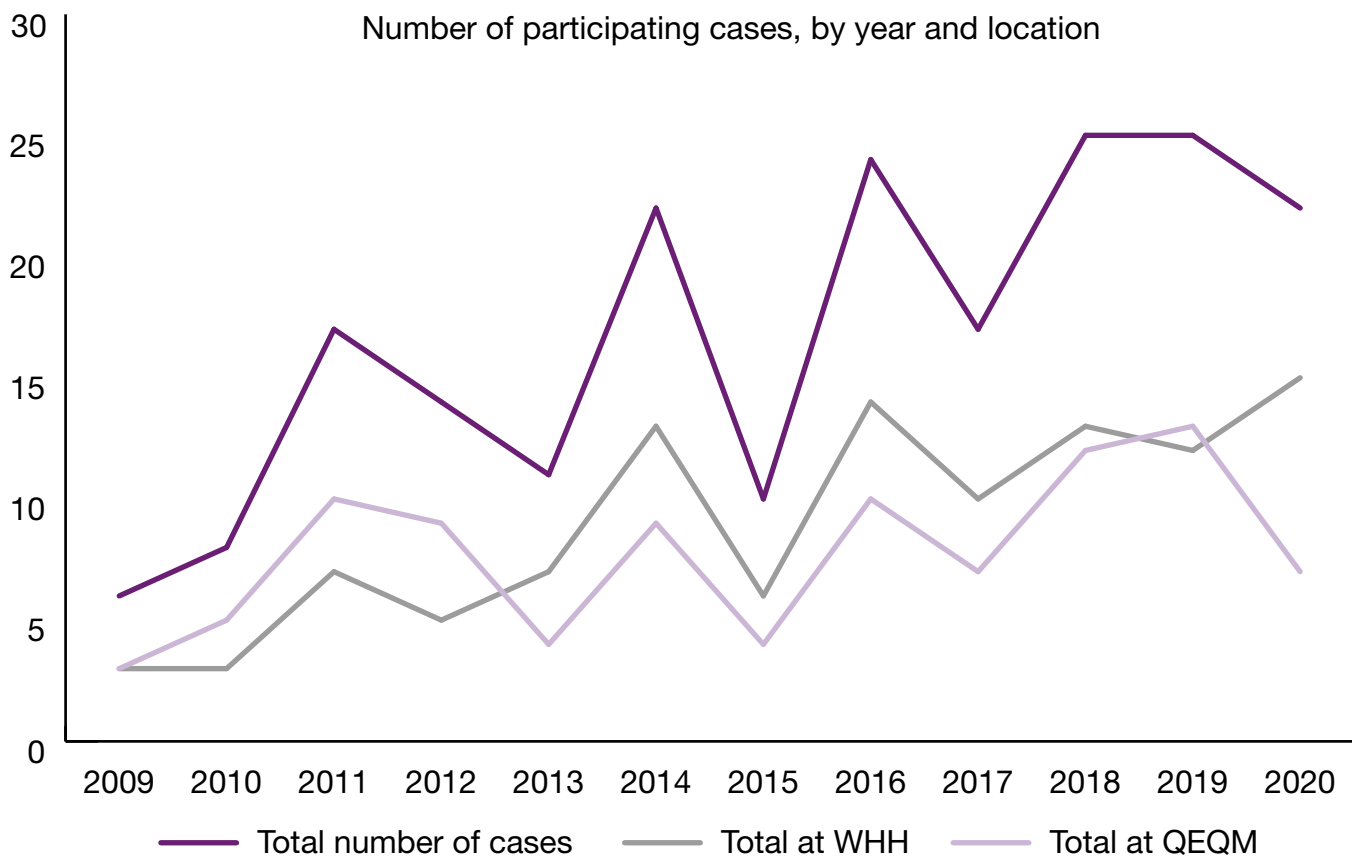


Figure 1: Cases reported to the Investigation by year and location

2.7 With the consent of the families involved, we carried out a thorough review of the clinical records of each woman and baby's care by the Trust's maternity services, adopting a systematic approach (as described in Appendix B). In addition to the clinical records, the Trust provided other documentation such as complaints correspondence, investigation reports and exchanges with GPs.

2.8 The Panel reviewed the records primarily to identify the presence of suboptimal care that might have led to a poor outcome in the period of pregnancy up to labour (antenatal), from the onset of labour through to delivery of the placenta (intrapartum) and in the hours and days after delivery (postnatal for mother; neonatal for baby).

2.9 The Panel came together to consider the evidence contained in the clinical records, with our understanding enhanced by what we had learned from the other sources of evidence. As a result, the assessment of each case reflects the judgement of the Panel collectively.

2.10 All the cases were graded using the CESDI scoring system previously used in *The Report of the Morecambe Bay Investigation*, published in March 2015. This defines four levels of suboptimal care based on their relevance to the outcome (see Table 1).

Table 1: CESDI scoring system

Level of suboptimal care	Relevance to the outcome
Level 0	No suboptimal care
Level 1	Suboptimal care, but different management would have made no difference to the outcome
Level 2	Suboptimal care, in which different management might have made a difference to the outcome
Level 3	Suboptimal care, in which different management would reasonably be expected to have made a difference to the outcome

2.11 In addition to grading the level of suboptimal care, the Panel determined the degree of harm in each case, using a classification adapted from the NHS NRLS definitions of degrees of harm (see Table 2).*

Table 2: Degrees of harm

Degree of harm	Outcomes	Impact on woman and/or baby
None	No harm	There was no impact on the woman or her baby
Minimum	Maternal injury; baby birth injury	The woman or her baby required extra observation or minor treatment
Moderate	Maternal injury; baby birth injury	There was short-term harm and the woman or her baby required further treatment or procedures
Severe	Maternal injury; brain damage, including HIE and/or cerebral palsy attributable to perinatal hypoxia	The woman or her baby suffered permanent or long-term harm
Death	Stillbirth; neonatal death; late neonatal death; maternal death	The woman or her baby died

* Although there are plans to replace the NRLS with the Learn from Patient Safety Events (LFPSE) service, which does not define degrees of harm in the way the NRLS does, the Panel found it helpful to use a form of assessment of harm that is recognisable and understood when reviewing the cases subject to our Investigation.

What the numbers tell us

Suboptimal care and associated outcomes: summary of the Panel's findings

Table 3: Degree of suboptimal care, Trust-wide

Suboptimal care	Relevance to the outcome	No. of cases Trust-wide	No. as a percentage
Level 3	Suboptimal care, in which different management would reasonably be expected to have made a difference to the outcome	69	34.2%
Level 2	Suboptimal care, in which different management might have made a difference to the outcome	28	13.9%
Level 1	Suboptimal care, but different management would have made no difference to the outcome	54	26.7%
Level 0	No suboptimal care	51	25.2%
Total		202	100%

2.12 The Panel's findings, set out in Table 3, mean that:

- **Had care been given to nationally recognised standards, the outcome could have been different in 97 of the 202 cases reviewed (48%).**
- **In 69 of these 97 cases, the outcome would have reasonably been expected to be different.**
- **In 28 of these 97 cases, it might have been different.**

2.13 The Panel found no differences to the outcomes or occurrence of suboptimal care over the time period covered by the Investigation (2009 to 2020). That is to say, we have not been able to detect any discernible reduction in suboptimal care or adverse outcomes over time, as evidenced by the cases we have assessed. Our assessment has also indicated that the outcomes found and patterns of suboptimal care concerned both QEQM and WHH.

2.14 Table 4 gives a breakdown of the range of outcomes in the assessed cases.

Table 4: Outcomes as reviewed by the Panel

Outcome	Total number of cases
Baby death (stillbirth or neonatal death)	65
Baby sustaining hypoxic or other injury during labour or birth	25
Maternal death	4
Injury to mother	28
Other physical harm (psychological harm is considered separately in Chapter 3)	32
No death or injury	48
Total	202

2.15 In relation to baby deaths, drawing upon our assessment of suboptimal care and the breakdown of outcomes, the Panel's findings mean that:

- **Had care been given to nationally recognised standards, the outcome could have been different in 45 of the 65 cases of baby deaths (69.2%).**
- **In 33 of these 45 cases, the outcome would have reasonably been expected to be different.**
- **In 12 of these 45 cases, it might have been different.**

2.16 In relation to cases of injury to babies, drawing upon its assessment of suboptimal care and the breakdown of outcomes, the Panel's findings mean that:

- **Had care been given to nationally recognised standards, the outcome could have been different in 12 of the 17 cases of brain damage (70.6%), including HIE and/or cerebral palsy attributable to perinatal hypoxia.**
- **In 9 of these 12 cases, the outcome would have reasonably been expected to be different.**
 - **In three cases, it might have been different.**

2.17 In respect of cases involving maternal injuries and deaths, drawing upon its assessment of suboptimal care and the breakdown of outcomes, the Panel's findings mean that:

- **Had care been given to nationally recognised standards, the outcome could have been different in 23 of 32 such cases (71.9%).**
- **In 15 of these 23 cases, the outcome would have reasonably been expected to be different.**
- **In eight cases, it might have been different.**

Illustrative cases of suboptimal care

2.18 The findings set out above are stark. But the impact of suboptimal care, while suggested by these findings, goes beyond mere numbers and can best be conveyed through a series of illustrative cases. These are just a few of the examples the Panel has studied, but serve to highlight some of the points that arose in many further cases. The first set comprises three examples of neonatal death (Illustrative Cases D, E and F) and one of antepartum stillbirth (Illustrative Case G).

Illustrative Case D

D's pregnancy was uneventful and she went into spontaneous labour around her due date. Progress was slow, and her baby developed signs of oxygen shortage. After significant delay in recognising the need for urgent delivery, an inexperienced locum doctor attempted an instrumental delivery, which was difficult and hazardous as the baby's head remained high. When this failed, D's baby was delivered by emergency caesarean section, with considerable damage and bleeding. The baby was in poor condition at birth. Resuscitation was inexpertly carried out, with significant delay in establishing an airway, and he died after a few days due to severe hypoxic brain damage.

Illustrative Case E

E gave birth to twins after an uncomplicated pregnancy and induced labour. After a few hours, she reported that the first twin's breathing was laboured and noisy, only to be told by a midwife that *"he's not grunting, he's singing"*. His temperature later dropped, suggestive of infection, and a medical assessment was requested. A middle-grade paediatric trainee attended two hours later but saw no grounds for concern, and significant further delay ensued before a consultant neonatologist initiated investigation and treatment for neonatal sepsis. The delay proved too much, however, and despite transfer to a specialist centre, the baby died of overwhelming streptococcal infection.

Illustrative Case F

F's first child was born by caesarean section following lack of progress after full dilation of her cervix. When she became pregnant again, F was keen to have a vaginal birth with as little intervention as possible. At her first meeting with her consultant, F and her partner were deeply disappointed to be advised that she should give birth in an obstetric unit, where she could be monitored effectively in view of the risk of uterine rupture.

The couple deferred their decision, but as F's due date approached, they decided they wanted their baby to be born in a midwifery-led unit alongside an obstetric unit, with a doula present. They were aware that this was against recommendations because of F's high-risk status. The couple met with the consultant midwife at the Vaginal Birth After Caesarean (VBAC) Clinic, who refused to book F for delivery in the midwife-led unit on the grounds of safety. When the couple resisted the recommendation of delivery in the hospital's obstetric unit, the midwife suggested that in that case they should consider a home birth.

The couple remained very averse to the obstetric unit, and a plan was drawn up with midwifery staff for a home birth. Despite the obvious risks, which had already been regarded as sufficient to close off the option of birth in a midwifery-led unit, no formal assessment of the risk to mother and baby of a home birth was made. Neither was any consideration given to allowing F to give birth in a midwifery-led unit as an exception to protocol.

F went into labour a few days after her due date and her contractions soon became strong. After some time, progress in labour slowed and F was transferred by ambulance to the nearest hospital obstetric unit. Once there, concerns about the baby's heart rate resulted in F being taken to theatre for an emergency caesarean section. Baby F was born with signs of brain damage and required specialist care. She died soon after.

Illustrative Case G

G progressed fairly uneventfully in her second pregnancy up to 36 weeks, when an ultrasound scan showed an excess of amniotic fluid around her baby. At 38 weeks, she reported reduced fetal movements, and although the baby's heart rate record (cardiotocography or CTG) showed no adverse features, she had a second episode of reduced movements two days later. A repeat ultrasound scan showed marked levelling off of the baby's growth. G recalls induction of labour being discussed in general terms, but felt concerned about the risk of cord prolapse, which she had been told was raised because of the excess amniotic fluid. There is no record of discussion of the risk of continuing with the pregnancy in light of the adverse findings of reduced growth, reduced fetal movements and excess amniotic fluid. Despite these obvious adverse factors putting her baby at risk, G was sent home with an appointment to return at 41 weeks. Two days before term, she attended again, having felt no fetal movements for a period of six hours. No heartbeat could be found.

2.19 The second set of illustrative cases comprises examples of HIE (Illustrative Case H) and maternal injury (Illustrative Case J).

Illustrative Case H

H experienced reduced fetal movements and attended QEQM. The CTG showed very abnormal features from the start and was seen by an obstetrician who recognised its nature but who was about to start another caesarean section. This situation should have been escalated immediately to the consultant on call but was not. In all, it took 70 minutes before the decision that an emergency caesarean section would be necessary was confirmed, the need for which should have been obvious to clinicians from the outset. Meanwhile, the baby's heartbeat had slowed significantly, and was undetectable as the caesarean section was about to commence. The baby was in very poor condition at birth, with profound hypoxia. There was delay in establishing an airway because the correct tube for intubation was not immediately available, but after eight minutes pulse and respiration had become established. The baby was cooled and transferred to WHH for neonatal intensive care. He suffered further problems related to severe HIE and has been left with significant brain damage.

Illustrative Case J

At 41 weeks, J attended for a booked induction of labour. Progress was slow in labour, and a caesarean section was undertaken. The baby was delivered in good condition, but there was significant bleeding from J's uterus because the incision had extended into the uterine artery on one side. The surgeon was inexperienced, and did not recognise the dangerous nature of the situation at first or the need to escalate to consultant level immediately. In trying to control the bleeding, a stitch was wrongly placed around the ureter on that side, jeopardising kidney function. J required emergency intervention by a urologist to conserve kidney function and by an interventional radiologist to embolise (create a blood clot in) the uterine artery to control bleeding. She recovered after a difficult postoperative course, including the need later to remove part of the placenta from her uterus, but was left with prolonged pain.

2.20 The final set of illustrative cases in this section comprises examples of maternal death (Illustrative Case K) and intrapartum stillbirth (Illustrative Case L).

Illustrative Case K

K was booked for an elective caesarean section. She had previously had an emergency caesarean section following a complicated pregnancy, and was at raised risk of venous thromboembolism, blood clots that may travel to the lungs and cause pulmonary embolism (a serious emergency). K's raised risk was not identified before the elective caesarean section, but it was noted on medical assessment on the first postoperative day, with an instruction that she should have ten days of preventive treatment with an anticoagulant. This was not acted upon, and K had no preventive treatment after the first postoperative day. Her discharge notification incorrectly stated that thromboembolism prevention was not required. Three weeks after the caesarean section, K collapsed at home and subsequently died from extensive pulmonary embolism.

Illustrative Case L

L, an older mother with a raised body mass index (BMI), was in her sixth pregnancy. Her last pregnancy had ended with an emergency caesarean section after prolonged spontaneous rupture of the membranes, with sepsis. As was routine, she was referred to the VBAC Clinic to discuss having a vaginal birth. There is no record that any of the additional risk factors particular to L were recognised or discussed with her, and she chose to follow the VBAC pathway. At two days post term, she had an induction of labour with a prostaglandin pessary. L reported excessive pain from the outset, which was unresponsive to tramadol and pethidine administered without an obstetric assessment. After four hours, labour was not progressing and she was still reporting excessive pain. She asked for a caesarean section, but her request was denied. After another four hours, a trace of the baby's heart was attempted (monitoring had been only intermittent despite the risk factors), but no heartbeat could be detected, and the death of her baby was confirmed. A consultant discussed the intended mode of delivery and offered a caesarean section, without apparently recognising the implications of the intrapartum death and L's severe pain. At caesarean section, three hours later, her uterus was found to be ruptured and her abdomen full of blood. L recovered after a difficult postoperative course.

Narrow escapes

2.21 The Panel found that, in a few cases, there was suboptimal care that did not lead to a poor outcome or which led to an outcome that could have been much worse. We do not consider these to be "near misses", things that were prevented from happening because they were identified in time and action taken; rather, they are examples of suboptimal care that went unnoticed, which purely by chance did not result in a poor or even grave outcome for the woman concerned. They are "narrow escapes". As such, they too have informed our view about the Trust's failure to ensure the provision of safe care to families. This point is exemplified by the following illustrative case, an example of a maternal injury considered by the Panel to be a narrow escape.

Illustrative Case M

When M's labour began, at 41 weeks in her first pregnancy, she went to hospital where her cervix was found to be almost fully dilated. She was pleased to be able to use the birthing pool, and soon began pushing. After about two and a half hours, her cervix was confirmed as fully dilated. However, there was no progress apparent and she began to become exhausted. She was transferred to obstetric care. Three hours after confirmation of the second stage of labour – which should not normally last for more than two hours in a first pregnancy – a plan was made to allow a further hour for the baby's head to descend. An epidural was then set up, and a further hour *"allowed for descent"*. After five hours of confirmed second stage labour, with the baby's head in a transverse position and still not descended into the pelvis, a trial of instrumental delivery was undertaken. There was no descent of the baby's head with four pulls on the forceps, and a caesarean section was undertaken after six hours of confirmed second stage labour. The mother suffered perineal damage from the attempted instrumental delivery, but fortunately her baby remained in good condition.

Failure to listen to parents

2.22 In assessing cases, it has been striking how the avoidable factors we identified match many of the issues of concern that families themselves brought to our attention in the listening sessions we held with them. It is clear to the Panel that women had raised many of these concerns with their doctors and midwives while they were receiving their care. This is an important point, not least because it emphasises the role of women themselves in achieving a good outcome.

2.23 An overriding theme to have come from the listening sessions is the tendency of midwives and doctors to disregard the views of women. In fact, in a significant number of cases, the Panel found compelling evidence that women and their partners were simply not listened to when they expressed concern about their treatment in the days and hours leading up to the birth of their babies, their concerns often dismissed or ignored altogether. In at least some of these cases, the Panel was able to draw a connection between that failure to listen and an adverse outcome.

2.24 The illustrative cases below provide examples of this theme. They describe the circumstances surrounding an antepartum stillbirth (Illustrative Case N) and a failure of neonatal diagnosis (Illustrative Case O). These are further examples of what the Panel found to be a failure to listen to women or other family members that contributed to an adverse clinical outcome.

Illustrative Case N

N's first pregnancy progressed normally until 37 weeks, when she reported abdominal pain and altered movements by her baby. She was admitted to hospital for observation. She was not in labour, and intermittent CTG recordings of her baby's heart were within normal limits. A blood test indicative of infection was noted in her records but was not followed up, and she was allowed home the following day with no further arrangements or follow-up scheduled other than a routine appointment in two weeks. When she attended at 39 weeks, N reported reduced movements again, and her baby's heart was not heard. A stillborn baby was delivered the following day. Subsequent post-mortem examination confirmed the presence of an acute infection of the membranes inside the uterus.

Illustrative Case O

Baby O was very quiet and lethargic, and hadn't fed since he was born. Just after 11pm, about three hours after delivery, he started to vomit and O called for help and asked for clean bedding. By 1am, he still hadn't fed and vomited again. O called for help again and told the midwives that something was wrong, that her baby hadn't fed and was vomiting green bile. She was told this was normal, and no checks were done or further enquiries made. In the morning, O told the nurse that she was really concerned, that her baby had been sick all night and still hadn't fed. This was at the change of shift and the sister who came on duty raised the alarm. Doctors attended immediately and inspected the sheets, removed the baby's nappy and asked whether he had passed a stool, which he had not. He was then transferred to the Intensive Therapy Unit. Baby O had been born with no anorectal canal and complete intestinal obstruction. It had taken 14 hours from his birth to identify this condition, rather than it being picked up by the midwife at the newborn check or later in response to the mother's concerns about his bilious vomiting. During this time, baby O's condition had deteriorated significantly because his developing electrolyte imbalance had not been corrected with intravenous fluids and attempted feeding had continued. He required specialist surgery at another hospital and prolonged follow-up.

Conclusion

2.25 This chapter has set out the Panel's assessment of the clinical outcomes experienced by the women and their families who contributed to our Investigation, and the extent to which these outcomes could have been different in the absence of suboptimal care. It shows that, in nearly half of the cases assessed by the Panel, the outcome could have been different had care been given to the standards expected nationally.

2.26 The findings on clinical outcomes are stark. But the issues go wider and deeper than the clinical practice evident in the cases we have assessed. In other cases, including the 54 where the assessment of suboptimal care was at Level 1 and different management would have made no difference to the clinical outcome (see Table 3), or in the 48 cases where the Panel found that there had been no injury to the mother or baby (see Table 4), the care provided fell short of expected standards of service. We repeatedly heard that women's confidence in their care, and in the Trust more widely, was lost because of poor communication, a failure to engage and an unwillingness to involve women in decisions about their care.

2.27 In particular, an overriding theme, raised with us time and time again, is the failure of the Trust's staff to take notice of women when they raised concerns, when they questioned their care, and when they challenged the decisions that were made about their care. This is considered in more detail in Chapter 3, along with other aspects of the families' experience.

Chapter 3: The wider experience of the families

“You go to hospital to trust people, because your life is in their hands, and you never expect one of your family members or you to be let down by the system like that; it’s really scary.”

“The experience has affected all of our family but particularly myself and [my daughter] ... she is my baby and I cannot do anything to take her pain [of her lost baby] away.”

“We want to move forward and actually live our lives a little bit. We don’t want this to be our lives ... we want to move on. It’s difficult; you’re stuck. You lose whatever you do. We feel like we’re not doing H justice or we’re not doing ourselves justice. Whatever you do, you can’t win.”

This chapter describes the wider experiences of the families beyond the clinical outcomes described in Chapter 2. It identifies six common themes:

1. Not being listened to or consulted with
2. Encountering a lack of kindness and compassion
3. Being conscious of unprofessional conduct or poor working relationships compromising their care
4. Feeling excluded during and immediately after a serious event
5. Feeling ignored, marginalised or disparaged after a serious event
6. Being forced to live with an incomplete or inaccurate narrative.

Illustrative cases show how these themes featured in individual situations. These are just a few of the many accounts that we heard. The Panel has been struck by the extent to which there has been a deep impact on the wellbeing of families that continues to this day, sometimes many years after the birth. This is described towards the end of the chapter.

Introduction

3.1 In this chapter, we set out what we learned from the families we spoke to about what was important to them while they were under the care of East Kent Hospitals University NHS Foundation Trust (the Trust); how they felt they were treated by the midwives, doctors and others who looked after them; and in what ways they felt let down. It should be said that, among the stories of individual and systemic failures, there were also examples of good care by individuals, as well as compassion and kindness.

3.2 Our starting point for the Investigation, and a core principle underpinning our work, was an acknowledgement that the experiences of women and their families were key to our gaining an understanding of what was happening in the Trust's maternity services during the period under scrutiny.

3.3 Equally important was the Panel's undertaking to carry out an expert clinical review of what had happened in each case, including selected interviews with staff. The Panel's meetings with families, referred to as family listening sessions and described below, provided the contextual information and a sense of families' own experiences. Both these were invaluable to the Panel in its later review of individual clinical notes and its ability to make broader judgements about women's clinical care and any consequences.

How we engaged

Family listening sessions

3.4 The women and their families were a primary source of evidence. In family listening sessions with Panel members, they shared their knowledge, experience and perceptions of the care they received, often providing poignant and moving descriptions of their treatment by those responsible for their care, in whom they had placed their trust. This process was sometimes difficult and painful and we are indebted to them for their courage and willingness to engage fully with the Investigation. Their accounts tell us much about the Trust's culture and organisational values throughout the period under scrutiny, as practised rather than espoused: in other words, the gap between what the Trust said it did and what it actually did. We believe that this gap itself contributed to the poor outcomes experienced by the women and their families who participated in our Investigation.

3.5 It is important to acknowledge the experiences of the husbands and partners whose contributions, in themselves, have been invaluable. Not only have they had to deal with their own sense of pain and personal loss, but they have also had to provide ongoing care and support to their wives and partners, many of whom continue to have difficulties. In addition, some of our couples have experienced relationship difficulties – particularly around intimacy – greater than those that might be expected following a normal pregnancy and birth, and continue to do so.

3.6 Every family was given the opportunity to meet members of the Panel in a family listening session, either by video (an imperative in the early months of the Investigation because of the Covid-19 pandemic) or, if they wished and it was possible, in person. Our early reservations about using video for such sensitive encounters were soon allayed, as the benefits of allowing people to contribute from the safety and security of their own homes became apparent and, without exception, they spoke freely and candidly about what had happened to them.

3.7 We were also careful to correlate what we heard in family listening sessions with what was recorded in the clinical notes in each case and, where necessary, to interview relevant staff about the events.

Trauma-informed counselling

3.8 Mindful of the additional anxiety and distress that might be caused to them by having to recount and possibly relive their experiences, we offered each family the opportunity to attend a session with an expert counsellor.

3.9 Like many who have experienced trauma, our women and families frequently described a sense of not being able to cope or to live their lives as they had before because of what had happened to them. The aim of our counselling was to support families as well as possible after they had relived their experiences with the Panel, seeking to increase their personal confidence in making decisions about how to manage the impact of the harm done to them. The counselling was the start of this process for some, while others were further on in their journey. For all, it was an opportunity to reflect and take stock.

3.10 We were struck by how many families took up the offer of counselling as a result of participating in a family listening session. We believe this, in itself, is a sign that these families had experienced a significant effect on their wellbeing. In total, 54 families (more than a quarter) attended counselling sessions, some more than once. In some cases, families were signposted to other counselling services for further suitable support.

Themes and behaviours

3.11 Putting aside issues relating to the technical aspects of clinical care, which are covered in Chapter 2, there are a number of overarching themes that characterise the experience of the participating families. This is particularly concerning, given that the cases span an 11-year period up to as recently as 2020. It suggests that the themes are symptomatic of deep-rooted and endemic cultural problems across the Trust, which continue to hamper staff and compromise the safety of maternity services.

3.12 Although there are overlaps across the range of themes in this context, they can be grouped into those that feature in the period up to and immediately after birth, and those that relate to families' experiences after a poor outcome.

3.13 From our analysis, each theme can be characterised by particular indicative behaviours. We believe these have been detrimental to the quality and safety of the care given to women, and to the overall experience of them and their families (see Table 5).

Table 5: Themes arising from family listening sessions

Theme: experience of women and their families	Indicative behaviours of staff
1. Not being listened to or consulted with	• Not listening to women's concerns or not taking them seriously, resulting in a failure to recognise warning signs or a deteriorating situation • Not taking the time to explain to women or their families what was happening or involving them fully in decisions about their care • Failing to keep accurate notes about what women themselves were saying and how they were feeling
2. Encountering a lack of kindness and compassion	• Showing a basic lack of kindness, care and understanding to women and their families • Making unkind or insensitive comments to women and their partners • Showing an indifference to women's pain • Failing to ensure or preserve women's dignity or provide for their basic needs • Placing women with other mothers and their newborn babies following the loss of their own baby or after a serious event • Putting pressure on families to consent to a post-mortem examination
3. Being conscious of unprofessional conduct or poor working relationships compromising their care	• Making rude, inappropriate or offensive comments to women and their partners • Behaviours or comments that undermined colleagues, including public disagreements and raising concerns directly with women about their care • Disagreements between individuals in the same or different professional groups about women's care, including giving mixed messages • Failing to pass on or act on information, including failing to hand over effectively at shift change or to communicate effectively between services • Shifting the blame for a poor outcome onto colleagues
4. Feeling excluded during and immediately after a serious event	• Not being told what was happening, or what had happened, when things went wrong • Leaving family members waiting and anxious for news

Theme: experience of women and their families	Indicative behaviours of staff
5. Feeling ignored, marginalised or disparaged after a serious event	• A collective failure to be open and honest or to comply with the duty of candour • A collective failure to act on or respond to concerns, including a poor or inadequate response to complaints • A tendency for the Trust to fail to take responsibility for errors or to show accountability • A failure to provide adequate follow-up support, including appropriate counselling
6. Being forced to live with an incomplete or inaccurate narrative	• Blaming women and families, or making them feel to blame, for what had happened to their baby • Not giving women and their families answers or reasons for why things had gone wrong

3.14 Each of these themes is considered in turn in the following pages. We have included a selection of illustrative cases and direct quotations from families relating to each theme, to add weight to our findings and because they speak for themselves.

3.15 It was common for families to experience behaviours spanning the range of the themes we identified, which had an additional and cumulative impact on them. A more in-depth illustrative case is included later in the chapter to demonstrate this.

Theme 1: Not being listened to or consulted with

3.16 As in previous investigations into maternity services, we have found strong evidence at East Kent maternity services of a failure to listen to women and their families.

3.17 We saw in Chapter 2 that not listening to women and their partners risks there being a poor clinical outcome, with the Panel finding examples of a clear link between a failure by clinical staff to take notice of women's concerns and the poor outcome they experienced. However, this recurring theme emerged from our review not just as one that had potential clinical consequences, but as one that had a broader and deeper impact on the families concerned.

3.18 Not being listened to or not feeling that they were involved in decisions about their care undermined women's confidence in those providing that care and caused them to feel uncared for and, in some cases, unsafe. This was particularly the case when the woman was aware that she was high risk or had been told by a doctor that her pregnancy was considered to be high risk.

3.19 This "not being listened to" took several forms. We saw a pattern of women, particularly first-time mothers, being made to feel patronised and demeaned when their concerns were dismissed as overreactions and unnecessary anxieties based on "first-time nerves". There were women whose concerns about the wellbeing of their unborn babies were ignored; and women on their second or later pregnancies whose personal knowledge, experience and understanding of their own bodies informed their convictions that something was wrong, but whose concerns were either ignored or dismissed. There were also women whose legitimate concerns about their newborn babies were not taken seriously.

Indicative behaviour: Not listening to women's concerns or not taking them seriously, resulting in a failure to recognise warning signs or a deteriorating situation

3.20 We heard about:

- Women's feelings or concerns about their symptoms being dismissed:
 - *"A lot of it was that no one listened, every time I went to hospital. If they had, it might have been a very different outcome."*
 - *"I know I haven't had a baby before but this is my body and I know what's going on, and this doesn't feel right, this doesn't feel safe. I was expecting to be in pain, I'm not stupid, but this feels unsafe, this amount of pain; and being told, 'you've never had a baby before, I don't know what you expected'."*
 - *"I was saying 'look, I'm really swollen', but they didn't listen, they didn't take on board the things I was pointing out."*
- Women's concerns about reduced fetal movements being ignored:
 - *"I just wish so hard that when I went and said she was not moving the way she should be, that if they'd listened to me seriously ..."*
 - *"I had gone into day care with reduced movements; having had babies before, I knew that was a big no-no and I was shocked really, the whole approach was very dismissive, I felt like I was wasting their time for being there."*
 - *"The last thing I wanted was to be sat at the hospital, when I already had a three-year-old at home. I wasn't there to waste their time. I was there because I thought something was genuinely wrong. Even if there was nothing wrong, and I was just being neurotic, they still could have done things to support you rather than just be completely dismissive ... There were so many things that could have been different, that would have helped me feel like I wasn't going completely mad and maybe prevented the outcome."*
- Women's assertions that they were in labour or that their waters had broken being dismissed:
 - *"My waters went at 18 weeks and I went to [the hospital] and told them and the whole time I was there, they just told me that they hadn't gone and I was like 'I think they have' but they didn't believe me at all; I think it was that night that they did a scan, and it came back that my waters had gone, so quite a distressing time, and all I was told was 'it's not too late to have an abortion if you want to'; the whole day, the whole night, that's all they kept offering me."*
 - *"My waters broke when I came out of the shower and I mentioned it to the nurse, and she was quite dismissive of it, thinking it was just water from the shower dripping off my body ... and I don't feel that anything was picked up then; obviously now, looking back, that was really key, for me to be monitored after that particular time."*
 - *"I was in a side room on a bed waiting for obs, but as I stood up, there was this big gush, you know, like water, and they told me I'd weed myself; and I said, look, I have not weed myself, I'm so sure this is my waters gone, I would know if I'd weed myself ... again, I'm still being dismissed."*

- Women's concerns about the progress of their labour or the delivery of their baby being dismissed:
 - *"No one was trying to make the situation any better, apart from telling me that I was doing it wrong, and I wasn't doing enough to get the baby out ... I didn't feel supported by anyone in the room or that anyone really cared when I was telling them 'my body is telling me this isn't going to happen'."*
- Women's concerns about their newborn babies being disregarded:
 - *"I felt everyone was quite patronising and playing it down and we were trying to tell them that something was wrong ... We could see the deterioration. We never saw the same midwife. When he didn't open his eyes, I spoke to two midwives, one said to the other 'first-time parents'."*

Indicative behaviour: Not taking the time to explain to women or their families what was happening or involving them fully in decisions about their care

3.21 We heard about:

- Women being left frightened or uncertain because of a failure to communicate with them effectively:
 - *"We weren't really told much but I was told that sepsis is the main killer of babies and as a new mum I was petrified."*
 - *"No-one was telling me what was actually going on, they were just telling me what they were doing. They weren't explaining things. I was clueless."*
 - *"Although they tell you things, they don't tell you things how you need to hear them."*
 - *"Every time I tried to sit up, I was physically forced back, to lie back down. I was having flashes in my brain of old films about mental hospitals and things where people are forced to lie down and strapped in, and that's what it felt like especially with all the wires."*
- A failure by doctors and midwives to explain risks and ensure that women were fully informed, including when seeking consent:
 - *"Nobody talked through the risks of a VBAC [vaginal birth after caesarean]. Had I known, I would not have put my baby at risk and would have elected for a C-section ... there was no discussion about any risks associated with VBAC induced pregnancies, or the fact that I was an older mum and overweight."*
- Women feeling patronised and that they were not getting answers to their questions:
 - *"Because of my age, I was 19, I think that made her feel she could get away with not explaining things to me; it was like she thought I was stupid and she knew better."*
 - *"She didn't give me any answers, which I think is a massive thing. If she had just explained her thought process, it would have helped so much."*
 - *"Above all, no matter how old you are, you should be listened to."*
 - *"My midwife wasn't interested in talking to me ... she would just say just speak to your doctor or have you had a look on Google; but you want reassurance."*

- A reluctance of staff to discuss women's birth plans or to try to comply with their wishes:
 - *"I got the impression that the decision was made there and then, anything I thought was pretty silly because she's the nurse and she knows better than me, because I'm just the mother; I came out thinking that I was banging my head against a brick wall, she just wasn't listening."*
 - *"It was a battle to be heard from day one, it was 'I'm the clinician, I'll make the clinical decision'."*
 - *"I didn't think they could do things to you after you said 'no', but they did. It makes me scared to give birth in future; it makes me feel like I would end up giving birth at home with no one there because I'm so scared of midwives just doing what they want and not having my best interests and not listening."*
 - *"When I asked about alternatives to induction, I was met with 'if you don't get induced and if anything happens, it'll be your fault'."*
 - *"It very much felt like it was something being done to you, and not something we were involved with. 'This is what has to happen, and because it has to happen it doesn't matter what you think. This is what the list says we need to do.'"*
- Women feeling pressured about the mode of delivery:
 - *"The sister just looked at her and she said 'that's a swear word in my ward; we don't talk about C-sections in this ward, you'll be alright, you will be able to push this baby out'."*
 - *"It felt a little bit like the choices were out of my hands; as a patient, you know nothing and they know everything."*
 - *"I can't explain it, but I had this feeling that I wanted the babies to be delivered and I wanted a C-section; I asked the staff and was told we don't do C-sections because the mother is uncomfortable, it's not about the mother."*
 - *"They threatened me, it felt like, with a caesarean. 'If you can't be bothered to deliver this baby on your own, we'll have to do a caesarean. Is that really what you want out of this situation?' As if I was somehow being lazy, or just not doing what I needed to do."*
 - *"At one point, X said to her, 'hang on, why are you going to try forceps now when we've just agreed to a C-section? My wife has said she doesn't want forceps, she would much prefer a C-section.' Maybe we were being naïve that we had some sort of a say in this. She turned around and really snapped back and told [him] off saying, 'I'm the clinician, I'll make the clinical decision', and then stormed out."*
- Women being poorly communicated with and browbeaten to give consent in emergency situations:
 - *"That ultimatum on the operating table with someone stood over you with a scalpel in one hand was just like something from a horror film. It was so scary. These women who had been treating me, by this point I thought that they would do anything to me without consent."*
 - *"The doctors were rushing around, using words that made X anxious and she couldn't understand what they were saying. They wanted her to sign papers to say that she was happy to go to theatre, but she didn't understand what was happening or what she was signing. She was crying and shaking."*

- *“The doctor turned around to me and went ‘you need to start thinking about your baby’. I wanted to know what was going to happen. I didn’t know if they were planning for me to have a caesarean. I didn’t know what I was signing for. I signed the form because I didn’t want them to think I wasn’t thinking about my baby.”*
- *“I remember one of the midwives saying do you understand what’s going on? And I just said, C-section ... they didn’t ask if it was ok to use forceps ... and that’s what they did. I didn’t understand why they did it without asking ... I felt violated.”*

Indicative behaviour: Failing to keep accurate notes about what women themselves were saying and how they were feeling

3.22 We heard about:

- Women’s concerns that their notes were inaccurate, with important aspects of their care missed out or incorrectly recorded:
 - *“So many times throughout the pregnancy I said I’m worried about this, I’m concerned about that, I’m not feeling great, but my notes just seem to say ‘mother was happy’.”*
 - *“They haven’t written any epidural request, any caesarean request, any help request. Nothing. They just did their own thing.”*
 - *“He [the consultant] went through my notes and said there is nothing in here that tells me about that [dysphasia]; and there was nothing in there that told him that her collarbone had broken and that we’d had an x ray – in her maternity notes – the slightly alarming thing for me is that, whatever happened, it hasn’t been recorded in the notes. To me, that’s alarming and it means that something’s wrong.”*

3.23 It is the Panel’s estimation that, in a significant proportion of cases, this failure by midwives and doctors to listen to what women were telling them was a feature of the care experienced.

3.24 Overall, we found “not being listened to” to be part of a broader tendency of clinical staff to fail to engage women in the management of their care.

Theme 2: Encountering a lack of kindness and compassion

3.25 The Nursing and Midwifery Council publishes professional standards which govern the activities and behaviours of nurses and midwives. Its first standard is *“treat people with kindness, respect and compassion”*.¹ Similarly, the General Medical Council publishes professional standards that govern the activities and behaviours of doctors. It states: *“You must make sure that your conduct justifies your patients’ trust in you and the public’s trust in the profession.”*²

3.26 The public might expect that kindness and empathy would characterise maternity and neonatal services anyway, without reliance upon a professional standard. Given the long-standing existence of professional standards set by regulatory bodies and the legitimate expectations of patients and their families, it is all the more concerning that lack of kindness and empathy features so heavily in our families’ accounts. We heard about behaviours of both midwives and doctors that fell some way short of those expected standards and legitimate expectations. In fact, in a majority of cases, families described aspects of their care that they felt were the result of unkindness and a lack of compassion and empathy.

Indicative behaviour: Showing a basic lack of kindness, care and understanding to women and their families

3.27 We heard about:

- Women and families who felt uncared for and unwanted by doctors and midwives:
 - *“They are meant to be there for you ... I was a first-time mum; I was worried and I didn’t know how it all worked. It was unbelievable how I was treated.”*
 - *“There were so many failures that it’s hard to sum up ... It wasn’t even the physical medical things that happened ... it was the treatment from the people, the way we were treated, the way we were spoken to, with no human decency whatsoever, no bedside manner, no consistency, no continuity of care, the list goes on and on. And I think that is the culture, that is the culture there. It is this conveyor belt, where they are so immune to it, they forget that the women are even there.”*
 - *“If they had just cared, it would have made the blow a little less; a bit of support, a hug, just something, but there was nothing. It was really hard.”*
 - *“I came away from the experience very scared and humiliated. That’s what I took away from the experience of childbirth.”*
 - *“The care for my son was second to none. The care for me was diabolical.”*
 - *“I’m a carer and if I had acted like some of the midwives I would have been taken into the office and disciplined.”*
 - *“It just felt like a really lonely and traumatic experience, which I feel like maybe if it had been a more experienced midwife or someone else there, that I would have got that reassurance and encouragement that is really important when you’re having a baby, let alone in traumatic circumstances.”*
 - *“I felt like I was a nuisance.”*
- An apparent lack of awareness or a failure to take account of pre-existing mental health conditions or personal histories which made women particularly vulnerable to feelings of fear or anxiety:
 - *“The feelings are so similar to the sexual abuse but this time I’m left with a physical disfigurement as well as the mental side of it.”*
 - *“They were going to do an internal; I am a survivor of childhood sexual abuse and it was a male midwife and a male doctor; it’s making me sweat just thinking about it ... it was horrible.”*
 - *“I used to suffer with mental health issues ... that was in my notes with my first pregnancy and it went on my notes for my second but my community midwife, who I have to say has been amazing afterwards, she did take it off my notes at one of my appointments and that’s concerning for me actually now, looking back ... I did bring it up with [name], one of the midwives at the hospital, she did go away and speak to a doctor, who she said said to her, just put her on Sertraline ... and I don’t want to go back on tablets, I spent a long time coming off tablets.”*
- The needs of family members not being met, and in particular a tendency to leave people waiting, knowing that something has gone wrong but not being given any information:
 - *“X was taken back to theatre and I went to the ward to find the rest of the family and the new baby. They had been told to wait in a four-bedded bay; they were standing*

in the space where X's bed would have been, huddled together and crying behind the curtains, surrounded by the three other women in that ward and their babies."

- *"No one said anything to me ... I think at that point it probably would have been better if I had been told, look, there is something serious, given I could have probably switched into a more supportive role ... I always look back and feel quite guilty that at that time I wasn't supportive enough and actually I was sitting there and I was just questioning everything and thinking well maybe I'm just being overly worried here and there is nothing. I would probably have preferred to have known at that point"* [the reflections of a woman's partner recalling the moment he realised that their baby was ill; it was several hours later that they were told the gravity of the situation].
- Women or their partners calling for help and feeling ignored when no one came:
 - *"Within minutes, I began to feel very unwell and began shaking violently and vomiting. We pressed the emergency buzzer, but no one came. X [her partner] then went out into the corridor to try to find someone to help, but could not find anyone, so was left to deal with the situation alone."*

Indicative behaviour: Making unkind or insensitive comments to women and their partners

3.28 We heard about:

- Women and family members feeling patronised, being ignored or "told off", or being subject to hurtful remarks:
 - *"Some parents just aren't supposed to have children"* [a woman recalling the comments of a doctor].
 - *"I was told at one point it was because I was fat. It wasn't even beating around the bush, saying 'because of your weight' or anything like that: it was 'well, because you're fat, that's how it is and we have to do different things'."*
- Women feeling that they were unimportant and too much trouble:
 - *"She said sorry for your loss, but our baby was dead and there were other babies who were still living that she needed to attend to."*
 - *"We have more important people on this ward, you are not the only one who is in need at this point"* [a woman recalling the comments of a midwife made to her while she was waiting for a blood transfusion].
 - *"They would make me feel terrible ... every time I went, they would make me feel like I shouldn't be there."*

Indicative behaviour: Showing an indifference to women's pain

3.29 We heard about:

- Women in acute pain feeling ignored and being left without appropriate pain relief, their pain sometimes being dismissed:
 - *"I wanted to die, I was in so much pain."*

- *“The pain was horrific pain but the midwives who examined me said I was fine. I was in so much pain that I couldn’t place my feet flat on the floor, but they just told me I was doing well. I felt like nobody was listening to me and they couldn’t be bothered.”*
- *“She said ‘you’ll have to wait, I’m busy, I’ve got other things to do’; and I waited two hours, I spent two hours crying in pain before I rang the bell again because I was too scared, in case she started having a go at me again.”*
- *“People give birth in Africa in mud huts without pain relief”* [a woman recalling the comments of a midwife made to her during her labour].
- *“I still have nightmares to this day, of feeling that pain so vividly.”*
- Women feeling pain because of a failed epidural or spinal,* or one that was wearing off:
 - *“He came and did these manual evacuations; my spinal had started to wear off a bit and he was going up with his hand right into my uterus and pulling out all the clots it was the most painful thing I’ve ever experienced in my whole life ... he was looking at me and said to me, Oh, is that painful? And I was like, yeah, your hand’s right up there, my spinal’s wearing off and I’ve just had surgery ... He didn’t seem to have any feeling ... The midwife said to me oh my God, they were looking horrified; they couldn’t hide their looks”* [a woman describing how a registrar proceeded with manual evacuation of placental tissue as her spinal was starting to wear off].
 - *“I lay down on the table and they started to do the cold spray, straight away I could feel it ... I kept saying I can feel this ... they didn’t listen to me, I said this about four or five times to the team, I can feel this, it’s not right. They didn’t listen ... They carried on, obviously, to cut me open. I could feel it all. My left side was slightly numb, I could feel everything on my right side. I felt the knife going in; I started to get hot and I could feel the blood draining from my face. I started to really panic and remember trying to push them off me ... I felt everything from there on, it was just an absolute nightmare.”*

Indicative behaviour: Failing to ensure or preserve women’s dignity or provide for their basic needs

3.30 We heard about:

- Women not being able to be accommodated in the labour ward:
 - *“I was told we have no beds and you’ll need to wait in the day care waiting area; I had a really bad feeling at that point and burst into tears ... nobody reassured me, I felt like there was no sympathy or empathy expressed by anyone. I was told sorry, that’s the only place we’ve got for you, so I sat out there all day. That’s basically where I sat for the rest of my time, until I had my daughter at about 4.00 in the afternoon ... from 7.00 in the morning, I had been looked at, assessed once ... they asked my partner to hold her so she didn’t fall to the floor, because I was standing up. There were no midwives around, they had to go and find somebody ... I had to ask for blankets ... there was no dignity, I had to ask somebody to cover me up.”*

* “Epidural” and “spinal” refer to forms of pain relief often used in labour or for obstetric procedures, involving an injection of anaesthetic around the nerve roots.

- Women's distress at their dignity not being preserved, for example by them being left for long periods in soiled bedding or in ward areas which did not provide for their privacy:
 - *"My blood was up the walls, on the ceiling; my sheets weren't changed."*
 - *"I know that doctors and midwives need to come and go, but the door was left open quite a few times, which was not very nice; there was no privacy – I think everyone in that hospital saw me in that bed. That was awful."*

Indicative behaviour: Placing women with other mothers and their newborn babies following the loss of their own baby or after a serious event

3.31 We heard about:

- The impact of the limitations of the two hospitals' premises on women who had just lost their babies, which meant they were placed in wards among other mothers with their newborns or had to carry their babies' bodies to other areas:
 - *"It is soul destroying to hear the cries of healthy babies being born knowing that your baby will be born silent."*
 - *"Spending about 24 hours on the labour ward listening to other babies crying was hell on earth."*
 - *"It didn't make it easy for us; having to come out and see lots of happiness and we were going through the worst point ever."*
 - *"As I stepped outside, one of the mums from the nursery next door came up to me and said 'oh, how's he doing', and I looked at her and said 'he's dead'. That should never have happened, for her."*
 - *"They were walking the same way we were going, turning around, staring. That will haunt me for the rest of my life because they knew I was carrying a baby that was not here. They were just watching me the entire time, walk through the corridor. She said to her husband, as I passed them, 'she's carrying a dead baby'. It was awful."*

Indicative behaviour: Putting pressure on families to consent to a post-mortem examination

3.32 We heard about:

- Newly bereaved parents feeling under pressure to consent to a post-mortem examination of their infant:
 - *"The pressure is unreal, for everything. Hours after we delivered him, they're there, 'do you want a post-mortem?'. This is stuff that I have never even thought to have done, and you're bombarding me with these questions."*
 - *"They wanted to know if we were happy for them to do a post-mortem and we were like, no, we don't want to have one, we don't want it to happen ... but they were like, ok, but it will really help other parents if you have one, and we were like, please do not ask, we do not want one ... and the next day, they asked us again, and we said we've already decided, do not ask us again, we do not want one, and we had to be quite firm ... that was quite hard because we felt they were pushing us into it."*

Illustrative Case P

At 29 weeks pregnant, P began to feel unwell with abdominal pains. She called maternity day care and was told to attend for observation and cardiotocography (monitoring of the baby's heartbeat). She told the midwife it felt like she was having contractions but the midwife was dismissive, saying it would be a urine infection and the doctor would give her antibiotics and send her home. P believed the midwife, despite her concerns.

Two hours later, P noticed that she was bleeding and, on examination, was found to be in labour. Baby P was delivered by caesarean section. After initially making good progress, the baby developed a severe infection and his condition worsened.

After ten days, a doctor informed P and her partner that treatment had failed and nothing further could be done.

"[They were] so blasé, [they] got the ultrasound scan and literally just said yes, that's infected, that's infected, his brain's covered in this, his heart's covered in that; I'll come back at ten o'clock when I've done my rounds and take the tubes out."

Afterwards, P sat with her dead baby in her arms with the other parents in the room listening to her *"howl from her soul"*.

Illustrative Case Q

At 17 weeks pregnant and bleeding heavily, Q was told to attend the maternity department. The person on reception was busy making arrangements to deliver a cake and made her wait. Placenta praevia was diagnosed and Q required an overnight stay.

Afterwards, at home, the bleeding resumed and Q found herself back in hospital. Suffering from a headache and feeling extremely thirsty, she called the midwife, who – in front of all those in the ward – said, *"Aren't you the woman who's going to have an abortion?"* Q was distraught: she had been told when she was first admitted that the viability of her pregnancy might be in question because of the heavy bleeding, but nobody had told her that she was at that stage.

A few hours later a consultant attended, who told her there had been a mistake, the midwife should not have spoken to her in that way and she had no need to worry. On her fifth day in hospital, Q was discharged and told to reschedule her 20-week scan, due in two weeks, because she was high priority. However, when she tried to bring the appointment forward, she was told this could not be done.

For the next three weeks, Q stayed at home, bleeding and suffering from headaches, scared of being a nuisance. She finally returned to the hospital and a scan revealed the presence of two large haematomas. After a week in hospital, she haemorrhaged and woke in theatre to confusion and panic. A consultant was present but there was no anaesthetist and there was a delay in obtaining the blood necessary for a transfusion.

Q's baby had not survived and she required a hysterectomy to control the bleeding; the consultant told her that, in their 30-year career, they had never had to perform one in such circumstances. The midwives told Q's husband: *"We're not set up for this, we haven't got the procedures."*

3.33 What the Panel has learned from its interviews with Trust staff is described in Chapter 4, so will not be covered here. However, we found evidence that the prevalent culture in the Trust has tolerated and fostered the unkind, uncompassionate and intolerant behaviours sometimes experienced by women and their families.

Theme 3: Being conscious of unprofessional conduct or poor working relationships compromising their care

3.34 Team conflicts pose a potential threat to the quality of relationships and communication between patients and staff, as well as to the quality of care. They can also make patients feel unsafe when they perceive that staff are not communicating with each other or working as a team. It is therefore unsurprising that a lack of teamwork and a failure to share information featured in the family listening sessions as matters of concern to the women and families who spoke to us.

3.35 We heard accounts of unprofessional conduct that were alarming to women and their families because they undermined their confidence in the doctors and midwives looking after them and, in some cases, made them question the safety of their care. For one family, these concerns were compounded by the comments of a consultant, overheard in a patient area, who was discussing with a colleague how unsafe the unit was and how they had reported it to senior management but had given up trying to raise it.

Indicative behaviour: Making rude, inappropriate or offensive comments to women and their partners

3.36 We heard about:

- Women or their partners being on the receiving end of inappropriate and unprofessional comments, which they found hurtful or offensive:
 - *“She’s making the wrong call here, and it’s going to be your wife’s fault when it all goes wrong”* [a woman’s husband recalling the comments of a midwife].
 - *“[They’re] all over the place because [they’ve] just come back from a cruise”* [a woman recalling the comments of a consultant about a colleague].
 - *“Is she normally this dramatic with pain?”* [a woman’s husband recalling the comments of a consultant].
 - *“I don’t have time for this. I have to get to Canterbury and the parking is bad”* [a woman recalling the comments of a consultant made during a consultation].
 - *“Under no circumstances can you leave this room. If you do, you are putting your unborn child at risk ... on your head be it”* [a woman recalling the comments of a consultant].

Indicative behaviour: Behaviours or comments that undermined colleagues, including public disagreements and raising concerns directly with women about their care

3.37 We heard about:

- Midwives complaining about doctors and other midwives behind their backs:
 - In one case, midwives referred to a consultant as having a *“God complex”*.

- Midwives ignoring the advice of doctors and taking contrary action:
 - *“I don’t agree with that, this is what we’re going to do”* [a woman recalling the comments of a midwife made after a consultant had explained their plan for her care and left the room].
- Doctors showing disregard for their midwife colleagues:
 - *“[They] told the midwives off in front of me.”*
- Doctors disagreeing within earshot of women and their families:
 - *“Don’t you dare argue this with a patient, this isn’t appropriate or professional”* [a woman recalling comments made by a consultant to a colleague, disagreeing about a baby’s transfer to the bereavement suite].
- Women being told “on the quiet” that their care had been substandard and they shouldn’t accept it:
 - *“There are things that should have been done differently. If you were a member of my family, I would not be happy with the care that you’ve had”* [a woman recalling the comments of a midwife after a bladder injury during a caesarean section].

3.38 In some cases, these behaviours reflected poor working relationships within and across professional groups. This theme is picked up below in reference to teamworking and information sharing, and in Chapter 4 on what we heard from staff. In any event, the impact of such behaviours on the women who witnessed them was such that they featured heavily in their accounts of what they experienced at the Trust. This laid bare for the Panel the extent and pervasive nature of the poor behaviours and teamworking in both maternity units, which the senior team failed to address with any degree of success.

Indicative behaviour: Disagreements between individuals in the same or different professional groups about women’s care, including giving mixed messages

3.39 We heard about:

- Doctors and midwives contradicting each other or disagreeing in the presence of women, which caused the women anxiety and made them lose confidence in their care:
 - *“I’m not dealing with this, I’m not going to be here while you do this”* [a woman recalling the comments of a midwife made to two consultants who were about to break her waters].
 - *“Women and their families are set up for misunderstanding. You’re on the back foot and need to reinterpret what you’ve been told.”*
 - *“In hindsight, it’s easy to see there was a bit of a tug-of-war between the midwives and the registrar.”*
 - *“The consultant came to see me and said that they wanted to keep me in overnight, and the midwife sent me home about an hour later. And the consultant had written in my notes that they wanted to keep me in overnight and the midwife sent me home, and there were no notes after that to say why. I had no explanation. They just sent me home.”*

Indicative behaviour: Failing to pass on or act on information, including failing to hand over effectively at shift change or to communicate effectively between services

3.40 We heard about:

- Failures to provide sufficient information at handover, or to document information in the notes at shift change alerting staff to a possible risk to mother or baby, resulting in poor continuity of care and compromising safety:
 - *“The shift changes were shocking, there was no communication between teams; the new team didn’t have a clue what we had been through during the previous three days.”*
 - *“Communication seemed to be the biggest issue on that day ... the night shift didn’t hand over all the details ... there was the potential there to record some things that would have made it an amber alert but it was ten hours before we finally got those antibiotics, which in my opinion was too late.”*
- A failure to pass on information to colleagues and teams, including to the delivery ward or community midwives, resulting in upsetting interventions by staff following the death of an infant:
 - *“Calm down everyone, you’re going to have a baby today” [a woman recalling the comments of a midwife made in the delivery suite prior to the planned delivery of her stillborn baby].*
 - *“There’s no loop, no one communicated properly ... they didn’t even think to tell my midwife that my baby had died, it took me to do everything ... [they] signed me up for groups for after I’d had R, being a young mum, and I got letters in the post from them inviting me to mums’ groups, because nobody told them that my son had died.”*

Indicative behaviour: Shifting the blame for a poor outcome onto colleagues

3.41 We heard about:

- Doctors and midwives trying to abdicate responsibility to others or shift the blame when things had gone wrong:
 - *“You could feel this cultural thing going on, where the consultants were saying ‘no, no, no, it’s the midwives’ and the midwives were saying ‘no, it’s not us’; and immediately, we got this little window into what was actually going on there.”*
 - *“We got taken to this tiny little box room and she just kept saying the whole time, ‘as long as you know, it is not our fault. It is no-one’s fault. It is just one of those things.’”*

Illustrative Case R

R was pregnant with twins. At her 20-week scan, slight ventriculomegaly (enlargement of the ventricles of the brain) was apparent in twin one, and this had become severe by her 24-week scan.

The consultant told R and her partner there was a 95% chance that twin one would be severely disabled, and it was likely that the other baby would be as well. The consultant also told the couple that they were being unfair on their older children by continuing the pregnancy and that termination of the entire pregnancy was recommended, as it was not viable.

Even though they believed it was no one's decision but their own, the couple felt they would be going against medical advice if they chose to continue with the pregnancy. They were referred to King's College Hospital in London where the range of possible outcomes was discussed, including a positive outcome. They were also told that selective termination of just one twin was an option; this had not been communicated to them before.

The couple moved areas and within a few weeks R had her first appointment at the local hospital. The perinatal and obstetrics and gynaecology consultants advised her that there was a possibility of complications, but that this wasn't guaranteed and every baby should be given a chance. The couple felt that they were being treated as intelligent people who were competent to make their own decisions.

The following week, R had a bleed and was admitted. After a month as an inpatient, she delivered two baby girls by caesarean section. Although one required resuscitation, the twins were both well and continue to thrive.

Illustrative Case S

Towards the end of an uneventful pregnancy, S developed a rash on her body, the cause of which could not be determined, and a decision was made for labour to be induced. The date was set and, early that morning, she called the hospital to check that she should come in. She was told that there were no beds available and to call back later.

Around 20 minutes later, S's waters broke; she called the hospital again and was advised to go to a neighbouring clinic to be checked. From the clinic, she was sent to hospital for additional monitoring, where it was confirmed that the baby's heart rate was slow, but she was wrongly told this was not a cause for concern.

S was sent home to allow labour to develop. That evening, having not felt her baby move for a while, she called the hospital again and was told to attend. She arrived as the night shift changeover was taking place. She was checked and found to be having contractions, but her labour was not progressing. S was attended by a student midwife, who applied Prostin gel to speed up her labour, and arranged for a birthing pool. The student midwife told S that it was likely she would end up having a caesarean section as her waters had broken more than 24 hours previously and her labour was not progressing.

Soon after, S was attended by a different midwife, who disagreed that a caesarean section would be necessary. S was given an epidural and labour augmented with Syntocinon; however, she felt very unwell as a result, and was shaking and vomiting.

The day shift ended, and S's care was handed over to a senior midwife, who told her that she had been left in a "ridiculous" situation and that she shouldn't have been kept on a drip, which clearly wasn't working as she was still in the same state of labour as she had been that morning, but was now exhausted and unwell.

Because labour was not progressing, a decision was made that delivery should be by caesarean section. S's epidural was topped up in preparation, but she felt very unwell again. No one seemed concerned or acknowledged that this was the second episode of these symptoms. One of the surgical team said: *"It happens, sometimes people are sick."*

Theme 4: Feeling excluded during and immediately after a serious event

3.42 In several cases, women became aware that something was going wrong in the course of their care, either as it was happening or shortly afterwards. They described a lack of compassion and a sense of being excluded as events unfolded or in the immediate aftermath. Sometimes, this failure to inform and consult them about a deteriorating situation extended to the woman's partner and other family members, who were left waiting for long periods in a state of ignorance and growing anxiety and fear.

Indicative behaviour: Not being told what was happening, or what had happened, when things went wrong

3.43 We heard about:

- Women and their partners or family members not being informed what was happening as events were unfolding:
 - *"No one talked to me at all through the operation ... I had the spinal block and no one told me what was happening. I was asking questions constantly ... I was trying to make sure that I stayed conscious so I could remember everything, and no one told me what was going on. I kept on peeking up and they kept on telling me to lie down. I just saw them covered in blood, up to their elbows covered in blood, having conversations about me saying, 'oh that's bad, that's bad, that's bad', but not telling me what was going on ... I was 100% sure I was going to die."*
 - *"My daughter went one way, my wife went the other, and I was left on my own, not knowing if my wife was alive or my daughter was going to be alive at the end of the day."*
 - *"I was just left for so long to my own devices. When the doctor came in, it was like no one wanted to tell me that he had died. They waited for me to go down to ultrasound, but by this point I knew something was up. I used to find [his heartbeat] at home on my own so I knew something wasn't right, but nobody was telling me."*

Indicative behaviour: Leaving family members waiting and anxious for news

3.44 We heard about:

- Women and their partners or family members not being informed after a serious event about what had happened:

- *“When I came around in recovery, I kept saying to them, ‘where is he, where’s my baby’. Nobody would look at me, nobody would tell me anything. It was only when X came in and I saw his face that I knew he was gone. They knew there and then that things had been done badly, because they wouldn’t even look at me.”*
- *“What was really strange, and what I really didn’t understand, is that no one was really willing to tell me anything, to explain to me what happened. They were really vague, and you would get different versions depending on what doctor you spoke to.”*

Illustrative Case T

T had had three previous caesarean sections and knew what to expect, but her reception at the hospital unsettled her. She and her partner found the surgeon arrogant, rude and unreceptive to questions, though the anaesthetist was more reassuring.

T was given pain relief and a screen was put up, but no one provided any explanation about the procedure and T wasn’t even aware when it had started. Then, as the baby was delivered, a midwife leaned over and said: *“I’m really sorry the paediatrician is not here yet, but he will be here.”* T didn’t know what to make of that.

The infant was born translucent, pale and white. He was taken away and T knew that something was wrong. She asked what was going on and what had happened, but was not given any information other than that it was a *“freak of nature”*, an *“accident”*.

It was nearly an hour before T was able to hold her baby. When he was put into her arms, she was shocked at his pallor. He was then taken for a blood transfusion. T asked for information and was told that the clinicians had cut through the placenta; she knew there had been a ten-minute gap between knife to skin and the baby being delivered, and felt panic at the thought that he had been without oxygen for ten minutes.

The hospital staff said they had performed a computerised tomography (CT) scan and the baby’s brain was fine, but T was worried about the possibility of brain damage. She kept asking if he was OK and was told that he had been given a CT scan which had come back clear. She later found out from her notes that he had received a cranial ultrasound, not a CT scan. After discharge, T contacted the hospital to inform them that her baby was *“juddery”* and his eyes weren’t right; she was told *“boys are lazy”*.

At the two-month check-up, T asked whether the ultrasound would definitely have detected damage and was told by the sonographer that this was not necessarily so. With a great deal of effort, T managed to secure a magnetic resonance imaging scan for her baby. The couple were informed on the telephone that their baby had suffered a cerebral infarction. They attended the William Harvey Hospital in Ashford (WHH) to see the scan and were shocked at the very large area of baby T’s brain that had been affected. They asked how extensive the damage was and were told *“work it out yourself”*. The hospital has never provided an account of what happened.

Theme 5: Feeling ignored, marginalised or disparaged after a serious event

3.45 As well as their frustration and anger about not being informed as events unfolded, families described a range of experiences of the Trust’s investigations process that followed. Some felt that the process had been reasonably open and fair, while others felt deeply distressed and aggrieved by it. Sometimes, where there had been a very serious adverse outcome, families lacked information about what to expect and what processes should and would be

followed, including how they would be involved. In general, there appears to have been a collective unwillingness to engage with families and a reluctance to invite them to contribute to investigations; some families were not even made aware that an investigation was taking place.

3.46 We also heard about the downgrading of incidents without proper explanation, and families' concerns about deaths that should have been reported to the coroner but were not.

3.47 It is clear to the Panel that this failure to engage with women and their families after a serious event – or to do so in a manner that did not take into account either their distress or their concerns about their care, or to provide appropriate and timely support – caused them additional harm. These types of responses, illustrated by the indicative behaviours for this theme, made it harder for women and their families to work towards regaining a sense of being able to cope or to return to the kind of lives they had prior to what happened to them.

Indicative behaviour: A collective failure to be open and honest or to comply with the duty of candour

3.48 At the time of writing this Report, it has been confirmed that, for some women, the Trust's failings have contributed to or caused the poor outcome experienced by them or their baby. In a few cases, this has been as a result of the Trust's own investigation; in others, it has followed a coroner's inquest or the interventions of a third party such as the Healthcare Safety Investigation Branch. However, there are many families who remain in the dark and who seek long overdue answers to their questions, as well as confirmation that any lessons learned have resulted in improvements.

3.49 We heard about:

- Failures to explain to women or their families what had happened or to apologise, and families being "fobbed off" when they sought answers to their questions:
 - *"When things go wrong, people should talk about it and learn. Nobody thought I was in labour, nobody said they had made a mistake, and these are the consequences."*
 - *"Although it was seven years ago for us, it is still burning in our hearts because we haven't had answers."*
 - *"WHH shut down to us, they were more concerned about us taking legal action than actually wanting to learn from A's death."*
 - *"We've heard lots of people say they knew the hospital was an unsafe place and the culture was wrong. When we complained about the basic things, like the cleaning of condemned mattresses, [senior nurse] said she was surprised, because the CQC [Care Quality Commission] were due and everywhere had been painted. It was like, we've done the painting, and it's all ok; like the Queen's coming to visit so we've done a bit of decorating."*
 - *"People think that we are on a witch hunt for the surgeon, but we are not that sort of family. We understand that things go wrong, but we are having a problem because they could have seen it from a different view."*

Indicative behaviour: A collective failure to act on or respond to concerns, including a poor or inadequate response to complaints

3.50 We heard about:

- A poor complaints process, with responses to complaints sometimes not being received, defensiveness and a “pick and choose” approach to what was covered in complaint responses:
 - *“If it’s a small company, you can go to the boss to complain that this has been terrible ... With something as big as the NHS, you’re fighting a losing battle.”*
 - *“I had made suggestions in my complaint, and I had made it clear how wonderful the people were that had helped me. My complaint wasn’t about the fact that this was maybe an error or a faulty device, my complaint was about the lying and blaming me and covering it up. That’s what’s really upset me about it.”*
 - *“We wrote a measured complaint after some time, we didn’t do it in raw emotion, we waited, and I think it was quite clear what we wanted out of it in terms of an apology and to know that things were going to improve and not just ignored or brushed under the carpet ... it took three attempts to send that letter in before someone replied to us and in the end it took me writing to the CEO of the hospital Trust, just to get a reaction and acknowledge that we’d written the complaint ... they went on to investigate it ... and it took another six months before we had our meeting.”*

Indicative behaviour: A tendency for the Trust to fail to take responsibility for errors or to show accountability

3.51 We heard about:

- A failure by the Trust to undertake robust investigations or to involve families:
 - *“People are investigating things by looking at the notes and we’re the ones who were with her, who could hear what she was saying and all the texts on her phone saying no one’s listening to me, everyone’s acting like it’s normal to feel like this.”*
- Delays in completing internal investigations, a defensive approach, and a reluctance to involve families, keep them informed of progress or report back to them, sometimes resulting in them fearing a cover-up:
 - *“It was literally like cloak and daggers, going round, trying to find out information and getting stuff from nurses who had put it by for us, who had photocopied things to try and give us the information we needed. We were getting no support from the management about anything at all.”*
 - *“Every time at the hospital, it always seems like one person is covering up for the next; they are a team and they work together, but they shouldn’t cover up when children are dying.”*
 - *“Their attitude was ‘we made a mistake, but it wasn’t that bad, and it won’t happen again’.”*
- The ongoing concerns and experiences of women being consistently ignored and invalidated after the event:

- *“They did their investigation ... I don’t know whether it’s ironic, but we got their response back, it was not good enough, I mean the response took over three months, but we got a response back the day before the Coroner’s court, but it was very very short, it was almost like bullet points, and we were like this is not good enough, straight away. So then we did a timeline, we did every question possible and the potential answers and we sent it to them ... so we are now waiting to see the response from that.”*
- A failure to demonstrate that the Trust has learned from serious incidents:
 - *“I just want to put things right for mums and babies. I just want to see things get better. Without accountability you can’t hold them to their promises and that’s why we’re here. I know people will promise you anything to get rid of you, but we really do need to get the accountability in order to get improvements – I don’t want differences, I don’t want changes, we want improvements.”*
 - *“What I can’t accept is that you refuse – you actively go out of your way to try and avoid learning from the situation, you actively try to cover it up, and that ultimately means it will happen again. That is something that I find unacceptable.”*

Indicative behaviour: A failure to provide adequate follow-up support, including appropriate counselling

3.52 We heard about:

- Inconsistencies in the referral process to the Birth Afterthoughts service; when families were referred, they often found it unhelpful or even detrimental to their recovery:
 - *“That appointment was more hurtful than anything else. The lady was trying her best but she didn’t have all the notes, some of the notes were in the wrong order. There were notes that contradicted each other ... we just came out and cried.”*
 - *“I asked for Birth Afterthoughts and was told that wasn’t suitable because I had a complaint in process.”*
- Poor and sporadic access to and quality of counselling for the mother, with non-existent provision for fathers; many families have resorted to sourcing counselling themselves:
 - *“There was no care, no support, it was very lonely.”*
 - *“I just left there and thought this was the biggest waste of time ever. Because you don’t really want to go back to that hospital anyway when something like that has recently happened, and to go there and they can’t even get your name right or the baby’s name right, or how far along you were in your pregnancy, it was insulting.”*
 - *“It [the follow-up] was really, really bad. It was terrible. When they answered the phone, they didn’t want to help, they didn’t want to know anything about it.”*
 - *“For my counselling after it, I put myself forward for the doctor ... I didn’t even really know I needed anything, and then I got myself in a really bad state one day and thought about harming myself and then I realised I needed help.”*
- Failures of the bereavement service to provide an adequate and supportive response:
 - *“We asked to see the bereavement counsellor, and she refused to see us because we weren’t having a funeral, she was like, well, there’s nothing I can do for you.”*

- *“I wanted to get some counselling, but the waiting times were months and months for those ... I had a bereavement counsellor but because it was covid times, it was all over the phone and it was quite distanced and it was a very lonely time. I didn’t really find the bereavement [counselling] terribly helpful ... in the end it felt I was left to my own devices.”*

3.53 Not being listened to, not being extended kindness and compassion, and feeling ignored or marginalised when accessing healthcare may leave patients who have uneventful care feeling insignificant and invisible. In those circumstances, it is not uncommon for patients to rationalise their responses as being the result of service pressures and to accept and normalise them.

3.54 However, when these responses occur after events that are traumatic, frightening or have a poor outcome, as was the case for families in our Investigation, there is an expectation that staff will do all they can to minimise any impact and will act with compassion and insight. When this does not happen, the impact is greater. We heard this in the accounts given by the women and their families, and saw it in their visible distress months and years after their experiences. They were left questioning why they were treated in such a manner and feeling diminished, powerless and even worthless, adding a layer of harm to what was already for many an almost unbearable event.

3.55 In common with other investigations, the trigger for regulatory scrutiny and the commissioning of this Independent Investigation came from individual families who had been failed by the Trust. It was their persistence and determination to get to the truth that has led us to where we are now. It is disappointing that families continue to have to do this to substitute for ineffective safety monitoring by trusts and regulators.

Theme 6: Being forced to live with an incomplete or inaccurate narrative

3.56 Many women were not party to the whole of their own or their baby’s experience, due to being sedated, not being in the same room as their baby or simply being too unwell to remember parts of what happened. In the absence of full and frank information from Trust staff, this left a space that was filled by women and families trying to make sense of what had happened and how and why it had happened.

3.57 Being left with so many questions about events that they were unable to answer naturally led women and families to seek answers from the Trust. These answers were not always forthcoming, were only partial, or in some cases were misleading. We heard of internal investigations failing to get to grips with what had happened, so that no meaningful explanation could be provided. This led to families resorting to working through and trying to make sense of clinical notes in order to piece together what had happened, or to get answers to their questions. In doing so, they often found that how they had felt at the time and what they had been telling the doctors and midwives were not reflected in their notes, adding to their frustration and anxiety.

3.58 In addition, being blamed by individual doctors or midwives for aspects of events, or being made to feel to blame for what had happened to their baby and being unable to challenge hierarchical systems and individuals with professional knowledge, left our families living with “what ifs”. This inevitably meant that they were forced to construct an uncertain or incomplete narrative about what had happened, due to the lack of facts, their sense of responsibility for events or simply the uncertainty with which they were left.

Indicative behaviour: Blaming women and families, or making them feel to blame, for what had happened to their baby

3.59 We heard about:

- Women and their partners being made to feel to blame and living with the guilt of believing that they were in some way responsible for the outcome or should have done more:
 - *“A member of staff said to me ‘is there anything that you think you could have done better?’, which stuck with me for months and months afterwards, I felt so guilty.”*
 - *“As I’m sitting here talking about what other humans could have done more, I still also feel myself that I could have done more as his mother, and I’m sure his dad feels the same, but this is what you’re left with.”*
 - *“To cover it up, to cover herself rather than try to stop it happening again, by blaming mums, I think this is something that happens. I think this is an ingrained thing, and that does cause damage, psychological damage. I am still upset now talking about it, but my son is okay.”*
 - *“The problems are ingrained, not listening to anyone and blaming the most vulnerable people at the most vulnerable time. They need to be doing the opposite of that. They need to be listening to the mums. They need to take accountability even if it’s human error. I would forgive anyone for a mistake, but lying and blaming is unforgiveable.”*

Indicative behaviour: Not giving women and their families answers or reasons for why things had gone wrong

3.60 We heard about:

- Families being left convinced that their baby’s death or injury was the result of failures in care because of the lack of information and attention provided by the Trust in the days, weeks and months after the death:
 - *“My opinion will always be that F died because somebody didn’t do their job properly; and that’s fine if you work in Sainsbury’s but when it comes to a family’s life; it has affected me, my husband, our son ... it’s devastating and it can’t be undone, it’s what we just have to live with.”*
 - *“What’s caused the suffering, and what is dangerous, is the lies and the falsifying the notes and blaming me to cover up for the human error or the device, and that being seen, when you make a complaint, as acceptable. I think that covering up and that blaming is really dangerous because we do not know what really happened.”*

3.61 The consequences for the families are profound. Living with a narrative that they know to be untrue or partially untrue, or never knowing for certain if things might have been different, has fractured their trust in healthcare professionals, often challenging previously held beliefs about who is trustworthy and who is not. Having these previous beliefs challenged, as well as feeling unable to construct a true explanation about a major event in their own lives – even when they may have been present – has undermined their confidence in their abilities, strengths and decision making.

3.62 We saw that this has often led to major changes in how families viewed themselves and others, and their ability to manage their lives. They were generally less trusting and confident in the ability of others to have their best interests at heart, even those closest to them. This additional harm has added to their grief, loss, physical disability or change in circumstances, with some families also experiencing major financial difficulties. In these circumstances, their ability to regain their capacity to cope has been severely hindered.

Illustrative Case U

Two weeks after her due date, U was booked in for an induction. Despite a sweep and two doses of Prostin, progress was slow, and U and her partner felt neglected as staff were busy with other patients. One midwife refused to carry out an internal examination of U that evening, even though one was overdue, and no examination took place before a second dose of Prostin was administered.

During the night, U woke in intense pain and experiencing contractions. As her contractions became more frequent and stronger, she asked again whether she would be examined but was made to feel like she was making a fuss. In the morning, U mentioned the pain she was experiencing and that her contractions were getting shorter. Then the contractions suddenly stopped and she experienced reduced fetal movement. The midwives said that her baby would be sleeping.

On the induction ward, U was monitored and there was still very little fetal activity. A midwife said she should stay on the trace for another ten minutes for a “sleep trace”. The monitor started to sound an alarm, and within minutes an emergency caesarean section was performed and baby U was delivered covered in meconium and requiring resuscitation. She was cooled straight away and had several seizures. Fortunately, she did not sustain any long-term damage.

U and her partner were informed that there had been a meeting about the event, but they were denied any details. Subsequently, they requested the minutes of the meeting but were told that these could not be found. They believe there was an investigation but the outcome was not shared with them. They queried the care provided on the evening prior to baby U’s delivery when the midwife refused to examine U, and the failure to properly monitor her to identify that the infant was in distress. However, they received no answers and no explanation of why the baby was born in such poor condition.

The couple indicated their intention to complain and asked to be put in touch with the Head of Midwifery; however, the hospital failed to contact them. Then, feeling that they had done all they could to obtain answers to their questions, they instructed a solicitor. The Trust called into question U’s account of events because it did not correlate with what was recorded in her notes. The couple were told that their legal claim could not succeed because their baby had survived without lasting damage. They agreed to mediation at the request of the Trust. However, on the day before the mediation, the Trust submitted additional paperwork and refused to be bound by the mediation’s outcome, leaving the couple without any determination and a hefty fee. They are left not knowing what happened and believing that the hospital is hiding something from them.

Many of the cases included all the above themes

3.63 Illustrative Case V is representative of many accounts we heard, in that it describes how one family experienced failures in care and poor behaviours of staff that cut across the range of themes we have identified. It is necessarily more detailed than the others in this chapter and, for that reason, all the more powerful.

Illustrative Case V

When V became pregnant, she was told that she was at high risk, so she was surprised that each time she attended for an appointment, she saw a different doctor. She experienced swelling in her face, feet and fingers, and breathlessness, headaches and tiredness. All of these symptoms and the extent to which she was struggling were dismissed as due to her weight.

“I felt like I was going to these appointments and was just being churned through a mill. I would sometimes sit for way past an hour past my slot time, to be measured and weighed and just told yes, just carry on, we’ll see you in four weeks. And I thought, you’ve not asked anything about what went on since the last appointment; I was saying things like ‘I’m really swollen’, but they didn’t listen, they didn’t take on board the things I was pointing out ... I was just told, no, you’re just fat.”

Near to her due date, V had an appointment with a new junior doctor, who told her that she had too much fluid, and that if she were to go into labour she was at risk of the fluid “gushing out of her”, possibly resulting in an accident to the umbilical cord. This alarmed her, and she worried that all she could do was ring for an ambulance if her waters broke.

By the time of her final consultant appointment, V was suffering from symphysis pubis dysfunction; her pelvis was extremely painful and she had difficulty walking. She told the consultant that she felt sure she would need a caesarean section, particularly given that her scans were showing her baby to be large. She was told that she should have no concerns about a natural birth and all would be fine.

“And again, I felt like, in that appointment, I was churned out, they didn’t have any time for my questions. That was my very last appointment with a consultant, and I was just totally disregarded. I really don’t even know why we bothered going, because everything that I was worried about, it was just ‘you’ll be fine, mother nature will take care of you’.”

V’s anxiety was compounded by her midwife, who told her that “it was not midwife territory” and “they’re not interested in having you under consultant care”. She told V that she too had raised concerns with the consultant, which were dismissed.

At 41 weeks pregnant, V was very unwell. Feeling “fobbed off” by the hospital, she went to see her GP, who sent her straight there, giving her a letter to take with her stressing the urgency of the situation due to her evident pre-eclampsia.

“I got there, and it was just the same as usual; it was the same ‘well, this is how it is at the end of your pregnancy, you’re not going to feel your best’. And I thought, there’s not feeling your best, and there’s feeling horrendous. One of the things that I really want to be highlighted is that there were so many times throughout the pregnancy when I said I’m worried about this, I’m concerned about that, I’m not feeling great, but my notes just seem to say ‘mother was happy’. And I wasn’t happy.”

The hospital consultant confirmed that V’s baby needed to be delivered in light of her pre-eclampsia. However, there was no room for her that day, nor the next, which was a Friday, so she would have to come back on Monday because they did not induce women over the weekend. The consultant organised for her to have a sweep and she was told that, if that brought on labour, she should go straight back to the hospital because a woman in labour could not be turned away. Her labour began that weekend.

“I had to go with ‘there’s no room at the inn’ and go home after the sweep, and I felt again that they were just not taking it seriously. I went home and I did go into labour

over the weekend. We went in on the Sunday morning, I think at a time that wasn't ideal, it was the changeover of the shift, and they actually said when we got there, 'oh, we've had such a long night'; and we were a bit apologetic. And I said, 'well I've had a long night too, we've not really had any sleep'. My contractions had started on and off and then really picked up in the early hours of Sunday morning, and they were like 'well, they're not that strong' and started to play it down immediately."

V was told by a midwife that she was not in labour because her contractions were mild and subsiding, and that she should go home and come back the next day, Monday, for her booked induction. The midwife asserted that, in her excitement to give birth, she was reading too much into the pains, which were not the real thing. V asked if she was going to be examined by the consultant, whom she had seen at the desk when she arrived and who had said she could stay if her cervix was dilated, but was told by the midwife that she did not need to be subjected to *"unnecessary poking and prodding"*. The midwife said: *"I can 100% guarantee that you're not dilated."*

"We were leaving, even though I was in pain, because we were not wanted there."

V went to bed. Later that day, she noticed that her abdomen had softened and dropped and there was no resistance or kicking back when she pressed it. She rang the hospital and explained that she hadn't felt her baby move for around six hours. The person on the telephone told her to come in and then hung up. On arrival, V, her partner and her mother were put in a room with other people. Looking back, she wonders whether it might have been better to place them in an empty room, given that she had told the hospital that her baby wasn't moving.

All the curtains were open as staff tried to find a heartbeat. Everyone was staring at them. When no heartbeat could be found, V became upset and the family were moved to another room for a scan. After what seemed like a long wait, a junior doctor arrived; the doctor wouldn't talk to them, look at them or give them any information, merely saying, *"well, give us a chance"* when they asked what was happening. Even though no heartbeat had been found, V was in a state of disbelief that something could be wrong.

"After a really long time, I'm guessing close to an hour, an obstetrician turned up and [they] scanned me. Again, there was no conversation. And then [they] said, 'you have to be very brave, because your baby has passed away, there's no heartbeat, your baby has died'. Everyone was crying but I said to [them] straight away, 'how did this happen, I was here this morning and you said everything was fine and I should go home'. And then [they] left the room, and I didn't see [them] again for six years until I was in a courtroom with [them]."

Having been told that there was no heartbeat, V was given a pessary to commence labour. She was told that as her cervix was already 5cm dilated, it would probably happen quite quickly.

"It's not really one of those things that you can measure because I know that people can go from zero to five centimetres in no time at all, but it plays on my mind that maybe if [the consultant] had just examined me in the morning, I would have been enough dilated to have stayed. And even if the outcome had been the same, that I'd have been left in that room all day on a monitor and he still died, I'd have felt that I was in the right place. Instead, we have all these 'what if' questions, which now we just have to live with and it's difficult to move past that."

V's labour was traumatic and began with a failure in communication that was most distressing for the family.

“When they came in, one of them said, ‘calm down everyone, you’re going to have a baby today’ and they hadn’t been told. Then she had a bit of her own meltdown because she felt so silly, and we ended up feeling sorry for her. It was such a mess. Sometimes, I think I don’t know what difference it would have made, for her coming and saying sorry for your loss, let’s help you, but at the same time, the two of them came in like a parade, like happy, happy, it was just awful.”

V spent 18 hours trying to deliver her infant because the hospital did not initially agree to a caesarean section. At one point, she lost consciousness – a terrifying experience for her partner. Finally, a caesarean section was carried out to deliver the stillborn baby. The surgeon told them that the baby shouldn’t have died, that he was a good size and healthy and they should take matters further.

“I had just delivered a stillborn baby and I was already being told, this isn’t right, something has gone wrong here. But we knew it, we knew it anyway, because we’d been to all these appointments, but nothing was put in place.”

Afterwards, V had to stay in hospital for a while. Being on the ward with no baby was particularly difficult, but it was during those few days that the couple experienced a growing awareness that things had gone wrong. The comments of one particular doctor stand out for them.

“[They] said to us ‘we can manage this in other pregnancies, we can give you a small dose of aspirin every single day and your pre-eclampsia will be managed; this won’t happen to you again, and I’m sorry it happened to you this time’. And then [they were] swept out of the room so quickly, as if we shouldn’t have been told that, because until then, pre-eclampsia just hadn’t been mentioned.”

Then, when V had returned home, she was telephoned by her midwife; her recollection of what the midwife said is as follows:

“I shouldn’t say this to you, but I think we’re friends now, you need to get a lawyer ... they’re covering things up and I shouldn’t tell you this and I don’t really want to talk about it anymore.”

The couple pursued a legal claim, but no fault in V’s care could be proved – not least because of the emphasis placed on her clinical notes, which the couple believe do not give an accurate picture of her condition or care. They are left with the belief that the management of V’s pregnancy was *“a mess from start to finish”*. They remain particularly upset that the hospital made an error regarding the gestation of their baby, whose post-mortem examination confirmed that he was far more advanced than had been recorded. Despite telling the hospital that her dates did not match theirs, V was left to go overdue, her baby *“fighting on for an extra two weeks”* before he died.

Over the last eight years, V and her partner have asked hundreds of questions about what went wrong and have still not had answers. They were told that nothing went wrong; it was one of those things. They have never received an apology.

Conclusions, including consequences and impact on wellbeing

3.64 The Panel has considered carefully the evidence provided through the family listening sessions, alongside the information obtained from reviewing clinical notes and other documentary sources. In doing so, it has identified a range of repercussions for women and their families. These families attribute the following consequences to the events they experienced and the actions of clinicians and other Trust staff:

- Not knowing if things might have been different; living with “what ifs”
- Feelings of guilt and responsibility for what happened
- Changes in personal beliefs about healthcare
- Mistrust of clinicians, institutions and the wider health system
- Feeling forced into a position where they sought legal advice to find out what had happened
- Loss of personal confidence
- Heightened emotions, including anger, rage and shame
- Self-blame for not raising concerns more forcefully or speaking up enough
- Panic attacks
- Not wanting more children or being frightened at the prospect of having another baby
- Needing to move away from the area or avoid being in proximity to the hospital
- Relationship difficulties, including some that have ended in separation, and difficulties with intimacy.

3.65 We would also like to highlight the additional guilt that many families have come to feel for not speaking up, when they have seen more recent cases come to light. We are absolutely clear that no family should feel that way: it is not up to families to correct the deficiencies of a Trust that has shown itself consistently incapable of learning.

3.66 Losing a baby or sustaining a life-changing injury during childbirth as a result of failures in clinical care has an emotional and psychological effect that most people would find hard to contemplate. However, the Panel is in no doubt that, on top of this, these women and their families experienced behaviours from clinical staff which failed to meet the standards required of them and rightly expected by the families.

3.67 We found that the impact on the wellbeing of women and their families was often compounded by the additional harm caused by the behaviours and attitudes of those responsible for communicating with and supporting them after the event. This included the doctors and midwives who had been directly involved in their care, as well as others who were acting on behalf of the Trust in a different capacity, such as those responsible for leading internal safety investigations or managing complaints.

3.68 This additional harm served only to worsen and magnify the families’ sense of pain, anger and injustice and hinder their ability to come to terms with what had happened to them and begin to live their lives fully again. The Panel is in no doubt that this could have been avoided had the initial response of the Trust and its staff been open and compassionate, with a focus on including and supporting women and their families.

Illustrative Case W

W sustained a life-threatening surgical injury, either during a caesarean section or afterwards during a procedure to stem heavy bleeding. After her discharge from hospital, she met with her consultant. They told her that they fully expected to see her in a few months, because “*you’ve still got everything, you can still have a baby, we’ll look after you*”. But the experience has left W terrified about becoming pregnant again. It appears that at no point was any explanation given that her continued bleeding had been due to surgical injury to her cervix and vagina.

“It just seemed that people would think that everything would be fine because I was alive and I would just move on and I shouldn’t be sad or upset or mentally scarred from it, from a traumatic experience, and for me I was robbed from having my second baby. I’ve always wanted a second baby and I will never do that, ever, and no one appreciates that side to it.”

3.69 In this chapter we have described the wider experiences of the families, setting out and providing evidence for the themes we have identified and the behaviours that are indicative of those themes. These experiences provide further evidence of care and treatment that fell short of what might reasonably be expected, and that in some cases contributed to the poor outcomes many families suffered.

3.70 In addition, we have made clear our finding that women and their families have suffered additional harm as a result of the behaviours and attitudes of the health professionals who were responsible for their care, as well as others at the Trust with whom they had interactions after the events. For some, this has had an impact on their wellbeing which continues to affect their lives today. It is the Panel’s view that aspects of the families’ experiences have been so damaging as to have had a profound and lasting effect on their health and wellbeing.

Chapter 4: What we have heard from staff and others

Alongside listening to families, the Investigation has conducted interviews with 112 current and former staff at East Kent Hospitals University NHS Foundation Trust (the Trust) and with others whose work brought them into contact with the Trust's maternity and neonatal services. This has been a key part of the Investigation. It is important to note that these interviews helped shape our findings as set out in Chapter 1 and that this chapter describes what we heard. This chapter should be read as performing that function, not as an indication of the Panel's own thinking and conclusions.

Introduction

4.1 Between October 2021 and June 2022, the Investigation Panel met with 90 different members of Trust staff, including midwives, neonatal nurses, obstetricians, neonatologists, paediatricians and other clinicians, as well as members of the Board, the Executive and other managers. The Panel met five of those people twice.

4.2 In addition, the Investigation interviewed 22 individuals who did not work at the Trust but whose role brought them into contact with the Trust in connection with the provision of maternity care, such as representatives from the Care Quality Commission (CQC), the Healthcare Safety Investigation Branch (HSIB), Clinical Commissioning Groups (CCGs) and NHS England/NHS Improvement (NHSE&I).

4.3 This chapter reflects what the Panel was told by those it interviewed. It does not contain the Panel's commentary or assessment of any of the information provided by staff and others except where explicitly stated, but it does focus on what the Panel heard about the problems and challenges facing the Trust. That is not to say that the Panel did not hear about positive aspects – the efforts made to improve the culture and service, the initiatives to support better performance and outcomes, and the commitment of the majority of staff to do their best for their patients.

4.4 In particular, the Panel was conscious that many interviewees understandably wished to put a positive light on subsequent improvements in services, but we found that this view was not generally borne out by other evidence.

History and structure

4.5 Many staff with whom the Panel met raised the fact that the Trust was previously three separate trusts: the Kent and Canterbury Hospital Trust, Thanet Healthcare Trust and South Kent Hospitals Trust. The three trusts merged in 1999 following a local review of services, "Tomorrow's Healthcare", and the resulting trust became one of the largest hospital trusts in the country at that time. The long-term outcome of the Tomorrow's Healthcare review on maternity

services was to focus obstetrics at Ashford's William Harvey Hospital (WHH) and Margate's Queen Elizabeth The Queen Mother Hospital (QEQM).

4.6 Each hospital had an obstetric unit. WHH had a Level 3 neonatal intensive care unit, which is suitable for all babies who do not require very specialised regional or national specialist care. QEQM had a Level 1 special care unit, suitable for low dependency care of babies born after 32 weeks of pregnancy. Dover and Canterbury hospitals operated standalone Midwifery-Led Units (MLUs) in the former obstetric units (later relocated alongside the obstetric units in WHH and QEQM).

What we heard from staff

4.7 The Tomorrow's Healthcare review was described by one clinician as *"a bruising period"* and by another as *"a very traumatic process, as it basically pitched all three Trusts against each other"*. The clinician told us:

[It was a] challenge to integrate the whole of the maternity services which were so divided before, and especially during, the Tomorrow's Healthcare consultations, and to bring some order to the whole Trust. It took years, not months, to bring understanding that they would have two units and it was no longer possible to have three.

4.8 The Panel heard about the challenges that merging the trusts brought. One member of the medical leadership team said: *"Moving from three relatively small organisations to one large organisation meant there was a lot to do in terms of healing rivalries, managing the communities and to some extent the staff."* Although effort was put in to build an *"East Kent focus"* across the Trust, many people reported that the hospitals remained quite separate, and in 2014 a CQC inspection report noted that the Trust still behaved like three separate organisations.

4.9 The Panel was told that the Trust *"had never really coped with the merger"* and that *"the merger is highly relevant to what goes on in the Trust day-to-day"*:

They were supposed to be one team but in reality that wasn't the case. Even the guidelines were different for each site until recently.

4.10 When the Trust became a Foundation Trust, the internal structure was relatively flat and involved clinical directorates; this, it was said, allowed people to participate in decision making. The application for foundation status resulted in Monitor* insisting on fewer management groups, which, the Panel heard, left senior staff (especially clinicians) feeling that they did not have a voice and were excluded from Trust business. The Trust moved the individual directorates into four (*"massive"*) divisions in 2011 as part of a reorganisation. The Women's Health directorate was rolled up in the Specialist Services division with renal, dermatology, cancer services and paediatrics – *"specialities that had nothing to do with each other, but that was the structure of the Trust at the time"*. The Panel heard:

- *"It felt like [women's services] were being put with other odds and ends – the elsewhere 'unfileable'."*
- *"... the voice of maternity services was diluted within that Division."*

* Monitor was an executive non-departmental public body of the Department of Health, responsible between 2004 and 2016 for ensuring that healthcare provision in NHS England was financially effective.

4.11 One Trust Board member commented that *“staff in maternity felt they were always the poor neighbour to cancer”*, and an obstetric consultant told the Panel that the Specialist Services division had far too wide a remit and resulted in people at divisional level taking their eyes off the ball in terms of maternity services. The Panel heard that the new director leads had little understanding of midwifery and maternity services, and *“the maternity unit was in disarray with few plans for the future”*.

4.12 In 2018, soon after the arrival of a new Chief Executive Officer (CEO), the Trust changed from directorates to clinically led care groups. This was intended as a move from a management-driven structure, in which clinicians supported managers, to one in which the clinicians delivering the services would be supported by their managers. There were initially seven care groups, but the Women’s and Children’s Health group was later split in two and there became eight. This was considered a positive development.

4.13 The Trust was described to the Panel as a *“challenged”* organisation typical of a cohort of trusts where there were significant performance and operational challenges, but where the underlying problem was really one of culture.

Poor staff morale

4.14 A member of staff who had been with the Trust for 20 years described the first ten years as *“generally good”*, but they resigned more recently due to a *“toxic culture”*. Working at the Trust during the reference period of the Investigation was said to be *“challenging”*.

4.15 One band 7 midwife[†] who had been at the Trust during the same period described the peaks and troughs: *“times when I felt positive and times when I felt rock bottom. It has always been that way at East Kent, good times and bad times.”* When they were going through a trough, when morale was low, people might not work as well as a team or they might be short-tempered. Those were the times when this midwife felt that teamworking was not good.

4.16 In 2014, following the CQC report, the executive team was described as *“demoralised and not working as a team”*. In the year that followed:

An awful lot of work took place to try and engage and improve the morale of staff, trying to bring together management and clinical staff. That was probably the biggest problem the organisation had, that there was this disconnect between the hierarchy of management and clinicians.

4.17 The Panel heard about a *“really bad period of time”* when there was a big change in managers and people didn’t have the experience to manage correctly or appropriately. This resulted in lots of disciplinary issues, and it affected morale because people were nervous and they weren’t *“nice”* to each other: *“It had a knock-on effect, like dropping a pebble in the water.”* We were told:

Everybody wants to get it right and everybody wants to give quality care. Nobody wants to cause any harm to people. When it does go wrong it has a massive effect on people’s wellbeing and morale. There was definitely a lack of understanding between divisional and Trust levels of management and what goes on on the shop floor. That lack of understanding would sometimes have a negative effect on things.

[†] Band 7 is a senior grade of midwife or nurse, still generally with clinical responsibilities.

4.18 One director attributed the causes of staff disenchantment across all sites to the Foundation Trust status requiring financial savings and the close scrutiny under which the Trust operated. Decisions taken by the Trust to improve efficiency and clinical systems were aimed at improving patient safety and clinical services but resulted in staff earning less money. Some staff expressed that they were unhappy with the new arrangements.

4.19 A member of staff decided to leave the Trust because it was “*trying to do too many things in too many places*”, not only from a workforce perspective but also from a financial perspective. Their view was that the models of care that were operating were not sustainable, and the cultural difficulties persisted:

[S]ome people were trying to deliver services that were really hard for them to deliver, and consequently, their behaviours and interpersonal relationships struggled and were damaged by that.

4.20 The Panel was told how perceived poor performance by people in senior positions negatively impacted staff morale, but that there had been more recent initiatives such as regular safety huddles that aimed to help develop and strengthen relationships between different disciplines and in all areas of maternity services.

4.21 One midwife, who had often raised concerns around consultant decision making, was told in relation to a poorly performing doctor that having “*someone was better than no-one*”. Those aspects were described as “*very challenging and demoralising*”.

4.22 This same point was echoed by a member of the medical team, who commented that, for the Trust, “*having bad clinicians is better than having no clinicians*”. They remembered a clinical member of the Trust Executive saying that a clinician who had been investigated by the General Medical Council (GMC) was “*just about good enough and that was all that could be expected at East Kent*”. The message given was that mediocre was acceptable, which was a depressing standard for clinicians to aspire to.

4.23 A senior obstetrician told the Panel that the staff were fundamentally good people who were placed in an impossible position because of the pressures of the roles they were asked to perform.

4.24 A member of staff told the Panel that the Trust and maternity services had a bad reputation and that there was a bad news story every week, which had a profound impact on morale:

It was hard to watch the media reports and see the Trust criticised. Staff morale was low and there were shockwaves among the staff. It was difficult for pregnant women to come into the hospital having seen the media reports. They would ask if they would be safe delivering there ... There was support, but the shockwaves that affected the shop floor weren't noticed.

4.25 One midwife working at the Trust throughout the Covid-19 pandemic noted that morale seemed worse at the time because of bullying and the questioning of practice in a “*personal and aggressive way that wasn't justified*”.

4.26 Another midwife, in commenting on the behaviour of senior midwives, told the Panel:

[S]enior midwives often came across as lazy, or they were just attending the ward to complete their hours.

4.27 Band 7 midwives told the Panel that they were held accountable for what other midwives were doing, when there should have been a level of individual accountability (they were “*getting the blame from everywhere*”). The band 7 group of midwives also felt very demoralised due to the scrutiny of maternity services.

4.28 Concerns about accountability were raised by another midwife in connection with the lack of personal professional responsibility on the part of some members of the midwifery team. This was attributed to low morale and poor management:

There has to be some accountability. Since the loss of supervision, there are no consequences for people not acting correctly.

Engagement and leadership

4.29 The biggest obstacle to implementing change – in particular the improvement plans in response to the 2014 CQC report and the Royal College of Obstetricians and Gynaecologists (RCOG) report in 2016 (see Chapter 1) – was the lack of staff engagement with the process. The Trust was described as reactive and not “*terribly forward-looking*” in changing the culture around staff engagement.

4.30 One Board and Executive member, commenting on the change to a managerially led divisional structure in 2011, told the Panel:

It would be unfair to say that was responsible for poor medical engagement because the poor medical engagement was there already, but it didn't help.

4.31 The Trust had poor medical engagement, the obstetrics and gynaecology department was described as “*dysfunctional*”, and poor behaviour and leadership by consultants adversely impacted patient care and safety. However, the Panel was told that, since 2018, there has been a change of emphasis within the Trust, with more clinicians prepared to step into clinical lead roles.

4.32 Another Board and Executive member found the Trust a very despondent place for all staff. Consultant engagement scores were very low and the culture came across as very negative. There was a historical lack of clinical leadership and of clinicians feeling accountable for what they did. The same Board and Executive member identified several dangers around the way in which clinical effort was focused, including the divisional structure and the need to turn the Trust from a managerial approach to a clinically led culture. This was described as a “*colossal*” piece of work, which lasted from 2018 well into 2019 and required the appointment of new clinical leaders, particularly in maternity services.

4.33 The Panel was told that consultants did not engage in clinical audit or clinical guideline development because there was no time written into their job plans for it. For the same reason, we were told, areas where one would expect consultants to lead – the development of clinical guidelines, conducting maternal death and perinatal investigations, and leading on perinatal meetings – were all led by midwives.

4.34 A lot of time was spent on incidents and complaints, with governance midwives being recruited to manage these alongside the consultant with responsibility for risk management and clinical governance. There was a lack of engagement from obstetricians on clinical governance and updating guidelines, “*leaving [the consultant] to do a lot of the work*”.

4.35 One consultant noted a difficulty in getting clinicians at QEQM to be part of an investigation into a neonatal incident, and told the Panel that this remains a challenge. The Panel heard that there was a greater focus on midwifery than on obstetrics, and that there was an expectation that engagement in serious incidents was the responsibility of midwifery rather than obstetrics.

4.36 The Panel heard that Women's and Children's Health, as part of the Specialist Services division, had two and a half days a year devoted to learning and considering incidents, complaints and feedback, including positive news. However, the Panel also heard that doctors never attended the meetings; only nurses and healthcare professionals attended (although this began to change later).

4.37 The Panel was told that there were "about three" cultural change programmes at the Trust that failed because of a lack of direction and leadership, and that the Trust paid lip service to cultural change but this was not sufficient. There was not enough commitment or engagement from leaders of the organisation.

4.38 Professor James Walker, the Clinical Director of Maternity Investigation at HSIB, commented:

They don't really have consultant supervision to try and support the service. Now whether that is because they haven't enough, or they don't have enough people interested or whatever, I don't know, but it took us a long time to get the obstetricians involved [with HSIB investigations]. Even now, we get the lead obstetrician there or the lead paediatrician comes in – I am not sure how much our messages are getting down into the shop floor. In other hospitals we present back, and we've got consultants, students, registrars, and student midwives in the room, and that is where these hospitals really take ownership of problems. It's interesting because people will then talk about the cases and the obstetricians and midwives will then realise the problems the others have, and that helps to move forward for solutions.

Staff behaviour and bullying

Relationships between professions

4.39 A senior clinician with a regulatory and oversight organisation told the Panel that East Kent maternity services had the worst culture they had seen in their long experience of working in hospitals with inappropriate cultures, and a "terrible culture between the medics and the midwives". Staff were not supportive or encouraging to each other and there was "a bullying culture"; "freedom to speak up at the Trust was not good". They said:

People's standards weren't what they should have been, and they didn't know what good looked like.

4.40 The relationship between midwives and doctors was described by one senior midwife as "cordial", and concern about difficulties with working relationships at the Trust featured prominently during staff interviews and was an issue raised across different levels of seniority.

4.41 The Chief Executive of the Nursing and Midwifery Council (NMC), Andrea Sutcliffe, told the Panel that "the relationship between midwives and obstetricians is absolutely critical".

4.42 Contrasting views were expressed about teamworking. Some said that teamworking between obstetricians and midwives had always been good. Nevertheless, the Panel was

repeatedly told of poor teamwork, particularly between different professions. The senior consultant obstetricians were described by one senior manager as *“extraordinarily challenging in their behaviours, lack of communication and teamwork”*:

Their behaviour was appalling, and they had no respect for their colleagues. Consultants did and do still refer to midwifery staff as “lazy fucking cunts”.[‡] They take no responsibility for their actions and blame colleagues for any challenges and failings ... such a rancorous, hostile environment creates a service ripe for error, risk and lapses in safety.

4.43 A senior member of the Executive noted the *“dysfunctional relationships within specialities”* and that, within maternity services, there were issues with obstetricians and midwives working together. A senior manager observed that *“doctors and midwives sat apart in meetings ... and clearly did not respect one another”*.

4.44 Doctors were said to have been overpowering in a lot of situations and women’s voices were discounted as a result. It took one midwife a very long time to feel confident enough to speak up to doctors because they came across as quite intimidating. The same midwife felt that the situation later improved, although women were still not always empowered by doctors. This point was echoed by another midwife to whom the Panel spoke. They described ineffective communication and discussions that were *“quite hierarchical ... Ultimately, decisions come from the top, rather than because staff communicate well and listen to each other.”*

4.45 A senior midwife spoke about the fact that many of the consultants working at QEQM are longstanding members of staff and have a more *“traditional”* model of working when they are on call overnight, and that because there are a few layers between midwives and the consultant (mostly filled by junior doctors), midwives can find it hard to reach a consultant at times. In contrast, the obstetric team had a greater opportunity for contact with consultants.

4.46 The Panel heard that there were set patterns for doing things and that it was difficult to introduce new ideas from elsewhere. A midwife at QEQM who had worked at the Trust for over 20 years told the Panel that they felt like *“an outsider”* for quite a few years. Students who came through the unit would be the trained midwives of the future; similarly, trainee doctors would often return as consultants once they had completed their training. The team was considered to be *“like a family”* and their strengths and weaknesses were well known.

4.47 The dynamics of the team affected decision making; this was recognised as *“not a safe way to practise”*. There was no multi-disciplinary team learning and there was very much a *“divide between disciplines”*. The Panel was told that the obstetricians had *“huddles”*, but these were a *“tick box exercise with no real value”*. One midwife commented that the relationship with the obstetricians could be challenging and it had a big impact on how midwives felt about their work. Some of the consultants were very unhappy about being questioned and would become stubborn and unwilling to back down. Another midwife mentioned that junior doctors felt *“bullied”* by the midwives, and the relationship with the obstetricians wasn’t very good.

4.48 A midwife who had been with the Trust for a lengthy period told the Panel that the lead clinician for obstetrics faced *“massive challenges”* with relatively little support, that there were some *“big egos”* among the obstetric consultants, and that to try to bring about change with these strong personalities present was very challenging. They also said that poor communication was a significant theme and spoke about how everyone knew that it would be a difficult day if a particular clinician was on duty.

[‡] The Panel deprecates the use of language that is disrespectful to other staff and demeaning to women; it is included here only to underline the extreme lack of respect and professionalism among some Trust staff.

4.49 Some consultant obstetricians were described as “*a bit dictatorial*”, and, while a lot of the team had gone on the “Human Factors” course to try to improve things, there was a cultural expectation of hierarchy. The hierarchy disempowered staff from speaking up and the Panel heard that it was hard to voice opinions without them being taken the wrong way.

4.50 A midwife said:

- “... the culture just continued. A lot of work with human factors was done but it never really seemed to translate into the management team.”
- “Years ago, the matrons used to go round and talked to all the staff first thing in the morning when they came on duty. They used to go and speak to the women to see if they’ve got any problems. A lot of complaints could also be addressed at that level before they got bigger. The management team now go to their office and don’t speak to anyone.”

4.51 One midwife commented that the Trust seemed to have forgotten the Human Factors principles in the past few years and that professional challenge was perceived as criticism. A consultant told the Panel: “*The Trust thinks if you send someone on a three-day training course in human factors, that their personality will change forever but that’s not going to happen.*” Another clinician expressed having limited confidence in the behaviour and competence of certain obstetricians.

4.52 A midwife spoke of the “*fear of speaking up*”. Instead of consulting staff and discussing how issues could be improved, staff were told what to do and viewed as “*negative*” if they proposed any alternatives:

Staff feel they don’t have a voice, that nothing will change and that if they don’t agree with instructions from above, they will be ostracised. Staff are desperate to get on with everybody at work which means that they say and do things that they don’t agree with. It hinders their ability to speak up when things aren’t as they should be.

4.53 The Panel heard examples of this behaviour, such as a staff member feeling as though they weren’t very good if they asked for a short break after ten hours of work instead of carrying on like the rest of the team, or a midwife admitting that they didn’t feel confident suturing a woman and facing a response like “*she’s been a midwife for years. What’s her problem?*”

4.54 The Panel was told of an occasion when a midwife had sought to explain to a consultant the adverse impact of the consultant’s late arrival on the operation of the clinic and associated services, in response to which the consultant wagged a finger in the midwife’s face and said: “*I am a consultant, and you can’t tell me what to do.*” The midwife was astounded that colleagues could speak and act in this way, but this kind of behaviour was described as “*relentless*”.

4.55 The Panel heard about conflict over patient management plans and midwives “*bracing*” themselves to discuss these cases. There were suggestions of pressure put on midwives to accept women into the low-risk pathway when they had not been risk assessed or they were outside the guidelines, and consultants challenging any resistance to this approach.

4.56 One member of staff told the Panel that many families had complained about staff arguing among themselves in front of women over whether to call for support and assistance from a more senior clinician, including in life-threatening situations.

4.57 Another midwife commented that, in the past, although members of the multi-disciplinary team were supposedly working towards the same goal, it felt as though they were on “*parallel tracks*” rather than on the same path. However, they thought that this was less the case more recently. The introduction of a preventive measure for rhesus disease was cited as an example of good collaborative working between midwives and obstetricians. The Panel was told that, in the recent past, “*it was definitely not a case of them and us*” and that things had improved, but there was still some way to go. The Panel was told that the change process had been aided by new staff thinking differently, having more enthusiasm and providing a lead for others to follow. A more recently appointed obstetrician had been particularly interested in leading on multi-disciplinary working.

4.58 The Panel heard contrasting views about multi-disciplinary working. On the one hand, we were told that the relationship between multi-disciplinary teams was positive; relationships with the neonatal team had “*always been good*” and anaesthetists were “*a great support to the labour ward*”. One senior member of staff suggested that the relationship between neonatology and obstetrics had always been good at QEOM, with communication between the teams if there were problems. The Panel was told of the recent appointment of obstetricians who had trained at East Kent maternity services and knew the units.

4.59 However, the Panel also heard numerous contrary accounts. It was said that there had always been friction between anaesthetists and other specialties: on one occasion a “*massive argument*” took place between an anaesthetist and a doctor in the middle of the corridor on the labour ward. We heard accounts of problems between midwives, obstetricians and neonatologists; neonatal provision at QEOM was not as “*supportive, available or accessible*” as it was at WHH. The obstetricians were described as “*challenging*” but nothing was done to address challenging behaviour.

4.60 The Panel heard that one perinatal meeting ended with a dreadful conversation and arguments with a senior midwife, who became very upset and went on sick leave. The issue was never addressed. We were also told that there were ongoing issues with communication between paediatricians and maternity services on the Kingsgate Ward; midwives were not listened to and were not taken seriously when concerns were raised. Paediatricians were also said to be slow to attend.

Challenging poor consultant behaviour

4.61 The Panel heard from a number of people about poor consultant behaviour and the difficulties in challenging consultants and addressing their behaviour. It was felt that the poor behaviour of consultants was dealt with very differently compared with the poor behaviour of midwives.

4.62 The Trust was said to have done little to change the poor working culture; instead, it tolerated bad behaviour, especially in relation to those who had been with the Trust for a long time or held a senior position. In 2019, a formal complaint was made about bullying at WHH; at that time, one consultant was known for making midwives cry in front of others, often at handovers. However, the Panel heard that nothing really happened when bad behaviour was reported. Some staff did not have faith in the Trust to make improvements.

4.63 Staff observed that the consultants who had worked there longer had a louder voice than the newer consultants, who struggled to find their way. When efforts were made to tackle poor behaviour, people backed away from the situation, or didn’t report it in the first place. Consultants’ poor behaviour was dismissed as “*just the way they were*”. Staff reported being

heckled, shouted at and having things thrown at them: *“it was accepted and allowed to happen, that was the way we worked”*.

4.64 The Panel heard that staff were not empowered to challenge consultants’ bad behaviour. The Panel heard instances of extremely poor behaviour from consultant obstetricians; one became rude and very personal with another member of staff who had tried to generate discussion in a large meeting around the findings of the Morecambe Bay report. No one intervened, although it became evident afterwards that there were people in the room who recognised that the behaviour had been unacceptable. This incident was one of the issues that prompted the Medical Director to invite the RCOG to conduct a review.

4.65 The Panel was told about clinical and behavioural concerns raised by one consultant about another, which they thought would be investigated by the Trust. The only feedback provided was that there was a communication issue and there would be training:

- *“After this there was reluctance for people to raise issues or make comments if they were asked further because of the way the process was done.”*
- *“If people get away with bad behaviour, they’re going to keep doing it.”*

4.66 Some midwives told the Panel that when they raised issues with their line manager, they would not hear about the outcome. The Panel heard that midwives often talked to each other about raising issues but questioned whether anything really changed. The person involved might be told off and improve for a few weeks, but then they would slip back into old habits. Behaviour was also explained away as *“it’s the way they are”*.

4.67 The lead CCG for maternity services pointed out that Medical Directors generally lacked the tools to be able to handle intransigent consultants. As an example, in 2020, there was a discussion with the Trust’s new Chief Medical Officer about an anonymous survey to identify problem consultants (whom people did not feel able to challenge and with whom they could not escalate issues). Although the problem consultants were known, no one was willing to raise a concern formally. The CCG also noticed a difference in the way in which nurses and doctors were treated in connection with serious incidents – nurses would potentially be disciplined, while doctors were merely asked to reflect (see “Culture of blame and handling complaints”, paragraphs 4.154–4.168).

Midwifery culture

4.68 The Panel heard about a lack of professional respect for midwives from the MLU and the community, and that their professional judgement was disregarded and dismissed in front of women.

4.69 The Panel was informed that there were several “freedom to speak up” issues raised from the maternity department at WHH. The issues related to bullying and behaviour. The Panel heard from one midwife that *“once that individual had the impact of their behaviour pointed out, they reflected and modified it. It just needed someone to point it out to them. There haven’t been any further concerns raised about the individuals’ behaviour.”* However, other midwives told us that bullying persisted and remained prevalent. There were also issues raised around rostering and equipment.

4.70 The Panel heard that, since 2012, the Trust had had a Medical Director for Governance and Patient Safety and two band 7 nurses as Freedom to Speak Up Guardians, although the latter had not had protected time to fulfil these roles. Only recently had the Trust appointed its

first full-time Freedom to Speak Up Guardian. A predominant theme at patient safety speak-ups was behaviour – not so much bullying as poor leadership and a reluctance or lack of skills to actively listen to what staff were saying. Poor behaviours existed *“at all levels of the organisation from top to bottom”* and the Panel heard that it was *“challenging when it is senior people who are bullying”*.

4.71 The Panel heard that there was discussion within the Trust on whether there was enough documented information to take people through a disciplinary process. However, although the Trust received a lot of information, staff were rarely prepared to put it in writing. We were told: *“The Trust sometimes moves the problem around but actually it’s about six months later and there are reports from the other site around the same issue.”*

4.72 The origin of different cliques of maternity staff was said to have dated back to the closure of the Canterbury site, when staff were moved to WHH and QEQM: *“In both hospitals, there were two circles of core staff that had been at William Harvey/QEQM and then the Canterbury staff. They didn’t get on well together.”*

4.73 A midwife who had worked at various sites and in various roles across the Trust told the Panel that the staff working at WHH had a reputation for being outspoken, and that allegations of bullying – in particular, more senior nurses treating junior staff with little respect – had circled the site for many years and had not been dealt with effectively. QEQM was considered to be friendlier, with less staff turnover and better working relationships, and new staff found it easier to settle in; it was suggested that this might be due to QEQM being a quieter site.

4.74 Staff told the Panel that *“senior midwives”* at WHH had a tendency to form *“cliques”* and that this could come across as threatening to more junior members of staff. They also told us that support workers had raised complaints about being treated unfairly compared with other groups of employees within the maternity unit. They indicated that, while there had been an improvement latterly at WHH in the way in which staff communicated with each other and mothers, it remained a concern. The Panel also heard that management *“cover themselves”* so that action would not be taken if the friend of a band 7 midwife did something wrong. One midwife was told expressly not to enter details of an incident on Datix (patient safety incident reporting software) as the band 7 midwife involved *“just forgot”* to take the required action.

4.75 One midwife described difficulties with the coordinator culture at WHH, with coordinators not listening to other team members or doing things in a set way. They were described as *“unhelpful and not hands-on”*, and they did not have the confidence of certain members of staff.

4.76 The Panel was told about midwives shouting and screaming at each other. A band 7 midwife spoke about witnessing a loud argument between a unit coordinator and a ward clerk, which prompted the band 7 midwife to close the doors around the ward to prevent women and families from hearing the argument. Afterwards, the band 7 midwife felt *“terrified by the way the coordinator spoke to [them] about having done this”*.

4.77 The Panel heard that a supervisory session for midwives was carried out at WHH and one of the questions asked was *“what is a good day for you”*. The response from one midwife was *“getting to the car, across the car park, at the end of the day without bursting into tears”*.

4.78 The Panel heard that student midwives did not feel valued by more senior staff members. Many student midwives did not feel welcomed and heard more senior members of the midwifery team gossiping about them. Another member of staff observed *“quite sharp questioning”* at WHH during handovers, which left staff feeling uncomfortable and feeling that they were being

judged rather than supported. The handover was described as a “*blood bath*”, with one member of staff telling the Panel that it was “*terrifying as [a] student*” and reporting being told off for showing a baby to the grandparents in the corridor, or for using someone else’s cup. The band 7 midwives were described as “*quite fierce*”:

As someone who was quite new to the profession, you would second guess yourself quite often to make sure you weren’t using someone’s cup or sitting in someone’s seat.

4.79 The culture of the Trust was also described as follows:

[There was] favouritism and some people are not treated fairly within midwifery ... there were [senior midwives] put in place who were bullies and they reported people who perhaps shouldn’t have been and others perhaps who shouldn’t be in the job.

4.80 More than one midwife identified challenges with internal recruitment: namely, that promotions were predictable and the same people would always be promoted. People with friends higher up in the maternity unit were said to get jobs before they had even been interviewed. Regarding senior management culture, we were told:

[I]f you’re friends with someone, you’ll get the job. It has been the case for quite a while that preferred candidates are coached for job interviews.

4.81 One midwife said that they did not apply for positions as they knew they would not be chosen. Another staff member had withdrawn from an application as their face didn’t fit:

At East Kent, if your face fits, you’ll get the job.

Bullying

4.82 The Panel was told that there were large numbers of staff who complained of bullying, harassment or discrimination. A member of the HR team commented on the high levels of bullying and harassment:

There were other issues but that was the most troubling because of the duty of care to the workforce and their perception of what it was like to work in that environment.

The same person told us that nobody got to grips with the situation or wanted to tackle it.

4.83 A member of the Executive told the Panel that the problem of bullying was “*well distributed*” across the organisation, and that it was not any worse in maternity than elsewhere. However, the Panel also heard:

[P]eople outside maternity would probably not have been aware of the bullying culture within midwifery and [the] difficulty with performance of obstetricians. There was a cloud of secrecy as staff members were involved in the disciplinary processes. It wasn’t openly discussed. They had to deal with individuals confidentially and professionally.

4.84 The Trust was said to be occupied with firefighting visible issues, such as the difficulties with the Accident and Emergency department (A&E), but did not address the underlying problem of the culture of the organisation, including bullying, harassment and discrimination. One midwife commented that the focus was on the little things to make it look good from the outside.

4.85 While complaints of bullying were often made by midwives, it should be noted that staff also spoke of bullying behaviours towards consultants and among members of the Executive. One consultant told the Panel that they were bullied by a senior midwife in the special care baby unit and by senior nurses. The Panel further heard of poor behaviours of non-executive directors at the Trust Quality and Safety Committee: *“The behaviour of the non-executive directors was appalling, rude, bullying. It was shameful.”* Sessions with registrars had been introduced to enable junior doctors to report concerns; these were then fed back to consultants to determine what needed to be done.

4.86 A CCG staff member told the Panel that, through quality visits, they had picked up on *“quite unpleasant”* bullying. One senior member of Trust staff described maternity services as *“a vipers’ nest”*, and another expressed the belief that the deaths of some babies could have been prevented had there not been a bullying culture within maternity services.

4.87 A midwife told the Panel that staff were not given any individual or constructive feedback to improve the results of the staff surveys. Band 7 midwives had occasional study days, annual supervisory reviews and either irregular appraisals or no appraisals at all. However, nothing was mentioned to identify that any improvement was needed in this area and the Panel heard that issues of bullying had not been raised as part of the appraisal process. In 2010, approximately 80% of staff had no appraisal at all.

4.88 The bullying culture at WHH was described as *“horrible”* and *“sickening”* and as persisting indefinitely. Between 2010 and 2012, an anonymous complaint was made to the Chief Nurse by junior midwives at WHH stating that the band 7 midwives were bullying them, forming cliques, excluding the junior midwives and creating a hostile *“in or out”* group dynamic. No one was named in the complaint. The Head of Midwifery wrote to all midwives across the Trust, urging them to speak to the Head of Midwifery directly. The Panel heard that one midwife left the Trust because of bullying.

4.89 The Panel heard that repeated concerns were raised about some staff members’ behaviour, but no action was taken in response. The Panel also heard that, in some cases, allegations of racial abuse were made against individuals, but there was no resolution and there was no structured way of dealing with allegations. Bullying and harassment policies required that an opportunity be provided for people to speak to each other in an informal way, to try to encourage them to understand the other person’s position. However, the inability of certain staff to communicate respectfully with each other was such an issue that they could not safely work on the same shift.

4.90 One midwife commented that bullying was a mindset. They told the Panel:

[[If people bully you, you’re part of that relationship ... there were people that I dreaded to work with, and I knew they would be short or cross ... but I just had to carry on doing the work ... you have to focus on the people that you’re caring for – sometimes, the management or whatever is happening in our sort of profession may be harrowing – there’s no staff, it’s difficult, there’s ... problems between managers and things that you have to really put into the background and try and focus on the care.

4.91 In 2014, an internal investigation into bullying began, carried out jointly by the then Head of Midwifery and the HR department. As a result of information obtained from the investigation, the Head of Midwifery was sufficiently concerned to recommend that the unit at WHH should be closed because of the risk to women.

4.92 The bullying was described as occurring more at WHH, where *“there were a lot of cliques”,* and where, *“as a junior midwife, you would hand over and you’d be berated ... and put down. I remember ... one time saying this lady’s been in second stage for two hours and the band 7 said, ‘she’ll end up in ITU and it’ll all be due to you’.”* The environment was described as *“toxic”,* and it was commented that *“Labour Ward and Post-Natal are high risk and high pressured enough without feeling scared to hand over”*. Cliques were prevalent in management and on the shop floor within midwifery. The Panel heard that, if a friendship group of midwives was on the same shift, the most difficult cases were delegated and shorter breaks given to the midwives outside the group. The Panel was told: *“It would depend on what mood the co-ordinators or some of the midwives were in on that day as to what you got ... If your face fitted you did really well.”* The existence of cliques was also an issue at QEQM, where one junior midwife noted that the culture in maternity services was *“hostile at times”*.

4.93 The Panel heard that the repercussion of making a complaint at WHH was to be given extra work. One midwife described feeling unable to tell the truth around the time of the 2014/15 investigation because, if they did, they would be bullied themselves. The midwife felt that they had no choice but to give a character reference to a band 7 midwife accused of bullying, although, really, they were *“dying to tell the truth”*.

4.94 The Panel was told that a number of anonymous letters were sent prior to the 2014/15 investigation but that the response from leadership at the time was that they would not do anything about it *“if no one is brave enough to put their name on these letters”*. Another senior midwife told the Panel that there was no recognition of, insight into or acknowledgement of the issue of bullying from obstetricians or midwives, and that people in senior positions did not respond appropriately to the situation.

4.95 A midwife at QEQM described a culture of *“playing the bullying card”,* and *“if you say something that I don’t like then I will accuse you of bullying me”*. In their view, this tactic put a halt to managing challenging situations, while attempts to introduce positive change were met with the response that *“you are picking on me”*.

4.96 In 2015, a collective grievance was raised by staff about the manner in which the 2014 internal investigation into bullying had been conducted. However, the grievance about the investigation process accepted the existence of serious bullying and dysfunctional behaviour within maternity services at WHH. The grievance also referred to the fact that:

An absence of senior support for staff at this present time has exacerbated an already difficult situation, as a result of which we believe there is a significant risk to our health and wellbeing, the patients we care for and the service as a whole.

4.97 The Panel was told that the Royal College of Midwives (RCM) represented some of the midwives who were subject to the investigation into bullying and that the RCM assisted with lodging a collective grievance.

4.98 A representative of the RCM told the Panel that the RCM had known before the collective grievance that there were challenging issues around midwifery leadership in the Trust at both WHH and QEQM. There were two big units operating without sufficient overall strategic leadership or strong management on either site. Cultural issues of bullying, harassment and poor staff engagement had been identified by RCM members, as well as being raised with the CQC.

4.99 The Head of Midwifery in 2014/15 told the Panel that they regretted going to the RCM for support with whistleblowing because the RCM advised them to resign and move on; if not, the RCM said that they would be unemployable in a senior position, and they should protect themselves. They told the Panel that it was really hard making the decision as they did not want to leave women vulnerable. However, they had been told by the RCM that whistleblowing was not in the public interest and they had to think of their career.

4.100 The Panel heard from Robert Eames, who worked as Associate Director of HR between 2014 and 2015, that “[the Head of Midwifery] *wasn’t part of the problem. I think [they] had a good go at trying to fix the cultural piece and the behaviours, but the team lashed out at [them].*”

4.101 A number of midwives told the Panel that 2014/15 was a very difficult and strange time in midwifery. One midwife thought that the bullying stopped when certain midwives were suspended. However, the Panel also heard that some obstetricians and some neonatologists did not think the correct midwives were suspended. Other midwives told us that the bullying persisted after 2016.

4.102 Some staff did not perceive the behaviours as bullying; the band 7 midwives were “*good at their jobs; they were just a bit fierce and a bit scary. If you had a problem, you could take one aside and talk to them ... they were strong, dominant women, commanding a unit.*” A midwife at WHH considered that band 7 midwives were often a target for accusations of bullying, because the nature of the role meant that they often had to tell staff to do things differently.

Lack of diversity and racial discrimination

4.103 The Panel was told that the Trust had been rated one of the worst in the country for workplace diversity and attitudes towards cultural difference. The QEQM midwifery unit was described by one member of staff as being “*often seen as a white-led midwifery unit*” that would benefit from having more people from different cultural backgrounds.

4.104 Complaints of discrimination were sometimes based on race. A member of the Executive recognised racial inequality in East Kent and the existence of racial tensions, which probably contributed to bullying in parts of the Trust. One midwife from an ethnic minority background had been to HR three times; however, on each occasion the complaint was reduced to an overreaction. On one occasion, a midwife was discriminated against when a coordinator, at a woman’s request, would not permit the woman to be looked after “*by anybody except an ‘English’ midwife*”. Concerns were also raised about management making offensive comments or jokes connected to race; however, these concerns were minimised and put down to staff just trying to be humorous. The Panel heard more than once that instances of personally offensive behaviour by consultants and midwives were not treated seriously.

4.105 Concern was expressed that the Trust’s attitude and lack of diversity were having an impact on patients as well as on staff. It was said that, at WHH, women who could not speak English or who were from different ethnic backgrounds were treated differently, as though they were at fault.

4.106 However, contrasting views were also expressed to the Panel. One senior member of staff from an ethnic minority background described not only being made to feel welcome but being positively favoured due to their heritage. Another member of staff told the Panel that they had not experienced any prejudice as a person from an ethnic minority background and felt happy when called to work at QEQM.

Consultant rotas and availability

4.107 Consultants identified challenges arising from the on-call rota. Prior to 2020, consultants would arrive around 8am and stay until 5pm or 6pm and then be on call from home. They covered other duties including gynaecology as well, limiting their presence on the labour ward.

4.108 One midwife told the Panel that the process for escalating a clinical issue was very clearly to the Senior House Officer (SHO; a junior doctor), then to the registrar, and then to the consultant, in that order:

I didn't escalate directly to the consultant because that wasn't the culture ... the issue was that consultants were at home in the night and so it was difficult to call them about a pathological CTG [cardiotocograph; a trace of fetal heart rate] if the registrar was busy with a case in theatre.

4.109 One consultant told the Panel that they escalated issues around lack of consultant availability, but that the process of trying to get these resolved took a long time because of the way in which consultants were treated (or needed to be treated). There was a lack of support provided to the junior doctors, and the Panel heard that “East Kent did not feel like a consultant-led service”.

4.110 A midwife told the Panel that, in 2016, after the RCOG report had been submitted, the consultants at WHH made a noticeable effort to be more visible and accessible while on call.

4.111 A junior doctor recalled that “consultants would point-blank refuse to come into the hospital after hours and would put other staff under intense pressure as a result”.

4.112 The Panel was told about one occasion when a woman who was 35 weeks pregnant and thought her waters had broken attended QEQM. The woman needed a speculum examination; however, the SHO hadn't been trained on how to do it. Although the consultant was called, they did not attend and the SHO sought advice from YouTube on how to do the procedure.

4.113 There was a reluctance among junior doctors and midwives to raise the issue – people did not want to complain about a consultant or be named as the person who had brought up the issue. A Trust Board member supported this view and told the Panel that it was very hard for their clinical leaders to call out bad behaviour in a way that was effective.

4.114 However, the Panel was also told by an obstetric consultant that, more recently, adverse publicity had resulted in consultants either being contacted more frequently, perhaps in circumstances where trainees could do what was necessary, or themselves being too cautious.

The separate operation of the WHH and QEQM sites

4.115 The Panel was told by a number of staff that, although the merger of the three different trusts to create the East Kent Trust occurred over 20 years ago, the Trust continued to operate as if there were three separate hospitals that ran independently of each other.

4.116 The Panel heard that staff in the Trust had never come to terms with the merger:

Ashford is still taking it hard, and Canterbury doesn't understand why they aren't the centre of the world. It is deep rooted.

4.117 More than one member of staff spoke about the Canterbury-centred nature of the Trust, which was an issue that needed addressing:

[The Trust] was run like three completely separate units, and nobody had really tried to merge it in any way. Canterbury was full of the great and the good consultant-wise, and they sort of looked down at Margate and Ashford and everybody knew that as well. The inter relationships were really difficult.

4.118 The Panel heard that there was no cross-site teamworking or shared learning. The sites “always ran distinctly, even down to different working policies”.

4.119 There was also a perceived inequality and an “us and them” culture between the two sites at Ashford (WHH) and Margate (QEQM). One member of staff told the Panel that, although QEQM was quite big, “it always felt like it was a bit of an afterthought”.

4.120 One member of the Executive commented:

[P]eople working in Margate don’t feel massively connected on a day-to-day basis with what’s happening in the William Harvey maternity and neonatal service. This should not be underestimated. It’s not an excuse for people not engaging and not following national guidance but it is a factor that cannot be ignored ... There is an element of clinical isolation at Margate whereby you don’t get an opportunity to see how things are done elsewhere and there isn’t much interchange ... However, you can also flip this round, and Margate has been able to find their own solutions to problems, and they are committed to their population who they live with and understand (whereas at William Harvey the atmosphere is not quite so embedded in the locale as Margate). When this works well it can be very powerful and a force of great good. But by the same token when it’s not quite right you can get quite a long way from what is best practice.

4.121 One experienced midwife told the Panel that there had always been a very different working pattern at the two sites, and this impacted on the midwives and on patient care. At QEQM, the consultants were not on the labour ward after handover; this also had an impact on the junior doctors, on their teaching and on the support available. Further, at WHH, regular ward rounds were conducted with the obstetricians; however, this was not the case at QEQM. Some staff at QEQM did not do ward rounds at all, although one midwife suggested that this had subsequently improved.

4.122 Another difference relates to the treatment of families following the loss of a baby. We heard that, for a number of years, the consultants at WHH have been speaking with families at around 6 to 8 weeks following the loss of a baby of 12 weeks’ or more gestation, so that the family could understand what happened and to discuss how the family would be looked after in their next pregnancy. However, the Panel heard that the doctors at QEQM have resisted this practice.

Training

4.123 A member of the Executive spoke of their concern that an organisational development programme was not introduced when the Trust was going through restructuring; instead, the restructure focused on moving people without developing them.

4.124 A senior clinician recognised that there were challenges in gaining experience and competence in neonatal intubation and in maintaining neonatal resuscitation skills as a general paediatrician at QEQM. Each consultant performed intubation of extreme premature babies approximately once a year, and there were not many other intubations during the year. This posed a risk of consultants gradually becoming deskilled over time, and there was a need to ensure that all staff were up to date with neonatal life support training.

4.125 The Panel was told that a simulation training programme to teach resuscitation techniques was introduced following the inquest into the death of baby Harry Richford. Consultants across the whole team participated in the simulation and the Panel was told there was a neonatal simulation held jointly with midwifery every other week.

4.126 The Panel also heard that there had been a robust in-house teaching programme for neonatology and paediatrics for some time. Other basic skills taught include airway skills on mannequins, resuscitation, non-labour emergencies in neonates and communication with midwives.

4.127 The Panel heard that, more recently, staff grade doctors who came from abroad, or trainees without experience working in the UK, were trained and rotated to the neonatal unit at WHH for experience; this also applied to non-trainee grades who lacked confidence in their skills.

4.128 Many midwives spoke about a lack of support during their training or when they first started in their roles and a lack of mentorship. One midwife who was appointed into a coordinator role had to teach themselves the leadership skills needed to maintain a safe service:

[S]ome band 5 midwives don't have professional resilience because they've not been taught how to develop it. It's a big jump from being a student to becoming a band 5 midwife.

Organisational issues

Culture of denial and resistance to change

4.129 The Panel heard about the “sense of optimism” in the Trust as it achieved Foundation Trust status in 2009. The Dr Foster Hospital Guide named the Trust as Overall Trust of the Year and Foundation Trust of the Year in England in 2010; however, this appeared to be a double-edged sword. One member of staff said that the Dr Foster recognition was:

... a bad thing and a major error. Complacency started to come in ... There were things the Board believed that were not true ... [P]eople had got into the wrong frame of mind. It was great to get awards if you were doing well, but not if it gave false assurance, and things were melting down behind the scenes.

4.130 One consultant felt that senior managers became arrogant as a result of the 2010 award and “shot down other people’s suggestions for further improvement as a result”. A senior member of the management team described the Trust as:

... riding on the Dr Foster’s award and felt itself to be quite above everything else ... the Dr Foster’s award was held up to every criticism.

4.131 Many staff, and others, spoke about a culture of denial at the Trust and a resistance to change. The Panel was told that, following the 2014 CQC inspection and report (which resulted in the imposition of Quality Special Measures), the reaction of the Trust was one of real defensiveness.

4.132 A member of the Executive who joined the Trust after the CQC report commented that the Board was “potentially in denial about the organisation”, which served to reinforce the disconnect between the Board and the wards. One manager told the Panel:

[T]he organisation was utterly floored and did not recognise the report. People were traumatised.

4.133 There was quite a strong feeling from Board members that the Trust was a victim, that “everyone was against them”, and that “things weren’t as bad as this”. Another senior manager commented:

[T]he Trust board were in complete denial and were shocked, angry and hurt. They disagreed with just about every point in the report.

4.134 The Trust went through the CQC reports:

- The Trust came up with “hundreds of challenges to the report, including grammatical/spelling issues ... rather than getting to the essence of the report or discussing what to do”.
- “It was not for nothing that the Trust was rated inadequate, yet they responded by sending back comments about commas and semi-colons, losing sight of the problem.”

4.135 We heard that the Trust did not use its staff surveys to identify issues, and that there were some very bad staff surveys that fed into the CQC report. The staff survey results in 2014 gave an indication of bullying; however, these results were not a one-off and bullying had been a common theme in previous surveys. We heard that “the trust central teams were in denial” and it seemed that they were not “systematically reviewing anything on a regular basis”.

4.136 Interviewees confirmed that staff survey results at the Trust were never very good. A member of the HR team told the Panel that, whenever they tried to discuss the results, “they weren’t necessarily what people wanted to see and hear. We were told there were lots of reasons why the results were invalid.” They told us that there was no desire on the part of the Board or the executives to think about the survey results and what they were telling the Trust:

This desire to give a rosy view was unhelpful ... it was unhelpful to patients too because it doesn’t provide a full picture of what is really going on in an organisation and the potential risks and issues.

4.137 In 2014/15, the then new Head of Midwifery identified cultural issues within maternity services; they described their reaction to East Kent maternity services to the Panel as being “the next Morecambe Bay”. One senior midwife told the Panel that staff were really shocked by this as they did not see the similarity: “things were being said that were very untrue”. The Panel also heard that East Kent was “equal to or worse than Morecambe Bay”, but:

[T]here was no recognition, insight or acknowledgment from the obstetricians or the midwives into any of the issues identified in the 2014 [CQC] report.

4.138 One clinician told the Panel that they did not recognise some of the issues that were highlighted in either the CQC or the RCOG report. A senior midwife remembered the RCOG report being dismissed by a senior consultant obstetrician as a “load of rubbish”. The midwife commented to the Panel that Trust obstetricians did not like the light being shone on them in that way.

4.139 Another clinician couldn’t recall the RCOG report being widely discussed, and they were not made aware of the report’s key findings or recommendations. Similarly, a junior doctor told the Panel that the report was not formally discussed with junior doctors. Another consultant told

the Panel that they believed the issue raised by the RCOG report around consultant availability was limited to just two consultants, one of whom left the Trust.

4.140 In 2018, the Trust's maternity services were rated by the CQC as "Requires Improvement", although reference was made to the introduction of multi-disciplinary training as a step in the right direction. We heard that the Board took reassurance from that, notwithstanding the lack of effective audit and quality assurance systems that was identified by the CQC.

4.141 Professor Walker, the Clinical Director of Maternity Investigation at HSIB, spoke of the initial defensiveness of the Trust in 2018 and of a lack of opportunity to engage with staff outside a small number of senior Trust staff. There was a meeting in the summer of 2019 between HSIB and members of the Trust's Executive, at which there was a lot of aggression and pushback by the Trust. Professor Walker told those present in the meeting: *"[L]ook, you've got a major problem at this hospital, which is going to escalate, and you'll hit the press by the end of 2019."*

4.142 Another HSIB officer told the Panel: *"There was denial in the Trust about the enormity of the underlying problems."*

4.143 The relationship with HSIB was described by a member of the Board and Executive as difficult. So too was the transition from a process whereby the Trust conducted investigations itself, with the benefit of having a relationship with the family involved, to outsourcing the process to HSIB. They commented that the HSIB process felt very impersonal, and people were defensive.

4.144 This defensiveness was echoed by another member of the Board, who described being *"blind-sided"* by HSIB's serious concerns in about 2019 that East Kent maternity services were at the top of the list for total body cooling (therapeutic hypothermia) and feeling disappointed that the Trust had not engaged appropriately with HSIB on the issue. There was an internal report to the Board in December 2019 addressing HSIB's concerns and citing improvements in certain areas (such as staff recognition of clinical deterioration or changes in the escalation process), although no evidence was provided and *"frankly the Board was not assured that what they were doing was enough"*.

4.145 A non-clinical member of the Board felt that the relationship with HSIB was not proactive and detected a reluctance within the Trust's clinical team to accept what HSIB was saying.

4.146 The Panel heard from Nick Hulme, a Trust Governor, that, even as recently as 2020, at Council of Governors meetings it was regularly highlighted that it was *"not fair"* that East Kent scored lower down the lists of trusts, given the large size of the Trust and that it had *"a lot of comorbidities"*. Mr Hulme told the Panel that governors were told to *"ignore the press"* because they had *"an agenda"*. Mr Hulme also told the Panel that he had been actively dissuaded from speaking to the Panel by a member of the Board, who told him that he *"would not add value"*.

4.147 Mr Hulme also told the Panel about an attitude within the Trust of *"well, as long as we're not bottom, that's alright"*. There was no ambition to be anything other than *"bang average"*, and the focus was on *"get to good"*. The Panel also heard from a Board member of a *"culture of failure for five or six years"*, with the Board being described in around 2017/18 as *"very fragile and brittle"*:

There were few people left in the Trust who knew what success looked like or who had experienced working in an organisation that was functioning effectively. It wouldn't be straightforward to change that.

4.148 The Panel heard of clinical leads who were resistant to change and reluctant to look outside the organisation or to be open to other ways of working. One manager was used to organisations seeking fresh eyes on incidents or complaints, but this was always resisted at the Trust.

4.149 The Panel was told that concerns about maternity services were raised with the executive team by the divisional management and by other functions within the Trust, such as clinical governance and patient safety, legal and HR, but nothing happened.

4.150 The Panel heard that the practice of the Trust was to discourage the reporting of screening issues to Public Health England, despite it being national policy to do so, and that a screening coordinator was reprimanded for involving Public Health England in a serious incident and was told not to report issues externally. The Panel heard that the culture in the past was to keep things in-house, but that this had improved more recently.

4.151 One consultant midwife sometimes found East Kent maternity services slow to adopt new national recommendations, for example about identifying women at risk of restricted fetal growth. They told the Panel that they would approach the governance team, maternity leadership and the obstetricians about making the recommended changes, but those approached would often produce counterarguments relating to equipment or resources for why the recommendations could not be implemented.

4.152 A member of staff who had rejoined the Trust in 2019 recognised positive changes that had occurred and noted that morale and staffing had improved. However, there was still a reluctance within the Trust to adopt new research and guidelines.

4.153 The Panel was told that, even in 2020, obstetricians and paediatricians had a focus on process rather than on outcomes. That included some of the work of the Birthing Excellence: Success Through Teamwork (BESTT) programme:

For example, they would try to decide whether a day or a day and a half of training per month was needed, instead of identifying the outcomes they needed to achieve and then basing the training requirement on those.

Culture of blame and handling complaints

4.154 The Panel heard from a number of people about a “blame culture” when things went wrong:

- *“Feedback was almost like a blame game where someone was at fault and had done something wrong, rather than giving feedback on how to improve when something happens.”*
- *“Raising complaints at the William Harvey was difficult as individual staff would feel blamed for mistakes.”*
- *“Ashford [WHH] is odd and the culture there is weird. They are less likely to support each other, and more likely to blame.”*
- *“Staff are less supported now by senior management than they have ever been, and there is a culture of blame and recrimination.”*
- *“There was often feedback, but it was not given in as supportive a manner as it could have been ... You were only called to see your supervisor if you had done something wrong ... I am open to scrutiny if there are lessons to be learnt but that doesn’t mean you’re a bad midwife or that you did it on purpose.”*

- “[Consultants] *take no responsibility for their actions and blame colleagues for any challenges and failings.*”
- “One particular paediatrician would often blame obstetricians for any deaths or serious incidents that arose.”
- “Historically there was a lot of jumping to conclusions and finger-pointing, whereas [more recently] there’s recognition that things aren’t black and white – that they can be complex, and you shouldn’t jump to conclusions.”

4.155 A midwife told the Panel of an incident when they were called before an obstetrician after a baby had become grey and floppy in recovery, and the obstetrician seemingly accused the midwife of doing something wrong (“*that baby was screaming and fine in theatre, what happened?*”). There was a similar account from another midwife where there was a poor outcome:

[T]he consultant stormed onto the ward the next day and demanded to know what I had done to produce this outcome.

4.156 A band 7 midwife told the Panel of the “*punitive approach*” to dealing with issues:

[T]here’s a lot of fear among staff about making mistakes and being told off, and this hinders their ability to learn.

4.157 The same member of staff told the Panel that there was “*no celebration*” of anything that was done well, and communication was not transparent. When a learning opportunity was identified, it felt like a punishment; the approach at the Trust’s maternity services was “*not healthy*”.

4.158 The Panel heard from a senior midwife about the difference in the treatment of midwives and doctors. Whenever there was a root cause analysis investigation, there were often outcomes for midwives such as referrals for supervision or reflection, or formal HR processes. However, for doctors, there would simply be an informal conversation:

This was why the midwives felt that there was a blame culture and that things were inequitable.

4.159 A separate senior midwife made the same point and described how issues raised with doctors wouldn’t go any further and there wasn’t any challenge to difficult obstetricians, whereas with midwives the outcomes were very structured, with a pathway and supervision.

4.160 We heard that a lot of disciplinary action was taken and that, at one disciplinary hearing, the Chair said: “*I don’t know why this has got this far. How did it get to this?*” When a midwife was referred to the NMC, the case manager came back and said: “*I’ve looked at everything and I don’t know why she was referred.*” We were told:

There was a knee-jerk reaction to punish people and it created a very unpleasant environment.

4.161 Others commented that, when things went wrong, there was no opportunity to debrief; the response was reactive rather than proactive. The Panel was told of a culture of blaming junior staff or locum doctors for whatever problems occurred within the Trust.

4.162 The Panel heard that some issues could escalate quite quickly, and that staff seemed to act on rumours rather than facts. A midwife could quickly be on an action plan after raising a

simple issue that they were not sure about, when “[it] *didn’t need to go that far*”. The Panel was told that midwives were hindered by fear: they worried about what people thought and said about them, and about things being done in the background that they were not aware of.

4.163 The Panel was told about a focus on documentation, and that this could distract from giving actual care, noticing when things deviated from the norm, or recognising when issues needed to be escalated. The Panel heard that midwives were sometimes too scared to press the emergency buzzer in case they were wrong, or to tell a more senior staff member on duty that they were unsure about a situation. This fear related to delivery suite coordinators and obstetricians as well as band 6 and 7 midwives.

4.164 There were approximately five to ten complaints each month about maternity services, mainly about communication and relationships. They covered:

... things like the fact that people didn’t feel involved in the decisions that were being made and hadn’t been provided with sufficient information.

4.165 We heard that a high proportion of complaints about maternity services concerned the midwives’ attitude towards and communication with younger women, who felt that things weren’t always explained well or that they weren’t listened to, helped with breastfeeding or given information about their baby. Other common themes reported to the Panel included pain relief and whether or not a caesarean section should have taken place.

4.166 A senior midwife commented that inappropriate staff behaviour was the most prevalent “*human factor*” at the Trust, and that it was not limited to midwives; complaints were also made against healthcare assistants, obstetricians and ultrasound staff. They commented that “*complaints as a result of poor behaviour impacted staff across the board*”.

4.167 The Panel was told that the obstetrics and gynaecology department had a “fix it” clinic every other Friday morning, where a consultant and specialist nurse would meet with women who were unhappy with their treatment and care. There was a six-month waiting list for the clinic, but the women “*had the opportunity to get stuff off their chest and try to sort something out*”.

4.168 The Panel was told that Trust staff had later come to see the importance of standing back and thinking about what the family’s needs were in situations where complaints were made, and the need for staff to take time to talk things through with the family, to listen to them, to understand what was important to them and how they were feeling, and then to respond to that, rather than assuming that they knew what was important.

External factors or problems as the staff saw them

Facilities and infrastructure

4.169 Infrastructure was cited as an issue for many services in the Trust. One member of the Board and the executive team talked about the estate:

[It is] profoundly challenging – it is difficult to attract clinicians and to provide good modern services.

4.170 Another Board member commented:

The maternity estate is tired, poor, and needs replacing and totally modernising. But it's not just maternity – the entire estate needs this.

4.171 Some members of staff talked about QEQM as “*falling apart*” and not “*fit for use*”. The Panel heard about the challenges presented by the size of the rooms and the lack of resuscitation trolleys on the ward.

4.172 We heard that theatre access was identified as a problem at QEQM: there is only a single theatre in the labour ward and, if there were a second emergency, it could take up to 30 minutes to organise and start operating in the main theatre.

4.173 One midwife referred to the “*struggle with the footprint of both the acute labour wards*”. The MLUs were new, but the majority of women were giving birth in environments that were not fit for purpose. Another senior midwife described the dated estate as a “*big problem*”.

4.174 A member of staff who worked in the MLU at WHH commented on the difficulty presented by having the MLU on a different floor of the hospital from the labour and postnatal wards:

The team felt disjointed ... The perception was that you didn't matter. It was difficult to keep the woman at the centre when you're juggling politics between two areas.

4.175 One consultant commented:

[A] lot of the labour beds have only 30% of space recommended by national guidance. This meant that if a baby was born in poor condition, midwives would have to run down the corridor to consultants as there was no space to treat the baby by the bedside.

4.176 The Panel heard that WHH would struggle to meet guidance recommendations that each labour bed should have a bath available.

4.177 We heard that there was only one toilet for staff across the whole unit at WHH, so if someone was working on the Folkestone Ward (which provided care for antenatal and postnatal admissions), they had to tell the other midwives that they were leaving the ward to go to the toilet. One midwife told the Panel: “*I feel like we're not well looked after as midwives.*”

4.178 The Panel heard that requests for a second obstetric theatre at WHH were declined because maternity services did not generate as much money as other departments.

4.179 The Panel was told by many interviewees that one of the problems at QEQM was that the resuscitation trolleys were outside the delivery rooms, and there were several cases where a baby was taken out of the room but their mother would hear things going on in the corridor that related to their baby, which was very distressing. The response of the Trust was that it couldn't do anything about it because, in its view, it was the nature of the Trust estate.

4.180 The Panel also heard from Mr Hulme, a Trust Governor, who commented:

[Y]es, the estate is in a mess and absolutely needs to be improved; they are awful but ... it is not impossible to do really good care just because the buildings are rubbish.

Geography

4.181 Some people who spoke to the Panel mentioned the challenges presented by East Kent's geography:

- *“The geographical location of the hospitals on two different sites is also a difficulty, as staffing levels and service quality need to be maintained across both sites.”*
- *“You can’t change the geography of the organisation. The challenge is how to ensure the right support is in there, given the geography.”*

4.182 A director observed:

[O]ne of the challenges for East Kent staff is that there are few alternative employment opportunities. A nurse working in Margate would have to commute eighty miles, e.g., to Medway [and back], if they wanted to work at another NHS trust. Professionals who train at Canterbury Christchurch University, e.g., radiographers and nurses, gain their practical experience in the Trust and then [are] likely [to] come to work for the organisation too ... staff tended to be inward-looking in their view as a result.

4.183 The Panel also heard comments that it is difficult to build strong organisational connections and shared values across separate sites. Some staff expressed doubt as to whether the Trust would be viable over the long term with two or three sites.

4.184 An experienced consultant told the Panel that the geography made the Trust difficult to work at:

[W]hen an incident does occur, managers become torn between multiple sites and must choose carefully where they spend their time.

4.185 The Panel was told by an experienced midwife of occasions when the labour ward at QEQM was closed due to safety reasons, requiring attendance at other sites. As the nearest labour ward is 30 miles away and women are often reluctant to travel to other sites, unplanned home births could result. Women were not routinely told that there was a risk of the labour ward being full before they entered the hospital or that being transferred to a different trust was a possibility. This was particularly a problem at Thanet, where many people do not have their own transport and therefore there was little possibility of reaching another trust in time to give birth safely.

4.186 A member of the Board and Executive described how the maternity case mix at the Trust changed between 2007 and 2015:

[T]here was more complexity, higher teenage pregnancies, higher than usual problems with smoking, obesity, and diabetes – all the social determinants of health. East Kent has both affluent areas and also a lot of deprived areas, particularly coastal areas. From a midwifery point of view there was a lot of complexity that people were managing. The Trust was tracking c-section [caesarean section] rates and intervention rates and they were tracking slightly higher than the national norm.

Staffing

4.187 A number of people to whom the Panel spoke commented on the difficulty of recruiting staff to the Trust, particularly at Margate:

- *“QEQM was always a difficult site to recruit to, on the extreme southeast of the country and a coastal community.”*
- *“Margate is the furthest place from London where people want to go and settle, and finding staff is not easy.”*

- *“One thing about the geography was that it was almost impossible to recruit staff to go to Margate, so the only staff they had were people who lived there, and they had been there a very long time. If you don’t get any turnover, then that brings about an issue.”*
- *“The biggest issue was staffing. Just prior to 2009 there was a large investment (almost £4M) into nursing and midwifery because the staffing levels were not safe. However, recruitment was a challenge given the geography of East Kent (coastal areas at one end of the country), and there was difficulty in recruiting both midwives and obstetricians, and the Trust was more reliant than it wanted to be on locums.”*

4.188 One senior consultant described QEQM’s middle grade medical staffing situation in 2012 as “dire”. However, we heard that, by the end of 2013, QEQM had a full set of middle grades and there was active recruitment of staff from abroad.

4.189 The picture presented to the Panel in some interviews was that, up to 2015/16, there were quite a few experienced middle grade doctors who had been at the Trust for a long time; and that from 2015/16 to 2019, there were a lot of rota gaps and there was a time when more than 50% of the rota was covered by locum doctors. Some consultant obstetricians told us that they were always worried when working with someone they had not met before and that they gave careful consideration to whether locums could be left unsupervised. These issues were escalated to the divisional Medical Director, but it was not felt that they were taken seriously enough by the Trust. We were told:

It was difficult to maintain quality with locums. This is not a problem unique to East Kent but the thing that set them apart was the scale of it – 40-50% of the shifts ... Trying to secure locums at short notice was an endless task.

4.190 A senior midwife described how the CQC’s intervention in 2014 and the adverse publicity facing the Trust caused difficulties in recruiting staff. They described the workforce as stable and structured prior to 2016, but after this there was a need to use significant numbers of locum doctors, which had a negative impact. The quality of some of the locums was described as “troubling” but it was “a case of having that locum or nobody”.

4.191 We heard that the Trust was spending about £17 million per annum in 2018 on locum doctors and agency staff, which was, according to one Board member, “bad for patient safety and continuity”. The Panel heard that there were constant challenges in keeping staff up to date.

4.192 The Trust was described by a regulator as “not a Trust that attracts quality staff from elsewhere”, and a midwife told the Panel that trainees did not want to come to East Kent as it is too far out of London.

4.193 The Panel was told that a benchmarking exercise within midwifery in 2020 had established that numbers of staff within the Trust’s midwifery unit were too low. A review of resources in the same period had established a need for specialists in mental health and heart monitoring, more core midwives, an additional community midwife, a Deputy Director of Midwifery, and two senior band 7 nurses to focus on patient experience and digitisation.

Leadership

4.194 The Panel was told that, following the achievement of Foundation Trust status in 2009, the period from then until 2014 was one of relative stability, and that at Board level things felt strong. However, one Board and Executive member reflected that staff morale was adversely affected by the impact of 5–6% efficiency savings year on year; the Board failed to recognise

this development, even though the signs were there in the staff survey results, which showed that stress and bullying increased during this period.

4.195 A non-executive director told the Panel that the Trust was “*too large, complex and diverse for the ability of the executive team*”:

It was just out of their league. It was just too big. The span and complexity was too large for them ... They weren't even firefighting. They were just on the ropes being punched the whole time.

4.196 It was said that individuals were doing the best they could; however, the system was letting them down. The lack of senior leadership training and senior leadership models was an issue. Also, we were told that the problems in maternity were:

... symptomatic of an organisation that is outwith the competence of the executive team.

4.197 One director during the period described the Board as:

... very dysfunctional; it was not united. They did not work well together, and they were very separate ... The chairman and the chief exec were pretty much not talking to each other.

4.198 It was commented that the quality of non-executive directors on the Board was variable and that they did not always provide the right kind of challenge. One member of staff described the non-executive directors as “*weak*”:

[T]hey didn't know what they were doing and didn't have enough challenge. They didn't know the data. Your non-execs are there to hold the executive to account in the right way and I didn't think that was happening enough.

4.199 The Panel heard about “*really awful reporting to the board*”:

There was no challenge or testing at executive level, and that's partly what got them into the mess that they got into ... Nobody really knew what the truth was about a problem.

4.200 A non-executive director with experience of both public and private sector boards commented that the Trust was just going through the motions.

4.201 The Panel also heard about communication breakdown between non-executive directors and the Executive Board. One non-executive director first became aware of issues in maternity services the day before a news story was about to break on the BBC website. On another occasion, the same person first learned of an issue after seeing the front page of a newspaper. It transpired that the Executive had known about this for a month but had not thought it appropriate to tell the non-executive directors.

4.202 Senior management were described as lacking people skills. One member of the Executive was described as a “*threatening*” presence throughout the Trust; the Panel heard that “*staff did not feel supported by [them]*”. Another member of the Trust Executive was described as “*overwhelmed*”, with a tendency to talk at people rather than engaging fully.

4.203 The Panel was told of a toxic culture and unhealthy tension between managers and clinicians, who had different priorities. The managers were quite wary of powerful clinicians:

[I]t led to a really unhealthy tension where people just tiptoed around the issues.

4.204 Of the culture, it was said:

[T]hey're [senior managers] really frightened of these people [consultants].

Changes at Board and senior management level

4.205 After the 2014 CQC report, the Trust lost its Chair, the Chief Executive, one of the joint Chief Operating Officers, the Director of Nursing and the Director of Finance. This heralded the start of a long period of instability at Board and senior management level which had:

... [a] tremendous impact ... Everything got put on hold because key people were not in post.

4.206 Since 2014, there have been three Chief Executives of the Trust, four Chairs of the Board, three Chief Nurses and four Heads of Midwifery (referred to since 2018 as Directors of Midwifery). A number of members of Trust staff identified that the level of turnover in key senior positions had had a detrimental impact on the effectiveness of the Board and Executive during this period. It was also said to comprise a disproportionate amount of the Council of Governors' work.

4.207 One member of the Board and Executive described the Chief Executive post as "undoable" and a case of "how long is the next one going to last". One Head of Midwifery was asked by a senior colleague on taking up their post, "how long are you going to stay?".

4.208 The result of so many changes within the management structure was that "people didn't have much confidence in the management team".

4.209 The Panel was told how tough it was to maintain momentum while losing people and continually having to develop new relationships; of the damaging impact of the constant changes of senior leaders; and how initiatives were regularly implemented and then abandoned with the next change of leader.

4.210 The Panel was told that the departure of the Chief Executive in 2017 was "catastrophic" and that "the visible loss of leadership had major consequences for the Trust": "conflict and difficult relationships" abounded and remained a problem for two years.

4.211 One senior midwife described how, every time someone new came in, the journey would start again, with new leaders wanting to know everything that had happened and changing priorities. It was a case of "that's not important, this is now important". The BESTT Maternity Transformation Programme that was launched in 2017 was cited as an example of a programme that had been owned by the staff but was now "shelved" and "just another example of not seeing something through".

4.212 Another senior midwife said:

[T]he goalposts were being moved quite a lot because there were new Heads of Midwifery coming in.

4.213 And another member of staff said, in reference to the six different Heads of Midwifery throughout the period of the Investigation:

[A] new incumbent would bring new ideas and then things would change again with the next person. It felt as though we were always trying to catch up.

4.214 The Panel heard that, both in the immediate aftermath of the 2014 CQC report and since, there had been a high turnover of non-executive directors, with some leaving because they had come to the end of their tenure but others leaving due to frustration or because the pressure of reputational issues was too much. Some non-executive directors chose to move on before the end of their term because they did not want to be associated with what was happening at the Trust.

4.215 We heard about the dangers of “hero leaders” who were expected to single-handedly reverse the fortunes of an organisation, only to be quickly and repeatedly replaced when they inevitably failed. We also heard of the need for a strong leadership team with a long-term strategic vision beyond the next two to three years.

4.216 Commenting on a whole series of changes of leadership, Professor Ted Baker, former Chief Inspector of Hospitals at the CQC, observed that stability and support from external parts of the system such as NHSE&I and the CCGs are required in order to turn a trust round from special measures:

If you look at East Kent ... there has been a whole series of changes of leadership and none of the leaders have stayed very long. That kind of chopping and changing leadership and people who go in to lead an organisation like that and have a two-year horizon in terms of what they want to achieve, are never going to drive the change you want. There's a history in some of these trusts that don't make progress, that when we find real problems – put them in special measures – the leadership changes and a new hero leader is brought in, whoever they may be, and they are going to sort it out. And two years later they have failed, and they move on quietly and someone else comes in. The misconception is: one, it's not one person, it has to be a team; two, it's not a hero leader, it's someone who is thoughtful and who is going to drive cultural change; and three, they need support, however good they are, from the external part of the system – NHSE&I, CCGs or ICSs [integrated care systems] now. They need to support them because taking a trust that is in special measures, that is inadequate and has really serious issues and turning it into a really good trust, is a huge job and a formidable challenge. It's not one person's job, and it's not something anyone can achieve easily.

4.217 Professor Walker, who had significant experience of investigating maternity incidents at the Trust with HSIB, offered this insight:

There were continued problems and with continued themes, which in fact have continued to this day ... A lot of big hitters come into East Kent to try and solve a problem, and in fact they make the problems worse because they obligate the Trust to spend a lot of money and time building structure, while not necessarily solving the problem on the shop floor. And so, the same problems on the shop floor, lack of support, lack of escalation, are still going on ... The appointment of a CTG midwife or a lead person in this, or having a committee in that, doesn't solve these problems ... A lot of the oversight groups spend their time trying to be reassured by what's going on, rather than finding out whether something is improving. They want people to say, “we've got this committee, we're looking at that, this is our report, this was our graph”, and everyone nods and says, “well, that's really good” and “let's move on” without looking to see whether things have changed ... What East Kent told us is that although there was leadership there, they weren't in touch with what was going on ... and they tended to believe what they were told.

4.218 The Panel was also told of a lack of stability within key clinical roles and that members of the Executive did not act as a single cohesive team providing a tier of support below the Chief

Executive. The size of the Trust, the portfolios of those working there and the expectations were said to be huge and potentially unworkable.

4.219 One experienced midwife told the Panel that they saw the situation deteriorate around 2015/16:

[T]here seemed to be a flurry of appointments made of people who had very little experience and it appeared almost as if they were trying to eradicate all previous managers and senior people from the team ... They were appointing people with no background experience and their lack of experience was reflected in what was happening on the shop floor unfortunately.

4.220 The Panel heard:

[T]he long history of reports of deep cultural issues in East Kent maternity services was related to instability in the leadership team. Other contributory factors were the fact that the two sites worked separately rather than together as one trust, and the large geographical spread of the trust. In 2018 there was more stability in the leadership, and it felt as though a shift in culture led to people working well together ... staff took more ownership of what was happening. There were obstetrics and midwifery leads for all pieces of work and if the focus of a project was on one site, then the other site had shadow leads for obstetrics and midwifery.

Clinical leadership

4.221 The Panel heard that doctors were not engaged in the management of the Trust, and a senior member of the Executive spoke of the difficulty in attracting good leaders as well as in having a body of consultants who were unwilling to be led.

4.222 Another member of the Executive highlighted several dangers related to the way in which the clinical effort was focused at East Kent maternity services – there was a historical lack of clinical leadership and “*it was much more controlling and quite negative*”:

There is a culture of politically aware bureaucrats versus clinicians who don't have the leadership skills.

4.223 The Panel was told of a reluctance on the part of staff within obstetrics to take on leadership roles, and that the midwives and obstetricians held their meetings in silos with very few multi-disciplinary meetings. One midwife described a Clinical Director within the obstetric team as like a “*lone ranger*”.

4.224 The Panel was told that consultants' views were not included in decision making, and without good clinical leadership in women's services, it was hard to get voices heard. It was noted that clinicians did not feel accountable for what they did, which led to consultants not being there when they were supposed to be.

4.225 One consultant told the Panel that they had told the RCOG that three colleagues should be sacked because “*they didn't have the same work ethic and responsibility*”.

4.226 Leadership within midwifery was described at times as resistant to challenge and favouring the status quo, which was a source of frustration. The Panel heard from senior midwives that there was a perception that the views of midwives were blocked and not

escalated appropriately due to “gatekeeping”. It was frustrating that midwifery did not have a voice at Board level.

4.227 The Panel heard positive comments about the leadership of midwifery more recently, with improvement in effective leadership, visibility and openness to challenge.

Financial Special Measures

4.228 The Panel heard that, immediately after exiting CQC special measures, and perhaps as a result of spending on the improvements required, the Trust was placed in Financial Special Measures by Monitor.

4.229 A Board member described the impact of being placed in Financial Special Measures in 2017 as like coming out of Quality Special Measures on a Tuesday and going into Financial Special Measures on a Wednesday. A number of Board and Executive members told the Panel that going straight into Financial Special Measures was not helpful. One said:

The organisation came out of special measures, and the next day they went into financial special measures, which was massively unhelpful and not necessary. It gave the organisation no time to take its breath ... This didn't directly lead to the problems within maternity services, but it is part of the context and the people who would have been doing work on maternity services were responding to financial special measures and all of the effort that required. Had the organisation been given time to breathe it may be that there would have been more focus on maternity issues.

4.230 The Panel was told about the significant impact that Financial Special Measures had on the transformation and improvement agenda, and on innovation; the Trust became very financially focused and operationally led. One member of the Board and Executive described the organisation as “controlling” and stated that, because of the problems with the finances and the buildings:

[P]eople couldn't see a way out. It felt very negative. Staff were not utterly disengaged but they were very despondent.

4.231 A member of the Board and Executive made the following points:

- The Trust has been in deficit since at least 2016 and the deficit target has been missed every year since 2017.
- The Trust has been aiming to make 4–5% efficiency savings each year (£30 million) and has sought to do this in a way that does not affect clinical services, for example by making structural changes that produce a saving on VAT.
- However, there have also been some cost efficiencies in clinical areas.

Governance

4.232 Members of the Executive spoke of the disconnect between ward and Board and of communication issues. One told the Panel:

It didn't help to have a disparate multi-site Trust. It didn't help that there were issues with medical engagement and a lot of turnover in the Board. It didn't help to have a bunch of people who, when the divisional structure came in, got put into roles without any development. One of the recurring themes in CQC inspections around the country is the

middleman, through whom nothing filters down or goes back up. Where organisations work well, the communication is great from ward to Board and Board to ward. It comes back to the multi-site structure – people need to walk around to see what’s going on. It is not enough to be in an office and do it by video link.

4.233 One member of the Board and Executive was aware, even before they joined the Trust, of the fact that the views of management were not shared by the staff. Another described sitting aghast as they listened to feedback provided by ward colleagues and feeling like they were not part of the same organisation. The executive team did not listen enough to what people were saying, and they did not talk to those on the ground. One senior executive observed:

[There was a] significantly different view between the board and the staff about the purpose of the organisation.

4.234 One clinician felt that certain sites were underrepresented within the Trust’s governance structure, with QEQM being under greater pressure because of recruitment issues and a lack of capacity for staff to participate in governance. Well-staffed sites, by comparison, had more time to focus on non-clinical issues.

4.235 The Panel was told by a Board member that the governance structures within the Trust were not sufficiently robust to allow assurance from ward to Board, and that the Board did not give consideration to this issue or to what it could do differently. Another member of the Board described the governance arrangements in 2018 as:

... like being in a car, when you move the gear lever, and nothing happens. The governance from board to trust and from ward to board had broken down and needed to be fixed.

4.236 Consistent with this observation, the Trust was described by regulators as an organisation that did not actively look for problems and issues to solve; rather, it waited for them to be pointed out. They suggested that the Trust needed to be problem sensing rather than comfort seeking in its approach.

4.237 A senior midwife told the Panel that maintaining compliance, receiving feedback and implementing lessons learned were some of the key priorities that were not always addressed. It appeared to them that sometimes the Trust was waiting for an incident to happen, rather than utilising the vast amount of patient safety incident data available to predict incidents.

4.238 A senior manager described governance within maternity services as:

... frightening, but they had normalised it and couldn’t see there were issues ... The leadership within maternity did not mix at all. Staff days and learning within the nursing teams was not embedded. It was very narrow in the way that it operated and didn’t invite people in.

4.239 A senior manager told the Panel that the Board “tended to deny there were problems and suppress discussions”. After the 2014 CQC report, Board committees were split so that the Quality and Safety Committee included nursing and medical staff but did not include divisional directors; this impacted the quality of the conversation and the decision making.

4.240 The Panel was told that the Executive had difficulty accepting the findings of the initial CQC review and “spent about six months quibbling over what was in the report”. It was said at the time of the report that “there was nothing of significance coming out of women’s services”.

One senior member of staff thought the Trust did not understand how much time was needed to take the actions forward.

4.241 Former Board members told the Panel that, between 2016 and 2018, maternity services featured very little in Board discussions and should have had a higher priority. The priority issues for the Trust in 2018 were described by a member of the Board as: safety, governance and finance – “*the core business of a hospital*” – but with specific focus on A&E (which was the worst in the country); cancer services (which were the fifth worst); and the response to treatment time (the Trust had the second longest waiting list in the country). It was accepted that maternity services did not consistently appear in governance sessions and that issues became diluted; their significance was not recognised as they were reported up through the chain and repeatedly summarised.

4.242 The Panel was told that the Board was looking for patterns and themes, but the mechanisms were not in place to identify them. It was recognised that clinical governance required improvement because the Trust did not have information flowing up and down the organisation between the point of care and the Board.

4.243 In terms of the Trust’s recognition of the wider significance of individual events, Professor Walker told the Panel:

They didn’t link [two maternal deaths] together ... They just saw them both as really unusual things that happened out of the blue ... [HSIB] tried to get across, yes there is a reason for it. It’s the systemic failure ... These were all, what used to be termed under old parlance, “latent errors” – errors waiting [to happen] ... It was almost like a journey of realisation for them that these things were repeated in the same way. The problem they tended to do was they blamed individuals. They blamed the locum, for instance, for the problems, instead of saying, “well, the locum only has a limitation in their ability and knowledge of the hospital”. What supervision or assessment did you make of that individual? Or did they just turn up on the night of their on call, without any orientation or anything like that? ... The Trust had to think about the systems approach and the preparation and making sure everything is in the right place. So that took quite a long time, really, for them to be convinced of that. Initially they kept on seeing them all as one-off events.

4.244 A Board and Executive member commented that the information flow seemed to be there but noted that the relative performance of the Trust was not known by the Board and that they were not aware that it was “*the worst performing*” trust in the country. They also told the Panel that the Board was concerned about whether it had sufficient information, which led to overcompensation by diving too much into the detail on issues, rather than standing back to understand what the information was telling them.

4.245 One Board member was aware before joining the Trust that it was one of the – if not the – “*most challenged trusts in the United Kingdom*”:

My initial impression was that there was a very severe problem with governance throughout the trust, throughout the three hospitals, and that was split into two groups. There was a structural problem and there was a deep-seated cultural problem. The structural problem was that the Board only met every two months, and this is a Board with five hospital sites with some of the most challenging performances in the country and quite clearly that was nowhere near enough ... But there appeared to be no recognition of what was needed

for a Board. There was no ownership of [Board] papers. The papers were often late. To be honest with you on closer questioning they could be inaccurate. They could be incomplete.

4.246 A different Board and Executive member expressed the belief that there remained issues around serious incident reporting and the level of visibility the system provided. They told the Panel that they became aware of baby Harry Richford's death only when they saw the first draft of the root cause analysis report in March 2018 and read it *"with mounting horror"*. They told the Panel:

[O]ne of the reasons it was so difficult was that obstetrics is largely a well-specialty. They were dealing with people who were well, and it can take time to pick up where things were not quite right. If activity or behaviour starts to become normalised, it needs someone to forcibly point it out, and that was part of the problem.

4.247 The Harry Richford case was not formally considered by the Board until late 2019, prior to the inquest into his death. In response to the inquest, the Panel was told that different workstreams were set up, including a prevention of future deaths workstream, to which the action plan relating to what happened in Harry's case was added. The neonatal resuscitation process was reviewed, as was the 21-point Prevention of Future Deaths report and the 2016 RCOG report (which included the issue of consultant presence on the labour ward).

4.248 Mr Hulme, a Trust Governor, was struck by the fact that there was no external benchmarking of serious incidents; the only information provided was the number and type of serious incidents. He found it was very difficult to unpick whether the Trust was improving over time or not. There was no focus on repeated serious incidents. Mr Hulme said:

That does not show a learning organisation if you're not tracking the number of times that a serious incident has happened ... Apparently there was no way ... of looking at SIs [serious incidents] adjusted for comorbidities, for the size of the Trust and see whether, as a trust, we're not just resting on our laurels and assuming that we've always got to have 50 SIs per quarter, and that's just what it is.

4.249 It was suggested that the Trust invest in a different methodology for looking at serious incidents, but *"that did not land well"* and an invitation to consider alternatives at a different trust was never taken up.

4.250 The Panel heard of concerns from midwives about how the organisation learned. Although HSIB reports were emailed, they were often not looked at or read. Although there had been improvements with the current risk team, there was no strong pathway for feeding back the learning from incidents. One midwife spoke of new guidelines being introduced in response to incidents but no one explaining why:

Staff aren't involved in improvement plans and yet they know what went wrong. They know how it could be fixed but they weren't invited to comment.

4.251 One member of staff described the Trust's learning from incidents as *"formulaic"*, a *"pray and spray"* approach with *"fingers being crossed, and a policy updated"*.

4.252 There was criticism of the divisional structure, which created an extra tier of management. The structure of the divisions was described to the Panel as follows:

Each [division] was led by a divisional director. They had a doctor as a clinical lead as well, and the relationships almost without exception, between the doctor and the manager,

were not good ... The divisional directors and doctors just didn't understand about working together.

4.253 An experienced midwife recalled when a divisional leader came to a supervisors' meeting and said: *"I'll be perfectly honest with you, I don't actually know what you do."* A senior midwife told the Panel the same thing: that the appointed divisional leaders had very little understanding of maternity services and the difficulties midwives face.

4.254 Another senior midwife reported that a divisional leader did not assist the midwifery team in implementing new recommendations following the public consultation on maternity services in 2011, and that the *"potential for improvement had been lost"*.

4.255 The Panel heard similar comments from Board members and managers:

- *"[O]ne of the challenges that East Kent has had with its divisional structure and then its care group structure, is that a lot of responsibility has been delegated to those divisions/groups but the Trust has not always had the process in place to provide central oversight of their effectiveness."*
- *"There was this centralised but non-integrated board approach, and then below them they had what they called autonomous divisions and these divisions genuinely believed that they didn't have any accountability, so this wasn't just maternity. There were issues with each of the divisions."*

4.256 Midwives informed the Panel of concerns around clinical governance and said that they had written to divisional management to highlight that there was only one midwife within governance, while the number of reportable incidents in maternity services was higher than in many other specialties. They told the Panel that the governance role was much too big for just one person, that complaints were not dealt with well, and that there was a lot of pushback from consultants.

4.257 Senior midwives told the Panel that governance had not been an integral part of maternity services and that it had not been a golden thread running through the division, as it should have been. They indicated that, because governance was performed for the whole of the specialist division (of which maternity services were just a part), the ownership of governance was not felt strongly within maternity services; there were a lot of gaps and not a lot of reporting. The Panel heard that Women's and Children's Health *"didn't have a fair place at the table"*. More recently, the placement of governance within maternity services was an improvement.

4.258 The same point was made by a director:

[T]he golden thread lacked breadth and depth. It was obvious that there was no way that a good or a bad point would be taken from the top and worked down through the trust and spread across so that there could be learning or replication of good practice. The Women's and Children's Division was the same as the others, urgent care was the same, it wasn't specifically a maternity issue.

4.259 Maternity services were described as more insular than other services within the Trust, and the reporting culture was not as strong or as open as it was in other services. One midwife commented that debriefing and governance were not things that East Kent maternity services did very well. One anaesthetist commented that obstetricians and midwives often had to be requested for the debriefing process; for some, the debriefing was not very important and could

wait. A difference in approach between midwives and doctors was also noted, with midwives reporting more incidents and very little incident reporting from doctors.

4.260 One Executive member expressed concern about risk-rating issues with Datix; however, the Board was not receptive to the suggestion that the Head of Midwifery should report directly to the Board as an additional route of escalation. The Board was also dismissive of introducing a non-executive director for women's health to whom people could speak if they weren't being heard. It was therefore felt that there were issues incapable of resolution or of being escalated upwards.

4.261 A midwife told the Panel that one of the barriers to reporting was the time needed to complete the details required in Datix, and that if someone were an hour late leaving their shift then it would be quite likely that they wouldn't report an incident, even though it should be recorded. It was also said that it remained common not to escalate issues through reporting, including through Datix reports.

4.262 The Panel was also told that governance was compromised by recruitment problems and constantly changing leadership.

Response to the Royal College of Obstetricians and Gynaecologists report

4.263 The RCOG review was commissioned in 2015 because of concerns about the culture of maternity services, clinical standards and quality, particularly at QEQM. A senior manager told the Panel that they knew there were issues: “[W]e needed something brutal to help them to change.”

4.264 A senior representative of the CCGs at the time told the Panel that the momentum for bringing in the RCOG came internally from the Medical Director within the Trust, who felt that it would be more credible to the obstetricians, particularly in QEQM, if they heard from their own professional group.

4.265 A senior midwife told us that the description of the behaviour of obstetricians within the RCOG report was accurate and said that the response to the report was not appropriate and that obstetricians did not engage with it. An Executive member similarly described the themes in the report as accurate and recalled a meeting being called with the whole executive team because the feeling was that the report was not being accepted:

The report's findings never resulted in an organisational approach to tackling the problem ... Efforts to improve the O&G [obstetrics and gynaecology] service were confounded by poor and unstable midwifery leadership and disengaged clinicians.

4.266 The Executive was asked to help get consultants to engage with the report. The Panel was told by a Board member that the main focus of the Board in relation to maternity services and its response to the 2016 RCOG report was the implementation of the BESTT programme in 2017 (which was described by one midwife as simply “*papering over cracks*”) and Human Factors training. Although the programme was considered a response to the RCOG report, it was built around the national agenda with specific areas of focus, and those involved in developing the BESTT programme were not provided with a copy of the RCOG report as it was considered “*outside of the scope of the project*”. RCOG recommendations were incorporated into a later phase of the BESTT programme in 2020 following the Harry Richford inquest.

4.267 The Panel was told that the RCOG report was never shared with the Trust Quality and Safety Committee, and that programmes such as the BESTT programme:

... seemed to indicate that matters were improving but it only involved recently appointed obstetricians and not the long-standing recidivists who were not going to change.

4.268 Other Board and Executive members told the Panel that the response to the RCOG report was merged into one improvement plan together with the actions in response to the CQC report and the Local Supervising Authority (LSA). They told us that, with hindsight, this might have meant that there was insufficient focus on maternity and neonatal services. The improvement plan was signed off by the Executive, scrutinised by the Improvement Board, and reviewed monthly by the CCGs (with respect to maternity services and obstetrics). However, it was felt that maternity services were never given any financial support and had to work within existing budgets. One Executive member considered the action plans in response to the RCOG report to be more a “tick box” exercise compared with the response to the CQC investigation. People only began taking it seriously with the triangulation of other reports.

4.269 Nobody in the Trust had been able to produce evidence of how the RCOG recommendations had been implemented and completed, and there had been no action plan endorsed at Board level to rectify the situation.

4.270 The response to the RCOG report was described by one non-executive director as follows:

At that point, the hairs were going up on the back of my neck really quickly now. I’m just thinking, “oh my word”.

4.271 The culture of the obstetrics and gynaecology service was put on the risk register by the governance and patient safety team, in response to what they believed was contained within the RCOG report, although the Panel heard that they were not permitted to read the report and were later asked to remove the obstetrics and gynaecology service from the risk register.

4.272 A consultant who was involved in a review of the RCOG report in 2019 found that the action plan drawn up in response was incomplete and that fewer than 25% of the actions were robust and signed off. The consultant did not know why this was the case and could only speculate that either it was not considered important or there was no time to carry out the work properly.

4.273 A Board and Executive member spoke about how they had more recently sought to identify the actions taken by the Trust in response to the RCOG report but could not find a comprehensive response, or evidence for decisions that had been taken, or evidence of the monitoring of those decisions. They suggested that, because of this failure, the absence of a central repository for recording information and the numerous changes of personnel, a lot of the work done at the time the RCOG report was provided had been lost. They told the Panel that it was not until five years after the RCOG report that there was an action plan in place to cover the recommendations it made.

4.274 The Panel heard that the RCOG had no further involvement after the report had been written. It was believed that the Trust did not contact the RCOG after 2016.

4.275 Despite the RCOG report having been provided in early 2016 and containing a number of complaints about consultants failing to respond to requests for assistance from junior colleagues, the Panel was told that the report was not provided to the GMC until 2020, some four years later. The Panel was also told that the GMC decided, following review, that the complaints did not require “fitness to practise” proceedings.

4.276 In addition, the Panel was told that the RCOG report was not provided to the CQC until it was presented as part of information supplied prior to the May 2018 inspection.

4.277 Following the RCOG report, it was recognised by a member of the Board and Executive that it was significant that the Chief Nurse at the CCGs had written to the Trust to say that they were concerned about the quality of the serious incident investigations.

Risk management

4.278 The Panel was told that part of the risk management strategy around 2012 involved making divisions responsible for their risks:

This gave management teams a broader range of responsibility, though clinicians saw risk as remaining the responsibility of trust management.

4.279 One midwife felt that people within the Trust didn't understand risk when the midwife joined in 2013, although this improved subsequently because the governance and risk obstetrician and midwife brought risk to the fore.

4.280 The Panel heard that there was one risk register for QEQM and another for WHH, and that issues on the risk registers did not necessarily come to the attention of the Risk Management Committee. The Panel heard that there was a monthly risk group meeting that lasted two hours. Corporate risks were reviewed at each meeting. Each care group had a risk register, but, depending on how many risks were on the register for each care group, it wasn't always possible to review every risk without extra time being allocated. Some maternity issues raised at the risk group – such as reading CTGs and resourcing – *“did not get the air time they needed to provide assurance for the board”*. However, there was acknowledgement from the Board about the importance of managing risk.

4.281 The risk register was sometimes updated to reflect the barriers to making changes, but it was *“underutilised and a bit hidden. It was all a bit of a mystery.”* One senior member of staff thought that the care groups did not understand what the risk register was for, how it could be used or how it could help. The Panel heard that some staff were unfamiliar with the risk register or completely unaware of it.

4.282 A number of safety management concerns were identified to the Panel, including:

- A lack of progress with the CQC recommendations
- The risk register being frequently out of date
- Out-of-date policy documents
- An insufficient budget
- A lack of action relating to the quality improvement programme.

4.283 One member of staff was shocked by the things band 7 midwives at WHH had to say about patient safety, such as *“what's that got to do with us?”*, and that one patient safety lead was not open to challenge.

4.284 The Panel heard that perinatal morbidity and mortality meetings had always taken place at the Trust and provided an opportunity for reflection and learning. The meetings were Trust-wide until around 2006/07, when they became local. We heard that QEQM had monthly meetings to discuss patients and that these meetings were attended by middle grade doctors,

neonatology consultants, midwives and obstetricians. The obstetricians also held their own discussions that did not necessarily involve paediatricians.

4.285 Staff perceived the discussions at these meetings differently. Some considered the meetings at QEQM to be open, with challenges to practice on both sides. However, others spoke of clashes between members of staff, with one particular paediatrician often blaming obstetricians for any deaths or serious incidents.

4.286 The Panel was told that handovers (between off-going shifts and on-coming shifts) were identified as an area of risk, as were delays in communication and issues with communication between disciplines. A consultant expressed frustration at the absence at either site of a multi-disciplinary team for high-risk pregnancies.

4.287 One staff member who had experience of working in another trust commented on the communication issues in East Kent maternity services. Their experience elsewhere was that communication was open and transparent and staff were kept in the loop about investigations and learning from them; however, it was not like that at East Kent maternity services, where the staff member knew only what happened during their shift and was not kept informed about the wider picture.

4.288 One midwife told the Panel that, although there were systems in place for midwives to learn from adverse outcomes (risk meetings and perinatal meetings), in reality they did not go to them. However, midwives had statutory study days, and these were well attended.

4.289 A consultant told the Panel that there had been improvement more recently:

Historically there was a lot of jumping to conclusions and finger-pointing, whereas now, there's recognition that things aren't black and white – that they can be complex, and you shouldn't jump to conclusions ... Before, people were told what to do rather than why things should be done. They came up with "quick reflex action points", rather than reflecting and agreeing a collaborative approach about how to address the issue ... Some changes didn't work as they were just reflex responses at the time. For example, following a case of uterine rupture during induction, one action was that all inductions should have 3 hourly CTGs in the lead-up to labour. However, in this case, there were lots of signs that other things were going on with the woman, such as poor pain control. The introduction of 3-hourly CTGs was more like a tick box exercise instead of doing holistic risk assessment continuously during the woman's induction and labour. In high risk cases of induction of labour, pain or uterine activity should immediately trigger the application of the CTG to monitor foetal wellbeing. By doing 3-hourly CTGs on everyone, they are taking their eye off the ball, instead of risk assessing the woman holistically every time they look at her. They need to unravel things and reflect on what the thought process was behind the action. They need to risk assess each woman.

Regulators and commissioners

4.290 A large number of organisations have been involved in supervision and regulation of NHS services: the GMC, the RCM, the RCOG, the NMC, the LSA, the CQC, HSIB, NHSE&I, CCGs and the Local Maternity System/Local Maternity and Neonatal System (LMS/LMNS). The Panel heard about the potential for confusion that this has caused, as well as the inability of the supervisory and regulatory bodies to bring about significant change over prolonged periods. We were told:

It isn't always helpful for individuals to have to deal with different organisations and the landscape is so confusing when you have a complaint about something significant that happened in your life. It is very difficult to pursue that.

4.291 Members of the Board and Executive described a very challenging relationship between the Trust and its regulators and commissioners. One told us that a decision had been taken by the Trust to “*fight the regulators*”, although this was a fight that could not be won and was a waste of resource and energy. The Panel was told separately that the Trust had considered taking legal action in response to the 2014 CQC report.

4.292 One member of staff expressed the following perception:

[T]he priorities of the regulators might not always be aligned with what is best for the patients. The regulators have their own set of challenges. They are balancing the politics and the requirements that are placed on them, along with the need to regulate organisations.

4.293 Managers within the Trust talked about how it was impossible to meet all of the regulators' expectations, but they said that nobody discussed whether this situation should be exposed:

[It] might not be the regulators' intention that they are not aligned, but they don't get to hear the things that they need to hear. People don't always get rewarded by being honest.

Clinical Commissioning Groups

4.294 A member of the Trust's Board and Executive commented that the four CCGs there had been in Kent all did things differently, making it hard to respond. The relationships were difficult:

[T]hey weren't all pulling in the same direction, and they were very focussed around money.

4.295 The Panel was told that, from the very beginning of the work of the CCGs (April 2013), the CCGs raised and escalated significant concerns about the Trust to NHS England (NHSE). Maternity cases were raised as an issue at every Quality and Compliance Steering Group, from the very first one in 2013, and within the CCGs' written escalatory reports to NHSE every single month. However:

- The CCGs' professional challenge “*was met with anger and defensiveness by the Trust, always, no matter whether it was a financial challenge or clinical challenge*”.
- “[Y]ou took a deep breath to have the conversations before you picked up the phone or you met with them.”

4.296 A then newly appointed member of the Executive told the Panel of their astonishment at the level of antagonism in the room when attending their first Quality Surveillance Meeting with the CCGs.

4.297 The CCGs were escalating issues long before the CQC report in 2014; however, they found it difficult to gain recognition of their concerns. It was suggested to the Panel that the very people to whom the CCGs were escalating their concerns, particularly around maternity services, were the individuals who had previously commissioned those services. This meant that they didn't have fresh eyes, nor the same sense of the need for action. We were told:

[W]e were escalating to people who had obviously done the same role as us, and had worked with the provider, and accepted that practice ... accepted that that was safe and hadn't escalated it, and now we were coming in saying that the same thing wasn't acceptable, so it was quite difficult politically to manage that situation ... we weren't getting anywhere through repeated escalation ... the lady who led the bomb-shell CQC inspection ... was instrumental in getting everybody on the same page.

4.298 Another CCG officer told the Panel that the key issue in 2013 was trying to get people to believe the CCGs' concerns. They couldn't be sure whether the problems at the Trust had been there for some time but had not been picked up (and the CCGs were able to identify them because they had the benefit of fresh eyes), or whether there had been a rapid deterioration just before the CCGs took over commissioning. They commented:

[S]ome days you almost felt like you were going mad because ... it just felt like people would not listen ... we continually raised concerns at meetings like the Quality Surveillance Group.

4.299 The Panel was told that "getting everyone on the same page" was crucial because, prior to the CQC inspection and report in 2014, some people were saying that the Trust wasn't as bad as the CCGs were saying, and it was crucial for the commissioning of recovery plans for there to be a common understanding. We were told:

[T]he Trust thought they were exemplars of best practice and there was a real arrogance back in 2013 ... they would say it in public meetings, "we are the best acute trust in the country, we are innovative, we are clinically excellent, we are the safest place to be" ... they would narrate it ... over and over to try and make it become fact ... you then had NHSE saying, "yeah we haven't really got any specific issue" ... and then you had us ... shouting, "... they're not financially stable, their leadership is falling apart ... they're not a cohesive leadership team ... they're not safe from a clinical and patient safety perspective ... there are many gaps, and then they've got big cultural issues, huge cultural issues around their geographical base".

4.300 However, the Panel was told that, even after the 2014 CQC report was published, there was no acceptance at Board level that it was accurate until there were major changes at Executive level in the Trust. The appointments of new members of the Executive contributed to a more collaborative relationship.

4.301 We heard that one of the things that the CCGs identified from the start in 2013 was that the Trust had a very high turnover of senior leaders in midwifery and lacked a Board lead for paediatrics. The Board lead for midwifery (the Chief Nurse) didn't have midwifery experience. The CCGs tried to work on these issues with NHSE.

4.302 Another Trust-wide issue that the CCGs identified through maternity services was the Trust's approach to serious incidents and learning: how it learned from incidents, near misses and when things went wrong. The Trust's approach was described to us as very tokenistic and it did not use nationally recognised practice or national templates. The CCGs had a battle with the Trust over everything surrounding this issue; the Trust did not identify learning, root causes or relevant systemic contributory factors. There was also evidence of a blame culture that focused much more on midwifery than on obstetrics, and there was an expectation that engagement in serious incidents was more the responsibility of midwifery than obstetrics. However, we also heard that the CCGs believed that, although early reports were not very good

and poor recommendations were made, progress was made later and the quality of reports started to improve.

4.303 A senior member of staff from the East Kent CCGs in 2018 told the Panel that their wider concerns about the Trust were in connection with:

- A large number of Never Events (safety incidents defined nationally as those that should never occur)
- A lack of learning from incidents and a failure to implement actions identified
- Cultural aspects such as a lack of challenge around serious incidents
- Long waits in A&E and poor-quality care
- Failures to follow up patients
- Concerns around medication doses
- Safeguarding and issues around security
- Infection control
- Poor communication with GPs
- A lack of proper processes for the supervision of staff
- Poor Friends and Family Test (patient experience) results
- Concern about the ability of the Trust to sustain a safe Intensive Therapy Unit service.

4.304 The Panel heard that there were also overarching issues around leadership and the ability of leadership to get to grips with the concerns, culture (particularly in relation to staff not feeling able to challenge) and learning (much of what was happening had occurred previously and there was a failure to learn and to implement actions to prevent the same mistakes from happening again).

4.305 A senior member of the CCG told the Panel that the CCG was concerned, as a commissioner, that the Board wasn't as informed as it could have been on some of the quality issues; there was awareness at committee level, but not once issues were escalated to Board level. This did seem to improve a bit as time went on; this appeared to be partly as a result of changes in leadership. There was also a worry about the number of issues that the leadership team was dealing with and its ability to get a grip on all the concerns: for example, the Medical Director, who had to contend with a challenged organisation across three sites, was also the Director of Infection Prevention and Control, and the CCGs had significant concerns about infection control.

4.306 The Panel was told that, at the end of 2019, the CCGs reported that the Board's oversight of maternity services had been poor, but that the situation had started to change; however, there was more external scrutiny happening at this time, so this may have been a factor in the improvement. The new Chief Nurse and a new Head of Governance, both of whom started around June 2019, seemed to make concerns more visible. Within maternity services there was an increase in serious incident reporting, which the CCGs believed was evidence of an improved safety culture (people were more willing to report incidents), there were better systems and training around CTG monitoring, and there were better induction processes for locum doctors. These actions, together with the work of the new Director of Midwifery, provided the CCG with assurance that things were progressing.

4.307 The CCGs raised concerns about leadership (including leadership capacity) with the Trust through discussions with the Medical Director and the Chief Nurse, in system oversight meetings and in the Quality Surveillance Group (QSG).

4.308 CCG officers observed that WHH was hampered by recruitment difficulties and that the midwives and consultants were committed to doing their best for the women using maternity services (“*they’re good people, they’ve got good intentions*”), but the system did not support them – the scale of the challenges at the Trust was so big, and the churn in leadership didn’t help. The CCGs’ view was that there was also a tendency to seek to resolve problems by appointing new leaders and, when they failed, to see those leaders as the problem rather than the underlying issues.

Care Quality Commission

4.309 The Panel heard:

[T]he relationship with CQC and the Trust was absolutely dreadful.

4.310 The 2014 CQC report identified a significant difference between the Board’s perception of how well the Trust was doing and what the CQC found on the ground, including the frustration of staff who described bullying behaviours and a fear of speaking out about things that were problematic. A senior CQC staff member who met with the Panel spoke of the importance of the freedom to speak up as part of a strong, positive safety culture that needed to be embraced more.

4.311 A senior CQC staff member also commented that maternity services and the Trust in general had been stuck at “Requires Improvement” since 2014/15 and that the basic underpinning drivers of quality were not being addressed sufficiently to move the Trust forward to what would be regarded as “Good”. It was suggested that this was partly due to the failure to develop a model of care for the large geographical area of East Kent, which is relatively remote from major population centres, and the absence of a long-term strategic plan.

4.312 We heard that, following the CQC report in 2014, the Trust Chief Executive had monthly meetings with Monitor that focused on Trust finances, the performance of A&E and the improvement plan. An Improvement Director was appointed.

4.313 There was a CQC inspection of children’s and young people’s services at the end of 2018. This raised significant concerns, and the Trust was rated “Inadequate” overall. The CQC issued a Section 64 letter (under the Health and Social Care Act 2008, this requires trusts to provide specific documents and information) as the information provided by the Trust didn’t answer the CQC’s questions. The CQC was not assured and issued urgent conditions.

Healthcare Safety Investigation Branch

4.314 The first HSIB maternity investigation involving the Trust was in April 2018. We were told:

The Trust was quickly branded an outlier as its referral rates were markedly higher than the trusts in the rest of the region.

4.315 We heard that HSIB had difficulties with its day-to-day operational relationship with the Trust. These included issues such as information requests, staff attending for interview, staff giving their consent to attend for interview and difficulty in getting support with this from the Trust’s senior leadership team. The Panel heard that the HSIB team had a “*very difficult reception from East Kent*”, despite its efforts to build good relationships: “*engaging with the governance team at East Kent would be difficult*”. This contrasted with other trusts. Consequently, HSIB investigations were delayed because the relationship wasn’t good from the outset. However, an HSIB investigator said that, when they were able to engage with more junior staff, these staff were open and honest.

4.316 In 2018, engagement between HSIB and the Trust included preliminary recommendations from an HSIB review of ten ongoing HSIB investigations, visits to the Trust in October and November (including a presentation on HSIB's work) and a round-table meeting with the Trust in December. The meeting in December identified emerging patient safety themes, including neonatal resuscitation, documentation processes and escalation during care; these were followed up in a letter to the Trust. However, it was clear that the Trust *"did not want to engage with HSIB at all"*.

4.317 The Panel heard that obstetricians did not attend any meetings with HSIB, although they were invited to do so. One HSIB investigator's assessment was that the obstetricians didn't want to engage in such discussions, rather than that they were excluded from doing so:

In 2018, obstetricians didn't see incidents – especially those involving midwifery – as anything to do with them.

4.318 The Panel was told by officers within HSIB that, by the end of 2018 (following seven or eight months of input), HSIB was identifying themes associated with maternity incidents and it had concerns about East Kent maternity services. Its concerns included: failures of escalation; unsupported junior staff; problems with locum doctors and a lack of proper supervision and assessment; the level of neonatal deaths at QEOM; neonatal resuscitation; CTG interpretation; triage, management of reduced fetal movement and ultrasonography; and the home birth and midwifery-led care environment, including fetal monitoring. We heard that HSIB was confident that it had identified the right themes:

[B]ut [HSIB] knew that they weren't being received very well at the Trust. The Trust was irritated with HSIB. It was as though the Trust thought that HSIB wasn't a regulator and what right did it have to be in the organisation, doing investigations and asking questions? East Kent wouldn't engage. By contrast, in other trusts, HSIB were being received openly, with a view to having a fresh set of eyes on the challenges.

4.319 There were several recurring themes in the cases that HSIB saw:

- **Escalation:** Recognising women and babies who were deteriorating, reporting this to more senior staff, and those more senior staff responding appropriately; there were also frequent problems with locum staff and how they were recruited.
- **Triage:** Particularly in relation to documentation. At times there was no record that calls from patients were made, who was taking the calls or what advice was being given to patients.
- **Neonatal resuscitation:** Concerns around the geography of the work (e.g. the location of resuscitation trolleys) and the impact on families (rather than concerns about the particular skills of individuals). There was no resuscitation trolley in A&E.

4.320 These issues kept appearing, which indicated to HSIB that sustained change was not happening in response to issues being raised. As time passed, HSIB formed the view that these were longstanding issues. HSIB had three main concerns with East Kent maternity services:

- A high number of referrals in comparison with other trusts – the numbers dropped after the first year and the Trust saw this as an improvement, but when HSIB triangulated this with other information, it was clear that cases just weren't being referred
- Recurring themes – indicating that lessons were not being learned
- Patient safety concerns.

4.321 By early 2019, there was still no improvement in the Trust's engagement with HSIB, so matters were escalated to HSIB's senior maternity team and the CQC. The Panel heard:

[N]o changes were being made at East Kent. The Trust had still not returned HSIB's initial roundtable letter, and the same patient safety themes were continuing to harm patients.

4.322 There was a meeting between HSIB and the Trust's senior leadership team, including clinical leadership, in June 2019; the meeting was described as "very difficult". By this time, the HSIB team had "grave concerns". The HSIB team were not made to feel welcome by the Trust (they were kept waiting for 45 minutes in a corridor) and were greeted in an "incredibly aggressive" manner by the Trust representatives, with one commenting that "I don't know why you are here" and that HSIB's recommendations were "not needed".

4.323 There was a "heated discussion" about one of the maternal death cases. There was denial in the Trust about the enormity of the underlying problems and HSIB was not seeing evidence that actions were being taken to change things. An HSIB investigator noted: "It felt like the issues were being given lip service."

4.324 As a reflection of the level of concern within HSIB about the performance of East Kent maternity services, a letter was issued to the Trust CEO in August 2019 by Sandy Lewis, Associate Director of the Maternity Programme at HSIB. This was considered a highly unusual step. The letter stated:

Given the gravity of the concerns raised and the lack of response to the issues raised, I consider that there may be a serious continuing risk to safety within your Trust.

4.325 The Panel heard that the Trust's referral rate was 50% higher than that of other trusts with which HSIB was engaged at that time and HSIB was concerned about the recurrence of issues about which it had already made recommendations. HSIB thought that Trust staff "weren't hearing them when they made recommendations".

4.326 HSIB set up quarterly meetings with the Trust from October 2019 for the purpose of monitoring improvements. At these meetings, overviews of national figures were provided together with common investigation themes. An HSIB investigator said:

Sadly, these meetings once again highlighted that the patient safety themes at East Kent were not changing.

4.327 The approach to maternal and neonatal safety was described as "tick-box": for example, following the introduction of safety huddles, poor escalation issues continued to arise, and the Trust's reaction was that it had "already implemented a solution, so nothing more could be done to improve the situation". However, several Trust staff stressed in their interviews with HSIB that the safety huddles were ineffective, as they were developed by senior leadership who did not understand experiences on the shop floor.

4.328 The Panel was told that the Trust also struggled with having a safe space where people could discuss concerns.

4.329 HSIB's clinical oversight concerns revolved around the lack of engagement between midwives and obstetricians and junior staff:

The two professional groups don't function as one team. They are separate. There are, of course, individuals who work well together. The result of this is that the two groups don't

provide effective safety for one another and mothers and babies. The communication between teams often leads to confrontation rather than reasoned discussion. They don't respect one another or have the confidence to challenge one another in a helpful and respectful way.

4.330 In addition, a senior HSIB investigator commented:

The Trust board saw patient safety issues as problems with individual staff, rather than as part of their role to improve systems and learning. Patient harm was seen as the shortcoming of staff on the shop floor. There seems to be a great disconnect between the senior team and general staff.

4.331 An HSIB investigator told the Panel that there was a strong culture of “*pushing things under the carpet*” and not listening to staff who raised concerns. We were also told of a striking disconnect between staff on the ground and the management team.

4.332 The investigator also commented that staff were not good at identifying their own problems. They stated that “*when they do look back they don't seem to be able to see what is glaringly obvious to others*”, and that the Trust had not maintained “*good, open, communicative*” relationships with families who had had bad outcomes, but that more recently this had improved.

4.333 Reflecting on how investigation reports were communicated to the staff who were required to implement them, a midwife cited the example of HSIB reports; the reports were available in hard copy, on a shared drive and circulated by email, but it was demanding for staff to absorb this information while delivering their roles, and quite a challenge to become aware of all the recommendations. It was difficult for staff to understand the detail and significance of the information without making further enquiries, and there was so much going on that information was not always properly digested. In general, recommendations were not conveyed simply and there were no bite-sized chunks of information for staff to digest.

4.334 While the number of referrals from East Kent maternity services had begun to decline and HSIB's relationship with the Trust to improve, Professor Walker explained that HSIB was still seeing “*some of the same problems coming through, particularly about support and staffing, their midwife led care services etc*”.

4.335 The Panel heard that the Trust's 72 hour reports were “*very poor*”; they didn't go into detail and HSIB provided training to help improve the quality. However, the reports remained poor. Initially, the Trust would not share these reports with HSIB. The Trust challenged why HSIB would need them and said that “*they aren't there to help you with your investigation*”.

4.336 HSIB still saw cases where women presented with symptoms that appeared to be an infection but were sent home without being seen by a senior person, only to return in a more serious state. Professor Walker commented that “*it is about proper assessment, risk assessment, escalation, and things like that ... but to be fair the numbers [became] less than they were*”.

4.337 The most prominent HSIB themes in 2018/19 were guidance, escalation, fetal monitoring, documentation and birth environments. The themes in 2019/20 were guidance, escalation, fetal monitoring, staffing and general clinical oversight.

4.338 Professor Walker told the Panel that, in the early years of HSIB (2018/19), it didn't know how to talk to other organisations. For example, HSIB was contacted by the CQC, which

enquired whether HSIB shared the CQC's concerns about the neonatal and paediatric services at the Trust. HSIB didn't know what information it was able to share and was anxious to maintain its independence. However, HSIB recognised that it had a duty to escalate concerns and found a way to do so without sharing case-specific facts.

Nursing and Midwifery Council

4.339 The Panel was told by Andrea Sutcliffe, the NMC's Chief Executive, that the NMC's involvement in either an individual case or a cluster of cases was dependent on the referrals that came through, which might be determined by lots of local factors. She told the Panel that, while many referrals might indicate a problem, it could be just as problematic if people weren't making referrals, because they weren't recognising problems and dealing with them. She added that, given the relatively small number of fitness to practise referrals made to the NMC, it was difficult to identify organisations with recurring problems. Referrals were affected by the leadership of organisations, and she thought that one of the issues with East Kent was the high turnover of Chief Nurses throughout the period.

4.340 Ms Sutcliffe told the Panel that the NMC received some referrals around maternity incidents at East Kent: "[I]t was very much on an individual basis, and our analysis shows that quite a lot of these referrals were coming through from families." In the case of baby Harry Richford, the family referral included four midwives and the NMC opened cases on a further three midwives as a consequence of that family referral. No referral was made by the Trust. Ms Sutcliffe commented:

Perhaps we should regard the referral of a practitioner to a regulator by a family as failure of the system. If something has gone wrong, the organisation itself should be dealing with that and doing so in a way that gives confidence to the family that the issues are being addressed appropriately and if there are issues that are to do with fitness to practise of an individual, they should be confident that that individual will get that referral. Whereas what often happens is that we get referrals from families when they've already been let down locally and so we're all compounding loss and distress as a consequence of that.

4.341 Ms Sutcliffe told the Panel that:

If people are scared of the regulator then they're not going to speak up when they should. They're not going to engage with our processes in a meaningful way when they should. One of the things we've been absolutely clear about is making sure that we are improving the fairness of those processes, looking at the context of what is happening and making sure that is fully and properly taken into account.

4.342 Ms Sutcliffe stressed the importance of regulators such as the NMC, GMC and CQC working together with trust organisations, to collaborate and share information, and to identify the indicators that might show that there is a problem. She told the Panel that the NMC set up its Employer Liaison Service in 2016 to feed back information to trusts, and to provide insight and support as well as helping in some of the training that they might need.

4.343 While continuing to stress the difficulties for a regulator of individuals to identify systemic issues (red flags) based on individual referrals, and the difficulties in taking action, Ms Sutcliffe told the Panel:

[I]t is probably fair to say that all of us, and the NMC is in and amongst that, could undoubtedly have done better in joining the dots earlier ... If I look back and think "what would we want to do differently now" we would want to have better collaboration.

General Medical Council

4.344 A senior GMC interviewee confirmed to the Panel that its focus is on the fitness of individual clinicians to practise. However, it receives significant and comprehensive feedback from approximately 60,000 trainees each year, and there had been no mention within that feedback of any issues with maternity services at the Trust. The fitness to practise data did not point to there being an issue either.

4.345 The Panel was told that the GMC gains information from its outreach function and the meetings with the Responsible Officer (RO) and Medical Director at trusts; these have been taking place since 2011/12. There are regular meetings to support ROs with fitness to practise issues and revalidation issues. As part of this work, the GMC has sought to address clinical leadership, which, it acknowledges, can be a difficult area for doctors.

4.346 There are other sources of information, such as revalidation data and surveys of trainee doctors (national training survey data). The GMC established an internal mechanism called the Patient Safety Intelligence Forum that gathers information on organisations and can lead to action such as talking to other organisations, or to instigating enhanced monitoring within the GMC's education functions.

4.347 We were told that the Trust was regarded within the GMC as a concern in general terms from around 2015, but not maternity services at that time. The longstanding challenges at East Kent were with recruitment and retention, the geography of the sites, and the use of locum doctors. However, the specific concerns about obstetrics and gynaecology were more recent. One GMC interviewee thought that they were not raised until early 2020, when the RO told the GMC about the CQC's and HSIB's involvement.

4.348 We were told by GMC staff that the fitness to practise data have not been informative because they involve such a small number of referrals. Making better use of the data would depend on linking them with other sources, and the GMC told us that it had put a lot of effort into working more closely with other regulators in terms of data sharing. The interviewee also made the point that the GMC is aware that teamworking issues can have a significant impact on patient care.

4.349 The Panel heard that information sharing has been challenging for the GMC, and is constrained by its precise legal powers.

4.350 The Panel also heard of the difficulties in dealing with behavioural issues among doctors, as follows:

[Within] healthcare regulation and oversight there are a myriad of organisations, and it can lack clarity as to who is doing what, and who is responsible for what ... it can be quite confusing, I think it is confusing for patients, and it can be confusing even amongst regulators – who precisely is doing what, and who is responsible for what? [The GMC is] responsible for individual doctors in terms of their fitness to practise and their revalidation etc., but where you are talking about lower-level behavioural issues, or cultural issues, or attitudinal issues that are not ideal, but you are not going to strike someone off, that can be a little bit tricky as to who is responsible for dealing with that.

Local Supervising Authority

4.351 The Panel heard that when the first Morecambe Bay recommendations were starting to be known, the LSA Midwifery Officer (LSAMO) began a gap analysis against the emerging findings.

This continued throughout the year and included the need to make sure that supervision was clear and complemented the clinical governance processes of trusts.

4.352 The first audit of the Trust carried out by the LSAMO was in 2012, and yearly thereafter. The Panel was told that the findings and recommendations of each audit were as follows:

- **2012:** The recommendations made by the LSA included better engagement with feedback from women (the Trust was not particularly strong on this at the time), ensuring one-to-one care in labour, and ensuring that meetings were held with individual midwives on an annual basis.
- **2013:** The LSA revised the supervisory audit to make it more specific to the standards and rules. The LSA also sought evidence prior to the audit – moving from a reassurance model to an assurance model. In looking at compliance with Birthrate Plus,[§] and at learning from incidents, there was a theme around disjointed supervision and clinical governance.
- **2014:** There was improved interface between governance and the supervisors of midwives, but there was still a need for more evidence. The LSAMO arranged an away day for the supervisors of midwives that was facilitated by the Trust and was centred on leadership and working towards improvements as a group. Around this time there was a lack of transparency within supervision generally (not limited to East Kent maternity services) and it was difficult to get people to say who had a problem and where the problem was. It was also a challenge to embed openness and transparency, and to share problems and issues so that improvements could be implemented and midwives could be supported in practice – this was what the teamwork was designed to address.
- **2015:** The audit showed that there was improved governance and that the Trust had a clear policy around governance – supervisors were reviewing all serious incidents. They still needed a little more evidence around this, but the situation was starting to improve. The LSA escalated to the lead CCG the need for a much clearer link between supervision and incidents; this escalation became part of the CQC action plan.
- **2016:** This was the final audit. The Trust was partially meeting most of the standards, but there was still work to be done to ensure that every midwife had an annual review and there were still some issues around making sure that governance was strengthened.

4.353 The Panel was informed that, in 2017, when the LSA ceased supervision, the action plan was handed over to the Trust; the final recommendations and action plan were also shared with the lead CCG.

4.354 The LSAMO told the Panel that they also provided education for supervisors of midwives and held monthly meetings so that good practice from the LSA's audits could be shared. Representatives of service users attended the meetings to provide information about the experiences of women who had used maternity services; this feedback looked positive for the Trust. However, the Panel heard that the supervisors of midwives would always comment about the birth environment, which was a longstanding issue for East Kent maternity services.

4.355 In the LSA's view, governance was also an issue. During this period, the Trust failed to achieve Clinical Negligence Scheme for Trusts (CNST) Level 3 (the best level of rating of risk management in a trust). Governance is at the core of a safe service, and a governance review

[§] A tool to estimate the desirable level of midwifery staffing, taking into account the size and complexity of a maternity service.

had recently been completed by the Maternity Improvement Advisor (MIA), although this could have happened earlier, had it been possible to put feet on the ground.

4.356 The Panel was also informed that a challenge of the LSAMO role was that they supervised a team of people within a trust but they had no formal management control, and the midwives only reported to the LSAMO through the statutory process. Other challenges included the length of time that investigations took and the fact that, although the outcome of any supervision investigation was shared with the trust involved, there was no reciprocal sharing of investigations by that trust, which would have provided greater context.

NHS England/NHS Improvement

4.357 A Trust Board and Executive member told the Panel that the Trust did not receive a great deal of support from NHSE&I.

4.358 Another member of the Trust Board and Executive told the Panel:

[T]rying to get the commissioners and NHSE&I to understand, as part of the clinical strategy, that the Trust could not continue to do loads of things in three places was a really long road.

4.359 We heard from a member of staff of a regulator that, as late as 2018/19, the safety structures within NHSE and NHSI (at that time two separate organisations) did not see the Trust as being a problem.

4.360 The remainder of this section of the chapter (to paragraph 4.385) records the observations of NHSE&I representatives, including an account of actions undertaken by NHSE and NHSI.

4.361 NHSE was alerted by HSIB about the lack of senior engagement in 2019. In response, an intelligence-sharing call was convened with NHS Resolution (NHSR), the CQC, HSIB and the CCGs, which identified the following issues:

- NHSR raised concerns about the Trust being an outlier for claims.
- The Richford family were concerned that the Trust wasn't meeting the requirements of NHSR and CNST. A whistle-blower had also raised concerns about adherence to CNST requirements.
- The CQC expressed frustration about the lack of information coming back to them.
- HSIB raised concerns about the number of cases being higher than the national average and about the "scattergun" nature of the response from the Trust, particularly in relation to the Harry Richford case. There was no evidence of lessons being learned and there were issues with the way in which the Trust was managing the relationship with the family.
- NHSE had concerns about reports from HSIB.
- The CCGs had concerns about how difficult it was to get information from the Trust, CTG monitoring, the multiple action plans, changes in Heads of Midwifery, and the Board not being sufficiently focused on maternity services. The lack of Board to ward oversight and the lack of escalation to the Trust Quality and Safety Committee and the Board were continuous themes.

4.362 A single-item Quality Surveillance Meeting was subsequently held on 10 December 2019 at WHH. HSIB, the CCGs, the CQC, members of the Trust Executive and clinicians from

maternity and paediatrics services attended. HSIB presented its concerns and there was a long presentation from the Trust. We were told by a senior NHSE&I representative that:

The trust seemed slightly defensive, as though they were trying to pretend there wasn't a problem. It also felt as though they were trying to do so much that they couldn't see the wood for the trees. They seemed to have difficulty honing-in on the issues highlighted by HSIB and on the cases and the learning from them.

4.363 After the meeting, there was further discussion among the partners. A senior NHSE&I representative told the Panel:

They were concerned about the pace of change, given the long history of problems in the Trust. For example, there had been a lack of action following the RCOG report of 2015. There was a lack of assurance about the changes that were needed. They felt concerned about relationships in the leadership, particularly in relation to the medical director and clinical director roles. HSIB indicated that the head of midwifery had engaged well with them but that she was probably the only one. There was no senior involvement in oversight.

4.364 There was a concern about reporting lines between the Director of Midwifery and the Chief Nurse:

There seemed to be a direct relationship between the director of midwifery and the chief executive, but where was the voice of nursing in that?

4.365 There were also concerns about whether the Trust was sufficiently focused on the issues that arose from the cases discussed at the meeting, such as escalation, CTG monitoring and fetal distress. It needed to step back and refocus on the key issues. The inquest into the death of baby Harry Richford was due in January 2020 and, as NHSE&I did not feel assured that the Trust had learned from the case, which had happened several years earlier, NHSE&I put some measures in place.

4.366 NHSE&I instigated the Maternity Safety Support Programme (MSSP) and arranged support from the regional team for the Trust Medical Director, the Chief Nurse and the Head of Midwifery to help them with the governance challenges. Actions and events included the following:

- The inquest took place in January 2020.
- The independent review of maternity services was announced in February.
- NHSR sought to recoup funding it had provided for CNST.
- The CQC did an unannounced inspection and produced findings.
- There was a joint relationship visit with the CQC.
- The Chief Midwifery Officer for NHSE&I and the Regional Chief Midwife visited the Trust at the end of January.
- There were meetings with the executive team.
- Additional external support was provided to the Trust, in the form of a former Head of Midwifery, a paediatrician, a neonatologist and an obstetrician.

4.367 A QSG review meeting was held in February 2020; by that stage, the Trust was “*feeling under siege*”. There was also increasing press attention. NHSE&I set up weekly East Kent huddles involving the GMC, the NMC, Health Education England, NHSI, the CQC and HSIB to share intelligence, help coordinate the number of requests being made of the Trust and allow the

Trust to remain focused on improvement. It specifically asked for an overarching plan that would bring together in one place responses to the RCOG report, work on coroners' cases, the BESTT programme and other relevant issues. It also requested a review of the medical workload, especially in relation to the balance between obstetrics and gynaecology. The Trust was working on an improvement model, but maternity services were just one of the Trust's challenges. It was also dealing with the pandemic and several other issues that had escalated.

4.368 The Panel heard from NHSE&I that trusts are often defensive under such circumstances, but that East Kent was particularly so. NHSE&I could see the lack of openness around the cases, and the Panel was told that the Board did not seem to be fully aware of the concerns about maternity services. The Trust wasn't open with stakeholders and providers either. We were told:

It felt like that at all levels. There was a lack of openness with families, through to lack of openness with stakeholders such as the CCG. It felt as though they didn't always get the information they should have done from the Trust.

4.369 The Panel was told that the Trust didn't identify problems partly because it didn't know about them and partly because it didn't want to declare them. For example, the Harry Richford case caught the Executive off guard, until it reached escalation point in October 2019. The Panel heard that:

Initially, when support was offered to the Trust, they were reluctant to accept it and it was as though they were trying to prove that there wasn't a problem. There was an acceptance issue. The region had to check regularly that the support was being used continuously.

4.370 In relation to dealing with inappropriate clinician behaviour, NHSE&I supported action in various ways:

The new medical director was doing a good job and making an impact, but this was [their] first medical director role and [they] needed their help with it. One of the planks of the maternity safety support programme was to help with the relationship issues between midwives and obstetricians.

4.371 We heard that NHSE&I also provided support to paediatrics. NHSE&I split the paediatric and maternity leadership to enable maternity services to have enough bandwidth to deal with their issues.

4.372 Throughout 2020, NHSE&I was concerned about how the Board was obtaining assurance about the experience of families and patients. It also had concerns about the governance of the organisation and some of the approaches to governance during the pandemic. NHSE&I's view was that the Trust had made some improvements, but the pace of change and oversight by non-executive directors were still concerns. Improvement directors were assigned to the organisation, to help with coordination of the various improvement activities, and Board advisers were provided. NHSE&I requested a rapid governance and leadership review of the organisation, which was done in the autumn. A regional director had fortnightly meetings with the organisation to provide enhanced oversight and to keep traction on the improvement programmes.

4.373 In response to these measures, NHSE&I began to see some improvement in maternity and infection prevention and control issues. The Trust became more open, and we were told that the Medical Director began to contact the regional NHSE&I if there were any issues. The Trust became more receptive to help and support when things went wrong. However, NHSE&I remained concerned about the pace of change. For example, there was a case of maternal

death on New Year's Eve in 2020, and although the Trust reported it immediately, it didn't think that there were any issues of concern. Yet a few days later, NHSE&I received a letter from HSIB that identified several issues of concern:

It seemed that depth of understanding and the ability to identify issues hadn't embedded yet. They had made a few steps forward, but it was not enough, and the pace of change remained a significant concern.

4.374 NHSE&I was concerned about the effectiveness of Board scrutiny, particularly via the Trust Quality and Safety Committee. Ward to Board escalation wasn't really happening:

On paper, the governance structure looked fit for purpose but under the surface, there were issues with people's understanding of the governance system and escalation. There was no common approach to safety across the organisation and there were issues around clarity of roles – especially between clinical roles at executive level.

4.375 The lack of escalation of these issues was attributed by NHSE&I to an ineffective governance mechanism and a lack of openness, which was apparent in incident reports. The culture of openness and learning had not fully embedded in the Trust and a fear of blame partly accounted for that, although NHSE&I had not seen any actual evidence of this.

4.376 In relation to governance structures and escalation in the Trust, there was concern about the strength of Board papers and the depth of information that went to Board committees:

Things might have been reported but may not have been in enough depth for oversight and scrutiny.

4.377 There was also concern about non-executive directors' scrutiny of papers in the Trust:

They asked lots of questions but that might have made it difficult to be open when things went wrong.

4.378 The Trust had gone through a restructure of care groups and NHSE&I had concerns about the strength of leadership in the maternity care group and concerns about what the different committees did:

There were a lot of sub-groups in maternity and [we] questioned their effectiveness as an eye into the organisation. Also, the fact that the same people were on different groups didn't necessarily make for a robust process.

4.379 A maternity improvement group was set up; NHSE&I told us it had made sure that it included someone from the CCGs and two representatives from NHSE&I to help them gain assurance and to act as critical friends.

4.380 NHSE&I had several concerns about nursing and midwifery in the Trust, including about nursing leadership on matters such as safeguarding and the Trust's ability to make progress on some of the issues in nursing and midwifery. NHSE&I was also concerned about:

... the relationship with the director of midwifery and where the executive clinical nursing role fed into that.

4.381 Based on many interactions with the Trust, there was a concern about some of the responses of the nursing leadership and its presence in the organisation. NHSE&I provided

support to the leadership, particularly to the Head of Midwifery. The NMC conducted a review to check if nurses and midwives were being referred from East Kent maternity services, and the CQC expressed concerns about midwives.

4.382 One thing that was heard from staff was the following point:

[D]espite the challenges, everybody was coming to work every day to do a really good job. There was something about how you balance what are really difficult stories for women, for their families, really difficult incidents, some of them quite historical, with the ability to celebrate the small success and incremental change. It didn't feel as though the Trust had that balance quite right. There was also a need to ensure that staff were briefed in order to support them with tricky conversations or queries from women who may be concerned at the quality of care from adverse media coverage.

4.383 The role of the NHSE&I Regional Chief Midwife for the South East was created in April 2020 to offer informal support to the Trust's Head of Midwifery on an ad hoc basis, mainly through the MSSP and meetings with the MIA on a weekly basis. The MIA relationship was key – they were there to support the Head of Midwifery, be a critical friend, and help them develop and work through the improvement plans.

4.384 The MSSP first went into the Trust as an action arising from the "Single Item" QSG in December 2019. A team went in to carry out a diagnostic assessment and the midwife lead for that team, along with an obstetrician, provided a report. There was also ongoing feedback and support. However, the pandemic hit and the MIA who carried out the diagnostic assessment was called back to their own organisation. Another MIA was sourced, commencing work in April 2020.

4.385 The feedback to the Regional Chief Midwife about the Trust at that time was that there was improvement although the pace was slow. The principal output from the "Single Item" QSG concerned consultant cover; in response, the Trust was introducing 24-hour support at WHH and improving how cover was provided at QEQM. There was also work around CTG monitoring, and around the aggregated action plan (linking to the Trust's Improvement Director).

Improvement initiatives and programmes

4.386 The Panel was told of improvements beginning in 2018 through the BESTT programme, including strengthened governance (midwife governance leads), the appointment of bereavement midwives, improved fetal monitoring, an improved dashboard, and the achievement of 100% one-to-one care.

4.387 Referring to the BESTT programme, the Panel was told:

[S]taff really engaged in it and were keen to be part of the change. By 2018, there were improvements in recruitment. People wanted to work at the trust and at interview, applicants were citing BESTT as a reason why they wanted to work in the trust's maternity services. They noted a big improvement in the trust's reputation on the recruitment front, and students who had trained elsewhere wanted to work there. There were significant improvements in staff survey results and staff felt more supported in engaging in improvement activities.

4.388 Professor Walker from HSIB told the Panel that one of the problems for trusts is the multiplicity of recommendations that have originated from all over the place, and some of the recommendations disagree with each other:

They're getting big hammers coming in and there are too many cooks ... The problem is that I'm not sure that their structures and their management structures are in place to encompass that and help the staff achieve that. I'm not sure if some of the changes they've brought in are achieving it ... I wasn't convinced that they were on the right track. There're lots of people doing things and committees doing things and people with oversight of things, but I'm not sure that the people on the ground floor are being encouraged to say, "yes you are good, you can be better, let's see how we can do this" ... I don't think the solutions are difficult. I think they're just fundamental and at grassroots level, like "let's build this up, let's build the teams, let's build their confidence, let's build the team working, the support". It's really from the bottom up that you want it, not from the top down.

4.389 An experienced midwife told the Panel:

You have to ask yourself, why is it that despite feedback after incidents, complaints, legal claims, despite the robust training programmes that you have in place, do behaviours not change? Why are we still seeing the same themes coming up, not just in one Trust but across the country?

4.390 The Panel was told by Professor Walker of his reaction to the focus on specific hospital trusts:

We've got to stop mentioning hospital names ... this is a maternity problem and we've got to take ownership of it throughout the maternity system. That doesn't mean every hospital is bad, but ... I think every hospital has got problems and I think we should be looking at that in a global way ... But I think we need to rethink how we disseminate information, and particularly how we train and implement change.

This chapter has explained that, alongside listening to families, the Investigation has conducted interviews with 112 current and former staff at the Trust and with others whose work brought them into contact with the Trust's maternity and neonatal services; and that this was a key part of the Investigation. We would like to thank everyone who was interviewed for their willingness to share their experience with the Panel for the purpose of this Investigation.

It is important to note that these interviews helped shape our findings as set out in Chapter 1 and that this chapter describes what we heard. This chapter should be read as performing that function, not as an indication of the Panel's own thinking or conclusions.

Chapter 5: How the Trust acted and the engagement of regulators

This chapter gives an account of how East Kent Hospitals University NHS Foundation Trust (the Trust) considered maternity and neonatal services and engaged with regulators and others. It draws upon documents and other information that the Investigation has received from the Trust and from organisations and individuals with whom it has engaged.

We refer throughout to the Board of Directors as “the Trust Board” or “the Board”.

This chapter sets out how the Trust conducted itself as reflected in its own documents. Nothing included in this chapter should be taken as expressing the Investigation’s own findings, except where explicitly stated: its findings are set out in Chapter 1 of this Report.

How the Trust managed maternity and neonatal services

5.1 The Board of the newly constituted East Kent Hospitals University NHS Foundation Trust met for the first time on 2 March 2009. This was the day it received its authorisation as a Foundation Trust.

5.2 As a Foundation Trust, the Trust enjoyed greater freedoms than a non-Foundation Trust, including more financial autonomy. The Trust’s Chair and Chief Executive, in their foreword to the 2008/09 Annual Report, said:

[W]e now have much greater involvement in our decision-making from local people, including patients and staff, through a new 32-strong Council of Governors, mostly elected by a membership that now exceeds 13,000. Being granted Foundation Trust status is recognition of the standards that have been achieved by the organisation through the expertise, hard work and dedication of our staff. We are now awarded greater freedom to govern ourselves in a way that is responsive and flexible to the changing needs of the people we serve, while continuing to ensure that healthcare is provided in a safe, effective and efficient manner.¹

5.3 The Trust Board met for a second time on 27 March 2009. In neither of these inaugural meetings did the Board agenda include consideration of maternity or neonatal services, nor have we seen any reference to them in the papers circulated for those meetings. It is clear from the Annual Report that the Trust was focusing its attention on national priorities, which at that time included waiting times, coronary heart disease and cancer, but not maternity services.

5.4 From the material seen by the Investigation, the first substantive reference to maternity services at the Trust was at the Board meeting on 28 August 2009. At that meeting, the Deputy Director of Nursing introduced a Serious Untoward Incident (SUI) report. Particular reference was made to the changes in reporting maternity cases to the Strategic Executive Information System (StEIS), which is supposed to capture all serious incidents; this had resulted in an

increase in the number of maternity cases on the system. As a result, it had been agreed with the Eastern and Coastal Kent Primary Care Trust (PCT) that from July 2009 only cases where concerns with practice had been raised would be recorded on StEIS. The meeting also noted that neonatal deaths were being monitored by the Trust's Audit Committee and that no formal report was required by the Board.

Internal review and report, 2010

5.5 The first indication of awareness of concerns about maternity services within the Trust came at the Board meeting on 24 September 2010, where the Medical Director gave an overview of a recent SUI within maternity. They reported that the Trust's internal monitoring process had highlighted an increase between April and August 2010 in the number of babies showing symptoms of hypoxic ischaemic encephalopathy (HIE), a type of brain damage that occurs when babies do not receive enough oxygen and/or blood circulation to the brain. They reported that an internal investigation involving a review of medical notes had commenced to establish the facts, and a formal report of findings would be brought to the Board in October 2010. They added that the PCT would be involved throughout the investigation and external midwifery support was also being sought. The Medical Director went on to report that external midwifery support had immediately been put in place at the William Harvey Hospital in Ashford (WHH) due to a concern regarding a potential decrease in skill mix at this unit, which would unfortunately have an adverse effect on other units. This was intended to be a temporary measure and would be reviewed once the internal investigation had ended. Monitor and the Care Quality Commission (CQC) had also been informed.

5.6 At its meeting on 27 October 2010, the Trust Board received a confidential interim report. The report stated that *"during Q1 a higher than expected term admission rate to NICU/SCBU [neonatal intensive care unit/special care baby unit] was noted and discussed at the perinatal mortality and morbidity meeting in July. No themes or common factors were identified."* It went on to state that *"concern was raised about midwifery staffing levels at WHH and a 'risk alert' was circulated to midwifery staff"*, and that:

... a decision was made to enhance midwifery levels at WHH pending the outcome of an internal review and to do so to close the Buckland Hospital [Dover] birthing unit to births to increase staffing levels at WHH. This was communicated as a SUI and both CQC and Monitor informed.

5.7 The interim report also stated that it *"does not enable any final conclusions as to the standard of care offered at this stage although a number of trends have emerged which largely reflect recognized risk factors for HIE"*. These were that *"46% of babies were born 'through' meconium stained liquor; 53% of mothers were either overweight or obese; 26% of babies showed signs of growth restriction (birth weight < 10th centile)"* and that *"to date 'no suboptimal' or 'minor suboptimal' care has been recorded in over 85% of cases"*.

5.8 The 2010 internal review examined the antepartum management of 91 babies who had an unexplained admission to the NICU or SCBU within the Trust between January and September 2010. In 40% of the cases reviewed, the review highlighted the presence of suboptimal care, and in a third of those cases the suboptimal care was considered possibly, probably or likely to have been a relevant factor in the outcome. Of the 91 babies reviewed, there were 16 perinatal deaths, and significant or major suboptimal care was noted in 4 of those cases. Six babies were identified as likely to have what the review describes as *"long-term handicap"*, and significant suboptimal care was identified in three of those cases.

5.9 More broadly, the review report raised significant concerns about midwifery and obstetric management, midwifery staffing and skill mix, and resuscitation of babies showing signs of shortage of oxygen. The report identified a number of themes, many of which are recurring issues in the reports, inspections and findings that took place between 2010 and 2020.

5.10 The report noted areas of commendable practice, including the prompt and effective response to potential or actual obstetric emergency situations.

5.11 In summarising its findings, the report addressed staffing issues and recommended an urgent review of midwifery staffing at the WHH site. It noted that midwives faced *“the challenge of caring for more than one high risk labouring woman at any one time”*, and that *“an informal poll of trusts in the South Thames region has revealed that staffing/patient ratios in EKHUFT [the Trust] are amongst the lowest in the region”*.

5.12 The report also noted that, where the review team identified areas of suboptimal practice, the staff involved received a letter advising them to address that area of their practice, which was copied to their supervisor. While there was a robust arrangement in place within the midwifery profession to learn from incidents and address areas of practice, the report noted that *“arrangements for medical staff are less robust and this will be reviewed”*.

5.13 The report included recommendations such as reminding staff to practise within guidelines, improving diagnosis of labour in low-risk settings, improving standards in fetal monitoring, reviewing clinical guidance and resuscitation arrangements where meconium is present, reviewing the process by which medical staff of all grades learn from adverse events, and reviewing the process of escalating concerns about the progress of labour to more senior staff on call.

5.14 The Medical Director introduced the final report of the neonatal admissions review at the Board meeting on 22 December 2010. They highlighted that there were concerns about midwifery and obstetric management and that *“midwifery staffing levels may limit the provision of safe care across obstetric birthing sites in East Kent”*. It should be noted that at this point in time there were four geographically separate maternity units: WHH, the Queen Elizabeth The Queen Mother Hospital at Margate (QEQM), Canterbury and Dover. This is what was deemed unsustainable, hence the relocation of the two standalone Midwifery-Led Units (MLUs) to be located alongside the obstetric units at WHH and QEQM. In response to a question from a non-executive director raising concerns about 40% of cases having suboptimal care, the Medical Director stated that *“this represented 1.9% of total births”* and that the Trust had not been identified as an outlier in national perinatal statistics.

5.15 The Trust Board was asked to note the recommendation that one standalone MLU remain closed until May 2011 while an urgent review of minimum midwifery staffing levels was carried out. An action plan resulting from this review would be presented to the Board.

5.16 The Assistant Head of Midwifery and the Clinical Director for Women’s Health presented the action plan at the Trust Board meeting on 28 January 2011. The Clinical Director for Women’s Health emphasised that *“the Trust was operating a safe staff to patient ratio”*. The Board formally noted the action plan.

Report to Monitor and review of maternity services

5.17 Monitor was responsible between 2004 and 2016 (when it became part of NHS Improvement (NHSI)) for authorising, monitoring and regulating NHS Foundation Trusts.

In January 2011, Monitor received an update on the maternity serious incident report described above. This stated that, in response to the findings of the report, the Trust was implementing changes to midwifery and obstetric practice. The Trust also recognised potential concerns with activity and midwifery staffing levels at the high-risk obstetric units.

5.18 The report to Monitor noted that, in view of these concerns, the Trust was carrying out further analysis of midwifery staffing levels at WHH and had embarked upon a review of maternity services across East Kent with the PCT, to be completed by May 2011. Until the outcome of this review was known, the Board had agreed to the closure to births of the MLU in Canterbury, while maintaining daytime services. The Board had also agreed to the reopening to births of the MLU in Dover, which had been closed in September 2010. The Trust maintained that these restrictions enabled the maintenance of enhanced midwifery staffing levels at the high-risk obstetric unit at WHH.

5.19 At the Trust Board meeting on 28 January 2011, the Medical Director reported that they had recently met with staff from the PCT who were carrying out the review of midwifery staffing levels. They referred to the need to inform the local authority's Health Overview and Scrutiny Committee of progress.

5.20 There was no further discussion of maternity services at the Trust Board until 24 June 2011, when a review of the configuration of maternity services was discussed. The review stated that it was the Trust's ambition to "provide 1:1 midwifery care in active labour corresponding to a midwife to birth ratio of 1:28 at all birth units in line with 'Safer Childbirth' recommendations".² The average ratio at WHH was 1:40, while at QEQM it was 1:35.

5.21 The options for consultation were discussed at the Board's meeting on 26 August 2011, where the recommendation was made to the Trust Board that:

[T]he most sustainable option would be to maintain all services except births and step-down postnatal care at both Dover and Canterbury. This will enable a midwife to birth ratio at Queen Elizabeth the Queen Mother hospital (QEQM) and WHH of 1:28 and will enable the QEQM co-located Midwifery Led Unit (MLU) to be opened.

This was recorded on the leaflet circulated for consultation as "Stop births at Dover and Canterbury centres but retain midwife-led antenatal care, day clinics and postnatal support. Open the new midwife-led service at Margate. Increase staffing levels to provide one-to-one care for all mothers." The Board agreed and consultation commenced on 14 October 2011.

5.22 After consultation, the preferred option was discussed and agreed at the Trust Board meeting on 27 April 2012. In discussion, the Assistant Head of Midwifery stressed that current services were not unsafe. They said that the driver behind the review was to ensure that services were equitable across the Trust, with all women receiving one-to-one care during labour. The Board agreed to the implementation of the preferred option. Although the issue of equitable provision across the Trust was reasonable and clearly dominated the Trust's response, it overlooked the accumulating evidence that there was more to the safety issues than that – in particular, the longstanding cultural problems subsequently described.

5.23 The Trust Board returned to the issue of maternity services on 26 October 2012, when they were featured in its regular "Patient Story" item. This focused on a positive story within maternity services at WHH: 24-hour visiting for patients and more male toilets. It was noted that the Trust had successfully recruited all the midwives who had completed their training at WHH.

5.24 There was no further reference to maternity services until the Trust Board meeting on 30 January 2014, when (under the “Questions from the Public” item) a Trust Governor referred to the Clinical Quality and Patient Safety Report (a Board paper) and the increase in incidents reported to be related to staffing levels. The Governor referred in particular to the Singleton Unit, an MLU at WHH which was fully staffed but reported 18 incidents related to staffing levels. The Chief Nurse agreed to find out the detail behind these incidents and to contact the Governor outside of the Board meeting.

5.25 The Trust Board returned to this theme at its meeting on 28 February 2014, when (again in the “Questions from the Public” item) it was reported that the trend of an increase in staffing incidents recorded had continued since January; this was due to a combination of sickness levels and maternity leave. The recruitment of 14 midwives was under way and the Trust was working through Human Resources (HR) to understand and address the underlying causes of the sickness levels.

5.26 The Canterbury and Coastal Clinical Commissioning Group (CCG) noted at its March 2014 Quality Performance Meeting that it was concerned about maternity services at the Trust. The CQC visited the Trust in the same month and rated it “Inadequate”, with maternity services rated as “Requires Improvement”, although the CQC report was not published until 13 August 2014.

5.27 In April 2014, the Local Supervising Authority (LSA),* then a designated function of NHS England (NHSE), commissioned a maternal death review, with a panel of clinicians responsible for the care of women during pregnancy and childbirth. The review considered six maternal deaths that occurred in Kent and Medway during the year from April 2012 to March 2013, *“in order to determine whether learning from these tragedies could help improve the future delivery of care”*.³

5.28 Quality Surveillance Groups (QSGs) were established by the NHS Commissioning Board (the predecessor to NHSE) in 2013. The intention was for local QSGs to be engaged in surveillance of quality at a local level, with the help of those closest to the detail and most aware of concerns. The members considered information and intelligence but also took coordinated action to mitigate quality failure. The meetings were chaired by the NHS Commissioning Board Area Director, Nursing Director and Medical Director.

Care Quality Commission report, 2014

5.29 The CQC published its findings on 13 August 2014. The overall rating for the Trust was “Inadequate”, with findings that it was inadequate in providing safe care and being well led, and that it required improvement to deliver effective and responsive services. Some of the key findings from the CQC were the following:

- There was a concerning divide between senior management and frontline staff.
- The governance assurance process and the papers received by the Board did not reflect the CQC’s findings on the ground.
- The staff survey illustrated cultural issues within the organisation that had been inherent for a number of years, reflecting behaviours such as bullying and harassment (staff engagement was among the worst 20% when compared with other similar trusts).

* LSAs were accountable to the Nursing and Midwifery Council (NMC), though their midwifery officers were employed elsewhere, latterly by NHSE. LSAs were responsible for producing supervisory audits of maternity services to ensure the provision of safe and high-quality midwifery care. They ceased to perform this function in 2017.

- Staff had contacted the CQC directly on numerous occasions prior to, during and since their inspections to raise serious concerns about the care being delivered and the culture of the organisation.
- Patient safety incidents were not always identified and reported, and staff use of the incident reporting system varied considerably across the Trust.
- The CQC saw limited evidence of how clinical audit was used to provide and improve patient care and saw examples of where audits had not been undertaken effectively and provided false assurance.
- The CQC found examples of poorly maintained buildings and equipment, and in some cases equipment that was not adequately maintained and was out of date and unsafe.

5.30 Maternity services were given the rating “Requires Improvement”.

5.31 The findings of the 2014 CQC report identified a significant difference between the Board’s perception of how well the Trust was doing and the experiences of the staff, who described bullying behaviours and a fear of speaking out about things that were problematic. In response to the report, the reaction of the Trust was one of real defensiveness and disbelief.

5.32 The improvement plan for the CQC (which embedded maternity services within it) was reported and discussed at Board level. However, the Board rarely dived into the detail of maternity and neonatal services, and its response was more about monitoring progress against the overall improvement plan (of which maternity and neonatal services were just a part).

5.33 There was a clear disconnect between ward and Board and a perception among midwives that their views were blocked and not escalated appropriately due to “gatekeeping”. Governance structures within the Trust were not sufficiently robust to allow ward to Board assurance, and the Trust was not willing or able to actively look for problems and issues to solve, but rather waited for them to be pointed out. The Trust needed to be problem sensing rather than comfort seeking in its approach.

5.34 Maternity services featured very little in Board discussions, despite the concerns that had been raised. Maternity services also did not feature consistently within governance sessions, and there was rarely detailed discussion about maternity and neonatal services at Board level. Issues became diluted, and their significance was not recognised as they were reported up through the chain and repeatedly summarised.

5.35 It remains a concern that a number of themes identified in the 2014 CQC report and in reviews since then have appeared during this Investigation. By way of example:

- At the time of the CQC’s initial investigations, staff commented that they were still unable to raise concerns due to the culture at the Trust. The Investigation has heard repeatedly that there was little or insufficient response when concerns were raised by staff.
- Policies were reported as being out of date long after the CQC’s initial inspection.
- Lack of support with training has been an ongoing issue (for example, staff being told off for asking questions), and some departments have only recently been requested to participate in formalised training.
- Bullying and harassment remain a significant concern of staff, with some stating that they continue to be negatively impacted as a result of raising a complaint. The suppression of dissent or complaints appears to be an ongoing issue.

- The CQC report identified staffing as an issue across all three sites (Ashford, Margate and Canterbury).

Follow-up to Care Quality Commission inspection, 2014

5.36 Maternity services were discussed again at the 26 September 2014 Trust Board meeting under the “Patient Story” item. The Chief Nurse presented a report which described the experience of a couple during the birth of their first child. The report highlighted the following issues: privacy and dignity not being maintained; a lack of information provided; unprofessional behaviour of some staff; and poor pain control. Since the concerns had been raised with the Trust, the couple had met with the matron and specific actions had been put in place. The Chief Nurse reported that this was not an isolated incident. Matrons and the Head of Midwifery would undertake improvements across all teams.

5.37 In discussion, one of the non-executive directors asked for assurance that there was sufficient resource available to embed the actions and learning highlighted in the “Patient Story”. The Chief Nurse stated that staff listening events held following a CQC inspection had enabled staff to discuss their experiences positively. The Chief Nurse added that there were historic cultural and leadership issues which needed to be addressed.

5.38 In October 2014, the regional QSG received a report on the maternal death review and current maternity risks from the LSA. The report identified the following causes for concern: no regional maternity lead in place, which was impacting on the Trust’s ability to focus on improvement, and a shortage in midwifery leadership.

5.39 The CCG reported in November 2014 that it was taking action following the CQC inspection. The local CCGs had been meeting with the Trust to gain assurance around both its progress in recruitment and its current birth to midwife ratios. The CCGs were working with the Trust to agree a new approach for holding the Trust to account for the quality of its maternity services, and would be implementing a revised maternity dashboard (a summary of maternity statistics) from the Clinical Network once published.

5.40 In January 2015, an East Kent Maternity Patient Safety Forum was established, following recommendations from the maternal death review.

Bullying and inappropriate behaviour within the Trust and maternity services

5.41 The very significant adverse impact of bullying and harassment, particularly at WHH, was referred to by many staff with whom the Investigation has spoken.

5.42 The 2013 national NHS staff survey recorded that staff engagement at the Trust was in the lowest 20% nationally. The percentage of Trust staff who had experienced harassment, bullying or abuse from other staff in the preceding 12 months (at 31% against a national average of 24%) was one of the Trust’s bottom five ranking scores, and it was identified within the survey report as a starting point for local action.

5.43 The position markedly deteriorated the following year (2014), when the national NHS staff survey recorded that the percentage of Trust staff who had experienced harassment, bullying or abuse from other staff in the preceding 12 months had increased to 42% (against

a national average of 23%). Overall staff engagement also deteriorated in 2014 and was again in the lowest 20% nationally. The percentage for staff harassment, bullying and abuse was identified again as one of the Trust's bottom five ranking scores, and again the survey report recommended action.

5.44 The 2014 CQC report published on 13 August 2014 (reflecting CQC inspection visits in March 2014) also identified bullying and harassment within the Trust as a key finding.

5.45 This Report has already referred (in paragraph 1.87) to an anonymous letter sent to the Chief Nurse on 27 October 2014 from a member of staff within maternity services at WHH, which said:

I work on maternity at the William Harvey. I'm ashamed to say that I feel intimidated at work. I have been made to look stupid in front of patients and other staff at work. I feel completely unsupported by our most senior staff. At times I dread going to work with certain people ... Management and those with authority are not approachable, there is a blame culture, a just get on with it and shut up attitude, slog your guts out and still get grief. It's ok if your face fits, we operate a one rule for one, and another rule for everyone else on maternity ... you need to know that at times the unit is an awful place to be.

5.46 In response to the issues of bullying and harassment raised within the national NHS staff surveys, the 2014 CQC report, the anonymous letter to the Chief Nurse and the concerns of the newly appointed Head of Midwifery (appointed on 1 July 2014), an investigation, led by the new Head of Midwifery and supported by HR, was opened to find out how it felt to work within the Trust's maternity services.

5.47 On 19 November 2014, following interviews with 30 staff, an interim report was provided to the Chief Nurse and Director of HR by a member of staff from the HR Business Partner (Specialist Services Division). The interim report included an account of the following behaviours and issues:

- Prickly, sharp, abrupt and sarcastic senior staff
- Instances of staff being shouted at, criticised and humiliated in front of others
- A daunting and unsupportive environment, with one person describing how they were frightened to attend work
- Staff feeling intimidated and undermined in front of patients, resulting in a loss of confidence and time off work with depression
- Allegations of racism.

5.48 The delivery of the report on 19 November 2014 prompted a meeting later that day between the Head of Midwifery, the Chief Nurse and others, in the course of which the Head of Midwifery was sufficiently concerned to express the view that maternity services at WHH were not safe for patients and should be closed.

5.49 In the event, maternity services were not closed, and the investigation continued. Some 110 members of staff were interviewed in November and December 2014, and just over half reported that they had experienced unsupportive behaviour while working in the Trust's maternity services.

5.50 On 6 February 2015, a consultant obstetrician and gynaecologist wrote to the CQC raising concerns. They had previously worked for the Trust but left because of "a downward spiral of staff morale following poor leadership".

5.51 Following this, the Trust management team received a letter dated 9 February 2015. The Trust has redacted the name of the writer, who stated:

I am writing to you on behalf of the midwives and their support staff at the William Harvey Hospital. Following a recent Supervisors Surgery staff have expressed their concerns and distress at the current working environment. I felt this needed to be brought to your attention before the situation deteriorates. The unanimous recommendations from the discussion at the supervisory surgery were: that the concerns stated needed to be escalated; that we should ask for a management meeting with the [names redacted] and Human Resources.

5.52 The writer made a number of requests in the letter, including: “Improved communication, where staff are listened to and heard with democratic decisions being made for the greater good rather than being dictated to.” The Trust responded on 16 February: “It has been decided to accept your letter as a raising concern and take forward in accordance with the Raising Concerns Policy and Procedure, a copy of which is provided for your information.”

5.53 On 29 December 2015, a Report Into Raising Concerns was sent to the relevant maternity staff identified in the letter of 9 February.

5.54 Further concerns were raised with the CQC on 23 March 2015, when a midwife rang to say that, following an incident at the hospital, which they described as an “error of judgement” on their part, they felt that they had been bullied and victimised as a consequence, in contrast to the Trust’s response to more serious incidents involving other staff. They said that they and their colleagues felt there was a culture of bullying at the Trust, that staff were afraid to raise concerns for fear of reprisal, and that such pressures were putting their ability to provide quality care in jeopardy.

5.55 The midwife said that, following the incident involving themselves, they had been redeployed in a similar role at QEQM; however, they said this was clearly a “punishment” for what they had done, even though their actions had not resulted in an SUI. The midwife added that they were in communication with the NMC in relation to their current issues and stated that it had told them that, based on their evidence, the hospital management did not appear to know what it was doing. The NMC can find no communication relating to this matter.

5.56 In March 2015, the Royal College of Midwives’ Regional Officer lodged a collective grievance on behalf of midwives at the Trust. The Trust has informed us that 51 staff signed this letter on 11 March 2015.

5.57 While the 2014 CQC inspection mainly focused on bullying and inappropriate behaviours within midwifery, these problems were not limited to that professional group. In 2015, the Trust commissioned the Royal College of Obstetricians and Gynaecologists (RCOG) to carry out a review and to report on a number of behavioural and performance issues, which included concerns about relationships between midwives and obstetricians (see paragraphs 5.77–5.98).

The Report of the Morecambe Bay Investigation, 2015

5.58 *The Report of the Morecambe Bay Investigation* into serious incidents in the maternity department at the University Hospitals of Morecambe Bay NHS Foundation Trust was published in early 2015. It found that the origin of the problems at the Trust lay in the seriously dysfunctional nature of its maternity service, where the following issues were identified:

- Clinical competence was substandard, with deficient skills and knowledge.
- Working relationships were extremely poor, particularly between different staff groups such as obstetricians, paediatricians and midwives.
- There was a growing move among midwives to pursue normal childbirth “*at any cost*”.⁴
- There were failures of risk assessment and care planning that resulted in inappropriate and unsafe care.
- The response to adverse incidents was grossly deficient, with repeated failure to investigate properly and learn lessons.

5.59 Of particular concern is the fact that, through the spring of 2015, the Head of Midwifery at the Trust had noted the issues and lessons identified within the Morecambe Bay report and sought to raise similar issues of concern with the Trust leadership, but they were not listened to.

5.60 The Head of Midwifery produced a risk assessment dated 11 May 2015 which stated that “*similarities exist between the dysfunctional elements of the Morecombe Bay O&G [obstetrics and gynaecology] / Maternity Services MDT [multi-disciplinary team] and those within the same department at East Kent Hospitals*”.⁵ The risk assessment went on to identify the following areas of risk:

- Poor clinical competence
- Insufficient recognition of risk
- Poor teamworking
- Inadequate clinical governance systems
- Poor-quality investigations – both internal investigations and those undertaken by supervisors of midwives
- Denial of problems
- Rejection of criticism
- Strong group mentality – “*musketees*”
- Distortion of truth
- Model answers
- Disappearance of records
- Conflict of roles.⁶

5.61 The risk assessment also noted that “*there were several missed opportunities in dealing with the issues at MB [Morecambe Bay] and it is questionable if a similar external review occurred here in EKHUFT [the Trust] Maternity Services whether similar missed opportunities would be uncovered*”.

5.62 The risk assessment produced by the Head of Midwifery scored the risk at the Trust as “*Extreme Risk – immediate action required*”.

5.63 The risk assessment was presented at a governance meeting on 12 May 2015, and the Head of Midwifery was due to present their assessment to a wider audience at an away day on 21 May 2015. However, this presentation did not take place.

Further concerns, 2015

5.64 Meanwhile, following the April 2015 regional QSG meeting, a conference call was held on 1 May 2015 between relevant stakeholders to discuss a paper that had been presented by the LSA Midwifery Officer (NHSE South). This identified the Trust as an outlier for maternity-related SUIs in 2014/15 and detailed concerns regarding the Trust's maternity performance: namely eight unexpected admissions to the NICU, two unplanned admissions to the Intensive Therapy Unit (ITU), two neonatal deaths and suboptimal care.

5.65 The intelligence-sharing call agreed that a "deep dive" into maternity services relating to these SUIs should be undertaken by external reviewers. NHSE helped to draw up the Terms of Reference (ToR) for this, and also identified the external clinical reviewers. The Canterbury and Coastal CCG agreed to take the lead. The review was planned to take place before the August CQC visit and the ToR constructed so live learning could take place. A letter from the CCGs to the Trust dated 3 June 2015 confirmed the ToR for an investigation into the management of serious incidents at the Trust.

5.66 The CCGs informed the June 2015 Kent and Medway QSG that the review was planned to take place during July. However, at the end of July the Trust advised NHSE that the "deep dive" was to be incorporated into a wider review of maternity services by the RCOG.

5.67 The meeting also heard that there had been seven serious incidents reported in 2015 involving maternity provision at the Trust.

5.68 On 21 May 2015, at a Closed Board[†] meeting, the Medical Director and the Acting Chief Nurse alerted the Board to cultural issues within obstetrics and gynaecology. A full investigation was taking place. In addition, the Trust was looking formally at serious incidents on StEIS. Early indications were that the situation had not changed.

5.69 The Thanet and South Kent Coast CCGs produced a report on 10 June 2015 which stated that maternity lessons from serious incident investigations were not being embedded. They also reported that the Deputy Head of Midwifery was currently acting as Head of Midwifery, with external support.

5.70 On 26 June 2015, at the Trust's Closed Board meeting, the Medical Director (under "Confidential Items") updated the Board on "*longstanding cultural issues*" in maternity services following concerns raised by staff to the CQC and the subsequent collective grievance (see paragraph 5.56). The situation had improved within maternity services, but further work was required.

5.71 The Trust had commissioned an external review of obstetrics, as, according to the Closed Board papers, "*mortality rates were above the national average*". This refers to the work of the RCOG, mentioned above.

5.72 In addition, a complaint had been received from a patient who had overheard a conversation between obstetricians about the safety of the service. Obstetricians were invited to discuss their concerns and a review of job plans was being undertaken.

5.73 One of the non-executive directors asked if the issues reported should have been visible through internal governance systems. The Medical Director explained that there had been a

[†] Trusts can hold part of their Board meetings in private. This has generally been referred to as the "Closed" part of the meeting or "Part 2" of the meeting.

long history of cultural issues and leadership gaps within the service, which unfortunately had become normalised. This had been evidenced by the CQC during its visit in 2014.

5.74 The CQC inspected the Trust in July 2015 and rated it as “Requires Improvement”. In August, the South Kent Coast and Thanet CCGs stated that they were undertaking further scrutiny following the receipt of a 72 hour report in relation to a maternity death SUI.

5.75 In September 2015, NHSE and NHSI noted that they were following up a perceived lack of pace between the Trust and the four local CCGs in jointly commissioning the RCOG clinical review into maternity services, particularly in agreeing the ToR and initiating a start date.

5.76 A regional QSG report in October 2015 stated that the Trust had reported a number of maternity serious incidents relating to cardiotocography (CTG) misinterpretations that had resulted in significant harm or death of a baby. The CCGs were not confident that training was effective and were seeking additional assurance.

Report of the Royal College of Obstetricians and Gynaecologists, 2016

5.77 The RCOG review was undertaken between 24 and 26 November 2015.

5.78 It was commissioned in response to concerns about the working culture within women’s services (including relationships between midwives and obstetricians), inconsistent compliance with national standards among obstetricians, poor governance in relation to serious incidents, staffing, education, supervision of obstetric middle grades and trainees, consultant accessibility and responsiveness, and consultant presence on the delivery suite. The RCOG reported in February 2016 and made 23 recommendations.

5.79 The RCOG report included the following findings:

- Major clinical guidelines for maternity did not reflect current evidence-based best practice. The majority of obstetric guidelines were written by midwives with a lack of obstetric engagement in guideline development. Despite the CQC’s recommendation in 2014 that clinical guidelines be updated, the RCOG found that some guidelines had long expired or were inaccurate. The RCOG emphasised that the successful implementation of guidelines required the consultants to take ownership.
- The LSA had in place measures to address the fact that the Trust was the second highest reporter of serious incidents in the area. Recommendations were made for the Trust to provide assurance of safe and effective maternity care services through identification, investigation and learning from the management of serious incidents and effective links with supervisory processes, with evidence of an active learning culture.
- In respect of root cause analysis (RCA) investigations, there was an apparent failure both to address medical practice issues and to make recommendations on issues perceived as not contributing to the outcome. If poor consultant performance was identified during an RCA investigation, the issue would not be reflected in the report’s action plans. There was also a perception by the RCOG assessors that only staff involved in an incident got a copy of the RCA report findings, and there was little evidence of wider learning across the two maternity units.
- At WHH, all obstetric consultants participated actively on the labour ward and consultant attendance for labour ward rounds was in accordance with Trust guidelines,

with consultants staying on site beyond their shift if necessary and attending the unit when requested out of hours. At QEQM, however, there were three to four consultants who consistently failed to follow Trust guidelines. The RCOG found that *“this unacceptable practice has continued not to be addressed despite repeated incident reporting with the result that this unit has developed a culture of failing to challenge these poorly performing consultants”*.⁷ The interviews conducted by the RCOG assessors revealed significant concerns about the failure of these three to four consultants at QEQM to conduct daily labour ward rounds, review women, make plans of care and attend when requested out of hours.

- Obstetric trainees on both sites reported problems with clinical supervision at weekends, while the absence of consultant input at QEQM during weekends caused increased pressure on trainees.
- While there was some evidence of good multi-disciplinary working, there was no evidence of escalation by either doctors or midwives to the consultant in cases of conflicting emergencies, and there was little evidence of the “fresh eyes” approach to managing complex cases.
- The assessors heard that consultant behaviour at meetings was perceived as disrespectful, but it was behaviour that was tolerated by the consultant workforce and not recognised as a problem. Consultants worked in silos and not between sites; consultants did not interact. The assessors felt that the consultant body should be more respectful and supportive of each other as individuals, and that consultants should aspire to work together between the two sites.
- Assessors repeatedly heard that medical and midwifery staff at both sites considered there was no point in reporting safety issues as no action would be taken by the Trust. In addition, “whistle-blowers” were made to feel unsupported by managers and got minimal or no feedback on the concerns raised. The assessors expressed concerns that staff on both sites were no longer raising concerns about unsafe practices, conduct or performance of colleagues that was affecting patient safety or care, because this had been done in the past without satisfactory resolution and had involved the harassment of staff.
- Other weaknesses identified by the RCOG assessors included a lack of engagement in national audits, poor labour ward facilities and environment on both sites, and high midwifery sickness rates across both sites.

5.80 In addition to a lack of consultant supervision, the RCOG report raised specific concerns about the use of locum registrars. Notably, even as early as around 2009, the Trust was said to be more reliant than it wanted to be on locums. At the time of the RCOG report:

- QEQM was found to be reliant on middle grade locum cover.
- The RCOG found inconsistency in consultant ward rounds on labour wards at both sites, though this was more apparent at QEQM. It also noted vulnerability of the QEQM unit out of hours due to non-attendance and/or reluctance to attend by on-call consultants when requested.
- Obstetric trainees on both sites reported problems with clinical supervision at weekends, including in the daytime, as they covered both obstetrics and gynaecology.
- Only consultants committed to teaching and supervision became educational trainee supervisors, and the RCOG assessors were concerned that this would result in consultants who were not committed to teaching and supervision being on call with middle grade locum doctors, potentially of unknown competence. This in turn would impact on the safety of care in the maternity unit.

5.81 The Investigation heard that, following submission of the report, the Trust had no further involvement with the RCOG despite the RCOG's attempted follow-ups. The Trust told the RCOG that it was unable to communicate how the recommendations were being taken forward because of an upcoming inspection by the CQC, and it did not respond to the RCOG's subsequent request for follow-up information. The Trust also failed to share the RCOG's report with the CQC.

5.82 Upon publication of the RCOG report, the Chief Nurse of the CCGs wrote to the Trust to express concern about the quality of the serious incident investigations. Ahead of a QSG intelligence-sharing call on 22 February 2016, it was made clear that the issues were longstanding and that there was a need for positive action. The CCG sent an email to the Acting Chief Nurse at the Trust.

5.83 A QSG intelligence-sharing call about maternity services took place on 22 February 2016. Following it, the Accountable Officer at South Kent Coast CCG emailed the Chief Nurse at the Trust, stating:

Having read the report my only non-clinical comment is that it is a really sad read. This is nothing that we didn't already know and were raising through other routes. The issues around consultant behaviour were visible to me when I was commissioning Maternity services. Whatever the outcome, I think there needs to be an understanding that this is very long standing and therefore the necessary change needs to be beyond what has previously been achieved. Obviously this was a theme through CQC and is being tackled in terms of midwifery culture already – but we would need positive assurance that the changes in train are having an impact and further work to capture the issues around consultants.

5.84 On 31 March 2016, in internal emails sent between the Medical Director, the Head of Midwifery and the Clinical Lead for Obstetrics, it was suggested that consultant cover on the labour wards exceeded RCOG guidelines at that time. From the Trust's perspective, "safety regarding the Consultant cover is not an issue". Rather, the issue was "engagement of Consultants with ward rounds and also about them being proactive, in a woman's management of care, rather than reactive – this was seen to be more of an issue on the QEQM labour ward site". In what might be perceived as a lacklustre response, the Trust reminded consultants in writing of Trust policy regarding on-call duties on labour wards. The Trust also committed to a two-week audit of consultants on both labour wards; the results identified no significant concerns with regard to consultant attendance or behaviour at WHH, but several concerns at QEQM in relation to consultant non-attendance. The Trust committed to a re-audit within six months.

5.85 The Investigation heard that findings around a culture of consultants being unwilling to attend were challenged by Trust staff. On publication, the report was dismissed and described as "a load of rubbish" by some senior obstetricians. A number of staff were also unaware of the report altogether.

5.86 The RCOG report was discussed at a Women's Health Business and Governance meeting on 5 April 2016. However, despite it having been commissioned by the Trust in the first instance, the report was met with resistance, as the following actions demonstrate:

- The Trust informed the RCOG report reviewers of 20 areas of perceived factual inaccuracies, and submitted a narrative pointing out the lack of benchmarking around safety issues and a lack of comment about the workforce.

- Those attending the meeting considered the RCOG's concerns regarding the length of the RCA process but felt the reviewers had not looked at all the medical notes and did not have a full picture.
- One recommendation was dismissed and surprise was expressed that the RCOG had not identified another issue as a strength.
- The draft action plan included circulation of the RCOG e-learning resources to be accessed by all consultants. However, it appears that these resources were only circulated in August 2016, approximately four months after the meeting.

5.87 On 6 April 2016, the Trust Quality Committee reported that initial information from the recent RCOG report showed that, in the Committee's view, the Trust did not have an unsafe maternity service, but there was improvement work to do around how the service was run in some areas. The Closed part of the Board meeting heard that the Trust was developing an action plan in response to the RCOG recommendations.

5.88 The view that the unit was not unsafe was restated by the Head of Midwifery at a Quality Committee meeting on 4 May 2016. They advised that when they had joined the Trust there had been leadership concerns; many staff in post were acting rather than substantive; there were many vacant substantive posts; there was poor compliance with audit findings and guidelines; there was a lack of equipment; and there was no progression of maternity services in line with national standards. They set out a list of achievements in the previous year, and a non-executive director congratulated them on leading a transformation from poorly led to well-led midwifery services. The agenda item concluded with the Chair recalling that there had been questions raised at the last meeting about whether this was a safe unit. The Head of Midwifery advised that it was. The meeting was told that, compared with national figures, there were low mortality rates for babies at the Trust.

5.89 While the Trust challenged the RCOG report and deemed itself not unsafe, it was felt by Thanet CCG in April 2016 that concerns about maternity services met the threshold for NHSE to call a risk summit.

5.90 An action plan specific to the RCOG report was created in May 2016, with actions to be implemented by the end of October 2016. However, the Panel heard that the RCOG action plan was "*more of a tick box*" in comparison with the CQC investigation. Subsequently, the decision was taken to address the RCOG report within the Trust's general improvement plan. The Panel was told that this meant the response to the RCOG report became diluted and there was insufficient focus on maternity issues.

5.91 The improvement plan was not implemented completely as there were difficulties in securing the full engagement of those at the Trust. The Panel heard that, had the plan been fully implemented on time, it would have "*done the job*". The improvement plan was then subsumed into the Birthing Excellence: Success Through Teamwork (BESTT) Maternity Transformation Programme in 2017. While it was considered a response to the RCOG report, the BESTT programme was built around a national agenda and some themes from the RCOG review were not included, such as halving the rate of stillbirths.

5.92 The risk arising from regulatory non-compliance in maternity was recognised as presenting an "extreme" risk, with potential harm to both pregnant women and neonates, and was approved as a risk for the Corporate Risk Register (CRR 26) in June 2016. This risk assessment was based on the report from the RCOG and gaps identified by the LSA. The challenges in embedding a "*mature and developed patient safety culture*" were approved as a separate "moderate" risk for the Corporate Risk Register in February 2017 (CRR 48), for reasons

including that the RCOG improvement plan was not being delivered on time and there was difficulty in gaining engagement among some teams, resulting in delays in prioritising quality transformation and education workstreams. The minutes from the March 2019 Board meeting record that the maternity residual risk score (under CRR 48) had been modified to a lower value following a positive visit from the CQC, and by April 2019 the risks relating to maternity services had been removed completely from the Corporate Risk Register.

5.93 In 2019, a review of the actions in response to the 2016 RCOG report found that these were incomplete and that fewer than 25% of the actions were robust and signed off. It was not until 2020, following the coroner's findings in respect of the death of baby Harry Richford, that every recommendation had a corresponding action. The RCOG recommendations were then incorporated into the next phase of the BESTT programme, which began in 2020. It was only in January 2020 that the RCOG report was shared with the General Medical Council (GMC).

5.94 Between publication of the RCOG report in February 2016 and July 2020, just 2 of the 23 recommendations could be evidenced as having been fully met, and only 11 were partially met. The Trust failed to successfully address the issues identified by the report, and any changes that were made were not sufficiently embedded to have any significant impact.

5.95 In a report produced by the Thanet and South Kent Coast CCGs on 10 August 2016, it is stated that a Trust maternity integrated action plan had been agreed in response to quality and safety issues highlighted in RCOG, LSA, CQC and Public Health England external reports and through performance monitoring. The Trust had also recently reported three SUIs in relation to births of twins and had identified some initial learning. The CCGs were seeking assurance through the Heads of Quality and Maternity meeting that learning and mitigating actions were in place during the investigations into the three SUIs.

5.96 Staff continued to raise concerns with the CQC. One example is a letter dated 4 August 2016 from a midwife who worked at the Trust from February 2010 until 2016. It is a long letter but highlighted concerns about the way the midwifery unit operated, including roster rules being broken, skill mix, staff not being consulted, requests for training being refused, a lack of equal opportunities in applying for jobs, high turnover of staff and some staff appearing to be uncaring. The writer acknowledged that these issues may appear trivial when viewed individually, but argued that one should take account of the bigger picture.

5.97 The CQC reinspected some of the Trust's services in September 2016, including maternity services, which it rated as "Requires Improvement" in a report published on 21 December 2016.

5.98 The Trust discussed the RCOG report at its meeting on 9 December 2016, when the Medical Director noted that the issues identified during that review were being addressed. The Chief Executive Officer (CEO) at the time acknowledged the work that was already under way to address the issues highlighted by the RCOG and proposed that concerns raised about engagement could be addressed outside of the Board meeting (via the Trust Quality Committee). NHSE reported in February 2017 that the Trust had stated that its RCOG action plan was being overseen by the clinical lead.

The death of baby Harry Richford

5.99 Harry Richford was born on 2 November 2017 at QEQM. He was the son of Sarah and Tom Richford.

Harry's delivery

5.100 Sarah had an uneventful pregnancy and was considered at low risk. She attended hospital two days before her due date when her contractions started but, following an examination, she was told that she could go home. She returned to the hospital later that evening as her contractions were becoming more painful, and she was admitted to the MLU at QEQM.

5.101 The following morning, 1 November, Sarah was moved to the labour ward for assessment due to lack of progress in labour. She was seen by a registrar, but she did not see a consultant obstetrician while on the labour ward. The CTG, which records fetal heartbeat and contractions, showed decelerations of the baby's heart rate and very frequent contractions suggestive of hyperstimulation of the uterus with Syntocinon, used to accelerate labour. A disagreement took place between the registrar and midwives – in front of Sarah and her family – regarding the appropriate rate of administration of Syntocinon for Sarah.

5.102 Sarah's care was handed over to a locum registrar who commenced a shift at 8pm on 1 November. Sometime around 2.15am, the locum registrar called the on-call consultant to report on Sarah's case – the cervix was fully dilated just before midnight, and she had started pushing just after 1am. The registrar's intention was to bring Sarah to theatre to attempt instrumental delivery for failure to progress and an atypical CTG. The consultant had not met or examined Sarah and was at home as usual when on call. The consultant said that they had offered to come into the hospital, but the registrar declined; it should be noted, however, that a registrar is not in a position to accept or decline a consultant's decision. The registrar was on their third night of providing locum cover at QEQM. The consultant had not worked with or supervised them previously.

5.103 Sarah was taken to theatre at about 3am, and the registrar attempted a forceps delivery, but was unable to lock the forceps blades. Sarah had signed a consent form for a caesarean section, and the locum registrar proceeded to a caesarean section. Up until this point, the atmosphere in theatre was *"not calm but being managed"*. The Panel heard that the tension in the room increased, and the atmosphere became panicked and uncomfortable. A more junior trainee doctor was instructed by the registrar to increase the size of the incision in Sarah's uterus but, having never done this before, they were not confident in doing so. The midwife who had been with Sarah since 8.30 the previous evening was instructed to push Harry's head back up the birth canal, something they had done only twice in their midwifery career.

5.104 Harry was delivered at 3.32am. The Panel heard that the scene in theatre was chaotic and had descended into people shouting at each other. At one stage there were between 20 and 25 people in theatre, but the consultant obstetrician was not yet in attendance. Harry was taken immediately to be resuscitated. The paediatric registrar who attended Harry was a relatively junior doctor and was unable to secure an airway. Harry's father, Tom, was escorted out of theatre, and Sarah asked to be anaesthetised, rather than stay conscious (*"I would rather not be in that room ... because I didn't feel safe"*). There was considerable delay in resuscitating Harry and intubation was not achieved for 28 minutes, when the anaesthetist, after administering a general anaesthetic to Sarah, left her side to assist with the resuscitation. The anaesthetist successfully intubated Harry and he was taken to the SCBU for cooling treatment.

The days following Harry's birth

5.105 The consultant obstetrician and the consultant paediatrician on call both spoke to the family after the delivery and told them that Harry was very unwell, and it was likely that he would have cerebral palsy. The consultant obstetrician assured the family that there was going

to be an investigation and told them that they were unhappy with what had happened. The consultant paediatrician told the family that they had looked at the team who had carried out the resuscitation and they had followed protocol. The family recall being told that the paediatric team *“did everything they could”*.

5.106 Harry was transferred by specialist ambulance to the NICU at WHH. Sarah and Tom followed later that day. They told the Panel that the week that followed was the worst of their lives. It was unclear whether Harry would survive, and he had seizures over the days that followed. Following an MRI scan showing the extent of damage caused to Harry’s brain, Harry died seven days later on 9 November 2017, being held in his parents’ arms for the first time since his birth. The cause of death was recorded as HIE.

Investigations following Harry’s death

5.107 The weeks, months and years that followed Harry’s death involved sustained efforts by his family to seek understanding and truth about what happened during his delivery.

5.108 Harry’s death was recorded as a serious incident, and the Trust conducted an RCA. The family had a number of queries which they addressed to the Trust following Harry’s death, and they believed that the RCA report would answer all their questions. When, after some delays, the report was made available to the family on 8 March 2018, it raised more questions for them than it answered.

5.109 The Panel heard that the RCA was complex, and more and more issues emerged which required resolution. The magnitude of the investigation was not appreciated by the Trust at the outset, and extensions to the deadline were required.

5.110 The RCA identified problems relating to Sarah’s and Harry’s care which echoed issues highlighted in the Trust’s internal neonatal admissions review in 2010 and the RCOG report in 2016. These included:

- Delay in diagnosing the onset of labour
- Failure to escalate issues to the obstetric team
- Disagreement and communication issues among midwifery and medical staff
- Escalation issues to obstetric consultant and paediatric consultant
- Incorrect CTG interpretation and classification
- Locum registrar on their third night at the Trust whose level of competency had not been assessed
- Difficulties in resuscitation
- Lack of consultant presence in theatre.

5.111 The sense from the family was that the RCA investigation and report were inadequate and did not tell the full truth about what happened to Harry or to Sarah. The family identified a number of errors within the RCA report, such as the level of qualification of the locum registrar, a statement that resuscitation had been carried out in accordance with national guidance, and the complete absence of any critical comment about the lack of consultant attendance. The placenta was not sent for pathological examination as it should have been, and it was acknowledged in the RCA report that it should have been sent for histology at delivery (*“especially when there is a poor and unexpected outcome at delivery of a baby”*).⁸ Notwithstanding this failing, the RCA included a comment that *“there is no suggestion that a detailed examination of the placenta would have provided any extra information”*.⁹

5.112 A meeting took place a few days later, on 14 March, between the family and the Trust to discuss the RCA's findings. This meeting appears to have been challenging for all involved (it was described to the Investigation by one member of staff as “a complete car crash” for the Trust). The meeting room furniture was disorganised, requiring the family to rearrange it when they arrived; one of the consultants arrived ten minutes late; and another consultant had to be called to attend from Ashford. There were disagreements among the clinicians within the meeting, and inaccuracies and inconsistencies in the report emerged throughout the meeting (for example, whether there were problems relating to CTGs within the unit). The family's impression was that they were treated poorly by the Trust, spoken to like children, and dismissed when they raised concerns.

5.113 A critical issue for the family was the Trust's failure to refer Harry's death to the coroner, a concern which was raised by Tom Richford shortly after Harry died. The RCA report addresses this question as follows:

The coroner was not informed as the cause of death was known to be hypoxia and death occurred later than 24 hours from birth. There was a clear sentinel event coupled with difficulty in resuscitation, this fits clearly with HIE. Again coupled with the MRI findings and the MRI report, there was no uncertainty with regards to causation and the death certificate.¹⁰

It should be clear that this is a wholly inadequate reason to evade referral to the coroner, when both mother and baby had been healthy at the onset of labour.

5.114 During the RCA meeting on 14 March 2018, the family raised their concerns again, and were told that Harry's case did not need to be reported to the coroner because the Trust knew the cause of death was HIE and death was, therefore, considered “expected” because he had been admitted to hospital with severe HIE. The family's natural concern was that the reason for the HIE, and the circumstances that caused it, were not fully understood and required close examination by a coroner. Indeed, the Trust's own internal documents following Harry's delivery identified the outcome as “unexpected”; however, his death was recorded on the death certificate as “expected”.

5.115 It was only following lengthy discussion at the RCA meeting, during which the Trust representatives finally accepted that Harry's death had been avoidable, that the Trust agreed to speak to the coroner. This action was noted within the RCA report as a recommendation, but it nevertheless took over five weeks, and much contact and follow-up from the family, before the case was referred.

5.116 This practice of delay and avoiding external scrutiny presented itself again in connection with the Trust's obligation to notify NHS Resolution (NHSR) about Harry's death. Under the early notification scheme, the Trust was required to notify NHSR of the death within 30 days. Following enquiries by the Richford family in 2019, it transpired that the notification was only sent to NHSR on 22 March 2018, one week after the RCA meeting with the family and 123 days after Harry had died.

5.117 In June and July 2018, the Trust commissioned independent medical reports into the care received by Sarah Richford and the neonatal resuscitation of Harry Richford. Both reports were critical of the treatment provided by the Trust, yet neither report was shared with NHSE or NHSI at the time. Derek Richford, one of Harry's grandfathers, made a complaint to NHSI in December 2018, raising concerns that the Trust was not learning from incidents. The response from the Medical Director was that lessons had been learned by the Trust, and that on receipt

of the report from the Healthcare Safety Investigation Branch (HSIB), which was due in January 2019, the Trust would put in place a further action plan.

5.118 HSIB is an organisation which acts independently to investigate incidents and develop recommendations to improve patient safety. The Richford family had referred Harry's case to HSIB in April 2018. When HSIB published its report into the care received by Harry and Sarah in January 2019, its findings included:

- The lack of review by a consultant obstetrician during labour
- The use of a CTG interpretation method that was not recommended by the National Institute for Health and Care Excellence
- A failure to meet the requirements of Trust guidance
- Use of a locum registrar without assessing competence or providing appropriate supervision
- The failure of the consultant obstetrician to be present in theatre in accordance with RCOG guidelines and Trust guidelines
- The failure to send the placenta for pathological examination in accordance with Trust policy
- Communication failings between consultants and registrars
- Issues around resuscitation.

5.119 The Richford family also contacted the CQC regarding Harry's case. The CQC's initial assessment was that the issues related to one doctor who had made a mistake, but there were no systemic issues to investigate. Again through the persistence of the Richford family, the issue was escalated to the CQC's Chief Inspector of Hospitals, and in October 2020 the CQC announced that it was prosecuting the Trust in connection with the care provided to Harry and Sarah Richford. In March 2021, the Trust pleaded guilty to an offence of failing to provide safe care and treatment, resulting in avoidable harm to Harry and Sarah. The Trust was fined £761,170.

5.120 Overall, the Richford family felt that the information they received from the Trust was not always truthful, and they had to press and fight to be provided with the information they were looking for about what had happened to Harry. An example relates to the incorrect information submitted by the Trust to Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK), which produces annual perinatal mortality surveillance reports. The MBRRACE-UK form for Harry dated February 2019 confirmed (among other inaccuracies) that the placenta had been sent for histology, that the case had been discussed with a coroner (although this was only done following pressure from the family) and that there was a final, agreed cause of death following the results of the inquest and all investigations. This was incorrect as the inquest did not take place until the following year.

The inquest

5.121 The inquest into the death of Harry Richford was held over three weeks in January 2020 before an assistant coroner. In their conclusion, the coroner found that "*Harry Richford's death was contributed to by neglect*". The coroner's report identified the following failures in Harry's care:

- *Harry was hyperstimulated by an excessive use of Syntocinon over a period of approximately ten hours.[‡]*
- *The CTG reading became pathological by 2am and Harry should have been delivered within 30 minutes, not 92 minutes later.*
- *The delivery itself was a difficult one. It should have been carried out by the consultant who should have attended considerably earlier than [they] did.*
- *The locum on duty that night was relatively inexperienced. [They] were not properly assessed, if at all and should not have been put in the position of being in charge unsupervised.*
- *There was a failure to secure an airway and achieve effective ventilation during the resuscitation attempts after birth leading to a prolonged period of postnatal hypoxia. The resuscitation afforded to Harry Richford failed to be of an appropriate standard.*
- *There was a failure in not requesting consultant [paediatrician] support earlier enough during the resuscitation attempts.*
- *There was a failure to keep proper account of the time elapsing during the resuscitation attempts with the result that control was lost.*

5.122 The coroner also issued a regulation 28 report – a report requiring action to prevent future deaths. This detailed 19 concerns identified during the inquest and the coroner’s recommendations as to how they could be addressed to prevent future deaths. The recommendations included:

- Action to ensure proper review and assessment of locums and a reminder that it is the supervising consultant’s responsibility to ensure the locum under their supervision is competent and experienced
- A review of Trust processes to ensure clarity around the actions required in the event of an obstetric concern or emergency developing
- A review of procedures to ensure staff understand the circumstances where consultant attendance is required
- Training and learning, including simulation training, covering neonatal resuscitation
- Cross-site paediatric working between QEQM and WHH
- Addressing confusion among staff regarding the guidelines and policies that apply to them, by reviewing staff awareness of governing clinical and operational guidance
- An audit of the quality of record keeping and documentation, as the record keeping on the obstetric unit was substantially substandard
- A review of Trust policies to ensure that the outcomes of independent reports are shared with Trust staff so that important learning takes place to prevent any future deaths.

The Trust’s response

5.123 The Investigation was told that Harry’s death “*caught the Executive off-guard*”. It was not raised in any detail with the Trust Board until late 2019, months before the inquest began and almost two years after Harry died. This was a significant failure of governance.

5.124 It was only in the aftermath of the coroner’s findings and the regulation 28 report that the Trust took meaningful action in response to the failings identified in the Richford case. The Trust

[‡] This was the terminology used, although it should be noted that the hyperstimulation is of the uterus not the baby, leading to hypoxia of the baby.

established a Learning and Review Committee (LRC) with separate workstreams to look at the myriad issues emerging from the Harry Richford inquest, as well as previous investigations such as the RCOG report, the Richford RCA and the HSIB report. The LRC reported to the Board on its implementation of recommendations and actions, and all actions were completed by June 2020, when the LRC became the Maternity Improvement Committee.

Subsequent internal and external scrutiny

5.125 At a QSG meeting on 13 December 2017, the CCG Governing Body's Integrated Quality and Performance Report reported that concerns about maternity safety at the Trust in relation to reporting and escalating incidents had been escalated to the Maternity Performance meeting. The Trust had confirmed that it was providing training and support for staff to change the reporting culture. The Trust had also reported a Never Event within maternity services. This related to an obstetric registrar stitching a vaginal tear using a vaginal tampon, which was then unintentionally left in place after the procedure.

5.126 On 8 December 2017, the Board reported that, to celebrate the BESTT Maternity Transformation Programme, the Chair of the Maternity National Transformation Board had visited the Trust to discuss its transformation work and achievements. The Board recognised the significant progress made by the maternity team as part of BESTT. It noted key achievements so far: 100% of staff had signed up to attend essential life support in obstetrics training; the number of quality assured trainers had increased from 9 in 2016 to 76; and £33,000 had been put towards ultrasound training so that every woman could have a 36-week scan.

5.127 The 6 April 2018 Trust Board meeting discussed an item called "Patient Experience Story". The Chief Nurse asked the Board to note that the learning from this experience had resulted in improvements in teamwork and communication. The patient reported a good experience during the birth of her daughter, but she had become unwell afterwards due to a retained placenta and postpartum haemorrhage. The patient observed a lack of communication between the team and herself. There was no leadership in the room and no clear decision making around the bed, with the main issue not being addressed quickly enough. The patient highlighted that her bed covered in her blood being wheeled into the room had been traumatic for her husband.

5.128 The Trust Chair noted that the story was of a classic postpartum haemorrhage that had been poorly managed. It had changed the way the team shared, learned and addressed mistakes. The learning from the case was that the patient had not felt safe, because the staff were not working together or communicating. It was important for the team to be aware of the finer details. The Head of Midwifery noted that "Human Factors" training (training in human interactions, such as communication and teamwork) was bringing together a cohesive and holistic training approach.

5.129 The BESTT Maternity Transformation Programme had started in 2017 and had brought about a cultural shift, which the Head of Midwifery hoped would continue as more simulation training took place. One of the non-executive directors asked whether any competency issues were being addressed with staff. The Head of Midwifery noted that individual competency elements were included in the action plan, as well as whole team learning.

5.130 The Trust Chair highlighted that the patient's story had shown clearly that the clinical team had not worked well together. The Medical Director noted that perinatal blood loss was a key

measure in the National Maternity and Perinatal Audit, and it was an area on which the Trust now performed particularly well.

5.131 At the Board meeting on 10 August, it was reported that the MBRRACE-UK report on perinatal mortality indicated that the Trust's stillbirth and neonatal mortality rate was above the national average. Investigation had revealed that most of this local variation related to congenital non-survivable conditions.

5.132 In August 2018, the QSG report stated that, following nine serious incidents being reported in the maternity service, the CCG did not have assurance regarding the safety and quality of maternity services at the Trust.

5.133 On 6 September, the Board reported that the CQC had identified maternity as "Requires Improvement". The Closed Board meeting noted that an improvement in maternity services had been recognised at WHH due to the transformational work that had taken place.

5.134 On 4 December 2018, Derek Richford submitted a complaint to the NHSI National Medical Director stating that the Trust was not learning from incidents. NHSI contacted the Trust's Medical Director, who reported that, following the RCA, two independent reviews had been undertaken, by an obstetrician from the Maidstone and Tunbridge Wells Trust and by a paediatrician from the Dartford and Gravesham Trust. They stated that lessons had been learned by the Trust and changes had been made to practice. The HSIB report was due in January 2019 and would contain an assessment, conclusion and recommendations regarding the standard of care received by Sarah and Harry Richford. Following this, the Trust would put in place an action plan. The Trust reported to NHSI that they had told the CCG of this. However, the CCG reported that they only became aware when they declined closure of the RCA due to a number of queries.

5.135 At the Closed Board meeting on 6 December, it was reported that, further to an outbreak of pseudomonas infection in the NICU, no new cases had been reported but the incident remained open until the origin of the infection had been identified. Further to two maternal deaths, the Medical Director explained that there would be a meeting with HSIB in the coming week to compare the Trust's investigation with the HSIB investigation.

5.136 In February 2019, NHSI received an email from the Trust's Quality Improvement Director highlighting current key quality concerns. Maternity was not highlighted as a concern. In March, the CCG reported that maternity services were improving under the new leadership model. However, in May 2019, a letter sent to the Accountable Officer for East Kent CCGs by the NHS England and Improvement (NHSE&I) Director of Commissioning Operations following a formal assurance meeting stated:

There remain some significant and persistent quality failures at EKHUFT, which whilst raised appropriately by the CCGs, you have not managed to get action to achieve sustained improvements in the provider. The performance indicators are poor across EKHUFT across a range of areas including; Cancer Waits, Delayed Cancer Diagnosis, Maternity Services, Mixed Sex Accommodation, Never Events and A&E. The CCG will need to ensure that it is taking clear oversight and leadership in these areas.

5.137 The Divisional Director for Women's and Children's Services returned to this theme at the Closed Board meeting on 4 July 2019. They confirmed that, following their report at the last meeting, they would be reviewing all the current referrals to the NMC, currently a total of ten.

5.138 The Chief Executive commented that, following the discussion at the Board meeting held that morning regarding staff who were under investigation, it was critical the Trust remained resilient as an organisation in supporting those staff and ensuring that the process was undertaken and completed promptly. The Trust needed to be robust in working with external agencies to ensure cases were investigated and closed as promptly as possible.

5.139 On 13 August 2019, the CEO of HSIB wrote to the CQC to say that HSIB had ongoing concerns around clinical safety for mothers and babies in the Trust and the Trust's response to these concerns, which they felt the CQC needed to be aware of.

5.140 On 27 August 2019, NHSE&I wrote to the Trust asking for an update on *"The impact of planned changes to improve labour ward senior medical cover"*. The Chief Nurse responded on 9 September that the Trust was considering extended consultant presence on the labour ward and a second registrar on shift. It was also reviewing guidelines on consultant out of hours cover or presence, and was sharing guidelines from neighbouring trusts for the clinical team to consider, which included examples of rotas.

5.141 The CQC wrote to the Trust on 1 October 2019 stating that it was opening a criminal investigation. The Regional NHSE&I Director referred to the letter as *"pretty unusual"*. In the same month, in a quality report to the NHSE&I Executive Quality Group, HSIB expressed concerns about senior medical cover on the Trust's labour wards.

5.142 At the Closed Board meeting on 10 October 2019, the Chief Nurse noted the current position with regard to the NMC and the 12 open cases for Trust staff, only two of whom remained employed with the Trust. There were five additional cases where the Trust was in liaison with the NMC.

5.143 HSIB returned to its concerns on 12 November, when it reported that the Trust was an outlier for referrals. It raised specific concerns about senior out of hours obstetric cover for the labour wards, escalation and CTG interpretation.

5.144 This culminated in a round-table discussion on 28 November 2019 about the Trust, where it was noted that there continued to be significant concerns with the lack of evidence that the Trust was learning from incidents in order to improve care. Following this, a report was commissioned by the Clinical Regional Quality Manager at NHSE&I. This was completed on 3 December 2019 and, in its introduction, the report said there was concern that there might be a risk to patient safety because the Trust's maternity services had not provided evidence that they were learning from serious incidents. It said that this related to a number of cases investigated by HSIB.

5.145 On 28 November, the Secretary of State for Health's Private Office contacted a Director in the Department of Health and Social Care (DHSC), to report that the Secretary of State:

... has asked about an operational incident at a maternity ward at William Harvey hospital in East Kent and whether we have any background. I'm afraid I don't have any further information but if this rings any bells and you are able to provide a factual briefing to share with the SoS I would be most grateful. We also have the option of putting this on the operational Quad agenda if you think it would be worth raising with Simon Stevens.

A colleague of the Director replied to say that DHSC was unaware of the incident.

5.146 On 29 November, the Private Office official shared a briefing from NHSE&I on the issue. They said:

[T]he SE region have taken the decision this week (Thursday 28 Nov) to convene a single-item QSG looking at maternity services at East Kent University Hospitals. This is because they were made aware by the HSIB that the trust's referral rate of cases for investigation was notably higher per 1000 births than the national average.

5.147 NHSE&I also referred to other actions that had been taken. First, HSIB had written to the CQC expressing its concern, which was the first time it had taken this step. In line with the general trend observed at the Trust, HSIB had referenced a specific death in November 2017, which would be subject to an inquest in January 2020. Second, the NHSE&I regional nursing team had led an intelligence-sharing call with system partners (HSIB, the CQC, NHSR and the CCG) to discuss their respective experiences and concerns, which informed the decision to refer the Trust to the QSG. The DHSC Director responded that “NHS should do QSG asap”, and this was relayed by the Private Office to the Secretary of State, who asked whether the QSG meeting was private. A member of the DHSC Director's team responded on 2 December: “The guidance is clear that the QSG meeting should be conducted in an environment of confidentiality and trust, where members feel able to speak frankly and openly about concerns.” They later confirmed that the meeting had taken place on 10 December.

5.148 On 7 December 2019, the Trust's Chief Executive wrote to the Director of Nursing Professional and System Development at NHSE&I:

Having so many regulators involved is difficult re coordination and perspective. Particularly HSIB who as a new organisation (and not a regulator as such) are confusing regarding their role. They also work more slowly as they are building their staffing and competence. In similar circumstances in the past, one of the regulators taking the lead, setting the tone and coordinating the information requests, has been helpful. (NHSR have also been involved in this one too). I think with Shrewsbury going on and the tragic case of the Richford family, one of who is making contact with all regulators, MPs, the press etc, it would be easy for this current set of concerns, to be inappropriately calibrated. East Kent has recent history of a negative kind, of that there is no doubt. It is after all why I ended up here in the first place. However, I can see that the improvement programme is biting and the new leadership, particularly since [the new Head of Midwifery] arrived, has been having a great effect in maternity. The consultant leadership has also been changed too.

5.149 On 12 December 2019, for the “Patient Story” item at the Board meeting, the Chief Nurse introduced Mrs X, who presented her daughter's experience in maternity services. Her daughter had been admitted for a planned induction and had also been diagnosed with pre-eclampsia, but did not receive the level of attention or pain relief she needed. Staff on the ward did not seem to have considered her additional needs and support requirements.

5.150 Mrs X stated that she had contacted the Maternity Matron to raise her concerns. The Maternity Matron had taken the time to listen to what she had to say. The Chief Nurse presented feedback to the ward staff in relation to lessons to be learned from this case, while keeping the patient and her family updated on the actions put in place. Mrs X emphasised the importance of staff considering the patient's perspective and taking into account any pre-existing mental health conditions when delivering care. The Chief Nurse also highlighted that it was vital that staff listened to patients, and drew attention to the importance of having robust handover procedures in place. Patients should have positive experiences while in hospital, and the Chief Nurse was always visible on the wards to allow poor experiences to be raised with them directly.

5.151 In December 2019, the Medical Director presented a report to the Closed Board meeting to inform the Board, following concerns raised by regulators, about trends in perinatal mortality,

external scrutiny and the actions being taken to mitigate risks to patient safety. Key specific issues included CTG interpretation, medical staffing cover and escalation. The Medical Director reported that actions to address these issues included adoption and rollout of physiology-based CTG interpretation, identification of gaps in medical staff cover and actions to address these, identification of additional support requirements, and provision of daily labour ward safety huddles during the day and out of hours.

5.152 The Medical Director referred to the RCOG report, which they said had resulted in the Trust adopting the BESTT improvement and transformation programme. The Chief Executive commented that it would be beneficial to review the BESTT programme and whether it had too large a focus and needed to be revised, defining a few specific key areas going forward. The Chief Executive emphasised the need to increase consultant presence on the labour wards, with a minimum requirement to recruit an additional two consultants. There was also a requirement for additional middle grade clinical support. This would, it was claimed, provide additional support for the oversight of locums.

5.153 On 17 December 2019, the Regional Chief Nurse of NHSE&I wrote to the Trust's Chief Executive, the Medical Director and the Head of Midwifery to follow up the "Single Item" QSG meeting on 10 December. The meeting acknowledged good progress made by the Trust on maternity services but outlined the following areas of concern: medical staffing, leadership, management of care, and learning from a recent coroner's case. NHSE&I listed the support it would like to offer.

5.154 An Extraordinary Trust Board meeting took place on 30 January 2020, with the single agenda item of maternity. The Trust has told us that it can locate no notes of this meeting, and that it was an informal meeting held to consider and discuss the next steps following the inquest into Harry Richford's death and to consider the setting up of an oversight group, with an external Chair reporting to the Board. This oversight group was subsequently established as the Trust's LRC.

5.155 The Board met again on 13 February 2020. The Chair reported that the format of this Board meeting would be amended, as the Board recognised and understood that recent media reports on the Trust's maternity services would have raised concerns with East Kent families who were either currently expecting a baby or who had been under the Trust's maternity care in the past. Acknowledging the importance of this issue, half of the Board meeting would be allocated to discussion and questions regarding maternity services. The Chair explained that the Chief Executive and Medical Director would present their respective reports, and time would be allocated to allow them to receive questions from members of the public. The remaining half of the Board meeting would be used to discuss the other agenda items.

5.156 The Chair extended apologies on behalf of the Board and the Trust to the family of baby Harry Richford for his tragic death and for their heartbreak. Recognising that the Trust had not always provided the right standard of care for every woman and baby in its hospitals, the Trust extended apologies wholeheartedly to those families for whom it could have done things differently. The Chair provided assurance that the Trust had made significant changes to its maternity services in recent years to improve the care of women and their families. The Trust would continue to work to improve its services, ensuring the provision of a high standard of care. It was working with the NHS Maternity Safety Support Programme, which was providing support to the Trust to make rapid and sustainable improvements to its services.

5.157 In the item "Chief Executive's Report", the Chief Executive expressed heartfelt condolences on behalf of the Trust, themselves and their colleagues to the family of Harry

Richford and to every family that had not received the level of maternity care they deserved. The Chief Executive acknowledged that any death, and particularly that of a baby, was tragic and touched everyone. They assured the public and the Board of the Trust's commitment to listening to feedback from patients and their families regarding any poor care received and their suggestions for improvement. As well as taking into consideration recommendations regarding areas of suggested improvements, the Chief Executive acknowledged the work required with regard to improving the Trust's culture and listening to patients and their families. They would be extending an invitation to the families who had lost a baby to meet them.

5.158 The Chief Executive reported serious concerns raised in 2014 about inadequate staffing, poor teamwork and inadequate equipment in the Trust's maternity services. This had resulted in the Trust being put into Quality Special Measures. They stated that, since they had been in post as the Trust's Chief Executive, a new maternity senior team had been introduced, with the appointment of a Head of Midwifery and a new leadership team. These changes had resulted in successful improvements to maternity services, as detailed in the Chief Executive's report. The Trust was recruiting six additional consultants as well as middle grade doctors to support the consultants and senior clinicians already in place.

5.159 The Chief Executive confirmed that the CQC was continuing to monitor and review the Trust's maternity services. The Trust was working closely with NHSE&I to support these ongoing reviews. The Trust was also working closely with HSIB, with quarterly meetings taking place.

5.160 The Chief Executive stated that an internal review had been put in place. Its aim was to review and confirm the steps implemented to ensure that the Trust moved in the right direction to achieve the necessary improvements in providing excellent standards of care to every mother and baby who used its services.

5.161 The Medical Director reported that they would be working with external support and would be reviewing all perinatal deaths to identify those that were preventable. The Chief Executive commented that the Trust's staff wished to be associated with a "Trust of excellence", and that all staff were focused and energetic in supporting this improvement programme and would not rest until the Trust, the public and regulators were confident that an excellent standard of care was being provided. The Panel was surprised that the Trust had not been doing all of this before, given how long it had been since very similar problems were first identified.

5.162 The Medical Director highlighted areas of improvement, which included medical engagement, incident reporting, availability and presence of consultants on the labour wards and escalation. They reported the actions recommended by the family at the inquest into the tragic death of Harry Richford and indicated that there had not been sustained and embedded learning within maternity services. The Trust recognised the importance of embedding learning and the need to make changes. The Medical Director also stated that the independent HSIB review of the Trust's maternity incidents reflected themes evident nationally.

5.163 Quarterly meetings were being held with HSIB and key recommendations included medical staff engagement, which, according to the Medical Director, had significantly improved. Other key elements included escalation and communication between staff and the two sites. The Medical Director confirmed that the coroner's conclusion had been received; this included 19 recommendations, of which 2 were national recommendations. The Richford family had also submitted 42 recommendations for the coroner to consider, covering six broad areas as detailed in the coroner's report. They also submitted for consideration support for bereaved mothers with regard to accommodation, a dedicated support worker and counselling. The Medical Director highlighted the changes that had been implemented to date in addressing these

recommendations, and concluded by stating that a programme of improvement work had been put in place around learning and support in midwifery, paediatrics and obstetrics. This would be overseen by the internal overview panel, chaired by an external obstetrician.

5.164 At the Closed Board meeting on the same day, the Medical Director confirmed the completion of the review of all RCAs between 2012 and 2019 in relation to perinatal deaths and identification of any potential avoidable deaths. They reported that 11 deaths had been identified as preventable, with a further 4 potentially preventable. The Chief Executive confirmed that 25 cases had been referred to HSIB, including cases of baby deaths and babies who had recovered after receiving neonatal therapeutic cooling. The Medical Director reported that quarterly meetings continued to be held with HSIB and that update reports from these meetings would be presented to the Trust Quality Committee.

5.165 The Chief Executive confirmed that an independent review into East Kent maternity services would be undertaken by Dr Bill Kirkup. This would include a review of perinatal deaths to identify any potential avoidable deaths.

5.166 On 5 March 2020, East Kent maternity services were discussed at a Health Overview and Scrutiny Committee (HOSC) meeting. The Trust's Deputy CEO introduced the item by saying that the Trust had recognised in 2015 that the position in maternity services needed to improve and had commissioned the RCOG to undertake a review. A HOSC member asked why things had gone so wrong despite the RCOG review taking place in 2015. The Medical Director explained that themes from that review had been repeated in subsequent reports, which suggested that any changes made had failed to be embedded.

5.167 Asked how East Kent residents could be assured that the Trust's Board was adequately monitoring the implementation of best practice, when it had failed to do so in 2015, the Deputy CEO explained that, following the coroner's report, the Trust had established an externally chaired Board (a sub-committee of the main Board) which in turn had seven "task and finish groups", each with their own area of focus. The Chair of the new Board was independent, in order to provide external opinion as well as assurance. The seven workstreams were being overseen by clinicians, which the Trust felt demonstrated a real shift. The Deputy CEO also felt it was important that the Trust accepted the additional clinical support on offer. The Medical Director pointed out that each of those present at the meeting was an East Kent resident and therefore had a vested interest in making the services the best they could be. A consultant said that, as a relatively new employee of the Trust, they felt that the employer was recruiting people with different skillsets in order to build its workforce and that it was being open about the challenges it was facing.

5.168 A consultant acknowledged that there were lots of things to be done, and they were having to be prioritised. Examples of actions that had been, or were being, taken included:

- Remote fetal monitoring (where consultants could monitor a fetus from any location)
- Further investment in training and development for both technical and non-technical skills
- Implementing controls to ensure increased consultant presence on the wards
- Appointment of three specialist midwives (one specialising in the Better Births agenda and two in fetal wellbeing)
- A piece of work to scope out continuing care and what that meant for women and families in East Kent

- Out of hours safety huddles to ensure ward leads had a strategic view of the service at that time
- Investing in and expanding the Getting It Right First Time programme
- The Chief Nurse holding “floor to Board” meetings to gather intelligence and ensure staff felt listened to.

5.169 Meanwhile, the RCOG had offered earlier in the year to provide support to the Trust. This culminated in a site visit to the Trust from 11 to 13 March 2020. The proposed output from this was a service development action plan, a governance action plan and a workforce action plan.

5.170 The Trust Board met again on 12 March 2020, when it received a report from the LRC. The Chief Executive asserted that this provided the Board and the regulators with assurance around transparency and openness, given that the internal review was being externally chaired and led by an independent community representative. The Chair of the LRC reported that they had met with the individual workstream leads and were confident that actions were being taken seriously and implemented. They explained the aim of the LRC in relation to reviewing the Trust’s response to the internal review and whether it had implemented the recommendations from previous historical reports. The LRC would also assess whether the BESTT improvement programme addressed these past and current action plans. The LRC would identify the information needed to assure the Board that the Trust’s maternity and neonatal services were safe, well led and sustainable. It was noted that the actions in relation to how the Trust employed locums were not yet complete, but the LRC was assured that these were being taken forward and were being appropriately prioritised.

5.171 A non-executive director asked whether there was sufficient engagement, openness, determination and commitment from the Trust’s clinicians to support and embed the improvement programme. The Chair of the LRC assured the Board of this commitment from the workstream clinical leads, who were fully engaged and appreciative of being given protected time to undertake this work.

5.172 There was further activity in DHSC relating to the publication of an HSIB report, including briefing to ministers on 24 March. The briefing stated that *“the summary report was produced by HSIB at the request of DHSC. It is not a routine report that HSIB would produce or publish under their maternity investigation programme as maternity reports are only shared with the family and trust. The report has been shared with the Trust.”* The briefing continued:

We have reviewed the contents of the report and do not think there is anything contentious in it or that it highlights issues that have not already been addressed with the Trust that would prevent it from publication. CQC have shared its report with the Trust and the Trust have published the letter from CQC on their website therefore publication of this report, would be consistent with their approach. The terms of reference for the independent review commissioned by NHS England are in the process of being agreed and this report is not dependent on the outcome of the review.

5.173 However, in light of the Covid-19 pandemic, DHSC officials advised that publication should be delayed, as it *“may detract media and public scrutiny from the vital work the Trust is doing to respond to the pandemic”*.

5.174 Ministers were again briefed on 25 March, with a draft response to a Prevention of Future Deaths report from the coroner in relation to Harry Richford. The briefing advised that the ministers' response:

... highlights the NHSEI and RCOG work on guidelines in relation to locum doctors in maternity services. In addition, the suggested response acknowledges the work undertaken by regulators and other national bodies to scrutinise and support the safety of maternity services at the East Kent Trust; as well as the commissioning by NHSEI of the independent investigation of East Kent maternity services led by Dr Bill Kirkup.

Chapter 6: Areas for action

Introduction

6.1 Chapter 1 of this Report sets out the findings of the Panel’s Investigation of maternity services at East Kent Hospitals University NHS Foundation Trust (the Trust). It describes how those responsible for the provision of maternity services failed to ensure the safety of women and babies, leading to repeated suboptimal care and poor outcomes – in many cases disastrous. It highlights an unacceptable lack of compassion and kindness, impacting heavily on women and families both as part of their care and afterwards, when they sought answers to understand what had gone wrong. It delineates grossly flawed teamworking among and between midwifery and medical staff, and an organisational response characterised by internal and external denial with many missed opportunities to investigate and correct devastating failings.

6.2 Chapters 2 to 5 provide the evidence to support these findings, gathered through family listening sessions, reviews of clinical records and interviews with managers, staff and others. We have reviewed the emerging findings against a large body of documentation provided to us by organisations with an interest in the Trust during the period under scrutiny.

6.3 As indicated in Chapter 1, this chapter puts forward an approach that is different from the norm: in particular, we have not sought to identify multiple detailed recommendations. NHS trusts already have many recommendations and action plans resulting from previous initiatives and investigations, and we have no desire to add to their burden with further detailed recommendations that would inevitably repeat those made previously, or conflict with them, or both. We take those previous recommendations and the resulting policy initiatives as a given.

6.4 Instead, we identify four broad areas for action based firmly on our findings but with much wider applicability. None is susceptible to easy analysis or a “quick fix”, but we believe that they must be addressed, because the simple fact is that the traditional approach has not worked: supposedly one-off catastrophic failures have continued to happen, despite assurances that each would be the last. The approach here aims to identify the fundamental problems that underlie these recurrences, however difficult.

Key Action Area 1: Monitoring safe performance – finding signals among noise

The problem

6.5 There is a dearth of useful information on the outcome of maternity services. This may be a surprising statement, because plenty of data are certainly collected; however, a large majority are process measures of dubious significance, such as caesarean section rates. The minority that are related to outcomes are high level and conceal events susceptible to clinical intervention among a larger, unrelated group, such as perinatal mortality.

6.6 The unit-level information that is available tends to be presented in the form of “league tables”, based on rankings in some form. These merely serve to conceal the variation between different units, with no indication of whether one or more units at the top or bottom of the rankings are there because they are outliers, or merely through chance. If units are presented only as part of a group, such as the top or bottom ranked 5%, interpretation is even more problematic for an individual unit.

6.7 The Trust exemplifies all these difficulties. It has used high-level information inappropriately as reassurance, taking comfort from the grouping that at least there were other trusts in the same boat. At times, it has used this false reassurance as a bolster against the plethora of evidence from other sources that there were very significant problems in its maternity services.

The future

6.8 There are huge benefits to the effective monitoring of outcomes. Clinicians can see where there is scope to improve effectiveness and address problems of service safety, and evidence from other specialties shows that – perhaps after a little early reluctance – they embrace this enthusiastically, with demonstrable improvement in outcomes and patient safety. Trusts can identify warning signs and take action where necessary, before problems and behaviour become embedded and perhaps intractable. Regulators, including NHS England (NHSE) and the Care Quality Commission (CQC), can identify units that are outliers and investigate appropriately before a trust descends into catastrophic failure. All parties can have a conversation based on relevant shared information about safety performance, rather than what otherwise might become a stand-off based on prejudice and refutation.

6.9 There are two overall requirements. The first is the generation of measures that are meaningful (that is, related clearly and straightforwardly to outcomes); risk adjustable (that is, they take into account the complexity of work in a unit and its effect on outcomes); and available (that is, they can be garnered from among the array of data already routinely collected, as we have no desire to suggest any data returns additional to the large array currently required). They must also be timely.

6.10 The second requirement is that the measures are analysed and presented in a way that shows both the effects of the random variation inherent in all measures, and those occurrences and trends that are not attributable to random variation. The random variation is often referred to as “noise”, and the outlying event as the “signal”. There are sound, statistically based approaches to detecting the signal among the noise, and presenting this graphically to show not only the level of variation but also the significant trends and outliers in the form of statistical process control charts and funnel plots. Useful work on these techniques is already being carried out by NHSE, but it is important that this is extended to clinically relevant outcome measures.

6.11 Deriving valid measures that meet these requirements is a little more problematic in maternity care than in some specialties because pregnancy and childbirth are physiological in most cases, and poor outcomes are less common. Perhaps this has underlain the lack of progress so far. It is, however, perfectly possible to overcome these problems and generate a suite of outcome measures available for the use of clinicians, units, trusts, regulators and the public. We have resisted the temptation to describe this as a “toolkit” because it is not something optional from which to pick and choose: the approach must be national, and it must be mandatory.

Recommendation 1

The prompt establishment of a Task Force with appropriate membership to drive the introduction of valid maternity and neonatal outcome measures capable of differentiating signals among noise to display significant trends and outliers, for mandatory national use.

Key Action Area 2: Standards of clinical behaviour – technical care is not enough

The problem

6.12 Caring for patients in any setting requires not only technical skills but also kindness and compassion. This is no less true for mothers and babies in maternity care. Yet we heard many graphic accounts, from staff as well as families, that showed just how far from the required standards behaviour had fallen at the Trust. Previous experience has shown the danger in assuming that such serious lapses of such a distressing nature are restricted to one trust alone.

6.13 Failing to meet basic standards of clinical behaviour has obvious effects on colleagues and those receiving care. Unprofessional conduct is disrespectful to colleagues and endangers effective and safe working; it undermines the trust of women. Lack of compassion significantly affects the wellbeing of women, often leading to unnecessary long-term harm. When families are treated unkindly in the aftermath of a safety incident, as is often evident, it compounds and prolongs the harm caused by the event itself. Failure to listen directly affects patient safety, as we found repeatedly in the Trust's maternity services, because vital information is ignored.

6.14 Because compassion is such an integral part of belonging to any caring profession, it is particularly difficult to comprehend how such failures can come about. Whether or not traits of empathy and compassion form part of the selection or assessment of new entrants, the need to be professional and to listen will surely be emphasised as part of initial education and training. What we saw and heard was that it was when clinicians were exposed to the behaviour of senior colleagues that their standards began to slip. The influence of role models, those whose positions more junior staff would aspire to fill one day, can be significantly greater than classroom teaching. If those role models themselves display poor behaviours, the potential is there for a negative cycle of declining standards.

6.15 Once such a negative cycle is established, it can prove remarkably persistent because of another feature evident in the Trust's maternity services: normalisation. Behaviour that would otherwise be challenged becomes tolerated, because "that's the way we do things here". In this way, inexorably, patterns of unprofessional behaviour, lack of compassion and failure to listen become accepted and embedded, to an extent that is genuinely shocking when seen through fresh eyes.

6.16 When such problems are brought to light, perhaps through whistleblowing or external review, they remain difficult to correct. We saw this exemplified in the Trust in the form of the grievance which stopped the investigation of bullying and harassment by midwives in its tracks, and in the failure to address grossly unprofessional conduct on the part of some consultant obstetricians who were refusing to fulfil labour ward responsibilities including attending when on call.

6.17 The Trust is far from alone in finding great difficulty in addressing unprofessional consultant behaviour. Consultants have, or perceive themselves to have, considerable freedom to act on their own responsibility without taking direction from others. The majority, of course, use this freedom wisely in line with their senior and highly qualified status; but in the minority who act unprofessionally, it serves as a shield to deflect any attempt to correct aberrant behaviour. A trust or its medical director who attempts to intervene has few sanctions available other than dismissal, with the prospect of facing lengthy processes and a likely loss at an employment tribunal against a strong legal defence funded by a protection society. This is such an unequal battle that a consultant subject to challenge is often advised to resign and claim constructive dismissal.

6.18 This is not to deny that consultants have sometimes been victimised by trusts, or that their employment rights must be protected fairly; nor is this a question of clinical competence. But it remains the case that a stubborn, poorly behaved consultant can cause havoc in a clinical unit that imperils its performance, as well as the wellbeing of staff and patients over a prolonged period. This cannot be right.

The future

6.19 Compassionate care lies at the heart of clinical practice for all healthcare staff. If some are able to lose sight of that, then it needs to be re-established and re-emphasised. Every interaction with a patient, mother and family must be based on kindness and respect. This will not be achieved through well-meaning exhortation in classrooms or by professional leaders, but through the attitudes and daily behaviour of clinicians themselves, at every level but most particularly those in more senior positions who are role models for less experienced staff.

6.20 Professional behaviour and compassionate care must be embedded as part of continuous professional development, at all levels. It must not be something learned during the earlier academic stages of training, only to be forgotten later.

6.21 There is a need for all staff to acknowledge and accept the authority of those in clinical leadership roles. These are not sinecures to be done for a couple of years on a rotating basis: they are integral to the effective and safe functioning of services. While some clinicians accept this, it is clear that many do not. Those in clinical leadership roles need to have the skills and time to carry them out effectively.

6.22 Reasonable and proportionate sanctions are required for employers and professional regulators so that poor behaviour can be addressed before it becomes embedded and intractable. The existence of such sanctions would itself act as a deterrent to the defiant reactions to challenge exhibited by an unreasonable minority.

6.23 The importance of listening to patients must be re-established as a vital part of clinical practice. This will require it to be embedded not only in continuous professional development, but also in the academic components of early training. The rapid rise in technical and diagnostic possibilities understandably puts pressure on academic curricula, but this must not be to the detriment of skills such as listening.

Recommendation 2

- Those responsible for undergraduate, postgraduate and continuing clinical education be commissioned to report on how compassionate care can best be embedded into practice and sustained through lifelong learning.
- Relevant bodies, including Royal Colleges, professional regulators and employers, be commissioned to report on how the oversight and direction of clinicians can be improved, with nationally agreed standards of professional behaviour and appropriate sanctions for non-compliance.

Key Action Area 3: Flawed teamworking – pulling in different directions

The problem

6.24 Clinical care increasingly depends on effective teamworking by groups of different professionals who bring their own skills and experience to bear in coordination. Nowhere is this more important than in maternity and neonatal services, but nowhere has it proved more problematic. Where it works well, care can be outstanding, but in almost every failed maternity service to date, flawed teamworking has been a significant finding, often at the heart of the problems.

6.25 Maternity services at the Trust were no exception. The Panel found that there was dysfunctional teamworking both within and across professional groups. The lack of trust and respect between midwives and obstetric staff, and between paediatric and obstetric staff, posed a significant threat to the safety of mothers and their babies. We found many examples of how this caused conflict, made staff feel vulnerable, prevented information from being shared, and encouraged complacency and a lack of accountability. After a safety incident, the most common response was to find somebody to blame for it – often the most junior midwife or doctor involved – preventing important lessons from being learned. The consequences for mothers and their babies were stark.

6.26 There is one feature of flawed teamworking that is particularly striking in maternity care: the divergence of objectives of different groups. A team that lacks a common purpose will struggle, working in an environment of competing interests which may rapidly descend into conflict, inappropriate hierarchies and power plays. It is evident that there was a struggle for “ownership” of maternity care in the Trust, and it is clear that this also applies elsewhere. Rather than contributing as equal partners, midwives may be encouraged to see themselves as being “there for women”, defending them from the “medicalisation” of maternity care. This polarisation of approach and objectives cannot help but put them in conflict with obstetricians.

6.27 In this context, the language used around “normal birth” may have significant unintended consequences, raising expectations among women and maternity staff that this is an ideal to be aspired to by all. But it is far from ideal for all, and promoting it unselectively can leave women feeling unfairly that they have failed in some way; in some cases it can expose them to additional risk.

6.28 Poor morale among obstetric trainees is a common feature and contributed significantly to the problems in the Trust’s maternity services. Trainees felt pressurised, unsupported and

obliged to carry out clinical tasks they were not ready for; unsurprisingly, there were recruitment difficulties and overuse of locum doctors who were not always properly assessed. Necessary changes to doctors' hours and training have had unintended consequences, including fragmenting care and increasing handovers. They have also removed the "firm" system previously in widespread use, which saw teams of staff with one or several consultants who would work together both in routine practice and while providing on-call services, offering support and increasing knowledge of capabilities and ways of working.

The future

6.29 We need to find a stronger basis for teamworking in maternity and neonatal services, based on an integrated service and workforce with common goals, and a shared understanding of the individual and unique contribution of each team member in achieving them. Crucially, this must be based on an explicit understanding of the contribution of different care pathways and when and how they are best offered. National guidance on this must be the same for all staff involved, and not suggest that there are different objectives for obstetricians and midwives.

6.30 Teams who train together work better together. The most frequent claim of joint training is that it is used in emergency drill training. This is very valuable, but it is not enough. There are opportunities at every stage of training – from undergraduate education onwards – not only to increase understanding of others' roles and responsibilities, but also to become used to working with other disciplines and the contributions they make.

6.31 We need to re-evaluate the changed patterns of working and training for junior doctors, and in particular how the unintended consequences of fragmentation of work and lack of support can be avoided or mitigated.

Recommendation 3

- **Relevant bodies, including the Royal College of Obstetricians and Gynaecologists, the Royal College of Midwives and the Royal College of Paediatrics and Child Health, be charged with reporting on how teamworking in maternity and neonatal care can be improved, with particular reference to establishing common purpose, objectives and training from the outset.**
- **Relevant bodies, including Health Education England, Royal Colleges and employers, be commissioned to report on the employment and training of junior doctors to improve support, teamworking and development.**

Key Action Area 4: Organisational behaviour – looking good while doing badly

The problem

6.32 The default response of almost every organisation subject to public scrutiny or criticism is to think first of managing its reputation, as is evident from a great many instances within the NHS and much more widely. Many risk registers will identify reputational damage in several contexts as something to be mitigated. If this were only a single part of a more complete response that was based on identifying failure and learning from it then it might be considered reasonable. But repeated experience says that it is not.

6.33 On the contrary, the experience of many NHS organisational failures shows that it is the whole basis of the response in many cases. Further, it has clearly led to denial, deflection, concealment and aggressive responses to challenge, in the Trust as elsewhere. Not only does this prevent learning and improvement, it is no way to treat families, who are heartlessly denied the truth about what has happened when something has obviously gone wrong, compounding the harm that they have already suffered. Refusal of scrutiny may extend to the manipulation of information for the CQC, and misrepresenting deaths (for example, as “expected”) to avoid inquests.

6.34 In the case of NHSE, there is a particular issue evident when a trust is in difficulties with clinical services: naturally, NHSE wishes to take decisive action and to be seen to do so, but its scope for intervention is limited when problems relate to clinical dysfunction. One of the few levers available is the replacement of chief executives and chairs, and we have seen evidence of a pattern of reaching for this lever repeatedly, with questionable consequences. Of course, there are questions of accountability for failing to act, as we have pointed out, and perhaps of competence; however, much more often it seems that neither is the reason, as individuals were simply moved to equivalent posts elsewhere. The only reasonable conclusion is that NHSE is espousing the idea that a fresh face, or faces, will solve the problems that others could not, described to us as the “heroic leadership” model.

6.35 There are two consequences evident. First, any steps towards recovery will be halted, as staff have to adapt to new ideas and new ways of working. Second, the incentive to be less than frank about emerging problems is intensified, as individuals naturally prefer stability, and having choice over their circumstances of departure.

The future

6.36 The balance of incentives for organisations needs to be changed. The need for openness, honesty, disclosure and learning must outweigh any perceived benefit of denial, deflection and concealment. The current small risk to an organisation does not match the risk of loss of public confidence in one of its vital services.

6.37 It seems that previous attempts to encourage organisations to change this behaviour by identifying the pernicious, damaging consequences for those harmed have not worked – even when taking into account the duty of candour in relation to individual clinical incidents, typically regarded as satisfied by a single conversation. It is time to introduce legislation to oblige public bodies and officials to make all of their dealings, with families and with official bodies, honest and open. This has previously been outlined in a Public Authority (Accountability) Bill, known colloquially as the “Hillsborough Law”.

6.38 When families experience harm, the response must be based on compassion and kindness as well as openness and honesty. Healthcare organisations have a lasting duty of care to those affected.

6.39 A review of the regulatory approach to failing organisations by NHSE would identify alternatives to the “heroic leadership” model, including the provision of support to trusts in difficulties and incentives for organisations to ask for help rather than conceal problems. The identification of problems should not be seen as a sign of individual or collective failure, but as a sign of readiness to learn.

Recommendation 4

- **The Government reconsider bringing forward a bill placing a duty on public bodies not to deny, deflect and conceal information from families and other bodies.**
- **Trusts be required to review their approach to reputation management and to ensuring there is proper representation of maternity care on their boards.**
- **NHSE reconsider its approach to poorly performing trusts, with particular reference to leadership.**

East Kent Hospitals University NHS Foundation Trust

6.40 For essentially the same reasons, we have not sought to set out a detailed list of things that the Trust must do – and the Trust has had numerous previous action plans that have not worked. Its problems are not susceptible to top-down point by point guidance: they are at once straightforward and deep-rooted. The new leadership of the Trust will read this Report and can see exactly what has gone wrong and what needs to be put right.

6.41 They are already aware that there are deep-seated and longstanding problems of organisational culture in their maternity units, and they can see spelled out in the words of families and their own staff the nature of the disgraceful behaviour and flawed teamworking that were previously left to fester. They will know what assistance they can commission from external bodies, including NHSE, and must receive full support. They must work in partnership with families who wish to contribute, and report publicly on their approach and its progress. We expect that staff will want to give their full engagement and cooperation, having seen the harm that resulted from previous behaviour that had become normalised.

6.42 The first step in the process of restoration is for all those concerned to accept the reality of what has happened. The time is past to look for missing commas in a mistaken attempt to deflect from findings. The damage caused to families is incalculable, and their courage in coming forward to ensure this came to light is exemplary, but it should not have been necessary. This must be acknowledged without further delay. Only then can the Trust embark on trying to make amends.

Recommendation 5

The Trust accept the reality of these findings; acknowledge in full the unnecessary harm that has been caused; and embark on a restorative process addressing the problems identified, in partnership with families, publicly and with external input.

Appendix A: Terms of Reference

Written Ministerial Statement

Written statement by Nadine Dorries, former Minister of State, Department of Health and Social Care, 11 March 2021

On the 13 February 2020 I confirmed in Parliament that, following concerns raised about the quality and outcomes of maternity and neonatal care, NHS England and NHS Improvement (NHSEI) have commissioned Dr Bill Kirkup CBE to undertake an independent review into maternity and neonatal services at East Kent Hospitals University NHS Foundation Trust (the Trust).

The Review will be known as the ‘Independent Investigation into East Kent Maternity Services’ (the Independent Investigation).

We take the patient safety concerns at East Kent maternity services very seriously. The Independent Investigation will provide an independent assessment of what has happened with East Kent Maternity and Neonatal Services and identify lessons and conclusions.

The Terms of Reference have been finalised now the views of the families affected have been taken into account and are published today on the Independent Investigation (Independent Investigation into East Kent Maternity Services: <https://iiekms.org.uk/>) and NHSE website (<https://www.england.nhs.uk/publication/independent-investigation-into-east-kent-maternity-services-terms-of-reference>). The Terms of Reference include the scope and arrangements that are to be put in place to support its functions and confirm the Independent Investigation will examine maternity and neonatal services in East Kent, in the period since 2009, when the Trust came into being, until 2020. The terms of reference include the scope and arrangements that are to be put in place and confirm the independent investigation will examine maternity and neonatal services in East Kent, in the period since 2009, when the Trust came into being, until 2020.

The Independent Investigation will draw conclusions as to the adequacy of the actions taken at the time by the Trust and the wider system and will produce a report to be disclosed first to the affected families and then to NHSEI as the commissioning organisation and then to the Department of Health and Social Care prior to publication.

The work of the Independent Investigation is expected to complete by the Autumn of 2022 and arrangements will be made for the final report to be presented to the Secretary of State; Ministers will subsequently publish the report to Parliament, and a response will be provided in due course.

A copy of the Terms of Reference will be deposited in the Libraries of both Houses.

Independent Investigation into East Kent Maternity Services

Terms of Reference

Introduction

- 1.** Following concerns raised about the quality and outcomes of maternity and neonatal care, NHS England and NHS Improvement (NHS E/I) have commissioned Dr Bill Kirkup CBE to undertake an independent review into maternity and neonatal services at East Kent Hospitals University NHS Foundation Trust (the Trust). The Review will be known as the 'Independent Investigation into East Kent Maternity Services' (the Independent Investigation).
- 2.** This is to set out the Terms of Reference for the Independent Investigation, including its scope and the arrangements that are to be put in place to support its functions, detailed in an accompanying Protocol.
- 3.** Dr Bill Kirkup is appointed by NHS E/I to chair the Independent Investigation into the management, delivery and outcomes of care provided by the maternity and neonatal services at East Kent University Hospitals NHS Foundation Trust during the period since 2009 (when the Trust came into being) drawing upon the methodology followed in the Morecambe Bay investigation.
- 4.** The Independent Investigation was also confirmed in Parliament on 13 February 2020 by Nadine Dorries, Minister of State for Patient Safety, Mental Health and Suicide Prevention. At the same time the Minister announced that the Chief Midwifery Officer, Jacqueline Dunkley-Bent, had sent an independent clinical support team to the Trust to provide assurances that all possible measures were being taken.

Scope

- 5.** The Independent Investigation will examine maternity and neonatal services in East Kent, in the period since 2009, by looking in particular at the following four layers:
 - i. What happened at the time, in individual cases, independently assessed by the investigation.
 - ii. In any medical setting, as elsewhere, from time to time, things do go wrong. How, in the individual cases, did the Trust respond and seek to learn lessons?
 - iii. How did the Trust respond to signals that there were problems with maternity services more generally, including in external reports?
 - iv. The Trust's engagement with regulators including the CQC. How did the Trust engage with the bodies involved and seek to apply the relevant messages? And what were the actions and responses of the regulators and commissioners?

Purpose

- 6.** The Independent Investigation will provide an independent assessment of what has happened with East Kent Maternity and Neonatal Services and identify lessons and conclusions. This includes:
 - A. Determining the systems and processes adopted by the Trust to monitor compliance and deliver quality improvement within the maternity and neonatal care pathway.
 - B. Evaluating the Trust's approach to risk management and implementing lessons learnt.

C. Assessing the governance arrangements to oversee the delivery of these services from ward to Board.

7. The Independent Investigation will draw conclusions as to the adequacy of the actions taken at the time by the Trust and the wider system. Taking account of improvements and changes made, the Independent Investigation will aim to provide lessons helpful to East Kent but also to share nationally to improve maternity services across the country.
8. The Independent Investigation will focus on the experience of the families affected and the actions, systems and processes of the Trust, (with reference to clinical standards for maternity and neonatal care during the period). The Independent Investigation will listen to the concerns of the affected families, use their experience to shape the key lines of enquiry and provide an opportunity for them to be heard. The Investigation should also consider the processes, actions and the responses of regulators, commissioners and the wider system as they are relevant to the provision of maternity and neonatal services at the Trust.
9. The Independent Investigation will produce a report to be disclosed first to the affected families and then to NHS E/I as the commissioning organisation and to the Department of Health and Social Care prior to publication. The Report will be published and presented to Parliament.
10. The Investigation will agree with NHS E/I steps it might take at the completion of its work to help ensure that the lessons identified are understood and acted upon. These steps might include presentations to NHS groups.

Timescale

11. The Independent Investigation will aim to complete its Terms of Reference by Autumn 2022.

Protocol

Access to documents

- All relevant NHS organisations, regulators and the Department of Health and Social Care are required and expected to cooperate with the Independent Investigation as is normal, professional practice, including supplying documentation, as and when requested by the Investigation.

Contact with families and the public

- The Independent Investigation team will be responsible for managing liaison with families whose cases are relevant to the Independent Investigation

Methodology and case review

- The Independent Investigation will decide how best to deliver its Terms of Reference including by drawing upon:
 - a. the experiences of families affected by maternity services in East Kent and the impact on those families looking as widely as necessary to understand the whole of that experience and impact;
 - b. the medical records of patients;
 - c. the corporate records showing how the Trust discharged its responsibilities for

maternity services, how it communicated and engaged with patients, their families and representatives and with regulators and others over concerns with maternity services;

- d. interviews with those whose work involved maternity services;
- e. interviews with regulators, NHS England and Improvement, HSIB and others;
- f. its assessment of what went wrong in individual cases and lessons aimed at ensuring improvements which should be made to maternity services in East Kent and elsewhere.
- In applying its methodology, the Independent Investigation will consider individual cases where there was:
 - i. a preventable or avoidable death;
 - ii. concern that the death may have been preventable or avoidable;
 - iii. a damaging outcome for the baby or mother;
 - iv. reason to believe that the circumstances shed light on how maternity services were provided or managed or how the Trust responded when things went wrong.
- The Independent Investigation will take account of other relevant work including the following but will be responsible for reaching its own assessment, findings and conclusions:
 - HSIB Reviews
 - The invited review by the RCOG in 2015/16
 - The invited RCPCH review in 2015
 - Perinatal Mortality Review Tool data and reports
 - Intelligence from the CQC/associated reports/recommendations
 - Letters and findings from HM Coroners
 - Each Baby Counts reviews (the Royal College of Obstetricians and Gynaecologists national quality improvement programme)

Resources and governance

- Resources for the Independent Investigation will be provided by NHS England and NHS Improvement. The Independent Investigation will establish with these resources a team with sufficient expertise and capacity to carry out the work
- The Chair will appoint those with appropriate experience in order to help deliver these terms of reference, including:
 - An expert panel and specialist advisers
 - Secretariat functions
 - Clinical input
 - Legal advice
 - Communication functions
 - Engagement with and support for families
 - Engagement with relevant staff from the Trust
 - Information governance and management

- The Independent Investigation team will keep in regular contact with NHS England and NHS Improvement via the SRO and their team but will not provide a running commentary on the Investigation's findings. Through this contact, NHS England and NHS Improvement will keep in touch with progress of the Independent Investigation, ensure that sufficient resources are available and are being deployed appropriately.
- If the Independent Investigation identifies areas of concern with current patient safety in East Kent Maternity Services, it will contact the Chief Midwifery Officer, Jacqueline Dunkley-Bent in her role described by the Minister in the House of Commons on 13 February 2020.

Consent and information governance

- Specific consent will be sought from the families for their information to be shared with the Independent Investigation team, if initial contact has been via NHS England/Improvement, or the Trust. The Independent Investigation will secure suitable consent from families for their information to be used as part of the investigation.
- The Independent Investigation will have an information handling and privacy policy that will set out the approach the Investigation takes to handling information appropriately and complying with information legislation.

Fact checking and opportunity to comment

- The Independent Investigation will notify individuals and organisations who are referred to in the investigation's conclusions and provide them with an opportunity to respond to any significant criticism proposed for inclusion in its Report.

Disclosure

- The arrangements will include disclosure first to the families and to NHS England, NHS Improvement and the DHSC so that they are aware of the content of the Report to be published.

1 The trust was placed on the Maternity Safety Support Programme which involves improvement advisors supporting the trust with maternity improvement.

Appendix B: How the Investigation conducted its work

The importance of independence

B.1 National Health Service England/National Health Service Improvement (NHSE&I) commissioned the Independent Investigation into East Kent Maternity Services in February 2020, following concerns raised by families and others about the quality and outcome of maternity and neonatal care at East Kent Hospitals University NHS Foundation Trust (the Trust).

B.2 From the outset, the independence of the Chair and the Panel of experts was considered key to ensuring the credibility of the Investigation and the confidence of any families who would be involved. A guiding principle was that, in search of the truth, the Investigation should go in whichever direction the evidence took it, both to maximise the likelihood that families would be provided with the information they needed to address their questions and concerns, and to ensure that the knowledge and insights gained would be of benefit to the Trust and the wider NHS. In practice, this meant that we would determine the process we would follow to establish the facts, we would speak without fear or favour, and we would not shy away from difficult or contentious issues.

B.3 Our process was designed to listen to families, to understand their concerns and the reasons why they felt so aggrieved and let down. It was with the families that we first shared messages and updates during the course of the Investigation; and it was with the families that we first shared our findings and recommendations at the conclusion of the Investigation.

B.4 We did this while maintaining independence and objectivity, which is what the families affected would have wanted and what the public would have expected. We endeavoured to maintain a balanced and proportionate approach, as well as a sustained and high-quality level of engagement with those directly affected, at all times showing sensitivity and understanding.

How we worked with families

“Families first” principle

B.5 The Investigation adopted a “families first” approach. This principle is not defined in statute but forms the basis of many investigations and inquiries: for example, it was included in the Terms of Reference for the Hillsborough Independent Panel formed in 2010 in response to the Hillsborough disaster of 1989, and it was used by the Gosport Independent Panel, which reported in 2018.

B.6 Not only did the “families first” principle guide our approach to the gathering and scrutiny of evidence, it also informed how we shared our findings. In particular, our intention

from the start was to make sure that families would be the first to hear the conclusions of our Investigation and to have access to the written Report.

B.7 For the purposes of investigating and reviewing the care families received, access to personal information was needed. To ensure that the Chair and the Panel had the operational independence to determine what lines of enquiry to follow and what evidence to gather and process, Data Controller status was conferred on the investigation team.

Engagement with families

B.8 As set out in our Terms of Reference, the Investigation was tasked with looking at individual cases where there had been: a preventable or avoidable death; a concern that the death may have been preventable or avoidable; a damaging outcome for the baby or mother; or reason to believe that the circumstances shed light on how maternity services were provided or managed or how the Trust responded when things went wrong. Understanding the experiences of the families was a key part of the Investigation process.

B.9 Early on, informal conversations with families took place to answer any questions they had about the Investigation and to assure them of its independence and determination to get to the truth. We also hoped that this would help build a relationship of trust and confidence and alleviate any concerns the families might have had about participating.

B.10 On 23 April 2020, we launched the Investigation formally and invited families who wished to share their experience of the maternity and neonatal services at the Trust during the period 2009 to the end of 2020 to contact us. Then, in October 2020, the Panel Chair appealed for other families to come forward if they wished to, mindful that there needed to be a cut-off date for families to be involved. One year later, on 23 April 2021, we stopped accepting new cases to the Investigation, except in exceptional circumstances where the Panel felt that the cases added significantly to the Investigation's findings.

B.11 The Investigation received approaches from three families who wished their cases to be considered but who, on assessment, were found to be outside the scope of the Terms of Reference. In two other cases, the Panel was not able to review the woman's care because their medical notes were not available. These five cases were therefore not included in the analysis undertaken for the purposes of Chapter 2 of this Report.

Consent

B.12 In every case, we obtained the written consent of each family to:

- Access their clinical records and other documentation relating to their case
- Approach relevant organisations that may have held personal data relevant to the Investigation, and for those organisations to share that personal data with the Investigation team
- Use the information we obtained about their case to develop questions or issues for other witnesses or organisations to answer or explore on an anonymised basis
- Include in the Investigation Report personal information about the experiences they shared with us, on an anonymised basis or with their additional consent if the information may be identifiable.

Family listening sessions

B.13 Our family listening sessions provided the opportunity for families to meet the Panel and talk about their experience of care at the Trust. We encouraged them to tell us what had happened in full, including the impact on themselves. The sessions took place between January and September 2021, and the majority were conducted via video. Where families preferred to meet the Panel in person, arrangements were made at their convenience. Each session was attended by at least two members of the Panel and one of the specialist advisers to the Panel. The Investigation's family engagement lead also attended.

B.14 The family listening sessions were deliberately unstructured, with families given free rein to speak as they wished; the Panel asked questions as the need arose in order to clarify or seek further information. Each session was recorded and families were made aware that all recordings would be destroyed in line with the Investigation's Data Handling and Privacy Information policy at the conclusion of the Investigation.

B.15 All the families who contributed to the Investigation through a family listening session were provided with a summary of their spoken account to ensure that it captured the key facts and essence of their experience. The Panel Chair agreed that any comments made by a woman or a family member during their family listening session would not be attributed to them in the Investigation's final Report without their express permission.

B.16 Families who did not wish to meet with the Panel were given other options: to submit information in writing or to give consent for their records to be looked at without any active participation on their part. A small number took up these offers.

B.17 Importantly, the family listening sessions included mothers, fathers and in some cases other family members. In preparing our Report, we have referred variously to mothers, women, fathers, partners* and, on occasion, husbands. In our use of terminology, we hope that we have followed accurately the circumstances of each family and their wishes. We have kept the terms used simple in order to aid the flow of the Report, but we are mindful of the possibility of situations where the term "birthing partner" would be more apt.

Trauma-informed counselling

B.18 Mindful of the additional anxiety and distress that might be caused to them by the necessity of having to recount and possibly relive their experiences and share personal details, we offered each family the opportunity to attend a session with an expert counsellor after they had met with the Panel. We selected a professional counsellor with extensive experience of working therapeutically with people who have been harmed during healthcare, with professional knowledge and experience as an academic, and with research expertise in trauma-informed counselling for healthcare harm.

B.19 Trauma-informed counselling is based on principles intended to "*promote healing and reduce the risk of retraumatisation for vulnerable individuals*".¹ This approach takes account of the events or series of events that contribute to a traumatic reaction and includes the principle that self-referenced trauma is as valid as that which is diagnosed clinically. In other words, despite the narrow medical definition of trauma, if people believe that they have suffered from trauma, they should be accepted as having done so. Given that so many families referred to their experience or aspects of their experience as being traumatic, this approach turned out to be wholly appropriate.

* The term 'partners' refers to married and unmarried partners, whether male or female.

B.20 Our counsellor was able to signpost families to other support, when additional or ongoing support was needed.

Individual disclosure

B.21 Because so many of the families had unanswered questions about the care they received or the outcome they experienced, the Investigation Chair undertook to meet with any family who wished to do so after publication of the Investigation Report, to answer any questions that the relevant family may wish to put to the Panel about their individual circumstances.

How we worked with the Trust

Clinical records review

B.22 With the consent of the families involved, as detailed above, and the full cooperation of the Trust, we carried out a thorough review of the clinical records of each woman's and baby's care. This included reviewing original hard copy clinical notes as well as accessing copies of them via a secure online portal.

B.23 The Panel members worked together to review individual records. They also had ongoing access to the online versions, to continue their work individually.

B.24 In addition to the clinical records, the Trust provided other documentation, such as complaints correspondence, investigation reports and exchanges with GPs, which helped the Panel build a picture of the woman's or baby's care and the events surrounding it.

Interviews with Trust Board members, senior managers and staff

B.25 Members of the Trust Board, the senior management team and staff were selected for interview with the Panel based on their period of employment with the Trust, their position (or positions) during that time, their involvement in governance and patient safety matters, and, in some cases, their involvement in particular cases reviewed by the Panel. Everyone invited was considered by the Panel to be in a position to provide information about the management, delivery and culture of the services under review, at both a service and a corporate level, during the period covered by the Investigation.

B.26 They were invited by letter to attend an interview with the Panel. The letter explained that the Investigation had conducted listening sessions with a number of affected families and now wanted to hear from past and present Trust staff, and others, who were involved in the delivery, management and/or regulation of maternity and neonatal services at the Trust during the period under scrutiny.

B.27 We recognised that individuals may wish to be accompanied by a friend, colleague or trade union official, and we offered them the option of bringing one person to support them. However, we were clear that their support person would not be able to answer questions or act in a representative capacity.

B.28 The interviews were arranged at a time convenient to the interviewee and the option was provided to attend in person or via video. Each interview was attended by at least two Panel members. In order to facilitate an open dialogue and to meet the Investigation's Terms of Reference, the Panel Chair agreed that any comments made by an individual during their interview would not be attributed to them in the Investigation's final Report without their express permission.

B.29 In advance of the interviews, individuals were provided with an outline agenda of the themes to be discussed. If they were being invited to discuss a particular case, they were provided with the details in order that they could prepare fully; they were also given access by the Trust to the relevant clinical records.

B.30 The interviews were recorded and a written summary of the interview was provided to each individual. They were made aware that all recordings would be destroyed in line with the Investigation's Data Handling and Privacy Information policy at the conclusion of the Investigation.

Review of Trust records and other material provided

B.31 Corporate records were reviewed to understand how the Trust discharged its responsibilities for maternity services and how it communicated and engaged with patients, with their families and representatives, and with regulators.

How we worked with stakeholders

B.32 An early task was to identify organisations that might have material pertinent to the matters under investigation or that could inform the work of the Investigation more broadly. These organisations were then contacted in order that the work of the Investigation and its Terms of Reference could be explained; we requested that no documents that might have a bearing on the Investigation should be destroyed.

B.33 Following on from this early contact, meetings were set up to establish with each organisation whether they had material of interest to the Investigation and to inform them that interviews might be needed with key staff to explore matters arising from our review of that material.

B.34 While documents were being provided to the Investigation for review, interviews with staff from stakeholder organisations were scheduled.

B.35 The interview process was similar to that described above. Interviews were arranged at a time convenient to the interviewee and the option was provided to attend in person or via video. Outline agendas were provided and the Panel Chair agreed that any comments made by an individual during their interview would not be attributed to them in the Investigation's final Report without their express permission.

B.36 The interviews were recorded and a written summary was provided to each individual. Participants were made aware that all recordings would be destroyed in line with the Investigation's Data Handling and Privacy Information policy at the conclusion of the Investigation.

How we assessed individual cases

B.37 Having reviewed the evidence gathered from families and Trust staff, the Panel met as a group to consider each case in turn and determine where care was suboptimal when assessed against the standards expected nationally and its relationship with the subsequent outcome. This multi-disciplinary process of assessment was key to the Investigation. The findings were structured according to the validated classification of suboptimal care adopted by the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI). Not only did this enable the

Panel to draw evidence-based conclusions about the overall quality and safety of care provided by the maternity and neonatal services at the Trust, but it also allowed us to ascertain the key facts in each case, in order that the Panel could report back to individual families about what had happened in their case.

B.38 The CESDI scoring system comprises four levels of suboptimal care based on the relationship to the outcome (see Table B1).

Table B1: CESDI scoring system

Level of suboptimal care	Relevance to the outcome
Level 0	No suboptimal care
Level 1	Suboptimal care, but different management would have made no difference to the outcome
Level 2	Suboptimal care, in which different management might have made a difference to the outcome
Level 3	Suboptimal care, in which different management would reasonably be expected to have made a difference to the outcome

B.39 In addition to grading the level of suboptimal care, the Panel determined the degree of harm in each case. For this purpose, we used a scoring system adapted from the NHS National Reporting and Learning System (NRLS) definitions of degrees of harm (see Table B2).[†]

Table B2: Degrees of harm

Degree of harm	Outcomes	Impact on woman and/or baby
None	No harm	There was no impact on the woman or her baby
Minimum	Maternal injury; baby birth injury	The woman or her baby required extra observation or minor treatment
Moderate	Maternal injury; baby birth injury	There was short-term harm and the woman or her baby required further treatment or procedures
Severe	Maternal injury; brain damage, including hypoxic ischaemic encephalopathy (HIE) and/or cerebral palsy attributable to perinatal hypoxia	The woman or her baby suffered permanent or long-term harm
Death	Stillbirth; neonatal death; late neonatal death; maternal death	The woman or her baby died

B.40 The Panel's conclusions drawn from its assessment of cases are set out in Chapter 2 of the Report.

[†] Although there are plans to replace the NRLS with the Learn from Patient Safety Events (LFPSE) service, which does not define degrees of harm in the way the NRLS does, the Panel found it helpful to use a form of assessment of harm that is recognisable and understood when reviewing the cases subject to our Investigation.

Organisations contacted by the Investigation

B.41 The organisations and stakeholders listed in Table B3 were contacted in order to provide evidence or other information in line with the Investigation's Terms of Reference. A number of these organisations have contributed information and documents to the Investigation, but a proportion of these stakeholders did not have any relevant documents to contribute.

Table B3: Organisations contacted by the Panel

Organisation name
Action against Medical Accidents (AvMA)
Birth Trauma Association
Bliss
British Medical Association
Care Quality Commission
Child Death Overview Panel
Department of Health and Social Care
Fairweather Solicitors
General Medical Council
Health and Safety Executive
Health Education England
Healthcare Safety Investigation Branch
Healthwatch
Her Majesty's Senior Coroner (Mid Kent & Medway, North East Kent, Central & South East Kent)
Kent Community Health NHS Foundation Trust
Kent County Council
Kent Police
Local Maternity System
Maternity Voices Partnership
MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK)
Medical Defence Union
Members of Parliament
National Childbirth Trust
National Guardian's Office
NHS England and NHS Improvement
NHS Kent and Medway Clinical Commissioning Group
NHS Resolution
Nursing and Midwifery Council
Parliamentary and Health Service Ombudsman

Public Health England
Royal College of Anaesthetists
Royal College of Midwives
Royal College of Nursing
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Sands (Stillbirth and Neonatal Death Charity)

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Mind the implementation gap

The persistence of
avoidable harm in the NHS



SAFETY FOR ALL

This report was published on the 7 April 2022 as part of the Safety for All campaign.

This Campaign is focused on driving awareness of the interrelationship between healthcare worker safety and patient safety, highlighting how poor healthcare worker safety standards and practice impact adversely on patient safety, championing the need for a systematic and integrated approach to improve safety practice in both healthcare worker safety and patient safety so that the sum is greater than the parts.

We are calling on the government and leaders in the health and social care sector to recognise that patient safety is to some degree dependent on the delivery of effective healthcare worker safety (and vice versa) and to implement nationwide standards, practice and structures on patient safety culture which take account and where possible align and combine both patient safety and healthcare worker safety.

The campaign is supported by Patient Safety Learning and the Safer Healthcare and Biosafety Network.



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Executive Summary

“To err is human, to cover up is unforgiveable and to fail to learn is inexcusable”
Sir Liam Donaldson

This report by Patient Safety Learning highlights a patient safety implementation gap in the UK that results in the continuation of avoidable harm.

Patient Safety Learning is a charity and independent voice for patient safety. Our vision is to help create a world where patients are free from avoidable harm. We believe that urgent system-wide change is needed, with the healthcare system designed with safety at its core. We must mitigate the risk of harm, so that healthcare is safe for patients and for the staff who work in it.

The report forms part of the Safety for All Campaign, which calls for improvements in, and between, patient and healthcare worker safety to prevent safety incidents and deliver better outcomes for all.¹

Avoidable harm in healthcare and the implementation gap

The World Health Organization states that unsafe care is one of the top ten leading causes of death and disability worldwide, with the NHS estimating that there are around 11,000 avoidable deaths annually due to safety concerns. However, despite a range of international and national initiatives aimed at reducing avoidable harm, it remains a persistent, wide-scale problem.

A key reason for this is the implementation gap, the difference between what we know improves patient safety and what is done in practice. In this report we highlight six specific policy areas where this gap acts as a barrier to patient safety improvement:

1. Public inquiries and reviews
2. Healthcare Safety Investigation Branch reports
3. Prevention of Future Deaths reports
4. When patients and families take legal action
5. Patient complaints
6. Incident reports

Having considered how the implementation gap manifests itself in these areas, we then highlight four common underlying themes:

- Absence of a systemic and joined-up approach to safety
- Poor systems for sharing learning and acting on that learning
- Lack of system oversight, monitoring, and evaluation
- Unclear patient safety leadership

Patient safety as a systems issue and recommendations

We argue that we need to take a systems-approach to improving patient safety.

We are calling the Government, parliamentarians, and NHS leaders to take action to address the underlying causes of avoidable harm in healthcare and inviting them to engage in a system-wide debate about how healthcare can reshape its approach to learning and safety improvement. We also detail specific recommendations relating to the areas of the

implementation gap highlighted in this report, which we hope can form part of a public discussion.

We will be writing to leadership organisations outlining these recommendations and welcome responses from them on our proposals.

- 1. Patient safety inquiries and reviews need system-wide commitment and resources, with effective and transparent performance monitoring to ensure that the accepted recommendations translate into action and improvement.**
- 2. HSIB reports and their recommendations need system-wide commitment and resources, with effective and transparent performance monitoring to ensure that their recommendations translate into action and improvement.**
- 3. The Coroner's Prevention of Future Deaths system needs to be improved so that recommendations for patient safety improvements and organisational responses to the reports can be easily accessed. Processes need to be in place to provide assurance that learning from causal factors of avoidable deaths is captured consistently and the insight from these cases is disseminated and acted upon across all healthcare organisations.**
- 4. NHS England and NHS Improvement and NHS Resolution need to work together to improve the process for identifying the causal factors of unsafe care identified through litigation, ensuring this can be disseminated widely and acted on to improve patient safety.**
- 5. The introduction of the new NHS Complaints Standards needs to be closely monitored, with clear guidance for organisations on how to implement this and clarity on who is responsible for this within the organisation. This should be accompanied by public transparent reporting by organisations on the rollout of the new standard, allowing for consistent monitoring and comparison.**
- 6. NHS England and NHS Improvement and the MHRA must ensure that the development of the new PSIRF and changes to the Yellow Card scheme have a core focus on learning for action and improvement to tackle the implementation issues highlighted in this report.**

Introduction

Avoidable unsafe care kills and harms thousands of people each year in the UK and costs the NHS billions of pounds for additional treatment, support, and compensation costs relating to litigation by those harmed. As well as the moral imperative to ensure that healthcare follows its founding value of ‘first do no harm’, there is a strong economic and social incentive to make improvements; resources will be better spent delivering excellent quality care and preventing avoidable harm rather than addressing the consequences of unsafe care.

In this report we outline all-too frequent examples of where we fail to learn lessons from incidents of unsafe care and fail to take the action needed to prevent future harm. In some cases, insights from patient safety incidents and recommendations are simply left in reports gathering dust on the shelf. In others, changes may be implemented at a local level, but remains siloed within specific organisations, with a lack of means or commitment to share them or take system-wide action. Frustratingly, time and time again we find ourselves aware of issues that cause avoidable harm but not taking action to address their causes.

We consider that a key reason for the persistence of avoidable harm is an ‘implementation gap’ in patient safety in the UK, the difference between what we know improves patient safety and what is done in practice. This report focuses on six specific policy areas where this gap exists and acts as a barrier to patient safety improvement. We highlight four common underlying themes that lead to patient safety learning and recommendations falling through this gap and consider what is needed to tackle this and turn recommendations and insights into action and improvement.

Avoidable harm in healthcare

Before discussing how the implementation gap manifests itself in healthcare, we need to be clear about what we mean by avoidable harm and the scale of this problem.

Healthcare is an incredibly complex industry and there are a wide range of different ways in which avoidable harm can occur, some examples of which include:

- Diagnostic errors – delayed, incorrect or missed diagnoses.
- Medication errors – relating to the prescription, dosage, route of administration or omission of medication.
- Unsafe surgery – incidents such as retained foreign objects, wrong site surgery and anaesthesia errors.
- Healthcare associated infections – developing either as a direct result of healthcare interventions or from being in contact with a healthcare setting, such as methicillin-resistance *Staphylococcus aureus* (MRSA).
- Communication and information errors – between healthcare professionals and patients or between healthcare professionals themselves.

Each year, millions of patients suffer injuries or die as a result of avoidable harm, with the World Health Organization (WHO) stating that unsafe care is likely one of the top ten leading causes of death and disability worldwide.² In high-income countries, it is estimated that one in every 10 patients is harmed while receiving hospital care.³ The harm can be caused by a range of adverse events, with nearly 50% of them being preventable.⁴

In the UK, the NHS estimates that there are around 11,000 avoidable deaths annually due to safety concerns.⁵ It is important to note that these figures were prior to the Covid-19 pandemic. We do not yet have estimates for the huge impact that the pandemic has had on patient safety, including the backlog in care and treatment.

Every avoidable death and disability is an unnecessary tragedy for patients, families and healthcare professionals. Beyond the cost in human lives, unsafe care also extracts other significant tolls, such as:

- The physical and psychological discomfort of patients who experience a long hospital stay or permanent disability because of errors.
- Loss of trust in the health care system by patients.
- Diminished satisfaction by both patients and health professionals.
- Loss of morale and frustration of health professionals at not being able to provide the best care possible.

Society also bears the wider cost of errors as well, in terms of lower levels of population health and indeed lost worker productivity.

Avoidable harm also comes with a huge financial footprint. The Organisation for Economic Co-operation and Development (OECD) estimates that the direct cost of treating patients who have been harmed during their care in high-income countries approaches 13% of health spending.⁶ A report last year by the G20 Health and Development Partnership forecast that patient safety issues would cost the global economy a staggering \$383.7 billion by 2022.⁷

These costs come from both the corrective action required in response to avoidable harm caused to patients and the costs of litigation and compensation. A recent inquiry by the Health and Social Care Select Committee highlighted that the bill for settling claims in the NHS in 2020/21 came to £2.26 billion, with a further £7.9 billion spent on compensation claims settled in previous years.^{8 9}

While avoidable harm continues to persist at such high levels, thousands of people each year will be harmed or die and scarce funds that could be spent to proactively improve the quality of care will instead be used to deal with the cost of error and harm.

Patient safety and the NHS

Awareness of the impact of avoidable harm in healthcare and the need to make significant improvements to patient safety is a well-established concept.

There was a growing recognition of this during the 1980s and 1990s. In 1999, the Institute of Medicine released a report, *To Err is Human*, which set out that hospital deaths from avoidable harm in the United States could be as high as 98,000 per year.¹⁰ At around the same time in the UK, the Chief Medical Officer published *An organisation with a memory*, analysing the scale and nature of avoidable harm in the NHS and the importance of understanding patient safety incidents and learning from errors.¹¹

Patient safety as a concept entered the mainstream of healthcare, and in the last twenty years there has been an increased consciousness of the need to better understand the causes of unsafe care and the action needed to reduce harm, with a range of new roles, programmes and initiatives created to this end.

Table 1: Patient safety

NHS definition:

“Patient safety is the avoidance of unintended or unexpected harm to people during the provision of health care. We support providers to minimise patient safety incidents and drive improvements in safety and quality. Patients should be treated in a safe environment and protected from avoidable harm.”¹²

WHO definition:

“Patient safety is a framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur.”¹³

At an international level, last year the WHO published its *Global Patient Safety Action Plan*, aimed at providing a framework for countries to develop their national patient safety plans over the next ten years.¹⁴ It sets out a vision of “a world in which no one is harmed in health care and every patient receives safe and respectful care, every time, everywhere”. Patient safety has also been recently recognised as a key issue for the G20, included in 2020 as one of the five priorities of G20 Health Ministers.¹⁵

In the UK, the national *NHS Patient Safety Strategy* was published in July 2019, describing how the NHS aims to improve patient safety over the next five to ten years.¹⁶

Table 2: The NHS Patient Safety Strategy

To continuously improve patient safety, the NHS Patient Safety Strategy states that it needs to build on two foundations: a patient safety culture and a patient safety system. It details three strategic aims to develop both foundations:

1. Insight – improving understanding of safety by drawing intelligence from multiple sources of patient safety information.
2. Involvement - equipping patients, staff and partners with the skills and opportunities to improve patient safety throughout the whole system.
3. Improvement - designing and supporting programmes that deliver effective and sustainable change in the most important areas.

This Strategy has resulted in a series of new initiatives aimed at improving our approach to patient safety, including:

- Development of a new patient safety incident reporting system.¹⁷
- A new framework for proposals for involving patients in patient safety.¹⁸
- Development of a new framework for reporting patient safety incidents.¹⁹

Another recent announcement aimed at improving patient safety in the NHS has been the decision to create the new role of Patient Safety Commissioner. This is a response to one of the main safety recommendations in the *First Do No Harm* report, published in July 2020 by the Independent Medicines and Medical Devices Safety (IMMDS) Review.²⁰

Table 3: The Independent Medicines and Medical Devices Safety Review

This review, led by Baroness Julia Cumberlege, examined how the healthcare system in England responded to reports about harmful side effects of medicines and medical devices, focusing on three specific interventions: Hormone pregnancy tests, Sodium valproate and Pelvic mesh implants.

These interventions had resulted in a truly shocking degree of avoidable harm to patients over a period of decades and the Review described the healthcare system's response to this as "disjointed, siloed, unresponsive and defensive". It set out nine patient safety recommendations of which the Government accepted four, accepted two in part, one in principle and rejected two.²¹ One of the recommendations accepted by the Government was:

"The appointment of a Patient Safety Commissioner who would be an independent public leader with a statutory responsibility. The Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices."

As part of the Medicines and Medical Devices Act 2021, the UK Government committed to establishing a Patient Safety Commissioner for England. The core role of the Commissioner will be "to promote the safety of patients in the context of the use of medicines and medical devices and to promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices".²² The Scottish Government also set out proposals to create a Patient Safety Commissioner as part of its Programme for Government 2020-21. Both these new posts were subject to consultation in 2021 and the Department of Health and Social Care is currently in the process of appointing the inaugural office holder in England.²³

It is clearly recognised, at both an NHS and Government level, that improving patient safety is a key challenge that faces the healthcare system. The implementation of the NHS Patient Safety Strategy and the creation of new Patient Safety Commissioners has continued to progress in that last two years, despite the enormous pressures and challenges faced by both the Department and the NHS as a result of the Covid-19 pandemic.

However, can we be confident that these initiatives will succeed where we have so far failed, in tackling the persistent and wide-scale problem of avoidable harm? We believe that this will not be achieved while the implementation gap in patient safety remains unaddressed. As we will outline next, this presents a significant barrier to the vision of continuously improving patient safety and delivering the NHS's commitment and plans for high quality care.

The implementation gap

The implementation gap, referred to in the *Global Patient Safety Action Plan* as the "knowing-doing gap", is the difference between what we know improves patient safety and what is done in practice.²⁴ This gap can emerge for a number of different reasons:

- Difficulties implementing changes across healthcare – it can be a complex task to change the ways of working and behaviour of many individuals and organisations.

- Patient safety guidance working in theory, but not in practice – actions that may appear to address patient safety issues failing to account for a wide variety of organisational context, culture, and capacities.
- Insights and learning remaining in silos – patient safety improvements remaining locked in specific organisations, with a lack of means or commitment to widely share and disseminate new knowledge.

This challenge is not unique to healthcare. In other safety-critical industries, such as aviation, construction, and nuclear power, eliminating causes of harm and prioritising safety is also of paramount importance. Though these industries differ significantly from healthcare, they face the same challenges in terms of translating the investigation and analysis of safety incidents into practical improvements. However, these industries are often far more effective at adopting a systems approach to this issue, which we will discuss later.

The implementation gap in the NHS was identified as far back as year 2000 in the Department of Health report *An organisation with a memory*:

“The NHS record in implementing the recommendations that emerge from these various systems is patchy. Too often lessons are identified but true ‘active’ learning does not take place because the necessary changes are not properly embedded in practice. Though there is some good evidence of meaningful medium and long-term change as a result of Confidential Inquiry recommendations, for example, these are rarely driven through into practice and the onus for implementation and prioritisation is very much on local services. Takeup can tend to ‘plateau’ once changes have been implemented by those who are most naturally receptive to them, and there is some evidence that progress nationally can slip back if efforts are not sustained.”²⁵

Over twenty years on, it is highly disconcerting that the findings of this report remain deeply relevant, with the implementation gap continuing to undermine our ability to translate insights and lessons from avoidable harm into safety improvements. Too often patients continue to experience harm from problems that have already been identified or addressed elsewhere.

This gap between learning and improvement exists at multiple levels. In this report we will focus on the policy issues and where the gap is broadly exhibited in relation to insights, learning and recommendations. There is much that needs to be done to ensure that the knowledge of best clinical practice is disseminated widely and implemented consistently. However, this report will focus on the systems and organisational implementation gap, the issues relating to specific clinical guidance are out of scope.

In this report we have chosen to focus on six specific areas where this gap exists on a policy level and acts as a barrier to patient safety improvement.

1. Public inquiries and reviews

Over the past twenty years there have been a considerable number of independent inquiries and reviews into serious patient safety failings in the UK.

In some cases, these have taken the form of statutory inquiries. These are governed by rules set out in the Inquiries Act 2005 with legal powers to require witnesses to give evidence and produce documents. There are also specific provisions regarding establishing their Terms of Reference and the procedures that they follow. A recent example of this is the Infected Blood Inquiry, examining the circumstances in which men, women and children treated by NHS were given infected blood and infected blood products, since 1970.

There have also been many non-statutory public inquiries. These are established by a Government minister, but not under an Act of Parliament. They possess a great degree of flexibility on procedure and rules, not being bound by the Inquiries Act, but are unable to compel witnesses to give or produce evidence relevant to their work. A recent example of this is the Independent Medicines and Medical Devices Review, detailed earlier in Table 3.

Table 4 below includes some of the key patient safety inquiries and reviews in England over the last decade. This is far from an exhaustive list, there have been many more before and during this time across the whole of the UK and covering a wide range of different services, which also have significant patient safety implications.

Table 4: Key patient safety inquiries in England (statutory and non-statutory) and reviews between 2010-2022

- 2012 – Winterbourne View Hospital: Department of Health review.²⁶
- 2013 – The Mid Staffordshire NHS Foundation Trust Public Inquiry.²⁷
- 2013 – Berwick review into patient safety.²⁸
- 2015 – The Morecambe Bay Investigation.²⁹
- 2018 – Independent review into Liverpool Community Health NHS Trust.³⁰
- 2018 – The Infected Blood Inquiry.³¹
- 2018 – The Gosport Independent Panel.³²
- 2020 – The Independent Inquiry into the issues raised by Paterson.³³
- 2020 – The Independent Medicines and Medical Devices Safety Review.³⁴
- 2022 – The Independent Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust.³⁵
- Ongoing – The Muckamore Abbey Hospital Inquiry.³⁶
- Ongoing – Essex Mental Health Independent Inquiry.³⁷
- Ongoing – Independent Investigation into East Kent Maternity Services.³⁸

Since the introduction of devolution there have been specific inquiries commissioned by the Welsh Government and the Scottish Government, such as the investigation of maternity services at the Cwm Taf University Health Board, and the Scottish Hospitals Inquiry.^{39 40} There are also significant wider points of patient safety insights and learning that can emerge from the reports by regulatory bodies, such as the Care Quality Commission (CQC), and invited reviews by Royal Colleges’.

Public inquiries and reviews can act as a vital source of insight and learning that can be applied to improve patient safety. They can be used consider in detail the most serious incidents of avoidable harm in healthcare, helping to establish a full series of events, identify points of learning, hold organisations to account and set recommendations to prevent a recurrence of similar failings in future.

However, they also form a major part of the implementation gap in patient safety policy in the UK. A key contributing part of this concerns the inconsistency in the approach to these inquiries. They can often vary significantly in format, process and outcomes depending on the terms of reference and the preferences of the Chair. These inconsistencies also apply to how their final reports are responded to by the Government. In its 2018 report, *Investigation into government-funded inquiries*, the National Audit Office noted:

“There is no specific guidance as to how government departments should respond to an inquiry, and the minister has discretion about how to respond. The government’s initial response to the inquiries included in our sample ranged from written or oral ministerial statements to Parliament to published reports. All inquiries were acknowledged in a statement to Parliament but, for those inquiries that made recommendations, varying levels of information were included in the government’s response.”⁴¹

For reports concerning patient safety issues, this means that responses can vary in terms of timeframes, details, and the approach taken to implementing recommendations. Processes can lack transparency and will often not provide any framework for subsequently monitoring and evaluating the effectiveness of the recommendations that have been implemented. Again, this absence of follow up has been noted by the National Audit Office:

“Once inquiries have concluded, there is no central repository or responsibility across government for tracking whether recommendations have been implemented and ensuring that inquiries have an impact”⁴²

This is not a new problem, with *An organisation with a Memory* noting in 2000 that “there has been little formal evaluation of these processes of inquiry to see what impact they have”.⁴³ Guidance provided in the Inquiries Act is quite broad, there is no rigid template and standards for how inquiries are undertaken, with much scope for interpretation by the Chair, nor any obvious quality assurance oversight. Given this, it is not possible to be assured that all inquiries fully identify the causal factors of avoidable harm and make recommendations that, if implemented, will address these. Simply put, we lack the tools to assess how effective inquiries recommendations are in addressing the patient safety problems they identify.

We also see specific themes around issues such as blame cultures and failure to listen to and respond to patient concerns occur time and again, which would seem to indicate that often recommendations fail to address the underlying causes of these issues.

Without a publicly available central repository and transparent reporting, we cannot easily assess how many of the same recommendations are being made and whether there is a systematic approach in place to implement recommendations. There is currently no way a patient, member of the public, parliamentarian, policymaker, or journalist to assess what recommendations have been implemented, whether in full, in part or not at all, across the whole of the NHS or individual organisations. This is a shocking conclusion that is an affront to all those patients and families who have been assured that ‘lessons have been learned’ and ‘action will be taken to prevent future avoidable harm to others’.

Considering one of the reoccurring themes in across patient safety inquiries and reviews, blame culture, in 2013 this was identified as one of the key issues in the Mid Staffordshire Inquiry and the subsequent Berwick Review. The Mid Staffordshire Inquiry highlighted that this was not a new issue, citing its appearance in previous reports:

*“The evidence to this Inquiry has shown that we have still not managed to move successfully away from the culture of blame which Professor Sir Liam Donaldson, in *Organisation with a Memory*, and Professor Sir Ian Kennedy, in the report of the *Bristol Inquiry*, were so keen to banish.”⁴⁴*

Seven years later, the Independent Medicines and Medical Devices Safety Review highlighted the continued persistence of this issue:

“We heard about the failure of the system to acknowledge when things go wrong for fear of blame and litigation. There is an institutional and professional resistance to changing practice even in the face of mounting safety concerns.”⁴⁵

Two years later, this was mentioned again in the Independent Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust, which highlighted fear of speaking out within the maternity services team, noting “a lack of psychological safety in the workplace, and limited the ability of the service to make positive changes”.⁴⁶

The importance of moving away from blame culture, towards a positive safety culture, is now identified as a key aim in the NHS Patient Safety Strategy. However, despite this coming up repeatedly as an underlying cause of avoidable harm over two decades of inquiries and reviews, we still only have in the NHS an outline of proposed activity around this. We are yet to see specific and robust measures proposed to address this, such as organisations publishing and reporting on goals to change culture and intervening where poor performance is identified. The results of the NHS Staff Survey over the last three years make clear that too many staff still do not feel safe about speaking up about errors, patient safety incidents and near misses.^{47 48 49}

Published in 2019, the NHS Interim People Plan reinforces the importance of culture and leadership’ changes in the NHS in England but offers few suggestions on *how* organisations should address this challenge. It states that its future full five-year plan will:

“...set out how we will embed the culture changes and develop the leadership capability needed to make the NHS the best place to work over the next five years.”⁵⁰

We await with interest the publication of plans for embedding culture change across the NHS, an essential foundation to patient safety. To date however, this still remains a clear example of an issue raised by multiple inquiries and reviews time and time again but that we struggle to address with practical action.

While we lack the means to assess and monitor the impact of recommendations from patient safety inquiries in a holistic and joined up manner, it seems unlikely that these underlying patient safety issues will be addressed. Without this, patient safety concerns will continue to fall through the implementation gap, with avoidable harm inevitably reoccurring for years to come.

Recommendation 1: Patient safety inquiries and reviews need system wide commitment and resources, with effective and transparent performance monitoring to ensure that the accepted recommendations translate into action and improvement.

2. Healthcare Safety Investigation Branch reports

The Healthcare Safety Investigation Branch (HSIB) came into operation in April 2017 as a division of NHS Improvement, with the aim of improving patient safety through independent investigations into NHS-funded care in England. This was modelled on the approach taken in other safety-critical industries, such as aviation, with learning-focused investigation bodies which are separated from processes that allocate blame, determine liability, or deliver justice.⁵¹

HSIB undertakes approximately 1,000 independent maternity investigations a year, which are referred to it directly by the NHS trust where the incident took place. These are not

directly published individually but are summarised by an annual publication highlighting outcomes and impacts, key themes, and priorities areas for future work.

Table 5: Healthcare Safety Investigation Branch

HSIB was formed in 2017 to help improve patient safety through independent investigations into NHS-funded care across England. HSIB is funded by the Department of Health and Social Care.

Its investigations primarily fall into one of two categories:⁵²

1. National investigations – any group, organisation or person can refer a patient safety concern to HSIB who then assess this against their investigation criteria before deciding whether to conduct a formal investigation.
2. Maternity investigations – these concern incidents in NHS maternity services that meet criteria set out within the Royal College of Obstetricians and Gynaecologists' 'Each Baby Counts' report or the MBRRACE-UK 'Saving Lives, Improving Mothers' Care' report. They are referred to them directly by the Trust where the incident took place.

The Health and Social Care Bill 2021-22 current proceeding through Parliament would give HSIB statutory independence as the new Health Service Safety Investigations Body (HSSIB). The new HSSIB will conduct investigations using 'safe space' powers, which prohibits, on a legal basis, the undisclosed disclosure of protected information held by HSSIB. Alongside this change, responsibility for maternity investigations will be transferred to a new Special Health Authority.⁵³

For its national investigations, proposals for these can be submitted to HSIB by any group, organisation, or person. HSIB then reviews these concerns against their investigation criteria before deciding whether to conduct a national investigation, the outcomes of which are published in reports on their website. These investigation reports have several key aspects in common:

- Use a specific 'reference event' to highlight the patient safety incident that is being investigated and its impact.
- An analysis of the key findings from reference event and consideration of the wider context around this.
- Safety recommendations and safety observations. Recommendations are directed at specific organisations who are asked to respond in 90 days of publication of the report. Safety Observations may or may not be directed at a specific organisation and require no formal response.

HSIB reports highlight important gaps in safety in the NHS in England and make well-informed and well-thought-out recommendations for improvement. However, in practice this is another area where there is a significant implementation gap.

A practical limit is that HSIB does not have the responsibility or authority to ensure that its patient safety recommendations are implemented. While organisations are asked to respond in 90 days to a national investigation recommendation, there is no compulsion for them to accept or implement the recommendation. There are also no criteria for responding, meaning if organisations do accept the recommendation, they are under no obligation to provide clear plans or timeframes for implementing them.

If it is not the responsibility of HSIB to make sure its recommendations are implemented, or to evaluate their impact and assessing their effectiveness, this begs the question, whose is it? Jeremy Hunt MP, Chair of the Health and Social Care Select Committee last year asked how many of the 1,500 maternity safety recommendations from HSIB had been implemented in full. The response from the Minister for Patient Safety and Primary Care, Maria Caulfield MP, responded as follows:

“Responsibility for monitoring the implementation of the Healthcare Safety Investigation Branch’s (HSIB) national patient safety recommendations rest with the recipient organisations. The National Patient Safety Committee, coordinated by NHS England and NHS Improvement, has established a pilot to examine how the implementation of all the HSIB’s national recommendations could be monitored, the potential resources required and information that may aid future evaluation. The National Patient Safety Committee’s draft report on the pilot is currently undergoing review and is expected to be finalised this year.

Responsibility for monitoring the implementation of the maternity safety recommendations made by the HSIB rests with individual National Health Service trusts. The HSIB works closely with trusts on addressing emerging themes from the investigations and has quarterly review meetings where trusts provide feedback on the actions being taken to implement the recommendations. The HSIB will raise any immediate concerns to the Department and NHS England and NHS Improvement via governance and assurance meetings.”⁵⁴

We appear to have no system of oversight in this area, no way of verifying that organisations are implementing safety recommendations from HSIB and no assessment of the effectiveness of actions to address the underlying causes of harm. This applies for actions are addressed to a specific organisation or where recommendations are made to the wider healthcare system more broadly.

Further to HSIB safety recommendations, there also appears to be a lack of clarity around the patient safety insights and learning drawn from their safety observations. It is not clear that there is any formal framework on a national level to consider these. It appears that these points are expressed in reports but then fall straight into the implementation gap, reliant on individuals or organisations deciding whether to consider any action at all. We consider this is far too ad-hoc an approach.

While HSIB plays an important role in investigating and uncovering serious patient safety issues, beyond the organisation promoting its own work, there appears to be a lack of a system-wide approach to sharing its findings and recommendations. This is coupled with a clear implementation gap, with a lack of means by which to assess this in a meaningful way.

Recommendation 2: HSIB reports and their recommendations need system wide commitment and resources, with effective and transparent performance monitoring to ensure that their recommendations translate into action and improvement.

3. Prevention of Future Deaths reports

When a patient dies because of avoidable harm, it is crucial that we learn and where possible implement changes to ensure that others are not similarly harmed. The findings and recommendations of Coroner’s Prevention of Future Deaths (PFD) reports can play a key role in this, helping to identify what went wrong and the actions needed to prevent a similar incident taking place in future. This does not just apply to the Trust in which the death

occurred, as learning may often be applicable beyond this organisation for wider system learning.

Table 6: Prevention of Future Deaths reports

There is a statutory duty for coroners to issue a PFD report to any person or organisation where, in the coroner's opinion, action should be taken to prevent future deaths.⁵⁵

The report must state the coroner's concerns and that in the coroner's opinion action should be taken to prevent future deaths. The report need not be restricted to matters causative (or potentially causative) of the death in question. The report must be sent to a person or organisation who the coroner believes has power to take such action. These reports are made publicly available on the Coroners Tribunals and Judiciary website with the organisations involved having a duty to respond within 56 days.

As with the work HSIB however, a significant gap emerges when it comes to the implementation of these reports' recommendations.

At an organisation level, how these reports are responded to appears to vary from trust to trust.⁵⁶ Nationally, there is no structured process for monitoring the implementation of safety recommendations contained in a PFD report. There is an open question about who is held accountable if the actions requested are not fully implemented, or if the response taken is ineffective. It is difficult to assess how healthcare providers go about this as there appears to be no specific system to monitor this.

There is also a barrier to sharing patient safety learning from PFD reports. Reports can often cover issues that may be applicable beyond the Trust where the death occurred. In some cases, these reports are sent to the organisation involved and a national body, such as the Department of Health and Social Care or the National Institute for Health and Care Excellence. While such organisations must formally respond, there is no set process for them to disseminate any guidance or changes that may result from this or report back on whether action has been taken.

Also, a Trust may take action to respond to the coroner's recommendation on a safety issue, which satisfies the coroner to the point where they feel that it is no longer necessary to issue a PFD report. In these cases, unless the Trust proactively shares this learning directly, the recommendation and action taken to address it may simply be lost, meaning the same incident could occur at another Trust in future.⁵⁷ In other cases the coroner may not recognise a point of wider learning and therefore may not send this to a national body who could potentially share this across the healthcare system.

Another factor that frustrates wider learning is that although these PFD reports are published online, they are not easily searchable or sharable. It is difficult to proactively draw out common themes, actions and response, highlighted in a recent thematic analysis of these reports published in the *Journal of Patient Safety And Risk Management*.⁵⁸ These limitations have also been recognised by the National Institute for Health Research School of Primary Care, who have now funded a separate website aimed at tracking and systematically analysing the information from PFD reports.⁵⁹

Further to this, it is not clear that NHS England and NHS Improvement currently undertake any central trend analysis or review to draw out common themes that may be applicable to all organisations, in the same way that the HSIB does when it publishes its investigation reports.

We currently lack assurance that safety recommendations arising from Coroners reports do not simply fall through the gaps in the system, resulting in preventable incidents of avoidable harm recurring.

Recommendation 3: The Coroner’s Prevention of Future Deaths system needs to be improved so that recommendations for patient safety improvements and organisational responses to the reports can be easily accessed. Processes need to be in place to provide assurance that learning from causal factors of avoidable deaths is captured consistently and the insight from these cases is disseminated and acted upon across all healthcare organisations.

4. When patients and families take legal action

When a serious incident in healthcare results in a clinical negligence claim, the processes around this can often provide an opportunity to understand what went wrong and the actions needed to prevent harm reoccurring. Such insights may often be applicable beyond the organisation in which the incident took place and provide a point for wider system learning.

NHS Resolution, the body responsible for providing expertise to the NHS on resolving concerns and disputes, identifies this as part its role. It publishes guidance on learning from clinical negligence claims and thematic reviews on specific areas of its work, such as *Learning from suicide-related claims* in 2018.^{60 61} While this work is important and commendable, there exists a significant implementation gap in this area regarding the learning which we draw from litigation processes.

Table 7: NHS Resolution

NHS Resolution is an arm’s-length body of the Department of Health and Social Care. It is responsible for providing expertise to the NHS on resolving concerns and disputes fairly, sharing learning for improvement and preserving resources for patient safety.⁶² It describes its key functions as:

1. Claims Management.
2. Practitioner Performance Advice.
3. Primary Care Appeals.
4. Safety and Learning.

Its fourth function is aimed at supporting “Claims Management service members to better understand their claims risk profiles to target their safety activity while sharing learning across the system”.

As the system currently operates, when clinicians are contacted as experts on litigation cases by a representative from the NHS Resolution ‘Panel of Solicitors’, as part of this process they are asked to feedback for any general points of learning to be shared across the NHS.

While this is a valuable approach in principle, in practice Patient Safety Learning has heard concerns from both clinicians and lawyers that their feedback has not been shared widely or acted on for improvement. We have contacted NHS Resolution about this process, who

have said that the primary way these general points of learning are fed back into the system is:

- Through their members – these are shared with NHS Resolution member organisations on individual cases, which can be used to subsequently inform their own organisational clinical governance and patient safety processes.
- For wider learning – these inform NHS Resolution's in-depth reviews and studies on specific subject areas.

NHS Resolution have advised us that due to the nature of the information involved in clinical negligence cases, for a combination of privacy, personal sensitivity, and legal reasons they are limited in the ways they can share these insights for learning and improvement.

While there is a degree of complexity involved with sharing such insights more widely, this still means we are missing an enormous and valuable opportunity to extract significant system-wide learning that could improve patient safety. These insights could be used to rapidly share information and opportunities for learning, and enable the Department of Health and Social Care, NHS England and NHS Improvement, CQC, HSIB, the incoming Patient Safety Commissioner's in England and Scotland, and others to identify emerging patient safety trends/concerns.

In its current form, we fail to fully utilise and implement learning from these processes, and we consider that this is an area that requires further review and action.

Recommendation 4: NHS England and NHS Improvement and NHS Resolution need to work together to improve the process for identifying the causal factors of unsafe care identified through litigation, ensuring this can be disseminated widely and acted on to improve patient safety.

5. Patient complaints

Complaints made about healthcare are potentially a powerful source for learning about avoidable harm. Shortfalls in the quality and safety of care that result in a complaint can present an opportunity to identify where problems have occurred in existing processes and procedures, enabling remedial action to be taken to prevent their reoccurrence. Learning from feedback from patients, including formal complaints, can help to identify both issues local to an organisation and those with wider applicability across the healthservice.

However, despite this potential as a source of patient safety insight, too often in healthcare these processes are viewed in a negative light or as a threat, with points for learning and improvement falling through the implementation gap.⁶³ This is an issue that comes up repeatedly when conducting investigations into major patient safety scandals.

The public inquiry into the Mid Staffordshire NHS Foundation Trust highlighted this issue, noting concerns that the Trust did not have a culture of listening to patients, along with inadequate processes for dealing with complaints. It stated that in the complaints that were responded to that “identifying issues and learning lessons” was not given a high enough priority.⁶⁴ The Inquiry made several specific recommendations aimed at creating an effective approach to handling patient complaints, which it described as:

“Patients raising concerns about their care are entitled to: have the matter dealt with as a complaint unless they do not wish it; identification of their expectations; prompt and thorough processing; sensitive, responsive and accurate communication; effective and implemented learning; and proper and effective communication of the complaint to those responsible for providing the care.”⁶⁵

Concerns about the failure of complaints processes to identify patient safety issues was also highlighted several years later by the IMMDS Review. It pointed to concerns about the complaints system as a whole, noting it was “both too complex and too diffuse” to promptly identify safety issues arising from a medication or device.⁶⁶ In common with the Mid Staffordshire Inquiry, the Review also noted serious concerns about patients not being listened to and the consequences this had for deterring future reporting:

“Dissatisfaction with how the system has responded to complaints, sometimes multiple, about named clinicians and individual Trusts has been a common thread throughout our engagement with those affected. If complainants feel their complaints are being disregarded unfairly they, and others, will be discouraged from reporting their concerns and the system’s culture of denial and resistance to acknowledging mistakes will continue unchallenged.”⁶⁷

Further to this, the Independent Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust, published in 2022, provides yet further evidence of complaints processes in the NHS failing patients. It highlighted concerns about a lack of senior oversight of complaints, an absence of transparency and dismissal of patient concerns. It raised specific concerns about a lack of learning from these processes, stating that:

“There is no evidence available that the Head of Midwifery, Director of Midwifery and Clinical Director were ever advisory on complaint responses before they were sent to the Trust’s Patient Experience Team for the then CEO’s signoff. Neither is there any evidence, that complaint themes and trends were analysed and used proactively to improve the service. Even in the latter years of the review period it was unclear what structure was in place for answering complaints and where the accountability lies.”⁶⁸

In response to this evidence that the existing patient complaints processes are not as effective as they should be and too often do not result in learning or improvement, there has been a recognition and acknowledgement of the need to change this.

In the wake of the Mid Staffordshire Inquiry, a Government commissioned review of NHS hospital complaints, co-chaired by Ann Clwyd MP and Tricia Hart, made a number of recommendations for change in complaints handling and procedures.⁶⁹ More recently the Parliamentary and Health Service Ombudsman (PHSO) have been piloting a new NHS Complaints Standards, which place a strong emphasis on senior leaders regularly reviewing what learning can be taken from complaints and how this can be used to improve services.⁷⁰ It sets out four criteria that define what an effective complaint handling system looks like:

1. Welcome complaints in a positive way
2. Is thorough and fair
3. Gives fair and accountable responses
4. Promotes a just and learning culture

While these principles are positive and admirable, the implementation gap in this area of patient safety has persisted despite many previous recommendations with similar aspirations, such as those from the Mid Staffordshire inquiry, as they have simply not been translated into change on the ground. The PHSO’s new standards, model procedure and guidance is currently being piloted at several sites and is due for rollout across the NHS in

2022. It is vital that the full rollout is effectively overseen, monitored, and evaluated if these aims are truly going to result in a move towards a complaints system and effectively seizes on the insights and learning from complaints processes to improve patient safety.⁷¹

Recommendation 5: The introduction of the new NHS Complaints Standards needs to be closely monitored, with clear guidance for organisations on how to implement this and clarity on who is responsible for this within the organisation. This should be accompanied by public transparent reporting by organisations on the rollout of the new standard, allowing for consistent monitoring and comparison.

6. Incident reports

A comprehensive approach to incident reporting is a crucial improvement tool in all safety-critical industries, alongside an open culture that supports the importance of this.⁷²

In the NHS, a key part of this is incident reports from individual organisations which are subsequently gathered and collated in the National Reporting and Learning System (NRLS). As noted earlier, NHS England is currently in the process of replacing this with its new Learn from patient safety events (LFPSE) service. This is being developed for use by patients and the public; while a public reporting facility does currently exist, it is not widely known, used nor do there appear to be reports published from this.

Table 8: National Reporting and Learning System

The NRLS is a central database of patient safety incident reports.⁷³

It was set up in 2003 by the National Patient Safety Agency, following the example set in other safety-critical industries like aviation and nuclear power.⁷⁴ It is a single national system for receiving incident reports from healthcare providers across the country, allowing patient safety for patterns, trends, and risks to be identified at a national level.

Most incidents are reported locally via risk management systems, providing the opportunity for local use before submission to the NRLS. From this system national patient safety alerts can be generated, requiring action to be taken by healthcare providers to reduce the risk of death or disability.

There is a separate incident reporting process regarding suspected side effects to medicine and medical devices, the Yellow Card scheme. This is operated by the Medicines and Healthcare products Regulatory Agency (MHRA), allowing voluntary reporting of problems by the public and healthcare professionals.

Table 9: The Yellow Card scheme

The Yellow Card scheme, run by the MHRA, can be used to report safety concerns in regard to:

- Medicines.
- Vaccines.
- Blood factor and immunoglobulin products.
- Herbal or complimentary therapies such as homeopathics.
- Medical devices.
- E-cigarettes including their refill containers (e-liquids).

The intention is that this system acts as an early warning for safety issues that may require further investigation. Reports are entered into a specialised database which the MHRA can then use to analyse reports and identify emerging safety issues that may require further investigation.⁷⁵

While these two systems provide, in theory, the means to gather patient safety insights and learning to inform improvement, questions are often asked as to how effective they are in reducing avoidable harm.

While incident reporting can provide a crucial tool for learning and improvement, there have been difficulties transferring this process from other safety-critical industries to healthcare, as noted by Dr Carl Macrae:

“...in translating incident reporting into healthcare from aviation, what was largely missed was that, in airlines and other industries, the rapid detection and resolution of safety issues depend on a deeply embedded and widely distributed social infrastructure of inquiry, investigation and improvement”⁷⁶

He notes that in healthcare much focus has been primarily on building the infrastructure for incident reporting systems and the inputs but less on the learning and outputs, that we have tended to “collect too much and do too little”.⁷⁷

The recently published report into cases of maternal and neonatal harm at Shrewsbury and Telford Hospital NHS Trust highlighted some of most serious problems incident reporting can encounter in the NHS. Despite the Trust having full reporting processes in place, the quality of investigations following these were poor and did not lead to learning and improvement. In its findings, the report noted that an external review by the Royal College of Obstetricians and Gynaecologists found that:

“... there was no culture of shared learning, that the RCAs often focused on the wrong issues, lacked system wide actions and focused instead on non-specific actions such as ‘share report widely’ and ‘learn from events’. There was no documentation that action plans were completed and recommendations often focused on individuals, rather than recommendations for system changes.”⁷⁸

Cultural issues can form a significant barrier to the effective use of incident reporting systems. One of these issues is that reporting is often misused as a form of reprimand or threat, leading one of the reporting systems most used in the UK, Datix, coming up time and time again as a verb with the threat “I’m going to Datix you”.⁷⁹ This can act as a detriment of reporting incidents for learning and action if involvement with this, or inclusion in a report, is associated with fear, retribution and blame.

Another cultural problem is the persistence of blame culture in parts of the NHS, resulting in a reluctance to report incidents, with staff concerned that they will not be treated fairly. This problem was highlighted in the recently published results of the NHS Staff Survey Results 2021, with over 160,000 of members of staff who responded not able to say that they would feel secure raising concerns about unsafe clinical practice.⁸⁰ In a closely related question of whether respondents felt safe to speak up about anything that concerns them in their organisation, 38% of respondents (approximately 240,000 members of staff) felt they could not say this was the case.⁸¹

NHS England and NHS Improvement is currently preparing to reform incident reporting with the creation of a new Patient Safety Incident Response Framework (PSIRF), outlining how providers should respond to patient safety incidents and how and when a patient safety investigation should be conducted.⁸² Recognising the need to reform the current approach to improve patient safety, and the implementation gap between investigating unsafe care and applying the learning for improvement, it has stated that:

“We know that organisations are struggling to deliver good quality investigations that consistently support the reduction of risk. As a result, opportunities to reduce patient safety incidents can be missed.”⁸³

It states that the new approach being taken by PSIRF’s:

“... refocuses systems, processes and behaviours on delivering a sustained reduction in risk, rather than simply applying a reactive, bureaucratic process that too often does not lead to change.”⁸⁴

PSIRF is being introduced in a phased approach: first supporting several ‘early adopter’ systems of healthcare providers and commissioners to do so and then using their experiences to inform its wider implementation across the NHS.

While the approach is commendable, a recent evaluation pilot highlighted concerns regarding the availability of training and investigation methodology.⁸⁵ This complex and NHS wide change needs to be well led and resourced to achieve its aims. Patient Safety Learning are working with its partners to monitor the implementation of PSIRF and assess the effectiveness of its ambition to close the ‘implementation gap’ from investigation and reviews of local incidents of avoidable harm. We will be reviewing with interest how the implementation of PSIRF is being supported monitored and evaluated against its ambitious aims to ensure that incident investigation and other sources of insight leads to action for improvement and the reduction of avoidable harm.

Turning to the Yellow Card Scheme, the IMMDS Review raised serious concerns about the effectiveness of this in preventing avoidable harm. In describing how the healthcare system struggles to identify medication and device safety issues, it said:

“For decades there has been something known as the ‘Yellow Card’ system through which clinicians, and indeed patients, can report suspected adverse reactions to treatment. But it is clear that there is gross under-reporting, and our complaints systems are both too complex and too diffuse to allow early signal detection.”⁸⁶

While noting improvements had made to the Yellow Card scheme to improve its accessibility, the report noted that this remained “not well recognised or routinely used” and not simply among patients, but also among healthcare professionals. Considering this criticism, the Government and MHRA have both outlined ongoing work and plans in place improve the Yellow Card scheme.⁸⁷

While incident reporting can be a vital source of learning and insights, the limitations in our current systems and how we follow up on incidents makes it difficult for us to comprehensively translate the data we collect into practical patient safety improvements. We think there are huge opportunities to use real time performance data, using Artificial Intelligence and other approaches, to proactively capture insights into the causes of avoidable harm, insights the NHS and from patients that can provide feedback on clinical performance and the safety in use of medical devices and drugs.

Recommendation 6: NHS England and NHS Improvement and the MHRA must ensure that the development of the new PSIRF and changes to the Yellow Card scheme have a core focus on learning for action and improvement to tackle the implementation issues highlighted in this report.

Common themes

Having considered these six areas where the policy implementation gap undermines our ability to translate patient safety insights and learning into practical improvements, several common themes emerge:

a) Absence of a systemic and joined-up approach

Across each of these areas there is a lack of coordination in how we respond to incidents of avoidable harm in healthcare and the insights and learning that emerge from them.

To take the example of public inquiries and reviews, in the absence of processes to track the implementation of their recommendations, we see both the Government and NHS time and time again respond through separate processes to individual reports that highlight similar systemic patient safety issues. Recurring themes include a blame culture deterring incident reporting and speaking up about safety issues, failure to listen to and dismissal of patient concerns and a lack of engagement by the organisation/s leadership in patient safety. Despite these common threads however, responses to these reports often appear to be dealt with in isolation, rather than considered as part of this wider context.

In a recent example of this, the Government's response to the Paterson Inquiry (published in February 2020) and the IMMDS Review (published in July 2020) were conducted through separate processes, which differed considerably, without reference to each other. While these concerned quite different medical interventions, they also featured significant common patient safety themes around failing to listen and learn from patients after incidents of harm, failing to learn from complaints and gaps in patient safety leadership.

If we are to effectively act on and implement the wide-ranging changes needed to improve patient safety, we need to ensure that the healthcare system's responses to serious patient safety failings do not simply focus on the latest report into avoidable harm. It is important that the Department of Health and Social Care considers recommendations that have been made by and accepted in the past, avoiding making the same recommendations without considering why change has failed to happen. Currently it is far from clear that inquiries and reviews where there are overlapping patient safety themes are being looked at in a coordinated fashion. The healthcare system needs to understand and address the barriers for implementing recommendations, not just continually repeat them.

b) Poor systems for sharing learning and acting on that learning

Another consistent theme across these different areas of the implementation gap is poor or absent systems to share patient safety insights and learning.

Too often when effective solutions are found to prevent avoidable harm there is simply a lack of means by which to share these more widely. This gap between learning and implementation means that while we may know what improves patient safety, this information can often remain siloed in specific organisations and health care systems, resulting in patients continuing to experience harm from problems that have already been addressed by others.

This is notable in the case of recommendations from coroners' reports, where there is no structured process for widely sharing the action taken to implement of safety recommendations contained in a PFD report beyond the organisation in question. This manifests itself in a different way in regards to cases where patients and families take legal action. While there are thematic reviews stemming from these cases and sharing learning, local learning and actions in response to incidents may often not be extracted from these processes and shared widely, with legal reasons cited as a barrier preventing this.

In the case of HSIB reports, while there more developed systems to share learning and insights in place, there are significant gaps. This is true of formal recommendations but is particularly pertinent when considering HSIB's safety observations. While theses may provide useful points of learning and improvement there appears to be no system to disseminate or act on these, beyond them being published towards the end of numerous patient safety reports.

In the absence of effective systems to share learning, and with gaps in existing systems, it becomes sadly inevitable that healthcare system continues to fail to learn from our mistakes and the same incidents of avoidable harm reoccur. As a result of this we not only do not always share knowledge of new risks and concerns, but also miss opportunities to learn from good practice. In some cases, organisations may have innovative responses to coroners or HSIB recommendations which improve patient safety. But without the mechanisms to share how this work is done, this knowledge can remain trapped within organisations.

Both our failures to share learning from mistakes and examples of good practice point to a wider challenge – we struggle in healthcare to share more generally, whether as a result of cultural resistance or simply a lack of capacity. At Patient Safety learning we recognise this issue and through our work have developed *the hub*, an online platform for patients, clinicians, managers, and health and social care system leaders to share learning about safety practice and performance.⁸⁸ However we also need the NHS to have better routes to share insights and knowledge for learning from avoidable harm and improvement.

c) Lack of system oversight, monitoring, and evaluation

In each of the six areas outlined in this report there is a clear problem of the overall healthcare system lacking the ability to monitor and evaluate the effectiveness of patient safety recommendations.

The recommendations of some inquiry reports are monitored, however for others the timeframes and progress associated with these are at best opaque. We just do not know whether action is being taken and how effective it is. As noted by the National Audit Office, there is no central means for tracking or monitoring whether recommendations have been implemented.⁸⁹

Considering patient complaints, there are significant variations amongst different hospitals concerning how they report on complaints, in terms of the data provided publicly, and what they do in response to these complaints. A recent report by Healthwatch England highlighted the difficulty this creates in analysing whether learning on patient safety issues raised from patient complaints translate into learning and practical improvements:

“Earlier this year, we asked hospital trusts a series of questions about their handling of complaints through a Freedom of Information request. In total we had responses from 120 trusts, with 78% telling us that they publish outcomes or learning taken from complaints. Worryingly, we were only able to find evidence of report on learning from complaints for 38% of trusts. This shows that although trusts may believe they are demonstrating learning, this information is not actually accessible to the public.”⁹⁰

In the case of recommendations from coroners’ PFD reports and HSIB reports, organisations have a duty to respond within a specific timeframe. However, once their response has been provided, the implementation of any changes is the responsibility of the organisation themselves and is not monitored. There are no means by which to verify their implementation or assess their effectiveness.

Frustration at this process can be seen in reports from coroners’ who express concerns that they are seeing deaths occur in similar circumstances without action being implemented to address these issues. Commenting in a PFD report into the death of a patient who fell five times during a hospital stay, Coroner Caroline Saunders noted in her matters of concern that:

“During the inquest I was presented with an action plan, however this is not the first action plan I have been presented with (in very similar circumstances) and sadly I am not convinced that this plan will prevent future deaths for the following reasons. The policies referred to above have been in place for several years. I am informed that although there is bespoke documentation training, all staff are trained in falls risk assessment from the time they are in nurse training. Therefore, it is not a lack of understanding or policies which have caused these failures.”⁹¹

In the case of HSIB reports, there is no existing system of oversight, no way of verifying that organisations are implementing safety recommendations from HSIB and no assessment of their effectiveness. As noted in the recent response to a parliamentary question by Jeremy Hunt MP, this is being explored by the National Patient Safety Committee, but at this time no firm proposals have been produced.

In many cases, we simply lack the tools to measure what action is being taken to implement the recommendations or to assess their impact in reducing avoidable harm in healthcare. This must be an urgent action for the NHS leadership.

d) Unclear patient safety leadership

The three themes above all feed into a broader issue, the weakness in system-level leadership for patient safety. This is not a new problem, previously identified in a 2018 report by the CQC, *Opening the door to change*, which stated:

“Arm’s-length bodies, including CQC, royal colleges and professional regulators, have a substantial role to play within patient safety, but the current system is confused and complex, with no clear understanding of how it is organised and who is responsible for what.”⁹²

At a national level in England, the approach is fragmented with no clear lead body. Different aspects of patient safety are monitored and overseen by the National Patient Safety Team in NHS England, the Healthcare Safety Investigation Branch, the CQC and the MHRA. There are separate regulators in Northern Ireland, Scotland, and Wales, all with patient safety responsibilities. This landscape will be further complicated with the creation of independent Patient Safety Commissioners in England and Scotland and the recently announced new Special Health Authority for Independent Maternity Investigations.⁹³

While there are undoubtedly reasons for this division in roles and responsibilities, persistent and new threats to patient safety are rarely neatly contained within a single domain or part of the UK. In this complex governance environment, there is no obvious central point that can identify and coordinate the response to the policy implementation gaps highlighted in this report.

In February 2021 the Government established a National Patient Safety Board, whose membership includes officials from the Department of Health and Social Care, NHS England and the CQC. Its role is set out in its Terms of Reference as:

“Programme Board to ensure key leaders and stakeholders are collectively involved in the development and progress of the NHS Patient Safety Strategy and the policy areas where there is a significant patient safety element, including maternity, complaints and clinical negligence cost reduction, as outlined in annex A. The Board will identify gaps and ensure collective action across Government to reduce barriers to the delivery of patient safety via collaboration, partnership and prioritisation across organisations and work programmes with joined up, forward looking planning.”⁹⁴

While this could potentially become a nascent central body for coordinating patient safety activity across the system, it is unclear to the extent to which it is likely to do so. It is currently not publicly promoted and there is little transparency around its activities and remit with no agendas, reports or minutes from its meetings currently published. Its role also appears focused solely on healthcare in England.

Another national body that exists is the National Quality Board. Formed in 2009, it:

“... champions the importance of quality and drives system alignment of quality across health and care on behalf of NHS England and Improvement, NHS Digital, the Care Quality Commission, the Office of Health Promotion and Disparities, the National Institute for Health and Care Excellence, Health Education England, the Department of Health and Social Care, and Healthwatch England.”⁹⁵

Its minutes and agendas are published in the public domain; however, it does not appear to have a remit to oversee the insights from inquiries, reports, and other sources of learning nor the performance management of recommendations to ensure learning and improvements for the reduction of avoidable harm.

With this fragmented approach to patient safety leadership, the Secretary of State for Health and Social Care currently lacks the levers and means to address the implementation gap outlined in this report and cannot with confidence assure current and prospective patients patient safety is being placed at the core of healthcare

Patient safety as a systems issue

Despite the growing recognition of the need to make significant improvements to patient safety, and the hard work of many people involved in the sector, avoidable harm continues to persist at an unacceptable rate, fed by its systemic causes. Patient Safety Learning believes that to address this we need to think and act differently, making a transformation change in our approach to patient safety.

Patient safety is typically seen as a strategic priority. This sounds important, but it means that, in practice, health and social care decision-makers will weigh (and inevitably trade-off) the importance of patient safety against other priorities, like finances, resources or efficiency.

We believe that patient safety is not just another priority: it is core to the purpose of health care. Patient safety should not be negotiable.

In doing this we need to address the underlying system causes of avoidable harm. In our report, *A Blueprint for Action*, underpinned by systemic analysis and evidence, we identify six foundations of safe care for patients and these practical actions to address them:⁹⁶

- 1) **Shared Learning** - organisations should set and deliver goals for learning, report on progress and share their insights widely for action. It is not enough to say, 'we've learned from incidents of unsafe care', we need to see action for improvement and impact.
- 2) **Leadership** - we emphasise the importance of overarching leadership and governance for patient safety. This is not just about governance; it is about behaviours and commitment too.
- 3) **Professionalising patient safety** - organisations need to set and deliver high standards for patient safety. These need to be used by regulators to inform their assessment of whether organisations are doing enough to prevent avoidable harm and assess whether they are safe.
- 4) **Patient Engagement** - to ensure patients are valued and engaged in patient safety, at the point of care, if things go wrong and for redesigning health care for safety.
- 5) **Data and Insight** - better measurement and reporting of patient safety performance, both quantitative as well as qualitative.
- 6) **Just Culture** - all organisations should publish goals and deliver programmes to eliminate blame and fear, introduce or deepen a Just Culture and measure and report progress.

Bridging the implementation gap

What does taking a systems approach, and placing patient safety as part of the purpose of health and social care, mean for tackling the implementation gap?

There is no silver bullet, the system-wide change we need detailed above goes far beyond the specific areas of concern highlighted in this report. We need to place patient safety and staff safety at the heart of our healthcare system. This also applies to all parts of the system,

including Integrated Care Systems set to become new statutory bodies from July 2022. We need everyone, politicians, policymakers, patients, families and communities, clinicians, managers, system and professional regulators, researchers and academics, and health and social care system leaders involved in this effort.

We are calling the Government, parliamentarians, and NHS leaders to take action to address the underlying causes of avoidable harm in healthcare and inviting them to engage in a system-wide debate about how healthcare can reshape its approach to learning and safety improvement. We also detail specific recommendations relating to the areas of the implementation gap highlighted in this report, which we hope can form part of a public discussion.

We will be writing to leadership organisations outlining these recommendations and welcome responses from them on our proposals.

Recommendations

- 1. Patient safety inquiries and reviews need system-wide commitment and resources, with effective and transparent performance monitoring to ensure that the accepted recommendations translate into action and improvement.**
- 2. HSIB reports and their recommendations need system-wide commitment and resources, with effective and transparent performance monitoring to ensure that their recommendations translate into action and improvement.**
- 3. The Coroner's Prevention of Future Deaths system needs to be improved so that recommendations for patient safety improvements and organisational responses to the reports can be easily accessed. Processes need to be in place to provide assurance that learning from causal factors of avoidable deaths is captured consistently and the insight from these cases is disseminated and acted upon across all healthcare organisations.**
- 4. NHS England and NHS Improvement and NHS Resolution need to work together to improve the process for identifying the causal factors of unsafe care identified through litigation, ensuring this can be disseminated widely and acted on to improve patient safety.**
- 5. The introduction of the new NHS Complaints Standards needs to be closely monitored, with clear guidance for organisations on how to implement this and clarity on who is responsible for this within the organisation. This should be accompanied by public transparent reporting by organisations on the rollout of the new standard, allowing for consistent monitoring and comparison.**
- 6. NHS England and NHS Improvement and the MHRA must ensure that the development of the new PSIRF and changes to the Yellow Card scheme have a core focus on learning for action and improvement to tackle the implementation issues highlighted in this report.**

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The Inquiry into Hyponatraemia-related Deaths

Report

January 2018

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The Inquiry into Hyponatraemia-related Deaths

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Preamble

- 1.1 In June 2001 nine year old Raychel Ferguson was admitted to the Altnagelvin Area Hospital in Derry. She underwent routine surgery but did not recover as expected. She vomited repeatedly and her condition deteriorated. Her parents voiced concern. Within 48 hours of admission Raychel had suffered brain death. Mr and Mrs Ferguson were not satisfied with the explanation they were given for her death.
- 1.2 In February 2003 the Coroner at Raychel's inquest found that her death had been caused by hyponatraemia brought about by an intravenous ('IV') fluid therapy which had given her inadequate sodium replacement in the context of vomiting and water retention. Reference was also made at the inquest to the death of another child in Northern Ireland from hyponatraemia, that of Adam Strain.
- 1.3 Mr and Mrs Ferguson were determined to question why their daughter had died. They were not alone. Investigative journalists at Ulster Television ('UTV') also questioned her death and broadcast a documentary in February 2003 drawing attention to hyponatraemia and the clinical failings in Raychel's case.¹
- 1.4 At the same time, and in response to the inquest, the Chief Officer of the Western Health and Social Services Council ('WHSSC') drew the Coroner's attention to the death in 2000 of a child called Lucy Crawford because her case had similarities to Raychel's. He asked whether an inquest into Lucy's death might not have saved Raychel.²
- 1.5 The UTV team then added Lucy's case to their investigation and, in October 2004, broadcast a further documentary entitled 'When Hospitals Kill' which examined the deaths of Raychel, Adam and Lucy.³ It claimed that all had died from hyponatraemia because all had been given too much of the wrong type of fluid. The programme raised concerns about a failure to learn

¹ UTV 'Insight' 27-02-03 'Vital Signs'

² 006-012-297

³ UTV 'Insight' 21-10-04 'When Hospitals Kill'. UTV also treated the issue in 'The Issue' 25-03-04.

lessons and the possibility that there had been a deliberate 'cover-up'. It criticised clinicians, Trusts and the Chief Medical Officer.

- 1.6 The programme provoked considerable media interest and public disquiet. Concern was widespread and Ms Angela Smith MP, then Minister with responsibility for Health in Northern Ireland, was obliged to take action. In November 2004 she announced that *"in pursuance of the powers conferred by Article 54 and Schedule 8 of the Health and Personal Social Services (Northern Ireland) Order 1972, the Department of Health, Social Services and Public Safety hereby appoints Mr John O'Hara QC to hold an Inquiry into the events surrounding and following the deaths of Adam Strain, Lucy Crawford and Raychel Ferguson."*⁴
- 1.7 The Minister emphasised that it is *"of the highest importance that the general public has confidence in the quality and standards of care provided by our health and social services."* The Department of Health, Social Services and Public Safety for Northern Ireland ('the Department'), recognising that public confidence in the Health Service had been undermined, granted the Inquiry broad terms of reference so as to permit the concerns of families and public alike to be addressed.
- 1.8 The terms of reference required inquiry into:
- (i) The care and treatment of Adam Strain, Lucy Crawford and Raychel Ferguson, with particular reference to the management of fluid balance and the choice and administration of intravenous fluids in each case.
 - (ii) The actions of the statutory authorities, other organisations and responsible individuals concerned in the procedures, investigations and events which followed the deaths of Adam Strain, Lucy Crawford and Raychel Ferguson.

⁴ 303-034-460

- (iii) The information and explanations given to the respective families and others by the relevant authorities.

Additionally, discretion was granted me to examine and report on any other matter I should think relevant and to make such recommendations to the Department as I should think fit.

- 1.9 The UTV documentary was also watched by the parents of Claire Roberts who had died in the Royal Belfast Hospital for Sick Children ('RBHSC') or ('the Children's Hospital') in 1996. Her death had not been reported to the Coroner and her parents had never really understood why she had died. When Mr and Mrs Roberts watched the programme they immediately recognised similarities with their own daughter's case and were prompted to ask questions. Subsequent investigation and inquest revealed that hyponatraemia had played a part in her death too. I added Claire's case to those I had been originally tasked to investigate because hyponatraemia was implicated and she had died in the same hospital as Adam. In addition to my obvious concern about the treatment Claire had received, I was troubled by the failure to report her death to the Coroner in 1996 and about what was revealed at her inquest 10 years later.
- 1.10 In May 2008, and for private reasons, Mr and Mrs Crawford requested that the Minister withdraw Lucy's case from the scope of my Inquiry. This request was respected and the terms of reference revised. However, concern was then raised that had the circumstances of Lucy's death been made known at the time of her death and had appropriate lessons been learnt, then the deficient therapy given Raychel 14 months later might have been avoided and her life spared. Accordingly it was urged upon me that examination of what happened after Lucy's death was integral to the Inquiry into Raychel's case and should therefore be pursued.
- 1.11 I found this persuasive, and having issued a consultation paper on the issue in 2009 and received extensive response, I decided in February 2010 that the terms of reference both permitted and required investigation into what

had transpired after Lucy's death.⁵ Accordingly, I directed that that part of her case be examined by the Inquiry.

- 1.12 In the course of conducting this Inquiry, 4 other deaths were brought to my attention. I considered them in detail and having satisfied myself that hyponatraemia was not implicated, determined that they required no further investigation. Notwithstanding, it cannot be assumed that there were no other child deaths in Northern Ireland from hospital related hyponatraemia during the period under scrutiny.
- 1.13 In examining the issues it also became necessary to determine whether the Department's 'Guidance on the Prevention of Hyponatraemia in Children,' issued in 2002, was being followed in Northern Ireland's hospitals. The death in 2003 of 15 year old Conor Mitchell in Craigavon Area Hospital was not a death from hyponatraemia but it was a case in which concerns were raised about whether the Departmental guidance had been followed properly, or at all. I directed that his case be examined in order to scrutinise an actual implementation of the hyponatraemia guidance and to ascertain whether concrete change in practice had resulted.
- 1.14 I think it important to acknowledge the role played by informed investigative journalism in revealing the extent of the hospital mismanagement in these sad cases. But for the UTV documentary, the close public scrutiny of this Inquiry would not have happened and Mr and Mrs Roberts might never have learnt what really happened to Claire. Whilst the process of inquiry has been long and costly and the amount of information gathered considerable, it is to be recognised that the essential issues as identified by the initial UTV investigation remain as they were. This Inquiry found a Health Service that had been largely self-regulating and unmonitored. In such circumstances the value of independent and inquiring journalism cannot be overstated.

⁵ 303-037-466

Process

Inquiry procedures

- 1.15 Upon appointment I directed the following protocols to govern procedures, namely:
- (i) General Procedure.
 - (ii) Oral Hearing.
 - (iii) Interested Parties.
 - (iv) Documents.
 - (v) Witnesses.
 - (vi) Experts.
 - (vii) Costs.
 - (viii) Disclosure.
 - (ix) Consultation with, and questioning of, Witnesses.

These protocols were amended from time to time as was necessary and are to be found on the Inquiry website at www.ihrdni.org

Counsel

- 1.16 Counsel were appointed to assist in identifying and investigating relevant issues, the analysis of evidence and the examination of witnesses at public hearings. Legal advices were sought from counsel and received. These duties were performed with great distinction by counsel to the Inquiry, Ms Monye Anyadike-Danes QC and her juniors, Martin Wolfe QC, Jill Comerton, David John Reid, James Anderson and John Stewart.

Solicitors

- 1.17 An immense debt of gratitude is owed Anne Dillon, Solicitor to the Inquiry. With patience and expertise she assisted and guided at every turn. She was preceded in this role with no less distinction by Fiona Chamberlain. The Inquiry also received the assistance of Brian McLoughlin, Htaik Win, Brian Cullen, Caroline Martin and Clare McGivern. To them I extend my gratitude.

The Secretariat

- 1.18 The Secretary to the Inquiry, Mrs Bernie Conlon, together with her deputies Ms Denise Devlin and Miss Leanne Ross rose to the formidable challenge of creating and managing the structures and office of the Inquiry. They were assisted by a dedicated and hard-working team. Their administration was one of great professionalism and the tasks performed by them, with efficiency and good grace, were beyond number. I particularly wish to place on record my admiration for the caring and sensitive support given intuitively by them to many of the witnesses to the Inquiry. Given the stresses and sensitivities involved this cannot have been easy and was of considerable assistance to all.

Conflict of Interests

- 1.19 All who worked for the Inquiry were required to and did sign a 'Declaration of Interests' for the purposes of confirming the credentials of independence underpinning the Inquiry.

Documentation

- 1.20 The Inquiry, having been established pursuant to the Health and Personal Social Services (Northern Ireland) Order 1972, enjoyed broad powers to compel the production of documents.
- 1.21 A very considerable volume of documentary evidence was received and collated. Documents were filed in an electronic management system, with

each page given a 9 figure identifying number, comprising a file number (first 3 figures), the document number (second 3 figures) and page number (final 3 figures). These are available on the website. Irrelevant and protected information was redacted. Documents and materials which were subject to legal privilege or which failed to satisfy the tests of relevance or fairness were excluded from consideration and do not appear on the Inquiry website.

- 1.22 In order to marshal and present aspects of the very extensive information gathered, a number of tables, schedules, charts and chronologies was compiled for summary and reference. These too may be found on the website.
- 1.23 The Inquiry website is the archive for documents released by the Inquiry. It includes transcripts of public hearings, openings, witness statements, exhibits, expert reports, medical notes and records, charts, schedules, briefing papers, memoranda and other relevant materials. This record amounts to more than 113,000 pages and 12,650 documents. All documents comprising the Inquiry record will be deposited with the Public Record Office for Northern Ireland and access to the website will be maintained within the Record Office web archive. Accordingly, it is unnecessary to append specific documents to this Report.

Expert witnesses, advisors and peer reviewers

- 1.24 Respected specialists were retained by the Inquiry to advice and report on relevant aspects of clinical care as well as hospital management and governance. Many of these experts gave evidence at the public hearings. Their invaluable contribution is gratefully acknowledged. In addition, a number of expert background briefing papers were commissioned advising on matters ranging from fluid management training for nurses (1975-2009)

to post-mortem practice, coronial process and statistics. They are to be found on the Inquiry website.⁶

1.25 I wish to acknowledge the guidance of the team of expert advisors who assisted the work of the Inquiry. To Dr Harvey Marcovitch in paediatrics, the late Dr Peter Booker in paediatric anaesthetics, Ms Carol Williams in nursing and Ms Mary Whitty and Mr Grenville Kershaw in health service governance and management, I owe a debt of gratitude. Independent of the Health Service in Northern Ireland the advisors submitted their assessment of matters to be considered at the public hearings. Their reports are to be found on the Inquiry website.

1.26 The work of the advisors was in turn 'peer reviewed' by leading international experts Dr Desmond Bohn (paediatric anaesthesia) and Dr Sharon Kinney (paediatric intensive care nursing). Their signal contribution is to be recognised.

1.27 Additionally, I received expert assistance in finalising my draft recommendations from Professor Gabriel Scally (Professor of Public Health and Planning and one time Regional Director of Public Health, NHS England 1996 – 2012) and Dr Tracey Cooper (Chief Executive for Public Health, Wales and former Chief Executive of the Health Information and Quality Authority, Ireland). They advised as to whether my draft recommendations were realistic and achievable and, where appropriate, suggested refinement.

Witnesses and Interested Parties

1.28 In accord with convention, the Inquiry sought and received an undertaking from the Director of the Public Prosecution Service that the evidence of witnesses would not be used in criminal proceedings against them.⁷ This was done to encourage co-operation.

⁶ http://www.ihrdni.org/background_papers.htm

⁷ 370-048-001

- 1.29 Evidence was sought initially from potential witnesses by way of detailed questionnaires known as witness statement requests. Supplementary witness statements were then sought to clarify and particularise. The Inquiry received 538 individual witness statements but some were of lesser importance than others and not all witnesses were asked to give oral testimony. A list of all who provided evidence to the Inquiry may be found at Appendices 4 and 5.
- 1.30 I designated family members and key witnesses ‘interested parties’ in accordance with protocol. Doctors, nurses, managers and healthcare professionals were named in this way together with the Department, HSC Trusts and others. Interested parties became entitled to legal representation at the public hearing, were allowed to make submissions, suggest lines of questioning and on occasion to question witnesses. A full list of those accorded interested party status is provided at Appendix 6

List of Issues

- 1.31 These reflected the terms of reference as revised and the evidence as received. They were subject to comment and suggestion from interested parties and are to be found on the Inquiry website.

Background

Hyponatraemia

- 1.32 The shared fate of Adam, Claire, Lucy and Raychel was to suffer hyponatraemia, a condition in which the concentration of sodium in the blood falls below safe levels. It can result from excessive sodium losses, caused for example by vomiting, or can arise in a number of different ways. One variant is dilutional hyponatraemia in which excess fluid in the system reduces sodium levels by dilution. The less sodium in the excess fluid, the greater the dilution. Excess fluid can be introduced by excessive intravenous infusion or can result from excess water retention, or a combination of both.

- 1.33 Children can react to illness or surgical stress with a recognised Syndrome of Inappropriate Anti-Diuretic Hormone secretion ('SIADH') which inhibits urine production and causes water retention. The resultant increase in the amount of water in the blood leads to dilution of its sodium concentration. This can become problematic if the sodium level is already low. Thus, for example, if sodium rich fluids lost through vomiting are replaced by sodium light fluids (such as an intravenous low saline solution) in the presence of anti-diuretic hormone activity, the inevitable result will be a lowering by dilution of already lowered sodium levels and ultimately a dilutional hyponatraemia. If left untreated, the fall in the sodium concentration will induce cerebral oedema causing raised intracranial pressure, respiratory arrest, coma and potential brain-stem death. The symptoms of hyponatraemia are often lethargy, headaches, nausea and vomiting. The severity of the symptoms relates to the rate at which the sodium level falls. A diagnosis is made easily by assessing the serum sodium levels. Accordingly, safe IV fluid management of a child with sodium losses cannot be assured without testing the sodium levels and understanding the fluid balance. Because such a patient is the subject of active fluid therapy, dilutional hyponatraemia should not happen in a hospital. It is a preventable hospital illness.

Solution No. 18

- 1.34 In each of the cases examined in this Report (excepting only Conor) the patient was given intravenous infusion of a fluid known as Solution No.18, so called because it contains only 0.18% sodium chloride. This is deemed a low saline or hypotonic solution because it contains only about 1/5 of the sodium and chloride found in blood. Because it is so low in sodium it cannot replace sodium lost through vomiting or diarrhoea and can, if administered excessively or too quickly, create a dilutional effect on sodium levels resulting in hyponatraemia. It is not dangerous of itself, but can become so if given inappropriately in the presence of established sodium losses or SIADH.

- 1.35 The risks of using low sodium solutions such as Solution No.18 and the dangers of dilutional hyponatraemia were understood from the early 1990s. In a leading paper published in the British Medical Journal ('BMJ') in 1992,⁸ Professors Arieff, Ayus and Fraser concluded that *"symptomatic hyponatraemia can best be prevented by not infusing hypotonic fluids to hospitalised children unless there is a clear cut indication for their use."*⁹ Notwithstanding and despite similar subsequent warnings in the medical literature, it is clear that even at the time of Raychel's death, Solution No.18 remained the standard IV solution for general use with children.
- 1.36 In consequence of Raychel's death, Dr Henrietta Campbell¹⁰ the Chief Medical Officer ('CMO'),¹¹ directed that the Department issue Guidance on the Prevention of Hyponatraemia in Children.¹² This was published in March 2002 specifically warning that *"hyponatraemia may occur in any child receiving any IV fluids... vigilance is needed for all children receiving fluids."* It gave clear advice for the regular monitoring of fluid balance, the regular evaluation of sodium levels and the accurate calculation of IV fluid requirements. Fluids were specifically to be prescribed as maintenance fluids to meet anticipated fluid requirements or as replacement fluids to replace fluids and sodium actually lost. This was a most valuable guideline and the first of its kind in the UK. The work of providing guidance was thereafter undertaken by the National Patient Safety Agency ('NPSA').¹³ By 2010 the Regulation and Quality Improvement Authority ('RQIA') was able to report that Solution No.18 had been removed from all clinical areas where children might receive treatment.¹⁴

⁸ 070-005-018

⁹ 070-005-018

¹⁰ 337-001-002

¹¹ 338-001-001

¹² 007-003-004

¹³ 303-026-350

¹⁴ 303-031-435

The Children

Adam Strain

1.37 Adam was born on 4th August 1991 and died on 28th November 1995 at the RBHSC having undergone renal transplant surgery. He was born with kidney abnormality and, having suffered multiple problems, was placed on the transplant register and admitted for kidney transplant on 26th November 1995. He did not survive surgery. As with the other cases being examined he received intravenous infusion of Solution No.18. His death was scrutinised at inquest and found to have been caused by cerebral oedema brought about by the acute onset of hyponatraemia suffered in consequence of an excess administration of fluids containing only very small amounts of sodium. There may also have been other factors combining with this underlying cause. The consultant anaesthetist responsible for the management of Adam's fluids refused to accept that Adam had suffered dilutional hyponatraemia.¹⁵

1.38 In the course of Adam's inquest, draft 'Recommendations for the Prevention and Management of Hyponatraemia arising during Paediatric Surgery'¹⁶ were submitted by the RBHSC paediatric anaesthetists in order to reassure the Coroner as to the future management of such cases. These recommendations specifically referenced Professor Arieff's paper on hyponatraemia and indicated that all anaesthetic staff would be made aware of the complications of hyponatraemia. The recommendations were not however circulated, and the opportunity to familiarise clinicians in the RBHSC and elsewhere with the risk to children of dilutional hyponatraemia in the context of IV infusion of hypotonic solution was lost.

Claire Roberts

1.39 Four months after the inquest into Adam's death Claire Roberts was also admitted to the RBHSC. She was nine years old and had a past history of

¹⁵ 093-038-238

¹⁶ 060-018-036

convulsions in early childhood. On 21st October 1996 she was referred by her GP to the RBHSC with symptoms of vomiting, malaise and drowsiness. In light of her medical history it was thought that she could be suffering seizures. She was admitted and placed on an IV infusion of Solution No.18. Her blood tests revealed slightly lower than normal sodium levels but her sodium was not then reassessed over the next 24 hours despite the fact that she was receiving a continuous infusion of Solution No.18. Her condition did not improve, her consciousness reduced and the doctors did not know what was wrong with her. No further tests were performed. She was then given too much of an anti-convulsant medication, her levels of consciousness declined further and early in the morning of 23rd October she suffered respiratory arrest and was transferred to the Paediatric Intensive Care Unit ('PICU') where she died. Her death was not reported to the Coroner and only a partial autopsy was performed. A death certificate was issued citing cerebral oedema and status epilepticus as the cause of her death. Mr and Mrs Roberts were led to believe that Claire may have suffered encephalitis.

- 1.40 Eight years later, having watched the UTV programme about the deaths of Adam, Lucy and Raychel and recognising similarities with Claire's case, Mr and Mrs Roberts contacted the RBHSC. They queried the management of her fluids and asked whether hyponatraemia might not have played a part in her death. Only then was the Coroner notified. He conducted an inquest in May 2006 and found that hyponatraemia due to SIADH had contributed to the cerebral oedema which caused her death. He also found an indeterminate contribution from meningo-encephalitis and status epilepticus.

Lucy Crawford

- 1.41 Lucy was born on 5th November 1998 and admitted to the Erne Hospital on 12th April 2000 with a history of drowsiness and vomiting. The vomiting may have caused dehydration and she was assessed an appropriate candidate for IV fluid replacement. Blood tests revealed normal sodium levels and an

IV infusion of Solution No.18 was commenced. However, she was given an excessive volume of Solution No.18 at an excessive rate. In the early hours of 13th April she suffered a seizure. Her serum sodium levels had fallen significantly since admission. She was transferred to PICU in the RBHSC where she was pronounced dead the following day. Her death was not formally notified to the Coroner. A hospital post-mortem was performed and a death certificate issued citing cerebral oedema due to dehydration and gastroenteritis as the cause of death. Lucy's parents were concerned with the treatment she had received at the Erne Hospital and did not feel that the cause of her death had been adequately explained to them.

- 1.42 The Erne hospital conducted a review of her case and sought the opinion of Dr Murray Quinn, Consultant Paediatrician of the Altnagelvin Area Hospital. He concluded that the cause of Lucy's seizure and cerebral oedema could not be determined with confidence but that her fluid therapy had been acceptable. There the matter would have rested but for the concern of Mr Stanley Millar,¹⁷ Chief Officer of the WHSSC, who referred her death to the Coroner. The subsequent verdict at inquest was that Lucy's death was caused by cerebral oedema due to acute dilutional hyponatraemia in the context of gastroenteritis. In terms, the Coroner found that the cerebral oedema had not been due to dehydration but rather to excessive rehydration with Solution No.18. Revised terms of reference restricted the Inquiry to an investigation of what had happened after Lucy's death and specifically to the failure to correctly identify the cause of her death.

Raychel Ferguson

- 1.43 Raychel was born on 4th February 1992 and enjoyed a childhood of excellent health. She was admitted to Altnagelvin Area Hospital on the evening of 7th June 2001 with pain on urination, stomach ache and nausea. She underwent an uneventful appendectomy that night. On admission her sodium levels had been normal and she was placed on an IV infusion of

¹⁷ 325-002-011

Solution No.18 which was re-commenced after surgery. The rate of fluid administration was marginally more than it should have been. Raychel vomited repeatedly over the course of the following day and her parents expressed concern. Notwithstanding that her condition deteriorated, her sodium levels were not reassessed, her fluid balance was not monitored and her IV infusion continued until she suffered a collapse in the early hours of 9th June. Her sodium levels were then found to be exceptionally low. She had acute hyponatraemia and was transferred to PICU at RBHSC where she was pronounced dead the next day. Raychel's parents did not feel they were given a satisfactory explanation. Her death was notified to the Coroner who found at inquest that she had died from cerebral oedema caused by hyponatraemia which had been caused in turn by a combination of inadequate electrolyte replacement in the face of severe post-operative vomiting and water retention resulting from anti-diuretic hormone activity.

- 1.44 After Raychel's death Altnagelvin reviewed her case and having identified shortcomings in clinical care, set about addressing them. It also took steps to draw the risks attaching to the infusion of Solution No.18 and hyponatraemia to the attention of the CMO and a wider medical audience. This prompted the Department to prepare its Guidance for the Prevention of Hyponatraemia in Children.

Conor Mitchell

- 1.45 Conor was born on 12th October 1987 with spastic tetraplegia, cerebral palsy and mild epilepsy. He was admitted onto an adult medical ward at the Craigavon Area Hospital ('CAH') on 8th May 2003 with a history of vomiting and malaise. He was given IV fluids but unlike the other children, received an isotonic solution rather than Solution No.18. Nonetheless, his condition deteriorated and his family expressed concern. He suffered two seizures in the evening and was transferred to PICU at the RBHSC the following day. He was pronounced dead on 12th May. His family were concerned about the care he had received. The Coroner commissioned expert opinion and conducted an inquest but the precise cause of Conor's

death remained unclear. There was cerebral oedema but no obvious cause. Notwithstanding that the Coroner considered the fluid management to have been acceptable, concerns were raised about whether the Department's hyponatraemia guidance had been followed properly, or at all, and whether the fluid therapy administered was appropriate.

- 1.46 It was a matter of particular interest to this Inquiry to determine whether the guidance introduced in consequence of Raychel's death was being followed. Accordingly, I directed investigation into the way in which the guidance had been issued by the Department and the means by which it had been implemented and enforced. Conor's case was selected for scrutiny so as to permit inquiry into how the hyponatraemia guidance had been introduced at CAH, whether Conor's treatment had been informed by it and whether any changes to practice or procedure had resulted. The terms of reference were accordingly amended so as to permit inquiry into *"the circumstances of the death of Conor Mitchell in the context of the guidelines on fluid management in children."*

The Department

- 1.47 One of the fundamental questions for this Inquiry was whether lessons could and should have been learned from the 'adverse incidents' described. Whilst clinicians and hospitals were obliged to investigate such incidents it was also necessary to consider whether responsibility for collecting information about such matters extended to the Department. It was necessary to understand the Departmental procedures for assuring delivery of safe healthcare and the extent to which information about healthcare problems, and specifically the deaths of Adam, Claire, Lucy and Raychel, became known to the statutory authorities, and what was done in response.
- 1.48 Having so closely examined all that had gone wrong it became equally necessary to determine whether it had been put right and to assess what the relevant statutory bodies had done to remedy matters in the years

following the period under review. I was interested to know, for example, if updated systems could be bypassed in a culture which concealed error.

1.49 Accordingly, and when examining the present Health Service and in exploring what might be achieved for the future, I considered that a different approach to information gathering was required of the Inquiry. In order that views could be more readily aired and ideas for improvement exchanged, I directed a forum for opinion and discussion with representatives from the Department, the Belfast Health & Social Care Trust ('BHSCT'), the Health and Social Care Board ('HSCB'), Action against Medical Accidents ('AvMA'), the Patient and Client Council ('PCC'), Regulation and Quality Improvement Authority ('RQIA') and others. Participants were not subject to criticism and it was hoped debate would emerge from the evidence already received, the agenda for discussion and my own questions. Parties were asked for up-to-date information and position papers about the current processes for ensuring the provision of satisfactory healthcare. In particular, submissions were invited in respect of my more significant concerns including the handling of complaints, the notification and investigation of Serious Adverse Incidents ('SAIs'), the involvement of families and the introduction of a legally enforceable duty of candour. The responses and position papers received were circulated amongst the interested parties and are to be found on the Inquiry website.¹⁸

1.50 Identification of relevant lessons for the future is necessarily dependent upon an understanding of the systems as they are today. The Inquiry has sought relevant up-to-date information and has attempted to note the changes which have occurred in the years since the deaths examined. Given the pace of reform and procedural change in the years since, this has been no easy task. This Report is not to be understood as intending a comprehensive and up-to-the-minute account of the current position.

¹⁸ <http://www.ihrdni.org/supp-eviden-additional-papers.htm>

Hearings

- 1.51 The public hearings were conducted over the course of 148 days at The Courthouse, Banbridge, County Down, from February 2012 to November 2013. In all, 179 witnesses gave evidence. Full transcripts of the hearings extending to over 32,000 pages may be found on the website, together with the written closing submissions of 37 of the interested parties.
- 1.52 In relation to all the cases under consideration (excepting Lucy) evidence was heard and examined in respect of both clinical and governance issues. Hearings were conducted on that basis and in that order. There was occasional and inevitable overlap between clinical and governance evidence. Senior Counsel to the Inquiry opened each stage with a full background statement identifying the facts and issues as then understood. These openings are to be found on the website. It was not the function of counsel to advance any particular case but to test the evidence and assist the process of the Inquiry.
- 1.53 All hearings were conducted openly and in public, save for one issue considered in private session in accordance with the requirements of the European Convention on Human Rights and two separate and specific orders of the High Court.¹⁹ This was done in an attempt to identify the possible whereabouts of the consultant responsible for Claire's care while protecting the privacy of other patients then receiving treatment within the RHBSC.
- 1.54 All witnesses were advised as to the general subject matter of questioning in advance. They were questioned by Inquiry counsel. On occasion I permitted the legal representatives of interested parties to pose questions when there was a reasonable basis so to do.
- 1.55 Salmon letters²⁰ were sent in confidence to those witnesses thought most likely to be criticised, so as to place them on notice. This is done in the

¹⁹ http://www.ihrdni.org/high_court_orders.htm *O'Hara v BHSCT* [2012] NIQ 575

²⁰ Letters of 'warning' compliant with the 'Salmon principles' set out in The Royal Commission on Tribunals of Inquiry Report, 1966.

interests of fairness. I directed such letters be sent to a number of individuals and organisations in accordance with the procedure for hearings.

- 1.56 Those who assisted the Inquiry and re-lived their experiences in public, did so with dignity and patience. The Inquiry is indebted to them for their invaluable assistance. In particular and in this regard I acknowledge the courage of family members and pay tribute to them.
- 1.57 The Inquiry also heard from a wide range of clinicians, healthcare professionals and independent expert witnesses. The experience of giving evidence in public was no doubt stressful for many and the Inquiry is grateful.

Evidence

- 1.58 The Public Inquiry process is investigative and inquisitorial and seeks to determine what has happened in order to better identify what may be learned. Accordingly, I have found myself in a very different position to a judge sitting in a court of law. In identifying what has gone wrong I have inevitably criticised some individuals and organisations, but my findings are not binding and are not determinative of liability.
- 1.59 This has not been an investigation into allegations of criminal wrongdoing. It has been an investigation into deficiencies in clinical performance and shortcomings in governance control and response. Accordingly, I did not think it correct to adopt the criminal standard of proof when making a finding of fact. I considered the civil standard of proof found on the balance of probabilities to be appropriate. Were it otherwise, my findings would be limited in number by the more onerous criminal burden of proof and would suffer a consequent reduction in scope to identify lessons. The drawing of lessons is the most important task of this Inquiry.
- 1.60 In applying the balance of probabilities as the standard of proof, I have borne in mind the concepts of 'common sense' and 'inherent improbability'

when reaching a finding of fact. In addition and for the avoidance of doubt, where I permit myself comment expressing suspicion or concern, it is because I think it relevant. It is not a finding of fact. I have striven at all times to be fair.

- 1.61 I have, of course, assessed the acts and omissions of all involved against contemporaneous expectations and standards and not against those of today. Where there was no consensus as to those standards I have taken that into account. I have not assumed that a written record is proof of its content any more than I have assumed that the absence of record means that something did not happen.
- 1.62 Passage of time and memory degraded some of the evidence. Given the absence of full investigation at the time of the deaths and the time since lapsed, this was a relevant consideration. Nonetheless, I was surprised at how little some witnesses found themselves able to recall.
- 1.63 I am conscious that the individuals who are criticised were not able to defend themselves as they might in adversarial proceedings and were circumscribed in their right to make representations. I am also aware that individuals who are criticised may attract adverse publicity affecting both reputation and career. Therefore where critical comment is made of an individual, it must be assessed in the context of the limitations of the process.

Costs

- 1.64 Inquiry costs are as set out at Appendix 10.

Report

- 1.65 This Report deals in turn with the deaths of Adam and Claire, the events that post-dated Lucy's death, Raychel's case and the fluid management and organisational issues presented by Conor's treatment.

- 1.66 The role and involvement of the Department in these specific cases and in general is dealt with in a separate chapter as is my assessment of the progress and current involvement of the Department and Health Service.
- 1.67 In general, and unless otherwise stated, I have accepted the evidence as recited. Whilst I have had regard to all the evidence and to the submissions made, I have not referenced it all in the Report or made fully reasoned decisions for each and every issue of fact because to do so would unduly extend the Report. Footnoted references are given for fact or quotation or otherwise to explain. Where significant dispute has arisen as to fact, I have given a fuller reasoning for my conclusion. It is important when considering my treatment of the facts as well as my comments, criticisms and conclusions, to read them in context, just as the Report itself must be read in its entirety.
- 1.68 The Report does in large measure deal with all those issues appearing in the list of issues. However, some matters once thought germane, were found on examination to have less relevance to the overall view, in which circumstances they do not always find detailed reference in the Report. It has been inevitable that some material and evidence will be referred to in more than one chapter. Whilst repetition has been kept to a minimum, in some contexts it has been permitted in aid of clarity.
- 1.69 I acknowledge the assistance of counsel to the Inquiry in the assessment of the evidence and its significance. However, the conclusions of the Report are mine and mine alone.

Recommendations

- 1.70 I set out my recommendations to strengthen and improve practice and systems in the hope that the failings found, cannot easily be repeated. The recommendations are presented in Chapter 9 of this Report. It is for the Department of Health to take them forward. Many will doubtless require significant detailed consideration to enable implementation. I expect the Department to indicate not only which of my recommendations it accepts

but also to make clear how and when implementation is to be achieved. Further and subsequent reports should then be made detailing progress towards implementation with a final published confirmation of same.

Delay

- 1.71 I accept there has been delay in the presentation of my Report. This is regrettable but has been due to a number of factors starting with the suspension of all work from October 2005 - May 2008 to allow a police investigation into the deaths of Adam, Lucy and Raychel. A detailed revision of the terms of reference, in consultation with all concerned, then followed. The scope of the terms of reference (both original and revised) required an ambitiously broad and time consuming range of investigation. Analysis of differing expert opinion in complex areas of hyper-specialism was particularly demanding. Differences of opinion required that not only the evidence and the clinical basis for conclusion be tested, but also underlying expert assumptions.
- 1.72 The scope of the Inquiry's work broadened to examine the deaths (in various respects) of five children over a period of eight years. The work of the Department and the Chief Medical Officer together with clinicians and administrators from the following came within the remit of the Inquiry's investigation:
- (i) Royal Belfast Hospital for Sick Children.
 - (ii) Royal Group of Hospitals Trust (now Belfast Health & Social Care Trust).
 - (iii) Eastern Health & Social Services Board (now Regional Health & Social Care Board).
 - (iv) Erne Hospital.
 - (v) Sperrin Lakeland Trust (now Western Health & Social Care Trust).
 - (vi) Altnagelvin Area Hospital.

- (vii) Altnagelvin Hospital Trust (now Western Health & Social Care Trust).
 - (viii) Western Health & Social Services Board (now Regional Health & Social Care Board).
 - (ix) Craigavon Area Hospital.
 - (x) Craigavon Area Hospitals Group Trust (now Southern Health & Social Care Trust).
 - (xi) Southern Health & Social Services Board (now Regional Health & Social Care Board).
- 1.73 In addition, there were other investigations into the circumstances of the children's deaths, namely at inquest and by the Police Service of Northern Ireland ('PSNI'). The General Medical Council ('GMC') also investigated the conduct of a number of doctors involved with the cases of Lucy and Raychel and the Nursing and Midwifery Council likewise considered complaints relating to nursing care in two of the cases. The detail and documentation thereby generated was all potentially relevant and was analysed in full. Where appropriate it was shared.
- 1.74 Apart from the very real difficulties experienced in gathering the evidence, investigating and analysing testimony, I found the writing of this report exceptionally time consuming. This was due to the mass and complexity of detail together with the nature and nuance of the evidence. I recognise that it has been delayed and regret that it has taken so long. I offer my sincere apologies for any additional distress which this has caused.

Conclusion

- 1.75 It is the task of an Inquiry to focus specifically on what has gone wrong, not on what has gone right and such close focus can act as a distorting lens. It is to be stressed that critical comment of an individual does not necessarily imply that the same individual has not otherwise made much positive contribution to healthcare or that the pressures of modern clinical practice

have been taken for granted. It is recognised that untoward clinical incidents can cause terrible suffering, not only for patients and their families but also to the clinical professions.

- 1.76 The purpose of identifying underperformance is to highlight acts or omissions, attitudes or assumptions to be avoided in the future. Whilst it is proper that individuals be accountable, it is also better to learn than to punish. To place undue emphasis on blame is to encourage the cycle of defensiveness, concealment, indifference to learning and further harm. There is much for all who work in the Health Service to reflect upon and learn from in the sad narratives of this Report. In addition, I recognise that others, including Her Majesty's Coroners, may draw insight and instruction from what has been revealed.
- 1.77 However, in each of the cases examined, deficiencies in practice and system did become apparent and in most cases the shortcomings were evident from the outset. Accordingly, I was surprised at how difficult it was to persuade some witnesses to be open and frank with the work of the Inquiry. All too often, concessions and admissions were extracted only with disproportionate time and effort. The reticence of some clinicians and healthcare professionals to concede error or identify the underperformance of colleagues was frustrating and depressing, most especially for the families of the dead children.
- 1.78 This remained largely the case until 30th August 2013 when Altnagelvin fully and publically accepted its responsibility for the death of Raychel Ferguson. Twelve years had passed since her death and ten years since the start of litigation.²¹ Altnagelvin's concession, whilst belated, was correct and was to be followed by the Belfast and Southern Trusts in October 2013 when they accepted full responsibility for the deaths of Adam and Claire and the failings revealed in Conor's case.²² They proffered formal apology for all the hurt caused by the acts and omissions of the Trusts. This was a

²¹ T-30-08-13 p.1

²² T-17-10-13 p.2 *et seq*

welcome and partial vindication of the work of the Inquiry but was achieved at considerable cost to all.

- 1.79 It should not have been so. Health service guidance for 25 years and more has repeatedly recommended transparency and openness in the interests of the patient. This has proved inadequate to the problem which is why this Report must recommend a statutory duty of candour in Northern Ireland.

ADAM STRAIN**Contents**

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Introduction

- 2.1 Adam Strain was born on 4th August 1991¹ and died on 28th November 1995 in the Royal Belfast Hospital for Sick Children (the ‘Children’s Hospital’) having undergone renal transplant surgery.² During his short life he lived with his mother and maternal grandparents in Holywood, Co Down. His devoted mother Debra Slavin paid warm tribute to her son, recalling that *“no matter what life threw at him he faced it with a smile, he was such a happy little boy who endured more in his four short years than most people go through in a lifetime.”*
- 2.2 Adam was born with cystic dysplastic kidneys and a medical abnormality known as vesico-ureteric reflux causing him repeated and damaging urinary tract infection.³ He endured five surgical operations to re-implant the ureter and another procedure to treat gastro-oesophageal reflux.⁴ On a number of occasions he became critically ill and was admitted into Intensive Care. Feeding and nutrition were problematic and it became necessary to administer gastronomy feeds. Eventually he refused all feeds and took nothing by mouth.⁵ His condition deteriorated and he suffered renal failure necessitating peritoneal dialysis. Adam produced urine of poor quality and was described as polyuric. His kidneys were unable to regulate the salt content of his urine very well and he had suffered acute hyponatraemia following surgery in November 1991. He was assessed a potential candidate for renal replacement (without which he would not have survived⁶) and was placed on the transplant register in July 1994.⁷
- 2.3 Throughout this period he was the patient of Professor Maurice Savage,⁸ Consultant Nephrologist, who co-ordinated his *“care, prescribed and monitored his dialysis treatment with support from a dietician, psychologist,*

¹ 050-022-061

² 070-001-001

³ 011-009-025

⁴ 011-009-025

⁵ 011-011-054 & 011-009-025

⁶ Professor Savage T-17-04-12 p.80 line 16

⁷ 016-042-078

⁸ 303-001-003

social worker, the renal nursing team, and of course his mother”⁹ who actually performed the home dialysis.

Expert reports

2.4 The Inquiry, guided by its advisors, engaged the following experts to address specific issues:

- (i) Dr Simon Haynes¹⁰ (Consultant in Paediatric Cardiothoracic Anaesthesia and Intensive Care, Freeman Hospital, Newcastle-upon-Tyne) who provided reports on anaesthetic matters.¹¹
- (ii) Dr Malcolm Coulthard¹² (Honorary Consultant Paediatric Nephrologist, Royal Victoria Infirmary, Newcastle-upon-Tyne) who reported on the roles and responsibilities of the nephrologists involved in Adam’s case and analysed the management of Adam’s fluid balance and electrolytes.¹³
- (iii) Professor John Forsythe¹⁴ (Consultant Transplant Surgeon, the Royal Infirmary of Edinburgh and Honorary Professor, University of Edinburgh) and Mr Keith Rigg (Consultant Transplant Surgeon, Nottingham University Hospitals NHS Trust), who provided joint reports addressing aspects of paediatric renal transplant surgery.¹⁵
- (iv) Professor Dr Peter Gross¹⁶ (Professor of Medicine and Nephrology, Universitätsklinikum Carl Gustav Carus, Dresden) who provided reports on hyponatraemia and fluid management.¹⁷
- (v) Ms Sally Ramsay¹⁸ (former Director of Nursing and Family Services and Director of Nursing, Quality and Clinical Support at Great

⁹ WS-002-1 p.2

¹⁰ 303-001-009

¹¹ File 204

¹² 303-001-008

¹³ File 200

¹⁴ 303-001-009

¹⁵ File 203

¹⁶ 303-001-008

¹⁷ File 201

¹⁸ 303-001-009

Ormond Street Hospital for Children, NHS Trust) who advised on nursing care at the Children's Hospital and in particular the care given Adam in November 1995.¹⁹

- (vi) Professor Fenella Kirkham²⁰ (Professor of Paediatric Neurology, Institute of Child Health, London and Consultant Paediatric Neurologist, Southampton General Hospital) who provided neurological opinion as to the effect of fluid infusion upon the brain and the possible contribution, if any, of venous obstruction to Adam's cerebral oedema.²¹
- (vii) Dr Waney Squier²² (Consultant Neuropathologist and Clinical Lecturer, John Radcliffe Hospital, Oxford) who advised on the histological slides of brain tissue and the autopsy photographs of Adam's brain.²³
- (viii) Dr Caren Landes²⁴ (Consultant Paediatric Radiologist, Alder Hey Children's NHS Foundation Trust) who reported on the chest x-rays taken at 13:20 and 21:30 on 27th November 1995.²⁵
- (ix) Dr Philip Anslow²⁶ (Consultant Neuroradiologist, Radcliffe Infirmary, Oxford) who interpreted CT scans dated 7th July 1995 and 27th November 1995.²⁷
- (x) Professor Dr Dietz Rating (Consultant in Paediatric Neurology at the Children's Hospital at the University of Heidelberg) who reported on neurological issues arising in Adam's case.²⁸

¹⁹ File 202
²⁰ 303-001-009
²¹ File 208
²² 303-001-009
²³ File 206
²⁴ 303-001-009
²⁵ File 207
²⁶ 303-001-009
²⁷ 206-005-109
²⁸ File 240

- (xi) Professor Aidan Mullan²⁹ (former Acting Chief Executive Officer and Director of Nursing and Clinical Governance, North Tees and Hartlepool NHS Trust) who provided his opinion on clinical governance issues.³⁰
- (xii) Mr Stephen Ramsden³¹ (Chief Executive Officer of the Luton & Dunstable Hospital NHS Foundation Trust), who reported on hospital management and governance issues.³²
- (xiii) Professor Sebastian Lucas³³ (Department of Histopathology, St Thomas' Hospital London) who commented on Adam's autopsy and other aspects of coronial autopsy practice.³⁴
- (xiv) Mr Geoff Koffman³⁵ (Consultant Transplant Surgeon at Guy's and St Thomas's NHS Foundation Trust) who provided a report on the transplant surgery.³⁶

2.5 The Inquiry also had the benefit of expert opinion commissioned by the Coroner and the Police Service of Northern Ireland ('PSNI') from:

- (i) Professor Peter Jeremy Berry (Professor of Paediatric Pathology, University of Bristol) who reported to the Coroner on 23rd March 1996.³⁷
- (ii) Dr Edward Sumner (Consultant Paediatric Anaesthetist at Great Ormond Street Childrens' Hospital) who reported for the Coroner on 22nd January 1996³⁸ and the PSNI in September 2005.³⁹

²⁹ 306-081-008

³⁰ File 210

³¹ 306-081-008

³² File 211

³³ 306-081-009

³⁴ File 209

³⁵ 303-001-010

³⁶ 205-002-009

³⁷ 011-007-020

³⁸ 059-054-109

³⁹ 094-002-002

- (iii) Mr Geoff Koffman (Consultant Surgeon at Guy's & St Thomas Hospital and Great Ormond Street Hospital, London) who provided a report to the PSNI on 5th July 2006.⁴⁰
- (iv) Dr John Alexander (Consultant Anaesthetist at Belfast City Hospital) who provided his expert opinion to the Coroner on 5th January 1996.⁴¹

Schedules compiled by the Inquiry

2.6 In an attempt to summarise the very considerable quantities of information received, the following schedules and charts were compiled:

- (i) Chronology of events (clinical).⁴²
- (ii) List of persons - clinical.⁴³
- (iii) Schedule detailing experience of the anaesthetists and surgeons involved.⁴⁴
- (iv) Schedule of anaesthetic nurses and trainee anaesthetists involved.⁴⁵
- (v) Schedule detailing education and training of doctors involved.⁴⁶
- (vi) Table detailing education & training of nurses involved.⁴⁷
- (vii) Chronology of hospital management and governance.⁴⁸
- (viii) List of persons - governance.⁴⁹

⁴⁰ 094-007-027
⁴¹ 059-057-134
⁴² 306-003-001
⁴³ 303-001-001
⁴⁴ 306-004-001
⁴⁵ 306-002-001
⁴⁶ 306-005-001
⁴⁷ 306-001-001
⁴⁸ 306-010-001
⁴⁹ 306-081-001

- (ix) Chronology relating to draft recommendations submitted to the Coroner.⁵⁰
- (x) Summaries of Inquiry expert opinion as to contributory factors to death, given before and after Newcastle-upon-Tyne meeting of experts (March 2012).⁵¹
- (xi) Glossary of Medical Terms⁵²

2.7 All of the above, together with the reports of the Inquiry experts, have been published on the Inquiry website.

The Paediatric Transplant Service

2.8 Professor Savage was appointed Consultant Paediatrician and Nephrologist at the Children's Hospital in 1980.⁵³ He is a Fellow of both the Royal College of Physicians ('RCP') and the Royal College of Paediatrics and Child Health ('RCPCH'). He is now Professor Emeritus of the Medical Faculty of The Queens University of Belfast. For 15 years he was the only consultant paediatrician and nephrologist working in Northern Ireland but was always careful to maintain his broader professional contacts through the European Society of Paediatric Nephrology.⁵⁴

2.9 A paediatric renal transplant programme was started in 1980 at the Belfast City Hospital ('BCH') which was, at that time, providing an established adult transplant service.⁵⁵ Professor Savage subsequently arranged for some paediatric renal transplants to be performed at the Children's Hospital as well. The first renal transplant involving a child younger than five years took place in the Children's Hospital in 1990.⁵⁶ Whilst the BCH (which was run by a different Trust to that of the Children's Hospital) was the recognised

⁵⁰ 306-122-001

⁵¹ 306-016-130 & 306-017-146

⁵² 303-002

⁵³ 306-018-004

⁵⁴ 306-018-001 *et seq*

⁵⁵ Mayes C, Savage JM. Paediatric renal transplantation in Northern Ireland (1984-1998). *The Ulster Medical Journal*. 2000; 69(2):90-96.

⁵⁶ 300-021-033

Renal Transplant Centre for Northern Ireland, it appears that the Royal Group Hospitals Trust (the 'Trust') assumed control of those paediatric renal transplants performed in the Children's Hospital.⁵⁷

- 2.10 Professor Savage became the moving force behind a gradual transfer of paediatric renal transplant surgery to the Children's Hospital. He explained that *"as we gradually developed the service... and as we gained the skill to dialyse and transplant smaller and smaller children, it became obvious that we should be taking those children into the environment of a children's hospital..."*⁵⁸
- 2.11 Paediatric renal transplants were a comparatively recent innovation in the 1980s and 1990s. Between 1984 and 1993 there were 1,406 paediatric renal transplants in the UK⁵⁹ of which less than 10% involved children under the age of five years. In Northern Ireland an Ulster Medical Journal review of the years 1984-98 recorded 77 transplants for patients under 18 years.⁶⁰
- 2.12 There was then comparative inexperience at both the BCH and the Children's Hospital in renal transplant surgery for children as young as Adam.⁶¹ There was no dedicated paediatric renal transplant surgeon and there had been no paediatric transplants involving a living donor.⁶² The provision of cadaveric transplants meant that the Paediatric Renal Transplant Service was reliant upon the availability of the necessary expertise and resources 'around the clock.' On occasion, the offer of a kidney had to be declined because of the lack of key nephrology or surgical staff or the want of a post-operative intensive care bed.⁶³
- 2.13 The British Association for Paediatric Nephrology produced a working party report in March 1995 on 'The Provision of Services in the United Kingdom

⁵⁷ 300-021-033

⁵⁸ Professor Savage T-17-04-12 p.12 line 1

⁵⁹ 'Audit of United Kingdom Transplants Support Service Authority' 1995

⁶⁰ Mayes C, Savage JM. Paediatric renal transplantation in Northern Ireland (1984-1998). *The Ulster Medical Journal*. 2000; 69(2):90-96.

⁶¹ Professor Savage T-17-04-12 p.15 line 12 *et seq*

⁶² Professor Forsythe T-03-05-12 p.173 line 5

⁶³ Mayes C, Savage JM. Paediatric renal transplantation in Northern Ireland (1984-1998). *The Ulster Medical Journal*. 2000; 69(2):90-96.

for Children and Adolescents with Renal Disease'⁶⁴ which provides insight into paediatric nephrology and transplantation practice at that time. It recommended that to accumulate and maintain expertise, a population base of 3 million was the minimum necessary to sustain a comprehensive paediatric renal service although a population of 4 million was deemed optimal. However, it was recognised that some exceptions to this proposition were necessary and on geographical grounds Northern Ireland was recognised as a justifiable exception, notwithstanding a population in 1995 of approximately 1.6 million.⁶⁵

2.14 Northern Ireland paediatric transplant statistics at that time reveal comparable outcomes to those recorded in other transplant centres in the UK.⁶⁶ Such is testimony to the work of Professor Savage and the anaesthetists, surgeons and nurses who collectively provided the paediatric renal transplant service. Accordingly, Dr Coulthard considered that the Children's Hospital did have the experience, infrastructure and case load to undertake paediatric renal transplants in 1995.⁶⁷ However, it was also clear that by 1995 the service required a second consultant to assist Professor Savage.

2.15 To that end Dr Mary O'Connor⁶⁸ was appointed as an additional Consultant Paediatric Nephrologist in the Children's Hospital on 1st November 1995.⁶⁹ She had trained under Professor Savage and advanced her specialism at the Southmead Hospital, Bristol.⁷⁰ She returned to Belfast a little less than four weeks before Adam was admitted.⁷¹ Her appointment gave Professor Savage a consultant colleague with whom to share the workload and develop the service.

⁶⁴ 306-065-001

⁶⁵ 'Population and Migration Estimates Northern Ireland' (statistical report, NISRA 2011)

⁶⁶ 306-065-027 & Transcript 17-04-12 p.24 line 21

⁶⁷ 200-007-111

⁶⁸ 303-001-002

⁶⁹ WS-014-1 p.2

⁷⁰ 306-030-001

⁷¹ WS-014-1 p.2

- 2.16 At that time Professor Savage prepared for transplant operations using a procedure protocol he had drawn up in 1990.⁷² This was a brief document developed as a checklist to be attached to the medical records of the patient in order to better inform the doctors and nurses involved.⁷³ Dr O'Connor brought to Belfast a copy of the protocol used in Bristol which had been updated to 1995 and was a more detailed and comprehensive guide. It set out very clearly the steps to be taken from point of acceptance of a donor kidney for transplant through to the post-operative care to be delivered.⁷⁴ This updated protocol was to be adopted in Belfast but not before Adam's death.⁷⁵
- 2.17 Likewise, developments emerging from other transplant centres had yet to be adopted in Belfast. An important innovation referred to by Professor Forsythe and Mr Rigg was the detailed consideration of a patient's case at the time of acceptance onto the transplant list.⁷⁶ This was to be undertaken by a multi-disciplinary team including nephrologists, surgeons and renal nurses in order to better identify patient-specific issues. These could range from assessments of urgency and general health to necessary preparatory procedures and surgical difficulties. A summary of these considerations might then attach to the medical record and thereby save the transplant team valuable time when an offer of a donor kidney was made. An inherent disadvantage of cadaveric transplant surgery is that the timing of the offer of the donor kidney is unpredictable. If a kidney is a reasonable match then the necessity to accept it places pressure on the transplant team to act quickly.⁷⁷ In such a context the advantage of preparatory work is clear.
- 2.18 I do not criticise Professor Savage's 1990 Protocol nor the absence of multi-disciplinary team input because these developments had not yet become

⁷² WS-002-2 p.52

⁷³ Professor Savage T-17-04-12 p.26 line 25

⁷⁴ WS-014-2 p.31

⁷⁵ WS-014-2 p.22

⁷⁶ Mr Rigg T-03-05-12 p.167-68

⁷⁷ Professor Forsythe T-03-05-12 p.172-73

standard by 1995. The existence of better practice elsewhere does not mean that the practices of the Children's Hospital were sub-standard.

July 1994 - November 1995

- 2.19 Professor Savage had lengthy discussions with Ms Slavin at the time Adam was placed on the transplant register.⁷⁸ She had volunteered donation of one of her own kidneys.⁷⁹ Professor Savage did not support this idea (although success rates were favourable) because Ms Slavin was a single mother and were complications to arise then her ability to care for Adam might be affected, and even if all went well she might take months to recuperate.⁸⁰ I cannot disagree with that approach.
- 2.20 Additionally, it has been suggested that the possibility of transfer to another transplant centre such as Great Ormond Street Hospital in London ought to have been discussed.⁸¹ However, Professor Savage maintained that he did not then believe that it was beyond the ability of local paediatric anaesthetists and surgeons with relevant experience to treat Adam and *“as there was only one venue for transplant surgery in Northern Ireland for a child of Adam's age, I did not offer Ms Slavin any other venue for the transplant.”*⁸² While this was not unreasonable it would have been better had he discussed it with her.⁸³
- 2.21 Professor Savage described how Ms Slavin was given a copy of the 'Kidney Transplantation in Childhood... a Guide for Families'⁸⁴ which explained that *“Placement on the transplant waiting list follows discussion with the kidney specialist and transplant surgeon.”*⁸⁵ Ms Slavin could not remember this document nor indeed any discussion with a transplant surgeon. Professor Savage conceded that *“the transplant surgeon did not participate in these multi-disciplinary team meetings, except by special arrangement, as he*

⁷⁸ WS-002-3 p.6

⁷⁹ Professor Savage T-17-04-12 p.68-69

⁸⁰ Professor Savage T-17-04-12 p.70

⁸¹ Professor Savage T-17-04-12 p.74 line 13

⁸² WS-002-3 p.11

⁸³ Professor Savage T-17-04-12 p.74 line 15

⁸⁴ City Hospital Nottingham - WS-002-3 p.124

⁸⁵ WS-002-3 p.127

*worked not on the Royal Victoria site but on the Belfast City site*⁸⁶ and accepted that *“it would have been better if one of the transplant surgeons had met Adam in advance... it’s one of my regrets that we didn’t have that arrangement.”*⁸⁷

2.22 Professor Savage acknowledged that he did not make a record of what he said to Ms Slavin⁸⁸ at that time but described how the relevant *“information is repeated and drip fed over many months, not just by me, but by our renal nurse specialists...in the ward and by our social worker, by perhaps the psychologist...so that information is generally reiterated and built up.”*⁸⁹

2.23 Photographs taken of Adam just a fortnight before his renal transplant show him looking happy and well. His mother described him, despite his renal problems, as being *“back on top form again. He was really well at that point.”*⁹⁰ Accordingly, it is clear that while Adam required a transplant he was not an emergency patient and, if a donor kidney was not a particularly good match, it did not have to be accepted. Of course, were a reasonable match to become available then it would have been a good time to proceed because he was comparatively well.

Offer of kidney, Sunday 26th November 1995

2.24 A donor kidney became available at the Glasgow Southern General Hospital at 01:42 on Sunday 26th November 1995 from a 16 year old who had enjoyed previous good health.⁹¹ The kidney was formally offered to Professor Savage and it seems that he discussed it first with Ms Slavin, then Dr Robert Taylor,⁹² the on-call Consultant Paediatric Anaesthetist at

⁸⁶ WS-002-3 p.19-20 & Professor Savage T-17-04-12 p.83 line 11

⁸⁷ Professor Savage T-17-04-12 p.89 line 9

⁸⁸ WS-002-3 p.11

⁸⁹ Professor Savage T-17-04-12 p.82 line 13

⁹⁰ WS-001-1 p.2

⁹¹ 306-007-043 & 059-006-012

⁹² 303-001-003

the Children's Hospital,⁹³ and then Mr Patrick Keane,⁹⁴ a Consultant Urologist at BCH with transplant experience.

- 2.25 Dr Taylor was an experienced consultant who had previously anaesthetised Adam but had not previously acted as lead anaesthetist in a renal transplant. Nonetheless, he was a consultant paediatric anaesthetist in a regional centre and one who had responsibility for critically ill children in intensive care. He should therefore have had the necessary skills to manage Adam safely.⁹⁵
- 2.26 Mr Keane had extensive experience of adult transplant surgery and had previously undertaken four paediatric transplants,⁹⁶ the most recent being only weeks before and on a three year old child.⁹⁷ He was therefore an appropriate surgeon in the local context.
- 2.27 Mr Keane required confirmation that the donor kidney was a reasonable match for Adam. Only limited information was available about donor size, age and anatomy. However, it was established that the tissue type match was an acceptable 50%⁹⁸ and that the kidney could be brought to Belfast within a cold ischaemic time ('CIT') of 24 hours.⁹⁹
- 2.28 On that basis Professor Savage conferred with Ms Slavin and decided to accept the kidney.¹⁰⁰ Adam was admitted to the Children's Hospital at 20:00 on 26th November 1995¹⁰¹ at which time the donor kidney had a CIT of about 19 hours. That was close to the 24 hour optimal CIT period within which to commence surgery.¹⁰²
- 2.29 There was some disagreement between Professor Savage and Mr Keane as to the extent of the surgeon's involvement in the decision to accept the

⁹³ 093-006-016

⁹⁴ 303-001-002

⁹⁵ 204-004-147

⁹⁶ 094-013k-083

⁹⁷ WS-006-2 p.12 & 301-047-414

⁹⁸ 059-006-012 & Professor Savage T-17-04-12 p.125 line 1

⁹⁹ WS-002-3 p.8

¹⁰⁰ WS-002-1 p.3

¹⁰¹ 057-006-007

¹⁰² WS-002-3 p.8

kidney.¹⁰³ I do not however, attach much significance to the lack of clear recollection¹⁰⁴ of the events of that Sunday evening, given that much time has passed since and those discussions became relatively unimportant given what was to happen in the next 24 hours.

- 2.30 Nor do I intend to analyse the much debated issue of the viability of the donor kidney given its CIT. Mr Keane believed that it was acceptable and Mr Koffman agreed.¹⁰⁵ Professor Forsythe and Mr Rigg did not think that they themselves would have accepted the kidney, but recognised that other UK transplant surgeons might have.¹⁰⁶ It had been removed from its donor early on the morning of 26th November 1995 and offered to Professor Savage in the afternoon, perhaps having already been offered elsewhere.¹⁰⁷ It was flown to Belfast with an intention of transplantation between 01:00 and 02:00 on 27th November.¹⁰⁸ However, and for reasons which remain unclear, the operation was delayed until approximately 08:00¹⁰⁹ by which time the CIT was approximately 30 hours. It is impossible to be certain that the kidney was viable at the time of implantation but the likelihood is that it was. Whilst a CIT of 30 hours was certainly less than ideal and more than Professor Savage would have wanted, it was not the cause of Adam's death. In addition, Mr Keane considered that the kidney was a sufficiently good match to warrant transplant.¹¹⁰ Expert evidence was received from those who agreed with this proposition and some who did not.¹¹¹ However, on the basis that it has not been strongly suggested that death was associated with transplantation of an unsuitable kidney, I do not intend to make any finding on this issue.

¹⁰³ WS-006-3 p.23 & Professor Savage T-17-04-12 p.131 line 24

¹⁰⁴ Professor Savage T-17-04-12 p.140 line 23

¹⁰⁵ 205-002-009

¹⁰⁶ 203-004-064

¹⁰⁷ Professor Savage T-18-04-12 p.14 line 17

¹⁰⁸ Professor Savage T-18-04-12 p.14

¹⁰⁹ 093-038-127 & WS-006-3 p.12

¹¹⁰ Mr Keane T-24-04-12 p.9 line 22

¹¹¹ 205-002-009 & Professor Forsythe T-04-05-12 p.16

Recruiting the transplant team

- 2.31 Professor Savage was responsible for bringing together the team for Adam's transplant and in particular for recruiting the anaesthetist and the surgeon.¹¹² Confirmation of operating theatre availability and a post-operative bed in the Paediatric Intensive Care Unit ('PICU') must also have been obtained.¹¹³
- 2.32 Discussions with Dr Taylor ensued and he *"agreed to provide general anaesthesia for Adam with an experienced senior registrar, Dr T Montague, experienced theatre nursing staff and the ready access to experienced surgeons, and nephrologists..."*¹¹⁴
- 2.33 Dr Terence Montague,¹¹⁵ a Senior Registrar in anaesthesia, was recruited by Dr Taylor directly. He had no previous experience of paediatric renal transplants¹¹⁶ and indeed *"from January 1995 until November 1995 [he] had not actually anaesthetised any children, supervised or unsupervised."*¹¹⁷ It seems that his commitment was for a limited period only¹¹⁸ because his 24 hour shift was to end at 09:00 on Monday 27th November.¹¹⁹ His contribution was not therefore intended to be significant.
- 2.34 Over the course of the Sunday evening Professor Savage continued to assemble the transplant team.¹²⁰ The details cannot now be recalled,¹²¹ but Mr Keane was to be assisted by Mr Stephen Brown,¹²² a senior Consultant Paediatric Surgeon who had operated on Adam before. Whilst his experience and familiarity with Adam ought to have recommended him, Ms Slavin was not informed of his inclusion and has said that she had previously made it clear to Professor Savage that she *"did not want Mr*

¹¹² WS-002-2 p.2-3

¹¹³ Professor Savage T-17-04-12 p.37 line 3

¹¹⁴ WS-008-1 p.4

¹¹⁵ 303-001-002

¹¹⁶ WS-009-1 p.4

¹¹⁷ WS-009-1 p.4

¹¹⁸ WS-009-1 p.3

¹¹⁹ WS-009-1 p.3

¹²⁰ WS-002-2 p.15

¹²¹ WS-002-2 p.15

¹²² 303-001-001

*Brown to be involved in any surgery with Adam because previous experience had left me with no faith in him.”*¹²³

- 2.35 Professor Savage conceded that he knew of Ms Slavin’s concerns, but it is not clear that he knew the full extent of them¹²⁴ and Mr Brown may not have been aware of these concerns at all. Indeed he said that had he known of her objection he would not have agreed to assist Mr Keane.¹²⁵ In any event the role of the assistant surgeon was limited and, given that Mr Brown had no previous transplant experience,¹²⁶ his role was always intended to be limited.
- 2.36 Even after Adam’s admission and until such time as the compatibility tests with the donor kidney had been satisfactorily concluded, there remained some uncertainty as to whether the transplant would proceed.¹²⁷ Professor Savage believed that a positive compatibility result was received at some time after 01:00 hours on 27th November.¹²⁸ It was then that he obtained Ms Slavin’s consent to surgery.¹²⁹

Consent process

- 2.37 The consent of a parent on behalf of a child to something so serious as transplant surgery is an important matter. The fact that Adam was on the transplant register with his mother’s approval did not mean that she would automatically consent to the surgery. Professor Savage had been closely involved with Adam’s care and it must therefore have seemed natural that he would obtain her consent. He explained that in 1995 it was not uncommon for the *“initial consent to be obtained by someone other than the surgeon carrying out the procedure”*¹³⁰ and accordingly he sought the consent.¹³¹ However, at that time Ms Slavin had neither spoken with the

¹²³ WS-001-1 p.2

¹²⁴ Professor Savage T-17-04-12 p.167 line 19

¹²⁵ Mr Brown T-01-05-12 p.9 line 6-11

¹²⁶ WS-007-1 p.3

¹²⁷ WS-002-2 p.13

¹²⁸ WS-002-2 p.13

¹²⁹ WS-002-2 p.12

¹³⁰ WS-002-3 p.27

¹³¹ WS-002-3 p.5

intended anaesthetist or surgeon nor, does she believe, discussed the risks involved,¹³² recalling *“the only complication that was discussed with me was that of rejection.”*¹³³ Professor Savage remembered things differently, believing that he had discussed with her the process of the operation, the suitability of the donor kidney and the likelihood of a successful transplant.¹³⁴ He believed that she *“was aware of risks associated with surgery”*¹³⁵ excepting only the risk of fluid mismanagement because he did not foresee that as a likely problem.¹³⁶

2.38 The signed consent form¹³⁷ is the sole record of their conversation and it contains scant detail. Likewise, Professor Savage was *“unable to identify in Adam’s notes any recording of the discussions... in relation to obtaining consent, nor in relation to the detail of the transplant surgery.”*¹³⁸ He explained that it was *“not my habit at that time to make such detailed notes, but would now be standard practice. Modern consent forms now require the list of potential complications discussed to be recorded. This was not so in 1995.”*¹³⁹

2.39 It was suggested that Mr Keane, as lead surgeon, should have obtained the consent.¹⁴⁰ It is clear that had Mr Keane or Dr Taylor spoken to Ms Slavin at that time they would then have had to examine Adam’s medical history and condition. That alone would have constituted an important step in preparation for the surgery and justification in itself for their engagement in the consent process.

2.40 My concern relates not so much to the fact that Professor Savage obtained the consent but rather that he did so before Ms Slavin had spoken to the surgeon or learned of the identity and experience of the transplant team. The Trust had at that time formally acknowledged that *“patients and their*

¹³² WS-001-2 p.7-8

¹³³ WS-001-2 p.5

¹³⁴ WS-002-3 p.5 & Professor Savage T-18-04-12 p.33

¹³⁵ Professor Savage T-18-04-12 p.48 line 5-15

¹³⁶ Professor Savage T-18-04-12 p.48 line 17

¹³⁷ 058-039-185

¹³⁸ WS-002-3 p.11

¹³⁹ WS-002-3 p.11

¹⁴⁰ 203-002-032

*families [are] entitled to be told the name and status of each person involved in their care.*¹⁴¹ Mr Keane considered that he ought to have been part of the process of consent¹⁴² and indeed Professor Savage had the opportunity to involve him.¹⁴³ In the circumstances, I consider that, on balance, it was inappropriate for Professor Savage to have proceeded to take the consent as he did.

- 2.41 Evidence revealed that a new and detailed consent form had been issued to the Trust by the Management Executive of the Department in October 1995 with the direction that it be introduced by 31st December 1995.¹⁴⁴ The fact that it was not used in relation to Adam five weeks before the deadline cannot be a matter for criticism. What is however a matter of much more particular concern, is that it took almost five years before it was eventually adopted in the Children's Hospital.¹⁴⁵

Overnight

- 2.42 Adam was admitted at about 21:00 hours on 26th November 1995 to Musgrave Ward in the Children's Hospital.¹⁴⁶ He was seen by Dr Jacqueline Cartmill¹⁴⁷ who prescribed fluids and took blood samples as part of routine pre-operative hospital procedures.¹⁴⁸ A normal serum sodium concentration of 139mmol/L was recorded.¹⁴⁹
- 2.43 Dr Coulthard gave it as his view that *"if you put all the evidence together as to what condition he was in when he went to theatre, everything else points to him being in a relatively good condition."*¹⁵⁰
- 2.44 In the early hours of Monday morning Dr Montague was contacted because of difficulty in re-siting the cannula used for the infusion of intravenous ('IV')

¹⁴¹ WS-061-2 p.42: 1993/94 Annual Report Royal Hospitals - 'Charter for Patients and Clients'

¹⁴² Mr Keane T-24-04-12 p.135 line 5

¹⁴³ Professor Savage T-18-04-12 p.32 line 4

¹⁴⁴ 305-002-004

¹⁴⁵ 210-003-022

¹⁴⁶ 057-013-017

¹⁴⁷ 303-001-002

¹⁴⁸ 058-035-144

¹⁴⁹ 058-035-144 as confirmed by Dr O'Connor T- 25-04-12 p.137 line 8

¹⁵⁰ 307-008-184

fluid.¹⁵¹ Adam was upset and crying.¹⁵² Dr Montague considered that if the paediatric doctors on the ward were unable to reinsert the cannula then it was unlikely that he could.¹⁵³ Accordingly, he telephoned Dr Taylor for advice and was told that Dr Taylor would attend to it in theatre. As Adam was distressed it was decided to leave it until then.¹⁵⁴

Preparation for theatre

2.45 Dr Haynes explained that *“preoperative assessment is an integral part of the anaesthetist’s duties... If not performed adequately, mistakes will inevitably be made.”*¹⁵⁵ Accordingly, and as part of that assessment, he would have expected Dr Taylor to have taken steps to ascertain the nature of Adam’s renal pathology, and to have noted his normal fluid balance, fluid intake, insensible fluid losses and urine production.¹⁵⁶ Furthermore, in his view, Dr Taylor should have taken time to understand Adam’s electrolyte requirements and the fact that he could not regulate urinary sodium losses and required sodium supplements to maintain normal sodium serum levels.¹⁵⁷ Dr Haynes emphasised that in particular Dr Taylor should have understood the *“central importance”*¹⁵⁸ of Adam’s previous history of hyponatraemia¹⁵⁹ and its implications for fluid management.

2.46 Dr Taylor did not attend on the Sunday evening to assess Adam or meet Ms Slavin. He now recognises that this *“was a mistake.”*¹⁶⁰ Had he done so he would have had time to examine the extensive case record and note that inadequate sodium administration and/or water overload had previously resulted in hyponatraemia (including one instance when he had himself administered the anaesthetic in December 1991).¹⁶¹ He could then

¹⁵¹ WS-009-1 p.3

¹⁵² 093-037-117

¹⁵³ Dr Montague T-11-05-12 p.27 line 17

¹⁵⁴ WS-009-1 p.3

¹⁵⁵ 204-004-163

¹⁵⁶ 204-004-163

¹⁵⁷ 204-004-163

¹⁵⁸ 204-002-023

¹⁵⁹ With serum sodium readings of below 120mmol/L

¹⁶⁰ Dr Taylor T-19-04-12 p.121 line 14

¹⁶¹ 200-002-047

have planned his IV fluid therapy in light of known risk and discussed any queries with Professor Savage.

- 2.47 Similarly, Mr Keane did not attend at the Children's Hospital on Sunday 26th November to meet with Adam and Ms Slavin.¹⁶² He apologised for this omission but was unable to explain it.¹⁶³
- 2.48 At one stage it had been hoped to operate at approximately 02:00 on Monday; it was then decided to start at 06:00¹⁶⁴ and finally surgery was rescheduled for 07:00.¹⁶⁵ Delay may have been justified in the hope of a well-rested transplant team but each delay increased the CIT. By 07:00 the donor kidney CIT was approximately 30 hours.
- 2.49 Professor Savage acted appropriately to ensure that Adam was in a suitable condition when he finally went to theatre. He had oversight of the overnight dialysis which was important because it affected both Adam's fluid balance and his serum sodium levels. Notwithstanding, there is no record of his fluid balance upon completion of the dialysis at 05:00¹⁶⁶ nor any indication of the urinary sodium concentration.¹⁶⁷ Whilst Professor Savage liaised with Dr Taylor and communicated relevant information including fluid status,¹⁶⁸ urine output,¹⁶⁹ and Adam's "*propensity to develop hyponatraemia*,"¹⁷⁰ Dr Taylor may not have been given the fullest of information¹⁷¹ and may not have read Professor Savage's Renal Transplant Protocol. In any event, Dr Taylor did not make any record of what Professor Savage did tell him.¹⁷²
- 2.50 Nonetheless, it remained Dr Taylor's responsibility to assess "*the preoperative condition of the patient, including liaison with referring*

¹⁶² Mr Keane T-24-04-12 p.108 line 23

¹⁶³ Mr Keane T-24-04-12 p.107

¹⁶⁴ 058-035-133

¹⁶⁵ 058-035-133

¹⁶⁶ Professor Savage T-17-04-12 p.100 line 2

¹⁶⁷ Professor Savage T-17-04-12 p.56-57

¹⁶⁸ Professor Savage T-18-04-12 p.94 line 2

¹⁶⁹ WS-002-1 p.3

¹⁷⁰ Professor Savage T-17-04-12 p.119 line 24

¹⁷¹ Dr Taylor T-20-04-12 p.28 line 15

¹⁷² Dr Taylor T-20-04-12 p.14 line 12

*clinicians... ensuring that appropriate fluid management took place in the hours leading up to the operation that the appropriate investigations had taken place and the results were obtained and noted...*¹⁷³

- 2.51 It was thus that Adam was submitted to a surgeon and a paediatric anaesthetist whose knowledge in respect of his case was what they had gathered on the telephone late the previous evening¹⁷⁴ and what they had learned when presented with his extensive medical record in theatre. That was less than adequate because Adam's medical history of multiple previous surgical interventions and occasional hyponatraemia made the surgery and anaesthetic more demanding and the nature of his renal condition meant that particular attention had to be paid to the detail of fluid and electrolyte replacement.¹⁷⁵ Dr Haynes suggested that the lead up to the transplant surgery meant that Dr Taylor *"put himself... on the back foot."*¹⁷⁶ I agree and believe that both Dr Taylor and Mr Keane were disadvantaged by inadequate preparation.

The operation

- 2.52 Adam entered the operating theatre at 07:00 hours.¹⁷⁷ Ms Slavin accompanied him. He was crying.¹⁷⁸ Professor Savage met with Dr Taylor in theatre¹⁷⁹ and *"having checked that he felt he had all the information he needed"* withdrew *"and let him get on with the essential things that he had to do..."*¹⁸⁰ Dr Taylor then anaesthetised Adam in the presence of his mother.¹⁸¹ No criticism is made of the induction of anaesthesia.
- 2.53 Throughout the transplant Dr Taylor was to take the lead in the *"monitoring of vital signs and fluid/blood management."*¹⁸² His task was to assess ECG, blood pressure, temperature, heart rate and central venous pressure

¹⁷³ 204-002-026

¹⁷⁴ Dr Taylor T-19-04-12 p.141 line 18

¹⁷⁵ 204-002-021

¹⁷⁶ Dr Haynes T-02-05-12 p.61 line 5

¹⁷⁷ 057-014-019

¹⁷⁸ 058-003-057

¹⁷⁹ Professor Savage T-18-04-12 p.116 line 18

¹⁸⁰ Professor Savage T-18-04-12 p.132 line 6-8

¹⁸¹ 011-014-096

¹⁸² WS-008-2 p.2

(‘CVP’)¹⁸³ in order to gauge the depth of anaesthesia and the stability of respiratory and cardiovascular systems. He was to make periodic checks on blood loss and urine output in order to manage fluids and perform blood gas tests for serum sodium concentration. In addition, he was to monitor the colour of blood, other losses and the general appearance of the veins so as to assess fluid replacement needs.¹⁸⁴ Dr Taylor claimed to have made pre-operative fluid calculations to inform his fluid management in respect of deficit, maintenance and blood loss.

2.54 Shortly after the anaesthetic was administered, arterial access was obtained in order to monitor the arterial blood pressure¹⁸⁵ and permit an assessment of electrolytes. Professor Savage recalled that he “*made it clear to Dr Taylor that it was important that his sodium and electrolytes were checked...*”¹⁸⁶ However, and significantly, this was not done. Mr Keane was unable to “*explain why Adam’s electrolytes were not checked when the central line was inserted. He should have had his electrolytes checked once the central or arterial lines were inserted.*”¹⁸⁷ Dr Taylor provided multiple explanations as to why he did not take a blood sample at that stage. However he has since acknowledged that he “*omitted doing blood samples as requested by Professor Savage*”¹⁸⁸ and should have sent “*a blood sample for electrolyte analysis... before starting the operation. I should also have sent other samples as necessary and used those results to adjust the rate and type of the intravenous fluids.*”¹⁸⁹ Given Adam’s history of electrolyte abnormality that was an important failure because it risked uncontrolled electrolyte disturbance during surgery.

2.55 In addition to the failure to measure Adam’s electrolytes after the induction of anaesthesia there was a failure to measure his urinary output during surgery. This was of particular importance for Adam because his urine

¹⁸³ WS-008-2 p.2
¹⁸⁴ WS-008-2 p.2
¹⁸⁵ 011-030-155
¹⁸⁶ WS-002-3 p.14
¹⁸⁷ WS-006-2 p.13
¹⁸⁸ Dr Taylor T-19-04-12 p.74 line 7
¹⁸⁹ WS-008-6 p.3

production was abnormal. Dr Haynes advised that *“Adam produced significant volumes of urine and his urinary output should have been monitored when possible during the operation and a urinary catheter should have been inserted following induction of anaesthesia prior to commencing surgery.”*¹⁹⁰ This was so that Dr Taylor might know the rate of fluid lost as urine in order to calculate the correct rate for the IV fluid infusion.

- 2.56 However, Adam’s urinary output remained unmeasured until a catheter was inserted by Mr Keane at about 10:30.¹⁹¹ Mr Keane indicated that whilst there was no contra-indication to inserting a urinary catheter immediately after Adam was anaesthetised¹⁹² he nonetheless felt that *“Adam’s urethra was very small and in my opinion urethral catheterisation was unnecessary. I wanted the bladder full.”*¹⁹³ However, it was the anaesthetist’s responsibility to manage fluid balance and that entailed monitoring the output of urine. Dr Taylor should have insisted that a urinary catheter be inserted for that purpose. He would then have been able to gauge the quantity of urine spent and review and adjust the volume of fluids Adam was receiving. Dr Taylor eventually conceded that this was *“another element of care that... left me unable to reassess and review my fluid administration during Adam’s procedure.”*¹⁹⁴

Fluids administered

- 2.57 Dr Taylor commenced an infusion of Solution No.18¹⁹⁵ in accordance with his own calculation of fluid requirements¹⁹⁶ predicated upon a maintenance rate of 200mls per hour.¹⁹⁷ He then administered 750mls of Solution No. 18 in the first hour of surgery¹⁹⁸ in order to restore perceived deficit, provide maintenance and replace insensible losses.¹⁹⁹ In total, he gave Adam

¹⁹⁰ 204-002-031

¹⁹¹ WS-006-3 p.8

¹⁹² WS-006-2 p.6

¹⁹³ WS-006-3 p.9

¹⁹⁴ Dr Taylor T-20-04-12 p.51 line 10

¹⁹⁵ 303-002-042 An IV solution containing 30mmol/litre of sodium and chloride or 1/5 the concentration occurring in natural body fluids such as blood.

¹⁹⁶ 058-003-005

¹⁹⁷ WS-008-2 p.31

¹⁹⁸ WS-008-5 p.5 & 058-003-005

¹⁹⁹ 011-014-101

1,500mls of Solution No.18 during surgery. Because Solution No. 18 contains one fifth of the sodium content of normal saline this equated to 300mls of normal saline and 1,200mls of “*free water*.”²⁰⁰ Other solutions given included 1,000mls of human plasma and 500mls of packed blood cells each containing similar levels of sodium to blood.²⁰¹

2.58 In justifying his fluid management Dr Taylor insisted that Adam would pass 200mls of dilute urine per hour²⁰² and that because of kidney disease this was a “*minimum loss*” which may indeed have been “*unlimited*”²⁰³ rendering Adam like a hole in a bucket which he was obliged to fill.²⁰⁴ Consequently he argued that Adam would not retain “*free water*” and could not therefore suffer dilutional hyponatraemia.²⁰⁵

2.59 Dr Coulthard’s expert opinion categorised this argument as “*without foundation*”²⁰⁶ and estimated urinary output as significantly less than 200mls. Indeed he was of the opinion that Adam’s urinary output was fixed,²⁰⁷ that the kidneys were working “*flat out*”²⁰⁸ and that if Adam were given more fluids than he could excrete, the surplus would be retained in the body.²⁰⁹

2.60 Dr Haynes said that he was amazed at the suggestion that Adam might have had an hourly urine output of 200mls which would amount to 4.8 litres per day. He was surprised that the “*simple arithmetic*” did not strike Dr Taylor as “*being extremely unusual and well beyond what would normally be expected, certainly for a 20-kilogram boy*.”²¹⁰

2.61 Only belatedly did Dr Taylor reconsider his position and acknowledge that Adam did in fact have a fixed urine output of 70-80mls per hour. He then

²⁰⁰ 201-006-176

²⁰¹ 058-003-005

²⁰² WS-008-2 p.6 & WS-008-3 p.12

²⁰³ 093-038-242

²⁰⁴ 093-038-195

²⁰⁵ WS-008-2 p.39

²⁰⁶ 200-002-056

²⁰⁷ Dr Coulthard T-08-05-12 p.168 line 22

²⁰⁸ 200-009-151

²⁰⁹ 200-002-045

²¹⁰ Dr Haynes T-02-05-12 p.128

conceded that his arguments about fluid requirements were wrong, that he “*wrongly estimated or calculated his urinary losses*”²¹¹ and that he administered Solution No.18 to Adam “*at a rate in excess of his ability to excrete it, particularly in the first hour of anaesthesia.*”²¹²

2.62 Such sodium as was lost in surgery through bleeding could not have been replaced by the low sodium Solution No.18. Whilst Solution No.18 may have served as a partial maintenance fluid it could never have been a sodium replacement fluid given the levels of sodium lost.

2.63 Dr Haynes considered that hyponatraemia was the inevitable consequence of administering the low sodium Solution No. 18 in significant volume.²¹³

2.64 In addition, expert evidence agreed that not only was the quantity of low sodium fluids administered excessive but the rate was “*dramatically fast.*”²¹⁴ This led to an acute fall in Adam’s serum sodium levels and as Dr Coulthard explained the “*absolutely critical element of management is about how quickly or how slowly you allow the sodium to fall. Letting the sodium fall quickly leads to cerebral oedema and brain death.*”²¹⁵ In the opinion of Mr Keane, Adam was given “*no chance.*”²¹⁶

2.65 When, at the end of surgery, Dr Taylor reversed the anaesthesia and removed the sterile towels from Adam’s face - Adam did not wake, he did not breathe. His pupils were fixed and dilated²¹⁷ and his face was markedly swollen.²¹⁸

2.66 Adam’s death was avoidable.

²¹¹ Dr Taylor T-19-04-12 p.26 line 1

²¹² WS-008-6 p.3

²¹³ 204-002-035

²¹⁴ 200-002-054

²¹⁵ 307-007-102

²¹⁶ Mr Keane T-23-04-12 p.29 line 24

²¹⁷ 058-035-135

²¹⁸ WS-008-2 p.45

Other fluid management issues

- 2.67 From the outset, Dr Taylor persistently raised misleading assertion and argument in defence of his fluid management, namely:

Fluid Deficit

- 2.68 Dr Taylor asserted that Adam was in fluid deficit before surgery and accordingly there was “*an urgency to replace this deficit so that Adam did not become dehydrated...*”²¹⁹ However, expert opinion agreed that Adam was in little or no fluid deficit and was not dehydrated when he arrived in theatre.²²⁰ Not only was Dr Taylor’s assumption that Adam required fluid to correct a deficit wrong, but the nature of the fluid he chose to correct it was also wrong.²²¹

Solution No. 18

- 2.69 Dr Taylor claimed that Solution No.18 was the fluid recommended by the British National Formulary²²² for the treatment of dehydration, however, as Dr Coulthard pointed out, the actual recommendation was for normal saline²²³ and the use of Solution No. 18 to “*replace his deficit*” was quite “*simply wrong.*”²²⁴ Further, Dr Taylor contended in his evidence that Solution No.18 was more widely used in 1995 than it is now. That proposition was accepted by Dr Haynes and others in their evidence but as Dr Haynes emphasised basic training warned against the inappropriate infusion of low sodium fluids.²²⁵

²¹⁹ WS-008-1 p.3

²²⁰ Dr Coulthard T-08-05-12 p.169 line 17

²²¹ 200-007-126

²²² 093-038-132

²²³ 200-005-094

²²⁴ 200-002-054

²²⁵ Dr Haynes T-02-05-12 p.24 line12

Blood Loss

- 2.70 Dr Taylor maintained that he administered fluids to replace what he categorised as a “*substantial ongoing blood loss*”²²⁶ which he estimated to be as much as 1,411mls.²²⁷ However, Mr Keane recalled “*no major bleeding in Adam’s case*”²²⁸ and Dr Haynes, having examined the evidence, ventured an informed guess of 800-1,000mls.²²⁹ Dr Taylor conceded in evidence that it was “*possible that there was an error on my measurement and otherwise of the blood loss.*”²³⁰

Monitoring the CVP

- 2.71 CVP readings were displayed throughout surgery and were an important guide for the safe management of Adam’s fluid balance.²³¹ Notwithstanding that the readings were high indicating fluid overload, Dr Taylor ignored them and insisted that a mis-siting of the CVP catheter had rendered the read-out inflated and unreliable.²³² Rather than remedy the problem or disregard the reading altogether, he chose to silence the alarm²³³ and reinterpret the unreliable figures.²³⁴ Dr Coulthard was simply unable to “*accept that it was good practice to assume that a monitoring system is not working, and to make clinical decisions that appear to conflict with its read-outs.*”²³⁵ Dr Haynes pointed out that if the CVP readings were wrong then that was all the more reason not to use them as the basis for reinterpretation.²³⁶ If Dr Taylor did not believe the reading he should have agreed with Mr Keane at the outset to rectify the problem.²³⁷ It is unlikely that time thus spent would have had “*significant negative impact.*”²³⁸ Mr Keane said that if the reading

²²⁶ 011-014-096
²²⁷ WS-008-1 p.7
²²⁸ WS-006-2 p.14
²²⁹ 204-006-337
²³⁰ Dr Taylor T-20-04-12 p.108 line 10
²³¹ 058-008-022
²³² WS-008-2 p.12
²³³ Dr Taylor T-06-09-12 p.137 line 10
²³⁴ Dr Taylor T-19-04-12 p.76 line 15
²³⁵ 200-002-055
²³⁶ 204-013-395
²³⁷ 204-004-155
²³⁸ 203-004-076

could not be relied on then *“the whole thing has to stop.”*²³⁹ Dr Coulthard considered the correct approach would have been to delay surgery until a satisfactory CVP reading was available. Somehow and in the event Dr Taylor reassured the surgeons and allowed his lack of concern to reassure Dr O’Connor.²⁴⁰ Dr Taylor now recognises that he *“shouldn’t have relied on that line at all”*²⁴¹ and ought to have considered ending the transplant because *“this potentially should have been a show-stopper.”*²⁴² Had he taken the time to resolve this issue he would then have had a reliable measure of vascular fullness and would have known that Adam did not need extra fluid.

Blood gas machine sodium level assessment

- 2.72 Dr Taylor failed to make an early assessment of Adam’s sodium levels during surgery. After some time he did despatch a blood sample for analysis by blood gas machine and received the result at 09:32. It recorded a sodium value of 123mmol/L.²⁴³ Not only was this reading very low but it revealed a significant drop from normal in only a matter of hours. Dr Taylor ignored this result because he said that it was his understanding that the blood gas machine did not always provide reliable results for serum electrolytes.²⁴⁴ However, Dr Coulthard has since calculated that the *“plasma sodium reading of 123mmol/L as measured is likely to be correct”*²⁴⁵ and should in any event should have prompted an urgent blood sodium assessment from the hospital laboratory to inform fluid management.²⁴⁶ Dr Haynes agreed, observing that even if blood gas testing is not very accurate it does alert the anaesthetist to potentially dangerous changes in sodium levels more quickly than laboratory testing and *“allows corrective action”*²⁴⁷ In Adam’s case it may also have allowed

²³⁹ Mr Keane T-26-04-12 p.95 line 6

²⁴⁰ Dr O’Connor T-25-04-12 p.129 line 14

²⁴¹ Dr Taylor T-19-04-12 p.82 line 1

²⁴² Dr Taylor T-19-04-12 p.82 line 1

²⁴³ 058-003-003

²⁴⁴ Dr Taylor T-20-04-12 p.103

²⁴⁵ 200-002-053

²⁴⁶ 200-004-085

²⁴⁷ 204-002-025

an opportunity to minimise his cerebral oedema.²⁴⁸ That was a missed opportunity. Dr Taylor belatedly acknowledged that he should have sent “a confirmatory sample to the lab. I did not do that and I regret that I did not do that”²⁴⁹ and further that he “should have done regular blood samples to adjust my fluids... and I also failed to do that.”²⁵⁰

Dr Taylor

2.73 In addition to proceeding without understanding Adam’s sodium levels or urine output and with a profound misunderstanding as to his fluid management, Dr Taylor was wrong to ignore the danger signals given by the CVP and the blood gas sodium analysis. Furthermore, it was wrong and misleading of him to insist upon justifying his clinical performance in the way he did and false to assure the Coroner, Adam’s mother and others that his management of Adam was “*caring, appropriate, expert and representative of the highest quality and intensity of care that I can provide.*”²⁵¹

2.74 Dr Taylor steadfastly maintained his baseless justifications for many years and only changed his position in late 2011 after he was provided with the Inquiry expert reports. In early 2012, and having received legal advice which was independent of the Trust for the first time, he made a written statement admitting error.²⁵² In April 2012, he acknowledged in oral evidence much that he had previously denied. He said:

“...I accept that it was my miscalculation of urine output that led me to give the inappropriate amount of fluids that led to a drop in his sodium called dilutional hyponatraemia which led to cerebral oedema.”²⁵³

²⁴⁸ 204-002-033
²⁴⁹ Dr Taylor T-20-04-12 p.105 line 9-10
²⁵⁰ Dr Taylor T-19-04-12 p.74 line 4
²⁵¹ 011-002-009
²⁵² WS-008-6
²⁵³ Dr Taylor T-19-04-12 p.40 line 5

- 2.75 However, Dr Taylor would not accept that Adam's death occurred in consequence of the dilutional hyponatraemia.²⁵⁴ He relied on the evidence of Professor Kirkham that it could not have been so. For the reasons set out in the section of this report entitled "*Fatal cerebral oedema: alternative causes and contributory factors*" (Para 2.177) I do not accept Professor Kirkham's analysis.
- 2.76 Dr Taylor's management of Adam's fluids before and during the surgery of 27th November 1995 defies understanding. In his oral evidence, Dr Taylor accepted that he could not understand it either, nor could he explain or justify what he did or how he subsequently defended it,²⁵⁵ except to say that he found it "*difficult to cope with [his] thought processes, going over such a devastating event. I think that has permitted me to say things that are clearly irrational, wrong, disturbed, confused, and I offer that as an explanation for making such really outrageous statements.*"²⁵⁶
- 2.77 I heard a lot of evidence from Dr Taylor but do not believe I was told the full story. Dr Taylor offered no insight into why he did what he did during Adam's transplant. Ms Slavin wanted to know why he had made so many mistakes.²⁵⁷ Inquiry counsel questioned how, given his experience and expertise, he could make such fundamental errors.²⁵⁸ Yet despite, or perhaps because, he provided so much evidence, Dr Taylor managed to keep his own thought processes obscure. Even though he now accepts what he did, he makes no attempt to explain it.
- 2.78 Dr Taylor made fatal errors in his treatment of Adam. I accept that this was most probably uncharacteristic²⁵⁹ and do not query his usual competence. However, and over and above the hurt inflicted on Adam's family by death, Dr Taylor caused significant additional pain by acting as he did to avoid his own responsibility.

²⁵⁴ Dr Taylor T-20-04-12 p.189 line 13

²⁵⁵ Dr Taylor T-19-04-12 p.56 line 24

²⁵⁶ Dr Taylor T-19-04-12 p.57 line 25

²⁵⁷ Dr Taylor T-20-04-12 p.154 line 10

²⁵⁸ Dr Taylor T-19-04-12 p.67 line 3

²⁵⁹ Dr Taylor T-19-04-12 p.58 line 23

Other issues

Assistant anaesthetist

- 2.79 A question arose as to when Dr Montague left the operating theatre and whether he was replaced. This became an issue of potential concern because Dr Taylor accepted that he had himself left the theatre from time to time²⁶⁰ and accordingly, if he had been without an assistant anaesthetist at any such time, responsibility for monitoring Adam would have fallen to the anaesthetic nurse who cannot now be identified.²⁶¹
- 2.80 Considerable efforts were made to establish the facts. Dr Montague probably left at some point between 09:00 and 09:30.²⁶² He is not to be criticised for leaving because he would not have done so without Dr Taylor's approval and there is no suggestion that that was withheld.²⁶³ The evidence does not suggest that Dr Montague was replaced. No trace of replacement has been found.
- 2.81 The necessity for an anaesthetist to replace Dr Montague is not to be assumed. It depended in part upon whether there was a nurse actually present and assisting Dr Taylor with the anaesthetic. The evidence agreed that there would have been three nurses in theatre, one of whom would have helped Dr Taylor. Whilst none could remember who was there, all agreed that the appropriate number of nurses was present. I therefore accept, on the evidence, that there was such a nurse.²⁶⁴ Her role was a relatively minor one in 1995. Some vagueness as to who was present is understandable, the absence of written record is not.
- 2.82 Furthermore, and given that Dr Montague was inexperienced and probably only there to train and gain experience, I believe that Dr Taylor was in

²⁶⁰ WS-008-2 p.9

²⁶¹ 306-002-003

²⁶² Dr O'Connor T-25-04-12 p.71 line 3

²⁶³ Dr Taylor T-20-04-12 p.60 line 11

²⁶⁴ Staff Nurse Popplestone T-30-04-12 p.60 line 1

charge of anaesthesia at all times during Adam's operation, irrespective of the presence or otherwise of any other doctor or nurse to assist him.

Communication between surgical and anaesthetic teams

2.83 The shared priority of surgeon and anaesthetist is patient safety. Accordingly effective exchange of patient information between them and their assistants is of particular importance.²⁶⁵ Expert witnesses to the Inquiry questioned whether the two teams communicated successfully during the transplant. Dr Haynes observed that *"reading and re-reading the various witness statements does not reassure me that surgeon and anaesthetist were working effectively together as a team, communicating well with each other."*²⁶⁶ Communication was critical in relation to blood loss,²⁶⁷ CVP readings and fluid management at the time of re-perfusion of the transplanted kidney.²⁶⁸ Mr Keane confirmed that communication between them may not always have been *"helpful"*²⁶⁹ but emphasised that if Dr Taylor did not understand what he was to impart then he was expected to ask.²⁷⁰ I believe that had Dr Taylor explained what he was doing and had better dialogue with the transplant surgeon then the risk of gross fluid mismanagement may have been reduced.

Determining what happened in the operating theatre

2.84 It might be expected that a detailed analysis of Adam's surgery would allow a clear understanding of events in theatre. However, establishing exactly what happened during surgery has proved to be one of the most difficult areas of the Inquiry's investigation. There are issues about which it is not possible to make a clear finding, even on the balance of probabilities. Some issues are more important than others but the overall number of them is significant. This is troubling because of a concern that the full truth of what

²⁶⁵ Mr Keane T-26-04-12 p.161 line 7

²⁶⁶ 204-006-334

²⁶⁷ Mr Keane T-26-04-12 p.41 line 20

²⁶⁸ Mr Keane T-26-04-12 p.160 line 1

²⁶⁹ Mr Keane T-26-04-12 p.157 line 1

²⁷⁰ Mr Keane T-26-04-12 p.158 line 18

happened in theatre may not have been revealed and that Adam's surgery may not have been as recorded by the doctors and nurses in the case notes, or as described by them in their written statements to the Coroner, the Police and this Inquiry or as recounted by them under oath.

2.85 Doubts as to the accuracy of the broad narrative first emerged from the evidence of the Regional Transplant Co-ordinator for Northern Ireland, Ms Eleanor Boyce (née Donaghy),²⁷¹ who made a statement to the Police Service of Northern Ireland ('PSNI') on 28th April 2006 recalling how Staff Nurse Joanne Sharratt (née Clingham)²⁷² had informed her, when Adam was still in theatre, that he might even then be brain-stem dead. Ms Boyce described how, on entering the theatre, she had found the mood very sombre. She believed the surgeons were at the operating table and although she could not say what they were doing or what stage had been reached²⁷³ she could *"...remember Patrick Keane (Surgeon) being at the table. There was another surgeon however I do not recall who it was. There were other staff present in the operating theatre; however I do not recall who they were. I remember when I was in the theatre wondering why they were continuing with the procedure if the child was supposed to be brain-stem dead."*²⁷⁴ She said that *"there was an awareness that we were dealing with a very serious situation."*²⁷⁵ Her presence in theatre was confirmed by Dr O'Connor²⁷⁶ but her account was flatly dismissed by everyone.

2.86 Notwithstanding that uniquely Ms Boyce was independent of the Trust and had no apparent reason to invent such an account, her very different recollection of surgery was not initially accorded particular significance beyond that of puzzling anomaly. However, her statement assumed greater significance when a pre-inquest consultation minute taken by Mr George Brangam's²⁷⁷ para-legal assistant, Ms Heather Neill, came unexpectedly to

²⁷¹ 306-081-005

²⁷² 303-001-003

²⁷³ 093-015-048

²⁷⁴ 093-016-049

²⁷⁵ Ms Boyce T-27-04-12 p.120 line 13

²⁷⁶ Dr O'Connor T-25-04-12 p.75 line 22

²⁷⁷ 306-081-006 The late Mr George Brangam, erstwhile partner in Brangam, Bagnall & Co Solicitors, retained by the Trust. His death precluded his giving evidence to the Inquiry

light in June 2012.²⁷⁸ On the 14th June 1996 she had recorded Dr Taylor and Professor Savage in discussion with Dr George Murnaghan,²⁷⁹ Dr Joseph Gaston²⁸⁰ and Mr Brangam and had noted an assertion that “*during the surgery when this kidney was failing to operate a needle was put into the artery and no blood came out and clearly the kidney was not working when the operation site was closed however, the performance of the kidney was no longer relevant at this stage.*”²⁸¹ This perplexed because it is so markedly at odds with the other evidence about what happened in theatre, with the possible exception of Ms Boyce’s account.

2.87 In particular the operation record, far from noting any concern with perfusion, records in Mr Keane’s hand that “*the kidney was perfused reasonably at the end.*”²⁸² Indeed, Mr Keane stated in his deposition for inquest that “*the operation was difficult but a successful result was achieved at the end of the procedure*”²⁸³ (by which he said he meant a “*technically successful result*”).²⁸⁴ Accordingly, had a needle been placed in the artery and no blood emerged so as to indicate that the “*kidney was not working*”,²⁸⁵ then that most certainly would have been recorded.

2.88 The possibility that an ‘unknown event’ had occurred in theatre, which was being concealed, focused attention on the totality of evidence in the search for answers. An unexpected degree of vagueness and inconsistency emerged. I found this very surprising because I had been told repeatedly that the death of a child in hospital is a rare event. It might therefore be supposed that those involved would remember with some clarity what had gone wrong, no matter whose fault it was or even if it was nobody’s fault. However, even the evidence identifying where the operation took place, when it took place and who was there, is worryingly unclear:

²⁷⁸ 122-001-001
²⁷⁹ 306-081-005
²⁸⁰ 306-081-003 to 004
²⁸¹ 122-001-005
²⁸² 059-006-013
²⁸³ 011-003-010
²⁸⁴ Mr Keane T-23-04-12 p.60 line 15
²⁸⁵ 122-001-005

- (i) There is no record as to which theatre was used. Not even the reported closure of the theatre²⁸⁶ after the catastrophic event generated any documentary evidence. The only available record is the swab count marked "*Theatre II.*"²⁸⁷ Doubt however emerged in oral evidence²⁸⁸ as to whether this could be correct.
- (ii) There is no reliable record as to who was present in theatre at the time of surgery. Dr Taylor believed that Dr Montague was replaced by a trainee anaesthetist. Despite extensive enquiry this individual could not be identified.²⁸⁹ Likewise, Dr Taylor indicated that an anaesthetic nurse was present. Again, despite exhaustive efforts by the Inquiry and the Directorate of Legal Services ('DLS'), that nurse remains unidentified.²⁹⁰ An auxiliary nurse would have been present in theatre²⁹¹ and another made entries in the record of blood loss.²⁹² These individuals also remain unidentified.²⁹³
- (iii) Additionally, there is a problem determining when surgery started and when it ended. Timings do not appear in the record and reliance must be placed upon the recollection of those involved. Professor Savage recalled that Adam was taken to theatre at 07:00.²⁹⁴ Mr Keane deposed that "*the operation started at 7.30am.*"²⁹⁵ Subsequently and upon reflection he stated "... *it would now appear that the surgery started at around 8:00am*"²⁹⁶ and then gave his "*best possible estimate... a start time of 8:10.*"²⁹⁷ Witnesses were at odds about the timing of events in surgery. Dr Taylor believed

²⁸⁶ 093-034-086

²⁸⁷ 058-007-020

²⁸⁸ Mr Brown and Dr Montague T-11-05-12 p.80 line 16-25 & other nurse witnesses - Patricia Conway T-30-04-12 p.41 lines 11-16, Nurse Popplestone T-30-04-12 p.63 lines 13-20, Margaret Matthewson T-30-04-12 p.107 line 21-108 line 9 & Dr Gibson's Report (059-069-162)

²⁸⁹ 306-002-004

²⁹⁰ 301-043-407 & 306-002-003

²⁹¹ Dr Taylor 20-04-12 p.78 line 12

²⁹² 058-007-021

²⁹³ Mr Keane T-24-04-12 p.124 line 11

²⁹⁴ 016-004-014

²⁹⁵ 011-013-093

²⁹⁶ WS-006-3 p.12

²⁹⁷ Mr Keane T-26-04-12 p.5 line 16

anastomosis²⁹⁸ occurred shortly after 09:30²⁹⁹ but Dr O'Connor was astounded that he should think that and said that it was not achieved until around 10:30.³⁰⁰ Dr Taylor was driven to concede "*discrepancy in the notes*"³⁰¹ and could neither recollect nor explain why nothing was seemingly done between 10:15 and 11:00.³⁰² The anaesthetic record ends at 11:00 when Dr Taylor administered drugs to reverse the neuromuscular blockade,³⁰³ however he was quite unable to explain what was done subsequently between then and midday.³⁰⁴

2.89 Furthermore, the evidence detailing events in theatre was contradictory.

- (i) Mr Keane has stated that when he left theatre "... *the kidney was reasonably well perfused.*"³⁰⁵ However, his deposition for inquest indicated that "*at the end of the procedure it was obvious that the kidney was not perfusing as well as it had initially done.*"³⁰⁶ Conversely, Staff Nurse Gillian Popplestone³⁰⁷ remembered "... *it was discoloured and then that seemed to subside.*"³⁰⁸ Other witnesses were similarly inconsistent in relation to the condition of the donor kidney. Dr O'Connor said it was described as "*bluish.*"³⁰⁹ Mr Brown in his statement to the PSNI recalled that "*from what I can remember the kidney turned pink... As far as I can remember the kidney remained pink....*"³¹⁰ Dr Taylor informed the Coroner that at around 10:00 the donor kidney was not looking good and not producing urine.³¹¹ Mr Keane recalled urine being produced whereas Mr Brown was clear that none had been produced.³¹²

²⁹⁸ 312-005-002
²⁹⁹ 122-001-003
³⁰⁰ Dr O'Connor T-25-04-12 p.124 line 12
³⁰¹ Dr Taylor T-06-09-12 p.59 line 23
³⁰² Dr Taylor T-06-09-12 p.70 line 22
³⁰³ 058-003-005
³⁰⁴ Dr Taylor T-06-09-12 p.146 line 2 & p.147 line 14 & p.149 line 2
³⁰⁵ WS-006-2 p.7
³⁰⁶ 011-013-093
³⁰⁷ 303-001-004
³⁰⁸ Staff Nurse Popplestone T-30-04-12 p.81 line 2
³⁰⁹ Dr O'Connor T-25-04-12 p.138 line 15
³¹⁰ 093-011-032
³¹¹ 011-014-101
³¹² 059-060-146 & Mr Brown T-01-05-12 p.102 line 21

- (ii) Neither the time of Mr Keane's departure from the operating theatre nor the time of wound closure is recorded. Mr Keane has stated that he left the operating theatre at "*approximately 10-30am*"³¹³ and yet when he gave his evidence at inquest he made no reference whatsoever to leaving early or of relying upon Mr Brown to close the wound and complete the operation.³¹⁴ Similarly Mr Brown, in his statement to the Coroner, made no reference to Mr Keane's departure before the end of transplant surgery or to the fact that he had closed the wound.³¹⁵ Subsequently, and in response to police questioning, he stated that "*it would appear to be the case that Mr Keane left myself to sew up the wound. I do not have any recollection of the end of the operation or the anaesthetist trying to bring Adam round.*"³¹⁶
- (iii) Mr Keane claimed to have left the theatre "*10 minutes prior to the end of the anaesthesia*" to attend an emergency³¹⁷ explaining that he had received a call from the BCH about "*a patient who was undergoing a percutaneous nephrolithotomy, was bleeding heavily in the operating theatre there and they needed help urgently.*"³¹⁸ Despite extensive enquiry this emergency was uncorroborated and remained a mystery until Mr Keane conceded that there may not have been an emergency at all but suggested that he might have returned to BCH for a scheduled operation for which he may already have been late.³¹⁹
- (iv) Mr Keane's surgical notes are poor and remarkably, Mr Brown made no notes at all.³²⁰ Professor Forsythe and Mr Rigg in their joint report describe the operating record as brief.³²¹ Whilst it does record key

³¹³ WS-006-2 p.7

³¹⁴ 011-013-093

³¹⁵ 059-060-146

³¹⁶ 093-011-032

³¹⁷ WS-006-1 p.3

³¹⁸ WS-006-2 p.7

³¹⁹ Mr Keane T-26-04-12 p.163-4

³²⁰ Mr Brown T-20-06-12 p.185 line 18

³²¹ 203-004-078

issues, lesser matters are omitted. Some entries lack detail, there is no timing for the beginning or end of anastomosis and no comment on the perfusion of the kidney after removal of the clamps. Furthermore, the post-operative assessment was not completed,³²² kidney performance at the end of surgery was left unrecorded and there is no post-operative management plan.

- 2.90 The inevitable suspicion was that Adam had suffered a failed transplant and had died earlier than previously indicated and in unclear circumstances. It is to be emphasised that none of the experts believe that the infarction of the kidney contributed to Adam's death. Accordingly, suspicion as to what else may have happened in theatre is almost certainly irrelevant to the history of the development of hyponatraemia, its role in Adam's death and the principal focus of this Inquiry. Nonetheless, the matter assumed considerable importance because it was so clearly relevant to the candour and credibility of all involved in the operating theatre. Were there to have been concealment of facts, such would only have been possible by an active conspiracy of silence and deceit involving all those doctors and nurses engaged in the operating theatre, and some perhaps who were not.
- 2.91 Such a proposition was entirely speculative but would perhaps have accounted for the unexplained delays in theatre, the inconsistencies relating to exchange of CVP values and the perfusion of the kidney, the poor operation notes, the departure of the lead surgeon, the failure of the surgical team to speak to Ms Slavin and the opinion of some experts as to the likely timings of kidney infarction³²³ and brain stem death.³²⁴ Accordingly, hearings were arranged³²⁵ and witnesses recalled in order that the matter be further examined in detail.
- 2.92 Those involved in the operating theatre had their recollection and previous evidence tested under focused examination. Inevitable minor discrepancies

³²² 058-003-006

³²³ 011-007-022

³²⁴ 200-022-267

³²⁵ In September 2012

were revealed but I found the general version of events to be as previously described and no new issues were revealed.

2.93 In particular the evidence of Ms Boyce and the consultation note of Ms Neill were subjected to the closest scrutiny.

- (i) Ms Neill was able and experienced and had recorded a minute of a private consultation between the Trust's witnesses and the Trust's solicitor. She made it for internal legal purposes without any intention of wider circulation. To that extent it might be thought to possess the detachment necessary to lend it weight. There is no reason to suspect that Ms Neill sought to distort or invent what was said at the meeting. It is hard, likewise, to comprehend how she might have misunderstood or misinterpreted what was said. Despite a lack of medical training, much of her note is self-evidently correct. However, the fact remains that identifiable mistakes do appear in the minute, there is re-ordering of subject matter by theme obscuring the nuance and context of the discussion and, with some rearrangement of punctuation and emphasis, less troubling meanings can be found in the controversial wording. The contentious account deals specifically with the surgeon's role but it must be noted that there was no surgeon at the meeting and no surgical perspective on the issue under discussion. Indeed the statement cannot be attributed with confidence to any one individual. The minute was not checked by Ms Neill's principal, Mr Brangam, nor was it circulated for comment or agreement. The account recorded differs so obviously from those depositions already held from the witnesses that Mr Brangam might have been expected to query this particular version of events. Ms Neill would, I am quite sure, have recorded any such discussion. None is noted. Accordingly, I conclude on the balance of probabilities, that the consultation note is not to be relied upon in its entirety and is therefore an unsound basis upon which to make a finding of fact.

- (ii) Ms Boyce did not make her statement recalling her presence in theatre until long after Adam's death. Whilst I do not doubt her sincerity, there was nobody who agreed with her recollection. The fact that it differs from everybody else's is a valid reason for taking it seriously but it is also a valid reason for suspecting its accuracy if it is not completely compelling. Ms Boyce gave evidence that she watched from a distance as surgeons worked with Adam and wondered why if he was already dead. Her account was based on what she sensed of the mood in theatre and interpreted in the light of what she remembered being told. If she had misunderstood the context then she may have misinterpreted the scene. She said that she remained in theatre until the end and did so because of her interest in Adam as a patient known to her. Her inability, however, to recall how long she stayed³²⁶ is hard to understand in the circumstances described, as indeed was her failure, then or at any time thereafter, to enquire about what had happened.³²⁷ If she had confused one memory with another that could lead to error. Very properly she accepted the possibility that her memory was wrong.³²⁸ On balance, and on the hearing of the evidence,³²⁹ I am unable to conclude that Ms Boyce's perception and recollection of what she witnessed necessarily reflects what actually occurred.

2.94 It is with frustration that I cannot make findings from the evidence as to what did happen at all times during Adam's surgery. The available evidence was degraded by the passage of time, the paucity of documentation, the absence of contemporary investigation, the number of inconsistencies and the decidedly poor quality of some of the oral testimony given at public hearings. However, I consider my inability to form a view after so rigorous an inquiry into the avoidable death of a child in Northern Ireland's Regional

³²⁶ Ms Boyce T-27-04-12 p.119 lines 10-13

³²⁷ Ms Boyce T-27-04-12 p.121 line 19

³²⁸ Ms Boyce T-27-04-12 p.129 line 20

³²⁹ In particular that of Dr O'Connor

Paediatric Centre to be, of itself, a grave indictment of both the Trust and its systems.

Early appraisal of condition and communication with Ms Slavin

- 2.95 The first assessment of the cause of Adam's death appears to have been made at the conclusion of surgery by Dr O'Connor when she *"was called back to theatre when the fixed dilated pupils were apparent."*³³⁰ She *"formed a view that he had cerebral oedema"*³³¹ and *"a significantly positive fluid balance."*³³² She proceeded to telephone Professor Savage who *"rapidly went to the intensive care unit and reviewed the situation, with her... with a rapid calculation we thought he had had 1,500ml of fluid more in than out... so at that stage with a low sodium and subsequently with a lower sodium coming back from the laboratory, I think Dr O'Connor and I felt that there was a situation where his fluid balance was excessive on the positive side. He had a lot of fifth normal saline and we felt he had probably got cerebral oedema and coned."*³³³ Dr O'Connor concluded that *"the picture seemed to be of fluid overload"*³³⁴ and felt that it was Professor Savage who was best placed to speak to Ms Slavin³³⁵
- 2.96 Professor Savage recalls discussing *"with Dr Taylor that Adam looked bloated and... would appear to [to have] had excessive amounts of fluid and that that was the cause of his cerebral oedema... I said that I believed that I then had to go and explain that to Debra Strain and asked him to accompany me."*³³⁶
- 2.97 Ms Slavin arrived at the PICU at 12:15. She saw Adam and was struck by *"how bloated he was."*³³⁷ She was met by Professor Savage, Dr Taylor and Staff Nurse Susan Beattie.³³⁸ Professor Savage explained to her that

³³⁰ Dr O'Connor T-25-04-12 p.112

³³¹ Dr O'Connor T-25-04-12 p. 114 line 21

³³² Dr O'Connor T-25-04-12 p.115 line 21

³³³ Professor Savage T-18-04-12 p.151 line 6

³³⁴ Dr O'Connor T-25-04-12 p.136 line 5

³³⁵ WS-014-2 p.4

³³⁶ Professor Savage T-22-06-12 p.14 line 3

³³⁷ WS-001-1 p. 2

³³⁸ 303-001-003

*“Adam had cerebral oedema with a swollen brain causing pressure on his vital centres,”*³³⁹ *“there had been an imbalance of fluids in his body”*³⁴⁰ and that *“hope of recovery was remote.”*³⁴¹ He told her that he did not yet understand why this had happened, principally because he felt that *“it did not seem an appropriate time to get into [dilutional hyponatraemia] with Mrs Strain, bearing in mind that I knew she would likely only remember the bad news that I was giving her.”*³⁴² She was informed by Dr Taylor that something was *“drastically wrong”* and that it was a *“one in a million thing.”*³⁴³ Dr Taylor has since apologised for *“this really quite silly statement”* of meaningless statistics.³⁴⁴

2.98 After the operation the surgeons did not speak to Ms Slavin. Mr Keane explained that whilst he would normally speak to the family, on this occasion and in his absence he *“expected Mr Brown to speak to Adam’s family.”*³⁴⁵ Mr Brown stated that he did not consider it his responsibility to speak to Adam’s mother because *“this was not a paediatric surgery operation, but a transplant.”*³⁴⁶ He subsequently acknowledged that he *“should have spoken to the mum because there was nobody else to speak to her.”*³⁴⁷ Expert evidence agreed that a surgeon would normally be expected to join in such a conversation.³⁴⁸ As Professor Savage observed in his oral evidence *“it would have been good if one of the surgeons had come and spoken to them, but they didn’t.”*³⁴⁹ I share this view and furthermore believe that active attempts should have been made to secure the attendance of one of the surgeons.

2.99 Mr Keane returned to the Children’s Hospital the following morning and having reviewed the notes,³⁵⁰ came to his own conclusion as to the cause

³³⁹ WS-002-1 p.4

³⁴⁰ 058-038-181

³⁴¹ WS-002-1 p.4 & 059-006-016

³⁴² Professor Savage T-22-06-12 p.16 line 20

³⁴³ WS-001-1 p.4

³⁴⁴ Dr Taylor T-20-04-12 p.136 lines 12-21

³⁴⁵ WS-006-2 p.7

³⁴⁶ WS-007-3 p.6

³⁴⁷ Mr Brown T-01-05-12 p.141 line 9

³⁴⁸ 200-007-118

³⁴⁹ Professor Savage T-18-04-12 p.158 line 11

³⁵⁰ Mr Keane T-23-04-12 p.30-1

of death. He spoke with Professor Savage and *“confirmed that I was seriously worried about what had happened in terms of the fluid management...”*³⁵¹ He said: *“all I can remember of the encounter was that he had his head buried. I think he was crying.”*³⁵²

2.100 Dr Terence Montague recalled how he *“came into the hospital the next morning and... met Dr Taylor in the theatre where the surgery had taken place... and he told me that Adam was likely to die, that Adam had cerebral oedema, and at that stage he was pointing out to me that the anaesthetic machine was being quarantined so that it could be examined...”*³⁵³

2.101 The 11:30 serum sodium test result was received at 13:00. It revealed a sodium value of 119mmol/L.³⁵⁴ Dr O'Connor noted this in the record at about 13:20,³⁵⁵ and entered a query as to whether this might not be a case of dilutional hyponatraemia.³⁵⁶

2.102 Neurological advice was sought from Dr David Webb³⁵⁷ who saw Adam at 19:30 on 27th November 1995. His examination, witnessed by Dr Rosalie Campbell,³⁵⁸ was the first part of the formal clinical assessment necessary to confirm brain stem death.³⁵⁹ Dr Webb spoke with the clinicians in PICU, examined Adam and reviewed the CT scan. He recorded that *“the examination is comparable with brain stem death 2° severe acute cerebral oedema. This may have occurred on the basis of unexpected fluid shifts – ‘osmotic disequilibrium syndrome.’”*³⁶⁰ It may be significant that he made no reference to Adam's hyponatraemia. He said *“if I'd been aware of the low sodium, I would have considered hyponatraemia to be the likely cause of the fluid shift.”*³⁶¹ Dr Webb should have been aware of Adam's low sodium reading. The notes clearly record the laboratory sodium results of

³⁵¹ Mr Keane T-23-04-12 p.31, line 14

³⁵² Mr Keane T-23-04-12 p.31 line 23

³⁵³ Dr Montague T-11-05-12 p.153-54

³⁵⁴ 058-040-186

³⁵⁵ Dr O'Connor T-25-04-12 p.117 line 5

³⁵⁶ 059-006-016, 058-035-138 & Dr O'Connor T-25-04-12 p.157 line 15

³⁵⁷ 303-001-003 Consultant Paediatric Neurologist

³⁵⁸ 303-001-001 to 002

³⁵⁹ 058-004-009 & 058-035-139

³⁶⁰ 058-035-140

³⁶¹ WS-107-2 p.4

119mmol/L. Dr Webb however, believed that he may not have appreciated this or may have been told that this result was unreliable, because he was prompted to conduct medical literature research in order to explain the brain swelling.³⁶² This is not necessarily convincing. A consultant paediatric neurologist asked for his formal opinion in relation to a brain stem death test would undoubtedly examine the notes and even if told that the sodium result was suspect, could not justify ignoring it. Dr Webb must be open to the criticism that he either did not properly review the notes, or alternatively, that he deliberately avoided entering a diagnosis of hyponatraemia with its inherent suggestion of fluid mismanagement.³⁶³

2.103 In making the necessary clinical assessment to confirm brain stem death, Drs Webb, Campbell and O'Connor had each to satisfy themselves that there was an underlying cause for the brain stem death and, importantly, that other potential reasons for coma, including metabolic causes or drugs, were excluded. The drug record should therefore have been double-checked and the metabolic disorder of hyponatraemia corrected before the tests were undertaken.³⁶⁴

2.104 Notwithstanding,³⁶⁵ Dr Webb recorded the brain stem death criteria to be fulfilled at 09:10.³⁶⁶ Consent was then sought from Ms Slavin to discontinue life support³⁶⁷ and this was done with Adam on her knee³⁶⁸ at 11:30 on 28th November 1995.³⁶⁹

2.105 Professor Savage then notified the Coroner because he "*knew that there had to be a coroner's inquest*"³⁷⁰ but did not seemingly report his views on the mishandling of fluids.³⁷¹ He then attended the post-mortem "*probably*

³⁶² WS-107-2 p.2

³⁶³ Dr Webb provided two witness statements to the Inquiry relating to the death of Adam Strain. For personal reasons he was unable to attend the oral hearings to give evidence.

³⁶⁴ 204-014-003 & 204-012-386 & Dr Haynes T -03-05-12 p.115 line 19

³⁶⁵ Dr Haynes T-03-05-12 p.112 line1

³⁶⁶ 058-004-009

³⁶⁷ WS-001-1 p.4

³⁶⁸ 016-004-015

³⁶⁹ WS-001-1 p.4 & 016-004-015

³⁷⁰ Professor Savage T-22-06-12 p.3 line 19

³⁷¹ 011-025-125

*just to make sure that the conclusions we had reached were correct*³⁷² and to ensure *“that Dr Armour understood my perception of the fluid balance situation.”*³⁷³ The pathologist Dr Alison Armour³⁷⁴ could not remember speaking with Professor Savage and does not appear to have understood the *“fluid balance situation”* until sometime later.³⁷⁵

2.106 Professor Savage wrote to the Strain family GP on 4th December 1995³⁷⁶ to advise as to the circumstances of Adam’s death. He did not however refer to the cause of death because he *“probably thought it would have been inappropriate for me to suggest a diagnosis in advance of the coroner’s inquest.”*³⁷⁷ Ms Slavin recalled that she *“knew that the cause of Adam’s death was the swelling of his brain but at no time do I recall anyone telling me that this had happened because he had been given too much fluid.”*³⁷⁸ Nor does it seem that anyone told her that Adam’s sodium levels had fallen so far and that he had severe hyponatraemia.³⁷⁹

2.107 There is no evidence to suggest any formal communication with Adam’s family by the Trust, not even a letter of condolence.

Adam Strain Governance

2.108 It is understandable and perhaps all too easy to make a mistake working in the complex field of medicine. However, after an unexpected death like Adam’s, it might have been expected, even by the standards of 1995, that those involved would openly and honestly analyse what had happened in order to minimise the risk of recurrence. Analysis should have taken place immediately, when memories were fresh, so that lessons could be learned straight away. A major failing in Adam’s case is that, according to the

³⁷² Professor Savage T-18-04-12 p.156 line 19

³⁷³ Professor Savage T-22-06-12 p.22 line 4

³⁷⁴ 303-001-001

³⁷⁵ Professor Savage T-22-06-12 p.22 line 6

³⁷⁶ 016-004-014

³⁷⁷ Professor Savage T-22-06-12 p.30 line 16

³⁷⁸ WS-001-1 p.4

³⁷⁹ 011-006-019

evidence, that analysis did not take place. How and why that happened will be explored below but central to it was reluctance to accept or attribute fault.

Adverse incident reporting

- 2.109 No Serious Adverse Incident ('SAI') report of Adam's death was made within the Children's Hospital or the Trust. There was, however, no formal requirement to do so at that time.
- 2.110 The Medical Director, Dr Ian Carson,³⁸⁰ explained that *"unexpected or unexplained deaths during or following anaesthesia and surgery would be reported externally to H.M. Coroner, and internally to Dr G Murnaghan in his capacity as Director of Medical Administration"*³⁸¹ but *"were not formally reported to the Medical Director as a routine."*³⁸² However, in the case of *"death where a doctor's practice is called into question or patients are put at risk, those are cases that quite definitely should have been referred to the Trust Medical Director"*³⁸³ and the Clinical Director of Paediatrics.³⁸⁴
- 2.111 An oral report of the death was made to Dr George Murnaghan who, in his capacity as Director of Medical Administration, was charged with risk management and the defence of medical negligence claims.³⁸⁵ He served on the Clinical Risk Management Group which was responsible for untoward incident reporting in clinical matters.³⁸⁶ He was, in addition, responsible for the Trust's engagement with the Coroner³⁸⁷ and the internal dissemination of lessons drawn from inquests.³⁸⁸ He was ideally placed to ensure that relevant issues were brought to the attention of all those who needed to know within the Trust. His reporting line was to the Medical Director,³⁸⁹ he sat in *"attendance at the Board,"*³⁹⁰ reported to the Hospital

³⁸⁰ 306-081-004

³⁸¹ WS-077-2 p.6

³⁸² WS-077-2 p.21

³⁸³ Dr Carson T-16-01-13 p.66 line 12

³⁸⁴ Dr Carson T-16-01-13 p.67 line 11

³⁸⁵ Dr Murnaghan T-25-06-12 p.33 line 19

³⁸⁶ WS-061-2 p.262

³⁸⁷ 011-025-125 & 093-025-068

³⁸⁸ WS-061-1 p.2

³⁸⁹ Dr Murnaghan T-25-06-12 p.2 line 9

³⁹⁰ Dr Murnaghan T-25-06-12 p.6 line 16

Council on behalf of the Medical Risk Management Group³⁹¹ and kept the Chief Executive “*in the loop*.”³⁹² His role was significant within the Trust. He was a link between clinicians and the Trust Board and the connection between the internal procedures of the Trust and the external requirements of the Coroner.

- 2.112 Dr Murnaghan liaised with Dr Gaston who, as Clinical Director of Anaesthetics, Theatre & Intensive Care (‘ATICS’), likewise held a ‘governance’ position in the Trust and was also Dr Taylor’s clinical lead. Dr Gaston was experienced in critical incident reporting, incident investigation and audit³⁹³ and was an appointed surveyor with Kings Fund Organisational Audit (‘KFOA’).³⁹⁴
- 2.113 Dr Gaston did not seek a written report in respect of this unexpected and unexplained death. Nor, would it seem, did he really expect one.³⁹⁵ He heard about the death from a nurse on a corridor.³⁹⁶
- 2.114 Notwithstanding, and within days, Professor Savage and Dr Taylor³⁹⁷ did submit written statements. They cannot however have been of much assistance to Drs Murnaghan and Gaston, omitting as they do all reference to hyponatraemia and any explanation for Adam’s unexpected death.
- 2.115 Professor Savage received a copy of Dr Taylor’s statement very soon after.³⁹⁸ He immediately informed Dr Murnaghan that there was an explanation for what had happened and stated his belief that “*Adam’s cerebral oedema and death were related to fluid mismanagement*.”³⁹⁹ Dr Murnaghan accepts that Professor Savage brought this to his attention.⁴⁰⁰

³⁹¹ Dr Murnaghan T-25-06-12 p.56 line 3 & WS-061-2 p.241

³⁹² Dr Murnaghan T-25-06-12 p.3 line 8

³⁹³ Dr Gaston T-18-06-12 p.76 line 23 & p.77 line 10 & p.105 line 12

³⁹⁴ Dr Gaston T-18-06-12 p.71 line 17

³⁹⁵ Dr Gaston T-18-06-12 p.114 line 17

³⁹⁶ Dr Gaston T-19-06-12 p.12 line 4

³⁹⁷ 059-066-153 & 059-067-155

³⁹⁸ 059-067-156

³⁹⁹ Professor Savage T-22-06-12 p.22 line 19

⁴⁰⁰ Dr Murnaghan T-25-06-12 p.119 line 5

- 2.116 Dr Murnaghan said that then *“informally, if not formally, I brought the matter up with the Medical Director, Dr Carson”*⁴⁰¹ and that he was *“almost certain that I would have told him that Dr Taylor had a different view... that the Coroner was involved and was going to hold an Inquest. And I do not know what we agreed after that.”*⁴⁰²
- 2.117 Dr Carson was very clear that Dr Murnaghan did not bring Adam’s death to his attention whether formally or informally until the time of the inquest.⁴⁰³ There is no evidence of any involvement of Dr Carson before then, whether as Medical Director or as a fellow anaesthetist. Had he been notified I believe he would have taken some action or at the very least sought some information - which he seemingly did not. The sole suggestion that he was notified was made by Dr Murnaghan, whose evidence on the point was far from compelling.⁴⁰⁴ He was unable to provide any detail about what was said or agreed or done in respect of this most important communication. On balance I do not believe that Dr Murnaghan reported Adam’s death to the Medical Director until very much later. Instead he proceeded to act without reference to Dr Carson.
- 2.118 Nor did Drs Murnaghan or Gaston report the death to the Clinical Lead of the Paediatric Directorate, the Director of Nursing or the Chief Executive.
- 2.119 The acting Clinical Lead of the Children’s Hospital⁴⁰⁵ was Dr Conor Mulholland.⁴⁰⁶ He had only recently assumed this responsibility in addition to his full time practice as a Consultant Paediatric Cardiologist and his role as Clinical Director in Cardiology and Cardiac Surgery.⁴⁰⁷ There was no written guidance to assist him in his duties as acting Clinical Director of

⁴⁰¹ Dr Murnaghan T-25-06-12 p.155 line 6
⁴⁰² Dr Murnaghan T-25-06-12 p.165 line 1
⁴⁰³ Dr Carson T-15-01-13 p.156 line 6
⁴⁰⁴ Dr Murnaghan T-25-06-12 p.152 line 15
⁴⁰⁵ The Directorate of Paediatrics
⁴⁰⁶ 306-081-004
⁴⁰⁷ Dr Mulholland T-21-06-12 p.141

Paediatrics.⁴⁰⁸ His principal administrative concerns at that time in the Children's Hospital were financial.⁴⁰⁹

- 2.120 With hindsight he accepted that he should have received a report into Adam's death⁴¹⁰ in order to understand what had happened.⁴¹¹ However, on hearing of the death, he assumed that the matter would be taken forward by Drs Murnaghan and Gaston,⁴¹² that the Medical Director would be informed⁴¹³ and that the death would be formally dealt with by the Coroner. On the basis of these assumptions he did nothing⁴¹⁴ and remained *"completely outside the loop on Adam Strain."*⁴¹⁵
- 2.121 Dr Mulholland had appointed Consultant Paediatric Anaesthetist Dr Peter Crean⁴¹⁶ to be his Sub-Director in the Children's Hospital with responsibility for anaesthetics. Dr Crean did not, however, report Adam's case within the Paediatric Directorate because he was accountable to Dr Gaston's ATICS Directorate⁴¹⁷ and the matter had already been reported to Dr Gaston.
- 2.122 The necessity for the Clinical Director of Paediatrics to become involved in the investigation of a death in the Children's Hospital was obvious, yet the system imposed no obligation to report the matter to him, gave him no guidance as to what was expected of him and left him no time from his other duties to engage. A structural confusion of reporting lines left him in ignorance and allowed others to proceed without him.
- 2.123 The Director of Nursing and Patient Services was Miss Elizabeth Duffin.⁴¹⁸ She reported to the Chief Executive, received reports from nurse managers and talked regularly with Drs Murnaghan and Carson.⁴¹⁹ Her responsibilities included clinical quality assurance and the Trust application

⁴⁰⁸ Dr Mulholland T-21-06-12 p.191 line 14

⁴⁰⁹ Dr Mulholland T-21-06-12 p.143 line 9

⁴¹⁰ Dr Mulholland T-21-06-12 p.173 line 11

⁴¹¹ Dr Mulholland T-21-06-12 p.174 line 1

⁴¹² Dr Mulholland T-21-06-12 p.173 line 2

⁴¹³ Dr Mulholland T-21-06-12 p.177 line 6

⁴¹⁴ Dr Mulholland T-21-06-12 p.178 line 9

⁴¹⁵ Dr Mulholland T-21-06-12 p.182 line 22

⁴¹⁶ 303-001-007

⁴¹⁷ Dr Crean T-20-06-12 p.5

⁴¹⁸ 306-081-005

⁴¹⁹ Miss Duffin T-26-06-12 p.36 line 16

for KFOA accreditation.⁴²⁰ Nonetheless, she also claimed to have heard nothing about Adam's death and to have learned nothing about it for many years.⁴²¹ She said she thought this "very strange"⁴²² and was quite unable to explain it given that she would have expected to hear about it on her own 'grapevine.'⁴²³

2.124 The Trust's Clinical Risk Management Group was charged on paper with responsibility for untoward clinical incident reporting. In reality this group does not appear to have fulfilled this function⁴²⁴ and its existence may have been largely aspirational.⁴²⁵ It was chaired by the Medical Director Dr Carson.⁴²⁶

2.125 Dr Carson was aware of the correct procedures for serious adverse incident reporting. He possessed the 'Risk Management in the NHS' manual⁴²⁷ received from the Management Executive of the Department in 1993-4.⁴²⁸ It provided guidance on clinical incident reporting⁴²⁹ as did KFOA in its published criteria for accreditation (1994).⁴³⁰

2.126 More current advices were also then available from The Report of the Independent Inquiry into deaths on the Children's ward at Grantham & Kesteven General Hospital (the 'Allitt Inquiry') also published in 1994.⁴³¹ In relation to clinical incidents it was emphatic that "*There must be a quick route to ensure that serious matters... are reported in writing to the Chief Executive of the hospital...All District Health Authorities and NHS Trust Boards should take steps immediately to ensure that such arrangements are in place*" These advices were not acted upon nor were policies for

⁴²⁰ Miss Duffin T-26-06-12 p.58 line 11

⁴²¹ Miss Duffin T-26-06-12 p.35 line 10

⁴²² Miss Duffin T-26-06-12 p.24 line 18

⁴²³ Miss Duffin T-26-06-12 p.27 line 20

⁴²⁴ WS-273-1 p.9

⁴²⁵ Dr Murnaghan T-25-06-12 p.71 line 12

⁴²⁶ WS-061-2 p.263

⁴²⁷ Dr Carson T-16-01-13 p.6 line 2

⁴²⁸ Dr Carson T-16-01-12 p.44 line 5

⁴²⁹ 306-117-013

⁴³⁰ 211-003-026

⁴³¹ 210-003-038

critical and serious clinical incident reporting developed within the Trust. That was primarily a failure of the Trust Board.

- 2.127 The lack of formal obligation and mechanism to report such a death to the Medical Director was an obvious deficiency in control and one which created a system dangerously vulnerable to abuse and failure. These systemic shortcomings are clear and should have been clear in 1995 not least to the Medical Director.
- 2.128 Notwithstanding the lack of leadership from the clinical directors on the Trust Board, Drs Murnaghan and Gaston both held ‘governance’ positions within the Trust and both knew from their professional experience that a potentially avoidable hospital death should be formally reported to the medical director. In Dr Haynes’ view that was just “*commonsense*.”⁴³² Dr Carson agreed, even “*in the light of very early developments in our clinical governance agenda*.”⁴³³ The failure of Drs Murnaghan and Gaston in this regard, foreshadows their later failures to investigate, manage and assess.

Investigation

- 2.129 The investigative response of the Trust was led by Dr Murnaghan in liaison with Dr Gaston.⁴³⁴ Dr Murnaghan acknowledged that where there “*was a possibility that medical care and treatment would have contributed to a death I would have expected that to be the cause of an investigation*.”⁴³⁵
- 2.130 There was no investigation of the case involving the Medical Director of the Trust.
- 2.131 There was no investigation of the case within the Paediatric Directorate. Dr Mulholland conceded that Adam’s case should have been discussed at a paediatric mortality meeting and that a written record should have been

⁴³² Dr Haynes T-03-05-12 p.129 line 7

⁴³³ Dr Carson T-15-01-13 p.160 line 5

⁴³⁴ Dr Gaston T-18-06-12 p.114 line 25

⁴³⁵ WS-273-1 p.4

kept.⁴³⁶ However, there is no record of any such meeting⁴³⁷ and Dr Mulholland did not believe that Adam's case was reviewed.⁴³⁸

2.132 There was no investigation of the case within nursing.⁴³⁹ Miss Elizabeth Duffin said that had she been notified she would have pursued a nursing investigation to *"to prevent something similar happening again."*⁴⁴⁰ That would indeed have been useful because then the nurses in theatre could have been identified from the *"record of the staffing in theatre."*⁴⁴¹ She said she would have expected Dr Murnaghan to involve nurses in his investigation⁴⁴² and expressed her dismay that he had failed to seek statements from the nursing staff.⁴⁴³

2.133 Mr Keane said that he *"would have expected a full clinical... investigation of this, with no lawyers..."*⁴⁴⁴ That didn't happen. Professor Savage expressed to the Inquiry his *"eternal regret that there wasn't a more detailed internal inquiry..."*⁴⁴⁵ and Mr Brown conceded that this was *"self-evidently unsatisfactory."*⁴⁴⁶

Dr Gaston's role in investigation

2.134 Despite the fact that Dr Gaston was an anaesthetist, he did not review the anaesthetic record.⁴⁴⁷ Dr Taylor explained his calculations⁴⁴⁸ but Dr Gaston neither assessed the intraoperative fluid balance nor made any search of the medical literature. He did, however, understand that there was a problem because he *"felt we needed an external assessor because it wasn't*

⁴³⁶ Dr Mulholland T-21-06-12 p.156 line 14
⁴³⁷ Dr Savage T-22-06-12 p.69 line 24
⁴³⁸ Transcript 21-06-12 p.156 line 11
⁴³⁹ Staff Nurse Popplestone T-30-04-12 p.95
⁴⁴⁰ Miss Duffin T-26-06-12 p.26 line 4
⁴⁴¹ Miss Duffin T-26-06-12 p.32 line 21
⁴⁴² Miss Duffin T-26-06-12 p.34
⁴⁴³ Miss Duffin T-26-06-12 p.32 line 11
⁴⁴⁴ Mr Keane T-10-09-12 p.38 line 25
⁴⁴⁵ Professor Savage T-22-06-12 p.68 line 4
⁴⁴⁶ Mr Brown T-01-05-12 p.151 line1
⁴⁴⁷ Dr Gaston T-19-06-12 p.15 line 10 et seq
⁴⁴⁸ Dr Gaston T-18-06-12 p.127 line 21

*particularly clear right at the beginning... and there were differences of opinion and it needed to be... clarified.”*⁴⁴⁹

2.135 Despite these differences of professional opinion, Dr Gaston did not commission an external assessment but rather arranged for an internal investigation to be conducted by his anaesthetic colleague Dr Fiona Gibson,⁴⁵⁰ because she was *“the one person... in Northern Ireland who would have experience of... major Paediatric Anaesthesia and who I considered independent...”*.⁴⁵¹ She was asked to review the processes and equipment involved in Adam’s case⁴⁵² and to discuss the matter with Dr Taylor.⁴⁵³ Her inspection took place on 2nd December 1995⁴⁵⁴ and focused on anaesthetic issues. She was not asked to speak to Professor Savage, Dr O’Connor or the surgeon.

2.136 At the same time Drs Gaston and Murnaghan instructed two Trust Technical Officers to check the equipment in the operating theatre.⁴⁵⁵ The lead technician Mr John Wilson⁴⁵⁶ was then a member of Dr Gaston’s ATICS Management team.⁴⁵⁷ Dr Gibson was not present when Messrs Wilson and McLaughlin⁴⁵⁸ carried out their inspection.⁴⁵⁹ Nonetheless, her report states that she *“was accompanied by Mr J. Wilson and Mr B. McLaughlin, senior Medical Technical Officers, on the site who carried out checks into the ventilators and other equipment in the theatre. The technical checks... found nothing at fault...”*⁴⁶⁰ Her report concluded that *“a very carefully thought out and well monitored anaesthetic was delivered with great care to fluid management”*⁴⁶¹ and that *“the protocols for*

⁴⁴⁹ Dr Gaston T-19-06-12 p.10 line 2

⁴⁵⁰ 303-001-002 due to ill health the late Dr Gibson was unable to provide oral evidence

⁴⁵¹ Dr Gaston T-19-06-12 p.20 line 13

⁴⁵² 093-026-069

⁴⁵³ 059-069-162

⁴⁵⁴ 059-069-161

⁴⁵⁵ 093-023-065c & 093-025-068b

⁴⁵⁶ 306-081-006

⁴⁵⁷ Dr Gaston T-18-06-12 p.99 line 24

⁴⁵⁸ 306-081-006

⁴⁵⁹ WS-109-1 p.3

⁴⁶⁰ 059-069-162

⁴⁶¹ 059-069-162

*monitoring, anaesthetic set-up and drug administration in this area are among the best on the Royal Hospital site...*⁴⁶²

2.137 Quite apart from Dr Gibson's praise for protocols which may be doubted to exist⁴⁶³ it is now clear that the relevant medical devices were not actually examined. Her conclusion that great care was paid to fluid management, is hard to comprehend in the absence of recorded urinary output. Her involvement was not independent and her conclusions were not reliable. Her worryingly uncritical report was submitted to Dr Murnaghan on 11th December 1995.⁴⁶⁴

Dr Gaston's approach

2.138 Dr Gaston believed strongly in Dr Taylor's outstanding professional ability⁴⁶⁵ and was concerned because *"there was more to this than just that event... there were issues about... a shortage of anaesthetists at that time."*⁴⁶⁶ He went further to say that should Dr Taylor *"stop giving anaesthetics... we probably would have had the collapse of anaesthesia and ICU in Northern Ireland."*⁴⁶⁷

2.139 Dr Gaston offered support to Dr Taylor and listened to his *"feelings about the anaesthetic, his feelings about what had happened, his feeling about how he was going to actually take it forward and how he would cope with it."*⁴⁶⁸ He did not question or pursue inconsistency between what he was being told and Dr Taylor's written statement nor draw it to the attention of anyone else. He now concedes that he should have done so.⁴⁶⁹

2.140 Dr Gaston thought *"it was important that Dr Taylor had an opportunity to speak to some of the people of a senior level... partly as a follow up to the*

⁴⁶² 059-069-162

⁴⁶³ 305-014-001

⁴⁶⁴ 059-065-151

⁴⁶⁵ Dr Gaston T-19-06-12 p.130 line 19

⁴⁶⁶ Dr Gaston T-19-06-12 p.113 line 6

⁴⁶⁷ Dr Gaston T-19-06-12 p.138 line 13

⁴⁶⁸ Dr Gaston T-19-06-12 p.24 line13

⁴⁶⁹ Dr Gaston T-19-06-12 p.65 line 16

*counselling type situation.*⁴⁷⁰ Accordingly, and rather than report the matter to the Medical Director and fellow anaesthetist Dr Carson, he approached an even more senior anaesthetic colleague Dr Samuel Morrell Lyons⁴⁷¹ (President of The Association of Anaesthetists of Great Britain and Ireland and Chairman of the Central Medical Advisory Committee of The Department of Health).⁴⁷²

- 2.141 Dr Gaston then led a delegation of Dr Lyons and Dr Murnaghan to speak with the Coroner. By that stage the Coroner had already commissioned expert opinion on Adam's case from consultant anaesthetist Dr John Alexander.⁴⁷³ Drs Gaston and Lyons cautioned the Coroner against relying upon such opinion because Dr Alexander had *"little if any experience in this very specialist field."*⁴⁷⁴ They urged upon the Coroner the importance of obtaining the opinion of a consultant paediatric anaesthetist. To that end, the Trust recommended that the Coroner approach Dr Edward Sumner.⁴⁷⁵
- 2.142 After the meeting the Coroner wrote that *"their considered view is that the death had nothing to do with anaesthetics."*⁴⁷⁶ I consider it remarkable that a senior Trust delegation to the Coroner could have felt confident to advance a *"considered view"* exonerating the anaesthetics on the basis of so little investigation. Dr Lyons has confirmed that he has *"no recollection of being involved in any formal review or interviews of any of the doctors involved in the care of Adam Strain,"*⁴⁷⁷ Dr Gibson's Report had not then been received,⁴⁷⁸ there had been no examination of the anaesthetic equipment and Dr Gaston had probably not even read the anaesthetic record.⁴⁷⁹ More troubling is Dr Murnaghan's tacit association with this view

⁴⁷⁰ Dr Gaston T-19-06-12 p.25 line 6

⁴⁷¹ 306-081-006

⁴⁷² 093-024-066 – (11th December 1995)

⁴⁷³ 303-001-010

⁴⁷⁴ 011-027-128

⁴⁷⁵ 303-001-010

⁴⁷⁶ 011-027-128

⁴⁷⁷ 093-024-067

⁴⁷⁸ 059-065-151: meeting with Coroner, Monday 11th December 1995

⁴⁷⁹ Dr Gaston T-19-06-12 p.15

given what he had been told by Professor Savage regarding Dr Taylor's mismanagement of the fluids.⁴⁸⁰

- 2.143 Dr Gaston was unrepentant when he gave evidence about how Adam's death was dealt with: *"Yes, it would have been better to have had an investigation, better to have a discussion, but it was important that Dr Taylor's confidence and his ability as an anaesthetist, was not damaged by the process. And I still believe... that today, and I think history backs that up."*⁴⁸¹ Such an approach may have seemed pragmatic to Dr Gaston but it was clearly wrong, even by the standards of 1995 to risk patient safety in the interests of a single individual, no matter how important. Long term confidence in, and respect for, the Health Service, depends upon proper response to critical incidents, rather than an approach which fails to engage with a problem in the hope that it will not recur.

Dr Murnaghan's role in investigation

- 2.144 Even though internal control systems within the Trust at that time were rudimentary, Dr Murnaghan's responsibilities were clear. He was to lead the Trust in assisting the Coroner and respond to the challenges of risk management and litigation.⁴⁸² It was his task to decide what and how to investigate. He might reasonably have been expected to analyse what had gone so tragically wrong. That is at least what Dr Armour, the pathologist, believed when she volunteered to Dr Murnaghan her willingness to attend any meeting to review Adam's case because she felt her *"opinion... relevant... and as such the case could be discussed in full."*⁴⁸³ Her input was not sought.
- 2.145 Dr Murnaghan has stated that *"no steps were taken apart from... involving... clinicians in discussion with pathologists and the anaesthetic technical staff in attempting to clarify the cause of death and thereby assist*

⁴⁸⁰ Professor Savage T-22-06-12 p.22 line 19

⁴⁸¹ Dr Gaston T-19-06-12 p.138 line 23

⁴⁸² 093-025-068

⁴⁸³ 059-063-149

*the Coroner...*⁴⁸⁴ If there were any such discussions they were neither recorded nor monitored. Almost nothing was put in writing. There was no multi-disciplinary meeting to discuss the issue, no consideration of the matter within the Paediatric Directorate and no involvement of nursing staff in any consideration of Adam's case.⁴⁸⁵ Dr Murnaghan did not even request a list of the staff on duty.

2.146 Dr Murnaghan explained that he did not fully review the death because "*it was a Coronial investigation, it wasn't my investigation.*"⁴⁸⁶ He worked on the assumption that the Trust had to await the views of the Coroner's experts.⁴⁸⁷ Such an approach was not only potentially dangerous but ran contrary to the specific advice of the Health and Personal Social Services ('HPSS') 'Complaint Procedure Guide'⁴⁸⁸ which stressed how important it was "*for the Trust... to initiate proper investigations regardless of the Coroner's inquiries.*"⁴⁸⁹

2.147 On 30th November 1995 the Coroner wrote to request that Dr Murnaghan obtain a statement from "*the technician responsible for the equipment in the theatre confirming that it was functioning properly.*"⁴⁹⁰ Dr Murnaghan did nothing. The Coroner wrote again to Dr Murnaghan on 8th December 1995 stressing that it was "*imperative that the equipment [is] now independently examined.*"⁴⁹¹ Dr Murnaghan decided instead to rely upon the internal investigation report submitted by Messrs Wilson and McLaughlin which clearly indicated that they had not been able to inspect all the equipment.⁴⁹² Notwithstanding, Dr Murnaghan then asserted that "*this examination observed [that] the equipment was found to be in satisfactory condition.*"⁴⁹³

484 093-025-068b
 485 093-025-068b
 486 Dr Murnaghan T-25-06-12 p.132 line 10
 487 Dr Murnaghan T-25-06-12 p.152 line 4
 488 314-016-001 (March 1996)
 489 314-016-010
 490 059-073-166
 491 011-025-125
 492 094-210-999
 493 WS-015-1 p.2

- 2.148 On 30th November 1995 the Coroner also requested that Dr Murnaghan forward statements from the clinicians involved as soon as possible.⁴⁹⁴ Dr Murnaghan sought only a limited number of statements, advising witnesses to restrict content to factual matter and exclude opinion. Dr O'Connor was not asked to make a statement.⁴⁹⁵ Dr Montague was not asked to make a statement.⁴⁹⁶ No member of the nursing team or technical staff was asked to make a statement.⁴⁹⁷ By so doing Dr Murnaghan allowed a restricted number of uninformative reports to be furnished to the Coroner on the basis that that was *"the information that was provided and I was the conduit for that information."*⁴⁹⁸
- 2.149 When Dr Murnaghan asked for Professor Savage's factual statement he advised him not to draw any conclusions because that was the role of the Coroner.⁴⁹⁹ Accordingly and notwithstanding that Professor Savage believed that Adam's death was due to fluid mismanagement,⁵⁰⁰ he made a statement on 28th November 1995⁵⁰¹ omitting not only his own opinion as to the cause of hyponatraemia but also the relevant known factual information relating to Adam's sodium levels and the quantities of fluid infused.
- 2.150 Mr Keane, who had likewise formed the view that Adam's death was due to fluid mismanagement, made a statement for the Coroner and failed to identify anything untoward. He was unable to explain this omission.⁵⁰²
- 2.151 On 6th December 1995 Dr Murnaghan wrote to Dr Webb requesting his statement for the Coroner.⁵⁰³ Dr Webb obliged and he too omitted all reference to Adam's hyponatraemia.

⁴⁹⁴ 059-073-166

⁴⁹⁵ Dr O'Connor T-20-06-12 p.115 line 6

⁴⁹⁶ Dr Montague T-11-05-12 p.153 line 18

⁴⁹⁷ 093-025-068b

⁴⁹⁸ Dr Murnaghan T-25-06-12 p.131 line 16

⁴⁹⁹ Professor Savage T-22-06-12 p.90 line 18

⁵⁰⁰ Professor Savage T-22-06-12 p.22 line 19

⁵⁰¹ 059-066-154

⁵⁰² Mr Keane T-23-04-12 p.71 line 22 *et seq*

⁵⁰³ 059-071-164

- 2.152 Mr Brown supplied his statement on 20th December 1995 to inform only that *“the transplantation procedure appeared to be technically satisfactory and at no stage during the operation was I conscious of any problem with his general condition.”*⁵⁰⁴ Mr Brown’s remarkable detachment extended so far as to even avoid any reference to the death.
- 2.153 Dr Taylor prepared his statement for Dr Murnaghan on 30th November 1995.⁵⁰⁵ He stated that he was unable to *“offer a physiological explanation for such severe pulmonary and cerebral oedema in the presence of normal monitoring signs.”*⁵⁰⁶ Given what Dr Taylor must have known of the abnormal CVP and sodium readings – that assertion was clearly suspect and should have prompted inquiry. Likewise, Dr Taylor’s claim that he *“regarded the fluids to be appropriate and discussed this with other doctors present in the theatre”*⁵⁰⁷ presented further obvious issues for discussion and enquiry which were seemingly ignored.
- 2.154 Dr Murnaghan’s failure, then and subsequently, to query the content of these statements, given what he had been told by Professor Savage, is remarkable. His failure to ask any questions about fluid management is striking. This cannot have been accidental. Not only did the Trust thereby disregard the opportunity to establish what had happened, but it denied the Coroner assistance he might reasonably have expected.

The Coroner’s expert anaesthetic reports received

- 2.155 On 5th January 1996 the Coroner forwarded to Dr Murnaghan⁵⁰⁸ a copy of the report he had received from Dr John Alexander, Consultant Anaesthetist.⁵⁰⁹ It concluded that Adam’s requirements *“led to the administration of a large volume of hypotonic (0.18%) saline which produced a dilutional hyponatraemia and subsequent cerebral oedema.”*⁵¹⁰

⁵⁰⁴ 059-060-146
⁵⁰⁵ 059-067-155
⁵⁰⁶ 059-067-156
⁵⁰⁷ 059-067-156
⁵⁰⁸ 059-057-134
⁵⁰⁹ 011-012-084
⁵¹⁰ 094-027-140

He cited Professor Arieff's paper in support. This was clear support for Professor Savage's stated opinion.

2.156 Dr Sumner's anaesthetic report was then received at the end of January 1996.⁵¹¹ It was even more damning in its conclusion and provided additional external confirmation for Drs Murnaghan and Gaston that Dr Taylor may have been wrong in both his anaesthetic and his argument. Even though Dr Murnaghan claimed that he would have gone to the Medical Director had anaesthetic colleagues advised him that something was seriously wrong,⁵¹² he still neglected to inform Dr Carson and no further steps were taken to question the clinicians or examine the case in the light of these reports. Dr Murnaghan's continued omission to report to the medical director is hard to understand unless it was to avoid the formalised response and investigation a medical director might expect. Dr Gaston was unable to explain his reason for not informing the Medical Director.⁵¹³

2.157 It should be noted that throughout this period, Professor Savage maintained contact with Adam's mother⁵¹⁴ and was content to discuss both Dr Alexander's and Dr Sumner's medical opinions with her *"provided that Dr Murnaghan was happy and there were no medico-legal reasons to suggest otherwise."*⁵¹⁵ He was cautious lest he say anything inappropriate from the point of view of the Trust,⁵¹⁶ perhaps because he knew that *"Debbie Strain, at that time, felt that someone should take the blame for what happened to Adam."*⁵¹⁷ He wrote to her to say that *"once the cause of Adam's death is established it is right we should try and work out why."*⁵¹⁸

2.158 Dr Murnaghan and Dr Gaston were part of the 'governance' investigation into Adam's death⁵¹⁹ but their failure to investigate was blatant. I believe their failure to conduct a thorough investigation was deliberate. Their

⁵¹¹ 059-051-106

⁵¹² Dr Murnaghan T-25-06-12 p.152 line 15

⁵¹³ Dr Gaston T-19-06-12 p.129 line 8

⁵¹⁴ 093-006-019

⁵¹⁵ 011-033-165

⁵¹⁶ Professor Savage T-22-06-12 p.31 line 22

⁵¹⁷ Professor Savage T-22-06-12 p.36 line 14

⁵¹⁸ 306-090-001

⁵¹⁹ Dr Gaston T-18-06-12 p.114 line 25

response to Adam's death was to commit as little to writing as possible and to reveal as little by investigation as was consistent with appearing to assist the Coroner. Realising, as they must have done, the vulnerabilities of the Trust to criticism, I interpret their actions on behalf of the Trust as essentially defensive. That was inappropriate. Whilst this failing was grave and principally the responsibility of Dr Murnaghan, I consider that all involved must bear responsibility because the necessity to investigate what had happened to Adam must have been obvious to all.

Assessment of Dr Taylor

2.159 Dr Murnaghan described an informal and off-the-record routine for managing the problem of the skilled doctor who has made a mistake. In such situations, he said the lead clinicians together with their colleagues might review the problem, the doctor and his performance. A decision would then be made amongst themselves about how best to proceed and *"almost certainly there might be an element of supervision."*⁵²⁰

2.160 It was in this context, and rather than report the death formally to the Medical Director, that I believe Dr Murnaghan allowed Dr Taylor's anaesthetic colleagues some control of the situation, not least because they were *"separately and severally... all totally supportive of Dr Taylor."*⁵²¹ Dr Murnaghan *"knew and had been reassured that Dr Taylor had never ever in all his time... in the Royal... ever had a problem... he was probably the most diligent of all the anaesthetists in the RBHSC."*⁵²² Indeed, Dr Taylor received support from the most senior anaesthetist in the Trust, Dr Dennis Coppel, who wrote to say that he did *"not believe on reading the information available to me that there is any negligence on your part and, to the contrary, you demonstrated considerable professional skills and expertise."*⁵²³

⁵²⁰ Dr Murnaghan T-25-06-12 p.35 line 17 *et seq*

⁵²¹ Dr Murnaghan T-25-06-12 p.157 line 23

⁵²² Dr Murnaghan T-25-06-12 p.155 line 15

⁵²³ 122-048-002

- 2.161 It was Professor Savage who sensed that Dr Taylor was “*ill advised*”⁵²⁴ by his anaesthetic colleagues. He suggested that “*...what was allowed to happen was that Dr Taylor did not get advice from anyone that said ‘look, the evidence from Dr Sumner, from the Autopsy, from Dr Savage, from Dr O’Connor is such that we think the position you are taking is untenable.’ No one ever said that to him, I don’t think. Therefore he was allowed to proceed down that road and, unfortunately, has got into the difficulties that he is now in.*”⁵²⁵
- 2.162 That was a mistaken approach. When Dr Sumner’s report confirming Dr Taylor’s error was received, Dr Murnaghan did nothing because “*Dr Taylor had a view which differed from Dr Sumner’s view and he received a degree of support from Dr Gaston in relation to that view... I wasn’t in a position to make a judgment on that.*”⁵²⁶ What I believe he should have done was to seek the opinion of someone who was in a position to make a judgment. That would then have obligated Dr Taylor to either accept his error or, if he wished to defend it, to do so from a position independent of the Trust.
- 2.163 To make matters worse, Dr Murnaghan did not assess Dr Taylor’s fitness to practice because he had been “*reassured that his colleagues were looking after him, overseeing his work.*”⁵²⁷ That approach meant that the safety of Dr Taylor’s patients may have become dependent upon the supervision his colleagues provided.⁵²⁸ That was unacceptable. Dr Murnaghan justified his actions on the basis that “*This was a singular aberration that he would have learned from as well as everybody else... He didn’t cause dilutional hyponatraemia again.*”⁵²⁹ However, Dr Murnaghan knew that Dr Taylor did not accept the aberration⁵³⁰ and could not therefore have been satisfied that lessons had been learned.

⁵²⁴ Professor Savage T-10-09-12 p.125 line 7
⁵²⁵ Professor Savage T-10-09-12 p.128 line 12
⁵²⁶ Dr Murnaghan T-25-06-12 p.185 line 16
⁵²⁷ Dr Murnaghan T-25-06-12 p.160 line 25
⁵²⁸ Dr Murnaghan T-25-06-12 p.162 line 4
⁵²⁹ Dr Murnaghan T-25-06-12 p.223 line 17
⁵³⁰ Dr Murnaghan T-25-06-12 p.221 line 8

2.164 Drs Gaston and Murnaghan failed to place patient safety before other interests. Dr Murnaghan has conceded that *“on reflection... we should have done things earlier and we didn’t do, even then afterwards, what we should have done. And I’m sorry.”*⁵³¹

Post-mortem

2.165 Adam’s death was reported to the Coroner on 28th November 1995.⁵³² Upon his instruction a post-mortem was carried out on 29th November 1995 at the Royal Victoria Hospital by Dr Alison Armour,⁵³³ a trainee Forensic Pathologist of Senior Registrar grade employed within the State Pathologist’s Department.⁵³⁴ She was at that time an experienced pathologist who had been a member of the College of Pathologists for a number of years. Dr Armour had 10 files of medical notes and records made available to her.⁵³⁵ She performed external and internal examinations⁵³⁶ and amongst other things noted *“complete infarction”* of the transplanted kidney.⁵³⁷

2.166 Dr Armour examined the brain on 12th January 1996⁵³⁸ noting swelling and *“massive cerebral oedema of the cortex and white matter.”*⁵³⁹ She subsequently described the severity of Adam’s cerebral oedema as *“the worst she had ever seen.”*⁵⁴⁰ Dr Armour sought the input and advice of others, namely Drs Mirakhur,⁵⁴¹ O’Hara⁵⁴² and Bharucha.⁵⁴³

2.167 Dr Murnaghan then made an approach to Dr Armour. He wrote to her on 7th February 1996 that *“I have spoken on the telephone with Bob Taylor and obtained his permission to share the attached with you on the*

⁵³¹ Dr Murnaghan T-11-09-12 p.181 line 14
⁵³² 011-025-125 & Professor Savage T-22-06-12 p.3 line 17
⁵³³ 011-010-034
⁵³⁴ WS-021-1 p.1
⁵³⁵ 011-010-033
⁵³⁶ 011-010-037-8
⁵³⁷ 059-039-088
⁵³⁸ 011-010-039
⁵³⁹ 011-010-040
⁵⁴⁰ 011-010-033
⁵⁴¹ 303-001-002
⁵⁴² 303-001-003
⁵⁴³ Dr Armour T-13-06-12 p.20 line 4

understanding that its contents are for your personal information and as a background briefing, in order to assist in coming to your conclusions in this difficult matter."⁵⁴⁴ His attachment was a note prepared by Dr Taylor pointing out the "*several major problems*"⁵⁴⁵ he had identified in the evidence of Drs Sumner and Alexander together with Dr Taylor's assertion that both experts had "*failed to comprehend the physiological difference in this case and have used dubious scientific argument in an attempt to explain cerebral oedema.*"⁵⁴⁶ If this was an attempt to influence Dr Armour it was to fail because she was quite confident that she "*did not agree with him and he knew I did not agree with him.*"⁵⁴⁷

- 2.168 Dr Armour completed her work and produced an Autopsy Report in which she referred to Professor Arieff's 1992 paper⁵⁴⁸ and formulated the cause of Adam's death as:

"1 (a) cerebral oedema due to

(b) dilutional hyponatraemia and impaired cerebral perfusion during renal transplant operation for chronic renal failure (Congenital Obstructive Uropathy)."⁵⁴⁹

She did not implicate the infarcted kidney in the cause of cerebral oedema or death.

- 2.169 The Autopsy Report is undated.⁵⁵⁰ Copies were sent to the Coroner on 22nd April 1996⁵⁵¹ and to Adam's mother, Dr Murnaghan and Dr Sumner.⁵⁵²

- 2.170 Dr Armour's reference to "*impaired cerebral perfusion*" arises from her identification of "*a suture in situ on the left side of the neck at the junction*

⁵⁴⁴ 059-052-107

⁵⁴⁵ 059-053-108

⁵⁴⁶ 059-053-108

⁵⁴⁷ Dr Armour T-13-06-12 p.88 line 25

⁵⁴⁸ 011-011-074: Arieff A. I., Ayus J. C., Fraser C. L. Hyponatraemia and death or permanent brain damage in healthy children. BMJ 1992; 304 :1218

⁵⁴⁹ 011-010-034

⁵⁵⁰ 011-010-041

⁵⁵¹ 011-059-124

⁵⁵² 011-061-196, 011-062-197 & 011-059-194

*of the internal jugular vein and the sub-clavian vein*⁵⁵³ which she thought had impaired the blood flow to Adam's brain. She believed that this had exacerbated the effect of the cerebral oedema and was thus relevant to her conclusions as to cause of death.

2.171 Evidence was received that the presence of such a suture was improbable.⁵⁵⁴ On this issue (which is relevant but not central to the investigation of Adam's death) I believe that Dr Armour's identification of a suture was mistaken. She subsequently acknowledged this herself, having considered the expert opinion of others.⁵⁵⁵

2.172 However and apart from that, her identification and analysis of the important issues was more than competent. Professor Sebastian Lucas advised the Inquiry as to the content of her report. He found her autopsy to have been "*performed competently*" and to have been "*internally consistent*."⁵⁵⁶ He stated that he would grade the report as "*good*" because it "*addressed the central issue and produced a coherent answer*."⁵⁵⁷

2.173 Dr Waney Squire also praised "*a very well worked commentary... Dr Armour has looked at the clinical story in some detail and she has done her best to make a detailed account of the factors which may have been relevant in death and how they fit in with what she has seen*."⁵⁵⁸ However, she believed the Autopsy Report was open to criticism in relation to the possible ligation of the left internal jugular vein and the failure to investigate the cause of infarction in the transplanted kidney.⁵⁵⁹ She also noted some inconsistency between contemporaneous notes and the Autopsy Report and questioned the involvement of Drs O'Hara and Bharucha without supporting documentation. Seemingly Dr Armour formed an opinion differing from that of Drs O'Hara and Bharucha. Dr Squire stated that in such a complex case "*specialist assistance should have been sought formally and the reports of*

⁵⁵³ 011-010-039

⁵⁵⁴ WS-228-1 p.2-3, WS-232-1 p.2 & WS-007-4, p.2

⁵⁵⁵ Dr Armour T-13-06-12 p.1 line 22

⁵⁵⁶ 209-001-005

⁵⁵⁷ 209-001-006

⁵⁵⁸ Dr Squire T-12-06-12 p.136 line 22

⁵⁵⁹ Dr Squire T-12-06-12 p.141 line 3

*those specialists included as signed reports within the final pathology report.”*⁵⁶⁰

2.174 The input of Drs O’Hara and Bharucha is unknown but it is clear that their input should have been recorded and Dr Mirakhur’s contribution formally incorporated by way of signed report.⁵⁶¹

2.175 Professor Lucas observed in relation to coronial autopsy practice at that time that there was “*no governance, no standard of quality demanded by Coroners, no obligatory linkage with feedback of autopsy findings with pre-mortem clinical practice and no agreed level of investigations for particular scenarios of death.*”⁵⁶² Furthermore, in 1995 the State Pathologists Department generally “*did their own neuropathology*”⁵⁶³ gave limited training,⁵⁶⁴ had no formal system of referral for expert opinion,⁵⁶⁵ did not retain a paediatric pathologist and did not attend mortality meetings for the purposes of clinico-pathological correlation.⁵⁶⁶ It is not believed that the State Pathologist reviewed Dr Armour’s report.⁵⁶⁷ It would therefore be harsh to criticise Dr Armour’s work. I find that her Autopsy Report was independent and, more importantly, correct in its principal finding.

2.176 Dr Armour’s Autopsy Report was received by Dr Murnaghan at the end of April 1996.⁵⁶⁸ It was in broad agreement with Dr Sumner and yet Dr Taylor’s performance was still not reviewed nor his fitness to practice assessed. The lessons to be learned from Adam’s death could have been learnt by the end of April 1996.

⁵⁶⁰ 206-004-030
⁵⁶¹ Dr Armour T-13-06-12 p.67 line 17
⁵⁶² 209-001-009
⁵⁶³ Dr Armour T-13-06-12 p.45 line 8
⁵⁶⁴ Dr Armour T-13-06-12 p.90 line 8
⁵⁶⁵ Dr Mirakhur T-12-06-12 p.31 line 8
⁵⁶⁶ Dr Armour T-13-06-12 p.37 line 20
⁵⁶⁷ WS-012-3 p.3
⁵⁶⁸ 059-039-083

Fatal cerebral oedema: alternative causes and contributory factors

2.177 Arising from the expert opinions received by the Inquiry, a range of potential alternate causes for Adam's fatal cerebral oedema emerged together with a number of possible contributory factors, including:

- (i) Pre-existing central nervous system condition.
- (ii) Acute cerebral venous sinus thrombosis.
- (iii) Chronic cerebral venous sinus thrombosis.
- (iv) Thrombosis of the paravertebral plexus.
- (v) Reduced jugular venous drainage or possible venous obstruction.
- (vi) Cerebral blood flow, anaemia and reduced cerebral O2 delivery/low CO2.
- (vii) Hypoxia.
- (viii) Posterior Reversible Encephalopathy Syndrome during surgery/hypertensive encephalopathy.
- (ix) Seizure(s) during surgery.
- (x) Halothane in anaesthetic giving rise to cerebral vasodilation.
- (xi) Dilutional anaemia.
- (xii) Head down position during surgery.

These were exhaustively considered and two schedules summarising contrasting expert views compiled.⁵⁶⁹ For the sake of completeness it may be stated that whilst the condition of the kidney did not contribute to death, the possibility cannot be discounted that dilutional hyponatraemia and

⁵⁶⁹ 306-016-130 & 306-017-146

cerebral oedema might have contributed to the non-functioning of the kidney.⁵⁷⁰

- 2.178 In addressing these many issues, the Inquiry sought the neurological opinion of Professor Kirkham, practising Consultant Paediatric Neurologist and Professor of Paediatric Neurology, as to the effect of the fluid infusion upon Adam's brain and the possible contribution of venous obstruction to the cerebral oedema.
- 2.179 Amongst other things, Professor Kirkham gave it as her opinion that hyponatraemia was not, in fact, the primary cause of Adam's death and that he would have survived had it not been for other and unrelated conditions. Whilst conceding the possibility that dilutional hyponatraemia was implicated in a secondary role, she advanced specific vascular pathologies as the likely primary cause of the fatal cerebral oedema.
- 2.180 Her views raised issues going to the heart of the work of the Inquiry. They contradicted the inquest verdict and the opinions of Drs Sumner, Armour and Alexander and ran expressly counter to the analysis and conclusions of Professor Dr Gross, Dr Coulthard and Dr Haynes. Whilst her opinion was unsupported by the neuro-pathological and radiological findings of Drs Squier⁵⁷¹ and Anslow,⁵⁷² it was apparent that her opinion could not be disregarded because her hypothesis could not be excluded. Accordingly, expert response to her opinion was sought and meetings arranged in early 2012 in order to explore the emerging difference in diagnosis.⁵⁷³
- 2.181 Consensus was not possible⁵⁷⁴ and the necessity for a second paediatric neurological opinion became obvious. Accordingly Professor Dr Dietz Rating of the Children's Hospital, University of Heidelberg⁵⁷⁵ was commissioned to analyse the evidence, consider the diagnosis and give his opinion. He too disagreed with Professor Kirkham, concluding that it was

⁵⁷⁰ Professor Forsythe T-04-05-12 p.145 line 8 & Professor Risdon T-03-05-12 p.38-39

⁵⁷¹ 208-003-050

⁵⁷² 208-004-051

⁵⁷³ 307-007-073, 307-008-162, 306-016-130 & 306-017-146

⁵⁷⁴ 306-017-146, 309-008-230 & 307-008-242

⁵⁷⁵ 306-097-001

the “*acute overload with free water, nothing else.*”⁵⁷⁶ Whilst I am unable to make a definitive judgment in such a complex field, I believe that the evidence nonetheless permits a finding on the balance of probabilities.

- 2.182 Professor Kirkham advanced her opinion because she was unable to accept the proposition that hyponatraemia alone could, on the balance of probabilities, have caused Adam’s death. This was on the basis that she could find no proof for it. She was very clear that available medical literature disclosed no data to confirm that such a large infusion of hypotonic fluid or such a drop in sodium levels had ever given rise to fatal cerebral oedema in the absence of another pre-existing brain compromise.⁵⁷⁷
- 2.183 Conceding that the literature did not extend much beyond Arieff “*and the number of cases reported is relatively small*”⁵⁷⁸ she argued that those patients comprising Professor Arieff’s study group must all have presented with other pre-existing risk factors and that dilutional hyponatraemia was not therefore the primary cause of their fatal cerebral oedemas. Examination of Professor Arieff’s paper, did not however appear to support this interpretation. It is further to be noted that Professor Arieff has not subsequently amended his central findings⁵⁷⁹ but has maintained his conclusion that the cause of cerebral oedema in such cases is the ill-considered use of hypotonic intravenous fluids. It is in any event unlikely that the literature could encompass cases directly comparable to Adam.⁵⁸⁰
- 2.184 Professor Kirkham pointed out that Adam had survived previous similar episodes of hyponatraemia and that there must therefore have been other factors involved. However upon analysis it was found that the rate of fall of his serum sodium levels was at least five times greater than that recorded

⁵⁷⁶ 240-002-045

⁵⁷⁷ Professor Kirkham T-14-01-13 p.54 line 1

⁵⁷⁸ Professor Kirkham T-15-01-13 p.41 line 9

⁵⁷⁹ Professor Dr Rating T-15-01-13 p.89 line 9. See also Moritz and Ayus (2005) – 208-007-084 & Halberthal, Halperin and Bohn (2001)

⁵⁸⁰ 307-007-094 & Professor Dr Rating T-15-01-13 p.32 line 22

for his previous episodes.⁵⁸¹ The rate of fall remained for Professor Dr Rating a key diagnostic feature.⁵⁸²

- 2.185 Nonetheless and proceeding on the basis that dilutional hyponatraemia was not the primary cause of death, Professor Kirkham gave her opinion, again on the balance of probabilities and largely on the basis that Adam presented with what may have been relevant risk factors, that he was likely to have suffered a cerebral venous sinus thrombosis ('CVST') and/or posterior reversible encephalopathy syndrome ('PRES') and that these pathologies caused the cerebral oedema. Whilst they might also have rendered Adam vulnerable to the effects of the dilutional hyponatraemia, she believed he would have survived but for the CVST and/or PRES.⁵⁸³
- 2.186 Whilst demonstrating that these conditions were possible and that there was no basis upon which to positively exclude them, she was unable to present evidence that Adam actually had them. In particular, there was no persuasive evidence that Adam was neurologically vulnerable⁵⁸⁴ or that he had suffered previous neurological disorder,⁵⁸⁵ or that he suffered any venous sinus thrombosis⁵⁸⁶ or any PRES event⁵⁸⁷ whether in isolation or together or at any time.
- 2.187 Professor Kirkham further advanced the proposition that hyponatraemia could not have been the primary causative factor unless hypoxia was also present.⁵⁸⁸ The evidence for hypoxia was equivocal⁵⁸⁹ and in any event the conclusion that dilutional hyponatraemia could not cause cerebral oedema without it, uncertain.⁵⁹⁰
- 2.188 Considerable debate surrounded the interpretation of the neuro-pathological investigations and whether or not the findings were more or

⁵⁸¹ 201-015-225

⁵⁸² 240-004-022 & 200-022-271 & Professor Dr Rating T-15-01-13 p.31 line 18 & 306-113-001

⁵⁸³ 208-007-112 & Professor Kirkham T-15-01-13 p.60 line 19.

⁵⁸⁴ 208-002-034

⁵⁸⁵ Professor Kirkham T-14-01-13 p.68 line 12

⁵⁸⁶ Professor Kirkham T-14-01-13 p.73 line 3 & p.72 line 22 & p.70 line 7

⁵⁸⁷ Professor Kirkham T-15-01-13 p.70 line 8

⁵⁸⁸ Professor Kirkham T-15-01-13 p.5 line 18

⁵⁸⁹ Professor Kirkham T-15-01-13 p.61 line 11 & 206-002-005 & 011-025-125

⁵⁹⁰ Professor Kirkham T-15-01-13 p.83 line 22 & 201-016-289

less typical or indicative of this condition or that. This provided no more conclusive evidence than imperfect analogies drawn from experimentation with piglets.⁵⁹¹ Diagnosis on the basis of risk factors led to analysis of the hypothetical. Ultimately the problem of diagnosis in the absence of comprehensive information became a matter for informed clinical interpretation of the patho-physiology.

- 2.189 In determining the causative factors for the acute event which befell Adam, the overload of approximately 5% of his own body weight in free water⁵⁹² cannot on the evidence be disregarded. Adam was well before he went to theatre, by common agreement received an excessive quantity of free water very much too quickly and within hours suffered acute hyponatraemia and was dead. It is hard not to make the connection given that no other cause can be demonstrated and dilutional hyponatraemia is recognised in the medical literature as a cause of potentially lethal cerebral oedema.
- 2.190 Professor Kirkham conceded very fairly that the infusion of so much free water may have been a factor in the fatal cerebral oedema.⁵⁹³ However she considered it rather more likely that the increase in Adam's blood pressure had given rise to a hypertensive encephalopathy and that was the major factor.⁵⁹⁴ However, as she herself pointed out, the evidence and the literature were not conclusive in supporting such a diagnosis. Nonetheless and on the balance of probabilities she preferred it.⁵⁹⁵
- 2.191 Professor Dr Rating remained at variance with Professor Kirkham. Whilst acknowledging the fine judgments inherent in defining the primary and secondary causes of cerebral oedema, he said that a conventional application of physiological rules permitted the conclusion that dilutional hyponatraemia alone could cause a fatal cerebral oedema.⁵⁹⁶ He said it was a diagnosis that he would accept immediately⁵⁹⁷ being for him "as a

⁵⁹¹ Professor Kirkham T-15-01-13 p.42 line 23

⁵⁹² 300-077-148

⁵⁹³ Professor Kirkham T-14-01-13 p.54 line 12 & Professor Kirkham T-15-01-13 p.84 line 15

⁵⁹⁴ Professor Kirkham T-15-01-13 p.100 line 15

⁵⁹⁵ Professor Kirkham T-15-01-13 p.70 line 8

⁵⁹⁶ 240-004-025 & Professor Dr Gross at 307-008-228 & Dr Coulthard at 307-007-094

⁵⁹⁷ Professor Dr Rating T-15-01-13 p.89 line 20

clinician the most logical and reliable explanation."⁵⁹⁸ Having reviewed the arguments and the theory he said he was "*not convinced*" that there was any other primary cause⁵⁹⁹ and that on the balance of probabilities, hyponatraemia was the primary cause of Adam's fatal cerebral oedema.

2.192 In this Professor Dr Rating was in accord with the other available expert comment as to the cause of death. All proposed that dilutional hyponatraemia was most probably the cause of Adam's fatal cerebral oedema. Accordingly, Professor Kirkham's rejection, on the balance of probabilities, of the consensus diagnosis in preference for a more speculative differential diagnosis could not stand without positive supporting evidence. That evidence was lacking.

2.193 Accordingly and given that there was broad agreement as to a plausible diagnosis and there was no compelling reason for me to prefer any other explanation, I conclude on the balance of probabilities that Professor Kirkham's opinion does not prevail.⁶⁰⁰

Inquest preparation

2.194 Dr Murnaghan had six months to prepare the Trust for Adam's inquest. His activity in meeting the Coroner and forwarding representations to Dr Armour may be contrasted with his inactivity elsewhere. Dr Murnaghan was aware of his obligation to assist the Coroner in clarifying the cause of death⁶⁰¹ but he took no further steps to formally investigate the death⁶⁰² or interview all those involved in order to clarify the conflicting opinions received.

2.195 Dr Murnaghan liaised with the Trust's Solicitor, Mr George Brangam, and arranged meetings with the Trust witnesses prior to inquest.⁶⁰³

⁵⁹⁸ Professor Dr Rating T-15-01-13 p.93 line 9

⁵⁹⁹ Professor Dr Rating T-15-01-13 p.91 line 5

⁶⁰⁰ In these circumstances I determined that no useful purpose was served by seeking Professor Kirkham's opinion as to the cause of Raychel Ferguson's death.

⁶⁰¹ 093-025-068b

⁶⁰² 093-025-068b

⁶⁰³ 059-036-069

Consultation with witnesses was undertaken in April⁶⁰⁴ and May 1996.⁶⁰⁵ Solicitor's advices were received.⁶⁰⁶ Mr Brangam advised Dr Murnaghan on 30th May 1996⁶⁰⁷ that Dr Sumner's views were capable of creating difficulties for the Trust at inquest and moreover that Professor Savage agreed with them. In addition Mr Brangam reiterated Professor Savage's suggestion that the Trust should adopt the attitude *"...that everyone concerned in the care of this child was devastated by his death and that where possible, answers will be provided to the queries raised by the solicitors on behalf of the next of kin."*⁶⁰⁸

2.196 Dr Taylor's attitude remained assertive and defiant throughout. He informed Dr Murnaghan that it was unacceptable *"to speculate on the cause of Adam's death without direct post-mortem evidence and by misrepresenting the quantities and types of fluids given."* He found *"several fundamental problems"* with Dr Armour's report and pointedly *observed that he "would hope that reasons [were] not being generated or misrepresented to suit the diagnosis."*⁶⁰⁹

2.197 Dr Murnaghan was all too keenly aware that Dr Taylor disagreed with both Dr Sumner and Professor Savage. His response was to arrange further discussion with Dr Taylor and Dr Gaston⁶¹⁰ to reconsider the issue of Adam's fluid management. A final meeting with the solicitor, Dr Taylor, Professor Savage and Dr Gaston was convened on 14th June 1996⁶¹¹ presumably in an attempt to establish an agreed position before proceeding to inquest, however, Dr Taylor refused to accept that there had been fluid overload or that Adam had suffered from dilutional hyponatraemia.⁶¹² The

⁶⁰⁴ 059-043-098

⁶⁰⁵ 059-030-061

⁶⁰⁶ 059-014-038

⁶⁰⁷ 059-020-046

⁶⁰⁸ 059-020-046

⁶⁰⁹ 059-036-072

⁶¹⁰ 059-017-043

⁶¹¹ 122-001-001

⁶¹² 122-001-004

most that seems to have been agreed was that they would not use the words “*fluid overload*.”⁶¹³

2.198 In Dr Murnaghan’s view “*the purpose of the meeting [was]... to inform the Trust’s legal advisor who was to ... represent the Trust at the Inquest.*”⁶¹⁴

Indeed Mr Brangam might, when informed of the contradictory opinions expressed by the Trust witnesses as to cause of death, have considered that a conflict existed in the Trust position and suggested separate legal representation for Dr Taylor at the inquest. He did not.

2.199 That was a very unsatisfactory position for the Trust and as Professor Savage observed “*it seemed to be that the people who were advising on the approach to the Coroner’s Inquest were saying ‘Dr Savage has that view, Dr Taylor has that view, and we must allow him to put that view forward.’*”⁶¹⁵ To have allowed a medical witness on behalf of the Trust to give evidence relating to the circumstances of a death which was known to be contrary to the beliefs of other medical witnesses appearing on behalf of the Trust was inappropriate. It conflicted the Trust’s position and encouraged witnesses to minimise rather than articulate the differences between them.

2.200 Dr Gaston did not attend the pre-inquest consultations as a potential witness but in his governance capacity as a clinical director.⁶¹⁶ Notwithstanding that he was aware of the differences of opinion between Professor Savage and Dr Taylor as to the cause of Adam’s death, he did not, even then, think it appropriate to inform the medical director but rather continued “*with a view to ensuring the evidence that was presented reflected fairly Dr Taylor’s position so that the Coroner had the opportunity to hear the other points of view...*”⁶¹⁷ I believe that Dr Gaston was principally motivated to support Dr Taylor at a time when he and Dr Murnaghan should have been primarily concerned with ensuring that all involved complied with

⁶¹³ 122-001-004

⁶¹⁴ Dr Murnaghan T-11-09-12 p.152 line 6

⁶¹⁵ Professor Savage T-10-09-12 p.126 line 5

⁶¹⁶ Dr Gaston T-11-09-12 p.42 line 21 & Dr Gaston T-19-06-12 p.111 line 12

⁶¹⁷ Dr Gaston T-11-09-12 p.43 line 2

their legal duty⁶¹⁸ to inform the Coroner about what they knew of the facts and circumstances of Adam's death.

Inquest into Adam's death

- 2.201 Adam's inquest opened on 18th June 1996 before H.M. Coroner, Mr John Leckey, and heard from a number of witnesses including Adam's mother,⁶¹⁹ Dr Armour,⁶²⁰ Dr Alexander⁶²¹ and Mr Keane⁶²² before resuming on 21st June 1996 to hear Dr Taylor⁶²³ and Professor Savage.⁶²⁴ No nursing or technical evidence was given. Mr Brown did not give evidence.
- 2.202 It is significant, that of the opinions expressed as to cause of death at inquest, it was Dr Taylor alone who dissented. He insisted that Adam's polyuric condition meant that he could not develop dilutional hyponatraemia and that this could not therefore have been the cause of death.⁶²⁵ Mr Keane did not proffer his opinion as to what had gone wrong and Professor Savage, whilst indicating his agreement with Dr Sumner⁶²⁶ was less critical of Dr Taylor's fluid management than might have been expected. Indeed, he was reluctant to say that there had been "*gross fluid overload*."⁶²⁷
- 2.203 During the course of the inquest, the Trust provided the Coroner with draft "*recommendations for the prevention and management of hyponatraemia arising during paediatric surgery*."⁶²⁸ These were signed by Dr Taylor and submitted as evidence of how such cases might be managed in the future.⁶²⁹ These recommendations were drafted by Dr Gaston,⁶³⁰ in liaison with Dr Murnaghan,⁶³¹ and endorsed by consultant paediatric anaesthetist

⁶¹⁸ Pursuant to section 7 of the Coroners Act (Northern Ireland) 1959.
www.legislation.gov.uk/apni/1959/15/section/7

⁶¹⁹ 011-009-025

⁶²⁰ 011-010-030

⁶²¹ 011-012-079

⁶²² 011-013-093

⁶²³ 011-014-019

⁶²⁴ 011-015-109

⁶²⁵ 011-014-098

⁶²⁶ 122-044-034

⁶²⁷ 122-044-035

⁶²⁸ 060-018-036

⁶²⁹ 122-044-048

⁶³⁰ 060-018-035 & WS-013-2 p.4

⁶³¹ 093-025-068b

Dr Seamus McKaigue.⁶³² The draft received the approval of Dr Crean⁶³³ who stated that the primary purpose of the recommendations was that they might be produced at Adam's inquest.⁶³⁴

- 2.204 The recommendations specifically claim to be made with regard to the Arieff paper and the circumstances of Adam's case and seek to reassure that in future all anaesthetic staff will be made aware of the complications of hyponatraemia and advised to act appropriately.
- 2.205 Professor Arieff's paper was referenced because it was the medical literature cited by Drs Alexander, Armour and Sumner in support of the conclusion that Adam's cerebral oedema was caused by dilutional hyponatraemia resulting from an excess administration of low sodium fluids. Dr Sumner described it as a "*very important paper on the subject - about which [there is] not much general knowledge.*"⁶³⁵
- 2.206 Rule 23(2) of The Coroner's (Practice and Procedure) Rules (Northern Ireland) 1963 allowed the Coroner discretion to report the circumstances of Adam's death to the relevant authorities, if he considered..."*that action should be taken to prevent the occurrence of fatalities*"⁶³⁶ The suspicion arose that the draft recommendations had been cynically provided to the Coroner in order to deflect him from issuing a Rule 23(2) report by reassuring that action would indeed be taken.
- 2.207 Evidence was received that the recommendations were not distributed beyond the same small group of anaesthetists which had drafted them in the first place.⁶³⁷ They were not circulated amongst other clinicians or paediatricians involved in paediatric surgery or amongst other paediatric anaesthetists. In fact, nothing was done with the 'recommendations.' Accordingly, their principal reassurance that "*all anaesthetic staff will be made aware of the paediatric phenomena [dilutional hyponatraemia] and*

⁶³² 303-001-002, 060-014-025 & 093-023-065b

⁶³³ 060-014-025

⁶³⁴ WS-130-1 p.16

⁶³⁵ 122-044-011

⁶³⁶ 303-052-715

⁶³⁷ WS-130-1 p.16

*advised to act accordingly*⁶³⁸ was almost certainly insincere. Given the lack of any subsequent dissemination of these recommendations or of *“the information contained in the paper by Arieff*⁶³⁹ it must be concluded that they were indeed drafted solely for production at the inquest and accordingly that their purpose must have been to provide comfort to the Coroner and dissuade him from making a Rule 23 report.

2.208 In the event, the Coroner was not convinced that such a report was necessary. He considered that Professor Savage's proposal *“to monitor electrolytes more closely”*⁶⁴⁰ was clear⁶⁴¹ and was persuaded *“that changes would be made in relation to the future management of cases such as that of Adam's.”*⁶⁴²

2.209 In an apparently separate exercise the same draft recommendations were then developed into a *“press release.”* This was forwarded to the Trust's Public Relations department on 21st June 1996⁶⁴³ *“in anticipation of media interest at the conclusion of the Inquest.”*⁶⁴⁴ It subsequently found reference in both the Belfast Telegraph⁶⁴⁵ and The Irish News.⁶⁴⁶ The press and public were thus given the same empty assurances as were given the Coroner. It was, indeed, an exercise in public relations.

2.210 With hindsight, it was also a wasted opportunity to familiarise clinicians in Northern Ireland with the risks of dilutional hyponatraemia in children. It was later noted by Mr Clive Gowdy⁶⁴⁷ that the references to hyponatraemia *“were of such general application to be of interest and significance to other hospitals likely to be treating young patients.”*⁶⁴⁸ The fact that Dr Mulholland, then acting Clinical Director for Paediatrics, and Dr Terence Montague, Senior Registrar in Anaesthetics at the Children's Hospital, were both

⁶³⁸ 011-014-107a

⁶³⁹ 011-014-107a & Dr Crean T-04-06-13 p.34 line 5

⁶⁴⁰ 122-044-034

⁶⁴¹ 122-044-051

⁶⁴² 006-015-311

⁶⁴³ 059-007-023 & WS-105-2 p.19

⁶⁴⁴ 305-020-001

⁶⁴⁵ 070-016-073

⁶⁴⁶ 070-016-070

⁶⁴⁷ Permanent Secretary, Department of Health, Social Services and Public Safety (DHSSPS) Northern Ireland

⁶⁴⁸ WS-062-2 p.10

unaware of the Arieff paper⁶⁴⁹ emphasises the importance of this missed opportunity, which may have been significant for the care Claire Roberts was to receive only months later in the Children's Hospital.

2.211 Mr Gowdy went further and observed that he would have expected a copy of the recommendations to be sent to the Department and to Dr Henrietta Campbell, the Chief Medical Officer ('CMO') because of regional implication and the desirability of wider dissemination. The CMO herself believed that had they been brought to her attention she would have considered them an appropriate matter for discussion within the Specialty Advisory Committees ('SAC') for anaesthetics and paediatrics.⁶⁵⁰

2.212 The Inquest verdict given on 21st June 1996 found the cause of Adam's death to be "*(A) Cerebral Oedema due to (B) Dilutional Hyponatraemia and impaired cerebral perfusion during renal transplant operation for a chronic renal failure (congenital obstructive uropathy).*"⁶⁵¹ The Coroner made an additional finding that the onset of "*gross cerebral oedema was caused by the acute onset of hyponatraemia from the excess administration of fluids containing only very small amounts of sodium.*"⁶⁵²

2.213 The Coroner's verdict was damning for Dr Taylor and the Trust.

Post-inquest

2.214 After the inquest, Dr Murnaghan noted that "*generally the outcome was satisfactory with fair write up in Friday evening's Telegraph.*"⁶⁵³ The newspaper report was headlined "*Death left me devastated - op doctor. Boy's death prompts action from Royal Hospital Trust.*"⁶⁵⁴ He telephoned the Editor of the Belfast Telegraph to thank him.

⁶⁴⁹ Dr Mulholland T-21-06-12 p.178 line 15 & Dr Montague T-11-05-12 p.158 line 5

⁶⁵⁰ WS-075-2 p.8

⁶⁵¹ 011-016-114

⁶⁵² 011-011-063

⁶⁵³ 059-001-001

⁶⁵⁴ 070-016-073

- 2.215 The Trust's solicitor, Mr Brangam, wrote to Dr Murnaghan on 2nd July 1996 hoping that *"everyone involved was satisfied by the way in which matters progressed and, indeed, I believe it is not without note that the Coroner did not issue a recommendation in this case, which I believe was in a large part due to the fact that the deponents gave their evidence in fair, objective and professional manner and at the same time were alert and aware of those issues which might cause an erosion of public confidence."*⁶⁵⁵ He also sought to place on *"record my appreciation for the sterling help and assistance given at the hearing of this matter by Dr Gaston."*⁶⁵⁶
- 2.216 Mr Brangam was to write further to Dr Murnaghan on 19th March 1997 in respect of the medical negligence claim brought by Adam's mother to advise that *"from a liability point of view, this case cannot be defended, and this is based largely upon the information given by one of the independent experts retained by H.M. Coroner at the Inquest. Additionally I believe that it would unwise for The Trust to engage in litigation in this matter given the particularly tragic circumstances of the death and the opportunity for the exploration of any differences of opinion which might exist between a number of the attending physicians."*⁶⁵⁷
- 2.217 The solicitor thus reveals what I believe to have been the Trust tactic at inquest. Given that Dr Sumner's views were likely to prevail and that there were issues which could cause an erosion of public confidence, it was decided to draw as little attention as possible to the differences of opinion between doctors lest the full extent of what may have gone wrong be explored. That was an approach which, in effect, withheld relevant information and analysis from the Coroner and discouraged review.
- 2.218 Dr Carson recalled *"Dr Murnaghan coming into my office after the Inquest to say basically, the Inquest went all right... satisfactory."*⁶⁵⁸ Having acknowledged that there could be nothing *"satisfactory"* about such a

⁶⁵⁵ 060-020-039

⁶⁵⁶ 060-020-039

⁶⁵⁷ 060-016-031

⁶⁵⁸ Dr Carson T-16-01-13 p.150 line 13

verdict from the point of view of the Trust, Dr Carson explained that Dr Murnaghan must have thought it “*went all right*” from the perspective of “*reputational risk - being damaged by an adverse outcome in an Inquest.*”⁶⁵⁹

- 2.219 I conclude that overall Dr Murnaghan engaged in a ‘damage limitation’ exercise to protect the reputation of the hospital. That was not the role of one who should have been motivated to assist the Coroner.

Informing the Medical Director

- 2.220 Dr Murnaghan informed Dr Carson about the inquest but did not seemingly communicate the crucial point that Dr Taylor had made a grievous error⁶⁶⁰ and refused to acknowledge it. Dr Carson explained that he had not been told that there was criticism of Dr Taylor⁶⁶¹ or that the Coroner had suggested a dissemination of information⁶⁶² and it was thus that he did not “*give any thought to a review or investigation of any sort into the case.*”⁶⁶³
- 2.221 However, Dr Murnaghan did inform Dr Carson that the inquest had raised risk management issues and Dr Carson seemingly agreed that this warranted a seminar as soon as possible with Drs Taylor, O'Connor, Mulholland and Gaston, Professor Savage and Mr Keane.⁶⁶⁴ This did not happen and Dr Carson did not pursue it. Nor did he ask to see the Coroner’s verdict⁶⁶⁵ or enquire if Dr Taylor accepted it.⁶⁶⁶ He asked no questions, sought no report, and made no report to the Board.
- 2.222 The absence of any engagement by the Medical Director, Dr Carson, with the issues generated by the Inquest verdict is extraordinary and may have had a major bearing on how the Trust responded to the Coroner’s finding, managed Dr Taylor and learned from the tragedy.

⁶⁵⁹ Dr Carson T-16-01-13 p.151 line 17

⁶⁶⁰ Dr Carson T-16-01-13 p.158 line 7

⁶⁶¹ Dr Carson T-16-01-13 p.159 line 11

⁶⁶² Dr Carson T-16-01-13 p.175 line 9

⁶⁶³ Dr Carson T-16-01-13 p.164 line 13

⁶⁶⁴ 059-001-001

⁶⁶⁵ Dr Carson T-16-01-13 p.155 line 25

⁶⁶⁶ Dr Carson T-16-01-13 p.156 line 24

Post-inquest response

2.223 It was Dr Taylor alone who had did not accept the finding of the Coroner.⁶⁶⁷ He continued to brazenly defend his position to both the PSNI and this Inquiry until he was finally obliged to concede error in February 2012.⁶⁶⁸ He did not, however, publically disagree with the inquest verdict and somehow managed to leave his colleagues unclear as to exactly what his position was.

2.224 It is to be regretted that the Trust took no formal steps to find out if Dr Taylor accepted the verdict.⁶⁶⁹ Mr Keane *“thought that the verdict of the inquest would have perhaps offered an opportunity for other people to talk to him”*⁶⁷⁰ but as Professor Savage recalled - *“the Coroner made his decision, we accepted it and things seemed to have ended there.”*⁶⁷¹

2.225 Mr Koffman was of the view that *“if the Coroner’s verdict was that this was an avoidable hyponatraemic death, it has to be accepted by the team. If you do not accept that, you cannot be part of that team. So I would immediately say he could do no transplant work. But the problem with hyponatraemic illness is that it could relate to any operation; it is not just specific to transplantation. So that is why there is a wider connotation.”*⁶⁷² I believe that was the proper response and the one which should have been adopted by the Trust in 1996. Until such time as the Trust could be confident that such an error would not be repeated, patient safety was potentially jeopardised. Steps ought to have been taken to formally assess and, if necessary, retrain Dr Taylor at that time. Instead, Dr Taylor was permitted to continue in his practice.

2.226 However in 1996, the Trust did not assess the clinical performance of its medical staff. Dr Gaston recalled *“no policy... for the appraisal of*

⁶⁶⁷ Dr Montague T-11-05-12 p.155 line 21 & Professor Savage T-18-04-12 p.171 line 12

⁶⁶⁸ WS-008-6 p.3

⁶⁶⁹ Dr Gaston T-11-09-12 p.108 line 20

⁶⁷⁰ Mr Keane T-26-04-12 p.171 line 10

⁶⁷¹ Professor Savage T-22-06-12 p.99 line 3

⁶⁷² Mr Koffman T-16-05-12 p.153-154

*anaesthetic staff after an unexpected death.*⁶⁷³ There was no external review and as Mr William McKee⁶⁷⁴ advised, no *“process of assessing and developing the competence of doctors outside the GMC.”*⁶⁷⁵ There was no referral to the General Medical Council (‘GMC’), whether by the Trust or its medical staff, notwithstanding the clear duty imposed by the GMC Code of Good Practice to protect patients when clinical performance was thought to pose a threat.⁶⁷⁶ Mr McKee stated that the Board *“relied on the wider clinical team to ascertain whether there should be a referral to the GMC.”*⁶⁷⁷ However, as Dr Murnaghan explained *“there wasn’t a culture of referral to the GMC.”*⁶⁷⁸ That must however have been known to all.

2.227 The consultant paediatric anaesthetists in the Children’s Hospital do not appear to have even considered referring Dr Taylor to the GMC. They did discuss Adam’s case⁶⁷⁹ but somehow allowed themselves to understand that whilst Dr Taylor may not have agreed with the Inquest verdict he did acknowledge error in respect of his care of Adam.⁶⁸⁰ They appeared to have been content to leave it at that without further reassurance as to his competency in fluid management.⁶⁸¹ In short, they appear to have trusted to luck.⁶⁸² Professor Savage and the nephrology team do not seem to have been so trusting and in consequence of Adam’s death they made it their *“business to be in theatre for the duration of every transplant and to have discussions with the Anaesthetist about the fluids beforehand and during and actively observe all the fluids that were given.”*⁶⁸³

2.228 I can only conclude that the Trust lacked a proper system to manage the consultant who failed to acknowledge error or the risk he might pose to patients or the extent to which further training might be necessary. The

⁶⁷³ WS-013-2 p.7
⁶⁷⁴ 306-081-006 Chief Executive, Royal Hospitals Trust
⁶⁷⁵ WS-061-2 p.17
⁶⁷⁶ WS-130-1 p.25
⁶⁷⁷ Mr McKee T-17-01-13 p.52 line 11
⁶⁷⁸ Dr Murnaghan T-25-06-12 p.212 line 23
⁶⁷⁹ Dr Crean T-20-06-12 p.51 line 17
⁶⁸⁰ Dr Crean T-20-06-12 p.25 line 11
⁶⁸¹ Dr Crean T-20-06-12 p.28 line 6
⁶⁸² Dr Crean T-20-06-12 p.28 line 3
⁶⁸³ Dr O’Connor T-20-06-12 p.104 line 17

Trust had no means of satisfying itself that the clinicians involved in the paediatric renal transplant programme were competent or that problems would be addressed. Because there was no proper review to identify poor performance, clinicians were left with only themselves to satisfy that the service they provided was of an appropriate standard. Left alone, not even a critical Coroner's verdict on a patient's death could prompt them to formally question their performance or refer to the GMC. This approach amounted to the Trust surrendering such mechanisms of risk management control as it claimed to a culture of uncritical medical self-regulation about which it did not enquire. This was a failure in leadership of the Medical Director, the Board of the Trust and the Chief Executive.

Post-inquest audit and review

- 2.229 The Inquiry was informed that the Paediatric Directorate held regular medical audit meetings in 1995.⁶⁸⁴ Indeed the Royal Hospitals Annual Report 1993-94 described "... sessions on case note review, discussion and presentation of audit projects... More recently there has been a move toward multi-disciplinary audit (clinical audit)..."⁶⁸⁵
- 2.230 There was no clinical audit of Adam's case before the Inquest because as Dr Taylor said he "*did not do anything in terms of clinical audit as it was a Coroner's case.*"⁶⁸⁶ Regrettably, he did nothing about a clinical audit of the case after the inquest either. Nor was Adam's case seemingly presented at any other Paediatric Directorate meeting.
- 2.231 Dr Taylor believed however that Adam's case could have been presented at an ATICS mortality meeting⁶⁸⁷ by Dr Gaston⁶⁸⁸ but was unable to identify any learning to have emerged from the meeting.⁶⁸⁹ That is probably because it was the meeting held on 10th December 1996 when Dr Gaston chose to openly praise the excellence of Dr Taylor's record keeping in the

⁶⁸⁴ 305-011-572

⁶⁸⁵ WS-061-2 p.58

⁶⁸⁶ WS-008-03 p.43

⁶⁸⁷ Dr Taylor T-21-06-12 p.109 line 20

⁶⁸⁸ Dr Taylor T-21-06-12 p.114 line 19

⁶⁸⁹ Dr Taylor T-21-06-12 p.115 line 19

context of assisting the Coroner's investigation.⁶⁹⁰ Given what was by then known about Adam's death I believe that this reveals an underlying institutionalised reluctance to admit major shortcomings. Furthermore, and given that Dr Taylor had not, at that stage, accepted the Coroner's verdict⁶⁹¹ I consider that proper discussion of the case should have focussed on Dr Taylor's position and how it might have been dealt with.

- 2.232 Dr Murnaghan described the response within the Trust to the introduction of clinical audit as slow and incorporating a *"touch of resistance."*⁶⁹² I find that the evidence revealed concrete resistance in 1996 to any meaningful audit, review or analysis of Adam's case.

Lessons

- 2.233 Ms Slavin observed that *"families may still be angry. However, if they can be assured, both that lessons have been learned and that changes have been made, then it may ease their grief and give them solace and closure."*⁶⁹³
- 2.234 In general, I agree with the view expressed to the Inquiry by Mr Ramsden that *"in 1995 I would have expected a more formal approach to the lessons learned to be taken by the RBHSC. I have seen no formal report from RBHSC summarising the incident, the lessons learned and an Action Plan for implementing improvement. In view of the seriousness of this case, I would have expected to see a report created by RBHSC in 1995, summarising all this... certainly such a report should then have commented on whether any broader lessons on fluid management and the prevention of hyponatraemia were needed."*⁶⁹⁴
- 2.235 At inquest the Coroner had a discussion with Dr Sumner about how Dr Sumner's views *"could be disseminated amongst the medical profession in*

⁶⁹⁰ WS-013-1 p.3

⁶⁹¹ Dr Taylor T-21-06-12 p.112 line 7

⁶⁹² Dr Murnaghan T-25-06-12 p.15 line 2

⁶⁹³ WS-001-2 p.17

⁶⁹⁴ 211-005-018

Northern Ireland.”⁶⁹⁵ The Coroner “assumed that the Royal Belfast Hospital for Sick Children would have circulated other hospitals in Northern Ireland with details of the evidence given at the inquest and, possibly, some ‘best practice’ guidelines”⁶⁹⁶ and further that he “attached great importance to [this] bearing in mind that the Royal Victoria Hospital was pre-eminently a teaching hospital.”⁶⁹⁷ He was to be disappointed. Mr McKee advised that “prior to July 2004 there was no formal mechanism or requirement within Northern Ireland to report lessons learned from Inquest.”⁶⁹⁸

2.236 Dr Murnaghan did not report the outcome of the inquest to the Trust Board and neither the Chief Executive nor the Clinical Director of Paediatrics⁶⁹⁹ was informed of the verdict or the Coroner’s intention that information be shared.⁷⁰⁰ Dr Gaston claimed not to remember the Coroner discussing how lessons might be shared⁷⁰¹ and gave no thought to the identification of lessons or the prevention of a possible recurrence.

2.237 In respect of learning lessons within the hospital, Mr McKee advised that “until 1999 the Director of Medical Administration ensured the internal dissemination of lessons learned from Inquests.”⁷⁰² There is no evidence that Dr Murnaghan did anything. Whilst he did discuss convening a seminar involving Professor Savage, Drs Mulholland, Gaston, O’Connor, Taylor, Hicks⁷⁰³ and Mr Keane to address “the other issues identified”⁷⁰⁴ he did not pursue the idea.⁷⁰⁵ Dr Murnaghan spoke of his “regret to this day that I forgot totally about this important issue.”⁷⁰⁶

2.238 With hindsight it is indeed to be regretted that Dr Murnaghan’s idea of a seminar was forgotten because the principal learning from the death was

⁶⁹⁵ WS-091-1 p.2
⁶⁹⁶ WS-091-1 p.4
⁶⁹⁷ Mr Leckey T-25-06-13 p.61 line 12
⁶⁹⁸ WS-061-1 p.2
⁶⁹⁹ Dr Mulholland T-21-06-12 p.178 line 22
⁷⁰⁰ WS-061-1 p.2
⁷⁰¹ Dr Gaston T-19-06-12 p.185 line 8
⁷⁰² WS-061-1 p.2
⁷⁰³ 306-081-004
⁷⁰⁴ 059-001-001
⁷⁰⁵ WS-015-2 p.20
⁷⁰⁶ Dr Murnaghan T-25-06-12 p.209 line 1

available and had been since January 1996 in the reports of Drs Alexander⁷⁰⁷ and Sumner.⁷⁰⁸ Both had relied for authority upon Professor Arieff's paper 'Hyponatraemia and death, or permanent brain damage, in healthy children' (1992)⁷⁰⁹ as indeed had Dr Armour and all the consultant paediatric anaesthetists in the Children's Hospital.⁷¹⁰ The Arieff paper therefore became the obvious basis for teaching about IV administration of hypotonic fluids and the risks of dilutional hyponatraemia in children. Dr Sumner could so easily have been invited to the Children's Hospital for an open discussion as to the issues arising. An invitation to Dr Armour or Professor Savage would have been simpler still.⁷¹¹

2.239 Arieff's study analysed a group of patients who had died or suffered brain damage from hyponatraemia. The paper had broad Children's Hospital application because none of Arieff's study group had undergone renal transplantation or even major paediatric surgery but had been hospitalised by minor fevers, appendicitis and other non-critical conditions. Most were admitted with symptoms of lethargy, emesis or weakness. It is to be remembered that only four months after Inquest, Claire Roberts was admitted to the Children's Hospital with symptoms of lethargy, emesis and nausea.⁷¹²

2.240 Drs Taylor, McKaigue and Crean, who had all felt it appropriate to endorse the draft recommendations for the Coroner with "*regard to the information contained in the paper by Arieff et al (BMJ 1992)*"⁷¹³ all still practiced in the hospital at the time of Claire's admission but had made no attempt to share Arieff's guidance or give any relevant training whatsoever in what was Northern Ireland's only regional paediatric training hospital. Dr Taylor conceded that "*it ought to have been read and understood and put into the*

⁷⁰⁷ 011-012-084

⁷⁰⁸ 011-011-053

⁷⁰⁹ 011-011-074

⁷¹⁰ 011-014-107a

⁷¹¹ Dr Armour T-13-06-12 p.111 line 6

In May 1997 Dr Alison Armour published an article about Adam's case in the Journal of Clinical Pathology (WS-012-1 p.8) "*to ensure that this would not happen again..*"

⁷¹² 090-011-013

⁷¹³ 011-014-107a

practice of all anaesthetists and paediatricians... who are looking after children in Northern Ireland.”⁷¹⁴

- 2.241 It is in this context additionally unsettling to record that Lucy Crawford was admitted to the Erne Hospital in 2000 with a history of lethargy, drowsiness and floppiness,⁷¹⁵ and Raychel Ferguson to the Altnagelvin Area Hospital in 2001 for an appendectomy.⁷¹⁶ They, and Claire, all presented with symptoms similar to those recorded in Arieff’s study and all were to receive IV infusion of the hypotonic Solution No.18.
- 2.242 Professor Arieff’s concluding paragraph now seems particularly relevant to the treatment given Claire in that he advised that *“when a paediatric patient receiving hypotonic fluid begins to have headache, emesis, nausea or lethargy the serum sodium concentration must be measured. Although these symptoms are somewhat non-specific, the diagnosis is easily established at minimal cost and with virtually no risk to the patient by evaluating plasma electrolyte values.”⁷¹⁷*
- 2.243 There was ample opportunity to direct and influence the learning from Adam’s case.⁷¹⁸ The lead members of Adam’s transplant team, Professor Savage, Dr Taylor and Mr Keane all held teaching posts at Queens University, Belfast.⁷¹⁹ Professor Savage chaired the Faculty of Medicine Education Committee in 1995⁷²⁰ and Dr Taylor served on the Education Sub-Committee of the Anaesthetics, Theatre and Intensive Care Directorate 1995-1997 and was in a position to influence post-registration training.⁷²¹ This additional aspect of Dr Taylor’s practice emphasises the importance which should have been attached to assessment of his clinical competence in respect of fluid management in the context of end-stage renal failure.

⁷¹⁴ Dr Taylor T-21-06-12 p.98 line 20

⁷¹⁵ 027-009-020

⁷¹⁶ 020-006-010

⁷¹⁷ 011-011-077

⁷¹⁸ Professor Savage T-22-06-12 p.119 line 9

⁷¹⁹ 306-018-004 & 306-019-010 & 306-023-003

⁷²⁰ 306-018-008

⁷²¹ 306-019-011

2.244 Indeed, Dr Haynes expressed concern about Dr Taylor's teaching role given the mistakes made by him in fluid management and his failure to acknowledge error.⁷²² However Dr Taylor, doubtless intending to reassure, claimed to have *"stuck to textbook teaching about the management of fluids."*⁷²³ That must, however, have meant that his teaching was then at odds with his explanations to the PSNI and this Inquiry. Dr Taylor categorised his *"answers to the Police as... irrational."*⁷²⁴ I categorise his answers as dishonest.

2.245 I believe that by refusing to accept Adam's dilutional hyponatraemia, Dr Taylor restricted the scope for learning. His opinion alone seems to have been a limiting factor because even eight years later when the Trust was asked by the Department whether anything had been learned from Adam's case, the Trust's Press and Public Relations Officer responded having *"just spoken with Dr Bob Taylor, Consultant Anaesthetist in PICU, who was involved in the management of Adam Strain and gave evidence at the Inquest. Following a detailed examination of the issues surrounding patient AS there were no new learning points, and therefore no need to disseminate any information."*⁷²⁵

2.246 The Coroner has said that *"looking back, it was one of the most important inquests I've ever held..."*⁷²⁶ It is therefore not only disappointing but disturbing that so little should have been learned from it. Dr Gaston considered that the responsibility for the failing to learn lessons was collective.⁷²⁷ I agree, but would add that those involved were not given the necessary guidance or leadership from within the Trust. In the light of the critical verdict at inquest, Drs Carson and Murnaghan should never have allowed so important a learning opportunity to go unexplored.

⁷²² Dr Haynes T-02-05-12 p.29 lines 6-14

⁷²³ Dr Taylor T-21-06-12 p.136 line 19

⁷²⁴ Dr Taylor T-21-06-12 p.138 line 1

⁷²⁵ 023-045-105

⁷²⁶ Dr Murnaghan T-25-06-12 p.132 line 9

⁷²⁷ Dr Gaston T-19-06-12 p.146 line 7

- 2.247 The learning to be extracted from Adam's death was left to the discretion of the doctors and the individual judgement of Dr Murnaghan.⁷²⁸ Those individuals could not be relied upon. Dr Murnaghan was still engaged in 'defending' the medical negligence claim and unlikely to draw attention to deficiencies in clinical care; Dr Taylor was still denying that Adam had dilutional hyponatraemia and the doctors involved remained predictably averse to focusing on clinical failings.
- 2.248 That Dr Murnaghan was expected to disseminate learning from inquests in addition to all his other responsibilities was unrealistic. That he should have been left alone to manage matters of such importance without reference to the Trust Board, confirms to me that the Board was not engaged with patient safety. From the point of view of the Children's Hospital that was deeply unsatisfactory.

Medical negligence litigation

- 2.249 No apology was given to Adam's mother as contemplated by 'The Complaints Procedure.'⁷²⁹ Her litigation was concluded by settlement on 29th April 1997 without admission of liability and subject to confidentiality.⁷³⁰ The terms of settlement appear to have been drafted by Mr Brangam and the confidentiality clause inserted on his advice.⁷³¹ Refusal to admit liability made it very much less likely that Ms Slavin would ever receive a clear explanation about her son's death and the imposition of confidentiality stifled discussion.
- 2.250 Mr Brangam had previously advised the Trust about handling complaints. He had observed that *"too often in the past clinicians seemed to entertain the notion that the complaints process of itself was threatening, potentially hostile and one where possibly too much information was given to complainants"* and advised that *"to say 'sorry' is not an admission of liability but rather ought to be seen as a proper and sympathetic approach to*

⁷²⁸ 211-005-017

⁷²⁹ WS-062-1 p.351

⁷³⁰ 060-013-024

⁷³¹ Dr Murnaghan T-25-06-12 p.226 line 2

*matters which may have caused a patient or their family concern.*⁷³² These advices were shared with Dr Murnaghan but do not appear to have tempered their shared approach to litigation which was directed at disposing of potentially embarrassing litigation as quietly and unapologetically as possible.

- 2.251 Ms Slavin expressed her frustration, annoyance and disappointment with a litigation settlement process which was confidential and did not admit fault.⁷³³ She said that *“the inquest and subsequent civil proceedings should have brought closure to my grief. They did not.”*⁷³⁴ It was not until 17th October 2013 that the Trust eventually offered Ms Slavin an admission of liability, an apology and an expression of sympathy.⁷³⁵ This could and should have been done after the Inquest in June 1996. The delay was inexcusable and further distress was unnecessarily caused.
- 2.252 On 12th November 2013 the Chief Executive of the Belfast Health and Social Care Trust⁷³⁶ Mr Colm Donaghy publically acknowledged that the way *“litigation has been handled by the Belfast Trust has added to the hurt and grief felt by the families... I wish to apologise unreservedly to the families for the unacceptable delay in the Belfast Trust accepting liability.”*⁷³⁷
- 2.253 That nothing was done to review the medical negligence claim after settlement or draw anything from it confirms my view that the way claims were processed acted as an obstacle rather than a support to the practice of learning from error. That was an obvious waste of opportunity for clinical improvement.
- 2.254 Dr Murnaghan's role as manager of litigation was untenable. His responsibility to defend claims against the Trust was in potential conflict

⁷³² 126-021-001

⁷³³ WS-001-2 p.16

⁷³⁴ WS-001-2 p.17

⁷³⁵ T-17-10-13 p.2-3

⁷³⁶ Which incorporated the former Royal Group of Hospitals Trust ('RGHT')

⁷³⁷ Mr Donaghy T-12-11-13 p.5 line 15

with his duties as impartial investigator of fact, facilitator to the Coroner and disseminator of learning. The arrangement did not work.

Response within paediatric renal transplant service

- 2.255 Professor Savage continued to lead the Paediatric Renal Transplant Service and to rely upon the services of Dr Taylor and Mr Keane. He and Dr O'Connor revised the 1990 Renal Transplant Protocol to ensure that, prior to being called for transplant, each child and family would meet with the surgeon and an individualised transplant plan would be prepared.⁷³⁸ They tried to make sure that Solution No.18 would not be administered⁷³⁹ and that urinary output and sodium concentrations would be measured.⁷⁴⁰
- 2.256 In April 2011 Dr O'Connor was able to advise that all 50 paediatric renal transplant patients operated on in the Children's Hospital since Adam's death had survived transplant surgery.⁷⁴¹ Dr Taylor performed the anaesthesia for six of them⁷⁴² and Mr Keane the surgery for two.⁷⁴³ Of the transplants performed in 2010-2012 she advised that *"100 per cent of the transplants are working, which equals the best results in the UK."*⁷⁴⁴

Other issues: unsatisfactory evidence

- 2.257 I found the evidence of the surgeons before this Inquiry to be so unsatisfactory as to justify my singling them out for specific comment. It was Dr Taylor who observed that *"It's very unusual for a patient of any age to die on the operating table and has a devastating effect on the operating department."*⁷⁴⁵ That might be thought self-evident. However, Mr Brown gave evidence from the perspective of one so little marked by the event as to be unable to recall almost anything of it. I did not always find that convincing and consider Mr Brown knew more than he was prepared to

⁷³⁸ Professor Savage T-22-06-12 p.130 line 4

⁷³⁹ Professor Savage T-17-04-12 p.62 line 14

⁷⁴⁰ Professor Savage T-18-04-12 p.77 line 14

⁷⁴¹ WS-014-2 p.20

⁷⁴² 301-047-414

⁷⁴³ Mr Keane T-24-04-12 p.6 line 9 & 301-047-414

⁷⁴⁴ Dr O'Connor T-25-04-12 p.182 line 3

⁷⁴⁵ Dr Taylor T-19-04-12 p.57 line 4

say. He did say by way of an unexpected aside that “*my mantra is I don’t know and I don’t remember.*”⁷⁴⁶ I found his attitude inappropriate.

2.258 By contrast it was Mr Keane’s evidence I found inappropriate. It was so undermined by inconsistency⁷⁴⁷ that only limited reliance could be placed on it. I formed the view that Mr Keane initially told Professor Savage the truth about Adam’s fluid overload but for ‘internal’ purposes only. Later, and for the ‘external’ purpose of inquest, he avoided what he knew to be true hoping that the Coroner would correctly identify the cause of death and relieve him of his obligation to assist.⁷⁴⁸ Then having stated “*as far as I was concerned the anaesthetic went ahead on a very difficult patient without any particular problems*”⁷⁴⁹ he placed himself in a position of inescapable inconsistency as far as this Inquiry was concerned. He failed in his professional duty to assist the Coroner and I believe he failed in his professional duty to assist me.⁷⁵⁰

Concluding remarks

2.259 Even though I found defensiveness, deceit and a strong inclination amongst colleagues to close ranks, I do not conclude that the Trust itself engaged in a systematic ‘cover-up.’ It is to be recognised that Dr O’Connor recorded the provisional diagnosis of dilutional hyponatraemia within hours of Adam’s admission to PICU. Dr Taylor carefully filed the anaesthetic notes and the CVP trace in the chart. The death was notified promptly to the Coroner who commissioned a post-mortem report, investigated and sought

⁷⁴⁶ Mr Brown T-01-05-12 p.102 line 21

⁷⁴⁷ For example, inconsistent evidence in relation to:

- (i) the decision to accept kidney (see: WS-006-3 p.23 & Mr Keane T-24-04-12 p.16)
- (ii) an arrangement to leave before the completion of surgery (see: Mr Keane T-24-04-12 p.83 line 15 & Mr Keane T-24-04-12 p.87 line 17)
- (iii) checking the catheter before inserting supra-pubic catheter (see: Mr Keane T-23-04-12 p.96 line 17 & WS-006-3 p.8)
- (iv) the CVP readings sought from Dr Taylor (see: WS-006-3 p.17 & Mr Keane T-23-04-12 p.117 line 12)
- (v) his role in wound closure (see: 093-010-030 & Mr Keane T-10-09-12 p.16 line 20)
- (vi) his reason for leaving the theatre before completion of surgery (see: WS-006-2 p.7 & Mr Keane T-26-04-12 p.163-64)
- (vii) non-participation in subsequent paediatric transplant surgery (see: 301-127-001 & Mr Keane T-24-04-12 p.17 & 301-047-414)

⁷⁴⁸ Mr Keane T-23-04-12 p.73 line 2

⁷⁴⁹ 059-034-067

⁷⁵⁰ 315-002-009

the views of consultant anaesthetist Dr Alexander. Dr Murnaghan and the paediatric anaesthetists advised the Coroner to obtain the additional expert advices of Dr Sumner. These independent reports were shared with Ms Slavin and Professor Savage was authorised to explain them to her. He met and corresponded with her. Neither the diagnosis nor the implications were concealed and Professor Savage advised her in February 1996 that *“after Adam came out of theatre and we knew his sodium was low we realised this was dilutional.”*⁷⁵¹ Thereafter Dr Armour’s Autopsy Report was forwarded to her.⁷⁵² Professor Savage placed on record his disagreement with Dr Taylor,⁷⁵³ advised the Trust’s solicitors accordingly and publically endorsed the conclusions of Dr Sumner at inquest.

It is, however, impossible to avoid the conclusion that the Trust, by its systems and employees, allowed the barest possible constructive response to Adam’s death. Lessons were not learned and that was to compound tragedy.

⁷⁵¹ 306-090-001

⁷⁵² 011-061-196

⁷⁵³ 059-003-005

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Introduction

- 3.1 Claire Roberts was born on 10th January 1987, the youngest child of Alan and Jennifer Roberts. She was admitted to the Royal Belfast Hospital for Sick Children (the 'Children's Hospital') on 21st October 1996¹ with symptoms of vomiting and lethargy and died there two days later.² Her death was not reported to the Coroner.³ The post-mortem examination was confined to her brain⁴ and a Death Certificate was issued citing cerebral oedema secondary to status epilepticus as the cause of death.⁵ Mr and Mrs Roberts never quite understood from what they were told at the Children's Hospital what had happened to Claire or why she had died.⁶
- 3.2 Eight years later, on 21st October 2004, they watched the documentary 'When Hospitals Kill' on Ulster Television. The programme focused on the deaths of Adam Strain, Lucy Crawford and Raychel Ferguson and on whether the circumstances of their deaths might have been the subject of a cover-up. Mr and Mrs Roberts were struck by similarities between Claire's death and those others featured in the programme. They contacted the Children's Hospital the next day.⁷ In consequence, Claire's death was re-considered and referred to the Coroner.⁸ An inquest was held in May 2006 and a verdict given that death was caused by:

“(a) cerebral oedema due to

*(b) meningoencephalitis, hyponatraemia due to excess ADH production and status epilepticus.”*⁹

1 090-014-020
2 090-009-011
3 090-045-148
4 090-054-185
5 091-012-077
6 WS-253-1 p.17
7 WS-253-1 p.17
8 089-004-008
9 091-002-002

The addition of Claire's case to the Inquiry

3.3 When this Inquiry resumed in 2008, having been stayed for three years to permit Police investigation into the other cases, I added Claire's death to those I had been tasked to investigate.¹⁰ I did so because hyponatraemia had contributed to her death and because she had died in the same hospital as Adam, just four months after the inquest into his death. In addition to my concern about the treatment Claire had received, I was troubled by the obvious failure to report Claire's death to the Coroner in 1996 and what was revealed at her inquest ten years later.

Expert reports

3.4 The Inquiry, guided by its advisors, engaged experts to appraise the involvement of the doctors and nurses involved in Claire's care, particularly the Consultant Paediatrician,¹¹ Consultant Paediatric Neurologist¹² and the nurses on duty in Allen Ward. The experts were:

- (i) Dr Robert Scott-Jupp¹³ (Consultant Paediatrician of Salisbury District Hospital) who reported on the role and responsibilities of the Consultant Paediatrician and on paediatric medical issues.¹⁴
- (ii) Professor Brian Neville¹⁵ (Consultant Paediatric Neurologist and Professor of Childhood Epilepsy, Institute of Child Health, University College London and Great Ormond Street Hospital), who advised on neurological issues and the role and responsibilities of the Consultant Paediatric Neurologist.¹⁶

¹⁰ 303-008-176

¹¹ Dr Heather Steen - 310-003-003

¹² Dr David Webb - 310-003-002

¹³ 310-003-007

¹⁴ File 234

¹⁵ 310-003-007

¹⁶ File 232

- (iii) Ms Sally Ramsay¹⁷ (Independent Children's Nursing Advisor) who provided a report on the nursing care.¹⁸

3.5 The Inquiry also engaged experts to address specific issues, including:

- (i) Professor Keith Cartwright¹⁹ (Consultant Clinical Microbiologist) who provided reports on the cerebral spinal fluid ('CSF') sample, the CSF report and changes in Claire's white blood cell count.²⁰
- (ii) Professor Brian Harding²¹ (Consultant Paediatric Neuropathologist and Professor of Pathology & Laboratory Medicine, University of Pennsylvania) who provided a supplemental report to that provided by him to the PSNI on 22nd August 2007²² dealing with the diagnosis of encephalitis in relation to neuropathological changes.²³
- (iii) Dr Waney Squier²⁴ (Consultant Neuropathologist and Clinical Lecturer, John Radcliffe Hospital, Oxford) who provided neuropathological opinion on histological slides.²⁵
- (iv) Dr Philip Anslow²⁶ (Consultant Neuroradiologist, John Radcliffe Hospital, Oxford) who interpreted the Computerised Tomography ('CT') scans of 23rd October 1996.²⁷
- (v) Dr Caren Landes²⁸ (Consultant Paediatric Radiologist, Alder Hey Children's NHS Foundation Trust), who examined and reported on chest x-rays taken at 03:50 and 07:15 on 23rd October 1996 and a CT scan taken the same day.²⁹

¹⁷ 310-003-007
¹⁸ File 231
¹⁹ 310-003-007
²⁰ File 233
²¹ 310-003-007
²² 096-027-357
²³ File 235
²⁴ 310-003-007
²⁵ File 236
²⁶ 310-024-009
²⁷ File 236-006
²⁸ 310-003-007
²⁹ File 230

- (vi) Dr Jeffrey Aronson³⁰ (Consultant Pharmacologist, Oxford University Hospitals NHS Trust) who provided a report on pharmacological issues and in particular the probable effects of the medication prescribed and/or administered.³¹
- (vii) Dr Roderick MacFaul³² (Consultant Paediatrician, now retired) who reported on governance considerations and in addition addressed incidental clinical issues.³³
- (viii) Professor Sebastian Lucas³⁴ (Professor of Clinical Histopathology and Consultant Histopathologist, Guys and St Thomas' Hospitals Trust, London) who provided expert opinion on the autopsy.³⁵
- (ix) Dr Audrey Giles (former Head of The Questioned Documents Section of the Metropolitan Police Forensic Science Laboratory; now Lead of the Giles Document Laboratory) who provided a handwriting analysis report.³⁶

3.6 In addition the Inquiry had the benefit of two further reports prepared for inquest, by:

- (i) Dr Robert Bingham³⁷ (Consultant Paediatric Anaesthetist at the Hospital for Sick Children, Great Ormond Street, London),³⁸ and
- (ii) Dr Ian Maconochie³⁹ (Consultant in Paediatric Accident and Emergency Medicine, St Mary's Hospital London).⁴⁰

³⁰ 310-003-007

³¹ File 237

³² 310-024-009

³³ File 238

³⁴ 310-024-009

³⁵ File 239

³⁶ File 241

³⁷ 310-024-010

³⁸ 091-006-023

³⁹ 310-024-010

⁴⁰ 091-007-031

Schedules compiled by the Inquiry

3.7 In an attempt to summarise the very considerable quantities of information received, a number of schedules and charts was compiled:

- (i) List of Persons - Clinical⁴¹ and Governance.⁴²
- (ii) Chronology of Events - Clinical⁴³ and Chronology of Hospital Management and Governance.⁴⁴
- (iii) Timeline of treatment (21st - 23rd October 1996).⁴⁵
- (iv) Schedule of Consultant Responsibility (22nd - 23rd October 1996).⁴⁶
- (v) Schedule of Medication.⁴⁷
- (vi) Schedule of Fluid and Medication Input.⁴⁸
- (vii) Timeline of Over-lapping Medication.⁴⁹
- (viii) Schedules of Expert Views on Cause of Death⁵⁰ & Cerebral Oedema.⁵¹
- (ix) Schedule of Glasgow Coma Scale ('GCS') scores (22nd October 1996).⁵²
- (x) Schedule of Recorded Sodium Levels (21st - 23rd October 1996).⁵³
- (xi) Schedule of Blood Cell Counts (21st-24th October 1996).⁵⁴

⁴¹ 310-024-001
⁴² 310-023-001
⁴³ 310-004-001
⁴⁴ 310-021-001
⁴⁵ 310-016-001
⁴⁶ 310-005-001
⁴⁷ 310-006-001
⁴⁸ 310-015-001
⁴⁹ 310-020-001
⁵⁰ 310-009-001
⁵¹ 310-019-001
⁵² 310-011-001
⁵³ 310-013-001
⁵⁴ 310-022-001

(xii) Cerebral Oedema Flow Chart.⁵⁵

(xiii) Glossary of Medical Terms.⁵⁶

3.8 All of the above schedules and reports have been published on the Inquiry website in accordance with Inquiry Protocol and procedures.

Clinical history prior to October 1996

3.9 When Claire was six months old, she suffered a number of seizures.⁵⁷ No clear cause was ever identified.⁵⁸ Her condition was assessed and controlled with Epilim (an anti-convulsant medicine) which stabilised her condition from July - September 1987.⁵⁹ The treatment worked allowing the Epilim to be reduced and then discontinued at least 18 months prior to her admission to the Children's Hospital in October 1996.⁶⁰ By then she had not suffered seizures of any sort for at least four years.⁶¹

3.10 Claire was also diagnosed with developmental delay and a moderate learning difficulty.⁶² She attended Tor Bank School, which was able to cater for her needs and where she thrived. She was described as a happy, loving, vibrant and active child who enjoyed all sorts of outdoor activities, adventure playgrounds, trampolines and her motorised bicycle. She was said to have made a positive impact on all who knew her.

3.11 In May 1996, she was seen by Dr Colin Gaston,⁶³ Consultant Community Paediatrician, in relation to behavioural issues. In his letter to Claire's GP, Dr Gaston referred to her as having both moderate learning and attentional difficulties and suggested a brief trial with a stimulant medication such as Ritalin.⁶⁴

⁵⁵ 310-014-001

⁵⁶ 310-007-001

⁵⁷ 099-059-075

⁵⁸ 090-035-120-123

⁵⁹ 090-015-026-027

⁶⁰ 099-006-008

⁶¹ 090-013-018

⁶² 090-013-018

⁶³ 310-003-004

⁶⁴ 090-013-018

- 3.12 Dr Gaston saw the family again on 1st August 1996 and discussed some additional options with them.⁶⁵ Claire was then treated with Ritalin on a daily basis until 2nd October 1996 but by the time of her admission to the Children's Hospital on 21st October, she was no longer taking any medication.⁶⁶

Admission to the Children's Hospital on 21st October 1996

- 3.13 On Friday, 18th October 1996, Claire suffered a loose bowel motion but without diarrhoea. The following day she visited her paternal grandparents for 3 or 4 hours⁶⁷ and came into contact with her 12-year-old cousin who had had a stomach upset earlier in the week. Claire spent the afternoon of Sunday, 20th October, with her maternal grandparents, having been to church in the morning. Her state of health over the weekend was regarded as normal⁶⁸ and she went to school as usual on Monday, 21st.
- 3.14 However, during the course of the school day, Claire's teacher noted her to be unwell and made a record in the homework diary, describing her as pale and lethargic.⁶⁹ When Claire returned home at approximately 15:15,⁷⁰ she vomited several times.⁷¹

Examination by GP

- 3.15 The family GP, Dr Deirdre Savage,⁷² was called and examined Claire at home at approximately 18:00. She noted *"No speech since coming home. Very lethargic at school today. Vomited x 3 – speech slurred. Speech slurred earlier."*⁷³
- 3.16 Dr Savage described Claire as pale and photophobic on examination. She was unable to find any neck stiffness but did think Claire's tone was

⁶⁵ 090-013-016

⁶⁶ 090-022-050

⁶⁷ WS-253-1 p.2

⁶⁸ WS-253-1 p.2

⁶⁹ WS-253-1 p.19

⁷⁰ WS-253-1 p.2

⁷¹ WS-253-1 p.2

⁷² 310-003-004

⁷³ 090-011-013

increased on the right side and suggested that Claire was perhaps post-seizure and/or had an underlying infection.⁷⁴ Mr and Mrs Roberts did not themselves think that she had suffered a seizure⁷⁵ but were advised to and did take Claire to the Children's Hospital.

Examination at Accident & Emergency

- 3.17 Claire entered the Accident and Emergency Department ('A&E') of the Children's Hospital at approximately 19:00 on Monday, 21st October 1996.⁷⁶ The initial nursing assessment recorded:

*"Medication- none... Epileptic... H/O off form and lethargy. GP referral with H/O seizure. Apyrexia O/A pale and drowsy. O/A mental handicap."*⁷⁷

- 3.18 She was seen by Senior House Officer ('SHO') Dr Janil Puthuchery⁷⁸ in A&E. This was his first posting and he had been there for 2 months.⁷⁹ He assessed Claire at 19:15⁸⁰ and took a history of severe learning difficulties and a past history of epilepsy. He noted that she was no longer taking anti-epileptic medication and had been fit-free for three years. Whilst he did not record diarrhoea, cough or pyrexia, he did note that she had been vomiting since earlier that evening and that her speech was very slurred. Indeed, he observed that she was hardly speaking.⁸¹
- 3.19 On examination, Dr Puthuchery noted that Claire was drowsy, tired and apyrexia, with no abnormality other than increased left sided muscle tone and reflexes. Whilst her pupils were reacting she did not like the light. Her tone was generally increased and her tendon reflexes were heightened on the left compared to the right. He observed Claire's plantar reflexes to be

⁷⁴ 090-011-013
⁷⁵ WS-253-1 p.2
⁷⁶ 090-010-012
⁷⁷ 090-010-012
⁷⁸ 310-003-002
⁷⁹ WS-134-1 p.2
⁸⁰ 090-012-014
⁸¹ 090-012-014

reduced bilaterally, in contrast to the GP's observation of some asymmetry.⁸²

- 3.20 Dr Puthuchear made a primary diagnosis of encephalitis on the basis of Claire's altered mental state. He noted the GP's finding of photophobia and her concerns about a possible fit or underlying infection.⁸³

Admission to Allen Ward

Examination by Dr O'Hare

- 3.21 Dr Bernadette O'Hare⁸⁴ was then asked to review Claire.⁸⁵ She was the on-call Paediatric Registrar and had been a Registrar since December 1995.⁸⁶ Dr O'Hare examined Claire at 20:00 and took a history from Mrs Roberts.⁸⁷ Her note refers to Claire having vomited on an hourly basis since 15:00. There is a record of slurred speech, drowsiness, a loose bowel motion 3 days before and having been off-form the previous day. The history records that Claire was usually capable of meaningful speech and made reference to the recent trial of Ritalin.⁸⁸
- 3.22 Dr O'Hare observed that Claire was unresponsive to her parents' voices, staring vacantly and responding only intermittently to deep pain stimulus.⁸⁹ She recorded Claire's pulse at 96 beats per minute, slowing to 80. This was within the normal range for a child of her age.⁹⁰
- 3.23 She made an initial working diagnosis of "1. viral illness 2. Encephalitis,"⁹¹ but then scored out her secondary diagnosis on the basis that it was unlikely in the absence of fever.⁹² In addition, Dr O'Hare thought that she must also

⁸² 090-011-013

⁸³ WS-134-1 p.7

⁸⁴ 310-003-002

⁸⁵ 090-012-014 & WS-134-1 p.5

⁸⁶ WS-135-1 p.2

⁸⁷ 090-022-050

⁸⁸ 090-022-050

⁸⁹ 090-022-051

⁹⁰ WS-135-1 p.7 - It should be noted in this context that a child with cerebral oedema and raised inter-cranial pressure might have been expected to have a slower pulse rate

⁹¹ 090-022-052

⁹² WS-135-1 p.3

have considered the possibility of sub-clinical seizures at that time, because she gave a direction that Claire be given diazepam in the event of such a seizure.⁹³

- 3.24 At about 20:45, Dr O'Hare decided to admit Claire.⁹⁴ Mr and Mrs Roberts were not expecting this.⁹⁵ Her admission was made under the care of Dr Heather Steen,⁹⁶ the on-call Consultant Paediatrician.⁹⁷ Dr Steen was not informed at that time or at any time that night about Claire's admission, condition or treatment.
- 3.25 Claire was formally admitted onto Allen Ward at 21:14.⁹⁸ Her nursing admission sheet was completed about 21:45 by her "accountable nurse"⁹⁹ Staff Nurse Geraldine McRandal.¹⁰⁰ The "reason for admission" was entered as "? seizure, vomiting."¹⁰¹
- 3.26 Mr and Mrs Roberts stayed with her until she fell asleep at about 21:00. Before they left the hospital, they were told that Claire had a viral infection. They felt relieved it was not meningitis.¹⁰²
- 3.27 Dr O'Hare directed a number of tests¹⁰³ including a full blood count, bacterial culture, viral titres and urea and electrolytes. It is likely that the blood sample for these tests was taken on Allen Ward at 22:30 at the same time as a cannula was inserted for IV fluids.¹⁰⁴ Claire was started on an IV infusion of Solution No. 18 at a rate of 64 mls per hour.¹⁰⁵
- 3.28 Dr Robert Scott-Jupp, Consultant Paediatrician, provided favourable expert comment on Dr O'Hare's "clear and competently set out" admission

⁹³ WS-135-1 p.3

⁹⁴ 090-012-014

⁹⁵ Mr and Mrs Roberts T-31-10-12 p.28 line 14

⁹⁶ 310-003-003

⁹⁷ 090-014-020

⁹⁸ 090-014-020

⁹⁹ 090-041-143

¹⁰⁰ 310-003-005

¹⁰¹ 090-041-142 to 143

¹⁰² 096-001-004

¹⁰³ 090-022-052

¹⁰⁴ 090-038-133

¹⁰⁵ 090-038-134

notes.¹⁰⁶ However, he considered her initial investigation “*somewhat limited*” and thought, albeit with hindsight, that a diagnosis of encephalopathy and/or status epilepticus might have been included.¹⁰⁷ In addition, he indicated that would have expected more extensive biochemical tests to have been performed.¹⁰⁸

3.29 Professor Brian Neville, Consultant Paediatric Neurologist, regarded Dr O’Hare’s examination of Claire to be “*competent*,”¹⁰⁹ but considered:

- (i) That hyponatraemia/cerebral oedema should have been considered as part of a differential diagnosis in light of Claire’s vomiting and reduced consciousness.¹¹⁰
- (ii) That Dr O’Hare should have contacted the on-call Consultant, Dr Steen.¹¹¹
- (iii) That a CT scan should have been performed to explore potential causes for Claire’s reduced consciousness.¹¹²
- (iv) That more extensive biochemical tests should have been undertaken.¹¹³

3.30 In considering these criticisms, I have taken account of the following:

- (i) Dr O’Hare’s competence has been acknowledged by both experts.
- (ii) Professor Neville’s specialism in paediatric neurology might lead him to be rather more alert to the range of possibilities than a paediatric registrar.

¹⁰⁶ 234-002-002

¹⁰⁷ 234-002-002

¹⁰⁸ 234-002-002

¹⁰⁹ 232-002-003

¹¹⁰ 232-002-003

¹¹¹ 232-002-004

¹¹² 232-002-004

¹¹³ 232-002-003

(iii) The Children's Hospital did not have the night staffing necessary to conduct the suggested steps.

(iv) There was ample opportunity for the suggested failings in Dr O'Hare's approach to be remedied the following day.

3.31 In her oral evidence, Dr O'Hare agreed that, whilst it would have been reasonable to perform liver function tests,¹¹⁴ her overall view was that the other tests suggested were matters to have been pursued the following morning had there been no improvement.¹¹⁵ This has some force. It is relevant that in oral evidence, both experts were less critical than they had been in writing. Indeed, Professor Neville accepted that, on reflection, a CT scan was not required on Monday night but remained of the view that it should have been performed as soon as possible the following day.¹¹⁶ By the time they gave their evidence, Dr O'Hare had given hers and explained in clear and reflective terms what she did and why. Her evidence was impressive as indeed was her engagement with the Inquiry in trying to understand how things had gone so terribly wrong. In the circumstances, I believe that it would be unfair to single her out for criticism.

3.32 There are many 'if onlys' about what happened to Claire, including that if only Dr O'Hare had contacted Dr Steen on the Monday night, as suggested by Professor Neville¹¹⁷ (but not Dr Scott-Jupp),¹¹⁸ Dr Steen might then have become involved from the start. However, I do not believe that it would be fair to blame Dr O'Hare in this regard because she could not possibly have known on the Monday night that at no point on the Tuesday would any consultant paediatrician have any contact with Claire.

¹¹⁴ Dr O'Hare T-18-10-12 p.138 lines 15-18

¹¹⁵ Dr O'Hare T-18-10-12 p.155 line 13

¹¹⁶ Professor Neville T-01-11-12 p.70 line 12

¹¹⁷ 232-002-007

¹¹⁸ Dr Scott-Jupp T-12-11-12 p.39 lines 1-9

Review at midnight

3.33 Dr O'Hare reviewed Claire at midnight. She found no signs of meningitis and recorded a slight improvement in responses. On that basis, she suggested that Claire be observed overnight and re-assessed in the morning.¹¹⁹

3.34 It is thought that shortly after midnight, the results of the blood tests became known. They were recorded in Claire's notes as:

*"NA [Sodium] 132↓ IC+ [Potassium] 3.8 U [Urea] 4.5 Gluc [Glucose] 6.6 Cr [Creatinine] 36 Cl [Chloride] 96 Hb [Haemoglobin] 10.4 PCV [Packed cell volume] 3^ WCC [White Cell Count] 16.5↑ Plate [platelets] 422.000."*¹²⁰

The entry was made immediately below the record of Dr O'Hare's midnight review. However, the entry is untimed with the result that the timing of the test sample itself is not immediately apparent. It is unclear who made the written entry¹²¹ but it does not seem to have been either Dr O'Hare or the SHO Dr Andrea Volprecht,¹²²

3.35 Of note, was the serum sodium reading of 132mmol/l¹²³ which was just below the normal range of 135-145.¹²⁴

3.36 Notwithstanding some difference of opinion, I accept that the slightly lowered sodium level was not one that should have triggered any further action or investigation that night. Furthermore, I accept that it was reasonable to leave the IV fluid infusion of Solution No. 18 unchanged at 64mls per hour.¹²⁵ However, I do find that the lowered serum sodium reading was a marker to be followed up the following morning.

¹¹⁹ 090-022-052

¹²⁰ 090-022-052

¹²¹ Dr O'Hare T-18-10-12 p.153 & Dr Volprecht T-01-11-12 p.17

¹²² 310-003-002

¹²³ 090-031-099

¹²⁴ 090-031-099

¹²⁵ 090-038-134

- 3.37 The other blood test result of note was the white cell count ('WCC') which was high at 16.5 (normal range 4 - 11).¹²⁶
- 3.38 Whilst Dr Volprecht did not enter the Urea &Electrolyte ('U&E') results into Claire's records, she did add the downward pointing arrow beside the "132" and the upward pointing arrow beside the "16.5" WCC, to indicate that the readings were outside the expected range.¹²⁷ The balance of the evidence was that this should have acted as a reminder the next morning to re-test to see if Claire's sodium had fallen further.¹²⁸ Indeed, Dr Volprecht assumed that a repeat U&E test would be undertaken in the morning.¹²⁹

Fluid management on 21st October 1996

- 3.39 On admission, Dr O'Hare had directed IV fluid management and suggested that any seizure activity be treated with intravenous diazepam. She also indicated the necessity to review after administration of fluids.¹³⁰
- 3.40 Claire's 'Nursing Care Plan' allowed for the administration of *'IV fluids as prescribed by doctor, according to hospital policy.'*¹³¹ Dr Volprecht seemingly made the IV Fluid Prescription for 500ml of Solution No. 18 at 64ml/h.¹³² It was at this rate that Solution No. 18 would continue to be infused until Claire was eventually transferred to the Paediatric Intensive Care Unit ('PICU').¹³³
- 3.41 Dr O'Hare considered that the prescription was correct for Claire's maintenance fluid requirements and was for a fluid in standard use in paediatrics in 1996.¹³⁴ Moreover, she indicated that it was not then conventional practice to restrict fluids in a child who was vomiting *"unless*

¹²⁶ 090-032-108 & 090-022-052

¹²⁷ 090-022-052 & Dr Volprecht T-01-11-12 p.17 line 17

¹²⁸ Dr Volprecht T-01-11-12 p.24 line 5

¹²⁹ Dr Volprecht T-01-11-12 p.19 line 1

¹³⁰ 090-022-052

¹³¹ 090-043-146

¹³² 090-038-134 equivalent to 65ml/kg /24h

¹³³ 090-022-060

¹³⁴ WS-135-1 p.11

*the electrolytes indicated that they were significantly hyponatraemic.*¹³⁵ Dr Steen agreed and described Claire’s fluid regime as “normal.”¹³⁶

Care and treatment overnight and into the morning of 22nd October 1996

‘Nursing Care Plan’

3.42 Claire’s ‘Nursing Care Plan’ was devised by Staff Nurse McRandal on admission and was subject to daily review.¹³⁷ It indicated the necessity to “*ensure safe administration of IV fluids*”¹³⁸ and noted the potential for further vomiting and seizures.¹³⁹ Observations were planned for every four hours to include temperature, pulse and respiration.¹⁴⁰

3.43 Otherwise planned “*Nursing Actions*” included,

- (i) Administering medicine as prescribed and observing effects.
- (ii) Recording an accurate fluid balance chart.
- (iii) Reporting abnormalities to doctor/nurse in charge.¹⁴¹
- (iv) Informing doctor of seizures.

3.44 The Inquiry nursing expert, Ms Sally Ramsay, was mildly critical of the planned frequency for vital sign observations¹⁴² but was otherwise generally positive about the plan for nursing care. In particular, she thought that the nursing actions were “*comprehensive*”,¹⁴³ were prepared “*in a timely manner*” and reflected the problems likely to be associated with a child who may have had seizures and had vomited.

¹³⁵ WS-135-1 p.12

¹³⁶ 091-011-067

¹³⁷ 090-043-145

¹³⁸ 090-043-146

¹³⁹ 090-043-146

¹⁴⁰ 090-044-147

¹⁴¹ 090-043-145

¹⁴² 231-002-023

¹⁴³ 231-002-019

Fluid balance measurement

- 3.45 Ms Ramsay considered that recording the urinary output of children receiving IV fluids is a nursing responsibility¹⁴⁴ and should have been done.¹⁴⁵ She noted that whilst nurses did make accurate entries of fluid intake¹⁴⁶ they failed to measure the output. They recorded it only as “PU” (‘passed urine’)¹⁴⁷ giving no indication of the volume of urine actually passed. In Ms Ramsay’s opinion this was “*not an accurate measurement of output*”¹⁴⁸ and indicated furthermore that “*urine output could easily have been measured by weighing nappies before and after use.*”¹⁴⁹
- 3.46 Additionally, she believed that in the case of a child with altered consciousness, the nurses should have been aware of the possibility of dehydration or fluid overload¹⁵⁰ and consequently of the importance of making an accurate fluid balance chart. However, as Ms Ramsay acknowledged, such failure was in keeping with custom and practice at that time.¹⁵¹ Indeed, and as Staff Nurse McRandal pointed out, had medical staff required a more accurate measurement of urinary output, they could have asked for it, as they sometimes did, but they did not.¹⁵²
- 3.47 The overnight nursing records indicate that between 22:30 on Monday and 07:00 on Tuesday, Claire suffered one medium and five small vomits.¹⁵³ These were recorded as bile stained¹⁵⁴ in contrast to her vomits at home, which had been described as non-bilious.¹⁵⁵ Ms Ramsay indicated that the volume of vomit was appropriately recorded, but considered that it would have been better had the colour of vomit been noted as well.¹⁵⁶

¹⁴⁴ 231-002-029
¹⁴⁵ 231-002-029
¹⁴⁶ 231-002-028
¹⁴⁷ 090-038-135
¹⁴⁸ 231-002-028
¹⁴⁹ 231-002-029
¹⁵⁰ 231-002-029
¹⁵¹ 231-002-028
¹⁵² WS-145-1 p.10
¹⁵³ 090-038-133
¹⁵⁴ 090-040-140
¹⁵⁵ 090-012-014
¹⁵⁶ 231-002-028

Care and treatment on the morning of 22nd October 1996

Nursing handover

- 3.48 Staff Nurse McRandal recorded at 07:00 the next morning 22nd October that Claire “*Slept well. Much more alert and brighter this morning*”.¹⁵⁷ She then handed care over to Staff Nurse Sara Jordan (née Field)¹⁵⁸ at about 07:45.¹⁵⁹ She told her that Claire had been admitted with suspected seizure activity and for the management of vomiting. She indicated Claire’s history of learning difficulties and previous seizure activity.¹⁶⁰ Whilst Staff Nurse Jordan could not recall any reference to a diagnosis of viral illness or encephalitis,¹⁶¹ she was given a sound ‘Nursing Care Plan’, Staff Nurse McRandal’s 07:00 entry and a verbal handover. That represented appropriate nursing teamwork.

Medical handover

- 3.49 Dr O’Hare had started work on Monday at 09:00 as the on-call registrar in Musgrave Ward.¹⁶² Later at 17:00, she assumed responsibility for all 120 hospital beds and A&E. It was thus that she came to see Claire in both A&E and on Allen Ward. During her night shift, she had the support of nursing staff, one SHO in A&E and one SHO on the wards. At 09:00 on Tuesday, instead of going home after 24 hours on duty, she started a further day shift. Accordingly, and in order to correctly perform all her formal handovers on the Tuesday morning, she would have had to visit a number of wards speaking to all those coming on duty, at a time when she herself was expected to start her next shift on Musgrave Ward.¹⁶³
- 3.50 Dr O’Hare’s ability to effect handovers was therefore compromised by unsatisfactory staffing levels. However, she indicated that she would have

¹⁵⁷ 090-040-140
¹⁵⁸ 310-003-005
¹⁵⁹ WS-148-1 p.6
¹⁶⁰ WS-148-1 p.6
¹⁶¹ WS-148-1 p.6
¹⁶² WS-135-1 p.2
¹⁶³ WS-135-2 p.5

made an informal handover had she been concerned about a patient.¹⁶⁴ Her fellow Paediatric Registrars, Dr Andrew Sands¹⁶⁵ and Dr Brigitte Bartholome,¹⁶⁶ both agreed that informal handovers were often conducted.¹⁶⁷

- 3.51 It seems to me that making even an informal handover would have been difficult, given Dr O'Hare's responsibilities from 09:00 on Tuesday. Her evidence was that, had she handed over to a doctor on Allen Ward, she would have indicated that she was unsure about Claire's condition and suggested a review at ward round.¹⁶⁸ I think it unlikely that she was able to conduct a handover. In any event, Dr Sands, the registrar who came on duty on Tuesday morning, gave evidence that when a ward round came to a new patient such as Claire, doctors would take a fresh history, investigate, examine and draw up their own management plan.¹⁶⁹ This seems close to the sort of review, which would have been urged on them in any event by Dr O'Hare, and one which would necessarily have entailed review of the blood test results.
- 3.52 The lack of clear procedure for handovers between doctors was a weakness in the clinical care provided. There would appear to have been too little focus on this critically important aspect of care. Despite the pressures of work, none of the clinicians engaged in Claire's case took responsibility to ensure that effective handover procedures were followed or that communication between doctors was better ordered.

Dr Steen's involvement in Claire's case

- 3.53 Dr Heather Steen remained the named Consultant Paediatrician responsible for Claire's care from the time of her admission on Monday evening to the time of transfer to PICU on Wednesday.¹⁷⁰ She did not

¹⁶⁴ Dr O'Hare T-18-10-12 p.175 line 21

¹⁶⁵ 310-003-002

¹⁶⁶ 310-003-003

¹⁶⁷ WS-137-1 p.33

¹⁶⁸ Dr O'Hare T-18-10-12 p.178 line 18-21

¹⁶⁹ Dr Sands T-19-10-12 p.48 line 20

¹⁷⁰ WS-143-1 p.3

attend upon Claire during that period. It is to be noted that Dr Steen may have been disadvantaged in giving her evidence by reason of ill health.

- 3.54 Normally, but not invariably, ward rounds were led by consultants but this did not happen in Claire's case. Her round was led by Dr Sands¹⁷¹ who was a paediatric registrar of limited experience having been appointed less than three months before after some four months as a locum registrar in paediatric cardiology.¹⁷² However, his evidence was that it was not unusual for him to lead a ward round in 1996 given the commitments of Dr Steen and others.¹⁷³
- 3.55 I have already indicated that Dr O'Hare was justified in not contacting Dr Steen on Monday night, but how was it that Dr Steen did not see Claire on the Tuesday? This was extensively considered.
- 3.56 Dr Steen's duties at that time involved taking a clinic outside the Children's Hospital at Cupar Street.¹⁷⁴ This was off-site, but not far from the hospital. Her clinic started at 13:00. Dr Steen's evidence was that before that, she would have been in the hospital and available to her patients, junior doctors and nurses, whether in person, by bleeper or telephone. She would thereafter have made contact with Allen Ward at approximately 17:30 when her clinic finished in order to discuss issues of concern and to decide whether she needed to return.¹⁷⁵
- 3.57 Dr Sands did not recall where Dr Steen was on the Tuesday. He stated that whilst he did not believe her to have been in the hospital, he thought she was nonetheless contactable by telephone.¹⁷⁶ There was some limited evidence to suggest that Dr Steen may have seen another patient on Allen Ward and in the same room as Claire in the morning¹⁷⁷ and some evidence to suggest that she was involved in the morning discharge of another

¹⁷¹ 090-022-052

¹⁷² WS-137-1 p.4

¹⁷³ Dr Sands T-19-10-12 p.57

¹⁷⁴ WS-143-1 p.3

¹⁷⁵ Dr Steen T-15-10-12 p.93

¹⁷⁶ WS-137-1 p.20 & p.42

¹⁷⁷ Dr Steen T-16-10-12 p.49-50

patient because she had noted a change in medication.¹⁷⁸ However, there is no record in Claire's medical or nursing notes of any contact with Dr Steen nor any discussion between her and any other member of the medical or nursing team before Claire's collapse on 23rd October.

3.58 Claire was however seen before midday by Dr Sands on his ward round, and having seen her, Dr Sands brought her case to the attention of Dr David Webb,¹⁷⁹ Consultant Paediatric Neurologist. If Dr Steen had been available, I believe that Dr Sands would have spoken to her as a matter of course and urgency. The fact that he did not leads me to conclude that, for whatever reason, Dr Steen was not available to Dr Sands. I do not know why that was and nor seemingly, does anyone else. On the totality of the evidence presented, I cannot say where Dr Steen was or what she was doing on the Tuesday morning.

3.59 Thus, whilst it is reasonable that Claire should not have been seen by Dr Steen on the evening of Monday 21st, it is a matter of significance and concern that she was not seen by her on Tuesday 22nd.

Ward round on morning of 22nd October 1996

3.60 Dr Sands was accompanied on his ward round by two SHOs, Dr Neil Stewart¹⁸⁰ and Dr Roger Stevenson.¹⁸¹ Staff Nurse Kate Linskey¹⁸² was also in attendance.¹⁸³ The round was running late, perhaps because, as Dr Sands suggested, he was slower than an experienced consultant.¹⁸⁴

3.61 Claire's parents arrived at approximately 09:30.¹⁸⁵ Although Staff Nurse McRandal's assessment at 07:00 was reasonably positive, Mr and Mrs Roberts were worried by Claire's appearance.¹⁸⁶ They found her lethargic

¹⁷⁸ Dr Steen T-16-10-12 p.49

¹⁷⁹ 310-003-002

¹⁸⁰ 310-003-003 & WS-141-2 p.2

¹⁸¹ 310-003-003 & WS-139-1 p.10

¹⁸² 310-003-006

¹⁸³ WS-148-1 p.11

¹⁸⁴ Dr Sands T-19-10-12 p.70 lines 4-10

¹⁸⁵ WS-253-1 p.6

¹⁸⁶ WS-253-1 p.6

and vacant¹⁸⁷ and did not think her anything like her usual self. The improvement they had hoped for was not apparent. They expressed their concern to Staff Nurse Jordan who brought it to the attention of Staff Nurse Linskey.¹⁸⁸

3.62 There are differing accounts of the events which then unfolded. Given the passage of time, that is not surprising. On many points, variance in the evidence is not important, but as will appear, there are areas where the differences are of significance.

3.63 The ward round note made by Dr Stevenson (and added to by Dr Sands) is as follows:

“W/R Dr Sands

Admitted ? Viral illness.

Usually very active, has not spoken to parents as per mother.

Wretching. No vomiting.

Vagueness /vacant (apparent to parents).

No seizure activity observed.

Attends Dr Gaston (UHD).

6 mths old seizures and Ix for this – NAD

U+E- Na+ 132. FBC- WCC ↑ 16.4 Gluc 6.6

O/E Aprexic on IV fluids

Pale colour. Little response compared to normal.

CNS Pupils sluggish to light.

Difficult to see fundi.

Bilat long tract signs.

Ears. Throat. Difficult to swallow. Full see.

¹⁸⁷ WS-148-1 p.10

¹⁸⁸ WS-148-1 p.17

*Imp Non fitting status/ [encephalitis/ encephalopathy]*¹⁸⁹

Plan Rectal Diazepam.

Dr Webb.

*D/W Dr Gaston re PmHx.*¹⁹⁰

- 3.64 Dr Sands' impression was that Claire was suffering from "*non-fitting status*"¹⁹¹ and the nursing record of the ward round notes "*Status epilepticus – non-fitting.*"¹⁹²

Discussions between Dr Sands and Claire's parents

- 3.65 Mr and Mrs Roberts do not think that the doctors spent very long with Claire, perhaps only ten minutes.¹⁹³ They were unable to specifically recall Dr Sands, but do remember introductions being made by the doctors, a history being taken (with which they take no issue) and an examination of Claire which was "*fairly quick.*"¹⁹⁴ They expressed concern to Dr Sands that Claire was unresponsive and not 'herself'.¹⁹⁵ They remember being told about some sort of internal fitting and that another doctor would be consulted.¹⁹⁶ They could not recall any discussion about blood samples and were given no sense that the situation was serious. On the contrary, their perception was that Claire had a 24/48 hour stomach bug.¹⁹⁷
- 3.66 Dr Sands however maintains that the possibility of an infection in the brain or encephalitis was discussed on the ward round and was likely to have been discussed with the parents.¹⁹⁸ Mr and Mrs Roberts do not believe that encephalitis was mentioned because the term sounded so serious to them and would have caused them such concern that they would remember.¹⁹⁹

¹⁸⁹ Words within square brackets were added to the record later. Please see section entitled "*Encephalitis/encephalopathy*" note" at page 31

¹⁹⁰ 090-022-052 to 053

¹⁹¹ 090-022-053 - continuous epileptic activity in the brain without clinical effect - see glossary.

¹⁹² 090-040-140

¹⁹³ WS-253-1 p.6 & WS-257-1 p.7

¹⁹⁴ Mr and Mrs Roberts T-31-10-12 p.43

¹⁹⁵ 091-004-006

¹⁹⁶ WS-253-2 p.2

¹⁹⁷ WS-253-1 p.8

¹⁹⁸ Dr Sands T-19-10-12 p.116

¹⁹⁹ Mr and Mrs Roberts T-31-10-12 p.48

Alternatively, Dr Sands suggested that not all discussions between doctors would necessarily have been within range of the family, perhaps deliberately, so as not to cause alarm.²⁰⁰

- 3.67 Dr Sands recalled his examination of Claire and remembered Mr and Mrs Roberts telling him that there had been no improvement since the previous night. He said that in fact he was concerned that he had not been alerted earlier to her condition because he too considered that she was unwell.²⁰¹ He believes that he spent upwards of 20 minutes with her²⁰² and agreed with Mrs Roberts that something was “*significantly wrong*.”²⁰³ Indeed, he thought it necessary to consult the Consultant Paediatric Neurologist, Dr David Webb and did so immediately. In such circumstances, Dr Sands does not appear to have adequately communicated his level of concern to Mr and Mrs Roberts.

Electrolyte testing

- 3.68 Dr Sands gave evidence about the timing of Claire’s blood test and the results. He said that he was aware that both the test and the results related to the night before²⁰⁴ and properly accepted that he should have repeated the blood tests on the morning of 22nd October.²⁰⁵ Further, and with the benefit of hindsight, he said it would have been appropriate at the time of the ward round to reconsider Claire’s fluid regime.²⁰⁶ He wondered whether there might not have been a separate ‘to do’ list which included further blood tests²⁰⁷ but I am not persuaded that there was and Dr Stevenson, who wrote the note, says there was not.²⁰⁸ Dr Sands was only one of a number of clinicians given the opportunity on 22nd October to repeat the U&E tests. Failure to do so was both individual and collective.

²⁰⁰ Dr Sands T-19-10-12 p.112

²⁰¹ Dr Sands T-19-10-12 p.92

²⁰² Dr Sands T-19-10-12 p.93

²⁰³ Dr Sands T-19-10-12 p.95

²⁰⁴ Dr Sands T-19-10-12 p.98

²⁰⁵ Dr Sands T-19-10-12 p.112

²⁰⁶ Dr Sands T-19-10-12 p.102

²⁰⁷ Dr Sands T-19-10-12 p.108

²⁰⁸ Dr Stevenson T-15-10-12 p.170

Diagnosis at ward round

- 3.69 Dr Sands said that his ward round impression of “*non-fitting status*”²⁰⁹ was informed by Dr Savage’s referral note, Mrs Roberts’ description of a history of seizures and Dr O’Hare’s direction to administer diazepam in the event of seizures.²¹⁰ That is understandable but seems to respond to only one of the previously suggested explanations for Claire’s presentation. However, Dr Sands’ said that a viral infection, specifically encephalitis, was considered and most probably discussed during the ward round although this may not be reflected in Dr Stevenson’s note.²¹¹
- 3.70 Dr Stevenson was unable to assist. He had no recall of the events of 22nd October or of Claire or her parents.²¹² He had a limited role on the ward round and had only been a SHO in paediatrics for two months.²¹³ Dr Stewart was however quite sure that not only was status epilepticus discussed²¹⁴ but encephalitis was also advanced at that time as a working diagnosis.²¹⁵

Actions taken after the ward round

- 3.71 The plan at ward round was to administer rectal diazepam, consult Dr Webb and discuss Claire’s previous medical history with Dr Colin Gaston. Dr Sands gave direction for hourly neurological observations to commence at 13:00²¹⁶ and then went to find Dr Webb. Critically it is to be noted that at that stage, the blood tests were not repeated, the fluid regime was left unchanged and there was no further investigation by CT scan or Electroencephalography (‘EEG’). Whilst the doctors did not know what was wrong with Claire, they agree that she was a cause for increasing concern.

²⁰⁹ 090-022-052-053

²¹⁰ Dr Sands T-19-10-12 p.112-113

²¹¹ Dr Sands T-19-10-12 p.116

²¹² Dr Stevenson T-15-10-12 p.130

²¹³ WS-139-1 p.2

²¹⁴ Dr Stewart T-06-11-12 p.15

²¹⁵ Dr Stewart T-06-11-12 p.19

²¹⁶ 090-039-137

Her condition had not improved since Monday evening, her parents were worried and now so too it would appear was Dr Sands.

3.72 Dr Sands said that he was concerned by her level of consciousness indicating that whilst not totally unresponsive²¹⁷ she was certainly not “*bright*.”²¹⁸ He confirmed that even though he did not know how ill she was, he felt that she was more than just a patient of concern.²¹⁹ He hoped and expected that Dr Webb would see her sooner rather than later.²²⁰ In fact, he went so far as to say that had he known that her parents intended to leave at lunchtime he would have advised them not to²²¹ because she was “*very unwell*.”²²²

3.73 I find it difficult to reconcile this evidence with Dr Sands’ failure to warn Mr and Mrs Roberts about how ill Claire was and his subsequent departure from the hospital at 17:00 without alerting them to his concerns. Dr Sands should have ensured that Mr and Mrs Roberts were properly informed as to Claire’s condition.

Decision to seek neurological opinion

3.74 Dr Sands explained that “*what I saw was outside my experience and I then contacted Dr Webb*”.²²³ There is some uncertainty about when they spoke. Dr Sands believed it was about midday²²⁴ because he had wanted to ask Dr Webb²²⁵ about the diazepam and he noted that this was not administered until 12:15.²²⁶ Alternatively, he speculated that he may have spoken initially to Dr Webb to get his approval for the diazepam and then spoken to him again later and in more detail.²²⁷

²¹⁷ Dr Sands T-19-10-12 p.137

²¹⁸ Dr Sands T-19-10-12 p.138

²¹⁹ Dr Sands T-19-10-12 p.132

²²⁰ Dr Sands T-19-10-12 p.35

²²¹ Dr Sands T-19-10-12 p.138

²²² 091-009-056

²²³ 091-009-059

²²⁴ Dr Sands T-19-10-12 p.33

²²⁵ Dr Sands T-19-10-12 p.34

²²⁶ 090-026-075 & 090-040-141

²²⁷ Dr Sands T-19-10-12 p.33-34

- 3.75 Dr Webb believed that, in all probability, he did not speak to Dr Sands until after he had given a pre-arranged talk between 12:45 and 13:30.²²⁸ Then, having spoken to him and with the understanding that there was a real problem, he went quickly to Claire and saw her around 14:00. I am unable to resolve this uncertainty but the point is that they did speak and Dr Webb became involved in Claire's care.
- 3.76 There is no record of their discussion. Dr Webb's thinks he was asked to advise on the possibility of non-convulsive seizures associated with a fluctuating level of consciousness against a background of seizures in infancy and a learning disability.²²⁹ He believes that he was told about both the sodium reading of 132 Mmol/L and the high white cell count but understood that these were results from that same morning rather than the night before.²³⁰ He was asked about medication and getting a CT scan. He believes that the differential diagnoses occurring to him at that time included the possibility of epilepsy, encephalopathy and encephalitis.²³¹
- 3.77 Dr Sands did not seemingly remember the discussion beyond the fact that it happened and may have been repeated and that they discussed why a CT scan might help.²³² He also said that whilst he suggested encephalitis, it would have been Dr Webb who proposed encephalopathy because he did not himself understand the condition.²³³ He could not actually recall being present when Dr Webb attended with Claire.
- 3.78 Dr Webb regarded his role as confined to assessment and the formulation of diagnosis and management plan for the assistance of the paediatric medical team.²³⁴ Dr Webb said that Dr Sands did not request that he take over Claire's case.

²²⁸ Dr Webb T-30-11-12 p.169

²²⁹ Dr Webb T-30-11-12 p.172

²³⁰ Dr Webb T-30-11-12 p.175-176

²³¹ Dr Webb T-30-11-12 p.173

²³² Dr Sands T-19-10-12 p.34

²³³ Dr Sands T-19-10-12 p.167-168;

²³⁴ WS-138-1 p.4

- 3.79 Dr Sands said that although he sought guidance from Dr Webb, he did not attempt to specify the role Dr Webb was to have in Claire's care, because that was something more usually discussed between consultants.²³⁵ He could recall no further communication with Dr Webb after their initial discussion.²³⁶ Nonetheless, he stated that Dr Webb's assessment of Claire may have lessened some of his own concerns²³⁷ because he would then have expected Dr Webb to direct the further investigations and provide further information to Claire's parents.²³⁸
- 3.80 At that time, and as and between Dr Sands and Dr Webb, a decision should have been taken to investigate further. That would probably have meant a CT scan to diagnose haemorrhage, hydrocephalus or cerebral oedema, or in the event of that proving inconclusive, an MRI scan. Professor Neville advised that an EEG was the only way to confirm non-convulsive status epilepticus.²³⁹ Until such tests were done, doctors were treating a "very *unwell*" child without really knowing what was wrong or doing anything to confirm a diagnosis. In addition and critically, active fluid and electrolyte management was being ignored.

"Encephalitis/encephalopathy" note

- 3.81 Mr and Mrs Roberts have since expressed concern about changes made to the ward round notes. The words "*encephalitis/encephalopathy*" have been added at a later time and in a different hand so as to augment Dr Sands' noted impression of "*non-fitting status*."²⁴⁰ Dr Sands indicated that he added this to the notes after he had spoken to Dr Webb.²⁴¹ Regrettably, he did not date or sign the addition.
- 3.82 Claire's parents became increasingly suspicious about this evidence and questioned whether the words might not have been added as late as

²³⁵ WS-137-1 p.17

²³⁶ WS-137-1 p.39

²³⁷ WS-137-1 p.51

²³⁸ WS-137-2 p.8

²³⁹ 232-002-002

²⁴⁰ 090-022-053. Please see paragraph 3.69

²⁴¹ WS-137-1 p.10

2004/05 so as to place Dr Sands and the hospital in a better light.²⁴² This suggestion was strongly denied by Dr Sands.²⁴³ One of the points made by Mr and Mrs Roberts was that Claire did not receive any treatment for encephalitis or encephalopathy until Dr Webb prescribed acyclovir at around 17:00 and accordingly to use these words at any earlier stage would be inconsistent with the logic of the record.²⁴⁴

3.83 The Inquiry engaged Dr Audrey Giles, a highly experienced forensic document analyst to examine this and other entries made by Dr Sands in order to determine when this controversial addition was made. Her findings were essentially inconclusive. She stated that *“I am unable to determine when the questioned entry “encephalitis/encephalopathy” in the Medical Notes was made by Dr Sands, or the entry “4pm” was made by Dr Webb, either in absolute terms or in relation to other entries made by him on these documents.”*²⁴⁵

3.84 I understand why Claire’s parents should question all that is said by the doctors who treated Claire. However, I do not accept this specific allegation against Dr Sands on the evidence before me. It is plausible that the additional words do indicate the differential diagnosis as suggested by Drs Sands, Stewart and Webb²⁴⁶ and that Claire did not receive the relevant treatment at the time because it was hoped that she would respond to another regime. I do not accept it proved that the disputed entry was made dishonestly or to mislead. It was, however, a yet further example of substandard record keeping.

²⁴² Mr and Mrs Roberts T-13-12-12 p.128

²⁴³ Dr Sands T-18-12-12 p.130

²⁴⁴ Mr and Mrs Roberts T-13-12-12 p.120

²⁴⁵ 241-001-008

²⁴⁶ Dr Sands T-19-10-12 p.168-9, Dr Stewart T-06-11-12 p.31-32 & WS-138-1 p.6

Care and treatment during the afternoon of 22nd October 1996

Dr Webb's attendance with Claire at 14:00

3.85 Dr Webb saw Claire at about 14:00.²⁴⁷ Her grandparents were with her at the time.²⁴⁸ Dr Webb may have been accompanied by Dr Stevenson and a nurse. It is unfortunate that Dr Sands does not appear to have attended but he was engaged elsewhere.²⁴⁹

3.86 The entry made by Dr Webb in the record was:

"Neurology – Thank you.

•9 yr old girl with known learning difficulties – parents not available. Grandmothers Hx - vomiting + listless yesterday pm – followed by prolonged period of poor responsiveness. On no AED.

•Note appeared to improve following rectal diazepam 5mg at 12.30pm.

O/E Afebrile. No meningism. Pale.

Rousable – eye opening to voice, Non-verbal, withdraws from painful stimuli. Reduced movements rt side? Antigravity all 4 limbs. Mildly increased tone both arms. Reflexes symmetrically brisk. Clonus – sustained both ankles. Toes ↑↑. Sits up – eyes open + looks vacantly. Not obeying commands. PEARL – 5mm. Optic discs pale. No papilloedema. Facial palatal + lingual movements appear (N).

Imp - I don't have a clear picture of prodrome + yesterday's episodes. Her motor findings today are probably long standing but this needs to be checked with notes. The picture is of acute encephalopathy most probably restricted in nature. I note (N) biochemistry profile.

Suggest

i) starting iv phenytoin 18mg/kg stat followed by 2.5mg/kg 12hrly. Will need levels 6hrs after loading dose

²⁴⁷ 090-040-141 & WS-138-1 p.5

²⁴⁸ Mr and Mrs Roberts T-31-10-12 p.59

²⁴⁹ Dr Sands T-19-10-12 p.26

ii) Hrly neurobs

iii) CT tomorrow if she doesn't wake up. D. Webb."²⁵⁰

- 3.87 Dr Webb maintained that the most likely explanation for Claire's presentation was a recurrence of seizures within a context of inter-current viral illness.²⁵¹ He agreed with Dr Sands that she was probably suffering semi-continuous non-convulsive seizures, which were contributing to her altered level of consciousness. It was these he attempted to treat.²⁵²
- 3.88 Dr Webb acknowledged his error in thinking that Claire's serum sodium result of 132mmol/L was from a test undertaken that morning rather than the previous evening. Indeed, he admits that had he understood that the results were from the previous evening, he "*would have requested an urgent repeat sample*"²⁵³ because Claire was receiving IV fluids and he could not therefore be confident that the sodium level was not relevant to her presentation.²⁵⁴
- 3.89 Dr Webb's confusion about the timing of the blood tests is a matter of significance and concern. Whilst the results were untimed in the medical record (and that is a notable deficiency), the very fact that they were the only results for a patient admitted the previous day should have caused him to double check the timings. Furthermore, the presence of the downward pointing arrow beside the sodium reading should have attracted his particular attention. In the circumstances he should have interrogated the notes for the time of the blood test.

EEG & CT Scan

- 3.90 Professor Neville, being of the view that an EEG was the only means to confirm non-convulsive status epilepticus,²⁵⁵ stated quite simply that Claire should not have been treated for status epilepticus without an EEG because

²⁵⁰ 090-022-054

²⁵¹ WS-138-1 p.10-11

²⁵² WS-138-1 p.10-11

²⁵³ 090-053-174

²⁵⁴ WS-138-1 p.21-22, p.69-70 & p.88

²⁵⁵ 232-002-002

anti-epilepsy medication can further reduce levels of consciousness.²⁵⁶ However, there was no EEG. Dr Webb said that he had intended an EEG for the following day should Claire still have been a cause for concern.²⁵⁷

- 3.91 In addition, Professor Neville was of the opinion that an urgent CT scan was indicated because Claire was suffering from unexplained reduced consciousness and a scan could confirm or exclude cerebral oedema or haemorrhage. He said it should have been carried out on the evening of 21st October,²⁵⁸ or at the latest, on the morning of 22nd October.²⁵⁹ In his view, the failure to do so was a “*major omission*.”²⁶⁰
- 3.92 Dr Webb did not think that either CT scan or EEG would have been of much assistance.²⁶¹ He thought the most likely diagnosis was non-fitting status and whilst that could have been confirmed by an EEG, resources were stretched.²⁶² He believed that had he insisted on an EEG that afternoon, it could have been arranged but at the cost of the operator working extra hours. Accordingly, he decided to wait until the following morning, taking the view that Claire was probably experiencing seizures because of a viral illness. He accepted that his suggestion “*CT tomorrow if she doesn’t wake up*”²⁶³ was poorly phrased but was really meant to indicate that she should have a CT scan if she did not improve.²⁶⁴
- 3.93 Is it fair to criticise Dr Webb for not directing an EEG or CT scan that afternoon? With hindsight, it is obvious that they were more urgently indicated than he thought and that they could have been arranged, however awkward that may have been. It is also acknowledged that Professor Neville, who was particularly critical in this regard,²⁶⁵ is rather more familiar with larger hospitals and their superior access to testing facilities. However,

²⁵⁶ 232-002-006

²⁵⁷ WS-138-1 p.67

²⁵⁸ 232-002-004

²⁵⁹ 232-002-007

²⁶⁰ 232-002-006

²⁶¹ Dr Webb T-30-11-12 p.225

²⁶² Dr Webb T-30-11-12 p.208

²⁶³ 090-022-054

²⁶⁴ Dr Webb T-30-11-12 p.216

²⁶⁵ 232-002-008

it was repeatedly asserted in evidence that while children can recover very quickly from illness, they can also deteriorate very rapidly. Claire was clearly very unwell and at best, Dr Webb had an insecure primary diagnosis of non-fitting status. Accordingly, I believe that he should have done more. He started Claire on anti-convulsant medication with hourly neurological observations at a time when he could and should have reviewed her fluid and electrolyte management and pursued additional investigation.

Phenytoin

- 3.94 Phenytoin was the anti-convulsant drug which was then prescribed for Claire by Dr Stevenson on Dr Webb's direction. It was administered intravenously from 14:45 onwards²⁶⁶ notwithstanding that there was some suggestion to Dr Webb that Claire might have improved.²⁶⁷
- 3.95 The treatment gave rise to the following specific concerns
- (i) Claire was given an overdose of the phenytoin. Her loading dose was incorrectly calculated by Dr Stevenson at 632mg rather than 432mg.²⁶⁸ His was an error in multiplication. Whilst there is confusion in the medical record about exactly how much phenytoin Claire was given and when, it is clear that an overdose was administered in keeping with Dr Stevenson's miscalculation. Notwithstanding, the expert evidence was that, in all probability, this overdose had no material effect on what was to happen.²⁶⁹
 - (ii) The phenytoin given would have acted in conjunction with diazepam administered at 12:15. Each would have had a sedating effect and together could have further affected her levels of consciousness. This is a matter of importance because her consciousness was

²⁶⁶ 090-026-075

²⁶⁷ Dr Webb T-30-11-12 p.214

²⁶⁸ 090-026-075 & 090-022-054

²⁶⁹ 232-002-009

already a cause for concern and was the subject of hourly Glasgow Coma Scale ('GCS') assessment.²⁷⁰

- (iii) Accordingly, the combined effect of the phenytoin and diazepam would have made it more difficult for doctors to assess the extent to which Claire's neurological impairment was due to her underlying illness. Furthermore, diazepam remains active for a prolonged period with the effects of a single dose persisting for up to two days. Claire's GCS score may thus have been compromised on an ongoing basis.²⁷¹

Seizures on 22nd October 1996

- 3.96 Mr Roberts left the hospital at 15:00 and Mrs Roberts remained with Claire. During the afternoon, Claire's condition deteriorated and she suffered a number of seizures.²⁷² These are noted on the 'Claire Roberts Timeline' in red.²⁷³
- 3.97 There is uncertainty about the precise number and timing of these events. Between 15:10 and approximately 15:25, seizures were noted in the 'Record of Attacks Observed'. Mrs Roberts herself noted one at 15:25.²⁷⁴ She thought it had lasted 5 minutes. Dr Sands does not believe he was present on Allen Ward when this seizure occurred and does not recall being informed.²⁷⁵ At 16:30, a further entry notes "*teeth tightened slightly*."²⁷⁶

Neurological observations during 22nd October 1996

- 3.98 Throughout Tuesday 22nd, the nursing observations relevant to Claire's neurological condition were collated for GCS assessment of her levels of consciousness.²⁷⁷ In a patient with reduced consciousness painful stimulus

²⁷⁰ 237-002-016

²⁷¹ 237-002-008

²⁷² 090-042-144

²⁷³ 310-001-001

²⁷⁴ 090-042-144

²⁷⁵ WS-137-1 p.49

²⁷⁶ 090-042-144

²⁷⁷ 310-007-003

is applied and the best visual, verbal and motor responses assessed and scored out of 15.²⁷⁸ The scale is modified for use in the very young by omitting one of the scores to give a total GCS score out of 14.²⁷⁹

3.99 Claire's GCS scores were recorded on an observation chart²⁸⁰ starting with a score of 9 at 13:00 and continuing at either a 6 or 7 for the next few hours. Whilst there is a subjective element to these scores, it remains clear that the lower they are the more worried a clinician should be. A score of 8 or less is consistent with the onset of coma.²⁸¹ Generalised entries in the record at that time appear to confirm Claire's loss of consciousness. Some entries are very telling, for example the clear contrast appearing between the record of "*Eyes open to pain*" at 14:30 and the subsequent failure of all further attempts to repeat this response.²⁸² In Professor Neville's view, any score between 9 and 12 required investigation and all below 9 demanded urgent intervention.²⁸³ He also stated that any drop in the GCS score (as for example that occurring at 21:00) should have prompted the SHO to contact the registrar or consultant.²⁸⁴

3.100 Ms Sally Ramsay considered that a GCS score of 8 in combination with complex IV therapy should have prompted discussion between nursing and medical staff about admission to PICU.²⁸⁵ However, the nursing notes do not suggest that these neurological observations were brought to the attention of the medical staff. In any event, and as Ms Ramsay pointed out, the charts would have been readily available for the doctors to check²⁸⁶ and because Claire was seen by doctors on at least seven occasions, they ought to have been aware of her vital signs and changed neurological status.²⁸⁷ These were warning signals.

²⁷⁸ 090-053-170 *et seq*

²⁷⁹ 090-053-171

²⁸⁰ 090-039-137

²⁸¹ 090-053-171

²⁸² 090-039-137

²⁸³ 232-002-016

²⁸⁴ 232-002-011

²⁸⁵ 231-002-031

²⁸⁶ 231-002-033

²⁸⁷ 231-002-033

Dr Webb's second attendance with Claire

- 3.101 At about 15:15, two letters from Dr Colin Gaston were faxed to the Children's Hospital in response to queries raised on the ward round. They were seen by Dr Stewart.²⁸⁸ Further information was provided about Claire's medical history with particular reference to her behavioural problems. This does not however appear to have prompted any further discussion or enquiry.
- 3.102 At some point in mid-afternoon, Dr Webb returned to see Claire.²⁸⁹ This demonstrated both his interest and concern, even if he did not record his attendance. He believes that he would have reviewed the nursing observations and GCS scores.²⁹⁰ Whilst he knew she was ill, he did not then consider that a transfer to PICU was warranted²⁹¹ but thought that she could be managed on the ward in accordance with his previous treatment plan.

Midazolam

- 3.103 Dr Webb did, however, direct that Claire be given another drug, midazolam. This was again on the basis that she was suffering from non-fitting status in the context of an "*intercurrent viral infection*."²⁹² Remarkably, Claire was then given another overdose, this time of midazolam and once again in error. The initial dose was given at "*0.5mg/kg*"²⁹³ rather than 0.12mg/kg, which was several times the recommended dosage.²⁹⁴
- 3.104 Dr Webb's evidence was that he had first encountered this drug during training in Canada but had not at that time previously prescribed it himself.²⁹⁵ Accordingly, he said he had to check the prescription with his Vancouver notes and then telephone the details to Dr Stevenson so that he

²⁸⁸ 090-013-016 to 019

²⁸⁹ 090-022-055

²⁹⁰ WS-138-1 p.31

²⁹¹ 090-053-175

²⁹² WS-138-1 p.11

²⁹³ 090-022-055

²⁹⁴ WS-138-1 p 32

²⁹⁵ WS-138-3 p.2

could write it up. It transpired however, that Dr Webb had himself directed the same drug be given to another patient and only a few days before.²⁹⁶ His recollection was therefore clearly unreliable.

- 3.105 None of the expert witnesses suggested that this overdose would have been fatal but Dr Aronson, Clinical Pharmacologist, stated without contradiction that such an overdose would increase sedation in a patient with reduced consciousness.²⁹⁷
- 3.106 I cannot determine definitively whether the error in prescription was Dr Webb's or Dr Stevenson's. It is possible that Dr Stevenson misunderstood the instructions given by telephone. However, Dr Webb had the opportunity to note the miscalculation of "0.5"²⁹⁸ in the record, both at 17:00 and again in the early hours of Wednesday morning. He raised no issue about it then or later at the inquest. Dr McFaul was of the opinion that the error should have *"been noted at the review of death in the audit meeting and reported as a major medicines error."*²⁹⁹ It was not raised at all until May 2012 when Mr Roberts drew it to my attention. That it should have been noticed by a layperson is telling.³⁰⁰
- 3.107 There was, however, a more fundamental problem with the administration of midazolam, which is whether it should have been prescribed at all. It was the third drug, after diazepam and phenytoin to be given Claire in the space of three to four hours on the basis that she had non-fitting status. That was the sole condition for which she was being treated despite the suspicion of encephalitis/encephalopathy and the absence of an EEG to confirm the diagnosis.
- 3.108 There was consensus of expert opinion that this approach was highly questionable and undertaken at a time when Dr Webb should have considered other diagnoses.³⁰¹ His assessment of Claire's condition would

²⁹⁶ WS-138-5 p.4

²⁹⁷ 237-002-012 to 014

²⁹⁸ 090-022-055

²⁹⁹ 238-002-180; Under the Management Executive Directive PEL (93)36 - (210-003-1137)

³⁰⁰ 403-005-001

³⁰¹ 232-002-010 & 234-002-009

very clearly have benefited from discussion with Dr Steen and/or Dr Sands but none such took place. That was a failure of all concerned. A joint discussion on 22nd October would have queried why Claire's condition remained so poor despite the treatment administered and that would almost certainly have led to a re-appraisal of diagnosis and a review of treatment.

Dr Webb's examination at 17:00

- 3.109 Dr Webb returned to see Claire for a third time at around 17:00. This was the only time he met Mrs Roberts on the ward. His note records that Claire flexed her left arm in response "*to deep supra orbital pain*" but she did not speak or respond to his voice.³⁰²
- 3.110 Dr Webb discussed Claire's background history with Mrs Roberts recording that Claire had had contact with a cousin on 19th October, that she had gastro-intestinal upset and loose motions on the Sunday (20th) and vomiting on the Monday (21st). Mrs Roberts rejected his note of "*loose motions on Sunday*" maintaining "*Claire had a smelly poo... on Friday...*"³⁰³ and Mr Roberts agreed.³⁰⁴ Dr Webb's note may not be reliable.
- 3.111 However, it was the suspected stomach upset that caused him to think that Claire might have a bowel infection, which had spread to her brain and caused meningo-encephalitis or encephalomyelitis.³⁰⁵ (Otherwise an Enteroviral infection³⁰⁶) Accordingly, he prescribed the anti-biotic cefotaxime and the anti-viral drug acyclovir.³⁰⁷ He directed blood, stool and urine checks and a throat swab for viral culture.³⁰⁸ However and on balance, he did not consider such a diagnosis very likely in the absence of fever, neck stiffness or photophobia.³⁰⁹

³⁰² 090-022-055

³⁰³ WS-257-1, p.10

³⁰⁴ WS-253-1, p.3 & WS-253-1, p.21: "*Claire only had one small loose bowel motion on the Friday, with normal bowel motions on Saturday, Sunday and Monday.*" See also 090-022-050 - Dr O'Hare's admission note made at 20:00 on 21st October 1996 which records a history of "*loose motion three days ago*"

³⁰⁵ 090-053-173 & WS-138-1 p.17

³⁰⁶ 310-007-003 & 090-053-173

³⁰⁷ 090-022-055 & 090-053-173

³⁰⁸ 090-022-055

³⁰⁹ 090-053-173

- 3.112 Notwithstanding, Dr Webb continued with the anti-convulsant medication.³¹⁰ He maintained that he had obtained a history from Mrs Roberts of a seizure affecting Claire's right side which had left him in no doubt that she had had a convulsive seizure on 21st October. It was this history in combination with Claire's ongoing altered awareness at 17:00 within a context of stable vital signs and intermittent mouthing movements that suggested to Dr Webb that she had ongoing sub-clinical seizure activity.³¹¹
- 3.113 He interpreted her GCS and Central Nervous Observations from 14:00 to 17:00 as reflecting a combination of ongoing non-convulsive seizure activity, post-ictal effects and the possible consequences of the anti-convulsant therapy (midazolam).³¹² He did not think her condition was due to raised inter-cranial pressure because his evaluation included an assessment of those features usually expected to be abnormal in the presence of raised intracranial pressure, citing in particular the absence of significant change in heart rate or blood pressure, a cessation of vomiting since his last examination and the fact that her reactive pupils were not enlarged.³¹³ He did not consider Claire's respiratory rates to be a cause for concern. Overall, he felt that her state was similar to that found on examination at 14:00 notwithstanding that her GCS score was potentially depressed by midazolam.³¹⁴ He stated that his diagnosis was predominantly that of an "*epileptic encephalopathy*"³¹⁵ with the impression that Claire was suffering subtle non-convulsive seizure activity triggered by recent inter-current viral infection.³¹⁶
- 3.114 However, and notwithstanding that her sodium levels had not been checked since the previous night, Dr Webb still did not direct a repeat blood test. Dr Sands attended a few minutes later at 17:15 and likewise failed to direct

³¹⁰ WS-138-1 p.42-3

³¹¹ (Dr Webb defined 'status epilepticus' as seizure activity lasting for more than 30 minutes. 090-053-173 & WS-138-1 p.39)

³¹² WS-138-1 p.17 & p.74-75

³¹³ WS-138-1, p.35

³¹⁴ WS-138-1 p.74-75

³¹⁵ WS-138-1 p.17

³¹⁶ 090-053-173

another blood test. He claimed to have been under the impression that a full blood test had been performed and that the results were awaited.³¹⁷ I cannot understand the basis for any such expectation from the entries in the record.

3.115 The experts agree³¹⁸ that more should have been done at 17:15. Indeed Drs Sands and Webb both now recognise this.³¹⁹ Each was then about to go off duty, even though Dr Webb remained the on-call paediatric neurologist. Notwithstanding and whilst the expert views do not entirely concur, I believe that the following should have been done:

- (i) Mr and Mrs Roberts should have been told that Claire was very ill and that diagnosis was unclear.
- (ii) The incoming nursing and medical staff should have been alerted to the seriousness of her condition and the uncertainty of diagnosis.
- (iii) Dr Steen should have been contacted and asked to return to discuss and review.
- (iv) Blood tests should have been carried out.
- (v) Diagnosis should have been reconsidered afresh.
- (vi) Claire's overall treatment should have been reviewed, including her drug regime and fluid management.
- (vii) A paediatric anaesthetist should have been asked to advise on admitting Claire to the PICU.

³¹⁷ WS-137-1 p.29

³¹⁸ 232-002-010 - Professor Neville believed that further assessment was required, including electrolyte testing, EEG, CT scan and drug review; and that any differential diagnosis should include causes of raised intracranial pressure.

234-002-007 - Dr Scott-Jupp considered that Dr Webb should have made it clear whether he had taken over Claire's care completely or was available only for specialist advice and he should have spoken to Dr Bartholome, the on-call Consultant Paediatrician or Dr McKaigue.

³¹⁹ Dr Sands T-19-10-12 p.203 line 21 & Dr Webb T-03-12-12 p.60 line 15

- (viii) An EEG should have been arranged, preferably that day but certainly before the following morning.
- (ix) A clear understanding should have been established as to who was responsible for Claire's care – whether it was the paediatric team or the neurology team.

Responsibility for the failure to take these steps lies overwhelmingly with Dr Webb and Dr Sands.

Discussions between Dr Steen and Dr Sands

- 3.116 Evidence was given by both Dr Steen and Dr Sands that they probably spoke by telephone at some point during the afternoon of 22nd October when Dr Steen was at the Cupar Street Clinic.³²⁰ I have some difficulty with such a proposition because although Dr Sands regarded Claire as the sickest child on the Ward³²¹ he is not thought to have spoken with Dr Webb. So how would his conversation with Dr Steen have gone? One possibility is that Dr Sands informed Dr Steen of Claire's condition and told her that he had obtained assistance from Dr Webb, but they agreed or Dr Steen decided that she did not need to return to see Claire. That does not seem likely in light of the detail he would necessarily have to have given about Claire's condition.
- 3.117 What makes more sense is that if there was a conversation, and I am not at all persuaded that there was, Dr Steen was not alerted to the seriousness of Claire's condition. This may have happened because even though Dr Sands recognised that Claire was "*very unwell*"³²², he was under the impression that he had effectively passed responsibility for Claire to Dr Webb and accordingly felt it was for Dr Webb to determine how to proceed and whether to recall Dr Steen. Meanwhile Dr Webb was unaware of Dr Sands' assumption and remained confident that he had not assumed

³²⁰ Dr Steen T-17-10-12 p.10, Dr Sands T-19-10-12 p.37 & WS-137-1 p.16

³²¹ Dr Sands T-19-10-12 p.233

³²² 091-009-056

responsibility for Claire. This is a more compelling explanation because it fits with both Drs Webb and Sands leaving the hospital between 17:00 and 18:00, Dr Steen staying at Cupar Street, the failure to warn the incoming medical team about the seriousness of Claire's condition, the failure to proceed to EEG or CT scan, the failure to make even preliminary contact with PICU and the extraordinary failure to communicate the gravity of the situation to Mr and Mrs Roberts.

- 3.118 I do not suggest that any one of these doctors was uncaring. Rather, I believe that the real danger of Claire's situation was not recognised, so that despite Dr Webb's repeated intervention, her condition was allowed to deteriorate. The doctors assumed that they could treat her the following day. I do not believe that it occurred to any of them that her life was in danger. Had it, then I am sure that they would all have done something very different. It is for these reasons that I conclude that if there was conversation between Dr Sands and Dr Steen, the reason it did not lead to the return of Dr Steen was that she was not given to understand that Claire was so seriously ill as to require her attendance.

Consultant responsibility

- 3.119 The issue arose as to who was primarily responsible for Claire's care. Clarity as to leadership is important for all concerned in patient care. Was it the paediatric medical team under Dr Steen (even in her absence) or did Dr Webb take over primary responsibility in consequence of his having treated Claire on a number of occasions?
- 3.120 Claire was formally admitted into the care of Consultant Paediatrician Dr Steen. There was no recorded or formal transfer to the neurology team. Dr Webb denied taking over responsibility and there is no evidence that he did. I can only conclude that Claire remained under the care of the paediatric team despite Dr Webb's active and specialist involvement.
- 3.121 Dr Sands may have been uncertain as to who the lead consultant was after Dr Webb had become involved, but such confusion does not appear to have

affected others. This issue was examined in detail at public hearings. Whilst Dr Sands might have made greater efforts to secure the attendance of Dr Steen, it would not appear that any particular nursing or medical failure resulted from confusion as to primary responsibility.

Nursing care during 22nd October 1996

Review of the 'Nursing Care Plan'

- 3.122 The Nursing Care Plan was to have been subject to daily review.³²³ However, it was neither reviewed nor amended after the ward round on the morning of 22nd, nor seemingly at any time thereafter. The 'Nursing Care Plan' does not plan for Claire's deterioration and remained therefore self-evidently unrevised.
- 3.123 Ms Ramsay stated that it was conventional practice to evaluate care on a regular basis. She said this should be done at the end of each shift at the very least and prior to handing over to another nurse.³²⁴ On this analysis, Claire's 'Nursing Care Plan' should have been reviewed at 08:00, 14:00 and 20:00 on 22nd October. Ms Ramsay further stated that the plan ought to have been revised in response to changes in Claire's care needs, such as those prompted by ongoing IV therapy, nursing observations and falling GCS scores.³²⁵
- 3.124 That the 'Nursing Care Plan' was not updated was an oversight in care. It is impossible to determine what difference, if any, regular updates of the 'Nursing Care Plan' might have made. It is however clear that the discipline of making regular written revisions to a plan, might draw attention to necessary nursing action. The nursing staff are to be criticised for failing to adhere to the necessary standards of their own 'Nursing Care Plan'.

³²³ 090-043-145

³²⁴ 231-002-012

³²⁵ 231-002-012

Care and treatment during the evening of 22nd October 1996

- 3.125 There is no evidence that there was any meaningful handover to the incoming nursing or medical teams between 17:00 and 18:00; meaningful in the sense that any single nurse or doctor was actually alerted to the seriousness of Claire's condition. There was a handover to Dr Joanne Hughes who attended to administer drugs,³²⁶ but no indication was given her as to the seriousness of Claire's condition. This further confirms the extraordinary failure to recognise just how sick and at risk Claire was.
- 3.126 Frustratingly, it has not been possible to identify the on-call consultant paediatrician for the night of Tuesday/Wednesday.³²⁷ This is a further and particular failure in the record keeping. The unidentified and unidentifiable consultant should have been the first point of contact for paediatric medical problems. There is no evidence to indicate whether the unknown paediatrician was informed of Claire's illness, or her deteriorating condition or whether there was any attempt to make contact when Claire's condition became critical. If there was a rota of on-call consultant paediatricians, it does not appear to have been used.³²⁸
- 3.127 The role of registrar on duty for Tuesday night was now the almost impossible task of Dr Brigitte Bartholome. She had the assistance of two SHOs, Dr Joanne Hughes and the same Dr Neill Stewart who had accompanied Dr Sands on the morning ward round.
- 3.128 Mr Roberts returned to be with Claire at 18:30. Between 18:30 and 21:15, Claire was reviewed by the nurses on duty but no concern was communicated to the family.³²⁹

³²⁶ 310-003-003

³²⁷ 302-068a-001

³²⁸ 302-068a-001

³²⁹ 089-012-035

Involvement of Dr Joanne Hughes

- 3.129 From 17:00 to 22:00 on Tuesday, 22nd October Dr Joanne Hughes was the sole SHO on the Paediatric medical wards.³³⁰ The only registrar available to her was Dr Bartholome. Dr Hughes was thus responsible for the 40-50 children who were already on the wards together with additional patients admitted through A&E.³³¹ She had at that time one years' experience in paediatrics. She said that she has no recall of the Tuesday night or of her role in Claire's care.³³² Whilst there had been a handover to her at around 17:00, that handover cannot have alerted her to the real seriousness of Claire's condition.
- 3.130 Dr Hughes administered anti-biotics to Claire at 17:15 and anti-viral medication at 21:30.³³³ Significantly, no other doctor saw Claire during that critical period between 17:30 and 23:00 when effective intervention might still have saved her life. That she failed to effectively intervene was not the fault of the then relatively inexperienced Dr Hughes. Opportunities had been missed throughout the day to direct Claire's treatment. It would be unfair to criticise an over-stretched SHO like Dr Hughes for failing to remedy the mistakes of more senior and experienced colleagues.

Further deterioration in Claire's condition and nursing care

- 3.131 Signs were however apparent that not only was Claire failing to respond positively to Dr Webb's drug treatment but she was in fact deteriorating. At 19:15, an entry was made in the 'Record of Attacks Observed' noting that Claire had "*teeth clenched and groaned.*"³³⁴ Dr Webb stated that he was unaware of this attack but would have expected to have been informed.³³⁵

³³⁰ Dr Hughes T-05-11-12 p.109

³³¹ Dr Hughes T-05-11-12 p.110

³³² Dr Hughes T-05-11-12 p.109

³³³ Dr Hughes T-05-11-12 p.151-153 & 090-026-077

³³⁴ 090-042-144

³³⁵ 090-042-144 & WS-138-1 p.43

Indeed the 'Nursing Care Plan' specified that nurses were to inform medical staff of seizures.³³⁶

- 3.132 A further attack was noted at 21:00 as an "*Episode of screaming and drawing up of arms. Pulse rate ↑ 165 bpm. Pupils large but reacting to light. Dr informed.*"³³⁷ However, Dr Hughes could not recall being informed³³⁸ and Dr Webb stated that once again he did not know of the seizure but once again would have expected to be told.³³⁹
- 3.133 Whilst Claire's temperature was noted at 20:30 and 22:30,³⁴⁰ respiratory observations were not recorded at 17:00, 18:00, 19:00, 20:00, 22:00 or 23:00. Ms Ramsay considered that they should have been noted and at least once every 30 minutes during intravenous infusion.³⁴¹ Furthermore, Ms Ramsay regarded the failure to record blood pressure at 22:00, 23:00 and midnight as "*serious omissions*" in the record keeping.³⁴²
- 3.134 Furthermore Ms Ramsay was clear that the nurses were under an ongoing duty to inform doctors about changes in Claire's condition, and in particular:
- (i) The seizure lasting 5 minutes at 15:10.³⁴³
 - (ii) The failure to pass urine for six hours by 17:00.³⁴⁴
 - (iii) The blood pressure reading of 130/70 at 19:00.³⁴⁵
 - (iv) The teeth clenching and groaning incident at 19:15.³⁴⁶

³³⁶ 090-043-145
³³⁷ 090-042-144
³³⁸ WS-140-1 p.28
³³⁹ 090-042-144 & WS-138-1 p.43
³⁴⁰ 090-039-137
³⁴¹ 231-002-026
³⁴² 231-002-02
³⁴³ 231-002-024 & 090-042-144
³⁴⁴ 231-002-030 & 090-038-135
³⁴⁵ 231-002-030 & 090-039-137
³⁴⁶ 231-002-025 & 090-042-144

- (v) The episode of screaming, the GCS score of 6 and the raised pulse rate at 21:00.³⁴⁷ (Whilst the nursing record does indicate, “*Dr informed*”³⁴⁸ this is not confirmed by the medical record).
- 3.135 Additionally Ms Ramsay believed that the episode of screaming at 21:00³⁴⁹ should have been documented. This was, she said, a significant error and represented a further failure in record keeping.³⁵⁰
- 3.136 Even allowing for subjective variation, the GCS numbers that evening were consistently low. They fell further at 21:00 to 6/7. Each GCS assessment presented clear warning. Dr Steen,³⁵¹ Dr Webb,³⁵² and Professor Neville³⁵³ all agreed that Claire’s management should have been discussed with a consultant when the GCS scores dropped at 21:00.
- 3.137 It was wholly improper that with a GCS score as low as 6 that Claire should have been left on the ward without urgent reappraisal. She had already received treatment for 24 hours and was not improving. Even if her levels of consciousness had been depressed by medication, there was no positive indication of progress and urgent action was imperative.
- 3.138 Whilst the nurses did not completely ignore Claire, it cannot be said that they responded to her clinical signs or recognised her danger. Any nurse who was in any doubt about what to do could always have sought advice from the night sister.³⁵⁴ The individual nurses charged with her care are to be criticised for their failure to make necessary observations with appropriate frequency, to respond to Claire’s very low GCS scores or to keep medical staff informed of her condition.

³⁴⁷ 231-002-025, 090-042-144, 090-042-144 & 090-039 to137

³⁴⁸ 090-042-144

³⁴⁹ 096-025-349

³⁵⁰ 231-002-025

³⁵¹ 091-011-068

³⁵² 091-011-068 & WS-138-1 p.86

³⁵³ 232-002-011

³⁵⁴ Ms Linskey T-30-10-12 p.25 line 8

Claire's parents leave for the night

- 3.139 Claire's family had been at her bedside since the morning. They were constantly available for consultation, reassurance or warning. At some time between 21:15 to 22:30 on the Tuesday night, Mr and Mrs Roberts decided to go home and informed the nurses that they were leaving. Neither doctor, nurse nor any other member of staff told Mr and Mrs Roberts that Claire was seriously ill and in danger.³⁵⁵ One of the saddest and most frustrating aspects of all is that they were allowed to leave expecting to find improvement the next morning.
- 3.140 In his witness statement to the Inquiry, Mr Roberts explained that they did not know that Claire had a neurological illness and were unaware of concern about her condition.³⁵⁶ Indeed, he felt so comfortable that night that he was able to watch 'A Question of Sport' on television with his son.³⁵⁷
- 3.141 I am satisfied that the nurses no more recognised the danger of Claire's deteriorating condition than the doctors did and because the doctors did not inform the nurses of the seriousness of her illness, it would be unfair to criticise the nurses alone in this regard. As Staff Nurse Lorraine McCann,³⁵⁸ who was on duty at that time acknowledged, the failure to inform Mr and Mrs Roberts was a collective failure.³⁵⁹
- 3.142 However, as a matter of course and at the very least Mr and Mrs Roberts should have been told that:
- (i) Claire was very unwell.
 - (ii) Diagnoses was unclear.
 - (iii) Further investigations were necessary, and

³⁵⁵ 091-004-006 & WS-253-1 p.11-12

³⁵⁶ WS-253-1 p.11

³⁵⁷ WS-253-1 p.11

³⁵⁸ 310-003-005

³⁵⁹ Staff Nurse McCann T-30-10-12 p.90 line 2

(iv) Transfer to PICU might be necessary.

3.143 That no one even so much as suggested concern, let alone danger to Mr and Mrs Roberts is profoundly unsettling. Claire's death must have been made even harder to bear by the thought that they could have stayed with Claire. Fundamental failures in communication with families was one of the most repeated, basic, depressing and serious deficiencies encountered by this Inquiry.

Attendance of Dr Hughes at 21:30

3.144 Dr Hughes saw Claire again at about 21:30 when she gave her anti-viral medication.³⁶⁰ She also took blood for general testing and to assess levels of phenytoin.³⁶¹ These had to be checked before additional phenytoin could be given. She did not make a record of her examination. Whilst this was an omission on her part, it was of little consequence. Nonetheless, she did have time to re-write the prescription sheet detailing the drug regime.³⁶² With more experience, time and support she might have pieced together the record of attacks, GCS scores, observations and general presentation to appreciate that something was seriously wrong and to make contact with Dr Bartholome.

3.145 The nursing notes record that at 23:00 Claire was given an additional dose of phenytoin³⁶³ to add to the bolus overdose already given by Dr Stevenson. This was administered before the results of the blood tests were received at 23:30. These revealed a phenytoin level of 23.4 mg/l which was in excess of the therapeutic range of 10-20 mg/l.³⁶⁴ In other words, Claire had already received too much of a drug, experts suggest she should not have been given in the first place and then she was given some more.

³⁶⁰ 090-026-077

³⁶¹ Dr Hughes T-05-11-12 p.155 line 21

³⁶² 090-026-077

³⁶³ 090-040-138

³⁶⁴ 090-022-056

- 3.146 More importantly, the blood test results revealed that her sodium levels had fallen and were now dangerously low at 121mmol/L. Claire was suffering severe hyponatraemia.

Attendance by Dr Stewart at 23:30

- 3.147 Dr Stewart saw Claire at about 23:30. He was by then the only doctor covering the Children's Hospital at SHO level outside A&E and PICU. His record of examination reads:

"Na 121 K 3.3 Urea 2.9 Creat 33 Phenytoin 23.4mg/l (10-20)

Hyponatraemia - ? Fluid overload $\bar{c}$ low Na fluids

? SIADH

Imp - ? Need for $\uparrow$ Na content in fluids

D/W Reg - $\downarrow$ Fluids to 2/3 of present value – 41mls/hr

*Send urine for osmolality"*³⁶⁵

- 3.148 This was an impressive analysis, particularly from an SHO with Dr Stewart's experience. Recognising that Claire was hyponatraemic, he suggested two causative mechanisms; one the type and volume of fluids under infusion and the other the Syndrome of Inappropriate Anti-Diuretic Hormone secretion ('SIADH'). His proposed response was first, to switch from Solution No. 18 to a fluid with a higher sodium content and secondly, to reduce the volume by a third.

- 3.149 He telephoned Dr Bartholome who directed him to reduce the fluids by a third but to continue with Solution No. 18. She also told him to give the next dose of phenytoin but to reduce the rate.³⁶⁶

- 3.150 It was thus that between 23:00 and 02:00, Claire received a further 56mls of Solution No.18 at about 18.5mls per hour, together with 7.6mls of 0.9% saline in conjunction with her midazolam infusion. In addition, she was

³⁶⁵ 090-022-056

³⁶⁶ Dr Stewart T-06-11-12 p.67

given 110mls of an unknown dilutant with the phenytoin infusion.³⁶⁷ Dr Scott-Jupp thought that the dilutant was probably 0.9% saline.³⁶⁸ These fluids amounted to a total of 173.5mls. Dr Scott-Jupp calculated that this was considerably more than the 41ml/hr intended and only slightly less than the rate as originally infused.³⁶⁹ He added that Claire also received about 133mls more than intended between 20:00 and 02:00 but considered it unlikely that this comparatively small excess would have made any significant difference.³⁷⁰

- 3.151 Dr Stewart believes that he informed Dr Bartholome about the drop in Claire's sodium levels, her GCS readings and the anti-convulsants administered. He fully expected her to come as soon as possible and to assume responsibility. Dr Stewart says that they did not however discuss moving Claire to PICU and then his duties called him elsewhere.³⁷¹

Involvement of Dr Bartholome

- 3.152 Dr Stewart did not re-visit Claire between 23:30 and 03:00 and Dr Bartholome did not go to Claire until about 03:00.³⁷² How can it possibly have been that Claire was not seen by a doctor during those critical 3½ hours? In part, it was due to chronic medical under-staffing at night³⁷³ and in part because Dr Bartholome could have done more. Her belief is that she must have been managing another emergency, most probably in A&E. That might very well have been the case but the expert consensus is that by 23:30 the time had most definitely come to call consultants and to contact PICU. Claire had been suffering sporadic attacks and her GCS scores and sodium levels were dangerously low. If Dr Bartholome was unable to see Claire then she should have called for consultant help or got Dr Stewart to make the call. Alternatively, she could have asked him to go

³⁶⁷ 090-038-135

³⁶⁸ 234-003-002

³⁶⁹ 234-003-002

³⁷⁰ 234-003-003

³⁷¹ Dr Stewart T-06-11-12 p.83 line 18 *et seq*

³⁷² 090-022-056

³⁷³ Dr Stewart T-06-11-12 p.39

back and check on Claire's condition or contact PICU. She did none of those things.

- 3.153 Dr Bartholome's failure to respond after 23:30 would be almost impossible to comprehend if she had been informed at the 17:00 handover as to exactly how ill Claire was. She cannot now recall the events of that night but I consider it most unlikely that she was informed about the seriousness of Claire's condition. Had she known how critical Claire was, she would have given priority to her care, most especially when she received Dr Stewart's report of deterioration.
- 3.154 The unavoidable truth is that Claire was deteriorating in plain sight of the doctors and nurses on Allen Ward. The signs were unambiguous but went unrecognised. I conclude that this arose, in part, from the failure of any single clinician to take primary responsibility for Claire's case. Dr Steen was not there and neither Dr Webb nor Dr Sands assumed overall charge or sought to secure Dr Steen's attendance or talk with Dr Bartholome. To make matters worse it would appear that there was no on-call paediatric consultant.
- 3.155 Leadership was absent from Claire's case and had been from the outset. No single experienced overview was brought to bear to correct, co-ordinate or make connections. None of the doctors treating Claire had individual 'ownership' of her case, none was motivated to push for EEG, CT or PICU and none imposed personal control over her care so as to ensure appropriate record keeping, regular observations or proper communication with Mr and Mrs Roberts.
- 3.156 There was no firm consensus about whether Claire could still have been saved at 23:30.³⁷⁴ However, and at the very least, the fall in her sodium levels could have been arrested by switching from Solution No. 18 and reducing the rate. Dr Stewart's plan to change the fluid and reduce the

³⁷⁴ 234-002-008 & 091-011-067

volume was preferable to Dr Bartholome's direction to continue with Solution No. 18 but at a lesser rate.

Respiratory arrest: 23rd October 1996

3.157 At 02:30, a nurse recorded that *"Slight tremor of right hand noted lasting few seconds. Breathing became laboured and grunting. Respiratory rate 20 per minute. O₂ saturations 97% - Claire stopped breathing."*³⁷⁵ Dr Bartholome was contacted and attended with Claire at 03:00. She made her sole entry in the medical chart:

*"3AM Called to see. Had been stable when suddenly she had a respiratory arrest and developed fixed dilated pupils. When I saw her she was Cheyne-Stoking and requiring O₂ via face mask. Saturation with bagging in high 90s. Good volume pulse. I attempted to intubate – not successful. Anaesthetic colleague came and intubated her orally with 6.5 tube. Transferred to PICU."*³⁷⁶

3.158 Dr Bartholome explained that her entry is to be understood as being a part of what she would have told staff in PICU.³⁷⁷ They would also have seen Dr Stewart's entry at 23:30 together with the earlier entries. Her use of the word *"stable"* to describe Claire's condition prior to collapse make no sense whatsoever.

3.159 Dr Bartholome telephoned Mr and Mrs Roberts to tell them that Claire had breathing difficulties and to come to the hospital as quickly as possible. She did this at about 03:45 and it was her last input into Claire's case.

3.160 The expert consensus is that Claire could not have been saved after her collapse and confirms that there can be no criticism of how Claire was treated in PICU.

³⁷⁵ 090-040-138

³⁷⁶ 090-022-056

³⁷⁷ Dr Bartholome T-18-10-12 p.88-89

Transfer to PICU and Dr Steen's examination of Claire

3.161 Claire was transferred to PICU at 03:25 on Wednesday 23rd October.³⁷⁸

3.162 Dr Steen was contacted. She responded immediately and was with Claire shortly before 04:00. This was the first time she had seen Claire. I also believe that it was probably the first time she knew anything about Claire. She made the following entry in the records at 04:00 :

"9½-year-old girl c̄ learning difficulties admitted 32 hours ago c̄ ↓ level of consciousness.

SB Dr Webb Δ acute encephalopathy ? aetiology. Covered c̄ acyclovir + cefotaxime. Loaded ĉ phenytoin + valproate added in @ 17:00 hrs.

11pm – phenytoin level = 23.4. Na+ 121. K+ 3.3. Fluids restricted to 2/3rd maintenance. Obs otherwise stable.

@3am Reg asked to see because of resp difficulties. Cheyne-Stoke breathing – intubated + transferred to ICU.

At present intubated + ventilated. Has had some Midazolam but it is no longer running. Pupils fixed + dilated. Bilateral papilloedema L>R. No response to painful stimuli. BP- 90/65 HR = 100/min.

Plan-Mannitol stat.

Dopamine infusion.

*Urgent CT scan."*³⁷⁹

3.163 Dr Steen explained that she compiled this entry from the notes, from what she was told by the doctors and nurses and her examination.³⁸⁰ It is a significant entry but not an exhaustive re-listing of every issue and concern. There is specific reference to the "acute encephalopathy" as noted by Dr Webb but none to the encephalitis included in Dr Sands' earlier entry (and about which I have already expressed my view). Importantly she refers to

³⁷⁸ 090-040-138-139

³⁷⁹ 090-022-057

³⁸⁰ Dr Steen T-16-10-12 p.28

the low sodium levels and the restriction of fluids as noted by Dr Stewart.³⁸¹
She examined Claire for raised intra-cranial pressure.

Dr Webb's attendance at 04:40, 23rd October

- 3.164 It would appear that, in consequence of a call from Dr Steen, Dr Webb came to the hospital as well. His entry in the notes, made at 04:40 and immediately after Dr Steen's, records:

"Neurology

SIADH – hyponatraemia, hypoosmolarity, cerebral oedema + coning following prolonged epileptic seizures

Pupils fixed + dilated following mannitol diuresis

No eye movements.

*→ For CT scan"*³⁸²

- 3.165 Dr Peter Kennedy,³⁸³ Registrar in Radiology, reported on the CT scan, which was performed at approximately 05:30.³⁸⁴ He noted severe cerebral oedema.³⁸⁵ Dr Webb recalled that at that point it was "*clear that Claire had sustained severe brain injury and was not going to survive.*"³⁸⁶

- 3.166 Claire did not recover. With the consent of her parents, ventilation was discontinued at 18:45 on 23rd October 1996³⁸⁷ and she died in PICU.

Brain stem death tests

- 3.167 As in Adam's case, there is an issue about the brain stem death tests. They were performed in Claire's case at 06:00 and 18:25 on 23rd October by Drs

³⁸¹ 090-022-057

³⁸² 090-022-057

³⁸³ 310-003-004

³⁸⁴ WS-167-1 p.2

³⁸⁵ 090-022-059

³⁸⁶ 090-053-168

³⁸⁷ 090-022-061

Steen and Webb and recorded on the standard 'Diagnosis of Brain Death' form.³⁸⁸

3.168 Dr Simon Haynes, Consultant Paediatric Anaesthetist, commented on the brain stem testing.³⁸⁹ He said, "*There has to be a certainty that there is no residual effect of any neuromuscular or sedative drugs or other intoxicating agents*" and "*then there has to be the exclusion of metabolic and biochemical causes of coma. And that exclusion has to be made before doctors making the test can go on and do the test.*"³⁹⁰

3.169 Dr Aronson considered that several of the anti-convulsant drugs administered to Claire could still have been having an effect even after 24 hours.³⁹¹ In the circumstances, it was necessary for both Drs Steen and Webb to carefully review Claire's recorded drug history and only to proceed to the brain stem death test when it was appropriate so to do. Additionally, even though Claire's sodium reading had risen to 129mmol/L by the time of the first test, it was still outside the normal range. Metabolic causes of coma could not therefore be completely excluded.

3.170 Notwithstanding, Dr Webb and Dr Steen determined that Claire fulfilled the criteria for brain stem death and signed the 'Diagnosis of Brain Death' form.³⁹² In particular, question 1(c) "*Could other drugs affecting ventilation or level of consciousness been responsible for her condition?*" was answered by them both in the negative.³⁹³ I think it is unlikely that these doctors could have been so confused by the slightly odd wording of this question to fail to understand it or its purpose. Dr Aronson was of the opinion that given that the phenytoin probably remained in Claire's system, question 1(c) could not properly have been answered in the negative.³⁹⁴ Question 1(f) then posed the question: "*Could patient's condition be due to*

³⁸⁸ 090-045-148

³⁸⁹ Dr Haynes T-03-05-12 p.106 to 112

³⁹⁰ Dr Haynes T-03-05-12 p.114 line 13-20

³⁹¹ 237-002-008 to 009

³⁹² 090-045-148

³⁹³ 090-045-148

³⁹⁴ Dr Aronson T-08-11-12 p.276 line 22

a metabolic/endocrine disorder?” This was also answered in the negative.³⁹⁵ The doctors made no reference to Claire’s hyponatraemia.

3.171 The protocol for certifying brain stem death requires strict adherence. Just as the protocol was not followed in Adam’s case, so too was there failure to comply in Claire’s case. I believe that it was inappropriate to start the tests before the effect of the phenytoin could be disregarded and incorrect to answer the questions as they did. It was not suggested that anything could have been done differently so as to affect the outcome but it was quite wrong for Dr Webb to record in his entry at 06:00 that Claire was “*under no sedating/paralysing medication*”³⁹⁶ when in all probability the drugs which he had prescribed the previous day were still in her system.

3.172 Dr Webb maintained that at the time of the tests he was unaware that Claire had been erroneously prescribed 120g of midazolam. I conclude therefore, that just as he may have failed to review Adam’s medical notes for his brain stem death test, so too did he fail to review Claire’s drug history. That such an error in prescription remained un-noted for so long further confirms that the drug record cannot have been subject to further or adequate review.

3.173 The ‘Diagnosis of Brain Death’ form concludes with the final question “*Is this a Coroner’s case*” which was answered in the negative and by Dr Steen alone.³⁹⁷

Discussions with Claire’s parents

3.174 Shortly after the CT scan confirmed Claire’s cerebral oedema, Drs Steen and Webb met with Claire’s parents. Mr Roberts recalled that Dr Steen informed him that Claire was brain dead and that “*everything possible had been done for Claire and nothing more could have been done.*”³⁹⁸ He remembered Dr Steen explaining that “*the virus from Claire’s stomach had*

³⁹⁵ 090-045-148

³⁹⁶ 090-022-058

³⁹⁷ 090-045-148

³⁹⁸ WS-253-1 p.14

spread and travelled into Claire's brain and caused a build-up of fluid."³⁹⁹

The Roberts family are emphatic that there was no mention of low sodium.

3.175 Mr and Mrs Roberts' evidence is supported by the Hospital Relative Counselling Record which noted that *"following CT scan Dr Steen and Dr Webb explained that Claire had swelling of the brain and could possibly be brain dead"* and when *"asked why her brain had swollen, it was explained it was probably caused by a virus."*⁴⁰⁰

3.176 However, Dr Webb considered that this was wrong and did not accurately reflect their conversation. He stated that *"... if a "virus" was discussed it was probably on the basis of a theory that a virus may have triggered Claire's seizures and her brain oedema."* Although he could not recall the detail of what was actually said about hyponatraemia and cerebral oedema, he believed that he *"would have indicated that the brain swelling was due to hyponatraemia"* and that he communicated his opinion as he had set it out in the medical notes,⁴⁰¹ namely *"SIADH- hyponatraemia, hypoosmolarity; cerebral oedema + coning following prolonged epileptic seizure."*⁴⁰²

3.177 Given the passage of time since 1996 and the traumatic events endured in the interim by Mr and Mrs Roberts, including the 2004 TV broadcast, the inquest and the police investigation, I do not assume that their evidence is necessarily always accurate. Dr Steen has suggested that she would have mentioned low sodium and that this might explain how Mr and Mrs Roberts identified a connection when they watched the documentary in 2004. Dr Steen believed furthermore that she would have mentioned low sodium in the context of SIADH rather than by reference to Solution No.18 because that was still a commonly used fluid at that time. However, neither Dr Steen nor Dr Webb made any note as to the advices given and the detail cannot now be recovered.

³⁹⁹ WS-253-1 p.14

⁴⁰⁰ 090-028-088

⁴⁰¹ 090-028-088 & WS-138-1 p.50-51 & p.55

⁴⁰² 090-002-057

3.178 Mr and Mrs Roberts were, as a matter of course, entitled to a straightforward explanation from Dr Steen as to the known causes of Claire's cerebral oedema. At that time all that was understood with any confidence was that hyponatraemia had probably contributed to the swelling of the brain. There is no good evidence that Dr Steen advised Claire's parents as to the role of hyponatraemia at that or indeed any other time. In the light of Dr Steen's subsequent failure to advise them as to the role of hyponatraemia, I conclude, on the balance of probabilities, that Mr and Mrs Roberts were not given an adequate or proper explanation as to what was known about the causes of Claire's death on 23rd October.

Involvement of the Coroner's Office

The legal duty to report

3.179 Claire's death was not referred to the Coroner. The Coroner's office was not notified of Claire's death until 2005. The relevant legislation in Northern Ireland, both then and now, is section 7 of the Coroner's Act (Northern Ireland) 1959 which provides that:

*"Every medical practitioner... who has reason to believe that the deceased person died, either directly or indirectly, as a result of violence or misadventure or by unfair means, or as a result of negligence or misconduct or malpractice on the part of others, or from any cause other than natural illness or disease for which he had been seen and treated by a registered medical practitioner within twenty eight days prior to his death, or in such circumstances as may require investigation (including death as the result of the administration of an anaesthetic) shall immediately notify the coroner within whose district the body of such deceased person is of the facts and circumstances of the death."*⁴⁰³

3.180 The following points emerge from that provision:

⁴⁰³ 170-001-008 & <http://www.legislation.gov.uk/apni/1959/15/section/7>

- (i) The duty to notify the Coroner is imposed on every medical practitioner and not just the named consultant. Accordingly, in Claire's case, it extended at the very least to Drs Steen and Webb.
- (ii) The death need only relate indirectly to any of the circumstances identified.
- (iii) The context for reporting a death includes not only negligence, misconduct or malpractice but also "*such circumstances as may require investigation.*"
- (iv) It is not only the death that is to be reported – but also "*the facts and circumstances*" of the death.
- (v) The report is to be made immediately.

Decision not to notify Coroner

- 3.181 It is necessary to set out the events which seemingly led to the decision not to report Claire's death to the Coroner.
- 3.182 By 04:00 on 23rd October, Claire was in reality, already dead. Quite apart from her family, this must have come as a shock to the doctors and nurses who were responsible for her care. It seems to have been completely unexpected – after all Claire had been at school on Monday and was dead by Wednesday. At 14:00 on Tuesday, Dr Webb had considered the option of a CT scan for the following day but had not felt the need to arrange it or an EEG more urgently. Both he and Dr Sands finished their duties by 18:00 and left the hospital in no doubt that Claire would be on Allen Ward the following morning. When Dr Steen and Dr Webb came into PICU in the early hours of 23rd October, they must have been asking how this could possibly have happened, whether there were matters to be investigated and whether or not her death raised questions about the care she had received on Allen Ward.

- 3.183 Instead, Dr Steen's evidence was that she was able to form so clear and confident a view as to the cause of Claire's death that she did not think it appropriate to contact the Coroner's office.⁴⁰⁴ Both she and Dr Webb conceded in their oral evidence that with hindsight they should have called the Coroner.⁴⁰⁵ I entirely agree that they should have but I do not accept that this is only apparent with the benefit of hindsight. There was not a single witness to the Inquiry who supported their decision not to contact the Coroner about Claire's death.
- 3.184 The decision is so questionable that it raises issues about the *bona fides* of Dr Steen in particular, but also of Dr Webb and others, because of their responsibility under Section 7. The Roberts family has come to believe that Claire's death was not notified to the Coroner in order to conceal the inadequacy of her treatment and the responsibility of the Trust for her death.⁴⁰⁶ If they are wrong, what was it in 1996, which allowed the doctors to think it unnecessary to contact the Coroner?
- 3.185 Dr Steen's evidence is that, in October 1996, she knew nothing about the death of Adam Strain in 1995 or anything about the outcome of his inquest four months before. Whilst this is very hard to believe, the shocking possibility remains that it may be true. If it is, it confirms that what happened in Adam's case was largely ignored in the Children's Hospital with the result that lessons were not learned beyond an extremely small group of people. Whilst it is to be recognised that there are obvious differences between Adam's case and Claire's, there were nonetheless sufficient lessons to be drawn in relation to the causation and early treatment of hyponatraemia in children to make it relevant for those caring for Claire.
- 3.186 On the morning of October 23rd, Dr Steen knew that Claire had suffered acute hyponatraemia and that this had been a contributory factor in the fatal cerebral oedema.⁴⁰⁷ Subsequently and with the benefit of hindsight,

⁴⁰⁴ Dr Steen T-18-12-12 p.56 line 24 & WS-143-1 p.73

⁴⁰⁵ Dr Webb T-03-12-12 p.232 line 25 & Dr Steen T-17-12-12 p.43 line 17

⁴⁰⁶ T-06-12-12 p.96

⁴⁰⁷ WS-143-1p.79

consultants and experts have expressed a range of opinion about what else may have been wrong with Claire but it is beyond dispute that hyponatraemia was identifiable and indeed identified on 23rd October as a factor in her death. The record contains Dr Stewart's query at 23:30, 22nd October about "*Hyponatraemia - ?Fluid overload [with] low Na fluids. ?SIADH,*"⁴⁰⁸ and Dr Steen noted Claire's hyponatraemia and fluid therapy at 04:00 on 23rd October as "*na + 121; fluids restricted to 2/3rd maintenance.*"⁴⁰⁹

- 3.187 Whilst Dr Steen was alert to the possibility of an excess infusion of hypotonic fluids, she could not then have formed any definite opinion in this regard. Indeed, the debate about the volume of fluid actually given Claire became very protracted and intense at the public hearings. I consider, that the conclusion to be drawn from the evidence is that there was indeed an excess of fluid, which on its own may not have been significant, but which became dangerous because Claire may have had SIADH causing retention of the fluids given intravenously.
- 3.188 SIADH was in the circumstances a matter for Dr Steen's consideration. It was a well-recognised medical complication arising when particular conditions affect the normal release of ADH. Such conditions include, amongst other things, infection, pain, stress and nausea. In such cases, a syndrome of inappropriate ADH can develop causing the kidneys to stop releasing fluids as normal resulting in a retention of fluids. In such a situation the infusion of low sodium IV fluids can only add to the volume of fluids retained and reduce the levels of sodium by dilution.
- 3.189 The consequence of not monitoring Claire's serum sodium levels, not understanding her fluid balance and not re-assessing her fluid regime was to permit the development of dilutional hyponatraemia. Even if Dr Steen did not arrive at such a conclusion at that time, she knew enough about the cerebral oedema and sodium levels and sufficient of the uncertainties and

⁴⁰⁸ 090-022-056 (for accuracy of transcription see WS-141-1 p.3)

⁴⁰⁹ 090-022-057

possibilities to understand that further investigation was most certainly indicated.

3.190 Further, and even if it is correct that Dr Steen was entirely unaware of Adam's death, Dr Webb was not. He had formally confirmed brain stem death in Adam on two occasions⁴¹⁰ and clearly understood the connection between dilutional hyponatraemia and cerebral oedema.⁴¹¹ He had read Adam's notes and provided the Coroner with a statement for inquest. Whilst he claimed to have "*no knowledge of the inquest findings in the case of Adam Strain.*"⁴¹² I found it hard to believe him. He appeared intent on distancing himself from Adam's case. He said that he doubted that he had received Dr George Murnaghan's⁴¹³ letter asking him for his statement about Adam⁴¹⁴ or that he received a written request to attend the pre-inquest consultation⁴¹⁵ or that a copy of Adam's post-mortem report was sent him⁴¹⁶ or that he was asked for additional comment in relation to the ongoing medical negligence claim.⁴¹⁷ I found this implausible.

3.191 Accordingly, I believe Claire's death must have come as a clear reminder to him of dilutional hyponatraemia, even if the cause was different. In his evidence, he suggested that in 1996 he did not realise that Claire had received excessive fluid. However, he had read the notes querying fluid overload and his own entry in the notes reveals a clear understanding of the underlying processes, namely "*SIADH, hyponatraemia, hypoosmolarity; cerebral oedema+coning following prolonged epileptic seizure*".⁴¹⁸

3.192 Just as Dr Webb sought to distance himself from any knowledge of Adam's case, he distanced himself from the decision not to refer Claire's death to the Coroner. On these issues, his evidence was likewise unconvincing.⁴¹⁹

⁴¹⁰ 058-004-009 & 058-035-139

⁴¹¹ Dr Webb T-03-12-12 p.246 line 3

⁴¹² WS-138-1 p.93

⁴¹³ 310-023-004

⁴¹⁴ Dr Webb T-03-12-12 p.259 line 25

⁴¹⁵ Dr Webb T-03-12-12 p.262 line 24

⁴¹⁶ Dr Webb T-03-12-12 p.264

⁴¹⁷ Dr Webb T-03-12-12 p.265 line 24

⁴¹⁸ 090-022-057

⁴¹⁹ WS-138-1 p.53 & Dr Webb T-03-12-12 p.232 *et seq*

He had made repeated efforts on Tuesday 22nd October to help Claire and had performed both brain stem death tests. Accordingly, it is most improbable that he should avoid discussion about whether the Coroner should be contacted.

- 3.193 Dr Webb's treatment of Claire was mostly for status epilepticus. He did not investigate other possibilities and without an EEG could not have been sure about his diagnosis of status epilepticus. By the time he left the hospital on Tuesday evening, he knew that Claire's response to the drug treatment was negligible. She then died overnight. In such circumstances, Dr Steen's conclusion that his unconfirmed diagnosis of status epilepticus was sufficiently evidenced as to leave nothing to raise with the Coroner is extraordinary and Dr Webb's failure to question it remarkable.
- 3.194 Neither Dr Webb nor Dr Steen addressed Claire's wholly unexpected deterioration from admission to collapse and both ignored the need to fully understand the mechanism whereby hyponatraemia might have developed. Neither seem to have questioned why there was no response to the treatment given and whether this might not indicate that the diagnosis was wrong. They seemingly failed to note or perhaps ignored the failings in the fluid therapy and the failing to repeat the blood test, either of which should have prompted referral to the Coroner. They also completely ignored, or failed to recognise, the lack of consultant input after Dr Webb's departure, the lack of medical attendance after Dr Stewart's intervention and the drug overdoses.
- 3.195 Dr Webb knew enough about Claire's case at that time to recognise that there may have been a problem in relation to her fluid and electrolyte management and to have appreciated that he could not explain with any confidence the cause of her SIADH.⁴²⁰ His failure in these circumstances, to notify the Coroner is hard to explain in professional terms. He was familiar with the process of a Coroner's inquest and had a duty under the legislation. On the balance of probabilities, I am forced to the conclusion

⁴²⁰ WS-138-1 p.47

that he did not refer Claire's death to the Coroner because of a reluctance to draw attention to possible failings in her treatment.

- 3.196 Drs Steen and Webb were wrong not to refer the death to the Coroner. Their decision was a breach of both statutory obligation and professional duty. It was, even by the standards of 1996, a gross error of judgement. Their reasons were hopelessly inadequate, their decision reached without proper reflection, and their evidence unconvincing.

Involvement of Dr McKaigue

- 3.197 One of those who treated Claire in PICU was Dr James McKaigue.⁴²¹ On the night of 22nd/23rd October, he was the on-call consultant paediatric anaesthetist and was contacted about Claire's condition. He examined Claire and reviewed her history. He noted at 07:10 that Claire's serum sodium was 121mmol/L "*presumably on basis of SIADH*" and that the "*CT scan shows severe cerebral oedema.*"⁴²²
- 3.198 Dr McKaigue claimed to have initiated a discussion about whether the Coroner should be informed or whether a death certificate could issue. It is to be recalled that he had an understanding of hyponatraemia, having been involved in Adam's case.⁴²³ However, Claire's case was different because she was thought to have encephalitis and status epilepticus in addition to hyponatraemia. These were indeed matters to be discussed and I accept that these conditions should have featured in any debate, but I do not accept that these diagnoses could have been accepted with any confidence at that time. In such circumstances, he should have ensured that Claire's death was reported to the Coroner.
- 3.199 However, Dr McKaigue concluded that the cause of Claire's death was known and had occurred naturally. He believed that she had status

⁴²¹ 310-003-003

⁴²² 090-022-058-060

⁴²³ He was also one of the joint authors of the RGHT statement submitted to the coroner at Adam Strain's inquest and made "*having regard to the information in the paper by Arieff et al (BMJ 1992)*" (011-014-107a & 060-014-025)

epilepticus and encephalitis and explained that Dr Steen had told him that these could bring on SIADH which could in turn cause cerebral oedema.⁴²⁴ For that reason he sensed no “*red flags*” indicating any necessity to notify Claire’s death to the Coroner. His approach ignored both the uncertainties and the very much more obvious conclusion that the cerebral oedema was caused by the hyponatraemia in the presence of SIADH and the administration of hypotonic solution and was therefore a death which could have been prevented.

- 3.200 Dr McKaigue’s position was further undermined by his own entry in the ‘PICU Coding Form’. There he made reference to hyponatraemia but not to status epilepticus or encephalitis.⁴²⁵ In all the circumstances, I consider that Dr McKaigue failed in his duty to ensure that Claire’s death was reported to the Coroner.

Involvement of Dr Robert Taylor

- 3.201 Dr Robert Taylor⁴²⁶ saw Claire in PICU at approximately 10:00 on 23rd October. He had more cause than most to be alert to the issues of dilutional hyponatraemia. Only four months had passed since the Coroner had conducted the inquest into the death of Adam Strain and Dr Taylor had signed a statement on behalf of the Trust “*having regard to the information in the paper by Arieff et al (BMJ 1992).*”⁴²⁷
- 3.202 He noted that Claire “*appears BS Dead informally. But only 7 hours post arrest. Na+129 (from 121).*”⁴²⁸ He may therefore be taken to have read the preceding entries in Claire’s medical notes and understood that hyponatraemia was probably responsible for the cerebral oedema and that issues of SIADH, fluid overload and fluid therapy were referenced. I find it hard to understand how he could not have wondered whether fluid and

⁴²⁴ Dr McKaigue T-17-10-12 p.220

⁴²⁵ 090-055-203

⁴²⁶ 310-003-004

⁴²⁷ 011-014-107a

011-011-074: Arieff A. I., Ayus J. C., Fraser C. L. Hyponatraemia and death or permanent brain damage in healthy children. BMJ 1992; 304 :1218

⁴²⁸ 090-022-061

electrolyte therapy had been correctly managed and whether notification to the Coroner was appropriate. Dr Taylor had no explanation beyond saying that it “... *didn’t strike a chord*...”⁴²⁹ I find that he too failed in his duty to notify the Coroner.

Certifying the cause of death

- 3.203 Dr Steen indicated that “*Once the serum sodium result of 121 was known, hyponatraemia would have been considered as a contributory factor in the cerebral oedema.*”⁴³⁰ However, when she completed the Medical Certificate of Cause of Death on 23rd October she certified that death was due to cerebral oedema secondary to status epilepticus.⁴³¹ This was despite the fact that the diagnosis of status epilepticus was unconfirmed in the absence of an EEG test. Furthermore, Dr Steen’s evidence that she did not include viral encephalitis in the death certificate because it was unconfirmed⁴³² only serves to emphasise the illogicality of her citing status epilepticus as a cause of death when it too was unconfirmed. The only confirmed diagnosis at that time was hyponatraemia but that, she specifically omitted from the death certificate.
- 3.204 Furthermore, and even if it had been appropriate to issue a Medical Certificate of Cause of Death, which it was not, Dr Steen may not have been qualified to sign it because she had not been directly involved in Claire’s care and accordingly lacked the necessary credentials⁴³³
- 3.205 Mr and Mrs Roberts were thus denied timely coronial investigation into Claire’s death and their suspicion of cover-up cannot be regarded as unreasonable. This made matters even worse for them.

⁴²⁹ Dr Taylor T-11-12-12p.77 line16

⁴³⁰ WS-143-1 p.79

⁴³¹ 090-022-061

⁴³² Dr Steen T-17-10-12 p.225 line 6

⁴³³ Article 25 of the Births and Deaths, Registration (Northern Ireland) Order 1976.

Brain only autopsy

Consent

- 3.206 On the evening of 23rd October, after the ‘Diagnosis of Brain Death’ form was completed but before Claire’s ventilation was discontinued, Dr Steen met with Mr and Mrs Roberts. She obtained their consent for a limited hospital post-mortem⁴³⁴ examination of Claire. The consent was signed by Mr Roberts and authorised a post-mortem examination restricted to the brain alone.⁴³⁵ This confirmed, in effect, that Claire’s death was not to be referred to the Coroner. Mr and Mrs Roberts are confident that Dr Steen told them at that time that a virus had caused a build-up of fluid on the brain and that the autopsy might identify the virus responsible.⁴³⁶ There was no mention of hyponatraemia.
- 3.207 The process of giving and taking a consent for post-mortem must be heart-rending and difficult but it was important that Mr and Mrs Roberts were given enough information to understand why the autopsy and its limitation were necessary and why the death did not need to be referred to the Coroner.
- 3.208 Mr Roberts recalls that he did not request any limitation to the post-mortem but that this was recommended by Dr Steen, who *“stated that there would be no need for an Inquest but the Hospital needed to carry out a brain only post-mortem.”*⁴³⁷ He described his *“understanding at that time was that doctors were aware of the reasons for Claire’s death, Dr Steen had explained that a virus had caused the fluid build-up around Claire’s brain. If I had been informed that there was any unknown or uncertainty regarding the cause of death then I would have consented to an Inquest.”*⁴³⁸ He said there were no discussions regarding the option of a full post-mortem.⁴³⁹

⁴³⁴ 090-022-061

⁴³⁵ 090-054-185

⁴³⁶ WS-253-1 p.15

⁴³⁷ WS-253-1 p.15

⁴³⁸ WS-253-1 p.15

⁴³⁹ WS-253-1 p.15

- 3.209 Dr Steen stated that she has “*no recollection of events but would assume I hoped to... determine if encephalitis was present... determine an underlying cause for seizures and developmental delay...*”⁴⁴⁰ Again, she made no record of the conversation or the reasons given.
- 3.210 Mr and Mrs Roberts were very clear in their evidence that nothing was said about the possibility of the post-mortem providing an explanation for Claire’s developmental delay. They stated that they would have wanted to know and it was definitely not raised.⁴⁴¹
- 3.211 Dr Steen advised that a limited post-mortem is most usually indicated when particular organs only are involved in the disease process and additional information as to cause of death, or underlying disorders, is to be obtained by examining those organs.⁴⁴² Accordingly, she said a post-mortem of the brain alone was appropriate in this case because the only additional benefit of a full post-mortem might have been the identification of an enterovirus⁴⁴³ from the content of the gut.⁴⁴⁴
- 3.212 I consider that a full post-mortem must not only allow positive identification of some factors but also the positive exclusion of others. Additionally, it might from the perspective of Dr Steen, have identified other non-brain related factors implicated in the suspected SIADH. A restriction of examination is a restriction of the potential for information. It seems that the Pathology Service was not consulted as to the limitation imposed upon the post-mortem.⁴⁴⁵ It was to subsequently note the consequence of limitation, stating that because “*as this was a brain only autopsy it is not possible to comment on other systemic pathology*”⁴⁴⁶
- 3.213 Dr Webb was unable to recall his input into the decision to limit the autopsy but stated that “*I believe I would have expected her post-mortem to have*

⁴⁴⁰ WS-143-1 p.72

⁴⁴¹ Mr and Mrs Roberts T-01-11-12 p.196 line 19 & WS-253-1 p.20-21

⁴⁴² WS-143-1 p.71

⁴⁴³ 310-007-003

⁴⁴⁴ WS-143-1 p.72 & Dr Steen T-17-10-12 p.190 line 5

⁴⁴⁵ WS-224-1 p.7

⁴⁴⁶ 090-003-005

been a full post-mortem."⁴⁴⁷ I share this view in light of the lack of certainty surrounding Claire's diagnoses at that time and the necessity to understand the reasons for her rapid and unexpected deterioration.

- 3.214 The advices given to Mr and Mrs Roberts were not recorded and the justification for pursuing a restricted hospital post-mortem was not documented. There was however no guidance to assist in this very important process. It is far from certain that Mr and Mrs Roberts were given sufficient information to allow them to give a fully considered consent to the post-mortem. That is regrettable.
- 3.215 That Dr Webb did not engage more in this process is surprising given both his involvement and his expectation that a full post-mortem might have been necessary. Yet again, he distanced himself and allowed Dr Steen to pursue her own course.

'Autopsy Request Form'

- 3.216 Dr Steen completed and signed the 'Autopsy Request Form' to be sent to the pathologist. It names the consultant as "*Dr Webb/Dr Steen*" and cites a clinical diagnosis of "*cerebral oedema 2° to status epilepticus ? underlying encephalitis.*" Dr Steen listed the clinical problems in order of importance as:

- "1 *Cerebral oedema.*
- 2 *Status epilepticus.*
- 3 *Inappropriate ADH secretion.*
- 4 *? viral encephalitis.*"⁴⁴⁸

- 3.217 Under "*history of present illness*", Dr Steen wrote:

"Well until 72 hours before admission. Cousin had vomiting and diarrhoea. She had a few loose stools and then 24 hours prior to admission started to vomit. Speech became slurred and she became increasingly drowsy. Felt

⁴⁴⁷ WS-138-1 p.91

⁴⁴⁸ 090-054-184

to have sub clinical seizures. Treated [with] rectal diazepam / IV phenytoin / IV valproate. Acyclovir + cefotaxime cover given. Serum Na⁺ dropped to 121 @ 23-30 hrs on 22-10-96. ?Inappropriate ADH secretion. Fluids restricted. Respiratory arrest 0300 23-10-96. Intubated + transferred. ICU – CT scan – cerebral oedema. Brain stem death criteria fulfilled @ 0600 + 18.15 hrs. Ventilation discontinued 18-45 hrs.”⁴⁴⁹

3.218 In the “*past medical history*” section she stated:

“Mental handicap

Seizures from 6 months – 4 years.”⁴⁵⁰

3.219 There was some criticism as to the accuracy of this undated form as completed by Dr Steen. It omits all reference to the treatment with midazolam (whether miscalculated or not) and remains silent as to the clinical diagnosis of hyponatraemia which was then thought a contributory factor to the cerebral oedema. Whilst the form does refer to sodium levels, suspected secretion of inappropriate ADH and restriction of fluids it fails to list hyponatraemia as a clinical problem or diagnosis. This is odd given the entries in the record made by Drs Stewart and Webb which both clearly cite hyponatraemia and the ‘Case Note Discharge Summary’ issued by PICU which recorded Claire’s death with a diagnosis including hyponatraemia.⁴⁵¹

3.220 My greater concern is that I believe that the form actually betrays the uncertainty that the consultants must have shared about the cause of death. Not only does it differ from the Death Certificate by including the clinical diagnosis of “? *Underlying encephalitis*”⁴⁵² but it expresses it in terms of a query. This uncertainty should have led to something more substantial than a request for a brain-only autopsy. It should, as a matter of course, have led to the Coroner. Again Dr Webb’s failure to involve himself in this

⁴⁴⁹ 090-054-183 to 184

⁴⁵⁰ 090-054-183

⁴⁵¹ 090-009-011

⁴⁵² 090-054-183

administrative process is as striking as Dr Steen's single-handed control of it.

Autopsy

- 3.221 The autopsy of the brain alone was carried out on 24th October by Dr Brian Herron⁴⁵³ who was then a senior registrar in neuropathology. The brain was cut on 28th November 1996 and the slides examined in January 1997. The final autopsy report was completed on 11th February 1997.⁴⁵⁴ In relation to matters arising from the autopsy, the expert evidence of Dr Waney Squier, Professor Brian Harding and Professor Sebastian Lucas was received.
- 3.222 In October 1996, the Neuropathology Service in Belfast comprised a team of three. It was headed by Dame Professor Ingrid Allen who was a leading figure in neuropathology within the United Kingdom and in addition to Dr Brian Herron, included at consultant level Dr Meenakshi Mirakhur,⁴⁵⁵ The service provided by these three specialists had been accredited in February 1996,⁴⁵⁶ a process which involved review of the Neuropathology Service to ensure that it met the standards of the time.
- 3.223 As the evidence unfolded from Drs Herron and Mirakhur and the three Inquiry experts, it became clear that the differences between them were limited. It is fair to acknowledge that the independent experts had significantly more time and opportunity to explore the issues in Claire's case than Drs Herron and Mirakhur had in 1996/7 when they were working in a hard-pressed service.
- 3.224 At the outset, they agreed that the purpose of an autopsy is to identify the cause of death. To that end, new cases are conventionally discussed by the neuropathology team who both welcome and expect discussion with the

⁴⁵³ 310-003-004

⁴⁵⁴ 090-003-003 (there is some question about this being the final report – it is neither signed or dated but for present purposes I will regard it as the final report).

⁴⁵⁵ 310-003-004

⁴⁵⁶ Dr Mirakhur T-30-11-12 p.24 line 9

clinical team. This can be useful before and after a post-mortem in order to help formulate opinion. In some cases, a draft autopsy report will be issued for discussion, to be finalised after clinical input.⁴⁵⁷

3.225 After a final report, there were then two further opportunities to discuss the case, namely:

- (i) The grand round which focussed on the learning and training issues emerging from cases such as Claire's. This would have been attended by the core neuroscience group including the pathologists and radiologists.⁴⁵⁸
- (ii) The audit/mortality meeting conducted by the paediatricians but which the pathologists might also attend. At such meetings, a number of cases were discussed. In the mid-1990s, such meetings were un-minuted at the behest of medical insurers who did not wish discussions to be recorded lest their insured be compromised.⁴⁵⁹

The significance of such discussions was the opportunity for those involved to question and probe how a disease or condition had developed, how a child was treated, how a death occurred and how things might be done better or differently in the future.

3.226 As outlined above, Dr Steen's 'Autopsy Request Form' identified four clinical problems.⁴⁶⁰ The evidence indicated the following in relation to each:

- (i) Cerebral oedema – this was clear to Drs Herron and Mirakhur and was confirmed by the Inquiry experts.⁴⁶¹

⁴⁵⁷ Dr Mirakhur T-30-11-12 p.10 line 2

⁴⁵⁸ Dr Mirakhur T-30-11-12 p.135 line 7

⁴⁵⁹ WS-156-2 p.6 & WS-224-4 p.5

⁴⁶⁰ 090-054-184

⁴⁶¹ Dr Mirakhur T-30-11-12 p.36 line 19 & Professor Lucas T-18-12-12 p.170 line 12

- (ii) Status epilepticus - the pathologists could make no finding because there was no EEG confirmation. The identification of status epilepticus was a matter for clinicians and not pathologists.
- (iii) Inappropriate ADH secretion – it was agreed in evidence that this could neither be proved or disproved at post-mortem even if it is a plausible diagnosis in the light of the cerebral oedema and hyponatraemia.⁴⁶²
- (iv) Viral encephalitis - Drs Herron and Mirakhur thought that there was mild inflammation of the brain perhaps justifying a 1 - 2 on a notional scale of 1 - 10.⁴⁶³ Such would indicate that there was some evidence of encephalitis, but only that. On looking at the same slides, Dr Squier and Professor Harding could not see this evidence at all. In any event, Drs Herron and Mirakhur agreed that for encephalitis to be identified as a factor contributing in any way to Claire's death, it would have to reach a minimum of 5 on such a scale.⁴⁶⁴ Since it did not do so, the effective result of the post-mortem was that encephalitis could not be confirmed as a cause of Claire's death.

3.227 In short, the only certain finding after the post-mortem was that Claire had cerebral oedema and hyponatraemia but this was already known. None of the three other clinical issues suggested by Dr Steen was established. In effect, the importance of the post-mortem was to exclude encephalitis as a cause of Claire's cerebral oedema. Unfortunately, the autopsy report as it was eventually drafted did not exclude encephalitis but allowed it as a possible diagnosis.

Autopsy report

3.228 Regrettably, the autopsy report⁴⁶⁵ repeats some of the factual error originating from Dr Steen's 'Autopsy Request Form', illustrating how easy it

⁴⁶² Dr Mirakhur T-30-11-12 p.36 line 2 & Dr Herron T-29-11-12 p.27 line 13

⁴⁶³ Dr Mirakhur T-30-11-12 p.138 line 18 & Dr Herron T-29-11-12 p.46 line 1

⁴⁶⁴ Dr Mirakhur T-30-11-12 p.38 line 3 & Dr Herron T-29-11-12 p.154 line 21

⁴⁶⁵ 090-003-003 *et seq*

is for a wrongly stated ‘fact’ to become validated by the process of repetition. It also introduced fresh error. Mr Roberts has indicated that the summary in Claire’s autopsy report is inaccurate in that:

- (i) It was wrong to state Claire was well until 72 hours before admission because she was well when she went to school on 21st October and it was only thereafter that she was noted to be unwell.⁴⁶⁶
- (ii) Claire’s cousin had a slight tummy upset, not the vomiting and diarrhoea as stated.⁴⁶⁷
- (iii) Claire did not have the same symptoms as her cousin nor the history of recent diarrhoea as noted. She did have one loose bowel movement but that was on the Friday.⁴⁶⁸
- (iv) Claire did not start to vomit 24 hours before admission; in fact, she did not start to vomit until 21st October.⁴⁶⁹
- (v) Claire did not have any seizures on 20th October.⁴⁷⁰

3.229 Nor, it should be emphasised, did Claire have the “*h/o epileptic seizures since 10 months of age*” as stated. Dr Squier was concerned with the comment that Claire had “*iatrogenic epilepsy since 10 months*”⁴⁷¹ as there was no evidence that she suffered any convulsions after the age of four (and her convulsions began at six months, not ten).⁴⁷² In addition, obvious error appears in the autopsy report revealing how little attention can have been paid to Claire’s medical chart. For example, the dates of admission and time of death are both incorrectly stated⁴⁷³ and no reference is made to Claire’s medication with midazolam.

⁴⁶⁶ WS-253-1 p.19

⁴⁶⁷ 091-003-004

⁴⁶⁸ WS-253-1 p.3

⁴⁶⁹ WS-253-1 p.3

⁴⁷⁰ 091-003-004 & 091-005-016

⁴⁷¹ 091-005-016

⁴⁷² 090-015-026

⁴⁷³ 090-022-050 to 061

- 3.230 Given that the autopsy was performed, in Dr Herron's words - *"to address the presence or absence of status epilepticus and encephalitis"*⁴⁷⁴ the erroneous introduction of an incorrect clinical history of diarrhoea and epilepsy is of concern. There can have been no check of the medical records against the 'Autopsy Report Form' and no discussion with the clinicians. It must be the responsibility of pathologists to gain familiarity with the case, satisfy themselves as to the information supplied and to seek assistance if necessary. Further, it should be the duty of the person preparing the report to sign it in order to confirm finality and authorship.⁴⁷⁵
- 3.231 The important part of the report is headed "comment" and states *"In summary, the features here are those of cerebral oedema with neuronal migrational defect and a low grade subacute meningoencephalitis [sic]. No other discrete lesion has been identified to explain epileptic seizures. The reaction in the meninges and cortex is suggestive of a viral aetiology, though some viral studies were negative during life and on post-mortem CSF. With the clinical history of diarrhoea and vomiting, this is a possibility though a metabolic cause cannot be entirely excluded. As this was a brain only autopsy, it is not possible to comment on other systemic pathology in the general organs. No other structural lesion in the brain like corpus callosal or other malformations were identified."*⁴⁷⁶
- 3.232 In the absence of any meaningful discussion between pathologist and clinician, the reference to *"low grade subacute menin[g]oencephalitis"* is susceptible to misinterpretation. Drs Herron and Mirakhur were clear in their evidence that even on their interpretation of the results; they could not say that Claire had encephalitis, much less that it contributed to her death.⁴⁷⁷ The Inquiry experts queried whether there was any evidence of encephalitis at all and are firm in their view that it definitely did not contribute

⁴⁷⁴ WS-224-1 p.7

⁴⁷⁵ 236-007-056

⁴⁷⁶ 090-003-005

⁴⁷⁷ Dr Mirakhur T-30-11-12 p.138 line 18 & Dr Heron T-29-11-12 p.146 line 3

to death. Professor Lucas's interpretation of "*low grade*" was that it meant that it was not at all clear that encephalitis was present in Claire's brain.⁴⁷⁸

3.233 The question has arisen as to whether Drs Herron and Mirakhur drafted their autopsy report to obscure rather than inform. It would appear that:

- (i) They introduced erroneous clinical information into their Report suggesting a possible viral aetiology.
- (ii) They produced a potentially misleading conclusion by way of comment suggestive of encephalitis.
- (iii) They do not appear to have carried out the usual tests for the diagnosis of encephalitis.
- (iv) They did not attempt to explain the causation of the cerebral oedema or to have sought specialist opinion in that regard.
- (v) They do not appear to have read the medical chart or taken any steps to satisfy themselves as to the information they were given.
- (vi) They do not appear to have asked for discussion or clarification at any time to ensure that a full and accurate account had been obtained.
- (vii) They failed to take any steps to review the case with the clinicians in the light of their examination.
- (viii) They were slow to produce the Report, denying it the topicality which might have made audit more likely.
- (ix) They failed to sign the Report.
- (x) They experienced difficulty in attributing authorship of the report as and between themselves.

⁴⁷⁸ 239-002-012

- (xi) They failed to send a copy of the Report to the family GP.
- (xii) Notwithstanding their uncertainty as to the cause of an unexpected child death, they did not refer the matter to the Coroner.

3.234 Whilst their report does not compare favourably with that produced by Dr Armour⁴⁷⁹ in Adam Strain's rather more complex case, it must be acknowledged that none of the Experts doubted their motivation. Whilst mild criticism was expressed about shortcomings in the autopsy report, Professor Lucas considered that the report broadly followed the 1993 Royal College of Pathologists Guidelines for Post-Mortem Reports.⁴⁸⁰ He did however; identify the lack of clinico-pathological correlation as a major shortcoming and the one which would have allowed the further discussion and review which was so very necessary.

Clinico-pathological discussion and audit presentation

- 3.235 All the pathology witnesses agreed that after the preparation of a preliminary report, it is important for the pathologist and the clinicians to meet, especially in a case such as Claire's where only limited insight has been gained into the cause of death.⁴⁸¹ Unless and until there is such a meeting, it is unlikely that there can be any satisfactory explanation as to causation such as might be given the parents.
- 3.236 The consensus of expert opinion was, that at that time and on the basis of what was known and the low sodium reading, the only conclusion that could have been reached with any confidence was that Claire had suffered hyponatraemia and that had caused her cerebral oedema. Beyond that there was no clear explanation as to the cause of death, save to say that it was not encephalitis. Nor could the pathologists confirm that the cause was SIADH, although that was a plausible cause of the hyponatraemia.

⁴⁷⁹ 303-001-001

⁴⁸⁰ 306-072-001

⁴⁸¹ Dr Herron T-29-11-12 p.17 line 2 & Dr Mirakhur T-30-11-12 p.44 line 7

Professor Harding also believed that one could suggest some form of encephalopathy but not much more.⁴⁸²

3.237 In such circumstances, it is striking that the clinicians do not appear to have made any response whatsoever in follow-up to the autopsy report. I was told that the report was sent to both Drs Steen and Webb but neither pathologist could remember any contact from these doctors afterwards. What happened instead was that Dr Steen wrote to the family GP and Dr Webb wrote to Mr and Mrs Roberts. The autopsy report was sent to neither.

3.238 In this context it should be stated that Dr McKaigue recalled Dr Steen presenting Claire's case for discussion at an audit meeting but could not remember any lessons being learned. Nor could he recall who was there or whether the autopsy report was available.⁴⁸³ Whilst this may be accurate, it may also be quite mistaken because Drs O'Hare,⁴⁸⁴ Webb,⁴⁸⁵ Sands,⁴⁸⁶ and Bartholome⁴⁸⁷ could not remember and Dr Steen could not help on the issue.⁴⁸⁸ If such a meeting was held, it cannot possibly have been with either Dr Mirakhur or Dr Herron in attendance, because either of them could have corrected the impression given by their autopsy report that encephalitis had contributed to Claire's death. If Dr Steen did make an audit presentation and nothing was learned, one has to question the value of such a meeting. There is no other evidence that Claire's case was subject to audit or review and correspondence from the Directorate of Legal Services ('DLS') suggests that no such meeting took place.⁴⁸⁹

3.239 I can only conclude that these responses to Claire's death reveal, even on the most charitable interpretation, a want of curiosity about why Claire died

⁴⁸² Professor Harding T-05-12-12 p.167 line 8

⁴⁸³ Dr McKaigue T-12-12-12 p.40 line 4

⁴⁸⁴ Dr O'Hare T-18-10-12 p.184 line 19

⁴⁸⁵ Dr Webb T-03-12-12 p.273 line 23

⁴⁸⁶ Dr Sands T-18-12-12 p.151 line 1

⁴⁸⁷ Dr Bartholome T-18-10-12 p.97 line 23

⁴⁸⁸ Dr Steen T-17-12-12 p.15 line 4

⁴⁸⁹ 302-075b-001. Dr McKaigue's claim echoes his "*vague memory that Dr Hanrahan presented Lucy Crawford's case at an audit meeting*" (WS-302-3 p.3) which proved unfounded. (Dr Hanrahan T-05-06-13 p.225 line 13 *et seq*)

and a lack of determination to identify the cause of her death and discover if things could be improved for the future.

Correspondence relating to autopsy report

3.240 Dr Steen wrote on 6th March 1997 to the Roberts family GP as follows:

*“Claire’s post-mortem results are now available. The cerebral tissue showed abnormal neuronal migration, a problem which occurs usually during the second trimester of pregnancy and would explain Claire’s learning difficulties. Other changes where [sic] in keeping with a viral encephalomyelitis meningitis. Doctor Webb and myself have since seen Claire’s parents and discussed the post-mortem findings with them. They are obviously both finding this an extremely difficult and traumatic time but do not want any further professional counselling at present, however they know our doors [are] open and we will be happy to see them if they want to discuss things further with ourselves. Mr Roberts wanted a short summary of the post-mortem report which Dr Webb will send to him shortly. If there are any concerns at all please do not hesitate to contact us.”*⁴⁹⁰

3.241 Dr Webb wrote on 21st March 1997 to Mr and Mrs Roberts as follows:

*“My sincere condolences after the loss of your daughter Claire. In summary the findings were of swelling of the brain with evidence of a developmental brain abnormality (neuronal migration defect) and a low grade infection (meningoencephalitis). The reaction in the covering of the brain (meninges) and the brain itself (cortex) is suggestive of a viral cause. The clinical history of diarrhoea and vomiting would be in keeping with that. As this was a brain only autopsy it is not possible to comment on other abnormalities in the general organs. No other structural abnormality in the brain has been identified.”*⁴⁹¹

⁴⁹⁰ 090-002-002

⁴⁹¹ 090-001-001

3.242 Both letters suggest that Claire's death was caused by encephalitis. Such a suggestion is a misleading interpretation of the autopsy report and on the evidence before me is clearly wrong. Any discussion between the doctors and the pathologists would have confirmed that. Furthermore, status epilepticus, which is the only entry apart from cerebral oedema on the death certificate issued by Dr Steen, is entirely omitted from these explanations given to the family and their GP. This suggests that, rather than add their clinical expertise and assessment to the information provided by the pathologists, Drs Steen and Webb decided to abandon their previous analysis in order to rely solely on a highly suspect interpretation of the post-mortem report. Their letters make absolutely no reference to hyponatraemia nor how it may have played a part in Claire's death. In addition, for Drs Steen and Webb to so pointedly omit all reference to those expressions of uncertainty contained in the autopsy report suggests that they were keenly aware of those issues. Again, this was an opportunity to report Claire's death to the Coroner and for that very reason. Again, these doctors failed in their duty.

Meeting with Mr and Mrs Roberts

3.243 Drs Steen and Webb met Mr and Mrs Roberts in March 1997 after the autopsy report had been released. The report was not shared with them. Mr Roberts recalled being told that Claire's death had been caused by a virus but that it could not be said which.⁴⁹² Mrs Roberts recalls leaving the meeting deflated because they still knew so little and could not understand how a virus could have taken Claire so quickly.⁴⁹³ It was, however, a source of comfort to her and her husband that Dr Steen had said that everything possible had been done for Claire.⁴⁹⁴ That was false comfort. No one could possibly look at what happened and say that everything possible had been done.

⁴⁹² WS-253-1 p.17

⁴⁹³ Mr and Mrs Roberts T-13-12-12 p.86

⁴⁹⁴ WS-253-1 p.17

3.244 If Claire's parents are correct, they were not properly informed as to the cause of death, the autopsy report was misrepresented and information about hyponatraemia was withheld. There was no record made of the meeting and Dr Steen cannot remember what was said but has stated "*I think the low sodium was mentioned to Claire's family. We didn't use the word 'hyponatraemia' and we don't particularly now.*"⁴⁹⁵ I prefer the account given by Mr and Mrs Roberts because it appears consistent with the letters written by Dr Steen and Dr Webb. Mr and Mrs Roberts were denied that which was their right, namely basic information about the reasons for their daughter's death. Dr Steen and Dr Webb failed in their duty to inform.

Dr Steen

3.245 The evidence relating to the procedural steps taken after Claire's death by the doctors in the hospital reveals how Dr Steen in particular appeared to take the lead at each stage. She acted without apparent interference from colleagues or management control. That a lone doctor was able to administratively process an unexpected and problematic death without supervision or second opinion and so shield it from proper inquiry must be a matter for concern.

3.246 Dr Steen was able to:

- (i) Decide against referring Claire's death to the Coroner and to enter this decision in the 'Diagnosis of Brain Death' form without the formal collaboration of Dr Webb, her co-signatory, or opposition from Drs Webb, McKaigue or Taylor.⁴⁹⁶
- (ii) Enter a cause of death in the 'Medical Certificate of Cause of Death' without reference to hyponatraemia, which was a known and probable factor in the death and to cite instead the unproven status epilepticus.

⁴⁹⁵ Dr Steen T-17-10-12 p.122 line 22

⁴⁹⁶ 090-045-148

- (iii) Inform Mr and Mrs Roberts that a virus was the likely cause of Claire's brain swelling, without reference to hyponatraemia or the other matters, which might properly have described the problems in treatment.⁴⁹⁷
- (iv) Complete the 'Autopsy Request Form' so as to communicate an incorrect history of illness, give emphasis to an inaccurate background of viral infection, minimise the period of hospitalisation, omit reference to the overdose of midazolam and fail to list the known hyponatraemia as one of the four main clinical problems.⁴⁹⁸
- (v) Fail to make any report of the death or the circumstances of death to the paediatric clinical lead, the medical director, the director of nursing or any other governance representative of the Trust.
- (vi) Fail to liaise with the pathologists in relation to the autopsy report, whether to correct known error or to clarify opinion.
- (vii) Fail to investigate, review or, in all probability, present or discuss Claire's case at a mortality meeting, grand round or other opportunity.
- (viii) Fail to review her decision not to refer to the Coroner in the light of the autopsy report and the continuing lack of certainty in relation to cause of death.
- (ix) Meet with Mr and Mrs Roberts (with Dr Webb) and fail to explain the true import of the autopsy report and to once again propose a viral cause for death.⁴⁹⁹
- (x) Write to Mr and Mrs Roberts in similar terms so as to mislead and yet again deny them the information to which they were entitled.⁵⁰⁰

⁴⁹⁷ WS-253-1 p.15

⁴⁹⁸ 090-054-183 to 184

⁴⁹⁹ WS-253-1 p.17

⁵⁰⁰ 090-004-006

- (xi) Fail to keep any note or record detailing what was said to Mr and Mrs Roberts.

- 3.247 Such singular response to Claire's death is very hard to explain on any other basis than that Dr Steen set out to conceal what she knew about the likely cause of Claire's death.
- 3.248 To that extent, I am persuaded that a 'cover up' was attempted by Dr Steen and to the extent indicated above, by Dr Webb. However, I do not consider that the Trust was complicit in any such attempt. Indeed, it is to be noted that Claire's discharge from PICU was documented as being a death from, amongst other causes, hyponatraemia. That was communicated within days to Claire's own family GP. Her condition, correctly diagnosed as including hyponatraemia, was clinically coded and recorded by the Trust and made available for reference and research. None of the directors of the Trust had any knowledge of her death. Such circumstances cannot be said to reflect a 'cover up' by the Trust.

Events in 2004

Mr and Mrs Roberts seek a meeting

- 3.249 In 2004, the UTV documentary rekindled Mr and Mrs Roberts' anguish and their memories of events in the Children's Hospital. They watched the programme on 21st October. It focussed on hyponatraemia and the deaths of Adam, Lucy and Raychel. They were prompted to ring the Children's Hospital the next day. They received a return call from Dr Nicola Rooney⁵⁰¹ with whom they met on 25th October.
- 3.250 Dr (now Professor) Rooney is a clinical psychologist who was, in 2004, the Psychology Service Manager in the Royal Group of Hospitals. It had been decided in advance of the broadcast that she would take the lead in responding to any enquiries generated by the programme. This was a helpful and well-conceived plan. It ensured that families who made contact

⁵⁰¹ 310-023-003

had an experienced and senior professional available to them. She, in turn, had the standing within the Trust to help families gain the information they needed. She also had significant experience in working with bereaved parents.⁵⁰²

3.251 Dr Rooney made a note of their meeting on 25th October which, it has been agreed, is accurate.⁵⁰³ It records that Mr and Mrs Roberts outlined the circumstances of Claire's admission to the hospital and her death. Dr Rooney was struck by their description of how they had gone home on the Tuesday evening, thinking that Claire's worst day was over, only to receive the completely unexpected call from the hospital at about 03:30 on Wednesday morning.⁵⁰⁴

3.252 She said, "*alarm bells rang for me when they said that they had left*" because she recognised that Mr and Mrs Roberts were not parents who would have left their daughter had they known how serious her condition was.⁵⁰⁵

3.253 Dr Rooney's plan to follow up on the meeting was set out in her contemporaneous note:

"? Deterioration - ? Misdiagnosed

? Role of fluid management in her deterioration

Action: I will order Medical Notes✓

Discuss with M.McBride and H.Steen✓

Do PT journey✓

? Fluid mgt

*Will liaise with Mr & Mrs Roberts."*⁵⁰⁶

⁵⁰² WS-177-1 p.5

⁵⁰³ WS-177-1 p.14-17

⁵⁰⁴ Dr Rooney T-13-12-12 p.15 line 21

⁵⁰⁵ Dr Rooney T-13-12-12 p.15 line 21

⁵⁰⁶ WS-177-1 p.17

Involvement of Professor Young

- 3.254 Dr Rooney proceeded to brief Dr Michael McBride,⁵⁰⁷ the Medical Director.⁵⁰⁸ He in turn emailed Dr Steen and asked her to review the notes with the proviso that *"If there is any reason to suggest that fluid and electrolyte management may have been a factor in this case, then I would suggest that you ask Peter Crean as the Clinical Governance Lead, Prof Ian Young, Elaine and Brenda Creaney to carry out a case note review to determine whether this case needs to be referred to the Coroner."*⁵⁰⁹
- 3.255 Dr McBride's suggestion that a multi-disciplinary group perform a case note review was both sensible and timely. In the event, it seems Dr Steen did not involve those individuals but enlisted Dr Sands to assist. Dr McBride did not pursue his proposal for more formalised review but requested that Professor Ian Young,⁵¹⁰ Consultant in Clinical Biochemistry,⁵¹¹ review the records and advise as to whether hyponatraemia and fluid balance could have played a part in Claire's death.⁵¹² Professor Young held joint appointments as an academic at Queen's University, Belfast and as a clinician with the Royal Group of Hospitals Trust ('RGHT'). He was eminently well-qualified to advise on this issue having significant expertise in hyponatraemia.
- 3.256 An issue arose about Professor Young's independence because he was described to Mr and Mrs Roberts as being independent of the Trust. That was not correct in the sense that a person who is employed by a Trust cannot be regarded as being independent of that Trust. However, Professor Young was independent in the sense that he had no engagement with the Children's Hospital, had not been involved in Claire's care and had no previous involvement with the clinical team.

⁵⁰⁷ 310-023-004

⁵⁰⁸ WS-177-1 p.54

⁵⁰⁹ WS-177-1 p.54

⁵¹⁰ 310-023-003

⁵¹¹ Also known as Chemical Pathology

⁵¹² Professor Young T-10-12-12 p.63 line 10

3.257 More importantly, he demonstrated his independence at that stage by advising Dr McBride that hyponatraemia may have made a significant contribution to Claire's death.⁵¹³ He said that it did not take him long, maybe not even an hour, to reach this conclusion having reviewed the notes.⁵¹⁴

3.258 On 6th December 2004, there was an 08:30 meeting between Dr McBride, Professor Young and Dr Rooney to discuss the role of fluid management in Claire's death.⁵¹⁵ By that stage, Dr McBride had read Claire's medical records.⁵¹⁶ Later, at 14:00, Professor Young and Dr Rooney met Dr Steen. Professor Young gave Dr Steen his opinion. He reported that her views on fluid management were rather different to his and that she would only acknowledge as a possibility the relevance of hyponatraemia. She maintained that status epilepticus and viral encephalitis were more likely to have been the significant causes.⁵¹⁷ At that point, the only option was to finally notify the Coroner of Claire's death. That step was however, delayed until they could speak with Mr and Mrs Roberts.

Meeting with Mr and Mrs Roberts

3.259 On 7th December, a meeting was arranged for Mr and Mrs Roberts with Drs Steen, Sands and Rooney, and Professor Young. I make the following points about that meeting:

- (i) Professor Young said that he would have preferred to have met the Roberts family alone. That was because his role was limited to the issues of fluid management and the question of whether hyponatraemia was a factor in Claire's death. He was to have no input into discussions about Claire's "*clinical journey*."⁵¹⁸
- (ii) It appears that a view was taken, that on balance, it might be better for Claire's parents to have a single stressful meeting with Professor

⁵¹³ 089-005-010
⁵¹⁴ Professor Young T-10-12-12 p.59 line 11
⁵¹⁵ WS-269-1 p.20
⁵¹⁶ 302-007-002
⁵¹⁷ Professor Young T-10-12-12 p.74 line 2
⁵¹⁸ 139-153-001

Young and the treating clinicians rather than separate stressful meetings.⁵¹⁹ I accept the legitimacy of that view.

- (iii) There is no reference in the minute of the meeting to the drug overdoses or the content of the medical record or autopsy report.⁵²⁰ Nor was any reference made to the inconsistency between Dr Steen's 'Medical Certificate of Cause of Death' citing status epilepticus and the letters from Drs Steen and Webb suggesting a viral cause for the death.
- (iv) There was no governance representation by or on behalf of Dr McBride or Dr Peter Crean,⁵²¹ the Clinical Governance Lead.

3.260 However, my main concern about the meeting is that there was no acknowledgement of any of the very many failings in care. In advance of the meeting, Dr Steen had taken time to prepare a document detailing Claire's treatment. That suggests that she had reviewed Claire's case and looked at it afresh. Any analysis of Claire's treatment would have revealed that she was not seen by a doctor between 23:30 on 22nd October and 03:00 on 23rd October. That was not mentioned to Mr and Mrs Roberts on 7th December 2004 any more than it was mentioned to them on 23rd October 1996. Moreover, whilst Dr Steen was able to tell this Inquiry that "*the minute we looked back at the case in 2004, in light of what we knew by 2004, it became very obvious that fluid mismanagement was a contributory factor to her underlying condition,*"⁵²² there was no acknowledgment at the meeting that Claire should have had a repeat blood test on the morning of 23rd October, even though Professor Young was already of the opinion that the "*monitoring of serum electrolytes did not occur with sufficient frequency given the severity of Claire's clinical condition.*"⁵²³ Dr Steen persisted with her explanation that "*viruses known as enterovirus can enter the body via*

⁵¹⁹ Professor Young T-10-12-12 p.71 line 15

⁵²⁰ 089-002-002

⁵²¹ 310-023-002

⁵²² Dr Steen T-17-10-12 p.143 line 15

⁵²³ WS-178-1 p.6

*the stomach and then cause swelling of the brain.*⁵²⁴ Furthermore, it was not even conceded (as queried by Claire's parents) that they should have been alerted to the seriousness of her condition before they left the hospital on Tuesday night. There are more examples but they all illustrate a lack of openness, especially on the part of Dr Steen.

3.261 That this was a very serious breach of duty and good faith becomes even more obvious when one considers that at that point Claire's death was about to be referred to the Coroner and Mr and Mrs Roberts had already indicated that they wished it referred to this Inquiry (which had been started some weeks before).

3.262 The Roberts' response to the meeting was a request for more information and answers to 10 specific questions.⁵²⁵ Their queries included issues such as:

- (i) The identity of the doctor co-ordinating Claire's treatment after 23:00.
- (ii) Why Claire's death was not reported to the Coroner.
- (iii) Why they were not told how ill Claire was.

They also raised detailed queries about fluid management, which showed how alert they were to this aspect of care. (In his evidence, Professor Young commented that when he saw this list he was amazed at how much they had taken in at the meeting).⁵²⁶ Their letter confirmed that they wished both the Coroner and this Inquiry to investigate Claire's death.

3.263 Formal notification of Claire's death was made to the Coroner on 16th December 2004.⁵²⁷ On 17th December 2004, Dr McBride wrote to Mr and Mrs Roberts "*Our medical case note review has suggested that there may have been a care management problem in relation to hyponatraemia and this may have significantly contributed to Claire's deterioration and*

⁵²⁴ WS-177-1 p.59

⁵²⁵ 089-003-006 to 007

⁵²⁶ Professor Young T-10-12-12 p.103 line 25

⁵²⁷ 140-074-001

death."⁵²⁸ (In this context "*care management problem*" is defined as "*actions or omissions by staff in the process of care.*")⁵²⁹

3.264 Dr Rooney then circulated the questions posed by Mr and Mrs Roberts to Professor Young, Mr Peter Walby⁵³⁰ of the Trust Litigation Office and Drs Steen, Sands and McBride.⁵³¹ On 12th January 2005, the Trust wrote to make its formal response to Mr and Mrs Roberts.⁵³² Although the letter was issued in Dr Rooney's name, it must largely have been the work of Dr Steen with contributions from Professor Young.⁵³³ Unfortunately, some of the content is highly questionable:

- (i) It states that the death was not referred to the Coroner in 1994 because the death was believed to be from viral encephalitis whereas and in fact the death certificate issued cited cerebral oedema secondary to status epilepticus.
- (ii) It wrongly claims that a diagnosis of encephalitis was confirmed at post-mortem.
- (iii) It asserts that Dr Bartholome co-ordinated Claire's treatment after 23:00 whereas she did not actually attend upon her until 03:00 by which time it was too late.
- (iv) It ignores other matters completely e.g. it simply did not address the question as to why Mr and Mrs Roberts had not been told how ill Claire was on the Tuesday evening in consequence of which they left her.

3.265 The letter was inaccurate, evasive and unreliable. To make matters worse, it was not only sent to Mr and Mrs Roberts but was also forwarded to the Coroner⁵³⁴ who must have assumed that it represented the Trust's

⁵²⁸ 089-005-010
⁵²⁹ WS-061-1 p.4
⁵³⁰ 310-023-003
⁵³¹ WS-177-1 p.45
⁵³² 089-006-012
⁵³³ 139-139-001
⁵³⁴ 090-048-152

considered assessment of the issues he was to investigate. Whilst Dr Rooney was well qualified to liaise with the Roberts family, she was not at all qualified to sign the 12th January letter. It should have been the work of an informed clinician. In this context, Dr Steen had responsibility in relation to the 'care management problem' and could not therefore have been the author of the letter, Professor Young was supposed to be independent of the hospital and it would have been inappropriate for the letter to come from the Litigation Management Office. Accordingly, more thought should have been given to the identity of the hospital representative taking responsibility for the content of this important letter and indeed, because of his personal involvement and earlier correspondence, Dr McBride should have signed the letter himself.

Other Trust responses

3.266 I think it relevant to make the following further observations about what was and what was not done in the Trust in 2004/5:

- (i) The initial responses of Dr McBride and Dr Rooney were in my view, both appropriate and effective for handling enquiries from the public. My criticism about what the family was told or not told is largely directed at Dr Steen. I am entirely satisfied that not only did she know more than she was prepared to disclose but that she actively misrepresented matters to the family.
- (ii) Furthermore, Dr Steen was permitted to make the initial case note review and influence the format of subsequent review, notwithstanding that Dr McBride recognised the possibility that the acts and omissions of clinicians contributed to Claire's death. His failure to insist upon his initial suggestion of multi-professional involvement was regrettable. The consequent case review, meeting with family, and letter of explanation were all undermined by a narrowness of focus and the views of Dr Steen. Had Dr McBride directed a broader review then Claire's parents might have received

better answers to their questions and the Coroner might have been more accurately informed as to the issues.

- (iii) DHSSPS guidance was available to Dr McBride in 'Reporting and Follow-Up on Serious Adverse Incidents', ⁵³⁵ which very clearly advised that *"In those situations where a body considers that an independent review is appropriate, it is important that those who will be conducting it are seen to be completely independent. In addition such reviews should normally be conducted by a multi-professional team, rather than by one individual. It is also important that the Department is made aware of the review at the outset."*⁵³⁶
- (iv) The question arises as to whether the Trust should have instigated its own belated review of what had happened by activating its recently introduced procedures for the investigation of adverse clinical incidents by root-cause analysis?⁵³⁷ In normal circumstances, the clear answer to this question would be yes. However, Mr and Mrs Roberts were anxious for this Inquiry to investigate Claire's death in the same way that it was intended it should investigate the deaths of other children. Dr McBride's evidence was that he decided against an adverse incident review within the Trust because of the likelihood of this Inquiry investigating Claire's case.⁵³⁸ Notwithstanding that he might otherwise have become better informed as to the issues, I do not think that it is fair to criticise that decision, any more than it is fair to criticise the Trust for a delay in formally reporting Claire's case to the Department when the Coroner and this Inquiry had already become involved.

Inquest preliminaries

3.267 Claire's inquest was held in May 2006. The Trust had 17 months from the date of referral to prepare for it. There are aspects of the preparation which

⁵³⁵ 314-009-001 - Circular HSS (PPM) 06/04

⁵³⁶ 314-009-004

⁵³⁷ 302-096-004

⁵³⁸ WS-061-2 p.422

concern me. Witness statements were gathered by Mr Walby who had become an associate medical director in the Litigation Management Office of the Trust in 1998 upon the retirement of Dr George Murnaghan. He was a consultant ENT surgeon who assumed the hospital litigation management work in addition to his full-time clinical duties. The witness statements obtained by him were intended to form the basis of the formal inquest depositions. They were transcribed by Mr Walby's office onto Police Service of Northern Ireland ('PSNI') pro-forma witness statement sheets and then forwarded to the Coroner. The impression thus given was that the PSNI had been involved in obtaining them. Not only had the Police not been involved but the Trust was actually opposed to the closer involvement of the police in hospital inquests.⁵³⁹ It is for the Coronial Service to decide how to take this issue forward but I note that in autumn 2003, a person described by HM Coroner Mr John Leckey as a senior detective had expressed concern about the very limited role of the police in the investigation of hospital deaths.⁵⁴⁰ I share that concern.

3.268 This leads to a second issue. One of the witness statements came from Dr Webb who was, at that time, working in Dublin. Dr Webb made the following concession in the statement he sent to Mr Walby: *"I made the mistake of not seeking an Intensive Care placement for Claire before I left the hospital on the evening of October 22nd..."*⁵⁴¹ In response Mr Walby deleted that part of the statement which referred to the *"mistake"* and returned it to Dr Webb⁵⁴² with the suggestion that it should read as follows: *"Although I did not seek an intensive care placement for Claire before I left the hospital on the evening of October 22 ..."*⁵⁴³

3.269 Mr Walby's suggested alternate wording was accepted by Dr Webb and became part of his formal deposition which was transcribed onto police paper and presented to the Coroner, who did not see the original

⁵³⁹ 129-006-001

⁵⁴⁰ 129-007-001

⁵⁴¹ 139-098-021

⁵⁴² 139-096-001

⁵⁴³ 139-098-021

statement.⁵⁴⁴ Mr Walby explained that he advanced his alternative to Dr Webb (who did not have to accept it) because, in his opinion, a witness statement should be factual and should not contain opinion or comment.⁵⁴⁵ This appears to me to be a difficult position to adopt. Dr Webb was not just an incidental witness to the death – he was both expert and the consultant paediatric neurologist who had been involved in the failed care of Claire.

3.270 Mr Walby said furthermore that he thought Dr Webb was being too harsh on himself.⁵⁴⁶ I do not share that opinion and do not think it for Mr Walby to judge. Since part of the purpose of an inquest is to identify things which have gone wrong so as to prevent recurrence, the Coroner is positively helped if an expert clinician suggests that treatment might have been better had he acted differently. I conclude that Mr Walby's intervention on this occasion was intended more to protect the Trust than to assist Dr Webb. It could not be said to have assisted the Coroner.

3.271 Mr Walby also provided the means whereby misleading information was supplied to the Coroner, namely Dr Rooney's letter.⁵⁴⁷ In addition, he forwarded a copy of the autopsy report to the Coroner, which also contained factual error originating from Dr Steen.⁵⁴⁸ Notwithstanding that Dr McBride took the view that a "*care management problem*" may have been implicated in Claire's death and that Dr Steen did not agree with this, Dr Steen was permitted to influence the information submitted to the Coroner and to edit and indeed approve Mr Walby's correspondence with the Coroner.⁵⁴⁹

3.272 There was potential for conflict between Mr Walby's job requirement, to "*assist H.M. Coroner with enquiries and the preparation of statements prior to inquests*" and at the same time to "*give advice and support to staff involved in... Coroner's cases.*"⁵⁵⁰ Mr Walby was in the unusually influential position where he could decide whether some witnesses provided

⁵⁴⁴ 139-095-001

⁵⁴⁵ Mr Walby T-12-12-12 p.133 line 2

⁵⁴⁶ Mr Walby T-12-12-12 p.134 line 12

⁵⁴⁷ 090-048-152

⁵⁴⁸ 089-004-008

⁵⁴⁹ WS-176-1 p.4 & 090-049-152 &139-148-001

⁵⁵⁰ WS-176-1 p.14

statements to the Coroner or not and furthermore where he could and did, edit, correct and partially redraft their statements.⁵⁵¹ He was so placed that he could protect the interests of the Trust at a time when his duty was first and foremost to assist the Coroner. The Trust should not have allowed the potential for such conflict to arise.

- 3.273 My general view on this issue was shared by the Coroner, Mr Leckey, who helpfully gave evidence. It was very clear from what he said, as it is from any analysis of the coronial process, that the public interest is protected if evidence is given frankly. He said that all clinical staff “*have to be totally transparent... not only for me exercising a judicial function, but for the bereaved family.*”⁵⁵² It is only in this way that a Coroner can properly analyse and understand a death such as Claire’s, help answer the questions of the bereaved and assist in the process of learning from experience. It is therefore a matter of critical importance that all proper assistance be given the Coroner with the utmost candour and that all hospital staff engaged in this process regard that as their paramount objective.

Inquest

- 3.274 Unfortunately, there is no formal transcript of the oral evidence given at inquest. However, such notes and minutes as do exist, strongly suggest that neither Professor Young, nor Drs Webb, Sands or Steen explained to the Coroner that Claire’s hyponatraemia was related to fluid or electrolyte mismanagement.⁵⁵³
- 3.275 The failure to repeat the initial blood test was an issue of mismanagement, which had to be addressed by the Trust. This was apparent during preparation for inquest. When the Litigation Management office sent witness statements to Professor Young (on 7th April 2006) for comment,⁵⁵⁴ he drew attention to what he termed “*substantial issues*” in Dr Webb’s

⁵⁵¹ 139-096-001 & 139-106-001

⁵⁵² Mr Leckey T-25-06-13 p.83 line 12

⁵⁵³ 140-043-007 & 097-012-110

⁵⁵⁴ 139-043-001

statement – namely his recognition that there had been a failure to take a routine electrolyte sample on the morning after admission and that it was indeed the hyponatraemia which had led to the cerebral oedema. Professor Young indicated that these issues “*could certainly become significant at the inquest*”⁵⁵⁵

3.276 In this connection, Dr Webb had specifically conceded in his statement to the Coroner that he had misunderstood the Monday night blood test as being a blood test from the Tuesday morning⁵⁵⁶ and that had he not so misunderstood it, he would have directed an urgent repeat blood test at about 14:00 on Tuesday. Professor Young agreed that this is indeed what should have been done⁵⁵⁷ and even Drs Steen and Sands were both to agree that the blood test should have been repeated long before Tuesday night.⁵⁵⁸

3.277 However, I find little evidence that Professor Young brought this matter to the attention of the Coroner. Instead and having agreed that Claire had the potential for electrolyte imbalance, he advised the Coroner that “*a blood sample every 24 hours would be good clinical practice.*”⁵⁵⁹

3.278 I consider that it was misleading to suggest to the Coroner that a blood sample once a day in such circumstances would have been good clinical practice.⁵⁶⁰ Notwithstanding the practice in other cases, it was not good clinical practice in the case of a child on low sodium intravenous fluids, with a neurological history, a low level of consciousness, a low sodium reading, an unknown fluid balance, and in circumstances where she was not responding to treatment.

3.279 Although Professor Young understood that his role was “*to assist on the key issues being drawn out at the Inquest.*”⁵⁶¹ there appear nonetheless to

⁵⁵⁵ 139-042-001

⁵⁵⁶ 139-098-020

⁵⁵⁷ Professor Young T-10-12-12 p.208 line 13

⁵⁵⁸ Dr Sands T-19-10-12 p.110 line 21 & Dr Steen T-17-12-12 p.11 line 5

⁵⁵⁹ 091-010-060

⁵⁶⁰ 140-043-007

⁵⁶¹ Professor Young T-10-12-12 p.205 line 25

be other examples where Professor Young failed to draw key issues to the attention of the Coroner. While the Medical Director, Dr McBride, informed Mr and Mrs Roberts that Professor Young's "*review has suggested that there may have been a care management problem in relation to hyponatraemia and that this may have significantly contributed to Claire's deterioration and death*"⁵⁶² Professor Young flatly denied contributing to this particular assertion⁵⁶³ and advised the Coroner that the death was not one which necessarily would have had to have been reported to the Coroner in 1996 because of a lack of awareness of hyponatraemia at that time.⁵⁶⁴ He told the inquest that he did not believe that there were lessons to be learned from Claire's case⁵⁶⁵ and gave further reassurance that Claire's fluid management was in keeping with the recommendations of 1996.⁵⁶⁶

- 3.280 In the light of this evidence,⁵⁶⁷ I am of the view that Professor Young shifted from his initial independent role advising Dr McBride to one of protecting the hospital and its doctors.

Inquest verdict

- 3.281 Claire's condition, diagnosis and treatment were not straightforward matters in October 1996. She had a history from earliest childhood of seizures and developmental delay. The cause of these has never been established. When she was admitted to hospital on 21st October her sodium level was only a little low at 132mmol/L. Hospital induced hyponatraemia from excessive administration of low sodium fluids was not the cause of that reading and as various experts, including Professor Neville pointed out, low sodium levels are a feature of neurological conditions.⁵⁶⁸ It was entirely reasonable for the admitting doctors to suspect status epilepticus and/or an encephalopathy such as encephalitis. The expert view was that these were perfectly rational differential diagnoses.

⁵⁶² 139-145-001

⁵⁶³ 097-012-113

⁵⁶⁴ 140-043-004 & 097-012-112

⁵⁶⁵ 097-012-112 & 140-045-004

⁵⁶⁶ 097-012-113

⁵⁶⁷ 140-043-003 *et seq*, 097-012-111 *et seq* & 091-010-060 *et seq*

⁵⁶⁸ Professor Neville T- 01-11-12 p.163

However, on the basis of the very much fuller evidence now available, I conclude that the only definite, known and proven causes of Claire's death were cerebral oedema due to hyponatraemia.

3.282 The inquest finding as to the cause of death was made in the following terms:

"1 (a) Cerebral oedema

Due to

*(b) meningo-encephalitis, hyponatraemia due to excess ADH production and status epilepticus."*⁵⁶⁹

On the evidence before me, I believe that finding is wrong.

3.283 It is certainly possible, if not probable, that Claire suffered from some form of encephalopathy but it does not appear to have been encephalitis and that cause of death cannot be advanced any further. It is noted that the Coroner's final formulation does not refer to encephalopathy but rather to meningoencephalitis. It is also possible that she suffered from status epilepticus but that likewise remains unproven.

3.284 In reaching this view, I have taken into consideration the evidence which the Coroner received from two additional experts; Dr Robert Bingham, Consultant Paediatric Anaesthetist at the Hospital for Sick Children, Great Ormond Street, London,⁵⁷⁰ and Dr Ian Maconochie, Consultant in Paediatric A&E medicine at St Mary's Hospital, London.⁵⁷¹ They both agreed to frame Claire's death in the following terms:

"I (a) cerebral oedema

(b) encephalitis/encephalopathy and hyponatraemia...

*II status epilepticus."*⁵⁷²

⁵⁶⁹ 091-002-002

⁵⁷⁰ 091-006-023

⁵⁷¹ 139-090-001

⁵⁷² 091-007-028

3.285 However, analysis of their evidence to the Coroner reveals uncertainty about what happened. It indicates that they were attempting to explain what might have happened as opposed to stating what was known to have happened. I understand that it is not so unusual for autopsies or inquests to end with only partial identification of the cause of death. This may be unwelcome and unsettling for the family, and that is unfortunate, but in Claire's case nothing further can be confirmed.

Internal response to inquest verdict

3.286 A further disturbing feature of this matter is that even after the inquest was completed and the Coroner had delivered his verdict and circulated his written finding, Mr Walby appeared keen to emphasise that there had been no criticism of the Trust's care of Claire. In an e-mail of 5th May 2006, he wrote:

*"This inquest ended on 4 May 2006 with no criticism of the Trust's care of this patient."*⁵⁷³

On 16th June 2006, he wrote to the Trust's then solicitor to state:

*"Evidence given at the inquest was not critical of the fluid management."*⁵⁷⁴

3.287 I do not believe that all of the many mistakes revealed to this Inquiry could possibly have come as a surprise to Drs Steen, Webb or Sands at the time of the inquest. Against such a background, Mr Walby's comments about the absence of criticism have a jarring note of satisfaction when he should have been deeply troubled by what had happened. Indeed, by that time he had already decided that the electrolyte management had been so mishandled that he would have to try to settle any claim brought against the Trust in negligence.⁵⁷⁵ He appears to have been more concerned with the interests and reputation of the Trust than with the lessons to be learned.

⁵⁷³ 139-163-001

⁵⁷⁴ 140-013-001

⁵⁷⁵ Mr Walby T-11-12-12 p.168 line 7

Governance: reporting Claire's death within the Trust

- 3.288 Dr Elaine Hicks⁵⁷⁶ had been appointed Paediatric Clinical Lead in the Children's Hospital on 1st October 1996.⁵⁷⁷ Her evidence was that she was not informed about Claire's death in 1996.⁵⁷⁸ Nor was the death reported to the Director of Nursing⁵⁷⁹ Miss Elizabeth Duffin⁵⁸⁰ or to the Director of Medical Administration Dr George Murnaghan, who then had charge of risk management.⁵⁸¹ Dr Ian Carson,⁵⁸² who was the Medical Director of the Trust in 1996, was similarly unaware of Claire's death.⁵⁸³ In his evidence to the Inquiry, he agreed that there was "*sufficient happening in Claire's case*"⁵⁸⁴ to mean that it should have been brought to the attention of the clinical director as a starting point. He agreed that the system "*did not do justice to Claire*"⁵⁸⁵ and that "*more could have been done and more should have been done.*"⁵⁸⁶ If it is correct, as I believe it to be, that few children die in the Children's Hospital, apart from those with terminal conditions, the failure to report Claire's death to Dr Hicks in particular, is impossible to comprehend unless there was a recognition that mistakes had been made and attention should not be drawn to them.
- 3.289 I am compelled to the view that clinicians did not admit to error for the obvious reasons of self-protection and that this defensiveness amounted to concealment and deceit. Such can have no place in the Health Service but appear nonetheless to have become established in this the regional paediatric training hospital.
- 3.290 The failure to report repeats in part what happened in Adam's case. The Director of Medical Administration, Dr Murnaghan, was aware of Adam's case and of the Coroner's damning conclusion delivered only months

⁵⁷⁶ 310-023-005
⁵⁷⁷ WS-264-1 p.2
⁵⁷⁸ Dr Hicks T-11-12-12 p.53 line 16
⁵⁷⁹ WS-265-1 p.3
⁵⁸⁰ 310-023-004
⁵⁸¹ WS-273-1 p.3
⁵⁸² 310-023-004
⁵⁸³ WS-270-1 p.3
⁵⁸⁴ Dr Carson T-15-01-13 p.151 line 67
⁵⁸⁵ Dr Carson T-15-01-13 p.151 line 15
⁵⁸⁶ Dr Carson T-16-01-13 p.11 line 23

before. Just as he took no steps to extract lessons from Adam's death, he took no steps to ensure that subsequent unexpected and unexplained deaths in the Children's Hospital were reported within the Trust.

3.291 Mr William McKee,⁵⁸⁷ who was, at the relevant time the Chief Executive of the Trust, acknowledged failings in Claire's case.⁵⁸⁸ Notwithstanding that he was unable to describe the duty of a clinician to report the sudden and unexpected death of a child patient at that time; he believed *"that it should have gone up the chain as far as the Medical Director."*⁵⁸⁹ He confirmed that no notification of her death was made to him but said that this did not surprise *"because of the predominance of clinical independence justified through the heavy, or almost entire, reliance on professional self-regulation. That was the dominant paramount culture at the time."*⁵⁹⁰

3.292 However, it appears that Mr McKee did little to lead clinicians away from their paramount culture of self-regulation, even so far as to ensure reporting to the Medical Director, or to encourage their acceptance of the structures of accountability around which the Trust purported to operate. In Claire's case, the clinicians were left to determine amongst themselves whether there had been mismanagement and if so, what they might do about it. In practical terms the lack of effective risk management controls meant that the Trust Board did not know what was happening in the Children's Hospital and had accordingly no effective means of satisfying itself that its patients were safe. I find that this was a failure in both leadership and governance.

3.293 The inclination not to draw attention to the shortcomings in Claire's case was encouraged by underdeveloped internal controls, poor leadership and the complicity of medical colleagues. This meant that lessons were not learned, poor standards were tolerated, the coronial system was undermined and grieving parents were misled.

⁵⁸⁷ 310-023-004

⁵⁸⁸ Mr McKee T-17-01-13 p.107 line 8

⁵⁸⁹ Mr McKee T-17-01-13 p.119 line 23

⁵⁹⁰ Mr McKee T-17-01-13 p.120 line 12

Adam Strain and Claire Roberts

- 3.294 Mr and Mrs Roberts were initially alerted to the possibility that Claire had been the victim of fluid mismanagement by the UTV investigative revelation of the similarities between the other deaths. Evidence has now revealed other similarities not then suspected.
- 3.295 Both Claire and Adam died in the same ward of the Children's Hospital within 11 months of each other. Some of the same doctors were on duty for each. Dr Taylor had involvement with both and Dr Webb carried out the final brain stem death tests. Trust risk management systems remained unchanged and the same individuals were responsible for 'governance' within the Trust.
- 3.296 Claire's admission to the hospital was only 4 months after Adam's inquest and at a time when the medical negligence claim relating to his treatment and death was ongoing. It might be supposed that Adam's death and the Coroner's very critical finding would have prompted reflection and debate about how to respond. Seemingly it did not. Even though the consultant paediatric anaesthetists now understood Professor Arieff's guidance and, possibly, as Dr Bartholome explained "*the events surrounding this inquest had been known to me and to most of the doctors in the Children's Hospital*"⁵⁹¹ there was no formal response by the doctors. Their inactivity went unnoticed by a Trust Board uninterested in learning from mistakes.
- 3.297 The failure of Drs Murnaghan and Carson to exploit the opportunity for learning, obvious from the tragic circumstances of Adam's death, had consequences not only for fluid therapy but also for the response of 'governance', which was allowed to repeat its earlier failings. In Claire's case, as in Adam's, there was significant failure to report, investigate or review. Those who should have been informed and involved were by-passed. Parents were not informed about the part played by sodium in the avoidable hospital deaths of their children. The performance of clinicians

⁵⁹¹ Dr Bartholome T-18-10-12 p.4 line 11

was not assessed, referrals were not made to the General Medical Council ('GMC') and patient safety was potentially jeopardised.

- 3.298 The question must be asked, how could hospital 'governance' within the Trust be so weak as to allow this to happen?

Governance 1995-96

- 3.299 It is to be emphasised that the failure of those doctors involved in the care of Claire and Adam to properly report, review or candidly advise the parents, was both individual and collective. Such basic aspects of professional practice were matters of common sense and well known to doctors. They were enshrined in the GMC code and the long-standing obligations of membership of professional bodies. The duty to refer a death to the Coroner was a matter of statute and the requirement to audit was often a contractual obligation.⁵⁹²
- 3.300 Professional guidelines at that time gave clear advice on many of the key areas of deficiency highlighted in Claire's case e.g. audit,⁵⁹³ record keeping,⁵⁹⁴ retention of medical records,⁵⁹⁵ communication between the clinician, nurse, parent, and pathologist,⁵⁹⁶ drug prescription checking,⁵⁹⁷ consultant responsibility, the organisation of cover for patients, inter-consultant handover arrangements and supervision of junior doctors,⁵⁹⁸ nursing accountability⁵⁹⁹ honesty in professional practice,⁶⁰⁰ reporting clinical performance jeopardising patient safety to employer or regulatory authority⁶⁰¹ etc. Similarly and at the time of Adam's case extant guidance

⁵⁹² WS-129-1 p.39

⁵⁹³ 314-001-004 'Good Medical Practice Guidelines for Doctors' General Medical Council, October 1995

⁵⁹⁴ 202-002-052 'Standards for Records and Record-Keeping' UKCC, April 1993

314-001-004 'Good Medical Practice Guidelines for Doctors' General Medical Council, October 1995

⁵⁹⁵ WS-251-1p.9 'Retention of Medical Records' Circular HSS (083) 1/83

⁵⁹⁶ 314-003-001 'Guidelines for Professional Practice' UKCC, 1996

314-001-006 'Good Medical Practice Guidelines for Doctors' General Medical Council, October 1995

239-002-014 'Guidelines for Post-Mortem Reports' Royal College of Pathologists, August 1993

⁵⁹⁷ 214-005-001 'Standards for the Administration of Medicines' UKCC, 1992

⁵⁹⁸ 314-001-001 *et seq* 'Good Medical Practice Guidelines for Doctors' General Medical Council, October 1995

⁵⁹⁹ 202-002-063 'Code of Professional Conduct' UKCC, June 1992

⁶⁰⁰ 314-001-012 'Good Medical Practice Guidelines for Doctors' General Medical Council, October 1995

⁶⁰¹ 314-001-009 'Good Medical Practice Guidelines for Doctors' General Medical Council, October 1995

was available to prompt the reporting⁶⁰² and investigation⁶⁰³ of his most unexpected death.

- 3.301 The failure to follow applicable guidance in Adam's case and in Claire's was a professional failure. Failure to regulate compliance with guidelines was a failure of both the clinician and the systems of internal control.

Weakness in systems of clinical risk management and internal control

- 3.302 The early 1990s was a period of significant restructuring of hospital management. A new beginning was intended and guidance became available promoting clinical risk management and quality control procedures to support the previously self-regulating clinician.⁶⁰⁴ Hospital governance was not therefore a new concept in 1996. However, it took longer for the Trust to engage with it than might have been expected and financial constraint slowed its introduction. Despite knowledge of what should be done⁶⁰⁵ and the introduction of formalised management structures, the development of functioning governance systems proved difficult. It was not seemingly a developed part of the control of services within the Children's Hospital at the time of Adam's admission. Although formal Trust publications and annual reports boasted of systems of governance control and quality assurance, the evidence before the Inquiry confirmed that the opposite was often the case.⁶⁰⁶ The Children's Hospital was subject to very weak governance control.

⁶⁰² 306-117-013

⁶⁰³ 314-016-010

⁶⁰⁴ E.g.

1989: 'Working for Patients: Medical Audit Working Paper 6' DoH (HMSO Cmd. 555)

1990: 'A Guide to Consent for Examination and Treatment' NHS Management Executive.

1991: 'Welfare of Children and Young People in Hospital' DoH (314-004-001)

1992: Northern Ireland- 'Charter for Patients and Clients' HPSS (306-085-001)

1993: 'Risk Management in the NHS' Manual (211-003-001)

1994: 'Allitt Inquiry' Report into Children's Ward at Grantham & Kesteven General Hospital NHS (210- 003-038)

1995: Northern Ireland 'Patient Consent Handbook' HPSS (306-058-002)

1996: 'Complaints. Listening... Acting...Improving - Guidance on Implementation of the HPSS Complaints Procedure' HPSS Executive (314-016-001)

⁶⁰⁵ Dr Carson T-15-01-13 p.126

⁶⁰⁶ Dr Murnaghan T-25-06-12 p.17-18 & Dr Murnaghan T-25-06-12 p.71 line 12

- 3.303 It is hard upon initial examination to understand how this could have been so, given that structures of responsibility and accountability were apparently in place, with governance committees and coordinators assigned to act within directorates led by clinical leads reporting to a medical director in turn accountable to the Trust Board and Chief Executive. The Board was committed to act within its 'Code of Conduct and Accountability'⁶⁰⁷ to *"provide active leadership of the organisation within a framework of prudent and effective controls to enable risk to be assessed and managed"* and its Chief Executive, Mr McKee was the principal accountable officer.
- 3.304 The Trust appeared outwardly confident at that time about its systems of quality control. The Royal Hospitals Annual Report 1993-1994 recorded the development of *"an effective organisational framework for medical audit which supports and encourages changes in clinical practice as a natural part of organisation-wide quality assurance."*⁶⁰⁸ The Trust mission statement proclaimed the *"fundamental purpose in the Royal Trusts [is] to provide the highest quality cost-effective healthcare... through exceptional service to our patients..."*⁶⁰⁹
- 3.305 The Trust even produced a Health and Safety Policy⁶¹⁰ in 1993 purporting to create a Medical Risk Management Group under the Chairmanship of the Medical Director. It was to have assumed specific responsibility for untoward incident reporting (clinical), clinical audit, complaints and medical negligence issues⁶¹¹ and to have been accountable to the Chief Executive and the Trust Board. Dr Murnaghan however, described the policy as *"aspirational."*⁶¹² In fact, the Group simply did not exist. Mr McKee wrote in his introduction to the policy that *"This Policy has my commitment and I expect all employees to give their commitment too."*⁶¹³ However, the evidence was that in this regard Mr McKee not only failed to give his

⁶⁰⁷ 210-003-009 and 'Codes of Conduct and Accountability' Circular HSS (PDD)8/1994, DHSS

⁶⁰⁸ WS-061-2 p.58

⁶⁰⁹ WS-061-2 p.26

⁶¹⁰ Approved by Hospital Council (WS-061-2 p.232)

⁶¹¹ WS-061-2 p.241

⁶¹² Dr Murnaghan T-25-06-12 p.71 line 12

⁶¹³ WS-061-2 p.235

commitment but failed also to encourage or ensure the commitment of others.

3.306 In 1995-96, the Trust made application to the Kings Fund Organisational Audit ('KFOA') for accreditation.⁶¹⁴ This allowed an opportunity to compare standards and systems with independent criteria. The Chief Executive personally oversaw the application⁶¹⁵ and the Director of Nursing personally managed it.⁶¹⁶ All concerned must thus have become familiar with the Kings Fund criteria, which covered a range of best practice from communication with patients and record keeping to adverse incident recording and audit.⁶¹⁷

3.307 The application to the Kings Fund did not succeed in 1995.⁶¹⁸ This does not surprise. Evidence was given that up-to-date governance guidance published in England was not felt to apply because it wasn't local,⁶¹⁹ the Northern Ireland patient consent guidance⁶²⁰ failed to 'cascade' to clinicians as directed,⁶²¹ the introduction of clinical guidelines in the Children's Hospital lagged behind that in England undermining attempts to audit by reason of a lack of agreed standards. There was no obligation to report adverse clinical incidents beyond choosing to make an entry in a book⁶²² and no mechanism to ensure serious matters were reported to the Medical Director or Chief Executive in line with extant recommendation.⁶²³ This was in a context where no obligation was felt by the newly created Trust to report any adverse clinical incident to the Department.⁶²⁴ The Trust Board dealt with administrative issues almost to the exclusion of patient matters. The Board minutes for November 1995 - December 1996 contain only two

⁶¹⁴ 305-001-001

⁶¹⁵ 305-008-560

⁶¹⁶ WS-061-2 p.8

⁶¹⁷ 211-003-024

⁶¹⁸ 305-001-001

⁶¹⁹ WS-061-2 p.7&14 & Mr McKee T-17-01-13 p.44 line 7 & p.51 line 5

⁶²⁰ 306-058-002

⁶²¹ Professor Savage - 18-04-12 p.65 to 66

⁶²² WS-061-2 p.168

⁶²³ 210-003-038: EL(94)16 'Report of the Independent Inquiry into Deaths on the Childrens' Ward at Grantham & Kesteven General Hospital' NHS Executive 1994 (the 'Allitt Inquiry') - *"There must be quick route to ensure that serious matters... are reported in writing to the Chief Executive of the hospital... NHS Trust Boards should take steps immediately to ensure such arrangements are in place."*

⁶²⁴ WS-061-1 p.2

references to specific clinical cases.⁶²⁵ Most disturbingly, the Chief Executive stated that he operated at that time on the basis that neither he nor the Trust Board had any responsibility for the quality of healthcare given to patients in the hospital.⁶²⁶

3.308 In this regard, evidence was received as to the responsibility of Trusts for the quality of hospital care at that time. The almost unanimous view, which I accept, is that Trusts were responsible for the quality of clinical care prior to the creation of a statutory duty of care under the Health and Personal Social Services Quality Improvement and Regulation (Northern Ireland) Order 2003.⁶²⁷ Indeed it is hard to understand how there could have been any confusion given the explicit advice provided to Trusts by the Management Executive that “*the primary accountability of Trusts*” to their commissioning Health Boards is for the “... *quality and efficiency of the service they provide.*”⁶²⁸

3.309 Financial constraint,⁶²⁹ a lack of appetite for change, the failure of political engagement⁶³⁰ and time limitations were all suggested as explanations for the failure to progress governance in the Trust. It must ultimately have been a matter of leadership. The primary focus of the Chief Executive’s leadership of the Trust was on financial and administrative issues. The clinical leadership on the Board, comprising the Medical Director, Dr Carson and the Director of Nursing and Patient Services, Miss Duffin failed to champion clinical issues and the primary obligation to the patient was left largely to the clinician to discharge. The care provided was not however properly audited and the outcomes were not reviewed. The situation therefore prevailed that those accountable for the provision of appropriate standards of care were often ignorant as to the quality of care actually

⁶²⁵ 305-016-012 & 305-016-084

⁶²⁶ Mr McKee T-17-01-13 p.48 line 7

⁶²⁷ <http://www.legislation.gov.uk/nisi/2003/431/contents/made>

⁶²⁸ WS-062-1 p.528

⁶²⁹ WS-077-2 p.8

⁶³⁰ Dr Carson T-15-01-13 p.127 line 25

provided. Unscrutinised, some doctors and nurses became defensive to criticism, protective of reputation and tolerant of less-than-best practice.

- 3.310 The failure to enforce prevailing guidance in 1996 suggests an institutional complacency. That recommendations on hospital risk management were not adopted earlier or brought to bear on hospital performance can be attributed to a failure within Trust leadership.
- 3.311 That failing was not however, limited to the 1990's. DHSSPSNI serious adverse incident investigation and reporting guidance was inadequately followed in 2004 when Claire's case was brought to the Trust's attention. This suggests that clinical governance had not even then become fully operational. Notwithstanding, the Annual Report 2004-05 claimed: *"In line with good governance and our commitment to openness and transparency, the Royal Hospitals acknowledges to patients and the public when things go wrong and systematically ascertains what happened, how it happened and why, so that we can do all that is possible to ensure lessons are learned to prevent a re-occurrence."*⁶³¹ Trust practice had yet to honour Trust claims.

Aftermath

Litigation

- 3.312 This Inquiry heard evidence relating to Claire's treatment and death between 24th September 2012 and 19th December 2012. As the evidence unfolded, the full extent of what had gone wrong emerged. When Mr and Mrs Roberts gave evidence on 13th December, they confirmed that they had not intended bringing a claim for medical negligence against the Trust.⁶³² All they wanted, they said, was for the doctors to admit that they had made mistakes. In the words of Mrs Roberts:

⁶³¹ 302-096-004

⁶³² Mr and Mrs Roberts T-13-12-12 p.143 line 2

“...everyone makes mistakes but all you have to do is hold your hands up.”⁶³³

3.313 It is difficult to appreciate the depth of dismay that the Roberts family must have felt by the end of the oral hearings. The revelation of the full scope of error and everything associated with those errors must have left them bewildered and suspicious about how so many clinicians and experts could have missed so much in 1995/96, during the 2004/05 investigation, at inquest and during the police investigation that followed.

3.314 I assume that there must then have been a re-appraisal by Mr and Mrs Roberts of their attitude towards litigation, because on 26th September 2013, their solicitors sent a letter of claim to the Trust.⁶³⁴ On 16th October, the Trust replied through the DLS to indicate that while the Trust could mount a defence on unspecified legal grounds, it did not intend to do so. Instead, the Trust's position was stated as follows:

“...We have obtained specific instructions from the Trust not to contest your clients' claim. The reason why this approach is being adopted is that the Trust acknowledges that there were shortcomings in the management of this patient and the Trust does not wish to in any way add to the distress of your clients by availing of any legitimate defences open to it in this action... Please also note that any offer of compensation in this case will be made in open correspondence as a means of demonstrating that the Trust is keen to deal with this matter in a wholly open and transparent manner.”⁶³⁵

3.315 This development was referred to at the public hearing the next day. On behalf of the Roberts family, Mr Stephen Quinn QC welcomed this public acknowledgement of failing and implied admission of liability together with the apology offered by the doctors and staff who had treated Claire.⁶³⁶

⁶³³ Mr and Mrs Roberts T-13-12-12 p.142 line 12

⁶³⁴ 302-185-003

⁶³⁵ 302-185-001

⁶³⁶ T-17-10-13 p.4 line 19

3.316 I consider that this was entirely the correct position for the Trust to adopt. I have to note however, that the preliminary remarks in the letter of 16th October contain the following unnecessary observations:

*"We note that the Roberts family now wish to make a claim for damages arising out of the death of their daughter. We note that the initiation of such a claim somewhat contradicts the earlier assertions of the family that they were not interested in claiming compensation but were only interested in getting at the truth."*⁶³⁷

3.317 The inclusion of such insinuation is regrettable. In all the circumstances of Claire's treatment and death and all that had ensued in the following years, those unnecessary observations were inappropriate and insensitive. On 12th November 2013, Mr Colm Donaghy, Chief Executive and Dr Anthony Stevens, Medical Director on behalf of the Belfast Health and Social Care Trust, (which incorporates the former RGHT), addressed the public hearings. Mr Donaghy commenced his opening statement by saying:

*"Let me begin by categorically stating that the Belfast Trust, on behalf of the former Royal Hospitals Trust, regrets most sincerely the pain and suffering experienced by the families of Adam Strain, Claire Roberts, Lucy Crawford, Raychel Ferguson and Conor Mitchell and apologises for all the shortcomings in care at the Royal Hospitals that have been identified either prior to this inquiry or during the hearings... The abject sorrow and grief felt by the families, I know, has not lessened with the passing of time. In fact, I fully accept that it is as raw today as it was then, exacerbated by the actions of the three Trusts involved."*⁶³⁸

3.318 Mr Donaghy then proceeded to acknowledge individual failings on the part of the Trust including the way in which the litigation had been handled. He said *"it is clear that... fluid management was poor... communication with the families was not sufficiently transparent, our medical and nursing staff missed the opportunity to reflect on what may have gone wrong... record*

⁶³⁷ 302-185-001

⁶³⁸ Mr Donaghy T-12-11-13 p.5 line 9-13

*keeping was incomplete and our governance was not sufficiently developed or robust. I also accept that reflective clinical practice and candour... was clearly missing.”*⁶³⁹ He further accepted that he was “... aware through this Inquiry that how litigation has been handled by the Belfast Trust has added to the hurt and grief felt by the families... I wish to apologise unreservedly to the families for the unacceptable delay in the Belfast Trust accepting liability.”⁶⁴⁰ After making his statement, Mr Donaghy and others from the Trust agreed to meet the families. As a result of those meetings, Mr Donaghy wrote to Mr and Mrs Roberts on 21st November 2013 to state that:

*“In relation to the letter from the Directorate of Legal Services, as I indicated to you on Friday, 15 November 2013, I believe that some of the wording in the letter is insensitive. I accept that your reason for pursuing Claire’s case is to, as far as possible, ascertain the truth.”*⁶⁴¹

3.319 Mr and Mrs Roberts were more than fully justified in that pursuit.

⁶³⁹ Mr Donaghy T-12-11-13 p.5 line 22 *et seq*

⁶⁴⁰ Mr Donaghy T-12-11-13 p.5, line 15

⁶⁴¹ 314-018-001

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Introduction and background

- 4.1 Lucy Crawford was born on 5th November 1998, the youngest of a family of three. She was admitted to the Erne Hospital Enniskillen on 12th April 2000, transferred the next day to the Royal Belfast Hospital for Sick Children ('RBHSC') and died on 14th April 2000.
- 4.2 Lucy's death was examined in the October 2004 UTV documentary '*When Hospitals Kill*'. It implicated hyponatraemia in her death and alleged a 'cover up.' Accordingly, Lucy's case fell within the original remit for consideration by this Inquiry.¹
- 4.3 The work of the Inquiry was stayed in 2005 to permit an investigation of her case by the Police Service of Northern Ireland ('PSNI'). Ultimately, the Public Prosecutions Service for Northern Ireland determined that there should be no prosecution. I was then contacted by Lucy's parents who informed me that for personal reasons they no longer wished Lucy's death to be investigated by the Inquiry. I reported the matter to the Minister who acceded to their wishes.
- 4.4 It was then urged upon me that any contemporaneous failure to acknowledge the relevance of hyponatraemia in Lucy's death could have influenced the lessons drawn from her death and might have contributed to the tragedy of Raychel's death 14 months later. After engaging in extensive consultation I decided in February 2010 that the terms of reference still required investigation into the aftermath of Lucy's death.
- 4.5 In this context, I considered the revised terms of reference required:

"an investigation into the events which followed Lucy's death such as the failure to identify the correct cause of death and the alleged Sperrin Lakeland cover up because they contributed, arguably, to the death of Raychel in Altnagelvin. This reflects the contention that had the circumstances of Lucy's death been identified correctly, and had lessons been learned from the way in which fluids were administered to her,

¹ 021-010-024 as published on 1st November 2004

defective fluid management would not have occurred so soon afterwards (only 14 months later) in Altnagelvin, a hospital within the same Western Health and Social Services Board area.”

- 4.6 Arising from this, the principal questions are whether the cause of Lucy’s death was clear at the outset; whether any of the participants knew or suspected that Lucy’s death was caused by mismanagement and if so, why this was not made known at the time. Further and in this context, whether there was a failure to ensure that the death was properly investigated and if so, why so?

Expert reports

- 4.7 In order to assist and advise, the Inquiry retained a number of experts. The experts were:

- (i) Dr Roderick MacFaul² (Consultant Paediatrician, retired) who provided expert comment on clinical and governance matters.³
- (ii) Professor Gabriel Scally⁴ (Director of WHO Collaborating Centre of Healthy Urban Environments) who reported on the responsibilities of the Trusts and the Boards and the DHSSPS in Northern Ireland at the time of Lucy’s death.⁵
- (iii) Professor Sebastian Lucas⁶ (Department of Histopathology, St. Thomas’ Hospital, London) who advised on issues arising from the autopsy.⁷
- (iv) Dr Simon Haynes⁸ (Consultant in Paediatric Cardiothoracic Anaesthesia & Intensive Care, Freeman Hospital, Newcastle upon Tyne) who provided his opinion on Lucy’s fluid management.⁹

² 325-002-013

³ File 250

⁴ 325-002-013

⁵ File 251

⁶ 325-002-013

⁷ File 252

⁸ 306-081-009

⁹ File 253

- 4.8 The Inquiry and its experts also reviewed reports commissioned by the Crawford family, the Sperrin Lakeland Trust ('SLT') and the Coroner. These were provided by:
- (i) Dr Dewi Evans¹⁰ (Consultant Paediatrician, Singleton Hospital, Swansea), who was engaged by Lucy's parents in connection with the prosecution of a clinical negligence claim.
 - (ii) Dr John Jenkins¹¹ (Senior Lecturer in Child Health and Consultant Paediatrician at Antrim Hospital), who reported to the Directorate of Legal Services on behalf of Sperrin Lakeland Trust ('SLT') in connection with defending the claim brought by Lucy's parents.
 - (iii) Dr Edward Sumner¹² (Consultant Paediatric Anaesthetist at Great Ormond Street Children's Hospital), who provided the Coroner with an opinion for the purposes of inquest.

Schedules compiled by the Inquiry

- 4.9 To marshal and summarise the large volume of information received, a number of schedules, lists and chronologies were compiled:
- (i) List of persons involved, cross-referencing statements and summarising roles.¹³
 - (ii) Schedule detailing Nomenclature & Grading of Doctors 1948 to 2012.¹⁴
 - (iii) Schedule detailing Nomenclature & Grading of Nurses 1989 to 2012.¹⁵
 - (iv) Chronology of clinical events.¹⁶

¹⁰ 325-002-013
¹¹ 325-002-013
¹² 325-002-013
¹³ 325-002-001
¹⁴ 303-003-048
¹⁵ 303-004-051
¹⁶ 325-003-001

(v) Consolidated Chronology: governance & lessons learned.¹⁷

(vi) Compendium Glossary of Medical Terms¹⁸

All of the above schedules, lists, chronologies and reports have been published on the Inquiry website in accordance with Inquiry protocol.

Cause of Death

4.10 The inquest into Lucy's death did not take place until February 2004, almost four years after her death. The verdict at inquest found that her death had been due to,

"I (a) Cerebral oedema (b) acute dilutional hyponatraemia (c) excess dilute fluid

*II. gastroenteritis."*¹⁹

4.11 Mr John Leckey, the Coroner for Greater Belfast found that:

"On 12 April 2000, the deceased, who was aged 17 months, was admitted to the Erne Hospital, Enniskillen with a history of poor oral intake, fever and vomiting. The vomiting was sufficient to have caused a degree of dehydration and she required intravenous fluid replacement therapy. It was believed she was suffering from gastroenteritis. Her condition did not improve and she collapsed at about 3.00 am on 13 April, developing thereafter decreased respiratory effort and fixed and dilated pupils. Whilst in a moribund state she was transferred by ambulance shortly after 6.00 am to the Royal Belfast Hospital for Sick Children. Her condition remained unchanged and after two sets of brain-stem tests were performed showing no signs of life, she was pronounced dead at 13.15 hours on 14 April. She had become dehydrated from the effects of vomiting and the development of diarrhoea whilst in the Erne Hospital and she had been given an excess volume of intravenous fluid to replace losses of electrolytes. The collapse which led to her death was a direct consequence of an inappropriate fluid

¹⁷ 325-004-001

¹⁸ 325-005-001

¹⁹ 013-034-130

replacement therapy in that the use of 0.18% saline to make up deficits from vomiting and diarrhoea was wrong, too much of it was given and there had been a failure to regulate the rate of infusion. This led to the development of dilutional hyponatraemia which in turn caused acute brain swelling and death. The errors in relation to the fluid replacement therapy were compounded by poor quality medical record keeping and confusion by the nursing staff as to the fluid regime prescribed.”

- 4.12 The findings of the Coroner were uncontroversial. Clinicians from the hospitals treating Lucy gave evidence at the inquest and accepted that the cause of the death was cerebral oedema due to hyponatraemia brought about in consequence of the infusion of excessive quantities of hypotonic fluid.²⁰ Why then did this consensus not emerge four years earlier and before Raychel was given inappropriate fluid therapy involving the same Solution No. 18, causing her to develop the same dilutional hyponatraemia within the same Western Health and Social Services Board (‘WHSSB’) area?

Lucy’s admission to Erne Hospital on 12th April 2000

- 4.13 Lucy was admitted to the Erne Hospital in Enniskillen on Wednesday 12th April 2000 at 19:30. She presented with a history of drowsiness and vomiting and was placed under the care of Consultant Paediatrician Dr Jarlath O’Donohoe.²¹ She was seen initially by the Senior House Officer (‘SHO’) in Paediatrics Dr Amer Ullah Malik.²² Dr Malik could not be contacted by the Inquiry after he provided an initial response to a request for a statement.²³

²⁰ Namely Dr Peter Crean (Consultant in Paediatric Anaesthesia and Intensive Care at the RBHS, Dr Thomas Auterson (Consultant Anaesthetist at the Erne Hospital), Dr Donncha Hanrahan (Consultant Paediatric Neurologist at the RBHSC and Dr John Jenkins (on behalf of the Sperrin Lakeland Trust).

²¹ 325-002-001

²² 325-002-001

²³ WS-285-1 p.1

Admitted by Dr Malik

- 4.14 Lucy's parents explained to Dr Malik that she had not been feeding well, had had fever and vomiting for 36 hours and been drowsy for 12 hours.²⁴ Dr Malik admitted Lucy and arranged for blood and urine tests. He considered her dehydrated and decided to administer IV fluids.
- 4.15 Lucy had no medical history to complicate her care. She presented with symptoms consistent with gastroenteritis causing her dehydration. Her admission was for the purposes of rehydration. Hers should have been a straightforward and routine admission.
- 4.16 Clinicians grade dehydration as mild, moderate or severe.²⁵ Severe dehydration carries the risk of shock. It is important to assess the dehydration to inform the fluid management. However, neither Dr Malik nor Dr O'Donohoe recorded their assessment. Indeed, it is unclear whether any formal assessment was made of Lucy's dehydration even though Dr O'Donohoe recalled that she had presented with a moderate dehydration.²⁶ Clearly, if an assessment was made it ought to have been recorded in her clinical notes. Dr MacFaul examined the records and concluded that Lucy had, at worst, moderate dehydration.²⁷ The evidence given at inquest by Drs Sumner²⁸ and Jenkins²⁹ agreed that she was mildly dehydrated.
- 4.17 Lucy's initial blood test sample was taken at 20:50 on 12th April 2000.³⁰ It revealed an elevated urea of 9.9mmol/L (a sign of dehydration³¹ and/or established shock³²) and a normal sodium reading of 137 mmol/L.

Attendance by Dr O'Donohoe and commencement on IV fluids

- 4.18 Upon admission Lucy was taking fluids orally and not therefore dependent upon intravenous ('IV') fluids. Between 21:00 and 22:00, she drank 50ml

²⁴ 027-009-020
²⁵ 250-003-021
²⁶ Dr O'Donohoe T-06-06-13 p.27 line 15
²⁷ 250-003-031
²⁸ 013-036-139
²⁹ 013-032-118
³⁰ 027-012-031
³¹ 250-003-021
³² 250-003-022

of juice and 100ml of Dioralyte.³³ Dr O'Donohoe said she drank enthusiastically.³⁴ She also passed a small amount of urine at 20:00.

- 4.19 Dr Malik was unable to insert the IV cannula³⁵ and Dr O'Donohoe was called³⁶ at about 21:00³⁷ (according to Dr Malik) or 21:30³⁸ (according to Dr O'Donohoe) to place the cannula in her arm. She was commenced on IV fluids between 22:30 and 23:00.

Intravenous fluid therapy

- 4.20 IV fluids are administered for various purposes:

- (i) As maintenance fluids to replenish normal ongoing losses from urine and insensible losses such as sweat.
- (ii) As replacement fluids to replace abnormal losses such as those suffered through vomiting or diarrhoea
- (iii) As resuscitation fluids in the management of circulatory failure whether in shock or when trying to prevent evolving shock.³⁹ This is commonly required when a patient is dehydrated.

Fluids received

- 4.21 Dr O'Donohoe claimed that he had intended that Lucy should receive a bolus of 100ml of normal saline in the first hour to be followed by Solution No.18 at 30ml per hour⁴⁰
- 4.22 However, it would appear that Lucy was given at least 400ml of Solution No.18 intravenously from 22:30/23:00 until she suffered a seizure at around 03:00. Her fluids were then changed to normal saline.

³³ 027-019-062

³⁴ Dr O'Donohoe T-06-06-13 p.26 line 6

³⁵ 027-017-058, 013-009-023

³⁶ 013-009-023, 013-018-066

³⁷ 013-009-023

³⁸ 115-051-001

³⁹ 250-003-030

⁴⁰ 027-010-024

4.23 Whilst Dr MacFaul described Lucy's fluid balance chart as "*confusing*"⁴¹ the following observations may be made with confidence:

- (i) It was acceptable practice at that time to administer a bolus of 100ml of normal saline as a replacement fluid followed by 30ml per hour of half normal (0.45%) saline or even Solution No. 18 as maintenance fluids.
- (ii) It was not appropriate to give Lucy a bolus of Solution No.18 as a replacement fluid for dehydration.⁴²
- (iii) It was not appropriate to give Lucy 100ml of any fluid after the first hour, and most certainly not Solution No. 18.
- (iv) If Dr O'Donohoe intended that Lucy should receive a bolus of 100ml of normal saline in the first hour to be followed by 30ml per hour of Solution No. 18 he ought to have communicated this in clear and certain terms to Dr Malik and the nursing staff and completed all the necessary documentation to that effect.
- (v) All fluids actually administered should have been accurately recorded so that there could be no misunderstanding as to what was received.

4.24 Dr O'Donohoe accepted that mistakes had been made in both the choice of Solution No. 18 and the rate at which it was administered. He stated that he had not intended Lucy to receive Solution No. 18 at a rate of 100 ml/hr and accepted that it was "*entirely inappropriate*."⁴³ He also accepted that he failed to ensure that his directions for Lucy were adequately understood.⁴⁴ His concessions are appropriate. However, there remained a dispute between him, the absent Dr Malik and Staff Nurse Brid Swift⁴⁵ as to the specifics of his fluid regime. This confirms the serious failure in both communication and record-keeping. However, given the limitations

⁴¹ 250-003-034

⁴² 250-003-030

⁴³ Dr O'Donohoe T-06-06-13 p.20 line 12

⁴⁴ Dr O'Donohoe T- 06-06-13 p.29 line 3

⁴⁵ 325-002-002

imposed by the terms of reference it is not appropriate for me to resolve this dispute between Dr O'Donohoe and his colleagues.

Infusion of normal saline

- 4.25 Having received an excessive volume of Solution No.18, Lucy suffered a seizure at approximately 02:55 on Thursday 13th April 2000.⁴⁶ Mrs Crawford called for help. Nurses arrived and Dr Malik attended soon afterwards. At around 03:20 Lucy suffered respiratory arrest and Dr Malik provided artificial respiration.⁴⁷
- 4.26 At the suggestion of Staff Nurse Thecla Jones,⁴⁸ Dr Malik changed the fluids⁴⁹ from Solution No.18 to normal saline. It would appear that he directed that this should run freely.⁵⁰ It is unclear how much normal saline was then given because the records are poor. Whereas Staff Nurse Siobhan MacNeill⁵¹ believed Lucy received 280mls,⁵² Dr Malik's note suggests that 500 mls had been administered in one hour⁵³ and the fluid balance chart indicates 810mls between 03:00 and 06:00.⁵⁴
- 4.27 Dr O'Donohoe was called and, if the records are correct, he arrived at 03:20.⁵⁵ He told the PSNI that he reduced the normal saline to 30ml per hour.⁵⁶ However, if he did, the change was not recorded and is contradicted by Staff Nurse MacNeill who stated that she administered the normal saline at 30 ml/hr from 04.50.⁵⁷ Moreover, the PICU fluid balance chart notes the reduction to 30ml/hr after 04:00.⁵⁸ To determine which, if any, of these accounts is accurate is academic because Lucy was already critically

⁴⁶ 027-010-024
⁴⁷ 027-017-057 & 027-010-024
⁴⁸ 325-002-002
⁴⁹ 115-014-002
⁵⁰ 115-014-002 & 027-017-057
⁵¹ 325-002-003
⁵² 115-016-002
⁵³ 027-010-024
⁵⁴ 027-025-076 & 115-014-002
⁵⁵ 027-010-022 & 027-010-024
⁵⁶ 115-051-002
⁵⁷ 115-016-002
⁵⁸ 027-025-076

overloaded with fluid. Furthermore and in all probability, she continued to receive too much fluid at too fast a rate even after her respiratory arrest.

- 4.28 Dr Thomas Auterson⁵⁹ (Consultant Anaesthetist) was contacted at 03:40 and arrived promptly to assist.⁶⁰ He observed Lucy's pupils to be fixed, dilated and unresponsive. He managed to intubate her but believes she was already beyond help. Nonetheless, he agreed with Dr O'Donohoe that she should be transferred to the Paediatric Intensive Care Unit ('PICU') at the RBHSC in case something more could be done for her. Lucy was then moved to intensive care for stabilisation and to await ambulance transfer to Belfast.

Sodium levels

- 4.29 Dr O'Donohoe ordered a repeat blood test⁶¹ and the results received at 04:26 indicate that her sodium level had fallen from 137mmol/l to 127mmol/l.⁶² Lucy, who had not been hyponatraemic on admission was suffering marked hyponatraemia after eight hours of hospital care. Disconcertingly the clinicians do not appear to have been curious as to why a moderately dehydrated patient should suffer a significant decline in her sodium level after her treatment had begun.
- 4.30 Whilst a sodium reading of 127mmol/l does not indicate dangerous hyponatraemia it should be noted that the saline solution prescribed by Dr Malik after her seizure would have raised her sodium levels and accordingly 127mmol/l is unlikely to have been her lowest reading.⁶³ Additionally, whilst a gradual decline from 137mmol/l to 127mmol/l over an extended period would probably have been manageable, the comparatively rapid decline suffered by Lucy was more dangerous.

⁵⁹ 325-002-002

⁶⁰ 013-007-020

⁶¹ 027-017-057

⁶² Result was timed at 04:26

⁶³ WS-278-1 p.10 & WS-302-2 p.3

Transfer to the Children's Hospital

- 4.31 Lucy was taken the 80 miles to the RBHSC and arrived soon after 08:00 on 13th April 2000. She was accompanied by Dr O'Donohoe and Staff Nurse MacNeill.
- 4.32 Upon arrival Dr O'Donohoe supplied the on-call Consultant Paediatric Anaesthetist Dr James McKaigue⁶⁴ with a short transfer letter⁶⁵ and a transfer form⁶⁶ detailing observations recorded en route.⁶⁷ However, the clinical records from the Erne Hospital together with her blood test results⁶⁸ and x-rays⁶⁹ were not provided.
- 4.33 Significantly, Dr O'Donohoe's transfer letter failed to refer to the results of the serum electrolyte tests⁷⁰ or to the type, rate and volume of the IV fluids administered.⁷¹ Such information was obviously relevant to the RBHSC clinicians who were taking over. Dr O'Donohoe explained that his was "*a brief note, written under very difficult circumstances*"⁷² and maintained that had circumstances been more favourable, his letter would have been more detailed.
- 4.34 I consider it regrettable that further detail was not given but do not take the view that this was an attempt to conceal medical error. Dr O'Donohoe was acting under stress in an emergency and in any event, the clinical notes were sent later by fax and Dr Auterson supplied the results of Lucy's repeat urea and electrolyte test.⁷³

⁶⁴ 325-002-004

⁶⁵ 061-014-038

⁶⁶ 061-015-040

⁶⁷ 061-016-041

⁶⁸ 027-012-031-032 (laboratory results showing the serum sodium levels of 137mmol/l and 127mmol/l respectively).

⁶⁹ 061-014-039 (Dr O'Donohoe's transfer letter) and 033-102-317 (Dr Auterson's statement to Mr Fee)

⁷⁰ 250-003-102 - para 533, Dr MacFaul has noted that it is not evident that Dr O'Donohoe informed PICU staff of the low blood sodium.

⁷¹ 250-003-102 - para 532, Dr MacFaul has identified the limited attention paid to Lucy's fluid management in the transfer letter.

⁷² Dr O'Donohoe T- 06-06-13 p.79 line 16

⁷³ 061-018-060 & 061-017-042

Admission to the Children's Hospital

- 4.35 Lucy was admitted to PICU under Dr Peter Crean⁷⁴ (Consultant in Paediatric Anaesthesia and Intensive Care). For reasons which are discussed in greater detail later in this chapter, this does not imply that Dr Crean was the lead clinician in respect of Lucy's care. In fact it was Dr Anthony Chisakuta⁷⁵ (Consultant in Paediatric Anaesthesia and Intensive Care) and Dr Donncha Hanrahan⁷⁶ (Consultant Paediatric Neurologist) who became most directly involved in her care. Dr McKaigue began an assessment of Lucy at 08:00 which was completed by Dr Chisakuta. Neither made any reference in their notes to Lucy's fluid regime at the Erne Hospital.
- 4.36 Lucy was then seen at 08:30⁷⁷ by SHO Dr Louise McLoughlin⁷⁸ and later on a ward round by Dr Caroline Stewart⁷⁹ (Registrar), Dr Dara O'Donoghue⁸⁰ (acting Registrar)⁸¹ and Dr Crean. Lucy's sodium level was recorded at 140mmol/l. Dr Crean noted that he was "*awaiting faxes of her notes from the Erne Hospital and she is to be reviewed by a Paediatric Neurologist this morning.*"⁸²
- 4.37 Dr Crean then made a telephone call to Dr O'Donohoe at the Erne Hospital to ask about Lucy's fluid therapy because he understood it to have been Solution No. 18 at 100ml/hr and naturally wanted clarification. This conversation must have taken place after Dr Crean received Lucy's Erne Hospital notes because they included the fluid balance chart. Dr O'Donohoe maintained that he told Dr Crean that he had directed "*a bolus of 100mls over 1 hour followed by 0.18% NaCl/Dextrose 4% at 30ml/hour.*"⁸³ Dr Crean does not remember the conversation.

⁷⁴ 325-002-005
⁷⁵ 325-002-004
⁷⁶ 325-002-005
⁷⁷ 061-018-058
⁷⁸ 325-002-004
⁷⁹ 325-002-005
⁸⁰ 325-002-006
⁸¹ 115-012-001
⁸² 061-018-065
⁸³ 027-010-024

- 4.38 Dr Crean then arranged for Lucy to be seen by Dr Hanrahan who saw her at 10:30⁸⁴ and recorded his differential diagnosis which included infection, haemorrhagic shock encephalopathy, metabolic disease and unrelated cerebral oedema.⁸⁵ He also noted that the *"findings would suggest that she shows no sign now of brainstem function."*⁸⁶ Dr Hanrahan did not identify hyponatraemia or fluid overload as contributory to the cerebral oedema but did express some uncertainty by noting *"no cause clinically evident as yet."*⁸⁷ He accepted that whilst he was aware of the fall in Lucy's sodium levels from 137mmol/l to 127mmol/l, he did not regard this as either marked or significant.⁸⁸

Death

- 4.39 Dr Hanrahan directed neurological investigation to include a Computerised Tomography ('CT') scan and an Electroencephalography ('EEG'). The scan revealed obliteration of the basal cisterns suggesting 'coning' and the EEG failed to register cerebral function.⁸⁹ He noted at 17:45 that her *"prognosis, in my opinion, is hopeless and indications are that she is brain dead."*⁹⁰ He then recorded that Lucy's parents were *"agreeable to her not being actively resuscitated"*⁹¹ should she deteriorate overnight. He made reference to the necessity to test for brain stem death and noted, *"If she succumbs, a PM would be desirable – coroner will have to be informed."*⁹²
- 4.40 Dr Hanrahan expressed the opinion that Lucy was effectively *"brain dead on arrival in Belfast"*⁹³ but that the 'sentinel event' had occurred at the Erne Hospital.

⁸⁴ 061-018-060

⁸⁵ 061-018-063

⁸⁶ 061-018-063

⁸⁷ 061-018-063

⁸⁸ 116-026-005

⁸⁹ 061-032-098

⁹⁰ 061-018-065

⁹¹ 061-018-066

⁹² 061-018-066

⁹³ 013-025-093

4.41 Formal brain stem testing⁹⁴ permitted pronouncement of death at 13:15 on 14th April 2000.⁹⁵ Mrs Crawford recalled that she and her husband were told by Dr Hanrahan that they “*should seek answers from the Erne Hospital as to what happened to Lucy.*”⁹⁶ This conversation took place immediately after her death.

4.42 Dr Hanrahan then made contact with the Coroner’s Office. Significantly, it was decided that Lucy’s death did not require a Coroner’s post-mortem but that a hospital post-mortem would suffice to clarify the cause of death. A death certificate was subsequently issued, but before the final post-mortem report was available. This recorded Lucy’s death as having been caused by,

“*I(a). Cerebral oedema
(b). due to (or as a consequence of) dehydration
(c). due to (or as a consequence of) gastroenteritis.*”⁹⁷

4.43 The clear consensus of those from whom I received evidence was that the cause of Lucy’s death should not have been stated on the death certificate in these terms because it made no sense to certify that the cerebral oedema was due to or a consequence of dehydration.

Opinions as to cause of death: Dr Auterson

4.44 Dr Auterson stated that after Lucy’s death he reviewed the fluid balance chart and the sodium readings and concluded that “*hyponatraemia played a significant part in Lucy’s deterioration and death.*”⁹⁸ Indeed, he said that even when he was attending Lucy he reached the conclusion that she had been given too much of the wrong fluid and that this was the most likely cause of her hyponatraemia.⁹⁹ Dr Auterson confirmed that he had reached this view, which he characterised as a “*strong suspicion,*”¹⁰⁰ on the morning

⁹⁴ 061-019-070

⁹⁵ 061-018-068

⁹⁶ 013-022-079

⁹⁷ 013-008-022

⁹⁸ WS-274-1 p.4

⁹⁹ WS-274-1 p.5

¹⁰⁰ Dr Auterson T-31-05-13 p.128 line 1

of Lucy's deterioration¹⁰¹ and that he became more confident in this opinion in the days that followed.¹⁰²

4.45 Dr Auterson said that he discussed the case informally with his anaesthetic colleagues in the day or two after the death.¹⁰³ He spoke to Dr Matt Cody who agreed with his suspicion "*that probably it was a fluid-related problem*"¹⁰⁴ and he discussed the case with Dr William Holmes who "*did not disagree with [his] presumptive diagnosis*" implicating the fluid management.¹⁰⁵

4.46 Dr Auterson was carefully questioned about this account:

"Q. So... based on her neurological status, based upon the electrolyte results and taking into account the information you gleaned from the fluid balance chart, you recognised that fluids had caused the hyponatraemia and the hyponatraemia had caused the cerebral oedema?"

A. Yes.

Q. That was your working diagnosis?"

A. Yes."¹⁰⁶

4.47 It is a matter for concern that Dr Auterson did not volunteer this opinion when he made his statement for the Erne Hospital Review into Lucy's death.¹⁰⁷ He recognises that his failure to report these concerns to the Medical Director reflects badly upon him¹⁰⁸ and is something for which he may be legitimately criticised.¹⁰⁹ He explained that he did not articulate his view that the IV fluids were the likely cause of the hyponatraemia because he regarded that as "*an obvious conclusion.*"¹¹⁰

4.48 Dr Auterson said that he expected others to form the same view. Dr O'Donohoe attended with him after Lucy's collapse and was also aware of

¹⁰¹ Dr Auterson T-31-05-13 p.127 line 21

¹⁰² Dr Auterson T-31-05-13 p.136

¹⁰³ WS-274-1 p.5

¹⁰⁴ Dr Auterson T-31-05-13 p.156 line 23

¹⁰⁵ Dr Auterson T-31-05-13 p.157 line 15

¹⁰⁶ Dr Auterson T-31-05-13 p.124 line 10-25

¹⁰⁷ 033-102-316

¹⁰⁸ Dr Auterson T-31-05-13 p.154

¹⁰⁹ Dr Auterson T-31-05-13 p.163

¹¹⁰ WS-274-1 p.7

the repeat sodium results. According to Dr Auterson they had a brief discussion at that time acknowledging that Lucy may have received too much fluid.¹¹¹ He believed that Dr O'Donohoe was aware of his suspicions¹¹² and indeed recognised what had gone wrong at that time.¹¹³ He subsequently assumed that Dr O'Donohoe would address this at the Review¹¹⁴ and accordingly did not discuss the matter further. Dr Auterson said, *"Without seeming flippant, it's the elephant in the room. Why did nobody else come to this conclusion?"*¹¹⁵

- 4.49 Dr O'Donohoe was dismissive of Dr Auterson's evidence and in particular his claim to have understood so quickly that fluid mismanagement had triggered the sequence of events which led to the cerebral oedema.¹¹⁶ Dr O'Donohoe insisted that Dr Auterson had not raised this suggestion at the time and emphasised that if Dr Auterson believed that Lucy had collapsed due to hyponatraemia he might have tried to remedy the situation by administering concentrated hypertonic saline, which he did not.¹¹⁷ Dr O'Donohoe specifically rejected Dr Auterson's account that they had discussed fluid mismanagement at the time of the resuscitation.¹¹⁸
- 4.50 I accept that the evidence of Dr Auterson is unsatisfactory in some important respects. Why, if he had formed so strong a suspicion about what had gone wrong in Lucy's case, did he not voice that suspicion to others outside his circle of colleagues in the Anaesthetics Department? However, it must be noted that in this, his approach is consistent with what was done by others. Dr O'Donohoe's statement for the Review did not address the fluid mismanagement issues and Dr Malik did not address fluids at all.
- 4.51 Additionally, I consider that Dr Auterson was honest in describing how he formed his early suspicion that mismanagement was implicated in Lucy's hyponatraemia. He has accepted, properly in my view, that it is not to his

¹¹¹ Dr Auterson T-31-05-13 p.139 line1
¹¹² Dr Auterson T-31-05-13 p.165 line 12
¹¹³ Dr Auterson T-31-05-13 p.137 line 7
¹¹⁴ Dr Auterson T-31-05-13 p.136 line 21
¹¹⁵ Dr Auterson T-31-05-13 p.153 line 12
¹¹⁶ Dr O'Donohoe T-06-06-13 p.52-53
¹¹⁷ Dr O'Donohoe T-06-06-13 p.53
¹¹⁸ Dr O'Donohoe T-06-06-13 p.58

credit that he failed to communicate his suspicions at the time. This was a significant omission on his part because it acknowledged his failure to be straightforward and frank when that was his clear professional duty.¹¹⁹

4.52 I wish to emphasise that criticism is not confined to Dr Auterson alone. Whilst he, by his evidence, chose to expose himself to criticism, others have implausibly maintained that they had no misgivings about the fluid therapy. I conclude that there was a reluctance on the part of those responsible for Lucy's care in the Erne Hospital to speak out about what may have caused her death most probably because there was a suspicion that fluid mismanagement was responsible.

4.53 I do not accept that the cause of death could not have been established promptly and accurately. It was entirely possible to reach the conclusion of mismanagement in the immediate aftermath of Lucy's death. It could and should have been established almost immediately because Dr Auterson was not alone in forming this suspicion.

Dr Asghar's opinion

4.54 Dr Mohammed Asghar¹²⁰ was a paediatrician at the Erne Hospital who was not involved in Lucy's care. Nonetheless, it would appear that he interested himself in Lucy's clinical notes and may have spoken to others about the standard of care provided to her. He wrote to the Chief Executive of the SLT, Mr Hugh Mills¹²¹ on 5th June 2000 in the following terms:

"Lucy was admitted in the ward with a history of vomiting. The SHO could not put up the IV line so he called Dr O'Donohoe who was on call that night. Dr O'Donohoe examined the child and put up the IV line. The SHO then got busy with the other three admissions. Dr O'Donohoe told the nurse to give fluids at 100mls per hour. At three o'clock in the morning the child got a convulsion and went into respiratory arrest. She was later transferred to Belfast where she died. A P.M. revealed cerebral oedema. This child might

¹¹⁹ 315-002-009

¹²⁰ 320-002-004

¹²¹ 325-002-008

have been given excess of fluids. All through the night fluids were running at 100mls per hour. After the child died in Belfast he made alterations in the chart. He wrote that he had ordered the fluids should be given as a bolus of 100mls and then at 30mls per hour. In fact, neither the SHO nor any of the nurses were told to give the fluids at 30ml per hour.”¹²²

- 4.55 Dr Asghar had no difficulty in recognising mismanagement of the fluids and the possible link between excess fluid and the cerebral oedema. His curiosity and desire to do the right thing stand in commendable contrast to those of his colleagues.

Dr Chisakuta’s opinion

- 4.56 At the RBHSC Dr Chisakuta performed the brain stem death tests with Dr Hanrahan.¹²³ He gave evidence that *“throughout the course of [his] clinical involvement in Lucy’s care on 14th April 2000 [he] was giving consideration to the cause of her condition.”¹²⁴*

- 4.57 Dr Chisakuta could not say for certain that he was involved in discussion with Dr C Stewart prior to her entering her clinical diagnosis in the autopsy request form, namely *“dehydration and hyponatraemia, cerebral oedema, acute coning and brain stem death.”¹²⁵* Nevertheless, he said that he probably would have agreed with that diagnosis because, *“From the medical clinical notes faxed to the PICU ... Lucy had clinical symptoms and signs of dehydration for which she was prescribed intravenous fluids.”¹²⁶* He went on to explain:

“The serum sodium level was noted to have decreased from 137 mmol/l (measured at 8.30pm on 12/04/00)¹²⁷ to 127 mmol/l (measured around 3.20am on 13/04/00)¹²⁸ a condition referred to as hyponatraemia.

¹²² 032-090-175

¹²³ WS-283-1 p.2

¹²⁴ WS-283-1 p.6

¹²⁵ 061-022-073

¹²⁶ 061-017-044 to 046

¹²⁷ 061-017-049

¹²⁸ 061-017-050

During the stress of illness, the body produces a chemical called Anti-diuretic hormone, which causes the kidneys to retain the water. This also might have contributed to an increase in body water. In this situation, water tends to move from outside the cells into the cells causing them to swell up, a condition called oedema. When this happens to the brain cells, it is referred to as cerebral oedema.

Cerebral oedema can lead to coning and brain stem death.

This sequence of events seems to me to fit Lucy's case so I speculate that if there was a discussion with Dr Stewart as has been suggested, that I would have been agreeing with her working pathogenesis.”¹²⁹

- 4.58 Dr Chisakuta accepted that the missing link in Dr C Stewart's description was an account of how Lucy could have gone from a state of dehydration to one in which she was suffering from hyponatraemia.¹³⁰ He said he would have wanted the fluid management problem to have been stated explicitly in the list of problems.¹³¹
- 4.59 In his evidence Dr Chisakuta was asked specifically whether at the time of Lucy's death he had any idea what the cause was. He told me that he knew that Lucy had died because her brain had coned due to the development of cerebral oedema and that while the cause of this “*could have been a combination of things*”¹³² he was aware that one of the possible factors was that “*she had lots of fluids in the other hospital.*”¹³³
- 4.60 Dr Chisakuta went on in his evidence to reiterate that he was “*conscious of the possibility that a possible or probable cause of Lucy's death was the volume of fluid that she had been given in the Erne.*”¹³⁴ He said that this concern about the standard of treatment Lucy received was in his mind from the 14th April 2000.¹³⁵

¹²⁹ WS-283-2 p.6

¹³⁰ Dr Chisakuta T-29-05-13 p.103 line 7

¹³¹ Dr Chisakuta T-29-05-13 p.105 line 2

¹³² Dr Chisakuta T-29-05-13 p.67 line 14

¹³³ Dr Chisakuta T-29-05-13 p.67 line 17

¹³⁴ Dr Chisakuta T-29-05-13 p.70 line 7

¹³⁵ Dr Chisakuta T-29-05-13 p.70-71

Dr Evans' opinion

4.61 Dr Evans was retained by solicitors acting on behalf of the Crawford family and asked to examine and report on the events leading to Lucy's death. He reported on 18th February 2001 that:

- (i) A combination of errors by clinicians at the Erne Hospital contributed significantly to Lucy's death.
- (ii) There was a failure to calculate the fluid replacement required by Lucy and document the results.
- (iii) There was a failure to give adequate instruction as to the type and volume of fluid indicated.
- (iv) The decision to use 0.18% NaCl ('Solution No. 18') was wrong, given the nature of Lucy's condition.
- (v) The decision to infuse Solution No. 18 at a rate of 100ml per hour was wrong.
- (vi) The decision to administer 500ml of 0.9% NaCl after her collapse was wrong.
- (vii) It is probable that the very significant change in her electrolytes was caused by the infusion of an excessive volume of dilute fluid and further that it could not be explained on the basis of "*some conjectural inappropriate ADH secretion.*"
- (viii) If Lucy had been managed according to the basic standards of district general hospital paediatric practice by deploying a bolus of isotonic intravenous solution (such as 0.9% NaCl or HAS) in a volume of 90ml-180ml, followed by 0.45% NaCl (with added potassium) at a rate of no more than 70ml/hr, she would not have developed cerebral oedema.¹³⁶

¹³⁶ 013-010-025 to 036

- 4.62 Dr Evans gave his opinion within a year of Lucy's death and within a short time of receiving her hospital notes. His views mirrored the findings which the Coroner was to reach at inquest some three years later. Dr Evans did not claim any particular expertise in the field of fluid management.

Dr Jenkins' opinion

- 4.63 The Directorate of Legal Services ('DLS'), on behalf of the SLT, commissioned a report from Dr Jenkins.¹³⁷ He concluded on 7th March 2002 that Lucy had been given the wrong fluids. Dr Jenkins was clear that she should have been given replacement fluid with higher sodium content than Solution No. 18. Ideally she should have been given normal saline. Acknowledging that "*it is always very difficult to understand an episode of sudden collapse,*" he expressed the opinion that the fall in Lucy's serum sodium and potassium "*raise[d] the question as to the fluid management in the period from insertion of the IV line at 2300 to the collapse at around 3.00am.*"¹³⁸

Dr Moira Stewart's opinion

- 4.64 In September 2000 the SLT requested the Royal College of Paediatrics and Child Health ('RCPCH') to conduct an external review into Dr O'Donohoe's competence and conduct.¹³⁹ The RCPCH nominated Consultant Paediatrician Dr Moira Stewart¹⁴⁰ to undertake this task.¹⁴¹
- 4.65 Dr M Stewart was asked to examine a number of cases in which Dr O'Donohoe had acted as Consultant. The focus of her review was the overall conduct and competence of Dr O'Donohoe. She was not asked to provide specific analysis of what had caused Lucy's death notwithstanding that part of her remit necessarily included Lucy's case. She was briefed

¹³⁷ 013-011-037

¹³⁸ 013-011-038

¹³⁹ 036a-009-016

¹⁴⁰ 325-002-010

¹⁴¹ 036a-010-019

with Lucy's medical notes, post-mortem report and a report provided the Trust by Dr Murray Quinn¹⁴² in connection with the Trust's internal Review.

4.66 Dr M Stewart's report was received in April 2001.¹⁴³ Whilst concern has been raised about possible delay by the RCPCH in presenting its report because it was published too late to be of assistance to those treating Raychel Ferguson in June 2001, I consider that Dr M Stewart is not to be faulted for the time she took to produce her report. This was difficult work and it was carried out with great diligence. She was asked to consider not only Dr O'Donohoe's competence in the context of Lucy's case but also in four other cases. She was obliged to devote appropriate time to each. There is no reasonable basis for suggesting that she ought to have produced a report prior to April 2001.

4.67 The report identified several possible explanations for Lucy's death including:

*"(ii) She had a seizure like episode due to underlying biochemical abnormality. Initial sodium was 137 mmol/L, and potassium 4.1 mmol/L at 10.30pm. At 3.00am, and after administration of 0.18% NaCl, the repeat sodium was 127, and potassium 2.5. Biochemical changes are often well tolerated and easily corrected with appropriate fluid replacement, although these results do show a change over a relatively short period of time."*¹⁴⁴

4.68 Dr M Stewart indicated that there were "*deficiencies in the prescription and recording of volumes of fluids*"¹⁴⁵ and emphasised that in cases of moderate or severe dehydration, the Advanced Paediatric Life Support ('APLS') guidelines specify the use of normal saline and not the low saline fluids given Lucy. In addition Dr M Stewart observed that even after collapse Lucy received 500mls of normal saline in one hour whereas the

¹⁴² 325-002-009

¹⁴³ 036a-022-039

¹⁴⁴ 036a-025-056

¹⁴⁵ 036a-026-060

appropriate volume should have been 20mg/kg.¹⁴⁶ In other words she considered that Lucy was also given an excessive volume of normal saline.

- 4.69 On 1st June 2001 Dr M Stewart met with Dr James Kelly,¹⁴⁷ the Medical Director of the SLT to discuss the report. His memorandum of their meeting noted that

*“Overall amount of fluids once started not a major problem but rate of change of electrolytes may have been responsible for the cerebral oedema. RVH ward guidelines would recommend N-Saline not 1/5th normal as the replacement fluid.”*¹⁴⁸

- 4.70 For her part, Dr M Stewart gave evidence that by the end of the meeting she had left Dr Kelly in no doubt that the likely cause of Lucy’s collapse was the fall in sodium levels caused by fluid mismanagement.¹⁴⁹ It was clear to me that Dr M. Stewart’s evidence was given with a confidence not apparent in her written report. As Dr Kelly maintained, at the meeting with him she only went so far as to say that fluid mismanagement leading to electrolyte derangement *could* have caused the terminal deterioration:

*“I think my understanding of it was that Dr Stewart’s telling me that 127, even in a child, you wouldn’t automatically expect a seizure, but the rate of change of electrolytes could have caused the seizure or likely caused the seizure. The issue for me was that did not go on to say, “This is clearly the cause of death or this is clearly the cause of very significant brain oedema.” That conversation didn’t follow from that...”*¹⁵⁰

- 4.71 On balance I am prepared to accept Dr Kelly’s evidence that Dr M. Stewart expressed her opinions with a measure of equivocation during their meeting. It was properly conceded on Dr M. Stewart’s behalf that *“she should have been more explicit as to how the hyponatraemia and the rate of change in electrolytes could have resulted from the high volume of*

¹⁴⁶ 036a-025-058

¹⁴⁷ 325-002-007

¹⁴⁸ 036a-027-067

¹⁴⁹ Dr M Stewart T-18-06-13 p.76 line 9

¹⁵⁰ Dr Kelly T-13-06-13 p.69 line 12

*Solution 18*¹⁵¹ Nevertheless, and whilst it appears that she did not express a definitive conclusion about the process leading to the cerebral oedema either in her report or in her discussions with Dr Kelly, I am satisfied that she did condemn Lucy's fluid regime.

- 4.72 Dr M. Stewart's conclusions reinforce my finding that the probable causes of Lucy's death were readily identifiable in the period immediately following her death. I conclude that not only could the Coroner's findings of 2004 have been made in 2000 had an inquest been conducted but that they were in fact reached with one degree of precision or another by Drs Auterson, Asghar, Chisakuta, Evans and M. Stewart.
- 4.73 Therefore, the question which must be asked is, why did an accurate assessment of the cause of Lucy's death not emerge at the outset whether at the Erne or at the RBHSC

Initial concerns expressed at the Erne Hospital

- 4.74 After Lucy had been transferred to the RBHSC Dr Crean made a telephone call to the Erne Hospital to clarify the detail of fluid management. He spoke to Dr O'Donohoe.¹⁵²
- 4.75 Dr O'Donohoe cannot remember the specific details of the conversation but accepts that it caused him to question whether Lucy had received the fluids he had intended for her.¹⁵³ He was prompted to check Lucy's notes to see what was recorded about her fluid therapy.¹⁵⁴ He discovered that Dr Crean was right to be concerned because the fluids given to Lucy before her collapse were recorded as having been infused at 100mls/hr.
- 4.76 It was in this context that he made the following retrospective entry in Lucy's notes:

"Yesterday Dr Peter Crean rang from PICU RBHSC to enquire what fluid regime Lucy had been on. I told him a bolus of 100mls over 1 hour followed

¹⁵¹ 400-034-007 - Submissions on behalf of Dr M Stewart

¹⁵² WS-292-1 p.5

¹⁵³ WS-278-1 p.4

¹⁵⁴ WS-278-1 p.5

by 0.18% NaCl/Dextrose 4% at 30 ml/hour. He said he thought that it had been NaCl 0.18%% Dextrose 4% at 100ml/hr. My recollection was of having said a bolus over 1 hour and 30ml/hour as above."¹⁵⁵

- 4.77 Dr O'Donohoe did not however make any contact with the RBHSC thereafter to confirm that Lucy had not been given the fluids intended or indeed to indicate any error. However, Dr Crean and others at RBHSC were already of the view that the fluids given were inappropriate.
- 4.78 Dr O'Donohoe did however report his concerns to his Medical Director Dr Kelly as a '*critical incident reporting*' on the 13th/14th April 2000.¹⁵⁶ He cannot now remember what he said to Dr Kelly but confirms that it related to the quantity of fluids given.¹⁵⁷ Dr Kelly recalled that Dr O'Donohoe indicated uncertainty about what had happened and raised several possibilities, including misdiagnosis, drug error and adverse drug reaction. Dr Kelly said that Dr O'Donohoe made it very clear to him that there had indeed been confusion in respect of fluids.¹⁵⁸
- 4.79 Additionally, Sister Etain Traynor¹⁵⁹ of the Erne Hospital, who had not been involved with Lucy's care, tried to find out what had happened. She checked the nursing record and fluid balance sheets and notwithstanding the "*minimal information recorded*"¹⁶⁰ approached the Clinical Services Manager Mrs Esther Millar¹⁶¹ to express her "*concerns that the IV fluids administered had (although not recorded or prescribed) may (sic) have contributed to the child's deterioration...*"¹⁶²
- 4.80 Sister Traynor said that she told Mrs Millar that if Lucy was given 100ml per hour for a number of hours then that would have been too much and "*may well have contributed to her collapse.*"¹⁶³ This was then reflected in the

¹⁵⁵ 027-010-024

¹⁵⁶ It is unclear from the evidence when precisely Dr O'Donohoe made his report to Dr Kelly. I note that in submissions on behalf of Dr Kelly the 13th April 2000 is put forward; submissions made on behalf of Dr O'Donohoe suggest the 14th April. In my view nothing of significance turns on this discrepancy.

¹⁵⁷ WS-278-1 p.6

¹⁵⁸ 116-043-003

¹⁵⁹ 325-002-003

¹⁶⁰ WS-310-1 p.3

¹⁶¹ 325-002-008

¹⁶² WS-310-1p.4

¹⁶³ Sister Traynor T-07-06-13 p.159 line 23

clinical incident report form compiled by Mrs Millar on 14 April 2000 which recorded, *“concern expressed about fluids prescribed/administered...”*¹⁶⁴

- 4.81 All of this confirms for me that very soon after Lucy's death Dr O'Donohoe knew that there had been error with the fluids and that concerns were being expressed by others within the hospital.

Discussion with Mr and Mrs Crawford at the Erne Hospital

- 4.82 Mr and Mrs Crawford contacted Dr O'Donohoe and requested a meeting to discuss their daughter's death.¹⁶⁵ They must have hoped to find out what had happened and why she died. They met in May 2000. It is not suggested that Dr O'Donohoe or the Trust sought to avoid such a meeting but there is no indication that anyone from the Trust actively pursued one.
- 4.83 Whilst it should have been the first step to giving Mr and Mrs Crawford a proper understanding of what had happened to Lucy, it was in fact a most unproductive meeting. Dr O'Donohoe arrived without Lucy's medical notes. Whilst acknowledging that this was a failing he said in explanation that he had *“tried unsuccessfully to retrieve Lucy's notes.”*¹⁶⁶
- 4.84 Mrs Crawford recalled how disappointing the meeting had been:

*“We asked him various questions surrounding Lucy's death. He said ‘he did not know’ or ‘did not understand it.’ Dr O'Donohoe did not have Lucy's notes with him. He said he had given them to Dr Kelly to check. We were left feeling totally deflated and in the dark surrounding the circumstances in which Lucy died.”*¹⁶⁷

- 4.85 Dr O'Donohoe accepted that he was unable to answer their questions, making it, even on his own admission, an unsatisfactory meeting.¹⁶⁸ He disputed the suggestion that he couldn't answer the questions because he didn't have access to the notes on the even more unsatisfactory basis that

¹⁶⁴ 036a-045-096

¹⁶⁵ WS-278-1 p.13

¹⁶⁶ WS-278-1 p.13

¹⁶⁷ 013-022-079

¹⁶⁸ Dr O'Donohoe T-06-06-13 p.166 line 11

even if he had had notes he still would not have been able to answer their questions.¹⁶⁹

4.86 Dr O'Donohoe's most unprofessional approach to meeting Mr and Mrs Crawford is confirmed by his failure to inform them about any mismanagement of the fluids or his telephone conversation with Dr Crean. That did not require access to Lucy's medical notes. Even if he did not then fully understand the part poor fluid management had played in Lucy's deterioration, a position about which I have some doubt, I consider that he had a clear obligation to admit that mistakes had been made and to assist Mr and Mrs Crawford to an eventual understanding of their significance. Dr O'Donohoe conceded that he ought to have told Lucy's parents about the fluids, if only to let them know that the intended Review process would have a focus as opposed to something that was "*undirected*."¹⁷⁰

4.87 However, Mr and Mrs Crawford are very clear that Dr O'Donohoe did not tell them that there would be a Review.¹⁷¹ Dr O'Donohoe maintains that he told them that he had "*asked Dr Kelly, as the Trust's Medical Director to look into the matter*."¹⁷² However he did accept that his choice of words may have been "*very unhelpful*" in actually describing the process of review.¹⁷³

4.88 The meeting with Lucy's parents was particularly unsatisfactory. Even, and perhaps most especially, at a first meeting they had the right to be told of the circumstances of their daughter's death and of the mismanagement of her fluid therapy. Dr O'Donohoe had a duty to explain fully what he knew to have happened.¹⁷⁴ They should furthermore have been advised explicitly about the Review of her case. That they were not so advised raises the concern that the issues were deliberately withheld so as to avoid blame and criticism.

¹⁶⁹ Dr O'Donohoe T-06-06-13 p.168 line 9-21

¹⁷⁰ Dr O'Donohoe T-06-06-13 p.169 line 6

¹⁷¹ 036c-017-042

¹⁷² Dr O'Donohoe T-06-06-13 p.168 line 16-17

¹⁷³ Dr O'Donohoe T-06-06-13 p.169 line 19

¹⁷⁴ 315-002-009 - GMC- Good Medical Practice (1998)

- 4.89 Mr and Mrs Crawford then went to see Dr Hanrahan at the RBHSC on 9th June and he in turn contacted Dr O'Donohoe to ask him to meet with them again. Dr O'Donohoe said that whilst he would arrange a further meeting, he would prefer to await the post-mortem report.¹⁷⁵
- 4.90 I accept that that was a sensible thing to do, particularly after the unsatisfactory first meeting. A delayed meeting would allow Dr O'Donohoe time to review Lucy's notes, consider the opinion of the pathologist and reflect upon the case in the light of his own direct involvement.
- 4.91 Regrettably, Dr O'Donohoe failed to make contact with the family to arrange a further meeting. He was unable to provide any explanation for this omission¹⁷⁶ but acknowledged that it was a failing on his part.¹⁷⁷ I consider that Dr O'Donohoe's refusal to tell Mr and Mrs Crawford what he knew and what they were entitled to know was inexcusable.
- 4.92 I do not underestimate how difficult such meetings must be for doctors, especially in the case of child death where there is no definitive explanation for the death. It must be even more difficult where clinical shortcomings are suspected. Nonetheless it remains vitally important that such meetings take place. Paragraph 18 of the contemporaneous General Medical Council ('GMC') code 'Good Medical Practice' required that where *"...a patient under 16 has died you must explain, to the best of your knowledge, the reasons for, and the circumstances of the death, to those with parental responsibility."*¹⁷⁸
- 4.93 A recurrent theme of this Inquiry has been the determination expressed by parents to ensure that lessons are learned so that the mistakes which led to the death of their child cannot be repeated. I have reached the view that once the possibility of error is openly acknowledged by clinicians there remains nothing to conceal and learning is incentivised. It is clear to me that one of the main obstacles to learning in these cases has been the

¹⁷⁵ 061-018-069

¹⁷⁶ Dr O'Donohoe T-06-06-13 p.167

¹⁷⁷ 400-033-004 - Submissions made on behalf of Dr O'Donohoe

¹⁷⁸ 315-002-009

failure by clinicians and others to inform families of suspected mismanagement at the earliest opportunity.

Review

4.94 It was entirely appropriate that the SLT should establish a formal Review in order to examine what had happened to Lucy.

4.95 It is to be recognised that at that time governance arrangements in Northern Ireland hospitals were not well developed. Mr Eugene Fee¹⁷⁹ (Acute Services Manager, SLT) explained that formal clinical and social care governance was not implemented until late 2000.¹⁸⁰ Nonetheless, arrangements for adverse clinical incident reporting were in place and Dr Kelly lost no time in bringing the matter to the attention of the Trust Chief Executive Mr Mills, requesting that the case be investigated by a senior Review Team. The Review was to be co-ordinated by Mr Fee with the assistance of Dr Trevor Anderson¹⁸¹ (Clinical Director for Women and Children's Directorate).

4.96 The stated object of the Review was:

"...to trace the progression of Lucy's illness from her admission to the Erne Hospital and her treatment/interventions in order to try and establish whether:

There is any connection between our activities and actions and the progression and outcome of Lucy's condition

Whether or not there was any omission in our actions and treatments which may have influenced the progression and outcome of Lucy's condition

*Whether or not there are any features of our contribution to care in this case which may suggest the need for change in our approach to the care of patients within the Paediatric Department or wider hospital generally."*¹⁸²

¹⁷⁹ 325-002-008

¹⁸⁰ Mr Fee T-13-06-13 p.103 line 16

¹⁸¹ 325-002-008

¹⁸² 033-102-264

4.97 Mr Mills noted on 20th April 2000 that, *“Mr Fee advised that the patient’s notes recorded a comment from Dr O’Donoghoe (sic) that he was uncertain about the instructions he gave staff about the rate of flow of I.V. fluids. Child had been given 100mls per hour for 4 hours. He states he meant this to be 100mls per hour for the first hour and 30mls per hour thereafter. However, when child collapsed anaesthetic support had prescribed more fluids. Post mortem results indicated cerebral oedema. Mr Fee felt he required advice from a Paediatrician. I agreed I would arrange this...”*¹⁸³

4.98 In order to secure expert Paediatric opinion, Mr Mills contacted Dr Murray Quinn (Consultant Paediatrician, Altnagelvin Area Hospital) who agreed to look at Lucy’s notes and to provide advice.¹⁸⁴ Mr Fee then wrote to Dr Quinn on 21st April 2000 that:

“I would be grateful for your opinion on the range of issues discussed which would assist Dr Anderson and my initial review of events relating to Lucy’s care. These were:

- (i) The significance of the type and volume of fluid administered*
- (ii) The likely cause of the cerebral oedema*
- (iii) The likely cause of the change in the electrolyte balance i.e. was it likely to be caused by the type of fluids, the volume of fluids used, the diarrhoea or other factors.*

*I would also welcome any other observations in relation to Lucy’s condition and care you may feel is relevant at this stage.”*¹⁸⁵

4.99 Mr Fee informed Mr Mills that he had spoken with the medical and nursing staff¹⁸⁶ and had requested written statements from six individuals.¹⁸⁷ It was agreed that a health visitor would be asked to communicate with the Crawford family and inform them that the circumstances of Lucy’s death were being examined.

¹⁸³ 030-010-017

¹⁸⁴ 030-010-018

¹⁸⁵ 033-102-296

¹⁸⁶ 030-010-017

¹⁸⁷ 030-010-018

4.100 At that stage, the Review appeared well founded in that it was being led by a senior hospital manager with the assistance of the relevant Clinical Director, it had the support and interest of both the Trust's Medical Director and Chief Executive, it was commencing its investigation promptly and within days of the adverse incident, it had the expertise of an external Consultant Paediatrician and had access to all relevant clinical and nursing staff. Furthermore, on the face of it a channel of communication had been established with Lucy's parents.

4.101 Regrettably, the Review failed to establish that any error was implicated in the sequence of events leading to the death or even that there were any significant shortcomings in care. The Review report findings were remarkably inconclusive. They indicated that:

*"Lucy Crawford was admitted to the Children's Ward, Erne Hospital on 12 April 2000 at approximately 7.30pm having been referred by her General Practitioner. The history given was one of 2 days fever, vomiting and passing smelly urine. The General Practitioner's impression was that Lucy was possibly suffering from a urinary tract infection. The patient was examined by Dr Malik, Senior House Officer, Paediatrics, who made a provisional diagnosis of viral illness. She was admitted for investigation and administration of IV fluids. Lucy was considered to be no more or less ill than many children admitted to this department. Neither the post-mortem result or the independent medical report on Lucy Crawford, provided by Dr Quinn, can give an absolute explanation as to why Lucy's condition deteriorated rapidly, why she had an event described as a seizure at around 2.55am on 13 April 2000, or why cerebral oedema was present on examination at post-mortem."*¹⁸⁸

4.102 In assessing the quality of the Review I have taken into account the under developed state of clinical governance, the lack of support for the role of Medical Director, the lack of training in the process of review¹⁸⁹ and that the more developed investigation techniques of today were not then available.

¹⁸⁸ 033-102-265

¹⁸⁹ Dr R. MacFaul T-27-06-13 p.120 line 12

Method

4.103 The Review method was to consider Lucy's case notes and post-mortem, obtain written statements from the relevant staff, engage Dr Quinn, discuss matters with the Ward Sister, Infection Control Nurse and Dr Quinn and consider his written report.¹⁹⁰

4.104 There was, however, only limited commitment to gaining a detailed account of the facts of the case. Dr Quinn asked Dr Kelly and Mr Fee whether there *"could there have been earlier seizures resulting in hypoxia for 15-20 minutes prior to catastrophic seizure event?"*¹⁹¹ The reviewers did not engage with his questions. They blandly reported that *"with the exception of Nurse McCaffrey's report, little detailed descriptions of the event are recorded and no account appears to be in existence of the mother's description, who was present and discovered Lucy in this state."*¹⁹² Seemingly no one sought more detailed descriptions or asked Lucy's mother.

4.105 Dr Quinn received no further instructions and this may have hampered his ability to form necessary conclusions. He certainly expressed his uncertainty in relation to key issues:

"Did the child have a seizure or did she "cone" at 3.00am?"

*I feel it is very difficult to say what happened in and around this time. It is certainly possible that she had a seizure and may even have had a period of time when she was hypoxic before medical attention was drawn to the fact that she was unwell. However I cannot say that this is the case. It may be that mother informed the ward staff immediately she noted the problem but again this is not clear to me from the notes provided."*¹⁹³

4.106 The obvious failure to identify and examine key aspects of the incident inhibited findings on fluid management issues. The Review catalogued much that was then unclear and required investigation, noting for example

¹⁹⁰ 033-102-265

¹⁹¹ 036a-047-101

¹⁹² 033-102-266

¹⁹³ 036a-048-105

that *“There was no written prescription to define the intended volume. There was some confusion between the Consultant, Senior House Officer and Nurses concerned, in relation to the intended volume of fluid to be given intravenously. There is a discrepancy in the running total of the intravenous infusion of solution 18 for the last 2 hours. There is no record of the actual volume of normal saline given when commenced on a free flowing basis.”*¹⁹⁴

- 4.107 However, having raised these issues there appears to have been little attempt to address them. What was the confusion between the Consultant, the House Officer and the Nursing team? What was the discrepancy in the record of infusion of Solution No. 18, and how did this occur? How much normal saline was administered? What did the treating clinicians consider to be mistakes and what did they think were the implications? None of these questions was satisfactorily explored by the Review and I am bound to ask why, because there was every prospect of obtaining the answers had the reviewers pursued them.
- 4.108 Dr Anderson was keen to emphasise the distinction between ‘investigating’ and ‘reviewing’ a case¹⁹⁵ just as Mr Fee insisted that he was conducting a ‘review’ rather than ‘investigating’ a death. Their evidence suggested that neither was determined to pursue critical questions.
- 4.109 Dr Quinn had asked how much normal saline had been administered because had Lucy received 500ml *“this may have affected the level of cerebral oedema experienced at post mortem.”*¹⁹⁶ However, the information was not provided to the satisfaction of Dr Quinn, causing him to observe in his report that he was *“not certain how much normal saline was run in...”*¹⁹⁷ This was a failure Mr Fee could not explain. That the Review should respond to Dr Quinn’s query about the administration of normal saline in such a casual manner is symptomatic of the general lack of thoroughness. Notwithstanding that the Review ought to have focussed on fluid management matters, Mr Fee and Dr Anderson allowed some

¹⁹⁴ 033-102-266

¹⁹⁵ Mr Fee T-13-06-13 p.116 line 5

¹⁹⁶ 036a-048-106

¹⁹⁷ 033-102-273

participants to avoid all mention of fluids. Extraordinarily, the Review was actually characterised by a general failure to describe fluid management error and the potential implications.

- 4.110 The Review had sought from each clinician a *“factual account of the sequence of events from their perspective.”*¹⁹⁸ This was interpreted narrowly and the co-ordinators accepted what was submitted without demur or follow-up. There was an obvious absence of rigour and clinical curiosity. It is troubling that having knowingly commenced a review into the fluid and electrolyte management of a patient who had died, that they did not ask more questions about the management or appraise the evidence in order to identify the limited co-operation which they had received.
- 4.111 Clinicians should have been specifically requested to explain and justify the fluids given and to articulate any concerns. Dr Malik’s approach should have been challenged and Dr Auterson asked to address the issues more specifically. The clinicians should not have been permitted to avoid proper explanation. It is a matter of concern that the reviewers should tolerate rather than challenge Dr O’Donohoe’s avoidance of the issues. He was asked neither for detail nor explanation as to what had happened. This was unacceptable and illustrates how timidly Mr Fee and Dr Anderson approached the Review.
- 4.112 Mr Fee agreed that the failure of clinicians to engage with the Review *“stares out at you”* from their statements.¹⁹⁹ However, it was their responsibility to ensure that the clinicians did not evade the issues. The clinicians should have been pursued and required to provide answers. Mr Fee could not account for this failure²⁰⁰ but insisted that it was not in consequence of any deliberate decision.²⁰¹
- 4.113 Mr Fee and Dr Anderson were responsible for a Review which was inadequate. This was a failure of the individuals and of governance. They

¹⁹⁸ 033-102-285

¹⁹⁹ Mr Fee T-13-06-13 p.145 line 7-8

²⁰⁰ Mr Fee T-13-06-13 p.146 line 7

²⁰¹ Mr Fee T-14-06-13 p.37 line 17

were inexperienced and untrained in the conduct of reviews of this nature and they were not assisted by the clinicians involved. They were possibly deflected by the misleading conclusions of Dr Quinn. However this can afford them only partial mitigation. Lucy's death was caused by a glaring medical error and if Mr Fee and Dr Anderson had thought about it they would have recognised that the clinicians were consistent in avoiding this central issue, and it would appear, deliberately so.

Dr O'Donohoe's contribution to Review

4.114 In assessing Dr O'Donohoe's contribution to the Review I have had regard to the findings reached by the GMC that his acts or omissions were not in Lucy's best interests and fell below the standard to be expected of a reasonably competent physician.²⁰² The GMC determined that Dr O'Donohoe had failed to calculate an acceptable plan of fluid replacement and had failed to ensure that nursing staff knew of an adequate fluid replacement plan and a system for monitoring its progress. Moreover, the GMC concluded that the entry made in Lucy's notes by Dr O'Donohoe on the 14 April 2000 following his conversation with Dr Crean, was both "inaccurate and misleading." Furthermore, it was found that the fluid therapy which Dr O'Donohoe "claimed to have ordered" was not communicated properly to those administering the fluid and was in any event, inappropriate.

4.115 It has been said on Dr O'Donohoe's behalf that his role in the events following Lucy's death was "*of a very limited compass*" and that he was only involved with the aftermath "*to a comparatively limited degree.*"²⁰³ I disagree with this analysis. Dr O'Donohoe could and should have played the central role in identifying the mismanagement in her care and in assisting the review to determine what it was that had caused her death. It is clear that he failed to fulfil that role.

²⁰² 163-005-001

²⁰³ 400-033-002 to 004 - para 7 & 25(4), Submissions made on behalf of Dr O'Donohoe

4.116 In his statement for the Review, Dr O'Donohoe rehearsed those fluids which he claimed to have directed Dr Malik to give Lucy, namely 100mls as a bolus over the first hour and then 30mls per hour thereafter.²⁰⁴ However, he knew very well that Lucy had not received those fluids. He had checked this issue after Dr Crean's telephone call and knew that Lucy had received Solution No. 18 at a rate of 100ml/hr until she suffered a seizure and that thereafter she had been given a large quantity of normal saline. He did not refer to these important matters in his statement. He knew that her fluid management was wrong and he avoided saying so.

4.117 Dr O'Donohoe, having stated that he could not remember why he did not particularise the fluids actually given,²⁰⁵ ventured to explain that he didn't know that Dr Anderson was conducting a Review on behalf of the Trust and that in any event Dr Anderson liked to receive short, factual reports.²⁰⁶ Ultimately, Dr O'Donohoe accepted in his evidence that his avoidance of all reference to fluid mismanagement in his statement was a failing and he expressed regret.²⁰⁷

4.118 It was said on Dr O'Donohoe's behalf that his mental and physical health had declined since the events in question and that his memory was in consequence impaired.²⁰⁸ While all of this may be so, I found his explanations implausible and bizarre. Dr O'Donohoe contended that at the time of Lucy's death it did not occur to him that her deterioration was "*a fluid balance issue*" although he accepted in retrospect that this is precisely what should have occurred to him at the time.²⁰⁹ He stressed that he did not think her repeat serum sodium level of 127mmol/l could be associated with "*such a profound catastrophic outcome.*"²¹⁰ In defence of his position Dr

²⁰⁴ 033-102-293

²⁰⁵ WS-278-1 p.8

²⁰⁶ Dr O'Donohoe T-06-06-13 p.148 line 1-8

²⁰⁷ 400-033-004 - Submissions made on behalf of Dr O'Donohoe

²⁰⁸ 400-033-002 - Submissions made on behalf of Dr O'Donohoe

²⁰⁹ Dr O'Donohoe T-06-06-13 p.13 – This position was consistent with his evidence before the General Medical Council by whom he was condemned for serious professional misconduct.

²¹⁰ Dr O'Donohoe T-06-06-13 p.100 line 8

O'Donohoe relied on the fact that the issues were not clarified by the post-mortem undertaken at the RBHSC.²¹¹

- 4.119 I do not consider that Dr O'Donohoe should necessarily have reached the initial conclusion that errors of fluid management caused the death. Rather, I believe that an experienced paediatrician with a developed understanding of this field of medicine should have suspected that fluid mismanagement could be implicated. Instead of engaging with the Review on this issue, he remained silent. This was unacceptable.

Dr Malik's contribution to the Review

- 4.120 Dr Malik submitted a statement for the Review²¹² but made no reference whatever to the fluids. His omission is extraordinary. His failure to engage was not challenged by those conducting the Review. At best, this was worryingly complacent.
- 4.121 Dr Malik had been present when Dr O'Donohoe gave his directions for Lucy's fluid management. So much is clear from Dr O'Donohoe²¹³ and Staff Nurse Swift.²¹⁴ However, Dr Malik stated that having admitted Lucy for "*administration of intravenous fluids*"²¹⁵ he was probably called away before Dr O'Donohoe directed Lucy's fluids.²¹⁶ Even if Dr O'Donohoe and Staff Nurse Swift are wrong and he was absent when the fluids were prescribed, Dr Malik nonetheless had the opportunity to identify the fluids because they were still running when he returned to see her at 03:00. I conclude that he knew what she had been given and ought to have said so in his statement.
- 4.122 Furthermore, Dr Malik's position that he "*did not mention the rate and volume of fluid actually received by Lucy as [he] was not the one who initiated the fluid regime*"²¹⁷ is disingenuous. The fact that Dr Malik did not

²¹¹ Dr O'Donohoe T-06-06-13 p.112 line 8

²¹² 033-102-281

²¹³ 033-102-293

²¹⁴ 033-102-295 & 033-102-290

²¹⁵ 033-102-281

²¹⁶ 033-102-281

²¹⁷ WS-285-1 p.9

initiate the pre-collapse fluids is irrelevant and merely avoids explanation of what he knew.

- 4.123 Dr Malik was likewise evasive in relation to the fluids administered after collapse. Staff Nurse Sally McManus²¹⁸ confirmed that Lucy's fluids were changed to normal saline with Dr Malik in attendance.²¹⁹ Accordingly, Dr Malik was probably responsible for that prescription and indeed he recorded the infusion of 500ml normal saline over 60 minutes.²²⁰ However, he chose not to mention it in his statement for the Review.
- 4.124 I consider that a remarkable and telling failure. The decision to discontinue Solution No. 18 and infuse as much normal saline as possible for an hour was a radical change in treatment and required clear explanation. Dr Malik ought to have particularised and justified the treatment he directed rather than omitting all reference to it.
- 4.125 Dr Malik said that he had only been asked to deal with his role in caring for Lucy and had not been asked for his view about the appropriateness of the treatment.²²¹ However I consider that it was his responsibility to inform the Review both about the treatment given and the reasons for that treatment. He was no mere bystander but an active participant.
- 4.126 Dr Malik said that he was reassured because his consultant Dr O'Donohoe had made the initial prescription and there were senior nurses present who would have challenged the treatment had they been concerned.²²² This is inconsistent with the explanation he gave to the GMC that *"...the nursing staff should not have started the fluid without written prescription; they should have been aware of the inappropriate amount of fluid regime and they should have queried it with me or the consultant."*²²³ His evidence and attitude confirms my suspicion that he was aware that the treatment

²¹⁸ 325-002-002

²¹⁹ 027-017-057

²²⁰ 027-010-024

²²¹ WS-285-1 p.10

²²² WS-285-1 p.10

²²³ WS-285-1 p.22

provided was open to criticism and that is why he was so unhelpful when asked to account for it.

- 4.127 In assessing Dr Malik's conduct, I take into account the fact that at the time of Lucy's death he was a relatively inexperienced paediatrician. His appointment to the Erne as an SHO appears to have been his first substantive appointment to a paediatric post in the UK.²²⁴ He did not give oral evidence and so his Inquiry witness statement could not be tested. Whilst I appreciate that it may have been difficult for him to travel from Pakistan, he made no application to be excused.
- 4.128 I conclude that Dr O'Donohoe and Dr Malik were aware that the fluid management was flawed. It is troubling that they should have deliberately avoided dealing with the issue for the Review. They disregarded their duty as doctors to co-operate fully with the Review and specifically not to withhold relevant information.²²⁵ They acted unprofessionally and by so doing undermined the critical process of review.

Dr Auterson's contribution to the Review

- 4.129 I have already reviewed Dr Auterson's engagement with the Review process.
- 4.130 He was at all times under a professional duty to make proper disclosure.²²⁶ In his evidence he admitted that he was ashamed by his failure to assist the Review but said that, "*There was no deliberate attempt on my part to conceal any facts. The fact that I did not mention fluid balance and possible errors on that in my report [for the Review], I can't explain it, it's a bad reflection on me.*"²²⁷
- 4.131 In many respects the motivation for Dr Auterson's silence is not the most important issue, but it does seem to me very likely indeed that he failed to

²²⁴ WS-285-1 p.18

²²⁵ 315-002-009 - GMC Good Medical Practice (1998)

²²⁶ 315-002-009

²²⁷ Dr Auterson T-31-05-13 p.153 line 23

inform management of Lucy's care because of a misplaced loyalty to colleagues.

Dr Murray Quinn's report for the Review

- 4.132 The decision to appoint an 'outside' Consultant Paediatrician to advise was sound in principle. However, Dr Quinn imposed limitations on his involvement. He did not wish to interview clinicians or meet the family. His was a paper exercise which involved examining the records, identifying issues, raising questions and attempting to draw conclusions. He was not asked for a formal medico-legal report. Such limitations were likely to reflect in the quality and completeness of his work.²²⁸ He maintained that the Trust knew what he was prepared to do and accepted his approach.²²⁹ This confirms the Trust's lack of ambition for the Review which undermined its prospects from the start.
- 4.133 Dr Quinn agreed that he was obliged to bring professional rigour to his task.²³⁰ His work may have been limited but he was to do it to the best of his professional ability. In the event, Dr Quinn was unable to identify the ultimate cause of the cerebral oedema.²³¹ That may have been understandable but his report made fundamental errors which served to mislead.
- 4.134 Dr Quinn was an experienced Consultant Paediatrician and the medical issues of gastroenteritis, dehydration, fluid and electrolyte therapy and cerebral oedema were all within his competence to analyse.²³² Nonetheless, errors appear in his report which individually and cumulatively gave the Trust reassurance when its clinicians ought to have been subject to criticism.
- 4.135 Dr Quinn categorised the use of Solution No. 18 to manage the fluids of a child with recent vomiting and diarrhoea as "*appropriate*."²³³ He later

²²⁸ Dr Quinn T-14-06-13 p.99 line 23

²²⁹ Dr Quinn T-14-06-13 p.99 line 14

²³⁰ Dr Quinn T-14-06-13 p.97-98

²³¹ 036a-048-106

²³² Dr Quinn T-14-06-13 p.109 line 19

²³³ 036a-048-104

acknowledged that this was wrong, explaining that he used “*this ‘appropriate’ term, which is maybe inappropriate, on the perception that the doctors in the Erne felt she wasn’t very sick, and therefore at that time were going to use fifth-normal saline for maintenance or mild dehydration.*”²³⁴

4.136 There are problems with this analysis because Dr Quinn knew from the notes that Dr O’Donohoe claimed to have intended a different fluid regime for Lucy not involving Solution No. 18 at 100ml/hr.²³⁵ Accordingly, Dr Quinn’s perception that the doctors thought her in a better state of health than she was, had no basis in fact. In any event, his report did not contain this explanation. If he believed that they used the wrong fluid because they underestimated the severity of her condition then it was his obligation to say so. He should not have engaged in an analysis on the basis that the doctors were correct in using Solution No. 18 when he recognised that this was in fact a mistake.

4.137 Dr Quinn accepted that Lucy had not been mildly dehydrated but was suffering dehydration in the order of 5%-10%. In such circumstances it was necessary to administer fluids containing more sodium than Solution No. 18.²³⁶ He should have made this observation and with force but did not. Dr Quinn sought unconvincingly to argue that it was at least possible that he could have told the Trust that the fluid should have been normal saline.²³⁷ However, the note of his meeting with Dr Kelly and Mr Fee on the 21 June 2000 clearly records him expressing a view that “*choice of fluid correct.*”²³⁸ Similarly, his report written the following day, described the choice of fluid as “*appropriate.*”²³⁹

4.138 Dr Quinn failed to adequately condemn the fluids given as excessive. Whilst he insisted that he had always taken the view that the volume of fluids administered “*was absolutely incorrect*”²⁴⁰ this does not emerge

²³⁴ Dr Quinn T-14-06-13 p.134-135

²³⁵ Dr Quinn T-14-06-13 p.121 line 19 & 027-010-024

²³⁶ Dr Quinn T-14-06-13 p.138 line 8

²³⁷ Dr Quinn T-14-06-13 p.148 line 10

²³⁸ 036a-047-101

²³⁹ 036a-048-104

²⁴⁰ Dr Quinn T-14-06-13 p.141 line 10

clearly from his report. It notes that Lucy received 100ml/hr of Solution No. 18 over a four hour period²⁴¹ but is silent as to whether Lucy's condition warranted the infusion of 100ml/hr. Moreover, Dr Kelly's note of their meeting on 21 June 2000 records Dr Quinn as indicating that "*fluid replacement 4 hours @ 100mls provided was greater than normal but not grossly excessive.*"²⁴² By contrast, Dr Quinn agreed in oral evidence that not only did Lucy receive the wrong fluid, but she received it at a rate (100ml/hr) which would only have been acceptable had she been much more dehydrated than he believed.²⁴³

4.139 Notwithstanding, that the volume of normal saline given was not clarified to Dr Quinn's satisfaction by the co-ordinators of the Review his working notes indicate that he was suspicious that 500ml had been administered.²⁴⁴ Regrettably, he did not use his report to highlight the basis for this justifiable concern, nor did he indicate that the infusion of such a volume could have contributed to the oedema. This was in strong contrast to the directness with which he gave his oral evidence when he described a volume of 500ml as "*massively excessive.*" He explained that running that volume into a sick child of Lucy's weight would place "*tremendous strain on the right side of the heart.*"²⁴⁵

4.140 Additionally, Dr Quinn reported that he would have been "*surprised*" if the volume of fluid given "*could have produced gross cerebral oedema causing coning.*"²⁴⁶ That this was his stated view is confirmed by Dr Kelly's note.²⁴⁷ Whilst Dr Quinn denied this,²⁴⁸ I am nonetheless satisfied that this was the impression given to Dr Kelly. In his discussions with the Trust as in his written report, Dr Quinn expressed himself in such a way as to mislead as to the appropriateness of the type and volume of fluids given and to

²⁴¹ 036a-048-104

²⁴² 036a-047-101

²⁴³ Dr Quinn T-14-06-13 p.173 line 19

²⁴⁴ WS-279-1 p.35

²⁴⁵ Dr Quinn T-14-06-13 p.126 line 17

²⁴⁶ 036a-048-105

²⁴⁷ 036a-047-101

²⁴⁸ Dr Quinn T-14-06-13 p.167 line 19

communicate a sense that the fluid therapy presented little cause for concern.

- 4.141 Dr Quinn also failed to recognise that because the normal saline was infused before the blood sample was taken, the serum sodium count could have been even lower than the 127mmol/l recorded. Whilst Dr Quinn admitted that he did not seek clarification in relation to the sequencing before writing his report,²⁴⁹ I received no adequate explanation from him as to why his written report should have so failed in analysis.

Criticisms of Dr Quinn

- 4.142 It has been suggested on Dr Quinn's behalf that it would be fair to criticise him for three errors only: describing the infusion of Solution No. 18 as "*appropriate*" because this was potentially misleading (albeit not intentionally so); for failing to state explicitly in his report that it was intended as a 'desk-top' review and not a medico-legal report; and for allowing himself to be persuaded to commit his thoughts to writing at all.²⁵⁰
- 4.143 I agree that these concessions were properly made, but there is an additional concern. Importantly, Dr Quinn failed to draw attention to what he knew to be a possibility, namely that the mismanagement of fluids could have caused the fatal cerebral oedema. In his defence Dr Quinn considered that he was not in a position to give an opinion on the likely cause of the cerebral oedema and coning because he had not been provided with all the necessary information.
- 4.144 Notwithstanding that Dr Quinn did not receive all the materials which would have been supplied to him had he been asked to conduct a detailed investigation and whilst accepting that Dr Quinn may not have been able to reach a definitive conclusion because he had not spoken to Lucy's mother, nursing staff or the clinicians involved, it is nonetheless clear, that he could have identified the poor fluid management and indicated that it could have

²⁴⁹ Dr Quinn T-14-06-13 p.117

²⁵⁰ 400-029-009 to 011 - Submissions on behalf of Dr Quinn

caused the cerebral oedema and coning.²⁵¹ He properly accepted that by omitting this from his report the Trust may have been falsely reassured.²⁵²

- 4.145 Dr MacFaul described Dr Quinn's report as "*wrong and misleading*." I agree with that view. Indeed, it is reasonable to conclude that the conclusions in his report about fluid management were directly contradicted in his oral evidence. I consider that his approach to the task demonstrated a reluctance to criticise other professional colleagues. This has been a recurring theme in this Inquiry. There were certainly deficiencies in the information supplied to him, but I take the view that he had sufficient information to be more critical of the treatment provided to Lucy, and that he ought to have alerted SLT to more problems than he did. He was keen to adopt a limited role and was insufficiently committed to his task to give the issues which confronted him the attention they deserved. He approached his obligation to report without due professionalism.

Independence of Dr Quinn

- 4.146 The appointment of Dr Quinn to assist with the Review has been questioned on the basis that he may have lacked the independence necessary to assess the issues with obvious detachment. It was of fundamental importance that he should express independent views without fear or favour and that there should be confidence that he was so doing.
- 4.147 Dr Quinn was at that time employed as a consultant in the Altnagelvin Area Hospital which was run, like the Erne Hospital, within the same WHSSB area. Additionally, Dr Quinn had previously provided paediatric services to the Erne Hospital and knew some of the clinicians who worked there including Drs Anderson and O'Donohoe. He knew Mr Mills both professionally and socially.
- 4.148 I am concerned there was no assessment by the Trust of the potential for conflict of interest.²⁵³ Dr Quinn was a very poor choice to conduct this work

²⁵¹ Dr Quinn T-14-06-13 p.150 & p.156 line 18 & p.154 line 22

²⁵² Dr Quinn T-14-06-13 p.163 line 22 & p.164 line 2

²⁵³ 162-002-006 - Dr Michael Durkin has commented that Dr Kelly, in his capacity as Medical Director, ought to have made such a record.

on behalf of Trust, not least because of his professional and social connections. The Trust is to be criticised for retaining an expert who was not transparently independent.

- 4.149 It is clear to me that Dr Quinn did not approach his task with the necessary degree of professional detachment. His familiarity with the organisation and the people who had retained him plainly influenced him. He has indicated that he was “*sweet talked*” into providing a written report for the Review against his better judgment.²⁵⁴ He should not have carried out this work on behalf of the Trust, and should not have been asked to do so.

Deployment of Dr Quinn’s Report by Sperrin Lakeland Trust

- 4.150 Mr Crawford made a formal complaint to the Trust on 22 September 2000 requesting that it investigate the “*inadequate and poor quality of care provided*.”²⁵⁵ He was entitled under the 1992 Patient’s Charter to expect that this would be dealt with quickly with a full investigation and written report to be issued within one month. Additionally, the Trust had been issued with Departmental guidance on handling complaints by the HPSS Executive in 1996.²⁵⁶ This emphasised as a “*key objective*” an approach which was honest and thorough.²⁵⁷

- 4.151 Mr Mills eventually made the Trust’s substantive response to Mr Crawford on 30 March 2001. He sought to reassure him that,

“the outcome of our review has not suggested that the care provided to Lucy was inadequate or of poor quality. As you will be aware, the Trust engaged an independent consultant, from another Trust, to review Lucy’s case notes and to advise us on this very question. We do however accept and acknowledge that the review has flagged up issues which the Trust will

²⁵⁴ In the UTV Insight documentary Dr Quinn used the term “*sweet talked*.” It was an unfortunate turn of phrase in this context. However, I note the submission made on Dr Quinn’s behalf that I should not place importance upon it. I agree that of itself, the use of the phrase does not assist me in coming to a determination in relation to whether his independence was compromised.

²⁵⁵ 015-014-114

²⁵⁶ 314-016-001 - Complaints: Listening...Acting...Improving. Guidance on Implementation of the HPSS Complaints Procedure.

²⁵⁷ 314-016-006

wish to address for the future. These include communication and written records, and are referred to in Mr Fee's report."²⁵⁸

- 4.152 The deliberate impression conveyed was that the independent expert's advice had established that there were no inadequacies in the care. Mr Mills did not tell Mr Crawford that the RCPCH had been asked to review Lucy's case as part of a broader appraisal of Dr O'Donohoe's competence. I am concerned that Mr and Mrs Crawford were encouraged to conclude that there had been a proper consideration of the issues surrounding their daughter's death and that the Trust was justified in defending the quality of care provided.
- 4.153 Mr Mills insisted that he was entitled to respond to the complaint in this way given what he knew at the time.²⁵⁹ He contended that it was only after engaging with the RCPCH, the litigation process and the inquest that the Trust could understand the inadequacy of the care.²⁶⁰
- 4.154 Nevertheless, there were problems with Mr Mills' decision to deploy Dr Quinn's report in response to Mr Crawford's complaint because it had not been commissioned or compiled for that purpose. Dr Quinn's report was a "*desk-top review*"²⁶¹ undertaken without detailed investigation for the purpose of "*highlighting issues rather than attempting to provide definite conclusions.*"²⁶²
- 4.155 Dr Quinn had very clearly not intended his report to be conclusive. It expressed uncertainties about whether Lucy had suffered a seizure, why she was floppy, what her mother had observed and even how much normal saline she had been given.²⁶³ Such statements as were obtained by Mr Fee and Dr Anderson were not shared with Dr Quinn. Dr Quinn had written that "*It is always difficult when simply working from medical and nursing records and also from not seeing the child to get an absolutely clear picture*

²⁵⁸ 015-034-146

²⁵⁹ Mr Mills T-17-06-13 p.143 line 21

²⁶⁰ Mr Mills T-17-06-13 p.144 line 2

²⁶¹ Dr Quinn T-14-06-13 p.106-107

²⁶² Dr Quinn T-14-06-13 p.102 line 17

²⁶³ 036a-048-105

*of what was happening...*²⁶⁴ His report raised more questions than it supplied answers.²⁶⁵ However, no such uncertainty was conveyed to Lucy's parents.

4.156 Furthermore, Dr Quinn's report did not absolve the Trust, and Mr Mills was wrong to suggest that it did not identify inadequacies in the care. Dr Quinn had "*questioned a lot of what had been done in terms of the record keeping and the IV fluids*"²⁶⁶ and for his part, Mr Fee was very properly prepared to accept that the failures identified by Dr Quinn's report were "*deficits in the quality of care provided to Lucy*."²⁶⁷

4.157 Mr Mills should not have suggested that Dr Quinn's report was an independent expert determination of the adequacy and quality of the care because it was not. It was misleading to suggest his reported view to Mr Crawford as an answer to the complaint. It was not. That the Trust chose not to furnish Mr Crawford with a copy of Dr Quinn's report compounds the obvious failure to respond with the openness and fairness expected of it by the Departmental guidance.²⁶⁸

Involvement of RBHSC and Mr and Mrs Crawford

4.158 Mr Fee acknowledged that there were no restrictions on how he or Dr Anderson should conduct their Review. Notwithstanding, the Review was markedly limited in the scope of its inquiry. Whilst the obvious first step would have been to approach the RBHSC for input²⁶⁹ this was not done and there is no good explanation as to why it was not done. Dr MacFaul believed it "*an outstanding deficit*" of the Erne Review process that the opinions of the RBHSC clinicians were not sought.²⁷⁰

4.159 Nor did the Trust formally notify Mr and Mrs Crawford of the Review process, invite them to participate in the Review or advise them as to the

²⁶⁴ 036a-048-106

²⁶⁵ 400-029-008 - Submissions on behalf of Dr Quinn

²⁶⁶ Dr Quinn T-14-06-13 p.181 line 8

²⁶⁷ WS-287-1 p.21

²⁶⁸ 314-016-018

²⁶⁹ Mr Fee T-13-06-13 p.149 line 1

²⁷⁰ 250-003-093

procedure and terms of reference. Dr Anderson²⁷¹ could not even recall any suggestion that they be involved in the Review process.²⁷² He accepted that Mrs Crawford should have been asked to participate.²⁷³ So too did Mr Fee²⁷⁴ and Dr Kelly.²⁷⁵ Mr Crawford did not even learn of the Review until almost four weeks after he had lodged his complaint.²⁷⁶

4.160 It could never have been a very meaningful Review without asking for Mr and Mrs Crawford's contribution. Lucy's parents had every right to be told that their child's death was to be investigated. In addition Mrs Crawford was a witness to key events. It is therefore remarkable that the final Review report should have expressed regret at the absence of an account of the seizure suffered by Lucy from Mrs Crawford.²⁷⁷ It should have been a straightforward matter to seek her input and it should have been done.

4.161 Dr Kelly, as Medical Director, was responsible for ensuring that the Review was effective and appropriate. His failure to ensure that the family was involved cannot be explained by reference to his inexperience in his role or by the demands of a busy professional life.²⁷⁸ Since the report of the Review referred explicitly to the absence of an account from Mrs Crawford, his failure to ensure that engagement defies common sense.

Report

4.162 At the conclusion of the Review it should have been obvious that it had failed to make clear findings. Whilst the conclusions ostensibly provided some reassurance, Dr Quinn's report left much to be investigated. Notwithstanding that it was clearly not too late to seek input from Mrs Crawford or to make a request for the opinion of the RBHSC clinicians,²⁷⁹ the report was finalised and published on 31st July 2000.

²⁷¹ WS-291-2 p.5

²⁷² Dr Anderson T-11-06-13 p.52 line 19

²⁷³ Mr Fee T-13-06-13 p.111-112

²⁷⁴ WS-287-1 p.16

²⁷⁵ Dr Kelly T-13-06-13 p.83 line 17

²⁷⁶ 015-020-121

²⁷⁷ 036a-053-125

²⁷⁸ 400-030-012 para 19-20 - Submissions made on behalf of Dr Kelly

²⁷⁹ 250-003-067

4.163 The Review report appears sanitised. It concluded that *“there was some confusion between the Consultant, Senior House Officer and nurses concerned in relation to the intended volume of fluid to be given intravenously.”*²⁸⁰ The problems were very much more profound than just volume or communication. It is accordingly a matter of concern that the findings of the Review were not shared or discussed with the clinicians in the Erne Hospital. Further error would then have been detected. If, for example, Dr Quinn’s report had been shown to Dr Auterson, he could have immediately pointed out the error in deeming the use of Solution No. 18 ‘appropriate.’

4.164 The Trust should have acknowledged the limitations of the Review and identified the need for further investigation. Mr Fee could not recall this being considered²⁸¹ but conceded, that with the benefit of hindsight, that he was,

*“... not now satisfied with the review we conducted or the conclusions we reached given the findings of the inquest. On reflection, we should have involved the family at the outset; the review should have been conducted using a more systematic approach such as a Root-Cause Analysis. The Team selected should probably have benefitted from the inclusion of a Paediatrician and an experienced paediatric nurse and perhaps the Medical Director. We probably relied too much on the external opinion without having the expertise to examine the opinion offered. The case should probably have been jointly reviewed or investigated by the two hospitals involved in Lucy’s care.”*²⁸²

4.165 Dr Anderson not only adopted this statement but said that he thought at the time that Dr Quinn’s conclusions were suspect but felt in no position to challenge them. He believed he discussed this with Mr Fee but Mr Fee had no recollection of this.²⁸³ Notwithstanding, the Trust regarded itself satisfied

²⁸⁰ 033-102-266

²⁸¹ Mr Fee T-14-06-13 p.44 line 19

²⁸² WS-287-1 p.20

²⁸³ Mr Fee T-14-06-13 p.46 line 21

with the work of the Review and answered Mr Crawford's complaint on that basis.

4.166 The Review report recommended that the family should be invited to a meeting to discuss its findings.²⁸⁴ However, the Trust did not send the report to the Crawfords but suggested instead that it would be shared with them at a meeting at which Trust officials would explain the findings.²⁸⁵ The Trust only finally shared the report in January 2001, six months after it had been finalised.

4.167 On the face of it the Trust wanted such a meeting in order to convey to the Crawfords a proper understanding of the Review's findings.²⁸⁶ However, I detect a determination on the part of the Trust to control the manner in which the family would receive and interpret the information to which they were entitled. This approach is confirmed by the fact that even when a copy of the report was finally made available, it was stripped of its recommendations together with the appendices and the report of Dr Quinn.²⁸⁷ There can be no justification for this and Mr Fee could offer no explanation.²⁸⁸

4.168 It was submitted on behalf of Dr Kelly that his failure to recognise the flawed nature of the Report at the time was in part understandable because he was reliant on the apparently conscientious work of Mr Fee and the appearance of the 67 page Review report complete with appendices and external paediatric opinion gave every impression of being comprehensive.²⁸⁹

4.169 I cannot accept this submission. Dr Kelly was the Trust Medical Director and had responsibility to ensure the adequacy of the Review. If Dr Kelly had adequately considered the Review report he could not have failed to recognise that it and the investigation were substandard. I accept that

²⁸⁴ 033-036-076

²⁸⁵ 015-019-119

²⁸⁶ 015-024-127

²⁸⁷ 015-028-133 to 136

²⁸⁸ Mr Fee T-14-06-13 p.71 line 17

²⁸⁹ I also note the reliance which Dr Kelly's legal advisors have placed on the report of Dr M.A. Durkin dated 22nd August 2011: 162-002-001. I have given full consideration to the opinions expressed by Dr Durkin.

serious adverse clinical incident reviews were not commonplace at that time but consider that there can be no excuse for a Medical Director who fails to recognise that obvious enquiries have not been made.

- 4.170 On one interpretation the Review was deliberately superficial and Dr Kelly knowingly accepted a flawed report because it helped to conceal the truth about what had happened to Lucy. That is not my conclusion. I do not believe that Dr Kelly conducted himself in that way. Rather, I accept that Dr Kelly, Mr Fee and Dr Anderson and the Trust took some steps to discover what had gone wrong. However, those steps were clearly not sufficient. They failed to uncover the glaring failures in the treatment of a girl who, apart from a minor ailment, was otherwise healthy, and who was rendered moribund as a result of that treatment a few hours after it was initiated. Nobody has suggested to the Inquiry that the cause of Lucy's death was difficult to discern. What was lacking was a willingness to involve the Crawford family and be open to the need to criticise those involved with Lucy's care.
- 4.171 I consider that Dr Kelly, on behalf of the Trust, presided over a process which was ineffective and which, as a consequence, failed to identify medical mismanagement in causing her death. He ought to have identified the need to initiate an external review to resolve the questions left unanswered by Dr Quinn. For those failures he is to be criticised.

Failure to disclose the findings of RCPCH Reports to Mr and Mrs Crawford

- 4.172 The initial failure of the SLT to be transparent and straightforward with Mr and Mrs Crawford was repeated when the Trust received the first RCPCH report which clearly challenged any perception that the care provided to Lucy was adequate. It was received by the Trust in late April 2001²⁹⁰ and dealt in part with Dr O'Donohoe's practice in the context of Lucy's treatment.

²⁹⁰ 036a-022-039

- 4.173 Dr M. Stewart reported “*deficiencies in the prescription and recording of volumes of fluids administered.*”²⁹¹ In particular she stressed that in cases of moderate or severe dehydration APLS guidelines recommended the use of normal saline and not Solution No. 18.²⁹² Her report also indicated that after collapse, Lucy was given an excessive volume of normal saline.
- 4.174 I consider that having received this report, the Trust was then subject to a continuing obligation to provide the family with this new information because it superseded both the Review findings and the response which Mr Mills had provided in answer to Mr Crawford’s complaint.
- 4.175 The RCPCH produced a second report for the Trust on the 7th August 2002.²⁹³ It went further than the first report to conclude that:
- “The prescription for the fluid therapy for LC was very poorly documented and it was not at all clear what fluid regime was being requested for this girl. With the benefit of hindsight there seems to be little doubt that this girl died from unrecognised hyponatraemia although at the time this was not so well recognised as at present.”*²⁹⁴
- 4.176 This was unequivocal external opinion that the hyponatraemia was a direct cause of death and that it was linked to the fluid regime.²⁹⁵ Dr Kelly regarded this as an advance on what was previously known, which was likewise acknowledged by Mr Mills.²⁹⁶ However, no one within the Trust sought to correct the view given to the Crawford family that Lucy had received an acceptable standard of care. All those who were involved on behalf of the Trust, particularly Dr Kelly and Mr Mills in this context, are to be criticised because all were under a duty to ensure that Mr and Mrs Crawford were not misled.

²⁹¹ 036a-025-060

²⁹² 036a-025-058

²⁹³ 035-021-074

²⁹⁴ 035-021-077

²⁹⁵ Dr Kelly T-13-06-13 p.77 line 19

²⁹⁶ Mr Mills T-17-06-13 p.163 line 22

- 4.177 As before, the report was not shared with Lucy's parents.²⁹⁷ Mr Mills explained that by the time the Trust received the RCPCH reports the family had commenced legal action against the Trust and that in this context he *"would have sought assurance that the reports were shared with the Trust's legal representatives for their advice."*²⁹⁸ There is no evidence that the Trust was advised against disclosing either report and indeed there are strong grounds for considering that the report should have been drawn to the attention of the Crawford's as part of the very process of litigation.
- 4.178 Accordingly, it seems likely that a decision was taken that the Crawford family should not see the reports. In addition, they were not disclosed to the Coroner and whilst it was argued that there was no legal duty to furnish the reports to the Coroner,²⁹⁹ I am left to consider the motivation for such deliberate non-disclosure to the next of kin. The obvious explanation is that they were deliberately withheld to keep from the Crawford family the known connection between medical mismanagement and the death of their daughter.
- 4.179 Mrs Crawford said that she and her husband *"were not listened to and sidelined in every way"* and that *"everyone was avoiding the most important issue, what happened to Lucy?"*³⁰⁰ Mr Mills, the Chief Executive of the Trust, was ultimately responsible for ensuring that there was a full and transparent engagement with Mr and Mrs Crawford. Regrettably, I must find that the Trust's engagement with them was reluctant, incomplete, defensive and misleading. The Chief Executive must bear responsibility for this failing.

Sperrin Lakeland Trust and the Western Health and Social Services Board

- 4.180 The SLT was directly accountable to the Department of Health and Social Services and Public Safety ('the Department') in respect of the provision

²⁹⁷ Dr Kelly T-13-06-13 p.80 line 14 - The accounts of Mr Mills and Dr Kelly suggest that a copy of the second report from the RCPCH was not even shared with the Western Health and Social Services Board, although in his evidence Dr Kelly recalled that he spoke to Dr McConnell and Mr Martin Bradley about the report in the context of achieving changes in the Paediatric Department of the Erne Hospital.

²⁹⁸ WS-293-1 p.18

²⁹⁹ 400-030-022 to 023 - Submissions made on behalf of Dr Kelly

³⁰⁰ 013-022-079

and management of services.³⁰¹ The main commissioner of those services was the WHSSB under a 'purchaser-provider' service agreement³⁰²

- 4.181 Whilst remaining accountable to the Department and with no accountability to the WHSSB in management terms, the Chief Executive of the Trust nevertheless continued to report to and discuss significant issues with the WHSSB because it required assurance that the services purchased were of appropriate quality. If problems arose in respect of those services, the WHSSB expected to be told. The WHSSB was thus able to exert influence over the Trust and require compliance with the terms of its service agreement which emphasised, amongst other things, the importance of effective clinical governance.³⁰³
- 4.182 It was in this context that Lucy's death was reported to the WHSSB. Dr William McConnell,³⁰⁴ then Board Director of Public Health, was informed on the day of Lucy's death.³⁰⁵ Mr Martin Bradley,³⁰⁶ then Chief Nursing Officer for the Board, met Mr Mills on 19th April and the death was discussed.³⁰⁷ Both Dr McConnell and Mr Bradley were responsible to Dr Thomas Frawley³⁰⁸ (General Manager, WHSSB) and he too was informed.³⁰⁹ The death became the subject of discussion at subsequent meetings between Trust and WHSSB officials.
- 4.183 Lucy's death was not, however, reported to the Department which was not notified until March 2003 when the Coroner informed Dr Henrietta Campbell,³¹⁰ the Chief Medical Officer ('CMO').³¹¹ The WHSSB expectation at the time was that the Trust would report such a serious clinical incident to both the Board and the Department.³¹² Mr Bradley considered a report to the Department was critical, because the

³⁰¹ 251-002-004

³⁰² WS-293-1 p.11

³⁰³ WS-308-1 p.67

³⁰⁴ 325-002-009

³⁰⁵ 030-010-017

³⁰⁶ 325-002-010

³⁰⁷ 030-010-017

³⁰⁸ 325-002-010

³⁰⁹ WS-308-1 p.9

³¹⁰ 337-001-002

³¹¹ 006-010-294

³¹² See, for example, the evidence of Mr Bradley T- 18-06-13 p. 112 line 7

*“Department also ultimately is in a better position [than the Board] to influence policy and to pick up on regional learning that needs to be implemented.”*³¹³ I accept this analysis.

- 4.184 Dr McConnell insisted that he advised Mr Mills to report Lucy’s death to the Department at that time, although the detail of his recollection was somewhat vague.³¹⁴ Mr Mills had no memory of this³¹⁵ and said that in any event at that time he would only have reported financial and strategic matters to the Department. He maintained that the Trust did not at that time report adverse clinical incidents to the Department and there was no expectation that it should.³¹⁶ He even questioned whether there was mechanism at that time to make such a report.
- 4.185 Indeed, there was then no designated reporting procedure by which Trusts might report serious adverse clinical incidents to the Department. Mr Bradley sympathised with Mr Mills and acknowledged that there was probably a lack of clear direction about how such matters could be reported.³¹⁷ However, I consider that it should have been natural to report to the Department. It did not make sense for the Trust to make a report to the WHSSB and not the Department because the Trust was directly accountable to the Department and that accountability was not solely limited to financial and strategic matters. Lucy’s death ought to have been reported to the Department in the same way as Raychel’s death was reported by Altnagelvin Hospital a year later.
- 4.186 The question arose as to whether the WHSSB had a responsibility to ensure that the Trust reported the death to the Department and to the Coroner.³¹⁸ I do not consider that it was any part of the Board’s duty to monitor the Trust so closely as to ensure that its experienced and well qualified health professionals performed routine reporting tasks.

³¹³ Mr Bradley T-18-06-13 p.113 line 20
³¹⁴ Dr McConnell T-19-06-13 p.30 line 12-14
³¹⁵ Mr Mills T-17-06-13 p.62 line 2-4
³¹⁶ Mr Mills T-17-06-13 p.54 line 1-15
³¹⁷ Mr Bradley T-18-06-13 p.115 line 1
³¹⁸ 251-002-007 to 008 & 015

4.187 The WHSSB did, however, recognise its responsibility to ensure that lessons were learned from adverse clinical incidents occurring within the undertakings of its service providers. Mr Bradley said that whilst the Board would not become involved in a clinical incident investigation it would certainly wish to consider any recommendations arising and if there were obvious problems it would have had a responsibility to raise those with the Trust.³¹⁹

4.188 Given that the Trust had reviewed the circumstances of Lucy's death, Dr Frawley expressed the view that the WHSSB should then have examined the outcome of that Review. He indicated that *"...where the investigation and its conclusions resulted in the preparation of a formal report, I would have had an expectation that the report would be shared with the Board in order to enable the Board to consider whether the Board needed to initiate any action in light of the report. In making such a judgment, I would seek the views of the relevant professional leads in the Board on whether the findings, conclusions and recommendations proposed by the Trust were a proportionate response to the incident that had been investigated."*³²⁰

4.189 It is unlikely that the Review report was forwarded on any formal basis to the WHSSB³²¹ but both Dr McConnell³²² and Mr Bradley³²³ informally obtained copies. Nevertheless the death and the Review findings ought to have come before the Board's Healthcare Committee for consideration.³²⁴

4.190 Dr McConnell accepted that he had a responsibility to bring known adverse clinical incidents to the attention of this Committee³²⁵ and he said that he would be *"amazed"* if that had not been done in this case.³²⁶ He said that he would generally have wanted to be reassured that a Trust had *"got to the bottom of a serious adverse incident"* and having done so he indicated

³¹⁹ Mr Bradley T-18-06-13 p.119 lines 14-17

³²⁰ WS-308-1 p.8

³²¹ WS-308-1 p.26

³²² WS-286-1 p.8

³²³ Mr Bradley T-18-06-13 p.131 line 11

³²⁴ Mr Bradley explained to me that the Healthcare Committee of the WHSSB was the appropriate mechanism within which a variety of professionals could meet to discuss the output from a Trust's review: Mr Bradley T-18-06-13 p.120 line 10

³²⁵ Dr McConnell T-19-06-13 p.7 line 14

³²⁶ Dr McConnell T-19-06-13 p.39 line 6

that he would have envisaged a role for the WHSSB in terms of reporting any lessons to other Trusts, other Boards and possibly to the Department.³²⁷

- 4.191 However, the Committee minutes make no reference to Lucy's case and there is no evidence to suggest that this important Committee ever discussed Lucy's death or its implications. Professor Scally considered it the responsibility of the WHSSB to point out "*significant deficiencies*" and that it was "*remiss of them*" not to do so in this case.³²⁸
- 4.192 Mr Bradley conceded that it was "*extraordinary*" that the WHSSB had not openly discussed the outcome of the Trust Review³²⁹ and properly acknowledged that the Board's handling of the report into Lucy's death was not "*its finest hour*."³³⁰
- 4.193 Such failure on the part of the WHSSB to ensure proper examination of the Review report was a serious neglect of its responsibilities. I consider that it is at least possible that had the report been deliberated upon in committee by experienced healthcare professionals they would have identified some of the most serious issues presented by Lucy's case and raised them, not only with the Trust, but with the Department.
- 4.194 Notwithstanding, the officers of the WHSSB were clearly concerned by Lucy's death. Mr Bradley visited the Paediatric Unit of the Erne Hospital to familiarise himself with where Lucy had been treated and subsequently worked with Directors of Nursing in the Board area to address some of the issues raised by Lucy's case including the importance of clinical records and the necessity to avoid ambiguity in prescribing.³³¹
- 4.195 Dr McConnell insisted that he discussed the Review report with Dr Kelly and told Dr Kelly that because the Review had failed to establish the cause of death, further work was necessary. Specifically, he claimed to have

³²⁷ Dr McConnell T-19-06-13 p.22 line 6

³²⁸ 251-002-011

³²⁹ Mr Bradley T-18-06-13 p.137 line 12

³³⁰ Mr Bradley T-18-06-13 p.148 line 13

³³¹ Mr Bradley T-18-06-13 p.144 line 24

recommended “a wider review” involving external independent experts³³² and indicated that Dr Kelly agreed with him and undertook to discuss it within the Trust.³³³ This indeed would have been sensible and appropriate.

4.196 Professor Scally expressed the view that the WHSSB should have exerted its influence over the Trust to ensure that it engaged with the RBHSC in order to establish an independent review of Lucy’s care with written terms of reference and appropriate expertise.³³⁴

4.197 However, the Trust instead chose to engage the RCPCH to review the general professional competence and conduct of Dr O’Donohoe. Whilst there was also good reason to commence such a review given broader concerns about Dr O’Donohoe’s practice, there was an equally pressing need to commission a specific investigation to address with precision the cause of Lucy’s death. In my view Dr McConnell should have done more to ensure that the Trust pursued further investigation of this kind.

4.198 Mr Bradley accepted that the WHSSB should have obtained the assurance of the Trust that further investigation would be undertaken to establish the cause of Lucy’s death.³³⁵ Dr McConnell and Mr Bradley, as the clinical professionals within the Board, should have ensured that the Trust was pressed to explain how this question was going to be addressed. Professor Scally considered that Dr McConnell (and indeed the Board in general) had “*significant positional and sapiential authority*” to advocate a thorough investigation of Lucy’s death.³³⁶

4.199 In addition, the WHSSB failed to hold the Trust to account for the procedural failings in its Review, the failure to gather relevant evidence, the failure to establish exactly what had happened and most especially the failure to identify mismanagement as a possible or probable cause of death. Furthermore, it ought to have considered whether Lucy’s death raised issues of more general application. Whilst I have no doubt that Dr

³³² WS-286-1 p.7

³³³ WS-286-2 p.5

³³⁴ 251-002-007-008 & 015

³³⁵ Mr Bradley T-18-06-13 p.141, line 22

³³⁶ 251-002-010

McConnell was troubled by the outcome of the Trust's Review, he failed to ensure that the Trust addressed the outstanding questions when he was in a position to do so.

- 4.200 The fact that the Board was not sent a copy of the second RCPCH Report³³⁷ was an additional failing on the part of the Trust. The first RCPCH report had been shared and Dr McConnell believed that he should certainly have received the second report³³⁸ but he had not even been informed that there was to be a second RCPCH review.³³⁹
- 4.201 Mr Mills recognised that the second RCPCH report contained new information and that the report ought properly to have been disclosed to the WHSSB.³⁴⁰ He could offer no explanation for this omission and appeared to accept that there could be no excuse for this failure. As I have also noted in connection with the Trust's failure to disclose this report to the Crawford family, it is impossible to escape the conclusion that the report was withheld from the WHSSB to conceal the connection between medical mismanagement and Lucy's death. Mr Mills is to be strongly criticised for this failure.

RBHSC: Consultant responsibility for Lucy's Care

- 4.202 Debate surrounded the question as to who had individual responsibility for Lucy's care after she was admitted to the RBHSC. She was documented as being admitted into the consultant care of Dr Crean³⁴¹ who saw Lucy at ward round soon after admission and spoke with her parents. He arranged for review by Paediatric Neurologist Dr Hanrahan and spoke with Dr O'Donohoe in the Erne Hospital about Lucy's fluid management upon receipt of her notes.
- 4.203 Dr Crean told me that whilst his name appears as Lucy's consultant on the admissions record, this was an administrative formality "*to designate a*

³³⁷ Dr McConnell T- 19-06-13 p.127 line 23

³³⁸ Dr McConnell T-19-06-13 p.130 line 24

³³⁹ Dr McConnell T- 19-06-13 p.128 line 25

³⁴⁰ Mr Mills T- 17-06-13 p.167 line 9

³⁴¹ 061-001-001

direct ICU admission” from another hospital.³⁴² He explained that notwithstanding that Lucy was jointly managed by the anaesthetists and Dr Hanrahan in PICU, the actions of Dr Hanrahan indicated to everyone that he was the consultant with actual charge of Lucy’s care.³⁴³ He conceded nonetheless that this ought to have been formalised with an entry in Lucy’s notes.³⁴⁴

- 4.204 Dr Hanrahan had been responsible for arranging the specialist neurological investigation and conducting the brain stem testing for death with Dr Chisakuta. Furthermore, after Lucy’s death Dr Hanrahan contacted the Coroner’s Office, arranged for the consent post-mortem and oversaw the certification of death. He communicated with Mr and Mrs Crawford.
- 4.205 For his part, Dr Hanrahan did not consider that he had been in charge. He took the view that the lead consultant was the paediatric intensive care consultant on duty at any particular time.³⁴⁵ On the day of Lucy’s admission that would have been Dr Crean, and on the following day Dr Chisakuta, although he admitted that he had not thought about it in that way at the time.³⁴⁶ Dr Hanrahan accepted that he had provided “*quite significant input*” but considered that Lucy’s care was jointly managed between himself and the “*intensivists*.”³⁴⁷ He insisted that at no time had he agreed to become lead consultant with responsibility for care.³⁴⁸
- 4.206 I consider this issue, from the perspective of this Inquiry’s terms of reference, to be something of an academic debate, though doubtless important in terms of clinical practice and hospital administration. I am told that things have changed in PICU and greater formality is now attached to the designation of patient specific lead consultants.³⁴⁹

³⁴² Dr Crean T-04-06-13 p.48 line 14

³⁴³ Dr Crean T-04-06-13 p.52 line 18-19

³⁴⁴ Dr Crean T-04-06-13 p.54 line 13-15

³⁴⁵ Dr Hanrahan T-05-06-13 p.17 line 2

³⁴⁶ Dr Hanrahan T-05-06-13 p.17 line 9

³⁴⁷ Dr Hanrahan T-05-06-13 p.18 line 23

³⁴⁸ Dr Hanrahan T-05-06-13 p.19 line 1-2

³⁴⁹ Dr Hanrahan T-05-06-13 p.15 line 16

- 4.207 In the event, Lucy was cared for by a team of specialist doctors comprising paediatric intensive care consultants, namely Dr Crean, Dr Chisakuta and to a lesser extent, Dr McKaigue, together with paediatric neurologist Dr Hanrahan who was assisted by his specialist registrar, Dr C. Stewart. The two disciplines worked together at the end of Lucy's life to perform brain stem testing. After confirmation of death, I consider that it was incumbent upon these same doctors to continue to work together to try to identify the cause of death, regardless of who might properly have been regarded as lead consultant.
- 4.208 In the event, Dr Hanrahan took the lead in managing important matters after Lucy's death. The opportunity existed to determine the cause of death. That was not, however, the responsibility of Dr Hanrahan alone. It is clear that there was a broader responsibility on the part of the clinical team and more generally within the RBHSC to discover the cause of death and determine whether there were any lessons to be learned.

RBHSC: Suspicions

- 4.209 The clinicians in the RBHSC quickly recognised inadequacies in the Erne Hospital fluid management. Dr Crean made the effort to contact Dr O'Donohoe because he was concerned, on the basis of Lucy's notes, as to how her fluids had been managed. It is likely that Dr Crean was aware that a child such as Lucy, suffering from fluid loss after a short but significant bout of gastroenteritis, should have been prescribed normal saline for replacement purposes and not large volumes of Solution No. 18. Indeed, at that time his colleagues were teaching students that hypotonic solutions should only be given for maintenance purposes, and never for replacement.³⁵⁰ Dr Crean said he was,

"...unable to recollect what my view was at that time. However, I anticipate that, on looking at the Erne fluid balance chart now, I would have had specific concerns regarding the administration of boluses of hypotonic fluids to children...The administration of large volumes of hypotonic solutions may

³⁵⁰ Dr Crean T-04 -06-13 p.24 line 5

*produce very low concentrations of electrolytes, in particular sodium, leading to undesirable fluid shifts...A fluid deficit would normally have been replaced with normal saline.*³⁵¹

- 4.210 I conclude that Dr Crean recognised, just as Dr Evans was to do, that the volume of hypotonic fluid given was wholly inappropriate and that Lucy had become hyponatraemic over a relatively short period of time. He would therefore probably have sensed that the fluid management was the cause of the hyponatraemia. It was disconcerting that Dr Crean should have given the impression during his evidence that at the time of treating Lucy he did not see very much wrong with how her fluids had been managed.³⁵² He explained that the use by paediatricians of a hypotonic solution (such as Solution No. 18) as a replacement therapy was “*a common fluid regimen that many of the paediatricians used at that time*” and one that he did not think he “*would have considered inappropriate for them.*”³⁵³
- 4.211 Dr Crean’s evidence was inconsistent with what he knew to be the correct approach to fluid management in a case such as Lucy’s, and inconsistent with his decision to make contact with Dr O’Donohoe.
- 4.212 Dr Crean also gave evidence that children were sometimes transferred to the RBHSC by paediatricians who were “*administering hypotonic solutions above maintenance*” and it was his practice and that of his colleagues to counsel them against the inappropriate administration of hypotonic fluids.³⁵⁴ Had he no such concerns about how paediatricians were using fluids he would not have engaged in such communication nor telephoned Dr O’Donohoe.
- 4.213 Accordingly, I have little doubt that Dr Crean was concerned when he understood the fluid therapy as administered by the Erne Hospital. His reservations would have been confirmed after talking to Dr O’Donohoe (if Dr O’Donohoe’s record of their discussion is correct) because, as he

³⁵¹ WS-292-1 p.6

³⁵² Dr Crean T-04 -06-13 p.93 line 17

³⁵³ Dr Crean T-04 -06-13 p.92 line 12

³⁵⁴ Dr Crean T-04 -06-13 p.127 line 12

acknowledged himself, the fluids seemingly intended for Lucy (a bolus of 100ml followed by Solution No. 18 at 30ml/hr) made no more sense than the fluids actually given (Solution No. 18 at 100ml/hr).³⁵⁵ Nonetheless, no concern was recorded at the RBHSC about the fluid therapy.

4.214 Whilst I am satisfied that Dr Crean recognised that Lucy's fluids had been mismanaged, I do not find that he decided that this was significant in terms of her deterioration and death. He maintained that he "*would never have considered a problem with the fluids with sodium of 127 in 2000*"³⁵⁶ and relied on medical literature to indicate that the majority of children developing hyponatraemic encephalopathy had sodium levels of 120mmol/L or less.³⁵⁷ He emphasised that although it is now known that dilutional hyponatraemia deriving from fluid imbalance was the primary factor in causing Lucy's cerebral oedema that is not what he thought at the time.³⁵⁸

4.215 Dr MacFaul confirmed that, "*A blood sodium level at 127mmol/l was not usually regarded as causative of cerebral oedema in the year 2000 although many intensivists and some paediatric neurologists were aware that a rapid fall could make worse an acute encephalopathy whatever its cause. This was not necessarily widely known in paediatric practice.*"³⁵⁹ Furthermore, Dr MacFaul observed that "*less prominence*" was given in the literature at that time to the significance of rapidity in the fall of blood sodium to the development of acute encephalopathy.³⁶⁰

4.216 It is a function of the treating clinician to assist the Coroner. It is in this respect that Dr Crean and his colleagues could have done more. Whilst I accept that dilutional hyponatraemia need not have been cited unequivocally to the Coroner as the cause of death, it is surprising that it was not advanced as a possible cause.

³⁵⁵ Dr Crean T-04 -06-13 p.95 line 4
³⁵⁶ Dr Crean T-04 -06-13 p.103 line 20
³⁵⁷ WS-292-2 p.4-5
³⁵⁸ Dr Crean T-04 -06-13 p.100 line 2
³⁵⁹ 250-003-121
³⁶⁰ 250-003-123

4.217 Fluid management was acknowledged by Dr Crean as his “core business.”³⁶¹ I believe that he did not think carefully enough about the part played by fluid therapy in the cause of Lucy’s condition. Had he done so, I am satisfied that he would have suspected a possible connection between the fluid therapy and the fatal cerebral oedema. I am also satisfied that together with his colleagues in the RBHSC who cared for Lucy, Dr Crean did not want to be seen to be exposing to critical scrutiny, the mistakes which were made in the Erne Hospital.

RBHSC: Failure to adequately consider the evidence

4.218 It is a matter of concern that notwithstanding that Lucy’s Erne Hospital records contained all the information necessary to permit the RBHSC clinicians to conclude that her sodium levels had probably dropped even lower than the 127mmol/L recorded, this does not appear to have been recognised.

4.219 Dr Crean said that despite having read Lucy’s notes many times he only realised that those notes revealed this likelihood when he was actually giving evidence to the Inquiry³⁶² although he had previously been aware of the issue because it had been raised by Dr Sumner. He accepted that had clinicians recognised at the time that the serum sodium had probably been lower than 127mmol/L then dilutional hyponatraemia would have been identified “as a more obvious cause of the development of cerebral oedema.”³⁶³ He admitted that they “did not fully consider the timing of the blood test taken around the time of her acute deterioration.”³⁶⁴

4.220 For his part, Dr Hanrahan said that he only realised that Lucy’s second blood sample was taken after the infusion of normal saline when he discussed it with Dr O’Donohoe in December 2004. It was then, he explained, that “everything [fell] into place.”³⁶⁵

³⁶¹ Dr Crean T- 04 -06-13 p.26 line 14

³⁶² Dr Crean T-04 -06-13 p.115 line 23

³⁶³ WS-292-1 p.12

³⁶⁴ WS-292-1 p.12

³⁶⁵ Dr Hanrahan T- 05 -06-13 p.211 line 1

- 4.221 I consider the failure by senior RBHSC clinicians to adequately consider Lucy's notes so as to determine the sequence of testing and treatment to be unacceptable. Notwithstanding that it has been suggested that other experts also failed to draw this particular conclusion,³⁶⁶ the omission is particularly troubling because the relevant information is detailed on the very same page which recorded the excessive administration of normal saline.³⁶⁷ This note ought therefore to have been the subject of particular scrutiny, especially when those treating her were struggling to understand the cause of her condition.
- 4.222 Dr MacFaul observed that *"in the absence of any other satisfactory explanation for Lucy's death a review by RBHSC of the fluid management in the Erne hospital was justified"*³⁶⁸ and indeed this ought to have been conducted when considering referral to the Coroner.³⁶⁹ He characterised the failure to seek further explanation for Lucy's death as *"a significant failing"* and whilst acknowledging that it was understandable *"in the context of the knowledge at the time"* not to appreciate the significance of the sodium level and rate of change, he insisted that a fluids review would have concluded that Lucy was *"overloaded with fluid"* and that this *"had probably been contributory or causative."*³⁷⁰
- 4.223 Dr Crean told me that he did not have the time to conduct a forensic investigation of the notes.³⁷¹ I do not accept that because he could have delegated this important task to a colleague. The same criticism applies to Dr Hanrahan, who may, because of the responsibilities he assumed after Lucy's death,³⁷² have been even more obligated to review the fluid management. Dr Hanrahan accepted that he could have been *"more*

³⁶⁶ It has been suggested in submissions on Dr Hanrahan's behalf (403-031-002) that even Dr Sumner *"proceeded on the basis that 127 was the base level for sodium."* However, I take the view that this is incorrect. Dr Sumner considered Lucy's notes and found in his report for the Coroner (at 013-036-140) that *"it is possible that the serum sodium had been lower [than 127], but increased during the administration of this huge volume of saline."* Regardless of whether the serum had been lower, and in my view it probably had been lower than 127 before the normal saline was administered, he believed that it was possible to explain the death on the basis of what he called a *"rapid and dramatic fall"* of sodium from 137 to 127 over the course of several hours.

³⁶⁷ Here, I am referring to the Erne Hospital nursing notes which had been forwarded to the Children's Hospital and which can be found at 061-017-050

³⁶⁸ 250-003-121

³⁶⁹ 250-003-121

³⁷⁰ 250-003-122

³⁷¹ Dr Crean T-04-06-13 p.112 line 17

³⁷² 250-003-121

*rigorous in questioning the timing of the sodium analysis in the Erne*³⁷³ and could indeed have identified the evidence suggesting a lower sodium level.³⁷⁴

RBHSC: Internal discussions

- 4.224 Dr Crean was not alone in recognising that Lucy's fluid therapy had not been properly managed. Dr C. Stewart recalled general agreement within the RBHSC that there had been mismanagement.³⁷⁵ She said that no one thought Lucy's fluid therapy appropriate and confirmed that this was recognised *"reasonably quickly in PICU."*³⁷⁶ However, Dr C. Stewart recalled that it was relatively common at that time to see children with low sodium³⁷⁷ and that the feeling amongst consultants was *"that they would have expected her sodium level to be much lower"* if it was going to cause cerebral oedema and collapse.³⁷⁸ In this regard her evidence was consistent with that of Dr Crean and Dr Hanrahan.
- 4.225 Dr Hanrahan told me that he was quite unaware of Dr Crean's conversation with Dr O'Donohoe on the morning of Lucy's transfer to the RBHSC.³⁷⁹ He said that whilst he was aware of the general view that Lucy's fluids had not been properly managed at the Erne,³⁸⁰ this did not cause him any great concern in the absence of a really low sodium reading.³⁸¹ At that time he said that he was *"fairly definite in [his] mind that this wasn't a fluid related problem..."*³⁸²
- 4.226 By contrast Dr Chisakuta admitted to having been concerned about the part fluid management may have played in Lucy's death³⁸³ but insisted that he was not sure about the cause of death. It was because of his uncertainty that he considered that the case ought to be reported to the Coroner. I am

³⁷³ Dr Hanrahan T-05-06-13 p.219 line 8

³⁷⁴ WS-289-1 p.26

³⁷⁵ Dr C Stewart T-29-05-13 p.177 line 6

³⁷⁶ Dr C Stewart T-29-05-13 p.171 line 24

³⁷⁷ WS-282-2 p.2

³⁷⁸ Dr C Stewart T-29-05-13 p.194 line 21

³⁷⁹ Dr Hanrahan T-05-06-13 p.44 line 23

³⁸⁰ Dr Hanrahan T-05-06-13 p.63 line 1

³⁸¹ Dr Hanrahan T-05-06-13 p.64 line 7

³⁸² Dr Hanrahan T-05-06-13 p.74 line 1

³⁸³ Dr Chisakuta T-29-05-13 p.67 line 18

entirely satisfied that Dr Chisakuta did consider Lucy's case in this way and do not find it surprising given the similar, if more confident conclusions reached independently by Drs Evans and Auterson.

- 4.227 It is disappointing therefore that Dr Chisakuta did not then raise his suspicions directly with his colleagues. He said he believed that Dr Crean had similar concerns³⁸⁴ and would be "*surprised*" if Dr Crean had not expressed them but could not actually remember him doing so.³⁸⁵ Whilst I am satisfied that Dr Crean had concerns about Lucy's fluid management and that it is likely that he discussed those concerns with his colleagues, I find no good evidence to suggest that Dr Crean expressed any view that the fluids were implicated in the death.
- 4.228 Additionally, Dr Chisakuta said that he discussed the death with Dr Hanrahan and the necessity that it be reported to the Coroner.³⁸⁶ Despite this, he acknowledged that he did not share with Dr Hanrahan his concern that poor fluid management had possibly been a cause of the cerebral oedema.³⁸⁷
- 4.229 Dr Hanrahan for his part recognised that he "*should have talked to a lot more people in a lot more detail*" about what had happened to cause Lucy's death³⁸⁸ and conceded that he "*should have investigated this more and the evidence may have been there if [he] had looked more carefully.*"³⁸⁹ I consider this concession appropriately made because he assumed the responsibility for contacting the Coroner's Office. His obligation was to inform the Coroner as to the facts and circumstances relevant to the death. It is unclear how he could have hoped to do so effectively without some investigation and the input of those senior colleagues with knowledge of Lucy's case.

³⁸⁴ Dr Chisakuta T-29-05-13 p.73 line 8

³⁸⁵ Dr Chisakuta T-29-05-13 p.91 line 2

³⁸⁶ Dr Chisakuta T-29-05-13 p.64-65

³⁸⁷ Dr Chisakuta T-29-05-13 p.71 line 10

³⁸⁸ Dr Hanrahan T-05-06-13 p.64 line 19

³⁸⁹ Dr Hanrahan T-05-06-13 p.75 line 12

- 4.230 The cause of Lucy's condition ought to have been the subject of urgent internal consideration by clinicians in the RBHSC on the day of her admission. Dr Crean's discussion with Dr O'Donohoe and his realisation that the fluid regime made no sense should have been the starting point for wider discussion. Her death ought to have made this a priority. Dr Crean should have told Dr Hanrahan about his conversation with Dr O'Donohoe and the significance of the fluid management errors could have been debated allowing Dr Chisakuta to ventilate his concerns. There might then have been agreement as to what further information could be obtained from the Erne Hospital, and precisely what the Coroner, the family, the Erne Hospital and RBHSC management should be told.
- 4.231 No such discussion took place. Lucy's death passed without appropriate thought or inquiry at Northern Ireland's only paediatric teaching hospital. Dr C. Stewart drafted a clinical diagnosis for the autopsy request form but such conversation as may have surrounded her formulation was no substitute for informed discussion about the cause of death. That there was an absence of a thorough multi-disciplinary discussion about Lucy's death has to be regarded as unacceptable.
- 4.232 It is a cause for real concern that experienced clinicians did not speak with each other about their reservations in such a case or even inform their own Medical Director. It has been suggested that because the treatment happened elsewhere they felt no pressing need for informed discussion or formal reporting within their own Trust. However none of the clinicians notified the SLT or the Crawford family GP either.

RBHSC: Discharge letter

- 4.233 The RBHSC did not issue a conventional discharge letter to either the GP or the referring Hospital.³⁹⁰ Dr MacFaul considered this omission unusual and referred to it as a "*significant deficiency*."³⁹¹ He indicated that the

³⁹⁰ Dr Chisakuta T-29 -05-13 p.117 line 22. Dr Chisakuta confirmed to me that the usual practice in 2000 was to issue a discharge letter to the patient's GP

³⁹¹ 250-003-117

discharge letter should have included some information about the patient's presentation and outlined the investigations, diagnosis and treatment.

- 4.234 Dr Chisakuta went further and said that in this instance it would have been appropriate to use the discharge letter to document concern about Lucy's treatment at the Erne.³⁹² Such would have enabled the GP to explain the position to Lucy's parents, support them in their bereavement and articulate matters of concern. Additionally, the discharge letter would have formally advised the SLT that there were concerns about the adequacy of Lucy's treatment.³⁹³
- 4.235 Dr Crean believed that it was essential to issue a discharge letter.³⁹⁴ He thought that an 'inpatient/outpatient advice note' had been sent by the RBHSC to Lucy's GP, although the evidence I received on this was very far from conclusive. In any event the advice note merely informed that the primary diagnosis was cerebral oedema with underlying viral gastroenteritis³⁹⁵ which Dr Crean accepted didn't "*give the whole story.*"³⁹⁶
- 4.236 Dr Hanrahan confirmed that "*the responsible clinician*" usually wrote the discharge letter³⁹⁷ and would normally try to telephone the deceased patient's GP.³⁹⁸ Whilst he accepted that he ought to have telephoned the GP he suggested that the task could equally have been performed by one of the intensive care practitioners and may perhaps have fallen "*between two stools.*"³⁹⁹
- 4.237 I consider that because Dr Hanrahan had been directly involved with Lucy's care at the end of her life, took the lead role in contacting the Coroner's Office, arranged the hospital post-mortem and oversaw the completion of the death certificate, he should also have telephoned the GP and assumed responsibility for drafting a suitably detailed discharge letter for the Erne

³⁹² Dr Chisakuta T-29 -05-13 p.118 line 3

³⁹³ 251-002-017

³⁹⁴ Dr Crean T-04 -06-13 p.143 line 8

³⁹⁵ 061-012-036

³⁹⁶ Dr Crean T-04-06-13, p.142 line 8

³⁹⁷ WS-289-2 p.6

³⁹⁸ Dr Hanrahan T-05 -06-13 p.164 line 8

³⁹⁹ Dr Hanrahan T-05 -06-13 p.164 line 9

Hospital and the GP. Alternatively, he could even have delegated this task to a suitably informed and qualified colleague.

- 4.238 The discharge letter was a critical communication and responsibility for the task ought to have been clear. That this routine task was not carried out is consistent with the other obvious failures by clinicians within the RBHSC to document, discuss and communicate their concern about how Lucy had been treated in the Erne Hospital. I cannot avoid the conclusion that the individual failures within the RBHSC to communicate that concern, cumulatively form a pattern of behaviour indicating reluctance to draw critical attention to the failures of other professional colleagues.

RBHSC: Failure to raise concerns directly with the Erne Hospital

- 4.239 The failure of clinicians at the RBHSC to communicate concerns about Lucy's treatment to Lucy's family doctor was matched by their failure to advise the Erne Hospital or the SLT. Dr Ian Carson,⁴⁰⁰ then Medical Director of the Royal Group of Hospitals Trust ('RGHT'), explained that he *"would have expected a consultant who had a patient referred to them to have had a continuing and an open communication with the referring consultant."*⁴⁰¹ He deemed this both a professional and an organisational expectation and thought it should have been relatively easy for the RBHSC to talk to the Erne about errors in the management of Lucy because it was not a case that had been badly managed in the RBHSC.⁴⁰²
- 4.240 Additionally, he considered that the RBHSC consultant in charge of Lucy's care should have advised him of any concerns. It would then have been appropriate for him (or the Chief Executive of the Trust) to write to the SLT to relay those concerns. He acknowledged that this *"probably should have been done."*⁴⁰³
- 4.241 Professor Scally also expressed the view that if staff at the RBHSC had any *"significant suspicion"* that *"Lucy's death was due to inadequate treatment"*

⁴⁰⁰ 325-002-009

⁴⁰¹ Dr Carson T-26 -06-13 p.27 line 13

⁴⁰² Dr Carson T-26 -06-13 p.32 line 5

⁴⁰³ Dr Carson T-26 -06-13 p.30 line 17

then there was an obligation to make a formal report to the SLT. He went on to explain *“that this expectation arises out of a general obligation in the case of a death that may have been caused by inadequate treatment and is reinforced by the RBHSC role as a regional centre of excellence.”*⁴⁰⁴

4.242 The evidence revealed that after Lucy was transferred from the Erne to the RBHSC there were in all five communications between the two hospitals.⁴⁰⁵ Significantly, in none of these interactions was the Erne asked to explain what had happened to Lucy or to justify its management of the case, and still less was it placed on formal notice of the concerns of medical mismanagement.

4.243 Dr Crean’s informal telephone contact with Dr O’Donohoe may nonetheless have caused him to draw Lucy’s case to the attention of Dr Kelly in order to prompt the Review at the Erne. However, I do not consider that Dr Crean’s conversation with Dr O’Donohoe satisfied the RBHSC obligation to formally report concerns in respect of the mismanagement of Lucy’s care. Dr Crean accepted that if the RBHSC was not going to investigate Lucy’s treatment because the problem had not been caused there, he should have satisfied himself that it was going to be properly investigated at the Erne.⁴⁰⁶

4.244 Asked why neither he or his colleagues informed the Erne Hospital that there were problems with Lucy’s care Dr Chisakuta said, *“I have no response to that”*⁴⁰⁷ which was at least an honest recognition that there was no good explanation for the failure. Both Dr McKaigue⁴⁰⁸ and Dr Hanrahan⁴⁰⁹ agreed that it should have been done. Dr Hanrahan went further and accepted that the matter should have been reported even if there was no consensus and even where there was no concern that the

⁴⁰⁴ 251-002-017

⁴⁰⁵ Dr Auterson contacted PICU on the 13 April relaying the results of the repeat blood tests, Dr Crean telephoned Dr O’Donohoe seeking clarification of the fluid regime, Dr Hanrahan telephoned Dr O’Donohoe advising that the Coroner had been informed and that a hospital post-mortem would be carried out with the consent of Mr and Mrs Crawford, an unidentified RBHSC clinician contacted the Erne Hospital on the 18th April 2000 to provide a verbal report in respect of the post-mortem and Dr Hanrahan telephoned Dr O’Donohoe again on 14th June 2000 to ask him to meet with Lucy’s parents again.

⁴⁰⁶ Dr Crean T-04 -06-13 p.150 line 6

⁴⁰⁷ Dr Chisakuta T-29 -05-13 p.116 line 9

⁴⁰⁸ Dr McKaigue T-30 -05-13 p.130-131

⁴⁰⁹ Dr Hanrahan T-05 -06-13 p.231-232

treatment had affected the outcome.⁴¹⁰ However, he said that he did not then know of the mechanism for making a report to a referring hospital.⁴¹¹ This admission reveals a surprising lack of knowledge on the part of an experienced, senior clinician.

4.245 Dr Crean acknowledged that when mistakes were made there was a tendency amongst clinicians to think that *“if I put my head above the parapet and say about this, they’ll shoot me for it.”*⁴¹² Nonetheless, Dr Crean denied that the silence of clinicians in the RBHSC amounted to a ‘cover-up’ and pointed to the fact that he had reported the circumstances of Raychel’s death to the Coroner the following year.⁴¹³ Whilst Dr Crean acted properly in respect of Raychel’s death, I consider that his failure and that of his colleagues to challenge the Erne about Lucy’s treatment was intentional so as not to draw wider attention to the clinical shortcomings in her treatment.

4.246 Dr Crean said that the RBHSC had no idea that the Erne Hospital was conducting a review. He explained that the *“crossover of information”* simply wasn’t there.⁴¹⁴ That neither hospital communicated with the other, only confirms for me that both hospitals were anxious to avoid scrutiny of the events which led to Lucy’s death, and had limited interest in gaining a full understanding of those events.

4.247 I consider that both the failure of the Erne Hospital and the RBHSC to communicate formally about Lucy’s case and the subsequent failure of the Erne to involve the RBHSC in its review, contributed to the overall failure to learn from her case and this may not have been without serious consequence.

RBHSC: Adverse Incident Reporting

4.248 No adverse incident report was made of Lucy’s death within the RBHSC or the RGHT. There was no formal requirement to do so at the time.

⁴¹⁰ Dr Hanrahan T-05 -06-13 p.232 line 3

⁴¹¹ Dr Hanrahan T-05 -06-13 p.233 line 9

⁴¹² Dr Crean T-04 -06-13 p.150 line 10

⁴¹³ Dr Crean T-04 -06-13 p.124 line 17

⁴¹⁴ Dr Crean T-04 -06-13 p.148 line 2

Notwithstanding, Dr Carson advised that in the event of a “*death or where a doctor’s practice is called into question or patients are put at risk, those are cases that quite definitely should have been referred to the Trust Medical Director*”⁴¹⁵ and the Clinical Director of Paediatrics.⁴¹⁶

4.249 A month after Lucy’s death the RGHT published its first adverse clinical incident reporting policy. Accordingly, and notwithstanding Dr Carson’s expectation of an informal notification, there can be no criticism of RBHSC clinicians for failing to make a policy compliant adverse incident report. Indeed, Dr MacFaul’s considered that the absence of an adverse incident report at the RBHSC “*was not unreasonable by the standards of the day.*”⁴¹⁷

4.250 Dr Crean suggested that even if the adverse incident reporting scheme had been operational at the time of Lucy’s death, it is unlikely that he would have made a report. He said that although he regarded the death as “*unexpected*” he did not then make the connection with the medical treatment given⁴¹⁸ and even if he had recognised that the medical treatment had caused or contributed to the death, the fact that she was treated in the Erne Hospital would not have prompted a report under the procedures.⁴¹⁹ Dr Chisakuta agreed.⁴²⁰

4.251 However, this was a death which was unexpected, and the cause of it was unknown. It was also a death which took place in circumstances where it was known that fluid therapy had been mismanaged. In failing to report such a death to their own medical or clinical directors the RBHSC clinicians repeated the pattern of non-reporting which so marked the RBHSC response to the deaths of Adam Strain and Claire Roberts. It had the effect of distancing those in positions of governance from suspicions of medical mismanagement and reducing the likelihood of a formalised response. This

⁴¹⁵ Dr Carson T-16-01-13 p.66 line 12

⁴¹⁶ Dr Carson T-16-01-13 p.67 line 11

⁴¹⁷ 250-003-007

⁴¹⁸ Dr Crean T-04 -06-13 p.146 line 15

⁴¹⁹ Dr Crean T-04 -06-13 p.147 line 2

⁴²⁰ WS-283-2 p.3

approach cannot have been accidental and had the consequence that there was a failure to adequately investigate and learn from Lucy's death.

Reporting the death to the Coroner's Office

- 4.252 The legal duty to report a death to the Coroner is imposed by section 7 of the Coroners Act (Northern Ireland) Act 1959⁴²¹ and requires "every *medical practitioner*" who "*has reason to believe*" that a person has died "*directly or indirectly*" from "*negligence*" or "*from any cause other than natural illness or disease...*" or in "*such circumstances as may require investigation*" to notify the Coroner "*of the facts and circumstances of the death.*"
- 4.253 Accordingly, the Erne clinicians were not absolved of responsibility to report Lucy's death just because the death occurred in the RBHSC. Nonetheless the normal practice in Northern Ireland was for a clinician at the hospital where a patient has died, to report the death to the Coroner.
- 4.254 The duty to report is a continuing one. Therefore, if at any stage after death a medical practitioner receives information giving rise to a 'reason to believe' then there is an obligation to notify the Coroner. Failure to make such a report is a criminal offence.
- 4.255 I should add that contact with the Coroner's Office need not necessarily be pursuant to the duty under the Coroners Act; contact could be made with the Coroner's Office in order to clarify whether a section 7 duty arises on the facts of any given case.⁴²²
- 4.256 Not only was there reason to believe that Lucy may have died as a result of negligence but there was also reason to believe that she may have died from a cause other than a natural illness or disease and in any event her death occurred in circumstances which clearly required investigation. It does not require the benefit of hindsight to conclude that it is obvious that

⁴²¹ <http://www.legislation.gov.uk/apni/1959/15/contents>

⁴²² I am referring here to the helpful submission made by Mr Nick Hanna QC on behalf of the Coroner: T-25-06-13 p.152-155

Lucy's death should have been formally reported to the Coroner pursuant to section 7.

- 4.257 Before Lucy died Dr Hanrahan had noted that *"if she succumb[s], a PM would be desirable – Coroner will have to be informed."*⁴²³ He explained that this was because, *"we didn't know what was going on"*⁴²⁴ and because *"Lucy had died within a short time of admission to hospital."*⁴²⁵ However, he said that in the event he contacted the Coroner's Office with an *"open mind"* in order to discuss whether formal reporting of the death was necessary.⁴²⁶
- 4.258 The evidence strongly suggests to me that when Dr Hanrahan contacted the Coroner's Office he did not do so in the belief that the circumstances of Lucy's death required him to make a formal report to the Coroner. Dr Hanrahan did not seemingly appreciate that a death in unusual and unexplained circumstances placed him under a duty to formally notify the Coroner. He was unfamiliar with his duty and had received no training in respect of his obligations.⁴²⁷
- 4.259 When Dr Hanrahan telephoned the Coroner's Office he was unable to speak to the Coroner but talked instead with Mrs Maureen Dennison⁴²⁸ who was a member of the Coroner's staff. In respect of the information supplied by Dr Hanrahan she recorded, *"Died 14.4.00 at RVH Childrens ICU. Gastro interitis (sic), dehydrated, brain swelling. Admitted Erin (sic) Hospital (2 days ago – transferred to RVH. Spoke to Dr Curtis."* The entry also noted *"D.C."* (Death Certificate).⁴²⁹
- 4.260 When questioned, Mrs Dennison thought that in all probability Dr Hanrahan was making a formal report pursuant to section 7 and not merely seeking guidance about whether it was necessary to make a report.⁴³⁰

⁴²³ 061-018-066

⁴²⁴ Dr Hanrahan T-05-06-13 p.89 line 17

⁴²⁵ WS-289-1 p.10

⁴²⁶ Dr Hanrahan T-05-06-13 p.101

⁴²⁷ Dr Hanrahan T- 05-06-13 p.98-99

⁴²⁸ 325-002-007

⁴²⁹ 013-053a-290

⁴³⁰ Mrs Dennison T-24-06-13 p.51

- 4.261 H.M. Coroner, Mr John Leckey, explained that it was the practice in his office that where there was doubt about whether a death should be dealt with by issuing an immediate death certificate or by Coroner's post-mortem then *"the advice of a pathologist in the State Pathologist's Department would be sought."*⁴³¹ In such circumstances clarification *"could be provided by the reporting Medical Practitioner speaking direct to one of the pathologists or the pathologist making contact with the reporting Medical Practitioner."*⁴³² The Coroner's Office would then normally be advised as to the outcome of such discussions.
- 4.262 It was entirely proper that at that time the Coroner should have had an administrative procedure in place for dealing with enquiries from the medical profession. Most such enquiries are likely to have been straightforward and need not have troubled the Coroner directly. However, Dr Hanrahan's contact with the Coroner's Office would undoubtedly have benefitted from the Coroner's own direct involvement. I have no doubt that had the Coroner been spoken to by Dr Hanrahan he would have decided to investigate the death.
- 4.263 In the event, Mrs Dennison could not remember what efforts she made to contact the Coroner⁴³³ and instead spoke to Dr Michael Curtis⁴³⁴ (Assistant State Pathologist) *"to get advice about this death."*⁴³⁵ She could not however, recall any direct contact between Dr Hanrahan and Dr Curtis.
- 4.264 The record made by Mrs Dennison supports her presumption that she contacted Dr Curtis and that he advised that a death certificate could be issued.⁴³⁶ She believed that she would then have returned to Dr Hanrahan and relayed what Dr Curtis had said.⁴³⁷ She could not remember ever

⁴³¹ WS-277-1 p.3
⁴³² WS-277-2 p.4
⁴³³ WS 276-1 Page 4
⁴³⁴ 325-002-007
⁴³⁵ WS-276-1 p.4
⁴³⁶ WS-276-1 p.4
⁴³⁷ WS-276-1 p.5

having put a clinician directly in touch with a pathologist in such circumstances.⁴³⁸

4.265 Dr Curtis said that as Assistant State Pathologist he was “*infrequently*” called upon by the Coroner’s Office to provide informal medical advice in relation to the cause of a death. However, he could not recall Dr Hanrahan or any conversation with him.⁴³⁹ Furthermore, he could not recall ever having spoken to a reporting clinician in this type of situation.⁴⁴⁰ In these important respects his evidence was consistent with that of Mrs Dennison.

4.266 The communication with the Coroner’s Office was entered in Lucy’s notes by Dr C. Stewart: “*Coroner (Dr Curtis on behalf of coroners) contacted by Dr. Hanrahan – case discussed, coroners PM is not required, but hospital PM would be useful to establish cause of death + rule out another Δ⁴⁴¹ Parents’ consent for PM ✓.*”⁴⁴²

4.267 This note could suggest that Dr Hanrahan discussed the case with Dr Curtis acting on behalf of the Coroner. Dr C. Stewart said she probably made the entry on the basis of what Dr Hanrahan told her.⁴⁴³ Dr Hanrahan could not recall his conversation with the Coroner’s Office⁴⁴⁴ but thought, on an interpretation of Dr Stewart’s note, that he must have discussed the death directly with Dr Curtis.⁴⁴⁵

4.268 I think it unlikely that Dr Hanrahan spoke directly to Dr Curtis. Both Dr Curtis and Mrs Dennison indicated it would have been unusual if the clinician and pathologist had been put in contact with each other through the Coroner’s Office and Mrs Dennison’s contemporaneous note strongly suggests it was she who spoke to Dr Curtis.

4.269 I am satisfied that Mrs Dennison did her conscientious best to convey to Dr Curtis the information Dr Hanrahan supplied to her and it is to be noted that

⁴³⁸ Mrs Dennison T-24-06-13 p.73 line 24

⁴³⁹ WS-275-1 p.5

⁴⁴⁰ Dr Curtis T-25-06-13 p.6-7

⁴⁴¹ Signifying Diagnosis.

⁴⁴² 061-018-067

⁴⁴³ Dr C Stewart T-29-05-13 p. 178 line 13

⁴⁴⁴ Dr Hanrahan T-05-06-13 p.100 line 7

⁴⁴⁵ 115-050-004

Dr Hanrahan did not even inform her about the known hyponatraemia which had been caused by clinical error. Whilst he accepted that this was a “very important omission”⁴⁴⁶ he sought to assure me that it was not deliberate. Taking into account the general failure to document let alone report the mismanagement of Lucy’s care despite the several opportunities available to him, I have struggled to find any good explanation for Dr Hanrahan’s omissions. Not surprisingly, Dr MacFaul was of the opinion that the hyponatraemia should have been reported.⁴⁴⁷

- 4.270 Furthermore, Dr Hanrahan did not convey his uncertainty as to the cause of death. Had he done so, it is probable that Mrs Dennison would have told Dr Curtis and he in turn would have advised referral to the Coroner. Dr Hanrahan accepted responsibility for a “*hopelessly incomplete report on Lucy’s death.*”⁴⁴⁸ He now recognises that the three conditions reported by him do not make sense as a cause of death and that he should have recognised that at the time.
- 4.271 Dr Hanrahan’s interaction with the Coroner’s Office was considered by the GMC who concluded that there was no evidence that he acted in bad faith or intentionally withheld information from the Coroner or Lucy Crawford’s parents as part of a deliberate cover-up. I agree that there is no clear evidence of bad faith on Dr Hanrahan’s part and I am persuaded that Dr Hanrahan’s decision to contact the Coroner’s Office at all indicates that he was not seeking to avoid coronial scrutiny of Lucy’s death altogether. However, having provided an incomplete account of the circumstances relevant to Lucy’s death to the Coroner’s Office, he must bear primary responsibility for the failure to subject the causes of Lucy’s death to appropriate scrutiny.
- 4.272 I am unable to determine from the evidence the actual advice provided by Dr Curtis excepting only that he probably advised that there was no impediment to issuing a death certificate. I am concerned, however, that

⁴⁴⁶ Dr Hanrahan T-05 -06-13 p.103 line 3

⁴⁴⁷ 250-003-139

⁴⁴⁸ Dr Hanrahan T-05 -06-13 p.106 line 14

Dr Curtis should have so advised without obtaining a better understanding of how the death had come about. Dr Curtis had limited expertise in paediatric cases and almost none in fluid management.⁴⁴⁹ He conceded that he would not have suspected fluid mismanagement in a cerebral oedema case unless he was specifically directed to it⁴⁵⁰ but maintained that had he been informed of hyponatraemia in the context of dehydration, he would have found that unusual and would have known to refer it to the Coroner.

- 4.273 Whilst I accept that Dr Curtis was doing his best to assist the Coroner's office and sought to advise appropriately, his approach was deficient. He should have insisted upon an explanation of the medical causes for death. Without a credible explanation it was inappropriate for him to advise that a death certificate could issue. Professor Lucas suggested that in the circumstances he should have inquired further into the causation of the brain oedema because whilst gastroenteritis can cause dehydration it cannot by itself lead to brain oedema.⁴⁵¹
- 4.274 In defence of his position, Dr Curtis emphasised that he did not appreciate that such reliance was being placed on his advice by the Coroner's Office.⁴⁵² Indeed, the situation should not have been allowed to arise since Dr Curtis and Mrs Dennison were not legally trained and therefore unqualified to advise Dr Hanrahan. It was not their responsibility to interrogate the information received in the context of the section 7 obligation.
- 4.275 Ultimately, Dr Hanrahan's interaction with the Coroner's Office resulted in him arranging for a consented post-mortem in order to clarify the cause of death, and a decision to issue a death certificate. It is a matter of concern that these actions took place without legal consideration or input from the Coroner. Whilst recognising that Dr Hanrahan did not provide Dr Curtis with a sufficient account of the circumstances relevant to Lucy's death, it

⁴⁴⁹ Dr Curtis T-25 -06-13 p.7-8

⁴⁵⁰ Dr Curtis T-25 -06-13 p.11 line 6-9

⁴⁵¹ 252-003-009

⁴⁵² Dr Curtis T-25 -06-13 p.15-18

must nonetheless be observed that a lack of adequate procedure in the Coroner's Office was a vulnerability in the system which allowed the case to escape the Coroner's jurisdiction at that important point in time.⁴⁵³

Subsequent Coronial involvement

- 4.276 Soon after Lucy's death, Mr Stanley Millar,⁴⁵⁴ Chief Officer of the Western Health and Social Services Council, was asked by the Crawford family to advise and help them. On the basis of what he was able to learn, he became concerned about the death and enquired about an inquest but was told that an inquest was unnecessary.
- 4.277 Subsequently, when he became aware of the fluid management issues which led to the death of Raychel Ferguson, he wrote on 27th February 2003 to inform the Coroner Mr Leckey that, *"Lucy was taken ill on 12 April 2000 and was admitted by her GP into Erne Hospital Enniskillen with relatively minor condition of vomiting. A drip was set up and the family was assured Lucy would be home next morning. During the early hours of 13 April 2000 Lucy fittted and collapsed. She was transferred to the Royal Belfast Hospital for Sick Children on a life support system. On 14 April 2000 the life support was switched off. A post mortem was undertaken and a 'swollen brain with generalised oedema' was discovered."*⁴⁵⁵
- 4.278 Mr Millar also emphasised to the Coroner that Lucy's death was unexplained and asked whether an inquest into her death in 2000/01 might have generated recommendations which could have saved Raychel's life. It was this communication which finally notified the Coroner of Lucy's death and prompted the investigation which was to lead to her belated inquest.
- 4.279 There was little in what Mr Millar communicated to the Coroner in 2003 which could not have been communicated to him by Dr Hanrahan and his colleagues at the time of Lucy's death in 2000. That Mr Millar had no

⁴⁵³ The Coroner's Office now employs a full-time medical officer and no longer relies upon informal assistance from the State Pathologist's Office.

⁴⁵⁴ 325-002-011

⁴⁵⁵ 013-056-320

medical training only serves to emphasise the failings of the medical profession in this regard.

RBHSC: Hospital Post-Mortem

- 4.280 Dr Hanrahan obtained the consent of Mr and Mrs Crawford to the hospital post-mortem.⁴⁵⁶ Dr C. Stewart noted that a hospital post-mortem would “*be useful to establish cause of death*”⁴⁵⁷ confirming that these doctors were unaware that their inability to establish the cause of death was the very reason why they should not have been pursuing the hospital post-mortem.
- 4.281 Professor Lucas was clear that if a doctor is properly able to request a consented post-mortem then he must be able to write the death certificate: “*Consented autopsies only take place where the cause of death is natural and satisfactory for registration i.e. a coroner has not taken the case on under his jurisdiction.*”⁴⁵⁸ Dr Crean did not know that this was happening and was surprised that Lucy’s death did not become a Coroner’s case. Quite properly, he understood that unexplained deaths should inevitably lead to Coroner’s post-mortems.⁴⁵⁹ He advised that when he finds himself unable to write a death certificate, he knows that a Coroner’s post-mortem is necessary.⁴⁶⁰
- 4.282 The post-mortem was conducted by Dr Denis O’Hara⁴⁶¹ who was an experienced consultant paediatric pathologist. He was briefed with the autopsy request form⁴⁶² which appeared both reasonably detailed and accurate. It described Lucy’s short history of vomiting and diarrhoea, referred to the IV fluids and noted the seizure with fixed and dilated pupils. The clinical diagnosis given was “*dehydration + hyponatraemia cerebral oedema-> acute coning and brain stem death.*”

⁴⁵⁶ 013-031-114

⁴⁵⁷ 061-018-067

⁴⁵⁸ 252-003-010

⁴⁵⁹ Dr Crean T-04-06-13 p.136 line 15

⁴⁶⁰ Dr Crean T-04-06-13 p.131 line 23

⁴⁶¹ 325-002-006

⁴⁶² 061-022-073

- 4.283 Dr C. Stewart was responsible for formulating this clinical diagnosis.⁴⁶³ Whilst she made reference to the condition of hyponatraemia, she insisted that she had not thought that Lucy had suffered dilutional hyponatraemia.⁴⁶⁴ She explained that the clinical diagnosis defined the clinical problems and did not explain what had caused them.⁴⁶⁵ Importantly, Dr O'Hara was not informed that there was any concern in relation to the management of Lucy's fluids.
- 4.284 Dr Hanrahan considered that it was Dr C. Stewart's responsibility (as the practitioner to whom he had delegated completion of the autopsy request form) to ensure that Dr O'Hara had all relevant materials. At the time of giving her evidence, Dr C. Stewart was unsure of the procedures which had been in place.⁴⁶⁶ I find that as the senior clinician, it was Dr Hanrahan's responsibility to ensure that Dr O'Hara received every assistance. Dr Hanrahan reasoned that if the pathologist felt that he required further information he could have asked for it.⁴⁶⁷ That was very far from adequate.
- 4.285 Professor Lucas explained that in his experience the usual practice involved the relevant clinicians attending the mortuary to view some or all of the post-mortem and discussing the findings with the pathologist. He added, *"It is at [the] CPC [clinico-pathological correlation] that all the issues in a case are discussed and resolved, as far as they are resolvable (for not all deaths do have a completely satisfactory pathophysiological explanation). The clinical presentation, laboratory data, imaging, differential diagnosis, and the autopsy results are considered all together to determine what actually happened to the patient who died; and they consider what can be learned from the case for future practice."*⁴⁶⁸
- 4.286 The necessity for clinico-pathological discussion was clear in Lucy's case and a matter of common sense. I consider that it was a basic professional obligation to convene such a meeting but Dr Hanrahan said that it simply

⁴⁶³ Known as the working pathogenesis
⁴⁶⁴ WS-282-2 p.3
⁴⁶⁵ WS-282-2 p.4
⁴⁶⁶ Dr C Stewart T-29 -05-13 p.186 line 12
⁴⁶⁷ Dr Hanrahan T-05 -06-13 p.145 line 18
⁴⁶⁸ 252-003-012

didn't occur to him. Clinicians were invited to attend with the pathologist for a review on the day of the post-mortem but Dr O'Hara was informed that no one would be in attendance.⁴⁶⁹

- 4.287 It is difficult to avoid the conclusion that as well as failing to disclose to Dr O'Hara the known deficiencies in Lucy's care, the RBHSC clinicians who cared for Lucy were not motivated to engage with him to discover what had happened to her. Dr Hanrahan said that it was unlikely that he even read the post-mortem report⁴⁷⁰ and certainly could not remember doing so.⁴⁷¹ Dr Chisakuta conceded that although he had cared for Lucy and was concerned that there may have been failures at the Erne Hospital, he did not seek to read the final post-mortem report. He admitted that such an omission was embarrassing.⁴⁷² There is no evidence to suggest that Dr O'Hara's findings were given any clinical consideration. This does not reflect well on any of the clinicians involved.

Dr O'Hara's post-mortem findings

- 4.288 The post-mortem report dated 13th June 2000 is inconclusive.⁴⁷³ Dr O'Hara was unable to explain the cerebral oedema but concluded that the presence of a "*pneumonic lesion within the lungs [has] been important as the ultimate cause of death.*"⁴⁷⁴ He commented that bronchopneumonia was "*well developed and well established*" and speculated that it might have been present prior to the original disease presentation. He did not know, because he had not been told, that Lucy's chest had been x-rayed at the Erne Hospital and was clear.⁴⁷⁵
- 4.289 Whilst any criticism of the late Dr O'Hara must be tempered by the fact that he can no longer explain his approach and conclusions, Professor Lucas advised that it was likely that the pneumonia was acquired in consequence of ventilator support in intensive care. He considered that Dr O'Hara's

⁴⁶⁹ 061-022-075

⁴⁷⁰ WS-289-2 p.3

⁴⁷¹ Dr Hanrahan T-05 -06-13 p.200 line 13

⁴⁷² Dr Chisakuta T-29 -05-13 p.106 line 9

⁴⁷³ 061-009-016

⁴⁷⁴ 061-009-017

⁴⁷⁵ 027-010-023

“most important act” should have been to examine the laboratory records, note the chronology of abnormal electrolytes and correlate that with what had happened clinically. He believed that Dr O’Hara had attached too much significance to the presence of pneumonia and had not sufficiently thought the case through.⁴⁷⁶

4.290 Mr Leckey became concerned when he read Dr O’Hara’s post-mortem report in 2003. He noted that whilst Dr O’Hara found the ultimate cause of death to be an oedema of the brain, he had obviously failed to establish the cause of that oedema.⁴⁷⁷ This was therefore a death which required investigation and as an experienced pathologist Dr O’Hara ought to have known to notify the Coroner himself.⁴⁷⁸ Had he done so, Mr Leckey would have inevitably directed his own post-mortem.

4.291 Dr O’Hara responded to the Coroner’s concern by providing a supplementary report indicating *“two potential pathological processes that could impinge upon the brain”* namely hyponatraemia and bronchopneumonia and concluding that it was difficult to know *“what proportion of the cerebral oedema can be described to each of these processes.”*⁴⁷⁹ Such analysis merely emphasises the inadequacy of his first report which failed to consider the significance of the known presence of hyponatraemia. Responsibility for that does not, however, rest solely with Dr O’Hara. He did not receive the assistance he had every right to expect from the clinical team led by Dr Hanrahan which had neglected to brief him with basic materials and thereafter failed to engage with him in the search for answers.

4.292 Dr Hanrahan, having initiated the post-mortem process on the basis that he *“didn’t have a clue”* why Lucy had died,⁴⁸⁰ now accepts that when the post-mortem did not identify the cause of her death he then ought to have referred the matter back to the Coroner’s office.⁴⁸¹ He failed so to do. The

⁴⁷⁶ 252-003-004

⁴⁷⁷ Mr Leckey T-25-06-13 p.184-185

⁴⁷⁸ Mr Leckey T-25-06-13 p.185 line 6

⁴⁷⁹ 013-017-065

⁴⁸⁰ Dr Hanrahan T-05-06-13 p.152-153

⁴⁸¹ Dr Hanrahan T-05-06-13 p.196 line 15. This was likewise the conclusion of the General Medical Council.

GMC, when it examined this issue, counselled Dr Hanrahan to ensure that the Coroner is informed of the conclusions reached by any hospital post-mortem if such circumstances arose in the future.⁴⁸²

RBHSC: Completion of the Death Certificate

4.293 Before the final post-mortem report became available, Dr O'Donoghue issued a medical certificate of cause of death on the 4th May 2000 certifying that Lucy's death was due to:

"I (a). Cerebral oedema

(b). due to (or as a consequence of) dehydration

*(c). due to (or as a consequence of) gastroenteritis."*⁴⁸³

4.294 That the certificate was issued when there was continuing uncertainty about the cause of death is another matter of real concern.

4.295 Dr O'Donoghue was marginally involved in Lucy's care before her death, in that he administered a hormone to her.⁴⁸⁴ For that reason he considered himself legally competent to sign the death certificate. Even if it might be said that he was legally competent to perform this role, Dr O'Donoghue certainly had no independent knowledge or understanding of the cause of the fatal cerebral oedema. I am satisfied, given the legal significance of the process, that a certificate should not be signed by a doctor who has no independent understanding of the causes of death.

4.296 Dr O'Donoghue said that he spoke to Dr C. Stewart⁴⁸⁵ and possibly to an intensivist in PICU⁴⁸⁶ before issuing the death certificate. He considered Lucy's hospital notes and the anatomical summary prepared by Dr O'Hara⁴⁸⁷ but did not read the autopsy request form which made reference to the hyponatraemia.⁴⁸⁸ He then "*presented the available information*" to

⁴⁸² 403-029-005

⁴⁸³ 013-008-022

⁴⁸⁴ Dr O'Donoghue T-31-05-13 p.44 line 23

⁴⁸⁵ Dr O'Donoghue T-31-05-13 p.32 line 13 (See also the entry in Lucy's notes at 061-018-068)

⁴⁸⁶ Dr O'Donoghue T-31-05-13 p.40 line 6

⁴⁸⁷ Dr O'Donoghue T-31-05-13 p.31 line 14

⁴⁸⁸ Dr O'Donoghue T-31-05-13 p.34 line 9

Dr Hanrahan who advised him as to the causes of death.⁴⁸⁹ Dr O'Donoghue then entered into Lucy's notes those causes as advised by Dr Hanrahan and transcribed them on to the death certificate.⁴⁹⁰

4.297 It is inconceivable that Dr O'Donoghue would have completed the death certificate without the involvement of his more senior colleagues.⁴⁹¹ I consider that in reality the certificate was formulated by Dr Hanrahan. In reality, he had ownership of that certificate even if he did not sign it.

4.298 The formulation of the cause of death appearing on the death certificate has been recognised as a nonsense. The cerebral oedema causing Lucy's death was not due to dehydration. Both Dr MacFaul and Professor Lucas characterised the formulation as "*illogical*" because cerebral oedema cannot arise in consequence of dehydration.⁴⁹²

4.299 That was the consensus view. Dr Crean recalled that in 2003 when he first read the certificate, "*it didn't make any sense*"⁴⁹³ and Dr Taylor agreed that it was "*not a correct cause of death*."⁴⁹⁴ Dr Chisakuta also accepted that Lucy did not die as a result of dehydration⁴⁹⁵ and observed that the death certificate could only begin to make sense if it explained that it was the treatment for dehydration which had given rise to the cerebral oedema.⁴⁹⁶

4.300 Only Dr McKaigue really sought to defend the content of the death certificate. He claimed that dehydration was a cause of the death, albeit indirectly, and suggested that there was, in any event, insufficient space on the death certificate for the certifying doctor to refer to the fluid mismanagement. I consider such arguments to be wholly without merit and think it telling, in the circumstances, that Dr McKaigue should have sought to defend the indefensible.

⁴⁸⁹ Dr O'Donoghue T-31-05-13 p.57 line 15

⁴⁹⁰ Dr O'Donoghue T-31-05-13 p.60 line 20 (See also the entry in Lucy's notes at 061-018-068)

⁴⁹¹ Dr O'Donoghue T-31-05-13 p.32 line 19

⁴⁹² 252-003-011 & 250-003-007

⁴⁹³ Dr Crean T-04-06-13 p.131 line 20

⁴⁹⁴ Dr Taylor T-04-06-13 p.214 line 20

⁴⁹⁵ Dr Chisakuta T-29-05-13 p.113 line 4

⁴⁹⁶ Dr Chisakuta T-29-05-13 p.112 line 17

- 4.301 Dr O'Donoghue explained that he allowed himself to certify an illogical cause of death because he acted under the direction of Dr Hanrahan who identified causes which he recognised as appearing in Lucy's notes.⁴⁹⁷ Dr O'Donoghue accepted that, "...it is likely, if I had scrutinised it in greater detail... that it would have become apparent that that does not make physiological sense."⁴⁹⁸ Dr O'Donoghue's duty as a doctor was to take reasonable steps to verify the cause of death before he signed the certificate.⁴⁹⁹ He should have given his task more consideration and challenged Dr Hanrahan's thinking, awkward though it may have been to ask questions of a senior colleague.
- 4.302 However, Dr O'Donoghue considered that because Dr Hanrahan was in charge of Lucy's care, it was Dr Hanrahan who bore the responsibility to ensure that her death was properly certified.⁵⁰⁰ I consider that Dr O'Donoghue is correct in this analysis. It is to be recognised in this context that Dr Hanrahan authorised Dr O'Donoghue to issue the certificate before the cause of death was known, before Dr O'Hara produced his final post-mortem report⁵⁰¹ and when the death certificate should not have been issued.⁵⁰²
- 4.303 Dr Hanrahan conceded that he handled the death certificate "*extremely badly*."⁵⁰³ He admitted that the content of the certificate was "*illogical and unhelpful*"⁵⁰⁴ and "*did not reflect the true chain of events in Lucy's death*."⁵⁰⁵ He accepted that the presence of "*cerebral oedema was not due to dehydration, but rather to excessive rehydration leading to hyponatraemia*."⁵⁰⁶ Dr Hanrahan said that he allowed the certificate to

⁴⁹⁷ Dr O'Donoghue T-31-05-13 p.74 line 20

⁴⁹⁸ Dr O'Donoghue T-31-05-13 p.75 line 15

⁴⁹⁹ 315-002-019 - General Medical Council – Good Medical Practice (1998)

⁵⁰⁰ Dr O'Donoghue T-31-05-13 p.43 line 16

⁵⁰¹ 061-009-017

⁵⁰² Dr Hanrahan T-05-06-13 p.157 line 21

⁵⁰³ Dr Hanrahan T-05-06-13 p.156 line 17

⁵⁰⁴ Dr Hanrahan T-05-06-13 p.157 line 3

⁵⁰⁵ WS-289-1 p.26

⁵⁰⁶ WS-289-1 p.20

issue because he “*was over-focussed on being kind to the parents*” who could not make their funeral arrangements without the death certificate.⁵⁰⁷

- 4.304 I am concerned that not only was the certificate issued in the absence of clarity around the cause of death, but that it was issued with an incorrect cause of death. I am satisfied that Dr Hanrahan knowingly permitted an inaccurate description of the cause of death to appear on the death certificate. That this happened is a matter for the gravest concern and cannot be excused by what I accept was his genuine sympathy for the family or a desire to help them expedite the funeral arrangements.
- 4.305 In its consideration of this issue, the GMC concluded that the entry on the death certificate was “*consistent with the findings of the preliminary post-mortem report*” and that therefore “*Dr Hanrahan cannot be regarded as having misled the Coroner in this regard.*”⁵⁰⁸ I reject this analysis. A death certificate should not have been written on the basis of a preliminary post-mortem report, and still less should the cause of death have been certified as it was. As I have indicated, the hospital post-mortem process did not identify the cause of Lucy’s death and therefore her case should have been reported back to the Coroner. The effect of the certification was to mislead the Coroner.
- 4.306 Dr Hanrahan now recognises that his conduct in this respect was indefensible. Not only did it have the effect of concealing the true cause of Lucy’s death but it also prevented, at that point in time, the further investigation of the death through the Coroner’s Office which was so obviously required. Accordingly, the clinical mismanagement which caused the cerebral oedema remained hidden until Mr Millar’s helpful intervention three years later.

RBHSC: Communication with Lucy’s parents

- 4.307 Dr Hanrahan had indicated to Mr and Mrs Crawford, even before Lucy had died, that they would have to go back to the Erne and to Dr O’Donohoe to

⁵⁰⁷ Dr Hanrahan T-05-06-13 p.156 line 19
⁵⁰⁸ 403-029-005

find out what had happened.⁵⁰⁹ Dr Chisakuta indicated that had it been his duty to speak to Mr and Mrs Crawford he would have told them that her fluid management at the Erne Hospital may not have been appropriate and that there was a concern that this may have contributed to the development of cerebral oedema.⁵¹⁰ It is not thought that Dr Hanrahan told them about any particular concern.

- 4.308 Dr Hanrahan met again with Mr and Mrs Crawford on the 9th June 2000.⁵¹¹ It is commendable that he initiated a meeting and it would appear that he was genuinely concerned for them. He made a short note after the meeting to record that he had gone “*over the events around Lucy’s death and encouraged them to re-attend with Dr O’Donoghue (sic) to clarify events in the Erne...*”⁵¹² Importantly, whilst this does not record discussion about fluid mismanagement, it does indicate that Dr Hanrahan tried to help Mr and Mrs Crawford obtain a fuller account of what had happened. After the meeting he contacted Dr O’Donohoe and secured his agreement to see them again. It was not his fault that Dr O’Donohoe did not honour that agreement.
- 4.309 Dr Hanrahan was conscious at that time that whatever had gone wrong had happened at the Erne.⁵¹³ Doubtless it was for that reason that he considered that Dr O’Donohoe should be involved in providing an explanation.⁵¹⁴ In June 2000 Dr Hanrahan knew more than enough about Lucy’s treatment to be concerned about it.⁵¹⁵ He was aware that there was discussion within the RBHSC about the errors even if he did not understand the connection between the poor fluid management and the development of the cerebral oedema.⁵¹⁶ He acknowledged that he should have informed Mr and Mrs Crawford of those concerns.⁵¹⁷ He said that whilst he might

⁵⁰⁹ Dr C Stewart T-29-05-13 p.202 line20

⁵¹⁰ Dr Chisakuta T-29 -05-13 p.80 line 8

⁵¹¹ 061-010-034

⁵¹² 061-018-069

⁵¹³ Dr Hanrahan T-05 -06-13 p.182 line 24

⁵¹⁴ WS-289-1 p.15

⁵¹⁵ WS-289-1 p.15

⁵¹⁶ Dr Hanrahan T-05 -06-13 p.178 -179

⁵¹⁷ Dr Hanrahan T-05 -06-13 p.183 line 13

have told them there was some concern about how Lucy's fluids were managed he could not be sure.⁵¹⁸

4.310 Dr Chisakuta observed that if Mr Crawford had been given such information he would likely have mentioned it when he wrote his letter of complaint to the SLT, which he did not.⁵¹⁹ Furthermore, had Dr Hanrahan suggested medical error to the Crawfords they would have pursued the issue with Dr O'Donohoe which they did not. I consider the strong likelihood is that Dr Hanrahan failed in his duty to tell the family that the fluids had been poorly managed. The parents had a right to that information and Dr Hanrahan had a duty to impart it.⁵²⁰

4.311 Mrs Crawford has stated that Dr Hanrahan merely directed them back to the Erne for answers.⁵²¹ Any further meeting with Dr O'Donohoe must have seemed pointless. Responsibility for this further failure in transparency and communication is not Dr Hanrahan's alone. There was a collective failure by all the RBHSC clinicians who had cared for Lucy to determine that concerns relating to Lucy's treatment and death would be explained to her parents and to ensure that it was done. This reflected the like failure at the Erne Hospital.

RBHSC: Audit/Mortality meeting

4.312 Dr Carson maintained that whilst there was no formal auditing of death certificates at that time in the RBHSC,⁵²² every death was considered and discussed at a mortality section meeting of the Clinical Paediatric Audit.⁵²³

4.313 Dr Taylor was the Paediatric Audit Co-ordinator in 2000 and responsible for chairing the mortality section of the Audit meeting.⁵²⁴ He explained that the purpose of the mortality section was *"to discuss the child's death for*

⁵¹⁸ Dr Hanrahan T-05-06-13 p.182 line 8

⁵¹⁹ Dr Chisakuta T-29-05-13 p.95-96

⁵²⁰ 306-085-014 - GMC Good Medical Practice (1998) & 315-002-007 - rights recognised by the Charter for Patients and Clients (1992)

⁵²¹ 115-002-002

⁵²² Dr Carson T-26-06-13 p.44-45

⁵²³ Dr Carson T-26-06-13 p.22

⁵²⁴ WS-280-1 p.3

learning purposes among the clinicians present.”⁵²⁵ All agreed that this was the purpose, in order as Dr Hanrahan put it, “to try and learn lessons and to see should anything alternative have been done.”⁵²⁶

4.314 The meetings convened monthly and lasted about half a day.⁵²⁷ Normally more than one death was discussed at each meeting. The mortality discussions were un-minuted but this practice was not untypical of arrangements elsewhere at that time.

4.315 Dr McKaigue explained that such discussions were,

“... an opportunity to present the events surrounding the death of patients in the Children’s Hospital, primarily to a wider body of doctors (multi-disciplinary). Further, at that time there was a push within Audit circles to establish audit as a multi-professional process (nurses and professions allied to medicine). Before the presentation, the presenter would have had to collate and organise in a logical way the different strands pertaining to the case. Presentations were a way of announcing that a patient had died under the said circumstances and what the cause of death was thought to be. The death was not only being reviewed by the presenter but also by peers and other disciplines, who could bring a different perspective to aspects of the case. Implicit in this process was the opportunity to learn and reflect from listening to the presentation and ensuing discussion. Individuals would have had different learning experiences according to their specialty, previous knowledge and experience.

Presentations were oral and usually facilitated by using computerised slides or an overhead projector and sometimes X-rays were displayed. For some presentations, radiologists and pathologists made a contribution. Patient details were anonymised.

The presentation would have consisted of a history including differential diagnoses, investigations and their results, when death occurred, the cause

⁵²⁵ WS-280-1 p.3

⁵²⁶ Dr Hanrahan T-05-06-13 p.233 line 20

⁵²⁷ Dr Crean T-04-06-13 p.152 line 20

of death and whether or not the Coroner had been advised of the death. The follow-up with the patient's family was also described. In addition to the facts presented, there would have been commentary by the presenter to emphasise significant points/issues (as they saw them), put things into context and interpret results, if necessary.

Discussions around each presentation consisted of contributions from attendees reflecting their related experiences of similar cases, or making reference to a journal article or latest guideline, which they personally would recommend as being helpful.

Questions were asked by attendees to get more information where they felt detail was lacking or did not understand something. Suggestions were made to improve shortcomings if an attendee felt that was warranted. Occasionally, there were disagreements between attendees over expression of an opinion. A detailed minute of the presentation or discussion was not made.”⁵²⁸

4.316 Dr Taylor agreed that every child death should have been presented and discussed within the mortality section of the meeting. He would have expected Lucy's death to have been presented by the lead consultant and pathologist⁵²⁹ who would then have answered questions from the clinicians present. He explained that the purpose of the discussion was to “review” the settled position after a death rather than to conduct an “investigation.”⁵³⁰ He said that mortality meetings were not “passive” but that “serious matters were discussed” and those who attended could say “stop” and ask that further investigations be conducted.⁵³¹

4.317 Dr Crean acknowledged that Lucy's case ought to have provoked a serious discussion about the content of the death certificate. He contended that if Lucy's case had been discussed, “people would have been jumping up and down asking all sorts of questions” and saying “this doesn't make sense.”⁵³²

⁵²⁸ WS-302-3 p.2-3

⁵²⁹ WS-280-1 p.3

⁵³⁰ Dr Taylor T-11-12-12 P.118, line 10-13

⁵³¹ Dr Taylor T-04 -06-13 p.203-204

⁵³² Dr Crean T-04 -06-13 p.153 line 17

He considered that such discussion would very probably have led to further and better investigation and possibly a referral back to the Coroner.⁵³³

- 4.318 The Inquiry was informed Lucy's death was discussed at an Audit meeting on the 10th August 2000.⁵³⁴ That is all. It has not been suggested that discussion of the death triggered the kind of response which Dr Crean spoke about.
- 4.319 The evidence suggests that Dr Crean, Dr Chisakuta or Dr Hanrahan could each have been regarded as 'lead consultant' for Lucy within the RBHSC and each would have had the requisite knowledge to present her case at the Audit meeting. Both Dr Crean⁵³⁵ and Dr Chisakuta⁵³⁶ thought that Dr Hanrahan should have presented it. Dr Hanrahan did not accept that this was necessarily the case but recognised that there ought to have been a discussion to decide who should.⁵³⁷ I consider that Dr Hanrahan was best placed to make the presentation but that the other doctors were also perfectly capable of doing so. I deprecate the failure of Drs Crean, Chisakuta and Hanrahan to decide who should undertake this important task.
- 4.320 I have considered a three page document said to be relevant to the Clinical Paediatric Audit meeting of 10 August 2000.⁵³⁸ There is an attendance sheet dated 10th August 2000⁵³⁹ indicating the attendance of thirty four persons. Only one of the clinicians who had cared for Lucy attended and that was Dr McKaigue who only saw her briefly upon arrival and did not treat her thereafter. The names of Drs Crean, Chisakuta, Hanrahan and O'Hara are absent from the attendance sheet. No apology is recorded from any of these doctors in relation to non-attendance.

⁵³³ Dr Crean T-04 -06-13 p.154 line 23

⁵³⁴ 061-038-123

⁵³⁵ WS-292/2 p.7

⁵³⁶ Dr Chisakuta T-29 -05-13 p.114 line 10

⁵³⁷ Dr Hanrahan T-05 -06-13 p.225 line 18

⁵³⁸ 319-023-004

⁵³⁹ 319-023-003

- 4.321 There is then a document described as the ‘minutes’ of the Clinical Paediatric Audit for 10 August 2000⁵⁴⁰ which records that “5 cases were presented and discussed” in the mortality section of the meeting. Neither the cases discussed nor the names of the presenting clinicians are given. An additional document described as a “redacted audit list”⁵⁴¹ contains a spreadsheet noting Lucy’s name, date of death, department where treated, named consultant and name of the pathologist conducting post-mortem.
- 4.322 If Lucy’s death was discussed at the Audit meeting in August 2000 or indeed at any other time, I would have expected some evidence identifying the clinician(s) presenting her case. The attendance sheet does not indicate the attendance of anyone who could have given that presentation.
- 4.323 Dr Crean accepted that it is unlikely that he was in attendance. He explained that circumstances could have arisen such as an emergency to prevent him attending.⁵⁴² Dr Chisakuta told me that he was not present at the Audit meeting⁵⁴³ and did not know whether Lucy’s death was discussed.⁵⁴⁴ Dr Hanrahan conceded that he “clearly wasn’t at it.”⁵⁴⁵
- 4.324 Dr McKaigue was at the meeting and stated that whilst he could have spoken about Lucy’s condition at the time of admission he did not present her case.⁵⁴⁶ He had no memory of the meeting but did admit to what he described as a “vague memory that Dr Hanrahan presented Lucy Crawford’s case at an audit meeting in the Children’s Hospital,” but could not say when that meeting took place.⁵⁴⁷
- 4.325 Dr Taylor cast doubt on whether the meeting on 10th August 2000 included presentation of Lucy’s death, reasoning that as Chairman of the meeting he would not have permitted “a case to be presented without at least two of the three major people involved.” He stated that it “defies logic to conclude

⁵⁴⁰ 319-023-004

⁵⁴¹ 319-023-005

⁵⁴² Dr Crean T-04-06-13 p.152-153

⁵⁴³ WS-283-1 p.12

⁵⁴⁴ WS-283-1 p.12

⁵⁴⁵ Dr Hanrahan T-05-06-13 p.225 line 4

⁵⁴⁶ WS-302-3 p.3

⁵⁴⁷ c.f. Dr McKaigue’s evidence discussed at para 3.239

that her case was discussed at that meeting."⁵⁴⁸ Like Dr Taylor, I cannot understand how Lucy's death could have been presented at an Audit meeting in the absence of Drs Crean, Chisakuta, Hanrahan and/or O'Hara.⁵⁴⁹

- 4.326 I conclude therefore that the Audit meeting of 10th August 2000 did not consider Lucy's death. I received no evidence to suggest that her death was discussed at any subsequent Audit meeting. It is very unsatisfactory that no one could explain why her death was not discussed. However, Lucy's death was no more considered at an audit meeting than the deaths from dilutional hyponatraemia of Adam Strain and Claire Roberts. It is hard not to discern a pattern of avoidance given that some of the same clinicians were involved.
- 4.327 The mortality section of the Audit meeting provided real opportunity to concentrate on how Lucy had died, to query what had happened and to derive some learning from the tragedy. The failure to present Lucy's death must deepen concern that some clinicians at the RBHSC did not wish to focus on the question of how she had died.
- 4.328 If Dr Taylor was aware that the presentation of Lucy's death had not occurred he ought to have taken steps to ensure that this was addressed. While I am satisfied that Dr Taylor had no formal authority to compel a presentation if Drs Crean, Chisakuta, Hanrahan and O'Hara were unable or unwilling to do it, pressure could and should have been applied. The failure of these doctors to arrange for an audit discussion and the consequence of that failure is disturbing. Each of these doctors was responsible for that failure. This was a real opportunity to learn from the tragedy of Lucy's case, but it was squandered.
- 4.329 The failure to ensure the formal presentation and informed discussion of Lucy's death was the failure of individuals within a weak governance system. The fragility of the system allowed clinicians to avoid audit

⁵⁴⁸ Dr Taylor T-04 -06-13 p.208 line 23

⁵⁴⁹ Dr Taylor T-04 -06-13 p.40 line 12

presentation without fear of sanction. Dr Carson said he did not have the staff to deliver “a *robust governance arrangement*.”⁵⁵⁰ It did not require staffing to discuss Lucy’s death in this context, just a willingness to do so.

Concluding Remarks

- 4.330 Having reflected upon the evidence, I am of the view that the poor care which Lucy received was initially and deliberately concealed by clinicians at both the RBHSC and the Erne Hospital from the family, the Coroner and the pathologist who all should have been told of the suspected mismanagement of fluids.
- 4.331 The failure by senior clinicians to address the issue with appropriate candour suppressed the truth and inhibited proper examination of what had gone wrong. The motivations for this concealment may be multiple, but I count amongst them a determination to protect professional colleagues from having to confront their clinical errors.
- 4.332 As a result the opportunity to learn lessons was disregarded and critical learning was lost to clinicians delivering fluid therapy to other children in Northern Ireland. When Raychel came to be treated in the Altnagelvin Hospital fourteen months later, Solution No. 18 was still being used without appropriate guidance as to the risks.

⁵⁵⁰ Dr Carson T-26 -06-13 p.23 line 3

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Introduction

- 5.1 Raychel Ferguson was born on 4th February 1992,¹ the fourth child and only daughter of Raymond and Marie Ferguson. In June 2001 Raychel was a happy, healthy 9 year old child and in her P5 year at St Patrick's Primary School, Pennyburn, Derry.²
- 5.2 On Thursday 7th June 2001, Raychel went to school as usual. She was in good spirits and won a medal in her school sports.³ Later, at about 16:30 she began to complain of stomach ache.⁴ Nevertheless, she played in and around the family home and ate normally. However, she continued to complain and Mrs Ferguson eventually made up a bed for her on the sofa.⁵ Her primary concern at that time was not that Raychel was in pain, but that she looked grey.⁶
- 5.3 Things did not improve and Mrs Ferguson decided to take Raychel to the Altnagelvin Area Hospital ('Altnagelvin'). She put her in the car and set off, collecting Mr Ferguson on the way. They arrived at the hospital shortly after 19:00.⁷ Mr Ferguson thought Raychel looked grey and unwell.⁸ He carried her into the Accident and Emergency Department ('A&E').
- 5.4 Within 48 hours Raychel was to suffer brain death in consequence of hyponatraemia. In this chapter of the report, I set out my findings in relation to her case.

Expert reports

- 5.5 The Inquiry, in examining Raychel's case and guided by its advisors, engaged the following experts to advise:

¹ 012-025-135
² 012-025-135
³ Mrs Ferguson T-26-03-13 p.10 line 5
⁴ 012-025-135
⁵ 012-025-135
⁶ Mrs Ferguson T-26-03-13 p.12 line 9
⁷ 012-025-136
⁸ Mr Ferguson T-26-03-13 p.13 line 10

- (i) Dr Robert Scott-Jupp⁹ (Consultant Paediatrician, Salisbury District Hospital, England) who provided reports on paediatric and general medical issues.¹⁰
- (ii) Mr George Foster¹¹ (Consultant General Surgeon, Countess of Chester Hospital, and Grosvenor Nuffield Hospital) who provided reports on the role and responsibilities of the surgical staff.¹²
- (iii) Dr Simon Haynes¹³ (Consultant in Paediatric Cardiothoracic Anaesthesia and Intensive Care, Freeman Hospital, Newcastle upon Tyne) who reported on anaesthetic as well as general management issues.¹⁴
- (iv) Ms Sally Ramsay¹⁵ (Independent Childrens' Nursing Advisor) who advised on questions of nursing.¹⁶
- (v) Dr Wellesley St. C. Forbes¹⁷ (retired Consultant Neuroradiologist, formerly of Salford Royal Hospitals NHS Foundation Trust and Manchester University Children's Hospitals NHS Foundation Trust) who reported on the Computerised Tomography ('CT') scans.¹⁸
- (vi) Dr Fenella Kirkham¹⁹ (Professor of Paediatric Neurology, Institute of Child Health, London and Consultant Paediatric Neurologist Southampton General Hospital), who provided a report on neurological issues arising.²⁰

⁹ 312-003-006

¹⁰ File 222

¹¹ 312-003-006

¹² File 223

¹³ 312-003-006

¹⁴ File 220

¹⁵ 312-003-006

¹⁶ File 224

¹⁷ 312-003-006

¹⁸ File 225

¹⁹ 312-003-006

²⁰ File 221

- (vii) Professor Charles Swainson²¹ (retired Consultant Renal Physician and Medical Director of the Lothian NHS Board, Edinburgh) who advised on governance.²²

5.6 The Inquiry also had the benefit of expert reports commissioned by the Coroner, the Police Service of Northern Ireland ('PSNI') and Altnagelvin, from:

- (i) Dr Brian Herron²³ (Consultant Neuropathologist, Royal Group of Hospitals) who provided the Autopsy Report following post-mortem on 11th June 2001.²⁴
- (ii) Dr Clodagh Loughrey²⁵ (Consultant Chemical Pathologist, Belfast City Hospital) who reported on 24th October 2001.²⁶
- (iii) Dr Edward Sumner²⁷ (Consultant Paediatric Anaesthetist at Great Ormond Street Childrens' Hospital) who provided reports to the Coroner on 1st February 2002²⁸ and to the PSNI in September 2005.²⁹
- (iv) Ms Susan Chapman³⁰ (Nurse Consultant for acute and high dependency care at Great Ormond Street Childrens' Hospital) who reported to the PSNI on 24th September 2005.³¹
- (v) Dr John Jenkins³² (Senior Lecturer in Child Health and Consultant Paediatrician) who provided reports dated 12th November 2002,³³ 27th January 2003³⁴ and 30th January 2003³⁵ for Altnagelvin.

²¹ 328-001-006
²² File 226
²³ 312-003-006
²⁴ 014-005-006 *et seq*
²⁵ 312-003-006
²⁶ 014-006-014 *et seq*
²⁷ 312-003-007
²⁸ 012-001-001
²⁹ 098-081-235, 098-093-341 & 098-098-373
³⁰ 312-003-007
³¹ 098-092a-328
³² 328-001-006
³³ 317-009-002 *et seq*
³⁴ 160-215-002
³⁵ 022-004-010

- (vi) Dr Declan Warde³⁶ (Consultant Paediatric Anaesthetist, The Childrens' University Hospital, Dublin) who provided Altnagelvin with a report in January 2003.³⁷
- (vii) Mr John Orr³⁸ (Consultant Paediatric Surgeon, Royal Hospital for Sick Children, Edinburgh) who reported to Altnagelvin on the treatment given Raychel on 30th January 2013.³⁹

Schedules compiled by the Inquiry

5.7 In an attempt to summarise the very significant quantities of information received, the following schedules and charts were compiled:

- (i) Chronology of events (Clinical).⁴⁰
- (ii) Timeline of Raychel's treatment.⁴¹
- (iii) Chronology and Clinical Timeline post-collapse 9th June 2001.⁴²
- (iv) Table of Clinicians duty times 7th – 9th June 2001.⁴³
- (v) Schedule of Observations.⁴⁴
- (vi) Schedule of Persons (Clinical).⁴⁵
- (vii) Schedule of Persons (Governance).⁴⁶
- (viii) Schedule of nomenclature and grading of doctors 1948 – 2012.⁴⁷
- (ix) Schedule of nomenclature and grading of nurses 1948 – 2012.⁴⁸

³⁶ 328-001-006
³⁷ 317-009-006 *et seq*
³⁸ WS-320-1 p.3
³⁹ WS-320-1 p.2 *et seq*
⁴⁰ 312-004-001
⁴¹ 312-001-001
⁴² 312-013-001
⁴³ 312-006-001
⁴⁴ 312-009-001
⁴⁵ 312-003-001
⁴⁶ 328-001-001
⁴⁷ 303-003-048
⁴⁸ 303-004-051

- (x) Consolidated Chronology of 'Governance' and 'Lessons Learned'.⁴⁹
- (xi) Table of Nurses' training and experience.⁵⁰
- (xii) Table of Trainee Doctors' training and experience.⁵¹
- (xiii) Glossary of Medical Terms.⁵²

All of the above have been published on the Inquiry website.

Raychel in A&E

- 5.8 Raychel was seen in A&E at 20:05 by Senior House Officer ('SHO') Dr Barry Kelly.⁵³ Whilst he had limited paediatric experience,⁵⁴ his role was confined to examination and onward referral for surgical opinion. Dr Kelly has no recollection of his involvement⁵⁵ but did make a record of his examination in the medical notes.⁵⁶
- 5.9 He noted a history of sudden onset abdominal pain from about 16:30 and increasing thereafter. Nausea was noted with "*pain on urination*."⁵⁷ Pain was found to be maximal over 'McBurney's Point' with clinical signs of tenderness in the right iliac fossa. On the basis of these findings, Dr Kelly noted his suspicion as "*Appendicitis? Surgeons*."⁵⁸ He arranged for blood and urine tests, referred Raychel for surgical assessment, and gave her cyclimorph to ease pain.⁵⁹ This appears to have been effective as Mrs Ferguson thought her "*back to normal after the injection*."⁶⁰
- 5.10 The only potential criticism of Dr Kelly relates to the painkiller. Cyclimorph is so powerful a morphine based drug that it risks compromising

⁴⁹ 325-004-001
⁵⁰ 312-007-001
⁵¹ 312-008-001
⁵² 312-005-001
⁵³ 312-003-002
⁵⁴ Dr Kelly T-05-02-13 p.7 line 17
⁵⁵ Dr Kelly T-05-02-13 p.11 line 19
⁵⁶ 026-006-010
⁵⁷ 020-006-010
⁵⁸ 020-006-010
⁵⁹ 020-006-010
⁶⁰ WS-020-1 p.2

subsequent medical assessment by masking clinical signs.⁶¹ This can be relevant in the diagnosis of appendicitis because clinical findings are important.⁶²

- 5.11 Any criticism of Dr Kelly must be extremely limited. It is not suggested that Raychel should not have been given a painkiller. It would have been inhumane not to attempt pain relief. Rather he should have opted for milder analgesia.⁶³ Whilst it would have been better if Dr Kelly had not prescribed as he did, it would be unfair, given the extent of his experience and the available textbook guidance⁶⁴ to criticise him. In any event, he referred Raychel to another SHO who specialised in surgery and one who could, if necessary, contact a registrar or consultant.⁶⁵

Diagnosis and admission for appendectomy

- 5.12 Dr Ragai Makar⁶⁶ qualified as a doctor in Egypt in 1989. During the 1990s he gained experience in general surgery and emergency medicine and practiced as a registrar. He came to the UK in 1997 and worked almost exclusively in short-term posts as an SHO before moving to Altnagelvin in August 2000 as an SHO in general surgery. He was therefore more experienced than most SHOs, but his experience with children was limited.⁶⁷
- 5.13 Upon request, Dr Makar saw Raychel and examined her on Thursday evening. He noted, but did not time, his examination in the record.⁶⁸ He found tenderness at the right iliac fossa with guarding and mild rebound. He did not believe that the painkiller hindered his diagnosis.⁶⁹ He noted normal blood test results⁷⁰ and ordered a repeat urine test.⁷¹

⁶¹ 223-002-006

⁶² Dr Scott-Jupp T-20-03-13 p.6 line 9

⁶³ 223-003-004

⁶⁴ WS-254-1 p.4 & p.11

⁶⁵ WS-254-1 p.4

⁶⁶ 312-003-002

⁶⁷ WS-022-2 p.2

⁶⁸ 020-007-011 & 020-007-012

⁶⁹ Dr Makar T-06-02-13 p.167 line 13

⁷⁰ 020-022-045 (including sodium at 137mmol/L. Normal sodium range 135-145mmol/L)

⁷¹ 020-007-012

- 5.14 Dr Makar concluded that Raychel had “*acute appendicitis/obstructed appendix*”⁷² and obtained Mrs Ferguson’s written consent to surgery.⁷³ Raychel was admitted to Ward 6 at 21:41 to fast and receive fluids in preparation for an appendectomy.⁷⁴ Dr Makar was to perform the operation himself.
- 5.15 Altnagelvin had only one childrens’ ward, Ward 6. It served both surgical and medical patients. Surgical patients were children admitted in relation to surgery and medical patients were those otherwise admitted for paediatric treatment. The ward could accommodate 43 children⁷⁵ but on 8th June 2001, there were only 23.⁷⁶ The majority of patients would normally have been medical cases.⁷⁷ Paediatricians were employed on Ward 6 to care for the medical patients. However, because there were no paediatric surgeons at Altnagelvin, children were operated on by general hospital surgeons and cared for on Ward 6 by the general surgical staff. The nurses, some of whom were trained childrens’ nurses, cared for both the medical and the surgical patients.
- 5.16 The on-call surgical consultant for the night of 7th June was Mr Robert Gilliland.⁷⁸ He was not consulted about the decision to operate and, in all probability, remained unaware of Raychel’s admission until Sunday 10th June.⁷⁹ The fact that he was Raychel’s named consultant did not necessarily mean that he would see her.⁸⁰ Dr Scott-Jupp considered that his non-attendance “*by the standards of the time, was acceptable practice.*”⁸¹ He should, however, have been informed of her case because his responsibility was, as he accepted, to “*oversee the totality of the patient’s care.*”⁸²

⁷² 020-007-012

⁷³ 020-008-015

⁷⁴ 020-001-001

⁷⁵ Sister Millar T-28-08-13 p.111 line 8

⁷⁶ 316-011-001

⁷⁷ Staff Nurse Noble T-26-02-13 p.103 line 8

⁷⁸ 312-003-002

⁷⁹ WS-044-1 p.4

⁸⁰ Staff Nurse Noble T-27-02-13 p.27 line 9 & Mr Gilliland T-14-03-13 p.136 line 21

⁸¹ 222-005-005

⁸² WS-044-2 p.13

- 5.17 The Ferguson family “*believe to this day that Raychel’s operation should never have taken place.*”⁸³
- 5.18 There are significant issues about the decision to proceed to surgery including:
- (i) Whether Dr Makar’s examination of Raychel could have been affected by the cyclimorph.
 - (ii) Whether Dr Makar should have requested an urgent urinalysis in light of Dr Kelly’s note of “*pain on urination*” and a finding of “+1” protein because these might have been suggestive of urinary tract infection.⁸⁴
 - (iii) Whether, because the Fergusons insist that Raychel was not in obvious pain at that time (and it is noted that Dr Makar did not record complaint), the decision to operate was premature.
 - (iv) Whether Raychel could have been observed overnight pending re-assessment in the morning.
 - (v) Whether, given a disagreement between the Fergusons and Dr Makar as to the basis upon which Mrs Ferguson gave her consent to surgery, a valid consent was given.
- 5.19 Dr Makar did not consider that the pain relief given Raychel interfered with his diagnosis. His belief is supported by subsequent medical literature which suggests that “*morphine effectively reduces the intensity of pain among children with acute abdominal pain and morphine does not seem to impede the diagnosis of appendicitis.*”⁸⁵
- 5.20 Dr Scott-Jupp discounted the likelihood of a urinary tract infection on the basis of negative leukocyte and nitrate counts⁸⁶ and in any event, Mr Orr said that if “*the urine was sent off to the lab for microscopy and thereafter*

⁸³ Mrs Ferguson T-26-03-13 p.175 line 20

⁸⁴ 223-002-005 & WS-320-1 p.4

⁸⁵ WS-044-3 p.10

⁸⁶ Dr Scott-Jupp T-20-03-13 p.11 line 4 & 020-016-031-2

*culture... that culture will take two or three days.*⁸⁷ It is hard, therefore, to criticise failure to pursue the possibility of urinary tract infection.

5.21 I heard conflicting expert opinion about the decision to operate. Dr Scott-Jupp said that *"by today's standards, a child such as Raychel presenting with those sorts of symptoms would be more likely to have been left overnight and reassessed in the morning... However, when that happens... they're taking a risk and the risk is that the condition can develop very rapidly, the appendix can burst."*⁸⁸

5.22 The surgeons, Mr Foster⁸⁹ and Mr Orr,⁹⁰ were of the view that it was premature to operate on the Thursday night given the available evidence⁹¹ and Mr Orr's opinion is noteworthy because it was commissioned by the Western Health and Social Care Trust ('WHSCT').⁹² However, both Mr Gilliland and Dr Scott-Jupp challenged this view⁹³ and in terms, described an appendectomy in such circumstances as routine practice. Dr Haynes, while questioning the wisdom of proceeding so quickly to surgery⁹⁴ did point out that *"it was not an unusual scenario."*⁹⁵

5.23 I have reservations about the decision to operate. However, given the conflicting expert evidence I do not formally criticise the decision. I am influenced in this regard by the generally accepted opinion that *"the conduct of the anaesthetic for Raychel's appendicectomy appears to have been completely satisfactory and the appendicectomy operation carried out with due care and attention."*⁹⁶ What went so catastrophically wrong in Raychel's case was not the surgery but the way she was cared for afterwards.

⁸⁷ Mr Orr T-21-03-13 p.40 line 19

⁸⁸ Dr Scott-Jupp T-20-03-13 p.18 line 11

⁸⁹ 317-007-001

⁹⁰ WS-320-1 p.18

⁹¹ Mr Foster and Mr Orr T-21-03-13 p.45 line 15

⁹² As successor to the Trust responsible for Altnagelvin in 2001

⁹³ 222-004-002 & Dr Scott-Jupp T-20-03-13 p.15 line 16

⁹⁴ 220-002-008 & Dr Haynes T-22-03-13 p.7 line 24

⁹⁵ 220-002-008

⁹⁶ 220-002-005: the view of Dr Haynes

- 5.24 While I understand why the Fergusons and some experts believe that Raychel should not have undergone surgery, my focus in this report is on hyponatraemia-related deaths and accordingly I will concentrate on the management of Raychel's fluids after the surgery and what led to the development of hyponatraemia.
- 5.25 There are however, two related issues about which I am critical. The first was a failure within Altnagelvin to follow relevant clinical recommendations and the second was Dr Makar's failure to make it clear to Mr and Mrs Ferguson that it was his intention to operate on Raychel that night.

NCEPOD Recommendations

- 5.26 In 1989 the Royal College of Surgeons published a 'Report of the National Confidential Enquiry into Perioperative Deaths' ('NCEPOD').⁹⁷ It specifically recommended that *"no trainee should undertake any anaesthetic or surgical operation on a child of any age without consultation with their consultant."*⁹⁸ This was to ensure that senior clinicians became involved with the care of children in surgery.
- 5.27 The data upon which NCEPOD made its recommendations derived from hospitals throughout the UK including Altnagelvin.⁹⁹ NCEPOD was in part funded by the Department in Northern Ireland.¹⁰⁰ Mr Orr described its report as a widely circulated *"wake-up call"* to surgeons and anaesthetists managing children.¹⁰¹ He said that he would be both surprised and worried if the 1989 Recommendations had not been adopted in Altnagelvin by 2001.¹⁰² Mr Foster agreed.¹⁰³ However, Mr Gilliland explained that *"they were not standard practice in Altnagelvin in 2001 and [suspected] that they had not been implemented elsewhere within N. Ireland at that time."*¹⁰⁴ I found this strange, indeed given that the 1999 Report on Paediatric Surgical

⁹⁷ 210-003-156

⁹⁸ 223-002-052

⁹⁹ 210-003-346

¹⁰⁰ Dr Carson T-30-08-13 p.28 line 5

¹⁰¹ Mr Orr T-21-03-13 p.46 line 23 & p.47 line 9

¹⁰² Mr Orr T-21-03-13 p.53 lines 14-18

¹⁰³ Mr Foster T-21-03-13 p.54 line 21

¹⁰⁴ WS-044-3 p.3

Services in Northern Ireland recommended adherence to this particular NCEPOD guideline¹⁰⁵ and Mr Panesar FRCS of Altnagelvin served on the working group responsible for that Report.¹⁰⁶

- 5.28 However, some support was offered Mr Gilliland by Dr Scott-Jupp who observed that NCEPOD reports carry more weight now than they did in 2001.¹⁰⁷ While I am pleased that is so, the suggestion that they did not carry significant weight in 2001 is alarming given that Altnagelvin was a teaching hospital and their purpose was to improve the quality of care.
- 5.29 As a direct result of Altnagelvin's failure to adopt the 1989 NCEPOD recommendations less than best practice was tolerated. Whilst Dr Makar should have known about the report and its recommendations, it appears that none of his employers in Northern Ireland from 1997 to 2001 brought it to his attention. This was a major failing in health service governance in Northern Ireland and not just Altnagelvin.
- 5.30 I cannot conceive of any reason for not adopting the NCEPOD guidance. Even were there compelling reason not to adopt an individual recommendation, such could not justify a rejection of the whole. Consultants and healthcare managers must ensure adherence to as many of such recommendations as possible because they are best practice standards. This was particularly important at Altnagelvin because, being so far from the specialist Children's Hospital in Belfast, it had to ensure that appropriate practices were in place to manage paediatric emergencies.
- 5.31 Had the NCEPOD recommendations been implemented, Mr Gilliland would have been consulted about the plan to operate. He had the right to know. His view was however, that in any event and even with hindsight, it was appropriate for the operation to proceed.¹⁰⁸ Notwithstanding, he should have been contacted at the time. The Chief Executive, Mrs Stella

¹⁰⁵ 224-004-100 & 121

¹⁰⁶ 306-079-037

¹⁰⁷ Dr Scott-Jupp T-20-03-13 p.17 line 3

¹⁰⁸ WS-044-2 p.8

Burnside,¹⁰⁹ acknowledged this shortcoming and said how “*sincerely sorry*” she was that the recommendations had not been followed.¹¹⁰

Consent

- 5.32 My second criticism relates to Dr Makar. The clear evidence of Mr and Mrs Ferguson is that they signed the consent form¹¹¹ on the understanding that Raychel would only go to surgery if her condition deteriorated. They did not therefore believe that there had been a decision to operate¹¹² and accordingly did not stay long with Raychel before going home.
- 5.33 Dr Makar’s evidence is that their understanding was mistaken because he had already decided to operate and that this should have been clear to them. He suggested that their only uncertainty might have been as to whether the operation would start that night.¹¹³
- 5.34 I am entirely satisfied from the evidence of Mr and Mrs Ferguson and more particularly from their behaviour that they did not believe that Raychel was going straight to theatre otherwise they would have stayed with her. I also think that it quite likely that Dr Makar did decide to operate from the outset, as he said he did. He gave the anaesthetist the impression that it was an urgent case¹¹⁴ and suggested that surgery should commence at the earliest opportunity after appropriate fasting.¹¹⁵ He communicated as much to the theatre nurse.¹¹⁶ I therefore conclude that when Dr Makar obtained the written consent he had not expressed himself as clearly as he should nor had he confirmed with the Fergusons their understanding.
- 5.35 It is accepted by the Fergusons that Dr Makar did discuss risk, both in relation to general anaesthesia and the removal of the appendix.¹¹⁷ However, there is contention about how those risks were explained.

¹⁰⁹ 328-001-002

¹¹⁰ Mrs Burnside T-17-09-13 p.58 line 22

¹¹¹ 020-008-015 & Mr and Mrs Ferguson T-26-03-13 p.17 line 15

¹¹² Mr Ferguson T-26-03-13 p.17 line 15

¹¹³ Dr Makar T-06-02-13 p.142 line 21 & 022-084-215

¹¹⁴ Dr Makar T-06-02-13 p.137 line 1

¹¹⁵ 020-009-017

¹¹⁶ Staff Nurse McGrath T-26-02-13 p.25 line 20

¹¹⁷ Mr Ferguson T-26-03-13 p.19 line 20

Difference of understanding and recollection is not unusual, which is why Dr Makar should have ensured:

- (i) that Mr and Mrs Ferguson had an absolutely clear understanding of what was to happen to Raychel before consenting, and
- (ii) that he documented their discussion about consent in the medical record.¹¹⁸

5.36 It is not at all clear however, that Mr and Mrs Ferguson would have actually withheld their consent had they understood Raychel was to undergo immediate surgery. They might, however, have refused consent had they understood the alternative of overnight observation but given that Dr Makar had already made the decision to operate that was not an option.

5.37 The consequence of this criticism is limited because what was to go wrong on Friday 8th June and Saturday 9th June did not follow from Dr Makar's inadequate communication with Mr and Mrs Ferguson.

Dr Makar and Dr Zawislak

5.38 Notwithstanding that Dr Makar was unaware at the time of the NCEPOD Recommendations, he subsequently claimed to have proceeded to surgery only after he had made two telephone calls to the on-call Surgical Registrar Dr Waldermar Zawislak¹¹⁹ in order to obtain permission.¹²⁰

5.39 Dr Makar said that he made this contact because *"it [was] the appendix and I gave him the criteria I used to diagnose appendix and I felt it needed to be done before midnight."*¹²¹ He said he also canvassed the alternative of delay until the morning¹²² but subsequently called Dr Zawislak to advise that he was proceeding to theatre that night.¹²³

¹¹⁸ WS-046-2 p.115 – In compliance with the Altnagelvin 'Policy on Consent to Examination or Treatment' (1996)

¹¹⁹ 312-003-002

¹²⁰ WS-022-2 p.19 & Dr Makar T-06-02-13 p.125 line 5

¹²¹ Dr Makar T-06-02-13 p.133 line 16

¹²² Dr Makar T-06-02-13 p.125 line 12

¹²³ Dr Makar T-06-02-13 p.125 line 23

- 5.40 However, Dr Zawislak disputed Dr Makar's evidence, maintaining:
- (i) He has no recollection whatever of being contacted by Dr Makar.¹²⁴
 - (ii) He was entirely unaware of Dr Makar's suggestion until 2013.¹²⁵
 - (iii) That had permission been given in the manner described it would have been recorded in the notes and it is not.¹²⁶
 - (iv) His role as registrar did not involve granting permission to operate in uncomplicated cases¹²⁷ and especially not to a surgeon as experienced as Dr Makar.
 - (v) Had Dr Makar sought his views, he would have examined Raychel himself and contacted the on-call consultant Mr Gilliland, which he did not.¹²⁸
 - (vi) Otherwise the only reason he could suggest why Dr Makar might have telephoned him, was to let him know he would be in theatre and accordingly otherwise unavailable.¹²⁹
- 5.41 Dr Zawislak accepted that he may have received a telephone call from Dr Makar.¹³⁰ I believe that this could have happened, but even if it did, I prefer Dr Zawislak's explanation that any such call would have been to alert him to what Dr Makar intended to do rather than seek his permission. It could not therefore satisfy the NCEPOD recommendation for pre-surgery consultation.

Pre-operative fluids

- 5.42 Having decided to operate, Dr Makar prescribed intravenous fluids to be administered pre-operatively. His initial prescription¹³¹ was for the isotonic

¹²⁴ Dr Zawislak T-05-02-13 p.24 line 25
¹²⁵ Dr Zawislak T-05-02-13 p.80 line 20
¹²⁶ Dr Zawislak T-05-02-13 p.78 line 25
¹²⁷ Dr Zawislak T-05-02-13 p.65 line 9
¹²⁸ Dr Zawislak T-05-02-13 p.73 line 12
¹²⁹ Dr Zawislak T-05-02-13 p.65 line 24
¹³⁰ Dr Zawislak T-05-02-13 p.24 line 25
¹³¹ WS-022-2, p.5

solution known as Hartmann's.¹³² However, he changed this prescription to Solution No.18 after a discussion with Staff Nurse Ann Noble¹³³ because she assured him that Solution No.18 was the accepted IV fluid for use on Ward 6.¹³⁴ The evidence confirmed that Solution No.18 was the IV fluid of choice on Ward 6 and had been for at least 25 years.¹³⁵

- 5.43 He amended his prescription, not only because of ward practice,¹³⁶ but also because he knew that the anaesthetic team would, in any event, make separate prescription for fluids intra-operatively and direct Raychel's fluids thereafter.
- 5.44 I do not criticise either Dr Makar or Staff Nurse Noble in this regard. His prescription for Solution No.18 was only to assume significance much later and after surgery, when not only the choice of fluid but also the rate as prescribed was to prove important.
- 5.45 Rates were calculated with reference to patient weight using a set formula.¹³⁷ Dr Makar prescribed 80mls per hour¹³⁸ which was more than the 65mls indicated by formula¹³⁹ and more than was necessary even allowing for a possible deficit.¹⁴⁰ The excess was, however, of little consequence at that time because Raychel was to receive only 60mls before the anaesthetic team assumed responsibility for her fluids and changed the prescription.¹⁴¹

Nursing care plan

- 5.46 Upon Raychel's admission onto Ward 6 Staff Nurse Daphne Patterson¹⁴² downloaded a computerised pro-forma episodic care plan ('ECP') for Raychel's abdominal pain.¹⁴³ By so doing Staff Nurse Patterson

¹³² 312-005-020

¹³³ 312-003-004

¹³⁴ WS-049-2 p.5 & Nurse Noble T-26-02-13 p.167 line 24

¹³⁵ WS-056-3 p.21

¹³⁶ Dr Makar T-06-02-13 p.183 line 18

¹³⁷ Dr Makar T-06-02-13 p.176 line 10

¹³⁸ 020-019-038

¹³⁹ 220-002-004, 223-002-013 & 224-004-017

¹⁴⁰ WS-035-4 p.2

¹⁴¹ 021-061-146

¹⁴² 312-003-004

¹⁴³ 020-027-056

automatically became Raychel's nominal 'named nurse.'¹⁴⁴ The ECP was designed to be regularly updated and adjusted to a patient's ongoing needs in order to guide nursing care. It was used to communicate accumulated patient information in print-out form at handover.¹⁴⁵ In connection with Raychel's IV fluid therapy, the plan directed that nurses should:

- (i) *"Observe/record urinary output"*¹⁴⁶
- (ii) *"Check the prescribed fluids, set rate & flow as prescribed, inspect infusion rate hourly, encourage oral fluids [and] record."*¹⁴⁷
- (iii) *"Encourage parental participation in care."*¹⁴⁸

The operation

5.47 Mr and Mrs Ferguson, having left the hospital believing that Raychel would not have surgery unless her condition deteriorated, then received a call that the operation was to proceed.¹⁴⁹ They managed to return before Raychel was taken to theatre. They did not enquire further because *"it was a hospital, we thought they know best, so we just went with it."*¹⁵⁰ Mrs Ferguson accompanied Raychel to the operating theatre with Staff Nurse Fiona Bryce.¹⁵¹ Raychel seemed *"a bit nervous."*¹⁵² She was anaesthetised by Dr Vijay Gund¹⁵³ who was assisted in part by Dr Claire Jamison.¹⁵⁴ Dr Makar performed the operation.

5.48 Dr Vijay Gund was an SHO in anaesthesia and had started at Altnagelvin just four weeks before.¹⁵⁵ Dr Jamison was his senior¹⁵⁶ and about to

¹⁴⁴ Staff Nurse Patterson T-04-03-13 p.30 line 25 & Mrs Margaret Doherty T-09-09-13 p.119 line 17

¹⁴⁵ Staff Nurse Bryce T-04-03-13 p.171 line 5

¹⁴⁶ 020-027-063

¹⁴⁷ 020-027-059

¹⁴⁸ 020-027-056

¹⁴⁹ Staff Nurse Patterson T-04-03-13 p.40 line 9

¹⁵⁰ Mrs Ferguson T-26-03-13 p.26 line 16

¹⁵¹ 312-003-004 & WS-054-1 p.3

¹⁵² Staff Nurse Bryce T-04-03-13 p.152 line 19

¹⁵³ 312-003-002

¹⁵⁴ 312-003-002 & Dr Jamison T-07-02-13 p.79 line 17

¹⁵⁵ WS-023-2 p.2-3

¹⁵⁶ Dr Gund T-05-02-13 p.144 line 15

become a registrar. She attended because she was free to assist and not because her presence was necessary.¹⁵⁷

5.49 The 1989 NCEPOD Recommendations applied to anaesthetists as well as surgeons. However, neither Dr Gund nor Dr Jamison was aware of the recommendations¹⁵⁸ but neither thought the case so complex as to warrant discussion with a consultant before proceeding to surgery.¹⁵⁹ As with Dr Makar, my criticism relates not to the actions of these two trainee doctors but rather the failure within Altnagelvin to implement the 1989 recommendations.¹⁶⁰

5.50 The operation went smoothly, starting at 23:40 and finishing about 00:20. It was unusual but not improper for paediatric surgery to start so late.¹⁶¹

5.51 Raychel received IV Hartmann's solution intra-operatively. There is no record of precisely how much she received which is an obvious failing in the anaesthetic documentation but one not seemingly that unusual for the time.¹⁶² In addition, Dr Gund noted "*Hartmanns 1 L*"¹⁶³ which was a potentially misleading entry because it is most improbable that Raychel received a full litre of Hartmann's during surgery. It was thus that after Raychel's death, Dr Jamison was asked to and did make "*Retrospective note dated 13/6/01. Patient only received 200mls of noted fluids below when in theatre. Litre bag removed prior to leaving theatre.*"¹⁶⁴ This was signed by her and countersigned by Dr Geoff Nesbitt,¹⁶⁵ Consultant Anaesthetist and Clinical Director in Anaesthesia and Critical Care. Whilst this unusual entry aroused considerable suspicion, it must be recognised that it very obviously identifies itself as a retrospective note and is clearly

¹⁵⁷ WS-024-2 p.5

¹⁵⁸ Dr Gund T-05-02-13 p.147 line 11 & Dr Jamison T-07-02-13 p.61 line 5

¹⁵⁹ Dr Gund T-05-02-13 p.145 line 8 & p.146 line 7 & Dr Jamison T-07-02-13 p.60 line 2 & p.65 line 24

¹⁶⁰ Dr Jamison T-07-02-13 p.64 line 8

¹⁶¹ Staff Nurse McGrath T-26-02-13 p.29 line 16

¹⁶² Staff Nurse McGrath T-26-02-13 p.41 line 9

¹⁶³ 020-009-016

¹⁶⁴ 020-009-016

¹⁶⁵ 312-003-003

dated. It is also now accepted as being most probably correct by Dr Gund.¹⁶⁶

- 5.52 Even though Dr Gund should have kept a better record of the fluids infused, it was the view of Dr Haynes that *“the anaesthetic administered by Dr Gund (including the fluid administered during the operation) was entirely appropriate and cannot be faulted.”*¹⁶⁷
- 5.53 Raychel took a little longer than expected to regain consciousness after surgery¹⁶⁸ but was ready to be returned to the ward by about 01:30. Whilst not particularly unusual¹⁶⁹ this caused her parents concern because they had understood from Staff Nurse Bryce that the surgery would take about an hour.¹⁷⁰ Staff Nurse Bryce thought it most unlikely that she would have given any such indication.¹⁷¹ I do not believe it necessary to examine this misunderstanding. I accept that Staff Nurse Bryce was trying to be helpful to Mr and Mrs Ferguson.
- 5.54 Post-operatively Dr Makar recorded that the appendix was *“mildly congested”* with an *“intraluminal faecolith.”* Accordingly, whilst the appendix was not inflamed, it was not normal.
- 5.55 Dr Makar did not speak to the Fergusons after the operation. He conceded that, had circumstances permitted, it would have been good practice but because he was the sole SHO in a busy hospital, he may not have been able to manage it.¹⁷²

Post-operative fluids

- 5.56 After the operation and while Raychel was still in the recovery room Dr Gund gave his prescription for Raychel's initial post-operative fluids.¹⁷³ He prescribed Hartmann's Solution to continue at the same rate as pre-

¹⁶⁶ Dr Gund T-05-02-13 p.188 line 18

¹⁶⁷ 220-002-014

¹⁶⁸ 020-009-017

¹⁶⁹ Staff Nurse McGrath T-26-02-13 p.50 line 2 & Dr Haynes T-22-03-13 p.65 line 17

¹⁷⁰ 095-001-002 & Mrs Ferguson T-26-03-13 p.29 line 12

¹⁷¹ Staff Nurse Bryce T-04-03-13 p.155 line 1

¹⁷² Dr Makar 06-02-13 p.212 line 11

¹⁷³ 020-021-040

operatively, namely the over-prescribed 80mls per hour. He was then told by Dr Jamison and Staff Nurse Marian McGrath,¹⁷⁴ that post-operative fluids were not prescribed by the anaesthetist but were managed by the doctors on the ward.¹⁷⁵ Dr Gund, being new to the hospital, acquiesced and deleted his prescription for Hartmann's. I am certain that he did so because he was new and assumed such a practice could only be at the direction of a consultant and that a ward doctor would take active responsibility for the post-operative fluids. He now accepts that he ought to have made his views about post-operative fluids better known,¹⁷⁶ not least because he could not have known how long it would be before a ward doctor would see Raychel nor in any event how any such doctor could have appreciated her individual fluid requirements.¹⁷⁷

- 5.57 Staff Nurse McGrath remembered the discussion with Drs Gund and Jamison.¹⁷⁸ She recalled pointing out that normally the pre-operative fluid regime was resumed after surgery, and that while Dr Gund indicated that he preferred Hartmann's, Dr Jamison told him that Hartmann's was not used on Ward 6. Staff Nurse McGrath had no doubt that Raychel would receive Solution No. 18 on the ward¹⁷⁹ and that is what happened.
- 5.58 Dr Jamison does not recall exactly what she said to Dr Gund but accepted that she might have told him that prescriptions for Hartmann's were regularly cancelled on Ward 6 and the fluids thereafter managed by the doctors on the ward.¹⁸⁰ It is not therefore surprising that Dr Gund should have felt there was little point in prescribing and left the fluids for ward management.
- 5.59 Staff Nurse McGrath said that anaesthetists who were new to the hospital were often surprised by this convention but nothing was done.¹⁸¹ Dr Jamison, herself, had no concerns "*because No.18 was commonly used at*

¹⁷⁴ 312-003-004

¹⁷⁵ WS-023-1 p.2 & WS-023-2 p.5

¹⁷⁶ Dr Gund T-05-02-13 p.211 line 6

¹⁷⁷ Dr Gund T-05-02-13 p.209 line 23

¹⁷⁸ Staff Nurse McGrath T-26-02-13 p.52 line 15

¹⁷⁹ Staff Nurse McGrath T-26-02-13 p.54 line 21

¹⁸⁰ Dr Jamison T-07-02-13 p.115 line 4

¹⁸¹ Staff Nurse McGrath T-26-02-13 p.66 line 18 *et seq*

that time in the ward which was a paediatric ward with experience in giving fluids to children.”¹⁸² However, she would not have prescribed it herself¹⁸³ and nor does it seem would any other anaesthetist.¹⁸⁴

- 5.60 When asked why nurses challenged doctor’s decisions on fluids, Staff Nurse Noble explained that *“previous to that if a child had been on other fluids, we would have been asked by our nursing seniors why that particular fluid had been used and why we hadn’t highlighted it to the doctors that Solution No.18 was always used on the paediatric ward.”¹⁸⁵*
- 5.61 Whilst it was not inappropriate for nurses to advise doctors about ward practice,¹⁸⁶ the choice of fluids remained the responsibility of the doctor. It was disturbingly clear from the evidence that Ward 6 nurses had very little understanding of the importance of the type and rate of post-operative IV fluids¹⁸⁷ let alone the Syndrome of Inappropriate Antidiuretic Hormone secretion (‘SIADH’). They were ignorant as to the effect of administering Solution No.18 intravenously.¹⁸⁸ Such lack of understanding should have been obvious. The anaesthetists should never have relinquished responsibility for directing the immediate post-operative fluids for their patients.
- 5.62 Of equal concern is that not only was the fluid as prescribed pre-operatively followed post-operatively, but so too was the rate.¹⁸⁹ That created a problem for two reasons. First because Raychel’s pre-operative hourly rate was already excessive at 80mls and secondly, because it was generally held to be good practice to reduce fluids post-operatively by 20% to 30% to avoid the risks of SIADH.¹⁹⁰

¹⁸² Dr Jamison T-07-02-13 p.133 line 13

¹⁸³ Dr Jamison T-07-02-13 p.117 line 17

¹⁸⁴ Staff Nurse McGrath T-26-02-13 p.10 line 23

¹⁸⁵ Staff Nurse Noble T-26-02-13 p.168 line 17

¹⁸⁶ Miss Ramsay T-19-03-13 p.70 line 14

¹⁸⁷ Staff Nurse Noble T-26-02-13 p.204 line 2 & Sister Millar T-28-02-13 p.51 line 11

¹⁸⁸ Staff Nurse Noble T-26-02-13 p.135 line 9 & Sister Millar T-28-02-13 p.21 line 15

Staff Nurse Bryce T-04-03-13 p.128 line 23 & Staff Nurse McAuley T-05-03-13 p.50 line 24 & Staff Nurse Gilchrist T-11-03-13 p.47 line 9

¹⁸⁹ Staff Nurse Noble T-26-02-13 p.198 line 15 & p.174 line 15

¹⁹⁰ 223-002-013 & WS-320-1 p.7 & 220-002-196 & Dr Haynes T-22-03-13 p.47 line 2 & p.51 line 13

- 5.63 Upon Raychel's return to Ward 6 the anaesthetic team ceded control of Raychel's fluids.¹⁹¹ There was then no prescription or clinical protocol to guide the post-operative management of Raychel's fluid therapy.¹⁹² Without any reference to her post-operative needs, she was re-subjected to her pre-operative fluids.
- 5.64 Dr Haynes considered this "*completely unsatisfactory*"¹⁹³ and Mr Foster described it "*a rather bizarre protocol... it doesn't make anaesthetic or surgical sense.*"¹⁹⁴ Mr Gilliland said that he was "*not aware of [this practice] and it would appear none of my surgical colleagues were aware of it, nor indeed Dr Nesbitt,*"¹⁹⁵ Dr Raymond Fulton¹⁹⁶ was "*surprised*"¹⁹⁷ and Miss Irene Duddy,¹⁹⁸ Director of Nursing¹⁹⁹ said that "*unless someone had brought that to my attention I would not have been aware of it.*"²⁰⁰
- 5.65 The evidence revealed that there was no clear delegation of the responsibilities for administering IV fluids. Fluid therapy was undertaken by the surgical, paediatric and anaesthetic specialties in conjunction with the nursing staff without agreed responsibilities or appropriate supervision.²⁰¹ Dr McCord was left to describe his "*perception... that one specialty was doing one thing, another specialty was doing another, and likewise they thought that we were doing one thing*"²⁰² – "*the fact is that we thought it worked, but it evidently didn't.*"²⁰³
- 5.66 I am critical of these Altnagelvin practices. The expert evidence was that the universal practice elsewhere at that time was for the anaesthetist to prescribe the initial post-operative fluids, which would continue until review, most probably at ward round. That was because it was only the

¹⁹¹ Staff Nurse McGrath T-26-02-13 p.13 line 1

¹⁹² Dr Jamison T-07-02-13 p.108 line 9 & Staff Nurse Noble T-26-02-13 p.177 line 11

¹⁹³ Dr Haynes T-22-03-13 p.33 line 24

¹⁹⁴ Mr Foster T-21-03-13 p.80 line 15

¹⁹⁵ Mr Gilliland T-28-08-13 p.32 line 2

¹⁹⁶ 328-001-001

¹⁹⁷ Dr Fulton T-04-09-13 p.63 line 3

¹⁹⁸ 328-001-003

¹⁹⁹ WS-323-1 p.30

²⁰⁰ Miss Duddy T-29-08-13 p.78 line 9

²⁰¹ 220-002-015

²⁰² Dr McCord T-13-03-13 p.21 line 1

²⁰³ Dr McCord T-13-03-13 p.21 line 11

anaesthetist who could know what the fluid requirements were. That that was not the practice in Altnagelvin was wholly unacceptable. Nobody was able to explain the origin of this practice,²⁰⁴ although it is clear that it had been followed for many years.²⁰⁵ I suspect that it had no reasoned basis because it makes no sense. The fact that this practice continued unquestioned and for so long reveals an absence of system and control and raises the fundamental question as to whether any consultant - surgeon, anaesthetist or paediatrician – actually understood what was going on. It would indeed have been a miracle if Raychel had been the only child placed at risk.

- 5.67 However, neither the type nor the rate of fluid given at that time would have mattered very much had it not been for a catalogue of further failure on the Friday.

Raychel's return to Ward 6 and the ward round

- 5.68 Raychel was sleepy when returned to the ward, opening her eyes only briefly for her parents.²⁰⁶ They stayed with her until about 06:00 when Mrs Ferguson left.²⁰⁷
- 5.69 Mr Ferguson recalled Raychel waking at about 08:00 in relatively good form. Staff Nurse Patterson "*helped Raychel sit up in bed and... told Raychel and her dad, [that] she was doing very well.*"²⁰⁸ Mr Ferguson went to buy her a colouring book. Thereafter, and presumably while he was away, Raychel vomited shortly after 08:00.²⁰⁹
- 5.70 After that she was well enough to get out of bed and sit colouring. The intravenous drip attached to her arm was infusing Solution No.18 at 80ml/h.
- 5.71 The evidence indicates:

²⁰⁴ Mr Gilliland T-14-03-13 p.178 line 17

²⁰⁵ Staff Nurse McGrath T-26-02-13 p.65 line 19 & Sister Millar T-28-02-13 p.53 line 3

²⁰⁶ Mr and Mrs Ferguson T-26-03-13 p.31 line 7

²⁰⁷ Mrs Ferguson T-26-03-13 p.32 line 6

²⁰⁸ Staff Nurse Patterson T-04-03-13 p.76 line 15

²⁰⁹ Staff Nurse McAuley T-05-03-13 p.81 line 10

- (i) Raychel was the only child on the ward to have undergone surgery overnight.
- (ii) At approximately 08:00 – 08:30 Staff Nurse Noble made a hand-over of Ward 6 to Sister Elizabeth Millar.²¹⁰
- (iii) Sister Millar deployed Staff Nurse Michaela McAuley²¹¹ as Raychel's principal carer.
- (iv) Between 08:30 and 10:00 a surgical SHO Dr M H Zafar,²¹² conducted the morning ward round with Sister Millar. Usually the ward round would have been taken by a registrar²¹³ but on this occasion, because Raychel was the only surgical patient on Ward 6²¹⁴ Dr Zafar was assigned by the registrar to conduct the round.²¹⁵ Dr Zafar was on a 6 month placement at Altnagelvin and was dealing with paediatric patients for the first time.²¹⁶
- (v) There is uncertainty as to whether Dr Zafar was aware of the 08:00 vomit²¹⁷ but in any event and given Raychel's clear signs of recovery, Dr Zafar directed a routine and gradual reduction of intravenous fluids with staged encouragement to take fluids orally. Normally after an uncomplicated appendectomy, the reduction of IV fluids would start in the morning and continue into late afternoon or early evening with the expectation that a patient such as Raychel would *"increase her drinking during the day; walk a short distance, and possibly eat something light later in the day."*²¹⁸ In the usual way, Raychel might then have been ready to go home on the Saturday or at the latest on Sunday. Indeed 80% of such children might have expected to be discharged within 48 hours.²¹⁹

²¹⁰ 312-003-004 & Sister Millar T-28-02-13 p.62 line 24

²¹¹ 312-003-005

²¹² 312-003-002

²¹³ Sister Millar T-28-02-13 p.109 line 7

²¹⁴ Dr Zafar T-01-03-13 p.184 line 24

²¹⁵ Dr Zafar T-01-03-13 p.183 line 2

²¹⁶ Dr Zafar T-01-03-13 p.108 line 15

²¹⁷ WS-025-1 p.3 & Sister Millar T-28-02-13 p.92 line 11

²¹⁸ 224-004-011

²¹⁹ Miss Ramsay T-19-03-13 p.19 line 14

- (vi) Sister Millar and her nurses were very familiar with such a plan for recovery.²²⁰
- (vii) Dr Zafar saw Raychel for no more than 5-10 minutes.²²¹ He did not concern himself with the rate or type of her IV fluids because she seemed well²²² and in any event he proposed to reduce her fluids and end her therapy.²²³ Accordingly, he made no new prescription for her fluids and they continued as before.
- (viii) Whilst it was comparatively unusual for Raychel to have been seen on a morning ward round by a SHO rather than a registrar,²²⁴ it did not then seem of particular significance given that there was no cause for concern on Friday morning and complications in such circumstances were rare.
- (ix) When Dr Zafar and Sister Millar were taking their leave of Raychel, Dr Makar arrived to enquire after her.²²⁵ This was both routine, lest there be complication and a courtesy. He spoke briefly to Mr Ferguson.
- (x) Dr Makar confirmed that "*Raychel was sitting up... she was pain free at that time.*"²²⁶
- (xi) Neither Sister Millar nor the doctors had any concerns at that time. In fact, Mr Ferguson telephoned his wife at about 09:30 and told her not to hurry to the hospital because Raychel was up and about.²²⁷

Underlying concerns

5.72 Underlying these apparently un-troubling circumstances were matters of real concern.

²²⁰ Sister Millar T-28-02-13 p.64 line 2
²²¹ Dr Zafar T-01-03-13 p.185 line 11
²²² Dr Zafar T-01-03-13 p.209 line 3
²²³ Dr Zafar T-12-03-13 p.206 line 14
²²⁴ Staff Nurse Noble T-26-02-13 p.189 line 2
²²⁵ Sister Millar T-28-02-13 p.106 line 21
²²⁶ Dr Makar T-13-03-13 p.174 line 20
²²⁷ Mr Ferguson T-26-03-13 p.35 line 12

- 5.73 The ward round was not taken by a consultant or a registrar but by a junior doctor with limited experience of children. Mr Foster found this concerning and *“entirely unsatisfactory and unsafe and evidence of disorganisation of the surgical services...”*²²⁸ Dr Haynes was of the view that the formal ward round should *“ideally [be] supervised directly by the responsible consultant.”*²²⁹
- 5.74 In addition, there was no formalised handover between the surgeon who performed the surgery and the surgeon who conducted the ward round. There was no continuity. They appear to have passed each other without conferring as to Raychel's fluid management. Had they done so, Dr Makar might have reconsidered the fluid therapy and the catastrophic outcome which was to ensue might have been avoided. Whilst neither Dr Makar nor Dr Zafar was aware of her fluid regime on the Friday morning, they each could have discovered it. That neither did was unacceptable.
- 5.75 This is to be understood in a context where the surgical patients on Ward 6 were cared for by the surgical team and not the paediatricians who were actually based on Ward 6.²³⁰ In practice, this meant that the surgical doctors might not always be available to their patients because they were elsewhere in the hospital.²³¹ Whilst such an arrangement was not unusual in district general hospitals it did pose risk and had given rise to nursing complaint.²³² This was an organisational shortcoming, which could keep surgical doctors from their patients and inhibit nurses from calling upon the medical doctors available on Ward 6.
- 5.76 Moreover, it was the most junior hospital surgical doctors who were relied upon for initial response to any summons in respect of the surgical patients on Ward 6. Mr Foster believed that *“junior house officers who had no experience of paediatrics should not have been first on call for surgical children.”*²³³ This was a further potential risk factor, not least because it was

²²⁸ 223-003-011

²²⁹ 220-002-008

²³⁰ Dr Johnston T-07-03-13 p.172 line 7

²³¹ Dr Zafar T-01-03-13 p.160 line 23 & Dr Scott-Jupp T-20-03-13 p.45 line 9

²³² Sister Millar T-01-03-13 p.60 line 19 & Dr McCord T-13-03-13 p.22 line 17

²³³ 223-003-013

these inexperienced doctors who had first oversight of the childrens' post-surgical fluid management.

- 5.77 Furthermore, significant differences had developed in the care given to the paediatric and surgical patients on Ward 6. Medical patients receiving IV infusion under the care of paediatricians were subject to routine blood tests every 24 hours.²³⁴ However, surgical patients were not. Accordingly, a child vomiting with gastroenteritis would have daily blood tests as a matter of course whereas a child who vomited after surgery would not. This was an alarming anomaly and it is not at all clear how or why this had arisen. Dr Haynes suggested that it "*occurred because of a lack of consultant ownership of the issue.*"²³⁵ Such a lack of organisational control of Ward 6 would have consequences for Raychel.
- 5.78 These were important matters of concern and each reveals not only underlying systemic weakness but also the lack of consultant leadership in the management of surgical patients on Ward 6.

Friday 8th June: nursing issues

Fluid balance chart

- 5.79 The importance of fluid balance should have been known to all nurses in 2001 having been taught for many years.²³⁶ It was the clear responsibility of nursing staff to enter relevant fluid information into the fluid balance chart. In 2001, this permitted the following to be recorded:
- (i) Type of fluid intake.
 - (ii) Amount of hourly fluid intake.
 - (iii) Type of output (i.e. vomit, urine etc.)
 - (iv) Amount of hourly fluid output.

²³⁴ Staff Nurse Noble T-27-02-13 p.129 line 4

²³⁵ 220-002-006

²³⁶ Professor Hanratty T-20-03-13 p.197 line 2

- 5.80 Fluid balance charts record information to guide fluid management. Accordingly and as Professor Hanratty observed “*measuring and recording intake and output [is] a very significant part of the continuing care of the patient.*”²³⁷ Had Raychel’s fluid balance chart been accurately compiled, it should have guided the nurses and doctors to an appreciation of what was happening to Raychel’s fluid balance in real time.

Recording fluid output

- 5.81 Some fluid information will always be imprecise. Unless the quantity of urine passed is actually measured, the entry can only really be “*PU*” (passed urine). The fluid output of a 9-year old girl toileted by her mother will go unrecorded unless the parent is advised to provide particulars. Mr and Mrs Ferguson were not so advised²³⁸ and, regrettably, even when such matters were brought to Sister Millar’s attention she neither noted nor investigated.²³⁹ Disturbingly she conceded that it was not always the practice on Ward 6 to record such an event.²⁴⁰ This was despite the requirement of the fluid balance chart and the specific direction of the ECP to “*observe/record urinary output.*”²⁴¹
- 5.82 Accordingly, neither the frequency nor quantity of urinary output was properly recorded. There is a single entry of “*PU*” timed at 10.00²⁴² but the Fergusons are sure that she also passed urine around noon and perhaps again in the early afternoon.²⁴³
- 5.83 Similarly, the quantification of vomit in the record is uncertain.²⁴⁴ A shorthand was devised on Ward 6 to record vomit quantity using the ‘+’ sign. Unfortunately this had not always been explained²⁴⁵ allowing nurses to interpret “*vomit ++*” as indicating anything from small to large.²⁴⁶

²³⁷ Professor Hanratty T-20-03-13 p.163 line 3

²³⁸ Staff Nurse Bryce T-05-03-13 p.39 line 12 & Mrs Ferguson T-26-03-13 p.78 line 23 & p.46 line 25

²³⁹ Sister Millar T-28-02-13 p.18 line 7 & p.115 line 3

²⁴⁰ Sister Millar T-28-02-13 p.80 line 4

²⁴¹ 020-027-063

²⁴² 020-018-037

²⁴³ Mrs Ferguson T-26-03-13 p.78 line 19

²⁴⁴ Staff Nurse Bryce T-04-03-13 p.169 line 24

²⁴⁵ Staff Nurse Patterson T-04-03-13 p.78 line 14

²⁴⁶ Sister Millar T-28-02-13 p.124 line 10 & Staff Nurse Bryce T-04-03-13 p.169 line 10

5.84 Imprecision as to quantity of output was not the only problem. Additionally and critically individual incidents of vomiting were not accurately recorded.

5.85 The fluid balance chart shows²⁴⁷:

- (i) “*Vomit*” around 08:00
- (ii) “*Large vomit*” around 10:00
- (iii) “*Vomited ++*” around 13:00
- (iv) “*Vomited ++*” around 15:00
- (v) “*Vomiting coffee grounds ++*” around 21:00
- (vi) “*Vomited small amount x 3*” around 22:00
- (vii) “*Small coffee ground vomit*” around 23:00.

5.86 I have no doubt that this record is incomplete. Evidence was given that Raychel vomited at about 18:00 but this was not recorded. Staff Nurse Sandra Gilchrist²⁴⁸ failed to note a vomit at about 20:30²⁴⁹ and additional vomit seen on pyjama top and pillowcase at 00:35 also went unrecorded.²⁵⁰ In addition, there were occasions when Raychel vomited into kidney dishes which were disposed of undocumented by the nursing staff.²⁵¹ Even allowing for some confusion as to timings, I am certain that the incidence of Raychel’s vomiting significantly exceeded that recorded in the fluid balance chart. Whilst I acknowledge the practical difficulties in accurately monitoring fluid balance, I can only agree with Staff Nurse McAuley that her “*documentation was poor.*”²⁵²

²⁴⁷ 020-018-037

²⁴⁸ 312-003-005

²⁴⁹ Staff Nurse Gilchrist T-11-03-13 p.66 line 22

²⁵⁰ Staff Nurse Gilchrist T-11-03-13 p.112 line 17

²⁵¹ WS-021-1 p.6-7 & Mrs Ferguson T-26-03-13 p.54 line 20

²⁵² Staff Nurse McAuley T-05-03-13 p.173 line 7

Recording fluid intake

- 5.87 The nursing staff did not seemingly attach particular importance to the fluid intake record either. Staff Nurse McAuley acknowledged that she had been aware that Raychel was “*taking sips*” and yet did not record them.²⁵³ Mr Ferguson recalled allowing Raychel some soft drink²⁵⁴ but this was not noted because he had not been told to tell the nurses.²⁵⁵ These particular omissions from the fluid chart are of little consequence given the minimal amounts involved but do highlight a nursing failure to advise the Fergusons as to the importance of fluid information.
- 5.88 Overall, there was a lack of due attention to fluid documentation. In consequence, the fluid balance chart could not have been relied upon to indicate Raychel’s fluid balance. This was a major deficiency in record-keeping and a significant failing in nursing for which Sister Millar was primarily responsible.

Repeated vomiting

- 5.89 Raychel’s fluid balance chart for 9th June records nine vomits in the 15 hours between 08:00 and 23:00. In addition there were, at the very least, three additional vomits. Whilst it was probably reasonable for the nurses to consider Raychel’s initial vomiting a normal post-operative response,²⁵⁶ this became an increasingly unlikely explanation as the day progressed. However, the nurses did not reconsider their initial perception and in the view of Mr Foster became “*locked into a mindset of what they expect to happen.*”²⁵⁷
- 5.90 As Mr Ferguson recalled “*every time Raychel vomited in the bowl, I would actually take it out and show it to them. And as far as I can remember... the only words... back, ‘its only natural. After an operation, she will be sick.*”²⁵⁸

²⁵³ Staff Nurse McAuley T-05-03-13 p.60 line 7

²⁵⁴ Mr Ferguson T-26-03-13 p.34 line 18

²⁵⁵ Mrs Ferguson T-26-03-13 p.53 line 4

²⁵⁶ Dr Scott-Jupp T-20-03-13 p.66 line 7

²⁵⁷ 223-002-017

²⁵⁸ Mr Ferguson T-26-03-13 p.54 line 3

- 5.91 Mr Orr said that *“alarm bells should have been ringing by lunchtime, if not after lunch, when there was the third vomit.”*²⁵⁹ Medical staff should then have been contacted. A doctor would then, according to Mr Orr, have taken *“blood for urea and electrolytes and... actively considered replacing the vomitus... with a solution such as normal saline and then altering the maintenance fluids as well.”*²⁶⁰ That would have saved Raychel.²⁶¹
- 5.92 The vomiting continued all day and the coffee ground vomiting which started at about 21:00²⁶² (or even earlier if Mr Ferguson is correct²⁶³) is a particularly disturbing feature. Mr Foster believed it an *“indication of significant or severe and prolonged vomiting and retching... it should have attracted serious attention as it is due to trauma to the gastric mucosa causing bleeding.”*²⁶⁴ Mr Orr considered it an alert *“to the fact that something unusual and abnormal is happening.”*²⁶⁵ Professor Mary Hanratty said that any coffee ground vomiting in a child should immediately prompt a nurse to contact an SHO.²⁶⁶
- 5.93 It did not however alarm the nurses on Ward 6. Staff Nurse Gilchrist, who noted this development *“thought maybe she had a wee tear when she was vomiting. That’s why it was all blood in it...”*²⁶⁷ She waited for another hour before she contacted a doctor. She simply did not think.
- 5.94 I must record that I reject emphatically the evidence given by Sister Millar²⁶⁸ and Staff Nurses Gilchrist,²⁶⁹ Noble²⁷⁰ and Roulston²⁷¹ that they considered that Raychel was suffering from conventional post-operative vomiting. I do not believe that they actually thought about it and that was the problem. Post-operative nausea and vomiting (‘PONV’) could not have explained

²⁵⁹ Mr Orr T-21-03-13 p.147 line 13

²⁶⁰ Mr Orr T-21-03-13 p.149 line 6

²⁶¹ Dr Scott-Jupp T-20-03-13 p.116 line 7

²⁶² 020-018-037

²⁶³ 095-005-018

²⁶⁴ 223-002-016

²⁶⁵ Mr Orr T-21-03-13 p.193 line 6

²⁶⁶ Professor Hanratty T-20-03-13 p.202 line 1

²⁶⁷ Staff Nurse Gilchrist T-11-03-13 p.75 line 1

²⁶⁸ WS-056-1 p.3

²⁶⁹ WS-053-2 p.6 & 098-293-771

²⁷⁰ WS-049-1 p.5

²⁷¹ 312-003-005 & WS-52-1 p.3

what was happening. Even if Raychel had suffered some post-operative vomiting, the overall frequency, duration and type of vomiting was of a very different order.

Failure to appreciate deterioration

5.95 It is a fundamental nursing task to monitor progress, identify deterioration and where necessary contact the doctor.²⁷² That requires ‘active’ observation.

5.96 Over the course of Friday, Raychel who had started her day contentedly colouring-in, became very ill. She stopped passing urine, became increasingly lethargic, vomited repeatedly, failed to respond to anti-emetics and vomited coffee grounds. She was very obviously not recovering as expected from her uncomplicated routine surgery.

5.97 Sister Millar has since acknowledged “*Raychel was... deteriorating earlier than we as nurses recognised.*”²⁷³ However, I heard evidence that Raychel’s condition was recognised, not just by family²⁷⁴ and friends,²⁷⁵ but also by strangers.²⁷⁶ I am struck by the contrast between the descriptions given by these witnesses and those proffered by the nurses.

5.98 I do not accept the nursing evidence that Raychel was well and presenting no real cause for concern²⁷⁷ and in this regard, I note the evidence of those nurses who sought retrospectively to diminish the importance of the vomiting.²⁷⁸ I believe that Staff Nurse McAuley must be wrong when she said that shortly before 20:00 she saw Raychel “*up and about, walking in the corridor*” and pointing things out to her brothers.²⁷⁹ On the balance of the evidence, I do not believe her to be correct.

²⁷² 224-002-021

²⁷³ Sister Millar T-01-03-13 p.83 line 5

²⁷⁴ 095-005-017 & 095-006-020 - Mrs Harrison

²⁷⁵ Mrs McCullagh (095-009-029)

²⁷⁶ 095-008-025 - Mr Stephen Duffy & 095-007-022 - Mrs Elaine Duffy

²⁷⁷ Staff Nurse McAuley T-05-03-13 p.189 line 14 & WS-056-1 p.4

²⁷⁸ Staff Nurse McAuley T-05-03-13 p.96 line 14 & Staff Nurse Gilchrist T-11-03-13 p.112 line 12 & p.87 line 23

²⁷⁹ WS-051-1 p.3 & Staff Nurse McAuley T-05-03-13 p.188 line 10

5.99 I also found disquieting the nurses' unquestioning belief that Raychel could come to no harm while on Solution No.18.²⁸⁰ That induced complacency.²⁸¹ I accept that because Solution No.18 was widely used, it was generally safe. I do not criticise the nurses for failing to appreciate that hyponatraemia was developing or even that her fluids were not replacing the sodium lost through vomiting. However, the nurses were obligated to monitor and respond. I find serious failure in each and every nurse caring for Raychel to:

- (i) Consider whether the care given was having the desired effect.
- (ii) Appreciate that her condition was deteriorating.
- (iii) Recognise that she was very ill.
- (iv) Understand that she needed the urgent attention of a capable doctor properly informed by nursing observation.

Accordingly, I criticise the nursing staff for failing to recognise and react to Raychel's illness.

Medical care: 8th June, post-ward round

5.100 In addition and over the course of Friday 8th June three junior doctors were involved in Raychel's care.

Dr Mary Butler

5.101 Dr Mary Butler²⁸² was a second year SHO with 4 months experience in paediatrics.²⁸³ She attended the daily ward round and covered the neonatal, special baby and day care units. She understood the management of fluids and electrolytes in children.²⁸⁴

²⁸⁰ Staff Nurse Roulston T-06-03-13 p.139 line 14 & Staff Nurse Noble T-26-02-13 p.205 line 10

²⁸¹ Staff Nurse Noble T-27-02-13 p.92 line 2 & p.133 line 9

²⁸² 312-003-002

²⁸³ Dr Butler T-11-03-13 p.3 line 5

²⁸⁴ Dr Butler T-11-03-13 p.9 line 21

5.102 Dr Butler's involvement with Raychel was brief. At around noon, she was on Ward 6 when Raychel's litre bag of Solution No.18 had almost emptied.²⁸⁵ She was asked by Staff Nurse McAuley to prescribe a replacement. She did so without investigating and probably without even seeing Raychel.²⁸⁶ She believes that she would have made some basic enquiries²⁸⁷ and if so, would probably have been told that according to the chart, Raychel had vomited twice.²⁸⁸ Such, she said, would not have caused her concern at that time.²⁸⁹ Had she been concerned, she would have contacted a surgical SHO or spoken to her paediatric registrar, which she did not.²⁹⁰

5.103 In the event Dr Butler assumed that the rate prescribed for the fluids had been properly calculated and accordingly issued a repeat prescription for Solution No.18.²⁹¹ She now recognises that she did so at a rate which was excessive and regrets that she did not double-check.²⁹² While Dr Butler could have been more pro-active, I believe it would be unduly severe to criticise her in the context of her response to a limited request on behalf of a patient who was not her own.

Dr Joseph Devlin

5.104 Dr Joseph Devlin²⁹³ was a Pre-Registration House Officer. He was in the first year of his first post-graduate post. In his first six months, he had undertaken very little paediatric work and in his second six months he could not remember any. He could hardly have had less paediatric experience.²⁹⁴ Mr Orr was of the firm opinion that such doctors required close supervision and support.²⁹⁵

²⁸⁵ Staff Nurse McAuley T-05-03-13 p.117 line 1

²⁸⁶ Staff Nurse McAuley T-05-03-13 p.120 line 6 & Dr Butler T-11-03-13 p.24 line 25

²⁸⁷ Dr Butler T-11-03-13 p.17 line 23

²⁸⁸ Sister Millar T-28-02-13 p.132 line 4

²⁸⁹ Dr Butler T-11-03-13 p.22 line 3

²⁹⁰ Dr Butler T-11-03-13 p.26 line 21

²⁹¹ 020-019-038 & Dr Butler T-11-03-13 p.30 line 4

²⁹² Dr Butler T-11-03-13 p.23 line 20

²⁹³ 312-003-002

²⁹⁴ Dr Devlin T-06-03-13 p.17 line 5

²⁹⁵ Mr Orr T-21-03-13 p.160 line 15

- 5.105 His involvement with Raychel appears to have been entirely unintended. Staff Nurse McAuley recalls that at about 15:00 she was alerted to Raychel's vomiting and, although not unduly concerned, thought it necessary to inform Sister Millar and contact a surgical JHO for an anti-emetic. Her evidence was that she tried repeatedly over the next 2-2½ hours to get a junior surgical doctor to come to Ward 6 but without success. Eventually Sister Millar saw Dr Devlin and directed that he be asked to "*give Raychel an anti-emetic.*"²⁹⁶
- 5.106 The Fergusons are sceptical that Staff Nurse McAuley made the efforts she described. They suspect that a doctor was only called after the vomit recorded at 17:00.²⁹⁷ I understand their scepticism; indeed how could a childrens' ward function, if a concerned and experienced nurse could not get hold of a junior doctor in over 2 hours?²⁹⁸ However extraordinary, and even in the absence of corroborative documentation²⁹⁹ I am inclined to believe Staff Nurse McAuley's evidence, which of itself must raise concerns about the provision of care to surgical patients on Ward 6. That was not the fault of Staff Nurse McAuley.
- 5.107 When Dr Devlin attended Raychel at 18:00, he was alone.³⁰⁰ That may have been unavoidable but it carried risk. A nurse should have attended with him because Raychel was not recovering as had been expected and he should have been told.³⁰¹ However, he was not and this very inexperienced doctor was left without any suggestion that there was much to worry about, apart from some vomiting³⁰² and on that basis, he gave the anti-emetic as indicated.³⁰³
- 5.108 As Dr Devlin explained "*I had absolute confidence... [in] my nursing colleagues ability to relay on any concerns to the oncoming doctor and I suppose at that time in my career I felt that the safety net would lie with the*

²⁹⁶ Sister Millar T-28-02-13 p.140 line 10 & Staff Nurse McAuley T-05-03-13 p.186 line 5

²⁹⁷ Mrs Ferguson T-26-03-13 p.71 line 7

²⁹⁸ Staff Nurse Noble T-27-02-13 p.64 line 14

²⁹⁹ Sister Millar T-28-02-13 p.145 line 5

³⁰⁰ Staff Nurse McAuley T-05-03-13 p.149 line 2

³⁰¹ Staff Nurse Roulston T-06-03-13 p.146 line 17 & Mr Foster T-21-03-13 p.164 line 5

³⁰² Dr Devlin T-06-03-13 p.64 line 5

³⁰³ 020-017-034

*senior staff... that systems... would be in place to prevent the tragic outcome...*³⁰⁴

- 5.109 Dr Devlin was the first doctor to see Raychel in almost 9 hours. He was inexperienced and had neither clinical guidelines, attendant nurses or the supervision of more senior clinicians to help him. That was unsafe. Dr Devlin recalled that Raychel vomited when he was with her³⁰⁵ but he did not understand what this might mean. He accepts that this should have been recorded but he thought this would be done by a nurse. It was not. With experience and hindsight, Dr Devlin accepts that he should have directed electrolyte tests. He also accepts that he should have recorded his intervention.
- 5.110 I have considered whether Dr Devlin should be criticised for his relative inaction. The expert evidence and his own evidence taken with that of other witnesses, including the nurses, persuades me that this would be unfair. Whilst he had an opportunity to help Raychel and did not, fault does not attach to the inexperienced Dr Devlin. He did what he was asked to do and moved on.
- 5.111 Dr Devlin believes that had he been called back to see Raychel four hours later, he might then have been more alert to her condition³⁰⁶ and would have been able to reassess. In terms, he was suggesting that the inexperienced doctor who is called to see a child once is at a major disadvantage. I think he is correct.
- 5.112 It is disturbing to record that after Dr Makar saw Raychel briefly on Friday morning, the only doctors to see her were JHOs and none of them saw her more than once. Raychel's deterioration was not observed over time by any one doctor.
- 5.113 It is the role of the nurse to monitor patient progress and communicate relevant observation to the junior doctor. Responsibility for management

³⁰⁴ Dr Devlin T-06-03-13 p.75 line 21

³⁰⁵ Dr Devlin T-06-03-13 p.61 line 4

³⁰⁶ Dr Devlin T-06-03-13 p.73 line 21

remains with the doctor who acts under the direction and supervision of more senior colleagues and the consultant. Unfortunately, Ward 6 was over reliant upon the services of very junior and inexperienced doctors and in Raychel's case, neither the nurses nor the senior surgical staff were supporting them. This was a deficiency in communication and system³⁰⁷ and carried risk.

Dr Michael Curran

- 5.114 Dr Michael Curran³⁰⁸ was a medical JHO³⁰⁹ with just 10 months experience and very little exposure to paediatric work.³¹⁰ Due to staff pressure, he was unexpectedly doing a locum in surgery on the Friday evening of 8th June and in contact with children for the first time in months.
- 5.115 Like Dr Devlin, he considered that his role as a JHO was task orientated. He performed specific duties delegated at ward round, such as carrying out blood tests, organising x-rays and preparing discharge letters.³¹¹ These tasks were performed at the behest of senior colleagues and the more experienced nurses.
- 5.116 Dr Curran had limited understanding of the risks posed by prolonged vomiting. He believed that the risk posed by vomiting and/or diarrhoea was dehydration and that the appropriate response was fluid replacement.³¹² He did not understand that prolonged vomiting depleted sodium levels³¹³ and was unsure of the causes of hyponatraemia.³¹⁴
- 5.117 Staff Nurse Gilchrist 'bleeped' Dr Curran at about 22:00³¹⁵ because of Raychel's continued vomiting and he attended. He could not recall any

³⁰⁷ Mr Orr T-21-03-13 p.135 line 15 & WS-320-1 p.15

³⁰⁸ 312-003-002

³⁰⁹ Mr Gilliland T-14-03-13 p.124 line 18

³¹⁰ Dr Curran T-07-03-13 p.5 line 20

³¹¹ Dr Curran T-07-03-13 p.36 line 15

³¹² Dr Curran T-07-03-13 p.33 line 24. n.b. The Ward 6 copy of Forfar & Arneil 'Textbook of Paediatrics' 1992 (321-004g-004) advised that in response to vomiting "*Electrolyte losses should be corrected.*"

³¹³ Dr Curran T-07-03-13 p.33 line 11

³¹⁴ Dr Curran T-07-03-13 p.29 line 10

³¹⁵ WS-053-1 p.3

particular conversation but believes he must have been told where to find Raychel and the medication he was to prescribe and administer.³¹⁶

5.118 Staff Nurse Gilchrist assumed that Dr Curran would assess Raychel.³¹⁷ However, she made no particular effort to speak to him³¹⁸ assuming “*he would have spoken to somebody.*”³¹⁹ In the circumstances, she should have prompted Dr Curran to assess Raychel, or at the very least shown him the fluid balance chart and informed him that the vomiting had not been controlled by the earlier anti-emetic. Staff Nurse Noble also had the opportunity to speak to Dr Curran.³²⁰

5.119 Mr Foster considered that “*Dr Curran and the nursing staff should have really been alarmed at this point.*”³²¹ Tragically they were not. Dr Curran’s attendance was to be the last opportunity for a doctor to respond to Raychel’s continuing deterioration. At that stage electrolyte testing would almost certainly have identified abnormally low sodium levels³²² and at 22:00 it may still have been possible to save her.³²³

5.120 Dr Curran is clear that he was not asked to assess Raychel’s condition and that no concern was expressed to him about coffee ground vomiting³²⁴ or deterioration.³²⁵ He said that had he been told of the coffee ground vomit or had he seen it recorded, he would have contacted an SHO immediately.³²⁶ He maintained that he was only asked to administer an anti-emetic which was a routine request.³²⁷ In that context, he believes that he would have performed only a very limited assessment. He would not have checked the fluid balance chart³²⁸ because he already knew she was vomiting. Accordingly, he prescribed and gave the anti-emetic, made an

³¹⁶ Staff Nurse Noble T-27-02-13 p.96 line 4 & Dr Curran T-07-03-13 p.55 line 6

³¹⁷ Staff Nurse Gilchrist T-11-03-13 p.93 line 1

³¹⁸ Staff Nurse Gilchrist T-11-03-13 p.95 line 15

³¹⁹ Staff Nurse Gilchrist T-11-03-13 p.110 line 23

³²⁰ Staff Nurse Noble T-27-02-13 p.132 line 14

³²¹ Mr Foster T-21-03-13 p.189 line 2

³²² Dr Scott-Jupp T-20-03-13 p.92 line 2 & Dr Haynes T-22-03-13 p.112 line 15

³²³ Dr Scott-Jupp T-20-03-13 p.116 line 7

³²⁴ Dr Curran T-07-03-13 p.76 line 22

³²⁵ Dr Curran T-07-03-13 p.63 line 3

³²⁶ Dr Curran T-07-03-13 p.76 line 13

³²⁷ Dr Curran T-07-03-13 p.56 line 20

³²⁸ Dr Curran T-07-03-13 p.75 line 11

entry in Raychel's drug record and left. He suggested that had the nurses been genuinely worried about Raychel, they would most certainly have informed him of their concerns and not just left out the anti-emetic for him, and in any event in such a situation he believed that they would have called someone rather more senior and experienced than he.³²⁹

5.121 Dr Curran is open to the criticism that, when asked to give an anti-emetic he neither read the notes in respect of the vomiting nor asked any questions. That was inadequate because the longer she vomited the more urgent did the need become to check her electrolytes. He did not know how long she had been vomiting³³⁰ or what had already been done about it.³³¹ The coffee ground vomit, which he accepts would have caused him concern, was recorded at 21:00 but he did not read the record. He did not know that her vomit was “++”³³² or that she had headaches. He conceded that would have been relevant.³³³ His obligation at 22:00 was greater than that imposed on Dr Devlin at 18:00 because Raychel's vomiting had continued and her failure to recover should have been even more obvious. Notwithstanding mitigating factors, including his own inexperience and the lack of nursing support, I criticise Dr Curran for not taking the care to recognise that the circumstances demanded more than just an anti-emetic. At the very least, the situation demanded the attendance of a more senior doctor.

Nursing communication

5.122 In considering how and why nursing staff failed to appreciate what was happening to Raychel, I consider the following deficiencies in communication to be relevant:

- (i) There was a failure to liaise properly with Mr and Mrs Ferguson whether to involve them in fluid management or to take advantage

³²⁹ Dr Curran T-07-03-13 p.92 line 3

³³⁰ Dr Curran T-07-03-13 p.65 line 5

³³¹ Dr Curran T-07-03-13 p.71 line 14

³³² 020-018-037

³³³ Dr Curran T-07-03-13 p.149 line 14

of their observations and opinions. Their input was not recorded, nor does it seem to have been taken seriously.

- (ii) Raychel's 'named nurse' was such a nurse "*in name only*"³³⁴ and did not communicate with the family. Whilst I can understand that the provision at all times of an informed named nurse³³⁵ is almost impossible, no real attempt was made to provide the channel of communication intended and Raychel was, in terms, denied her right to a named nurse under the Patient's Charter.³³⁶
- (iii) There was nursing failure to speak to Drs Devlin and Curran to provide or discuss appropriate information.
- (iv) Nurses failed to communicate adequately with each other especially at handover. When Staff Nurse Bryce came on duty at 19:45, she was not informed that Raychel was still vomiting.³³⁷ Such a failure to communicate verbally was important because nurses did not conventionally consult patient records at handover.³³⁸ It should be noted that in November 2000 an assessment of the quality of nursing on Ward 6 specifically identified as a "*negative*" the fact that "*the retiring and oncoming nurses in charge do not make walking rounds of the patients together.*"³³⁹ This was not seemingly addressed.
- (v) Even had nurses sought to rely upon the fluid balance chart, it would have been found wanting. Regrettably, inaccuracy in this important regard was an established feature on Ward 6. An audit in November 2000³⁴⁰ identified patients on Ward 6 with "*intake/output charts [which] had information missing (7 were incomplete out of 14).*"³⁴¹ This deficiency should have been attended to and before Raychel's

³³⁴ Mrs Margaret Doherty T-09-09-13 p.119 line 17
³³⁵ Mrs Margaret Doherty T-09-09-13 p.114 line 10
³³⁶ 306-085-010 & 317-042-001 & 321-068-005
³³⁷ WS-054-2 p.6
³³⁸ Staff Nurse McAuley T-05-03-13 p.68 line 6
³³⁹ WS-323-1 p.39
³⁴⁰ WS-323-1 p.42
³⁴¹ WS-323-1 p.45

admission.³⁴² It was not.³⁴³ Mrs Margaret Doherty,³⁴⁴ the Clinical Services Manager ('CSM') has since acknowledged that in this regard "*not sufficient was done and I should have stepped in.*"³⁴⁵

- (vi) Furthermore, the nursing notes could not have been relied upon. They failed to record the attendance of the three junior doctors on 8th June. Mr Foster concluded that "*more detailed records throughout the 8th would have assisted the nursing staff to detect an ongoing deterioration throughout the afternoon and evening of the 8th.*"³⁴⁶
- (vii) The ECP which was intended to communicate current care requirements was not updated. It neither referred to the continued vomiting³⁴⁷ nor indicated any need to monitor the effectiveness of anti-emetics. It did not therefore communicate the evolving situation as it was meant to. Staff Nurse Noble conceded that Raychel's care plan should have been individualised.³⁴⁸
- (viii) In addition, entries in the care plan were inaccurate. The ECP, when updated at about 17:00 by Staff Nurse McAuley for her 20:00 handover³⁴⁹ recorded "*observations appear satisfactory. Continues on PR flagyl. Vomit x 3 this am, but tolerating small amounts of water this evening.*"³⁵⁰ She later conceded that this was "*not right*"³⁵¹ because it ignored Raychel's afternoon vomiting and hinted at recovery on the basis of a largely non-existent fluid intake. On the basis of this information, Staff Nurse Gilchrist said she "*would have believed*" that Raychel's vomiting had been brought back under control.³⁵² It did not even suggest, let alone inform, the incoming night staff as to the problems that were developing.

³⁴² WS-323-1 p.42

³⁴³ Sister Millar T-28-08-13 p.120 line 14

³⁴⁴ 328-001-002

³⁴⁵ Mrs Margaret Doherty T-09-09-13 p.103 line 11

³⁴⁶ 223-003-002

³⁴⁷ 224-002-019

³⁴⁸ Staff Nurse Noble T-26-02-13 p.155 line 18

³⁴⁹ Staff Nurse Noble T-27-02-13 p.35 line 4

³⁵⁰ 020-027-064

³⁵¹ Staff Nurse McAuley T-05-03-13 p.172 line 21

³⁵² Staff Nurse Gilchrist T-11-03-13 p.63 line 8

- (ix) Nursing care plans had previously been the subject of a benchmarking exercise against other hospitals in 2000 which had identified *“problems... as a result of not individualising care plans”*³⁵³ and recommended that nurses be made *“aware of the need to update and change care plans when there is a change in treatment.”*³⁵⁴ Regrettably, this was not heeded any more than the internal 1999/2000 Nursing Record Audit which found a mere 44% compliance with individualisation of care plans.³⁵⁵

5.123 That no effective steps were taken to rectify such known deficiencies was a further and significant failing for which the Director of Nursing, Miss Duddy, must bear ultimate responsibility.

Events after 21:00 on 8th June

5.124 The development of coffee ground vomiting, which was noted in the fluid balance chart from 21:00, did not prompt consideration of the possible implications.

5.125 Raychel's vomiting intensified between 21:00 and 23:00 hours. Mr Ferguson was by then increasingly alarmed by Raychel's condition and *“told nurse Noble that Raychel was complaining of a sore head and was bright red in the face. Nurse Noble said she would come and give Raychel a paracetamol and did so a short time later...”*³⁵⁶ – *“She appeared to me to be laid back and not concerned at all about my daughter.”*³⁵⁷ Nurse Noble accepted that *“he told me the facts, yes... I just felt Raychel had had a particularly poor post-operative first day and that I would try and relieve the symptoms...”*³⁵⁸

5.126 At 21:15 Staff Nurse Gilchrist recorded of Raychel *“colour flushed → pale, vomiting ++ c/o headache”*³⁵⁹ and at about 21:30 hours, Mr Ferguson

³⁵³ WS-323-1 p.49

³⁵⁴ WS-323-1 p.50

³⁵⁵ 321-068-006

³⁵⁶ 095-005-019

³⁵⁷ WS-021-1 p.9

³⁵⁸ Staff Nurse Noble T-27-02-13 p.74 line 17

³⁵⁹ 020-015-029

telephoned his wife to voice his frustration and concern – *“she’s starting to throw up blood on the bed and they’re not listening to me at all.”*³⁶⁰ Nurse Noble recalled that *“Mr Ferguson did not express to me at that time how much he was concerned.”*³⁶¹ Staff Nurse Gilchrist could not *“agree that we weren’t taking her condition seriously... After her periods of vomiting I told him... that I was going to contact the surgical doctor to come and assess her. So, I was taking his concerns on board.”*³⁶² It was Dr Curran who attended but Mr Ferguson’s concerns were not communicated to him.

5.127 Mrs Ferguson returned at 22:00 to find Raychel very restless and with something trickling from the side of her mouth. The Fergusons now believe that she was beyond saving at that stage. In fact, they think she may have been beyond saving from about 17:00. It is not clear to me that their belief is medically correct³⁶³ but the experts agree that Raychel was, by that stage, increasingly threatened by an excessive infusion of hypotonic fluid in the context of SIADH and prolonged vomiting.

5.128 By that stage of the evening Raychel’s vomiting was clearly both severe and prolonged³⁶⁴ and yet, despite further vomiting at 23:00, and 00:35 on Saturday morning, the nurses still did not call a doctor. Dr Scott-Jupp was of the view that they should have.³⁶⁵ Staff Nurse Noble has accepted that with *“hindsight... yes, we probably should have called a doctor back to re-evaluate the effectiveness of the anti-emetic, but because the amounts were less... we thought things were settling down.”*³⁶⁶

5.129 Mr and Mrs Ferguson, who had spent all Friday at Raychel’s side, whether in turns or together, recall that they eventually left the hospital at about 00:40.³⁶⁷ They did so because they had been reassured by nursing staff that Raychel had settled and would sleep for the night.³⁶⁸ I am certain that

³⁶⁰ 095-002-007 & Mr Ferguson T-26-03-13 p.103 line 18

³⁶¹ Staff Nurse Noble T-27-02-13 p.74 line 14

³⁶² Staff Nurse Gilchrist T-11-03-13 p.82 line 2

³⁶³ Dr Haynes T-22-03-13 p.139 line 20

³⁶⁴ Mr Foster and Mr Orr T-21-03-13 p.197 line 21

³⁶⁵ Dr Scott-Jupp T-20-03-13 p.107 line 5

³⁶⁶ Staff Nurse Noble T-27-02-13 p.104 line 7 & Staff Nurse Gilchrist T-11-03-13 p.114 line 22

³⁶⁷ Mrs Ferguson T-26-03-13 p.116 line 2

³⁶⁸ Mr Ferguson T-26-03-13 p.115 line 3

the Fergusons would have stayed had they had even the slightest suspicion that Raychel was in danger. That they were allowed to leave was another failing in nursing.

5.130 Soon thereafter, Raychel became “*restless again*” and was possibly “*behaving funny, ? confused*.”³⁶⁹ This was reported to Staff Nurse Noble³⁷⁰ by Staff Nurse Bryce and although there is disagreement about the detail of this development, it nonetheless should have been taken seriously. In the circumstances, it should have prompted an immediate call for medical assistance. Instead, Staff Nurses Gilchrist and Bryce were asked to look after Raychel while Staff Nurse Noble took an extended tea break.³⁷¹ Raychel then vomited again. Staff Nurse Bryce described her as being “*a little unsettled*”³⁷² and took no action.

5.131 By then, over 24 hours had passed since surgery and Raychel was still vomiting. She had headaches, was flushed and unsettled. She had probably not passed urine for 12 hours and was still receiving Solution No.18 at 80mls per hour. As time progressed and as Raychel’s condition deteriorated, the deficiencies in nursing become ever more obvious and serious. Mrs Ferguson felt “*Raychel was dying slowly in front of us and not one person... was even concerned*.”³⁷³

Final collapse: 03:00 9th June

5.132 Professor Arieff had observed in 1992, that “*headache, nausea, emesis, weakness and lethargy are consistent symptoms of hyponatraemia in children. If the condition is allowed to go untreated there can follow an explosive onset of respiratory arrest, coma and transtentorial cerebral herniation*.”³⁷⁴

³⁶⁹ 316-085-013

³⁷⁰ 316-085-013

³⁷¹ Staff Nurse Noble T-27-08-13 p.169 line 3

³⁷² WS-054-1 p.3

³⁷³ Mrs Ferguson T-26-03-13 p.185 line 10

³⁷⁴ 220-002-204

- 5.133 At 03:00, Auxiliary Nurse Elizabeth Lynch³⁷⁵ alerted Staff Nurse Noble to the fact that Raychel was fitting.³⁷⁶ She was found in a tonic state lying in a left lateral position with her hands and feet tightly clenched. She had been incontinent of urine. Staff Nurse Noble immediately sought the help of the nearest doctor³⁷⁷ who was Dr Jeremy Johnston,³⁷⁸ a paediatric SHO on Ward 6.³⁷⁹ It was the first time he had been called upon to care for a paediatric surgical patient.³⁸⁰
- 5.134 Dr Johnston's intervention has been praised.³⁸¹ At that time, he had almost completed his three-year training as an SHO. Notwithstanding that he had only specialised in paediatrics since February 2001, he was very much more experienced than Drs Devlin or Curran.
- 5.135 Dr Johnston administered diazepam rectally and then intravenously.³⁸² This quieted the seizure but Raychel was unresponsive and oxygen was given. Her vital signs were assessed and in the absence of raised temperature, Dr Johnston became concerned that there might be a critical underlying cause.³⁸³ He astutely identified electrolyte abnormality as the principal differential diagnosis³⁸⁴ and directed a Urea & Electrolyte ('U&E') test. Approximately 30 hours had passed since Raychel's blood had last been tested.
- 5.136 Dr Johnston needed senior surgical assistance as a matter of urgency and asked Dr Curran to get it.³⁸⁵ Dr Curran contacted Dr Zafar,³⁸⁶ who said he would "*come as soon as possible*."³⁸⁷ Dr Johnston then awaited the senior surgical support, but it did not materialise. Dr Curran did not go beyond Dr Zafar to contact a registrar or consultant and just hoped that Dr Zafar would

³⁷⁵ 312-003-005

³⁷⁶ Staff Nurse Noble T-27-02-13 p.144 line 12

³⁷⁷ Staff Nurse Noble T-27-02-13 p.146 line 1 & WS-029-1 p.2

³⁷⁸ 312-003-003

³⁷⁹ 312-003-003

³⁸⁰ Dr Johnston T-07-03-13 p.177 line 4

³⁸¹ 223-002-022

³⁸² 012-013-014

³⁸³ Dr Johnston T-07-03-13 p.183 line 2

³⁸⁴ 020-007-013

³⁸⁵ WS-029-2 p.9

³⁸⁶ Dr Curran T-07-03-13 p.111 line 5

³⁸⁷ Dr Zafar T-12-03-13 p.166 line 12 & Dr Curran T-07-03-13 p.112 line 2

arrive.³⁸⁸ Dr Zafar contacted nobody and Dr Johnston was left to cope with this major clinical event by himself. In the meantime he concentrated on *“getting the ECG, chasing up blood results”*³⁸⁹ and maintaining her airway.

5.137 Staff Nurse Noble telephoned Mr and Mrs Ferguson at about 03:45.³⁹⁰ There is disagreement as to whether Staff Nurse Noble attempted contact earlier.³⁹¹ I am inclined to the Fergusons’ account and it is very clear that Mr Ferguson got to the hospital as soon as he could.

5.138 At about 04:00 hours, Dr Johnston was obliged to go and get a senior doctor himself. He found Dr Bernie Trainor,³⁹² the SHO in paediatrics, in the neonatal unit.³⁹³ Dr Johnston explained the situation and they swapped roles so that Dr Trainor could go to Raychel. It was then that the results of the blood test came back recording a sodium level of 119mmol/L.³⁹⁴ This was lower than Dr Trainor had ever seen.³⁹⁵ She asked for a repeat test because the result was so abnormal she felt it could be wrong.³⁹⁶ It only confirmed Raychel’s acute hyponatraemia.³⁹⁷

5.139 Raychel’s oxygen saturation levels were dipping. She was transferred to the treatment room. Dr Trainor telephoned the on-call consultant paediatrician, Dr Brian McCord³⁹⁸ who came as quickly as he could.³⁹⁹ Raychel suffered a respiratory arrest and Dr Aparna Date,⁴⁰⁰ anaesthetist, attended.⁴⁰¹ Raychel was intubated⁴⁰² and her fluids adjusted to restrict the rate and increase the sodium.⁴⁰³ Mr and Mrs Ferguson were with her.⁴⁰⁴

³⁸⁸ Dr Curran T-07-03-13 p.123 line 16
³⁸⁹ Dr Johnston T-07-03-13 p.209 line 24
³⁹⁰ 095-005-019
³⁹¹ Staff Nurse Noble T-27-02-13 p.152 line 11 & Mr Ferguson T-26-03-13 p.122 line 9
³⁹² 312-003-003
³⁹³ Dr Trainor T-12-03-13 p.41 line 2
³⁹⁴ 020-022-042
³⁹⁵ Dr Trainor T-12-03-13 p.56 line 10
³⁹⁶ Dr Trainor T-12-03-13 p.48 line 3
³⁹⁷ 020-015-024
³⁹⁸ 312-003-003 & 012-036-170
³⁹⁹ Dr McCord T-13-03-13 p.48 line 7
⁴⁰⁰ 312-003-003
⁴⁰¹ WS-031-1 p.2
⁴⁰² 020-023-048
⁴⁰³ 020-015-025
⁴⁰⁴ Dr Johnston T-07-03-13 p.220 line 15

CT scans

- 5.140 When Dr McCord examined Raychel at 05:00 on 9th June, her pupils were fixed and dilated.⁴⁰⁵ Her condition was almost certainly irretrievable.⁴⁰⁶ He noted “*marked electrolyte disturbance with profound hyponatraemia*”⁴⁰⁷ and arranged a CT scan.
- 5.141 Despite the extreme seriousness of the event, the on-call surgical consultant did not attend. Mr Foster was in no doubt that he should have⁴⁰⁸ and in no doubt that he should have been summonsed. Mr Orr agreed.⁴⁰⁹ However, Dr Naresh Kumar Bhalla,⁴¹⁰ the Surgical Registrar who was there, explained that he did not call his consultant surgeon because he thought it a metabolic or septic issue and not a surgical one.⁴¹¹ Notwithstanding that there was no specific call for surgical expertise at that time, I find the absence of the on-call surgical consultant very surprising. It was not only a remarkable detachment by the surgical team from their patient, but also from Mr and Mrs Ferguson who were seemingly ignored by them.
- 5.142 Indeed, Mr Foster thought “*the absence of a senior member of the surgical team must have been noticed by everybody*”⁴¹² and believed that a senior surgical doctor “*should have spoken to the family and appraised them of the fears and anxieties of the whole of the team.*”⁴¹³ However, it was left to Staff Nurse Noble and Dr Trainor to speak to Mr and Mrs Ferguson and advise them that Raychel was being stabilised, that further tests were being undertaken and that it was the anaesthetic team that was looking after her.⁴¹⁴

⁴⁰⁵ 012-036-171

⁴⁰⁶ 220-003-018 & Dr Trainor T-12-03-13 p.85 line 18 & Mr Foster T-21-03-13 p.229 line 7

⁴⁰⁷ 012-036-171

⁴⁰⁸ 223-002-026

⁴⁰⁹ WS-320-1 p.15

⁴¹⁰ 312-003-003

⁴¹¹ WS-034-2 p.5

⁴¹² Mr Foster T-21-03-13 p.215 line 3

⁴¹³ Mr Foster T-21-03-13 p.214 line 15

⁴¹⁴ Dr Trainor T-12-03-13 p.91 line 18

- 5.143 The CT scan was thought to suggest sub-arachnoid haemorrhage⁴¹⁵ with evidence of cerebral oedema. Dr Nesbitt, Consultant Anaesthetist arrived and discussed the scan via image linking with neurosurgeons at the Royal Victoria Hospital ('RVH'). They suggested that there was "*possibly a subdural empyema (an area of infection)*"⁴¹⁶ for which surgical intervention might have been possible.
- 5.144 Mrs Ferguson recalled Dr McCord telling them that Raychel's brain was clear and that if Raychel's sodium could be controlled "*that would be better.*"⁴¹⁷ It is not at all clear that Mrs Ferguson knew what sodium was⁴¹⁸ but nonetheless she drew reassurance from this and reacted to "*thank God, Raychel's brain is clear – she will be alright.*"⁴¹⁹ She now considers that it was wrong of Dr McCord to give her hope at that time. Dr McCord said he would not have intended to deliberately mislead⁴²⁰ but nor would he have wished to "*remove all hope.*"⁴²¹ He accepted that he might have allowed an undue expectation⁴²² for which he offered his apology.⁴²³
- 5.145 Mrs Ferguson remembered "*a doctor in ICU with a beard said that she was very seriously ill and that there was a lot of pressure inside her head and that they would operate to reduce the pressure.*"⁴²⁴ Raychel's aunt, Ms Kay Doherty⁴²⁵ "*felt this was the first bit of information that we were given as to Raychel's condition and as to what was going to happen to her...*"⁴²⁶ However, Mrs Ferguson also recalled "*a wee nurse coming up. When she put her hand on my knee and she said that she was so sorry and I remember saying to my sister, 'she's going on as if Raychel's dead.'*"⁴²⁷ No

⁴¹⁵ 020-015-026 & 021-065-155

⁴¹⁶ WS-035-1 p.2

⁴¹⁷ 012-028-146

⁴¹⁸ Ms Kay Doherty T-18-09-13 p.155 line 2

⁴¹⁹ WS-020-1 p.19

⁴²⁰ Dr McCord T-13-03-13 p.109 line 1

⁴²¹ Dr McCord T-13-03-13 p.121 line 15

⁴²² Dr McCord T-13-03-13 p.109 line 16

⁴²³ Dr McCord T-13-03-13 p.147 line 15

⁴²⁴ 012-028-146

⁴²⁵ 328-001-001

⁴²⁶ WS-326-1p.7

⁴²⁷ Mrs Ferguson T-26-03-13 p.136 line 5

one took responsibility for communication with the family at that dreadful time and Mrs Ferguson could only sense mixed messages.⁴²⁸

- 5.146 A second and enhanced CT scan was sought to exclude the possibility of sub-dural empyema and haemorrhage. It was performed at 08:51⁴²⁹ by Dr Cyril Morrison,⁴³⁰ Consultant Radiologist, who reported that “a *sub-dural empyema* [is] *excluded*.”⁴³¹ He discussed it with Dr Stephen McKinstry⁴³² of the RVH who considered that “*the changes were in keeping with generalised brain oedema (swelling due to increased fluid content) and that there was no evidence of haemorrhage*.”⁴³³
- 5.147 Mr Bhalla remembered “*I was there... we got the report that the second CT scan confirmed that it was cerebral oedema and there was no haematoma there*”⁴³⁴ - “*it was quite clear that she had got a very bad prognosis*.” It was understood that she would not survive.⁴³⁵
- 5.148 Dr Nesbitt did not, however, have quite the same understanding. Whilst he knew that empyema was excluded, he remained under the impression that a diagnosis of subarachnoid haemorrhage was possible⁴³⁶ and surgical intervention, an option.

Transfer to the RBHSC

- 5.149 The decision was taken at 09:10 to remove Raychel to Paediatric Intensive Care Unit (‘PICU’) in Belfast.⁴³⁷ Such a transfer was indicated whether subarachnoid haemorrhage was excluded or not because as Dr Bhalla recalled “*all of them said she needs intensive care, conservative management*”⁴³⁸ and the only ICU for children was in Belfast.⁴³⁹

⁴²⁸ Mrs Ferguson T-26-03-13 p.136 line 11

⁴²⁹ 020-026-055

⁴³⁰ 312-003-004

⁴³¹ 020-026-055

⁴³² 312-003-005

⁴³³ WS-037-1 p.2

⁴³⁴ Mr Bhalla T-14-03-13 p.45 line 20

⁴³⁵ Mr Bhalla T-14-03-13 p.46 line 19

⁴³⁶ Dr Nesbitt T-03-09-13 p.20 line 9 & p.25 line 20

⁴³⁷ 020-024-052

⁴³⁸ Mr Bhalla T-14-03-13 p.48 line 13

⁴³⁹ WS-035-2 p.21 & Dr Trainor T-12-03-13 p.94 line 11

- 5.150 However, Mrs Ferguson believed that a “cover-up began on the morning Raychel was being transferred to the Royal. We now know the situation was hopeless... Altnagelvin just sent her to Belfast so that it could be recorded that Raychel died there; there was no hope for her.”⁴⁴⁰
- 5.151 However, Mr Orr doubted that the consultants at Altnagelvin “could be absolute in their opinion until they knew what the assessment was of Raychel in the Childrens’ Hospital”⁴⁴¹ and as Dr Nesbitt recalled, she was sent to Belfast because “neurosurgeons had asked that we transfer her to their care.”⁴⁴² In such a situation, I can understand that no one would want to abandon hope.
- 5.152 Transfer documentation was initially prepared on behalf of Dr Nesbitt citing “? Meningitis ? Encephalitis” as the suggested diagnoses, and “? sub-achnoid hae”⁴⁴³ as the finding on investigation. Dr Trainor then drafted the referral letter for the Royal Belfast Hospital for Sick Children (‘RBHSC’) summarising known and relevant information. She detailed the treatment with Solution No.18, the IV infusion rate, Raychel’s repeated vomiting and the sudden drop in her sodium levels to 118mmol/L.
- 5.153 Raychel arrived at the RBHSC at 12:30. She was formally admitted under the care of Dr Peter Crean,⁴⁴⁴ Consultant in Paediatric Anaesthesia and Intensive Care. She had no purposeful movement.⁴⁴⁵ Her serum sodium level was then 130mmol/L⁴⁴⁶ and her diagnosis “? Hyponatraemia.” Dr Dara O’Donoghue⁴⁴⁷ assessed her as having “coned with probably irreversible brain stem compromise.”⁴⁴⁸ She was admitted for “neurological assessment and further care.”⁴⁴⁹

⁴⁴⁰ Mrs Ferguson T- 26-03-13 p.176-7

⁴⁴¹ Mr Orr T-21-03-13 p.228 line 23

⁴⁴² WS-035-2 p.21. See also Dr Crean T-11-09-13 p.32 line 11

⁴⁴³ 012-002-073

⁴⁴⁴ 312-003-005

⁴⁴⁵ 012-032-159

⁴⁴⁶ 012-032-159

⁴⁴⁷ 312-003-005

⁴⁴⁸ 063-009-023

⁴⁴⁹ 063-015-035

- 5.154 Distressingly, Mr and Mrs Ferguson travelled to Belfast believing that Raychel was to have surgery. They recall that when they arrived at the RBHSC Dr Nesbitt told them that Raychel had *“a good journey up and that there was plenty of movement, that’s a good sign.”*⁴⁵⁰ Kay Doherty also remembered him saying *“she’s in the best place.”*⁴⁵¹
- 5.155 The Ferguson family feel that they were misled and given further false hope by the transfer to Belfast and the encouraging reference to movement. Dr Nesbitt maintained however that *“the movements, which were evident prior to transfer, remained. I do not believe that I placed undue emphasis on these movements and there was no inference that there had been any recovery. It is very much regretted that Mr and Mrs Ferguson took this meaning.”*⁴⁵² At that stage, Raychel was still capable of reflex movement.⁴⁵³ I think it most unlikely that Dr Nesbitt could or would have misinterpreted this.⁴⁵⁴
- 5.156 I do not believe that there was any deliberate attempt to give the Ferguson family false hope. The transfer to Belfast alone may have done that. It is however clear that communication should have been better and more considered. Dr Nesbitt acknowledged this when he observed how the circumstances of that day emphasised for him *“the importance of effective communication with distraught family members.”*⁴⁵⁵ The question of who should have spoken to the Fergusons, when and in what terms, was not considered at that time. One consequence of this was that the relationship of trust between the Altnagelvin doctors and the Ferguson family was critically undermined.
- 5.157 By way of contrast, when Mr and Mrs Ferguson met with Drs Crean and Hanrahan⁴⁵⁶ at PICU they were told in clear terms that *“Raychel is critically ill and the outlook is very poor.”*⁴⁵⁷ This was recorded in the medical chart

⁴⁵⁰ Mr Ferguson T-26-03-13 p.148 line 13
⁴⁵¹ Ms Kay Doherty T-18-09-13 p.157 line 3
⁴⁵² WS-035-3 p.2
⁴⁵³ Dr Haynes T-22-03-13 p.152 line 6
⁴⁵⁴ Dr Haynes T-22-03-13 p.153 line 3
⁴⁵⁵ WS-035-3 p.3
⁴⁵⁶ 312-003-005
⁴⁵⁷ 063-009-021

and is confirmed by the counselling record.⁴⁵⁸ Dr O'Donoghue also met with the family. The Fergusons appreciated this straightforwardness and make no criticism of the way they were treated by the clinicians at the RBHSC.⁴⁵⁹ Mr Foster agrees and noted that Mr and Mrs Ferguson were treated with *"all possible care and sensitivity at the RBHSC."*⁴⁶⁰

5.158 Mrs Ferguson gave evidence that *"I don't remember whether it was Dr. Crean or Mr. Hanrahan, they kept going over about the vomiting, what kind of vomiting, how many vomits, what time was there blood in the vomit, they just kept repeating these questions... and... 'What's Altnagelvin trying to do here, pass the buck?'"*⁴⁶¹ and *"this should never have happened."*⁴⁶² Dr Hanrahan, however had no recollection of this and Dr Crean thought it most unlikely. He said *"the main thrust of what we were doing at that time was to take the family through a terrible journey."*⁴⁶³

5.159 Drs Crean and Hanrahan performed the first brain stem death test at 17:30 9th June and noted brain death.⁴⁶⁴ Their second test of 09:45 the following morning confirmed *"no evidence of brain function... she is brain dead."*⁴⁶⁵

5.160 Mr and Mrs Ferguson were advised that nothing could be done. With their consent and Raychel on her mother's knee⁴⁶⁶ and with her family beside her, ventilation support was discontinued at 11:35.⁴⁶⁷ Raychel was pronounced dead at 12:09, 10th June 2001.⁴⁶⁸

5.161 The Coroner's office was notified.⁴⁶⁹

⁴⁵⁸ 063-009-021 & 063-022-049

⁴⁵⁹ Mr and Mrs Ferguson T-26-03-13 p.160 *et seq*

⁴⁶⁰ 223-002-027

⁴⁶¹ Mrs Ferguson T-26-03-13 p.161 line 19 & p.162 line 11

⁴⁶² Mrs Ferguson T-26-03-13 p.164 line 10

⁴⁶³ Dr Crean T-11-09-13 p.24 line 20

⁴⁶⁴ 063-010-024 & 012-032-160

⁴⁶⁵ 063-012-024

⁴⁶⁶ Mrs Ferguson T-26-03-13 p.184 line 21

⁴⁶⁷ 063-016-040 & 063-017-042

⁴⁶⁸ 063-017-041

⁴⁶⁹ 063-012-026

Discharge advices

- 5.162 Altnagelvin was obliged to issue a formal hospital discharge letter and summary to Raychel's GP but this was not done. As before, this was a particular failing in documentary compliance which had been previously identified by audit⁴⁷⁰ but not addressed.
- 5.163 Nor did Mr Gilliland contact Raychel's GP,⁴⁷¹ despite the fact that he had previously *"telephoned quite a number of general practitioners about deaths of their patients."*⁴⁷² He did not call her because *"Raychel had died elsewhere and I simply didn't think to do so."*⁴⁷³ He did however tell her *"in casual conversation"* when they met at the supermarket.⁴⁷⁴
- 5.164 Further, and notwithstanding that Mr Gilliland recognised his responsibility for Raychel's care⁴⁷⁵ and his duty under the General Medical Council ('GMC') 'Good Medical Practice' code to *"explain, to the best of [his] knowledge, the reason for and the circumstances of the death to those with parental responsibility"*⁴⁷⁶ he made no contact with the Ferguson family because again he did not think to do so.⁴⁷⁷ He made no expression of condolence. Professor Swainson believed that Mr Gilliland should have met the family and within days.⁴⁷⁸ Such would have been proper and if properly done could have been helpful.
- 5.165 Irrespective of whether the RBHSC might also have been expected to give full discharge details to the family GP, it was most important in the circumstances that Altnagelvin itself advise the family doctor because the Fergusons might have needed support in their bereavement and the GP was likely to be involved.⁴⁷⁹

⁴⁷⁰ 321-068-004

⁴⁷¹ Mr Gilliland T-28-08-13 p.64 line 3 & p.64 line 3 & p.68 line 15

⁴⁷² Mr Gilliland T-28-08-13 p.97 line 13

⁴⁷³ Mr Gilliland T-28-08-13 p.97 line 17

⁴⁷⁴ Mr Gilliland T-28-08-13 p.64 line 9

⁴⁷⁵ Mr Gilliland T-14-03-13 p.217 line 25

⁴⁷⁶ Mr Gilliland T-28-08-13 p.81 line 1

⁴⁷⁷ Mr Gilliland T-14-03-13 p.83 line 4

⁴⁷⁸ Professor Swainson T-19-09-13 p.98 line 2

⁴⁷⁹ Professor Swainson T-19-09-13 p.45 line 3

Altnagelvin governance framework

- 5.166 The Altnagelvin Hospitals Health & Social Services Trust (the ‘Trust’) was created on 1st April 1996⁴⁸⁰ and made accountable to the Department of Health and Personal Social Services & Personal Safety, Northern Ireland (‘DHSSPSNI’ otherwise ‘the Department’).⁴⁸¹
- 5.167 The Trust’s main commissioner of services was the Western Health & Social Services Board (‘WHSSB’)⁴⁸² under a ‘purchaser-provider’ Service Agreement⁴⁸³ which required of it a commitment to a *“clinical governance programme [which] must include key elements such as processes for recording and deriving lessons from untoward incidents, complaints and claims; a risk management programme; effective clinical audit arrangements; evidence based medical practice and a supportive culture committed to the concept of life-long learning.”*⁴⁸⁴
- 5.168 Whilst the Trust operated independently of the WHSSB and without managerial accountability, it was nonetheless required to *“share details of its quality framework”* with the WHSSB⁴⁸⁵ and maintain liaison *“to ensure that the services it provides meet the needs of the resident population.”*⁴⁸⁶
- 5.169 Oversight was also given the Western Health & Social Services Council (‘WHSSC’) established to *“keep under review the operation of the health and personal services in its area and to make recommendations for the improvement of these services.”*⁴⁸⁷
- 5.170 The Trust was led by a Board of Executive and Non-Executive Directors. Mrs Burnside as Chief Executive was the *“accountable officer”*⁴⁸⁸ *“responsible for the management and leadership of the services provided”* and *“bore ultimate responsibility for the overall quality and quantity of the*

⁴⁸⁰ 321-004gj-008

⁴⁸¹ 321-004fa-001

⁴⁸² 321-004fa-001

⁴⁸³ 321-028-002 *et seq*

⁴⁸⁴ 321-028-004

⁴⁸⁵ 321-028-009

⁴⁸⁶ 321-004fa-002

⁴⁸⁷ WS-093-1 p.2

⁴⁸⁸ WS-046-1 p.3 & 321-050-002

services...”⁴⁸⁹ She was herself accountable to the Chairman of the Trust Board and to the WHSSB.⁴⁹⁰

- 5.171 There were two Executive Directors bearing particular responsibility for clinical matters, namely the Medical Director, Dr Fulton and Miss Duddy, Director of Nursing.
- 5.172 Dr Fulton was responsible for the efficiency of clinical services, audit and professional standards. His task was to facilitate communication between clinicians and management.⁴⁹¹ He monitored “*the quality of medical care*”,⁴⁹² investigated serious clinical incidents⁴⁹³ and advised the Trust Board on medical issues, complaints, appraisal of medical performance and medical issues arising from litigation.
- 5.173 Miss Duddy provided professional leadership for nursing and advised the Board on nursing matters. She and Dr Fulton were jointly accountable to the Board for the quality of care and overall risk management.⁴⁹⁴ Mrs Therese Brown,⁴⁹⁵ the Risk Management Co-ordinator (‘RMCO’) had responsibility for “*establishing systems for assessing, preventing and responding to [clinical] risk.*”⁴⁹⁶ The task of managing standards and guidelines and administering the audit team fell to the Clinical Effectiveness Co-ordinator, Mrs Anne Witherow.⁴⁹⁷
- 5.174 Responsibility for overseeing operational management lay with the Hospital Management Team⁴⁹⁸ comprising the Clinical Directors and Clinical Service Managers of the individual clinical directorates.⁴⁹⁹ The role of the Clinical Director was one of leadership within a directorate and included those “*issues relating to standards of care or poor performance.*”⁵⁰⁰ The CSM was

⁴⁸⁹ WS-046-2 p.8

⁴⁹⁰ WS-046-2 p.5

⁴⁹¹ 321-004gh-005-007

⁴⁹² WS-043-1 p.3

⁴⁹³ WS-043-1 p.3

⁴⁹⁴ WS-323-1 p.3

⁴⁹⁵ 328-001-002

⁴⁹⁶ WS-322-1 p.31

⁴⁹⁷ 328-001-003 & WS-322-1 p.5

⁴⁹⁸ 321-004gj-011

⁴⁹⁹ 321-004gj-011

⁵⁰⁰ WS-035-2 p.4

*“the practitioner responsible for day-to-day management of the directorate.”*⁵⁰¹

- 5.175 The Surgery and Critical Care Directorate was responsible for the provision of Raychel’s surgical care and was under the clinical directorship of the late Mr Paul Bateson. Care for paediatric patients on Ward 6 was provided within the Women & Children’s Care Directorate under the directorship of Dr Denis Martin⁵⁰² but was in reality directed by the CSM Mrs Margaret Doherty.⁵⁰³ Whilst she reported to Dr Martin she was accountable to the Director of Nursing. This was in contrast to the Clinical Directors who were both *“responsible and accountable to the lead Clinical Director.”*⁵⁰⁴

Altnagelvin clinical governance - June 2001

- 5.176 In April 2001 the Department, recognising that *“governance arrangements are already in place to ensure overall probity, transparency and adherence to public service values”*, published for consultation ‘Best Practice Best Care’ proposing a more formalised *“system of clinical and social care governance backed by a statutory duty of quality.”*⁵⁰⁵
- 5.177 In preparing to comply with this new statutory accountability for patient care,⁵⁰⁶ the Trust recorded in its Annual Report 1998-99 that *“a clinical governance strategy has been developed... which details the structures and processes required to ensure that patients will receive the highest quality of care with the best clinical outcomes.”*⁵⁰⁷
- 5.178 The Trust made a commitment to the success of clinical governance⁵⁰⁸ and by June 2001 claimed to have introduced a range of policy initiatives, including amongst others:

⁵⁰¹ 321-004-009

⁵⁰² 328-001-003

⁵⁰³ WS-336-1 p.26 & Sister Millar T-28-08-13 p.125 line 1 & 321-022-001

⁵⁰⁴ 321-004gd-001

⁵⁰⁵ WS-068-1 p.14: ‘A Framework for Setting Standards, Delivering Services and Improving Monitoring and Regulation in the HPSS’

⁵⁰⁶ ‘Clinical and Social Care Governance Circular’ HSS (PPM) 10/2002

⁵⁰⁷ 321-004gi-044

⁵⁰⁸ 321-004fg-001

- (i) Proposed Strategy for Implementing Clinical Governance, September 1998.⁵⁰⁹
- (ii) Clinical Governance Committee, 1998-99.⁵¹⁰
- (iii) Clinical Governance 'Steering Group'.⁵¹¹
- (iv) Policy for Reporting of Clinical Incidents and Critical Incident Protocol, February 2000.⁵¹²
- (v) Procedure for appraisal of staff pursuant to DHSSPSNI consultation document⁵¹³ by 2000.⁵¹⁴
- (vi) Policy for the Management of Clinical Risk, including arrangements for the management of legal claims, October 1997.⁵¹⁵
- (vii) Clinical Negligence Scrutiny Committee.⁵¹⁶
- (viii) Clinical Incident Review Committee.⁵¹⁷
- (ix) Procedure for Handling Complaints, Enquiries and Commendations, May 1996.⁵¹⁸
- (x) Patients' Forum.⁵¹⁹
- (xi) Multi-disciplinary Clinical Audit Committee with Clinical Audit Co-ordinator and Clinical Effectiveness Co-ordinator, 1998-99.⁵²⁰
- (xii) Patient Case Note Standards, May 1996.⁵²¹

⁵⁰⁹ 321-004fg-001

⁵¹⁰ 321-004gj-042

⁵¹¹ 321-004gr-008

⁵¹² 321-004ff-001 & 022-109-338

⁵¹³ 321-004fi-001 - 'Confidence in the Future...On the Prevention, Recognition and Management of Poor Performance of doctors in Northern Ireland' 2000. Chief Executive Mrs Burnside served on the Working Group responsible for this development of these proposals.

⁵¹⁴ 321-004gj-044

⁵¹⁵ 321-004fd-001

⁵¹⁶ WS-323-1 p.14

⁵¹⁷ WS-323-1 p.14

⁵¹⁸ 321-004fb-001

⁵¹⁹ WS-323-1 p.14

⁵²⁰ 321-004gi-044

⁵²¹ 321-014c-001

- (xiii) Regular appraisal for trainee doctors, 1997.⁵²²
- (xiv) Junior Doctors' Handbook and a staff 'Hotline' to assist communication, 1998.⁵²³
- (xv) Trust Scrutiny Committee.⁵²⁴

5.179 In addition, doctors were individually subject to wide ranging and long established codes of professional self-regulation, not least from the GMC, Royal Colleges and published guidance. Nurses were subject to the United Kingdom Central Council for Nursing, Midwifery and Health Visiting ('UKCC') 'Code of Professional Conduct'⁵²⁵ and standing guidelines for professional practice.⁵²⁶ Additionally within Altnagelvin, nurses were said to be subject to annual performance and training requirement appraisals,⁵²⁷ benchmarking exercises against best practice guidance,⁵²⁸ a "*cascade system of dissemination*" for external guidance,⁵²⁹ and auditing "*of nursing and medical records*."⁵³⁰

5.180 Notwithstanding that the Trust made application for the King's Fund Organisational Audit ('KFOA') accreditation in 1998,⁵³¹ achieved a number of charter standards and "*full CPA accreditation of all departments*" in 2001-02,⁵³² the extent to which policy and strategy was actually put into practice is uncertain.

5.181 It took time and money to integrate clinical governance into the hospital system and money was not always available.⁵³³ For Sister Millar in Ward 6, clinical governance in 2001 was "*very much in its infancy but we were striving to get our heads round it*."⁵³⁴ Altnagelvin did not publish a clinical

⁵²² WS-328-1 p.12

⁵²³ 321-004fk-001

⁵²⁴ 321-004fd-005

⁵²⁵ 202-002-058

⁵²⁶ 314-003-001

⁵²⁷ WS-323-1 p.8

⁵²⁸ WS-046-2 p.18 & WS-329-1 p.5

⁵²⁹ WS-323-1 p.19

⁵³⁰ WS-329-1 p.12

⁵³¹ 321-004fg-003

⁵³² 321-004gt-001

⁵³³ 317-006-004 & 316-006g-003

⁵³⁴ Sister Millar T-28-08-13 p.102 line 3

and social governance report until 2003 some 5 years after making public its strategy for implementing clinical governance.

- 5.182 Even though the evidence confirmed that the implementation of clinical governance was not so complete as was claimed, it is however clear, that at the time of Raychel's death, those within Altnagelvin who were charged with the governance response to her death, knew or ought to have known what constituted good practice.

Initial RBHSC response

- 5.183 On the day of Raychel's death, 'rumour' spread from the RBHSC that her fluids had been mismanaged.⁵³⁵ Sister Millar recalled "*a nurse in the intensive care in the Children's [Hospital] in Belfast said when Raychel arrived and there was handover, that she was on the wrong fluid.*"⁵³⁶ Mr Gilliland recalled "*discussion between our own medical staff and the doctors in the RBHSC about the probable cause of Raychel's death. I believe I was made aware of the discussions sometime on 11 June...*"⁵³⁷ and "*some of that discussion had been critical.*"⁵³⁸
- 5.184 By the Monday morning Mrs Burnside was also aware of Raychel's death. She recalled the "*'rumour' from PICU that the 'wrong fluids' had been used. This 'rumour' emerged from a nurse in PICU responding to an inquiry from Altnagelvin Ward Nurse on the child's state, on the Sunday.*"⁵³⁹
- 5.185 Inconsistency about the origin of the rumour is not surprising but does draw attention to the more important fact that the RBHSC did not inform Altnagelvin in writing that the "*wrong*" fluids had been used.
- 5.186 Professor Swainson, noting the absence of a formal RBHSC discharge summary for Altnagelvin, said he would have expected "*a full analysis of the cause(s) of the cerebral oedema and the role of acute hyponatraemia*

⁵³⁵ 021-020-041

⁵³⁶ Sister Millar T-01-03-13 p.64 line 23 & cf WS-344-1 p.3

⁵³⁷ WS-044-4 p.11

⁵³⁸ WS-044-4 p.11

⁵³⁹ 021-020-041

*in that. The evidence that Altnagelvin Trust heard only through an informal conversation between nurses is surprising and disturbing.”*⁵⁴⁰

5.187 Professor Scally also considered that there should have been formal communication because a professional obligation to do so arose when a death may have been caused by mismanagement. He believed this obligation was *“reinforced by the RBHSC role as a regional centre of excellence.”*⁵⁴¹ Dr Ian Carson,⁵⁴² then Medical Director of the Royal Group of Hospitals Trust (‘RGHT’), agreed that concerns should have been communicated.⁵⁴³ Professor Swainson believed it would have been proper for the complications of care to be communicated *“so that the doctors who referred [her could] understand what exactly has happened or at least... the Royal Belfast Hospital’s interpretation of that.”*⁵⁴⁴ However, Dr Crean said it was not the *“culture at the time. That’s not the way we did our business...”*⁵⁴⁵

5.188 The sole RBHSC communication was to Raychel’s GP and indicated only that Raychel had been *“transferred from Altnagelvin hospital with seizures/ hyponatraemia/cerebral oedema/fixed dilated pupils. Certified as dead on 10/6/01 @ 12:09 hours. For Coroner’s P.M.”*⁵⁴⁶ No reference was made to mismanagement.

5.189 Notwithstanding that the death was the subject of discussion within the RBHSC,⁵⁴⁷ Raychel’s death was not made the subject of a Critical Incident Report or Review, because as Dr Crean explained *“if an adverse event occurred in RBHSC and it was considered to have led to an unexpected death, then it would have been reported. However, I do not believe an event occurring in another hospital would have been reported.”*⁵⁴⁸ This was the same unacceptable explanation as was offered in respect of Lucy’s death

⁵⁴⁰ 226-002-010

⁵⁴¹ 251-002-017

⁵⁴² 328-001-004

⁵⁴³ Dr Carson T-30-08-13 p.19 line 25

⁵⁴⁴ Professor Swainson T-19-09-13 p.44 line 18

⁵⁴⁵ Dr Crean T-11-09-13 p.128 line 23

⁵⁴⁶ 317-041-001

⁵⁴⁷ Dr Taylor T-18-09-13 p.62 line 2

⁵⁴⁸ WS-038-3 p.6

occurring the previous year.⁵⁴⁹ Furthermore, it contravened RGHT's own Adverse Incident Reporting policy.⁵⁵⁰

- 5.190 Whilst there was a clear lack of full and formal communication and that is to be criticised, it must nonetheless be emphasised that the RBHSC immediately notified the Coroner of Raychel's death, informally communicated suspicion of mismanagement to both Altnagelvin and the Coroner⁵⁵¹ and subsequently discussed Raychel's case at an Audit Meeting on 10th April 2003.⁵⁵²

Altnagelvin's Critical Incident Review

- 5.191 Likewise, within Altnagelvin, there was no formal adverse incident report of Raychel's death. This was in contravention of the internal reporting policy *"that any clinical incident should be reported on the appropriate documentation."*⁵⁵³
- 5.192 However, Mrs Burnside immediately and very properly asked Dr Fulton *"to investigate this very serious event in [his] role as Medical Director."*⁵⁵⁴ To that end he, and Mrs Therese Brown the RMCO, decided to formally review Raychel's case in accordance with the Altnagelvin Critical Incident Protocol.⁵⁵⁵ This procedure was broadly based on recommendations extracted from a 'Clinical Governance' textbook by Myriam Lugon⁵⁵⁶ and developed by Dr Fulton,⁵⁵⁷ Mrs Brown⁵⁵⁸ and Miss Duddy.
- 5.193 Professor Swainson thought that it was *"in general a good protocol."*⁵⁵⁹ However, it has proved difficult to determine the extent to which it was actually followed because there is so little documentation. It might be thought that such a serious case involving numerous clinical witnesses and

⁵⁴⁹ Dr Crean T-04-06-13 p.147 line 24

⁵⁵⁰ WS-292-2 p.45 & 321-074-001

⁵⁵¹ 012-052c-275

⁵⁵² 063-037-095

⁵⁵³ 321-004ff-002

⁵⁵⁴ WS-043-1 p.3

⁵⁵⁵ 026-012-016

⁵⁵⁶ WS-043-1 p.2 1999 p.94-96 & Mrs Brown T-02-09-13 p.39 line 7

⁵⁵⁷ Dr Fulton T-04-09-13 p.22 line 18

⁵⁵⁸ Mrs Brown T-02-09-13 p.38 line 25

⁵⁵⁹ Professor Swainson T-19-09-13 p.73 line 14

multiple issues of fact would have generated copious documentation and opinion. However, that was not the case. Dr Fulton did not take notes⁵⁶⁰ and there is no written report of the review.

5.194 Notwithstanding, Dr Fulton immediately sought *“to form an accurate account of the events leading to Raychel’s death while it was clear in everyone’s memory. I was also keen to ascertain whether lessons could be learned so that a recurrence of this tragic event could be avoided.”*⁵⁶¹ He convened a critical incident review meeting for 12th June. Speed was important and Dr Fulton achieved it.

5.195 Dr Fulton initially assured this Inquiry that Mrs Brown contacted the relevant staff, who all agreed to attend⁵⁶² and that he noted those who attended and what they said.⁵⁶³ However, he has since recognised that not all relevant witnesses were contacted, that he made no record of those who did attend, that he did not note what was said and that, in terms, he has no reliable recollection of his review.⁵⁶⁴ It is however clear that *“only the staff present at the Critical Incident Meeting were interviewed...”*⁵⁶⁵ and absent from the Review were the surgeons Bhalla, Zafar and Zawislak,⁵⁶⁶ Drs Curran, Devlin,⁵⁶⁷ Gund,⁵⁶⁸ Jamison,⁵⁶⁹ Johnston,⁵⁷⁰ Trainor,⁵⁷¹ Butler,⁵⁷² Kelly,⁵⁷³ and Date,⁵⁷⁴ and Staff Nurses Patterson,⁵⁷⁵ McGrath,⁵⁷⁶ McAuley and Roulston.⁵⁷⁷

⁵⁶⁰ Dr Fulton T-04-09-13 p.49 line 2

⁵⁶¹ WS-043-1 p.4

⁵⁶² WS-043-1 p.4

⁵⁶³ WS-043-1 p.4

⁵⁶⁴ WS-043-2 p.1-3 & Staff Nurse Noble T-27-02-13 p.185 line 9

⁵⁶⁵ WS-043-3 p.11

⁵⁶⁶ Dr Zawislak T-05-02-13 p.85 line 17

⁵⁶⁷ Dr Devlin T-06-03-13 p.3 line 18

⁵⁶⁸ Dr Gund T-05-02-13 p.184 line 1

⁵⁶⁹ Dr Jamison T-07-02-13 p.95 line 17

⁵⁷⁰ Dr Johnston T-07-03-13 p.224 line 24

⁵⁷¹ Dr Trainor T-12-03-13 p.101 line 24

⁵⁷² Dr Butler T-11-03-13 p.35 line 14

⁵⁷³ WS-254-1 p.6

⁵⁷⁴ WS-031-2 p.6

⁵⁷⁵ Ms Patterson T-04-03-13 p.112 *et seq*

⁵⁷⁶ Staff Nurse McGrath T-26-02-13 p.94 line 13

⁵⁷⁷ Staff Nurse McAuley T-05-03-13 p.202 line 3 & Staff Nurse Roulston T-06-03-13 p.151 line 24

- 5.196 Further and notwithstanding the suggestion of criticism from the RBHSC,⁵⁷⁸ Mr Bateson, the Clinical Director of Surgery, did not attend the Critical Incident Review despite his responsibility for the surgical team treating Raychel. Nor was there any involvement from Dr Martin, the Clinical Director charged with leadership of the paediatric department.⁵⁷⁹ Miss Duddy, the Director of Nursing, did not attend the meeting or learn of Raychel's death until "*sometime after the critical incident meeting.*"⁵⁸⁰
- 5.197 Mr Gilliland did attend but did not contribute. He did not speak to his doctors,⁵⁸¹ review their performance,⁵⁸² or ensure their attendance at the Critical Incident Review. He said that he "*didn't think about doing that at the time, nor did [he] necessarily feel that it was [his] role to call the people to that meeting.*"⁵⁸³ However, Mrs Doherty, Mrs Witherow, and Staff Nurses Noble, Gilchrist and Bryce were present together with Sister Millar and Auxiliary Nurse Lynch.
- 5.198 Given the rumour that Raychel had been given the "*wrong*" fluid it is surprising that no input was sought or received from the RBHSC. There was no request for RBHSC notes and the Trust's solicitor was not invited to attend.⁵⁸⁴ This was however the first time a formal Critical Incident Review had been convened at Altnagelvin⁵⁸⁵ and as Professor Swainson observed "*to be fair to the people concerned, and to do that well, you do need a bit of experience.*"⁵⁸⁶

Critical Incident Review meeting

- 5.199 Dr Fulton said that "*from the start we knew why Raychel had died, we knew about the low sodium and the cerebral oedema. So to some extent we were working backwards.*"⁵⁸⁷ He recalled how "*subdued and shocked all the*

⁵⁷⁸ WS-044-4 p.11

⁵⁷⁹ Dr Fulton T-04-09-13 p.18 line 19 & WS-335-1 p.7

⁵⁸⁰ WS-323-1 p.23

⁵⁸¹ Mr Gilliland T-28-08-13 p.72 line 1 & p.69 line 2

⁵⁸² Mr Gilliland T-28-08-13 p.72 line 6

⁵⁸³ Mr Gilliland T-28-08-13 p.75 line 17

⁵⁸⁴ Mrs Brown T-02-09-13 p.49 line 7

⁵⁸⁵ Dr Fulton T-09-04-13 p.27 line 1

⁵⁸⁶ Professor Swainson T-19-09-13 p.83 line 14

⁵⁸⁷ Dr Fulton T-04-09-13 p.51 line 13

nurses and doctors appeared at the start of the meeting. It was clear... that they regarded this as a very serious and highly unusual event.”⁵⁸⁸ He stressed “that the purpose of the meeting was to establish facts and not to blame individual staff members. This was the approach recommended for Critical Incident investigations to allow staff to give essential information in a non-judgmental atmosphere.”⁵⁸⁹

- 5.200 The meeting was not minuted. Dr Fulton “*explained at the start of the meeting that Mrs Brown would take minutes. This caused anxiety and started a discussion about the need for legal advice before proceeding. I was concerned that this would delay the investigation.*”⁵⁹⁰ Accordingly, he chose to continue which was proper but I consider that the reluctance of those present to allow any record of the proceedings is indicative of defensiveness from the outset.

Fluids

- 5.201 In preparation for the review meeting Dr Nesbitt conducted some preliminary research and noted “*evidence relating to problems with low sodium containing solutions in children.*”⁵⁹¹ Some of the relevant medical literature was available at the meeting.⁵⁹²
- 5.202 Mr Makar recalled that “*most of the discussion was about the type of fluid*”⁵⁹³ and Dr Fulton recalled how “*Dr Nesbitt also felt a low sodium solution such as Solution 18 could be unsuitable for post-operative children as they were predisposed to hyponatraemia. However, he was aware that the use of Solution 18 was common practice in such situations in other hospitals in Northern Ireland. Dr Nesbitt offered to ring other hospitals in Northern Ireland to establish the current use of Solution 18.*”⁵⁹⁴

⁵⁸⁸ 095-011-049
⁵⁸⁹ WS-043-1 p.5
⁵⁹⁰ WS-043-3 p.11
⁵⁹¹ WS-035-2 p.13
⁵⁹² Dr Fulton T-04-09-13 p.72 line 7
⁵⁹³ Mr Makar T-13-03-13 p.190 line 1
⁵⁹⁴ WS-043-1 p.7

- 5.203 The review considered Raychel's notes and scrutinised the volume of IV fluids administered. There appears to have been consensus that mistakes had been made.⁵⁹⁵ Dr Fulton remembered that "*Dr Nesbitt reviewed the infusion rate of Solution 18 and felt it was too high for Raychel's weight.*"⁵⁹⁶ The retrospective and clarifying annotation of the record was made at this time by Drs Nesbitt and Jamison.

Electrolytes

- 5.204 Dr Fulton remembered that "*Sister Millar clearly stated that the blood electrolytes should have been checked in the afternoon because of the continued vomiting*"⁵⁹⁷ and that "*medical help should have been called earlier.*"⁵⁹⁸

Documentation

- 5.205 Sister Millar's "*main concern at that meeting was our failure in the documentation.*"⁵⁹⁹ She felt that the urinary output and the vomiting "*could have been better documented.*"⁶⁰⁰ Staff Nurse Noble recalled agreement in relation to this.⁶⁰¹

Vomiting

- 5.206 Dr Fulton stated that the nurses at the Review "*agreed that the vomiting was prolonged but not unusual after this type of surgery. They did not believe that the vomiting was excessive though they may not have witnessed all the vomit*"⁶⁰² Sister Millar recalled differences of opinion between the nurses as to how much Raychel had vomited, and "*there may have been a problem with the documentation of the vomit.*"⁶⁰³

⁵⁹⁵ Staff Nurse Noble T-27-02-13 p.168 line 8

⁵⁹⁶ WS-043-1 p.7

⁵⁹⁷ WS-043-3 p.15

⁵⁹⁸ Dr Fulton T-04-09-13 p.56 line 18

⁵⁹⁹ Sister Millar T-01-03-13 p.63 line 24

⁶⁰⁰ Sister Millar T-28-08-13 p.130 line 10

⁶⁰¹ Staff Nurse Noble T-27-02-13 p.191 line 18 & Staff Nurse Noble T-27-02-13 p.179 line 19

⁶⁰² WS-043-3 p.14

⁶⁰³ Sister Millar T-28-08-13 p.131 line 6

- 5.207 Dr Fulton found it *“hard to form a clear opinion of the volume of vomit... and the frequency”*⁶⁰⁴ not least because the nurses also indicated that *“the Ferguson family told them during 8 June that they... believed that Raychel’s vomiting was repeated and severe.”*⁶⁰⁵ Dr Fulton was therefore *“unable to reconcile the different views of the nurses and the family over the severity of the vomiting”*⁶⁰⁶ and could not *“appreciate which side was right.”*⁶⁰⁷
- 5.208 The review took no further steps to investigate the severity of the vomiting. It did not seek to interview the Ferguson family or the junior doctors and gave no consideration to the engagement of external experts.

Care of surgical patients on Ward 6

- 5.209 Sister Millar took the opportunity to emphasise that she *“had for some time been unhappy with... the system within the hospital for caring for surgical children.”*⁶⁰⁸ *“There was always a difficulty in getting doctors.”*⁶⁰⁹ It *“was my impression that there just weren’t enough.”*⁶¹⁰ *“I had spoken about this before.”*⁶¹¹
- 5.210 In addition, staff Nurse Noble suggested that the responsibility for overseeing fluid management should not rest with inexperienced JHOs⁶¹² because assisting such junior doctors placed additional burden on the nursing staff. Sister Millar expressed her view that it *“was totally unfair that the nurses had such responsibility for the surgical children. I felt it was unfair. I felt that we had to be the lead all the time in looking after the surgical children. We are nurses, we are not doctors. And whilst we do our very best, I don’t think we should be prompting doctors.”*⁶¹³ Dr Fulton could not

⁶⁰⁴ Dr Fulton T-04-09-13 p.53 line 14

⁶⁰⁵ WS-043-3 p.15

⁶⁰⁶ WS-043-3 p.15

⁶⁰⁷ Dr Fulton T-04-09-13 p.54 line 11

⁶⁰⁸ Sister Millar T-01-03-13 p.57 line 6

⁶⁰⁹ Sister Millar T-01-03-13 p.57 line 11

⁶¹⁰ Sister Millar T-01-03-13 p.59 line 24

⁶¹¹ Sister Millar T-01-03-13 p.60 line 19

⁶¹² Staff Nurse Noble T-27-02-13 p.175 line 20

⁶¹³ Sister Millar T-01-03-13 p.58 line 7

however recall this matter being raised with quite the force described by the nurses.⁶¹⁴

Informal review

5.211 At or about the same time and in an unrelated initiative, Mrs Margaret Doherty, the CSM, asked Sister Kathryn Little⁶¹⁵ to interview Staff Nurse Noble, review the patient notes and prepare a preliminary report.⁶¹⁶ Regrettably, this did not come to the attention of either Mrs Brown⁶¹⁷ or Dr Fulton⁶¹⁸ in time to be incorporated into the work of the formal review.⁶¹⁹ The CSM did not share it with Miss Duddy or pass on the information in her possession.⁶²⁰ Her investigation ended when she *“was told it was the Risk Management that were taking it over.”*⁶²¹

5.212 Professor Swainson considered that, at the same time and in the same way, the surgeons should have been internally reviewing the case for their own benefit and assisting Dr Fulton in his review.⁶²² It was, he said, a *“huge opportunity for learning.”*⁶²³ Neither Mr Bateson nor Mr Gilliland availed of the opportunity.

Action plan

5.213 In consequence of the review, Dr Fulton prepared and agreed a plan of action.⁶²⁴ He instituted a number of rapid and appropriate responses to address shortcomings recognised at review. It was decided:

- (i) To review the evidence about the use of Solution No.18 and to suggest change if indicated.⁶²⁵

⁶¹⁴ Dr Fulton T-04-09-13 p.64 line 6

⁶¹⁵ 328-001-003

⁶¹⁶ 316-085-009 & 316-085-011

⁶¹⁷ Mrs Brown T-02-09-13 p.74 line 13

⁶¹⁸ Dr Fulton T-04-09-13 p.40 line 6

⁶¹⁹ Mrs Brown T-02-09-13 p.74 line 14

⁶²⁰ Mrs Margaret Doherty T-09-09-13 p.77 line 16

⁶²¹ Mrs Margaret Doherty T-09-09-13 p.82 line 13

⁶²² Professor Swainson T-19-09-13 p.81 line 8

⁶²³ Professor Swainson T-19-09-13 p.76 line 18

⁶²⁴ 026-011-014

⁶²⁵ 022-108-336 & WS-035-2 p.33

- (ii) To display a wall chart detailing correct rates for IV infusion.
- (iii) To institute daily U&E assessments.
- (iv) To monitor and record all urinary and vomit output.⁶²⁶
- (v) To review the fluid balance documentation.
- (vi) To remove JHOs from the care of paediatric surgical patients.⁶²⁷
- (vii) To actively consider whether the anaesthetic team should assume responsibility for initial post-operative fluids.⁶²⁸

5.214 Despite the non-involvement of key personnel and the failure to make a record or produce a report, it should be recognised, as Dr Haynes did, that *“the Critical Incident Inquiry at Altnagelvin was convened at the first possible opportunity and... it is clear from the agreed action points... that the incident was treated with the utmost gravity...”*⁶²⁹ Mr Foster thought *“it was excellent that instant action was taken”* especially to remove JHOs from the care of paediatric surgical patients.⁶³⁰ The review was a timely response and did valuable work. It genuinely strove to prevent recurrence.

Systemic analysis

5.215 It has been noted that matters were not analysed in line with the then emerging methods of root-cause analysis. Professor Swainson advised that *“root cause analysis was a common methodology in Trusts in 2001 and does not appear to have been carried out.”*⁶³¹ It was not however common in Northern Ireland.

5.216 Dr McCord observed that Raychel’s death was caused by *“all the factors coming together.”*⁶³² This should have been apparent at the outset. In such circumstances and notwithstanding a lack of the precise skills necessary to

⁶²⁶ WS-043-3 p.15

⁶²⁷ Staff Nurse Noble T-27-02-13 p.125 line 5

⁶²⁸ WS-043-3 p.14 & Dr Makar T-13-03-13 p.192 line 1 & 026-005-006

⁶²⁹ 220-002-006

⁶³⁰ Mr Foster T-21-03-13 p.143 line 11

⁶³¹ 226-002-024

⁶³² Dr McCord T-13-03-13 p.143 line 22

perform root-cause analysis⁶³³ there could and should have been a broader consideration of the factors combining to permit the catastrophic outcome. Such might have included:

- (i) Communication between consultant and trainee at time of emergency admission and proposed operation.
- (ii) Supervision of junior doctors.
- (iii) Consultant responsibilities in respect of fluids.
- (iv) Communication between clinicians and parents.
- (v) Post-take ward round and consultant review.
- (vi) Appreciation of deterioration.
- (vii) Lines of communication when recovery plans do not go as expected.
- (viii) Implementation of external practice recommendations.
- (ix) Failure to address deficiencies identified by practice audit.
- (x) Concerns arising from aspects of nursing practice as outlined above at paragraph 5.122.
- (xi) Questions of overarching responsibility for paediatric surgical patients, their IV fluid therapy and the potential problems associated with adult surgeons providing part-time surgery for children.

5.217 I do not believe it would have been unreasonable for the Chief Executive, Mrs Stella Burnside, to expect some consideration of these matters given that she had herself contributed in May 2000 to the consultation document 'Confidence in the Future'⁶³⁴ which recommended that⁶³⁵:

⁶³³ Mrs Brown T-02-09-13 p.84 line 5

⁶³⁴ 321-004fi-001

⁶³⁵ 321-004fi-029

- (i) Senior doctors give clear guidance and supervision to junior doctors in training when tasks are delegated.
- (ii) Clear leadership roles and responsibilities be identified and established in clinical teams.
- (iii) Participation in clinical audit be made compulsory for all doctors.

With hindsight, Mrs Burnside regretted that she had not asked an external expert to join the review.⁶³⁶

Report of discontinuance of Solution No.18 at RBHSC

- 5.218 Dr Nesbitt having researched the medical literature, made enquiries about post-operative fluid management practice in other Northern Ireland hospitals. He reported to Dr Fulton and Mrs Brown on 14th June 2001 that at *“the Children’s Hospital anaesthetists have recently changed their practice and have moved away from No.18 Solution... to Hartmann’s Solution. This change occurred six months ago and followed several deaths involving No.18 Solution.”*⁶³⁷
- 5.219 The RVH records seemingly confirm a decline in the use of Solution No. 18 in the months prior to Raychel’s death.⁶³⁸ Dr Carson gave it as his understanding *“that a decision was taken by anaesthetists in the RBHSC to change their use of No.18 solution. This decision was taken at a local level within the RBHSC.”*⁶³⁹ He felt that in those circumstances *“there would be justification”* for informing other hospitals of this change.⁶⁴⁰
- 5.220 Dr Fulton was disappointed that the RBHSC had not informed Altnagelvin at the time about such an important matter of patient safety⁶⁴¹ and Dr Nesbitt believed that had Altnagelvin known of the RBHSC move towards

⁶³⁶ Mrs Burnside T-17-09-13 p.81 line 9
⁶³⁷ 022-102-317
⁶³⁸ 319-087a-001 & 319-087c-003 & 321-073-001
⁶³⁹ 326-003a-001
⁶⁴⁰ Dr Carson T-30-08-13 p.40 line 6
⁶⁴¹ Dr Fulton T-04-09-13 p.77 line 6 et seq

discontinuance of Solution No.18 at the time, they would have considered it *“a strong message and one we would have acted on”*⁶⁴²

5.221 Dr Elaine Hicks,⁶⁴³ Clinical Director of Paediatrics at RBHSC, whilst herself unable to recall any change in the use of Solution No.18⁶⁴⁴ did agree that it would be reasonable to criticise the RBHSC if, as the Regional Paediatric Centre, it had made a significant change in its practice and failed to advise other hospitals.⁶⁴⁵ However, it is to be recognised that there were no systems in place at that time to formally disseminate such information and the responsibility may not have been fully understood within the RBHSC. The matter might most appropriately have been made the subject of a report to the Department but no guidance was available and as Dr Crean said there was no *“culture at the time to do things like that.”*⁶⁴⁶

5.222 Although no explanation for this change was forthcoming from any source within the RBHSC, I am satisfied from the evidence that there was a move away from the use of Solution No.18 and for clinical reasons. Exactly what those reasons were is a matter of speculation.⁶⁴⁷ The catalyst may have been the publication in the British Medical Journal (‘BMJ’) of Halberthal’s article on the use of hypotonic solutions and hyponatraemia in March 2001.⁶⁴⁸ It was therefore a learning issue which should have been shared with other hospitals. That was in part the role of the RBHSC as the regional centre and a role which was subsequently acknowledged by the Department when it published its own guidelines on hyponatraemia.⁶⁴⁹

Written report

5.223 Altnagelvin’s critical incident protocol specified that *“the Chief Executive will be kept informed by the RMCO throughout the investigation.”*⁶⁵⁰ Dr Fulton and Mrs Brown gave the Chief Executive an oral briefing on the evening of

⁶⁴² WS-035-2 p.34

⁶⁴³ 328-001-004

⁶⁴⁴ WS-340-1 p.2

⁶⁴⁵ Dr Hicks T-07-06-13 p.43 line 12

⁶⁴⁶ Dr Crean T-11-09-13 p.68 line 14

⁶⁴⁷ 321-073-001 & WS-360-1 p.2 & Dr Taylor T-18-09-13 p.8 line 7

⁶⁴⁸ 036a-056-142 & Dr Taylor T-18-09-13 p.16 line 12

⁶⁴⁹ 077-005-008

⁶⁵⁰ 022-109-338

the Critical Incident Review.⁶⁵¹ There was no written summary of the case, or of the review or action plan, nor any briefing paper for the Chief Executive in preparation for her next Board meeting.⁶⁵² Whilst Mrs Brown did provide a written update for the Chief Executive on 9th July,⁶⁵³ I am struck by the general lack of documentation.

5.224 Having initiated the Critical Incident Review in the context of suspected clinical mismanagement, Mrs Burnside should have expected and required a critical incident report. She did not⁶⁵⁴ and despite the Critical Incident Protocol requirement,⁶⁵⁵ to “*provide the Chief Executive with a written report with conclusions and recommendations within an agreed timescale*”,⁶⁵⁶ none was offered her. Mrs Brown accepted that this “*should have been done*”⁶⁵⁷ and that it was her responsibility.⁶⁵⁸ Dr Fulton felt that in the circumstances he probably should have done it himself⁶⁵⁹ and accepted that this failure was a “*deficit*.”⁶⁶⁰ Remarkably, Mrs Burnside did not herself consult the protocol for guidance.⁶⁶¹ She fully acknowledged her failing in this regard.⁶⁶² I consider that this confirms a lack of commitment to the processes of clinical governance at that time. Nonetheless, Mrs Burnside said she “*felt fully informed...*”⁶⁶³

5.225 Subsequently however, she was to erroneously recount her “*clear understanding that the Critical Incident Review established that Raychel’s care and treatment were consistent with custom and practice,*”⁶⁶⁴ that “*an unusual or idiosyncratic response had precipitated the leading to the tragic death*”⁶⁶⁵ and that “*there were no indicators of persistent patterns of poor care to cause the alarm bells or to trigger an external review.*”⁶⁶⁶ I believe

651 Dr Fulton T-04-09-13 p.70 line 5
652 Mrs Brown T-02-09-13 p.106 line 17
653 022-097-307
654 Mrs Burnside T-17-09-13 p.68 line 21
655 022-109-338
656 022-109-338
657 Mrs Brown T-02-09-13 p.83 line 14
658 Mrs Brown T-02-09-13 p.82 line 4
659 Dr Fulton T-04-09-13 p.10 line 3
660 Dr Fulton T-04-09-13 p.11 line 6
661 Mrs Burnside T-17-09-13 p.84 line 10
662 Mrs Burnside T-17-09-13 p.70 line 8
663 Mrs Burnside T-17-09-13 p.93 line 13
664 WS-046-2 p.14
665 WS-046-2 p.26
666 WS-046-2 p.25

that had an appropriate written report been submitted to the Chief Executive she could not have made such ill-informed statements.

- 5.226 The Director of Nursing was responsible for the implementation of the Critical Incident Protocol. However, she made no attempt to find out what had been learned at the Review,⁶⁶⁷ did not ask to see the statements of her nurses⁶⁶⁸ and took no steps to request a written report.⁶⁶⁹ Whilst she accepted criticism in this regard,⁶⁷⁰ she was unable to explain herself. Accordingly, Miss Duddy made no report on the nursing issues to the Chief Executive or the Board and was not in a position to reassure as to the nursing on Ward 6.⁶⁷¹ The Board meeting minutes for July 2001, which would have confirmed what was disclosed about Raychel's death are missing. Miss Duddy said she could "*only assume that someone got access to them and didn't replace them.*"⁶⁷² In such circumstances, I consider it unlikely that the Board could have been sufficiently informed to know whether the clinical services for children were safe or not.
- 5.227 Additionally, it is much to be regretted that at that time, no one thought to advise Mr and Mrs Ferguson as to the causes of their daughter's death or the findings at review. The clinical shortcomings and the agreed action plan were not explained. They should have been and such silence could not easily have been maintained had a written report been available. It is easy to understand how, in such circumstances, the failure to report in writing might be interpreted as defensive.
- 5.228 A written report would have been an effective channel of communication with the Ferguson family. Professor Swainson observed that "*in my experience over many, many years [families] have always said that what they are interested in is... what is being done to stop that happening again to anybody else... communicating with them broadly the lessons learned*

⁶⁶⁷ Miss Duddy T-29-08-13 p.49 line 9 & Mrs Margaret Doherty T-09-09-13 p.85 line 14

⁶⁶⁸ Miss Duddy T-29-08-13 p.47 line 25

⁶⁶⁹ Miss Duddy T-29-08-13 p.47 line 5

⁶⁷⁰ Miss Duddy T-29-08-13 p.56 line 21

⁶⁷¹ Miss Duddy T-29-08-13 p.76 line 16

⁶⁷² Miss Duddy T-29-08-13 p.62 line 5

*and what has been put in place... is a key piece of the interaction with the family.”*⁶⁷³

Actions: post-review

- 5.229 Professor Swainson also advised that *“a Critical Review would typically meet again after a few weeks to check that the agreed actions had been completed and begin the task in determining what went wrong.”*⁶⁷⁴ Dr Fulton agreed that this *“would have been a very good idea.”*⁶⁷⁵ However no such meeting took place nor indeed was there any surgical consideration of the issues whether at morbidity/mortality meetings or audit.⁶⁷⁶
- 5.230 Dr Fulton’s action plan was not however forgotten and work started on its implementation. Mrs Brown was able to give an ‘update report’ to Mrs Burnside on 9th July 2001 confirming daily U&E checks for post-operative children receiving IV fluids⁶⁷⁷ and display of a chart detailing IV infusion rates,⁶⁷⁸ confirmation was given that these matters had been brought to the attention of junior surgical doctors.
- 5.231 She also reported the decision to discontinue the use of Solution No.18 for paediatric surgical patients. This had not proved straightforward because *“one of the surgeons [was] not supporting this change”*⁶⁷⁹ on the basis that *“he saw no reason to change and was happy to use No.18 Solution.”*⁶⁸⁰ Further review of the medical literature ensued and then, with some reservation, Hartmann’s rather than Solution No.18 eventually became the post-operative fluid for paediatric surgical patients in Altnagelvin. This was the determined achievement of Dr Nesbitt and was to eventually result in the complete removal of Solution No.18 from Ward 6.⁶⁸¹ In this he was

⁶⁷³ Professor Swainson T-19-09-13 p.97 line 2

⁶⁷⁴ 226-002-023

⁶⁷⁵ Dr Fulton T-04-09-13 p.69 line 24

⁶⁷⁶ Miss Duddy T-29-08-13 p.109 line 23

⁶⁷⁷ 022-097-307

⁶⁷⁸ 026-009-010

⁶⁷⁹ 022-097-307

⁶⁸⁰ WS-035-2 p.30

⁶⁸¹ Dr Nesbitt T-03-09-13 p.228 line 19

ahead of his time. It was to take until December 2012 for the British National Formulary for Children⁶⁸² to follow suit.

- 5.232 The update report also recorded the work of the CSM, the Clinical Effectiveness Co-ordinator and some of the nursing staff in relation to fluid balance issues.⁶⁸³ They had agreed detailed matters relating to the management of fluids,⁶⁸⁴ fluid balance sheets, quantification of vomit volume and the necessity to encourage doctors to record and document.⁶⁸⁵
- 5.233 Additionally, they considered important organisational matters including the concern of *“nursing staff that surgeons are unable to give a commitment to children on Ward 6”* and made a request that *“paediatricians maintain overall responsibility for surgical children on Ward 6?”*⁶⁸⁶ The Director of Nursing took no part in these discussions.⁶⁸⁷ Dr Fulton *“didn’t call a meeting but in retrospect, I should have because that seemed to be raising an increasing concern.”*⁶⁸⁸ This confirms that the Critical Incident Review should indeed have reconvened to finish its work.

Arranging to meet Mr and Mrs Ferguson

- 5.234 Immediately after the Critical Incident Review, Mrs Burnside, having received her oral briefing and reviewed *“the issues and actions identified from the analysis”*⁶⁸⁹ and *“knowing the child should not have died”*⁶⁹⁰ and being conscious of a *“duty of care to the parents and family”*⁶⁹¹ wrote on 15th June 2001 to Mr and Mrs Ferguson to *“express to you my sincere sympathy following the death of your daughter Rachel [sic]. We are all deeply saddened and appreciate the loss you must be feeling. The medical and nursing staff who cared for Rachel would like to offer you both their sincere condolences and they would also like to offer you the opportunity*

⁶⁸² 311-048-001

⁶⁸³ 022-097-307

⁶⁸⁴ Mrs Margaret Doherty T-09-09-13 p.86 line 10

⁶⁸⁵ Sister Millar T-28-08-13 p.146 line 15

⁶⁸⁶ 022-097-307

⁶⁸⁷ Sister Millar T-28-08-13 p.160 line 12

⁶⁸⁸ Dr Fulton T-04-09-13 p.86 line 23 & Dr McCord T-13-03-13 p.22 line 17

⁶⁸⁹ 098-267-722

⁶⁹⁰ Mrs Burnside T-17-09-13 p.114 line 1

⁶⁹¹ 098-267-722

*to meet with them if you feel this would be of any help. If you wish me to arrange this for you please contact my department...*⁶⁹²

5.235 Mrs Burnside acknowledged that *“at the time I wrote the letter I really had very limited knowledge”*⁶⁹³ – *“but I did know that I would have to meet with the family because this family would want explanations.”*⁶⁹⁴ Professor Swainson considered it *“very good of the Chief Executive to take that lead in this particular circumstance.”*⁶⁹⁵

5.236 Mrs Ferguson remembers that *“as time went on, I was getting more annoyed because at this stage Raychel had died and was buried and we still did not know what had happened... We got the letter on the 15th, I remember phoning Altnagelvin, it was a while after that, and I wanted to have a meeting.”*⁶⁹⁶ The family quite simply *“wanted to know why Raychel had died.”*⁶⁹⁷

5.237 Contact was made and a meeting arranged for Monday 3rd September 2001 at the hospital. Mrs Burnside explained that *“it was our practice to be open with patients and their families if and when there was an untoward event.”*⁶⁹⁸ This was therefore the opportunity for Altnagelvin to openly and honestly explain the circumstances of Raychel’s death to her family.

Monday 3rd September meeting

5.238 The meeting took place and was minuted⁶⁹⁹ by Altnagelvin’s ‘Patient Advocate’ Mrs Anne Doherty.⁷⁰⁰ Her note has been accepted as reliable.⁷⁰¹ In attendance were Mrs Ferguson, her brother,⁷⁰² her sister Kay Doherty, Dr Ashenhurst, the family GP, a family friend and Ms Helen Quigley of the WHSSC. Mrs Burnside attended with Drs Nesbitt and McCord, Sister Millar

⁶⁹² 022-085-225

⁶⁹³ Mrs Burnside T-17-09-13 p.137 line 21

⁶⁹⁴ Mrs Burnside T-17-09-13 p.137 line 7

⁶⁹⁵ Professor Swainson T-19-09-13 p.103 line 11

⁶⁹⁶ Mrs Ferguson T-26-03-13 p.167 line 17

⁶⁹⁷ Ms Kay Doherty T-18-09-13 p.169 line 15

⁶⁹⁸ 098-267-724

⁶⁹⁹ 022-084-215

⁷⁰⁰ 328-001-002/ No relation to Kay Doherty

⁷⁰¹ Staff Nurse Bryce T-04-03-13 p.179 line 12

⁷⁰² Ms Kay Doherty T-18-09-13 p.167 line 14

and Staff Nurse Noble. Mrs Burnside explained it was the *“staff who had been involved in Raychel’s care and who wished to meet the family [who] attended the meeting.”*⁷⁰³

5.239 On this occasion the Patient Advocate was not representing the interests of the Ferguson family, nor was she present as an independent advocate but attended at the request of the Chief Executive *“to take minutes.”*⁷⁰⁴ Notwithstanding that Mrs Burnside intended her *“to make whatever notes [she] needed for her to be able to work with the family and support them in whatever way”*⁷⁰⁵ she gave her no instructions to that effect. Accordingly, Mrs Anne Doherty did not introduce herself then or at any time to the Ferguson family⁷⁰⁶ and made no contribution to the meeting.⁷⁰⁷ Subsequently she did not share her minutes with Mrs Ferguson⁷⁰⁸ but sent them directly to Drs Nesbitt and McCord and Sister Millar⁷⁰⁹ and showed them to the Chief Executive.⁷¹⁰ She did not support the family.

5.240 That was a mistake because as Professor Swainson observed *“given the importance, given the sensitivity, given the high emotional state of some of the people participating in that meeting particularly from the family’s perspective, the Patient Advocate had a very important role, particularly if she’d had a pre-meeting with the family because that would have enabled her in advance to understand what the family’s complaints, concerns and enquiries were. It would have enabled her to help them frame them in a way that the senior people at the meeting would understand.”*⁷¹¹

5.241 Notably absent from the meeting were Mr Gilliland and his surgical team. He had been invited to attend but declined on the basis that he had not treated Raychel and thought there was little he could do to ease Mrs Ferguson’s grief.⁷¹² In so doing he acted against the express advice of his

⁷⁰³ WS-046-1 p.6

⁷⁰⁴ WS-325-1 p.4 & 321-076-006

⁷⁰⁵ Mrs Burnside T-17-09-13 p.139 line 13

⁷⁰⁶ WS-326-1 p.5

⁷⁰⁷ Mrs Anne Doherty T-09-09-13 p.22 line 16

⁷⁰⁸ Mrs Anne Doherty T-09-09-13 p.24 line 22

⁷⁰⁹ 321-076-008

⁷¹⁰ WS-325-1p.4 & Mrs Anne Doherty T-09-09-13 p.34 line 2

⁷¹¹ Professor Swainson T-19-09-13 p.108 line 4

⁷¹² Mr Gilliland T-14-03-13 p.217 line 15

Medical Director, Dr Fulton.⁷¹³ Mr Gilliland explained that he *“didn’t think there was a particular surgical issue. I understand now... that there were surgical issues and that there were questions that the family wished to have answers... if they feel that I have let them down at that particular moment in time then I am very sorry.”*⁷¹⁴ Raychel was a surgical patient and suffered from inadequate surgical care. I consider that Mr Gilliland’s failure to attend was a failure of both professional duty and hospital governance.

5.242 Neither the Medical Director nor the Director of Nursing attended the meeting. No external expert or independent figure of authority was in attendance. None of the doctors responsible for treating Raychel before her collapse was present. The meeting convened without Raychel’s medical notes. Furthermore, Mrs Burnside had no record of the Critical Incident Review and claimed not to know that there was disagreement between her nurses and the family about the extent of Raychel’s vomiting.⁷¹⁵ The Chief Executive had neither prepared for nor been briefed for the meeting.

5.243 Nor were the other Altnagelvin representatives prepared.⁷¹⁶ Dr McCord recalled *“there was no agenda, no plan, no prior thought as to who was going to speak. The setting wasn’t good, we arranged ourselves... in a cold blue coloured room, it was an echoey Portakabin.”*⁷¹⁷ Sister Millar recalled she *“didn’t know why [she] was attending or what [she] was supposed to do.”*⁷¹⁸ Professor Swainson considered a *“pre-meeting would have been essential... a central part of the preparation.”*⁷¹⁹

5.244 Mrs Burnside said *“I look back now and think, why didn’t I postpone the meeting, why didn’t I structure it, why didn’t I see what state Mrs Ferguson was in, did we have all of the information that was available? All of those*

⁷¹³ Mr Gilliland T-28-08-13 p. 91 line 6

⁷¹⁴ Mr Gilliland T-14-03-13 p. 216-217

⁷¹⁵ Mrs Burnside T-17-09-13 p.145 line 18

⁷¹⁶ Mrs Burnside T-17-09-13 p.154 line 11

⁷¹⁷ Dr McCord T-10-09-13 p.183 line 1

⁷¹⁸ Sister Millar T-28-08-13 p.156 line 7

⁷¹⁹ Professor Swainson T-19-09-13 p.113 line 19

are lessons that sadly I have learnt and sadly Mrs Ferguson has suffered with, and I'm profoundly sorry that that is so."⁷²⁰

5.245 The meeting cannot have been easy for any of the participants and obviously required care and sensitivity on the part of Altnagelvin. It was necessary for them to effectively communicate the harsh facts of Raychel's death, meaningfully discuss failings in her care and at the same time support a deeply stressed family. Training and preparation for such a difficult meeting were essential.

5.246 A serious breakdown in communication and understanding seems to have occurred at the meeting because Mrs Ferguson recalled leaving *"the meeting totally confused, believing it to be pointless. I remember feeling a sense of Raychel being blamed for her own death or that we were in some way responsible."*⁷²¹ She said *"I look back on this meeting now with some disgust, anger and annoyance, to me it was just a beginning of a cover-up by Altnagelvin Hospital..."*⁷²² *"Even to this day I really do find it very hard not to get agitated and angry looking back at the behaviour of Altnagelvin at that meeting. Their behaviour was appalling as they knew, or must have known, full well what happened to Raychel by that stage."*⁷²³

5.247 This impression of the meeting was not however shared by Mrs Burnside who said that they met *"with the clear understanding that our hospital had not managed to care for that child in a way that would have prevented her dying."*⁷²⁴ She believed *"Mrs Ferguson was given our honest understanding of the issues..."*⁷²⁵ and recalled having offered *"explanations around the following issues, namely the process of Critical Incident Review, the research findings on post-operative reaction leading to hyponatraemia, our subsequent actions to prevent risk of recurrence, and the measures in place to monitor improvement."*⁷²⁶

⁷²⁰ Mrs Burnside T-17-09-13 p.160 line 5

⁷²¹ WS-020-1 p.20

⁷²² WS-020-1 p.20

⁷²³ WS-020-1 p.21

⁷²⁴ Mrs Burnside T-17-09-13 p.114 line 8

⁷²⁵ WS-046-2 p.27

⁷²⁶ WS-046-1 p.7

5.248 Sister Millar supported this account and said that Dr Nesbitt acknowledged deficiencies, was very sympathetic and gave an apology.⁷²⁷ She recalled a *“very long account... I thought it was very fair, I thought it was honest and I thought he was open.”*⁷²⁸ Dr Nesbitt agreed, thinking *“we had been open and honest and helpful”*⁷²⁹ and had *“a clear memory of discussing the reason why I thought Raychel had died... this was not recorded”*⁷³⁰ and Staff Nurse Noble specifically recalled *“Dr Nesbitt saying that she had got a little bit too much fluid.”*⁷³¹

5.249 However, the minute of the meeting records a very different conversation. It makes no reference to the Critical Incident Review, or of failings identified, actions taken or measures put in place. It records nothing about Altnagelvin’s *“subsequent actions to prevent risk of recurrence,”*⁷³² noting only that *“Mrs Burnside said... the hospital would look at things and see if there were ways of improving care.”*⁷³³

5.250 I found it telling that Raychel’s GP, Dr Ashenhurst, had *“no recollection of deficiencies in the care of Raychel being mentioned at the meeting by the representatives.”*⁷³⁴

5.251 Furthermore, I do not consider Sister Millar a reliable witness given that even after she had learned of the many failings in Raychel’s care, she continued to assert to this Inquiry her confidence that Raychel had *“received the highest standard of care from nursing staff in Ward 6”*⁷³⁵ and that she *“had been recovering very well on Friday the 8th.”*⁷³⁶

5.252 The minutes record some most unsatisfactory questions and answers:

⁷²⁷ Sister Millar T-01-03-13 p.79 line 23 *et seq*

⁷²⁸ Sister Millar T-01-03-13 p.82 line 19

⁷²⁹ Dr Nesbitt T-03-09-13 p.240 line 18

⁷³⁰ WS-035-2 p.24

⁷³¹ WS-049-4 p.13

⁷³² WS-046-1 p.7 & Mrs Burnside T-17-09-13 p.155 line 25

⁷³³ 022-084-221

⁷³⁴ WS-333-1 p.3

⁷³⁵ WS-056-1 p.9

⁷³⁶ WS-056-1 p.9

- (i) *“Why did the nurses not look about her when she was so sick and had a sore head? Dr Nesbitt said that on the day following surgery, the first post op. day, people can be sick and have a sore head.”⁷³⁷*
- (ii) *“Raychel was bringing up blood when she vomited why was this? Dr Nesbitt said that when you are vomiting the back of your throat can become irritated and can bleed.”⁷³⁸*
- (iii) *“Mrs Doherty asked what were Raychel’s sodium levels the first time they were done? What is routine? What checks do you do? Dr McCord said bloods are checked routinely on admission. 36 hours prior to this Raychel’s bloods were normal.”⁷³⁹*

5.253 No sincere attempt was made to answer the family’s reasonable questions about the evaluation of Raychel’s sodium levels or her therapy. The minutes record Dr Nesbitt’s questionable explanations⁷⁴⁰ that *“the reason why they were not done routinely is that it requires a needle into the vein to take the blood”⁷⁴¹* and *“the fluids used are the standard across the country... nothing we were doing was unusual.”⁷⁴²* Such understanding Mrs Ferguson may have had as to what happened to her daughter cannot have been assisted. Indeed as her sister Kay Doherty concluded *“we had no more knowledge leaving than what we had when we went in.”⁷⁴³*

5.254 I am satisfied that the Altnagelvin representatives knew a very great deal more than they were prepared to tell the Ferguson family. Only weeks before Mrs Burnside had herself received background briefing on hyponatraemia and been informed that *“the problem today of dilutional hyponatraemia is well recognised...”⁷⁴⁴*

⁷³⁷ 022-084-217
⁷³⁸ 022-084-217
⁷³⁹ 022-084-220
⁷⁴⁰ 022-084-215
⁷⁴¹ 022-084-220
⁷⁴² 022-084-223
⁷⁴³ WS-326-1 p.6
⁷⁴⁴ 021-056-135

- 5.255 In addition and at about the same time as the meeting⁷⁴⁵ Dr Nesbitt was preparing a PowerPoint presentation about Raychel's case entitled "*Fatal Hyponatraemia following surgery*."⁷⁴⁶ In this he identified shortcomings in her treatment and in particular noted that she was a risk patient for SIADH,⁷⁴⁷ had received excessive maintenance fluids,⁷⁴⁸ that her fluid balance documentation was deficient⁷⁴⁹ and that there had been a failure to test her U&Es.⁷⁵⁰ In addition, he made reference to the British Medical Journal "*Lesson of the Week*" which had appeared only two months before Raychel's admission and specifically warned not to "*infuse a hypotonic solution if the plasma sodium concentration is less than 138mmol/L*."⁷⁵¹ These were matters which were not shared with Mrs Ferguson either at the meeting or indeed at any time thereafter as they could and should have been. Even Mrs Burnside "*perceived... that the family was concerned that we weren't telling everything*."⁷⁵²
- 5.256 Mrs Kay Doherty suggested to this Inquiry that "*if they had said openly, and told us... that they had a meeting and that they had discovered problems and they had found things weren't done right, that simple care was not given to Raychel... I don't think we'd all be sitting here today if they had been open and honest with us in that meeting*."⁷⁵³ Regrettably, the Altnagelvin approach demonstrated only limited understanding of what the meeting was really for and what the needs of the family were.
- 5.257 The meeting lasted one hour and fifteen minutes.⁷⁵⁴ Mrs Ferguson gave evidence that "*Dr McCord has told us personally that the meeting was a disaster*."⁷⁵⁵ Unsurprisingly, the Ferguson family did not seek any further meeting with the Chief Executive or the doctors and nurses of Altnagelvin.

⁷⁴⁵ Dr Nesbitt T-03-09-13 p.115 line 10

⁷⁴⁶ 095-010-046ag

⁷⁴⁷ 021-054-120

⁷⁴⁸ 021-054-128

⁷⁴⁹ 021-054-124

⁷⁵⁰ 021-054-124

⁷⁵¹ 070-023b-217

⁷⁵² Mrs Burnside T-17-09-13 p.163 line 11

⁷⁵³ Ms Kay Doherty T-18-09-13 p.184 line 11

⁷⁵⁴ 022-084-224

⁷⁵⁵ Mr and Mrs Ferguson T-26-03-13 p.177 line 14

5.258 Not only did the meeting achieve little that was useful but it actually gave rise to distrust, suspicion and anger, I attribute this to lack of preparation and transparency compounded by insensitivity and poor communication skills. Further, I conclude that relevant information was withheld from the Ferguson family. Such was a serious breach of trust and professional duty and violated Mrs Ferguson's right to know. Mrs Burnside was present, in charge and responsible.

The Ferguson family contact RBHSC

5.259 The Ferguson family, having failed to obtain the answers they wanted from Altnagelvin, sought a meeting with Dr Crean of the RBHSC. This prompted him to contact the Coroner on 11th October 2001 to emphasise that *"there was mismanagement of this case in the Altnagelvin Hospital... The fluid balance was the key to why her condition deteriorated – dilutional hyponatraemia."*⁷⁵⁶

5.260 It was very proper that Dr Crean should have brought this to the Coroner's attention. Nonetheless, there remains the question as to whether he should not also have brought it to the attention of Mr and Mrs Ferguson. He had been Raychel's admitting Consultant to the RBHSC, had joint care of her⁷⁵⁷ and should have felt a general professional obligation, as well as a duty, under paragraph 23 of the GMC's 'Good Medical Practice,' to tell them.⁷⁵⁸ However, the idea of a meeting was not pursued by the Fergusons and the opportunity was lost. It would be harsh to criticise in this regard but it is a matter which should have been considered.

Altnagelvin dissemination

5.261 By way of contrast to the way Altnagelvin communicated with the family, it made admirable, early and sustained efforts to bring her death and the risks

⁷⁵⁶ 012-052c-275

⁷⁵⁷ Dr Crean T-11-09-13 p.19 line 9

⁷⁵⁸ 314-014-012 & Dr Carson T-30-08-13 p.24 line 3

connected with the use of Solution No.18 to the attention of interested parties outside Altnagelvin.

- 5.262 On 18th June 2001, Dr Fulton attended a meeting of hospital Medical Directors in Belfast. It was chaired by Dr Carson, Medical Director of RGHT and Medical Advisor to the Chief Medical Officer ('CMO'). Before the meeting and in conversation with Dr Jim Kelly, Medical Director of the Erne Hospital⁷⁵⁹ Dr Fulton discovered that they had each in their respective hospitals experienced fluid balance problems associated with the use of Solution No.18 and that each had learnt from separate sources that Solution No.18 had been discontinued at the RBHSC.⁷⁶⁰
- 5.263 Dr Kelly believes, in this context, that he told Dr Fulton about the death of a child patient (Lucy Crawford). Dr Fulton is very clear that he did not.⁷⁶¹ The evidence does not convince that Dr Fulton knew about Lucy's case at that time and indeed none of his subsequent actions or communications suggest that he did.
- 5.264 Drs Fulton and Kelly decided that the matter should be raised at the meeting. Dr Fulton recalled how he then outlined the circumstances of Raychel's death and "*told the medical directors present at the meeting that in my opinion there was evidence that Solution 18 was hazardous in post-operative children*"⁷⁶² and "*that there should be regional guidelines.*"⁷⁶³ He recalled other anaesthetists at the meeting acknowledging some 'near misses' in this context.
- 5.265 The meeting was un-minuted and whilst Dr Fulton believes that he referred to the discontinuance of Solution No.18 at the RBHSC, Dr Carson has no such recollection and could "*nearly honestly say that was not raised with me.*"⁷⁶⁴ In any event, Dr Carson acted promptly upon the matter and almost

⁷⁵⁹ Dr Kelly T-13-06-13 p.23 et seq
⁷⁶⁰ Dr Fulton T-04-09-13 p.88 line 18
⁷⁶¹ Dr Fulton T-04-09-13 p.90 line 14
⁷⁶² 095-011-054
⁷⁶³ 012-039-179
⁷⁶⁴ Dr Carson T-30-08-13 p.81 line 10

immediately brought the issue of hyponatraemia and low saline solutions to the attention of Dr Henrietta Campbell, the CMO.

5.266 On 22nd June 2001 Dr Fulton telephoned Dr Campbell personally to inform *“her of circumstances of the death [and] suggested she should publicise the dangers of Hyponatraemia when using low saline solutions in surgical children. I said there was a need for regional guidelines. Dr Campbell suggested that CREST (Regional Guidelines Group) might do this.”*⁷⁶⁵

5.267 Dr Fulton also telephoned Mr Martin Bradley,⁷⁶⁶ Chief Nursing Officer of the Western Area Health Board and notified him of Raychel’s death.⁷⁶⁷

5.268 Additionally he made contact with Dr William McConnell,⁷⁶⁸ Director of Public Health WHSSB, about the case and forwarded the BMJ extracts about hyponatraemia. Dr McConnell in turn raised the matter at the next meeting of Northern Ireland’s Directors of Public Health on 2nd July 2001 in the presence of both the Chief and Deputy Chief Medical Officers. He described the *“recent death in Altnagelvin Hospital of a child due to Hyponatraemia caused by fluid imbalance. Current evidence shows that certain fluids are used incorrectly post operatively. It was agreed that guidelines should be issued to all units.”*⁷⁶⁹ Dr McConnell described this as *“the usual method at that time of raising professional or clinical concerns which had arisen at any one Board, but which potentially, had wider relevance.”*⁷⁷⁰

5.269 On 5th July 2001, Dr McConnell also wrote to his fellow Directors of Public Health enclosing Dr Fulton’s extracts from the BMJ and recommending that the matter be brought to the attention of paediatricians generally. Dr McConnell suggested that for *“more specific information... Dr Fulton would*

⁷⁶⁵ 012-039-180
⁷⁶⁶ 325-002-010
⁷⁶⁷ 095-011-055
⁷⁶⁸ 328-001-005
⁷⁶⁹ 320-080-005
⁷⁷⁰ WS-047-1 p.3

*be happy to discuss this with anyone.*⁷⁷¹ The issue was thus quickly and efficiently disseminated.

- 5.270 Dr Fulton kept his Chief Executive informed of these developments and she in turn reinforced his approach by writing to the CMO to emphasise her concern *“to ensure that an overview of the research evidence is being undertaken. I believe that this is a regional, as opposed to a local hospital issue, and would emphasise the need for a critical review of evidence. I would be extremely grateful if you would ensure that the whole of the medical fraternity learned of the shared lesson.”*⁷⁷² The CMO responded by setting up a working group to draft guidelines and indicated that Dr Nesbitt would be involved.
- 5.271 Taking the issue directly to the CMO was a central part of Altnagelvin’s alert to the medical profession about the risks of hyponatraemia and Solution No.18. They are to be praised particularly, because as Professor Swainson pointed out, *“there was no explicit duty on the Trust to communicate a rare fatal event to the Board or to the Department or more generally.”*⁷⁷³
- 5.272 These very public responses to Raychel’s death stand in disquieting contrast to the failure of the RGHT to share the information about dilutional hyponatraemia and Solution No.18 which had emerged from Adam’s inquest. It provides illustration of how rapid and widespread reporting of a clinical danger can stimulate rapid and meaningful response.

Chief Medical Officer’s Working Group on Hyponatraemia

- 5.273 Preparation of clinical guidelines did not normally come within the CMO’s remit⁷⁷⁴ but she made an exception for hyponatraemia and personally oversaw the process *“because of the level of concern expressed by people at Altnagelvin.”*⁷⁷⁵

⁷⁷¹ 022-094-303

⁷⁷² 022-093-301

⁷⁷³ 226-002-025

⁷⁷⁴ WS-075-2 p.5

⁷⁷⁵ WS-075-2 p.6

- 5.274 Her Working Group first met on 26th September 2001⁷⁷⁶ and drew on the specialism of Drs Taylor, Nesbitt, Loughrey, Crean and Jenkins, amongst others. These doctors had knowledge not only of hyponatraemia and of Raychel's case but also individually of at least some of the other cases being scrutinised by this Inquiry.⁷⁷⁷ Dr Nesbitt confirmed that "*Raychel was mentioned at the meeting because I kept on and on about it.*"⁷⁷⁸
- 5.275 The Working Group produced draft guidelines for the prevention of hyponatraemia in November 2001. However, the draft failed to address Dr Nesbitt's concern that Solution No.18 was of itself a major factor in children's post-operative hyponatraemia. Dr Nesbitt wrote again to the Chair of the Working Group to express disappointment that the guidance made no reference to Solution No.18 and asked "*what evidence do you need exactly. We had a child who died and for that reason I feel strongly that No.18 Solution is an inappropriate fluid to use...You can be sure that it will remain highlighted as a risk in any protocol produced by Altnagelvin Hospital.*"⁷⁷⁹ He was determined that "*Solution No.18 should be named and shamed.*"⁷⁸⁰
- 5.276 However, when the Department published its guidance on the 'Prevention of Hyponatraemia in Children' in March 2002⁷⁸¹ it provided general advices only and did not warn specifically against the use of Solution No.18. The guidelines acknowledged the regional role of the RBHSC by indicating that "*in the event of problems that cannot be resolved locally, help should be sought from Consultant Paediatricians/Anaesthetists at the PICU, RBHSC.*"⁷⁸²

⁷⁷⁶ 007-048-094

⁷⁷⁷ 328-003-001

⁷⁷⁸ Dr Nesbitt T-03-09-13 p.161 line 8

⁷⁷⁹ 007-003-005

⁷⁸⁰ Dr Nesbitt T-03-09-13 p.175 line 18

⁷⁸¹ 077-005-008

⁷⁸² 006-054-438

Post-mortem

5.277 Dr Brian Herron,⁷⁸³ Consultant Neuropathologist⁷⁸⁴ and Dr Al Husaini,⁷⁸⁵ Pathologist, conducted the post-mortem examination of Raychel at the request of the Coroner.⁷⁸⁶ They found diffuse cerebral oedema but no evidence of subarachnoid haemorrhage. They sought the additional opinion⁷⁸⁷ of Dr Clodagh Loughrey,⁷⁸⁸ Consultant Chemical Pathologist, as to the cause of Raychel's hyponatraemia.⁷⁸⁹

5.278 Incorporating her advices, Dr Herron then formally reported his opinion that the cause of death was cerebral oedema secondary to acute hyponatraemia.⁷⁹⁰ He attributed her "*low sodium*" to three factors as identified by Dr Loughrey,⁷⁹¹ namely:

- (i) Infusion of low sodium fluids post-operatively
- (ii) Profuse vomiting in post-operative period
- (iii) Secretion of anti-diuretic hormone.

Preparation for inquest

5.279 In the immediate aftermath of Raychel's death, it had been clearly understood within Altnagelvin that the Coroner had been notified and there were questions of mismanagement. It must have seemed probable that an inquest would be held. Notwithstanding the necessity to gather statements for Critical Incident Review, there was then an even more onerous obligation to obtain statements for inquest.

5.280 Doctors were bound by section 7 of the Coroner's Act (Northern Ireland) 1959 to notify the Coroner of the "*facts and circumstances*" of a death where the doctor had "*reason to believe that the person died, either directly or*

⁷⁸³ 312-003-006
⁷⁸⁴ 312-003-006
⁷⁸⁵ 328-001-004
⁷⁸⁶ 014-005-006
⁷⁸⁷ 014-005-009
⁷⁸⁸ 312-003-005
⁷⁸⁹ 012-063g-322
⁷⁹⁰ 014-005-013
⁷⁹¹ 022-070-179

indirectly as a result of...negligence... or in such circumstances as may require investigation.” Doctors were furthermore obligated by paragraph 32 of the GMC’s ‘Good Medical Practice’ code to “assist the Coroner... by offering all relevant information to an inquest.”⁷⁹²

- 5.281 Mrs Brown⁷⁹³ collected statements for inquest and, although untrained,⁷⁹⁴ guided Altnagelvin and its personnel through the coronial process. She assisted the Coroner in gathering evidence for inquest.⁷⁹⁵ She played a central role liaising with clinicians, solicitors, the Coroner and the Trust Board.⁷⁹⁶
- 5.282 Although Mrs Brown characterised herself as merely “a post-box in getting statements”⁷⁹⁷ she did in fact volunteer to the Coroner those she thought should provide statements and accordingly, had an input into who might give evidence. Additionally she checked the witness statements⁷⁹⁸ and suggested amendments⁷⁹⁹ allowing her an input into the evidence itself. She also forwarded statements to the Trust’s solicitors for approval.⁸⁰⁰
- 5.283 In the week following the Critical Incident Review Staff Nurse Noble and Sister Millar⁸⁰¹ submitted their written statements to Mrs Brown.⁸⁰² Remarkably neither nurse made any reference to the consensus reached at the Critical Incident Review that Raychel had been given too much fluid or that her electrolytes had gone unmeasured in the context of prolonged vomiting.⁸⁰³ Such omission is troubling but that it should pass unquestioned by Mrs Brown is a matter of real concern because she too had been involved with the review. It hints at an understanding that substandard

⁷⁹² 314-014-014 – Issued May 2001

⁷⁹³ WS-322-1 p.24

⁷⁹⁴ WS-322-1 p.23

⁷⁹⁵ WS-322-1 p.24

⁷⁹⁶ WS-322-1 p.24

⁷⁹⁷ Mrs Brown T-02-09-13 p.118 line 4

⁷⁹⁸ WS-322-1 p.24

⁷⁹⁹ Mrs Brown T-02-09-13 p.130 line 25

⁸⁰⁰ WS-322-1 p.24

⁸⁰¹ 022-100a-313

⁸⁰² 021-069-160

⁸⁰³ Sister Millar T-28-08-13 p.137 line 7

treatment might be discussed within the hospital but not volunteered in writing to outsiders.

5.284 Scrutiny of Staff Nurse Noble's statement bearing the date 14th June 2001 and intended for the Coroner⁸⁰⁴ reveals that small but significant changes have been made to her original statement also dated 14th June 2001.⁸⁰⁵ Whilst she offered no explanation for these amendments beyond the suggestion that they may have been made to improve readability, it is clear that her revisions serve to distance her nurses from the warning signals of Raychel's deterioration. This was consistent with a general reluctance within Altnagelvin to concede any shortcomings in writing. Mrs Brown did nothing to discourage this approach.

5.285 Indeed, it appears to have been a part of Mrs Brown's role to ensure that clinicians did not easily make personal admissions of error. The Altnagelvin 'Junior Doctors' Handbook' specifically directed that doctors should *"not release any report to the police or coroner without showing it first to the Trust RMCO. This is particularly important when the family of the deceased have employed a barrister to represent them in court, or if you feel that an allegation of medical negligence will be made in court."*⁸⁰⁶

5.286 Dr McCord and Nurse Michaela Rice⁸⁰⁷ also provided statements in June 2001.⁸⁰⁸ Remarkably, no further statements were taken by Mrs Brown at that time, whether from the consultant responsible for Raychel's care or the doctors who had treated her before collapse.

5.287 The Coroner wrote to Mrs Brown on 17th October 2001 advising *"that questions must be asked regarding the management of this child whilst a patient at Altnagelvin Hospital... It would greatly assist me if you would arrange to let me have as soon as possible statements from all those concerned with the case..."*⁸⁰⁹ Three weeks passed before Mrs Brown

⁸⁰⁴ 012-008-100
⁸⁰⁵ Staff Nurse Noble T-27-08-13 p.151-56
⁸⁰⁶ 316-004a-026
⁸⁰⁷ 312-003-005
⁸⁰⁸ 022-104-319 & 022-099-311
⁸⁰⁹ 022-081-212

wrote to a small group of clinicians requesting statements with the reassurance that *"your report will be forwarded to our solicitor prior to release to the Coroner."*⁸¹⁰ She chose not to ask those doctors who had attended upon Raychel on 8th June.⁸¹¹ The Coroner was thereafter obliged to repeatedly remind Mrs Brown on 29th November,⁸¹² on 5th December,⁸¹³ and 11th December 2001⁸¹⁴ to forward the statements. When Mrs Brown received a statement from Dr Johnston, on 21st December 2001,⁸¹⁵ she noted his reference to Drs Curran and Zafar and wrote *"I have not requested reports from these doctors, as they have not written in the notes."*⁸¹⁶ I find it extraordinary that six months after Raychel's death and the Critical Incident Review and even when confronted with a potentially controversial inquest that Mrs Brown should not have identified the clinicians involved. Dr Zafar was the most senior member of the surgical team to have seen Raychel on 8th June⁸¹⁷ and he saw her again after her collapse on 9th June. Had a documented review been undertaken or had Mrs Brown been genuinely motivated she would have known who the relevant clinicians were and would have already held statements from them.

5.288 On 25th January 2002, Mrs Brown purported to send nine witness statements to the Coroner⁸¹⁸ but her letter enclosing the nine statements went *"astray."*⁸¹⁹ She did, however, forward her draft list of witnesses for the Coroner from which she omitted all the surgical doctors.

5.289 On 25th March 2002, Mrs Brown finally received Dr Zafar's statement.⁸²⁰ It was not her fault that all he could contribute was that *"I saw Rachael [sic] Ferguson on 8th June 2001, who had appendectomy operation on 7th June*

⁸¹⁰ 022-079-207

⁸¹¹ Dr Devlin T-06-03-13 p.3 line 4 & Dr Curran T-07-03-13 p.1 line 18

⁸¹² 022-072-187

⁸¹³ 022-070-170

⁸¹⁴ 022-068-167

⁸¹⁵ 012-013-114

⁸¹⁶ 160-207-001

⁸¹⁷ 020-007-013

⁸¹⁸ 022-054-151

⁸¹⁹ 012-050g-246

⁸²⁰ 160-239-001

2001. *On my ward round she was free of pain and apyrexial, plane [sic] was to [sic] continuous observation.*⁸²¹

5.290 The inquest was listed for 10th April 2002. It was not, however, until 6th March 2002 that a 'complete' set of Altnagelvin statements was forwarded to the Coroner.⁸²² The inquest hearing was adjourned.⁸²³ Mrs Brown wrote to Dr Zafar returning his *"draft statement. Please amend. I enclose a statement from Dr Johnston."*⁸²⁴ Dr Zafar duly obliged adding a paragraph⁸²⁵ derived from Dr Johnston's statement⁸²⁶ which was then sent unsigned to the Coroner.⁸²⁷

5.291 The gathering of written statements for the Coroner lacked rigour and mirrored the collection of written evidence for Critical Incident Review. What was required was clear. That which was gathered in writing was not. I do not believe that was entirely accidental.

Altnagelvin writes to the Coroner

5.292 On 11th December 2001, the Coroner engaged Dr Edward Sumner to investigate Raychel's death on his behalf.⁸²⁸ Dr Sumner reported in February 2002 that Raychel had died from coning in consequence of cerebral oedema caused by hyponatraemia⁸²⁹ and that the *"hyponatraemia was caused by a combination of inadequate electrolyte replacement in the face of severe post-operative vomiting and the water retention always seen post-operatively from inappropriate secretion of ADH"*⁸³⁰ The Coroner forwarded this to Mrs Brown on 18 February 2002.⁸³¹

5.293 On 12th March 2002, Mrs Brown advised the Chief Executive that *"some of the clinical staff have come back and advised me that there are factual*

⁸²¹ 160-239-001
⁸²² 022-038-099
⁸²³ 021-001a-002
⁸²⁴ 021-001a-002
⁸²⁵ 021-059-143
⁸²⁶ 021-058-141
⁸²⁷ 022-023-064
⁸²⁸ 012-067u-365
⁸²⁹ 012-001-001
⁸³⁰ 012-001-005
⁸³¹ 160-197-001

inaccuracies in [Dr Sumner's] Report."⁸³² It is remarkable that not even in these circumstances did Mrs Burnside insist on a written report of her own Critical Incident Review.

5.294 Mrs Brown drew those claimed inaccuracies to the attention of the Trust solicitor,⁸³³ who then wrote to the Coroner on 29th March stating that *"the Trust has taken this tragic incident very seriously and has fully and promptly investigated this matter"*⁸³⁴ and *"fully accepts that the cause of death in this case was cerebral oedema due to hyponatraemia... It is also accepted that the vomiting experienced by the Deceased was a contributory factor in that it would have contributed to some extent to the net sodium loss from the extracellular fluid. Further, it is accepted that the use of Solution 18...in order to provide post-operative maintenance and replacement fluids was a contributory factor in bringing about a reduction in the concentration of sodium in the extracellular fluid."*⁸³⁵

5.295 However, the solicitor then proceeded to very pointedly question Dr Sumner's opinion that Raychel had suffered very severe and prolonged vomiting. This had not been amongst those inaccuracies drawn to her attention by Mrs Brown. She wrote *"this conclusion is strongly disputed by the Trust. The nurses who were caring for the Deceased during the relevant period have been interviewed in detail about this matter and they are all of the opinion that the vomiting suffered by the Deceased was neither severe nor prolonged."*⁸³⁶ She concluded her letter by claiming that *"the Trust wished me to bring these matters to your attention well in advance of the hearing of the inquest."*⁸³⁷

5.296 Notwithstanding these assertions, Mrs Brown was very clear in her evidence that the nurses *"were never interviewed in detail."*⁸³⁸ Furthermore, Sister Millar had *"no recollection of being separately interviewed"*⁸³⁹ and in

⁸³² 022-036-097

⁸³³ 160-183-001

⁸³⁴ 160-163-002

⁸³⁵ 160-163-001

⁸³⁶ 160-163-003

⁸³⁷ 160-163-004

⁸³⁸ Mrs Brown T-02-09-13 p.144 line 5

⁸³⁹ Sister Millar T-28-08-13 p.161 line 25

any event, Staff Nurse Noble considered Raychel's vomiting to have been both severe and prolonged.⁸⁴⁰ I conclude that in respect of this claim alone the letter was factually incorrect and had therefore, as Mrs Brown put it "a *potential to mislead*."⁸⁴¹

5.297 The Chief Executive maintained that she had not seen the letter⁸⁴² and did not "*believe the Trust would have sanctioned the letter. I think the Trust would have briefed the legal advisor about their concerns and the legal advisor would have, within their expertise, laid out those concerns as they interpreted them.*"⁸⁴³ She said she took the "*dimmiest view*" of any intention to mislead.⁸⁴⁴ So do I, not least because the Ferguson family had received Mrs Burnside's personal assurances that they "*could have confidence that their concerns would be addressed thoroughly through the Coroner's court.*"⁸⁴⁵

5.298 The Coroner's response to Altnagelvin's solicitor's letter was terse: "*So far as the point you made regarding vomiting I have no objection to receiving evidence from any nurses who are in a position to give relevant evidence.*"⁸⁴⁶ The Coroner met with the Ferguson family on 3rd April 2002 and adjourned the inquest to allow them legal representation.⁸⁴⁷

5.299 Efforts were then made to gather evidence to corroborate the solicitor's assertions. Mrs Brown sought a statement from Staff Nurse Gilchrist in the following terms: "*Dr. Nesbitt and I met with the barrister yesterday. The barrister feels it is important that we counteract the comments made by Dr. Sumner, the independent expert in relation to the allegation of excess vomiting. To do this he feels it is important that we bring along the nursing staff. If nursing staff do not attend then it would be difficult for anyone to explain what is meant by the ++ in the notes. The Barrister is endeavouring to get permission from the Coroner for the nurses to attend. I require a*

⁸⁴⁰ Staff Nurse Noble T-27-02-13 p.172 line 6 & Staff Nurse Noble T-27-08-13 p.202 line 2

⁸⁴¹ Mrs Brown T-02-09-13 p.152 line 16

⁸⁴² Mrs Burnside T-17-09-13 p.192 line 5

⁸⁴³ Mrs Burnside T-17-09-13 p.240 line 22

⁸⁴⁴ Mrs Burnside T-17-09-13 p.192 line 8

⁸⁴⁵ WS-046-1 p.7

⁸⁴⁶ 022-026-069

⁸⁴⁷ 098-137-425

*statement from you on your involvement as soon as possible.*⁸⁴⁸ Staff Nurse Gilchrist duly supplied a statement,⁸⁴⁹ purporting to have been “*written on 10th June 2001*”⁸⁵⁰ confirming that she had not been concerned by Raychel’s vomiting because it was not unusual in post-operative children. However, when she came to give evidence to this Inquiry she accepted that “*Raychel’s vomiting was severe and prolonged.*”⁸⁵¹

Altnagelvin reviews progress and prepares for inquest

5.300 Dr Fulton having retired from his post as medical director, nonetheless arranged a pre-inquest meeting on 9th April 2002 with the Altnagelvin witnesses, namely Mr Gilliland and Drs Nesbitt, McCord and Makar.⁸⁵² On the same day he reviewed the implementation of his action plan.⁸⁵³ This was an important review and examined the plan in light of the Department’s Guidelines on Hyponatraemia⁸⁵⁴ and considered the availability of surgeons for paediatric patients and their responsibilities in respect of fluid therapy. It laid the basis for a new clinical protocol to be agreed in May 2002 between surgeons, anaesthetists and paediatricians in respect of paediatric IV fluid therapy.⁸⁵⁵ This was a local protocol of real value⁸⁵⁶ and provides demonstrable evidence of the sincerity of professional intent at Altnagelvin in almost everything except the open acceptance of error and the transparent provision of information and respect to the Ferguson family.

5.301 Meanwhile, Mrs Brown co-ordinated the Altnagelvin preparation for inquest.⁸⁵⁷ In addition to challenging any suggestion of a failure to respond to Raychel’s vomiting she started to bring together evidence to mitigate Altnagelvin’s position. To that end, Dr Fulton, having failed to prepare a written report of his Critical Incident Review for his Chief Executive, now provided a statement for the Coroner detailing his work investigating “*the*

⁸⁴⁸ 022-017-056

⁸⁴⁹ 098-293-771

⁸⁵⁰ Mrs Brown T-02-09-13 p.75 line 9 & Dr Fulton T-04-09-13 p.50 line 11

⁸⁵¹ Staff Nurse Gilchrist T-11-03-13 p.134 line 6

⁸⁵² 022-029-073

⁸⁵³ 026-002-002 & 022-092-299

⁸⁵⁴ 022-025a-068 & WS-046-2 p.132

⁸⁵⁵ 160-143-003

⁸⁵⁶ 021-052-113 & 021-050a-108 & 077-004-005

⁸⁵⁷ Dr Fulton T-04-09-13 p.108 line 7 & p.109 line 1

*circumstances of her death within the hospital and... recommendations for any action to prevent recurrence.*⁸⁵⁸ Although Dr Fulton was not on the list of witnesses, his statement was forwarded to the Coroner who was asked to confirm that he would be called to give evidence.⁸⁵⁹ The Coroner replied that *"so far as Dr. Fulton is concerned whilst it is not strictly necessary for him to give evidence, I can understand why the Trust might wish to put in evidence the response to the death of Rachel [sic]."*⁸⁶⁰ The Coroner thus allowed him to be called as a witness.

5.302 In addition, on 1st May 2002, Dr Nesbitt wrote to the CMO *"to know if any... guidance was issued by the Department of Health following the death of a child in the RBHSC which occurred some five years ago and whose death the Belfast Coroner investigated. I was unaware of the case and am somewhat at a loss to explain why. I would be grateful if you could furnish me with any details of that particular case for I believe that questions will be asked as to why we did not learn from what appears to have been a similar event."*⁸⁶¹ The CMO responded by reassuring Dr Nesbitt that *"This Department was not made aware of the case at the time either by the Royal Victoria Hospital or the Coroner. We only became aware of that particular case when we began the work of developing guidelines following the death at Altnagelvin."*⁸⁶²

5.303 Mrs Brown was then able to advise the Chief Executive that *"the positive aspects of the case are... the action taken following the death and again it is hoped that Dr. Fulton will be able to give evidence in relation to his actions following the tragic incident. The other positive note is the letter dated May of this year from Dr. Campbell to Dr. Nesbitt and the barrister is keen to*

⁸⁵⁸ 022-089-295
⁸⁵⁹ 012-070k-397
⁸⁶⁰ 160-106-001
⁸⁶¹ 022-091-298
⁸⁶² 022-090-297

*exploit this issue.*⁸⁶³ To that end Dr Nesbitt's letter to the CMO⁸⁶⁴ and her reply⁸⁶⁵ were sent directly to the Coroner himself.⁸⁶⁶

Altnagelvin commissions independent expert opinion

- 5.304 The inquest was re-listed for 26th November 2002.⁸⁶⁷ Counsel retained to act on behalf of the Trust directed that the Trust's solicitor obtain a report *"from an independent Consultant Paediatric Anaesthetist who should comment [on] management of this case, the contents of Dr. Sumner's report and the steps taken by the Trust following this incident to ensure that such an incident could not occur again..."*⁸⁶⁸
- 5.305 On 1st November 2002⁸⁶⁹ the Trust's solicitor sought the independent expert opinion, not of a consultant paediatric anaesthetist, but of Dr John G. Jenkins,⁸⁷⁰ who was a consultant paediatrician. He was nonetheless well qualified, being a member of the CMO's Working Group on Hyponatraemia⁸⁷¹ and the same expert who had some months before provided the same solicitors with a report on the care, treatment and death of Lucy Crawford.⁸⁷²
- 5.306 He was briefed with a full Schedule of Documents⁸⁷³ excepting only that Dr Fulton's Critical Incident Review plan was omitted⁸⁷⁴ and disturbingly a copy of Altnagelvin's 'draft press statement'⁸⁷⁵ for release after inquest, included. This statement asserted that *"it is important to be aware that the procedures and practices put into effect in the care of Raychel following her operation were the same as those used in all other area hospitals in Northern Ireland."* This inclusion was inexcusable in that not only was it known to be untrue but it blatantly suggested Altnagelvin's preferred opinion to the independent

⁸⁶³ 022-017-052

⁸⁶⁴ 022-091-298

⁸⁶⁵ 022-090-297

⁸⁶⁶ 012-070k-396

⁸⁶⁷ 012-056-286

⁸⁶⁸ 022-019-060

⁸⁶⁹ 172-002-001

⁸⁷⁰ 312-003-007

⁸⁷¹ WS-059-1 p.1

⁸⁷² 013-011-037

⁸⁷³ 172-002-002

⁸⁷⁴ Dr Jenkins T-10-09-13 p.131 line 13

⁸⁷⁵ 172-002-043

witness. Although this was Dr Jenkins' first experience of drafting a report for an inquest,⁸⁷⁶ he wisely "*didn't really take notice of it.*"⁸⁷⁷

5.307 Dr Jenkins' initial view was that Raychel's vomiting "*needed to be looked at in more detail as a particularly important aspect*"⁸⁷⁸ and "*an area which required clarification. Dr Sumner had reached a view which differed from that of the staff who'd been providing care, so... it was important that this was something which needed to be elucidated.*"⁸⁷⁹ Accordingly, he concluded his opinion dated 12th November 2002 by observing that "*while it was possible in retrospect to form the opinion reached by Dr. Sumner that Raychel must have suffered severe and prolonged vomiting, this does not seem to have been the assessment of her condition made by experienced staff at the relevant time*" and it was thus "*important that further details are obtained of relevant nursing and medical procedures and management in relation to fluid administration and post-operative monitoring of fluid intake, urine output and other losses such as vomiting. In particular information needs to be obtained regarding the local policy for post-operative fluid administration in children. Was the prescribed regime in this case in keeping with this guidance?*"⁸⁸⁰ However, no further information on these important matters was to be forthcoming to Dr Jenkins.⁸⁸¹

5.308 His opinion may not have been thought sufficient for Altnagelvin's purposes because on 3rd December 2002 another report was commissioned, this time from Dr Declan Warde,⁸⁸² of the Children's University Hospital Dublin who was a Consultant Paediatric Anaesthetist.⁸⁸³ Dr Warde, having agreed to "*attend the inquest hearing on behalf of the Trust*" was specifically asked to "*comment on the treatment provided and the issues raised by Dr. Sumner.*"⁸⁸⁴ The inquest was further adjourned to 5th February 2003.⁸⁸⁵

⁸⁷⁶ Dr Jenkins T-10-09-13 p.92 line 11

⁸⁷⁷ Dr Jenkins T-10-09-13 p.82 line 2

⁸⁷⁸ Dr Jenkins T-10-09-13 p.84 line 20

⁸⁷⁹ Dr Jenkins T-10-09-13 p.90 line 22

⁸⁸⁰ 022-010a-041

⁸⁸¹ Dr Jenkins T-10-09-13 p.91 line 12

⁸⁸² 312-003-007

⁸⁸³ 160-083-001

⁸⁸⁴ 160-083-001

⁸⁸⁵ 012-059-292

- 5.309 Dr Warde's report was received by the Trust solicitor on 19th January 2003.⁸⁸⁶ He gave it as his opinion that Raychel had *"died as a result of developing cerebral oedema secondary to acute hyponatraemia, which was itself caused by a combination of severe and protracted post-operative vomiting, SIADH and the administration of intravenous fluid with a low sodium content."*⁸⁸⁷ This was even less supportive of Altnagelvin's position than Dr Jenkins' opinion and flatly contradicted the contention that the vomiting was neither severe nor prolonged. The Report was sent to Dr Jenkins who was asked for *"any further comments which you have which might assist the Trust."*⁸⁸⁸ The wording of this request is regrettable because it was open to misinterpretation and in any event, Dr Jenkins' paramount responsibility was always to assist the Coroner.
- 5.310 Dr Jenkins commented on 27th January 2003 that *"Dr. Warde again makes reference to the significance of the vomiting. I pointed out in my report of 12th November 2002 the importance of seeking further information regarding the frequency and severity of Raychel's vomiting in the opinion of senior staff... I have also not been provided with any further details of relevant nursing and medical procedures and management in relation to fluid administration and post-operative monitoring of fluid intake, urine output and other losses such as vomiting."*⁸⁸⁹
- 5.311 On 28th January 2003, the Trust's solicitors informed Dr Warde that his services were not required at the inquest⁸⁹⁰ and Dr Jenkins' attendance for 5th February was confirmed.⁸⁹¹
- 5.312 Dr Jenkins then produced his third and final report dated 30th January 2003⁸⁹² from which he omitted much that he had been included in his earlier reports. All reference to Raychel's vomiting, the amount of fluid administered and his requests for further information was excised. He

⁸⁸⁶ 160-046-001
⁸⁸⁷ 022-006-023
⁸⁸⁸ 160-045-001
⁸⁸⁹ 022-004-013
⁸⁹⁰ 160-044-001
⁸⁹¹ 012-070b-386
⁸⁹² 022-004-010

made no mention of Dr Warde's report and concluded that "*having carefully studied the statements provided by the doctors and nurses involved in Raychel's care my opinion is that they acted in accordance with the established custom and practice in the Unit at that time.*"⁸⁹³

5.313 Dr Jenkins' "best guess" as to how this came about was "*that I was asked to re-format my report and to concentrate on the aspects of the development of guidance*"⁸⁹⁴ and accordingly, "*my third report, the report for the Coroner, was specifically addressing the broader issues.*"⁸⁹⁵ This was regrettable because an independent expert can never be truly independent if placed under direction. Dr Jenkins having been asked for "*an independent view re treatment for inquest hearing*"⁸⁹⁶ and having agreed to prepare a report on the matter⁸⁹⁷ was perhaps naive in the circumstances to consider that the Trust "*was within their rights to advise me as to what aspects of the matter I should provide a report on for the Coroner.*"⁸⁹⁸ It appears likely that 'editorial' control was exerted by lawyers representing Altnagelvin.⁸⁹⁹ Entitlement to legal privilege was asserted by Altnagelvin which frustratingly precluded any further investigation of this important matter.

5.314 It was Dr Jenkins' third report alone which was sent to the Coroner⁹⁰⁰ and subsequently incorporated into his deposition at inquest.⁹⁰¹ The Coroner was thus led to believe that the sole expert opinion held by Altnagelvin was Dr Jenkins' third report⁹⁰² and that represented the totality of his relevant opinion.

5.315 Dr Jenkins was able "*in retrospect*" to appreciate that it would have been "*very sensible*"⁹⁰³ to include his own observations where relevant for the

⁸⁹³ 022-004-011

⁸⁹⁴ Dr Jenkins T-10-09-13 p.106 line 11

⁸⁹⁵ Dr Jenkins T-10-09-13 p.108 line 11

⁸⁹⁶ 160-113-002

⁸⁹⁷ 172-002-001

⁸⁹⁸ Dr Jenkins T-10-09-13 p.104 line 2

⁸⁹⁹ Dr Jenkins T-10-09-13 p.114 line 22

⁹⁰⁰ 012-070b-386

⁹⁰¹ 012-030-153

⁹⁰² 012-070b-386

⁹⁰³ Dr Jenkins T-10-09-13 p.106 line 24

Coroner and recognised *“in retrospect that it would have been a more sensible thing”*⁹⁰⁴ not to omit comment previously considered relevant.

5.316 Significantly, the Trust did not share Dr Warde’s report with the Coroner either. Nor was it shared with the Ferguson family (or indeed later with the PSNI). The Coroner was not told that Altnagelvin was in possession of an opinion from a second consultant paediatric anaesthetist let alone one which supported Dr Sumner’s views. A decision must have been taken to withhold the report. Dr Nesbitt believes *“that this would have been a decision made by the Chief Executive”*⁹⁰⁵ but Mrs Burnside claimed *“no knowledge of why and how it did not go to the Coroner.”*⁹⁰⁶ Others said that this non-disclosure was upon the advice of the Altnagelvin’s legal advisors⁹⁰⁷ acting in liaison with Mrs Brown.⁹⁰⁸ It was not at all what the Coroner expected of them.⁹⁰⁹ Mr Leckey acknowledged that *“there may be an issue raised of privilege. What I would say is, are we not investigating in this case the death of a child and let’s not dwell on legal niceties first. We want to get to the truth.”*⁹¹⁰

5.317 Professor Swainson advised that *“the principle I would adhere to is that you make a full disclosure of whatever information you have because of two reasons. One is it helps the process, it can only be helpful. Secondly, if you don’t, it’ll come out later anyway... So my overriding principle is that in these circumstances your duty is to assist the Court, or whatever, as far as you are able. I have been advised by my solicitors previously not to either submit a report or submit it in a different form and I’ve been happy to discuss that, but I have never agreed to not submitting a report that was available that would have been of clear relevance to court proceedings.”*⁹¹¹

5.318 Had Altnagelvin been sincerely motivated to assist the Coroner it would undoubtedly have shared Dr Warde’s publicly funded expert opinion with

⁹⁰⁴ Dr Jenkins T-10-09-13 p.109 line 6

⁹⁰⁵ WS-035/2 p.31

⁹⁰⁶ Mrs Burnside T-17-09-13 p.164 line 5

⁹⁰⁷ Mrs Brown T-02-09-13 p.177 line 5 & Mrs Margaret Doherty T-09-09-13 p.43 et seq

⁹⁰⁸ Dr Fulton T-04-09-13 p.112 line10

⁹⁰⁹ Mr Leckey T-25-06-13 p.110 line 8 & p.109 line 23

⁹¹⁰ Mr Leckey T-25-06-12 p.109 line 23

⁹¹¹ Professor Swainson T-19-09-13 p.134 line 17

him, just as the Coroner shares with the public those expert opinions commissioned by him.⁹¹² It is hard to understand what public interest is served by withholding such a report. Notwithstanding that Altnagelvin was not legally obliged to submit Dr Warde's report – it is hard not to conclude that the wrong approach was taken.

- 5.319 The Altnagelvin preparation for inquest was calculated and defensive. I interpret the actions of those involved on behalf of Altnagelvin as having been primarily motivated by a misguided desire to avoid the risk of criticism and to portray the hospital in the best possible light. If a culture of defensiveness characterised the responses of the clinicians involved it also marked those engaged with this aspect of governance.
- 5.320 Additionally, I wish to record my disappointment that the Trust should have withheld documentation from this Inquiry on the basis of legal privilege. This has not assisted. It can only inflame suspicion of 'cover-up'. Whilst I fully recognise the Trust's legal right to assert privilege I do not necessarily consider it ethical. In this context, I am influenced by the contrast between Altnagelvin's promises of unqualified co-operation with the work of the Inquiry and the reality. In November 2004, the Trust issued a statement to the press assuring that "*Altnagelvin will co-operate fully and without equivocation with this Inquiry*"⁹¹³ and in addition Mrs Burnside wrote to me personally "*that Altnagelvin will give its fullest co-operation to the Inquiry team.*"⁹¹⁴ Lest there could have been any doubt the Trust solicitors then also wrote to the Ferguson family solicitor on 30th June 2005 to confirm "*it is our client's intention and duty to assist the Inquiry in every way possible and to participate fully in its investigations.*"⁹¹⁵ It is therefore a matter of regret that Altnagelvin should, for whatever reason, have failed to honour its pledges.

⁹¹² 012-070p-405

⁹¹³ 021-010-025

⁹¹⁴ 021-009-021

⁹¹⁵ 326-002-001

Inquest

- 5.321 The inquest into Raychel's death opened on 5th February 2003 before H.M. Coroner, Mr John Leckey,⁹¹⁶ and heard evidence over the course of 4 days from 16 witnesses including Mrs Ferguson. Whilst there is no formal transcript of the proceedings, a very full note was taken by the Trust's solicitor.⁹¹⁷ Expert evidence was received from Drs Herron, Sumner and Jenkins.
- 5.322 Dr Heron's autopsy findings were unchallenged and Dr Jenkins having listened to the evidence of Dr Sumner "*suddenly realised that Dr Sumner and indeed Dr Warde had evidence [918] to support their conclusions and I was content with that evidence.*"⁹¹⁹ Accordingly, he "*stated that he concurred with all the views expressed by Dr. Sumner.*"⁹²⁰ This was very proper, not least because the Coroner did not have the benefit of Dr Warde's evidence.
- 5.323 Furthermore, Dr Jenkins made reference in his evidence to the "*tragic death of two children in Northern Ireland*" from hyponatraemia.⁹²¹ This, which was an intended reference to Lucy Crawford's death, was misunderstood as a reference to Adam Strain, and Lucy's death remained unknown to the Coroner. This was unfortunate given that it was known to Altnagelvin's legal advisors.
- 5.324 No evidence was given by the doctors who had actually seen Raychel on Ward 6 on 8th June 2001. Evidence was, however, received from Drs Gund, Jamison, Johnston and Trainor who neither cared for Raychel on the ward nor attended the Critical Incident Review. Drs McCord, Nesbitt and Fulton together with Mr Gilliland did however give evidence.

⁹¹⁶ 328-001-005

⁹¹⁷ 160-010-001 *et seq*

⁹¹⁸ 160-010-015: i.e. the evidence relating to the abnormality of the electrolyte results which was interpreted as indicative that the vomiting must have been severe (Dr Jenkins T-10-09-13 p.116 line 6)

⁹¹⁹ Dr Jenkins T-10-09-13 p.117 line 7

⁹²⁰ 012-064-323

⁹²¹ 022-004-011

- 5.325 Mr Foster was concerned that two key members of the surgical team failed to attend.⁹²² Dr Makar was on leave and Dr Zafar was sitting exams.⁹²³ This was regrettable but consistent with the established detachment of the surgical team from the case. It did not however unduly concern the Coroner or prevent him from reaching a finding.⁹²⁴
- 5.326 Dr Nesbitt who was Altnagelvin's new Medical Director, was the most senior Trust representative at the inquest. He chose not to tell the Coroner about those deficiencies in treatment identified by him and described in his PowerPoint presentation. Whilst he conceded that there were no blood tests on 8th June⁹²⁵ he did not indicate that he regarded this as relevant or a failing. Whilst he steadfastly maintained that he "*did not withhold anything from the Coroner*"⁹²⁶ it is clear that he could have volunteered more. Whilst it may not have made any difference I am of the view that he could and should have proffered more information to the Coroner about what he knew to be relevant.
- 5.327 The Coroner was given the perspective of the surgical team by Mr Gilliland who gave evidence that he was "*not sure blood test should have been done as vomiting common and [Raychel was] being treated appropriately,*"⁹²⁷ that it was "*not commonplace to measure urine output in routine appendectomy*",⁹²⁸ that he "*would not expect a member of surgical team to be told child vomited*"⁹²⁹ and that Dr Curran, who had prescribed the second anti-emetic did not, as a junior, need to "*pass decision to a senior.*"⁹³⁰ Given what Mr Gilliland must have known about Dr Fulton's action plan to address the clinical failings identified at Critical Incident Review,⁹³¹ I consider his evidence to have been generally unhelpful and in some respects to have been misleading.

⁹²² 223-002-029

⁹²³ 223-002-029

⁹²⁴ 160-010-032

⁹²⁵ 160-010-038

⁹²⁶ Dr Nesbitt T-03-09-13 p.156 line 11

⁹²⁷ 160-010-041

⁹²⁸ 160-010-041

⁹²⁹ 160-010-042

⁹³⁰ 160-010-042

⁹³¹ Mr Gilliland T-14.03.13 p.164 line 11

- 5.328 Both Dr Nesbitt and Mr Gilliland were subject to the GMC obligation to “assist the Coroner by... offering all relevant information to an inquest or inquiry into a patient’s death.”⁹³² I do not believe that they honoured that obligation.
- 5.329 Sister Millar and Staff Nurses McAuley and Noble gave the nursing evidence. Sister Millar said the “nurses [were] experienced, childrens’ trained”,⁹³³ that Raychel’s case was not unusual,⁹³⁴ that she “was happy she would be fine”⁹³⁵ and she had “seen many children vomit post-appendectomy... have seen patients vomit more.”⁹³⁶ They agreed that Raychel’s vomiting had not been a cause for concern.
- 5.330 Sister Millar told the Coroner that the record of vomits was not unusual.⁹³⁷ She failed to mention that the fluid balance documentation was poor⁹³⁸ or that the Ferguson family had been concerned about its severity.⁹³⁹ Nor was the Coroner told that an internal Critical Incident Review had agreed that the vomiting was prolonged.
- 5.331 The Coroner was further led to believe by Sister Millar that junior surgical doctors were readily available for their surgical patients on Ward 6,⁹⁴⁰ notwithstanding that she had made their non-availability an issue at the Critical Incident Review.⁹⁴¹ Sister Millar accepted that she ought to “have expanded”⁹⁴² on these matters for the Coroner. I consider that her failure ‘to expand’ was disingenuous and a breach of her professional duty of truthfulness.⁹⁴³
- 5.332 Staff Nurse McAuley also gave evidence that Raychel’s vomiting was not unusual and had given her no cause for concern.⁹⁴⁴ Staff Nurse Noble told

⁹³² 314-014-014

⁹³³ 160-010-047

⁹³⁴ 160-010-047

⁹³⁵ 160-010-050

⁹³⁶ 160-010-051

⁹³⁷ 160-010-051

⁹³⁸ Sister Millar T-28-08-13 p.172 line 18

⁹³⁹ Sister Millar T-28-08-13 p.174 line 4

⁹⁴⁰ 160-010-050

⁹⁴¹ 022-097-038

⁹⁴² Sister Millar T-28-08-13 p.172 line 4

⁹⁴³ UKCC ‘Guidelines for Professional Practice’ (1996) 314-003-016

⁹⁴⁴ 160-010-051

the Coroner that she had nursed patients who had vomited more and that it was “*not unusual to have patients who vomited post-operatively.*”⁹⁴⁵

5.333 It is hard to conceive that these witnesses could have agreed one thing at Critical Incident Review and then said another at inquest had the Critical Incident Review been recorded and a report prepared.

5.334 Nonetheless, and having heard this evidence the Coroner seemed to have little difficulty in reaching the verdict that Raychel’s “*hyponatraemia was caused by combination of inadequate electrolyte replacement in the face of severe post-operative vomiting and water retention resulting from the inappropriate secretion of ADH (anti-diuretic hormone).*”⁹⁴⁶ He thus firmly rejected the Altnagelvin contention that the vomiting was “*neither severe nor prolonged*”⁹⁴⁷ and confirmed that the electrolyte replacement therapy was inadequate in the circumstances. It was a damning verdict on the care and treatment given Raychel at Altnagelvin.

RBHSC engagement with inquest

5.335 The RBHSC was also represented at the inquest and Dr Crean was its only witness. In preparation for the hearing Mr Brangam, its solicitor, wrote to Mr Walby of the RGHT Litigation Management Office that “*At first blush I cannot see how the Trust can be implicated in the tragic circumstances surrounding the treatment given to the child and the subsequent demise at RBHSC. Dr. Crean has indicated to me that the facts surrounding an earlier matter (Adam Strain deceased) were not on all fours with the present case, but, I believe, it would be prudent for you to speak directly with Dr. Ian Carson in relation to this matter, particularly, given it would appear that the Department has some knowledge of the circumstances surrounding this particular incident.*”⁹⁴⁸ Dr Carson was by then Deputy Chief Medical Officer.⁹⁴⁹

⁹⁴⁵ 160-010-055

⁹⁴⁶ 012-026-139-140

⁹⁴⁷ 160-163-003

⁹⁴⁸ 064-022-063

⁹⁴⁹ 306-088-002

- 5.336 The RGHT interest in distinguishing Raychel's case from Adam's might suggest that it considered itself vulnerable to the criticism that the cases were so similar that the lessons from Adam's case ought to have been applied to Raychel's. This mirrored Dr Nesbitt's concern that Altnagelvin should avoid criticism for having failed to learn from Adam's case.
- 5.337 Mr Walby advised the solicitor that he had "*spoken to Dr. Crean and he will stick to his brief at the Inquest...*"⁹⁵⁰ Dr Crean's evidence at the inquest dealt only with the facts of Raychel's case. He did not volunteer any criticism of Raychel's care nor make any connection with Lucy's case. He said it did not occur to him.⁹⁵¹
- 5.338 After the inquest Mr Brangam advised Mr Walby that "*I cross examined Dr. Sumner in relation to the Adam Strain case and I asked him to distinguish and differentiate between the two cases.*"⁹⁵² In the event the RBHSC was not criticised by the Coroner and Mr Walby thanked Mr Brangam "*very much for minding our back at this inquest.*"⁹⁵³

Altnagelvin's public response to inquest

- 5.339 Before the inquest, Altnagelvin had declined to provide any meaningful comment to the press on the basis that it was inappropriate at that time.⁹⁵⁴ Mrs Burnside told her Board that "*the Trust's only comment to any media inquiry will be to again offer our sympathy and regret to the family.*"⁹⁵⁵ However and inconsistently, Mrs Burnside also described how "*we did try to brief the media off the record, trying to give them information that would be helpful. None of that information was ever used in the media. And one does not want to be standing up saying 'this is our position' when what you're dealing with is a tragedy and absolute grief.*"⁹⁵⁶ This has parallels with the quiet briefing given to Dr Jenkins of Altnagelvin's press release and gives

⁹⁵⁰ 064-019-054

⁹⁵¹ Dr Crean T-11-09-13 p.99 line 5

⁹⁵² 064-016-050

⁹⁵³ 064-014-046

⁹⁵⁴ 023-002-002

⁹⁵⁵ 321-058-011

⁹⁵⁶ Mrs Burnside T-17-09-13 p.200 line 24

rise to the uncomfortable sense that Altnagelvin was attempting a ‘damage limitation’ exercise.

5.340 After the inquest, Altnagelvin nonetheless issued the press statement as previously drafted proclaiming it *“important to emphasise that the clinical practices used during Raychel’s care, following her operation, were at that time accepted practice in all other Area Hospitals in Northern Ireland.”*⁹⁵⁷

This failed to reflect the evidence. It ignored the Coroner’s finding of inadequate electrolyte replacement and contradicted Altnagelvin’s own review findings.

5.341 The press release was drafted by the Altnagelvin Communications Manager, Ms Marie Dunne⁹⁵⁸ who *“worked directly to the Chief Executive”*.⁹⁵⁹ The Chief Executive herself approved the press release.⁹⁶⁰ It is a matter of the gravest concern that a formal public communication issued in the name of a HSC Trust should mislead.

5.342 The Chief Executive had been very aware that Raychel’s inquest might *“attract substantial media attention”*⁹⁶¹ and her Communications Department circulated advice within the hospital entitled ‘Potential Media Questions (and some suggested answers) arising from the Raychel Ferguson inquest and our Statement.’ It included the following:

“How can the public be sure that there are no other ‘procedures and practices’ in Altnagelvin that might lead to this kind of tragedy happening again?”

Suggested answer - The public should be reassured that Altnagelvin practices in accordance with the highest professional standards as required by the various Royal Colleges in the United Kingdom. We constantly audit

⁹⁵⁷ 160-016-002

⁹⁵⁸ 328-001-003

⁹⁵⁹ WS-332-1 p.4

⁹⁶⁰ Mrs Burnside T-17-09-13 p.205 line 13

⁹⁶¹ 321-058-011

*our work against these standards and ensure we keep up to date with the new developments and new treatment options.”*⁹⁶²

5.343 Fortunately, the public was not given this particular ‘reassurance’ because the evidence received revealed a very different reality within Altnagelvin. The relevant Royal College of Surgeons NCEPOD guidance was either unknown or ignored⁹⁶³ and far from auditing compliance with NCEPOD recommendation, the evidence suggested that it was unlikely that the Clinical Audit Committee at Altnagelvin was aware of the NCEPOD report.⁹⁶⁴ I received evidence that Altnagelvin had no “*clear systems for ensuring compliance with relevant UK professional guidance,*”⁹⁶⁵ no central library where Royal College guidelines were stored or assessed,⁹⁶⁶ and “*no written protocols, guidelines, guidance or practice documents in relation to clinical audit.*”⁹⁶⁷ Like many of Altnagelvin’s claims to clinical governance activity, this was unfounded.⁹⁶⁸ This cannot have been unknown to Mrs Burnside.

5.344 Accordingly, the Communications Department, and by extension the Chief Executive,⁹⁶⁹ is open to the criticism of encouraging Trust employees to make public statements which mislead. The Chief Executive was, at all times, bound by the code of public service values⁹⁷⁰ requiring that “*public statements and reports issued by the Board should be clear, comprehensive and balanced, and should fully represent the facts.*”⁹⁷¹ Whilst public confidence in the Health Service is important, it must never be pursued without strict regard for the truth.

⁹⁶² 023-018-030

⁹⁶³ Miss Duddy T-29-08-13 p.107 line 11

⁹⁶⁴ Mrs Brown T-02-09-13 p.92 line 17

⁹⁶⁵ 226-002-015

⁹⁶⁶ 316-006e-002

⁹⁶⁷ 321-004f-004

⁹⁶⁸ Mrs Brown T-02-09-13 p.95 line 15

⁹⁶⁹ Miss Duddy T-29-08-13 p.114 line 24

⁹⁷⁰ Mrs Burnside T-17-09-13 p.7 line 6

⁹⁷¹ 306-096-004

Meeting with WHSSC

5.345 After the inquest the WHSSC formally sought a meeting with Altnagelvin in order to *“learn of the Altnagelvin perspective of the tragedy and... to be informed of the facts and to help members to restore public confidence, which I am informed has been damaged.”*⁹⁷² On 19th February 2003 Mr Stanley Millar,⁹⁷³ Chief Officer of the WHSSC and other members of the Council met with Mrs Burnside, Miss Duddy and Dr Nesbitt.⁹⁷⁴ It was noted that *“The Trust provided a copy of a press statement”*⁹⁷⁵ to the WHSSC. This was in fact the same misleading statement as released the previous week.⁹⁷⁶ Mrs Burnside was unable to give any satisfactory explanation for this.⁹⁷⁷ That it should be offered by the Chief Executive to the WHSSC gives rise to the profoundest disquiet.

5.346 Mrs Burnside maintained that the information given the WHSSC was *“full and frank”*⁹⁷⁸ and whilst Dr Nesbitt did provide his PowerPoint presentation⁹⁷⁹ explaining some of the shortcomings in Raychel’s case, Mrs Burnside nonetheless *“explained the outcome of the Coroner’s inquest which did not apportion blame to the Trust.”*⁹⁸⁰ This was sadly yet another misrepresentation.

5.347 I find in the approach of Altnagelvin, whether it be to Mr and Mrs Ferguson, the Coroner, the WHSSC or this Inquiry, a defensiveness and willingness to mislead. It came from the top as this meeting demonstrated. Mrs Burnside, the Chief Executive, was responsible and implicated. She is to be criticised.

⁹⁷² 014-012-022

⁹⁷³ 328-001-005

⁹⁷⁴ 014-016-028

⁹⁷⁵ 014-016-028

⁹⁷⁶ 023-003-003

⁹⁷⁷ Mrs Burnside T-17-09-13 p.217 line 21

⁹⁷⁸ Mrs Burnside T-17-09-13 p.219 line 13

⁹⁷⁹ 021-054-117

⁹⁸⁰ 014-016-028

Lucy Crawford

5.348 Mr Millar, having reflected upon what he had been told, wrote to the Coroner on 27th February 2003 about the death of Lucy Crawford: *“following the Raychel Ferguson Inquest I, with other members of the WHSSC, received a briefing on the events which led up to Raychel’s death. I was struck by the similarities in the two tragedies... I am left with two questions which you may be able to answer. (1) Are there direct parallels in the events leading up to the death of both girls? (2) Would an Inquest... in 2000/2001 have led to... recommendations from the....⁹⁸¹ Inquest being shared at an earlier date and a consequent saving of her life?”⁹⁸²* It is troubling that it should have been a lay person rather than a doctor who brought Lucy’s death to the attention of the Coroner.

5.349 The Coroner forwarded Mr Millar’s letter to the CMO⁹⁸³ and sought Dr Sumner’s opinion about Lucy’s case. The contribution made by the late Mr Millar was important and is to be praised.

Chief Medical Officer

5.350 In the aftermath of Raychel’s inquest Dr Campbell, the CMO gave media interviews, including one to UTV on 25th March 2004.⁹⁸⁴ In it she expressed regret for the tragedy of Lucy and Raychel’s deaths and said that *“the rarity of these two events was the abnormal reaction which is seen in a very few children in the normal application [of fluids].”⁹⁸⁵* This was inconsistent with the Coroner’s finding.

5.351 Mr and Mrs Ferguson, already convinced that their daughter’s death would have been avoided but for a ‘cover up’ in Lucy’s case, then lodged a formal complaint about the CMO with the GMC on 6th November 2004.⁹⁸⁶ Amongst their grievances, they asserted⁹⁸⁷ that the CMO knew, or ought to

⁹⁸¹ Words omitted to convey clearly intended meaning

⁹⁸² 013-056-320

⁹⁸³ 006-010-294

⁹⁸⁴ 006-037-375

⁹⁸⁵ 006-037-377

⁹⁸⁶ 068-013-022

⁹⁸⁷ 068-013-022

have known, that the deaths of Lucy and Raychel were caused by the administration of the wrong type and volume of fluid and not by an “*abnormal reaction*”⁹⁸⁸ and that she had therefore misrepresented the facts to the media.

5.352 The CMO countered that she had been “*completely clear in both interviews that both deaths were preventable and hence clearly accepted by implication that they were caused by clinical mistakes*”⁹⁸⁹ and “*there was no intention on her part to mislead or misrepresent the facts.*”⁹⁹⁰

5.353 The GMC having heard the matter found that the CMO’s reference to an “*abnormal reaction*” was “*misleading*”⁹⁹¹ in that it “*appeared to contradict*” the Coroner’s finding, that the interviews were “*open to misinterpretation*” and that she had handled them “*inappropriately*”.⁹⁹² However, the panel found no evidence that the CMO had engaged in ‘cover-up’ or that her actions warranted a formal warning. She was invited to reflect upon the finding and the concerns of Mr and Mrs Ferguson. The complaint was closed.

Litigation

5.354 Altnagelvin had a Clinical Negligence Scrutiny Committee⁹⁹³ in 2001 and a policy deeming it “*extremely important that claims for negligence are managed appropriately to increase public confidence and respect.*”⁹⁹⁴ Clear guidance on claims management was then available to it, not least from the 1996 ‘HPSS Complaints Procedure’ which advised that “*where the Trust/Board accepts that there has been negligence a speedy settlement should be sought*”⁹⁹⁵ and the HPSS Protocol on Claims Handling⁹⁹⁶ which “*recommended that in each and every case where it is realised that defence*

⁹⁸⁸ 006-037-377

⁹⁸⁹ 104-026-519

⁹⁹⁰ 104-026-522

⁹⁹¹ 104-022-446

⁹⁹² 104-022-447

⁹⁹³ WS-323-1 p.14

⁹⁹⁴ 321-004fd-004

⁹⁹⁵ 314-016-017

⁹⁹⁶ 317-037-001

will be difficult to sustain, consideration be given to admitting liability and attempting to reach settlement.”⁹⁹⁷

5.355 From the outset, Altnagelvin thought it likely that the Fergusons would litigate.⁹⁹⁸ On 1st May 2003, Mr and Mrs Ferguson’s solicitors asserted by letter of claim *“our client’s instructions that the death of their daughter was occasioned by the negligence, breach of duty and/or breach of statutory duty... in or about the provision of medical treatment.”*⁹⁹⁹

5.356 Given the findings at critical incident review, the consensus of expert opinion, the Coroner’s damning verdict and Mrs Burnside’s view that Altnagelvin *“would be moving to settle this litigation at the soonest opportunity”*,¹⁰⁰⁰ I cannot understand why liability was not then accepted and settlement pursued.

5.357 However, Altnagelvin responded with a comprehensive denial of liability. It’s solicitor wrote to Mr and Mrs Ferguson’s solicitor to state in the clearest terms that Altnagelvin did *“not accept that it, or its staff, were negligent or that, if there was any failure to apply appropriate standards, that the failure caused or contributed to the death of Raychel Ferguson and therefore liability is denied.”*¹⁰⁰¹ This denial prompted the Fergusons to commence legal proceedings on 5th May 2004.¹⁰⁰²

5.358 Mrs Brown, by then promoted to Risk Management Director,¹⁰⁰³ again liaised with the Trust’s solicitor about Raychel’s case but did not seek any further information or advices.¹⁰⁰⁴ Nonetheless, complete denial remained Altnagelvin’s response to the Ferguson claim then and for the many years thereafter and even when confronted by the PSNI and the process of this Inquiry.

⁹⁹⁷ 317-037-010

⁹⁹⁸ WS-046-2 p.28 & Mrs Burnside T-17-09-13 p.224 line 14 & WS-043-3 p.11

⁹⁹⁹ 024-001-001

¹⁰⁰⁰ Mrs Burnside T-17-09-13 p.224 line 16

¹⁰⁰¹ 326-002-002

¹⁰⁰² 024-019-031

¹⁰⁰³ 024-002-002

¹⁰⁰⁴ Mrs Brown T-02-09-13 p.188 line 1

- 5.359 It is not therefore surprising that Mr and Mrs Ferguson should have become incensed by Altnagelvin's refusal to accept responsibility for their daughter's death.¹⁰⁰⁵ They thought it inexcusable¹⁰⁰⁶ and I agree. The hospital's response was unnecessary and caused additional anguish.
- 5.360 The Ferguson family had to listen to almost all the evidence given to this Inquiry before Altnagelvin finally conceded liability on 30th August 2013. A formal statement was then made that *"the Trust,¹⁰⁰⁷ having taken into account the evidence heard during this Inquiry, including independent expert evidence and the interim comments of the Chairman, formally admits liability. The Trust apologises unreservedly for Raychel's death and regrets any further hurt or distress that the delay in admitting liability has caused the family."*¹⁰⁰⁸ Whilst very welcome, admission did not have to await this Inquiry but could have been made ten years earlier.
- 5.361 In my view the denial of liability was unjustified, contrary to guidance, contrary to policy and the product of engrained defensiveness. It ran expressly counter to Altnagelvin's own publically expressed desire *"to encourage a culture of honesty and openness where mistakes and untoward incidents are identified quickly and dealt with in a positive and responsive way."*¹⁰⁰⁹ It is a good example of how failure by a Trust Board to follow the clear guidance given it can erode the confidence and respect necessary for the efficient functioning of the Health Service.
- 5.362 No explanation was given as to why liability was not accepted earlier. Given the widespread public interest in Raychel's case, whether at inquest, on TV, through the CMO or this Inquiry - the decision to deny liability must have been sanctioned by Mrs Burnside. As there was no basis upon which to contest the claim I can only conclude that the Trust repudiation of liability was made for tactical reasons. If so, the Trust was cynical in its disregard

¹⁰⁰⁵ Mr and Mrs Ferguson T-26-03-13 p.179 line 13 *et seq*

¹⁰⁰⁶ Mrs Ferguson T-26-03-13 p.179 line 16

¹⁰⁰⁷ By August 2013 Altnagelvin had been included within the new Western Health & Social Care Trust

¹⁰⁰⁸ Dr Carson T-30-08-13 p.1 *et seq*

¹⁰⁰⁹ 321-004fd-002

of Mr and Mrs Ferguson and acted in violation of the values of public service. Responsibility would lie with the Chief Executive.

Conclusion

- 5.363 The introduction of clinical governance was complex, time consuming and expensive.¹⁰¹⁰ Resources were limited and the hospital was stressed. Miss Duddy had multiple roles to fulfil and Dr Fulton was a part-time Medical Director. Notwithstanding that the implementation of clinical governance was at a comparatively early stage, the Altnagelvin Annual Reports¹⁰¹¹ and the Director of Nursing¹⁰¹² both confidently described a developed and functioning hospital clinical governance system at the time of Raychel's admission. The evidence convinced otherwise. The lack of functioning controls and the unstructured responses to Raychel's death do not substantiate the claims.
- 5.364 Neither the Clinical Governance Committee¹⁰¹³ nor the Risk Management and Standards Committee actually came into existence until after Raychel's death¹⁰¹⁴ and the Clinical Incident Committee met only quarterly.¹⁰¹⁵ It did not minute its transactions,¹⁰¹⁶ and did not review Raychel's case because it was defined as a critical incident rather than a clinical one.¹⁰¹⁷ Needless to say, there was no Committee for Critical Incidents.¹⁰¹⁸ The claims for clinical governance far exceeded the reality.
- 5.365 In consequence, clinical governance controls were weak. This was well demonstrated by the repeated failure to remedy deficiencies identified in bench-marking exercises, to implement external guidance or even adhere to internal protocols. Quality assurance had decidedly not been achieved

¹⁰¹⁰ Dr Carson T-30-08-13 p.5 line 18

¹⁰¹¹ 321-004gj-042

¹⁰¹² Miss Duddy T-29-08-13 p.11 line 20 *et seq* & p.87 line 7 & p.88 line 7

¹⁰¹³ 321-004gj-042

¹⁰¹⁴ Mrs Brown T-02-09-13 p.24 line 20 & p.23 line 9 & Dr Fulton T-04-09-13 p.2 line 5

¹⁰¹⁵ Mrs Brown T-02-09-13 p.14 line 3

¹⁰¹⁶ Mrs Brown T-02-09-13 p.14 line 13

¹⁰¹⁷ Mrs Brown T-02-09-13 p.17 line 20

¹⁰¹⁸ Mrs Brown T-02-09-13 p.20 line 9

at Altnagelvin. That was significant because such controls reveal frailties in a system before they can be revealed by tragedy.

5.366 At the same time, lax leadership and management problems characterised Altnagelvin's paediatric surgical service from the ward up. Miss Duddy visited Ward 6 only sporadically¹⁰¹⁹ and although she met with her Clinical Services Manager and Clinical Effectiveness Co-ordinator¹⁰²⁰ and believed that nursing issues would get to her and that she could assure the Trust Board as to nursing standards,¹⁰²¹ that was clearly not the case.

5.367 Nursing problems were not being addressed. Miss Duddy conceded that she was not even aware that her nurses had difficulties accessing surgical doctors *"until after the Critical Incident Review by which time the Medical Director was already dealing with the issue."*¹⁰²² Her nurses had no opportunity for *"formal meeting between nursing staff, paediatric medical staff and surgical consultant staff"*¹⁰²³ in order to address issues of joint concern.¹⁰²⁴ The established management lines led them to the Clinical Services Manager and the Director of Nursing by-passing Dr Martin,¹⁰²⁵ the Clinical Director, the consultant paediatricians and most particularly the Clinical Director of Surgery. A line management disconnect existed which did not facilitate escalation of such matters directly to Dr Fulton and he remained unaware of the situation.¹⁰²⁶ This was a genuine systemic problem because *"the medical director must be confident that effective systems and effective clinical leadership are in place for each and every clinical service within the Trust."*¹⁰²⁷

5.368 Lack of consultant engagement and control was well illustrated by the multi-disciplinary mismanagement of Raychel's fluid therapy. The obvious necessity was that all should understand their role and responsibility in each

¹⁰¹⁹ Miss Duddy T-29-08-13 p.20 line 6 & Sister Millar T-28-08-13 p.114 line 11

¹⁰²⁰ Miss Duddy T-29-08-13 p.17 line 18

¹⁰²¹ Miss Duddy T-29-08-13 p.17 line 23

¹⁰²² Miss Duddy T-29-08-13 p.26line 17

¹⁰²³ Mr Gilliland T-28-08-13 p.11 line 3

¹⁰²⁴ Mr Gilliland T-28-08-13 p.7 line 8

¹⁰²⁵ Mrs Burnside T-17-09-13 p.22 line 10

¹⁰²⁶ Dr Fulton T-04-09-13 p.16 line 14

¹⁰²⁷ 317-034-014 per Lugon

aspect of such patient care. That was a matter for the leadership of the responsible consultant¹⁰²⁸ as well as the consultants more generally. That was not given. That medical and surgical patients on Ward 6 should be subject to different blood test regimes points to a further obvious failure by the consultants to engage and give direction.

5.369 Weak leadership of the surgical team was revealed, not least by the complete absence of consultant or registrar from Raychel's care from admission to collapse, in circumstances where Mr Gilliland was largely unaware of the competence of his junior doctors and had no means of assessing the capability of the nurses upon whom his patients and doctors were so dependent.¹⁰²⁹

5.370 These and other shortcomings in clinical governance, leadership and consultant engagement permitted significant clinical vulnerabilities to develop. Cumulatively this allowed clinical error and increased the risk of catastrophic outcome. It is for these reasons that I do not believe that any single individual can be blamed for the tragedy of Raychel's death but rather that the responsibility for what happened is collective.

Concluding remarks

5.371 After Raychel's inquest the Coroner wrote to Dr Campbell on 11th February 2003¹⁰³⁰ to pass on Dr Sumner's praise for the Department's 'Guidance on the prevention of Hyponatraemia in Children' and his view that in this respect "*Northern Ireland was ahead of the rest of the UK.*" He expressed his hope that the guidance might be drawn to the attention of the CMOs for England and Wales, Scotland and the Republic of Ireland.

5.372 I have no doubt that the Department's guidelines may have saved lives and owe their existence, in no small measure, to the professional and responsive actions of Drs Fulton and Nesbitt.¹⁰³¹ As Professor Swainson recognised, theirs "*was a significant and highly commendable set of actions*

¹⁰²⁸ 314-014-015

¹⁰²⁹ Mr Gilliland T-28-08-13 p.20 line 14

¹⁰³⁰ 006-002-156

¹⁰³¹ Professor Swainson T-19-09-13 p.142 line 7

which have improved considerably the quality of care across the province and reduced the risk of hyponatraemia."¹⁰³² The very fact that praise is so obviously due in this regard draws attention to the overall inconsistency of the governance response to Raychel's death at Altnagelvin.

- 5.373 The timely Critical Incident Review and action plan together with the alert given the wider medical community as to the risks arising with Solution No.18 stand as good examples of clinical governance in action. However, there persisted an obdurate reluctance amongst clinicians to openly acknowledge specific failings in Raychel's care, whether to her family, the Coroner or the public. That was wholly reprehensible. The inclination of clinicians to avoid criticism in this way conflicts with patient interest and must not be tolerated in the Health Service.
- 5.374 The proper approach should of course, and at all times have been, that which was suggested to Altnagelvin at the outset of its engagement with clinical governance, namely that *"the actions of the organisation must be transparent and if negligence is identified during the investigation, this should not be hidden as it will serve no purpose and undoubtedly these facts will come to light during the legal process."*¹⁰³³

¹⁰³² 226-002-006

¹⁰³³ 317-034-004

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Introduction

- 6.1 Conor Mitchell was born on 12th October 1987. When he was 6 months old he was diagnosed with cerebral palsy, which limited his physical development. He also had a history of mild epilepsy. He was described as extremely intelligent with a great enthusiasm for sports and games and a determination for independence.¹ In spite of his disability “*Conor was extremely healthy...*”²
- 6.2 On 27th April 2003 Conor became unwell and complained of a sore throat. He vomited, was lethargic and suffered periodic discomfort.³ He failed to recover and over the course of the next 10 days was managed at home with antibiotics prescribed by his GP.⁴
- 6.3 On 8th May 2003, Conor was seen by the family GP, Dr Doyle,⁵ who referred him to the Royal Belfast Hospital for Sick Children (‘RBHSC’).⁶ However Conor’s mother wanted him to be seen as soon as possible and took him to the Accident & Emergency Department (‘A&E’) of the Craigavon Area Hospital (‘Craigavon’).
- 6.4 On arrival Conor was examined⁷ by Senior House Officer (‘SHO’) Dr Suzie Budd,⁸ who took blood samples and, noting that he was pale, unresponsive and showing signs of dehydration⁹ gave him a bolus of IV fluids.¹⁰ Dr Budd then tried to refer Conor to the paediatric team but was advised that, because he was 15 years old, he was too old to be admitted to a paediatric ward.¹¹

¹ 087-001-003

² 087-001-002

³ 087-002-015 to 018

⁴ 087-002-015 to 018

⁵ 327-003-001

⁶ 088-002-022

⁷ 087-028-131

⁸ 327-003-003

⁹ 087-028-131

¹⁰ 087-029-133 & WS-352-1 p.7

¹¹ WS-357-1 p.4 - Dr Michael Smith described how the hospital followed the relevant guideline at the time in which the upper age limit was the day before the patient’s 14th birthday

- 6.5 Notwithstanding that he had the physiology of an 8 year old,¹² Conor was admitted for observation into the Medical Admissions Unit ('MAU')¹³ which was an adult ward. He was given further IV fluids.¹⁴
- 6.6 During the course of the afternoon and early evening, Conor's condition seemingly deteriorated and at 20:30 he suffered two seizures in quick succession and stopped breathing.¹⁵ Conor was intubated and ventilated and admitted to the Intensive Care Unit ('ICU').¹⁶ A Computerised Tomography ('CT') scan was performed.
- 6.7 At approximately 12:00 the following day, 9th May, Dr Charles McAllister,¹⁷ Consultant in charge of ICU, requested that Conor be transferred to the Paediatric Intensive Care Unit ('PICU') at the RBHSC.¹⁸ The transfer was accepted by Dr Anthony Chisakuta,¹⁹ the RBHSC Consultant Paediatric Anaesthetist who had also treated Lucy after her transfer from the Erne Hospital in April 2000.
- 6.8 Upon admission to PICU, Conor was examined by Dr James McKaigue,²⁰ Consultant Paediatric Anaesthetist. He was alert to the involvement of hyponatraemia in the deaths of Adam Strain and Claire Roberts and had had involvement with Lucy in April 2000. Thereafter, and on 12th May 2003, Conor was also examined by Dr Robert Taylor²¹ who by that time may be credited with significant expertise in hyponatraemia.
- 6.9 In light of the CT scan and findings on examination, brain stem death tests were conducted on 12th May 2003. There was no hope and the decision was taken to discontinue treatment. Conor was pronounced dead at 15:45.²²

¹² Dr Budd WS-352-1 p.6

¹³ 087-014-079

¹⁴ 087-015-082

¹⁵ 087-024-114

¹⁶ 087-024-115

¹⁷ 327-003-004

¹⁸ 087-043-181

¹⁹ 327-003-006

²⁰ 327-003-006 & 092-017-039

²¹ 092-017-057

²² 092-017-058

- 6.10 Formal notification of the death was made to the Coroner and after due investigation, the cause of Conor's death was found at inquest in June 2004 to have been:

"I (a) Brain stem failure.

(b) Cerebral oedema.

(c) Hypoxia, ischemia, seizures and infarction.

*II Cerebral palsy."*²³

Conor's Terms of Reference

- 6.11 Whilst hyponatraemia due to fluid mismanagement was not implicated in Conor's death, I added Conor's case to the remit of this Inquiry because of concern that his fluid therapy had not been managed in accordance with the Department of Health, Social Services & Patient Safety, Northern Ireland ('the Department') 'Guidance on the Prevention of Hyponatraemia in Children' (the 'Guidelines') issued only 14 months before.²⁴

- 6.12 The Minister authorised the inclusion of Conor's death within this Inquiry.²⁵ I explained in February 2010, that

"It is obviously a matter of concern if guidelines which have been introduced as a result of a previous death or deaths and which are aimed at avoiding similar events in the future, are not properly communicated to hospital staff and followed.

It is relevant to the investigation to be conducted by the Inquiry, whether and to what extent the guidelines were disseminated and followed in the period after they were published. Another matter of interest is whether the fact that Conor was being treated on an adult ward, rather than a children's ward, made any difference to the way in which it would appear that the guidelines were not followed.

²³ 087-057-221

²⁴ Progress Hearing T-30-05-08 p.6

²⁵ Progress Hearing T-30-05-08 9.6

Accordingly, the Inquiry will investigate the way in which the guidelines were circulated by the Department, the way in which they were made known to hospital staff and the steps, if any, which were taken to ensure that they were being followed. While this is an issue of general importance, it will be informed by an examination of the way in which the guidelines were introduced and followed in Craigavon Area Hospital in May 2003.”²⁶

- 6.13 Accordingly, in this chapter of the report, I examine Conor’s case with predominant focus on the extent to which the clinicians who cared for Conor at Craigavon complied with the published Guidelines. Other matters are dealt with for purposes of context only. I do so with reference to paragraph 4.2 of the List of Issues (excluding reference to the RBHSC), namely:

“Investigation into the care and treatment that Conor received in 2003 in relation to the management of fluid balance:

- (1) What understanding those who cared for and treated Conor had of fluid management issues raised by his condition.*
- (2) To what extent fluid management and record keeping was covered in the teaching/training of [those]... who treated Conor.*
- (3) To what extent the care and treatment which Conor received, both in Craigavon Hospital and the RBHSC, was consistent with the then teaching/training on fluid management and record keeping, in particular the Guidelines.*
- (4) Whether the fact that Conor was admitted to an adult ward was relevant to whether the Guidelines were adhered to.”*

- 6.14 I examine Conor’s fluid management at Craigavon from admission to respiratory arrest taking into account the procedures and advices set out in the Guidelines and consider whether Craigavon took appropriate steps to disseminate and implement the Guidelines into clinical practice. Unlike the other cases covered by this report, I do not make any findings as to the clinical aspects of care, save for fluid management and make no findings

²⁶ 327-004-001-002

as to the cause of death. While I am conscious that some other issues are very important to Conor's family (for example the issues of seizures and communication), I do not make any findings in respect of these matters.

- 6.15 It is be acknowledged at the outset that the Southern Health and Social Care Trust ('the Trust')²⁷ and some Craigavon doctors and managers, made relevant concessions at public hearings in October 2013 which proved of considerable assistance to the Inquiry. I commend the Trust and the clinicians for taking such a sensible and constructive approach before this Inquiry.

Expert reports

- 6.16 The Inquiry was guided by the expert reports received from Dr Robert Scott-Jupp,²⁸ Consultant Paediatrician at Salisbury District Hospital and dated 19th September 2013²⁹ and 11th October 2013.³⁰
- 6.17 The Inquiry also had the benefit of the report of Dr Edward Sumner (Consultant Paediatric Anaesthetist at Great Ormond Street Childrens' Hospital) who reported to the Coroner in November 2003.³¹

Schedules compiled by the Inquiry

- 6.18 In an attempt to summarise the significant quantities of information received, the following schedules and charts were compiled:
- (i) List of Persons involved in Conor's case.³²
 - (ii) Chronology of Events (Clinical).³³
 - (iii) Schedule of Guideline Requirements and Conor's Treatment.³⁴

²⁷ As successor to the former Craigavon Area Hospital Group Trust.

²⁸ 327-003-008

²⁹ 260-002-001

³⁰ 260-004-001

³¹ 087-056-213

³² 327-003-001

³³ 327-002-001

³⁴ 327-008-001

All of the above are available on the Inquiry website.

Guidelines on the Prevention of Hyponatraemia

- 6.19 I have commended Altnagelvin hospital for bringing the death of Raychel Ferguson and the risks connected with the use of Solution No.18 to the attention of interested parties across Northern Ireland. Their response led to the creation of the CMO's Working Group on Hyponatraemia and the production of the Guidelines. It may be useful to recall how this came about as context for Conor's case.
- 6.20 In June 2001 Dr Raymond Fulton, Medical Director at Altnagelvin, disclosed the circumstances of Raychel Ferguson's death to a meeting of Medical Directors³⁵ and suggested that there should be guidance to regulate fluid management in paediatric cases. He indicated that he considered Solution No.18 to be hazardous for use with post-operative children.³⁶ He also notified Dr Henrietta Campbell,³⁷ the Chief Medical Officer ('CMO') and reiterated his belief that regional guidelines were required.³⁸
- 6.21 The CMO sought background information and received Dr Taylor's paper 'Hyponatraemia in Children'³⁹ on 30th July 2001. She then directed her Deputy, Dr Paul Darragh⁴⁰ to assemble a Working Group to examine the issue of hyponatraemia in children and to make recommendations in relation to paediatric fluid management.⁴¹ Dr Darragh asked Dr Miriam McCarthy,⁴² Senior Medical Officer, to convene the Group⁴³ "... to consider how best practice could be brought to bear on the problem and to explore whether further advice needs to be issued by the DHSS&PS at this time to the profession."⁴⁴

³⁵ 012-039-179

³⁶ 095-011-055

³⁷ 337-001-002

³⁸ 012-039-180

³⁹ 043-101-223

⁴⁰ 337-001-002

⁴¹ 075-082-329

⁴² 337-001-002

⁴³ WS-080-1 p.2

⁴⁴ 007-050-099

- 6.22 A number of highly experienced clinicians were then invited to attend an initial meeting on 26th September 2001 to be chaired by Dr Darragh.⁴⁵ It is to be noted that Dr Darrell Lowry,⁴⁶ Consultant Anaesthetist at Craigavon, was present.⁴⁷ It was agreed at that meeting that regional guidance was indeed required for paediatric fluid management and Drs Crean, Jenkins, McAloon and Loughrey undertook to draft the Guidelines.
- 6.23 Following further meetings involving the Department, Directors of Public Health, the Paediatric Anaesthetic Group, the Specialty Advisory Committees and the Clinical Resource Efficiency Support Team, the CMO published the Guidelines on 26th March 2002. They were drawn to the attention of a very wide range of practising clinicians and healthcare professionals in Northern Ireland, including medical and nursing directors and consultants⁴⁸ on the basis that *“Hyponatraemia can be extremely serious and has in the past few years been responsible for two deaths among children in Northern Ireland.”*⁴⁹
- 6.24 The CMO issued the Guidelines with the specific instruction that they be *“prominently displayed in all units that accommodate children”*⁵⁰ and that they should complement local protocols. Importantly, it was stressed that steps be taken to *“audit compliance with the guidance and locally developed protocols...”*⁵¹
- 6.25 Published in the form of an A2 sized poster,⁵² the Guidelines provided advice in relation to baseline assessment, fluid requirements, fluid therapy, monitoring and advice. In terms they required that:
- (i) Weight and serum sodium levels be measured and recorded before commencement of IV fluids.

⁴⁵ 007-048-094
⁴⁶ 327-003-004
⁴⁷ WS-350-1 p.4
⁴⁸ 007-001-001
⁴⁹ 007-001-001
⁵⁰ 007-001-002
⁵¹ 007-001-001
⁵² 007-003-004

- (ii) Fluid needs be assessed by a doctor competent in determining the fluid requirements of a child patient.
- (iii) Replacement fluids be considered and prescribed separately to reflect fluid loss, both in terms of volume and composition.
- (iv) Maintenance fluids be dictated by sodium, potassium and glucose requirements.
- (v) The clinical state of the patient be monitored and fluid balance assessed at least once every 12 hours and that biochemistry sampling be carried out at least once every day.
- (vi) Advice and clinical input be obtained from a senior member of medical staff.⁵³

6.26 It was unusual for the CMO to issue guidelines on clinical issues. Accordingly, it should have been very clear to healthcare trusts that particular attention should be paid to implementation.

6.27 Furthermore, and given that the CMO directed that the Guidelines be “*prominently displayed in all units that may accommodate children*”,⁵⁴ it was clear that each and every hospital should display the Guidelines in all areas, including A&E and adult wards, where children might receive treatment. It should have been obvious that it would not suffice to display the Guidelines in children’s wards alone and very evident that the Guidelines should be introduced to all clinical staff who might become engaged in the fluid management of children.

6.28 It is in this context that I examine how Craigavon responded to the publication of the Guidelines, what it did to implement them and how that was to influence the fluid therapy received by Conor.

⁵³ 007-003-004

⁵⁴ 007-001-001

Conor's Treatment at Craigavon

A&E

- 6.29 Upon admission to A&E Conor underwent routine blood tests and was prescribed intravenous fluids.⁵⁵ The fluids were documented on a fluid intake/output chart.⁵⁶
- 6.30 It was subsequently observed that he appeared to be having seizures.⁵⁷
- 6.31 Dr Scott-Jupp considered Conor's A&E fluid management with reference to the Guidelines. He considered that the requirements of the Guidelines had been complied with in respect of baseline assessment but expressed the following concerns about Conor's management in the A&E Department:
- (i) That it was unclear whether it was Conor's actual weight or an estimate that had been recorded.⁵⁸
 - (ii) That an arterial gas sample taken at 10:59 had been relied upon as an accurate indicator of Conor's sodium levels for the purposes of his fluid management, when such tests were known to be potentially unreliable.⁵⁹
 - (iii) That the fluids administered to Conor in A&E were given "as a *replacement not a resuscitation fluid*"⁶⁰ indicating confusion between resuscitation and replacement fluids.⁶¹
 - (iv) That normal saline ought to have been administered in compliance with the Guidelines when Conor was thought to be in shock⁶² (notwithstanding that he considered Hartmann's an acceptable fluid to use in the circumstances).⁶³

55 088-002-020
 56 088-004-063
 57 087-027-127
 58 260-002-012
 59 260-002-012
 60 260-002-013
 61 260-002-015
 62 260-002-016
 63 260-002-016

- (v) That Conor's *"clinical state, particularly his degree of dehydration, was not well monitored"* and that *"no attempt was made to quantify his urine output prior to his arrival at hospital."*⁶⁴
- (vi) That the monitoring of Conor's clinical state did not adhere to the Guidelines in consequence of which there was *" failure to make a more accurate assessment of his state of hydration [which] could have led to either excessive or inadequate fluid replacement, or to replacement with fluid that contained an inappropriate electrolyte content."*⁶⁵
- (vii) That Conor did not have his fluid requirements assessed by a Paediatrician and that none of the doctors attending Conor in A&E were *"likely to have had the necessary skills, particularly in assessing a disabled child."*⁶⁶
- (viii) That *"neither the ED (emergency department) staff, nor the adult medical doctors who subsequently saw him, were best placed to manage his fluids after the immediate resuscitation."*⁶⁷

6.32 Notwithstanding that the Trust rejected some of this criticism⁶⁸ I share Dr Scott-Jupp's concerns in respect of the management of Conor's fluids within A&E.

Admission to MAU

6.33 Dr Budd had tried to refer Conor to the Paediatric team⁶⁹ because she *"...considered that given that he had the physiological status of an 8 year old he would benefit from care under the specialist paediatric team. I intended him to be admitted there..."*⁷⁰ However, and notwithstanding

⁶⁴ 260-002-017
⁶⁵ 260-002-018
⁶⁶ 260-002-013
⁶⁷ 260-004-006
⁶⁸ 260-003-005
⁶⁹ 087-029-013
⁷⁰ WS-352-1 p.6

referral of this issue to the Paediatric Consultant, the Paediatric Admissions SHO declined to admit Conor because he was over 13 years of age.⁷¹

6.34 Conor was therefore transferred to MAU and prescribed antibiotic medication and further fluids.⁷² It is to be noted that Dr Catherine Quinn,⁷³ the Medical SHO, recognised that “... *My first fluid prescription (3 litre normal saline over 24 hours, or 125ml / hr) was based on a usual fluid regime for an adult patient. I did not make any additional calculations. This fluid prescription was not appropriate for Conor's size. This was highlighted by Dr Murdock during his review and I subsequently changed the prescription to a reduced volume and infusion rate on his advice...*”⁷⁴

6.35 At that stage Conor’s mother Ms Mitchell expressed concern about Conor’s condition and made a request that he be transferred to the RBHSC.⁷⁵ In response Dr Marian Williams,⁷⁶ SHO, attended upon Conor at or about 20:30. She witnessed an episode of stiffening following by a prolonged seizure during which Conor stopped breathing.⁷⁷ An urgent CT scan was undertaken which was thought suggestive of subarachnoid haemorrhage. However, Dr Cooke, the Consultant Neurologist in the Royal Victoria Hospital (‘RVH’) who also saw the scan, did not consider surgical intervention to be indicated.⁷⁸

6.36 In the circumstances it is unsurprising that Conor’s mother should have expressed her unhappiness with the care given.⁷⁹ Dr Scott-Jupp examined the management of Conor’s fluids in MAU with reference to the Guidelines and notwithstanding that the baseline assessment was properly conducted, he made the following criticisms in relation to the care given in MAU:

⁷¹ WS-352-1 p.6
⁷² WS-356-1 p.4
⁷³ 327-003-005
⁷⁴ WS-356-1 p.5-6
⁷⁵ 087-002-020
⁷⁶ 327-003-006
⁷⁷ 087-035-164
⁷⁸ 088-004-055
⁷⁹ 087-001-008

- (i) It was clear that *“the formula given in the Guideline was not used to calculate his maintenance fluids.”*⁸⁰
- (ii) An adult medical SHO and Registrar were unlikely to have had the necessary skills to assess the fluid requirements of a disabled child.⁸¹
- (iii) There was a failure to distinguish between maintenance and replacement fluids.⁸²
- (iv) There was no estimate of fluid output and no calculation of estimated replacement requirement.⁸³ In particular *“the need for replacement fluids should have been assessed before the initial infusion was started and then again at intervals during the day by clinically assessing his state of hydration and his urine output.”*⁸⁴
- (v) There is uncertainty as to the volume of fluid actually received by Conor between 11:20 and 19:40.⁸⁵
- (vi) There was a failure to record the physical signs of dehydration.⁸⁶
- (vii) There was a failure to take urine samples for the purpose of osmolarity or biochemistry analysis so as to assess whether fluid replacement was required.⁸⁷
- (viii) The use of the antibiotic Ciproxin was inappropriate in the paediatric setting and contributed to Conor’s fluid load.⁸⁸
- (ix) The rationale for this prescription was undocumented.

⁸⁰ 260-002-013

⁸¹ 260-002-012 to 013

⁸² 260-002-013

⁸³ 260-002-015

⁸⁴ 260-002-014

⁸⁵ 260-002-014

⁸⁶ 260-002-017

⁸⁷ 260-002-018

⁸⁸ 260-004-005

- (x) There was failure to ensure that Conor was reviewed by a more senior member of staff, most particularly in order to determine whether Conor was experiencing seizure activity.⁸⁹

6.37 I share Dr Scott-Jupp's concern about Conor's fluid management in MAU. However it is important to note that Dr Scott-Jupp did not "*consider that inappropriate fluid management was a contribution to [Conor's] death.*"⁹⁰

Admission to the Intensive Care Unit and PICU

6.38 Conor was transferred to Craigavon ICU at 22:00. Dr McAllister⁹¹ assessed Conor's score on the Glasgow Coma Scale ('GCS') as 3/15, made a detailed examination and found almost no neurological response to stimulation.⁹² Conor's basic brain stem responses were tested and Dr Richard Brady,⁹³ SHO, recorded that "*all appearances are that this unfortunate young fellow is brain stem dead.*"⁹⁴

6.39 After additional neurological examination, consultation with Dr Anthony Chisakuta⁹⁵ at RBHSC and discussion with Conor's family, the decision was made to request Conor's transfer to PICU at the RBHSC⁹⁶ "*in view of weight and complex problems.*"⁹⁷

6.40 When Conor was admitted to PICU at 19:00 on 9th May 2003 it was noted that his neurological condition remained unchanged. It was then that the Paediatric Anaesthetists took the view that Conor "*cannot survive this episode.*"⁹⁸ At 15:15 the decision was made to discontinue treatment and Conor was pronounced dead at 15:45 on 12th May 2003.⁹⁹

⁸⁹ 260-002-018
⁹⁰ 260-004-005
⁹¹ 327-003-004
⁹² 088-004-055
⁹³ 327-003-003
⁹⁴ 088-004-056
⁹⁵ 325-002-004
⁹⁶ 088-004-057
⁹⁷ 088-004-059
⁹⁸ 092-017-057
⁹⁹ 092-017-058

Post-mortem and inquest

- 6.41 Dr Janice Bothwell,¹⁰⁰ RBHSC Consultant Paediatrician, reported Conor's death to the Coroner's Office with a clinical assessment of "*Brainstem dysfunction with cerebral oedema. Cause of cerebral Oedema related to (1) Viral illness (2) Over-rehydration/inapprop fluid management; (3) status epilepticus → causing hypoxia.*"¹⁰¹
- 6.42 The Coroner directed a post-mortem examination which was conducted by Dr Brian Herron¹⁰² (who had likewise performed the post-mortems on Claire Roberts and Raychel Ferguson) and once again sought the opinion of Dr Edward Sumner.¹⁰³ Dr Herron presented his autopsy report on 3rd March 2004 and concluded that death had been caused by cerebral oedema.¹⁰⁴ However, he expressed uncertainty as to the underlying cause of the cerebral oedema. He nonetheless suggested that the seizures may have been an important factor in the death.¹⁰⁵
- 6.43 The Coroner, Mr John Leckey, conducted an inquest on 9th June 2004 and found the cause of Conor's death to be:
- "I (a) Brain stem failure.*
- (b) Cerebral oedema.*
- (c) Hypoxia, ischemia, seizures and infarction.*
- II Cerebral palsy."*¹⁰⁶
- 6.44 It is relevant to note that Mr Leckey concluded that "*the fluid management at Craigavon Area Hospital was acceptable.*"¹⁰⁷ In this he was informed by Dr Sumner's evidence that the fluid management in Conor's case had indeed been "*acceptable.*"¹⁰⁸ However, and notwithstanding his evidence,

¹⁰⁰ 327-003-006
¹⁰¹ 087-137c-455
¹⁰² 327-003-007
¹⁰³ 327-003-008
¹⁰⁴ 087-055-204
¹⁰⁵ 087-055-204
¹⁰⁶ 087-057-221
¹⁰⁷ 087-057-223
¹⁰⁸ 087-038-173

Dr Sumner took the unusual post-inquest step of writing to the Coroner, the CMO and Dr John Jenkins¹⁰⁹ to express misgivings about Craigavon's approach to fluid management:

*"Having got home from Conor Mitchell's inquest, I feel I must communicate my great unease. This is the fourth inquest I have attended in Belfast where sub-optimal fluid management has been involved...There was no calculation of the degree of dehydration nor the fluid deficit and no calculation of the maintenance fluids for a 22kg child. You will see from the enclosed copy of the fluid charts that the first prescription is not even signed. In my opinion the initial rate of infusion was unnecessarily high... there was a lapse in infusion for some hours... The basis of these amounts makes no sense to me at all. There was no note of volumes or urine passed, even though it was collected and I could not even find a basic TPR chart...My overall impression from these cases is that the basics of fluid management are neither well understood, nor properly carried out."*¹¹⁰

- 6.45 It is therefore clear that there were significant failings in relation to Conor's fluid management. The fluid record did not adhere to the Guidelines, there was confusion in respect of both prescription and appropriate fluid and there was a failure to ensure that Conor was reviewed by senior staff.

- 6.46 It is surprising that both Dr Sumner and the Coroner should have described Conor's fluid management as "acceptable" when Conor's fluids were clearly not managed in accordance with the Guidelines. However, I accept that the concerns expressed by Dr Sumner in private correspondence, were his considered appraisal, upon reflection, of the treatment given to Conor at Craigavon.

- 6.47 Whilst recognising Dr Scott-Jupp's opinion that inappropriate fluid management did not contribute to Conor's death, I nonetheless find that the treatment failed to comply with the Guidelines. Notwithstanding that the Trust does not accept all the criticisms levelled by Dr Scott- Jupp, I conclude

¹⁰⁹ 327-003-007

¹¹⁰ 087-062i-247 to 248

that there was failure to assess Conor's degree of dehydration and a failure to calculate maintenance fluids. Additionally there is uncertainty as to the rate and duration of infusion and a failure to document urine output. In short, the basics of fluid management were neither well understood nor well performed by clinicians in A&E and MAU.

- 6.48 It must therefore be asked how the clinicians in Craigavon could have so failed in these respects.

Implementation of the Guidance on the Prevention of Hyponatraemia

- 6.49 The CMO wrote to Trust Chief Executives on 4th March 2004 “...to ask you to assure me that... these guidelines have been incorporated into clinical practice in your Trust and that their implementation has been monitored. I would welcome this assurance and ask you to respond in writing before 16th April.”¹¹¹ The Trust Medical Director, Dr Caroline Humphrey,¹¹² replied to the CMO on 7th April 2004 to assure her that “The guidance on the prevention and management of hyponatraemia in children was taken forward in Craigavon Area Hospital Group Trust by a group of senior clinicians including our Consultant Clinical Biochemist, a consultant representative from Accident & Emergency, two senior paediatricians and a consultant anaesthetist. The guidelines... have been adopted throughout the Trust including where children are treated by surgical teams.”¹¹³ Dr Humphrey also assured the CMO that the Guidelines were included in the induction given to junior doctors and had been subject to audit.¹¹⁴

- 6.50 Whilst the Trust has provided documentation to indicate that basic teaching was provided in relation to hyponatraemia and fluid management, no evidence has been forthcoming to indicate that anything was actually done in connection with the implementation of the Guidelines.¹¹⁵

¹¹¹ 007-067-137

¹¹² 327-003-004

¹¹³ 007-073-145

¹¹⁴ 007-073-145

¹¹⁵ 329-018-006

- 6.51 Rather, Dr Humphrey gave evidence that she was in fact unclear as to who was responsible for the implementation of the Guidelines and did not actually know what was done about them.¹¹⁶ In light of this evidence, her assurances to the CMO are a matter of serious concern, most especially given that the Trust has conceded that the Guidelines were not properly implemented at Craigavon.
- 6.52 Whilst the Trust attempted to suggest that Dr Humphrey had based her responses to the CMO “*on informal assurance mechanisms*”¹¹⁷ it is clear that there was no basis for such assurances and they should not have been given. Whilst the failure to implement the Guidelines was an abrogation of responsibility, the deliberate attempt to mislead the CMO was a grave breach of professional duty and a failure in public service.
- 6.53 It would appear that the Chief Executive Mr John Templeton,¹¹⁸ the Medical Director Dr William McCaughey,¹¹⁹ and the Directors of Nursing Ms Bridie Foy¹²⁰ and Mr John Mone,¹²¹ “*had the key responsibility for dissemination, implementation and monitoring of the guidelines.*”¹²² Dr McCaughey indicated “*that details of implementation were appropriately delegated*”¹²³ to “*Clinical Directors in all specialties.*”¹²⁴
- 6.54 He identified Dr Martina Hogan¹²⁵ as the consultant coordinating implementation within paediatrics.¹²⁶ Dr Hogan “*advised that Dr Bell initiated dissemination and implementation of Actions arising from the Guidelines...*”¹²⁷ Mr Ivan Sterling and Dr Jeff Lee, the Clinical Directors of A&E and MAU respectively¹²⁸ could not recall any direction about the

¹¹⁶ WS-354-1 p.6

¹¹⁷ 340-001-009

¹¹⁸ 327-003-008

¹¹⁹ 327-003-004

¹²⁰ 327-003-002

¹²¹ 327-003-003

¹²² 329-018-007

¹²³ WS-369-1 p.7

¹²⁴ WS-369-1 p.4

¹²⁵ 327-003-003

¹²⁶ WS-369-1 p.5

¹²⁷ 329-032a-001

¹²⁸ 329-032a-001 to 002

implementation of the Guidelines¹²⁹ and the Trust was “unable to provide clarity on the units in which the 2002 Guidance was displayed...”¹³⁰

6.55 It would however seem at least possible that the Guidelines were displayed because it is recorded¹³¹ that the Clinical Services Manager, Mrs Eileen O'Rourke¹³² asked Nursing Sisters to check whether the Guidelines posters were on display on each ward.¹³³ Unfortunately Mrs O'Rourke was unable to recall the response elicited and there is no record.¹³⁴

6.56 Irrespective of the Trust's subsequent acknowledgment of failings in this regard, the evidence reveals a confused detachment amongst senior staff in Craigavon as to what was to be done with the Guidelines:

- (i) Mr Templeton, the Chief Executive of the Trust, while conceding that he held a joint responsibility for implementing the Guidelines and that he was made aware of the Guidelines by the Medical Director, understood it to be managed “under the direction of the Chief Medical Officer.”¹³⁵
- (ii) Dr McCaughey could not recall where the Guidelines were displayed¹³⁶ or what was done to develop or introduce compliant protocols.¹³⁷
- (iii) Ms Foy, Director of Nursing, accepting that she had joint responsibility for the implementation of the Guidelines,¹³⁸ had no recollection of seeing the Guidelines¹³⁹ let alone taking any steps to implement them.¹⁴⁰

¹²⁹ 329-032a-001 to 002

¹³⁰ 329-018-007

¹³¹ 329-014-122

¹³² 327-003-007

¹³³ 329-014-122

¹³⁴ WS-370-1 p.4

¹³⁵ WS-371-1 p.3

¹³⁶ WS-369-1 p.6

¹³⁷ WS-369-1 p.6

¹³⁸ WS-367-1 p.6

¹³⁹ WS-367-1 p.4

¹⁴⁰ WS-367-1 p.5

- (iv) Mrs O'Rourke, the Clinical Services Manager, stated that she had *"no recall of receiving this information"*¹⁴¹ and could not remember if she *"forwarded the posters or whether they were sent to the Sisters from the Director..."*¹⁴²
- (v) Mr Mone told the Inquiry that he had no recollection of the Guidelines.¹⁴³

6.57 This was a failure in both individual and collective leadership.

Evidence of the clinicians and nurses

6.58 This unsatisfactory situation was confirmed by the evidence of the clinicians who cared for Conor in both A&E and MAU.

- (i) Dr Budd, who was responsible for providing Conor's initial intravenous fluids in A&E, told the Inquiry that she was not aware of the Guidelines at the time of Conor's admission.¹⁴⁴
- (ii) Dr Catherine Quinn, Medical SHO in MAU, said that she was not aware of the Guidelines before seeing Conor, was not aware of them on display in MAU and had received no formal training in the application of the Guidelines.¹⁴⁵
- (iii) Dr Andrew Murdock,¹⁴⁶ who as Specialist Registrar in Gastroenterology and General Internal Medicine had advised Dr Quinn in relation to managing Conor's intravenous fluids,¹⁴⁷ could not recall the Guidelines being brought to his attention or seeing the Guidelines on display in MAU or indeed in any other area of the hospital where he worked.¹⁴⁸

¹⁴¹ WS-370-1 p.3

¹⁴² WS-370-1 p.4

¹⁴³ WS-375-1 p.5

¹⁴⁴ WS-352-1 p.10

¹⁴⁵ WS-356-1 p.9

¹⁴⁶ 327-003-005

¹⁴⁷ 087-025-117

¹⁴⁸ WS-355-1 p.14-15

- (iv) Dr Marian Williams, SHO in Paediatrics who attended Conor, could not recall whether the Guidelines were brought to her attention at that time¹⁴⁹ or indeed if they were on display in MAU.¹⁵⁰
- (v) Sister Irene Brennan (née Dickey),¹⁵¹ the senior nurse on duty in MAU, acknowledged that the Guidelines were not followed in Conor's case because the nurses in MAU were unaware of their existence.¹⁵² They had not been brought to their attention¹⁵³ and were not on display.¹⁵⁴
- (vi) Staff Nurse Francis Lavery¹⁵⁵ who had been on duty, could not recall receiving any specific training in relation to the fluid management of paediatric patients.¹⁵⁶ He stated that the Guidelines were not brought to his attention before Conor's admission¹⁵⁷ and confirmed that they were not on display in MAU.¹⁵⁸
- (vii) Sister Lorna Cullen¹⁵⁹ was the Ward Sister in MAU. She had no involvement in Conor's case.¹⁶⁰ Notwithstanding that she was the Ward Sister, she stated that the Guidelines were not brought to her attention¹⁶¹ and were not displayed in MAU.¹⁶² Nor was she aware of any other location within the hospital where the poster was displayed.¹⁶³
- (viii) Staff Nurse Barbara Wilkinson¹⁶⁴ was on duty in MAU. She was unaware of the Guidelines at that time and did not recall receiving

¹⁴⁹ WS-358-1 p.5
¹⁵⁰ WS-358-1 p.7
¹⁵¹ 327-003-002
¹⁵² WS-353-1 p.13-14
¹⁵³ WS-353-1 p.12
¹⁵⁴ WS-353-1 p.13
¹⁵⁵ 327-003-002
¹⁵⁶ WS-351-1 p.6
¹⁵⁷ WS-351-1 p.10
¹⁵⁸ WS-351-1 p.12
¹⁵⁹ 327-003-002
¹⁶⁰ WS-374-1 p.4
¹⁶¹ WS-374-1 p.6
¹⁶² WS-374-1 p.7
¹⁶³ WS-374-1 p.8
¹⁶⁴ 327-003-003

any training as to their use or application¹⁶⁵ and confirmed that the poster was not on display.¹⁶⁶

- (ix) Staff Nurse Ruth Bullas¹⁶⁷ ¹⁶⁸ formally admitted Conor to MAU and likewise advised that she was unaware of the Guidelines at the time and could recall no training in respect of them.¹⁶⁹

6.59 The evidence is clear that the CMO's instruction that the Guidelines be disseminated, implemented and developed was ignored. This was wholly unacceptable and a significant failure on the part of Trust. The acting Medical Director Dr McCaughey, the Directors of Nursing Ms Foy and Mr Mone, and the Chief Executive, Mr Templeton were in post and responsible.

Decision to admit Conor to an adult ward

6.60 The decision to admit Conor onto an adult ward was the subject of debate. Dr Scott-Jupp was of the view that Conor should have been managed in a paediatric setting which would have benefited his treatment in that:

- (i) Greater attention might have been given to an early diagnosis of urinary tract infection.
- (ii) A different antibiotic requiring less fluid would probably have been prescribed.
- (iii) It is likely that he would have been treated throughout with normal saline.¹⁷⁰

6.61 Notwithstanding that the Trust took issue with Dr Scott-Jupp's view as to the appropriateness of Conor's admission onto an adult ward,¹⁷¹ Dr Scott-Jupp maintained that "*it should have been obvious to all concerned that this*

¹⁶⁵ WS-377-1 p.7

¹⁶⁶ WS-377-1 p.8

¹⁶⁷ 327-003-002

¹⁶⁸ Staff Nurse Bullas was subsequently removed from the nursing register by the Nursing and Midwifery Council following an upheld complaint raised by Ms Mitchell that she had failed to document concern about Conor's seizures or to escalate them to a senior member of staff.

¹⁶⁹ WS-376-1 p.8

¹⁷⁰ 260-004-006

¹⁷¹ 260-003-006

was a very immature, child-like 15 year old.” He said he would “*have expected greater flexibility both at Craigavon and in Belfast. I do not believe age cut-offs should have been so rigidly applied.*”¹⁷² It is not without relevance that despite his age RBHSC took account of his physiology and admitted Conor into PICU.¹⁷³

6.62 The unfortunate result was that Conor was treated in A&E and in MAU by doctors and nurses who were ignorant of the Guidelines, in consequence of which:

- (i) The management of Conor’s fluids, whilst not the cause of his deterioration or death, was non-compliant and sub-standard.
- (ii) The appropriate formula for calculating maintenance fluids was not used.
- (iii) Conor’s fluid output was neither measured nor recorded.
- (iv) The entries in the fluid record are unclear to the point that they obscure how much fluid Conor received and when.

6.63 However, it is to be noted that within the Paediatric Department, Dr Michael Smith¹⁷⁴ recalled that the Guidelines were displayed on the ward.¹⁷⁵ Dr Hogan stated that she was trained in the use and application of the Guidelines.¹⁷⁶ Dr Barbara Bell¹⁷⁷ said that she received a copy of the Guidelines and had personally ensured that they were clearly visible in all paediatric clinical areas.¹⁷⁸

6.64 Whilst there was uncertainty as to whether protocol was developed to complement the Guidelines as requested by the CMO,¹⁷⁹ it would nonetheless appear that a protocol for the management of intravenous fluids in children had been developed by Drs Smith and Lowry following

¹⁷² 260-002-021

¹⁷³ 088-004-073

¹⁷⁴ 327-003-006

¹⁷⁵ WS-357-1 p.10

¹⁷⁶ WS-368-1 p.5

¹⁷⁷ 327-003-003

¹⁷⁸ WS-364-1 p.4

¹⁷⁹ WS-354-1 p.11 & 329-018-006 & WS-369-1 p.6

Raychel Ferguson's death and before the Guidelines were published.¹⁸⁰ Their protocol emphasised the need to calculate maintenance fluids separately from replacement fluids and contained a table to aid the proper approach to fluid management.¹⁸¹

- 6.65 I can only therefore conclude that had Conor been admitted to the paediatric ward as Dr Budd intended, he may very well have been cared for by medical staff familiar with the Guidelines and received appropriate fluid therapy. There might also then have been better engagement with Conor's mother.
- 6.66 This was an inconsistency which effectively meant that different paediatric patients could receive different treatment in different parts of the same hospital with potentially different outcomes. Such variation in the potential for appropriate treatment within a major hospital is troubling. That such a situation could develop reveals dangerous systemic vulnerabilities for which the Chief Executive, Mr Templeton, must bear responsibility.

Serious Adverse Incident Procedure

- 6.67 Craigavon had policy and procedure in place in 2003 for adverse incident reporting. However, Conor's death was not reported as an adverse incident¹⁸² notwithstanding that the RBHSC reported both the fact of his death and the fluid mismanagement to the Coroner.
- 6.68 The decision not to report Conor's death as a Serious Adverse Incident ('SAI') was subsequently defended in correspondence by Dr Humphrey to Dr A.M. Telford, Director of Public Health, Southern Health and Social Services Board on the basis that fluid management issues were not in fact implicated in the cause of death.¹⁸³ Ignoring the fact that Conor's death was most unexpected and warranted investigation on that basis alone,

¹⁸⁰ 329-014-001 & WS-350-1 p.5

¹⁸¹ 329-014-004

¹⁸² 329-022-001

¹⁸³ 329-022-017

there was a failure to adequately review Ms Mitchell's express dissatisfaction and the uncertainties in clinical diagnosis.

- 6.69 Ms Mitchell continued to express her concern about the fluid management in correspondence with Mr Templeton in 2004 and 2005.¹⁸⁴ It was not until Conor's case was added to the work of this Inquiry that the Trust belatedly acknowledged that it *"can now be considered a serious adverse incident as defined in Circular HSS (PPM) 06/04."*¹⁸⁵ This was an incident and a complaint which ought to have been thoroughly investigated. At the very least the Trust would then have been alerted to some of the many deficiencies now revealed.

Admissions by the Trust

- 6.70 The Trust properly issued the following apology in respect of its many failings in relation to the Guidelines:

"The Southern Health and Social Care Trust, which includes the legacy Craigavon Area Hospital Trust... accepts that the DHSSPS 2002 guidelines on the prevention of hyponatraemia in children were applicable to Conor Mitchell. The trust accepts that for various reasons, which will be the subject of this inquiry, the directions of the Chief Medical Officer as contained in these guidelines and accompanying correspondence were not properly implemented in the medical assessment unit or emergency department of Craigavon Area Hospital at this time and that staff in those areas were not made aware of or trained by the legacy trust in the implementation of these guidelines. We would contrast that situation with the Southern Trust's response to the DHSSPS 2007 guidelines. 'The trust accepts that throughout his course of management in Craigavon Area Hospital in 2003, it was the trust's responsibility to ensure the clinicians and nurses who were looking after Conor Mitchell had the guidelines in the forefront of their minds when treating him and the trust accepts that these clinicians and nurses should have had this guidance available to them when treating Conor.

¹⁸⁴ 329-022-021 to 033

¹⁸⁵ 329-022-018

Although there is nothing to indicate that the failure to comply with the guidelines resulted in Conor's death, the trust fully acknowledges its liability for the failures and shortcomings that occurred in the implementation of the DHSSPS 2002 guidelines on the prevention of hyponatraemia in children, both generally and specifically, in relation to Conor's care. The trust apologises to Conor's family for the failings referred to above and again offers our sincere sympathies to Conor's family."¹⁸⁶

- 6.71 The family welcomed this admission and apology¹⁸⁷ and hoped that it would avoid "*extensive investigations on certain issues*" by the Inquiry and result in savings in public funds.¹⁸⁸ It was agreed that the admissions rendered it unnecessary for the treating clinicians to give oral evidence.¹⁸⁹
- 6.72 Instead, I directed that the Trust provide written submissions detailing how and why it failed in Guidelines implementation and its omission to deal with the case as a SAI. In addition I sought particulars of those arrangements now in place in Craigavon to implement the Guidelines.
- 6.73 A paper was submitted by the Trust on 21st October 2013 indicating that:
- (i) "*There may have been a perception at the time of the dissemination of the 2002 Guidelines that the guidelines were not applicable to adult medicine and therefore appropriate dissemination and training in the guidelines was not highlighted...*"¹⁹⁰
 - (ii) "*Clear compliance and assurance processes should have been put in place to ensure that nurses and doctors in all areas where there was the potential for children to be treated were aware of and trained in the guidance.*"¹⁹¹

¹⁸⁶ T-17-10-13 p.6-7

¹⁸⁷ T-24-10-13 p.7

¹⁸⁸ T-17-10-13 p.7-8

¹⁸⁹ T-18-10-13 p.2

¹⁹⁰ 340-001-004

¹⁹¹ 340-001-004 to 005

- (iii) *“Assurance arrangements should have been agreed by both the Medical Director and Nursing Director...”¹⁹²*
- (iv) *“There appears to have been a breakdown in communication in relation to individual's roles and responsibilities regarding the dissemination of the guidelines.”¹⁹³*
- (v) *“There appears to have been a perception by the Director of Nursing that it was the CSM's responsibility to implement the guidelines... in the absence of a clear assurance framework there was confusion of roles and responsibilities between the Director of Nursing and the CSM.”¹⁹⁴*
- (vi) *“That the governance arrangements within the Trust had not matured sufficiently to ensure an integrated approach to Governance. This resulted in the risk that the guidelines would not be disseminated down both nursing and medical lines simultaneously.”¹⁹⁵*
- (vii) *“There is no documented evidence or audit trail to evidence that Paediatric nurses were trained specifically on the 2002 fluid management guidelines.”¹⁹⁶*
- (viii) *“In retrospect both Dr McCaughey and Dr Humphrey advised that they based their assurances [to the CMO] with regards to the implementation of the 2002 guidelines on informal assurance mechanisms.”¹⁹⁷*
- (ix) *“It is evident in hindsight that Conor's case would meet the criteria for review as a SAI with respect to point 8 of Circular HSS (PPM) 06/04 Reporting and Follow up on Serious Adverse Incidents: Interim Guidance... Therefore in not reporting Conor's case as an SAI at the*

¹⁹² 340-001-005

¹⁹³ 340-001-006

¹⁹⁴ 340-001-006 to 007

¹⁹⁵ 340-001-007

¹⁹⁶ 340-001-007

¹⁹⁷ 340-001-009

time there was a lost opportunity to identify and share learning across the region.”¹⁹⁸

6.74 On 23rd October 2013 I sought clarification on these submissions so as to confirm my interpretation of the Trust concessions.¹⁹⁹ At public hearing on 24th October 2013 it was furthermore accepted by the Trust that:

- (i) Clinicians in wards other than the paediatric ward were not made aware of or trained in the implementation of the Guidelines, including A&E and MAU where children would be treated.
- (ii) The Guidelines were not implemented within nursing practice in Craigavon, including paediatric nursing.
- (iii) That there was no basis for the Medical Director, Dr Humphrey, whether alone or with input from Mr McCaughey, to give assurance to the CMO that there had been implementation of the Guidelines at Craigavon.
- (iv) That a SAI investigation should have been conducted into the unexpected death of Conor under Circular HSS (PPM) 06/04 or the Trust’s own policy.²⁰⁰

Subsequent developments

6.75 The Trust approach was of assistance. The Mitchell family then responded and stated that they wanted *“to see measures put in place that will prevent similar tragedies occurring in the future...”*²⁰¹

6.76 It therefore became important to consider whether or not measures are now in place in Craigavon to ensure that paediatric fluid therapy is managed in accordance with the Guidelines.

¹⁹⁸ 340-001-010

¹⁹⁹ 340-008-001

²⁰⁰ T-24-10-13 p.19 line 21

²⁰¹ T-24-10-13 p.8 line 15

- 6.77 I was informed that the Guidelines were superseded in 2007 by guidelines deriving from the NPSA Patient Safety Alert 22.²⁰² The approach taken by the Trust in light of Safety Alert 22 was described as including the presentation of an action plan to the Trust Board, the creation of a Working Group led by the Medical Director, a training programme, compliance audits and an independent review of the Alert.²⁰³
- 6.78 On 30th October 2007 the Trust reported that Solution No.18 had been removed from general use in Craigavon and new fluid balance and prescription sheets were under consideration.²⁰⁴ A “*Hyponatraemia Meeting*” was held in January 2008 to consider how all 14-16 year old patients would receive treatment in accordance with the Guidelines irrespective of where they were treated.²⁰⁵ Audits to ensure compliance were carried out in October 2007²⁰⁶ and March 2008.²⁰⁷
- 6.79 The Trust also adopted a ‘Paediatric Intravenous Infusion Policy’ in October 2009 detailing the medical procedures for prescription, monitoring and review of intravenous infusions for children and young people²⁰⁸ together with nursing procedures for the administration of fluids. Guidance was given as to the recognition of hospital acquired hyponatraemia.²⁰⁹ In terms, the policy directed that nurses should consult the chart to satisfy themselves that prescriptions complied with the 2007 Guidelines before administering IV fluid and that they should carry out appropriate assessments, report changes in the child’s condition and provide handover briefings to incoming staff.
- 6.80 The policy also contained an ‘incident trigger’ list²¹⁰ with an associated reporting mechanism²¹¹ to alert clinicians to:

²⁰² 303-028-367
²⁰³ 329-020a-001
²⁰⁴ 329-020a-012
²⁰⁵ 329-020a-001
²⁰⁶ 329-020a-042
²⁰⁷ 329-020a-038
²⁰⁸ 329-020a-125
²⁰⁹ 329-020a-133
²¹⁰ 329-020a-145
²¹¹ 329-020a-146

- (i) Any episode of hospital acquired hyponatraemia in children receiving IV fluids.
- (ii) Any failure to check electrolytes at least once in every 24 hours in children receiving intravenous fluids.
- (iii) The use of any IV fluid other than as outlined in the 2007 Guidelines.

6.81 Mandatory training for all medical and nursing staff in the management of IV fluids for children and young people was also stipulated by the policy.²¹² The Inquiry has been provided with comprehensive documentation setting out these requirements. Moreover in relation to the clinical governance procedures set out in the policy, the evidence suggests that the Trust has undertaken audits every year since 2010 to assess compliance with the 2007 Guidelines²¹³ together with an “*Audit of Hyponatraemia*.”²¹⁴

6.82 The Trust advised that the audit results are shared within a multi-disciplinary team and discussed at clinical governance meetings.²¹⁵ This in conjunction with developing external guidance has led to additional changes in practice including:

- (i) The development and implementation of a revised fluid balance chart.
- (ii) The development and implementation of guidelines for peri-operative fluid management in children to “*provide guidance and reduce the risk of harm associated with intravenous fluid administration to the paediatric patient in the peri-operative phase*.”²¹⁶
- (iii) Further review of the paediatric intravenous infusion policy.

²¹² 329-020a-173

²¹³ 329-020a-004

²¹⁴ 329-020a-122

²¹⁵ 329-020a-008

²¹⁶ 329-020a-163

- 6.83 A Review of the Trust's 'Incident Management Policy' was completed in January 2013²¹⁷ and found *"clear guidance on incident reporting, investigation and the dissemination of learning from incidents and SAI's."*²¹⁸ Likewise, assurances were given that since April 2012 the Trust has had a procedure²¹⁹ *"in place to ensure the systematic and integrated approach for the implementation, monitoring and assurance of clinical standard and guidelines."*²²⁰
- 6.84 Accordingly, the Trust expressed the hope that it had been able *"... to demonstrate that they have reflected on their roles and responsibilities at this time and have identified and agreed on those factors which may have had an influence, or may have contributed to the failings in the dissemination and implementation of the guidelines in the Emergency Department and Medical Assessment Unit of CAH and furthermore the opportunities missed in the sharing of learning with regard these failings."*²²¹
- 6.85 On this basis I am of the view that the Trust has learned lessons and has implemented appropriate change in the years since Conor's tragic death.

Concluding remarks

- 6.86 Whilst I welcome the Trust concession that clear compliance and assurance processes in respect of the Guidelines should have been agreed and put into operation by the Medical Director and Nursing Directors, such concession cannot serve to avoid the just and appropriate criticism that Conor's treatment failed to comply with the Guidelines.
- 6.87 It is now acknowledged that there was a breakdown in communication between those in positions of governance as to their roles and responsibilities. This was a systemic failing for which the Chief Executive must bear responsibility.

²¹⁷ 340-001-012

²¹⁸ 340-001-012

²¹⁹ 304-001-003 & 340-005-001

²²⁰ 340-001-013

²²¹ 340-001-013

- 6.88 There was potentially dangerous variation in the care and treatment afforded young people admitted to Craigavon which was a serious systemic weakness.
- 6.89 The false assurance given the CMO that the Guidelines had been adopted and audited was a serious breach of professional duty and public service values.
- 6.90 Had the Trust conducted the SAI investigation of Conor's unexpected death, which it now accepts it should have done, it would have learned lessons to the benefit of all. That opportunity was lost.
- 6.91 Notwithstanding shortcomings and deficiency, the evidence as to policy, protocol, training, audit and review in the years since Conor's death, has provided some reassurance that lessons have been learned from this tragedy. Appropriate measures have been taken within Craigavon.

CONOR MITCHELL**Contents**

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Introduction

- 6.1 Conor Mitchell was born on 12th October 1987. When he was 6 months old he was diagnosed with cerebral palsy, which limited his physical development. He also had a history of mild epilepsy. He was described as extremely intelligent with a great enthusiasm for sports and games and a determination for independence.¹ In spite of his disability “*Conor was extremely healthy...*”²
- 6.2 On 27th April 2003 Conor became unwell and complained of a sore throat. He vomited, was lethargic and suffered periodic discomfort.³ He failed to recover and over the course of the next 10 days was managed at home with antibiotics prescribed by his GP.⁴
- 6.3 On 8th May 2003, Conor was seen by the family GP, Dr Doyle,⁵ who referred him to the Royal Belfast Hospital for Sick Children (‘RBHSC’).⁶ However Conor’s mother wanted him to be seen as soon as possible and took him to the Accident & Emergency Department (‘A&E’) of the Craigavon Area Hospital (‘Craigavon’).
- 6.4 On arrival Conor was examined⁷ by Senior House Officer (‘SHO’) Dr Suzie Budd,⁸ who took blood samples and, noting that he was pale, unresponsive and showing signs of dehydration⁹ gave him a bolus of IV fluids.¹⁰ Dr Budd then tried to refer Conor to the paediatric team but was advised that, because he was 15 years old, he was too old to be admitted to a paediatric ward.¹¹

¹ 087-001-003

² 087-001-002

³ 087-002-015 to 018

⁴ 087-002-015 to 018

⁵ 327-003-001

⁶ 088-002-022

⁷ 087-028-131

⁸ 327-003-003

⁹ 087-028-131

¹⁰ 087-029-133 & WS-352-1 p.7

¹¹ WS-357-1 p.4 - Dr Michael Smith described how the hospital followed the relevant guideline at the time in which the upper age limit was the day before the patient’s 14th birthday

- 6.5 Notwithstanding that he had the physiology of an 8 year old,¹² Conor was admitted for observation into the Medical Admissions Unit ('MAU')¹³ which was an adult ward. He was given further IV fluids.¹⁴
- 6.6 During the course of the afternoon and early evening, Conor's condition seemingly deteriorated and at 20:30 he suffered two seizures in quick succession and stopped breathing.¹⁵ Conor was intubated and ventilated and admitted to the Intensive Care Unit ('ICU').¹⁶ A Computerised Tomography ('CT') scan was performed.
- 6.7 At approximately 12:00 the following day, 9th May, Dr Charles McAllister,¹⁷ Consultant in charge of ICU, requested that Conor be transferred to the Paediatric Intensive Care Unit ('PICU') at the RBHSC.¹⁸ The transfer was accepted by Dr Anthony Chisakuta,¹⁹ the RBHSC Consultant Paediatric Anaesthetist who had also treated Lucy after her transfer from the Erne Hospital in April 2000.
- 6.8 Upon admission to PICU, Conor was examined by Dr James McKaigue,²⁰ Consultant Paediatric Anaesthetist. He was alert to the involvement of hyponatraemia in the deaths of Adam Strain and Claire Roberts and had had involvement with Lucy in April 2000. Thereafter, and on 12th May 2003, Conor was also examined by Dr Robert Taylor²¹ who by that time may be credited with significant expertise in hyponatraemia.
- 6.9 In light of the CT scan and findings on examination, brain stem death tests were conducted on 12th May 2003. There was no hope and the decision was taken to discontinue treatment. Conor was pronounced dead at 15:45.²²

¹² Dr Budd WS-352-1 p.6

¹³ 087-014-079

¹⁴ 087-015-082

¹⁵ 087-024-114

¹⁶ 087-024-115

¹⁷ 327-003-004

¹⁸ 087-043-181

¹⁹ 327-003-006

²⁰ 327-003-006 & 092-017-039

²¹ 092-017-057

²² 092-017-058

- 6.10 Formal notification of the death was made to the Coroner and after due investigation, the cause of Conor's death was found at inquest in June 2004 to have been:

"I (a) Brain stem failure.

(b) Cerebral oedema.

(c) Hypoxia, ischemia, seizures and infarction.

*II Cerebral palsy."*²³

Conor's Terms of Reference

- 6.11 Whilst hyponatraemia due to fluid mismanagement was not implicated in Conor's death, I added Conor's case to the remit of this Inquiry because of concern that his fluid therapy had not been managed in accordance with the Department of Health, Social Services & Patient Safety, Northern Ireland ('the Department') 'Guidance on the Prevention of Hyponatraemia in Children' (the 'Guidelines') issued only 14 months before.²⁴

- 6.12 The Minister authorised the inclusion of Conor's death within this Inquiry.²⁵ I explained in February 2010, that

"It is obviously a matter of concern if guidelines which have been introduced as a result of a previous death or deaths and which are aimed at avoiding similar events in the future, are not properly communicated to hospital staff and followed.

It is relevant to the investigation to be conducted by the Inquiry, whether and to what extent the guidelines were disseminated and followed in the period after they were published. Another matter of interest is whether the fact that Conor was being treated on an adult ward, rather than a children's ward, made any difference to the way in which it would appear that the guidelines were not followed.

²³ 087-057-221

²⁴ Progress Hearing T-30-05-08 p.6

²⁵ Progress Hearing T-30-05-08 9.6

Accordingly, the Inquiry will investigate the way in which the guidelines were circulated by the Department, the way in which they were made known to hospital staff and the steps, if any, which were taken to ensure that they were being followed. While this is an issue of general importance, it will be informed by an examination of the way in which the guidelines were introduced and followed in Craigavon Area Hospital in May 2003.”²⁶

- 6.13 Accordingly, in this chapter of the report, I examine Conor’s case with predominant focus on the extent to which the clinicians who cared for Conor at Craigavon complied with the published Guidelines. Other matters are dealt with for purposes of context only. I do so with reference to paragraph 4.2 of the List of Issues (excluding reference to the RBHSC), namely:

“Investigation into the care and treatment that Conor received in 2003 in relation to the management of fluid balance:

- (1) What understanding those who cared for and treated Conor had of fluid management issues raised by his condition.*
- (2) To what extent fluid management and record keeping was covered in the teaching/training of [those]... who treated Conor.*
- (3) To what extent the care and treatment which Conor received, both in Craigavon Hospital and the RBHSC, was consistent with the then teaching/training on fluid management and record keeping, in particular the Guidelines.*
- (4) Whether the fact that Conor was admitted to an adult ward was relevant to whether the Guidelines were adhered to.”*

- 6.14 I examine Conor’s fluid management at Craigavon from admission to respiratory arrest taking into account the procedures and advices set out in the Guidelines and consider whether Craigavon took appropriate steps to disseminate and implement the Guidelines into clinical practice. Unlike the other cases covered by this report, I do not make any findings as to the clinical aspects of care, save for fluid management and make no findings

²⁶ 327-004-001-002

as to the cause of death. While I am conscious that some other issues are very important to Conor's family (for example the issues of seizures and communication), I do not make any findings in respect of these matters.

- 6.15 It is be acknowledged at the outset that the Southern Health and Social Care Trust ('the Trust')²⁷ and some Craigavon doctors and managers, made relevant concessions at public hearings in October 2013 which proved of considerable assistance to the Inquiry. I commend the Trust and the clinicians for taking such a sensible and constructive approach before this Inquiry.

Expert reports

- 6.16 The Inquiry was guided by the expert reports received from Dr Robert Scott-Jupp,²⁸ Consultant Paediatrician at Salisbury District Hospital and dated 19th September 2013²⁹ and 11th October 2013.³⁰
- 6.17 The Inquiry also had the benefit of the report of Dr Edward Sumner (Consultant Paediatric Anaesthetist at Great Ormond Street Childrens' Hospital) who reported to the Coroner in November 2003.³¹

Schedules compiled by the Inquiry

- 6.18 In an attempt to summarise the significant quantities of information received, the following schedules and charts were compiled:
- (i) List of Persons involved in Conor's case.³²
 - (ii) Chronology of Events (Clinical).³³
 - (iii) Schedule of Guideline Requirements and Conor's Treatment.³⁴

²⁷ As successor to the former Craigavon Area Hospital Group Trust.

²⁸ 327-003-008

²⁹ 260-002-001

³⁰ 260-004-001

³¹ 087-056-213

³² 327-003-001

³³ 327-002-001

³⁴ 327-008-001

All of the above are available on the Inquiry website.

Guidelines on the Prevention of Hyponatraemia

- 6.19 I have commended Altnagelvin hospital for bringing the death of Raychel Ferguson and the risks connected with the use of Solution No.18 to the attention of interested parties across Northern Ireland. Their response led to the creation of the CMO's Working Group on Hyponatraemia and the production of the Guidelines. It may be useful to recall how this came about as context for Conor's case.
- 6.20 In June 2001 Dr Raymond Fulton, Medical Director at Altnagelvin, disclosed the circumstances of Raychel Ferguson's death to a meeting of Medical Directors³⁵ and suggested that there should be guidance to regulate fluid management in paediatric cases. He indicated that he considered Solution No.18 to be hazardous for use with post-operative children.³⁶ He also notified Dr Henrietta Campbell,³⁷ the Chief Medical Officer ('CMO') and reiterated his belief that regional guidelines were required.³⁸
- 6.21 The CMO sought background information and received Dr Taylor's paper 'Hyponatraemia in Children'³⁹ on 30th July 2001. She then directed her Deputy, Dr Paul Darragh⁴⁰ to assemble a Working Group to examine the issue of hyponatraemia in children and to make recommendations in relation to paediatric fluid management.⁴¹ Dr Darragh asked Dr Miriam McCarthy,⁴² Senior Medical Officer, to convene the Group⁴³ "... *to consider how best practice could be brought to bear on the problem and to explore whether further advice needs to be issued by the DHSS&PS at this time to the profession.*"⁴⁴

³⁵ 012-039-179

³⁶ 095-011-055

³⁷ 337-001-002

³⁸ 012-039-180

³⁹ 043-101-223

⁴⁰ 337-001-002

⁴¹ 075-082-329

⁴² 337-001-002

⁴³ WS-080-1 p.2

⁴⁴ 007-050-099

- 6.22 A number of highly experienced clinicians were then invited to attend an initial meeting on 26th September 2001 to be chaired by Dr Darragh.⁴⁵ It is to be noted that Dr Darrell Lowry,⁴⁶ Consultant Anaesthetist at Craigavon, was present.⁴⁷ It was agreed at that meeting that regional guidance was indeed required for paediatric fluid management and Drs Crean, Jenkins, McAloon and Loughrey undertook to draft the Guidelines.
- 6.23 Following further meetings involving the Department, Directors of Public Health, the Paediatric Anaesthetic Group, the Specialty Advisory Committees and the Clinical Resource Efficiency Support Team, the CMO published the Guidelines on 26th March 2002. They were drawn to the attention of a very wide range of practising clinicians and healthcare professionals in Northern Ireland, including medical and nursing directors and consultants⁴⁸ on the basis that *“Hyponatraemia can be extremely serious and has in the past few years been responsible for two deaths among children in Northern Ireland.”*⁴⁹
- 6.24 The CMO issued the Guidelines with the specific instruction that they be *“prominently displayed in all units that accommodate children”*⁵⁰ and that they should complement local protocols. Importantly, it was stressed that steps be taken to *“audit compliance with the guidance and locally developed protocols...”*⁵¹
- 6.25 Published in the form of an A2 sized poster,⁵² the Guidelines provided advice in relation to baseline assessment, fluid requirements, fluid therapy, monitoring and advice. In terms they required that:
- (i) Weight and serum sodium levels be measured and recorded before commencement of IV fluids.

⁴⁵ 007-048-094
⁴⁶ 327-003-004
⁴⁷ WS-350-1 p.4
⁴⁸ 007-001-001
⁴⁹ 007-001-001
⁵⁰ 007-001-002
⁵¹ 007-001-001
⁵² 007-003-004

- (ii) Fluid needs be assessed by a doctor competent in determining the fluid requirements of a child patient.
 - (iii) Replacement fluids be considered and prescribed separately to reflect fluid loss, both in terms of volume and composition.
 - (iv) Maintenance fluids be dictated by sodium, potassium and glucose requirements.
 - (v) The clinical state of the patient be monitored and fluid balance assessed at least once every 12 hours and that biochemistry sampling be carried out at least once every day.
 - (vi) Advice and clinical input be obtained from a senior member of medical staff.⁵³
- 6.26 It was unusual for the CMO to issue guidelines on clinical issues. Accordingly, it should have been very clear to healthcare trusts that particular attention should be paid to implementation.
- 6.27 Furthermore, and given that the CMO directed that the Guidelines be “*prominently displayed in all units that may accommodate children*”,⁵⁴ it was clear that each and every hospital should display the Guidelines in all areas, including A&E and adult wards, where children might receive treatment. It should have been obvious that it would not suffice to display the Guidelines in children’s wards alone and very evident that the Guidelines should be introduced to all clinical staff who might become engaged in the fluid management of children.
- 6.28 It is in this context that I examine how Craigavon responded to the publication of the Guidelines, what it did to implement them and how that was to influence the fluid therapy received by Conor.

⁵³ 007-003-004

⁵⁴ 007-001-001

Conor's Treatment at Craigavon

A&E

- 6.29 Upon admission to A&E Conor underwent routine blood tests and was prescribed intravenous fluids.⁵⁵ The fluids were documented on a fluid intake/output chart.⁵⁶
- 6.30 It was subsequently observed that he appeared to be having seizures.⁵⁷
- 6.31 Dr Scott-Jupp considered Conor's A&E fluid management with reference to the Guidelines. He considered that the requirements of the Guidelines had been complied with in respect of baseline assessment but expressed the following concerns about Conor's management in the A&E Department:
- (i) That it was unclear whether it was Conor's actual weight or an estimate that had been recorded.⁵⁸
 - (ii) That an arterial gas sample taken at 10:59 had been relied upon as an accurate indicator of Conor's sodium levels for the purposes of his fluid management, when such tests were known to be potentially unreliable.⁵⁹
 - (iii) That the fluids administered to Conor in A&E were given "as a *replacement not a resuscitation fluid*"⁶⁰ indicating confusion between resuscitation and replacement fluids.⁶¹
 - (iv) That normal saline ought to have been administered in compliance with the Guidelines when Conor was thought to be in shock⁶² (notwithstanding that he considered Hartmann's an acceptable fluid to use in the circumstances).⁶³

55 088-002-020
 56 088-004-063
 57 087-027-127
 58 260-002-012
 59 260-002-012
 60 260-002-013
 61 260-002-015
 62 260-002-016
 63 260-002-016

- (v) That Conor's *"clinical state, particularly his degree of dehydration, was not well monitored"* and that *"no attempt was made to quantify his urine output prior to his arrival at hospital."*⁶⁴
- (vi) That the monitoring of Conor's clinical state did not adhere to the Guidelines in consequence of which there was *" failure to make a more accurate assessment of his state of hydration [which] could have led to either excessive or inadequate fluid replacement, or to replacement with fluid that contained an inappropriate electrolyte content."*⁶⁵
- (vii) That Conor did not have his fluid requirements assessed by a Paediatrician and that none of the doctors attending Conor in A&E were *"likely to have had the necessary skills, particularly in assessing a disabled child."*⁶⁶
- (viii) That *"neither the ED (emergency department) staff, nor the adult medical doctors who subsequently saw him, were best placed to manage his fluids after the immediate resuscitation."*⁶⁷

6.32 Notwithstanding that the Trust rejected some of this criticism⁶⁸ I share Dr Scott-Jupp's concerns in respect of the management of Conor's fluids within A&E.

Admission to MAU

6.33 Dr Budd had tried to refer Conor to the Paediatric team⁶⁹ because she *"...considered that given that he had the physiological status of an 8 year old he would benefit from care under the specialist paediatric team. I intended him to be admitted there..."*⁷⁰ However, and notwithstanding

⁶⁴ 260-002-017
⁶⁵ 260-002-018
⁶⁶ 260-002-013
⁶⁷ 260-004-006
⁶⁸ 260-003-005
⁶⁹ 087-029-013
⁷⁰ WS-352-1 p.6

referral of this issue to the Paediatric Consultant, the Paediatric Admissions SHO declined to admit Conor because he was over 13 years of age.⁷¹

6.34 Conor was therefore transferred to MAU and prescribed antibiotic medication and further fluids.⁷² It is to be noted that Dr Catherine Quinn,⁷³ the Medical SHO, recognised that “... *My first fluid prescription (3 litre normal saline over 24 hours, or 125ml / hr) was based on a usual fluid regime for an adult patient. I did not make any additional calculations. This fluid prescription was not appropriate for Conor's size. This was highlighted by Dr Murdock during his review and I subsequently changed the prescription to a reduced volume and infusion rate on his advice...*”⁷⁴

6.35 At that stage Conor’s mother Ms Mitchell expressed concern about Conor’s condition and made a request that he be transferred to the RBHSC.⁷⁵ In response Dr Marian Williams,⁷⁶ SHO, attended upon Conor at or about 20:30. She witnessed an episode of stiffening following by a prolonged seizure during which Conor stopped breathing.⁷⁷ An urgent CT scan was undertaken which was thought suggestive of subarachnoid haemorrhage. However, Dr Cooke, the Consultant Neurologist in the Royal Victoria Hospital (‘RVH’) who also saw the scan, did not consider surgical intervention to be indicated.⁷⁸

6.36 In the circumstances it is unsurprising that Conor’s mother should have expressed her unhappiness with the care given.⁷⁹ Dr Scott-Jupp examined the management of Conor’s fluids in MAU with reference to the Guidelines and notwithstanding that the baseline assessment was properly conducted, he made the following criticisms in relation to the care given in MAU:

⁷¹ WS-352-1 p.6
⁷² WS-356-1 p.4
⁷³ 327-003-005
⁷⁴ WS-356-1 p.5-6
⁷⁵ 087-002-020
⁷⁶ 327-003-006
⁷⁷ 087-035-164
⁷⁸ 088-004-055
⁷⁹ 087-001-008

- (i) It was clear that *“the formula given in the Guideline was not used to calculate his maintenance fluids.”*⁸⁰
- (ii) An adult medical SHO and Registrar were unlikely to have had the necessary skills to assess the fluid requirements of a disabled child.⁸¹
- (iii) There was a failure to distinguish between maintenance and replacement fluids.⁸²
- (iv) There was no estimate of fluid output and no calculation of estimated replacement requirement.⁸³ In particular *“the need for replacement fluids should have been assessed before the initial infusion was started and then again at intervals during the day by clinically assessing his state of hydration and his urine output.”*⁸⁴
- (v) There is uncertainty as to the volume of fluid actually received by Conor between 11:20 and 19:40.⁸⁵
- (vi) There was a failure to record the physical signs of dehydration.⁸⁶
- (vii) There was a failure to take urine samples for the purpose of osmolarity or biochemistry analysis so as to assess whether fluid replacement was required.⁸⁷
- (viii) The use of the antibiotic Ciproxin was inappropriate in the paediatric setting and contributed to Conor’s fluid load.⁸⁸
- (ix) The rationale for this prescription was undocumented.

⁸⁰ 260-002-013
⁸¹ 260-002-012 to 013
⁸² 260-002-013
⁸³ 260-002-015
⁸⁴ 260-002-014
⁸⁵ 260-002-014
⁸⁶ 260-002-017
⁸⁷ 260-002-018
⁸⁸ 260-004-005

- (x) There was failure to ensure that Conor was reviewed by a more senior member of staff, most particularly in order to determine whether Conor was experiencing seizure activity.⁸⁹

6.37 I share Dr Scott-Jupp's concern about Conor's fluid management in MAU. However it is important to note that Dr Scott-Jupp did not "*consider that inappropriate fluid management was a contribution to [Conor's] death.*"⁹⁰

Admission to the Intensive Care Unit and PICU

6.38 Conor was transferred to Craigavon ICU at 22:00. Dr McAllister⁹¹ assessed Conor's score on the Glasgow Coma Scale ('GCS') as 3/15, made a detailed examination and found almost no neurological response to stimulation.⁹² Conor's basic brain stem responses were tested and Dr Richard Brady,⁹³ SHO, recorded that "*all appearances are that this unfortunate young fellow is brain stem dead.*"⁹⁴

6.39 After additional neurological examination, consultation with Dr Anthony Chisakuta⁹⁵ at RBHSC and discussion with Conor's family, the decision was made to request Conor's transfer to PICU at the RBHSC⁹⁶ "*in view of weight and complex problems.*"⁹⁷

6.40 When Conor was admitted to PICU at 19:00 on 9th May 2003 it was noted that his neurological condition remained unchanged. It was then that the Paediatric Anaesthetists took the view that Conor "*cannot survive this episode.*"⁹⁸ At 15:15 the decision was made to discontinue treatment and Conor was pronounced dead at 15:45 on 12th May 2003.⁹⁹

89 260-002-018
 90 260-004-005
 91 327-003-004
 92 088-004-055
 93 327-003-003
 94 088-004-056
 95 325-002-004
 96 088-004-057
 97 088-004-059
 98 092-017-057
 99 092-017-058

Post-mortem and inquest

- 6.41 Dr Janice Bothwell,¹⁰⁰ RBHSC Consultant Paediatrician, reported Conor's death to the Coroner's Office with a clinical assessment of "*Brainstem dysfunction with cerebral oedema. Cause of cerebral Oedema related to (1) Viral illness (2) Over-rehydration/inapprop fluid management; (3) status epilepticus → causing hypoxia.*"¹⁰¹
- 6.42 The Coroner directed a post-mortem examination which was conducted by Dr Brian Herron¹⁰² (who had likewise performed the post-mortems on Claire Roberts and Raychel Ferguson) and once again sought the opinion of Dr Edward Sumner.¹⁰³ Dr Herron presented his autopsy report on 3rd March 2004 and concluded that death had been caused by cerebral oedema.¹⁰⁴ However, he expressed uncertainty as to the underlying cause of the cerebral oedema. He nonetheless suggested that the seizures may have been an important factor in the death.¹⁰⁵
- 6.43 The Coroner, Mr John Leckey, conducted an inquest on 9th June 2004 and found the cause of Conor's death to be:
- "I (a) Brain stem failure.*
- (b) Cerebral oedema.*
- (c) Hypoxia, ischemia, seizures and infarction.*
- II Cerebral palsy."*¹⁰⁶
- 6.44 It is relevant to note that Mr Leckey concluded that "*the fluid management at Craigavon Area Hospital was acceptable.*"¹⁰⁷ In this he was informed by Dr Sumner's evidence that the fluid management in Conor's case had indeed been "*acceptable.*"¹⁰⁸ However, and notwithstanding his evidence,

¹⁰⁰ 327-003-006
¹⁰¹ 087-137c-455
¹⁰² 327-003-007
¹⁰³ 327-003-008
¹⁰⁴ 087-055-204
¹⁰⁵ 087-055-204
¹⁰⁶ 087-057-221
¹⁰⁷ 087-057-223
¹⁰⁸ 087-038-173

Dr Sumner took the unusual post-inquest step of writing to the Coroner, the CMO and Dr John Jenkins¹⁰⁹ to express misgivings about Craigavon's approach to fluid management:

*"Having got home from Conor Mitchell's inquest, I feel I must communicate my great unease. This is the fourth inquest I have attended in Belfast where sub-optimal fluid management has been involved...There was no calculation of the degree of dehydration nor the fluid deficit and no calculation of the maintenance fluids for a 22kg child. You will see from the enclosed copy of the fluid charts that the first prescription is not even signed. In my opinion the initial rate of infusion was unnecessarily high... there was a lapse in infusion for some hours... The basis of these amounts makes no sense to me at all. There was no note of volumes or urine passed, even though it was collected and I could not even find a basic TPR chart...My overall impression from these cases is that the basics of fluid management are neither well understood, nor properly carried out."*¹¹⁰

- 6.45 It is therefore clear that there were significant failings in relation to Conor's fluid management. The fluid record did not adhere to the Guidelines, there was confusion in respect of both prescription and appropriate fluid and there was a failure to ensure that Conor was reviewed by senior staff.
- 6.46 It is surprising that both Dr Sumner and the Coroner should have described Conor's fluid management as "acceptable" when Conor's fluids were clearly not managed in accordance with the Guidelines. However, I accept that the concerns expressed by Dr Sumner in private correspondence, were his considered appraisal, upon reflection, of the treatment given to Conor at Craigavon.
- 6.47 Whilst recognising Dr Scott-Jupp's opinion that inappropriate fluid management did not contribute to Conor's death, I nonetheless find that the treatment failed to comply with the Guidelines. Notwithstanding that the Trust does not accept all the criticisms levelled by Dr Scott- Jupp, I conclude

¹⁰⁹ 327-003-007

¹¹⁰ 087-062i-247 to 248

that there was failure to assess Conor's degree of dehydration and a failure to calculate maintenance fluids. Additionally there is uncertainty as to the rate and duration of infusion and a failure to document urine output. In short, the basics of fluid management were neither well understood nor well performed by clinicians in A&E and MAU.

- 6.48 It must therefore be asked how the clinicians in Craigavon could have so failed in these respects.

Implementation of the Guidance on the Prevention of Hyponatraemia

- 6.49 The CMO wrote to Trust Chief Executives on 4th March 2004 "...to ask you to assure me that... these guidelines have been incorporated into clinical practice in your Trust and that their implementation has been monitored. I would welcome this assurance and ask you to respond in writing before 16th April."¹¹¹ The Trust Medical Director, Dr Caroline Humphrey,¹¹² replied to the CMO on 7th April 2004 to assure her that "*The guidance on the prevention and management of hyponatraemia in children was taken forward in Craigavon Area Hospital Group Trust by a group of senior clinicians including our Consultant Clinical Biochemist, a consultant representative from Accident & Emergency, two senior paediatricians and a consultant anaesthetist. The guidelines... have been adopted throughout the Trust including where children are treated by surgical teams.*"¹¹³ Dr Humphrey also assured the CMO that the Guidelines were included in the induction given to junior doctors and had been subject to audit.¹¹⁴

- 6.50 Whilst the Trust has provided documentation to indicate that basic teaching was provided in relation to hyponatraemia and fluid management, no evidence has been forthcoming to indicate that anything was actually done in connection with the implementation of the Guidelines.¹¹⁵

¹¹¹ 007-067-137

¹¹² 327-003-004

¹¹³ 007-073-145

¹¹⁴ 007-073-145

¹¹⁵ 329-018-006

- 6.51 Rather, Dr Humphrey gave evidence that she was in fact unclear as to who was responsible for the implementation of the Guidelines and did not actually know what was done about them.¹¹⁶ In light of this evidence, her assurances to the CMO are a matter of serious concern, most especially given that the Trust has conceded that the Guidelines were not properly implemented at Craigavon.
- 6.52 Whilst the Trust attempted to suggest that Dr Humphrey had based her responses to the CMO “*on informal assurance mechanisms*”¹¹⁷ it is clear that there was no basis for such assurances and they should not have been given. Whilst the failure to implement the Guidelines was an abrogation of responsibility, the deliberate attempt to mislead the CMO was a grave breach of professional duty and a failure in public service.
- 6.53 It would appear that the Chief Executive Mr John Templeton,¹¹⁸ the Medical Director Dr William McCaughey,¹¹⁹ and the Directors of Nursing Ms Bridie Foy¹²⁰ and Mr John Mone,¹²¹ “*had the key responsibility for dissemination, implementation and monitoring of the guidelines.*”¹²² Dr McCaughey indicated “*that details of implementation were appropriately delegated*”¹²³ to “*Clinical Directors in all specialties.*”¹²⁴
- 6.54 He identified Dr Martina Hogan¹²⁵ as the consultant coordinating implementation within paediatrics.¹²⁶ Dr Hogan “*advised that Dr Bell initiated dissemination and implementation of Actions arising from the Guidelines...*”¹²⁷ Mr Ivan Sterling and Dr Jeff Lee, the Clinical Directors of A&E and MAU respectively¹²⁸ could not recall any direction about the

¹¹⁶ WS-354-1 p.6

¹¹⁷ 340-001-009

¹¹⁸ 327-003-008

¹¹⁹ 327-003-004

¹²⁰ 327-003-002

¹²¹ 327-003-003

¹²² 329-018-007

¹²³ WS-369-1 p.7

¹²⁴ WS-369-1 p.4

¹²⁵ 327-003-003

¹²⁶ WS-369-1 p.5

¹²⁷ 329-032a-001

¹²⁸ 329-032a-001 to 002

implementation of the Guidelines¹²⁹ and the Trust was “unable to provide clarity on the units in which the 2002 Guidance was displayed...”¹³⁰

6.55 It would however seem at least possible that the Guidelines were displayed because it is recorded¹³¹ that the Clinical Services Manager, Mrs Eileen O'Rourke¹³² asked Nursing Sisters to check whether the Guidelines posters were on display on each ward.¹³³ Unfortunately Mrs O'Rourke was unable to recall the response elicited and there is no record.¹³⁴

6.56 Irrespective of the Trust's subsequent acknowledgment of failings in this regard, the evidence reveals a confused detachment amongst senior staff in Craigavon as to what was to be done with the Guidelines:

- (i) Mr Templeton, the Chief Executive of the Trust, while conceding that he held a joint responsibility for implementing the Guidelines and that he was made aware of the Guidelines by the Medical Director, understood it to be managed “under the direction of the Chief Medical Officer.”¹³⁵
- (ii) Dr McCaughey could not recall where the Guidelines were displayed¹³⁶ or what was done to develop or introduce compliant protocols.¹³⁷
- (iii) Ms Foy, Director of Nursing, accepting that she had joint responsibility for the implementation of the Guidelines,¹³⁸ had no recollection of seeing the Guidelines¹³⁹ let alone taking any steps to implement them.¹⁴⁰

¹²⁹ 329-032a-001 to 002

¹³⁰ 329-018-007

¹³¹ 329-014-122

¹³² 327-003-007

¹³³ 329-014-122

¹³⁴ WS-370-1 p.4

¹³⁵ WS-371-1 p.3

¹³⁶ WS-369-1 p.6

¹³⁷ WS-369-1 p.6

¹³⁸ WS-367-1 p.6

¹³⁹ WS-367-1 p.4

¹⁴⁰ WS-367-1 p.5

- (iv) Mrs O'Rourke, the Clinical Services Manager, stated that she had *"no recall of receiving this information"*¹⁴¹ and could not remember if she *"forwarded the posters or whether they were sent to the Sisters from the Director..."*¹⁴²
- (v) Mr Mone told the Inquiry that he had no recollection of the Guidelines.¹⁴³

6.57 This was a failure in both individual and collective leadership.

Evidence of the clinicians and nurses

6.58 This unsatisfactory situation was confirmed by the evidence of the clinicians who cared for Conor in both A&E and MAU.

- (i) Dr Budd, who was responsible for providing Conor's initial intravenous fluids in A&E, told the Inquiry that she was not aware of the Guidelines at the time of Conor's admission.¹⁴⁴
- (ii) Dr Catherine Quinn, Medical SHO in MAU, said that she was not aware of the Guidelines before seeing Conor, was not aware of them on display in MAU and had received no formal training in the application of the Guidelines.¹⁴⁵
- (iii) Dr Andrew Murdock,¹⁴⁶ who as Specialist Registrar in Gastroenterology and General Internal Medicine had advised Dr Quinn in relation to managing Conor's intravenous fluids,¹⁴⁷ could not recall the Guidelines being brought to his attention or seeing the Guidelines on display in MAU or indeed in any other area of the hospital where he worked.¹⁴⁸

¹⁴¹ WS-370-1 p.3

¹⁴² WS-370-1 p.4

¹⁴³ WS-375-1 p.5

¹⁴⁴ WS-352-1 p.10

¹⁴⁵ WS-356-1 p.9

¹⁴⁶ 327-003-005

¹⁴⁷ 087-025-117

¹⁴⁸ WS-355-1 p.14-15

- (iv) Dr Marian Williams, SHO in Paediatrics who attended Conor, could not recall whether the Guidelines were brought to her attention at that time¹⁴⁹ or indeed if they were on display in MAU.¹⁵⁰
- (v) Sister Irene Brennan (née Dickey),¹⁵¹ the senior nurse on duty in MAU, acknowledged that the Guidelines were not followed in Conor's case because the nurses in MAU were unaware of their existence.¹⁵² They had not been brought to their attention¹⁵³ and were not on display.¹⁵⁴
- (vi) Staff Nurse Francis Lavery¹⁵⁵ who had been on duty, could not recall receiving any specific training in relation to the fluid management of paediatric patients.¹⁵⁶ He stated that the Guidelines were not brought to his attention before Conor's admission¹⁵⁷ and confirmed that they were not on display in MAU.¹⁵⁸
- (vii) Sister Lorna Cullen¹⁵⁹ was the Ward Sister in MAU. She had no involvement in Conor's case.¹⁶⁰ Notwithstanding that she was the Ward Sister, she stated that the Guidelines were not brought to her attention¹⁶¹ and were not displayed in MAU.¹⁶² Nor was she aware of any other location within the hospital where the poster was displayed.¹⁶³
- (viii) Staff Nurse Barbara Wilkinson¹⁶⁴ was on duty in MAU. She was unaware of the Guidelines at that time and did not recall receiving

¹⁴⁹ WS-358-1 p.5
¹⁵⁰ WS-358-1 p.7
¹⁵¹ 327-003-002
¹⁵² WS-353-1 p.13-14
¹⁵³ WS-353-1 p.12
¹⁵⁴ WS-353-1 p.13
¹⁵⁵ 327-003-002
¹⁵⁶ WS-351-1 p.6
¹⁵⁷ WS-351-1 p.10
¹⁵⁸ WS-351-1 p.12
¹⁵⁹ 327-003-002
¹⁶⁰ WS-374-1 p.4
¹⁶¹ WS-374-1 p.6
¹⁶² WS-374-1 p.7
¹⁶³ WS-374-1 p.8
¹⁶⁴ 327-003-003

any training as to their use or application¹⁶⁵ and confirmed that the poster was not on display.¹⁶⁶

- (ix) Staff Nurse Ruth Bullas¹⁶⁷ ¹⁶⁸ formally admitted Conor to MAU and likewise advised that she was unaware of the Guidelines at the time and could recall no training in respect of them.¹⁶⁹

6.59 The evidence is clear that the CMO's instruction that the Guidelines be disseminated, implemented and developed was ignored. This was wholly unacceptable and a significant failure on the part of Trust. The acting Medical Director Dr McCaughey, the Directors of Nursing Ms Foy and Mr Mone, and the Chief Executive, Mr Templeton were in post and responsible.

Decision to admit Conor to an adult ward

6.60 The decision to admit Conor onto an adult ward was the subject of debate. Dr Scott-Jupp was of the view that Conor should have been managed in a paediatric setting which would have benefited his treatment in that:

- (i) Greater attention might have been given to an early diagnosis of urinary tract infection.
- (ii) A different antibiotic requiring less fluid would probably have been prescribed.
- (iii) It is likely that he would have been treated throughout with normal saline.¹⁷⁰

6.61 Notwithstanding that the Trust took issue with Dr Scott-Jupp's view as to the appropriateness of Conor's admission onto an adult ward,¹⁷¹ Dr Scott-Jupp maintained that "*it should have been obvious to all concerned that this*

¹⁶⁵ WS-377-1 p.7

¹⁶⁶ WS-377-1 p.8

¹⁶⁷ 327-003-002

¹⁶⁸ Staff Nurse Bullas was subsequently removed from the nursing register by the Nursing and Midwifery Council following an upheld complaint raised by Ms Mitchell that she had failed to document concern about Conor's seizures or to escalate them to a senior member of staff.

¹⁶⁹ WS-376-1 p.8

¹⁷⁰ 260-004-006

¹⁷¹ 260-003-006

was a very immature, child-like 15 year old.” He said he would “*have expected greater flexibility both at Craigavon and in Belfast. I do not believe age cut-offs should have been so rigidly applied.*”¹⁷² It is not without relevance that despite his age RBHSC took account of his physiology and admitted Conor into PICU.¹⁷³

6.62 The unfortunate result was that Conor was treated in A&E and in MAU by doctors and nurses who were ignorant of the Guidelines, in consequence of which:

- (i) The management of Conor’s fluids, whilst not the cause of his deterioration or death, was non-compliant and sub-standard.
- (ii) The appropriate formula for calculating maintenance fluids was not used.
- (iii) Conor’s fluid output was neither measured nor recorded.
- (iv) The entries in the fluid record are unclear to the point that they obscure how much fluid Conor received and when.

6.63 However, it is to be noted that within the Paediatric Department, Dr Michael Smith¹⁷⁴ recalled that the Guidelines were displayed on the ward.¹⁷⁵ Dr Hogan stated that she was trained in the use and application of the Guidelines.¹⁷⁶ Dr Barbara Bell¹⁷⁷ said that she received a copy of the Guidelines and had personally ensured that they were clearly visible in all paediatric clinical areas.¹⁷⁸

6.64 Whilst there was uncertainty as to whether protocol was developed to complement the Guidelines as requested by the CMO,¹⁷⁹ it would nonetheless appear that a protocol for the management of intravenous fluids in children had been developed by Drs Smith and Lowry following

¹⁷² 260-002-021

¹⁷³ 088-004-073

¹⁷⁴ 327-003-006

¹⁷⁵ WS-357-1 p.10

¹⁷⁶ WS-368-1 p.5

¹⁷⁷ 327-003-003

¹⁷⁸ WS-364-1 p.4

¹⁷⁹ WS-354-1 p.11 & 329-018-006 & WS-369-1 p.6

Raychel Ferguson's death and before the Guidelines were published.¹⁸⁰ Their protocol emphasised the need to calculate maintenance fluids separately from replacement fluids and contained a table to aid the proper approach to fluid management.¹⁸¹

- 6.65 I can only therefore conclude that had Conor been admitted to the paediatric ward as Dr Budd intended, he may very well have been cared for by medical staff familiar with the Guidelines and received appropriate fluid therapy. There might also then have been better engagement with Conor's mother.
- 6.66 This was an inconsistency which effectively meant that different paediatric patients could receive different treatment in different parts of the same hospital with potentially different outcomes. Such variation in the potential for appropriate treatment within a major hospital is troubling. That such a situation could develop reveals dangerous systemic vulnerabilities for which the Chief Executive, Mr Templeton, must bear responsibility.

Serious Adverse Incident Procedure

- 6.67 Craigavon had policy and procedure in place in 2003 for adverse incident reporting. However, Conor's death was not reported as an adverse incident¹⁸² notwithstanding that the RBHSC reported both the fact of his death and the fluid mismanagement to the Coroner.
- 6.68 The decision not to report Conor's death as a Serious Adverse Incident ('SAI') was subsequently defended in correspondence by Dr Humphrey to Dr A.M. Telford, Director of Public Health, Southern Health and Social Services Board on the basis that fluid management issues were not in fact implicated in the cause of death.¹⁸³ Ignoring the fact that Conor's death was most unexpected and warranted investigation on that basis alone,

¹⁸⁰ 329-014-001 & WS-350-1 p.5

¹⁸¹ 329-014-004

¹⁸² 329-022-001

¹⁸³ 329-022-017

there was a failure to adequately review Ms Mitchell's express dissatisfaction and the uncertainties in clinical diagnosis.

- 6.69 Ms Mitchell continued to express her concern about the fluid management in correspondence with Mr Templeton in 2004 and 2005.¹⁸⁴ It was not until Conor's case was added to the work of this Inquiry that the Trust belatedly acknowledged that it *"can now be considered a serious adverse incident as defined in Circular HSS (PPM) 06/04."*¹⁸⁵ This was an incident and a complaint which ought to have been thoroughly investigated. At the very least the Trust would then have been alerted to some of the many deficiencies now revealed.

Admissions by the Trust

- 6.70 The Trust properly issued the following apology in respect of its many failings in relation to the Guidelines:

"The Southern Health and Social Care Trust, which includes the legacy Craigavon Area Hospital Trust... accepts that the DHSSPS 2002 guidelines on the prevention of hyponatraemia in children were applicable to Conor Mitchell. The trust accepts that for various reasons, which will be the subject of this inquiry, the directions of the Chief Medical Officer as contained in these guidelines and accompanying correspondence were not properly implemented in the medical assessment unit or emergency department of Craigavon Area Hospital at this time and that staff in those areas were not made aware of or trained by the legacy trust in the implementation of these guidelines. We would contrast that situation with the Southern Trust's response to the DHSSPS 2007 guidelines. 'The trust accepts that throughout his course of management in Craigavon Area Hospital in 2003, it was the trust's responsibility to ensure the clinicians and nurses who were looking after Conor Mitchell had the guidelines in the forefront of their minds when treating him and the trust accepts that these clinicians and nurses should have had this guidance available to them when treating Conor.

¹⁸⁴ 329-022-021 to 033

¹⁸⁵ 329-022-018

Although there is nothing to indicate that the failure to comply with the guidelines resulted in Conor's death, the trust fully acknowledges its liability for the failures and shortcomings that occurred in the implementation of the DHSSPS 2002 guidelines on the prevention of hyponatraemia in children, both generally and specifically, in relation to Conor's care. The trust apologises to Conor's family for the failings referred to above and again offers our sincere sympathies to Conor's family."¹⁸⁶

6.71 The family welcomed this admission and apology¹⁸⁷ and hoped that it would avoid "*extensive investigations on certain issues*" by the Inquiry and result in savings in public funds.¹⁸⁸ It was agreed that the admissions rendered it unnecessary for the treating clinicians to give oral evidence.¹⁸⁹

6.72 Instead, I directed that the Trust provide written submissions detailing how and why it failed in Guidelines implementation and its omission to deal with the case as a SAI. In addition I sought particulars of those arrangements now in place in Craigavon to implement the Guidelines.

6.73 A paper was submitted by the Trust on 21st October 2013 indicating that:

- (i) "*There may have been a perception at the time of the dissemination of the 2002 Guidelines that the guidelines were not applicable to adult medicine and therefore appropriate dissemination and training in the guidelines was not highlighted...*"¹⁹⁰
- (ii) "*Clear compliance and assurance processes should have been put in place to ensure that nurses and doctors in all areas where there was the potential for children to be treated were aware of and trained in the guidance.*"¹⁹¹

¹⁸⁶ T-17-10-13 p.6-7

¹⁸⁷ T-24-10-13 p.7

¹⁸⁸ T-17-10-13 p.7-8

¹⁸⁹ T-18-10-13 p.2

¹⁹⁰ 340-001-004

¹⁹¹ 340-001-004 to 005

- (iii) *"Assurance arrangements should have been agreed by both the Medical Director and Nursing Director..."*¹⁹²
- (iv) *"There appears to have been a breakdown in communication in relation to individual's roles and responsibilities regarding the dissemination of the guidelines..."*¹⁹³
- (v) *"There appears to have been a perception by the Director of Nursing that it was the CSM's responsibility to implement the guidelines... in the absence of a clear assurance framework there was confusion of roles and responsibilities between the Director of Nursing and the CSM..."*¹⁹⁴
- (vi) *"That the governance arrangements within the Trust had not matured sufficiently to ensure an integrated approach to Governance. This resulted in the risk that the guidelines would not be disseminated down both nursing and medical lines simultaneously..."*¹⁹⁵
- (vii) *"There is no documented evidence or audit trail to evidence that Paediatric nurses were trained specifically on the 2002 fluid management guidelines..."*¹⁹⁶
- (viii) *"In retrospect both Dr McCaughey and Dr Humphrey advised that they based their assurances [to the CMO] with regards to the implementation of the 2002 guidelines on informal assurance mechanisms..."*¹⁹⁷
- (ix) *"It is evident in hindsight that Conor's case would meet the criteria for review as a SAI with respect to point 8 of Circular HSS (PPM) 06/04 Reporting and Follow up on Serious Adverse Incidents: Interim Guidance... Therefore in not reporting Conor's case as an SAI at the*

¹⁹² 340-001-005

¹⁹³ 340-001-006

¹⁹⁴ 340-001-006 to 007

¹⁹⁵ 340-001-007

¹⁹⁶ 340-001-007

¹⁹⁷ 340-001-009

time there was a lost opportunity to identify and share learning across the region.”¹⁹⁸

6.74 On 23rd October 2013 I sought clarification on these submissions so as to confirm my interpretation of the Trust concessions.¹⁹⁹ At public hearing on 24th October 2013 it was furthermore accepted by the Trust that:

- (i) Clinicians in wards other than the paediatric ward were not made aware of or trained in the implementation of the Guidelines, including A&E and MAU where children would be treated.
- (ii) The Guidelines were not implemented within nursing practice in Craigavon, including paediatric nursing.
- (iii) That there was no basis for the Medical Director, Dr Humphrey, whether alone or with input from Mr McCaughey, to give assurance to the CMO that there had been implementation of the Guidelines at Craigavon.
- (iv) That a SAI investigation should have been conducted into the unexpected death of Conor under Circular HSS (PPM) 06/04 or the Trust’s own policy.²⁰⁰

Subsequent developments

6.75 The Trust approach was of assistance. The Mitchell family then responded and stated that they wanted *“to see measures put in place that will prevent similar tragedies occurring in the future...”*²⁰¹

6.76 It therefore became important to consider whether or not measures are now in place in Craigavon to ensure that paediatric fluid therapy is managed in accordance with the Guidelines.

¹⁹⁸ 340-001-010

¹⁹⁹ 340-008-001

²⁰⁰ T-24-10-13 p.19 line 21

²⁰¹ T-24-10-13 p.8 line 15

- 6.77 I was informed that the Guidelines were superseded in 2007 by guidelines deriving from the NPSA Patient Safety Alert 22.²⁰² The approach taken by the Trust in light of Safety Alert 22 was described as including the presentation of an action plan to the Trust Board, the creation of a Working Group led by the Medical Director, a training programme, compliance audits and an independent review of the Alert.²⁰³
- 6.78 On 30th October 2007 the Trust reported that Solution No.18 had been removed from general use in Craigavon and new fluid balance and prescription sheets were under consideration.²⁰⁴ A “*Hyponatraemia Meeting*” was held in January 2008 to consider how all 14-16 year old patients would receive treatment in accordance with the Guidelines irrespective of where they were treated.²⁰⁵ Audits to ensure compliance were carried out in October 2007²⁰⁶ and March 2008.²⁰⁷
- 6.79 The Trust also adopted a ‘Paediatric Intravenous Infusion Policy’ in October 2009 detailing the medical procedures for prescription, monitoring and review of intravenous infusions for children and young people²⁰⁸ together with nursing procedures for the administration of fluids. Guidance was given as to the recognition of hospital acquired hyponatraemia.²⁰⁹ In terms, the policy directed that nurses should consult the chart to satisfy themselves that prescriptions complied with the 2007 Guidelines before administering IV fluid and that they should carry out appropriate assessments, report changes in the child’s condition and provide handover briefings to incoming staff.
- 6.80 The policy also contained an ‘incident trigger’ list²¹⁰ with an associated reporting mechanism²¹¹ to alert clinicians to:

²⁰² 303-028-367
²⁰³ 329-020a-001
²⁰⁴ 329-020a-012
²⁰⁵ 329-020a-001
²⁰⁶ 329-020a-042
²⁰⁷ 329-020a-038
²⁰⁸ 329-020a-125
²⁰⁹ 329-020a-133
²¹⁰ 329-020a-145
²¹¹ 329-020a-146

- (i) Any episode of hospital acquired hyponatraemia in children receiving IV fluids.
- (ii) Any failure to check electrolytes at least once in every 24 hours in children receiving intravenous fluids.
- (iii) The use of any IV fluid other than as outlined in the 2007 Guidelines.

6.81 Mandatory training for all medical and nursing staff in the management of IV fluids for children and young people was also stipulated by the policy.²¹² The Inquiry has been provided with comprehensive documentation setting out these requirements. Moreover in relation to the clinical governance procedures set out in the policy, the evidence suggests that the Trust has undertaken audits every year since 2010 to assess compliance with the 2007 Guidelines²¹³ together with an “*Audit of Hyponatraemia*.”²¹⁴

6.82 The Trust advised that the audit results are shared within a multi-disciplinary team and discussed at clinical governance meetings.²¹⁵ This in conjunction with developing external guidance has led to additional changes in practice including:

- (i) The development and implementation of a revised fluid balance chart.
- (ii) The development and implementation of guidelines for peri-operative fluid management in children to “*provide guidance and reduce the risk of harm associated with intravenous fluid administration to the paediatric patient in the peri-operative phase*.”²¹⁶
- (iii) Further review of the paediatric intravenous infusion policy.

²¹² 329-020a-173

²¹³ 329-020a-004

²¹⁴ 329-020a-122

²¹⁵ 329-020a-008

²¹⁶ 329-020a-163

- 6.83 A Review of the Trust's 'Incident Management Policy' was completed in January 2013²¹⁷ and found *"clear guidance on incident reporting, investigation and the dissemination of learning from incidents and SAI's."*²¹⁸ Likewise, assurances were given that since April 2012 the Trust has had a procedure²¹⁹ *"in place to ensure the systematic and integrated approach for the implementation, monitoring and assurance of clinical standard and guidelines."*²²⁰
- 6.84 Accordingly, the Trust expressed the hope that it had been able *"... to demonstrate that they have reflected on their roles and responsibilities at this time and have identified and agreed on those factors which may have had an influence, or may have contributed to the failings in the dissemination and implementation of the guidelines in the Emergency Department and Medical Assessment Unit of CAH and furthermore the opportunities missed in the sharing of learning with regard these failings."*²²¹
- 6.85 On this basis I am of the view that the Trust has learned lessons and has implemented appropriate change in the years since Conor's tragic death.

Concluding remarks

- 6.86 Whilst I welcome the Trust concession that clear compliance and assurance processes in respect of the Guidelines should have been agreed and put into operation by the Medical Director and Nursing Directors, such concession cannot serve to avoid the just and appropriate criticism that Conor's treatment failed to comply with the Guidelines.
- 6.87 It is now acknowledged that there was a breakdown in communication between those in positions of governance as to their roles and responsibilities. This was a systemic failing for which the Chief Executive must bear responsibility.

²¹⁷ 340-001-012

²¹⁸ 340-001-012

²¹⁹ 304-001-003 & 340-005-001

²²⁰ 340-001-013

²²¹ 340-001-013

- 6.88 There was potentially dangerous variation in the care and treatment afforded young people admitted to Craigavon which was a serious systemic weakness.
- 6.89 The false assurance given the CMO that the Guidelines had been adopted and audited was a serious breach of professional duty and public service values.
- 6.90 Had the Trust conducted the SAI investigation of Conor's unexpected death, which it now accepts it should have done, it would have learned lessons to the benefit of all. That opportunity was lost.
- 6.91 Notwithstanding shortcomings and deficiency, the evidence as to policy, protocol, training, audit and review in the years since Conor's death, has provided some reassurance that lessons have been learned from this tragedy. Appropriate measures have been taken within Craigavon.

THE DEPARTMENT OF HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY FOR NORTHERN IRELAND

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Introduction

7.1 What happened immediately after Raychel's death illustrates what can be achieved when such a death is reported promptly. The Department responded quickly and decisively to analyse and issue guidelines. However the deaths of Adam, Claire and Lucy were not formally reported to the Department and it remained seemingly unaware of them at the time. So why did the Department fail to ensure that it was notified about such serious adverse incidents?

Expert reports

7.2 The Inquiry was guided by the reports of:

- (i) Professor Gabriel Scally¹ (Professor of Public Health and Planning, Director of WHO Collaborating Centre for Healthy Urban Environments, University of the West of England) who examined the responsibilities and accountabilities of HSC Trusts, Health Boards and the DHSSPS in Northern Ireland.²
- (ii) Professor Charles Swainson³ (onetime Consultant Renal Physician and Medical Director, Lothian NHS Board, Edinburgh) who considered the issues of governance arising from Raychel Ferguson's case.⁴
- (iii) Professor Aiden Mullan⁵ (former acting Chief Executive Officer and Director of Nursing and Clinical Governance, North Tees & Hartlepool NHS Trust) who provided advices on governance matters relating to Adam Strain.⁶

7.3 The Inquiry was also assisted by expert background papers received from:

¹ 337-001-005
² 341-002-001 & 341-003-001
³ 328-001-006
⁴ 226-002-001
⁵ 306-081-008
⁶ 210-003-001

- (i) Dr Jan Keeling⁷ (Paediatric Pathologist) on systems and procedures for disseminating information derived from post-mortem examinations.⁸
- (ii) Dr Bridget Dolan⁹ (Barrister and Assistant Deputy Coroner) on UK practice and procedure on the dissemination of information from inquests.¹⁰

Schedules compiled by the Inquiry

7.4 In an attempt to summarise all the information received, the following schedules were compiled:

- (i) List of persons involved.¹¹
- (ii) Chronology.¹²
- (iii) Structure of the Health Service in Northern Ireland (pre-2007).¹³
- (iv) HSC Trust areas in Northern Ireland.¹⁴
- (v) Commissioning structure for HSC services in Northern Ireland.¹⁵
- (vi) Membership of Chief Medical Officer's Working Group on Hyponatraemia.¹⁶

⁷ 306-081-010
⁸ 308-020-295
⁹ 306-081-010
¹⁰ 303-052-715
¹¹ 337-001-001
¹² 337-003-001
¹³ 303-039-505
¹⁴ 300-001-001
¹⁵ 303-040-506
¹⁶ 328-003-001

Department's responsibility for clinical services

- 7.5 At the time of the children's deaths, as now, the Department and the Minister bore ultimate responsibility and accountability for the healthcare provided to patients in Trust hospitals.¹⁷
- 7.6 Article 16(1) of the Health & Personal Social Services (Northern Ireland) Order 1972¹⁸ created 4 Health and Social Services Boards, namely the Northern, Southern, Eastern and Western. The Department made provision for and oversaw the Health Service through those four regional Boards. Subsequent re-structuring was undertaken, broadly following that in the rest of the UK, to re-constitute the Boards as commissioning bodies, responsible for assessing local requirements and purchasing healthcare and social services from the hospitals, which re-emerged as Trusts.
- 7.7 Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991¹⁹ created the new Health and Social Services Trusts to provide the health services. The Chair of each Trust was appointed by the Minister and was directly accountable to the Minister.²⁰ The Trusts were established as 'autonomous self-governing' bodies, independent of the Boards but with 'arms-length' accountability to the Department.
- 7.8 The Department described this re-ordering in 'HSS Trusts: A Working Guide,' 1991 noting that *"A key element of the changes is the introduction of HSS Trusts. They are hospitals and other units which are run by their own Boards of Directors; are independent of Health and Social Services Board Management; ... Trusts differ in one fundamental respect from directly managed units – they are operationally independent..."*
- 7.9 The understanding at the time was that, whilst standards of clinical care remained primarily the responsibility of consultants within the Trusts,²¹ the

¹⁷ 333-001-003 & 306-083-003

¹⁸ <https://www.legislation.gov.uk/nisi/1972/1265/contents>

¹⁹ <http://www.legislation.gov.uk/nisi/1991/194/contents/made>

²⁰ Mr Hunter T-04-11-13 p.50 line 2

²¹ WS-348-1 p.3

Trusts were accountable to the Boards and the Department retained a leadership role in respect of the whole Health Service.²²

- 7.10 The Department was responsible for articulating the directions of its Minister and the Permanent Secretary was accountable for the management and organisation of the Department. He was supported by the Departmental Board which included a Chief Medical Officer ('CMO'), a Chief Nursing Officer ('CNO') and his most senior officials. The Department formulated and implemented policy, allocated resources and established the context and objectives for the Health and Personal Social Services ('HPSS').
- 7.11 The CMO led the medical service within the Civil Service and was responsible for advising the Minister and the Department on matters relating to public health. The CMO from 1995-2006 was Dr Henrietta Campbell.²³ It was envisaged that she would provide a link between the Minister and the medical profession.²⁴ Ultimate responsibility for the Department lay with the Permanent Secretary.
- 7.12 The Department did not assume general operational responsibility in relation to the HPSS but did on occasion issue guidance and instruction for HSS Trusts. The Department created a Management Executive to oversee performance of the HSS Trusts.²⁵ One of the main objectives of the Management Executive was to ensure that standards were raised and quality improved in accordance with Departmental policy.²⁶ Until 2000 it was responsible for the communication of Departmental policy and instruction to the Trusts.
- 7.13 The relationship of accountability between the Management Executive and the Trusts was set out in an 'Accountability Framework for Trusts' (1993).²⁷ It indicated that whilst the *"primary accountability of Trusts is for the*

²² Mr Elliott T-05-11-13 p.70 line 16

²³ 337-001-002

²⁴ WS-075-2 p.2

²⁵ WS-062-2 p.3

²⁶ WS-002-2 p.3

²⁷ 323-001a-002 - Circular METL 2/93

*quantity, quality, efficiency of the service they provide*²⁸ (and this lay to the Boards) the Department was to retain “*ultimate legal responsibility for the functions and will wish to ensure that both Boards and Trusts are discharging their responsibilities.*”²⁹ In broad terms, the Department planned to appraise itself of patient care issues and hold the Trusts to account through their relationship with the Boards.³⁰ This was to be “*a light touch*” approach.³¹ However, the Management Executive retained a degree of direct management accountability in relation to the Trusts³² and reserved the right, in certain and exceptional circumstances (including those relating to patient care), to intervene in the affairs of a Trust.³³ In short, the Department was responsible for holding the whole system to account.³⁴

- 7.14 However, in respect of the specifics of Departmental monitoring of the performance of the Trusts, Professor Scally noted that the ‘Accountability Framework’ did not indicate any particular focus on patient care issues.³⁵ The question therefore arose as to how the Department ensured that the Trusts discharged their responsibilities in respect of the quality of healthcare and in particular why it did not know about the hospital related deaths from hyponatraemia in the very hospitals for which it was responsible? Accordingly, Professor Scally examined the question of how the Department knew what was going on in hospitals prior to 2003 in terms of the quality of care.³⁶

Serious Adverse Incident reporting to Department

- 7.15 Professor Scally advised that there was no requirement during the period under review for Boards or Trusts to notify the Department about “*potentially avoidable deaths or other instances of serious clinical failure.*”³⁷

²⁸ 323-001a-003
²⁹ 323-001a-003
³⁰ Mr Simpson T-08-11-13 p.6 line 20 & WS-349-1 p.5
³¹ WS-084-2 p.4
³² 306-083-003
³³ WS-348-1 p.14
³⁴ WS-348-1 p.4 & WS-308-1 p.11
³⁵ 341-002-002
³⁶ 341-002-002
³⁷ 341-002-004

Whilst there had hitherto been formal requests that hospitals report untoward incidents to their Board,³⁸ he noted that the *“changes in accountability that took place with the creation of Trusts altered the position whereby the Boards had been responsible for occurrences within their directly managed units. It appears that once hospitals became Trusts they ceased to report serious untoward incidents to the Boards.”*³⁹

- 7.16 Even though Trust lines of accountability remained initially to the Boards, there would appear to have been no attempt at that time to develop alternative replacement notification systems. Further and importantly, given that the Boards no longer received reports, no requirement was introduced to ensure reporting to the Department.⁴⁰ This was a vulnerability and not without consequence.
- 7.17 Professor Swainson considered it: *“regrettable in hindsight that there was not a clear framework that would have ensured that serious clinical incidents were reported by Trusts and disseminated to the other Trusts. Wide sharing of serious incidents can stimulate quicker and national efforts to reduce harm.”*⁴¹
- 7.18 This omission is to be seen in a context where functioning systems already existed to notify the Department of adverse incidents relating to equipment, supplies,⁴² food, buildings and plant⁴³ or affecting patients⁴⁴ in psychiatric or special care hospitals.⁴⁵ The Department was part funding⁴⁶ a number of national reporting systems for deaths including National Confidential Enquiry into Perioperative Deaths (‘NCEPOD’)⁴⁷ and systematically receiving reports of maternal deaths, stillbirths and deaths in infancy for

³⁸ 341-002-005
³⁹ 341-002-005
⁴⁰ 341-002-006
⁴¹ 226-002-010
⁴² WS-062-1 p.13 & 210-003-1132
⁴³ WS-062-1 p.13.
⁴⁴ WS-062-1 p.3
⁴⁵ WS-062-1 p.34
⁴⁶ WS-075-1 p.13 & p.32
⁴⁷ WS-062-1 p.3

inclusion in the UK Confidential Enquiry into Stillbirths and Deaths in Infancy.⁴⁸

7.19 However, the absence of any formal reporting requirements to the Department was, in the view of Mr Clive Gowdy (Permanent Secretary in the Department 1997-2005)⁴⁹ consistent with the intention that Trusts should operate with maximum freedom and autonomy.⁵⁰ Notwithstanding external developments, including the disturbing 1994 Report into the Deaths of Children in the Grantham and Kesteven General Hospital (the Beverley Allitt inquiry), which stressed that *“reports of serious untoward incidents to District and Regional Health Authorities should be made in writing and through a single channel which is known to all involved,”*⁵¹ nothing substantive was done.

7.20 By comparison, Regional Directors of the National Health Service Executive in England were directed in 1995 to establish notification systems for serious untoward incidents.⁵² The English regions, all of which were significantly larger than Northern Ireland, proceeded to put systems, albeit imperfect, into place. Within Northern Ireland, and notwithstanding that the Management Executive *“received a constant flow of documentation, particularly from England, in respect of initiatives that were being taken there,”*⁵³ the then Permanent Secretary Mr Alan Elliott⁵⁴ indicated that *“it didn’t occur to anyone to say that there should be a system.”*⁵⁵ Mr John Hunter,⁵⁶ Chief Executive of the HPSS Management Executive, was unable to advance any explanation as to why this was so.⁵⁷

⁴⁸ WS-075-1 p.13

⁴⁹ 337-001-001 & 323-027e-003

⁵⁰ WS-062-1 p.3

⁵¹ 341-002-007 & Mr Elliott T-05-11-13 p.21 line 14

⁵² 341-003-009

⁵³ Mr Hunter T-04-11-13 p.10 line 20 & p.27 line 5. Documentation included the ‘Risk Management in the NHS’ manual (1994) (211-003-001) recommending a comprehensive incident reporting system as the foundation of a good tracking system. This was forwarded by the Management Executive to the RGHT (Dr Carson T-16-01-13 p.4 to 5).

⁵⁴ 337-001-003

⁵⁵ Mr Elliott T-05-11-13 p.66 line 19

⁵⁶ 337-001-003

⁵⁷ Mr Hunter T-04-11-13 p.31 line 19

7.21 In 1998 the Department commissioned the consultants 'Healthcare Risk Resources International' to survey risk management in the HPSS.⁵⁸ Mr Gowdy recalled that it reported '*a general perception that there might have been a significant level of under-reporting of adverse incidents.*'⁵⁹ In the light of such intelligence, the Department could not safely assume that it would be informed of potentially serious patient care issues. Notwithstanding, it made no policy change and gave no direction for adverse incident reporting.

7.22 In 2000 the Department of Health ('DoH') in London published 'An Organisation with a Memory' specifically recommending more comprehensive systems for reporting and analysis of adverse events.⁶⁰ The Department did not follow suit but did publish for consultation 'Confidence in the Future' in relation to the problem of poor medical performance.⁶¹ It recommended, amongst other things, Serious Adverse Incidents ('SAI's') recording as an aid to the identification of the under-performing doctor. Additionally, the Department published for consultation 'Best Practice, Best Care' in 2001 noting in particular the necessity for "*a clear line of accountability from front line delivery back to the Executive*"⁶² and the requirement to monitor adverse events. Formal reporting requirements were not however introduced until 2004.⁶³

7.23 In the absence of a formal system, informal channels of communication were used. Trust Chief Executives and Clinical Directors could bring significant untoward clinical incidents to the attention of the CMO at any time.⁶⁴ Indeed, Raychel's death was reported in just such a way. It was in this context that Mr Gowdy said that he "*would certainly have expected the*

⁵⁸ 338-006-107

⁵⁹ WS-062-1 p.4 – "*The major deficiency relates to the very limited and therefore probably significant under-reporting of clinical incidents and near misses.*"

⁶⁰ Professor Scally noted that the NHS 1995 Regional serious untoward incident reporting scheme had informed the recommendations of 'An Organisation with a Memory'. (341-003-004).

⁶¹ 333-184-001

⁶² WS-068-1 p.49

⁶³ WS-062-1 p.321 - Circular HSS (PPM) 06/04. Professor Mullan pointed out that 'An Organisation with a Memory' referred to Department of Health guidance for untoward incident reporting in England issued in 1955, which was still current in 2000.(210-003-038).

⁶⁴ 010-023-150 & WS-075-1 p.3

*Trusts to have informed the Department of all of them.*⁶⁵ Moreover he “assumed that the informal system was working effectively because [he] was being told of serious things”⁶⁶ estimating that he had been informed of approximately two deaths during his eight years as Permanent Secretary.⁶⁷ Upon reflection he recognised that he had been “lulled into a false sense of security by the fact that [he] was getting reports about serious incidents from some of the Chief Executives and chairs.”⁶⁸ Both Mr Paul Simpson,⁶⁹ former Chief Executive of HSS Executive,⁷⁰ and Mr Gowdy accepted with hindsight that it was not an effective system.⁷¹

7.24 Dr Campbell acknowledged that the informal mechanisms of adverse incident reporting “were found to be totally inadequate and recognised by myself as such in 1999.”⁷² She fairly conceded that she could not “defend the fact that it took until 2004 to put a proper system in place.”⁷³ As Mr Gowdy observed “you don’t know what you don’t know, so you need to have a system to find out.”⁷⁴ The Department did not know, did not have a system and did not find out.

7.25 While Trusts and Boards were clearly accountable to the Department and the Department had a clear role in overseeing the functioning of the Health Service, Professor Scally nonetheless believed that the Trusts did not generally understand that the Department might have had an interest in the occurrence of these deaths.⁷⁵ It was not made clear. He concluded “that there was no effective system in place in Northern Ireland prior to 2003 and ...no significant efforts had been made at any stage to develop comprehensive and effective notification systems. This would appear to be borne out by a briefing for the Minister prepared within the Department in

⁶⁵ WS-062-2 p.10

⁶⁶ Mr Gowdy T-06-11-13 p.100 line 2

⁶⁷ Mr Gowdy T-06-11-13 p.96 line 19

⁶⁸ Mr Gowdy T-06-11-13 p.96 line 8

⁶⁹ 337-001-003

⁷⁰ Mr Simpson T-08-11-13 p.14 line 19

⁷¹ Mr Gowdy T-06-11-13 p.112 line 17

⁷² Dr Campbell T-07-11-13 p.62 line 3

⁷³ Dr Campbell T-07-11-13 p.74 line 4

⁷⁴ Mr Gowdy T-06-11-13 p.111 line 2

⁷⁵ 341-002-018 & Dr Jenkins T-10-09-13 p.73 line 25

2004. The opening sentence reads: ‘There is no unified reporting of untoward incidents in the HPSS to the Department.’⁷⁶ Indeed it was noted within the Department at that time that reporting of adverse incidents was “patchy” and the Minister was thought to be “somewhat vulnerable to the accusation that the Department is not aware what is going on as regards serious incidents.”⁷⁷

- 7.26 I consider that in the circumstances it should have been obvious to the Permanent Secretary Mr Gowdy, his predecessor Mr Alan Elliott,⁷⁸ the Chief Executive of the Management Executive, the CMO and the other senior Departmental officials, that untoward clinical events were not being routinely reported to the Department. I do not understand how they could have thought otherwise. Professor Scally characterised the approach to adverse incident reporting as “fragmented and incoherent”⁷⁹ and the evidence confirmed that. In such circumstances it was foreseeable that hospital related child deaths might not be brought to the Department’s attention. The Department appeared to proceed on the basis of ‘hear no evil, see no evil’.

Other channels of information

- 7.27 It has to be recognised that even had a structured system of SAI reporting been in place, there is no absolute certainty that the deaths of Adam, Claire or Lucy would have been formally notified to the Department.
- 7.28 There were however other means whereby the Department might have hoped to gain some information about what was happening in Trust hospitals and to learn whether things were going wrong. Mr Elliott expected that the Department would have been informed of those deaths where

⁷⁶ 341-002-006

⁷⁷ 010-025-180

⁷⁸ Permanent Secretary 1987-1997

⁷⁹ 341-002-006

medical mismanagement was implicated, through complaints, inquests and legal action.⁸⁰ There were also other sources of information.

Complaints

- 7.29 The Department was clearly interested in complaints as part of its wider interest in Risk Management, not least because they could inform as to the nature of those risks. In 1992 the Government published 'The Citizen's Charter for Patients and Clients'⁸¹ setting out the standards of treatment to be expected from the HPSS and indicating what to do if those standards were not met. The section entitled 'If Things Go Wrong' outlined a patient complaints procedure and indicated that final referral lay to the Chief Executive of the HPSS Management Executive.⁸²
- 7.30 In 1995-1996 the Department published the HPSS Complaints Procedure⁸³ and followed it up with further 'Guidance on Handling HPSS Complaints.'⁸⁴ It reviewed the HPSS Complaints Procedure in 2002 and established a Regional Complaints Review Group.
- 7.31 Whilst Mr Crawford did attempt to invoke the HPSS Complaints Procedure in relation to Lucy, the system was not engaged in the cases of Adam, Claire or Raychel. Accordingly, and although the complaints procedure represented an important part of the Department's 'quality agenda', it was not always used and could not therefore have been relied upon to alert the Department to particular issues of patient safety.

Inquests

- 7.32 Dr Campbell expressed the view that the inquest system in Northern Ireland was *"another way of bringing into the open issues which are of concern"* and *"is one that I feel that people should have been using properly."*⁸⁵

⁸⁰ WS-348-1 p.7

⁸¹ 306-085-001

⁸² 306-085-014

⁸³ 126-004-001

⁸⁴ 333-294-001

⁸⁵ 069a-033-084

However there was no formal mechanism to inform the Department about Coroner's findings in healthcare related inquests.⁸⁶ Nor were patient safety matters arising from inquests routinely notified to the Department or circulated to the HPSS.

7.33 This lack of procedure became evident at Adam's inquest. The Royal Group of Hospitals Trust ('RGHT') 'recommendations' which Mr Gowdy considered "*of such general application as to be of interest and significance to other hospitals likely to be treating young patients*"⁸⁷ and which he expected to be "*at least copied*" to the Department and "*ideally*" to have been the subject of prior discussion with the CMO, were not seen by the Department at all. There was no mechanism for communication, which was why, as the Coroner was later obliged to point out to Dr Campbell "*an inquest should not be seen as the means of disseminating medical knowledge.*"⁸⁸

7.34 That inquests were not used to gather or share information is to be regretted. Their value as a resource for learning was very clearly demonstrated in April 2005⁸⁹ by Dr Angela Jordan, Specialist Registrar in Public Health Medicine, when she presented an analysis of the "*key learning points*" deriving from the evidence given at the inquests of Adam, Raychel and Lucy.⁹⁰

Litigation

7.35 During the period under review claims administration was managed by individual Trusts and Boards. There was no centralised approach and the Department played no active role in the management of litigation or claims. The detail and outcome of individual cases was not collated by the Department and the potential for monitoring HPSS failings not exploited. Whilst the Department did issue a HPSS Protocol on Claims Handling⁹¹ this

⁸⁶ WS-062-1 p.4

⁸⁷ WS-062-1 p.10

⁸⁸ 006-004-282

⁸⁹ 320-126-114

⁹⁰ 320-126-124

⁹¹ 317-039-001 - Circular HSS (F) 20/98

did not stimulate much more than a “*few examples of a claims management policy*.”⁹² In 2002 the Northern Ireland Audit Office (‘NIAO’) published an assessment of the medical negligence system and expressed surprise at the absence of central collection of data.⁹³ When rather later, attempts were made to collect the information offered, difficulties were encountered and a Departmental memo of July 2005 records concern about “*the quality and accuracy of this data*.”⁹⁴ This did not therefore constitute a reliable channel of information.

Meetings

- 7.36 The Department held formal accountability reviews with the Boards⁹⁵ but not with the Trusts.⁹⁶ The CMO did however meet Trust Medical Directors on a regular basis⁹⁷ and there were other less formal discussions with Board and Trust officers.⁹⁸ Routine meetings were also held with organisational, educational and professional leaders including Directors of Public Health and representatives of the Health and Social Care Councils.⁹⁹ Dr Campbell described this as “*a fairly well trampled pathway in that the Directors of Public Health quite often brought issues to me of concern, not just of serious clinical incidents ...*”¹⁰⁰ The CNO used a ‘Nurse Leaders Network’ to communicate directly with senior nurses.¹⁰¹
- 7.37 Individual committees provided direct clinical advice to the Department.¹⁰² They included the Central Medical Advisory Committee (CMAC)¹⁰³ and the CMO’s Special Advisory Committees (SACs).¹⁰⁴ Their meetings mixed formal and informal business but did provide a useful means whereby

⁹² 127-004-098
⁹³ 341-002-009
⁹⁴ 330-108-006.
⁹⁵ WS-084-2 p.6 & WS-066/1 p.63
⁹⁶ WS-362-1 p.10-11
⁹⁷ 021-018-037
⁹⁸ WS-348-1 p.5 & Mr Hunter T-04-11-13 p.89
⁹⁹ WS-361-1 p.8
¹⁰⁰ Dr Campbell T-07-11-13 p.54 line 20
¹⁰¹ WS-082-2 p.13
¹⁰² 320-104-009
¹⁰³ Mr Hunter T-04-11-13 p.36 line 2
¹⁰⁴ Mr Hunter T-04-11-13 p.19 line 7 & 320-110-001

clinical information could pass from Trusts to Department.¹⁰⁵ However, they were unstructured and had no secretarial support. It was in the context of such a meeting that the initial report of Raychel's death was made.¹⁰⁶ Notwithstanding that the meeting enabled effective reporting in that case, the arrangement of committees and meetings failed to convey any hint to the Department of the other deaths from hyponatraemia.

Audit

- 7.38 The routine collection and systematic analysis of data by audit reveals incidents of note and is an invaluable source of information. The 1989 NCEPOD Report, which was part-funded by the Department, stressed the importance of information systems and audit for clinical quality assurance.¹⁰⁷ The Department recognised clinical audit as an integral part of a functioning healthcare system and emphasised the importance of clinical audit programmes in its Management Plans from 1995/96.¹⁰⁸ The Management Executive sought to encourage multi-professional audit.¹⁰⁹ However, in practice audit took a very long time to become established¹¹⁰ and Professor Scally noted the absence of a generalised culture of participation in structured systems of clinical audit.¹¹¹ Indeed, the evidence repeatedly revealed deficiencies in the systems of audit as implemented and little indication that the Department was receiving regular audit analysis.¹¹²

Other

- 7.39 The Department also received information directly from members of the public, elected representatives and special interest groups. The CMO was lobbied by practitioners in relation to specific issues¹¹³ and the Department

¹⁰⁵ 320-018-001 & Mr Elliott T-05-11-13 p.14 line 7

¹⁰⁶ Dr Fulton T-04-09-13 p.87 line 18

¹⁰⁷ 210-003-012

¹⁰⁸ 306-083-001

¹⁰⁹ 333-129-011

¹¹⁰ 320-067-007

¹¹¹ 341-002-016

¹¹² 320-067-007

¹¹³ WS-076-2 p.13

sought to be attentive to media coverage and public debate.¹¹⁴ There were also diverse Health Service statistics and confidential reports from whistle-blowers.¹¹⁵ However useful, these were random conduits of information.

Risk Management, Clinical Governance and the Statutory Duty of Quality

- 7.40 The absence of any reliable system whereby the Department might learn of catastrophic clinical mismanagement reflected the broader reality that care quality was not being adequately monitored in the hospitals themselves. Professor Scally observed that there is little *“to indicate that there was a firm expectation that either Health and Social Services Boards or Trusts would be subject to any systematic monitoring of the quality of care provided to patients or in respect of their handling of adverse clinical events.”*¹¹⁶
- 7.41 The HPSS ‘Charter for Patients and Clients’ published in 1992 contained the personal pledge of the Minister for Health and Social Services *“to all citizens that services in Northern Ireland will continue to match the very best available in the rest of the United Kingdom.”*¹¹⁷ During the 1990s and early 2000s the Department did act to promote risk management controls and clinical governance. In so doing it almost always followed, at some remove, the lead of the DoH in London. For example, the DoH published ‘Working for Patients’ in 1989 to introduce a comprehensive system of medical audit¹¹⁸ and in Northern Ireland, the HPSS Management Executive published its plans for audit in the Management Plan for 1995/6–1997/8.¹¹⁹
- 7.42 In 1997 the DoH published ‘The New NHS – Modern and Dependable’ introducing clinical governance to the rest of the UK. Within Northern Ireland, and notwithstanding the findings of ‘Healthcare Risk Resources International’¹²⁰ the Department did not move to introduce a system of

¹¹⁴ Mr Gowdy T-06-11-13 p.104 line 13

¹¹⁵ 403-019-001

¹¹⁶ 341-002-003

¹¹⁷ 306-085-003 & Mr Hunter T-04-11-13 p.22 line 20

¹¹⁸ 210-003-012

¹¹⁹ 306-083-001

¹²⁰ WS-062-1 p.4

clinical governance in Northern Ireland until 2001 when it published 'Best Practice, Best Care' for consultation. Whilst it did not then give any particulars, it did propose "a system of clinical and social care governance, backed by a statutory duty of quality..."¹²¹

- 7.43 In 2002 a NIAO report¹²² noted the limited progress actually achieved in the implementation of risk management¹²³ and indicated that "We would therefore expect the department to be able to provide positive assurance of substantial progress in risk management within HPSS bodies by 2003 at the latest."¹²⁴ The Department sent out a circular requiring HPSS organisations to adopt the model of risk management used in Australia and New Zealand.¹²⁵
- 7.44 Early in 2003 the Department published 'Clinical and Social Care Governance: Guidelines for implementation.'¹²⁶ The Northern Ireland guidelines for clinical governance emerged some four years after their NHS counterpart.
- 7.45 In addition HPSS organisations became subject to the statutory duty of quality in April 2003. The introduction of the statutory duty was to allow Mr William McKee,¹²⁷ former Chief Executive of the RGHT to claim that as Chief Executive of a Trust Hospital he bore no responsibility for the quality of care in his hospital prior to the enactment of the statutory duty. He said that "in 1993/1994... and subsequently for many years I was specifically not held responsible for clinical safety, clinical quality, clinical matters."¹²⁸ He maintained furthermore that the Board of the Trust had no such responsibility either¹²⁹ and that the Trust only became responsible for clinical quality when the statutory duty was enacted.¹³⁰

¹²¹ WS-068- p.14

¹²² 338-006-062

¹²³ Mr Gowdy T-06-11-13 p.48 line 1

¹²⁴ 338-006-091

¹²⁵ WS-075-1 p.56

¹²⁶ 306-119-001

¹²⁷ 306-081-006

¹²⁸ Mr McKee T-17-01-13 p.6 lines 1-4

¹²⁹ Mr McKee T-17-01-13 p.16 line 4

¹³⁰ Mr McKee T-17-01-13 p.7 line 13

- 7.46 Mr Gowdy was however most firmly of the view that both the Chief Executive and the Trusts were responsible for clinical care and clinical outcomes before the 2003 Order. He observed that *“the raison d’être of the Trusts concerned was to deliver effective clinical care to sick or injured people and it is rather difficult to see how they might argue that they had no interest in, or responsibility for, the quality of the service they were providing.”*¹³¹ He understood the legislation to formalise the existing position as set out by the Accountability Framework, namely that *‘the primary accountability of Trusts is with the quantity, quality, efficiency of the service they provide’*.
- 7.47 As Senior Counsel for the Department put it *“we simply don’t accept that any person or anybody involved in the Health service can walk away and say ‘I have no responsibility’.”*¹³² I consider that self-evidently correct.
- 7.48 The introduction of clinical governance in Northern Ireland required an understanding of the arrangements already in place. To that end Deloitte & Touche were commissioned to evaluate existing clinical and social care governance.¹³³ Its report in 2003 identified a lack of both understanding and implementation of clinical and social care governance and noted in particular a lack of co-ordinated activity in relation to risk, risk registers and risk audits.¹³⁴ Mr Gowdy acknowledged that the report *“certainly would have suggested that we didn’t know enough about how they were progressing...”*¹³⁵ The consultants indicated that the position in Northern Ireland was comparable to that pertaining in England a few years before.
- 7.49 Whilst Professor Scally did recognise some positive and timely Trust activity in relation to the introduction of clinical governance, he nonetheless singled out the Department’s very clear leadership role and identified a departmental failure to provide the necessary impetus to progress clinical governance at anything other than a very slow pace. He observed that by

¹³¹ WS-062-2 p.4

¹³² David McMillen QC T-04-11-13 p.77 line 10

¹³³ WS-075-1 p.76

¹³⁴ WS-075-1 p.100

¹³⁵ Mr Gowdy T-06-11-13 p.79 line 4

2003 *“there was a significant gap between the progress in Northern Ireland and that achieved in England and Scotland”* and argued that *‘given the size of the province it would be a reasonable assumption that it would have been possible, if the will and competence had existed, to put in place within a short period of time a comprehensive clinical governance structure.’*¹³⁶

7.50 Mr Hunter acknowledged that the responsibility for *“driving those changes rested with the Department from the Minister down.”*¹³⁷ Dr Campbell accepted *“it as a corporate responsibility across the Department”*¹³⁸ and Mr Paul Simpson (from 1997 Chief Executive HSS Executive and Deputy Secretary HPSS Management Group) conceded that leadership within the Department could have been better.¹³⁹

7.51 Mr Gowdy maintained that *“there was no lack of will, there was no lack of direction. There was a very clear desire to move this agenda forward and, unfortunately, it didn’t happen and I find that disappointing.”*¹⁴⁰ The Department contended that comparisons with progress in England and Scotland were misleading and that there was no proper evidence base for such an exercise. It was suggested that because the Department was responsible for social care in addition to healthcare, that the extra responsibility made comparison inappropriate¹⁴¹ and furthermore, it advised that the alternation of direct rule with devolution in the 1990s and 2000s, had hindered progress.¹⁴²

7.52 Whilst I accept these broad distinctions and recognise constant financial constraint,¹⁴³ I do not accept that circumstances in Northern Ireland should have unduly delayed the implementation of systems to improve the quality of care, still less the introduction of reporting procedures whereby the Department might have learned what was happening in the hospitals for

¹³⁶ 341-002-023

¹³⁷ Mr Hunter T-04-11-13 p.92 line 25

¹³⁸ Dr Campbell T-07-11-13 p.12 line 9

¹³⁹ Mr Simpson T-08-11-13 p.24 line 12

¹⁴⁰ Mr Gowdy T-06-11-13 p.83 line 15

¹⁴¹ Mr Gowdy T-06-11-13 p.82 line 1

¹⁴² Mr Gowdy T-06-11-13 p.48 line 1 & Dr Campbell T-07-11-13 p.21 line 18

¹⁴³ Mr Gowdy T-06-11-13 p.72 line 20 & Mr Simpson T-08-11-13 p.18 line 22

which it was responsible.¹⁴⁴ I do not suggest that the Department should have introduced comprehensive SAI reporting in the mid-1990s, but do consider that the absence of any reliable means of learning about hospital related child deaths indicates a serious failure on the part of the Department.¹⁴⁵

Quality of Care

- 7.53 Departmental engagement with issues of quality of care appeared to lack constancy in terms of focus. Whilst the Department did, for example, issue important guidance in relation to standards and quality of healthcare, it did not maintain proper checks to ensure that its guidance was being heeded. Notwithstanding that the Department would request confirmation of compliance in respect of its more important guidance, Mr Gowdy indicated that many of the directions and guidelines issued “*were not subject to any specific monitoring.*”¹⁴⁶ The Department proceeded on the assumption that HPSS organisations would comply.
- 7.54 Such an assumption was unwise because the evidence disclosed failures to comply with Departmental guidance. Guidelines for Consent were issued on 6th October 1995 with explicit instruction that “*Health and Social Service Boards/HSS Trusts are asked to ensure that procedures are put in place to ensure the consent is obtained along the lines set out in the Handbook...*”¹⁴⁷ and that “*Boards/HSS Trusts ...confirm by 31 December 1995 that this has been done.*”¹⁴⁸ In this instance Mr Gowdy “*expected that it would have been followed up and followed up fairly quickly,*”¹⁴⁹ However, this specific direction was ignored by RGHT and almost five years passed before this important¹⁵⁰ guidance was adopted at RBHSC.¹⁵¹ The Department did not know because it had failed to follow-up either confirmation or

¹⁴⁴ Mr Hunter T-04-11-13 p.31 line 19 & Dr Campbell T-07-11-13 p.30 line 19

¹⁴⁵ Professor Dame Judith Hill T-04-11-13 p.140 line 24

¹⁴⁶ WS-062-2 p.11

¹⁴⁷ 305-002-003

¹⁴⁸ 305-002-004

¹⁴⁹ Mr Gowdy T-06-11-13 p.131 line 25

¹⁵⁰ Mr Hunter T-04-11-13 p.102 line 17

¹⁵¹ 210-003-022

implementation. Overall it was apparent that the Department did not accord particular priority to the quality of care in the Health Service.

- 7.55 Those charged with leadership within the Department were aware of the importance of quality of care and the DoH commitment to introduce clinical governance. To achieve such slow progress on such key government patient care policies indicates failure in Departmental leadership. The failure was corporate and so too is the responsibility.

Professor Scally's Conclusion

- 7.56 Overall, and in answer to the primary question, Professor Scally concluded that the *“Department had no effective means of knowing what was going on in hospitals prior to 2003 in terms of quality of care”* given the absence of:

“a. a culture of universal participation in a structured system of clinical audit,

b. a broad based system of surveillance and analysis of serious untoward incidents/adverse events,

c. quality of care as a major focus for the Department and its professional advisory systems, and

*d. the timely implementation of clinical governance from 1998 onwards...”*¹⁵²

Accordingly he did not find it surprising *“that the series of deaths from hyponatraemia did not come to the attention of the department in a systematic fashion.”*¹⁵³

Knowledge of the deaths

- 7.57 Whether by systematic means or otherwise, the deaths of all the children should have been reported. Mr Gowdy indicated that he would *“certainly”*

¹⁵² 341-002-019

¹⁵³ 341-002-019

have expected the Department to have been informed of them all¹⁵⁴ and Mr Colm Donaghy, Chief Executive of the Belfast Health and Social Care Trust, on behalf of the former RGHT, apologised for the lack of communication with the Department.¹⁵⁵

- 7.58 However, as the evidence unfolded, and despite Departmental denials, it became necessary to consider whether the Department might not in fact have known about the deaths of Adam, Claire and Lucy prior to Raychel's death in 2001.

Adam Strain

- 7.59 Just as Adam's death was not formally reported within the RGHT, it was not formally reported to the Department. The findings at inquest were not shared and there was no other obvious communication of information. The CMO stated that the *"Department was not made aware of the case at the time by either the RVH or the Coroner. We only became aware of that particular case when we began the work of developing guidelines following the death at Altnagelvin."*¹⁵⁶ However, this assertion came to be questioned.
- 7.60 During Adam Strain's inquest on 21st June 1996 the RGHT provided the Coroner with draft 'Recommendations for the Prevention and Management of Hyponatraemia arising during Paediatric Surgery.'¹⁵⁷ They were drafted by Dr Joseph Gaston,¹⁵⁸ approved by Dr Peter Crean¹⁵⁹ and signed by Dr Robert Taylor.¹⁶⁰ Notwithstanding that they purported to indicate how such cases might be managed in the future,¹⁶¹ they were not circulated among other clinicians or submitted to the Department. Mr Gowdy observed that the references to hyponatraemia in the recommendations *"was of such general application as to be of interest and significance to other*

¹⁵⁴ WS-062-2 p.10

¹⁵⁵ Mr Donaghy T-12-11-13 p.6 line 13

¹⁵⁶ 006-002-117

¹⁵⁷ 060-018-036

¹⁵⁸ 306-081-003, 060-018-035 & WS-013-2 p.4

¹⁵⁹ 303-001-007 & 060-014-025

¹⁶⁰ 303-001-003 & 011-014-107a

¹⁶¹ 122-044-048

*hospitals*¹⁶² and that he would have expected a copy to be sent to the Department because of the regional implication.

- 7.61 The CMO herself believed that had they been brought to her attention she would have regarded them as an appropriate matter for consideration by her Specialty Advisory Committees for Anaesthetics and Paediatrics.¹⁶³ In this connection it is to be noted that Drs Gaston, Crean and Taylor had all been one-time members of these committees¹⁶⁴ and Dr Crean accepted that the case for guidelines on fluid management and hyponatraemia would have been an appropriate matter for discussion.¹⁶⁵
- 7.62 I do not however consider it likely, given their earlier disinclination to share their recommendations, that they notified the Department's SACs about Adam. The committees were not well suited for the purposes of such communication. Dr Miriam McCarthy¹⁶⁶ indicated the *"view among Departmental colleagues and SAC members was that the frequency of meetings (most were annual) meant the meetings were not designed to facilitate a response to the wide range of issues arising between meetings and for which alternative mechanisms were needed."*¹⁶⁷
- 7.63 It also became apparent that Dr Gaston had involved the senior hospital anaesthetist, Dr Samuel Morrell Lyons,¹⁶⁸ in the aftermath of Adam's death.¹⁶⁹ He was, amongst other things, Chairman of the Central Medical Advisory Committee of the Department.¹⁷⁰ Whilst this could speculatively be interpreted as some form of indirect 'reporting' to the Department, I do not believe that to have been the case. Dr Lyons had very little engagement with the facts of the case¹⁷¹ and there is nothing to suggest that he understood matters much beyond what Dr George Murnaghan¹⁷² and Dr

¹⁶² WS-062-2 p.10

¹⁶³ WS-075-2 p.8 & 320-110-001

¹⁶⁴ 075-076-287

¹⁶⁵ Dr Crean T-11-09-13 p.12 line 22

¹⁶⁶ 337-001-002

¹⁶⁷ WS-080-2 p.19

¹⁶⁸ 306-081-006

¹⁶⁹ Dr Gaston T-19-06-12 p.2 line 8

¹⁷⁰ 306-081-006 & 093-024-066

¹⁷¹ 093-024-067

¹⁷² 306-081-005

Gaston were telling him and there is no reason to suppose that they told him more than they told anyone else in a position of governance. I do not consider that the Department was thereby informed about Adam's case.

Claire Roberts

- 7.64 Claire's death was not formally reported to the Department until 28th March 2006¹⁷³ when the Trust reported it as a SAI pursuant to interim guidance HSS (PPM) 06/04.¹⁷⁴ Notwithstanding that the report could and should have been made in 2004, her case had already come within the scope of this Inquiry and the Department was therefore on notice. This was however another example of RGHT failure to follow guidance and Departmental failure to check that its requirements were being met.

Lucy Crawford

- 7.65 There is no evidence that Lucy's death was reported at the time to the Department. In February 2003 Mr Stanley Millar¹⁷⁵ Chief Officer of the WHSSC notified the Coroner of Lucy's death.¹⁷⁶ The Coroner copied Mr Millar's letter to the CMO on 3rd March.¹⁷⁷ The Department therefore maintained that it did not become aware of Lucy's case until March 2003.
- 7.66 However, Dr Campbell wrote an article about Lucy's death for the 'Irish News' on 21st May 2004 in which she stated that *"In fact, the Coroner referred Lucy's case to me as long ago as June 2001..."*¹⁷⁸ Whilst she quickly corrected this to read 'March 2003',¹⁷⁹ it nonetheless gave rise to suspicion that the Department was in possession of information earlier than claimed and at a date before the death had been properly explained to Lucy's parents.

¹⁷³ 322-070-003

¹⁷⁴ 322-070-001

¹⁷⁵ 325-002-011

¹⁷⁶ 013-056-320

¹⁷⁷ 006-010-294

¹⁷⁸ 004-010-154 – Dr Campbell made a similar assertion in an interview with UTV on 25-03-04 (006-037-376).

¹⁷⁹ 004-010-155

- 7.67 Relevant in this context was the suggestion by Dr William McConnell¹⁸⁰ that Mr Hugh Mills¹⁸¹ had telephoned the Department about Lucy.¹⁸² Mr Mills was very clear that he had not¹⁸³ and Dr McConnell could provide no further detail. Notwithstanding that Mr Thomas Frawley¹⁸⁴ of the WHSSB “*would have expected the Trust to notify the DHSSPS of an ‘untoward death’ such as that of Lucy Crawford*”¹⁸⁵ he did not believe that the Trust had reported Lucy’s death to the Department.¹⁸⁶ There is no evidence that any other member of the Sperrin Lakeland Trust’s senior management reported Lucy’s death and Mr Mills confirmed that the Trust’s review of the case was not drawn to the Department’s attention either.
- 7.68 It is difficult therefore to conclude that the Department was aware of either the facts or import of Lucy’s case before it was drawn to the Dr Campbell’s attention by the Coroner and the Coroner could not have done so before he himself was informed in February 2003. The fact that Dr Campbell had always been clear that it was the Coroner who informed her about Lucy and this had always been capable of corroboration, suggests to me that her statements were simply confused as to dates. She is unlikely to have known about Lucy in 2001.

Chief Medical Officer’s Working Group on Hyponatraemia

- 7.69 In 2001, Dr Ian Carson,¹⁸⁷ Medical Director of RGHT, was also serving as Special Advisor to the CMO.¹⁸⁸ It was in this capacity that he was informed on 18th June 2001 that Raychel had died of hyponatraemia and that her death was linked to fluid management with low saline solution.¹⁸⁹ He brought the matter to the immediate attention of Dr Campbell and

¹⁸⁰ 325-002-009

¹⁸¹ 325-002-008

¹⁸² WS-286-2p.4

¹⁸³ WS-293-3 p.3

¹⁸⁴ 325-002-010

¹⁸⁵ WS-308-1 p.14

¹⁸⁶ WS-308-1 p.21

¹⁸⁷ 306-081-004

¹⁸⁸ WS-077-3 p.1

¹⁸⁹ 012-039-179

suggested that in the circumstances, it might be appropriate to provide regional guidance.

- 7.70 On 27th July 2001 Dr Campbell sought background information and asked if there was *“anyone at RBHSC who could put together a short paper on this?”*¹⁹⁰ Dr Taylor was asked¹⁹¹ and his paper entitled ‘Hyponatraemia in Children’¹⁹² was e-mailed by Dr Carson to the CMO on 30th July 2001 with the observation that *“The problem today of ‘dilutional hyponatraemia’ is well recognised (See reference to BMJ Editorial). The anaesthetists in RBHSC would have approximately one referral from within the hospital per month. There was also a previous death approx. six years ago in a child from the Mid Ulster. Bob Taylor thinks that there have been 5-6 deaths over a 10 year period of children with seizures...”*¹⁹³
- 7.71 Dr Campbell was assisted within the Department by Senior Medical Officer Dr McCarthy.¹⁹⁴ She considered Dr Taylor’s briefing and thought it *“very helpful”*¹⁹⁵ but did not attempt to learn any more about the deaths referred to. Nor does it seem that Dr Campbell¹⁹⁶ or Dr Carson,¹⁹⁷ or anyone else in the Department asked any questions about the alarming numbers of deaths from dilutional hyponatraemia thus brought to their attention.
- 7.72 Dr Carson interpreted the deaths to have occurred in the UK, not least because *“if there’d been five or six deaths over a ten year period in the Royal Belfast Hospital for Sick Children, I would have known about it.”*¹⁹⁸ Taking account of the deaths now known and another referenced by Dr Taylor, it is possible that there were five deaths within ten years in RBHSC.¹⁹⁹ Notwithstanding, I fully accept that Dr Carson did not know about those deaths. In any event, the Department had clearly been informed that the

¹⁹⁰ WS-330-1 p.10

¹⁹¹ WS-330-1 p.10

¹⁹² 043-101-223

¹⁹³ 021-056-135

¹⁹⁴ WS-080-2 p.3

¹⁹⁵ WS-080-2 p.7

¹⁹⁶ Dr Campbell T-07-11-13 p.115 line 3

¹⁹⁷ WS-331-1 p.4 & Dr Carson T-30-08-13 p.98 line 7

¹⁹⁸ Dr Carson T-30-08-13 p.96 line 23

¹⁹⁹ Dr Carson T-30-08-13 p.98 line 11 *et seq*

problem of dilutional hyponatraemia was implicated in more than a single death in Northern Ireland.

- 7.73 Dr Campbell then gave direction that a Working Group should develop and provide guidelines for safe paediatric fluid management and the avoidance of hyponatraemia.²⁰⁰ On 14th August 2001 the task of co-ordinating production of the guidelines was delegated to Dr McCarthy.²⁰¹ It was, she indicated, *“a task and finish group established only to develop guidance on the prevention of hyponatraemia.”*²⁰²
- 7.74 The Working Group assembled on 26th September 2001²⁰³ and included a number of clinicians, familiar not only with hyponatraemia but also with some of the other deaths concerning this Inquiry, including Claire and Lucy.²⁰⁴ The question therefore arose as to whether their work within a Departmental group placed the Department on notice of the other deaths known to them. Of particular interest was whether group members discussed amongst themselves the deaths known to them. If they did, they might have been sharing information about the deaths of Claire and Lucy within a Departmental context which had not been disclosed to their grieving families or the Coroner and which would not be disclosed for some considerable time to come.
- 7.75 Of particular interest was the involvement of Drs Taylor, Nesbitt,²⁰⁵ Crean, Jenkins²⁰⁶ and Loughrey.²⁰⁷ Dr Taylor was more than fully aware of Adam’s case and had examined Claire in PICU.²⁰⁸ As Paediatric Audit Co-ordinator he may possibly have learned of Lucy’s death.²⁰⁹ Dr Crean treated both Lucy²¹⁰ and Raychel²¹¹ and was aware of the fluid issues in Adam’s case.²¹²

²⁰⁰ 075-082-329

²⁰¹ WS-080-1 p.2 & WS-075-1 p.6

²⁰² WS-080-2 p.5

²⁰³ 007-048-094

²⁰⁴ 328-003-001

²⁰⁵ 328-003-001

²⁰⁶ 328-003-001

²⁰⁷ 328-003-001

²⁰⁸ WS-157-1 p.2

²⁰⁹ 061-038-123

²¹⁰ 013-021-071

²¹¹ 012-032-159

²¹² 060-014-025

His name appears as Claire's Consultant in her Discharge Summary.²¹³ Dr Nesbitt not only knew about Raychel's case but had advised his Medical Director on 14th June 2001 of "... *several deaths involving No.18 Solution.*"²¹⁴ Dr Loughrey was the Chemical Pathologist who advised the Coroner about the cause of hyponatraemia in Raychel's case and Dr Jenkins was known for his particular interest in fluid and electrolyte management and was to be asked in February 2002 to provide expert opinion in Lucy's case.²¹⁵ Mr G Marshall FRCS was also included. He was from the Erne Hospital where Lucy had been treated.

- 7.76 When asked whether the Working Group considered the deaths of Adam, Claire or Lucy, the Department maintained that "*the CMO's Hyponatraemia Working Group was set up to develop guidance on the prevention of hyponatraemia and not to consider the case of any specific child.*"²¹⁶
- 7.77 Professor Swainson nonetheless considered that it would have been logical for the group to consider those deaths specifically known by group members to be due to hyponatraemia because he did not "*think you can divorce the context in which you are doing the work from the work itself. And I still think you'd want to test the assumptions and the conclusions you are coming to against your experience of those cases.*"²¹⁷
- 7.78 Further suspicion arose because Dr Jenkins told UTV that the Working Group had been set up after it was recognised that both Raychel and Lucy had died with hyponatraemia.²¹⁸ Dr Jenkins corrected himself, explaining that he had become confused as to when he had found out about the deaths and that he had not in fact known about Lucy's death at the time of his contribution to the Working Group.²¹⁹

²¹³ 090-009-011

²¹⁴ 022-102-317

²¹⁵ Dr Jenkins T-10-09-13 p.25 line 5

²¹⁶ 009-014-022

²¹⁷ Professor Swainson T-19-09-13 p.127 line 15

²¹⁸ 069a-056-181

²¹⁹ 074-016-071 & Dr Jenkins T-10-09-13 p.19 line 18

- 7.79 In preparation for the first meeting of the group, Dr Taylor prepared a presentation on “*Hyponatraemia in Children*”²²⁰ which he sent to the Department on 18th September 2001.²²¹ Dr McCarthy noted the content of the presentation.²²² It placed hyponatraemia in the context of the administration of excessive maintenance fluids²²³ and incorporated detailed information on the ‘Incidence of Hyponatraemia at RBHSC.’ Remarkably it omitted the deaths of Adam, Claire and Lucy. In the event, his presentation was not given, perhaps because, as Dr Taylor explained, his figures were based on incomplete data.²²⁴
- 7.80 The Deputy CMO Dr Paul Darragh²²⁵ chaired the first meeting of the Working Group on 26th September 2001.²²⁶ Dr Taylor described those patients most at risk and advised that it was “*a problem that has been present for many years.*”²²⁷ Dr McCarthy recalled “*Dr Taylor advising attendees of the increased identification of cases of hyponatraemia in the RBHSC, including 2 cases resulting in fatality.*”²²⁸
- 7.81 Dr Taylor undertook to report Raychel’s case to the Medicines Control Agency (MCA).²²⁹ He wrote to the MCA on 23rd October that he was: “*conducting an audit of all infants and children admitted to the PICU with hyponatraemia. My initial results indicate at least two other deaths attributed to the use of 0.18NACL/4% glucose*”²³⁰ (emphasis added). This correspondence was then shared with Drs Jenkins, Nesbitt and McCarthy²³¹ and may thus have been the origin of Dr Jenkins’ belief that the working group had been set up after the deaths of two children in Northern Ireland. If so, his confusion is then more readily understood.

²²⁰ 007-051-101

²²¹ 007-051-100

²²² WS-080-2 p.7

²²³ 007-051-106

²²⁴ Dr Taylor T-11-12-12 p.151 line 8

²²⁵ 337-001-002

²²⁶ 007-048-094

²²⁷ Dr Taylor T-18-09-13 p38 line 10

²²⁸ WS-080-2 p.13

²²⁹ WS-008-1p.18

²³⁰ 012-071e-412 nb emphasis added

²³¹ 007-032-059

- 7.82 Within the Department the correspondence “*would have been noted and filed.*”²³² Throughout work on the guidelines, Dr McCarthy regularly discussed progress with Dr Campbell, providing her with updates and drafts as appropriate.²³³
- 7.83 It is clear that Raychel’s death was discussed²³⁴ and whilst discussion of broader incidence may have been vague, it is also clear that the group knew that it was addressing a problem that extended beyond Raychel’s death alone.²³⁵ It is in this context that it might be thought to have been natural for individual members to discuss the overall incidence of deaths and compare and contrast the rather different cases of Adam and Raychel, and possibly also Claire and Lucy, to better understand the issues arising. Even Dr Campbell agreed that it “*would be unnatural for them not to put that into the pot.*”²³⁶ As Dr Darragh put it “*all doctors always talk about their individual experiences.*”²³⁷
- 7.84 In the event, Dr Darragh noted that “*given Dr Taylor’s presentation ...there were clearly likely to be other cases emerging but the important step of producing guidelines was the appropriate step to be taking at regional level at that time.*”²³⁸ Accordingly, it was agreed that simple guidelines were required and that in order to move quickly, a small sub-group would undertake the drafting of the guidelines together with an audit protocol.
- 7.85 Notwithstanding Dr Taylor’s contribution, he was not included in the drafting sub-group. Instead, Drs McCarthy, Jenkins and Crean met on 10th October 2001 with Dr Jarlath McAloon²³⁹ who was co-opted for additional paediatric perspective. The sub-group decided to proceed by way of e-mail communication as a “*virtual group*”²⁴⁰ in order “*to facilitate more rapid*

²³² Dr McCarthy T-31-10-13 p.46 line 14

²³³ WS-080-1 p.4

²³⁴ 001-078-270

²³⁵ Dr McCarthy T-31-10-13 p.12 line 17

²³⁶ Dr Campbell T-07-11-13 p.117 line 2

²³⁷ Dr Darragh T-30-10-13 p.158 line 17

²³⁸ WS-076-2 p.12

²³⁹ 337-001-004

²⁴⁰ WS-080-2 p.9

progress in developing the guidance."²⁴¹ This limited the scope for group discussion and indeed subsequent communication does not appear to have been general. As Dr McAloon recalled his *"responses were channelled through Dr McCarthy's office and I am not aware of who saw them."*²⁴²

7.86 Dr McAloon considered that his role *"was to provide comments from the perspective of a general paediatrician who would be expected to implement the guidance once produced"*²⁴³ and recalled *"the initial face-to-face brainstorming meeting to help identify key components needing to be addressed in the guideline."*²⁴⁴ Notwithstanding that Dr Jenkins *"regarded it as [his] responsibility to test the guidance against the knowledge that [he] had"*²⁴⁵ he did not expect others in the group to mention individual cases or test the draft against such cases.²⁴⁶ He acknowledged that *"it would have been easier, for doctors to have shared that type of information in a face-to-face meeting other than in e-mails."*²⁴⁷ The focus, he said *"was on the guidelines, not on any individual case."*²⁴⁸ The guidance was intended for the generalist junior doctor and not the specialist²⁴⁹ and accordingly the drafting group concentrated on the key general principles to be applied to all children receiving IV fluids.

7.87 Dr Crean thought that *"we probably were all drawing on our own expertise with children we had managed."*²⁵⁰ It is to be noted that apart from Dr Crean, no other member of the drafting sub-group had managed any of the children known to have died. Notwithstanding that Dr Crean could have drawn on his own expertise, there is no indication that he shared his knowledge in respect of individual cases. Indeed, the evidence of Drs Jenkins,²⁵¹

²⁴¹ WS-082-2 p.9

²⁴² WS-363-1 p.8

²⁴³ WS-363-1 p.8

²⁴⁴ WS-363-1 p.9

²⁴⁵ Dr Jenkins T-10-09-13 p.27 line 8

²⁴⁶ Dr Jenkins T-10-09-13 p.71 line 15

²⁴⁷ Dr Jenkins T-10-09-13 p.32 line 11

²⁴⁸ Dr Jenkins T-10-09-13 p.72 line 7

²⁴⁹ Dr McCarthy T-31-10-13 p.34 line 22

²⁵⁰ Dr Crean - T-11-09-13 p.90 line 9

²⁵¹ Dr Jenkins T-10-09-13 p.71 line 15

Crean,²⁵² Nesbitt²⁵³ and Taylor²⁵⁴ agreed that the Working Group did not at any time discuss or consider the deaths of Adam, Claire or Lucy.

- 7.88 This does seem odd, not least because there were some within the group who were interested in other cases. On 30th November 2001 Dr Loughrey e-mailed Dr McCarthy to enquire whether she was aware of *“the death of a four year child in what sound like very similar circumstances in Northern Ireland in 1996.”*²⁵⁵ Dr McCarthy then discussed the cases of Adam and Raychel with the Coroner²⁵⁶ and received copies of Adam’s autopsy report and Dr Edward Sumner’s²⁵⁷ report which were relayed to Dr Campbell.²⁵⁸ There is however no reference to either Claire or Lucy in any of the extended threads of e-mail correspondence seen by this Inquiry.
- 7.89 Dr McCarthy circulated a *“final draft”* of the guidelines to the group on 7th November.²⁵⁹ Dr Loughrey expressed disappointment that it did not positively discourage the use of hypotonic fluids because she believed this was *“a major (if not the major) factor in the demise of the child in Altnagelvin”*²⁶⁰ Dr Crean did not agree, arguing that advice on specific IV fluids should not be given when *“there is not really any evidence to suggest that one solution is more or less harmful than another.”*²⁶¹ Dr Loughrey countered that she felt so strongly about referencing the risk associated with Solution No.18, that if it was not included, she would wish to be disassociated from the guidelines.²⁶² This was an issue that was discussed in detail²⁶³ and given the genuine disagreement it would seem to have presented an obvious opportunity to test the draft guidelines against known cases. Indeed, Dr McCarthy recognised that *“the patient’s illness, condition, age, post-op status and serum sodium all play a role in dictating*

²⁵² WS-038-3 p.8

²⁵³ Dr Nesbitt T-03-09-13 p.124 line 14

²⁵⁴ Dr Taylor T-18-09-13 p.130 line 15

²⁵⁵ 007-025-048

²⁵⁶ 006-056-440

²⁵⁷ 303-001-010

²⁵⁸ WS-075-1 p.3

²⁵⁹ WS-035-2 p.347

²⁶⁰ 007-025-048

²⁶¹ 007-014-029

²⁶² 007-013-027

²⁶³ WS-080/2 p.11

*the choice of fluid.*²⁶⁴ Whilst Dr Darragh conceded that this would have been both useful and obvious, it was seemingly not done.²⁶⁵ In this context, I consider it very likely that had the known deaths been referred to, then some reference would appear in at least one of the multiple threads of e-mail correspondence. However there is no such reference.

7.90 Dr McCarthy said that *“information on previous deaths was absolutely not shared in that group. When I now see what people knew, it is a surprise to me that that wasn’t, but that is the reality.”*²⁶⁶ Indeed she said she found it *“inexplicable more than anything”*.²⁶⁷

7.91 On the evidence before me I cannot therefore be persuaded that the Department can be fixed with notice of the deaths of Claire or Lucy in this context. A combination of urgency to complete the guidelines, the distancing effect of individual communication by e-mail, the obscuring effect of Dr Taylor’s purported ‘Incidence of Hyponatraemia at RBHSC’, Dr Crean’s silence and the busy professional lives of all concerned probably inhibited the sort of exchanges that might have been thought obvious. The absence of any evidence to the contrary supports this conclusion.

7.92 The Department issued its ‘Guidance on the Prevention of Hyponatraemia in Children’ in March 2002. Dr Campbell published it with her direction that *“Fluid protocols should be developed locally to compliment the Guidance and provide more specific direction to junior staff... It will be important to audit compliance with the Guidance and locally developed protocols and to learn from clinical experiences.”*²⁶⁸ The Working Group ceased to exist on publication²⁶⁹ and did not produce the *“audit protocol”* agreed at its first meeting. Nor did it offer any guidance as to how fluid protocols might be developed locally. Dr McCarthy thought that they *“would probably follow*

²⁶⁴ 012-062-314

²⁶⁵ Dr Darragh T-30-10-13 p.180 line 25

²⁶⁶ Dr McCarthy T-31-10-13 p25 line 17

²⁶⁷ Dr McCarthy T-31-10-13 p.75 line 21

²⁶⁸ 007-001-001

²⁶⁹ WS-080-2 p.6

*up in due course...*²⁷⁰ They did not and with hindsight that is a matter for regret.

- 7.93 Notwithstanding, it is to be recognised that the CMO's guidelines placed Northern Ireland, in the view of Dr Sumner, "*ahead of the rest of the UK*."²⁷¹ This was achieved with speed and efficiency. It was a significant achievement and properly worthy of praise because, as Professor Swainson observed, the guidelines "*have improved considerably the quality of care across the province and reduced the risk of Hyponatraemia*."²⁷²

Chief Medical Officer

- 7.94 Unfortunately, and undermining her important work in publishing the guidelines, Dr Campbell gave a series of extraordinary interviews to the media in the aftermath of the inquests into the deaths of Raychel and Lucy. Rather than communicating in order to inform and reassure, she made statements which so inflamed the suspicion and distrust of Mr and Mrs Ferguson and Mr & Mrs Slavin that they called for her resignation in December 2004.²⁷³ Such was Mr & Mrs Ferguson's disquiet at what she had said that they asserted that she was engaged in a cover-up and referred her conduct to the GMC.²⁷⁴

- 7.95 Transcripts of two BBC and two UTV interviews, together with another given to a journalist,²⁷⁵ reveal carelessness as to facts and an inappropriate defensiveness about clinical treatment. Whilst they mislead and are troubling in their lack of professionalism, they do not constitute a cover-up. In this regard it is to be emphasised that Dr Campbell made clear her view that "*the deaths of Lucy and Raychel may indeed have been entirely preventable*,"²⁷⁶ that "*if we'd had an early inquest into Lucy's death, then it*

²⁷⁰ Dr McCarthy T-31-10-13 p.79 line 13

²⁷¹ 006-002-156

²⁷² 226-002-006

²⁷³ 073-037-162

²⁷⁴ 068-013-022

²⁷⁵ To: Trevor Birney of UTV 17-02-03 (069A-033 078), To: Audrey Carville of BBC Radio Ulster Evening Extra 18-03-04 (034-151-407), To: Julian O'Neill of BBC Newsline 18-03-04 (023-020-044), To: Fearghal McKinney of UTV 'The Issue' 25-03-04 (006-037-375), To: Denzil McDaniel of 'The Impartial Reporter' 25-05-04 034-142-372.

²⁷⁶ 034-151-407

might have been that the death of Raychel might never have happened,”²⁷⁷ that “anybody reading those [Coroner’s] reports would say and agree with the coroner that the management of the fluids could have been much much better and that it was inadequate.”²⁷⁸

7.96 In addition she stated on the record that *“It’s quite clear that there was no process for the reporting of Lucy’s death to me, nor indeed the outcome of any investigation,”²⁷⁹ “I absolutely agree that if we had in place a system for the reporting of all ...untoward deaths, that we could have begun to learn lessons earlier”²⁸⁰ and “Our role as the Department is development of strategy and policy and a strategy and policy on proper investigation is what we need to do.”²⁸¹*

7.97 However and at the same time she repeatedly misinformed her interviewers and the public. She appeared intent on distancing the Health Service from responsibility and understating the known risks of hyponatraemia so as appear an apologist for much that had happened. That she repeatedly allowed herself to be exposed in this way for interview was an error of judgement and what she said is a cause for concern.

7.98 Amongst other things she claimed:

(i) *“...when untoward and rare events happen we need to find a way of learning from them. Now they only happen every 5 or every 10 years.”²⁸²* This can only have been invented. Not only was there no reliable system to inform her of such events, but an internal Departmental e-mail from the following year records Dr Campbell as estimating the *“numbers of serious untoward incident deaths reported to her...about 3-4 annually”²⁸³*

²⁷⁷ 023-020-045

²⁷⁸ 034-142-378

²⁷⁹ 034-142-387

²⁸⁰ 006-037-379

²⁸¹ 034-142-393

²⁸² 069A-033-078

²⁸³ 010-030-188

- (ii) That Adam “*was an entirely different clinical situation*”²⁸⁴ to Raychel – “*From what I know of the clinical details the case 7 years ago was of a child who was already very ill...I think it is important to recognise that in this case here we had a normal healthy child so therefore something had to be looked at...they needed to consider what measures needed to be put into place in order to prevent that happening again.*”²⁸⁵ The suggestions that Adam was a victim of his pre-existing condition and not blatant clinical error, that he was not sufficiently normal or that his case was less deserving of investigation in order to prevent recurrence are erroneous and insulting.
- (iii) “*with Lucy we saw the first case of what was a very rare occurrence written up in the medical journals only recently...*”²⁸⁶ Dr Campbell was fully aware of the earlier case of Adam, had been briefed with Professor Alan Arieff’s paper published 12 years before and had been advised by Dr Carson of the previous incidence of death.
- (iv) Speaking of Lucy and Raychel she said “*The rarity in this event and you do have to return to the medicine, the physiology behind these 2 events... was the abnormal reaction which is seen in a very few children to the normal application...*”²⁸⁷ Asked to comment on this assertion, Dr Dewi Evans²⁸⁸ indicated that the statement was wrong and it would worry him that it was made by the CMO for Northern Ireland.²⁸⁹
- (v) “*What we now know is, that the fluids which were given to Lucy were the ones that were being used in ordinary custom and practice throughout the whole of the National Health Service except for one or two practitioners who’d begun to recognise this issue of*

²⁸⁴ 069A-033-079

²⁸⁵ 069A-033-079

²⁸⁶ 006-037-375

²⁸⁷ 006-037-377

²⁸⁸ 325-002-013

²⁸⁹ ‘When Hospitals Kill’-UTV-‘Insight’- 21-10-04

hyponatraemia where the body goes through this abnormal response in just a very few cases and you begin to get oedema or swelling of the brain. Now in retrospect, and knowing all the evidence that has been published since Lucy's case and over the last four years, we now know that that condition exists, that it can happen, albeit in a very few patients..."²⁹⁰ Dr Campbell appeared to reject the Coroner's findings at inquest. Lucy's death resulted from clinical error not abnormal response. It was disingenuous of her to suggest that the excessive fluids given Lucy were standard because she was more than fully aware of the distinction between type and volume of fluid. It was misleading to assert that only one or two practitioners were alert to the issue, given that she knew Professor Arieff's paper had been published in the British Medical Journal.²⁹¹ Further and in any event it was quite wrong to characterise hyponatraemia as an abnormal response and dishonest to suggest that the condition was not known to exist in 2000.

- (vi) That this was not inadvertent error is clear from the CMO's repeated assertions that the mismanaged fluid therapy was somehow normal and the risks negligible "*...the fluids that we are talking about, that Lucy got, were in general use and ...one in 300 of children who were getting those fluids would develop hyponatraemia...and ten percent of those would go on to have a fatal reaction.*"²⁹²
- (vii) When asked whether an investigation or inquest should not have been held earlier in Lucy's case she said that "*the coroner did not feel at that time that an inquest was required...*"²⁹³ Later the same day she said that "*on looking back at the issues, I think if we'd had an early inquest into Lucy's death, then it might have been that the death of Raychel might never have happened...What the coroner*

²⁹⁰ 034-151-407

²⁹¹ In this regard it is informative to note that the connection between fluid mismanagement and dilutional hyponatraemia was made very quickly in each of the cases of Adam, Claire, Lucy and Raychel. Furthermore, in the cases of Claire and Lucy the diagnosis was made by doctors who had not yet attained consultant status.

²⁹² 034-142-377

²⁹³ 034-151-408

*has now agreed is that he will draw to our attention very early on those deaths about which he has concern.*²⁹⁴ This suggested that the lack of a timely inquest was the responsibility of the Coroner rather than of the clinicians themselves and furthermore carried the implication that, but for the Coroner's decision, Raychel might have lived. The Coroner immediately wrote to her and protested that *"in the interview you gave on BBC television you mentioned that the death of Raychel Ferguson could have been prevented if the full circumstances of the death of Lucy Crawford had been known sooner and you mentioned the desirability of there having been an earlier inquest into Lucy's death. I believe the papers I have provided you with explain what happened when Lucy's death was reported to my office and why a coroner's post-mortem examination was not then ordered."*²⁹⁵ Further and by way of additional information he added *"When he gave evidence in the inquests in to the deaths of Adam Strain, Raychel Ferguson and Lucy Crawford, Dr Sumner was at pains to state that his views on fluid management of children did not constitute 'new' medical knowledge."*²⁹⁶

7.99 Dr Campbell has since indicated her deep regret for what she said and for causing the Ferguson family additional distress. She said that *"on reflection I realise -- I realised much after the interviews -- that some of the things that I said could have been misunderstood in terms of what I was trying to say. They were very poorly crafted."*²⁹⁷ She accepted that she *"was ill-prepared"*²⁹⁸ and took *"full responsibility for saying things in a way which could have been misinterpreted. That was never my intention and it has cast a shadow over my life since."*²⁹⁹

7.100 Dr Campbell's approach bore many of the same characteristics as marred those meetings arranged by clinicians with Mr and Mrs Ferguson and Mr

²⁹⁴ 034-151-408 & 023-020-045

²⁹⁵ 006-004-282

²⁹⁶ 006-004-282

²⁹⁷ Dr Campbell T-07-11-13 p.165-166

²⁹⁸ Dr Campbell T-07-11-13 p.167 line 19

²⁹⁹ Dr Campbell T-07-11-13 p.168 line 2

and Mrs Roberts. Defensiveness continued even after mismanagement had been revealed and when inaccuracy and evasion could only exacerbate suspicion. Whilst such failures in communication may be ascribed to lack of preparation and a desire to deflect criticism, it must be stated that in my view they also proceed from arrogance and complacency. The CMO's public statements were a further manifestation of a culture which has revealed itself to this inquiry at every level of the Health Service.

CURRENT POSITION

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Introduction

- 8.1 In order to discover whether the many deficiencies uncovered by this Inquiry have been addressed, and to understand what the relevant statutory bodies have done and could still do to improve matters, I decided upon a different approach for inquiry. I convened forum sessions for opinion and discussion, with representatives from the Department of Health ('the Department'), the Belfast Health & Social Care Trust ('BHSCT'), the Health and Social Care Board ('HSCB'), the Public Health Agency ('PHA'), the Patient and Client Council ('PCC'), Action against Medical Accidents¹ ('AvMA') and others. Exchanges of opinion were encouraged from the evidence received, the agenda for discussion and questions arising. Participants were immune from criticism. Statutory bodies and others were asked for up-to-date position papers to detail current systems and problems. In particular, submissions were invited in respect of my more significant concerns, including the reporting and investigation of Serious Adverse Incidents ('SAI's'), the involvement of families, the handling of complaints and the introduction of a legally enforceable duty of candour. The responses and position papers received were shared with interested parties and are to be found on the Inquiry website.
- 8.2 Formulation of relevant recommendations is dependent upon an understanding of systems as they are today, notwithstanding that some problems appear constant. The Inquiry sought relevant up-to-date information and has attempted to note the changes occurring in the years since the deaths examined. Given the pace of procedural reform in the years since, this has been no easy task. For this reason this chapter of the Report is not to be understood as intending a comprehensive and up-to-the-minute account of the current position.
- 8.3 In Chapter 9 of this Report I set out my recommendations to strengthen and improve both practice and system. Although much has been achieved, much remains to be done. I recognise the obvious difficulties inherent in

¹ A UK charity offering independent advice and support to people affected by medical accidents.

translating recommendation into effective change and have come to believe that the best prospect for continued improvement rests with the focused involvement of families and a Health Service leadership which is zealous about learning from error.

- 8.4 Even brief analysis of this Report will reveal the recurrent themes so clearly marking the cases examined. I believe that the issues of competency in fluid management, honesty in reporting, professionalism in investigation, focus in leadership and respect for parental involvement to be the most obvious raised. They are also the most important because they are individually and collectively critical to learning from error.
- 8.5 Ultimate accountability for learning from error in the healthcare service rests with the Department and the Minister. The Department must ensure that, having issued standards, the policies of the 'arms-length' HSC organisations are compliant and quality assured. The key question is, as posed by Permanent Secretary Dr Andrew McCormick, "*How can we know if arms-length bodies are actually fulfilling the guidance and directions issued by the Department?*"² With so large and complex a system, quality assurance must come from active oversight, audit and review.
- 8.6 It is in this context that I have considered, in so far as I have been able, the steps taken by the Department and other statutory bodies to minimise the likelihood of recurrence. By drawing on the evidence received, weaknesses can be identified and recommendations made to further protect the patient interest. In this respect the evidence received and the frank views expressed during panel session discussions have been of real assistance.

Progress in hyponatraemia practice and guidance

- 8.7 In April 2007 the Department circulated 'Safety Alert 22' from the National Patient Safety Agency ('NPSA') about the risk of hyponatraemia to children receiving IV infusions.³ The removal of Solution No. 18 from general use

² Dr Andrew McCormick T-15-11-13 p.10 line 21

³ 330-167-001

was directed and warning posters placed in all paediatric units.⁴ Trusts were instructed to develop local protocol⁵ and audit their own compliance.⁶ Alert 22 guidance was then issued by the Department in September 2007 as 'Parenteral Fluid Therapy (1 month – 16 years): Initial Management guideline'.⁷ The BHSCT was able to confirm that Solution No 18 had been removed from all general areas where children were treated.⁸

- 8.8 The Regulation & Quality Improvement Authority ('RQIA') reviewed compliance with 'Safety Alert 22' in June 2008⁹ and found it wanting. It reviewed and reported again in May 2010 on the 'Implementation of recommended actions outlined within NPSA Alert 22 throughout HSC Trusts and independent hospitals in Northern Ireland'¹⁰ and concluded that compliance with Alert 22 had, by then, been substantially achieved and that there was good operational control of IV fluid administration to children. It concluded that clinicians were aware of the Guidelines and that nursing staff had received training in paediatric fluid administration. Notwithstanding, it made recommendations to consolidate progress. The Guidelines were amended in 2010¹¹ and the Department requested the Northern Ireland Medical & Dental Training Agency ('NIMDTA') provide the relevant training for medical undergraduates and junior doctors.¹²
- 8.9 There were also Guideline and Implementation Network ('GAIN')¹³ audits in 2012¹⁴ and 2014 measuring adherence with the IV fluid guidance developed from Alert 22.¹⁵ The 2012 report found that the IV fluids in use were compliant with recommendations even if some further improvement

⁴ 303-026-350

⁵ 330-135-002

⁶ 330-167-002

⁷ 303-059-817

⁸ 330-134-001

⁹ 303-058-776

¹⁰ 303-031-415

¹¹ 303-060-818 - Guidance on Parenteral Fluid Therapy for Children & Young Persons (Aged over 4 weeks and under 16 years)

¹² 330-152-003

¹³ GAIN was established as a partnership body of the Department in 2007. It works closely with the Department's Standards and Guidelines Quality Unit. It receives programme funding to conduct regional audits and where necessary produce local guidelines for the HSC.

¹⁴ 333-165-001

¹⁵ 303-060-818

was required to achieve 100% overall compliance. Progress was maintained in 2013 with a revised 'Regional Fluid Balance and Prescription Chart for Children and Adults' and the wall chart for 'Parenteral Fluid Therapy for Children and Adults (aged over 4 weeks and under 16 years)' was updated in September 2014.

- 8.10 GAIN conducted a follow-up audit in 2014 *"to examine whether the administration of IV Fluids to children and young people (aged over 4 weeks and under 16 years) is safe and meets quality standards."*¹⁶ Overall compliance was again found to have improved but adherence was not yet 100%. Nonetheless and importantly it found *"that the prescription of fluid type, particularly to those deemed to be at particular risk of developing hyponatraemia was always found to be appropriate..."*¹⁷ and that *"young people being cared for in an adult ward appear to have received the same standard of care as children being cared for in paediatric wards."*¹⁸
- 8.11 However, the report did make some recommendations concerning regularity of assessment and the proper completion of documentation. The HSCB/PHA then published further guidelines for use with the chart in 2015 and BHSCT issued its own 'Policy for recording fluid prescriptions and balance charts.'¹⁹
- 8.12 GAIN recommended additional hospital auditing of IV fluid management in children. To that end a Paediatric IV Fluid Audit Improvement Tool ('PIVFAIT') has now been devised and introduced to all HSC Trusts to provide local assurance in relation to the administration of IV fluids to children and young people.²⁰
- 8.13 National Institute for Health and Care Excellence ('NICE') has since published 'Clinical Guideline NG 29'²¹ for 'Intravenous fluid therapy for children and young people in hospital' which received the endorsement of

¹⁶ 403-011-009
¹⁷ 403-011-003
¹⁸ 403-011-006
¹⁹ 401-001an-001
²⁰ 401-001ao-001 & 404-001i-011
²¹ 404-001e-001

the Department in September 2017.²² The regional Fluid Balance and Prescription Chart for children and young people has now been revised in line with NG 29²³ and amended wall charts detailing parenteral fluid therapy for those aged over 4 weeks and under 16 years have been circulated for display in all areas where such patients are treated. Trusts have been requested to disseminate these charts and, given their regional importance, have been required to formally advise the Department as to anticipated dates of implementation and assure HSCB/PHA as to implementation. BHSCT intermittently updates its 'Policy for Recording Fluid Prescription and Balance Charts.' It is due for further review in 2018.

- 8.14 The Chief Medical Officer ('CMO') has requested the RQIA undertake 'a snapshot review/audit' of paediatric IV fluid practice. Such a review will examine the implementation of NG 29 together with the effectiveness of the wall-charts, Fluid Balance & Prescription Charts ('FB&PC's') and PIVFAIT. RQIA has indicated that the review "*will take place in spring 2018*".²⁴
- 8.15 This may be timely because, in November 2017 the RQIA published an 'Unannounced Hospital Inspection Report - Royal Belfast Hospital for Sick Children – 3-5 May 2017'.²⁵ Whilst generally reassuring it did identify some ongoing deficiencies. It specifically recommended that "*assurance audits should be carried out to ensure fluid balance charts are appropriately completed in line with best practice.*"²⁶ It also noted a lack of clear nursing leadership.²⁷
- 8.16 It is clear that very considerable professional attention has been devoted to protecting children undergoing fluid therapy and significant progress has been made. However, there can be no room for complacency because total patient safety cannot be assured. I consider that such therapy must therefore always be subject to scrutiny, which is why I recommend that all

²² 403-001-001 & 404-001k-001

²³ 403-001-006

²⁴ 404-002b-008

²⁵ 403-028-001

²⁶ 403-028-038

²⁷ 403-028-014

children's wards should have a senior lead nurse to provide the active leadership necessary to reinforce nursing standards and to audit and enforce compliance with guidance.

Training in fluid management and the prevention of hyponatraemia

- 8.17 In 2015 the HBSC/PHA assimilated all up-to-date regional IV fluid guidance and training packages into one document to ensure consistency in both competency assessment and training. The 'Competency Framework for Reducing the Risk of Hyponatraemia'²⁸ specifies that "*All prescribers caring for children are required to be competent in prescribing IV fluids appropriately and safely.*"²⁹ Competency in fluid management is reliant upon training.
- 8.18 Within Belfast, the current BH&SCT induction process for relevant trainee doctors requires that they provide "*evidence of completion of the BMJ Learning Module on Hyponatraemia.*"³⁰ The British Medical Journal ('BMJ') e-learning module 'Reducing the risk of Hyponatraemia when administering intravenous fluids to children'³¹ is designed to teach "*the dangers of hypotonic fluids in children, and how to diagnose and treat acute hyponatraemic encephalopathy*" and is based on the 2015 NICE guidelines. It usefully incorporates four clinical case studies referencing the regional paediatric fluid balance chart. Whether this training is sufficiently focussed on paediatric fluid prescribing has recently been questioned by foundation doctors at RBHSC.³² The RQIA has recommended that BH&SCT review and improve the induction programme to ensure training is appropriate.³³
- 8.19 Importantly present learning is available to all medical staff in Northern Ireland, just as most of the required training material is now available on-line. In terms of continuing professional education, the Competency Framework requires that "*all staff... should revisit the module, once every*

²⁸ 403-006-001 (reviewed September 2017)

²⁹ 403-006-006

³⁰ <http://www.belfasttrust.hscni.net/about/Inductionfortraineddoctors.htm> - Point 3

³¹ <http://learning.bmj.com/learning/module-intro/hyponatraemia.html?moduleId=5003260>

³² 403-028-019

³³ 403-028-020

*three years as a minimum. Evidence of completion should be submitted... during annual appraisal.*³⁴ Relevant training presentations are also posted on the BHSC intranet, including 'How to prescribe IV medicine infusions on a medicines kardex and/or daily fluid balance and prescription sheet'.

- 8.20 It is recognised that these programmes are for doctors in Northern Ireland as opposed to those clinicians who have trained outside the UK (as was the case with some doctors treating Raychel at Altnagelvin and both Raychel and Lucy at the Royal Belfast Hospital for Sick Children ('RBHSC')). The General Medical Council ('GMC') has sought to address this issue and continues to scrutinise the content and quality of induction and continuous professional development programmes.
- 8.21 With regard to the training of nurses in fluid management, Professor Hanratty found that the RQIA reviews brought focus to both training and practice. She noted a *"flurry of activity to include training and policy development...evident from the number of new documents and training materials during 2008/09. The universities have included sessions in pre-registration programmes. In-service training records demonstrate that nurse managers are requesting training sessions on the topic. Discussions with nurse managers indicate that there have been shared learning sessions on both hyponatraemia and record keeping attended by junior doctors and nurses."*³⁵
- 8.22 Professor Charlotte McArdle, the Chief Nursing Officer ('CNO'), stressed that training is now within the undergraduate programme and that the Northern Ireland Practice & Education Council for Nursing & Midwifery ('NIPEC') is conducting a quality assurance review of the paediatric fluid management training course. Within the Trusts, and as early as 2010, the Southern Health & Social Care Trust ('SHSCT') developed a nursing

³⁴ 403-006-005

³⁵ 308-004-086

Competency Framework 'For the Prescription, Administration, Monitoring and Review of IV Fluids for Children and Young People.'³⁶

- 8.23 There is additional ongoing education by way of induction programmes, shared learning and continuing professional development. BHSCT has introduced both an e-learning module and specific 'awareness' training for all RBHSC nursing staff, with a 'Hyponatraemia – How to complete a Paediatric Fluid Balance Chart'³⁷ module. It can be accessed on the BHSCT intranet. I would recommend that all Health & Social Care ('HSC') Trusts ensure that relevant nursing staff access such e-learning.
- 8.24 A repository of HSC resources relating to hyponatraemia has been made available on the PHA website at www.publichealth.hscni.net/directorate-nursing-and-allied-health-professions/nursing/central-repository-hsc-resources-relating.³⁸ This webpage brings together both regional and national guidance relating to hyponatraemia, including links to NPSA Patient Safety Alert 22, BMJ e-Learning module, competency framework, regional wall chart, FB&PC and associated training, RQIA reports, GAIN audit reports, NG29 and advice on how to prescribe IV medicines.

Some progress in matters of clinical relevance

- 8.25 Just as poor record keeping emerged as a recurrent theme in the cases examined by this Inquiry, so too was it identified as an issue in 5 out of 11 public healthcare Inquiries during the period 2003-08.³⁹ It was therefore very important that the CNO should have launched a 'Recording Care Project' ('the Project') to raise the standard of nursing records. The project has been extended to encompass all acute paediatric wards in Northern Ireland. Through a process of audit, benchmarking and professional review⁴⁰ the Project has successfully demonstrated improvement in specific areas of practice. In conjunction, NIPEC has actively supported

³⁶ 330-016-004
³⁷ 401-001an-003
³⁸ 401-002i-001
³⁹ 330-022-025
⁴⁰ 330-018-001

improvement and developed tools for audit. The Department has promoted benchmarking through its 'Essence of Care' programme. The Nursing and Midwifery Council ('NMC') issued updated and detailed guidance on 'Record Keeping' in 2010⁴¹ and the BHSCT has since published 'Good Record Keeping – a Simple Guide' with Guideline posters.⁴²

- 8.26 Also of relevance is the recent development by the HSC Safety Forum (Paediatric Collaborative) of a standardised Physiological Early Warning Scores System ('PEWS') to assist in the early identification of deterioration in the child patient and to encourage the timely escalation of concern. A regional protocol has been agreed for its use.⁴³ The same collaborative has also worked with parent representatives to design a safety poster 'You Know Your Child Best' to encourage greater parental collaboration in care. In 2014 a small multi-disciplinary group within RBHSC instituted the practice of daily PICU Safety Briefings. This innovation has proved useful and the practice has now been adopted within other clinical areas of RBHSC including Allen Ward.
- 8.27 Notwithstanding, the RQIA unannounced inspection of RBHSC in 2017 found "...completion of paediatric early warning scores was not always present. Robust systems to assure that best practice is followed are not in place and ...limited documented evidence of communication with parents..."⁴⁴ Whilst improvement has been achieved, shortcomings in documentation and communication persist. Rigorous audit must become routine.
- 8.28 In developing its 'Strategy for Paediatric Healthcare Services (2016-2026)' the Department specifically recognised some important interdependencies between paediatric services and other healthcare services, for example access to laboratory and diagnostic services, anaesthetic services and intensive care.⁴⁵ Focus on interaction is important for patient safety and

⁴¹ 330-020-053
⁴² 401-001an-001
⁴³ 401-001s-001
⁴⁴ 403-028-014
⁴⁵ 403-020-013

the identification of systemic weakness. It is encouraging that it should inform strategy.

- 8.29 Importantly, the Department Strategy has also made it a Key Strategic Objective that *“every child who is admitted to a paediatric department should be seen by a paediatric practitioner at ST4⁴⁶ or equivalent (including advanced children’s nurse practitioner)⁴⁷ within four hours of admission and by a consultant within 24 hours of admission”⁴⁸* It is Departmental intention that this very important objective be kept under review. I consider it should also be subject to routine audit.

Age appropriate care

- 8.30 In 2012 RQIA carried out a Baseline Assessment of the Care of Children under 18 Admitted to Adult Wards in Northern Ireland⁴⁹ and found that in 2009-2010, 3,933 children aged under 18 were cared for on adult wards. Whilst these patients were mostly adolescents and could, on occasion, be justifiably cared for in an adult setting, the figures are nonetheless disquieting given what was disclosed by Conor Mitchell’s case. The RQIA Report noted inconsistent age limits for admission onto paediatric wards and recommended regional agreement in this regard.
- 8.31 In 2012 HSCB issued guidelines on ‘Delivering Age Appropriate Care’⁵⁰ to ensure that children up to their sixteenth birthday would almost always *“be cared for in a paediatric environment.”⁵¹* All HSC Trusts must satisfy the HSCB Director of Commissioning as to compliance with this important patient care requirement.⁵² However, difficulties have been experienced with physical infrastructure, staffing levels and the lack of available beds.⁵³ Some Trusts have indicated that they are *‘working on it’⁵⁴* and the RQIA has

⁴⁶ Assessment by ST4 or equivalent within 4 hours of admission means that in practical terms there should be a St4 practitioner or higher, resident in the hospital.

⁴⁷ Advanced nurse practitioner, staff grade or associate specialist doctor or doctor in training at ST4 or higher.

⁴⁸ 403-020-041

⁴⁹ 260-003g-001

⁵⁰ 401-001i-001

⁵¹ 401-001i-001

⁵² 401-001a-018

⁵³ 403-028-028

⁵⁴ 401-001a-018

suggested that BHSCT “*work with key stakeholders to address these issues*”.⁵⁵

- 8.32 There remains inconsistency between HSC Trusts as to the age limit for paediatric admission to hospital. The RBHSC admits children up to 13 years on to the paediatric medical/surgical wards and up to 14 years from the emergency department. Most other regional hospital paediatric units in Northern Ireland admit up to the 16th birthday. Recognising that some clinical conditions necessitate flexibility, the Department has now made it a key strategic objective within the Paediatric Strategy that “*Children (from birth up to 16th birthday) should usually be cared for by the paediatric team in paediatric settings, and those aged 16-17 years should be managed in age-appropriate settings within either paediatric or adult settings. In all cases, children and young people should have treatment and care delivered to them in an age-appropriate environment*”⁵⁶
- 8.33 The HSCB Commissioning plan for 2016-2017⁵⁷ requires that HSC Trusts make effective arrangements to ensure that children and young people receive age-appropriate care and that the regional upper age limit for paediatric services of 16th birthday is implemented. Trusts are required to demonstrate how the upper age limit of 16th birthday is actually operated in practice and those arrangements in place to ensure that children admitted to hospital up to their 16th birthday are cared for in an age-appropriate environment, by staff with paediatric expertise and with input from paediatricians where necessary.⁵⁸ The new Children’s Hospital to be built in Belfast is planned to provide care for children up to the age of 18 years.⁵⁹
- 8.34 This is an important patient safety issue and clearly not one that has been forgotten. HSCB and PHA have established forums with both professional and managerial representation to discuss just such issues arising in paediatric service provision. HSCB and HSC Trusts must continue to

⁵⁵ 401-028-029

⁵⁶ 403-020-036

⁵⁷ 403-021-001

⁵⁸ 403-021-053

⁵⁹ 403-020-014

pursue solutions. I recommend that HSC Trusts should publish their policy and arrangements for ensuring that children admitted to hospital are cared for in age-appropriate settings and the RQIA should review progress on implementation of the regional guidelines.

Importation of external guidance

- 8.35 Given the relative size of Northern Ireland it is important that it learns from the experience of other healthcare systems. To that end, the Department has maintained contact with the former NPSA and has arranged with the Health Care Quality Improvement Partnership to share in the Confidential Inquiries programme. In 2006 the Department introduced procedure to review and endorse healthcare guidance and patient safety alerts from NICE and NPSA.
- 8.36 External guidelines and NCEPOD Reports are received by the Department for consideration and the Department directs HSC Trusts to implement recommendations as appropriate and within stated periods. Confirmation of implementation is almost always required. In 2007, the CMO instituted the HSC Safety Forum to assist Trusts in the implementation of patient safety recommendations. It is for the HSCB to assess the implementation and provide assurance to the Department that the HSC Trusts have acted as required.⁶⁰
- 8.37 The Department created the Guideline and Audit Implementation Network ('GAIN') in 2007 by amalgamating CREST, the Regional Multi-Professional Audit Group and the Northern Ireland Regional Audit Advisory Committee. GAIN has an important scrutiny and quality improvement role through auditing. It promotes good practice by publishing the results and facilitating the implementation of regional guidelines. It also promotes operational standards not yet covered by NICE. Importantly, GAIN also trains HSC staff in clinical audit and systematic review.

⁶⁰ 401-002w-012

- 8.38 BHSCT also has a Standards and Guidelines Committee to ensure the timely implementation and monitoring of external guidance.⁶¹ It was this committee that responded to NPSA advices by issuing policy on ‘the administration of IV fluids to children aged from one month until the 16th birthday’.⁶² The BHSCT has also formed a Therapeutic Review Steering Group to audit compliance with NICE.⁶³ These systems ought to allow the BHSC Trust Board assurance that external guidelines are both implemented and monitored.
- 8.39 The Department identified external evidence of good practice as a “*key driver for change in paediatric healthcare service provision*”⁶⁴ in its ‘Strategy for Paediatric Healthcare Services Provided in Hospitals and in the Community (2016-2026)’⁶⁵ In November 2011 the Department announced the development of a ten-year strategy ‘Quality 2020’ to raise standards, measure improvement and transform culture. Coincidentally, much work has also recently been completed in England relevant to the ‘Quality 2020’ project which will prove of considerable assistance.⁶⁶
- 8.40 In October 2016 the Department launched a ten year ‘transformation’ programme ‘Health and Wellbeing 2026: Delivering Together’ which encompasses the concept of a Regional Improvement Institute.⁶⁷ A 12 month progress report on this initiative was published in October 2017.⁶⁸

⁶¹ 332-039-001

⁶² This was written by Drs Crean and Steen.

⁶³ 332-025-007

⁶⁴ 403-020-014

⁶⁵ 403-020-001

⁶⁶ [Care Quality Commission Briefing: Learning from serious incidents in NHS acute hospitals, June 2016;](#)
[Care Quality Commission Review: Learning, candour and accountability, December 2016](#)
[PHSO Review: Quality of NHS complaints investigations: Government response to the Committee’s First Report of Session 2016-2017;](#)
[House of Commons Public Administration and Constitutional Affairs Committee: Will the NHS never learn? Follow-up to PHSO report ‘Learning from Mistakes’ on the NHS in England, 31 January 2017;](#)
[National Quality Board: National Guidance on Learning from Deaths, first edition March 2017.](#)

⁶⁷ 404-002b-002

⁶⁸ 403-025-001

Serious Adverse Incidents

- 8.41 Consideration of the reporting and investigation of Serious Adverse Incidents ('SAIs') has been central to the work of this Inquiry.
- 8.42 The Department issued the first regional guidance for SAI management in 2004. This was consolidated by 'Reporting and Follow-up on Serious Adverse Incidents' in March 2006.⁶⁹ Further advices followed on 'How to Classify Adverse Incidents and Risk'⁷⁰ and additional procedure was then introduced to promote learning from SAIs⁷¹ and guidance with templates for incident investigation reports was published in September 2007.⁷² Individual trusts then introduced their own protocols.⁷³
- 8.43 Overall, Departmental strategy was set out in 'Safety First: A framework for sustainable Improvement in the HPSS' (2006)⁷⁴ which emphasised the objective of an open and fair culture within HPSS. The promotion of adverse incident reporting together with improved investigation and sharing of learning were accorded particular importance in this context.
- 8.44 In 2013 the Department published 'Investigating Patient or Client Safety Incidents' outlining the Memorandum of Understanding entered into with the Coroners Service and the Health and Safety Executive for Northern Ireland in relation to liaison arrangements for joint or simultaneous SAI investigations.⁷⁵
- 8.45 Responsibility for the management and follow-up of SAIs was transferred in 2010 from the Department to HSCB and PHA working collaboratively with RQIA. The HSCB/PHA became responsible for monitoring Trust responses to adverse incidents and providing assurance to the Department on the application of procedure. Importantly, it became responsible for ensuring that Trusts were implementing recommendations from SAI reviews. The

⁶⁹ 330-061-001

⁷⁰ 330-062-001

⁷¹ 330-063-001

⁷² 330-133-065

⁷³ 330-133-042

⁷⁴ 333-117-001

⁷⁵ 403-013-001

HSCB published an 'Assurance Framework' to formally articulate the quality assurance available to Trust Boards.

- 8.46 A regional system for the reporting of all SAIs to the HSCB was established and a 'Procedure for the Reporting and Follow-Up of SAIs' was issued by HSCB to all Trusts in 2010. It was reviewed and revised in 2013⁷⁶ and again in November 2016.⁷⁷ It remains under 'continuous review.' The Procedure outlines a process which, if followed, would answer many of the concerns raised by the findings of this Inquiry.
- 8.47 The Procedure and guidance are informed by the NPSA 'Being Open Framework' (2009) and the Health Service Executive 'Open Disclosure National Guidelines' (2013) and are expressly based on the principles of openness, responsibility to share learning and necessity to continually review both reporting and investigation. In order to provide regional consistency it provides clear procedures for reporting, reviewing and the implementation of learning. It sets out necessary definitions, roles and responsibilities. There are model SAI notification forms and forms for use in both 'interface' incidents⁷⁸ and 'never events'.⁷⁹ Criteria are given for proportionality in investigation and provision is made for the involvement of families and 'lay people'. There is guidance on post-incident debriefing, independence in investigation, root cause analysis, significant event audit, Datix coding forms, joint investigations and timescales. The form and content of an Incident Review Report and Action Plan are set out. Guidelines and checklists for engagement with families are appended. Completion of these checklists is mandatory. Advice is given on meeting a family after a death and examples of open communication are helpfully appended. The Guide for HSC Staff on 'Engagement/Communication with the Service User/Family/Carers following a serious adverse Incident' is attached and updated to November 2016.⁸⁰ Guidelines to ensure best

⁷⁶ 401-001au-001

⁷⁷ 403-003-001

⁷⁸ An incident which has occurred in one hospital but which is identified in another.

⁷⁹ <https://www.health-ni.gov.uk/sites/default/files/publications/health/HSC-SQSD-56-16.pdf>

⁸⁰ 403-003-075 - Developed by HSCB, PHA, PCC and RQIA

practice are given and truthfulness, timeliness and clarity are emphasised. Assistance for families is suggested and details are given of the help available from the PCC. An information leaflet designed to advise families about the SAI process is now available.⁸¹

- 8.48 The Procedure introduced the role of the HSCB 'Designated Review Officer' ('DRO') to oversee Trust SAI procedures, scrutinise findings and identify regional learning.⁸² The DRO, in the case of a child death where fluid mismanagement or nursing failure is suspected, would be a Consultant in Public Health who would work with a Nurse Consultant and a Pharmacist.⁸³ A new practice protocol for DROs was issued in April 2017.⁸⁴
- 8.49 The terms of reference for an investigation, timescales for reporting, extent of family involvement and identity of those investigating must all be agreed with the DRO. The DRO will then consider the SAI report and, if content with both investigation and recommendations, will formally conclude the SAI process. The DRO consults other relevant organisations including RQIA to ensure that reasonable action has been taken to reduce the risk of recurrence and that learning of broader implication has been disseminated. Thereafter further action is to be monitored by the Trust itself.
- 8.50 Workshops were organised to discuss implementation of the new SAI process attended by governance leads from HSCB/PHA, the six HSC Trusts and the Department.⁸⁵ HSCB also organise SAI follow-up exercises with checklists for systematic monitoring.
- 8.51 HSCB/PHA seeks to maintain focus on the central problem of learning from SAIs with a weekly HSCB Senior Management Team review of Trust SAI reports and healthcare related Coroner's reports. Regular and formal liaison is maintained with other relevant organisations including RQIA, NIMDTA and NIPEC. 'Learning Reports' on SAIs are published bi-

⁸¹ 401-001aa-001

⁸² 331-009-001

⁸³ 331-013-002

⁸⁴ <http://insight.hscb.hscni.net/information-for-designated-review-officers-dros/>

⁸⁵ 404-001j-007

annually.⁸⁶ The most senior level of management is involved so as to provide assurance. In an attempt to enhance learning from less serious incidents, a project within the 'Quality 2020' programme is examining different methods of sharing the analysis of investigation.⁸⁷

- 8.52 The Regional SAI Review Group considers individual SAI investigations and decides if further action is necessary. Specific advice can be given Trusts by way of a 'Learning Letter'. Notwithstanding "*judicious use*" of learning letters, the Review Group still "*issues around one learning letter a month.*"⁸⁸ Thereafter it requires appropriate assurance that the trust has acted as required.⁸⁹
- 8.53 SAIs, complaints and the reports of the regional SAI review group are considered by the HSCB/PHA Quality Safety and Experience Group which seeks to identify broader regional concerns. Although RQIA does not receive acute hospital SAI reports it does provide two members of the HSCB Regional Adverse Incident Steering Group which also reviews a selection of investigation reports to assure appropriate scrutiny of themes, trends, practice and learning. Thereafter, the Safety Quality and Alerts Team ('SQUAT') implements and quality assures the Alerts, Guidance and Learning Letters arising from SAIs.
- 8.54 HSCB/PHA have developed a newsletter, in addition to other channels of regional communication, to disseminate SAI learning to all levels of healthcare staff. 'Learning Matters' is accessible on line.⁹⁰ Learning is also shared through SAI regional training events, Trust SAI workshops, Regional Governance Leads workshops, good practice letters and the implementation of specific recommendations. HSCB also publishes standardised hospital mortality rates benchmarked against rates in

⁸⁶ 401-001n-001 & 404-001j-001

⁸⁷ 404-002b-001 – 'Testing methods to learn from adverse incidents.'

⁸⁸ Dr Carolyn Harper T-14-11-13 p.42 line 24

⁸⁹ Dr Carolyn Harper T-14-11-13 p.45 line 5

⁹⁰ The 5th edition of Learning Matters, April 2016 covered, amongst other topics, the Prescription of IV Fluids. http://www.publichealth.hscni.net/sites/default/files/Learning_Matters_Issue_5.pdf page 4

England. These would appear to indicate that death rates in Northern Ireland are comparable to or lower than those in England.

- 8.55 Whilst many of the deficiencies and vulnerabilities exposed in the course of this Inquiry have thus seemingly been addressed by changes in guidance, practice and procedure, it must nonetheless be observed, that the ultimate effectiveness of the learning derived from SAIs remains largely unknown.

HSC Trust SAI process

- 8.56 HSC Trusts have now developed individual protocols to guide reporting, review and learning from adverse incidents. All were found to be comparatively up-to-date when listed in the Regional Learning System Project Report in May 2015.⁹¹ Nonetheless there was clear disparity as and between the HSCT Trusts in relation to the breadth and depth of policy and guidance. Development of procedures for more uniform adoption across HSC Trusts was therefore recommended in the interests of regional consistency.⁹² The Department advised in November 2017 that *“work is ongoing to develop and agree regional adverse incident guidelines and procedures for adoption across the HSC.”*⁹³ I consider this to be work of great importance.

- 8.57 It is to be noted that BHSCT procedures are both comprehensive and subject to oversight. The Trust approved its ‘Serious Adverse Incident Procedure’ in 2016.⁹⁴ Within the RBHSC every child death is to be assessed and in each instance of unexpected death, a SAI investigation is initiated and the families advised. The Trust in such circumstances will meet with the Medical Officer from the Coroner’s Office to examine the potential for shared learning and all such deaths are discussed at the monthly Morbidity and Mortality meeting. The Procedure provides for family input and feedback with opportunity given to discuss concerns and make contact with a bereavement co-ordinator. The BHSCT Coroner Liaison

⁹¹ 401-002w-026

⁹² 401-002w-009

⁹³ 404-002b-002

⁹⁴ 401-001ab-001

Office collaborates with the Bereavement Co-ordinator to support families involved with inquests.

- 8.58 BHSCT has also set out a 'Board Assurance Framework'⁹⁵ incorporating SAI procedures, complaints, patient experience and the processes for the identification and dissemination of learning. It is encouraging that the Assurance framework specifically references *"the three landmark reports in 2013 on quality and safety in the NHS (Francis Report, Keogh Review and the Berwick Report) all recommended the development of an organisational culture which prioritises patients and quality care above all else..."*⁹⁶
- 8.59 The RBHSC has an Assurance Sub-Committee and a Governance Group reviewing SAIs, complaints, audit, quality improvement and policy. In addition BHSCT has established specific responsibility groups to consider, supervise and provide assurance. These include the SAI Group, Claims Review Group, Complaints Review Group, Outcomes Review Group, Standards and Guidelines Committee, Safety and Quality Steering Group, Safety Improvement Team, Strategic Group for Quality, Improvement and Development, Deteriorating Patient Group, External Reports Review Group, Patient and Public Involvement Group, Quality Improvement Strategy Group, Learning from Experience Steering Group, Patient and Client Experience Working Group and the Bereavement Fora.
- 8.60 The Department has instituted an 'Early Alert System' whereby Trusts can notify the Department directly of incidents for immediate attention. The Permanent Secretary said *"that happens quite regularly...that's normal practice now."*⁹⁷
- 8.61 Importantly, I have now been assured that all deaths in the RBHSC are *"reviewed irrespective of whether there have been any concerns about the quality of care"*⁹⁸ Whilst ostensibly reassuring, it must be observed that the same was misleadingly claimed in relation to RBHSC at the time of the

⁹⁵ 401-001aw-001 (2016-17)

⁹⁶ 401-001aw-011

⁹⁷ Dr Andrew McCormick T-15-11-13 p.16 line 2

⁹⁸ Mr Colm Donaghy T-12-11-13 p.9 line 9

deaths of Adam, Claire and Lucy. Their deaths were not reviewed. Notwithstanding that review meetings are now minuted, they are not recorded.⁹⁹ Given the value of accurately recording clinical response to patient death and given the very modest cost, I would recommend that all such reviews be digitally recorded.

Adverse incident database

- 8.62 Each Trust maintains its own adverse incident database using DATIX risk management software to record and manage relevant information about incidents, claims, complaints, risks, alerts, inquests and requests. However, it was reported that even though the same software is used, different Datix adverse incident classification codes are employed by different HSC Trusts.¹⁰⁰ The resultant inconsistency in classification¹⁰¹ means that the system cannot constitute a conventional database or permit easy regional analysis.
- 8.63 The Department chairs a Regional Information Group which exercises oversight of data standards and has an ICT Implementation Plan.¹⁰² It has recognised that *“much remains to be done in order to have a truly connected and e-enabled service.”*¹⁰³ Presumably to that end and in response to the May 2015 recommendations of the ‘Regional Learning System Project Report’,¹⁰⁴ it has recently carried out a ‘scoping exercise’ to *“review and agree datasets, including classifications within services and then regionally to ensure consistency of reporting.”*¹⁰⁵
- 8.64 If it has not already done so, it should act with despatch to fully merge data and intelligence so as to permit scrutiny of overall performance and the identification of emerging patient safety issues. HSC organisations should synchronize electronic patient safety incident and risk management

⁹⁹ Mr Colm Donaghy T-12-11-13 p.69 line 7

¹⁰⁰ 401-001a-022

¹⁰¹ 323-037f-001

¹⁰² 403-020-052

¹⁰³ 403-020-052

¹⁰⁴ 401-002w-044

¹⁰⁵ 404-002b-002

software systems, codes and classifications to enable plain oversight of regional patient safety information.

Familiar problems

- 8.65 Notwithstanding that SAI reporting is mandatory, it would be unwise not to assume that there is still under-reporting. There are a number of obvious explanations for non-reporting, including failure to recognise the SAI, poor understanding of how and what to report and time pressures. However, individuals fear blame and the system is not proof against avoidance and manipulation. The SAI Procedure presents a number of critical decision making points open to 'subjective interpretation' and the exercise of 'discretion'. These include whether to report, who should investigate, what the investigation should pursue, the appropriate level of investigation and whether the level of investigation should be raised in response to evidence.
- 8.66 Notwithstanding considerable efforts to change hospital culture, familiar problems persist. For example the RQIA review of 2008 found *"little evidence of a reporting culture for incidents relating to intravenous fluids and hyponatraemia."*¹⁰⁶ The HSC Staff Survey of 2012 reported that *"only 42% of staff agree that their organisation does not blame or punish people involved in errors, near misses or incidents."*¹⁰⁷ The PAC reported that *"Whistle blowers still face real problems in speaking out ... a 'culture of fear' still exists in many parts of the HSC sector"*¹⁰⁸ The NIAO reported in 2014 that *"given the experience of the Turnaround Team in the Northern Trust and the RQIA inspection findings in the Belfast Trust, the culture within HSC bodies is still one of concern."*¹⁰⁹ The Regional Learning System Project Report of May 2015¹¹⁰ noted staff reporting *"that they would be concerned that there would be a risk to their professional reputation or registration as a result of reporting and that they might be blamed."* Indeed clinicians

¹⁰⁶ 303-030-382
¹⁰⁷ 403-016-064
¹⁰⁸ 403-018-006
¹⁰⁹ 403-016-067
¹¹⁰ 401-002w-001

themselves acknowledged in 2015 that “*When dealing with SAIs there is a culture of blame which needs to be changed.*”¹¹¹

8.67 In April 2014 the Minister, responding to criticism of the Health Service, instructed HSC Trusts to review their handling of all SAIs reported between 2009 and 2013. As a part of this ‘look-back exercise’ the Minister requested that the RQIA scrutinise each of those reviews. It did so and reported in December 2014.¹¹²

8.68 In general terms, its review was rigorous and its findings encouraging. However during the exercise, Trusts uncovered cases which should have been classified and reported as SAIs but which were not. Included was one death which required retrospective notification to the Coroner.¹¹³ Amongst other specific issues identified and relating to SAI management was difficulty experienced in obtaining independent expertise for the more complex investigations and staff who wished “*to examine potential legal issues with their advisors before becoming involved in an investigation.*”¹¹⁴ The RQIA report was provided to Sir Liam Donaldson to inform his subsequent review of HSC governance arrangements.

8.69 Current guidance indicates that an SAI investigation will take up to twelve weeks depending on the seriousness and complexity of the case. More significant cases reviewed by root cause analysis may take longer with the agreement of the DRO. HSCB advise that “*in most instances SAI reports will have been finalised by the time the Coroner investigation is underway. However, the timing of SAI reviews and Coroner investigations may mean that it is a draft SAI report that is available to the Coroner. Any future review of the SAI procedure will continue to emphasise timeframes.*”¹¹⁵

8.70 It is reassuring that there will continue to be an emphasis on timeframes because when investigative journalists¹¹⁶ filed a Freedom of Information

¹¹¹ 403-017-013

¹¹² 401-003b-001

¹¹³ 401-003e-044

¹¹⁴ 401-003e-039

¹¹⁵ 404-001a-004

¹¹⁶ <http://www.thedetail.tv/articles/healthcare-investigations-face-serious-delays>

request of HSC Trusts as to the *“longest time periods taken to complete SAls within their catchment areas?”* responses indicated that some SAI reviews by BH&SCT took up to 3 years to complete. Whilst the quality of investigation remains the paramount objective, timeliness is important for both learning and public confidence. The Department is aware that there is scope for improvement and has asked GAIN to advise on the basis of an *“examination of good practice on SAls (or SIs) elsewhere in the UK and internationally.”* Notwithstanding, it remains most probable that improved resources and training could improve the efficiency of investigation.

- 8.71 In order to obtain assurance that current SAI procedures are working, continuous audit and review is required of reporting, investigation, analysis and response. In order to measure the engagement of Trust Boards, the involvement of families and the effectiveness of remedial action, it will be necessary to monitor practice. Since late 2015 RQIA has conducted unannounced inspections of acute hospitals in order to assess the quality of services. The report of its 2017 inspection of RBHSC gives valuable insight. Such inspections are an important development and because I believe that there should be additional and increased external monitoring of the entire SAI process, I would propose that the scope and remit of the RQIA be extended to encompass this important work.

Adverse incident investigation

- 8.72 The work of this Inquiry has shown that vulnerabilities in patient care systems are more likely to be the cause of a SAI than individual error. For that reason, I consider that improvement in investigation would be meaningfully assisted by further and advanced training in Root Cause Analysis. This would intensify the search for the underlying and interconnected causes of adverse incidents rather than fuelling fears of individual blame.
- 8.73 Investigation is sensitive to human input and the oversight provided by individual DROs may not always be consistent. Accordingly the independence of investigators is essential to achieve satisfactory

investigation and ensure that it is seen as such. I consider that the most serious AIs should therefore be investigated by wholly independent teams from outside Northern Ireland because, as Dr Carson on behalf of RQIA observed, *“Northern Ireland is quite a small community, everybody has worked with everybody else at some stage or another..”*¹¹⁷ Mr Peter Walsh, Chief Executive of AvMA, thought that would add a *“tremendous amount to the process”*¹¹⁸ so that there could be *“no perception of, let alone real, conflict of interest.”*¹¹⁹ I agree and believe that it would engender public confidence in the findings. An investigation team, independent of individuals, Trusts, the HSCB and the Department, would be able to investigate all parts of the Northern Ireland healthcare system without any taint of conflict of interest. Such an approach might be pursued with the newly established Healthcare Safety Investigation Branch from England. Collaboration could prove instructive for all concerned.

- 8.74 The wisdom of involving families in review and investigation has been amply confirmed by evidence before this Inquiry. Parents are experts in respect of their own children and often close observers of the care given. Ms Slavin had real understanding of the nature of Adam’s renal problems, Mrs Crawford was an eye witness to a key event, Ms Mitchell was the first to voice concern about Conor,¹²⁰ Mr Roberts’ attention to detail identified an overdose and Mr and Mrs Ferguson could have accurately described the deterioration of their daughter’s condition. In addition, all could have given invaluable advice about how not to communicate. In terms of reviewing care and contributing to improved patient safety the value of their potential contribution was too obvious not to have been actively pursued.
- 8.75 Whilst I was assured by Dr Carolyn Harper, Executive Medical Director of PHA, that there is increasing involvement of families at all stages of the investigation process,¹²¹ I nonetheless make several recommendations to

¹¹⁷ Dr Carson T-13-11-13 p.17 line 3

¹¹⁸ Mr Peter Walsh T-11-11-13 p.82 line 16

¹¹⁹ Mr Peter Walsh T-11-11-13 p.83 line 22

¹²⁰ 087-002-020

¹²¹ Dr Harper T-14-11-13 p.46 line 5

ensure that families are accorded all proper respect and managed for the potential they offer. Indeed, some families may even wish to maintain involvement after the conclusion of an investigation in order to satisfy themselves fully that lessons have been learned. Such might make a further and valuable contribution.

Translation of learning into improvement

- 8.76 Systems designed to translate learning from SAIs into improved practice were said to have been strengthened in recent years. In 2012, the PHA advised the Department that all trusts had confirmed “*robust systems in place for the dissemination of learning from adverse incidents.*”¹²² However, what was wanting was reliable evidence about the current monitoring and effectiveness of these systems. This issue lies at the heart of the Inquiry’s work and the requirement of families to know that the tragedy of their child’s death cannot happen again.
- 8.77 In October 2012 the Northern Ireland Audit Office reported on ‘The Safety of Services Provided by Health and Social Care Trusts.’¹²³ It noted the absence of a monitoring system to collate patient safety information from across the HSC service and concluded that the regional sharing of ‘lessons learned’ was not as structured or as comprehensive as it could be. The Comptroller and Auditor General told the Northern Ireland Public Accounts Committee in November 2012 that “*the Department still lacks a reliable means of tracking the progress of health and social care services in improving the safety of those receiving care or in holding service providers accountable for minimising preventable harm.*”
- 8.78 Inability to demonstrate effective dissemination of learning from the SAI process is not a problem unique to Northern Ireland. The House of Commons Public Administration Select Committee received evidence in

¹²² 330-057-001

¹²³ 403-026-001

2014-15 that the “*failure to learn from incidents and disseminate lessons has been a longstanding weakness of the NHS.*”¹²⁴

- 8.79 In 2013 RBHSC attempted to address this issue by publishing a strategy indicating by means of flow-chart the distribution of relevant learning within the Children’s hospital. In 2016 BHSC introduced its ‘Policy for Sharing Learning’ particularising the communication of learning and providing templates for dissemination.¹²⁵ It encompasses learning from complaints, mortality reviews, audit, litigation and SAs. The SA Review Board provides evidence to the Assurance Committee that risks revealed by the process are addressed. Importantly the Policy describes a regional process for information sharing through HSCB as well as the Department and proposes a central repository of learning on the intranet.
- 8.80 The Department has commissioned two regional studies from GAIN¹²⁶ to specifically examine the learning extracted from SAs involving the death of a patient.¹²⁷ Both exercises are to be pursued in partnership with HSCB and the HSC Trusts.
- 8.81 I have sympathy with the busy clinician working in the pressurised Health Service who is expected to learn rapidly from the dissemination of guidance. Given that corrections to clinical care are not always straightforward or intuitive, it follows that clinicians may require time and space to consider, discuss and assimilate learning from SAs. I consider it proper that such should be provided within contracted hours.
- 8.82 In addition, Trusts do not appear to be obligated to provide assurance to the families of victims of clinical mismanagement that lessons have been learned or that that learning is practiced. It is in this context that the work of a Child Death Overview Panel could be important. Such a panel is comprised of individuals from a range of different organisations and professions. It specifically considers the anonymised details of death,

¹²⁴ 403-027-049

¹²⁵ 401-001at-001

¹²⁶ Now conjoined with RQIA.

¹²⁷ 401-003i-001

howsoever caused, to determine whether learning exists such as might prevent another death. The introduction of this process in Northern Ireland under the Safeguarding Board for Northern Ireland has proved problematic¹²⁸ and the Department and PHA may now assume responsibility.¹²⁹ This would enable additional oversight and the potential for additional assurance that lessons have indeed been learned.

- 8.83 Trusts should publish current policy on learning from SAI deaths (especially child deaths) and thereafter not only publish the detail of all such deaths but also what has been learned from them.

Family involvement

- 8.84 The Permanent Secretary said he believed *“very strongly that the best chance we have of securing sustained improvement is through very open involvement ...making it easier for patients and families to be...aware ...and to feedback views...”*¹³⁰ and the CNO, Professor McArdle, said *“... we all believe that the patient’s voice has to be front and centre in everything that we do.”*¹³¹
- 8.85 In 2009 the Department published standards for ‘Improving the Patient and Client Experience’ in an attempt to define appropriate respect, attitude, behaviour and communication. This was very necessary because, as the evidence confirmed, shortcomings in communication fuel suspicion.
- 8.86 BHSCT developed a ‘Being Open Policy – saying sorry when things go wrong’¹³² to encourage open disclosure to patients and families involved in adverse incidents. It emphasises that healthcare professionals must understand that good communication engenders trust and that openness is important. In December 2014 the policy was made available as an e-learning module. It advises on communication with patients and families and emphasises quick and open disclosure so that transparency is

¹²⁸ 404-002h-001 Jay Report 2016 – ‘A Review of the Safeguarding Board for Northern Ireland’

¹²⁹ 404-002b-004

¹³⁰ Dr Andrew McCormick T-15-11-13 p.72 line 5

¹³¹ Ms McArdle T-15-11-13 p.65 line 4

¹³² 332-027-001 & 401-001ad-001 - 2011/2014 and revised 2015

understood. Specific guidance is given for sharing information with additional advices on ‘being open’ in the event of a death. It carries links to the Ombudsman’s ‘Guidance on Issuing an Apology’. The Trust Board is charged with promoting both it and a policy known as ‘Involving You’ which seeks to enhance ‘user’ involvement.¹³³

- 8.87 Notwithstanding, difficulties continue to surround the problem of communication with patients and families in the context of SAIs¹³⁴ and HSCB/PHA has produced further guidance (2015) in the form of a checklist to guide and monitor engagement with patients and families. Notwithstanding, it must be recognised that a list does not equip staff to manage difficult conversations with empathy and credibility. Successful interaction at times of distress is difficult, which is why training is critical to ensure the skills and awareness necessary to adequately inform a family and engage with it in the process of investigation and learning.
- 8.88 Whilst Dr Harper of PHA stressed that medical training has advanced in recent years *“particularly in the aspect of communication skills and interpersonal skills”*¹³⁵ and that communication training is now given all trainee clinicians, Dr Anthony Stevens, Medical Director of BHSCCT conceded that *“there are real areas particularly round engagement with families, where we recognise we’ve still got a great deal to do.”*¹³⁶ It is in this context that I recommend that training in communication skills be accorded enhanced priority.
- 8.89 I believe that there is also scope for the experience of patients and families to be heard within the Department. I believe that this is a deficiency and one which should be addressed.

¹³³ 332-013-001

¹³⁴ 348-010d-001

¹³⁵ Dr Harper T-14-11-13 p.58 line 3

¹³⁶ Dr Stevens T-12-11-13 p.95 line 20

Complaints

- 8.90 In 2009 the Department issued 'Complaints in HSC: Standards & Guidelines for Resolution and Learning' to replace the 1996 HPSS Complaints Procedure and established a HSC Complaints Policy Liaison Group in 2011. Departmental policy now requires involvement of the complainant and encompasses advocacy services and staff training. Complainants can get independent advice from the PCC and are now advised of their right to refer their complaint to the Ombudsman.¹³⁷ The Department has tried to secure patient engagement through community exercises, such as '10,000 Voices' and 'Family and Friends Test.' Policy on complaints continues to evolve.
- 8.91 HSCB has sought to improve the content of feedback to complainants and has held annual 'Complaint Learning Events'¹³⁸ with 'patient-centred' advice for healthcare professionals coupled with specific guidance on communication and bereavement support. Learning materials are also available on the HSCB intranet and there is an Annual Complaints Report.¹³⁹
- 8.92 Actual complaints are used as the basis for learning. In one instance, a family complained about poor communication in the context of a relative's deterioration and death. In consequence the Trust provided specific training to the staff on the proper conduct of such difficult and timely conversations.¹⁴⁰ Mr John Compton, Chief Executive, of HSCB also described a seminar where patients recalled good and bad experiences for the benefit of clinicians which resulted in "*interplay between them and the staff about what would make it better*".¹⁴¹ These are important initiatives in

¹³⁷ Who, unlike his predecessor the NI Commissioner for Complaints, can now publically report the outcome of complaint investigation. Public Services Ombudsman Act (Northern Ireland) 2016 - <http://www.legislation.gov.uk/nia/2016/4/contents/enacted>

¹³⁸ 401-001b-001

¹³⁹ 401-001e-001 & 404-001c-001 & 404-001d-001

¹⁴⁰ 404-001c-009

¹⁴¹ Mr Compton T-14-11-13 p.31 line 17

feedback and learning and represent an approach which is obvious and should be encouraged.

- 8.93 The HSCB is responsible for reviewing HSC Trust response to complaints in order to identify trends. It makes regular performance reports to the Department. It advises on the numbers and categories of complaints together with response times and learning outcomes. HSCB reported on the 'Process for Evaluation of Complaints in HSC: Standards and Guidelines for Resolution and Learning' in 2011 and concluded that, whilst HSC organisations do learn from complaints, there is a need to advise staff and patients of that learning. The HSCB/PHA Annual Quality Report 2014-2015 noted that *"Service user feedback has demonstrated that further work is required to promote the visibility and accessibility of the Complaints Process."*
- 8.94 HSCB subsequently produced an updated 'Policy for HSCB staff on the management of complaints' in April 2016. It set out revised standards and guidelines promoting accessibility, advocacy services, appropriate investigation, involvement of lay persons, independence of experts, opportunities for shared learning and speedier resolution. It provides flow-charts to detail procedures. The 2016 HSCB Policy explains that *"The operation and effectiveness of the HSC Complaints Procedure will be monitored continuously. A Regional Complaints Group...has been established and will meet on a quarterly basis to consider analysis of information pertaining to...HSC Trust complaints...the Regional Complaints Group will identify what learning should be cascaded regionally to ensure policies and practices are amended as a result of complaints."*¹⁴² Auditing of complaints handling has been introduced.¹⁴³
- 8.95 The PCC is the main healthcare 'consumer' organisation in Northern Ireland. It has responsibility for representing the interests of the patient and for supporting public involvement in decisions about care. The PCC has no

¹⁴² 403-004-013 to 014

¹⁴³ 404-001c-005

power to investigate complaints but has a statutory duty to assist those who wish to make a complaint. It has a permanent seat at the monthly meetings of the HSCB board responsible for oversight of HSC complaints.¹⁴⁴ All HSC Trusts are required to publish annual reports on complaints and submit them to the PCC. The PCC also publishes an annual report on complaints. In 2015-16 it reported that *“families and carers do not feel that they are being kept adequately informed about the progress of their treatment and care”*.¹⁴⁵

- 8.96 The Northern Ireland Commissioner for Complaints¹⁴⁶ also reports annually and has recorded the growing numbers of healthcare related complaints. In 2014/15 he referred *“to an underlying issue in many complaints, being a breakdown in trust between the patient/family and the HSC organisation”*¹⁴⁷ and expressed concern that all but one of the complaints received by him of complaint mismanagement was upheld.¹⁴⁸
- 8.97 Independent Advocacy services have an important role in communication and in connecting the experience of patients and families to the improvement of care. The RQIA has included a Review of Advocacy Services for Children and Adults in its 2015-2018 review programme.¹⁴⁹
- 8.98 BHSC introduced its ‘Policy and Procedure for the Management of Complaints and Compliments’ in 2010¹⁵⁰ indicating appropriate responses and time frames. A Complaints Review Group assured the investigation, analysis and follow-up from complaints. However, in order to more effectively involve the complainant and investigate the complaint, BHSC introduced a largely revised ‘Policy and Procedure for the management of Comments, Concerns, Complaints & Compliments’ in 2017.¹⁵¹ Emphasis is placed on effective communication, with appropriate meetings, agreed

¹⁴⁴ Mr Compton T-14-11-13 p.9 line 9 & p.11 line 8

¹⁴⁵ 403-008-011

¹⁴⁶ Now the Ombudsman

¹⁴⁷ 401-001e-015

¹⁴⁸ 401-001e-016

¹⁴⁹ 401-003d-015

¹⁵⁰ 332-014-001

¹⁵¹ 404-003b-001

agendas and recording. Specific requirements are given as to roles and responsibilities, the complaint investigation process and the types of resolution possible and responses to be given. Not only is outcome monitored for pattern but it is also measured for efficiency, learning and complainant satisfaction.

- 8.99 Given the problems of trust and communication which still seem to undermine the investigation of complaints, Mr Walsh, urged me strongly to the view that there ought to be standards for complaint investigations which should include the early involvement of the family.¹⁵² I agree and consider that there should be a charter to particularise the rights of the family or patient in relation to complaints and further that those Trusts, which have not already published their responsibilities to families in respect of complaints, should do so now. Clarity about the process can only assist. Information encourages inclusion and families and patients should always be included in the investigation of patient safety issues.
- 8.100 Complaints present a valuable source of insight into patient safety problems and should be analysed as such. I am advised (as of November 2017) that *“the Department has commenced, in liaison with HSC Trusts, the piloting of the use of Healthcare Complaints Analysis Tool...for more meaningful analysis and comparison of data from complaints within and across Trusts.”*¹⁵³ This could prove of considerable benefit for both individual Trusts and regional learning.

The Duty of Candour

- 8.101 Of all the themes emerging from the evidence to this Inquiry, the most disquieting has been the repeated lack of honesty and openness with the families. In his report on the Mid Staffordshire NHS Foundation Trust Public Inquiry, Robert Francis QC found the same problem. In consequence, he recommended that a statutory duty of candour be imposed in situations where it was suspected or believed that death or serious injury had been

¹⁵² Mr Peter Walsh T-11-11-13 p.8

¹⁵³ 404-002b-003

caused to a patient by an act or omission of a healthcare organisation or its staff. He proposed that in such circumstances the patient or family should be informed of the incident and given an explanation. He believed furthermore that the duty of candour should be imposed on registered healthcare professionals, NHS healthcare organisations and private providers.

8.102 Since then there has been a prolonged debate as to whether those recommendations should be implemented in their entirety, whether the duty should apply to both individuals and organisations and exactly what the threshold definition of harm should be. In England a statutory duty has been enacted for organisations but not for individuals and in Wales the position has not progressed beyond White Paper proposals. In Scotland, a duty of candour will come into force in April 2018 but will differ from the English model in minor but significant respects.¹⁵⁴

8.103 In Northern Ireland, Jim Wells MLA (then Minister for the Department), informed the Assembly on 27th January 2015 that *“a statutory duty of candour will be introduced in Northern Ireland. There should be no ambiguity in respect of my expectation regarding the crucial elements of patient safety, which are openness and transparency.”*¹⁵⁵

8.104 The Department advised that in November 2017 it *“continues to develop policy to support the introduction of a statutory duty of candour in Northern Ireland. Initial comparisons of the approaches adopted in other jurisdictions and a workshop with HSC colleagues has highlighted a number of issues which require further consideration before we will be in a position to take our proposals to Minister, including definitions of harm, apologies etc. There is learning to be had from the experience of colleagues in other jurisdictions and we are examining the evidence presented during the associated Parliamentary sessions and the difficulties/successes of implementing their legislation to further inform our options. The Department will need to*

¹⁵⁴ <http://www.legislation.gov.uk/asp/2016/14/contents/enacted>

¹⁵⁵ <http://data.niassembly.gov.uk/HansardXml/plenary-27-01-2015.pdf> page 2

consider the introduction of a statutory duty that is straightforward and brings value to existing principles of openness and transparency and the individual duty of candour.”¹⁵⁶

- 8.105 Whilst the issues involved are not straightforward and there are matters for legitimate debate, the unfortunate truth to be drawn from this Inquiry is that there are too many people in the Health Service who place reputation before honesty and avoidance of blame before duty. All that is required is that people be told honestly what has happened and a legally enforceable duty of candour for individuals will not threaten those whose conduct is appropriate. The duty was not imposed upon clinicians in England on the basis that they are already placed under an ‘ethical duty’ of honesty by their professional organisations. I consider that such an argument would be stronger, had the evidence to this Inquiry not revealed obvious weakness in the call of ‘ethical duty’.
- 8.106 Whilst Mr Walsh did indicate some recent improvement in levels of openness towards families, he believed that that improvement had not been consistent. It is to encourage consistency in openness and to avoid any ambiguity in expectation that I endorse the Francis recommendations.¹⁵⁷ I recommend that a duty of candour attach to individuals as well as organisations in the event of death or serious harm and that criminal sanctions should apply.
- 8.107 It will be necessary to provide specific guidance on implementation and compliance. The duty should be entrenched by Trust Directors appointed with specific responsibility for candour. Procedures should be audited, not only by HSC Trusts but also by the RQIA. It will be necessary for a regulatory body, such as the RQIA, to undertake enforcement. There should be willingness to prosecute in cases of serious non-compliance.

¹⁵⁶ 404-002b-009

¹⁵⁷ Recommendations 181-183

Whistleblowing

8.108 Patient safety is the concern of everyone working in the Health Service and accordingly it must be the duty of everyone to raise patient safety concerns. However, because it has been found necessary to encourage whistleblowers, the Department has directed that Trusts develop policies enabling staff to raise concerns about questionable practice.¹⁵⁸ The RQIA issued guidance for whistleblowers and published its 'Review of Whistleblowing Arrangements in Health and Social Care in Northern Ireland' in September 2016.¹⁵⁹ It made eleven recommendations, seven of which the Department maintains "*are either fully implemented or on target to be implemented*" as at November 2017.¹⁶⁰ This impetus should be maintained. In every hospital there should be real or virtual individuals to whom concerns can be taken easily and without formality. There should be training and the system should be as responsive as possible.

Appraisal of clinical performance

8.109 The Department has developed procedures to address concerns about poor medical performance. 'Maintaining High Professional Standards' gives guidance for managing under-performance and allows Trusts access to the National Clinical Assessment Service. This complements recently introduced professional revalidation for practicing doctors.¹⁶¹ There is now a statutory duty¹⁶² to ensure that doctors undergo regular appraisal, that action is taken in respect of any lack of fitness to practice and that relevant concerns are referred to the GMC. The re-validation process became operational within the BHSCT by 2013 and has since been extended to the rest of Northern Ireland. It considers feedback from colleagues and feedback from patients.¹⁶³ The GMC has appointed a Liaison Advisor in Northern Ireland to assist with formal referrals to the GMC. Whilst the

¹⁵⁸ 403-019-001

¹⁵⁹ 401-003x-001

¹⁶⁰ 404-002b-003

¹⁶¹ 332-030-001

¹⁶² <http://www.legislation.gov.uk/nidsr/2010/9780337981302/body>

¹⁶³ Dr Michael McBride T-15-11-13 p.28 line 19

overall number of recent referrals has been too small to reveal trends, the procedure itself provides additional quality assurance.

- 8.110 Management of poor nursing performance is now also the subject of process and protocol.¹⁶⁴ Each Trust has disciplinary and capability procedures and can make referral to the NMC.¹⁶⁵ All nurses are required to undergo annual appraisal with their line manager.

Leadership

- 8.111 Evidence received by this Inquiry revealed numerous failings in leadership. These included failure to supervise nursing staff, consultant failure to direct care or give leadership in the event of unexpected death, failure of those in governance to demonstrate appropriate behaviour, failure of Directors of Nursing to provide visible leadership, failure of a HSC Trust Chief Executive to accept responsibility for the quality of care given children in his hospital and failure by the Department to hold the Health Service to account in respect of the quality of care or secure the timely introduction of clinical governance. Such attitudes and behaviours influence hospital cultures.
- 8.112 Building a culture where the natural response to error is to learn from it, is therefore very much the responsibility of leadership at every level. Change in culture will take time and expert leadership. Leadership has now been exercised by the Department in setting the direction of quality improvement. The Directors of each HSC Trust now have the major role to play in achieving the appropriate learning culture within each organisation. The best leadership is critical and there should be investment in the best.
- 8.113 The Permanent Secretary observed that *“leadership is not about position, it’s about behaviours that drive each individual to do the right thing all the time...”*¹⁶⁶ I believe that to achieve the ‘right thing’ that there should be visible leadership at every level of an organisation. Leaders at all levels and especially at Board level must not be inaccessible. They should do

¹⁶⁴ 332-033-004

¹⁶⁵ 332-038-001

¹⁶⁶ Dr Andrew McCormick T-15-11-13 p.99 line 7

more than appear on the occasional senior management 'walk-round'.¹⁶⁷ Senior managers should be observable to the 'front-line' encouraging learning and discouraging blame. They should welcome concerns and give feedback on improvement. They should demonstrate confidence in transparency by commending staff who speak out. They should communicate in the clearest terms that it is safe to raise concerns.

- 8.114 Clinical leadership should encourage those who care for patients to improve their care. Senior clinicians should be role models. They should challenge defensiveness and ensure that every opportunity for improvement is taken.
- 8.115 The BHSCT has introduced a 'Clinical Engagement and Leadership' programme and a 'Leadership Attributes Framework.' The Department published a HSC Collective Leadership Strategy in October 2017.¹⁶⁸ Whilst such initiatives respect the broad importance of leadership, I believe that there is nonetheless a pressing necessity to strengthen leadership at each and every level. I recommend that improvement in leadership now be accorded the utmost priority.

Death certification

- 8.116 Both the Luce Review (2003) and the Shipman Inquiry (2003) considered issues of death investigation and certification and made recommendations for Northern Ireland. Recognising the problem of inaccuracy in certification,¹⁶⁹ the Department issued guidance for both completion of the Medical Certificate of Cause of Death ('MCCD') and notification to the Coroner in 2008. The Coroner's Service published a 'Best Practice' guide in 2009 and appointed a Medical Officer to assist the coroner in identifying issues of clinical concern. Notwithstanding, the senior Coroner had to ask

¹⁶⁷ 401-001ag-001

¹⁶⁸ 403-024-001

¹⁶⁹ 338-012-001

the Board and the CMO in 2014 to remind doctors of their duty to notify the coroner of all deaths which might be SAI related.¹⁷⁰

- 8.117 Within the BHSCT there was no systematic way of collecting details of MCCDs or notifications to the Coroner for the purposes of review. It was therefore difficult to assure that every death and certification had been clinically scrutinised. Accordingly, and at the instigation of the Department, a Death Certification Implementation Working Group was established to improve assurance of the certification process.
- 8.118 In 2016, the Department issued comprehensive, detailed and step-by-step guidance on the 'Child Death Reporting Process'¹⁷¹ and the BHSCT in turn adopted clear policy on 'Actions Following a Patient's death' with advice on what, when and how to report to the coroner. Updated training has been provided to all junior doctors to ensure a proper understanding of the responsibilities attaching to completion of the MCCD. Further training programmes are being developed. The MCCD has been re-designed to collect additional information enabling audit and improved assessment of medical compliance with statutory obligation.¹⁷²
- 8.119 In April 2017 the CMO then issued further guidance on reporting child deaths.¹⁷³ Child deaths in hospital are to be recorded by means of the Regional Mortality and Morbidity Review System ('RM&MRS')¹⁷⁴ which standardises procedures and permits review of all hospital deaths and death certificates.
- 8.120 The process means that all child deaths in hospital are recorded by means of a step-by-step computerised procedure on the RM&MRS. The consultant will particularise and certify the details as accurate. The system will generate the MCCD or a clinical summary where the death is to be referred to the coroner. The consultant must record all contact with the Coroner's

¹⁷⁰ 401-002d-001

¹⁷¹ 401-001av-001

¹⁷² 401-002b-017

¹⁷³ 404-002e-001

¹⁷⁴ 401-002h-001

Office and cite an identifying reference provided by the Coroner's Death Reporting Team. If the death meets SAI criteria the consultant must initiate the SAI process. The consultant must then forward the case to the designated Mortality and Morbidity ('M&M') lead for discussion and review at the next M&M meeting. SAI investigation reports will be listed for the next M&M meeting which will thus review all child deaths and any completed SAI investigations occurring since the previous meeting. The M&M lead will cause a multi-disciplinary review of the clinical history, cause of death, avoidable factors, discussions with the Coroner, lessons learned and actions required.

- 8.121 All child deaths must be reviewed within 12 weeks. This includes those deaths reported to the Police Service of Northern Ireland ('PSNI') or the Coroner as well as those investigated as an SAI or subject to post-mortem. This is to ensure that learning is disseminated as soon as possible. Should it appear to a M&M meeting that a case should be reported as a SAI or to the Coroner, then this must be done immediately. Only when the M&M has completed its review and each step of the process has been completed can a child death notification form issue. It is sent to the Trust governance team and/or audit unit and served on the HSCB/PHA.
- 8.122 The RM&MRS will thus routinely collect information from certificates, reports to the coroner, consultant reviews, mortality meetings, inquest findings, action plans, learning reports and other relevant sources.¹⁷⁵ The information will be consolidated and made available for scrutiny. The system provides a means to assure that the process of certification can be relied upon and that notifiable deaths are reported to the coroner. The information, if properly interpreted, should provide reasonable assurance to public and Trust board members alike, that such deaths in their hospitals as do result from unsafe care are identified, analysed and learned from.
- 8.123 Implementation of the system was complete by March 2017. In November 2017 there were reported to be *"over 150 teams across the 5 HSC Trust*

¹⁷⁵ 401-002r-006

hospitals using the system with a recording rate of over 80%”. HSC Trusts were said to be “establishing mechanisms to ensure they oversee/monitor outcomes from the M&M process.”¹⁷⁶ This is a most valuable development and its operation and effectiveness should be subject to regular internal and external audit.

- 8.124 Notwithstanding the advances inherent in this system, I would nonetheless recommend the appointment of an Independent Medical Examiner, at least until such time as the RM&MRS has proven its reliability. A Medical Examiner can reconsider the consultant input and the MCCD, and with full access to the medical records, can pursue queries with the certifying doctor and the family of the deceased. The Examiner can refer uncertain cases to the coroner for further investigation and assist in the important task of pattern recognition.

Issues of coronial involvement

- 8.125 A most important part of the Coroner's role in relation to deaths associated with clinical mismanagement, is the power to alert relevant authority to the potential to prevent further fatality.¹⁷⁷ The Coroner can do this by way of a formal report made pursuant to Rule 23(2) of The Coroner's (Practice and Procedure) Rules (Northern Ireland) 1963.
- 8.126 However, the Department advised that “... *there is no standardised approach to how [Rule 23] reports are made. In some cases correspondence is addressed to the Minister, on other occasions information is provided for the Chief Medical Officer or some other senior officials, and in some instances there is no mention that the referral is being made under Rule 23(2).*”¹⁷⁸ In recognition of the weaknesses of such an approach the Department indicated that it would seek agreement on standardising referral of Rule 23 Reports.

¹⁷⁶ 404-002b-006

¹⁷⁷ 303-052-715

¹⁷⁸ 401-002r-005

- 8.127 The Coronial Service has indicated that Rule 23 Reports are now sent to the Department with a requirement that it respond giving both proposed action and timetabling. Copies of the report and response are sent to other interested parties to stimulate appropriate action.¹⁷⁹ The Coroner will then seek assurance from the Department and HSC Trust that learning has indeed been, or will be, put into practice. This feedback is important. It was these channels of communication that the Coroner regretted were not available to him following the Inquest into Adam's death.
- 8.128 Furthermore, the Coronial Service has confirmed in that "*Work is underway to ensure that there is proper feedback and follow up to Rule 23 Reports taking account of best practice in other jurisdictions*".¹⁸⁰ Additionally, inquest findings which may have implications for health care are forwarded by the Coroner's Office to HSCB where they are reviewed through the SAI process. These procedures are detailed in HSCB 'Paper on communication Pathways between the Coroner's Office, PHA and HSCB.'¹⁸¹ Additional measures have been agreed enabling the Coroner's Medical Officer to notify healthcare authorities of emerging trends.

Disclosure of relevant documents to the Coroner

- 8.129 The right to assert entitlement to legal privilege in respect of certain documents and so withhold them from a coroner's investigation into a health care related death, highlights a tension between transparency and important legal principle. A coroner has no power to order the production of documents and HSC Trusts are under no general legal duty to disclose relevant expert opinions to the Coroner. This is notwithstanding obligation to assist the coroner and the fact that such reports are publically funded. Nor is a Trust under any duty to advise the Coroner that such experts could be called to give evidence at inquest. Furthermore, an organisational duty

¹⁷⁹ 401-004a-002

¹⁸⁰ 401-004a-002 August 2016

¹⁸¹ 401-001f-001

of candour might not necessarily obligate disclosure because it would relate to factual information rather than an expert expression of opinion.

- 8.130 Whilst the Department maintains “*a presumption in favour of disclosure as a matter of general principle, the matter of whether to claim privilege is one for a Trust to consider based on its own legal advice,*”¹⁸² the CMO nonetheless expressed the view that “*it should never be the case that we have information in relation to the circumstances and death of a patient which is not shared fully, frankly and openly with the coroner to inform and assist him in his investigations and determination of the cause of death.*”¹⁸³
- 8.131 BHSCT is said to share all such reports with the Coroner.¹⁸⁴ I believe that is the preferred approach. However, and in order to acknowledge the claims of both transparency and privilege, I would recommend that HSC Trusts claiming privilege in respect of a document relevant to the proceedings of an inquest, should inform the Coroner as to both the existence and nature of the document.
- 8.132 The Department should, in any event, issue guidance to HSC Trusts on the approach it would wish adopted.

Regular external review

- 8.133 Cumulatively, the measures introduced over recent years have very significantly reduced the risk of harm to children and young people receiving IV fluids. Additionally where a SAI does occur, there are greatly improved mechanisms to identify it, investigate it, learn from it and reduce the risk of recurrence. That so much has been done, taught and published and that so many more SAIs and complaints are reported, all confirm that the Health Service environment has most definitely been transformed since the period under review.

¹⁸² 333-342-011

¹⁸³ Dr Michael McBride T-15-11-13 p.79 line 14

¹⁸⁴ Mr Colm Donaghy T-12-11-13 p.81 line 20

- 8.134 Whilst I am able to conclude that lessons have been learnt, I cannot conclude that all risk of recurrence has been eliminated. Given that the provision of health care is an immense and complex task, I can only agree with Dr Carson when he observed “*one can never give full assurance that full compliance will ever be achieved.*”¹⁸⁵
- 8.135 Accordingly, it remains critical to keep building upon the very real progress made and to further undermine the remnant culture of clinical defensiveness. To that vital end, future progress should be subject to regular external review.

¹⁸⁵ Dr Carson T-13-11-13 p.47 line 10

RECOMMENDATIONS

9.1 The lessons of these sad cases must be learnt because it cannot be assumed that such tragedy could not happen again. Although much has been achieved, much remains to be done. These recommendations have been guided by the following principles:

- (i) That healthcare services exist to serve the patient.
- (ii) That quality of healthcare is dependent upon both clinical and non-clinical services.
- (iii) That the particular needs of children must be addressed.
- (iv) That leadership and candour must be accorded the utmost priority if the fullest learning is to be gained from error.
- (v) That progress should be subject to regular external review.

9.2 I believe that parents must be involved in the implementation of these recommendations. It is to be recognised that improvement cannot be achieved without expenditure. These recommendations have not been costed.

Recommendations

Candour

1. A statutory duty of candour should now be enacted in Northern Ireland so that:
 - (i) Every healthcare organisation **and** everyone working for them must be open and honest in all their dealings with patients and the public.
 - (ii) Where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or

its staff, the patient (or duly authorised representative) should be informed of the incident and given a full and honest explanation of the circumstances.

- (iii) Full and honest answers must be given to any question reasonably asked about treatment by a patient (or duly authorised representative).
 - (iv) Any statement made to a regulator or other individual acting pursuant to statutory duty must be truthful and not misleading by omission.
 - (v) Any public statement made by a healthcare organisation about its performance must be truthful and not misleading by omission.
 - (vi) Healthcare organisations who believe or suspect that treatment or care provided by it, has caused death or serious injury to a patient, must inform that patient (or duly authorised representative) as soon as is practicable and provide a full and honest explanation of the circumstances.
 - (vii) Registered clinicians and other registered healthcare professionals, who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare organisation by which they are employed has caused death or serious injury to the patient, must report their belief or suspicion to their employer as soon as is reasonably practicable.
2. Criminal liability should attach to breach of this duty and criminal liability should attach to obstruction of another in the performance of this duty.
 3. Unequivocal guidance should be issued by the Department to all Trusts and their legal advisors detailing what is expected of Trusts in order to meet the statutory duty.

4. Trusts should ensure that all healthcare professionals are made fully aware of the importance, meaning and implications of the duty of candour and its critical role in the provision of healthcare.
5. Trusts should review their contracts of employment, policies and guidance to ensure that, where relevant, they include and are consistent with the duty of candour.
6. Support and protection should be given to those who properly fulfil their duty of candour.
7. Trusts should monitor compliance and take disciplinary action against breach.
8. Regulation and Quality Improvement Authority ('RQIA') should review overall compliance and consideration should be given to granting it the power to prosecute in cases of serial non-compliance or serious and wilful deception.

Leadership

9. The highest priority should be accorded the development and improvement of leadership skills at every level of the health service including both executive and non-executive Board members.

Paediatric - clinical

10. Health and Social Care ('HSC') Trusts should publish policy and procedure for ensuring that children and young people are cared for in age-appropriate hospital settings.
11. There should be protocol to specify the information accompanying a patient on transfer from one hospital to another.
12. Senior paediatric medical staff should hold overall patient responsibility in children's wards accommodating both medical and surgical patients.

13. Foundation doctors should not be employed in children's wards.
14. The experience and competence of all clinicians caring for children in acute hospital settings should be assessed before employment.
15. A consultant fixed with responsibility for a child patient upon an unscheduled admission should be informed promptly of that responsibility and kept informed of the patient's condition, to ensure senior clinical involvement and leadership.
16. The names of both the consultant responsible and the accountable nurse should be prominently displayed at the bed in order that all can know who is in charge and responsible.
17. Any change in clinical accountability should be recorded in the notes.
18. The names of all on-call consultants should be prominently displayed in children's wards.
19. To ensure continuity, all children's wards should have an identifiable senior lead nurse with authority to whom all other nurses report. The lead nurse should understand the care plan relating to each patient, be visible to both patients and staff and be available to discuss concerns with parents. Such leadership is necessary to reinforce nursing standards and to audit and enforce compliance. The post should be provided in addition to current staffing levels.
20. Children's ward rounds should be led by a consultant and occur every morning and evening.
21. The accountable nurse should, insofar as is possible, attend at every interaction between a doctor and child patient.
22. Clinicians should respect parental knowledge and expertise in relation to a child's care needs and incorporate the same into their care plans.

23. The care plan should be available at the bed and the reasons for any change in treatment should be recorded.
24. All blood test results should state clearly when the sample was taken, when the test was performed and when the results were communicated and in addition serum sodium results should be recorded on the Fluid Balance Chart.
25. All instances of drug prescription and administration should be entered into the main clinical notes and paediatric pharmacists should monitor, query and, if necessary, correct prescriptions. In the event of correction the pharmacist should inform the prescribing clinician.
26. Clinical notes should always record discussions between clinicians and parents relating to patient care and between clinicians at handover or in respect of a change in care.
27. Electronic patient information systems should be developed to enable records of observation and intervention to become immediately accessible to all involved in care.
28. Consideration should be given to recording and/or emailing information and advices provided for the purpose of obtaining informed consent.
29. Record keeping should be subject to rigorous, routine and regular audit.
30. Confidential on-line opportunities for reporting clinical concerns should be developed, implemented and reviewed.

Serious Adverse Clinical Incident Reporting

31. Trusts should ensure that all healthcare professionals understand what is expected of them in relation to reporting Serious Adverse Incidents ('SAIs').
32. Failure to report an SAI should be a disciplinary offence.

Serious Adverse Clinical Incident Investigation

33. Compliance with investigation procedures should be the personal responsibility of the Trust Chief Executive.
34. The most serious adverse clinical incidents should be investigated by wholly independent investigators (i.e. an investigation unit from outside Northern Ireland) with authority to seize evidence and interview witnesses.
35. Failure to co-operate with investigation should be a disciplinary offence.
36. Trust employees who investigate and accident should not be involved with related Trust preparation for inquest or litigation.
37. Trusts should seek to maximise the involvement of families in SAI investigations and in particular:
 - (i) Trusts should publish a statement of patient and family rights in relation to all SAI processes including complaints.
 - (ii) Families should be given the opportunity to become involved in setting the terms of reference for an investigation.
 - (iii) Families should, if they so wish, engage with the investigation and receive feedback on progress.
 - (iv) A fully funded Patient Advocacy Service should be established, independent of individual Trusts, to assist families in the process. It should be allowed funded access to independent expert advice in complex cases.
 - (v) Families in cases of SAI related child death should be entitled to see relevant documentation, including all records, written communication between healthcare professionals and expert reports.

- (vi) All written Trust communication to parents or family after a SAI related child death should be signed or co-signed by the chief executive.
 - (vii) Families should be afforded the opportunity to respond to the findings of an investigation report and all such responses should be answered in writing.
 - (viii) Family GPs should, with family consent, receive copies of feedback provided.
 - (ix) Families should be formally advised of the lessons learned and the changes effected.
 - (x) Trusts should seek, and where appropriate act upon, feedback from families about adverse clinical incident handling and investigation.
38. Investigations should be subject to multi-disciplinary peer review.
39. Investigation teams should reconvene after an agreed period to assess both investigation and response.
40. Learning and trends identified in SAI investigations should inform programmes of clinical audit.
41. Trusts should publish the reports of all external investigations, subject to considerations of patient confidentiality.
42. In the event of new information emerging after finalisation of an investigation report or there being a change in conclusion, then the same should be shared promptly with families.

In the event of a Death related to a Serious Adverse Clinical Incident.

43. A deceased's family GP should be notified promptly as to the circumstances of death to enable support to be offered in bereavement.

44. Authorisation for any limitation of a post-mortem examination should be signed by two doctors acting with the written and informed consent of the family.
45. Check-list protocols should be developed to specify the documentation to be furnished to the pathologist conducting a hospital post-mortem.
46. Where possible, treating clinicians should attend for clinico-pathological discussions at the time of post-mortem examination and thereafter upon request.
47. In providing post-mortem reports pathologists should be under a duty to:
 - (i) Satisfy themselves, insofar as is practicable, as to the accuracy and completeness of the information briefed them.
 - (ii) Work in liaison with the clinicians involved.
 - (iii) Provide preliminary and final reports with expedition.
 - (iv) Sign the post-mortem report.
 - (v) Forward a copy of the post-mortem report to the family GP.
48. The proceedings of mortality meetings should be digitally recorded, the recording securely archived and an annual audit made of proceedings and procedures.
49. Where the care and treatment under review at a mortality meeting involves more than one hospital or Trust, video conferencing facilities should be provided and relevant professionals from all relevant organisations should, in so far as is practicable, engage with the meeting.
50. The Health and Social Care ('HSCB') should be notified promptly of all forthcoming healthcare related inquests by the Chief Executive of the Trust(s) involved.

51. Trust employees should not record or otherwise manage witness statements made by Trust staff and submitted to the Coroner's office.
52. Protocol should detail the duties and obligations of all healthcare employees in relation to healthcare related inquests.
53. In the event of a Trust asserting entitlement to legal privilege in respect of an expert report or other document relevant to the proceedings of an inquest, it should inform the Coroner as to the existence and nature of the document for which privilege is claimed.
54. Professional bereavement counselling for families should be made available and should fully co-ordinate bereavement information, follow-up service and facilitated access to family support groups.

Training and Learning

55. Trust Chairs and Non-Executive Board Members should be trained to scrutinise the performance of Executive Directors particularly in relation to patient safety objectives.
56. All Trust Board Members should receive induction training in their statutory duties.
57. Specific clinical training should always accompany the implementation of important clinical guidelines.
58. HSC Trusts should ensure that all nurses caring for children have facilitated access to e-learning on paediatric fluid management and hyponatraemia.
59. There should be training in the completion of the post-mortem examination request form.
60. There should be training in the communication of appropriate information and documentation to the Coroner's office.

61. Clinicians caring for children should be trained in effective communication with both parents and children.
62. Clinicians caring for children should be trained specifically in communication with parents following an adverse clinical incident, which training should include communication with grieving parents after a SAI death.
63. The practice of involving parents in care and the experience of parents and families should be routinely evaluated and the information used to inform training and improvement.
64. Parents should be involved in the preparation and provision of any such training programme.
65. Training in SAI investigation methods and procedures should be provided to those employed to investigate.
66. Clinicians should be afforded time to consider and assimilate learning feedback from SAI investigations and within contracted hours.
67. Should findings from investigation or review imply inadequacy in current programmes of medical or nursing education then the relevant teaching authority should be informed.
68. Information from clinical incident investigations, complaints, performance appraisal, inquests and litigation should be specifically assessed for potential use in training and retraining.

Trust Governance

69. Trusts should appoint and train Executive Directors with specific responsibility for:
 - (i) Issues of Candour.

- (ii) Child Healthcare.
 - (iii) Learning from SAI related patient deaths.
70. Effective measures should be taken to ensure that minutes of board and committee meetings are preserved.
 71. All Trust Boards should ensure that appropriate governance mechanisms are in place to assure the quality and safety of the healthcare services provided for children and young people.
 72. All Trust publications, media statements and press releases should comply with the requirement for candour and be monitored for accuracy by a nominated non-executive Director.
 73. General Medical Council ('GMC') 'Good Medical Practice' Code requirements should be incorporated into contracts of employment for doctors.
 74. Likewise, professional codes governing nurses and other healthcare professionals should be incorporated into contracts of employment.
 75. Notwithstanding referral to the GMC, or other professional body Trusts should treat breaches of professional codes and/or poor performance as disciplinary matters and deal with them independently of professional bodies.
 76. Clinical standards of care, such as patients might reasonably expect, should be published and made subject to regular audit.
 77. Trusts should appoint a compliance officer to ensure compliance with protocol and direction.
 78. Implementation of clinical guidelines should be documented and routinely audited.

79. Trusts should bring significant changes in clinical practice to the attention of the HSCB with expedition.
80. Trusts should ensure health care data is expertly analysed for patterns of poor performance and issues of patient safety.
81. Trusts should ensure that all internal reports, reviews and related commentaries touching upon SAI related deaths within the Trust are brought to the immediate attention of every Board member.
82. Each Trust should publish policy detailing how it will respond to and learn from SAI related patient deaths.
83. Each Trust should publish in its Annual Report, details of every SAI related patient death occurring in its care in the preceding year and particularise the learning gained therefrom.
84. All Trust Boards should consider the findings and recommendations of this Report and where appropriate amend practice and procedure.

Department

85. The Department should appoint a Deputy Chief Medical Officer with specific responsibility for children's healthcare.
86. The Department should expand both the remit and resources of the RQIA in order that it might (i) maintain oversight of the SAI process (ii) be strengthened in its capacity to investigate and review individual cases or groups of cases, and (iii) scrutinise adherence to duty of candour.
87. The Department should now institute the office of Independent Medical Examiner to scrutinise those hospital deaths not referred to the Coroner.
88. The Department should engage with other interested statutory organisations to review the merits of introducing a Child Death Overview Panel.

89. The Department should consider establishing an organisation to identify matters of patient concern and to communicate patient perspective directly to the Department.
90. The Department should develop protocol for the dissemination and implementation of important clinical guidance, to include:
 - (i) The naming of specific individuals fixed with responsibility for implementation and audit to ensure accountability.
 - (ii) The identification of specific training requirements necessary for effective implementation.
91. The Department, HBSC, PHA, RQIA and HSC Trusts should synchronise electronic patient safety incident and risk management software systems, codes and classifications to enable effective oversight and analysis of regional information.
92. The Department should review healthcare standards in light of the findings and recommendations of this report and make such changes as are necessary.
93. The Department should review Trust responses to the findings and recommendations of this Report.

Culture and Litigation

94. The interests of patient safety must prevail over the interests engaged in clinical negligence litigation. Such litigation can become an obstacle to openness. A government committee should examine whether clinical negligence litigation as it presently operates might be abolished or reformed and/or whether appropriate alternatives can be recommended.
95. Given that the public is entitled to expect appropriate transparency from a publically funded service, the Department should bring forward

protocol governing how and when legal privilege entitlement might properly be asserted by Trusts.

96. The Department should provide clear standards to govern the management of healthcare litigation by Trusts and the work of Trust employees and legal advisors in this connection should be audited.

APPENDICES

GLOSSARY OF ACRONYMS

ADH	Antidiuretic Hormone
Altnagelvin	Altnagelvin Area Hospital
AHHSST	Altnagelvin Area Hospitals Health and Social Services Trust
APLS	Advanced Paediatric Life Support
AS	Adam Strain
ASIS	Anterior Superior Iliac Spine
AST	Aspartate Aminotransferase
ATICS	Anaesthetics, Theatre and Intensive Care
A&E	Accident and Emergency
AvMA	Action against Medical Accidents
BCH	Belfast City Hospital
BHSCT	Belfast Health and Social Care Trust
BL	Barrister-at-Law
BMJ	British Medical Journal
BNF	British National Formulary
CBE	Commander of the Most Excellent Order of the British Empire
CAHGT	Craigavon Area Hospital Group (HSS) Trust
CGs	Clinical Guidelines
CIT	Cold Ischaemic Time
CM	Conor Mitchell
CMO	Chief Medical Officer

GLOSSARY OF ACRONYMS

CMV	Cytomegalovirus
CNO	Chief Nursing Officer
CNS	Central Nervous System
CPA	Care Programme Approach
CPP	Cerebral Perfusion Pressure
CR	Claire Roberts
CREST	Clinical Resource Efficiency Support Team
CRP	Creactive Protein
CSF	Cerebral Spinal Fluid
CSM	Clinical Services Manager
CT	Computerised Tomography
CVP	Central Venous Pressure
CVST	Cerebral Venous Sinus Thrombosis
Dept	Department
DHSSPS	Department of Health, Social Services and Public Safety (the Department)
DHSSPSNI	Department of Health, Social Services and Public Safety Northern Ireland
DLS	Directorate of Legal Services
DoH	Department of Health
DRO	Designated Review Officer
DSO	Departmental Solicitors Office

GLOSSARY OF ACRONYMS

ECP	Episodic Care Plan
EEG	Electroencephalography
ENT	Ear, Nose and Throat
FB&PCs	Fluid Balance and Prescription Charts
FRCS	Fellowship of the Royal Colleges of Surgeons
GAIN	Guidelines Audit and Implementation Network
GCS	Glasgow Coma Scale
GFR	Glomerular Filtration Rate
GP	General Practitioner
GMC	General Medical Council
HLA	Human Leucocyte Antigen
HM Coroner	Her Majesty's Coroner
HPPF	Human Plasma Protein Fraction
HPSS	Health and Personal Social Services
HSC	Health and Social Care
HSCB	Health and Social Care Board
HSC Trust	Health and Social Care Trust
HSE	Health Service Executive
ICP	Intracranial Pressure
ICT	Information and Communications Technology
ICU	Intensive Care Unit

GLOSSARY OF ACRONYMS

IHRD	Inquiry into Hyponatraemia-related Deaths
IV	Intravenous
JHO	Junior House Officer
JVP	Jugular Venous Pressure
KFOA	Kings Fund Organisational Audit
LC	Lucy Crawford
MAP	Mean Arterial Pressure
MAU	Medical Admissions Unit
MCA	Medicines Control Agency
MCCD	Medical Certificate of Cause of Death
Mmol/l	Millimoles per litre
MDU	Medical Defence Union
MRI	Magnetic Resonance Imaging
M&M	Mortality and Morbidity
NCP	Nursing Care Plan
NCEPOD	National Confidential Enquiry into Perioperative Deaths
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIMDTA	Northern Ireland Medical and Dental Training Agency
NMC	Nursing and Midwifery Council
NPSA	National Patient Safety Agency

GLOSSARY OF ACRONYMS

OTC	Ornithine Transcarbamylase
PCC	Patient Client Council
PEWS	Physiological Early Warning Scores System
PHA	Public Health Agency
PICU	Paediatric Intensive Care Unit
PIVFAIT	Paediatric IV Fluid Audit Improvement Tool
PNS	Peripheral Nervous System
PONV	Post-Operative Nausea and Vomiting
PRES	Posterior Reversible Encephalopathy Syndrome
PSNI	Police Service for Northern Ireland
PU	Passed Urine
QC	Queens Counsel
RCA	Root Cause Analysis
RCP	Royal College of Physicians
RCPCH	Royal College of Paediatrics and Child Health
RBHSC	Royal Belfast Hospital for Sick Children
RDW	Red Cell Distribution Width
RF	Raychel Ferguson
RCPCH	Royal College of Paediatrics and Child Health
RGHT	Royal Group of Hospitals Trust
RMCO	Risk Management Co-Ordinator

GLOSSARY OF ACRONYMS

RM&MRS	Regional Mortality and Morbidity Review System
RQIA	Regulation and Quality Improvement Authority
RVH	Royal Victoria Hospital
SAC	Special Advisory Committees
SAI	Serious Adverse Incident
SHO	Senior House Officer
SIADH	Syndrome of Inappropriate Antidiuretic Hormone Secretion
SHSCT	Southern Health and Social Care Trust
S/N	Staff Nurse
SLT	Sperrin Lakeland Trust
SQUAT	Safety Quality and Alerts Team
STP	Sodium Thiopentone
UKCC	United Kingdom Central Council for Nursing, Midwifery and Health Visiting
UTI	Urinary Tract Infection
U&E	Urea and Electrolyte
WCC	White Cell Count
WHO	World Health Organisation
WHSCT	Western Health and Social Care Trust
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WHSSC	Western Health and Social Services Council
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GLOSSARY OF ACRONYMS

ADVISORS, EXPERTS AND PEER REVIEWERS

Appointed Expert Advisors	
The late Dr Peter Booker	Consultant Paediatric Anaesthetist
Mr Grenville Kershaw	Consultant Health Service Governance and Management
Dr Harvey Marcovitch	Consultant Paediatrician
Ms Mary Whitty	Consultant Health Service Governance and Management
Ms Carol Williams	Nursing Consultant

Peer Reviewers	
Dr Desmond Bohn	Consultant Paediatric Anaesthetist
Dr Sharon Kinney	Consultant Paediatric Intensive Care Nursing

Experts Advising the Inquiry	
Dr Philip Anslow	Consultant Neuroradiologist
Dr Jeffrey Aronson	Consultant Pharmacologist
Professor Keith Cartwright	Consultant Clinical Microbiologist
Dr Malcolm Coulthard	Honorary Consultant Paediatric Nephrologist
Dr Wellesley St C Forbes	Consultant Neuroradiologist (retired)
Professor John Forsythe	Consultant Transplant Surgeon
Mr George Foster	Consultant General Surgeon

ADVISORS, EXPERTS AND PEER REVIEWERS

Experts Advising the Inquiry	
Dr Audrey Giles	Forensic Document Analyst
Professor Alan Glasper	Professor of Children's & Young Peoples Nursing
Professor Dr Peter Gross	Professor of Medicine and Nephrology
Professor Brian Harding	Consultant Paediatric Neuropathologist and Professor of Pathology & Laboratory Medicine
Dr Simon Haynes	Consultant in Paediatric Cardiothoracic Anaesthesia and Intensive Care
Professor Fenella Kirkham	Professor of Paediatric Neurology, Institute of Child Health
Mr Geoff Koffman	Consultant Transplant Surgeon
Dr Caren Landes	Consultant Paediatric Radiologist
Professor Sebastian Lucas	Professor of Clinical Histopathology and Consultant Histopathologist
Dr Roderick MacFaul	Consultant Paediatrician
Professor Aidan Mullan	Acting Chief Executive Officer and Director of Nursing and Clinical Governance
Professor Brian Neville	Consultant Paediatric Neurologist and Professor of Childhood Epilepsy
Mr Stephen Ramsden	Chief Executive Officer
Ms Sally Ramsay	Independent Children's Nursing Advisor
Professor Dr Dietz Rating	Consultant in Paediatric Neurology
Mr Keith Rigg	Consultant Transplant Surgeon
Professor Gabriel Scally	Professor of Public Health and Planning, Director of WHO Collaborating Centre for Healthy Urban Environments
Dr Robert Scott-Jupp	Consultant Paediatrician

ADVISORS, EXPERTS AND PEER REVIEWERS

Experts Advising the Inquiry	
Dr Waney Squier	Consultant Neuropathologist and Clinical Lecturer
Professor Charles Swainson	Consultant Renal Physician and Medical Director (retired)

Other Expert's Reports Considered	
Dr John Alexander	Consultant Anaesthetist
Professor Peter Jeremy Berry	Professor of Paediatric Pathology
Dr Robert Bingham	Consultant Paediatric Anaesthetist
Ms Susan Chapman	Nurse Consultant for Acute and High Dependency Care
Dr Dewi Evans	Consultant Paediatrician
Dr Brian Herron	Consultant Neuropathologist
Dr John Jenkins	Senior Lecturer in Child Health and Consultant Paediatrician
Dr Clodagh Loughrey	Consultant Chemical Pathologist
Dr Ian Maconochie	Consultant in Paediatric Accident and Emergency Medicine
Mr John Orr	Consultant Paediatric Surgeon
Professor Rupert Risdon	Consultant Forensic Paediatric Pathologist
Dr Edward Sumner	Consultant Paediatric Anaesthetist
Dr Declan Warde	Consultant Paediatric Anaesthetist

ADVISORS, EXPERTS AND PEER REVIEWERS

Experts who provided Background Papers to the Inquiry	
Professor Sir Alan Craft	Emeritus Professor of Child Health and Honorary Consultant Paediatrician
Dr Bridget Dolan	Barrister and Assistant Deputy Coroner
Professor Mary Hanratty	Director of Nursing and Midwifery Education (retired)
Dr Jan Keeling	Paediatric Pathologist
Dr Michael Ledwith	Expert in Teaching of Fluid Balance and Sodium Management in Northern Ireland

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Dr John Alexander	Consultant Anaesthetist BCH	AS	120
Dr Trevor Anderson	Clinical Director of Women and Children's Services Erne Hospital	LC	291
Dr Philip Anslow	Consultant Neuroradiologist	AS	
Dr Alison Armour	Senior Registrar Forensic Medicine State Pathologist's Department	AS	012
Dr Jeffrey Aronson	Consultant Pharmacologist	CR	
Dr Mohammed Asghar	Staff Grade Paediatrician Erne Hospital	LC	
Dr Elma Ashenhurst	Raychel Ferguson's GP	RF	333
Dr Thomas Auterson	Consultant Anaesthetist Erne Hospital	LC	274
Dr Brigitte Bartholome	Paediatric Registrar RBHSC	CR	142
Mr Paul Bateson (Deceased)	Clinical Director of Surgery	RF	
Ms Susan Beattie	Staff Nurse RBHSC	AS	118
Dr Barbara Ann Bell	Consultant Paediatrician CAH	CM	364
Mr Naresh Kumar Bhalla	Surgical Specialist Registrar Altnagelvin	RF	034
Dr Hoshang Bharucha	Consultant Pathologist RVH	AS	249
Dr Robert Bingham	Consultant Paediatric Anaesthetist	CR	
Dr Janice Bothwell	Paediatric Consultant RBHSC	CM	
Mrs Eleanor Boyce (nee Donaghy)	Transplant Co-ordinator BCH	AS	100

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Mr Martin Bradley	Director of Health Care & Chief Nurse WHSSB	LC	307
		RF	
Dr Richard Brady	SHO CAH	CM	
Mr George Brangam (Deceased)	Brangam Bagnall & Co Solicitor	AS	
		RF	
Ms Irene Brennan (nee Dickey)	Senior Nurse CAH	CM	353
Mr Stephen Brown	Consultant Paediatric Surgeon RBHSC & Ulster Hospital	AS	007
Mrs Therese Brown	Risk Management Co-ordinator AHHSST	RF	322
S/N Fiona Bryce	Staff Nurse Altnagelvin	RF	054
Dr Suzie Budd	Staff Grade Doctor CAH	CM	352
S/N Ruth Bullas	Staff Nurse CAH	CM	376
Mrs Stella Burnside	Chief Executive AHHSST	RF	046
Dr Mary Butler	SHO Paediatrics Altnagelvin	RF	026
Dr Henrietta Campbell	Chief Medical Officer, DHSSPS (Jan 1995 to Feb 2006)	AS	
		LC	
		RF	
		CM	
		Dept	075
Dr Rosalie Campbell	Locum Consultant Anaesthetist RBHSC	AS	117
Dr Ian Carson	Medical Director, RGHT & Chairman, RQIA (2006 to present)	AS	077
		CR	270
		RF	331
		LC	306
		Dept	077
		Current	077

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Dr Jacqueline Cartmill	SHO in Paediatrics RBHSC	AS	003
Ms Susan Chapman	Nurse Consultant for Acute and High Dependency Care	RF	
Dr Anthony Chisakuta	Consultant in Paediatric Anaesthesia & Intensive Care RBHSC	LC	283
		CM	
Dr Matt Cody	Consultant Anaesthetist Erne Hospital	LC	
Mr John Compton	Chief Executive HSCB (retired)	Current	
Mrs Patricia Conway	Staff Nurse RBHSC	AS	060
Dr Cooke	Consultant Neurologist RVH	CM	
Dr Dennis Coppel	Consultant in Paediatric Anaesthesia RVH	AS	
Dr Malcolm Coulthard	Honorary Consultant Paediatric Nephrologist	AS	
Mrs Mae Crawford	Lucy Crawford's Mother	LC	
		Current	
Mr Neville Crawford	Lucy Crawford's Father	LC	
Dr Peter Crean	Consultant in Paediatric Anaesthesia & Intensive Care RBHSC	AS	130
		CR	168
		LC	292
		RF	038
		Dept	
Mrs Lorna Cullen	Ward Manager CAH	CM	374
Dr Michael Curran	JHO Surgery Altnagelvin	RF	028
Dr Mike Curtis	Assistant State Pathologist State Pathologist's Office, Belfast	LC	275
Dr Paul Darragh	Deputy Chief Medical Officer DHSSPS	Dept	076
		CM	

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Dr Aparna Date	Specialist Registrar Altnagelvin	RF	031
Mrs Maureen Dennison	Administrative Staff Coroner's Office	LC	276
Dr Joseph Devlin	JHO Altnagelvin	RF	027
Mrs Margaret Doherty	Clinical Services Manager Paediatrics AHSST	RF	336
Mrs Anne Doherty	Patient Advocate AHSST	RF	325
Mrs Kay Doherty	Mrs Ferguson's sister	RF	326
Dr Bridget Dolan	Barrister and Assistant Deputy Coroner	Dept	
Mr Colm Donaghy	Chief Executive BHSCT	AS	
		CR	
		Dept	
Dr Doyle	GP, Moores Lane Surgery, Lurgan	CM	
Miss Irene Duddy	Director of Nursing AHSST	RF	323
Miss Elizabeth Duffin	Director of Nursing & Patient Services RGHT	AS	245
		CR	265
Mr Stephen Duffy	Visitor to Altnagelvin at time of Raychel's stay	RF	
Ms Elaine Duffy	Visitor to Altnagelvin at time of Raychel's stay	RF	
Mrs Marie Dunne	Communications Manager AHSST	RF	332
Mr Alan Elliott	Permanent Secretary, DHSSPS (Jul 1987 – Mar 1997)	Dept	348
Dr Dewi Evans	Consultant Paediatrician.	LC	
		Dept	

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Mr Eugene Fee	Director of Acute Hospital Services & Director of Nursing SLT	LC	287
Mr Raymond Ferguson	Raychel's father	RF	020
		Dept	
		Current	
Mrs Marie Ferguson	Raychel's mother	RF	021
		Dept	
		Current	
Professor John Forsythe	Consultant Transplant Surgeon	AS	
Mr George Foster	Consultant General Surgeon	RF	
Miss Bridie Foy	Deputy Director of Nursing CAH	CM	367
Dr Thomas Frawley	Area Manager WHSSB	LC	308
		Dept	
Dr Raymond Fulton	Medical Director AHHSST	RF	043
		CM	
Dr Joseph Gaston	Consultant Anaesthetist & Clinical Director of Anaesthesia, Theatres & Intensive Care RGHT	AS	013
		Dept	
Dr Colin Gaston	Consultant Paediatrician Ulster Hospital	CR	166
Dr Fiona Gibson (Deceased)	Consultant Anaesthetist Royal	AS	
S/N Sandra Gilchrist	Staff Nurse Ward 6 Altnagelvin	RF	053
Mr Robert Gilliland	Consultant Surgeon Altnagelvin	RF	044
Dr Audrey Giles	Giles Document Laboratory handwriting analysis Expert	CR	
Mr Clive Gowdy	Permanent Secretary, DHSSPS (Mar 1997 to Jul 2005)	AS	
		Dept	062

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Professor Dr Peter Gross	Professor of Medicine and Nephrology	AS	
Dr Vijay Kumar Gund	SHO Anaesthesia Altnagelvin	RF	023
Dr Donncha Hanrahan	Consultant Paediatric Neurologist RBHSC	LC	289
		RF	039
Professor Mary Hanratty	Director of Nursing and Midwifery Education (retired)	LC	
		RF	
		Current	
Professor Brian Harding	Consultant Paediatric Neuropathologist and Professor of Pathology & Laboratory Medicine	CR	
Dr Carolyn Harper	Executive Medical Director Public Health Agency	Current	
Ms Margaret Harrison	Raychel's godmother	RF	318
Dr Simon Haynes	Consultant in Paediatric Cardiothoracic Anaesthesia and Intensive Care	AS	
		CR	
		RF	
Dr Brian Herron	Senior Registrar Neuropathology RVH	CR	224
	Consultant Neuropathologist RVH	RF	041
		CM	
Dr Elaine Hicks	Consultant Paediatric Neurologist RBHSC	AS	244
		CR	264
		RF	340
Professor Dame Judith Hill	Chief Nursing Officer, DHSSPS (Sep 1995 - Feb 2005)	Dept	082
Dr Martina Hogan	Lead Clinician in Paediatrics CAH	CM	368
Dr William Holmes	Consultant Anaesthetist Erne Hospital	LC	
Dr Joanne Hughes	Paediatric SHO RBHSC	CR	140

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Name	Position	Chapter	Witness Statement Number
Dr Caroline Humphrey	Medical Director CAH	CM	354
Mr John Hunter	Chief Executive HPSS Management Executive (1990 – 1997)	Dept	349
Dr M Al-Husaini	Neuropathologist Royal Group of Hospitals	RF	
Dr Claire Jamison	SHO Anaesthesia Altnagelvin	RF	024
Dr John Jenkins	Consultant Paediatrician Antrim Area Hospital Senior Lecturer in Child Health QUB	RF	059
		LC	
		CM	
		Dept	
Dr Jeremy Johnston	SHO Paediatrics Altnagelvin	RF	029
Ms Thecla Jones	Staff Nurse Erne Hospital	LC	
Dr Angela Jordan	Specialist Registrar Public Health Medicine	Dept	
Ms Sara Jordan (nee Field)	Staff Nurse RBHSC	CR	148
Mr Patrick Keane	Consultant Urologist BCH	AS	006
Dr Jan Keeling	Paediatric Pathologist	Dept	
Dr Barry Kelly	SHO Altnagelvin	RF	254
Dr James Kelly	Medical Director SLT	LC	290
		RF	
Dr Peter Kennedy	Radiology Specialist Registrar RBHSC	CR	167
Professor Fenella Kirkham	Professor of Paediatric Neurology, Institute of Child Health	AS	
Mr Geoff Koffman	Consultant Transplant Surgeon	AS	
Mr Francis Lavery	Staff Nurse CAH	CM	351

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Name	Position	Chapter	Witness Statement Number
Mr John Leckey	HM Coroner for Greater Belfast	AS	091
		CR	
		RF	090
		LC	277
	Senior Coroner for NI	CM	
Dr Jeff Lee	Clinical Director CAH	CM	
Ms Kate Linskey	Staff Nurse RBHSC	CR	248
Miss Kathryn Little	Paediatrics Nursing Sister AHHSST	RF	345
Dr Clodagh Loughrey	Consultant Chemical Pathologist BCH	RF	045
		CM	
		Dept	
Dr Darrell Lowry	Consultant Anaesthetist SHSCT	CM	350
Professor Sebastian Lucas	Professor of Clinical Histopathology and Consultant Histopathologist	AS	
		CR	
		LC	
Ms Elizabeth Lynch	Nursing Auxiliary Altnagelvin	RF	055
Dr Samuel Morrell Lyons	Consultant Cardiac Anaesthetist RGHT	AS	
		Dept	
Dr Roderick MacFaul	Consultant Paediatrician	CR	
		LC	
Ms Siobhan MacNeill	Staff Nurse Erne Hospital	LC	
Dr Ian Maconochie	Consultant in Paediatric Accident and Emergency Medicine	CR	
Mr Ragai Reda Makar	SHO Surgery Altnagelvin	RF	022
Dr Amer Ullah Malik	SHO Paediatrics Erne Hospital	LC	285

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Mr G Marshall	Consultant Surgeon Erne Hospital	Dept	
Dr Denis Martin	Clinical Director Women & Children's Care AHHST	RF	335
Ms Margaret Mathewson	Theatre Staff Nurse RBHSC	AS	101
Dr Charles McAllister	Consultant CAH	CM	
Dr Jarlath McAloon	Consultant Paediatrician Antrim Area Hospital & Chair, Paediatric Fluid Therapy Working Group	CM	
		Dept	363
Professor Charlotte McArdle	Chief Nursing Officer, DHSSPS (Mar 2013 – to present)	Current	
S/N Michaela McAuley (nee Rice)	Staff Nurse Altnagelvin	RF	051
Dr Michael McBride	Medical Director RGHT (2002 – 2006)	CR	269
	CMO, DHSSPS (Sept 2006 – to present)	Current	
Ms Teresa McCaffrey	Staff Nurse Erne Hospital	LC	
Ms Lorraine McCann	Staff Nurse RBHSC	CR	151
Dr Miriam McCarthy	Senior Medical Officer, DHSSPS (Oct 1998 - Apr 2006)	Dept	080
		CM	
Dr William McCaughey	Consultant Anaesthetist & Medical Director CAH	CM	369
Dr William McConnell	Director of Public Health WHSSB	LC	286
		RF	
		Dept	
Dr Brian McCord	Consultant Paediatrician Altnagelvin	RF	032

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Dr Andrew McCormick	Permanent Secretary DHSSPS (Jul 2005 – Jun 2014)	Current	
Mrs Teresa McCullagh	Visitor to Altnagelvin at time of Raychel's stay	RF	319
S/N Marian McGrath	Theatre Nurse Altnagelvin	RF	050
Dr James Patrick McKaigue	Consultant Paediatric Anaesthetist RBHSC	AS	129
		CR	156
		LC	302
		CM	
Mr William McKee	Chief Executive RGHT	AS	061
		CR	271
		Dept	
Dr Stephen McKinstry	Consultant Neuroradiologist RGHT	RF	037
Mr Brian Francis McLaughlin	Chief Medical Technical Officer BHSCT	AS	109
Dr Louise McLoughlin	Paediatric SHO RBHSC	LC	
Ms Sally McManus	Staff Nurse Erne Hospital	LC	
Ms Geraldine McRandal	Staff Nurse RBHSC	CR	145
Sister Elizabeth Millar	Ward Sister Altnagelvin	RF	056
Mrs Esther Millar	Clinical Services Manager Erne Hospital	LC	312
Mr Stanley Millar	Chief Officer WHSSC	RF	093
		LC	
		Dept	
Mr Hugh Mills	Chief Executive SLT	LC	293
		Dept	
Dr Meenakshi Mirakhur	Consultant Neuropathologist RGHT	AS	223
		CR	247

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Ms Joanna Mitchell	Conor's mother	CM	
		Current	
Ms Judy Mitchell	Conor's grandmother	CM	
Mr John Mone	Director of Nursing CAH	CM	375
Dr Terence Montague	Senior Registrar Anaesthesia RBHSC	AS	009
Dr Cyril Morrison	Consultant Radiologist Altnagelvin	RF	036
Dr Connor Mulholland	Clinical Director - Paediatrics (Acting) RBHSC	AS	243
Professor Aidan Mullan	Acting Chief Executive Officer and Director of Nursing and Clinical Governance (former)	Dept	
Dr Andrew Murdock	Specialist Registrar CAH	CM	355
Dr George Murnaghan	Director of Medical Administration RGHT	AS	015
		CR	273
		Dept	
Mrs Heather Neill	Para-legal Assistant to Mr George Brangam Brangam Bagnall & Co	AS	260
Dr Geoff Nesbitt	Consultant Anaesthesia & Critical Care & Clinical Director Altnagelvin	RF	035
		Dept	
Professor Brian Neville	Consultant Paediatric Neurologist and Professor of Childhood Epilepsy	CR	
S/N Ann Noble	Staff Nurse Altnagelvin	RF	049
Mr John Orr	Consultant Paediatric Surgeon	RF	
Dr Mary O'Connor	Consultant Paediatric Nephrologist RBHSC	AS	014

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Dr Dara O'Donoghue	Clinical Fellow in Paediatric Intensive Care RBHSC	RF	040
	SHO / Acting Registrar in Paediatrics RBHSC	LC	284
Dr Jarlath O'Donohoe	Consultant Paediatrician Erne Hospital	LC	278
Dr Denis O'Hara (Deceased)	Consultant Paediatric Pathologist RGHT	AS	
		LC	
Dr Bernadette O'Hare	Specialist Paediatric Registrar RBHSC	CR	135
Mrs Eileen O'Rourke	Clinical Services Manager CAH	CM	370
Mr KJS Panesar	Consultant Surgeon	RF	
S/N Daphne Patterson	Staff Nurse Altnagelvin	RF	048
S/N Gillian Popplestone	Staff Nurse RBSHC	AS	010
Dr Janil Puthucheary	SHO RBHSC	CR	134
Ms Helen Quigley	WHSSC	RF	
Dr Murray Quinn	Consultant Paediatrician Altnagelvin	LC	279
Dr Catherine Quinn	SHO CAH	CM	356
Ms Sally Ramsay	Independent Children's Nursing Advisor	CR	
Mr Stephen Ramsden	Chief Executive Officer	AS	
Professor Dr Dietz Rating	Consultant in Paediatric Neurology	AS	
Mr Keith Rigg	Consultant Transplant Surgeon	AS	
Mr Alan Roberts	Claire's father	CR	253
		Dept	
		Current	

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Mrs Jennifer Roberts	Claire's mother	CR	257
		Dept	
Professor Nichola Rooney	Consultant Clinical Psychologist RBHSC	CR	177
Mrs Avril Roulston	Staff Nurse Altnagelvin	RF	052
Dr Andrew Sands	Paediatric Registrar RBHSC	CR	137
Professor Maurice Savage	Consultant Paediatric Nephrologist RBHSC Professor of Paediatrics QUB	AS	002
Dr Deirdre Savage	GP Castlereagh Medical Centre	CR	160
Professor Gabriel Scally	Professor of Public Health and Planning, Director of WHO Collaborating Centre for Healthy Urban Environments	LC	
		RF	
		Dept	
Dr Robert Scott-Jupp	Consultant Paediatrician	CR	
		RF	
		CM	
Mrs Joanne Sharratt (nee Clingham)	Paediatric Renal Nurse Co-ordinator RBHSC	AS	102
Mr Paul Simpson	Deputy Secretary, DHSSPS Former Chief Executive, HSS Executive	Dept	084
Mrs Debra Slavin	Adam's mother	AS	001
		Dept	
		Current	
Dr Michael Smith	Consultant Paediatrician CAH	CM	357
Dr Waney Squier	Consultant Neuropathologist and Clinical Lecturer	AS	
		CR	
Dr Heather Steen	Consultant Paediatrician RBHSC	CR	143
Mr Ivan Sterling	Clinical Director CAH	CM	

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Dr Anthony Stevens	Medical Director BHSCT	CR	
		Dept	
		Current	
Dr Roger Stevenson	Paediatric SHO RBHSC	CR	139
Dr Caroline Stewart	Specialist Registrar RBHSC	LC	282
Dr Moira Stewart	Consultant Paediatrician RCPCH	LC	298
Dr Neil Stewart	SHO RBHSC	CR	141
Dr Edward Sumner	Consultant Paediatric Anaesthetist	AS	
		LC	
		RF	
		CM	
		Dept	
Professor Charles Swainson	Consultant Renal Physician and Medical Director (retired)	RF	
		Dept	
Ms Bridget Swift	Staff Nurse Erne Hospital	LC	311
Dr Robert Taylor	Consultant Paediatric Anaesthetist RBHSC	AS	008
		CR	157
		LC	280
		RF	330
		CM	
		Dept	
Dr Anne Marie Telford	Director of Public Health SHSSB	CM	
Mr John Templeton	Chief Executive Officer CAHGT	CM	371
Dr Bernie Trainor	SHO Paediatrics Altnagelvin	RF	030
Ms Etain Traynor	Paediatric Ward Sister Erne Hospital	LC	310

PERSONS REFERRED TO IN THE REPORT

Name	Position	Chapter	Witness Statement Number
Dr Andrea Volprecht	Paediatric SHO RBHSC	CR	136
Mr Peter Walby	Associate Medical Director Litigation Management Office RGHT	CR	176
		RF	341
Mr Peter Walsh	Chief Executive AvMA	Current	
Dr Declan Warde	Consultant Paediatric Anaesthetist	RF	
Dr David Webb	Consultant Paediatric Neurologist RBHSC	AS	107
		CR	138
S/N Barbara Wilkinson	Staff Nurse CAH	CM	377
Dr Marian Williams	SHO CAH	CM	358
Mr John James Wilson	Chief Medical Technical Officer RGHT	AS	110
Mrs Anne Witherow	Clinical Effectiveness Co-ordinator Altnagelvin	RF	329
Professor Ian Young	Professor of Medicine, QUB Consultant in Clinical Biochemistry & Director of Research & Development BHSCT	CR	178
Mr Muhammad Zafar	SHO Altnagelvin	RF	025
Mr Waldemar Zawislak	Surgical Registrar Altnagelvin	RF	314

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Dr John Alexander	WS-120-1
	WS-120-2
	WS-120-3
Dr Gareth Allen	WS-033-1
	WS-033-2
Mr John Allen	WS-067-1
Mrs Karen A Allen	WS-213-1
Miss Nicola Allen	WS-221-1
Dr Kuki Anand	WS-347-1
Dr Trevor Anderson	WS-291-1
	WS-291-2
Dr Alison Armour	WS-012-1
	WS-012-2
	WS-012-3
	WS-012-4
Dr Elma Ashenhurst	WS-333-1
Dr Thomas Auterson	WS-274-1
	WS-274-2
Dr Brigitte Bartholome	WS-142-1
	WS-142-2
Mr Evan Bates	WS-266-1
Mrs Susan Beattie	WS-118-1
Dr Amit Bedi	WS-192-1
Dr Barbara Ann Bell	WS-364-1
Professor Peter Jeremy Berry	WS-018-1
	WS-018-2

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Dr Naresh Kumar Bhalla	WS-034-1
	WS-034-2
Dr Sanapla Bhanumurthy	WS-119-1
Dr Chitra Bharucha	WS-229-1
Dr Hoshang Bharucha	WS-249-1
Dr Meenakshi Bhat	WS-116-1
Mr Jonathon Bill	WS-068-1
Ms Tracy Blue	WS-161-1
Dr Andrew Boon	WS-321-1
	WS-321-2
Mr Victor Boston	WS-011-1
	WS-011-2
	WS-011-3
Ms Eleanor Donaghy (nee Boyce)	WS-100-1
	WS-100-2
	WS-100-3
	WS-100-4
	WS-100-5
Ms Karen Boyd (nee Taylor)	WS-150-1
Mr Martin Bradley	WS-307-1
Dr Sarah Branch	WS-179-1
Mrs Irene Brennan (nee Dickey)	WS-353-1
Mr Stephen Brown	WS-007-1
	WS-007-2
	WS-007-3
	WS-007-4
	WS-007-5

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Mrs Therese Brown	WS-322-1
Mr Andrew Browne	WS-072-1
S/N Fiona Bryce	WS-054-1
	WS-054-2
Dr Suzi Budd	WS-352-1
S/N Ruth Bullas	WS-376-1
Dr Helen Bunting	WS-197-1
Mrs Stella Burnside	WS-046-1
	WS-046-2
Dr Mary Butler	WS-026-1
	WS-026-2
Dr Henrietta Campbell	WS-075-1
	WS-075-2
	WS-075-3
Dr Rosalie Campbell	WS-117-1
	WS-117-2
Dr Ian Carson	WS-077-1
	WS-077-2
	WS-077-3
	WS-077-4
	WS-270-1
	WS-306-1
	WS-306-2
	WS-331-1
Mr Gerry Carson	WS-267-1
Dr Jacqueline Cartmill	WS-003-1
	WS-003-2
	WS-003-3

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Mrs Helen Chambers	WS-300-1
Dr Anna Chillingworth	WS-365-1
Dr Anthony Chisakuta	WS-283-1
	WS-283-2
	WS-283-3
Mrs K M Chivers	WS-211-1
Dr R C N Clarke	WS-155-1
Mr Gordon Clarke	WS-268-1
Mr John Cole	WS-086-1
Ms Angela Colhoun	WS-303-1
Mr Gerry Collins	WS-069-1
Dr Fiona Connolly	WS-196-1
Mrs Patricia Conway	WS-060-1
	WS-060-2
	WS-060-3
Miss Mary A Coogan	WS-206-1
Dr Peter Crean	WS-038-1
	WS-038-2
	WS-038-3
	WS-130-1
	WS-168-1
	WS-168-2
	WS-168-3
	WS-292-1
	WS-292-2
Mrs Lorna Cullen	WS-374-1

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Ms Dympna Curley	WS-299-1
Dr Michael Curran	WS-028-1
	WS-028-2
Dr Mike Curtis	WS-275-1
	WS-275-2
Dr Paul Darragh	WS-076-1
	WS-076-2
Dr Aparna Date	WS-031-1
	WS-031-2
Dr Jonathan Davis	WS-366-1
Mr Peter Deazley	WS-074-1
Mrs Maureen Dennison	WS-276-1
Dr Joseph Devlin	WS-027-1
	WS-027-2
Mrs Deborah Dines	WS-112-1
Mr Kevin Doherty	WS-313-1
Mrs Ann Doherty	WS-325-1
Mrs Kay Doherty	WS-326-1
Mrs Margaret Doherty	WS-336-1
S/N Margaret Dooher	WS-344-1
Mrs Rosaleen Dowdall	WS-215-1
Mrs Katherine Dowdie (nee Knaggs)	WS-103-1
	WS-103-2
Miss Irene Duddy	WS-323-1
Miss Elizabeth Duffin	WS-245-1
	WS-265-1

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Mr William Dukelow	WS-372-1
Mrs Clare L Dunn	WS-218-1
Mrs Marie Dunne	WS-332-1
Dr Leslie Dyer	WS-235-1
Mr Alan Elliott	WS-348-1
Mr Eugene Fee	WS-287-1
	WS-287-2
Mrs Marie Ferguson	WS-020-1
Mr Raymond Ferguson	WS-021-1
Miss Bridie Foy	WS-367-1
	WS-367-2
Dr Thomas Frawley	WS-308-1
Dr Raymond Fulton	WS-043-1
	WS-043-2
	WS-043-3
Mr David Galloway	WS-066-1
Dr Caroline Gannon	WS-281-1
	WS-281-2
	WS-281-3
Dr Philip Gardiner	WS-328-1
Dr Joe Gaston	WS-013-1
	WS-013-2
Dr Colin Gaston	WS-166-1
Mrs E Gawley	WS-216-1
S/N Sandra Gilchrist	WS-053-1
	WS-053-2

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Mr Robert Gilliland	WS-044-1
	WS-044-2
	WS-044-3
	WS-044-4
Dr Helen Gilliland	WS-190-1
Mrs J M Gilmour	WS-208-1
Mr Clive Gowdy	WS-062-1
	WS-062-2
Mr Brian Grzymek	WS-361-1
Dr Vijay Kumar Gund	WS-023-1
	WS-023-2
Ms Cathy Hall	WS-104-1
	WS-104-2
Mrs L Hall	WS-220-1
Mr Andrew Hamilton	WS-070-1
Dr Donncha Hanrahan	WS-039-1
	WS-039-2
	WS-289-1
	WS-289-2
Mrs Margaret Harrison	WS-318-1
Dr Brian Herron	WS-041-1
	WS-224-1
	WS-224-2
	WS-224-3
	WS-224-4
Dr Marie Hickey	WS-200-1
Dr Elaine Hicks	WS-244-1
	WS-264-1
	WS-338-1
	WS-340-1

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Mr Don Hill	WS-063-1
Professor Dame Judith Hill	WS-082-1
	WS-082-2
Mr David Hill	WS-181-1
Dr Martina Hogan	WS-368-1
Mr John Hood	WS-246-1
Mrs C A Huddleson	WS-209-1
Dr Joanne Hughes	WS-140-1
Dr Caroline Humphrey	WS-354-1
Mrs M B Humphries	WS-207-1
Miss Maria B Hunt	WS-219-1
Mr John Hunter	WS-349-1
Dr Joan Hutchinson	WS-327-1
Ms Elizabeth Jackson	WS-144-1
Ms Margaret Jackson	WS-262-1
	WS-272-1
Mrs Karin Jackson	WS-297-1
Dr Claire Jamison	WS-024-1
	WS-024-2
Dr John Jenkins	WS-059-1
	WS-059-2
Dr Jeremy Johnston	WS-029-1
	WS-029-2
Professor Patrick Johnston (deceased)	WS-256-1
Ms Sara Jordan (nee Field)	WS-148-1

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Mr Patrick Keane	WS-006-1
	WS-006-2
	WS-006-3
Dr Michaeline Kelly	WS-201-1
Dr Barry Kelly	WS-254-1
Dr James Kelly	WS-290-1
	WS-290-2
Dr Peter Kennedy	WS-167-1
Dr Catherine Kerr	WS-193-1
Dr Bhuvaraha Krishnamurthy	WS-204-1
Dr Manisha Kumar	WS-205-1
Dr Jayne Larkin	WS-097-1
Mr Francis Lavery	WS-351-1
Mr John Leckey	WS-090-1
	WS-091-1
	WS-091-2
	WS-277-1
	WS-277-2
Ms Kate Linskey	WS-248-1
Miss Kathryn Little	WS-345-1
Dr Paul Loan	WS-360-1
Miss Audrey Lockhead	WS-226-1
Dr Clodagh Loughery	WS-045-1
Dr Darrell Lowry	WS-350-1
	WS-350-2
Dr Stephen Luney	WS-186-1

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Ms Elizabeth Lynch	WS-055-1
	WS-055-2
Ms Denise Lynd	WS-296-1
Dr Jeremy David Lyons	WS-188-1
Mr A & Mrs M Magill	WS-259-1
Dr Peter Maguire	WS-202-1
Dr Ragai Reda Makar	WS-022-1
	WS-022-2
	WS-022-3
Mrs Angela M Malcolmson	WS-214-1
Dr Amer Ullah Malik	WS-285-1
Dr Margaret Mark	WS-081-1
Mr Paul Martin	WS-085-1
Mrs Dorothy Martin	WS-183-1
Dr Denis Martin	WS-335-1
Ms Margaret Mathewson	WS-101-1
	WS-101-2
	WS-101-3
	WS-101-4
Ms Barbara Maxwell	WS-146-1
Dr Jarlath McAloon	WS-363-1
Dr John McAteer	WS-203-1
S/N Michaela McAuley (nee Rice)	WS-051-1
	WS-051-2
Dr Michael McBride	WS-269-1
	WS-269-2
Dr Michael McBrien	WS-194-1

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Mr William McCallion	WS-232-1
	WS-232-2
Mr Noel McCann	WS-065-1
Ms Lorraine McCann	WS-151-1
Dr Miriam McCarthy	WS-080-1
	WS-080-2
Dr William McCaughey	WS-369-1
Mrs Elisabeth V McClure	WS-212-1
Dr B McConnell	WS-047-1
Dr William McConnell	WS-286-1
	WS-286-2
Dr Brian McCord	WS-032-1
	WS-032-2
	WS-032-3
	WS-032-4
Mrs Teresa McCullagh	WS-319-1
S/N Marian McGrath	WS-050-1
	WS-050-2
Mr John McGrath	WS-362-1
Dr James Patrick McKaigue	WS-129-1
	WS-156-1
	WS-156-2
	WS-156-3
	WS-302-1
	WS-302-2
	WS-302-3

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Mr William McKee	WS-061-1
	WS-061-2
	WS-271-1
Mrs Mary McKenna	WS-346-1
Dr Stephen McKinstry	WS-037-1
Dr Charles McKinstry	WS-111-1
	WS-111-2
	WS-111-3
	WS-111-4
Dr Jean McKnight	WS-114-1
Mr Brian Francis McLaughlin	WS-109-1
	WS-109-2
Mrs Frances J McMahon	WS-210-1
Mrs Deirdre McMullan	WS-182-1
Dr David McNamee	WS-189-1
Ms Geraldine McRandal	WS-145-1
Dr Thomas Melaugh	WS-334-1
Sister Elizabeth Millar	WS-056-1
	WS-056-2
	WS-056-3
Mrs Esther Millar	WS-312-1
Mr Stanley Millar	WS-093-1
Mr Hugh Mills	WS-293-1
	WS-293-2
	WS-293-3
Dr Meenakshi Mirakhur	WS-223-1
	WS-247-1
	WS-247-2

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Dr David Mitchell	WS-230-1
Dr Glenda Mock	WS-078-1
Mr John Mone	WS-375-1
Ms Barbara Money Penny	WS-304-1
Dr Terence Montague	WS-009-1
	WS-009-2
	WS-009-3
Dr Cyril Morrison	WS-036-1
Dr Norman Morrow	WS-079-1
	WS-079-2
Mr Kevin Mulhern	WS-089-1
Dr Connor Mulholland	WS-243-1
	WS-243-2
Dr Andrew Murdock	WS-355-1
Dr George Murnaghan	WS-015-1
	WS-015-2
	WS-273-1
Mrs Catherine Murphy	WS-005-1
	WS-005-2
	WS-005-3
	WS-005-4
	WS-005-5
Ms Rachel Murphy	WS-152-1
Mrs Heather Neill	WS-260-1
Dr Geoff Nesbitt	WS-035-1
	WS-035-2
	WS-035-3
	WS-035-4
Mr G S Nesbitt	WS-252-1

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
S/N Ann Noble	WS-049-1
	WS-049-2
	WS-049-3
	WS-049-4
Dr Mary O'Connor	WS-014-1
	WS-014-2
	WS-014-3
	WS-014-4
Dr Dara O'Donoghue	WS-040-1
	WS-040-2
	WS-284-1
	WS-284-2
Dr Jarlath O'Donohoe	WS-278-1
	WS-278-2
Dr John O'Hanlon	WS-187-1
Dr Bernadette O'Hare	WS-135-1
	WS-135-2
Dr Sean O'Hare	WS-295-1
Dr John O'Hare	WS-343-1
Dr D O'Neill	WS-004-1
	WS-004-2
	WS-004-3
Dr Hugh O'Neill	WS-191-1
Mrs Eileen O'Rourke	WS-370-1
Mr John Orr	WS-320-1
Dr Michael Parker	WS-324-1
S/N Daphne Patterson	WS-048-1
	WS-048-2
Dr Lionel Paxton	WS-185-1

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Ms Angela Pollock	WS-225-1
	WS-225-2
S/N Gillian Popplestone	WS-010-1
	WS-010-2
	WS-010-3
Dr Tracey Power	WS-064-1
Dr Janil Puthucheary	WS-134-1
Dr Murray Quinn	WS-279-1
	WS-279-2
Dr Catherine Quinn	WS-356-1
Mr Francis Rice	WS-083-1
Ms Bridget Rippley (nee O’Rawe)	WS-309-1
Professor Risdon	WS-098-1
Mr Alan Roberts	WS-253-1
	WS-253-2
Mrs Jennifer Roberts	WS-257-1
	WS-257-2
Mr W & Mrs E Roberts	WS-258-1
Miss Y Rodgers (nee Bradley)	WS-222-1
Professor Nichola Rooney	WS-177-1
Ms Sandra Ross	WS-153-1
Mrs Avril Roulston	WS-052-1
	WS-052-2
Mr Tommy Ryan	WS-125-1
	WS-125-2
	WS-125-3
Dr Andrew Sands	WS-137-1
	WS-137-2
	WS-137-3

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Professor Maurice Savage	WS-002-1
	WS-002-2
	WS-002-3
	WS-002-4
	WS-002-5
Dr Deirdre Savage	WS-160-1
Dr Abdusamea Shabani	WS-231-1
Mr Colm Shannon	WS-088-1
Dr Peter Sharpe	WS-359-1
Mrs Joanne Sharratt (nee Clingham)	WS-102-1
	WS-102-2
Mr Peter Shaw	WS-106-1
	WS-106-2
	WS-106-3
Dr Michael Shields	WS-301-1
Mr Paul Simpson	WS-084-1
	WS-084-2
Mrs Debra Slavin	WS-001-1
	WS-001-2
	WS-001-3
Dr Michael Smith	WS-357-1
	WS-357-2
Mrs F Smyth	WS-217-1
Ms Suzanne Spence	WS-159-1
	WS-159-2
Dr Michael Stafford	WS-234-1

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Dr Heather Steen	WS-143-1
	WS-143-2
	WS-143-3
	WS-143-4
Dr Roger Stevenson	WS-139-1
	WS-139-2
	WS-139-3
Dr Caroline Stewart	WS-282-1
	WS-282-2
Dr Moria Stewart	WS-298-1
	WS-298-2
	WS-298-3
Dr Neil Stewart	WS-141-1
	WS-141-2
Mr R J Stewart	WS-228-1
Mr Dean Sullivan	WS-071-1
Dr Edward Sumner	WS-019-1
	WS-057-1
Dr Louise Sweeney	WS-242-1
Ms Bridget Swift	WS-311-1
Dr Robert Taylor	WS-008-1
	WS-008-2
	WS-008-3
	WS-008-4
	WS-008-5
	WS-008-6
	WS-008-7
	WS-008-8
	WS-157-1
	WS-157-2
	WS-280-1
	WS-280-2
	WS-330-1
Mr John Templeton	WS-371-1

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Mrs Glenda Thompson	WS-236-1
Dr Bernie Trainor	WS-030-1
	WS-030-2
Dr Etain Traynor	WS-310-1
	WS-310-2
Dr John Trinder	WS-199-1
Dr Andrea Volprecht	WS-136-1
Mr Peter Walby	WS-176-1
	WS-176-2
	WS-176-3
	WS-176-4
	WS-341-1
	WS-341-2
	WS-341-3
Dr Declan Warde	WS-339-1
Dr David Webb	WS-107-1
	WS-107-2
	WS-138-1
	WS-138-2
	WS-138-3
	WS-138-4
	WS-138-5
Dr David Wheeler	WS-180-1
Ms Margaret Wilkin	WS-154-1
S/N Barbara Wilkinson	WS-377-1
Mr Noel Williams	WS-251-1
	WS-251-2
Mr Danny Williams	WS-294-1

PERSONS WHO PROVIDED WITNESS STATEMENTS

Name	Witness Statement Number
Dr Marian Williams	WS-358-1
Mrs Doreen Wilson	WS-087-1
Mr John James Wilson	WS-110-1
	WS-110-2
Mrs Anne Witherow	WS-329-1
Dr Donald Wright	WS-198-1
Professor Ian Young	WS-178-1
	WS-178-2
	WS-178-3
	WS-178-4
	WS-178-5
	WS-178-6
	WS-342-1
	WS-342-2
Mr Muhammad H Zafar	WS-025-1
	WS-025-2
Mr Waldermar Zawislak	WS-314-1

WITNESSES WHO GAVE ORAL EVIDENCE

Name	Oral Hearing Date	Case evidence heard in
Dr Trevor Anderson	11-Jun-2013	LC
Dr Alison Armour	13-Jun-2012	AS
Dr Jeffery Aronson	08-Nov-2012	CR
Dr Thomas Auterson	31-May-2013	LC
Dr Brigitte Bartholome	18-Oct-2012	CR
Dr Kumar Naresh Bhalla	14-Mar-2013	RF
Mr Michael Bloomfield	14-Nov-2013	Current
Mrs Eleanor Boyce (nee Donaghy)	27-Apr-2012	AS
Ms Karen Boyd (nee Taylor)	29-Oct-2012	CR
Mr Martin Bradley	18-Jun-2013	LC
Mr Stephen Brown	01-May-2012	AS
	20-Jun-2012	
	07-Sep-2012	
Ms Therese Brown	02-Sep-2013	RF
Ms Fiona Bryce	04-Mar-2013	RF
	05-Mar-2013	
Mrs Stella Burnside	17-Sep-2013	RF
Dr Mary Butler	11-Mar-2013	RF
Dr Henrietta Campbell	07-Nov-2013	Dept
Dr Rosalie Campbell	17-May-2012	AS
Dr Ian Carson	15-Jan-2013	AS
	16-Jan-2013	CR
	11-Jun-2013	LC
	26-Jun-2013	
	30-Aug-2013	RF
	13-Nov-2013	Current
Dr Jacqueline Cartmill	18-May-2012	AS
Professor Keith Cartwright	07-Nov-2012	CR
Dr Anthony Chisakuta	29-May-2013	LC
Mr John Compton	14-Nov-2013	Current
Mrs Patricia Conway	30-Apr-2012	AS

WITNESSES WHO GAVE ORAL EVIDENCE

Name	Oral Hearing Date	Case evidence heard in
Dr Malcolm Coulthard	08-May-2012	AS
	09-May-2012	AS
Dr Peter Crean	20-Jun-2012	AS
	04-Jun-2013	LC
	11-Sep-2013	RF
Ms Brenda Creaney	12-Nov-2013	Current
Dr Michael Curran	07-Mar-2013	RF
Dr Mike Curtis	25-Jun-2013	LC
Dr Paul Darragh	30-Oct-2013	Dept
Mrs Maureen Dennison	24-Jun-2013	LC
Dr Joe Devlin	06-Mar-2013	RF
Ms Ann Doherty	09-Sep-2013	RF
Mrs Kay Doherty	18-Sep-2013	RF
Mr Kevin Doherty	24-Jun-2013	LC
Mrs Margaret Doherty	09-Sep-2013	RF
Mr Colm Donaghy	12-Nov-2013	Current
Ms Irene Duddy	29-Aug-2013	RF
Ms Elizabeth Duffin	26-Jun-2012	AS
	10-Dec-2012	CR
Mr Alan Elliott	05-Nov-2013	Dept
Mr Eugene Fee	13-Jun-2013	LC
	14-Jun-2013	
Mr & Mrs Ferguson	26-Mar-2013	RF
Professor John Forsythe & Mr Keith Rigg	03-May-2012	AS
	04-May-2012	
Dr George Foster	21-Mar-2013	RF
Dr Thomas Frawley	20-Jun-2013	LC
Dr Raymond Fulton	04-Sep-2013	RF
Dr Caroline Gannon	02-Jul-2013	LC
Dr Joseph Gaston	18-Jun-2012	AS
	19-Jun-2012	
	11-Sep-2012	
Ms Sandra Gilchrist	11-Mar-2013	RF

WITNESSES WHO GAVE ORAL EVIDENCE

Name	Oral Hearing Date	Case evidence heard in
Mr Robert Gilliland	14-Mar-2013	RF
	28-Aug-2013	
Mr Clive Gowdy	06-Nov-2013	Dept
Professor Peter Gross	09-May-2012	AS
Dr Kumar Vijay Gund	05-Feb-2013	RF
Dr Donncha Hanrahan	05-Jun-2013	LC
Professor Brian Harding	05-Dec-2012	CR
Dr Carolyn Harper	14-Nov-2013	Current
Dr Simon Haynes	02-May-2012	AS
	03-May-2012	
	22-Mar-2013	RF
Professor Mary Hanratty	20-Mar-2013	RF
Dr Brian Herron	29-Nov-2012	CR
Dr Elaine Hicks	11-Dec-2012	CR
	07-Jun-2013	LC
Mr David Hill	15-May-2012	AS
Professor Dame Judith Hill	04-Nov-2013	Dept
Mrs Mary Hinds	14-Nov-2013	Current
Dr Joanne Hughes	05-Nov-2012	CR
Ms Maeve Hully	11-Nov-2013	Current
Mr John Hunter	04-Nov-2013	Dept
Dr Paul Jackson	12-Nov-2013	Current
Ms Margaret Jackson	06-Dec-2012	CR
Dr Claire Jamison	07-Feb-2013	RF
Dr John Jenkins	10-Sep-2013	RF
Dr Jeremy Johnston	07-Mar-2013	RF
Ms Sara Jordan (nee Field)	29-Oct-2012	CR
Dr Barry Kelly	05-Feb-2013	RF
Dr James Kelly	12-Jun-2013	LC
	13-Jun-2013	
Professor Fenella Kirkham & Professor Dr Dietz Rating	14-Jan-2013	AS
	15-Jan-2013	
Mr Geoff Koffman	16-May-2012	AS

WITNESSES WHO GAVE ORAL EVIDENCE

Name	Oral Hearing Date	Case evidence heard in
Mr Patrick Keane	23-Apr-2012	AS
	24-Apr-2012	
	26-Apr-2012	
	07-Sep-2012	
	10-Sep-2012	
Mr John Leckey	25-Jun-2013	LC
Ms Kate Linskey	30-Oct-2012	CR
Professor Sebastian Lucas	18-Dec-2012	CR
Dr Roderick MacFaul	13-Nov-2012	CR
	14-Nov-2012	
	19-Dec-2012	
	27-Jun-2013	LC
Dr Ragai Reda Makar	06-Feb-2013	RF
	13-Mar-2013	
Mrs Margaret Matthewson	30-Apr-2012	AS
	11-Sep-2012	
Mr Hugh Mills	17-Jun-2013	LC
Ms Elizabeth Millar	28-Feb-2013	RF
	01-Mar-2013	
	28-Aug-2013	
Ms Meenakshi Mirakhur	12-Jun-2012	AS
	30-Nov-2012	CR
Dr Terence Montague	11-May-2012	AS
Dr Norman Morrow	05-Nov-2013	Dept
Dr Connor Mulholland	21-Jun-2012	AS
Professor Aidan Mullan	17-Jan-2013	AS
Dr George Murnaghan	25-Jun-2012	AS
	11-Sep-2012	
	12-Dec-2012	CR
Ms Catherine Murphy	27-Apr-2012	AS
Ms Barbara Maxwell	30-Oct-2012	CR
Professor Charlotte McArdle	15-Nov-2013	Current
Ms Michaela McAuley (nee Rice)	05-Mar-2013	RF

WITNESSES WHO GAVE ORAL EVIDENCE

Name	Oral Hearing Date	Case evidence heard in
Dr Michael McBride	17-Dec-2012	CR
	15-Nov-2013	Current
Mr William McCallion	11-May-2012	AS
Ms Lorraine McCann	30-Oct-2012	CR
Dr Miriam McCarthy	31-Oct-2013	Dept
Dr William McConnell	19-Jun-2013	LC
Dr Brian McCord	13-Mar-2013	RF
	10-Sep-2013	
Mr Andrew McCormick	15-Nov-2013	Current
Ms Marian McGrath	26-Feb-2013	RF
Dr James Patrick McKaigue	12-Dec-2012	CR
	30-May-2013	LC
Mr William McKee	17-Jan-2013	AS & CR
Ms Geraldine McRandal	29-Oct-2012	CR
Mrs Heather Neill	06-Sep-2012	AS
Dr Geoff Nesbitt	03-Sep-2013	RF
Professor Brian Neville	01-Nov-2012	CR
	05-Nov-2012	
	04-Dec-2012	
Ms Ann Noble	26-Feb-2013	RF
	27-Feb-2013	
	27-Aug-2013	
Dr Mary O'Connor	25-Apr-2012	AS
	20-Jun-2012	
Dr Dara O'Donoghue	31-May-2013	LC
Dr Jarlath O'Donohoe	06-Jun-2013	LC
Dr Bernadette O'Hare	18-Oct-2012	CR
Dr Donagh O'Neill	15-May-2012	AS
Mr John Orr	21-Mar-2013	RF
Ms Daphne Patterson	04-Mar-2013	RF
Ms Angela Pollock	30-Oct-2012	CR
Mrs Gillian Popplestone	30-Apr-2012	AS
	11-Sep-2012	

WITNESSES WHO GAVE ORAL EVIDENCE

Name	Oral Hearing Date	Case evidence heard in
Dr Murray Quinn	14-Jun-2013	LC
Ms Sally Ramsay	08-Nov-2012	CR
	19-Mar-2013	RF
Professor Dr Dietz Rating & Professor Fenella Kirkham	14-Jan-2013	AS
	15-Jan-2013	
Professor Risdon	03-May-2012	AS
Mr Keith Rigg & Professor John Forsythe	03-May-2012	AS
	04-May-2012	
Mr & Mrs Roberts	31-Oct-2012	CR
	01-Nov-2012	
	12-Dec-2012	
Professor Nichola Rooney	13-Dec-2012	CR
Mrs Avril Roulston	06-Mar-2013	RF
Dr Andrew Sands	19-Oct-2012	CR
	18-Dec-2012	
Professor Maurice Savage	17-Apr-2012	AS
	18-Apr-2012	
	22-Jun-2012	
	10-Sep-2012	
Professor Gabriel Scally	01-Jul-2013	LC
Dr Robert Scott-Jupp	12-Nov-2012	CR
	04-Dec-2012	
	20-Mar-2013	RF
Mrs Joanne Sharratt (nee Clingham)	27-Apr-2012	AS
Mr Peter Shaw	17-May-2012	AS
Mr Paul Simpson	08-Nov-2013	Dept
Dr Mike Smith	24-Oct-2013	CM
Dr Waney Squier	12-Jun-2012	AS
	05-Dec-2012	CR

WITNESSES WHO GAVE ORAL EVIDENCE

Name	Oral Hearing Date	Case evidence heard in
Dr Heather Steen	15-Oct-2012	CR
	16-Oct-2012	
	17-Oct-2012	
	17-Dec-2012	
	18-Dec-2012	
Dr Anthony Stevens	12-Nov-2013	Current
Dr Roger Stevenson	15-Oct-2012	CR
	16-Oct-2012	
Dr Caroline Stewart	29-May-2013	LC
Dr Moira Stewart	18-Jun-2013	LC
Dr Neil Stewart	06-Nov-2012	CR
Professor Charles Swainson	19-Sep-2013	RF
Dr Robert Taylor	19-Apr-2012	AS
	20-Apr-2012	
	21-Jun-2012	
	06-Sep-2012	
	11-Dec-2012	CR
	04-Jun-2013	LC
	18-Sep-2013	RF
Dr Bernie Trainor	12-Mar-2013	RF
Dr Etain Traynor	07-Jun-2013	LC
Dr Andrea Volprecht	01-Nov-2012	CR
Mr Peter Walby	11-Dec-2012	CR
	12-Dec-2012	
Mr Peter Walsh	11-Nov-2013	Current
Dr David Webb	30-Nov-2012	AS
	03-Dec-2012	CR
Mr Noel Williams	22-Jun-2012	AS
Professor Ian Young	10-Dec-2012	CR
Dr Muhammad H Zafar	01-Mar-2013	RF
	12-Mar-2013	
Mr Waldermar Zawislak	05-Feb-2013	RF

PERSONS AND ORGANISATIONS GRANTED INTERESTED PARTY STATUS

Adam Strain
Dr Alison Armour
BHSCT
Mr Stephen Brown
Dr Ian Carson
Dr Joseph Gaston
Mr Patrick Keane
Dr Terence Montague
Ms Catherine Murphy
Mr George Murnaghan
Mr William McKee
Dr Mary O'Connor
Professor Maurice Savage
Ms Debra Slavin
Dr Robert Taylor

Claire Roberts
Dr Brigitte Bartholome
BHSCT
Dr Ian Carson
Ms Elizabeth Duffin
Ms Elaine Hicks

PERSONS AND ORGANISATIONS GRANTED INTERESTED PARTY STATUS

Claire Roberts
Ms Margaret Jackson
Ms Sara Jordan
Mr George Murnaghan
Dr Michael McBride
Ms Lorraine McCann
Dr James McKaigue
Mr William McKee
Ms Geraldine McRandal
Dr Bernie O'Hare
Ms Angela Pollock
Mr & Mrs Alan Roberts
Professor Nichola Rooney
Dr Andrew Sands
Dr Heather Steen
Dr Roger Stevenson
Dr Robert Taylor
Mr Peter Walby
Dr David Webb
Professor Ian Young

PERSONS AND ORGANISATIONS GRANTED INTERESTED PARTY STATUS

Events Following Lucy Crawford's Death
Dr Trevor Anderson
Dr Thomas Auterson
BHSCT
Mr Martin Bradley
Dr Ian Carson
Dr Anthony Chisakuta
Dr Peter Crean
Dr Mike Curtis
Dr Thomas Frawley
Dr Donncha Hanrahan
HSCB
Dr James Kelly
Mr John Leckey
Dr James McKaigue
Dr Dara O'Donoghue
Dr Jarlath O'Donohoe
Dr Murray Quinn
Dr Caroline Stewart
Dr Moira Stewart
Dr Robert Taylor
Ms Etain Traynor
WHSCB

PERSONS AND ORGANISATIONS GRANTED INTERESTED PARTY STATUS

Events Following Lucy Crawford's Death
WHST

Raychel Ferguson
Dr Naresh K Bhalla
BHSCT
Ms Therese Brown
Ms Fiona Bryce
Ms Stella Burnside
Dr Mary Butler
Dr Ian Carson
Dr Peter Crean
Dr Michael Curran
Dr Joseph Devlin
Ms Anne Doherty
Ms Margaret Doherty
Ms Irene Duddy
Mr & Mrs Raymond Ferguson
Dr Raymond Fulton
Ms Sandra Gilchrist
Dr Robert Gilliland
Dr Claire Jamison

PERSONS AND ORGANISATIONS GRANTED INTERESTED PARTY STATUS

Raychel Ferguson
Dr John Jenkins
Dr Jeremy Johnston
Dr Barry Kelly
Ms Elizabeth Lynch
Ms Elizabeth Millar
Ms Michaela McAuley
Dr Brian McCord
Ms Marian McGrath
Dr Geoff Nesbitt
Ms Ann Noble
Ms Daphne Patterson
Ms Avril Roulston
Dr Robert Taylor
Dr Bernie Trainor
WH SCT

Conor Mitchell
Ms Irene Brennan
Dr Suzie Budd
Ms Ruth Bullas
Ms Bridie Foy

PERSONS AND ORGANISATIONS GRANTED INTERESTED PARTY STATUS

Conor Mitchell
Dr Caroline Humphrey
Dr Jeff Lee
Ms Joanna Mitchell
Mr John Mone
Dr Andrew Murdock
Dr William McCaughey
Mrs Eileen O'Rourke
Dr Caroline Quinn
Mr Ivan Sterling
Mr John Templeton
Mrs Barbara Wilkinson

DHSSPS
Dr Henrietta Campbell
Dr Ian Carson
DHSSPS
Mr Clive Gowdy
Mr John Hunter
Dr Norman Morrow
Mr Paul Simpson

SCHEDULES COMPILED BY THE INQUIRY

Adam Strain
Chronology of events (clinical)
List of persons – clinical
Schedule detailing experience of the anaesthetists and surgeons involved
Schedule of anaesthetic nurses and trainee anaesthetists involved
Schedule detailing education and training of doctors involved
Table detailing education & training of nurses involved
Chronology of hospital management and governance
List of persons – governance
Chronology relating to draft recommendations submitted to the Coroner
Summaries of Inquiry expert opinion as to contributory factors to death, given before and after Newcastle-upon-Tyne meeting of experts (March 2012)
Glossary of Medical Terms

Claire Roberts
List of Persons – Clinical
List of Persons – Governance
Chronology of Events - Clinical
Chronology of Hospital Management and Governance
Timeline of Treatment
Schedule of Consultant Responsibility (22 nd - 23 rd October 1996)
Schedule of Medication
Schedule of Fluid and Medication Input
Timeline of Over-lapping Medication

SCHEDULES COMPILED BY THE INQUIRY

Claire Roberts
Schedules of Expert Views on Cause of Death & Cerebral Oedema
Schedule of Glasgow Coma Scale ('GCS') scores (22 nd October 1996)
Schedule of Recorded Sodium Levels (21 st - 23 rd October 1996)
Schedule of Blood Cell Counts (21 st -24 th October 1996)
Cerebral Oedema Flow Chart
Glossary of Medical Terms

Events following Lucy Crawford's death
List of persons involved
Schedule detailing Nomenclature & Grading of Doctors 1948 to 2012
Schedule detailing Nomenclature & Grading of Nurses 1989 to 2012
Chronology of Clinical Events
Consolidated Chronology: Governance and Lessons Learned
Compendium Glossary of Medical Terms

Raychel Ferguson
Chronology of Clinical Events
Timeline of Treatment
Chronology and Clinical Timeline Post-Collapse 9 th June 2001
Table of Clinicians duty times 7 th – 9 th June 2001
Schedule of Observations
List of persons – Clinical

SCHEDULES COMPILED BY THE INQUIRY

Raychel Ferguson
List of persons – Governance
Schedule detailing Nomenclature & Grading of Doctors 1948 to 2012
Schedule detailing Nomenclature & Grading of Nurses 1989 to 2012
Consolidated Chronology: Governance and Lessons Learned
Table of Nurses' training and experience
Table of Trainee Doctors' training and experience
Compendium Glossary of Medical Terms

Conor Mitchell
List of persons – Clinical
Chronology of Clinical Events
Schedule of Guideline Requirements and Conor's Treatment

Department of Health
List of Persons
Departmental Chronology
Structure of The Health Service in Northern Ireland (pre-2007)
HSC Trust Areas in Northern Ireland
Commissioning structure for HSC Services in Northern Ireland
Membership of Chief Medical Officer's Working Group on Hyponatraemia

LEGAL REPRESENTATIVES

Adam Strain		
Interested Party	Solicitor	Counsel
Dr Alison Armour	Carson McDowell	Mr G Boyle
BHSCT	DLS	Mr G McAlinden QC Mr M Lavery BL
Mr Stephen Brown	Kennedys	Ms L Woods
Dr Ian Carson	McKinty Wright	Mr T McGleenan QC
Dr Joseph Gaston	McKinty Wright	Mr T McGleenan QC
Mr Patrick Keane	Carson McDowell	Mr R Millar BL
Dr Terence Montague	Carson McDowell	Mr D Dunlop
Ms Catherine Murphy	Campbell Fitzpatrick	Mr C Campbell BL
Dr Mary O'Connor	Kennedys	Mr D Bradly
Professor Maurice Savage	Kennedys	Mr M Fortune
Ms Debra Slavin	Hunter Associates	Mr S Quinn QC Mr D McBrien BL
Dr Robert Taylor	BTO	Mr M Uberoi

Claire Roberts		
Interested Party	Solicitor	Counsel
Dr Brigitte Bartholome	Carson McDowell	Mr S Green
BHSCT	DLS	Mr G McAlinden QC Mr M Lavery BL
Dr Ian Carson	McKinty Wright	Mr T McGleenan QC
Ms Sara Jordan (nee Field)	Campbell Fitzpatrick	Mr C Campbell BL

LEGAL REPRESENTATIVES

Claire Roberts		
Interested Party	Solicitor	Counsel
Ms Lorraine McCann	Campbell Fitzpatrick	Mr C Campbell BL
Ms Geraldine McRandal	Campbell Fitzpatrick	Mr C Campbell BL
Dr Bernie O'Hare	Tughans	Ms L Woods Mr P Fernando
Ms Angela Pollock	Campbell Fitzpatrick	Mr C Campbell BL
Mr & Mrs Alan Roberts	Ferguson & Co	Mr S Quinn QC Mr M McCrea BL
Dr Andrew Sands	Carson McDowell	Mr S Green
Dr Heather Steen	Kennedys	Mr M Fortune
Dr Roger Stevenson	Carson McDowell	Mr J Counsell
Dr Robert Taylor	BTO	Mr M Uberoi
Dr David Webb	Tughans	Mr C Sephton QC Ms M O'Rourke QC

Events following Lucy Crawford's Death		
Interested Party	Solicitor	Counsel
Dr Trevor Anderson	McKinty Wright	Mr T McGleenan QC
BHSCT	DLS	Mr G McAlinden QC Mr M Lavery BL
Dr Ian Carson	McKinty Wright	Mr T McGleenan QC
Dr Mike Curtis	BTO	Mr J Leonard
Dr Donncha Hanrahan	McKinty Wright	Mr T McGleenan QC
HSCB	DLS	Mr B Lockhart QC Mr M Lavery BL

LEGAL REPRESENTATIVES

Events following Lucy Crawford's Death		
Interested Party	Solicitor	Counsel
Dr James Kelly	Carson McDowell	Mr S Green
Dr Jarlath O'Donohoe	Kennedys	Mr M Hayton QC Mr M Fortune
Dr Murray Quinn	Carson McDowell	Mr J Counsel
Dr Moira Stewart	Tughans	Mr R Davies
Dr Robert Taylor	BTO	Mr M Uberoi
WH SCT	DLS	Mr G Simpson QC Ms J Simpson BL

Raychel Ferguson		
Interested Party	Solicitor	Counsel
BH SCT	DLS	Mr G McAlinden QC Mr M Lavery BL
Ms Fiona Bryce	Campbell Fitzpatrick	Mr C Campbell BL
Mr & Mrs Raymond Ferguson	Desmond J Doherty	Mr M Topolski QC Mr S Quinn QC Mr J Coyle BL
Ms Sandra Gilchrist	Campbell Fitzpatrick	Mr C Campbell BL
Dr John Jenkins	Carson McDowell	Ms K Gollop
Ms Elizabeth Lynch	Campbell Fitzpatrick	Mr C Campbell BL
Ms Elizabeth Millar	Campbell Fitzpatrick	Mr C Campbell BL
Ms Michaela McAuley (nee Rice)	Campbell Fitzpatrick	Mr C Campbell BL
Ms Marian McGrath	Thompson McClure	Mr M Egan BL

LEGAL REPRESENTATIVES

Raychel Ferguson		
Interested Party	Solicitor	Counsel
Ms Ann Noble	Campbell Fitzpatrick	Mr C Campbell BL
Ms Daphne Patterson	Campbell Fitzpatrick	Mr C Campbell BL
Ms Avril Roulston	Campbell Fitzpatrick	Mr C Campbell BL
WH SCT	DLS	Mr M Stitt QC Mr M Lavery BL

Conor Mitchell		
Interested Party	Solicitor	Counsel
Ms Ruth Bullas	Kennedys	Ms L Woods
Ms Joanna Mitchell	Jones & Co	Mr S Quinn QC Ms S Ramsey BL
SH SCT	DLS	Mr G McAlinden QC Mr M Lavery BL

DHSSPS		
Interested Party	Solicitor	Counsel
Dr Henrietta Campbell	Tughans	Mr D McMillen QC Mr D Sharpe BL
Dr Ian Carson	McKinty Wright	Mr T McGleenan QC
DHSSPS	DSO	Mr S Shaw QC Mr D McMillen QC Mr D Sharpe BL

GLOSSARY OF MEDICAL TERMS

Term	Definition
Ablation	The removal of material from the surface of an object by vaporization, chipping, or other erosive process.
Abnormal cerebral venous drainage	Blood is drained from the brain through a network of veins & venous sinuses ('lakes'). Much of the blood eventually drains into the jugular veins. Blockage of a jugular vein, for example because of thrombosis after previous cannulation, results in blood finding alternative pathways.
Acetylcholine	A chemical neurotransmitter in both the peripheral nervous system (PNS) and central nervous system (CNS), facilitating the passage of the electrical potential across the gap between contiguous nerve fibres.
Acute tubular necrosis	The kidney consists of about a million microscopic units, each consisting of a glomerulus – a tuft of tiny blood vessels and a tubule – a hollow tube carrying the fluid filtered from blood which will go to make up urine. An event causing disruption and death of the cells lining the tubules and which leads to kidney failure has been termed acute tubular necrosis, although the term is now regarded as archaic.
Acyclovir or Aciclovir	An antiviral drug with specific activity against Herpes virus. Due to relative freedom from side effects, it may be used in treating unexplained neurological ('brain') disease in case virus is responsible.
Adalat	A tablet form of the drug, nifedipine. It is used in the treatment of high blood pressure & in the prevention of angina.
Adenosine	A nucleoside comprising a molecule of adenine attached to a ribose sugar molecule. Adenosine plays an important role in biochemical processes, such as energy transfer.
Adhesion	The abnormal union of two normally separate tissues.
Adrenals	The glands on top of the kidneys that produce four different hormones.
Adventitia	The outermost connective tissue covering of any organ, vessel, or other structure.
Aetiology	The cause or origin of a disease.
Agglutination	Adherence of small bodies in a fluid.
Agonist	A chemical that binds to a receptor of a cell and causes a response in that cell. Agonists often mimic the action of a naturally occurring substance.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Albumin	A protein soluble in water and present in all body tissue (egg-white is mostly albumin). Albumin in the blood is important in maintaining oncotic pressure. Albumin preparations can be given intravenously to boost blood volume when dangerously low.
Ambulatory	Designed for or available to patients who are not bedridden.
Aminoacidopathy	Disorders due to a defective enzymatic step in the metabolic pathway of one or more amino acids or in a protein mediator necessary for the transport of certain amino acids in or out of cells.
Ammon's horn sclerosis	The most common type of neuropathological damage seen in individuals with temporal lobe epilepsy. This type of neuron cell loss, primarily in the hippocampus, can be observed in approximately 65% of people suffering from this epilepsy.
Ammonia	A colourless pungent gas consisting of nitrogen and hydrogen. Ammonia is a cerebrotoxicant and a high level in the blood causes a degenerative brain lesion. High blood levels of ammonia can occur in a number of diseases of the liver, in portacaval shunts, urea poisoning and liver dysfunction.
Amnesia	A condition in which memory is lost.
Amylase	Any of a group of proteins found in saliva and pancreatic juice and which assist in the conversion of starch to sugar.
Anaemia	A decrease in haemoglobin, the red pigment in blood which carries oxygen to tissues and carries away carbon dioxide.
Anaphylaxis	A serious allergic reaction that is rapid in onset and may cause death.
Anastomosis	The surgical connection of two structures, eg connections between blood vessels or between other tubular structures such as intestine.
Anatomical	Pertaining to anatomy or to the structure of the body.
Angiography	A medical imaging technique using an intravenous dye to visualize the inside, or lumen, of arteries, veins or heart.
Anoxia	An extreme form of hypoxia or "low oxygen".
Antecubital fossa	The triangular cavity at the front of the elbow that contains a tendon of the biceps muscle, the median nerve and the brachial artery.
Anterior superior iliac spine (ASIS)	The hip bones located towards the front of the body.
Antidiuretic hormone (ADH)	Also known as vasopressin, a chemical hormone produced by the hypothalamus at the base of the brain. One of its effects is to inhibit the production of urine by stimulating the kidney tubules to reabsorb some of the water otherwise destined to be passed as urine.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Anti-rejection therapy	The use of certain drugs after transplantation to prevent rejection of the transplanted organ.
Anuria	Failure to produce urine, generally due to kidney failure. Production of an abnormally low volume of urine is termed oliguria.
Aorta	The largest artery in the body – arising out of the left ventricle of the heart, arching leftwards and backwards through the chest to lie alongside the backbone. It exits the chest through a gap in the diaphragm muscle and continues along the spine until it splits into the two common iliac arteries at the level of the umbilicus. Through its branches it provides arterial blood to all the organs of the body.
Apnoea	Cessation of breathing.
Apoptosis	The process of genetically programmed cell death.
Appendicectomy (American English: Appendectomy)	The surgical removal of the appendix. This procedure is normally performed as an emergency intervention when a patient is suffering from inflammation of the appendix (appendicitis).
Apyrexia	Having normal human body temperature.
Aquaporins	The proteins embedded in the cell membrane which regulate the flow of water.
Aqueous solutions	Solutions containing material dissolved in water.
Arachidonic acid	A polyunsaturated fatty acid present in the membranes of body cells.
Arginine vasopressin	A synthetic form of ADH, used in the treatment of diabetes insipidus (a condition where the patient does not produce his or her own ADH).
Artefact	A false object or test result, eg when faulty preparation of a specimen for microscopic examination allows contamination and a misleading result.
Artefactual	Of or relating to an error in perception of information.
Arterial anastomosis	The surgical joining together of two arteries (or one artery that has been severed).
Arterial blood pressure	The pressure on the blood flowing through arteries. It is conventionally described by two figures eg 120/70, where the 120 is the pressure at maximum contraction of the heart ventricles (systolic pressure) and the 70 the pressure at the moment of greatest relaxation (diastolic pressure).
Arterial line	A hollow tube passed through the skin into an artery in order to sample blood, measure pressure and/or deliver injectable material.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Ascites	The accumulation of fluid in the abdominal cavity.
Aspartate aminotransferase (AST)	An enzyme normally present in body serum and other tissue, particularly in that of the heart and liver.
Aspiration	The removal of a gas or fluid by suction.
Astrocyte	The star-shaped glial cells in the brain and spinal cord which perform many functions including repair of the brain and spinal cord.
Ataxic	The loss of ability to coordinate muscle movement.
Atracurium	A muscle relaxant of short to intermediate duration used by anaesthetists in surgery or intensive care. It assists intubation and artificial ventilation. It is used to relax stomach muscles and the diaphragm to permit surgery within the abdominal cavity.
Atrophy	A wasting away of an organ or part or a failure to grow to normal size in consequence of disease.
Atropine	A drug, prepared originally from the plant Belladonna, which relaxes muscles not under conscious control, particularly those of the intestines, bladder and stomach. It also reduces the production of saliva and sweat. It was used as premedication before an anaesthetic but is now rarely used for that purpose. It increases heart rate so may be used to oppose certain other anaesthetic drugs having the opposite effect.
Augmentin	A brand of the antibiotic co-amoxiclav. It combines amoxicillin, a derivative of penicillin and clavulinic acid which enhances its effectiveness. It can be given by injection or by mouth.
Autopsy	A post mortem assessment or examination of the body to determine the cause of death.
Axon	A long, slender projection of a nerve cell, or neuron, that conducts electrical impulses away from the neuron's cell body or soma.
Azathioprine	A drug prescribed to transplant recipients to inhibit rejection of the transplanted tissue. It is one of a group of drugs called immunosuppressants.
Basal cistern	A wide cavity where the arachnoid (a layer of membranes that contain the central nervous system) extends between the two temporal lobes.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Basal ganglia	A group of cell collections (nuclei) in the brain. Situated at the base of the forebrain and strongly connected with the cerebral cortex, thalamus and other brain areas, they are associated with a variety of functions, including voluntary motor control and procedural learning.
Baxter's solution	Solutions used in peritoneal dialysis.
Bergman glia	See Glial.
Bilateral fundal haemorrhages	Fundal haemorrhage is a sign of trauma or damage to the blood vessels at the back of the eye. It is indicative of a lack of oxygen or a catastrophic fall in blood pressure. Bilateral means 'on both sides of the body.'
Bilateral Papilloedema	Swelling of the optic discs and diagnostic of severe raised intracranial pressure
Bilateral reimplanation of ureters	Ureters are the muscular tubes, one on each side of the body, which carry urine from the kidney to the bladder. When a kidney is transplanted, its ureters have to be sewn into the recipient's bladder or reimplanted.
Blood gas analyser	A device used to measure the partial pressures of oxygen and carbon dioxide in a blood sample. It also measures the acidity of blood and gives an indication of the concentrations of electrolytes (chemicals such as sodium) and haemoglobin. It is often used as a 'near-patient' device as well as in laboratory use.
Blood groups	The four main groups are O, A, B and AB
Bolus	A single dose given rapidly, most usually referred to in intravenous use.
Bone profile	A blood test analysing chemicals and providing information about the quality of bones. Important in the treatment of renal failure where calcium loss occurs.
Boyd's equation	A rapid method of calculating body surface area from height and weight and read from a chart. Surface area is often used to calculate drug dosage, especially in children.
Brachiocephalic vein	A vein which supplies blood to the right arm, head and neck.
Brain-stem death	Brain damage causing irreversible loss of brain function and rendering the individual incapable of life without the aid of a ventilator.
Brain stem death test	A series of tests performed by two doctors, some hours apart, to confirm brain stem death.

GLOSSARY OF MEDICAL TERMS

Term	Definition
British National Formulary (BNF)	A publication of the British Medical Association & Royal Pharmaceutical Society of Great Britain listing all drugs available for use and detailing the licensed reasons for use, side-effects, contraindications, dosages and methods of administration.
Bronchiolitis	Inflammation of the bronchioles.
Bronchopneumonia	Inflammation of the lungs.
Broviac line	An intravenous catheter most often used for the administration of medication and the withdrawal of blood for analysis. Broviac lines may remain in place for extended periods and are used when long-term intravenous access is required.
Bulbar function	The function of the cranial nerves IX, X, XI and XII.
Calcification	The deposit of calcium salts in the body tissue, normally the bones and teeth.
Cannula	A short, narrow hollow tube which can be inserted into a blood vessel and used to take samples or deliver medication. If a cannula becomes dislodged allowing fluids to escape and enter tissue outside a blood vessel, then it must be removed and replaced.
Capillary	The terminal vessels uniting the arterial with the venous systems of the body.
Capillary refill	The rate at which blood refills empty capillaries. It may be measured by holding the hand higher than the heart and pressing the soft pad of a finger until it turns white and noting the time to re-colour once pressure is released. Normal capillary refill time (crt) is less than 2 seconds.
Cardiac arrest	A sudden cessation of cardiac function resulting in loss of effective circulation.
Cardiac resuscitation	An emergency procedure involving external cardiac massage and artificial respiration in an attempt to restore circulation of the blood and so prevent death or brain damage from lack of oxygen.
Cardiomegaly	A medical condition wherein the heart is enlarged.
Carina	The point of division of the main airway.
Carotid artery	One of two paired arteries (left and right) supplying the head and neck with oxygenated blood.
Catarrh	A disorder of inflammation of the mucous membranes.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Catecholamines	Molecules with a nucleus consisting of benzene with two hydroxyl side groups and a side-chain amine. They include dopamine and the “fight-or-flight” hormone adrenaline released in response to stress.
Catheter	Hollow tubes, longer than cannulas, which are inserted into the body, eg cardiac catheters which are passed along a vein into the heart, suprapubic catheters which are inserted above the pubic bone into the bladder to drain urine, urethral catheters passed into the urethra, ureteric catheters which are passed from the bladder up the ureters to inject material or sample urine from the kidney.
Cefotaxime sodium (Claforan)	An antibiotic used in the treatment of infections of the respiratory tract.
Central nervous system (CNS)	The brain and spinal cord.
Central venous line	A cannula or catheter passed into a large vein, often in the neck and threaded up into the vena cava, the major vein draining into the heart. The line can be used to judge heart and circulation function by measuring pressures.
Central venous pressure (CVP)	A measure of the pressure of blood in one of the main veins draining into the heart (superior or inferior vena cava). It is measured through a central venous line and is affected by various factors, including whether or not the circulation requires more fluid for the heart to pump blood effectively or whether the circulation is overloaded. An understanding of CVP is of value to anaesthetists in adjusting intravenous fluid replacement.
Cerebellar tonsil	A rounded lobule on the under surface of each cerebellar hemisphere.
Cerebellum	A region of the brain having an important role in motor control and cognitive function.
Cerebral	Of or relating to the brain or cerebrum.
Cerebral autoregulation	An adaptive mechanism that plays an important role in maintaining an appropriate blood pressure within vessels supplying brain tissue.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Cerebral oedema	An excess of fluid within and around brain cells. It has many causes, including infections such as meningitis, a prolonged epileptic fit or starvation of the brain's oxygen supply. It can result from Hyponatraemia. Because the brain is within a rigid skull, any increase in its volume in consequence of oedema causes increased pressure on the brain which in turn, restricts the amount of venous blood draining from the brain and further increases the oedema. The eventual result is that parts of the brain are forced by the pressure down through the foramen magnum, the hole in the base of the skull, impairing blood supply to the brainstem and leading to loss of control over the heart, blood pressure and breathing. Sudden death may result.
Cerebral palsy	An umbrella term encompassing a group of non-progressive, non-contagious motor conditions which cause physical disability in human development.
Cerebral perfusion pressure (CPP)	The net pressure gradient causing blood flow to the brain (brain perfusion).
Cerebral venous sinus thrombosis (CVST)	A rare form of stroke that results from thrombosis (a blood clot) of the dural venous sinuses, which drain blood from the brain. Symptoms may include headache, abnormal vision, any of the symptoms of stroke and seizures. Intracranial pressure may rise causing papilloedema (swelling of the optic disc).
Cerebrospinal fluid (CSF)	A clear, colourless, body fluid, that occupies the subarachnoid space and the ventricular system around and inside the brain and spinal cord. In essence, the brain "floats" in it.
Cerebrovascular disease	A group of conditions affecting the circulation of blood to the brain.
Cervical cord	That part of the spinal cord situate in the neck.
Chemoreceptor	A sensory receptor that converts chemical signals into electrical potential. In more general terms, chemoreceptors detect certain chemical stimuli in the environment.
Cheyne-Stokes respiration	An abnormal pattern of breathing characterized by progressively deeper and sometimes faster breathing, followed by a gradual decline and then a temporary stop called an apnea. The pattern is repeated with each cycle taking between 30 seconds and 2 minutes.
Chiari malformation	A malformation of the brain consisting of a downward displacement of the cerebellar tonsils through the foramen magnum (the opening at the base of the skull).
Cingulate gyrus	A part of the brain situate in the medial aspect of the cerebral cortex and considered part of the limbic lobe.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Circle of Willis	A circle of arteries supplying blood to the brain and named after Thomas Willis (1621–1675), an English physician.
Circulating nurse ('runner')	An operating theatre nurse who is not 'scrubbed up' and can therefore handle non-sterile material unlike the operating surgeons or the scrub nurse. The circulating nurse has many tasks, including weighing discarded swabs to assess blood loss, the connection of replacement fluid to drips and fetching equipment. The circulating nurse can also assess or measure the amount of blood or other fluids draining from catheters etc.
Circulatory arrest	An alternative phrase for 'cardiac arrest'.
Circulatory resuscitation	See 'cardiac resuscitation'.
Cirrhosis	A consequence of chronic liver disease characterized by replacement of liver tissue by fibrosis, scar tissue and nodules leading to loss of liver function.
Claforan	An antibiotic used in the treatment of severe infection of the lung, throat, ear or urinary tract.
Clonus	A succession of intermittent muscular contractions and relaxations usually resulting from a sustained stretching stimulus and often a sign of brain or spinal cord disease.
Clotting	The formation of a jellylike substance within a blood vessel causing a stoppage of the blood flow, also called coagulation.
Coagulation screen	A standard set of blood tests performed in a haematology laboratory to detect abnormality in the blood clotting system.
Cockcroft-Gault formula	A method of calculating creatinine clearance (see below) from the blood creatinine level and the individual patient's age, height and weight.
Cogwheel rigidity	The tension in a muscle which gives way in little jerks when the muscle is passively stretched.
Cold ischaemic time ('CIT')	Ischaemia means a deficient blood supply which can lead to cell damage. If a tissue is kept cold, it can withstand ischaemia for longer than at body temperature. It is therefore important when performing a transplant operation to keep the donor organ cold. The cold ischaemic time is relevant in assessing the viability of a donor organ. The CIT is calculated from the time of removal from the donor to time of insertion into the recipient and anastomosis of the arteries.
Colloid	A substance evenly and microscopically dispersed throughout another substance.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Coma	A profound state of unconsciousness associated with depressed cerebral activity from which the individual cannot be aroused.
Common iliac arteries	Two large arteries originating from the aortic bifurcation at the level of the 4 th lumbar vertebra.
Common iliac vein	The left and right common iliac veins lie on either side of the pelvis, and meet in the lower back, at the level of the fifth lumbar vertebra, to form the inferior vena cava, the main vein returning blood from the legs & lower trunk to the heart.
Co-morbidity	The presence of one or more disorders (or diseases) in addition to a primary disease or disorder or the effect of such additional disorders or diseases.
Congenital	Existing at or dating from birth.
Congenital nephrotic syndrome	A generic term for several conditions characterised by abnormally functioning glomeruli in the kidneys and which are present at birth.
Congenital obstructive uropathy	Any condition present at birth in which drainage of urine from the kidney is obstructed at a point between the kidney pelvis and urethra.
Coning/coned (Otherwise known as 'transforaminal herniation')	A shorthand term used to describe the downward displacement of the brain stem into the foramen magnum (the hole in the base of the skull). It is caused by raised intracranial pressure and can kill.
Contractile Proteins	The proteins responsible for the contraction of muscle tissue.
Convulsion	An involuntary contraction or series of contractions of the voluntary muscles, also called a seizure.
Corpus callosum	A wide, flat bundle of neural fibres beneath the cortex connecting the left and right cerebral hemispheres and facilitating inter-hemispheric communication.
Cortex	The tissues forming the outer part of an organ e.g. the cerebral cortex of the brain.
Cranial	Adjective relating to the cranium or skull.
C-reactive protein (CRP)	A globulin found in the blood in some cases of inflammation.
Creatinine	A product of protein which can be measured in blood and urine. The higher the blood creatinine (and the lower the urinary creatinine) the poorer the kidney function. By calculating the 'creatinine clearance' a measure of kidney function can be obtained.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Cross-matching	A method of comparing a patient's blood or tissue with that of a potential donor to ensure organ compatibility.
Crystalloid	A substance that in solution can pass through a semipermeable membrane and be crystallized. The physical opposite of a crystalloid is a colloid, which does not dissolve and does not form true solutions.
CT (computerised tomography) scan	An imaging technique relying on a computerised analysis of multiple x-rays, taken at different levels and reconstructed to depict a two- or three-dimensional image.
Cushing response	A physiological nervous system response to increased intracranial pressure (ICP) resulting in widening pulse pressure, irregular breathing and a reduction of the heart rate. It is usually seen in the terminal stages of acute head injury and may indicate imminent brain herniation.
Cyanosis	The appearance of a blue or purple coloration of the skin or mucous membranes due to reduced oxygen levels within the tissues close to the skin surface.
Cyclase	An enzyme that catalyses a chemical reaction to form a compound.
Cycles of dialysis	In peritoneal dialysis, fluid is run into the peritoneal cavity (inside of the abdomen) left for a time and then run out again. The process is repeated with each repetition being referred to as a cycle.
Cyclimorph	Medication containing morphine and cyclizine. Morphine belongs to a group of strong painkilling medicines called opioids and cyclizine is an anti-sickness medicine.
Cyclizine	An antihistamine drug used to treat nausea, vomiting and dizziness.
Cyclosporine	An immunosuppressant drug used in organ transplantation to prevent rejection.
Cystatin C	A protein which when measured in a blood sample provides an accurate assessment of kidney function.
Cytology	The medical and scientific study of cells.
Cytomegalovirus (CMV) titre	A common virus but one which rarely causes disease in healthy people. It is, however, potentially dangerous for those whose immune system is not working well, either from disease or the use of immunosuppressive drugs eg those who have received transplants. To determine if a transplant donor or recipient has been infected, the concentration of antibody to the virus can be measured. This is called CMV titre.
Cytoscopy	An examination of the inside of the bladder and urethra.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Decerebrate movement	The cerebrum is the part of the brain controlling all voluntary activity. If the cerebrum is not functioning adequately as a result of disease, toxin, seizures etc. characteristic muscle spasms can result in movement of an individual, intermittently or continuously into abnormal posture.
Decompensation	Inability of the heart to maintain adequate circulation, manifested by difficulty in breathing, venous engorgement and oedema.
Deep white matter	Brain tissue composed of myelin-coated nerve cell fibres. White matter carries information between the nerve cells in the brain and the spinal cord. The inner portion of the cerebrum is composed of white matter.
Dehydration	A deficiency of fluid in the body caused by insufficient intake, excessive output or both. Minor degrees of dehydration are common in illness and may be of no consequence. However an increase in dehydration, especially in combination with abnormality of blood chemistry (eg high or low sodium) may result in a deterioration of various body functions.
Dentate nucleus	The largest single structure linking the cerebellum to the rest of the brain. It is located within the deep white matter of each cerebellar hemisphere.
Desmopressin acetate/DDAVP	A drug used to regulate urine production.
Dextrose	An alternative term for 'glucose'.
Dextrostix	A blood test used to measure levels of sugar in the bloodstream.
Dialysate	A fluid used for peritoneal dialysis (see Cycles).
Diastole	The period of time when the heart fills with blood after systole (contraction).
Diazepam (Diazemuls)	A benzodiazepine (psychoactive) drug commonly used in the treatment of anxiety, insomnia and seizures. Diazepam can be administered as a slow intravenous injection or as a continuous intravenous ('IV') infusion.
Diencephalon lesion	Any tissue abnormality in that part of the brain which includes the thalamus.
Diffuse oedema	Oedema is an abnormal accumulation of fluid within the body. It can be localised or involve the whole body.
Dilutional hyponatraemia	See hyponatraemia

GLOSSARY OF MEDICAL TERMS

Term	Definition
Dioralyte	A proprietary powder containing glucose and salts in concentrations which, when dissolved in water, represent the best way of restoring by mouth fluids lost through diarrhoea, vomiting etc.
Disseminated intravascular coagulation (DIC)	A medical condition which develops when the normal balance between bleeding and clotting is disturbed.
Distension	The state of being distended or swollen.
Diuresis	Urine production as an aspect of fluid balance.
Dopamine	A drug used in resuscitation and intensive care and given by IV infusion. It is a heart stimulant and in low doses may increase the blood supply to vital organs by dilating blood vessels.
Double or triple lumen line	A cannula or catheter with two or three separate channels allowing separate routes for sampling, measurement and drug delivery.
Dura mater or dura	The outermost of the three layers of the meninges surrounding the brain and spinal cord.
Dysplasia	An abnormality in the development of tissue or an entire organ.
Dysplastic kidneys	Kidneys containing abnormal tissue. The condition arises before birth and the kidneys are often very small and function poorly.
Dysuria	Painful or difficult urination.
Effacement	The shortening or thinning of a tissue.
Electroencephalography (EEG)	The recording of electrical activity across the scalp.
Electrolytes	The elements of the common salts in blood ie sodium, potassium, chloride and bicarbonate.
Embolus	Any detached travelling intravascular mass carried by circulation, which is capable of clogging arterial capillary beds.
Emesis	Vomiting.
Encephalitis	The inflammation or infection of the brain usually caused by a viral or bacterial infection.
Encephalopathy	Brain disease, damage, or malfunction. Encephalopathy can present a very broad spectrum of symptoms ranging from memory loss or subtle personality change to dementia, seizures, coma or death.
Endonucleases	The enzymes that cleave the bond within a polynucleotide chain.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Endoscopy	An examination inside the body using an endoscope, an instrument used to examine the interior of a hollow organ or cavity of the body. Unlike most other medical imaging devices, endoscopes are inserted directly into the organ.
Endothelium	The thin layer of cells that line the interior surface of blood and lymphatic vessels.
Endotracheal tube	A catheter that is inserted into the trachea for the primary purpose of establishing and maintaining a patent airway.
Enteral Feeding	The act of giving a patient a liquid, low residue food through a naso- or oro-gastric feeding tube.
Enteroviruses	A family of viruses which tend to invade the central nervous system through the gut.
Eosinophilic	The staining of certain tissues or cells, after they have been washed with eosin, a dye.
Epidemiology	That branch of medicine dealing with the study of the causes, distribution and control of disease within populations.
Epidural	A form of regional analgesia involving an injection of drugs through a catheter placed into the epidural space.
Epilepsy	A recurrent and paroxysmal disorder of sudden onset and spontaneous cessation caused by occasional, sudden, excessive, rapid and local discharge of nerve cells in the grey matter (cortex) of the brain.
Epileptogenic	Capable of producing epileptic seizures.
Erythrocyte	A red blood cell.
Erythropoietin	The hormone that regulates red blood cell production.
Excitotoxicity	The pathological process by which nerve cells are killed by excessive stimulation by neurotransmitters such as glutamate.
Expiration	The movement of air out of the bronchial tubes and through the airways. Breathing out.
External iliac artery	Each of the two common iliac arteries (see above) divide into two in order to form the external iliac arteries which run from the lower back to the groin where they continue as femoral arteries.
Extracellular fluid	The fluid outside body cells. That within blood vessels is intravascular and the remainder is interstitial.
Extra-ocular	Relating to the six muscles that control the movements of the eye.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Extraperitoneal procedure	An operation in which the peritoneal cavity is not entered. The peritoneum is a membrane which envelopes the inner surface of the abdomen.
Exudation	The process by which some of the constituents of blood pass slowly through the walls of small blood vessels in the course of inflammation.
Faecolith	A hard mass of faecal matter.
Femoral artery	A general term for the large arteries in the thigh.
Fentanyl	A potent, synthetic narcotic analgesic with a rapid onset and short duration of action.
Fibrinogen	A soluble plasma glycoprotein, synthesised by the liver, which is converted into fibrin during blood coagulation.
Fixed, dilated pupils	The pupils of the eyes contract and dilate in response to light and the distance of focus. Severe damage to the brain stem results in a failure in these responses and the pupils remain large.
Fixing of the brain	The process by which the brain is treated in a solution of formalin for up to two weeks in order to assist neuropathological examination.
Flumazenil	A medicine used to reverse the effects of benzodiazepines after sedation, general anesthesia or overdose.
Fluoroscopy	An imaging technique commonly used to obtain real-time moving x-ray images of internal body structures.
Foley catheter	A flexible tube passed through the urethra and into the bladder.
Foramen magnum	A large hole in the base of the skull. It where the brainstem merges into the upper part of the spinal cord.
Fractional excretion rate	A rate calculated as the proportion of sodium passing through the kidney and filtered into the urine. It is useful in evaluating acute kidney failure.
Free radicals	Where radicals are atoms, molecules, or ions with unpaired electrons or an open shell configuration, free radicals may have positive, negative, or zero charge. With some exceptions, the unpaired electrons cause radicals to be highly chemically reactive.
Free water	The theoretical proportion of water in blood or urine which can be recognised or calculated as containing no dissolved solutes.
Frontal white matter	The nerve fibres within the frontal lobe of the brain.
Full blood picture	A laboratory blood test to determine the proportions of all the components of blood.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Fundoplication	Suturing the fundus of the stomach around the gastroesophageal junction to treat gastroesophageal reflux. It can be performed by open surgery or laparoscopy.
Fundoscopy	A test permitting examination of the inside the fundus of the eye and other structures using an ophthalmoscope (or funduscope).
Fundus	The place on the retina opposite the pupil through which nerve fibres and blood vessels traverse the retina.
Ganglion	A biological tissue mass, most commonly a mass of nerve cell bodies.
Gastroenteritis	Infection or irritation of the digestive tract.
Gastroesophageal reflux disease	The chronic symptoms of or mucosal damage caused by stomach acid rising from the stomach into the oesophagus.
Gastrointestinal losses	The loss of fluid and electrolytes from the gut, usually by the production of faeces or, in abnormal circumstances, by vomiting and/or diarrhoea.
Gastro-intestinal tract	The tubular passage of mucous membrane extending from the mouth to the anus.
Gastrostomy tube & button	A plastic tube inserted through the wall of the abdomen into the stomach for feeding. The tube ends at a flat disc sewn onto the abdomen (the button) to which a feeding tube can be attached.
Gentamycin	An antibiotic, given by intravenous or intramuscular injection, used in the treatment of significant infection by certain bacteria, such as pseudomonas and klebsiella.
Glasgow Coma Score	An internationally accepted measure of consciousness, the lower the score the lower the level of consciousness.
Glial	The non-neuronal cells that provide support and protection for neurons in the brain and for those neurons in other parts of the nervous system such as in the autonomous nervous system.
Gliososis	The proliferation of astrocytes in damaged areas of the central nervous system.
Glomerular filtration rate (GFR)	The rate at which the kidneys filter out fluid free from fats, protein or cells is termed the GFR and is a measure of the adequacy of kidney function.
Glomerulus	One of the 2 million filtering units in the kidney into which blood comes into contact.
Glutamate	Alternative word for glutamic acid which is a non-essential amino acid. In neuroscience, glutamate is an important neurotransmitter and plays an important role in learning and memory.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Glycolysis	The metabolic pathway converting glucose into pyruvate (an organic acid).
Glycopyrrolate	An atropine-like drug used to increase heart rate, commonly to oppose the action of certain other anaesthetic drugs which have the opposite effect.
Grey matter	A major component of the central nervous system, consisting of neuronal cell bodies, in contrast to white matter, which does not.
Guarding	A sign often detected during an examination for physical pain whereby the patient involuntarily contracts muscles.
Gyrus	A ridge on the cerebral cortex. It is generally surrounded by one or more sulci.
Haematemesis	The vomiting of blood.
Haematocrit	A measure of the proportion of blood which is solid (that is consisting of blood cells) and liquid (plasma) and determined by spinning a small blood sample in a centrifuge. It is used as a crude measure of hydration.
Haematoma	A localised collection of blood outside the blood vessels, usually in liquid form within the tissue. This distinguishes it from an ecchymosis, which is the spread of blood under the skin in a thin layer, commonly called a bruise.
Haemodynamics	The study of the forces and physical mechanisms concerned with the circulation of the blood.
Haemoglobin	The red pigment in blood which carries oxygen to tissues and takes away carbon dioxide.
Haemoptysis	The coughing up of blood or bloody sputum from the lungs or airway.
Haemorrhage	The escape of blood from any blood vessels, normally in response to trauma.
Haemorrhagic shock	Shock resulting from reduction of the volume of blood in the body due to haemorrhage.
Hagen–Poiseuille equation	A physical law providing the pressure drop for a fluid flowing through a long cylindrical pipe. The assumptions of the equation are that the flow is laminar, viscous and incompressible and the flow is through a constant circular cross-section which is substantially longer than its diameter.
Halothane	An inhalational general anaesthetic.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Hand ventilated	The artificial ventilation produced by squeezing a rubber bag connected to a mask or tube delivering air and/or oxygen to a patient.
Hartmann's solution	An intravenous solution containing sodium chloride (salt), sodium lactate, potassium & calcium chloride. The sodium concentration is similar to that of the blood.
Hepatocyte	A cell of the main tissue of the liver.
Hepsal (Heparin sodium)	A flushing solution used to maintain the patency and prevent blockages within intravenous devices.
Herniation and compression of the brain stem	See coning.
Herpes	Any one of several viral diseases causing the eruption of small blister like vesicles on the skin or mucous membranes.
Heterogeneous	Relating to lack of uniformity of or within a substance. Its opposite is homogeneous, where there is uniformity in composition or character.
Heterozygous	The two different genes controlling a specified inherited trait.
Hindbrain	That part of the brain which includes the medulla, pons and cerebellum.
Hippocampus	A major component of the brain. It belongs to the limbic system and plays important roles in the consolidation of information from short-term memory to long-term memory.
Histological slides	Thin slices of tissue applied to a microscopic slide which are then viewed through a microscope.
Histology	The microscopic study of tissue and organs at the cellular level.
Histopathology	The microscopic examination of tissue in order to detect the manifestations of disease.
Homeostasis	The property of a system that regulates its internal environment to maintain a stable, constant condition.
Homocysteine	A non-protein amino acid.
Human leucocyte antigen (HLA)	Complex antigens, being proteins capable of inciting an immune reaction and found in most tissues of the body, are important in determining organ transplant compatibility. Incompatibility between donor and recipient HLA can cause rejection.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Human plasma protein fraction (HPPF)	A mixture of albumin, other proteins and saline used in the emergency treatment of bleeding until replacement donor blood becomes available.
Hydrolysis	A chemical reaction during which molecules of water are split.
Hyperammonaemia	An abnormally high level of ammonia in the blood.
Hypercapnia	Also known as hypercarbia, a condition where there is excess carbon dioxide (CO ₂) dissolved in the blood.
Hypercarbia	See Hypercapnia above.
Hypercoagulability	An abnormality of blood coagulation that increases the risk of thrombosis (blood clots in blood vessels).
Hyperkalemia	The condition in which the concentration of the electrolyte potassium (K ⁺) in the blood is elevated.
Hypernatraemia	A concentration of sodium in the blood which is higher than normal. It is caused either by excessive salt intake or by water loss in excess of that of salt.
Hypertension	A state of raised blood pressure.
Hypertonic infusion	The delivery of an intravenous fluid which has a higher osmotic pressure than blood. Osmotic pressure develops when there are more molecules on one side of a semi-permeable membrane, such as a cell wall, than the other. The result is that water tends to flow through the membrane into the more concentrated solution until the concentrations are equal on both sides of the membrane.
Hypertonicity	The state of being hypertonic or having extreme muscular or arterial tension.
Hypervolemia (fluid overload)	The condition of an excess of fluid in the blood.
Hypocapnia	The presence of abnormally low levels of carbon dioxide in blood.
Hypoglycemia	A state produced by a lower than normal level of blood glucose.
Hypokalaemia	The condition of below normal levels of potassium in the blood serum.
Hyponatraemia	A serum concentration of sodium below the normal range which may be produced by dilution of the blood, excessive water retention, excessive sodium loss or occasionally inadequate salt intake.
Hypothalamus	The part of the fore-brain containing nerve centres for the regulation of vital processes e.g. body temperature and sexual function.
Hypothermia	A core body temperature of less than 35 degree Celsius.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Hypotonic	A solution which has a greater osmotic pressure than another.
Hypovolaemia	A reduction in the volume of circulating blood causing the body to compensate by increasing the heart rate in order to pump more blood and by contracting small blood vessels to divert flow to major vessels and vital organs. Ultimately, this 'compensation' cannot be maintained and the patient goes into shock.
Hypoxia	A reduction in the amount of oxygen available in the body so as to adversely affect normal vital organ function (typically used with reference to the brain).
Hypoxic damage	The damage caused to any organ by the effect of hypoxia (see above).
Hypsarrhythmia	An abnormal pattern seen on EEG and frequently encountered in cases of infantile spasm. Diagnostic of status epilepticus.
Iatrogenic	Induced by a physician.
Idiopathic	An adjective to indicate that which <i>arises spontaneously or from an obscure or unknown cause</i> .
Ileus	An intestinal obstruction causing colic, vomiting and constipation.
Iliac fossa	The internal concavity of the iliac bone of the pelvis. It contains within it organs such as the ilium, caecum and appendix. The right iliac fossa is the most common site of pain and tenderness in acute appendicitis.
Infarcted	Tissue that has died through failure of its blood (and therefore oxygen) supply.
Infusion	The intravenous or subcutaneous injection of one of a variety of solutions used in the treatment of dehydration and/or electrolyte imbalance or as a vehicle for medication.
Ingestion	The oral taking of substances into the body.
Intercurrent	A disease or condition affecting a person already suffering from something else.
Insensible losses	Fluids lost as sweat, in the breath or in the normal stool.
Inspiration	The movement of air from the external environment through the air ways and into the alveoli of the lungs (breathing in).
Interstitial fluid	See extracellular fluid.
Intestinal colick	Associated with severe abdominal pain.
Intracellular fluid	See extracellular fluid.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Intracerebral	Occurring or situated within the cerebrum.
Intracranial	Within the skull.
Intracranial hypertension	Abnormally high blood pressure within the skull.
Intracranial pressure (ICP)	The pressure inside the skull and thus within the brain tissue and cerebrospinal fluid (CSF).
Intraluminal	Within the space of an object or structure.
Intraperitoneal space	See extraperitoneal.
Intrauterine	Of or related to the uterus.
Intravascular	Of or relating to the blood vessels.
Intravenous	Inside a vein.
Intubated	The introduction of a tube (endotracheal or ET tube) through the mouth or nose and into the larynx in order to provide an airway when resuscitating or artificially ventilating a patient.
Ion	An atom or molecule in which the total number of electrons is not equal to the total number of protons, giving it a net positive or negative electrical charge.
Ipsilateral cranial nerve	The cranial nerve which is on the same side as another structure.
Ischaemia	A restriction in blood supply, generally due to factors in the blood vessels, with resultant damage or dysfunction of tissue.
Ischaemic-hypoxic damage	A brain injury resulting from reduction in blood flow (ischaemia) & lack of oxygen (hypoxia). It is usually caused by cardiac arrest or profound hypotension.
Isotonic solution	A solution with broadly the same osmolar pressure (and thus the same sodium concentration) as blood plasma.
Jugular vein	Any of several large veins of the neck which drain blood from the head.
Jugular venous pressure	The indirectly observed venous pressure wave occurring in the external jugular veins of the neck.
Ketones	Poisonous acidic chemicals produced by the body when fat instead of glucose is burned for energy.
Lactic acidosis	A physiological condition characterized by low pH in body tissues and blood accompanied by an accumulation of lactate.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Laminar	Flat.
Laparotomy	The surgical opening of the abdomen.
Leigh's disease	A rare neurometabolic disorder affecting the central nervous system and characterized by movement disorders.
Leucocytes	White blood cells
Leukoaraiosis	Nonspecific changes in the cerebral white matter.
Leukoencephalopathy	Any of a group of diseases affecting the white matter of the brain.
Ligation	The creation of a ligature or suture typically tied around a vessel to seal it off.
Liver function test	Any one of several tests used to evaluate various functions of the liver, including metabolism, storage, filtration and excretion.
Lumbar	The region of the back lying lateral to the lumbar vertebrae.
Lumbar epidural	The placement of a cannula into the epidural space (near but outside the spinal cord) through which drugs can be delivered to produce anaesthesia of the lower part of the body without necessarily having to render the patient unconscious.
Lumen line	A line inserted into a tubular structure, such as an artery or intestine.
Lymph nodes	The swellings which occur at various points in the lymphatic system through which lymph (a watery fluid derived from blood and absorbed food material) drains.
Macrophages	Those cells whose role it is to engulf and digest cellular debris and pathogens.
Macroscopic	Observable by the naked eye.
Macular rash	A skin eruption where the lesions are flat and less than 1cm in diameter.
Maintenance rate	The IV fluid rate which provides for ongoing and insensible losses in a patient who is not dehydrated and not suffering other abnormal body fluid loss. It is calculated by reference to weight or body surface area.
Major surgery	(a) A surgical operation within the abdominal, pelvic, cranial, or thoracic cavities. (b) A procedure which constitutes a hazard to life or the function of an organ or of tissue. (c) Any surgical procedure that involves general anaesthesia or respiratory assistance.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Mallory Weiss tear	A small tear in the distal oesophageal mucosa.
Mammillary bodies	A pair of small round bodies, located on the undersurface of the brain and forming part of the limbic system.
Mannitol	An osmotic diuretic being a solution of very high molecular weight and designed to provoke rapid excretion of free water through the kidney when given intravenously. It is used in emergency treatment of cerebral oedema and raised intracranial pressure.
McBurney's point	A site of extreme sensitivity in acute appendicitis and situated in the normal area of the appendix.
Mean Arterial Pressure (MAP)	The average arterial blood pressure in an individual during a single cardiac cycle.
Measles	An infection caused by a virus giving rise to a characteristic skin rash known as an exanthem.
Mediastinum ('mediastinal')	A non-delineated group of structures in the thorax and surrounded by loose connective tissue.
Medulla oblongata	The lower half of the brainstem.
Medullary	Of or relating to the medulla (inner core) if any body part or organ.
Medullary Cystic (kidney disease)	An inherited kidney disorder characterized by cysts in both kidneys and tubulointerstitial sclerosis, leading to end-stage renal disease.
Membrane pump	A diaphragm pump.
Meninges	The three membranes that envelop the brain and spinal cord.
Meningitis	An infection or inflammation of the meninges (see above).
Meningococcal	Of or relating to the meningococcus bacterium, which causes cerebrospinal meningitis.
Meningoencephalitis	A condition which simultaneously both resembles meningitis, which is an infection or inflammation of the meninges and encephalitis, which is an infection or inflammation of the brain.
Mesenchyme	A type of undifferentiated loose connective tissue. The term mesenchyme refers to the morphology of embryonic cells.
Mesenteric adenitis	Inflammation of any of the several folds of the peritoneum which connect the intestines to the dorsal wall.
Metabolic acidosis	A pH imbalance in which the body has accumulated excess acid and has inadequate bicarbonate to neutralize it.
Metabolic coupling	The transfer between tissue cells in contact of low molecular weight metabolites such as amino acids.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Metabolic disease	Any of the diseases or disorders that disrupt normal metabolism ie the process of converting food to energy on a cellular level.
Metabolic regulation	The process of metabolism which allows organisms to respond and interact with their environment.
Metabolism	The chemical reactions occurring in living organisms to sustain life.
Methylprednisolone	A synthetic drug typically used for its anti-inflammatory effects.
Microbiology	The branch of biology concerned with the study of microorganisms, including bacteria and viruses.
Microglia	A type of cell that is the resident of the brain and spinal cord and acts as the first and main form of active immune defence in the central nervous system.
Microvascular	Of or relating to the small blood vessels.
Midazolam	A short-acting drug in the benzodiazepine (psychoactive) class used in the treatment of acute seizures, insomnia for inducing sedation before medical procedures.
Mitochondrion (plural mitochondria)	A membrane-enclosed organelle found in most eukaryotic cells. Mitochondria are sometimes described as "cellular power plants" because they generate adenosine triphosphate (ATP) which is used as a source of chemical energy.
Mmol/l	Millimoles per litre. A millimole is one thousandth of a mole. A mole is the amount of any substance that contains 60,000,000,000,000,000,000,000 molecules or atoms.
Monro-Kellie principle	The hypothesis that the cranial compartment is incompressible and the volume inside the cranium is fixed. The cranium and its constituents (blood, CSF, & brain tissue) create a state of volume equilibrium so that any increase in volume of one of the cranial constituents must be compensated by a decrease in the volume of another.
Multivariate	Of or relating to a number of different variations.
Mumps	An acute inflammatory contagious disease caused by a paramyxovirus and characterized by swelling of the salivary glands and sometimes also of the pancreas, ovaries or testes.
Myelin	An electrically insulating material that forms a layer or myelin sheath, usually around only the axon of a neuron. It is essential for the proper functioning of the nervous system.
Myelinolysis	A neurological disease caused by severe damage of the myelin sheath.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Myogenic	Of or giving rise to the formation of muscle tissue.
Na ⁺ and K ⁺ electrodes	The parts of a piece of laboratory apparatus which measure concentrations of sodium (Na ⁺) and potassium (K ⁺).
Nail bed stimuli	Pressure to the nail bed provokes pain. An individual's response depends upon brain function, so the test is used to assess the severity of coma.
Necrosis	The premature death of cells and living tissue, caused by factors external to the cell or tissue.
Neonatal	Of or relating to the first 28 days of an infant's life.
Neonate	Refers to an infant in the first 28 days after birth.
Neostigmine	A drug used by anaesthetists to reverse the action of certain muscle relaxants (e.g. atracurium). It acts within a minute of being injected intravenously and lasts 20-30 minutes. It is used at the end of an operation to enhance recovery.
Nephrogenic diabetes insipidus	A condition in which the kidney is unable to respond to the hormone vasopressin (ADH). Patients cannot retain water so are at risk of dehydration. It is usually congenital and is characterised by excessive passage of urine (polyuria) and thirst (polydipsia) leading to episodes of hypernatraemia, dehydration, fever, constipation and vomiting.
Nephrology	The branch of medicine concerned with the study and management of kidney disease.
Nephrons	The 2 million individual microscopic filtering units of the kidneys which consist of glomeruli and tubules.
Nephrostogram	A radiograph of the kidney after a contrast agent has been administered through a nephrostomy tube.
Nephrostomy	An artificial opening created between the kidney and the skin which allows for the drainage of urine directly from the upper part of the urinary system.
Neuroblastoma	A malignant growth comprising embryonic nerve cells.
Neuroimaging	Non-invasive methods of visualizing the central nervous system, especially the brain, by various imaging modalities.
Neurology	The branch of medical practice concerned with the study of the nervous system and its disorders.
Neuromuscular	Of or relating to nerves and muscles.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Neuromuscular blockade	The process by which drugs are delivered to induce temporary muscle paralysis. Always given in conjunction with drugs to induce sleep and prevent pain.
Neuron	An electrically excitable cell that processes and transmits information by electrical and chemical signalling.
Neuronal migration defect (or disorder)	A congenital brain abnormality caused by the abnormal migration of neurons in the developing brain and nervous system.
Neurones	Also known as a nerve cell, this is a basic cellular building block of the nervous system which contains billions of neurones.
Neuropathology	The study of diseased nervous system tissue, usually conducted by small surgical biopsies or brain autopsy.
Neuropathy	Damage to nerves of the peripheral nervous system.
Neuropeptides	Any of several types of molecules found in brain tissue, composed of short chains of amino acids including endorphins and vasopressin.
Neuroradiology	The branch of radiology concerned with diagnosing diseases of the nervous system.
Neurosurgery	Any surgery involving the brain, spinal cord or peripheral nerves.
Neutrophils	White blood cells with cytoplasmic granules that consume harmful bacteria, fungi and other foreign materials.
Nifedipine	A medicine used to lower hypertension and treat angina (chest pain).
Non-convulsive / non-fitting Status Epilepticus	A series of rapidly repeating seizures without convulsive motor activity. Consciousness is not regained between seizures.
Non-pulsatile	The term 'pulsatile' indicates a state of rhythmic pulsation e.g. the heart beat. A non-pulsatile wave form implies interruption to the expected rhythm pattern.
Norepinephrine	Also called noradrenaline it is a molecule with multiple roles including those of hormone and a neurotransmitter.
Normotensive	Of or relating to normal values of blood pressure.
Nuclei	The control centre of a cell containing the cell's chromosomal DNA.
Nucleolysis	The process by which the nucleus of a displaced intervertebral disc is dissolved by disease.
Nutrison	A nutritional supplement containing protein, carbohydrates, fats, vitamins & minerals which provides 750 kilocalories per 500 mls.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Obstetrics	The branch of medicine concerned with pregnancy and childbirth, including the study of the physiologic and pathologic function of the female reproductive tract & the care of the mother and foetus throughout pregnancy, childbirth and the recuperative period following delivery.
Obstructive uropathy	A condition in which the flow of urine is blocked, causing it to back up and injure one or both kidneys.
Occipital horn syndrome	A deficiency in copper excretion causing skeletal deformity.
Occipital lobe	The visual processing centres situated at the back of the cerebral hemispheres of the brain.
Oedema or Oedematous	The excessive accumulation of serous fluid in the intercellular spaces of tissue.
Oliguria	A significant reduction from normal in the volume of urine passed.
Ondanestron	An antiemetic for the treatment of nausea and vomiting.
Opioid	A psychoactive chemical that works by binding to opioid receptors providing pain relief.
Orchidopexy	A surgical procedure to move an undescended testicle into the scrotum and permanently fix it there.
Organelle	A specialised part of a cell with a specific function and usually separately enclosed within its own lipid bilayer.
Organic acid	An acid containing one or more carbon atoms.
Organic aciduria	Excessive excretion of one or more organic acids in the urine.
Ornithine transcarbamylase (OTC) deficiency	A rare metabolic urea-cycle disorder. The urea cycle is a series of five liver enzymes that rid the body of ammonia. When one of these enzymes is missing or deficient, ammonia accumulates in the blood and travels to the brain, causing coma, brain damage and death.
Osmolality	A measure of the osmoles (the number of moles of a chemical compound that contribute to a solution's osmotic pressure) of solute per kilogram of solvent (osmol/kg or Osm/kg).
Osmolarity	Osmolarity is an estimation of the osmolar concentration of plasma and is proportional to the number of particles per litre of solution; it is expressed as mmol/L.
Osmosis	The passage of water molecules through a semi-permeable membrane such as a cell wall. This occurs when one fluid contains fewer molecules of dissolved solids than the other.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Osmotic disequilibrium syndrome	Where the osmotic equilibrium normally present between two fluid compartments is no longer present.
Osmotic fluid shift	The movement of water across a semi permeable membrane which has the result of tending to equalise the osmotic pressure across the membrane.
Osmotic myelinolysis	A neurological disease caused by severe damage to the myelin sheath of nerve cells in the brainstem.
Osmotic oedema	Oedema caused through osmosis.
Otic	Of or relating to, or located near to, the ear.
Oxidative	Alternative term for redox- which describes all chemical reactions in which atoms have their oxidation state changed.
Oxygen saturation	Oxygen is carried in the blood bound to haemoglobin. If all the available haemoglobin is attached to oxygen then that represents 100% saturation. If the patient is deprived of oxygen so that blood mixes with arterial blood, then the saturation will fall. Saturation is normally above 95% and offers a guide to the adequacy of a patient's oxygenation.
Oxygenation	Saturation with oxygen.
Pancreatitis	Inflammation of the pancreas.
Papilloedema	Swelling of the optic disc due to raised intra-cranial pressure.
Paraventricular	Alongside a ventricle..
Paravertebral plexus	A network of nerves creating a nerve trunk travelling along the length of the vertebral column.
Parenchymal	The bulk of a substance.
Parenteral	Taken into the body or administered in a manner other than through the digestive tract eg intravenous or intramuscular injection.
Parietal	Anything pertaining to the wall of a cavity.
Pathogenesis	The mechanism by which a disease is caused.
Pathology	The science of the causation and effect of disease.
Pathophysiology	The physiological processes associated with disease or injury.
PCO2	An abbreviation for the partial pressure of carbon dioxide. It is commonly measured in blood to determine the adequacy of respiration.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Peduncle	A stem, through which a mass of tissue is attached to a body eg cerebral peduncles.
Peptides	Short polymers of amino acid monomers linked by peptide bonds. They are distinguished from proteins on the basis of size, typically containing less than 50 monomer units.
Percutaneous nephrolithotomy	A surgical procedure to remove stones from the kidney by way of a small puncture incision.
Perfusion	The transfer of fluid through a tissue eg blood through a kidney.
Peribronchial thickening	The build-up of excess fluid or mucus in the small airway passages of the lung causing localized lung collapse.
Perinatal	The period immediately before and after birth.
Peripheral perfusion	The amount of blood circulating in small arteries, arterioles and capillaries. If the circulation is placed under stress and insufficient blood is pumped then these small blood vessels close down in order to preserve blood supply to vital organs.
Perirenal fat	A structure between the renal fascia and renal capsule of the kidney.
Perisylvian Syndrome	An extremely rare neurological disorder characterized by partial paralysis of muscles on both sides of the face, tongue, jaws and throat giving rise to difficulties in speaking, swallowing and/or epilepsy.
Peritoneal dialysis	Dialysis is an intervention whereby surplus fluid and waste in the blood is removed, should the kidneys be unable to perform this task.
Peritoneal dialysis catheter	A plastic tube inserted through skin and muscle into the peritoneal cavity. Dialysis takes place through this catheter.
Peritoneal dialysis cyclor PAC-X	A machine which automatically performs the cycles of peritoneal dialysis allowing patients to undergo treatment overnight and so reducing interference with daytime activity.
Peritonitis	Inflammation of the peritoneum.
Periumbilical	Located near the central area of the abdomen
Perivascular	The periphery of the circulatory system and typically the blood vessels.
pH	A measure of the acidity or basicity of an aqueous solution. Pure water is said to be neutral, with a pH close to 7.0 at 25 °C (77 °F). Solutions with a pH less than 7 are said to be acidic and solutions with a pH greater than 7 are basic or alkaline. Blood pH is a guide to cell functioning.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Phenotype	An individual's characteristics as determined by the interaction between his genotype and the environment.
Phenytoin sodium	A commonly used antiepileptic.
Phonology	The discipline of linguistics concerned with speaking.
Physiological	Pertaining to the normal functioning of an organ as governed by the interaction between its physical and chemical conditions.
Pial	Of or relating to the pia mater or pia, the delicate innermost layer of the meninges (the membranes surrounding the brain & spinal cord).
Plantar reflex	A reflex elicited when the sole of the foot is stimulated with a blunt instrument. Whilst normally a downward response, an upward movement may indicate disease of the brain or spinal cord.
Pneumonic	Pertaining to pneumonia, an infection of the lung.
Pneumothorax	Each lung is coated with a membrane (pleura) which is continuous over the inner surface of the chest (thorax). As the lungs expand & contract with breathing, the two layers of the pleura slide over each other and there is no real space between them. If the lung is punctured air enters this potential space and because it is under pressure, the lung under it collapses. This is termed pneumothorax (<i>'air in the chest cavity'</i>).
Polyuria/Polyuric	The production of an excessive amount of urine as seen with chronic renal failure, diabetes mellitus or diabetes insipidus.
Pons in toto	A portion of the hindbrain connecting the cerebral cortex to the medulla oblongata. It also serves as a communications and coordination centre between the two hemispheres of the brain.
Post-mortem	An examination of the dead body to determine the cause of death.
Posterior cranial fossa	A part of the intracranial cavity, located between the foramen magnum and tentorium cerebelli containing the brainstem and cerebellum.
Posterior reversible encephalopathy syndrome (PRES)	A syndrome characterised by headache, confusion, seizures and visual loss. It may occur in consequence of a number of causes.
Postictal Acute Encephalopathy	A sudden degenerative disease of the brain which appears post-seizure.
Post-ictal	Following a seizure
Prednisone (prednisolone)	A potent steroid medication given by mouth for its anti-inflammatory and/or immunosuppressive properties. The intravenous version is methylprednisolone.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Prodrome	An early symptom (or set of symptoms) which might indicate the onset of a specific disease before more definite symptoms occur.
Prolene	A synthetic suture used for skin closure and general soft tissue approximation and ligation.
Prophylactic	Any medical or public health procedure undertaken to prevent, rather than treat a disease.
Protease	Any enzyme that conducts proteolysis ie the protein catabolism by hydrolysis of the peptide bonds linking amino acids together in the chain of the protein.
Proteinuria	The presence of excessive amounts of protein in the urine.
Pseudolaminar necrosis	The uncontrolled death of cells in the cerebral cortex of the brain. It is seen in the context of cerebral hypoxic-ischemic insults e.g. strokes.
Pulmonary	Of, relating to, or affecting the lungs.
Pulmonary interstitial Oedema	An oedema caused when the capacity of the lymphatics to drain the interstitial fluid is exceeded.
Pulmonary oedema	The presence of excessive fluid within the lung tissue.
Purkinje cells	A class of neurons located in the cerebellar cortex.
Pyelogram	A procedure for obtaining x-ray images of the urinary tract. A radio-opaque medium is injected into a vein and when excreted by the kidneys it shows on x-rays. Any abnormality in the structure or foreign body is outlined by the dye.
Pyknosis	The irreversible condensation of the nucleus of a cell undergoing necrosis
Pyloric stenosis	A narrowing of the passage between the stomach and the small intestine. The condition affecting infants during the first weeks of life can be surgically corrected.
Pyrexia (or fever)	A fever characterised by an elevation of temperature above the normal range of 36.5–37.5°C.
Pyruvic acid	An organic acid having an important role in several metabolic pathways.
Radial artery	The artery that arises from the brachial artery at the level of the neck of the radius. It is felt in the wrist as ‘the pulse.’
Radiology	A medical specialty employing the use of imaging to both diagnose and treat disease.
Raised intracranial pressure	See cerebral oedema

GLOSSARY OF MEDICAL TERMS

Term	Definition
Rarefaction	The reduction of a medium's density or the opposite of compression.
Rebound	A reverse response occurring upon withdrawal of a stimulus.
Rebound tenderness	A clinical sign detectable upon physical examination of the abdomen. It refers to pain upon <i>removal</i> of pressure rather than the <i>application</i> of pressure to the abdomen.
Recannalise	The process of restoring flow to or reuniting an interrupted bodily tube e.g. an artery.
Red blood cells (erythrocytes)	Bi-concave non-nucleated cells containing the red pigment haemoglobin which carries oxygen and carbon dioxide between the lungs and the body tissues.
Red cell distribution width (RDW)	A measure of the variation in size of red blood cells.
Rehydration	The process of restoring water balance to the body tissues and fluids. Rehydration can be by oral intake or by the intravenous infusion of fluids.
Renal	Relating to the kidney.
Renal & extra renal losses	Fluid leaving the body as urine is renal loss and all other losses (sweat, vapour in breath, fluid in faeces etc) are extrarenal.
Renal arteries	The vessels which emerge from the aorta to supply blood to the kidneys. Sometimes there is more than one such artery leading to each kidney.
Renal dysplasia	See dysplastic kidneys
Renal tubule	See acute tubular necrosis.
Reperfusion	Damage to tissue caused when blood supply returns to tissue after a period of ischemia or lack of oxygen. The absence of oxygen and nutrients from blood during the ischemic period creates a condition whereby the restoration of circulation results in inflammation and oxidative damage.
Replacement rate (for IV fluids)	In the calculation of intravenous fluid rates it is usual to replace abnormal losses already experienced, for example by vomiting; to allow for the normal fluids required by the body and to make up for continuing abnormal losses, for example by diarrhoea. These are respectively, replacement, maintenance and continuing losses.
Respiratory arrest	The cessation of breathing.
Respiratory pressure waves	The component of a pulsatile pressure wave provoked by the lungs expanding and contracting.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Respiratory rate	The rate at which air passes into and out of the lungs. This occurs 18 times a minute in a healthy adult at rest.
Resuscitation	Methods of revival for a patient in cardiac or respiratory failure.
Reticular formation	That part of the brain concerned with the waking/sleeping cycle and the filtering of incoming stimuli.
Retromandibular vein	A vein formed by the union of the superficial temporal and maxillary veins which descends in the substance of the parotid gland beneath the facial nerve.
Reye's syndrome	A metabolic disorder principally affecting the liver and brain, marked by the rapid development of life-threatening neurological symptoms.
Right & left fundi	A fundus (pleural fundi) usually refers the interior surface of the eye opposite the lens and includes the retina and optic disc. It can be viewed through an ophthalmoscope.
Rotavirus	A genus of viruses of the family Reoviridae having a wheel-like appearance and causing acute infantile gastroenteritis and diarrhoea.
Routes of Medication	The method by which medication is administered to a patient eg <i>Topical</i> where a substance is applied to a localized area of the body, <i>Oral</i> being through the mouth or <i>Per Rectum</i> , through the rectum.
Salaam attacks (or infantile spasms)	A rare type of epilepsy usually starting in the first eight months of life.
Schwartz formula	A method of calculating glomerular filtration rate (see above) in a child with reference to blood levels of creatinine and height.
Sclerosis	A hardening of tissue or other anatomical features.
Scoliosis	A condition in which there is curvature of the spine.
Scrub nurse	An operating theatre nurse who has access to the instruments and the exposed parts of the body ('the operative field'). Accordingly and in order to be sterile, they 'scrub' their hands and arms prior to surgery, wear a sterile gown and gloves and are masked. They may not touch any unsterile area during the procedure.
Sentinel Event	Any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient which is unrelated to the natural course of illness.
Sepsis	A bacterial infection in the bloodstream or body tissues.
Septicaemia	A systemic disease caused by the multiplication of microorganisms in the blood. Also called blood poisoning or septic fever.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Serology	The scientific study of blood serum and other bodily fluids. Used in practice to refer to the diagnostic identification of antibodies in the serum.
Sickle cell disease	A group of inherited blood disorders characterized by chronic anaemia, acute episodes of limb or joint pain and occurring with complications due to associated organ and tissue damage.
Sodium chloride 0.18% / dextrose 4%	A solution for IV use containing 30 mmol/litre of sodium and chloride or one-fifth of the concentration in 'natural body fluids' such as blood.
Sodium measurement (mmol/litre)	The concentration of sodium in solution is expressed as the number of milliosmoles in each litre (mOsmol/L). An osmole is a unit used to define chemicals which can contribute to osmosis and represents the number of osmotically active particles which, when dissolved in 22.4 L of solvent at 0 degrees Centigrade, exert an osmotic pressure of 1 atmosphere. A milliosmole is 1/1000 of an osmole.
Sodium thiopentone (STP)	A rapid-onset short-acting drug used to induce general anaesthesia.
Sodium valproate	An anti-convulsive drug.
Sphenopalatine artery	An artery of the head.
Status epilepticus	Repeated epileptic fits without return to consciousness in between. Breathing stops between each fit and the body is deprived of oxygen causing damage to the brain.
Stenosis	An abnormal narrowing in a blood vessel or other tubular organ or structure.
Stereomicroscope	An optical microscope, often referred to as the "light microscope" to magnify small samples.
Sternomastoid	A paired muscle in the superficial layers of the anterior portion of the neck. It acts to flex and rotate the head.
STP	Abbreviation of sodium thiopentone, a drug used to induce anaesthesia intravenously. Also an acronym for Standard Temperature & Pressure.
Striatum	A subcortical part of the forebrain.
Stroke	The sudden and localised death of brain cells due to inadequate blood flow.
Subacute	A description applied to a disease, the duration of which persists between the acute and chronic.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Subarachnoid	The space within the brain between the arachnoid membrane and the pia mater (the delicate innermost layer of the meninges).
Subclavian	The area beneath the clavicle (collar bone).
Subclinical	Without clinical presentation
Subcutaneous	Any part of the body found beneath the skin.
Sub-dural empyema	An intracranial focal collection of purulent material located between the dura mater and the arachnoid mater
Subependymal zone	The cell layer surrounding the lateral ventricles in the brain.
Subpial	Within the space of the brain that separates the pia from the underlying neural tissue.
Subventricular	A paired brain structure situated throughout the lateral walls of the lateral ventricles of the brain.
Sulci	Depressions or fissures in the surface of an organ, especially the brain.
Superior sagittal sinus	A space located within the head along the attached margin of falx cerebri. It allows blood to drain from the lateral aspects of anterior cerebral hemispheres to the confluence of sinuses.
Supraorbital	The region immediately above the eye sockets.
Suprapubic	Relates to the abdomen in its lower part, immediately above the pubic bones.
Suprapubic catheter	See Catheter
Surgical cut-down	A minor surgical procedure whereby a small incision is made in the skin and the underlying tissues are separated so as to expose a blood vessel and so enable the insertion of a cannula into the vessel.
Synapse	A junctional structure in the nervous system that permits a neuron to pass an electrical or chemical signal to another cell.
Syncope	A short loss of consciousness caused by a temporary lack of oxygen in the brain.
Syncytium	A multinucleate cell which can result from multiple cell fusions of uninuclear cells (i.e. cells with a single nucleus).

GLOSSARY OF MEDICAL TERMS

Term	Definition
Syndrome of inappropriate antidiuretic hormone secretion (SIADH)	The Antidiuretic hormone (ADH) is produced by the pituitary gland and has the effect of inhibiting urine production and causing water retention. It is released in response to a range of stimuli including damage to the brain, lung disease, individual drugs, surgery, trauma and in relation to certain glandular disorders. The effect of a SIADH is retention of fluid leading to falls in blood osmolality and blood sodium levels relative to the amount of water present. This will result in dilutional hyponatraemia.
Syntax	The study of the principles and rules for constructing phrases and sentences in natural languages. The term <i>syntax</i> is also used to refer directly to the rules and principles that govern the sentence structure of language.
Tachypnoea	Rapid breathing.
Temporal	Referring or relating to the muscles, bone or blood vessels around the temple.
Tentorium	The internal framework of supporting tissue within the skull formed by ingrowths of the exoskeleton.
Tetraplegic	Paralysis of all four limbs, also known as quadriplegic.
Thalamus	One of two masses of grey matter (brain cells or neurons) lying on either side of the third ventricle of the brain. Important for sensory impulses.
Theatre runner	See Circulating Nurse.
Thoracic	Relating to the chest.
Thromboembolism	A clot in the blood that blocks a blood vessel.
Thrombosis	The formation of a blood clot within the vessels or heart.
Titre	The concentration of a substance in a solution or the strength of such a substance determined by titration.
Tonic	Characterised by continuous tension or contraction of muscles, as a convulsion or spasm.
Tonsillectomy	The surgical removal of the tonsils.
Torsion	Where a cord or vessel twists thereby cutting off blood supply to a particular area of the body.
Toxicology	The scientific study of poisons, their detection, effects and methods of counteraction.
Toxin	A poison, especially a protein or conjugated protein produced by certain animals, higher plants and pathogenic bacteria.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Trachea	The medical term for 'windpipe'.
Transducer	Any part of the body which converts one form of energy into another.
Transuretero-ureterostomy	A ureterostomy is a surgical operation in which the ureter is brought to the body surface to drain, often because of an obstruction in its lower part or in the bladder. If the operation is performed through an endoscope passed through the urethra and bladder into the ureter it is a transureteric operation.
Trigeminal nerve (the fifth cranial nerve)	A nerve containing both sensory and motor fibres. It is responsible for sensation in the face and certain motor functions such as biting, chewing and swallowing.
Tympanometry	An examination used to test the condition of the middle ear and the mobility of the eardrum and/or the conduction bones by creating variations of air pressure in the ear canal.
Uncal	Pertaining to the uncus, being the hook-like anterior end of the hippocampal gyrus on the temporal lobe of the brain.
Upper respiratory infection	Any infection of the upper respiratory tract.
Upregulation	The increase of a cellular component.
Uraemia	The illness accompanying kidney failure (also called renal failure), confirmed by an increase in blood urea, a nitrogenous waste product associated with the failure of this organ.
Urea	A crystalline substance of the chemical formula $\text{CO}(\text{NH}_2)_2$, derived from protein. It is the chief waste product discharged from the body in the urine.
Urea cycle defect	A disorder caused by a deficiency of one of the enzymes in the urea cycle responsible for removing ammonia from the blood stream.
Ureteric catheter	See Catheter
Ureteric stents	A semi rigid hollow tube which can be placed in a hollow organ, such as the ureter so as to bypass or prevent obstruction.
Ureterostomy	The creation of a stoma (a new, artificial outlet) for a ureter or kidney. The procedure is performed to divert the flow of urine away from the bladder when the bladder is absent or not functioning.
Ureters	The tubes which carry urine from the kidneys to the bladder.
Urethral catheter	See Catheter
Urethral valve	An obstructing membrane in the posterior male urethra occurring as an abnormality in development.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Urinalysis	A contraction of urine analysis, or tests for pH (acidity) or the presence of protein, sugar or ketones.
Urinary tract	The passage from the pelvis of the kidney through the ureters, bladder and urethra to the external urinary opening.
Urinary tract infection (UTI)	An infection of one or more structures in the urinary system.
Uropathy	A disease of the urinary system.
Vacuolation	A small cavity in the cytoplasm of a cell, bound by a single membrane and containing water, food, or metabolic waste.
Valium	See 'diazepam'.
Vancomycin	An antibiotic infused intravenously in the treatment of serious infections.
Varicella	A highly infectious viral disease, known commonly as chickenpox.
Vascular	Relating to the blood vessels.
Vascular anastomosis	Connecting two blood vessels (or the cut ends of one vessel) together.
Vasoconstriction	The narrowing of the blood vessels resulting from contraction of the muscular wall of the vessels.
Vasodilation	The widening of blood vessels resulting from relaxation of smooth muscle cells within the vessel walls.
Vasopressin	A hormone secreted by the posterior lobe of the pituitary gland that acts to constrict blood vessels and raise blood pressure. It reduces the excretion of urine and is also called antidiuretic hormone.
Vena cava (pl. venae cavae)	Two large vessels which open into the right atrium of the heart and return venous blood from the whole body (except the lungs). That which drains vessels from the head, neck and upper limbs is called the superior vena cava and that draining from the trunk and lower limbs is the inferior vena cava.
Venous blood	The blood found in the veins.
Venous sinus	A large vein or channel for the circulation of venous blood.
Ventilation	A procedure, usually carried out in an intensive care unit, by which a device called a 'ventilator' takes over a patient's breathing.
Ventilatory support	Breathing assistance to enable sufficient air entry into their lungs, commonly achieved by the use of a mechanical ventilator delivering oxygen and air through an endotracheal tube.

GLOSSARY OF MEDICAL TERMS

Term	Definition
Ventricle	The pumping chambers of the heart.
Ventricular system	A set of structures containing cerebrospinal fluid in the brain. It is continuous with the central canal of the spinal cord.
Vesicoureteral reflux	An abnormal movement of urine from the bladder into ureters or kidneys.
Vessel occlusion	A blockage in a blood vessel usually with a clot. An occluded vessel creates eddies in the normally laminar flow of blood currents.
Virology	The study of viruses and viral diseases.
Viscosity	A measure of the resistance of a fluid deformed by either shear or tensile stress, but commonly and for fluids only, viscosity is descriptive of "thickness" or "internal friction".
Vitreous humour	The clear gel that fills the space between the lens and the retina of the eyeball.
Voltarol (diclofenac)	A proprietary brand of non-steroidal anti-inflammatory drug taken to reduce inflammation and as an analgesic to reduce pain.
White blood cells (leucocytes)	The cells within the blood which contain no haemoglobin and are therefore colourless. They are important in the prevention and response to infection.
White cell count (WCC)	A blood test which determines the number of white blood cells in a blood sample.
Zeroing	A monitor such as that measuring central venous pressure (CVP) is conventionally operated so that zero represents the level of the right atrium, the chamber into which the venae cavae return blood. Should that level change, for example if the bed or trolley on which the patient lies is raised or lowered, then the device has to be adjusted or rezeroed to maintain the zero point.

INQUIRY COSTS

Area of Expenditure	Total
Inquiry Legal Team	4,718,361
Inquiry Administration	1,993,385
Families Legal Costs	2,558,596
Oral Hearing ICT Costs	1,066,689
Accommodation	1,674,702
Other Costs	1,802,835
Total	13,814,568¹

¹ These figures include estimates to the end of December 2017. There will be further expenditure by the Inquiry after publication to include winding up costs and placing the Inquiry record with the Public Records Office of Northern Ireland.

INDEPENDENT NEUROLOGY INQUIRY

Report
June 2022

Volume 1

www.neurologyinquiry.org.uk

Independent Neurology Inquiry

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The Independent Neurology Inquiry

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THE INQUIRY TEAM

Chairman of the Inquiry

Mr Brett Lockhart QC was called to the Bar of Northern Ireland in 1982 and to the Inner Bar in 2006. He is a commercial lawyer with extensive experience of working for leading Northern Ireland companies and public bodies and has widespread experience as a commercial mediator. He is also a designated arbitrator for the Motor Insurers Bureau. Actively involved in education, he is a former Chairman of the Board of Governors at Methodist College Belfast and was a member of the Board of De La Salle College Belfast.

Inquiry Co-Panellist

Professor Hugo Mascie-Taylor was trained as a Consultant Physician and is a revalidated medical practitioner. He has worked at local, regional, national, and international levels, as a provider, a commissioner, and a regulator. He was Medical Director of a large teaching Trust, of the NHS Confederation, of Monitor (NHS national regulator) and Ernst Young. He was appointed by the Secretary of State as Trust Special Administrator in Mid Staffordshire, and by the Deputy Premier in Western Australia to chair the Independent Oversight Committee. He has carried out clinical governance reviews in several organisations and systems across the World.

Counsel to the Inquiry (from 2020 to 2021)

Christine Smith QC was called to the Bar of Northern Ireland in 1985 and to the Inner Bar in 2011. From 2012 to 2017 she acted as Senior Counsel to the Inquiry into Historical Institutional Abuse and was also Senior Counsel for the Department of Finance in the Inquiry into the RHI scheme in Northern Ireland. She was a Commissioner of the Criminal Cases Review Commission and stepped down from her role as Counsel to the Inquiry to commence her current role as Chair of the Urology Services Inquiry in March 2021.

Solicitor to the Inquiry

Mr Mark Scott qualified as a Solicitor in 2010 and as a solicitor advocate in 2014. He has experience in the areas of clinical negligence, governance and regulatory law and health and social care law.

Secretary to the Inquiry

Ms Quinn is a qualified auditor and senior civil servant. She has been a member of the Northern Ireland Civil Service since 1987, having served in a wide range of posts across three government departments.

Legal team

The Inquiry legal team comprised:

- Mr Andrew Beech BL
- Ms Laura Curran BL
- Ms Emma McIlveen BL and
- Dr Leah Treanor BL

Secretariat Staff

The Secretariat team comprised:

- Mr William Jordan
- Mr Stephen Magee
- Miss Victoria Mullan
- Ms Stephanie McGall
- Mrs Rose McShane

The Inquiry Panel wish to convey its thanks to the Northern Ireland Assembly Hansard team for provision of transcription services, during the period while the Assembly was dissolved, Gwen Malone Stenography Services, in particular Mrs JoAnne McAlister, and Mrs Rosemary Tollerton for secretarial services.

INTRODUCTION

The events, which led to Northern Ireland's largest ever patient recall caused, and continue to cause, significant public consternation. This consternation is most acutely felt by the patients and families of those who had their diagnosis and treatment reviewed. The recall involved patients who had been under the care of Dr Michael Watt, formerly a Consultant Neurologist employed by the Belfast Trust. When the outcomes of the patient recall were subsequently published they revealed that a considerable number of patients had been misdiagnosed and/or mistreated.

The announcement of the Inquiry:

The announcement of the recall process was followed shortly afterwards on 10th May 2018 by the announcement by Mr Richard Pengelly, then Permanent Secretary at the Department of Health, of a non-statutory public inquiry. The decision to hold a public inquiry of this type was driven by the fact that the Northern Ireland Assembly was at that time suspended and there was no Health Minister in place. The Inquiry was subsequently converted to a statutory public inquiry by the Minister of Health, Robin Swann MLA, on 11th of December 2020.

The Terms of Reference:

The Terms of Reference are enclosed at appendix A. In essence, the Inquiry was tasked with assessing the extent to which it was known or should have been known prior to November 2016 that there was a problem or potential problem with Dr Watt's practice. The Inquiry was to determine whether the Belfast Trust should have instigated an earlier and more thorough investigation arising out of complaints, concerns or related circumstances which existed prior to November 2016. November 2016 was a significant date because in that month a GP contacted the Belfast Trust identifying concerns about Dr Watt's practice.

The Inquiry was also tasked with reviewing the role of extant governance processes which were in place to maintain standards of professional practice. Appraisal was specifically identified as requiring review and the Inquiry also considered it appropriate to look at the related processes of revalidation. These processes are explained and commented upon in the relevant chapter of in the report.

The Inquiry had to establish what ‘related concerns and circumstances’ existed prior to November 2016. As the evidence to the Inquiry developed, it became clear that work performed by Dr Watt outside the Belfast Trust in the independent sector, regulatory investigation by the General Medical Council, the use of epidural blood patching, and his prescribing of particular treatments were all circumstances that required consideration.

The Inquiry was also to evaluate the corporate governance in the period from November 2016 up to the announcement of the recall in May 2018. The decisions taken in this period included issues relating to restrictions placed on Dr Watt’s practice, investigations into his practice, communicating with other relevant bodies within the healthcare system, and ensuring the ongoing care and treatment of Dr Watt’s patients.

Dr Michael Watt:

The Terms of Reference and, in particular, the preamble, make it clear that the clinical practice of Dr Michael Watt was being investigated by the General Medical Council (GMC) and by his then employer, the Belfast Trust¹. The preamble explained that the Inquiry “*would consider the role of the Belfast Trust as an employer in terms of professional practice in the context of the Trust’s system of governance*”.

Great care was taken to explain to witnesses that it was not the role of the Inquiry to investigate Dr Watt’s clinical practice. Despite such explanation the Inquiry often had to manage public expectations of its role. Expectations only increased when it became apparent that an application for voluntary erasure by Dr Watt was acceded to by a Medical Practitioner’s Tribunal in 2021. That decision was the subject of a judicial review which was due to be heard in the High Court at the time of this report going to print.

The Inquiry engaged with Dr Watt’s lawyers at various times and documentation was obtained which was of assistance. Further, in March 2021, the Inquiry issued a Notice under the Inquiries Act 2005, directing Dr Watt’s attendance. In response to the Notice, the Inquiry received a detailed medical report advising that Dr Watt was not fit to give evidence. After obtaining a number of further medical reports, the Inquiry reluctantly accepted that Dr Watt would be unable to engage with its work². The Inquiry was still satisfied that it could fulfil its Terms of Reference as the focus was on the relevant governance arrangements. The Inquiry was able to rely on various documents that it had obtained including a transcript of an interview given by Dr Watt as part of an investigation under the Maintaining High Professional Standards framework.

¹ The details in respect of the related reviews and investigations that arose out of the same circumstances as the Inquiry are set out at pages 4-7 of the Guide to the Inquiry Questionnaire. See Appendix E.

² The detailed steps taken by the Inquiry in an attempt receive evidence from Dr Watt are set out in a letter of 11th October 2021 sent by the Inquiry Chairman to a number of patients who were concerned about Dr Watt not giving evidence. See Appendix F.

The work of the Independent Neurology Inquiry:

The Inquiry began its work by identifying organisations that may have held relevant documentary evidence. This included the Belfast Trust, as Dr Watt's employer and also the independent sector organisations where he worked, namely the Ulster Independent Clinic, Hillsborough Private Clinic and Orthoderm. Collating the documentary and oral evidence proved to be an evolutionary process which included other organisations beyond those referred to previously. This included other health trusts in Northern Ireland, the General Medical Council, the Regulations and Quality Improvement Authority, the Health and Social Care Board³, National Clinical Assessment Service⁴ and the Northern Ireland Department of Health.

In addition to obtaining relevant documents the Inquiry also identified individuals who could provide oral evidence. This included those who worked in neurology such as the consultants, registrars and nurses along with those who were responsible for managing and governing the healthcare system of which neurology was a part. Relevant individuals from the various organisations, including those referenced above, were identified as the Inquiry progressed.

The Inquiry held its first oral evidence session on 5th September 2018. In total the Inquiry held 214 oral evidence sessions and received in excess of 147,000 pages of documentary evidence. The total cost of the Inquiry is £3.2million⁵.

The standard of proof applied has been the normal civil standard. As appropriate with any non-statutory Inquiry, the evidence obtained was unsworn. By the time that the Inquiry was converted into a public Inquiry it would have been highly problematic to alter the existing methodology given the stage the Inquiry had reached⁶.

The Involvement of Patients:

From the outset the Inquiry has focused on the importance of the patient voices. A questionnaire was devised for patients and their families in consultation with patient bodies and political representatives. The questionnaire was launched on 8th October 2018 and 240 responses were received. All responses were reviewed. Some contained information which was highly relevant to the Inquiry and others contained information that related to the work

3 The Health and Social Care Board was dissolved on 1st April 2022 and its functions transferred to other bodies as per the terms of Section 1 of the Health and Social Care Act (Northern Ireland) 2022.

4 Previously known as NCAS and now renamed Practitioner Performance Advice.

5 This includes projected in-year costs along with costs associated with the winding up of the Inquiry.

6 The Inquiry Chairman issued a public statement on 11 January 2021 setting out the significance of the Inquiry being converted from non-statutory to statutory. See Appendix B.

of other organisations. Questionnaires were shared with the GMC on 110 occasions, with the Belfast Trust on 110 occasions, with the RQIA on 5 occasions and with other bodies/Trusts on 5 occasions. 35 patients gave oral testimony to the Inquiry and this is explained and elaborated on in the patient chapter. The evidence provided considerable assistance to the Inquiry Panel in understanding the context and identifying lines of enquiry.

Updating Politicians:

The Inquiry recognised the importance of keeping political representatives apprised of progress. As the Northern Ireland Assembly was suspended the Inquiry Panel met with local politicians who had a responsibility for health care within their parties on 5 separate occasions.⁷ Following the restoration of the Assembly, the Inquiry Panel met with members of the Health Committee in July and October 2020. At all times the aim has been to communicate effectively with political representatives as to the work and progress of the Inquiry. It is important, however, to stress, that the Inquiry was able to carry out its work independently and was not subject to interference in its work from any politician or government department.

Maxwellisation:

In accordance with its legal obligations, the Inquiry also ensured that prior to the publication of this report individuals and organisations who were subject to express and significant criticism had the opportunity for comment. The Inquiry took time to carefully consider the comments that were received before finalising this report.

Ordering of the Report:

To make the report as easy to read as possible the approach has broadly been to structure the report around particular issues that became increasingly more relevant as the Inquiry progressed. The chapters start with an explanation of their context and how they fit within the Terms of Reference. In many instances there is overlap between the chapters and particular incidents or events are detailed or referenced multiple times. Where such events or incidents give rise to criticism of individuals or organisations, the repeating of any criticisms in multiple chapters should not be interpreted as increasing the level of criticism. Three specific chapters address periods of time where the Inquiry Panel has concluded that there were missed opportunities to have earlier or more thorough investigations into Dr Watt's practice.

⁷ 27th June 2018; 27th September 2018; 22nd January 2019; 29th May 2019; and 20th November 2019.

Previous Reviews into the Health and Social Care System in Northern Ireland:

A review of any health trust in Northern Ireland and its governance is by definition a challenging assignment. The Inquiry was immediately conscious of other relevant reports which have been commissioned by the Department of Health or Health Ministers and was at pains to reflect upon these before commencing its work. In a report commissioned by the then Minister for Health, Edwin Poots, MLA by Sir Liam Donaldson entitled *“The Right place, The Right Time”* and published in December 2014, Sir Liam referred to the *“complex interweaving of responsibilities for patient safety amongst the central bodies responsible for the health and social care system in Northern Ireland.”* He concluded:

In the end we believe action is imperative for two reasons. Firstly the present central arrangements are byzantine and confusing; secondly, the overwhelming need is for development of the present system to make it much more successful in bringing about improvement.

On 4th November 2015, the then Minister for Health, Simon Hamilton MLA, announced that in response to recommendation 1 of **The Right Time, The Right Place** report by Sir Liam Donaldson, he would appoint an expert, clinically led panel to consider and lead an informed debate on the best configuration of Health and Social Care services in Northern Ireland. The subsequent Bengoa report was published in October 2016. To the date of going to publication the recommendations of Bengoa remain work in progress and the structural reform of the health and social care system has not taken place as perhaps envisaged. The Inquiry hopes that within the ambit of the Terms of Reference this report can contribute to the evolution of change and ultimately improve patient safety for the benefit of all.

Recommendations:

The Inquiry has identified numerous learning points and sought to make recommendations. The learning points are interwoven in the commentary throughout the various chapters of the report. The recommendations arise from the totality of the evidence and whereas some are a direct response to a particular single issue others attempt to address broader or more diverse matters. The theme that cuts across all the recommendations, whether expressly or implicitly, is the paramountcy of patient safety in all decisions at every level of healthcare organisations.

EXECUTIVE SUMMARY

General Conclusions:

- 1 The systems and processes in place to assure the public in respect of patient safety prior to November 2016 failed. The extent of problems with Dr Michael Watt's practice only began to come to light following a concern being raised with the Belfast Trust by a GP. While one process or system failure may not be critical, the synergistic effect of numerous failures ensured that a problem with an individual doctor's practice was missed for many years and, as this Inquiry finds, opportunities to intervene, particularly in 2006/2007, 2012/2013, and earlier in 2016 were lost.
- 2 Inquiry Panel was asked in the Terms of Reference to determine whether there were complaints, or related concerns and circumstances which should have alerted the Belfast Trust to instigate an earlier and more thorough investigation into the circumstances which led to the recall of patients in May 2018. The Inquiry has concluded that the Trust could and should have intervened earlier but failed to do so.
- 3 The failures identified by this Inquiry Panel are not confined to the Belfast Trust. The Inquiry has concluded that the combined effect of an inadequate investigation into a highly relevant clinical complaint in 2012 by the Regulator (the General Medical Council); the failure to disclose significant complaints by the Ulster Independent Clinic, where Dr Watt had a substantial private practice; alongside failures of other HSC Trusts to identify or communicate concerns, compounded a pre-existing problem in the Belfast Trust. Generally, the inability of the systems then in place to identify a pattern of concern was a conspicuous problem. Information was essentially retained in silos. Communication between different organisations and between management levels within organisations was poor and inadequate.
- 4 The recent response to the global pandemic by the health service, and the esteem in which the caring professions are held by the general public, illustrate just how critical they are to our society. Healthcare professionals deserve to be treated fairly. At the same time, it was universally acknowledged by all witnesses to the Inquiry, that patient safety should be the paramount concern and the standard by which governance and systems are assessed.
- 5 Although not every step taken post November 2016 was correct (especially communicating adequately with patients) the Inquiry Panel believes that the Belfast

Trust got key decisions right after November 2016. The partial restriction of Dr Watt in December 2016 followed by the commissioning of a report into his practice by the Royal College of Physicians¹, the full restriction on his practice in July 2017 and the decision to initiate a large-scale patient recall in May 2018 were appropriate and served to protect patients. Patients will, however, rightly point to the many years when problems that emerged with Dr Watt were not addressed, opportunities were missed and such inaction was to the significant detriment of patients.

The Importance of Patient Voices:

- 6 At the outset of this Inquiry, and throughout its deliberations, the Inquiry Panel was determined to hear the voices of patients, many of whom have been deeply affected by the recall process. It is, therefore, appropriate that the chapter addressing the evidence of patients is the first chapter of this report.
- 7 The Inquiry wishes to gratefully acknowledge the many patients who submitted evidence throughout the duration of the Inquiry. The amplification of patient voices was also assisted by various organisations, such as the MS Society and the Patient Client Council, who were invaluable in helping the Inquiry communicate appropriately and effectively with patients. It is significant that patient evidence continued to be submitted right up until the deadline in August 2021.
- 8 It was the desire to focus on patient safety, which led the Inquiry Panel, at the earliest stage of its hearings, to encourage necessary changes to be implemented immediately and on an ongoing basis, rather than await the publication of a report. This was communicated to relevant organisations when the Inquiry was non-statutory, but the aim remained throughout the course of the Inquiry. Such an approach emerged from the wide experience of the Panel Member, Professor Mascie-Taylor, in medical governance and addressing the hospital crisis in Mid-Staffordshire. The Belfast Trust responded positively, and this report will highlight some of the changes that have already been commenced or implemented².

¹ The Royal College of Physicians report identified significant problems with Dr Watt's practice. It was not the role of the Inquiry to make findings of fact in respect of his clinical practice. Nevertheless, the report provided necessary context for the work of the Inquiry in reviewing the relevant governance systems.

² To assist with investigating complaints the Belfast Trust has now implemented a clinical record review. To protect against the risk of lone working, additional peer review is being incorporated in the Trust through an initiative known as 'Building Effective Teams'. To enable the Medical Director at the Trust to be able to access accurate and useful information on a clinician's practice a live professional governance reporting system has now been put in place.

The Terms of Reference and Dr Watt:

- 9 The Inquiry Terms of Reference did not require it to adjudicate on the medical practice of Dr Watt. His practice was being investigated by the General Medical Council (“GMC”) and employer led processes under Departmental Guidance on “Maintaining High Professional Standards in the Modern HPSS” (“MHPS”).³ Both of those processes came to an end without being able to explore the clinical issues that arose because of the ill health of Dr Watt. Unfortunately, it was not possible for the Independent Neurology Inquiry to fill the gap that emerged. It would, therefore, have been inappropriate for the Inquiry to encroach on the GMC’s remit or employer-led processes referred to in the Terms of Reference.
- 10 This report makes extensive reference to Dr Watt. The Inquiry’s Terms of Reference refer to “*circumstances which led to the recall of patients in May 2018*”. It was clear to the Inquiry that the reference to “*circumstances which led to the recall*” was referring to the practice of Dr Watt. The fact that Dr Watt ultimately was medically unfit to give evidence to the Inquiry was a source of significant and understandable public concern.
- 11 The focus of the Inquiry was properly on systems and governance, the extent to which the extant structures proved effective prior to and after November 2016 and the handling by the Belfast Trust of any previous complaints and concerns. It is, of course, recognised that it would have been preferable to hear directly from Dr Watt. However, the Inquiry did obtain access to the Verita report, which had been commissioned by the Belfast Trust in 2019 as part of the MHPS process. The report contained detailed evidence given by Dr Watt and his response to some of the specific controversies that had emerged, including his use of blood patch procedures. The Inquiry has been able to consider this information and has found that Dr Watt’s comments do assist in understanding the relevant events. The Inquiry has also been able to take evidence from witnesses across the full spectrum of those involved in the matters relevant to the Inquiry’s Terms of Reference at all levels within the Belfast Trust and across the Health and Social Care sector.
- 12 The Inquiry Panel has analysed the information, which was held by the Belfast Trust throughout the period under review. There was sufficient information accessible prior to November 2016 to demonstrate a pattern of potential aberrant practice. Part of this information was collated, but not all. Key information was known to only one or a small number of individuals, who commonly analysed that information in a vacuum and determined that it was a one-off, insufficiently serious, or irrelevant, without the benefit of the broader picture. This resulted in concerns not being

3 Health & Personal Social Services.

escalated, and when they were, not being analysed in their full and proper context. The problems in the Trust systems are illustrated graphically by the fact that it was a General Practitioner and not someone from within the Belfast Trust, who approached the Medical Director's Office in November 2016 with concerns about Dr Watt's practice.

- 13 A compounding problem from as early as 2006 was the development of a narrative around Dr Watt, which influenced many of those who were tasked to consider issues that arose. The perception that Dr Watt's clinical ability was not in question contributed to a consistent conclusion that Dr Watt's problems were essentially administrative. Consequently, when issues with a clinical dimension were raised, they were often prematurely dismissed without adequate investigation or explained in a manner which ended further investigation. This in turn impeded the ability to discern a pattern when subsequent or further issues arose or were identified. The evidence collated revealed that Dr Watt had a history of either failure to comply with or unreasonable delay in providing or undertaking annual appraisals; reports requested by, for instance, the Coroner, the GMC, insurance companies and patients; and responses to complaints. There was a failure to recognise that a disregard for these matters led to, in some cases, real issues for patients. The delays did not result in managers looking past his 'administrative' issue to appropriately consider if the approach was also mirrored in his clinical practice.
- 14 The Inquiry Panel acknowledges that in reviewing the evidence, it has had the benefit of hindsight. Every effort has been made to prevent this reality from engendering any degree of bias, but there will be a concern that the advantage obtained from what some doctors referred to colloquially as "*the retrospectoscope*" produces a clarity that is removed from what could reasonably have been observed at that time. The Inquiry Panel has sought to take the advantage it had into account when making judgements about a situation. It should be borne in mind that those tasked with making decisions about Dr Watt's practice (particularly prior to November 2016) were doing so in real time, unaware of the full extent of the problems that would subsequently come to light, and without the time or specificity given to this Inquiry in completing its work.
- 15 It should also be stated at the outset that the task of the Inquiry was focused on the governance of the Belfast Trust. The Inquiry Panel was not required to carry out a comparative exercise with other Health and Social Care Trusts, either in Northern Ireland or their equivalents in the UK generally. That said, the Inquiry Panel believes that problems observed will not be unique to the Belfast Trust.

16 It is inevitable that the report criticises individuals as well as systems and processes. The Inquiry observed that some of those it criticises have made substantial contributions and worked tirelessly to enhance healthcare and, in recent times, to mitigate the problems which have arisen. As the chapter on November 2016–May 2018 outlines, it was a GP who raised concerns about Dr Watt’s practice directly with the Belfast Trust Medical Director’s Office. These concerns resulted in a partial restriction on clinical practice being imposed in December 2016 and led to investigations over the subsequent months and a full restriction on clinical practice in July 2017. During the period from December 2016 to May 2018 (when the neurology patient recall was announced) a number of critical actions were taken which addressed the concerns which had arisen with Dr Watt’s practice. These included:

- (i) The commissioning of a report in December 2016 from two Northern Ireland based consultant neurologists who were employed in other NHS Trusts, confirmed problems with other aspects of Dr Watt’s practice beyond the diagnosis of SIH.

The spreadsheet devised and drawn up by Dr Thomas Peukert, on his own initiative, which revealed the number of cases where the diagnosis of spontaneous intracranial hypotension (“SIH”) by Dr Watt had not been accepted by Dr Peukert. Dr Peukert was a consultant neurologist in the Belfast Trust who, in December 2016, had been tasked with approving Dr Watt’s treatment of patients diagnosed with SIH.

- (ii) The decision to invite the Royal College of Physicians to carry out a case note review of a sample of Dr Watt’s practice following receipt of the report at (i) above.
- (iii) The full clinical restriction of Dr Watt’s practice in July 2017.

Integrated Governance:

17 On 29th October 2018, Dr Tony Stevens, the former Medical Director of the Belfast Trust, gave evidence to the Inquiry, which, included the following observation:

You cannot subdivide clinical governance, professional governance and corporate governance.

I have always felt that clinical governance was corporate governance for doctors ... I have always believed firmly in the concept of integrated governance, that there was no simple divide between aspects of corporate governance.

- 18 The Inquiry Panel agrees and believes that a failure by a clinician to take seriously administrative and appraisal obligations may be indicative of an attitude which needed to be challenged more robustly at an earlier stage. Proper enforcement of a medical practitioner's administrative and appraisal obligations is a critical component in the relationship between the Trust, as employer, and the consultant as employee. Although it is much easier to view in retrospect, the combination in Dr Watt's case of lone working, consulting with perhaps the highest number of neurology patients, and persistent administrative failure should also have given rise to questions about the oversight of Dr Watt's clinical practice.

Medical Culture & Medical Managers:

- 19 At the heart of the problems identified in this report was a medical culture, which had not yet come to terms with a managed system. The Inquiry Panel heard from a wide range of witnesses, and it was apparent that the commitment of doctors and other health professionals to their patients is, by any standard, impressive. Medical professionals were, however, apprehensive in raising a concern about the practice of a colleague or querying discrepancies that arose, which did not directly touch upon the welfare of their own patient. It was clear that senior managers were too often reluctant to manage doctors and were easily deflected by the raising of any clinical dimension to an issue of concern. Correspondingly, many doctors who took on a management role were accustomed to operating collegially and consensually and found the responsibilities of management did not easily fit into that extant culture.
- 20 Evidence reveals that clinical directors are expected to fulfil a significant management role at the same time as practising as a doctor. The posts are taken up by busy clinicians, who are given limited hours to carry out the role. The Inquiry Panel's assessment of the evidence is that this resulted in an impoverished understanding of management by doctors and, in some cases, a sense that the focus of the role is to represent the interests of one's specialty. The Inquiry Panel concluded that the role was often taken on by senior doctors out of a sense of duty. As the posts were for a period of 3 years, the perception developed that those senior clinicians have an obligation to take their turn. At the end of the 3-year period, a clinical director will normally go back to full time clinical practice.
- 21 The fact that a consultant may be outstanding as a clinician does not necessarily translate to being competent as a manager. The roles are distinct and require very different skill sets. This has not been adequately understood either by the higher echelons of Trust management, or by the medical profession. In the view of the

Inquiry Panel, an unjustified reliance is placed on the structures created when there is often a disconnect between the policy of the Trust and the managerial approach taken within a specialty. The Inquiry was tasked to consider only the position within Neurosciences but has no reason to believe that the situation is otherwise in different medical specialties.

- 22 The sense within the Trust is that because consultants are highly trained and academically able individuals, they will be able to move easily into a management role. Training for the role needs to be strengthened and an understanding of the accountability aspects of management reinforced. The reality is that for a clinical director or a clinical lead to hold his/her own colleagues managerially to account, in the system that currently operates, is a challenging requirement. For those doctors who have advanced further in medical management and who are more removed from day-to-day interaction with colleagues, the difficulties of managing colleagues are less acute.
- 23 The position of the Medical Director is, in the view of the Inquiry Panel, the critical role in the current structure from a patient safety perspective. The importance of disclosing relevant information to the Medical Director's Office cannot be overstated. In the case of Dr Watt, the Inquiry Panel believes that without the then Medical Director's response in December 2016, to concerns that had been raised, and more particularly in July 2017, there is no guarantee that the problems identified in the recall would have necessarily emerged.
- 24 A pre-existing and deeply rooted medical culture which inhibits a flow of relevant information to the Medical Director's Office was, in the view of the Inquiry Panel, a major factor in failing to identify potential problems with Dr Watt at an earlier stage. Consultants are used to having ultimate personal responsibility for their patients. In relation to clinical care, they are at the head of a clear linear decision-making structure. This contrasts with their role as an employee within a managed organisation where the flow of information is more restricted, and as the Inquiry Panel has found, clinical management roles lack the same clarity. This leads to friction within the broader management framework.
- 25 The evidence received by the Inquiry Panel would suggest that many doctors, by training, impose their own filters and thresholds of proof that often have the unintended consequence of failing to escalate concerns. Such an approach impedes pattern recognition. Information, which, when collated and analysed together may give rise to concern, has been excluded because a doctor has concluded that a concern he or she had, is not sufficiently serious to escalate.

- 26 In a sense, doctors conflate the approach they take to their own practice and the clinical judgements they make on a daily basis, with the view they take if they have a concern about the practice of a colleague. The filter applied seeks to have the maximum degree of investigation and assurance before committing to a position. With their own patient(s), that may not present a difficulty; they have the benefit of full medical notes and records, a detailed examination and full history and a clinician, fully briefed, can consider the appropriate treatment. In contrast, when coming across an issue of concern with a colleague, the doctor sees only in part, rarely has access to the medical notes and records, has not conducted a full examination or taken a full history and is, by definition, not in as good a position to make a judgement.
- 27 In such circumstances, doctors appear wary of committing themselves to a position. A concern identified may fail to meet the threshold in their own mind. Consequently, matters which may urgently need investigation or a further review, are passed over. Such an approach is not the standard imposed by regulators or required by employers. If a concern is reasonable, it should be escalated and checked. It is not the function of the doctor concerned to reach a definitive view or conduct an investigation.
- 28 The current system seeks to model a collective leadership approach. The triumvirate structure with separate medical, general management and nursing lines of authority reporting to a Co-Chair (Medical) and Co-Director (General Manager) under the respective oversight of the Medical Director and a Director at Board level is purposely collegiate. The danger is, however, that when everyone is responsible, no one is responsible, and the evidence given to the Inquiry catalogues a number of occasions where information was shared, and/or lines of accountability appeared not to have been understood.
- 29 A narrative developed following the announcement of the recall process in April 2018, that nothing of substance regarding Dr Watt's practice was known by the Trust until a concern was raised by a GP in November 2016. This Inquiry has found that such an understanding was far removed from the actual position. Information was held, both inside and outside the Belfast Trust, which if it had been properly collated and analysed, could have led to earlier intervention.

Concerns Raised:

- 30 The Inquiry also considered in detail the question of concerns being raised by various medical personnel including registrars and nursing staff. The Inquiry found

significant evidence that concerns had been raised and had not been appropriately managed or further escalated on numerous occasions. In 2013 a registrar raised a serious concern with the then Clinical Lead in Neurology about a pregnant woman having been diagnosed with epilepsy, and prescribed medication accordingly, when the evidence suggested she should not have been diagnosed. In the same year, another registrar went to the Clinical Director about various aspects of Dr Watt's practice, but the matter was not escalated or recorded. In 2015 the same registrar raised concerns with the Training Programme Director, but again the matter was not properly recorded and in the same year another registrar also gave evidence about raising a concern, albeit that there was confusion as to what had been said or communicated. The reasons for this are multi-factorial but include a failure on the part of those in clinical management to properly understand their role and the actions to be taken upon receipt of a concern.

- 31 Communication problems between those in primary care and those in secondary care were highlighted at the outset of the Inquiry. Some of the main themes that have been outlined in the Medical Culture chapter illustrate the difficulties faced by GPs in raising issues with consultant specialists. It was a matter of surprise that several GP witnesses disclosed that they were unaware of who to raise concerns with, and further alarming that attempts by GPs to raise concerns about Dr Watt floundered because of both reticence by the GP or ignorance by the person receiving the concern as to what should happen to the information. It is the case, however, that it was a GP, who ultimately raised the first series of index cases with the Medical Director's Office in November 2016, thus beginning the chain of events that led to the neurology patient recall in May 2018.

The Complaints System:

- 32 A particular focus of this report is on the complaints system in place and the concerns that were raised but not further escalated or examined. The failure to learn from complaints was one of the more disturbing aspects of the investigation conducted by this Inquiry. Time after time, information was raised in a patient complaint, which needed to be independently investigated. Consistently the answer given to the complainant was obtuse and unhelpful.
- 33 The approach within Neurosciences was that, when a complaint was received from the Belfast Trust Complaints Department, the Service Manager or Assistant Service Manager would then seek the views of the clinician who was the subject of the complaint. In Dr Watt's case, his response was almost invariably to justify the

position he had taken. The Manager would then draw up a detailed chronological list of the patient's attendances with the hospital, treatment prescribed, and advice given, and the letter would be started and finished with a profuse apology for the hurt feelings of the complainant. If there was a clinical component to the complaint the Clinical Director would have been asked to review the response letter. There was confusion as to what extent the Clinical Director was fully analysing the clinical issues raised by the complaint. The letter would then be reviewed by the Co-Director and Director before issue to the complainant.

- 34 When the process was reviewed by the Inquiry, a pattern emerged which raised fundamental questions. Despite the fact that numerous complaints had been made the complaints analysed against Dr Watt did not result in any findings and until February 2016, no independent reports had been commissioned to examine the merits of any clinical complaint against him.
- 35 The results of such an approach were, however, apparent. Information which needed to be analysed and which pointed to aberrant practice was ignored, misunderstood, or did not get to the right person. The Datix system, which was meant to log all complaints often failed to record or log appropriately the complaints against a particular doctor if the person inputting the data was insufficiently specific. It was often difficult for the Medical Director to have a broad overview of a doctor's practice. Information remained in silos, whether in the Datix system, the Complaints Department, the Service Manager's office or, on one occasion, even the Medical Director's Office. The disjointed nature of the extant system was best illustrated by the fact that the Medical Director sought to assure the public in May 2018 that there was no red flag in the complaints relating to Dr Watt. Such a statement, though given in good faith, was demonstrably and clearly wrong when the information obtained by the Inquiry was evaluated.
- 36 What is apparent from the evidence is that there was no consistent method of dealing with clinical complaints and the emphasis remains on timely resolution. The Inquiry Panel has found instances, where the Complaints Department and the appropriate Directorate failed to adequately identify and address the clinical questions raised in the complaint, seek an independent view or learn from any issue of concern that arises.
- 37 The sober reality is that the complaints system within the Belfast Trust was inadequate in terms of identifying patient safety concerns. Little seemed to have been learned, even though, properly analysed, many complaints highlighted concerning patterns of potentially aberrant practice on the part of Dr Watt. It is hard not to conclude

that the system, as operated within the timeframe to be assessed by this Inquiry, made it more difficult to identify problems. Instead of recognising that a well-run complaints system can be perhaps the most effective way of identifying aberrancy, the approach was focused on responding within stipulated time periods and “resolving” complaints. The Inquiry Panel accepts that this focus emanates from the Department of Health complaints handling policy common to all Trusts but, somehow, the opportunity for learning from complaints often seems to have been missed. The Inquiry also recognises that steps have been taken by the Belfast Trust to improving its complaints system and a recommendation has been made which asks the Department to evaluate this initiative and consider extending it to other Trusts if appropriate.

- 38 The Regulator bears a heavy responsibility to ensure that doctors who are practising outside the bounds of clinical norms are identified and appropriate action taken. In this case, a clinical complaint regarding Dr Watt, which was forwarded to the GMC in 2012, was essentially dismissed with general advice and guidance. A GMC internal review of that decision in 2019 concluded that the case had not been properly investigated and recognised that if the matter had been decided again, the outcome would probably have been different. It transpired that the GMC decision in 2012 was influential to the outcome of a parallel investigation within the Belfast Trust on other matters relating to Dr Watt. The series of events is illustrative of the connectedness of various organisations. If information is not shared appropriately, then the opportunity for identifying concerns is correspondingly diminished.

Missed Opportunities:

- 39 In December 2006 / January 2007, Dr Watt came to the attention of the then Medical Director due to a series of administrative concerns. At or about the same time, the Trust, including the Medical Director, was involved in handling two significant and complex clinical complaints relating to Dr Watt. Dr Watt also received a five-year warning from the GMC, but this warning was not communicated to Dr Watt’s line managers in the Trust. There was sufficient information within the Trust, from which a pattern could have been identified and in turn led to a deeper examination of Dr Watt’s practice at this early juncture.
- 40 In January 2012, Dr Watt came to the attention of the then Medical Director after a complaint was received by the GMC from a patient, INI 45, who had seen Dr Watt at Hillsborough Private Clinic. Despite the Belfast Trust carrying out two separate informal investigations into Dr Watt under the “Maintaining High Professional

Standards” procedure, and his practice being under consideration at the Doctors & Dentist in Difficulty Meetings (“DDCRM”), Dr Watt was subsequently revalidated in September 2013. Further, there was relevant information within the Ulster Independent Clinic relating to a complaint which was not brought to the attention of the Belfast Trust. Within Neurosciences in this period registrars had raised concerns about Dr Watt’s practice with management, but these were not escalated to the Medical Director in the Belfast Trust. If the various strands of information, which were available in 2012 and 2013 had been fully analysed, there was every opportunity that aberrant practice could have been spotted and appropriate action taken to assure the safety of patients and perhaps to assist and support Dr Watt.

- 41 In February 2016, the Trust received a concern in relation to the practice of Dr Watt, which was subsequently considered by an independent expert. At the same time, the Medical Director’s Office was aware of administrative issues in relation to appraisal, a report for the coroner and an anonymous complaint. Information was held within Neurosciences which did not reach the Medical Director’s Office. This concerned other complaints and concerns with regards to the prescription of HIG. These concerns were discussed with Dr Watt in August 2016. Concerns in relation to the proliferation of Blood Patching and prescribing of Alemtuzumab which were within the knowledge of a number of individuals, went largely unchallenged and were also not escalated to the Medical Director’s Office. There was sufficient information with the Trust that action could have been taken before a GP raised concerns in November 2016. Further, additional concerns and complaints relating to diagnosis and treatment of Dr Watt’s patients, were known about in other Health Trusts and within the Ulster Independent Clinic but the information was not shared with the Belfast Trust.

Appraisal and Revalidation:

- 42 In the case of Dr Watt, the failure over so many years to promptly undergo appraisal has been the subject of public comment by politicians and others. While the Inquiry Panel shares many of the concerns regarding Dr Watt’s failure to be appraised, it is important to properly grasp the purpose of appraisal and the reassurance that revalidation can offer. While the Inquiry believes that both appraisal and revalidation are useful exercises, which have a significant role to play in terms of raising overall standards, the Inquiry Panel also is of the view that an incorrect public understanding of the purpose behind both appraisal and revalidation can lead to confusion, which ultimately does not serve the interests of patients.

- 43 As far as the public are concerned, great weight is to be afforded to the system of appraisal which was established at the same time as the inquiries into the Shipman case, chaired by Dame Janet Smith. At that time, there was an intense public concern that aberrant practice amongst medical practitioners must be effectively identified and addressed. A system of revalidation every five years was subsequently initiated in statutory form.
- 44 Appraisal for doctors is not a performance management process, where a clinical manager such as a clinical director will set goals and analyse the performance of a subordinate. The process is carried out by a colleague trained as an appraiser who will seek to assist the doctor to self-reflect on his/her clinical practice. The appraiser does not necessarily have to be from the same specialty as the appraisee or even be a doctor. Such a system is undoubtedly beneficial in improving the quality of a doctor's work but no doctor in their evidence to the Inquiry thought the system was designed to identify, or was in any way effective at identifying, aberrant practice.
- 45 Revalidation every 5 years is a much more formal process with a greater emphasis on the views of patients and colleagues. It requires the Responsible Officer to make a formal recommendation to the GMC as to whether the doctor should be revalidated. In the Northern Ireland Health and Social Care Trusts, the Responsible Officer is ordinarily the Medical Director, to whom the doctor is also accountable as an employee. In the view of the Inquiry Panel annual appraisal remains the main building block of revalidation. As set out in the Recommendations, the Department of Health and the GMC should clarify whether in their view these processes are sufficient to ensure that aberrant practice will be identified. If these processes are in themselves inadequate, then the Department and the GMC should specify what mechanisms should be put in place to achieve this necessary objective

The Independent Sector:

- 46 While this report is primarily focused on the Belfast Trust, evidence was obtained which brought into sharp focus the regulation and governance of the independent sector in which Dr Watt practised for many years. The Terms of Reference specifically ask the Inquiry to look at related concerns and circumstances, which should have alerted the Belfast Trust to instigate an earlier and more thorough investigation. In the view of the Inquiry Panel, this includes the independent sector because Dr Watt had a substantial private practice and the communication between the independent sector and the Belfast Trust was relevant at various key junctures.

- 47 Independent sector organisations where Dr Watt worked rely, in most instances, on the Medical Director of the relevant Trust as the Responsible Officer of an individual doctor with practising privileges at their institution. At revalidation and during annual appraisal, a clinician is required to carry out a whole of practice review, which includes any private practice. At the same time, independent sector organisations rely on the submission of a practising privileges document, which requires annual appraisal and revalidation. In Dr Watt's case, appraisals were missed over various lengthy time periods without sanction by either the Trust or the independent sector providers. Further, relevant clinical complaints were not disclosed by the independent sector provider to the Responsible Officer. It is illogical for an independent sector provider to rely on the approval of a particular doctor by the Responsible Officer, while at the same time failing to ensure that highly relevant matters are not brought to the attention of the same Responsible Officer.
- 48 Critical information at key times was not passed on to the Belfast Trust by the Ulster Independent Clinic. The information may have altered the outcome of an earlier investigation under MHPS, then being conducted in the Belfast Trust. Fundamentally, the independent sector has tended to view itself as providing facilities for consultants to practice, rather than properly recognising its role as a medical hospital or clinic where the public expect the same standards of patient safety and governance as one would find in the National Health Service.

Lone Working:

- 49 While many of the areas investigated by the Inquiry within the ambit of the Terms of Reference required detailed and painstaking analysis, there were other aspects of the review carried out, which highlighted obvious problems. One such example was the inpatient neurology teams to which consultant neurologists were assigned. By reason of the untimely death of one neurologist and the retirement of another, Dr Watt was the sole remaining member of Team A, while Teams B and C both comprised normally five consultant neurologists each. This situation was in place since 2012 and the Inquiry Panel considers it significant that Dr Watt was essentially working on his own for a period between 2012 and July 2017, (when he was clinically restricted). This arrangement does not seem to have been reflected upon or regarded by management as unusual or problematic. The fact is, however, that the Inquiry is satisfied that the isolation of Dr Watt contributed to the problems that developed in his practice. Regular interaction with colleagues tends to prevent deviation from the norm and is one of the main protections which can prevent aberrant practice.

Recommendations have been made, which seek to ensure that team working and peer review amongst specialist consultants is regarded as a priority requirement for all consultants.

Blood Patching Procedures:

- 50 A particular focus of public concern related to the extraordinary increase in the treatment of patients by Dr Watt using a blood patch in the period from 2014 to 2017.
- 51 It is not unusual for doctors to develop new or expand existing treatments to address a difficult and chronic problem. While the Inquiry is not in a position to make any definitive assessment in relation to the alleged under-diagnosis of the leakage of cerebrospinal fluid in a person's spine, the Inquiry does note that some of the medical literature, particularly in the USA, did suggest that the prevalence of SIH in populations is under-diagnosed.
- 52 The Inquiry recognises that the development of evidence-based medicine with a particular focus on MRI and CT-imaging has been a feature of medical practice in the last 20 years. For older neurologists, including Dr Watt, there would have been a greater emphasis on observation of the success of treatment for a working diagnosis as a more common way of establishing a definitive diagnosis in their early practice. The Inquiry Panel was told by almost every neurologist that the practice of neurology is complex and difficult.
- 53 Dr Watt gave a clear explanation to the Verita case investigators who had been carrying out an MHPS investigation on behalf of the Belfast Trust. Dr Watt was fully aware that the guidelines emphasised the importance of imaging evidence in a case of SIH. Although the relevant literature recognised that patients could develop the condition in the absence of imaging evidence, there was a much greater focus on history and examination required before such a conclusion could be reached. Dr Watt noted that it had worked, as he put it, "*like a charm*" with one patient and this had encouraged him to utilise the procedure in many other instances. As Dr Watt explained, the blood patch procedure was being used as essentially "*a diagnostic tool*". The problem with such an approach was that Dr Watt did this independently and did not consult with other colleagues nor did he have accompanying medical audit to verify and analyse the cases, which had resulted in the procedure. Consequently, at one point, the dramatic rise in blood patch procedures between 2014 and 2017 was truly extraordinary.

- 54 It is also important to stress that the increase in blood patch procedures in Belfast as a result of Dr Watt's initiative was carried out in plain sight of his colleagues and other medical staff. At no point did Dr Watt seek to hide what he was doing and indeed gave three separate presentations during the Neurosciences Grand Round on specific cases, which involved a possible diagnosis of SIH. The Grand Round was attended by consultants, registrars, and student doctors within neurosciences. One of these presentations was after he was partially restricted in 2016. On another occasion at a neurology consultants' meeting, Dr Watt's consultant colleagues were forced to confront the number of blood patch procedures taking place, because of the impact on other elective procedures. Rather than interrogate the diagnosis leading to the need for a blood patch procedure, the number of repeat procedures, or the procedures for which each consultant was responsible, it appears that hypotheses possibly explaining the increase provided reassurance. The focus across doctors and managers in Neurology was on securing sufficient capacity for the procedures and ensuring they did not disproportionately impact other routine procedures, such as lumbar punctures.
- 55 None of the existing management arrangements were effective in querying or questioning the proliferation of blood patch procedures by Dr Watt. The then Assistant Service Manager did ask critical questions, but these were never adequately considered. The Ward Sister also highlighted obvious queries about the procedure because the number of blood patches being carried out by Dr Watt put a significant strain on existing resources, and the arrangements for treatment could only be described as "chaotic". Some personnel, such as Dr Watt's secretary, were put under intolerable pressure to assist and cope with a large volume of patients who were turning up unexpectedly for the treatment.
- 56 It was only when Dr Peukert decided to keep detailed records on a spreadsheet of all the patients he had been asked to review, after concerns regarding blood patching were raised in December 2016, that the true scale of the problem became apparent. Dr Peukert's careful records revealed that the majority of patients who were being proposed for a blood patch procedure, did not have supportive imaging evidence, which would normally be a necessary indicator of the condition. The challenge that arises is how existing systems within the Trust can identify and address a situation where an unusual treatment suddenly increases to an extraordinary degree. The evidence given to this Inquiry suggests that, until Dr Peukert developed his spreadsheet, the Trust had limited understanding of the scale of the problem. In the view of the Inquiry Panel, that failure to understand was compounded by a

medical culture, which discouraged concerns being escalated or the questioning of the actions of such a senior consultant.

Prescribing:

- 57 The prescribing of disease modifying drugs such as Alemtuzumab for the treatment of multiple sclerosis or the infusion of Human Immunoglobulin (“HIG”) was another area where Dr Watt was a clear outlier. Despite significant budgetary restraints, the pattern of prescription was identifiable and obvious. Management appeared reluctant to challenge a senior consultant’s prescribing pattern when there should at least have been queries raised. The Clinical Director and Clinical Lead adopted a model where consultant consent was a pre-requisite to progress. If one or two doctors refused an initiative proposed, such as a prescribing panel, then no panel could be set up.
- 58 A public health doctor highlighted to the Health and Social Care Board and the Belfast Trust an unusually high prescribing pattern with regard to HIG. This was largely dismissed by the Clinical Director as a naturally occurring variance between the practice of different consultant neurologists and challenged no further. Where the indications for treatment were less clear, a process of approval by a consultant in management was implemented. This became a ‘rubber stamping exercise’ with highly limited practical value, rather than a tool to provide assurance as to the appropriateness of treatment.

Confidentiality:

- 59 The Inquiry has noted the extent to which concern about compliance with General Data Protection Regulations (“GDPR”), and Data Protection legislation more generally, has strongly influenced administrative action. Insofar as such concerns have obstructed the collation and retention of medical records, then the potential also exists for patient safety to be undermined. The Inquiry is of the view that, in too many instances, decisions are taken which are not required by the relevant legislation.
- 60 A refrain regularly repeated to the Inquiry was that an individual or an organisation had been prevented from sharing information because of confidentiality concerns. This may have been in relation to patient records, appraisal documentation completed by a doctor or access to the electronic care record by medical practitioners working in the independent sector, the storing of complaints data and numerous other scenarios.

- 61 When the Inquiry was non-statutory, it was discovered that the Department of Health had obtained access to a report prepared for the Belfast Trust pursuant to the MHPS process. The Department had no objection to disclosing the detailed report, which included Dr Watt's response to a number of highly relevant matters to the Inquiry. Dr Watt's lawyers, on the instruction of his medical protection organisation, raised strong objection, as a matter of principle, to the Inquiry having sight of the documentation. This was on the grounds that the MHPS process was confidential. Proceedings were subsequently issued in the High Court between Dr Watt and the Department; although the hearing did not proceed, because the Inquiry was then converted to a statutory inquiry with the ability to enforce the production of documents. The issues raised in the proceedings highlighted the importance of confidentiality as a critical consideration in a wide variety of circumstances. The over-reliance on confidentiality norms poses real challenges for the evaluation and governance of clinical practice and for any retrospective analysis such as that conducted by the Inquiry.
- 62 The Inquiry took the view that if patient safety was truly the paramount concern, then confidentiality and issues arising in relation to the sharing and retention of data would need to be more closely examined. Such was the importance of the issue that the Inquiry instructed David Scofield QC (now Mr Justice Scofield) and Alistair Fletcher BL to provide an opinion on the legal issues that can arise. A wide variety of possible scenarios focusing on the retention of data by the Responsible Officer of a Trust was considered in the opinion. In each scenario, the opinion found that, subject to certain basic safeguards, data could be retained. The opinion stated in conclusion:
- As a matter of general principle there are justifications for collating and retaining the information that the Inquiry envisages should be made available to, and kept by, the responsible officer. It is likely that the great majority of this information will already be held by the relevant Trust, albeit perhaps not in any centralised or organised manner. If the Trust is permitted to retain the data in the first instance, then there should be no issue with the responsible officer collating it under their auspices, on the basis that the Trust is in reality the controller for GDPR purposes. In our view, the obligations under the 2010 Regulations give additional justification for the retention of data by the Trust through the responsible officer in the cases discussed above.
- 63 The Inquiry Panel believes that, if patient safety is going to genuinely be the paramount concern, much more needs to be done to dismantle some of the impediments to adequate and effective communication between those charged with

ensuring safety. It cannot be right that information is retained in different ‘silos’, and that key personnel, and especially the Responsible Officer, are unable to access highly relevant data for reasons which are in no way persuasive. The Inquiry has uncovered numerous index examples of situations, where, if information has been appropriately shared, those charged with ensuring patient safety would have been able to make an informed decision. As it was, the Responsible Officer/Medical Director was unaware of critical information before November 2016.

Specific Conclusions:

- 64 The public and, in particular, patients who were affected, rightly demand to know why the problems in Dr Watt’s practice were not identified and dealt with at a much earlier juncture. This report will give a detailed account of how those problems went unidentified for so many years.
- 65 The evidence obtained by the Inquiry and the report of the Royal College of Physicians revealed problems, including a range of unusual features, in Dr Watt’s practice that went largely unnoticed or unchallenged by other consultants. Such practices included:
 - (i) The dramatic increase of blood patch procedures and diagnoses of cases of SIH to the point where Belfast seemed to have an incidence beyond any assessment in the medical literature or in the experience of other neurologists (see chapter on Blood Patching).
 - (ii) Definitive diagnoses being given in the absence of objective imaging without a sufficient patient history to justify a blood patch procedure.
 - (iii) Using blood patch procedures diagnostically and in a manner which was outside the guidelines.
 - (iv) A preference for immediately prescribing second line drugs at the earliest opportunity. An example is the prescription of Alemtuzumab for Multiple Sclerosis.
 - (v) The prescription of HIG treatment in grey area cases to the point where, for many years, Dr Watt was an obvious outlier.
 - (vi) A marked reluctance in some cases to diagnose a functional neurological disorder.
 - (vii) A willingness to circumvent established procedures for transfer between the independent sector and the NHS.
 - (viii) Over confidence in diagnosis and treatment and an unwillingness to change opinion.

- 66 The Inquiry Panel has commended some of the actions taken by the Belfast Trust after November 2016. It rejects, however, a narrative that this was the first time that issues of concern about Dr Watt's practice were apparent. There was sufficient information to give rise to questions and led to a more thorough investigation into his clinical practice much earlier than November 2016. In particular, the Inquiry has concluded significant opportunities were missed to identify a pattern of potential aberrant practice in 2006/2007, 2012/2013 and earlier in 2016.
- 67 The fact that the Trust did not appreciate that there was a great deal in Dr Watt's clinical background that was highly relevant to the issues that emerged in November 2016, was a failing which was contributed to by other organisations, including the UIC, GMC and other Trusts.
- 68 While the Terms of Reference of the Inquiry are focused on the effectiveness of governance, the ultimate purpose of the Inquiry is to establish the facts as to what happened. The Inquiry Panel has, as a result of this detailed process, made 76 recommendations which, if implemented, should significantly reduce the risk of a recurrence of similar events and improve patient safety.

RECOMMENDATIONS

NI Department of Health:

- (1) The NI Department of Health and the GMC should issue a joint public statement for the benefit of public and patients making clear the extent to which they consider whether the processes of medical appraisal and revalidation, currently extant, are sufficient to ensure that aberrant practice will be identified. If those processes are in themselves inadequate, the statement should specify what mechanisms should be put in place to achieve this necessary objective.
- (2) The NI Department of Health should remind healthcare organisations that, whilst they should work collaboratively with the GMC, it is the healthcare organisations that remain responsible for the safety of their patients and accountable for managing their employees.
- (3) The NI Department of Health should ensure that healthcare organisations in their management of clinicians, or any other employees, apply the following principles:
 - (i) ‘You cannot unknow what you know’. (Anyone made aware of any patient safety issue must appropriately address it, and not avoid it). Conversations cannot be regarded as “informal” or “off the record”, with no action taken.
 - (ii) Where a healthcare professional raises a concern with a clinical director and lead clinician (or any other manager), then the responsibility for dealing with the concern should rest with the person receiving the concern. The detail of the concern should be discussed with a senior medical manager (Medical Director or Deputy Medical Director).
 - (iii) When a patient safety issue is raised, a comprehensive file note should be retained in a place where it can be easily accessed and interrogated by the relevant personnel, as discussed in the legal advice at Appendix H.
- (4) The NI Department of Health should review its guidance in relation to complaints, to ensure that patient safety is the overriding objective.
- (5) The NI Department of Health’s performance management of Trusts’ response to complaints should not overly focus on timelines and resolution. Greater emphasis should be placed on learning, detecting misconduct or poor practice and improving services.

- (6) The NI Department of Health should make clear how, when investigating complaints, healthcare organisations should detect and investigate poor practice.
- (7) The NI Department of Health should update its guidance to ensure that the view of the clinician who is the subject of a complaint should always be sought and taken fully into account but should never be determinative of the healthcare organisation's response.
- (8) The NI Department of Health should ensure that all employing organisations have in place an appraisal process, which enables them to better assure patient safety, in line with the accountability of the organisation. This process should be the same type of process as for all other employees and should be conducted routinely by the line manager, who should take expert specialist advice if required.
- (9) The NI Department of Health should update appraisal guidance and documentation to ensure that when the line manager conducts the appraisal, the appraisee should certify that they have declared any risk to patient safety of which they are aware. This should include the details of all complaints and concerns in relation to their own practice, but also any concerns they have regarding any other clinician's practice.
- (10) The NI Department of Health should ensure that if any clinician who, as part of their continuing professional development, believes that it would also be beneficial to have a developmental reflective appraisal performed by another clinician within the same specialty or subspecialty, then the employing organisation should encourage, support and facilitate this.
- (11) The NI Department of Health should oversee the putting in place of a formal protocol to assist clarity of understanding and timely sharing of information between Independent Healthcare Providers and Responsible Officers. The overriding objective of the protocol should be to enhance patient safety through a consistent spirit of openness and transparency.
- (12) The NI Department of Health should ensure that all healthcare providers, both NHS and independent sector, will have full and unhindered access to the integrated Electronic Care Record, having sought the relevant permissions from the patient (with an appropriate division of costs).
- (13) The NI Department of Health should ensure that until the electronic care record is available, then there should be direct access to patient notes and records between the NHS and the independent sector to facilitate patient safety, having sought the relevant permissions from the patient.

- (14) The NI Department of Health should review and evaluate the progress made by the Belfast Trust in developing new information gathering and governance processes¹.
- (15) The NI Department of Health should emphasise to healthcare organisations the potential dangers of lone working and to develop guidance on the many ways in which it can be avoided.
- (16) The NI Department of Health should ensure that the confidentiality dimension of the MHPS process is always subordinate to patient safety considerations.
- (17) The NI Department of Health should review paragraph 39 of MHPS and issue guidance on the appropriate balance between confidentiality for the clinician and safety for the patients.
- (18) The NI Department of Health should oversee the establishment of a group to consider the balance between the fair treatment of clinicians and the safety of patients under MHPS. The group should focus on reducing the complexity of processes and re-evaluating the degree of confidentiality. The group would benefit from input from appropriate experts to include Human Resource expertise and Medical Directors.
- (19) The NI Department of Health should initiate a detailed review in relation to the role of clinical directors and clinical leads to address issues arising from this report and their training needs.
- (20) The NI Department of Health should ensure that Trust Boards have a Safety and Quality Sub-Committee, which has a similar status to the Audit Committee.
- (21) The NI Department of Health should clarify with the Trust Boards the nature of their accountability for patient safety.
- (22) The NI Department of Health should issue guidance to healthcare organisations about the information to be given to patients when a clinician's practice is restricted in any way.
- (23) The NI Department of Health should review (and if necessary, change) the early warning alert process and the serious adverse incident process to assure itself that these processes are clear, well understood and operate in the interests of patients.
- (24) The NI Department of Health should remind commissioners of healthcare that they have a responsibility to commission safe care and, therefore, to be assured of the safety provided by any Independent Healthcare Provider.

¹ To assist with investigating complaints, the Belfast Trust has implemented a clinical record review. To protect against the risk of lone working, additional peer review is being incorporated in the Trust through an initiative known as 'Building Effective Teams'. To enable the Medical Director at the Trust to be able to access accurate and useful information on a clinician's practice, a live professional governance reporting system has been put in place.

Healthcare Organisations:

- (25) Healthcare organisations should collate, store and have readily available all relevant information in relation to a clinician's practice.
- (26) Healthcare organisations should ensure that if their Medical Director, or any other senior manager, becomes aware of a concern about a clinician in another healthcare organisation, then they should promptly inform the Medical Director of that clinician's employer, and also the clinician's Responsible Officer. They are not required to exercise judgement, merely to pass on the information.
- (27) Healthcare organisations should recognise that when it proves necessary to restrict part of a clinician's practice, then there may or may not be implications for other aspects of his/her practice. Healthcare organisations should take immediate steps to assure themselves that other aspects of the practice are safe, and if in doubt, should restrict the whole practice until the necessary assurance has been gained.
- (28) Healthcare organisations should ensure that in the event of any form of restriction being imposed on a clinician, the GMC is immediately informed of that restriction.
- (29) Healthcare organisations should ensure that when they are asked to disclose information about a clinician's practice to the GMC, the information is fulsome, accurate and up to date, and no judgement is applied to its likely relevance.
- (30) Healthcare organisations should promptly investigate patient safety concerns. The existence of a separate legal process (such as a Coroner hearing or litigation including criminal proceedings) should not prevent a healthcare organisation from investigating promptly patient safety concerns, including concerns about a clinician's practice, and without waiting for the outcome of any separate legal process. The paramount concern should always be the safety of patients.
- (31) Healthcare organisations should ensure that when there is a clinical component to the complaint, the response to the complainant should be signed off by the Clinical Director, who should be accountable for the quality of the response. The Clinical Director should determine whether they are competent to assess the quality of the response themselves, or whether they need help and support from elsewhere. They may find the support internally within the Trust, but if the issue appears to be a serious one, or if the expertise does not exist within the Trust, then the Clinical Director, in liaison with the Medical Director, should have the option to seek independent advice from elsewhere.

- (32) Healthcare organisations should ensure that complaints are either upheld, dismissed or appropriately determined and this conclusion shared with all parties including the complainant.
- (33) Healthcare organisations should ensure that any investigation undertaken into patient safety issues has clear terms of reference, a robust process and the findings recorded and kept on file.
- (34) Healthcare organisations should ensure that when it proves necessary to take advice from an external expert, then clear terms of reference should be developed so that all relevant questions are posed and fully addressed.
- (35) Healthcare organisations should share necessary data to ensure patient safety. Data protection concerns should be subordinate to patient safety.
- (36) Healthcare organisations should make clear to their employees or clinicians that when an issue is raised that might have patient safety implications then a robust process needs to be put in place to provide positive assurance that patient safety is secure, rather than assuming that there is an alternative explanation.
- (37) Healthcare organisations should ensure that when a patient or their family are seen following a complaint, then an agreed process needs to be followed. The individuals meeting with the patients, or their carers, should be clear about their roles, about what is to be said to the patients and carers, and the desirable outcomes. A comprehensive note of the meeting should be made and retained.
- (38) Healthcare organisations should clarify their own policies regarding raising concerns and communicate details of these to their employees on a regular basis.
- (39) Healthcare organisations should provide both the appraiser and the appraisee with all relevant information in advance of an appraisal being carried out, with all such information being retained. The appraisal folder should not be treated as confidential to the appraisee.
- (40) Healthcare organisations should ensure that refusal or failure by a clinician, without good reason, to carry out an annual appraisal should result in a careful scrutiny of the clinician's broader practice by the organisation, who should regard the failure to follow policy as a performance issue. The healthcare organisation should also notify the GMC of all such occurrences without delay.
- (41) Healthcare organisations (employers) Boards, or at least one designated non-executive member of a Board, should be made aware of the fact that a consultant

has had their practice partially or wholly restricted. (In some circumstances this requirement may be met by the MHPS process).

- (42) Healthcare organisations should make every effort to provide consultants with opportunities to avoid lone working. It should be made clear that consultants do not have the right of veto, and that complicated “workarounds” are rarely required or acceptable.
- (43) Healthcare organisations should make it clear that all managers have a responsibility to ensure and assure themselves of patient safety. This is a proactive process to be undertaken by general managers as well as clinical managers.
- (44) Healthcare organisations should make it clear that it is the role of all managers to balance competing demands and to be held to account for doing so appropriately.
- (45) Where a healthcare organisation establishes any committee or group to assist with the management of concerns in relation to a clinician’s practice, they should ensure that it has clear terms of reference, robust processes and a widespread understanding of their remit and role. Adequate minutes should be retained detailing the decisions taken and clearly setting out any action points arising. If the role of the Committee is advisory, then this should be made clear in the terms of reference, with particular clarity in relation to whom the Committee is advising and whether, in any circumstances, it has executive responsibility. Any clinician whose practice is being considered at such a group or committee described above should be informed and provided with appropriate details.
- (46) Healthcare organisations should make it clear to clinicians that they are expected to follow national and local patient management guidelines. (If there are pressing reasons in an urgent case then a consultant can prescribe outside the guidelines and explain fully in the notes why they have done so, expecting to be held to account for their decision).
- (47) Healthcare organisations should ensure that if a consultant’s clinical practice is clearly different from that of his or her peer group without immediately obvious explanation, then the matter should be investigated to provide assurance that the practice is safe (the assumption should be that it may not be safe, and this assumption remains until assurance has been gained). Independent Healthcare Providers should inform the Responsible Officer.
- (48) When a healthcare organisation becomes aware, by any means, of an unexplained and marked change in a clinician’s practice, then the management within the

relevant service area should assure themselves that such a change is justified, with the main concern being patient safety.

- (49) Healthcare organisations should have an enforceable process and policy for the introduction of new procedures, which should include the requirement for peer review and signing-off by the Clinical Director / Lead. (The NI Department of Health should assist by developing, in consultation, a specimen policy).
- (50) Healthcare organisations should have a process and policy for the introduction of new drugs, which should include peer review and Pharmacist input, and be summarised in an enforceable formulary.
- (51) Healthcare organisations should ensure that newly introduced therapies are the subject of early clinical audit processes.
- (52) Healthcare organisations should ensure that all patients undergoing procedures of any type should be subject to a standard booking process.
- (53) Healthcare organisations should recognise that, whilst patient consent to review their notes is always desirable, if there are urgent matters of patient safety to be resolved then the need for consent should be overridden. The decision to do this should be endorsed by an appropriate non-executive director.
- (54) Healthcare organisations should make certain that those to whom a clinician is managerially accountable should be made aware of any restriction, sanction or warning in place.
- (55) Healthcare organisations should ensure that when they are asked to disclose information about a clinician's practice to the GMC, that such information is fulsome, accurate and up to date, and no judgement applied to its relevance.
- (56) Healthcare organisations should liaise when a clinician's practice is restricted and should follow any restriction that has been imposed.

General Medical Council and Regulation:

- (57) The GMC should work with organisations such as the Faculty of Medical Leadership and Management, experienced Responsible Officers, representatives of the independent sector and lay representatives to review the existing revalidation guidance and determine the minimum data set for every doctor required to enable Responsible Officers to make the necessary judgement about recommendation for revalidation.

- (58) The GMC should update its guidance to Responsible Officers to ensure that they have sufficient information provided directly from independent healthcare providers.
- (59) The GMC should disclose to the Responsible Officer all the information it holds about a doctor to enable the Responsible Officer to make a fully informed judgement about their recommendation for revalidation.
- (60) The GMC should ensure that Responsible Officers are aware that failure by a clinician to engage with appraisal can result in the withdrawal of their licence to practice without engaging Fitness to Practise procedures.
- (61) The GMC should have the name of every doctors' Responsible Officer prominently displayed on their website. They should periodically remind doctors of the need to inform either the Responsible Officer or a senior medical manager (Medical Director or Deputy Medical Director, who should share information with the Responsible Officer) if they have a concern about a doctor's practice.
- (62) The GMC should remind doctors that they have a professional duty to report concerns and have a low threshold for doing so. They are not required to investigate themselves, merely to report.
- (63) The GMC should hold doctors who fail to report concerns to account.
- (64) The GMC should review Paragraph 25(c) of Good Medical Practice to assess the effectiveness of the advice contained within that paragraph and publish its conclusions.
- (65) The GMC should consider establishing a helpline to help doctors in relation to the handling of concerns.
- (66) The GMC should review its practice in relation to the retention of historical information held in relation to individual clinicians, including previous referrals from employers (and others), with a view to strengthening pattern recognition by the GMC itself.
- (67) The GMC should notify every organisation in which a clinician practices of the existence of any warning it issues, clarifying its impact and purpose and the consequences of further issues emerging.
- (68) When the GMC reviews its own decision-making under Rule 12 of its Fitness to Practise Rules, it should publish the outcome of the review.

Independent Sector:

- (69) Independent Healthcare Providers should publish the criteria used, which allow clinicians to practice on their premises.
- (70) Independent Healthcare Providers should ensure that full compliance with all these criteria should be continually monitored and enforced. If a clinician fails at any time to fully conform with the criteria, then they should be immediately stopped from practising in the relevant Independent Healthcare Provider and the clinician's Responsible Officer informed.
- (71) Independent Healthcare Providers should require clinicians to immediately notify them of any complaints or concerns received in respect of their work at the private clinic or private hospital.
- (72) Independent Healthcare Providers should, themselves immediately inform the clinician's Responsible Officer of the existence and detail of all complaints or concerns in relation to the clinician.
- (73) Independent Healthcare Providers should ensure that their Boards and Governance Committees keep detailed notes in respect of the investigation, outcome and any action points relating to complaints or concerns about an individual consultant/clinician.
- (74) Independent Healthcare Providers should provide the Responsible Officer with the full report that follows any investigation into a complaint or a concern, as soon as it becomes available. (The fact that litigation or a court hearing is pending does not constitute a valid reason for deferring sending the relevant information to the Responsible Officer).
- (75) Independent Healthcare Providers should accept responsibility for all aspects of patient safety within their organisation. The clinical governance arrangements of all Independent Healthcare Providers, including a named accountable officer, should be clearly stated on their website.
- (76) Healthcare organisations should join the relevant trade association or representative body and follow the standards it sets.

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CHAPTER 1 – THE EVIDENCE OF DR WATT'S PATIENTS

- 1.1 The Inquiry Panel determined at an early stage that it wanted to hear from Dr Watt's patients. Although the Inquiry was not tasked with assessing individual patient treatment from a medical perspective, the Terms of Reference were interpreted to give the maximum focus possible on patient experience, even if the main thrust of the Inquiry was to consider the governance systems within the Belfast Trust and beyond.
- 1.2 Ultimately, all the recommendations proposed by this Inquiry are advanced to assist and strengthen patient safety and to try and ensure that potentially aberrant practice can be identified and addressed within the existing systems as early as possible. To exclude or minimise the experience of patients would have been to undermine the purpose of the Inquiry and introduce an artificial dichotomy, which could only further alienate those who had suffered as a result of the misdiagnoses and mistreatment highlighted during the neurology recall process.
- 1.3 When the Inquiry was set up in May 2018, there was no Northern Ireland Assembly in place and, therefore, no Minister of Health. Nevertheless, the Inquiry Panel believed that it was incumbent upon it to engage with politicians, as representatives of the people impacted and to meet with those representatives nominated by their political party as spokespersons on health.
- 1.4 The Inquiry team, with the assistance and input of political representatives and the neurological charities formulated a questionnaire to facilitate patient engagement. A copy of this questionnaire, along with the Guide to the Questionnaire, can be found at Appendix 1. The questionnaire was well received by patients and 240 questionnaires were returned to the Inquiry, all of which were treated as written evidence and reviewed in full.
- 1.5 It is further important to note that the neurological charities greatly helped the Inquiry by providing it with invaluable guidance on how to engage with patients with neurological conditions. Some also assisted patients to fill out questionnaires and promoted the entire process through their office / groups and support networks. This was greatly appreciated.
- 1.6 It was not possible for the Inquiry to receive oral evidence from each of the patients who submitted questionnaires. In deciding who should be called to give evidence, the Inquiry focused on patients who raised concerns about their experience of

Neurology Services prior to the recall being announced in May 2018. There was a particular interest in those patients who had concerns which arose prior to November 2016 (when Dr Watt's practice started to come under scrutiny following receipt of several index concerns from a General Practitioner – see the Part A chapter for details).

- 1.7 The Inquiry requested that 35 individual patients give oral evidence. 35 patients accepted this invitation and only 2 declined.¹ The summaries have all been anonymised and assigned a designated number. The Inquiry Panel was acutely aware that some patients whose evidence is included would have preferred to be mentioned by name, whereas others did not wish to have their identity revealed. After careful consideration, the Inquiry Panel decided that the best approach was to use designated numbers. Throughout the report there are references 'INI 1' etc. The use of such numbers was also necessary for complainants whose complaint was reviewed by the Inquiry but who did not give evidence. It is important that anyone reading the report recognises that every INI number in this chapter refers to a patient (or relative of a patient), and every such individual patient, like every other patient utilising the healthcare system, expected to receive appropriate care and treatment. The use of designation numbers should not be viewed as an attempt to de-personalise the individual patients and their relatives. The Inquiry Panel observed the courage of patients and relatives who came forward and assisted the Inquiry by giving their evidence. The accounts that have been specifically referenced in this chapter have also been sent to the patients (or the relatives of patients) whose evidence has been referenced.
- 1.8 The Inquiry Panel also wishes to acknowledge the value and assistance of the evidence obtained from patients. On numerous occasions, patient testimony provided direction to the Inquiry in terms of opening a line of enquiry and providing critical context to the questions of governance outlined in the Terms of Reference. The examples outlined in this chapter are illustrative and they provide only a sample of the evidence that was obtained.
- 1.9 The issue of greatest interest to patients was their experience and clinical management. A number also gave pertinent evidence in respect of the governance of the system. This added valuable context to the deliberations of the Inquiry Panel and triggered further lines of investigation. Each of the patient accounts below concludes by explaining the relevance of the evidence to the Inquiry.

¹ The Inquiry did not believe it was appropriate to compel patients to give evidence. In those cases where the patient declined, the Inquiry had full access to the relevant written material which assisted in understanding the governance questions that arose.

- 1.10 It is properly a matter for the Belfast Trust (employer) and the General Medical Council (regulator) to investigate and adjudicate on clinical decision-making and/or professional conduct of individual clinicians. That said, the Inquiry Panel sought and invariably received permission from patients to pass on any relevant evidence to both the Belfast Trust and the General Medical Council (“GMC”) and, where relevant, to the Regulation & Quality Improvement Authority (“RQIA”) and Department of Health. During the Inquiry, relevant information from patients was passed to the GMC on 110 occasions, the Belfast Trust on 110 occasions the RQIA in 8 instances and 5 times with other Trusts or relevant bodies.
- 1.11 In an interview with Radio Ulster on 5th October 2021, INI 124, a patient who had been significantly impacted by the recall, articulated in a most compelling manner, the disappointment and distress of patients who had, the previous day, been informed that the Medical Practitioners Tribunal (“MPT”) had acceded to an application by Dr Watt’s lawyers that Dr Watt be voluntarily erased from the medical register. In a similar interview on BBC Newsline, another patient, INI 106, also cogently expressed the frustrations of patients that they would not have a hearing on the competence and capability of Dr Watt. The effect of this decision by the MPT, which was decided after a private hearing, was to effectively prevent the GMC from presenting its substantive case to the MPT. This included statements of many of the patients involved in the recall process and who had already given evidence to this Inquiry.
- 1.12 INI 124 highlighted in her interview on Radio Ulster the number of times over the preceding years that patients had been informed that regulatory matters were within the domain of the GMC, and that this Inquiry was focused on governance matters. The fact that no hearing took place on Dr Watt’s fitness to practise was extremely unfortunate. The Inquiry understands that it would have been possible to have proceeded in Dr Watt’s absence and notes that it was argued by the GMC that it was in the public interest that the case should have continued in such a manner. Somewhat unusually, the GMC issued a public statement on 4th October 2021 highlighting their “*extreme disappointment*” that a hearing had not taken place. The Inquiry Panel shares that disappointment and believes that the inability of patients to see Dr Watt’s practice assessed by an independent tribunal was a bitter blow to them and brought into sharp focus the fact that there has been no public assessment of Dr Watt’s practice.
- 1.13 Patients are not, and cannot be, responsible for the safety of the health system. That sits with those responsible for governing the system. The fact is, however, that when

patients describe issues that may reflect a lack of safety, they must be heard, and appropriate action initiated. There is a detailed chapter of the report where careful consideration is given to the role of the complaints system. It is vital that the existing system is resourced and properly utilised, where appropriate, particularly in respect of potential patient safety concerns.

Accounts from Patient Questionnaires:

- 1.14 It is important to acknowledge that the accounts of patients were many and varied. Inevitably, because one is quoting patients directly, much of the evidence is sharply critical of Dr Watt. While the overwhelming preponderance of the evidence received from patients has been critical, the Inquiry has also received robust and positive testimony from patients and a patient group known as *'We Support Dr Watt'*, who were impressed with Dr Watt's ability as a clinician.
- 1.15 The concerns of the *'We Support Dr Watt'* group were helpfully summarised by the Patient Client Council in a letter to the Inquiry of 10th August 2018:
- That there has been a general lack of support offered to patients affected by the recall and review process.
 - That having been recalled and reviewed there is little follow up by the Trust to cope with a change in diagnosis and to provide information on a forward treatment plan.
 - That some patients contest the new diagnosis and - having had medications and treatment reviewed - feel that this has had a detrimental effect on their health.
 - That patients have already been subject to an unreasonable wait because the Trust took no steps to ensure continuity of care for the period that Dr Watt was suspended.
 - That the Trust is slow to respond to complaints made by patients affected who are at present receiving a standardised response.
- 1.16 The Inquiry also received accounts from the relatives of deceased patients. There is presently a separate review in relation to deceased patients being carried out by the RQIA. Consequently, this category of patients is outside this Inquiry's remit except where circumstances give rise to issues of governance for relevant organisations. The Inquiry noted that family members of deceased patients were often anxious to give evidence to the Inquiry and their determination to do so was impressive.

- 1.17 The Inquiry further observed the frustration that some patients felt prior to the recall. This referred to the period from July 2017 when Dr Watt was fully restricted from clinical practice and, as a result, not seeing any patients. As this occurred before the announcement of the recall in May 2018, the issues raised fell within the Inquiry Terms of Reference.
- 1.18 The question of communication with Dr Watt's patients in the period December 2016 to May 2018 is considered in detail in the Part A chapter. The Inquiry Panel looked in some detail at how patients were informed of difficulties that had emerged and the impact that this had on patients.
- 1.19 The Inquiry also received several comments about the conduct of the recall itself, but as this was outside the Terms of Reference, it was decided by the Inquiry Panel that the evidence was not relevant to the work of the Inquiry.
- 1.20 There were also several patients who were concerned about the non-availability or limited availability of the blood patching service within the Belfast Trust from late 2016 onwards. As this happened prior to the announcement of the recall, this was regarded by the Inquiry Panel as a matter, which needed to be considered by the Inquiry.
- 1.21 A range of issues all relating to epidural blood patching is considered in the specific chapter on Blood Patching.

The Evidence of Individual Patients to the Inquiry:

- 1.22 As pointed out above, it was not possible to receive oral evidence from each of the patients who submitted questionnaires. That is not, however, to diminish the importance of the written evidence received by the Inquiry in the responses to the questionnaire. In particular, the responses provided considerable context to what had transpired and often eloquently articulated the difficulties that people experienced or in some cases laud the care they had received.
- 1.23 Dr Watt did not give evidence to the Inquiry. The reasons for this are explored in the introduction to the report. The Inquiry has had access to a vast amount of detailed written evidence, and this includes an interview, which touches upon salient issues of concern given by Dr Watt in May 2019, as part of a Maintaining High Professional Standards investigation. While it would have been helpful to hear Dr Watt's response to the issues raised by patients, the Inquiry Panel is confident that the absence of oral testimony to the Inquiry by Dr Watt has not undermined its ability to produce a meaningful report or fulfil its Terms of Reference.

INI 4:

- 1.24 On 5th September 2018, INI 4 told the Inquiry Panel that in 2015 his mother was referred to a geriatrician, who arranged further investigations with Dr Watt. She attended the Neurology outpatient clinic at the Belfast Trust. INI 4 described the experience as follows:

... It was clear it was a very busy clinic. She was taken through (a) patient questionnaire by a nurse initially ... When Dr Watt came into the room, he said you have epilepsy straight away. I assume the nurse had taken the questionnaire to him and he'd taken the decision prior to coming into the room. We then naturally were shocked as there was no family history. Dr Watt referred to epilepsy of old age being quite common. He seemed sure and confident of his position ... On leaving, we were shocked but reassured that there was a diagnosis and treatment to bring about improvement.

- 1.25 INI 4 stated in evidence that his mother continued to deteriorate both mentally and physically. As a result, INI 4 contacted his mother's GP in or around January 2016. INI 4 informed the Inquiry Panel that:

A young GP, Dr Claire McNeill of Ballygomartin Practice said, "Oh Michael Watt, we have concerns". That was around January 2016. She also said she didn't like Lamictal for older people or for youngsters and that "we think Dr Watt is rushing to epilepsy diagnosis". She also indicated that the Practice had wider concerns about his diagnoses of epilepsy in other patients and medication, mentioning children in particular.

- 1.26 This patient's family gained the clear impression from Dr McNeill that her practice had broader concerns about Dr Watt's diagnoses:

A family member in conversation with Dr McNeill, got the impression that the Ballygomartin Practice had concern and discussions about Dr Watt's diagnoses. They made it clear to my [family member] that they had held a case review regarding Dr Watt in the practice.

- 1.27 INI 4 said that his mother had a further appointment with Dr Watt in March 2016. He stated:

I wasn't there but my sisters attended with my Mum. My youngest sister put Dr Watt under some pressure. He was insistent Mum had epilepsy but would write a prescription for something else if they wanted. My sister asked him about the MRI scan. He wasn't aware of it. Dr Watt hadn't seen the MRI scan. My sister insisted that he looked at it, which he then appeared to do. He was quite insistent his diagnosis was right and that Lamictal was the right approach.

- 1.28 After learning about Dr Watt's restriction from clinical practice, INI 4 stated:

When the story broke, I rang the Department [of Health]. My one concern was in relation to deceased patients and that they could have been missed in the review ... When I passed on my concerns, I received a standard complaints response letter from the BHSCCT. I told them I wasn't raising a complaint but rather trying to ensure that deceased patients were not forgotten.

- 1.29 The evidence of INI 4 led the Inquiry to an important line of investigation into the extent to which concerns about Dr Watt existed outside of the Belfast Trust and more especially among some General Practitioners. More detailed commentary on this is set out in the Concerns chapter.

INI 5:

- 1.30 INI 5 first saw Dr Watt at the Royal Victoria Hospital She told the Inquiry Panel on 21st September 2018:

I explained to Dr Watt that I ... had been having symptoms including forgetfulness, breathless, numbness face, finger and toes along with fatigue.

- 1.31 Approximately one month later, INI 5 returned to see Dr Watt. She recalled:

I explained how the symptoms were worsening from my last visit ... and Dr Watt said it would be likely that I had an inflammation of the spinal cord caused by either an autoimmune disease or perhaps a virus. He ordered a number of blood tests. He decided that to relieve the numbness he would prescribe a 5-day course of steroids and that this is how he would treat an MS relapse. He said that the symptoms would go away and if they never came back, it was not MS. If within the year it reappeared, then he would query MS again.

- 1.32 Following the appointment with Dr Watt, INI 5 told the Inquiry Panel:

I received a message from my GP to say he could not give me (the prescription) because he did not recognise this as an appropriate dose and was waiting to hear back from the neurologist to clarify.

- 1.33 When INI 5 went to pick up her prescription:

... it was not there. The GP called me into his office to ask me what was going on as he hadn't even received any information at all from neurology at this point. He hadn't heard back from Dr Watt since he left the message.

- 1.34 In addition, INI 5 stated that the pharmacist prescribing the medication also queried the dose. Following this experience, INI 5 told the Inquiry Panel that she informed her GP that she:

Was never seeing Dr Watt again ... wanted referred to a different neurologist in a different hospital ... and thought he too readily prescribed a heavy drug.

- 1.35 In November 2010, INI 5 complained to the Belfast Trust. In correspondence to the Belfast Trust on 8th February 2011, INI 5 emphasised:

I spoke at length with you about the incorrect diagnosis made by Dr Watt and his unwillingness to consider any alternative diagnosis even when questioned.

- 1.36 Further details relating to the handling of the INI 5 complaint can be found in the Complaints chapter. As the evidence developed, the Inquiry also established that the investigation and documenting of INI 5's complaint happened in and around the same time as other key events. These events are explored in the 2012-13 Missed Opportunities chapter.

INI 46:

- 1.37 INI 46 contacted the Inquiry via email on 8th October 2018. She stated:

I was a private patient of Dr Watt in May 2008. He diagnosed me with epilepsy, but it is something we as a family jokingly questioned over the years. However, in light of recent allegations what was a joke now is a realistic possibility. The major concern with this lies that I was medicated through two pregnancies and there is a possibility I didn't have to be. Both those children have neurological issues now.

The issue I'm having is as I was a private patient, the NHS will not assist me in seeking a review. The Ulster Independent Clinic where I saw Dr Watt are saying that he simply rented a room and as I wasn't under active review with him, I didn't qualify for a recall and so they have said they can't help.

- 1.38 INI 46 attended the Inquiry on 13th November 2018 and informed the Inquiry Panel that she first saw Dr Watt at the Ulster Independent Clinic ("UIC") in 2008 and was diagnosed with epilepsy. When the news of the patient recall broke, INI 46 contacted UIC. She described her experience as follows:

They seemed to give me the impression that they were caught off guard. They didn't really have anything in place as such. They would take my details, and someone would phone me back. Someone phoned me back and the explanation was ... that I was classed as a discharged patient and therefore I didn't qualify

for review, that essentially Dr Watt just rented a room from them, and they didn't have responsibility.

1.39 INI 46 further stated:

I feel like I have fallen through the cracks. I wasn't an NHS patient so I don't fall under the patient recall and the Ulster Independent Clinic say they are only recalling patients under active review which I wasn't and so I have nowhere to turn with my concerns.

1.40 Overall, she described the interaction with UIC as *"a very frustrating process" and in her opinion they were "so unhelpful and dismissive"*. INI 46 described Dr Watt as follows:

Dr Watt, whenever I saw him was a lovely man ... maybe that is how, if there is a problem, maybe that is how it has gone on so long ... I had no reason to question my diagnosis at the time. I never brought it up before because I was respectful of the medical profession. If a doctor tells me something, I go, "yes of course". It is that aspect of authority that goes with the medical profession and I didn't have a real reason to question it.

1.41 The Inquiry Panel was keen to ensure that INI 46 was seen as part of the neurology patient recall. On 14th November 2018, Professor Mascie-Taylor wrote to Dr Adrian Mairs, Public Health Agency, highlighting INI 46's situation and requesting that consideration be given to her inclusion within the recall process. The Inquiry Panel was subsequently informed that INI 46 had been recalled and her diagnosis and treatment reviewed.

1.42 This evidence, combined with other concerns raised by a neurologist who gave evidence to the Inquiry caused Professor Mascie-Taylor to write to the Belfast Trust asking for a review of the prescription of epileptic medication regarding certain patients.

1.43 The evidence of INI 46 also led the Inquiry along an important line of investigation into the responsibilities of the independent sector. More detailed commentary on this and similar issues is set out in the Independent Sector chapter.

INI 77:

1.44 On 19th November 2019, INI 77 informed the Inquiry Panel that she saw Dr Watt at UIC in 2013. She described her experience as follows:

[Dr Watt] didn't actually have the actual scan in front of him but he had the letter explaining it. What he said that day was, "no, I don't think it is Multiple

Sclerosis. It depends on the person's interpretation of the scan ... each person could interpret it differently" ... He asked me to walk across the floor and basically that was it. I was so surprised that I wasn't told you would need to have further tests done or anything. It wasn't even brought into it.

1.45 INI 77 gave evidence that she was not happy with Dr Watt's approach. On leaving the consultation, she stated: *"I came out (of the consultation) saying he didn't ask the right questions, he didn't go deep enough"*. She further told the Inquiry Panel that the private consultation with Dr Watt lasted 15 minutes at most.

1.46 INI 77 told the Inquiry Panel that she was subsequently seen by other consultant neurologists who were unsure whether she had multiple sclerosis ("MS"). As a result, INI 77 was referred to see Dr Gavin McDonnell, Consultant Neurologist, at the Belfast City Hospital.

1.47 In or around December 2015, INI 77 stated that Dr McDonnell examined her and came to the view that he thought she did have MS. She recalled:

He was 90% certain on reading the exact same as Dr Watt had read ... he put me through a lumbar puncture and MRI ... he was certain then.

1.48 On 3rd February 2016, INI 77 complained by email to UIC in the following terms:

I contacted your clinic for an appointment in 2013 for a referral with Dr Watt, regarding MRI scans which suggested MS. I then had an appointment with Dr Watt who asked a few questions and then told me I did not have MS.

I would now like you to inform Dr Watt that he was wrong & that after further scans and a lumbar puncture, I do actually have [Relapsing Remitting MS]. I find it appalling that a doctor like him asked so few questions and made his assumptions based on the very little information he asked and a quick review of my own MRI scan. If he had at least asked me to have further tests & came to this conclusion, I could understand this. Taking all this into consideration, I feel that Dr Watt should refund the fee which was paid to him at the time for his appalling diagnosis. I look forward to hearing from you.

1.49 UIC responded:

Further to your recent correspondence which I forwarded to Dr Watt, I write to inform you that Dr Watt is very sorry that you were disappointed with your consultation ... as requested and as a "without prejudice" gesture of goodwill, he has asked that the enclosed cheque be forwarded to you.

1.50 The governance of the Independent Sector, including the management of complaints, is addressed in detail in the Independent Sector chapter. The Inquiry

later established that the timing of INI 77's complaint was especially relevant and further commentary on the failure by UIC to communicate this complaint to Dr Watt's Responsible Officer in the Belfast Trust can be found in the 2016 Missed Opportunities chapter.

INI 22:

- 1.51 INI 22 informed the Inquiry Panel on 20th November 2018 that Dr Watt diagnosed her with multiple sclerosis. She described the process of her diagnosis as follows:

When I was first diagnosed by Dr Watt, he simply told me I had MS which I was totally unprepared for ... I had attended the appointment alone and the consultation with Dr Watt lasted no more than 3 minutes.

- 1.52 She described her experience of appointments as follows:

Once I attended an appointment at the [Royal Victoria Hospital] and was seen within 30 minutes, on all other occasions, I waited a minimum of 2 hours 30 mins, even when I did get to see Dr Watt it was never any longer than 5 minutes, generally more like he put his head in the door and said carry on with what you're doing to the nurse.

- 1.53 INI 22 informed the Inquiry Panel that she didn't raise concerns *"because (she) felt that this was simply the level of neurology care that was provided and that was simply the way it was ... I didn't know who to complain to"*.

- 1.54 INI 22 expressed the following view about nurses that worked alongside Dr Watt:

You got shrugs of shoulders and acceptance of the fact that this was the way it was.

- 1.55 INI 22's evidence provided the Inquiry with evidence indicating that there may have been an issue with the volume of patients attending Dr Watt's clinics and was relevant to the chapter on Lone Working and Practice Visibility.

INI 106:

- 1.56 INI 106 informed the Inquiry Panel on 3rd December 2018 that she attended her GP in May 2016. INI 106 stated that she was shortly thereafter referred for a consultation with an ENT consultant in UIC. INI 106 told the Inquiry Panel that, at a review appointment, the consultant requested an urgent MRI and walked her down the corridor to Dr Watt who was holding a clinic there. At the time, INI 106 recalled that her head pain was so bad that she was barely able to be upright.

1.57 INI 106 gave evidence that Dr Watt saw her immediately and having heard the history of her symptoms diagnosed a Cerebrospinal Fluid (“CSF”) leak. She stated that this diagnosis took approximately 5 minutes. INI 106 went on to say that Dr Watt proceeded to give her his mobile number and told her to WhatsApp him the results of the MRI which was due later that day. That afternoon, INI 106 stated that she messaged Dr Watt to advise him that she had further deteriorated and was completely unable to be upright and that the MRI results were clear. INI 106 stated that Dr Watt advised her to get herself to A&E to be admitted for an Epidural Blood Patch.

1.58 Between June and November 2016, INI 106 told the Inquiry Panel that she received four blood patches. INI 106 further told the Inquiry Panel:

My diagnosis, on the basis of symptomatic low CSF pressure was unable to be confirmed by diagnostic tests ... Also at the start of my blood patches, I was not tested clinically by measuring the opening pressure.

1.59 INI 106 also gave evidence that she *“was given an epidural blood patch, which was not recorded in her medical notes”*.

1.60 Following her first blood patch, INI 106 said that she noticed a difference in her symptoms. Indeed, after receiving the first blood patch, she stated:

Within a couple of hours, I was actually sat up in the bed and was able to eat sitting up and was able to leave the bed and go out to the toilet. It made such a difference. Prior to that I wasn’t able to be upright.

1.61 However, when asked how long the improvement in her condition lasted, INI 106 responded:

It is very difficult to be clear about this because immediately after that I had meningitis, clinical meningitis brought on by the blood patch, and after that I had a lot of side effects from that.

1.62 In September 2016, following discharge after her third blood patch, INI 106 stated she was unable to get any help when she phoned Ward 4E that she had just left hours earlier. INI 106 felt that she had no way of getting any help or advice so she waited all night and returned to the ward the next morning because she knew Dr Watt was on duty that weekend and would be doing his ward round. INI 106 believed that she had no other option than to present herself directly to the ward.

1.63 INI 106 described her third blood patch procedure as follows:

It was horrendously painful. It was like a red-hot knife going from the top of my head to the bottom of my spine. I screamed aloud repeatedly in terrible pain,

but Dr Watt continued to administer more blood ... Dr Watt stayed with me while I lay flat for an hour afterwards because as I was not an inpatient, I had no nursing care. He said he would not be recording this Blood Patch because it was so close to the previous one 3 days earlier. I went home an hour later and for months I suffered dreadful pain in my brain, which felt like it was burning. I needed ice packs and a fan 24 hours a day for weeks. The other symptoms were also severe and constant, unable to tolerate noise, sudden overheating, bladder dysfunction urinating every 30 minutes, unable to walk any distance, needing a wheelchair to get to hospital appointments, unable to sleep. I was given no pain relief and no way of getting help from Neurology.

- 1.64 Given the fact that her symptoms were continuing, INI 106 sought help from her GP. On 3rd November 2016, INI 106's GP sent a letter to Dr Watt asking for a review and expressing INI 106's concern that another blood patch, possibly a cervical one, was being planned, despite the symptoms she was experiencing.
- 1.65 INI 106 further told the Inquiry Panel that she also attended Dr Watt privately at UIC on 23rd November 2016. At this appointment, INI 106 stated that Dr Watt told her that he was going to do a fourth blood patch as an outpatient at the end of November.
- 1.66 INI 106 described her fourth blood patch as follows:

On 28th November 2016, I was given a 4th Epidural Blood Patch by Dr Watt and an attending nurse in the Programmed Treatment Unit [in the Royal Victoria Hospital] at 8.30am. After this procedure, I was unable to get up to go home because I experienced violent electric shock type pains darting very quickly through my brain, so I had to lie down again. This repeated each time I tried to sit up and I then became nauseous. I was very frightened about what was happening in my brain, and I asked Dr Watt what was happening. He said he didn't know but he didn't like the look of me. He admitted me immediately into the adjoining discharge lounge for patients waiting to go home. Dr Watt left, and I remained there for the rest of that day until the ward was closing for the night. At the end of the evening, I Whatsapped Dr Watt to ask if anyone was coming to see me as the ward was closing. At the last minute, Dr John? from Neurology came to assess me and said I was unfit to be discharged and I was transferred to another adjoining ward which was described to me as a "pop up" ward. I was very frightened about what was happening in my brain, and I was very annoyed that there was no input from Dr Watt or Neurology throughout that day, especially as the reaction to this blood patch was inexplicable and alarming causing an unplanned emergency admission.

1.67 During these months, INI 106 recalled that: *“she must have been in A&E eleven or twelve times”*. On one occasion, INI 106 gave evidence that a clinician said to her, *“you know Michael is just going to patch you again”*. INI 106 stated that she was aware of this and asked for less risky alternatives; the clinician² responded, *“do you know how risky this is”*? INI 106 further recalled this clinician having stated that other neurologists *“wouldn’t touch this procedure with a barge pole”*. INI 106 informed the Inquiry Panel that this was the first person who pointed out the risks of the blood patch procedure.

1.68 INI 106 gave further evidence that Dr Watt also considered a fifth blood patch. INI 106 outlined the conversation between herself and Dr Watt as follows:

I was very concerned because Michael had said to me “next time I am going up, I am going to do a cervical” and I said, “really, do you have to”? And he said, “well it’s not working, is it”?

1.69 As an outpatient, INI 106 felt she was repeatedly unable to access advice or help from Neurology about ongoing acute pain and a range of other associated symptoms. Throughout her involvement with Neurology Services, INI 106 stated that she was exasperated by the lack of aftercare, advice or support for blood patch patients. INI 106 also felt isolated and unsupported due to the lack of knowledge among clinicians about her condition. INI 106 was of the view that that the unfamiliarity of GPs with the condition and side effects following the procedure led to a gap in care. INI 106 said the following about her GP:

My GP phoned me after I had my first blood patch and came home, and she said “[patient’s name], I am reading here in your notes that it says you have had an epidural blood patch. What is an epidural blood patch? I have never heard of it. What is it and what is a leak? What is going on”? I am not saying that against her. She is a good doctor. But that is the experience of CSF leak patients throughout.

1.70 During her Inquiry Panel hearing, INI 106 told the Inquiry Panel that she, therefore, turned to Facebook groups to receive support. She stated that there is an international Facebook group for CSF leaks. There is also a specific group for the UK and a separate one for Northern Ireland. When asked whether the blood patches were effective, INI 106 commented:

I think the first blood patch worked ... I don’t know. Nobody even tried to explain that. I think the first blood patch worked and I think it was right. I think

² INI 106 believed that this clinician was a registrar in Neurology. Attempts were made to identify the doctor in question but were unable to confirm their identity.

after that successive blood patches were making me worse each time, and the symptoms that I was then coping with were from being over patched.

- 1.71 INI 106 stated that she was due to be reviewed by Dr Watt on 4th November 2017. She described her experience around this time as follows:

With no letter of appointment forthcoming, I made many phone calls to his secretary and was told that Dr Watt was not available. I was not given access to any other neurology consultant. Eventually, I wrote to Dr McDonnell on 23rd January 2018 complaining about the lack of ongoing care due to the continuing absence of Dr Watt and that I had ongoing issues which needed attention. He replied that he had arranged for me to be seen by another neurology consultant. The recall was then announced, and I was seen by Dr Peukert on 15th May 2018.

- 1.72 After the news broke, INI 106 stated that she contacted Dr Watt and said *“I am not sure what is happening to you or what is going on about the investigation into the blood patches, but I feel for you. You have been very kind to me”*.
- 1.73 INI 106 further commented that Dr Watt was *“a nice guy and he is genuinely concerned and genuinely kind and doing whatever he can to alleviate pain and suffering”*. However, from a governance perspective, INI 106 believed that Dr Watt was severely overworked, his caseload was not managed and there was no oversight.
- 1.74 The evidence of INI 106 detailed her experience of blood patching. The issues in respect of the use of this procedure including the involvement of nursing staff and registrars is explored in the chapter on Blood Patching. The concern of patients having limited or no access to blood patches, and communication with those patients by the Trust following the imposition of a partial restriction on Dr Watt in December 2016, is explored further in the Part A chapter.

INI 3:

- 1.75 INI 3 gave evidence to the Inquiry Panel on 15th November 2018. Following an MRI scan for suspected spontaneous intracranial hypotension (“SIH”), INI 3 was informed that there was no abnormality visible, but that, in any event, Dr Watt wished to proceed with an epidural blood patch, which was carried out on 1st February 2016 by Dr Watt. INI 3 described the procedure as follows:

Dr Watt carried out this procedure on his own, there were no other medical professionals present throughout this procedure, nor did any other medical professional assist Dr Watt in any aspect of this procedure. I was led to believe that this was a fairly routine procedure, with very minimal risks involved.

However, I have subsequently learned that this is not the case. ... During the course of the blood patch procedure, I felt horrendous pressure in my back, hips and legs and my urinary frequency was extremely urgent. I spent over 10 gruelling hours in the [Programmed Treatment Unit] on the day of this procedure, a procedure where I was informed would only last 2 hours at the very most. I was screaming in pain, holding onto the cot rails in extreme agony to the point where my mother had to walk away so that I would not see her distressed or crying. ...My mother sought out a nurse, who then rang for a member of Dr Watt's team to come down to see me as I began to violently shake. They prescribed Tramadol then left. When I was discharged home that evening, I spent the next 5 days in bed.

1.76 INI 3 further told the Inquiry Panel:

At the next review appointment, I informed Dr Watt that since having the blood patch that I was having issues with walking, I kept falling downstairs, my urinary frequency was very urgent. Then in the months that followed, I required the use of walking aids as well as a wheelchair. In May 2016, Dr Watt went back to his initial diagnosis of Hashimoto's Encephalopathy, which was disproved in 2014. I raised this with Dr Watt, however, I was told that the treatment of IVIG would help me and "make me better". I proceeded with the IVIG treatment on 20.5.16.

1.77 INI 3 stated that Dr Watt subsequently:

Stated that the treatment hadn't worked and then went back to the diagnosis of spontaneous intracranial hypotension, and he wanted to do a further blood patch.

1.78 With regards to the proposed second blood patch, INI 3 gave evidence as follows:

I raised concerns again about this with Dr Watt regarding having a second blood patch, especially after the first one left me in so much pain and unable to walk properly. Dr Watt informed me that it can take a few times of having this procedure before it worked. I initially agreed to a second blood patch, this time Dr Watt stated he wanted to inject the blood both into my neck and my spine. After my partner and family raised serious concerns with me regarding how the first blood path had affected me, I then decided against having a further blood patch. I informed Dr Watt of this decision, told him of all of my concerns and reasons for not proceeding, and asked that I was removed from the list. However, Dr Watt ignored my wishes and continually wrote in my clinic file, "arrange further patch", after I especially told him I did not want this treatment.

1.79 INI 3 stated that she had enquired with Dr Watt about pregnancy, and he advised: *"wait until you are fixed"*.

- 1.80 INI3 subsequently received correspondence from the Belfast Trust on 30th November 2017 and in written evidence to the Inquiry, INI 3 stated:

In November 2017, Dr Mark Michelson wrote to me on behalf of the Belfast Trust stating the requirement for Epidural Blood patching was under investigation by the Royal College of Physicians. This concerned me and caused me to be alarmed as I had this procedure. I raised these concerns with my GP, he received the same letter, however, he couldn't offer any further information.

- 1.81 The Inquiry subsequently spoke with INI 3's GP, but his recollection of the conversation was limited. INI 3 further stated:

I also contacted Dr Watt's secretary to relay my concerns on numerous occasions by telephone. I was continually told that Dr Watt was not under investigation, that he was off sick and would be returning in the New Year.

- 1.82 And further:

After obtaining my medical records and attending the review appointment as part of the recall, I again was extremely concerned. A meeting was arranged with [the Belfast Trust] on 15/6/18 I raised various concerns at this meeting, however received very little information or answers.

- 1.83 INI 3 summarised her experience to the Inquiry Panel as follows:

I feel that my whole experience with the Neurology service has been nothing short of appalling. I have been badly let down at every opportunity from the beginning of my care. I have been put through unnecessary treatment, medication as well as a procedure that I should never have had...It took me to get my local MLA involved for me to get any form of response from the Trust, however, even this proved very difficult at times ...

- 1.84 INI 3 provided the Inquiry Panel with minutes from her meeting with the Belfast Trust together with a response from the Belfast Trust to a Freedom of Information request which she submitted. The information obtained on the number of blood patches performed by Dr Watt was of significant value to the Inquiry. The evidence of INI 3 was also useful to the Inquiry in exploring the use and extent of epidural blood patch treatments within the Belfast Trust. These events are explored further in the Blood Patching chapter. The reference at paragraph 76 to the use of IVIG (human immunoglobulin) and the oversight of same, also became of interest to the Inquiry and this is discussed further in the Prescribing chapter.

INI 104:

- 1.85 On 6th December 2018, INI 104 informed the Inquiry Panel that Dr Watt diagnosed her with MS during her first appointment with him at UIC. She described the experience as follows:

I went in and gave him the GP referral letter and he read it. He said, “I see here it says on the letter that your mum and your brother both have MS”. I said yes. He said, “who are they treated by”? I responded, “actually yourself, that’s why I’ve come to you”. He asked me who they were, and I gave him my mum and my brother’s name and he knew them straight away. He said, well you know what we’re looking at then, don’t you? I said, “I am hoping that it is not”. He just went through history and things like that ... He just said he was going to arrange for me to have an MRI scan and a lumbar puncture and an evoked response test. He said he felt it was all very expensive, which it was, and he would transfer me over to the NHS waiting list. He said he would put me straight away on the register for disease modifying therapies because it takes three months for you to be approved on that and he felt that by the time the tests all came back that I could just move straight on to therapies ... I specifically asked him, because I knew with my mum’s history and stuff, I said to him, “if it is not MS what else could it be if the tests came back clear”? He said he would be “highly, highly surprised if the tests came back clear”.

- 1.86 In her questionnaire, INI 104 further stated:

As soon as my MRI came back clear in October/November 2013, I raised a concern as I felt I should have had some lesions on my scan, eventually all tests (lumbar puncture, evoked eye response test) came back clear and once the MS Nurse contacted me to arrange an appointment to start Disease Modifying Therapy I said to her that I felt I may not have had MS. She discussed with Dr Watt who said that- “How did they diagnose patients when they didn’t have medical tests?

- 1.87 INI 104 gave evidence to the Inquiry Panel:

I didn’t know where I was with him. He wasn’t very clear in what he was saying sometimes. We went in and he went through my MRI scan, and he said there’s no lesions, but there were white dots which are high density ... he walked on out. The nurse came in and said, right we are going to bring you in to start the treatment. And I said to her, do I have MS? She said, “what did Dr Watt say”? My partner and I both said, “we have no idea what he said”. He came back in and said to me “you have MS”. I said, “right, ok. are you sure”? And he said “yes”. I started the disease modifying therapies and said to [the nurse], “look I don’t believe this. Everything has come back clear. How can I possibly have

MS? I actually said to Dr Watt, and he said, what did they do in the days when they didn't have MRIs? He said "your family history".

- 1.88 INI 104 recalled: *"I always said I did not have MS to (Dr Watt) and the nursing staff at the clinic but was told I was in denial"*.
- 1.89 INI 104 informed the Inquiry Panel that she specifically stated that she told the nurse that she did not have MS. In response, she stated that the nurse replied, *"Dr Watt was an expert in his field"*. In INI 104's opinion, *"the nurses ... had complete faith in Dr Watt"*. The Inquiry Panel explored INI 104's evidence with the relevant nurse on 10th April 2019. She informed the Inquiry Panel that she only vaguely remembered INI 104. When questioned, she stated that she never had any concerns about any diagnosis of any patient by Dr Watt and, further, could not remember anybody querying their diagnosis.
- 1.90 INI 104 said that she challenged Dr Watt on several occasions about her diagnosis of MS. She recalled:
- Dr Watt stated, *"you're in denial, you are in denial"*. When I wanted to stop the medication, I always got told *"you're going to end up like your mummy"*. My mummy is extremely disabled. Even though I knew in my heart I didn't have it, there was that wee bit of fear if you took a relapse what was going to happen then ... I had to leave my job ... My family were petrified I was going to end up like their nanny.
- 1.91 INI 104 further informed the Inquiry Panel about a time that she bumped into Dr Watt in the corridor in the Royal Victoria Hospital and he said to her, *"look, another consultant probably wouldn't have diagnosed you as quickly as I did"*.
- 1.92 When reviewed as part of the recall, INI 104 stated that she was informed that she did not have MS. She described the impact as follows:
- Devastated because so much of my life had been put on hold, things I could do, jobs I lost out on. There's so many other ... my career I had ... I lost all that ... I was registered disabled for five years.
- 1.93 The use of Disease Modifying Treatments is explored in more detail in the chapter on Prescribing. The evidence given by INI 104 is also relevant to issues arising in the Concerns, Lone Working and Practice Visibility and Medical Culture chapters.

INI 117:

- 1.94 INI 117 attended the Inquiry Panel hearing with her mother on 10th December 2018. She told the Inquiry Panel that she had a long complex medical history. She

was initially seen by Dr Paul McMonagle, Consultant Neurologist although whilst under his care she also received treatment from Dr Watt. After having three epidural blood patches Dr Watt then took over her care. She recalled Dr McMonagle saying: *“This has gone beyond the scope of my expertise, so I am going to now transfer you to Dr Watt”*. Upon transfer to Dr Watt’s care, INI 117 stated that he recommended a blood patch. INI 117’s mother described their desperation as follows:

I can remember the conversations ... the turning point when I thought, there’s a wee bit of hope in their conversations now ... When we saw the first consultant, they just said, “too many complications” and then, maybe 10 days later, I was talking to a doctor and she said, “so many complications” And that’s how desperate we were, I said “so many”, “so many” is not “too many” ... and that’s when I saw there is a wee chink here that we could start bringing me back to life and that’s how we worked through this, you know ... step by step.

- 1.95 INI 117 gave evidence that she received 5 blood patches between May 2016 and March 2017. In this regard, INI 117’s mother stated:

We were initially happy to go on with [the blood patches] up until blood patch number three really. When four failed, we were starting to get worried about it. And then five came, she was seriously ill. So, we knew that was going to be the end.

- 1.96 INI 117 informed the Inquiry Panel that she received the fifth blood patch on her neck and that was the worst one. She further stated that Dr Watt had also planned to give a sixth blood patch using the Intracranial Pressure monitor, but she refused to have the procedure.

- 1.97 With regards to raising concerns, INI 117’s mother told the Inquiry Panel:

It’s very difficult to say to the doctor, we want to go elsewhere, especially when you have long term health problems, you that you are going to be coming back. We didn’t want to offend anybody.

- 1.98 INI 117 further stated that she travelled to London to get a second opinion within the private sector, where a specialist told her: *“I certainly won’t be doing any more blood patching”*.

- 1.99 INI 117’s mother further stated:

We have never really had any problem with Dr Watt. We liked him and when [my daughter] said stop, he stopped ... and he was always, you know, just I thought he was a bit light-hearted on the blood patch number(s) ... he was in very good form, and he was always optimistic. But we were desperate. We are coming in here, we are expecting now, *“Is this going to work?”* ... He said

“some people think because I act as if I am unconcerned that I am unconcerned ... but he said, “just because I act as if I am unconcerned doesn’t mean to say I am unconcerned” ... All that suffering and we were sort of grateful at the same time because we were desperate for solutions, and we were worried about offending people because we are going to have to come back to them.

- 1.100 She went on to say the following about Neurology Services:

So, it’s not so much Dr Watt. We just felt that the whole system up there was a bit, you know. A visitor said to me one day. “Sometimes you get the impression here that one doesn’t know what the other is doing”, and that’s nothing to do with Dr Watt. It was just chaos. It was always busy, and patients were in distress, and there was a lot of noise and especially whenever you would have procedures done you wanted silence. I mean it was a terrible place to be you know.

- 1.101 Having received INI 117’s evidence, the Inquiry subsequently established that her treatment, including the use of multiple epidural blood patches, had been presented by Dr Watt to his colleagues at a Neurosciences meeting in 2017. The Blood Patching chapter further explores this matter.

INI 125:

- 1.102 On 21st January 2019, INI 125 gave evidence to the Inquiry Panel that she first saw Dr Watt at UIC in February 2017. During her first consultation, INI 125 told the Inquiry Panel that Dr Watt informed her that she had a condition called “*spontaneous intracranial hypotension*” and told her that the only option was a blood patch.
- 1.103 INI 125 gave evidence to the Inquiry Panel that Dr Watt confirmed SIH at the follow up appointment. INI 125 stated that she explained to Dr Watt that she was frightened and confused and asked whether he could suggest any medication which would alleviate the pain. In response, INI 125 stated that Dr Watt told her to drink plenty of coffee. INI 125 told the Inquiry Panel that at no stage was the blood patch procedure explained to her.
- 1.104 INI 125 described an appointment at the Royal Victoria Hospital in May 2017 as follows:

I spoke with a nurse that was at the clinic that day and I explained my concerns with her, and I told her how reluctant I was to get the procedure done but felt I had no other option. Her response to me was “don’t tell anyone I told you this, but my advice would be definitely don’t get the blood patch done. I have seen the results”.

INI 125 could not recall the name of the nurse who told her this. She did, however, stress to the Inquiry Panel that: *“We really hope that this nurse doesn’t get into any bother over this ... because I thought it was very nice of her what she actually did in the first place ... I thought it was very brave of her to say what she said ... as far as I was concerned, she was doing above and beyond what she had to do”.*

- 1.105 INI 125 told the Inquiry Panel that several weeks later her husband contacted Dr Watt and told him that she felt she had no option but to go ahead with the blood patch as the pain was continuing. She recalled:

My husband rang Dr Watt and confirmed I was going to go ahead with the blood patch even though I was scared and knew nothing about the actual procedure. He told my husband that it now had to be rubber stamped by a second consultant and gave my husband Dr Stephen Hunt’s number and I made an appointment to see him on the 3rd April 2017 at UIC. During that appointment with Dr Hunt, I showed him the scan of the brain (which had previously been shown to Dr Watt), he discussed the procedure for the blood patch and following a series of questions, Dr Hunt confirmed that he would not rubber stamp the blood patch.

- 1.106 INI 125 stated that Dr Hunt confirmed that she did not have SIH. In relation to her thoughts about Dr Watt, INI 125 commented:

I put my whole trust in him as you just assume consultants are the experts and in most cases I think they are. I just did not think a top neurologist could get something so badly wrong.

- 1.107 INI 125 told the Inquiry Panel that she was subsequently diagnosed with chronic daily headaches in September 2018. The referral to Dr Hunt and the issues which ensued following the partial restriction imposed on Dr Watt in December 2016 (relating to the diagnosis and treatment of SIH) are discussed in the Part A chapter.

INI 123:

- 1.108 INI 123 informed the Inquiry Panel on 8th January 2019 that she experienced severe head pain in June 2016. She stated that she was unable to remain upright and had to lie flat. After the pain continued for several days, she attended A&E where a doctor examined her and suspected SIH. She further recalled that a CT scan of her head was carried out and arrangements were made for admission and MRI imaging.
- 1.109 INI 123 gave evidence that she was subsequently informed that the MRI confirmed a diagnosis of SIH and that she would be transferred to the Royal Victoria Hospital

when a bed was available. She was informed that she would be under the care of Dr Watt.

- 1.110 Dr Watt carried out two blood patch procedures. INI 123 described the first blood patch as follows:

Dr Watt carried out the blood patch procedure. He inserted 40 ml of blood. [A registrar] took the blood from my arm for the procedure. This treatment was carried out in a small room no larger than a small storeroom. No other witnesses were present, and it did not appear to be a particularly suitable or sterile environment. I did not sign any consent form and the procedure was carried out within 45 minutes of first meeting Dr Watt. I was not given any instructions about after care and the nurses on duty seemed unaware of how to care for patients after this procedure.

- 1.111 Three days later, INI 123 stated that Dr Watt performed a second blood patch:

Another blood patch procedure was carried out on Monday morning - another 40 mls. This procedure was very painful and difficult. There were repeated attempts to insert the needle in my spine and it caused intense pressure and pain in my head, shoulders and neck. It felt like my head was going to explode and the pressure was unbearable. I remained lying flat for most of the day as I felt very unwell. In the evening, I had an episode of intense pain in my head and neck. It felt like my head and neck were in spasm and I was unable to move my head.

- 1.112 INI 123 commented:

I do feel that, even amongst ... the nursing staff I don't feel like anybody on that ward really had an awareness of why we were there.

- 1.113 With regards to the environment in which blood patch procedures were carried out, INI 123 stated:

That Friday afternoon, Dr Watt arrived by the bedside, spoke for 30 minutes, said, "Come on, we'll go and do it now". You stood and waited ... And I mean, the room was literally down a corridor in - I can only describe it as a store cupboard. I was surprised. I thought, Right Ok, but again, your trust is there.

- 1.114 Following her discharge from hospital, INI 123 told the Inquiry Panel that she experienced intense headaches and daily pain. She stated that she contacted her GP for assistance but her GP had never heard of the condition and was unable to help. Ultimately, INI 123 stated that she returned to A&E as she felt that was the only option to access any information or help from the neurology team. She described this situation as *"psychologically distressing and unfair to be left feeling that there was nowhere to go for medical assistance"*.

- 1.115 INI 123 further told the Inquiry Panel that Dr Watt had recommended another blood patch as she still had head pain. She informed the Inquiry Panel that appointments were arranged twice but, on both occasions, she cancelled the appointments as she could not face the procedure again and she suspected that her ongoing symptoms were as a result of the second patch.
- 1.116 INI 123 told the Inquiry Panel that before the news broke about Dr Watt, she was also annoyed about the lack of communication from the Belfast Trust in relation to the situation with regards to Dr Watt being absent. This was the period between July 2017 and May 2018. INI 123 highlighted that she was not given any information about why Dr Watt was not seeing patients and was not given any advice about how to access help. Further, she was not transferred to the care of another neurologist or given an indication as to how long it would be until she would be seen again. Additionally, there was no helpline or information line.
- 1.117 In May 2018, INI 123 stated she was informed by a friend that Dr Watt was being investigated and patients were being reviewed. INI 123 felt that this information should have been relayed to patients first, not announced via the media. In relation to why INI 123 did not raise her concerns, she commented:

I did not raise my concerns about the blood patches and lack of care at the time because I trusted implicitly in the ability, expertise and honourable intentions of those treating me. I was also concerned that because of the rarity of my condition, if I disputed the recommended treatment or was seen as a ‘difficult patient’, I would not be able to access treatment. I was repeatedly told that it was such a rare condition that not many neurologists knew how to treat or deal with it. I believed all this to be true and desperately needed help. I was not very knowledgeable at that time about my condition and believed everything I was told.

- 1.118 In relation to her diagnosis, INI 123 stated:

I think it was the correct diagnosis because I can’t compare the head pain to anything else and the symptoms absolutely fitted. It was Stand up. Bang! Lie down again and there was nothing - no headache tablet, nothing - other than lying flat that made any difference whatsoever.

- 1.119 Overall, INI 123’s opinion was that her *“genuine feeling about Dr Watt ... I don’t truly believe he was trying to cause harm”*. Her evidence was relevant to the chapter on Blood Patching and the Part A chapter.

INI 124:

- 1.120 INI 124 informed the Inquiry Panel that she arranged an appointment to see Dr Watt at UIC. INI 124 described her first appointment as follows:

At that first visit, within 10-15 minutes of seeing me, Dr Watt gave me his diagnosis. After he carried out a quick physical examination, we sat down at his desk ... Without hesitation he told me that he believed that I had Motor Neurone Disease, which is one of the most horrible diagnoses that exists ... the diagnosis was pronounced with such surety. There were no “ifs” and “buts”.

- 1.121 INI 124 commented:

How such a diagnosis could be given so easily, without tests being done, is shocking. But this was an experienced consultant neurologist giving me this diagnosis and we believed him.

- 1.122 INI 124 further told the Inquiry Panel that her diagnosis was never questioned:

After that first visit Dr Watt never examined me again. I wondered why he never tested my muscle strength again. My big regret is that I should have questioned this. As a nurse, I should have known better but when you are in the hands of an experienced consultant neurologist you just try to accept his pronouncements.

- 1.123 INI 124 added:

What is very clear is that the power in the word of a consultant is enormous. I and a host of health professionals just accepted Dr Watt’s diagnosis as true. I was at the mercy of the so-called expert. When I saw all the health professionals (MNDA specialist nurse, the MNDNI Regional Care Development advisor, the Occupational Therapist, the Physiotherapist, and Speech Therapist) swinging into action after Dr Watt’s pronouncement, I never doubted that I had MND.

- 1.124 INI 124 further added:

The specialist nurse comes to your home every three months or so ... you wonder if she wouldn’t have wondered.

- 1.125 Following her diagnosis, INI 124 informed the Inquiry Panel that she “*ended up spending almost £10,000 of (her) own money on ... renovations*” to ensure her home was suitable for someone with an MND diagnosis. She also stated that she banked her voice, discussed peg tube feeding and palliative care decisions and explained the diagnosis to her grandchildren. INI 124 described the impact as follows:

I have been having panic attacks that I have never had in my life before. I have had an irrational fear about being left on my own. I have been angry at myself

for being gullible and believing Dr Watt. I have blamed myself for not asking for a second opinion. At times, I have found it hard to sleep. I feel very anxious. From being someone who never had mental health issues and who had worked hard mentally to come to terms with my MND diagnosis ... I am now mentally fragile and feel very vulnerable.

1.126 INI 124 further stated:

If out of this Inquiry there is better accountability for consultants that would be something good. How could Dr Watt ask for tests to be done and then when a fellow consultant does the tests and gives the results, he ignores the results? And no one in the neurology department picked up on that.

1.127 INI 124 also informed the Inquiry Panel that she had trouble obtaining her medical notes from UIC. She stated:

I've been in touch with the Ulster Independent Clinic to ask could I see what Dr Watt wrote about that first visit ... They said he's holding on to those. He hasn't released them is what they told me.

1.128 The Inquiry followed up with UIC in respect of INI 124's notes. In a letter of 6th February 2019 from lawyers acting on behalf of UIC, it was stated:

As the Inquiry is aware, UIC does not hold the notes & records concerning [INI 124]. Those notes and records are retained by Dr Watt. As evidenced to [INI 124], the Clinic did make repeated requests to Dr Watt for the notes. These have now been made available and were posted to [INI 124].

1.129 The Independent Sector chapter explores relevant issues including the holding of patients' notes and the sharing of information.

INI 105:

1.130 INI 105 attended the Inquiry Panel hearing alongside her children on 8th January 2019. Her account of meeting Dr Watt was as follows:

We paid to see Michael Watt at the Ulster Independent Clinic ... he didn't carry out any tests, asked [my husband] to lie on the couch and he looked at [his] stomach. [My husband] showed him the fasciculations on his arms. He told me to help [my husband] up from the couch while he went back and sat at the desk. He said, "He's got Motor Neuron Disease". I asked about what happens now and he said, "If there's anything you really want to do, do it now" ... then he said, "I'll get you into the Royal at the beginning of next week to do some tests, because you're going to need a breathing machine and a feeding tube peg put into your stomach."

- 1.131 She commented: *"We were out of the office and back in the car within ten minutes. His whole attitude was cold and flippant. [My husband] and I were struck dumb, having just been given the devastating news that [my husband] had MND and we knew it was an incurable, terminal condition"*. INI 105 further told the Inquiry Panel:

During our first appointment with Michael Watt, he told us he was the "Northern Ireland Expert" in MND. However, during a home visit from [an] MND nurse ... she advised us to change doctors ... At our next outpatient appointment with Michael Watt, where he again sat behind his desk and didn't examine [the patient], I told him what the MND nurse had said about [changing doctors] and he said, "if you want to change, change". We were very quickly dismissed from his office.

- 1.132 During a meeting with Dr Watt, INI 105 told the Inquiry Panel that she explained that the fasciculations weren't getting any better despite the medication. She recalled Dr Watt's response: *"he told me, the only time you need to worry about them is when they stop. They stopped on 4th September 2016; the day [my husband] died ... This conversation has haunted me ever since"*. When asked why she didn't raise concerns, she stated: *"I think, overall, none of us, really, as just ordinary people, would complain about a doctor ... you don't do it"*. She added:

While I don't doubt [my husband's] diagnosis, the manner in which he and his family were treated by Michael Watt was totally unacceptable and less than professional ... While I appreciate that almost 3000 patients who are still alive have had to be reassessed, I appeal to the Inquiry to not forget about those who have already died and their families who are suffering with grief which has been compounded by the need for this inquiry and the ongoing media coverage.

- 1.133 The experience of the INI 105 family, the perception of their role as patient/carer and the difficulty in raising concerns is included as an index example of a particular genre of evidence from some patients.

INI 177:

- 1.134 INI 177 told the Inquiry Panel on 25th February 2019:

I asked Dr Watt about a second opinion, and he told me that there was no point in getting another opinion because I was so rare - maybe one in 100,000 or even one in a million so there was no point. Sadly, I listened.

- 1.135 INI 177 further stated:

Then, at the behest of medical friends outside Northern Ireland who were concerned at my condition, we decided that I would get a second opinion in

London and I attended, privately ... at Queen Square in London ... [the doctor] reviewed my MRI scans ... and he was surprised that a CT scan had not also been performed on the area of the lesion, which is an established aid in diagnosing a meningioma where a biopsy cannot be performed. We didn't know that.

- 1.136 INI 177 went on to say that she then attended a further consultation with Dr Watt. She recalled:

I had sent him a medical report and imaging reports from my second opinion in London by post ... so he'd had a little bit of time to look at it before I went. He reluctantly agreed that the Queen Square diagnosis was correct.

- 1.137 INI 177 described the impact as:

I was very upset, obviously, and my husband and myself complained to him that a CT scan should have been carried out at the beginning and that I would not have had a high dose steroid and immunosuppressant treatment for over a year. I don't know what the side effects of that have been.

- 1.138 INI 177 also told the Inquiry Panel about the difficulties in getting an extra contractual referral. The Inquiry Panel was informed by INI 177's husband that the referral to London was never made. INI 177, therefore, had to pay privately for her treatment in London.

- 1.139 INI 177 commented:

I think the key point we will want to make: the system- whether it's a system or its Dr Watt ... the system on attempting to get extra-contractual referrals was not working properly, and either they didn't understand it or they were trying to (avoid it?) ... because of the misdiagnosis. During this period, my condition worsened significantly, and the meningioma had grown.

- 1.140 Her husband further stated:

I wouldn't like the Extra-contractual referral to dominate ... what (we) have given you today. We are much more concerned about the system and how diagnoses come and all that sort of stuff.

- 1.141 The difficulties experienced by patients in getting a second opinion are discussed at various points in the Complaints and Concerns chapters.

INI 87:

- 1.142 The Inquiry heard from the parents of INI 87, who told the Inquiry Panel on 11th March 2019:

Dr Watt diagnosed our son as having epilepsy. Even though this was a life changing condition, our son was just glad to know what was wrong with him, although he never fully came to terms with it. Dr Watt prescribed medication and reviewed our son on a three-monthly basis, or before this if there were any problems. There was little or no improvement in our son's condition and a scan then revealed an arachnoid cyst on the left temporal lobe of our son's brain. Dr Watt thought the best way forward was to refer our son to Mr Stephen Cooke, neurological surgeon [at the Royal Victoria Hospital].

1.143 INI 87's mother gave evidence that:

Since as far back as early 2005, our son and I had spoken to Dr Watt regarding taking him into hospital and taking him off all the medication and starting from scratch. Dr Watt's reply to this was - but sure he likes his tablets. My son and I were both concerned about the levels of medication with no improvement in his medical condition.

1.144 Sadly, INI 87 died in 2006. INI 87's mother commented:

I feel that basic good practices and procedures were not in place to monitor our son in the community especially with such high levels of medication. In other words, the system failed our son and our whole family ... his symptoms at the time of and well before his sudden death consisted of the following: right side weakness, trailing his leg, purplish discolouration in his arms and especially his hands, sweating, dramatic weight loss, loss of appetite, depression, headaches, pains, seizures, dizziness and visual disturbances. I understand that some of these symptoms can be attributed to side effects of his medication - in other words the medication appeared to be causing more problems than cures.

1.145 The tragic death of INI 87 is commented upon further in the 2006-07 Missed Opportunities chapter.

INI 286:

1.146 In the early stages of its work, the Inquiry Panel became aware of a concern raised by three clinicians in the Northern Trust relating to the practice of Dr Watt. It became clear that the concerns arose after a complaint was made by a patient and his family about the care provided in the Northern Trust. To assist with understanding how the complaint arose, the Inquiry made contact with INI 286 (the patient) and his family who had assisted in making the said complaint. INI 286 and his family accepted the invitation and attended the Inquiry to give oral evidence.

1.147 The mother of INI 286 told the Inquiry Panel on 5th November 2019:

My son ... was first admitted to Antrim Area Hospital with what appeared to be seizures on 23rd August 2014 ... Since then, we have been seeking medical attention for him to try and find out exactly what his condition is and what treatment he needs to give him a better quality of life.

1.148 INI 286's mother stated: *"About a week later ... my son took what appeared to be a stroke at home, his face fell on left side, he was disorientated, couldn't lift his arms, didn't know who people were"*.

1.149 The Inquiry Panel was informed that their son first went to see Dr Watt at UIC. INI 286's mother recalled: *"after [Dr Watt] listened to my son's symptoms, he told us he had had a stroke, no doubt about it. He gave us a prescription for Aspirin and another blood thinner"*.

1.150 Subsequently, INI 286's mother stated:

Slow progress was being made until July 2015, my son was very sleepy all week, on the Sunday, he fell and shortly after he couldn't get up, his speech went, he couldn't swallow his spittle, he had pins and needles in head and arms.

1.151 At this stage, INI 286's mother informed the Inquiry Panel that their son was reviewed by a Consultant Geriatrician in the Northern Trust. She did not consider that INI 286 had suffered a stroke and according to INI 286's mother, the plan was for discharge with referral to physiotherapy and psychiatry.

1.152 The complaint raised by INI 286 and the subsequent concerns raised by the consultants in the Northern Trust, led to an independent report being commissioned. The significance of this report and the handling of these concerns is commented upon in the Concerns chapter and the 2016 Missed Opportunities chapter.

Conclusions:

1.153 The Inquiry Panel was struck by the determination of the patients of Dr Watt to ensure that issues were properly investigated and that lessons will be learned from this Inquiry. At critical junctures, groups of patients of Dr Watt have publicly articulated understandable frustrations at delays and maintained a focus on ensuring the timely publication of the Inquiry report.

1.154 The Inquiry Panel regrets that not every questionnaire response or oral testimony could be included in the actual report. The Inquiry Panel wishes to record its profound gratitude for those who responded to the questionnaire and especially the

patients who gave oral evidence. The information obtained had a genuine impact on the Inquiry and strengthened the determination of the Inquiry Panel to ensure that it produced a meaningful report, which advanced the primary objective of improving patient safety.

- 1.155 Ultimately a decision had to be made on whether the oral evidence was sufficiently germane to the Terms of Reference that it should be included in this chapter. At an early stage, it seemed appropriate to include the testimonies of each patient who was invited to give evidence. On reflection, however, it was decided to restrict patient extracts in the report to those accounts which had led to a specific train of enquiry relevant to the Terms of Reference.
- 1.156 It is the case that it was often patient accounts that led to some of the most critical evidence being evaluated. At every stage, the Inquiry Panel has sought to keep at the forefront of its deliberations, the basic premise that the Inquiry will only have limited value if it does not ultimately result in patient safety being improved. Each process currently relied on to govern the Belfast Trust, and to oversee the activities of its consultants, must be viewed through that lens.
- 1.157 The Inquiry wishes to pay its own tribute to the resilience and determination of so many patients who ensured that the patient voice was never ignored or side-lined. Many patients had been understandably reluctant to question the expertise of a well-respected neurologist. Some stated they did have a concern but felt conflicted raising it with a trusted consultant. The situation was compounded by the complexity of neurological conditions and the additional difficulties sometimes encountered in confidently identifying a specific diagnosis.
- 1.158 The Inquiry Panel also recognises that as with many other sub-specialties, neurology was under the most intense pressure. Waiting list times for an appointment became an increasing problem, to the point where, at times, the situation had become chronic. This state of affairs has only worsened since the advent of this Inquiry, and it is recognised that intense work will be required to ameliorate the situation. In such a highly pressurised environment, it could be tempting to focus almost exclusively on seeing patients and de-prioritising some of the governance concerns raised in this report. That would be a mistake. Concerns that quality and safety improvement initiatives had not been given "*primacy of focus*" were highlighted in Sir Liam Donaldson's report in December 2014. Many of those same issues, including clinical leadership and cultural change, feature prominently in this report. Addressing the current challenges must include at the heart of any co-ordinated response, a particular focus on improving patient safety.

CHAPTER 2 – COMPLAINTS

Introduction:

- 2.1 A central aspect of Part B of the Inquiry Terms of Reference was to review the Belfast Trust's handling of relevant complaints or concerns in relation to Dr Watt, identified or received prior to November 2016. To determine and assess whether the handling of complaints was appropriate, it is necessary to give an overview of how the system in place at the time handled the complaints that it received.

Department of Health Guidance:

- 2.2 The Health and Social Care Complaints Procedure, *'Complaints in Health and Social Care: Standards and Guidelines for Resolution and Learning'* was developed and published in 2009 by the Department of Health and applies to all Health and Social Care bodies including the Belfast Trust. This document replaced the former Health and Social Care (HSC) Complaints Procedure 1996 that applied equally to all HSC organisations and aimed to provide a streamlined and consistent process. According to the introduction to the revised Guidance in 2019:

The HSC Complaints Procedure (published 2009) was developed in conjunction with HSC organisations and publicly consulted on before being finalised and published. It reflected the changing culture across HSC services and demonstrated an increased emphasis regarding the promotion of and need for safety and quality in service provision as well as the need to be open and transparent; and to learn from complaints and take action in order to reduce the risk of recurrence.

- 2.3 The 2019 revision did not alter the key principles set out in the 2009 Complaints Procedure renamed *'Guidance in relation to the Health and Social Care Complaints Procedure'* (*"HSC Complaints Procedure"*). The revision set out the aims of the process as:

- A strengthened more robust local resolution stage
- An enhanced role from commissioners in monitoring performance management and learning
- Improved arrangements for driving forward quality improvements across the HSC
- Improved arrangements for the delivery of responses to complaints

2.4 The 8 specific standards of the HSC Complaints Procedure are:

- Accountability
- Accessibility
- Receiving Complaints
- Supporting Complainant and staff
- Investigation of complaints
- Responding to Complaints
- Monitoring
- Learning

2.5 Much of the framework of the 2009 Procedure and 2019 Revision is laudable and coherent. The focus of the Inquiry was, however, on Investigating Complaints and in the Recording of Information. The former is one of the 8 standards for complaint handling. The latter is relevant to a number of the standards and, in particular, monitoring.

2.6 Section 3 of the 2019 Revision sets out the criteria by which organisations must operate in relation to investigation. The purpose of investigation is not only resolution but also to:

- Ascertain what happened or what was perceived to have happened
- Establish the facts
- Learn lessons
- Detect misconduct or poor practice
- Improve services and performance

2.7 Paragraph 3.27 states:

Whoever undertakes the investigation should seek to understand the nature of the complaint and identify any issues not immediately obvious. Complaints must be approached with an open mind, being fair to all parties. The complainant and those identified as the subject of a complaint should be advised of the process, what will and will not be investigated, those who will be involved, the roles they will play and the anticipated timescales. Everyone involved should be kept informed of progress throughout ...

- 2.8 At the completion of the investigation, the investigator should prepare the draft report/response with a view to recording and explaining the conclusions reached following investigation of the complaint. Paragraph 3.33 of the 2009 Guidance notes:

Where the complaint involves clinical/professional issues, the draft response must be shared with the relevant clinicians/professionals to ensure the factual accuracy and to ensure clinicians/professionals agree with and support the draft response.

- 2.9 In section 4, it is noted that each HSC organisation has a legal duty to operate a complaints procedure and is required to monitor how they deal with and respond to complaints.

4.2 HSC organisations are also required to keep a record of all complaints received, including copies of all correspondence relating to complaints. HSC organisations must have effective processes in place for identifying and minimising risk, identifying trends, improving quality and safety and ensuring lessons are learnt and shared. HSC organisations must ensure regular and adequate reporting on complaints in line with agreed governance arrangements...

4.4. The HSC must ensure they have the necessary technology/information systems to record and monitor all complaints. For the purposes of measuring the effectiveness of the procedures, HSC organisations must maintain systems ...

- 2.10 The legal framework in respect of complaints in the Health & Social Care sector is set out at Annex 2 of the 2019 Revision. The Inquiry Panel notes the provisions of the Health & Social Care Complaints Procedure Directions (NI) 2009. Of note is the general duty of the various HSC bodies, including the Trusts, to co-operate, answer questions, attend meetings reasonably required and provide information to the body carrying out the investigation. Regulation 6 requires each HSC body to appoint a senior person within the organisation to take responsibility for ensuring compliance with the arrangements made under the regulations.

- 2.11 A specific requirement at Regulation 11 is that the Complaints Manager shall send to the complainant a written acknowledgement of the complaint within two working days of the date on which the complaint was made. Further, at Regulation 14, the Complaints Manager must ensure a written response is prepared to the complaint which summarises the nature and substance of the complaint, describes the investigation and summarises its conclusions. At Regulation 14(4), it is stated:

The response must be sent to the complainant within 20 working days beginning on the date on which the complaint was made or, where that is not possible, the

complainant must be notified of the delay and the full response issued as soon as reasonably practicable.

System for Handling Complaints within Belfast Trust:

- 2.12 In considering whether the handling of the complaints by the Trust was appropriate, the Inquiry looked carefully at how complaints received in relation to Dr Watt were dealt with and collated. The system relied on a Complaints Department that received all manner of complaints from car parking to catering. The focus was on ensuring that complaints were answered within 20 days¹. If it was determined that a complaint was relevant to a particular service area, then the details are forwarded to the relevant Service Manager who, together with the Assistant Service Manager, will investigate the matter.
- 2.13 The draft response was then checked by the Co-Director for the Acute and Unscheduled Services, and ultimately by the relevant Director of Acute Services. The purpose of this exercise was to try and ensure that the response was appropriate and had addressed the issues raised. Information on previous complaints is stored on the Datix system², which is a central record of all complaints in the Trust.
- 2.14 The Inquiry Panel was focused less on the actual outcome of the complaint and more on the methodology utilised and the arrangements made for evaluation and assessment of the issue. In particular, the Inquiry looked at evidence of complaints with a clinical dimension to see to what extent they produced a pattern of concern or enabled learning to take place. Further, the Inquiry Panel looked at the arrangements made to collate the complaints and has sought to address whether the systems utilised permit the relevant decision-makers and, especially the Medical Director to have access in a compendious way to the complete picture regarding a particular doctor.
- 2.15 The aim of the complaints system, in accordance with the Department of Health Guidance, is to satisfy the complainant and ensure that the Trust learns from the complaint. On reflection, the system should also be, if properly evaluated, an early indicator of aberrant practice. It is this aspect, and the importance of Trust learning, that is most relevant to the Inquiry's Terms of Reference. While the satisfaction of a complainant's grievance is undoubtedly an important facet of any process, the Inquiry has not sought to determine such matters as they are outside the Terms

¹ This is the response time laid down by Reg 14(4) of the Health and Social Care Complaints Procedure Directions (Northern Ireland) 2009. See 16 *supra*.

² The Datix system is a computerized record of all complaints received within the Trust. It used by the Health Trusts across the UK.

of Reference. The relevant complaints have, therefore, been assessed with a view to identifying whether, if evaluated, they could have been useful indicators of a developing problem.

- 2.16 The Inquiry has obtained evidence relating to the handling of complaints in Neurology, specifically those relating to Dr Michael Watt. Nevertheless, much of the evidence is, in the Inquiry's view, likely to have a wider significance within the Trust or other Trusts. There is no reason to believe that the practice in other Service Departments materially differs from that which pertained in Neurology.
- 2.17 The ability of the Datix system (referred to at 13 above) to collate information and operate an accessible search facility became a focus of concern, as outlined below in the History of Disclosure to the Inquiry.
- 2.18 If the relevant complaint had a clinical dimension, then the views of the treating clinician would normally have been sought and his/her response included in a prepared draft. Within the Neurosciences Division, the Clinical Director was asked on occasion to check a draft response, especially if there had been a clinical issue raised. In the evidence of the Clinical Director, Dr John Craig, this was to 'sense check' the draft. Without access to the patient's medical notes and records he did not regard the check as a proper review of the case. The then Assistant Service Manager, Clare Lundy, in her evidence of 25th May 2021, described the 'check' in more elevated terms as, *"What's your opinion? What's your thought? Can you review this?"* What is clear at this remove is that there was confusion between the Clinical Director and other managers as to what was required and expected.³
- 2.19 In written evidence submitted by the Trust on 4th April 2021, the Trust pointed out that since 2012 the complaints policy of the Belfast Trust was that *"there would be consideration of the proposed complaints response by a similarly qualified clinician to the person complained about"*. The Trust submitted that this supported Ms Lundy's understanding of why she was sending complaints identified as having a clinical aspect to Dr Watt's then Clinical Director for review.

Action taken by the Belfast Trust since the commencement of the Inquiry:

- 2.20 During the first year of the Inquiry, when it was non-statutory, the Inquiry Panel encouraged action to be taken before the publication of the report in areas where problems could be easily identified. Complaints was one such area. Although the

³ In written evidence from Mrs Bernie Owens dated 19th May 2022 Mrs Owens pointed out that she was surprised to note Dr Craig's description of a "sense check" and that she took a level of assurance of Dr Craig had been involved in checking a response.

Inquiry is not in a position to evaluate the actions taken, the Inquiry Panel strongly welcomes the many initiatives taken partly as a result of early interaction with the Inquiry by the Belfast Trust.

- 2.21 The Belfast Trust also made the point in written evidence of 4th April 2022 that the Departmental Guidance is silent on how one should specifically address clinical complaints. No doubt the Guidance could have addressed this, but the Inquiry Panel notes that the Guidance is replete with standards and aims and the implementation of same is left to the individual Trusts. The Belfast Trust has sought to develop clarity to this aspect of its complaints policy and provided details of the initiative that has been taken.
- 2.22 The Inquiry noted an internal audit report in April 2016 which found that there was a “limited assurance” in respect of the Belfast Trust Management of complaints. The Trust set out in detail the actions that had been taken subsequent to that internal audit report⁴.
- 2.23 An enhancement of the 2020 Belfast Trust Complaint’s policy took place in 2020. This introduced a “Clinical Record Review” which required review by a peer who reported to the relevant Clinical Director for any complaint that related to the quality of treatment or care. In February 2019 a template developed by Dr Jack was piloted for the testing of the Clinical Record Review and in July 2019, 28 complaints made against Dr Watt were reviewed to test the efficacy of the Clinical Record Review. This resulted in a recommendation that the introduction of a Clinical Record Review should be considered for the future management of all clinical complaints within the Belfast Trust. On 8th April 2020 a new 2020 complaints policy entitled Policy and Procedure for the Management of Complaints and Compliments and containing the Clinical Record Review Mechanism was signed off by the Medical Director and the Chief Executive and in May 2020 was formally introduced into the Belfast Trust and had been relaunched in June 2021 following an audit to evaluate compliance. Although the Inquiry is not in a position to evaluate the actions taken, the Inquiry Panel strongly welcomes the initiatives taken partly as a result of early interaction with the Inquiry.

⁴ This report triggered the commissioning of a benchmarking review of complaints management systems and processes in October 2016. The review was published in April 2017 and included recommendations for potential improvements to complaints processes. A further review of the Complaints policy was carried out in 2017 and a new policy was adopted in March 2017. The clinical complaint peer review mechanism continued in its original form in a new paragraph 11, which sought to strengthen the investigation process. The Belfast Trust’s Shared Learning Group was expanded to include learning arising from complaints. In April 2017 there was a further review by Internal Audit which reported a finding of satisfactory assurance in relation to the Belfast Trust’s management of complaints. In August 2017 Quality Assurance checklists were developed to assist staff in providing “consistent and robust” complaint responses. In April 2018 the Trust’s weekly governance teleconference was expanded to include discussion and escalation of key governance issues arising from complaints and Northern Ireland Ombudsman cases. In May 2018 the effectiveness and focus of the Belfast Trust Complaints review Group was considered. This resulted in the establishment of a “Service user Experience Feedback Group” to inform learning. In November 2018 the Complaints Department began providing monthly update reports to the Directorates to support greater monitoring and management of complaints and assist Directors to identify trends. In December 2018 a retrospective manual review of complaints files was commenced by the Complaints Department to identify all doctors named in complaints to ensure that medical staff were appropriately linked to the relevant complaint entry in Datix.

History of Disclosure during the Inquiry:

- 2.24 The Inquiry was announced in May 2018 and, at that stage, in line with the Trust's existing policy, earlier complaints received prior to 2007, would have been destroyed. The Inquiry was able to obtain access to a records tracker, which identified the numbers of those complaints. Using Datix identifiers provided on the records tacker, the Inquiry was able to obtain a brief description of the substance of some of the complaints. It is fair to say that most of the earlier complaints appear to relate to waiting times, both for the appointment to take place and at the clinic itself, together with a lesser number, which had concerns about Dr Watt's attitude.
- 2.25 The Inquiry has no way of knowing as to whether there was information contained within files which would have been relevant. The entries on the Datix system were not detailed and did not permit a proper evaluation of the complaint, or an analysis, which may have been useful in identifying trends. The Inquiry Panel does note, however, that one complaint (INI 409) was deemed important enough to have been raised with the then Medical Director, Dr Michael McBride, by the Patient Liaison Manger, Pauline Webb, in December 2006; the handwritten note of which refers to the lack of physical examination being carried out. There may well have been 'red flags' among these complaints.
- 2.26 Such information must be maintained and retained in an accessible way. Dr McBride stated in his evidence to the Inquiry on 7th November 2019:
- Simply having numbers of complaints on a sheet tells me absolutely nothing. I can understand why the patient elements of a complaint might be destroyed, in terms of – in the interests of the patient – and GDPR, and all the rest of it, and data protection. But in terms of the findings from a complaint or elements, which may be relevant to a doctor's continuing practice, my strong view, although I have not thought about this before, would be that that absolutely should be retained, you know there is intelligence within this which at least the analysis of that and the output of that should be retained, if only from the point of view of learning for the individual doctor in reflective practice.
- 2.27 The Inquiry must also record that following the announcement of the Independent Neurology Inquiry in May 2018, the Permanent Secretary of the Department of Health, Mr Richard Pengelly, wrote to the Chief Executive of the Belfast Trust, Mr Martin Dillon, to ensure *"that the Trust take action to secure all records and communications related to complaints and adverse incidents involving Dr Watt"*. The Trust confirmed on 24th May 2018 that *"action had been taken to secure all records and communications relating to complaints and adverse incidents involving Dr Watt"*.

- 2.28 The Trust subsequently became aware in late 2018 that the Neurosciences Service Manager had disposed of the personal office records relating to neurology complaints in September 2018. An explanation was provided to the Inquiry Panel on 12th February 2019 and an Investigator, independent of the Trust, immediately commenced an inquiry into the destruction of the material. This report was forwarded to the Inquiry on 19th April 2019. The material destroyed was, according to Mr Gerry Atkinson, the then Service Manager, in line with the extant policy that documentation over 10 years old could be destroyed in accordance with the Trust's *Records Retention and Disposal Policy & Schedule*. Mr Atkinson did not believe he had been informed of the directive from Mr Pengelly or anyone discussing the content with him.
- 2.29 The Investigator made various recommendations and the Records Retention Policy is discussed in the conclusion section to this chapter. While the Trust acted swiftly to address the incident that had occurred, it appears that there was a failure by Trust management to properly communicate the contents of the directive from Mr Pengelly, which permitted Mr Atkinson to destroy material that, although not containing patient records, did include Mr Atkinson's personal office records, some of which may have been relevant to the Inquiry. It does appear that as these were not original records that the Inquiry was still able to piece together the relevant evidence. The question of the storage of complaint material remains an important question to be considered.
- 2.30 The Inquiry was anxious to ensure that all the relevant complaint material was provided. Unfortunately, despite strenuous efforts, in particular, by Ms Clare Lundy, the former Assistant Service Manager and now Service Manager, some complaints were still being uncovered in September 2021, over 3 years after the commencement of the Inquiry. As and when information was discovered, it was disclosed immediately. The greater problem, however, was that the systems then in operation did not give confidence that the relevant information could be obtained by the appropriate decision-maker at the right time allowing for pattern recognition.
- 2.31 The Inquiry would often discover, by reference to other documentation, that a complaint had been made, which had not been disclosed by the Trust. By way of example, on 16th May 2019, the Trust's solicitor responded to a query from the Inquiry as to why complaints by INI 284 and INI 440 had not been disclosed. The explanation provided by the Senior Manager in Complaints was as follows:

First of all I would like to give an assurance that every effort was made, and continues to be made by the complaints team to provide any and all information

requested by the Inquiry. I would apologise for any issues regard to these 2 complainants.

The complaints case previously provided by the complaints department regarding MW arose from 2 sources:

a) Listings provided by Ken Fullerton in September 2018 identifying complaints for whom complaints files were to be copied and submitted – see attached emails. Neither [INI 284] or [INI 440] were named on any of these lists and so would not have been included at that time.

b) The Complaints team ran searches on the Datix complaints modules both for BHSC and legacy Trusts to identify all complaints where MW (and the other Neurology Consultants) were specifically linked (via the “Employee screen” option on Datix). None of the complaints associated with [INI 284] or [INI 440] were linked to MW on the system and so would not have been extracted by Datix when the reports were run. There are unfortunately limitations on the ability of Datix to extract complaint cases against specific parameters and given the volume of complaints received each year it would not be practicable to manually review each and every one retrospectively.

- 2.32 In June 2020, the Inquiry was concerned that an index complaint (INI 87) was not included in the complaints that had been disclosed. An explanation was sought and given by the Trust’s solicitor:

[The parents of INI 87] contacted the Belfast Trust following the coverage of the recall in May 2018. At this time the Medical Director’s office obtained the [INI 87] complaint file from the complaints department in order to review the case and respond to [the parents of INI 87] (as per the reference to Mr Watson on the list which you supplied to me in your email). As a result of this, the [INI 87] complaints file was not with the other complaints files, which Dr Fullerton obtained from the complaints department for the purpose of copying and collating the Trust’s submissions to the Inquiry. Although, as mentioned above, you will note that the fact that there was such a complaint was included in the summary page which you provided to us. The commission of the [INI 87] complaints file from the Trust submissions was an oversight and the Trust would wish to apologise to the Inquiry for this. The Trust had not realised the documentation had been omitted and assumed that the details had gone to the Inquiry, not least in the context of the various discussions there were about the case.

- 2.33 Subsequently, a further complaint regarding INI 436 was discovered. In a letter of explanation from Mrs Bernie Owens, now the Deputy Chief Executive in the Belfast Trust, it was stated:

The Complaints Department of the Belfast Trust uses an electronic database, Datix, to log complaints. For each complaint entered on Datix there is a significant number of data entry fields available that could be completed by the member of staff inputting the data. One of the available data entry fields is where you can enter the name of a medical professional associated with a complaint. This field was not used by the inputter when the case of [INI 436] was entered on Datix in 2015. Therefore, in 2018, when the Complaints Department carried out an electronic search to identify complaints received by the Belfast Trust relating to Dr Watt, the complaint of [INI 436] did not appear amongst them.

- 2.34 The Belfast Trust's problem with identifying all the complaints relating to Dr Watt was further compounded when, in May 2021, shortly before Ms Lundy appeared again before the Inquiry Panel, it transpired she had uncovered, from her own search, further complaints that had not been disclosed, namely INI 441 and INI 450. The Inquiry Panel wish to acknowledge the careful searches that were carried out by Ms Lundy and accept that there was no question of any attempt to withhold information, although it was disappointing that the Inquiry was into its third year before the information was received. The evidence now obtained, however, reinforces overall concerns about the effectiveness of the complaints system and the ability of the Trust and especially the Medical Director, to be clearly sighted on each of the complaints, which have been made against a specific doctor.
- 2.35 In September 2021, in response to issues flagged by the Inquiry, the Trust disclosed 5 lever arch files holding material relating to 100 complaints identified as potentially relevant, following a manual review of all complaint files within neurosciences. Of these, 21 were identified as directly relevant to the Inquiry Terms of Reference. Mrs Owens explained:

The Belfast Trust recognises that the electronic search of the Datix system (together with the provision of some complaints material from within Neurosciences, such as recently provided by Ms Lundy) is insufficient to provide the Inquiry with a high level of assurance that, as far as possible, all relevant complaints relating to Dr Watt have been provided. Consequently, the Belfast Trust has, amongst other things, put in train a manual review of all complaint files relating to Neurosciences held by the Complaints Department for as long as the Belfast Trust has available records (from circa 1996). This significant piece of work is being carried out urgently. It has involved relevant staff coming in on the weekend to conduct and complete the task. The work is ongoing.

- 2.36 The history of disclosure is important because it demonstrates a more significant problem with the collation of records, the triangulation of data and the ability of

the Trust to obtain information which might identify a pattern of practice. This is commented upon further below.

Complaints Regarding Dr Watt:

- 2.37 This chapter records chronologically each of those complaints involving Dr Watt within the system, which have been disclosed to the Inquiry and which relate either to the quality of the patient/client relationship, the delay in providing reports and/or questions around clinical diagnoses and treatment.

INI 403:

- 2.38 On 26th February 2001, the patient complained about the fact that there was an issue with a diagnostic lumbar puncture, which had been performed by a registrar. The substance of the complaint was the lack of interest allegedly displayed by Dr Watt, who also had not responded to communication.
- 2.39 The letter of complaint composed by the patient's wife, was forwarded to the Chief Executive of the Royal Victoria Hospital on 26th February 2001. The patient's wife stated that the lumbar puncture carried out had caused significant complication and was eventually rectified by a consultant with greater experience. In relation to Dr Watt, the correspondence highlighted the fact that, in the past, Dr Watt had gone out of his way to be helpful to the patient. Attempts, however, to contact Dr Watt to discuss the complications proved problematic. The patient stated:

... I will reiterate my complete disbelief at the lack of interest apparently being displayed by Dr Watt. Between us [INI 403] and I have made at least half a dozen or more phone calls to Dr Watt's secretaries, firstly Pauline and now Katrina. Both girls assured us that Dr Watt would be informed of [INI 403's] situation. If he has received these communications why is he not responding? We just cannot understand any of this, and as we see it, he is the only person with the knowledge of [INI 403's] health record who can help him.

Maybe it is necessary to state this:- If somebody has made an error of judgement regarding the lumbar puncture, surely this is something that can happen anywhere, anytime.

If the 'mistake' is rectified or attempts are made to retrieve the situation then that mitigates the initial wrong – we are all human. I cannot accept this – I must get something done about it – somehow.

My only concern, and that of my husband, is that an infection of some kind or another could have set in, with all of the complications that that could bring. There has to be a reason for the pain. I am really worried, and nobody seems to be remotely interested, or care. I need a immediate response to help [INI 403], and this course of action seems to be the only one open to me. I hope and pray that you will do something quickly, before something happens that cannot be fixed ...

- 2.40 The then Associate Medical Director, Mr Peter Walby, intervened and spoke to Dr Watt about the matter developing into a more difficult situation. He suggested, in a letter of 30th October 2001, that a meeting should be set up with the patient, Dr Watt and Mrs Pauline Webb, the Patient Liaison Officer. The matter was eventually resolved when Dr Watt met with the patient and Mrs Webb in January 2002. This is one of the early complaints, which was not destroyed in accordance with Trust policy. The Inquiry Panel noted the difficulty in getting Dr Watt to engage, which resulted in this complaint being escalated to the Medical Director amongst others, and the need to involve the Medical Director to ensure that a response was obtained from Dr Watt.

INI 404:

- 2.41 The next complaint of note is that of the husband of INI 404, who on 24th February 2003 wrote to the Chief Executive regarding his wife. In late November 2002, INI 404 consulted Dr Watt at the Hillsborough Private Clinic regarding an ongoing back problem. The complaint stated that Dr Watt had recommended an MRI scan, which took place at Northern MRI on 5th December 2002. The report was posted to Dr Watt on 11th December 2002. Despite numerous efforts to obtain a review appointment from Dr Watt in relation to the contents of the MRI report, Dr Watt did not follow up with his views on the report.
- 2.42 In January 2003, the patient had an accident and required a hip replacement. She was hospitalised for 7 days and was scheduled for surgery on 27th January. When the anaesthetist learned that the patient suffered from spinal stenosis and had undergone a recent MRI scan, he requested a copy of the MRI scan as a matter of urgency. The patient's husband complained that the MRI scan was only delivered to the ward just prior to the surgery and there was no communication from Dr Watt. The complaint was summarised at the end of the letter:
- We paid £125.00 for the initial appointment with Dr Watt, and a subsequent amount of £500.00 for the MRI scan and there has been NO follow-up as promised and agreed.

- My wife continues to suffer with her back and we have had NO consultation regarding any possible treatment or recommendations for future treatment.

2.43 The Patient Liaison Office explained to the patient's husband that, as the complaint emerged from a private consultation, it fell outside the HPSS complaints procedure. The matter was referred to the then Medical Director, Dr Michael McBride, who wrote a note on the memorandum stating: *"1 File re Michael Watt – I need to meet with him. 2 Copy to Jim Morrow/David Adams"*.

2.44 The matter had been flagged to Dr McBride by Mrs Webb *"because of the number of similar NHS complaints we have received in this office"*. In his evidence to the Inquiry Panel, Dr McBride could not remember the complaint specifically, but confirmed that the writing on the memo was his. He stated in his evidence of 7th November 2019:

I had put a lot of confidence – quite rightly so – in the professionalism of **Caroline Lee and Pauline Webb, who, you know, did not sort of, you know, bring these matters** to my attention routinely clearly signalling here that there'd been a number of similar complaints into the office, and, I mean, I acted on the back of that by indicating that I felt I needed to meet with Michael Watt and copied it to his CD and Divisional Director.

2.45 Mr David Adams, the then Divisional Director, told the Inquiry on 8th January 2020 that he did not remember the meeting *"but I'm sure it happened because, you know, we were all at Michael, myself and Peter Walby, everybody"*.

2.46 The Inquiry Panel accepts at this remove, and in the absence of a contemporaneous note, it is not surprising that neither Dr Adams nor Dr McBride can recall any meeting with Dr Watt. On balance, it is likely to have taken place, given Dr Adams' statement, but the Inquiry Panel have concluded that even if it had taken place, it had little or no influence on Dr Watt, as evidenced by subsequent events.

INI 405:

2.47 On 10th October 2003, INI 405 wrote to the hospital. Having got an appointment to see Dr Watt on 12th December 2002, INI 405 presented with complex symptoms and had an interaction with, perhaps, a registrar, who, according to INI 405, was extremely sceptical about the range of symptoms being described. When introduced to the Neurologist, who it would appear was Dr Watt, it was alleged that Dr Watt quickly concluded that INI 405 required an urgent MRI on her neck to ascertain damage.

It was suggested that this could be obtained privately. INI 405 decided to obtain a private MRI and Dr Watt saw her again on 15th May 2003. INI 405 complained at the attitude of Dr Watt, and it transpired eventually that she believed that she may require an operation on her neck. Generally, the handwritten complaint is difficult to decipher. A summary was prepared by an unknown author when the complaint was received, stating as follows:

- The staff attitude of the lady doctor on 12.12.02.
- Dr Watt then saw the patient and requested an urgent MRI scan of the neck.
- She heard nothing and phoned MRI who had no trace of a request for her – she then appears to have arranged a private MRI scan.
- When she attended for this there was no information from the consultant.
- She seen [sic] Dr Watt again on 15.05.03 who laughed all of the time he was giving her a poor diagnosis.
- She wrote to Dr Watt on 10.07.03 and never got a response.
- She now has an apt for 19.11.03.

2.48 Dr Watt, responding to the complaint on 2nd January 2004, in a letter to Mr Peter Watson, then Sub-Divisional Manager in Neurosciences & Fractures, stated:

I am sorry that she found my manner on 15th May 2003 and the attitude of the lady doctor she saw on 12th December 2002 disagreeable. As far as the MRI request if [sic] concerned it would not be unusual for the staff in the MRI unit to be unable to trace the request form. There are several possible explanations for this including difficulty locating the form in the MRI unit, delays in the internal post or a delay at our end in sending the form. Regarding the private MRI, fortunately or unfortunately the speed of response of the private MRI unit means that it can be difficult to get forms to them in time. Regarding the letter of the 10th July I do not generally reply to letters from patients and instead prefer to discuss matters at outpatients. She had an appointment for 19th November 2003 but failed to attend for this.

I can only once more apologise that she was unhappy with our efforts although she [sic] happily she does not appear to have come to any harm as a result.

2.49 A final response issued, signed by the Chief Executive of the Trust, on 26th January 2004. This indicated that Dr Watt had hoped to discuss this matter at an outpatient appointment on 19th November 2003, but that INI 405 failed to attend. The letter indicated that Dr Watt was sorry that his manner was found to be disagreeable and that it would not be unusual for there to be issues with MRI referrals.

INI 408:

- 2.50 On 28th April 2005, Mark Robinson MLA wrote to the Chief Executive of the Royal Group of Hospitals Trust (“RVH”), William McKee, in respect of a decision by his constituent’s doctors to discontinue regular doses of Beta Interferon. Mr Robinson stated that INI 408 was in: *“the advanced stages of this debilitating and devastating illness”* (multiple sclerosis) and that INI 408 relied on Beta Interferon to *“sustain even the smallest modicum of what little remains of his quality of life”*.
- 2.51 Mr Robinson had already complained to the then Chief Medical Officer and the Northern Ireland Ombudsman. He informed Mr McKee that INI 408 had obtained a private prescription of the drug and that this had greatly assisted. As his constituent had already spent thousands of pounds on private prescriptions, the essence of the complaint was that the NHS should pay for the treatment.
- 2.52 The Patient Liaison Manager, Pauline Webb, wrote to Mr Peter Watson, then the Manager of the Head and Skeletal Division in the RVH. Dr Hawkins and Dr Watt were contacted for their comments on the complaint. A detailed response from Dr Hawkins was received on 9th June 2005, in which Dr Hawkins set out a detailed medical history and noted that INI 408 had been admitted in October 2003. Dr Hawkins further stated:
- During his admission I spoke many times to his father about the fact that Interferon was probably no longer working ... Interferon was stopped during his admission and then started again from the supply that he had at home during his admission. It was then stopped around the time of his discharge after further and [sic] consultation with his parents.
- Clearly outside the prescribing criteria because he was barely able to stand with help and even with the help of two people he was unable to walk ...
- He was subsequently seen [sic] one of my colleagues Dr Michael Watt and Interferon was prescribed privately. I cannot account for how the Interferon has been prescribed privately since he is well outside the prescribing ABN Guidelines for Interferon as recommended by the ABN.
- 2.53 A letter was forwarded by the Director of Nursing, Mrs KMD O’Brien, on 28th June 2005. This correspondence, drafted by Mr Peter Watson, incorporated the substance of Dr Hawkins’ response. However, while noting that the *“prescribing was ceased given that he was outside of the prescribing criteria”*, the final line of Dr Hawkins’ response, relating to his inability to account for the private prescribing, was omitted.

- 2.54 Following a further letter from Councillor Robinson of 27th July 2005, the Patient Liaison Office wrote to Mr Robinson on 14th September assuring him that the matter was *“still under investigation by the relevant Directorate”*. On 5th October, the Chief Executive responded and after repeating Dr Hawkins’ original comments, stated:

Given that [INI 408] is now attending Dr Watt privately we are not aware of the current situation.

- 2.55 The matter was then taken up by the Northern Ireland Ombudsman, but it was decided on 7th September 2006 not to proceed further.
- 2.56 From the perspective of the Inquiry Panel, the obvious discrepancy between Dr Hawkins and Dr Watt on the prescription of Beta Interferon was a matter, which required to be investigated, especially as Dr Hawkins was stating clearly that he could not account for how interferon has been prescribed privately since the patient was *“well outside the prescribing ABN guidelines”*. It may also have been early evidence that Dr Watt was prescribing outside the Guidelines. While it is recognised that this might have been clinically justified in the specific case, the issue needed to have been investigated and reassurance obtained.
- 2.57 The papers disclosed make it clear that Dr Watt was asked for his views. There is also reference to correspondence from Dr Watt, but this was, however, no longer in the file that was discovered. This case is commented upon further in the 2006-2007 chapter.

INI 396:

- 2.58 A complaint was received on 14th March 2005. The patient had attended Antrim Area Hospital for a suspected TIA in October 2004. He was assured he would see a neurologist within 6 weeks. An appointment was eventually given on 3rd August 2005, which was then postponed until 5th October 2005. The patient could not get cataract surgery until seen by a neurologist. As a result of the complaint, an earlier appointment was arranged for 9th May 2005.

INI 406:

- 2.59 INI 406 required a report for the Northern Ireland Compensation Agency. The first request for a report from Dr Watt was made on 26th April 2005. INI 406 wrote again in September 2005 and Jeffrey Donaldson MP then wrote on the patient’s behalf on 4th October 2005. A complaint was made to the Royal Victoria Hospital in September 2005. In her letter of complaint, INI 406 stated:

We have a lot of financial commitments with which I have now fallen behind with payment. It would really help if this claim was to be settled. However the Compensation Agency have informed me that they have received no reply from yourself and they have sent you a reminder. Could I please ask you to reply to them as soon as possible, as the pressure and stress being put on myself by this is affecting my epilepsy and my relationship with my family. As I am currently attending a psychiatric nurse for treatment of depression I hope you understand why I feel the need to contact you on this and will do what you can to reply to the Agency as soon as possible.

- 2.60 Mr Walby, the Associate Medical Director for Litigation, was advised of this complaint. The medical report was eventually forwarded in November 2005 and a letter from the Chief Executive of the Royal Group of Hospitals, Mr William McKee, was forwarded to Mr Donaldson MP apologising for the delay.

INI 407:

- 2.61 INI 407 had critical illness cover. She was seen by Dr Watt in July 2005 and the relevant forms from Legal & General were forwarded to Dr Watt at that time. Dr Watt did not respond, and a complaint was made on 28th November 2005. Mr Walby spoke with Dr Watt in March 2006, by which stage Dr Watt indicated that he had sorted the issue some months previously. Investigation found that the forms to the insurance company were completed on 14th February 2006, with a further copy faxed to the insurance company on 9th March 2006. On 6th April 2006, Mr William McKee wrote to INI 407 apologising that the forms had not been completed and stating bluntly: *“the reason for the delay was due to Dr Watt not completing the forms”*.
- 2.62 As discussed in the 2006-2007 chapter, neither INI 406 nor INI 407 were brought to the attention of the GMC, who were investigating Dr Watt at that time. Further, there seems to have been limited attempts by the Trust to identify, investigate or tackle a pattern of behaviour by Dr Watt which was flagged to the Medical Director’s Office years previously by Mrs Webb in relation to INI 404. On 8th January 2020, in his evidence to the Inquiry Panel about the number of early complaints, the Associate Medical Director, Mr David Adams, stated:

... you have the advantage here of seeing all these in one place at one time. We didn’t have that, unfortunately. It’s a very important point because if the system were working properly, they would all be in a file accessible to everyone. And they would say there’s a problem here that needs sorted out.

INI 411:

- 2.63 INI 411 attended Dr Watt's clinic on 4th July 2005. When a history was taken of INI 411's unexplained falls, Dr Watt attributed this to "*many years of alcohol abuse*". INI 411 had, in fact, not had a drink problem since 1988. Dr Watt prescribed tablets for epilepsy with a review in two months. INI 411 complained about Dr Watt's attitude. In an internal email of 14th February 2006, Dr Watt stated to Shauna Bradley from the Complaints Department:

What exactly is the complaint? As far as I can understand it is a report of some parts of the consultations. I'm sure what they say is right – I had misunderstood the history regarding her alcohol intake and admitted this when I reviewed her and, as far as I can recall, apologised at the time.

- 2.64 In a letter of 27th February 2006, which addressed additional areas regarding INI 411's care, Mr McKee stated:

The issues surrounding your attendance at the neurology outpatient clinic have also been reviewed. It was not Dr Watt's intention to upset you in any way and I am sorry if you were unhappy with Dr Watt's attitude.

INI 222:

- 2.65 The next complaint was intensively examined by the Trust and the Inquiry inspected a substantial amount of documentary evidence relating to it and spoke to a number of witnesses about their involvement with its investigation.
- 2.66 On 20th June 2006, INI 222 wrote to the Chief Executive of the Royal Hospitals, Mr McKee. The significance of the complaint was that it came from a member of the medical staff. This was a clear allegation of misdiagnosis and the manner in which the complaint was dealt with was of interest to the Inquiry.
- 2.67 In her letter of complaint, INI 222 stated:

It is with some professional reluctance that I have decided to formalise in writing my extreme disappointment and discontent at my neurology care over the last two years. I feel the need primarily as a patient, but also as a member of medical staff to vocalise these concerns so that perhaps some lessons may be learnt from my misdiagnosis, unsatisfactory management and the level of communication I experienced under the care of Dr Michael Watt and his team.

After great deliberation and with a certain element of desperation and extreme frustration during a bout of ill health in January 2006, I sought a second opinion. Following further and repeat investigations, I have recently been informed

that I was inaccurately diagnosed with Multiple Sclerosis and inappropriately advised to commence beta Interferon in December 2004. I still don't fit the diagnostic criteria now! ...

2.68 INI 222 then set out a detailed list of the issues and questions about her care:

- (i) Following her MRI scan, Dr Watt informed INI 222 that she had a 50% chance of developing MS. This information was delivered in the middle of a corridor in a busy ward.
- (ii) Outpatient follow-up was arranged for 5 months later without giving timescales for recovery process.
- (iii) According to INI 222, more prompt assessment would have allowed for consideration of IV immuno-globulin therapy.
- (iv) INI 222's condition deteriorated towards the end of November 2004. INI 222 believed her symptoms could be attributed to autonomic dysfunction from her brain stem lesion.
- (v) INI 222's diagnosis of MS was made entirely on temporal separation from two similar episodes with incomplete recovery in between.
- (vi) Postural hypotension remained a significant problem from November 2004, which was reported at INI 222's clinical appointment in January 2005. Dr Watt's response to this was alleged to be inadequate and there was no suggestion of further treatments.
- (vii) INI 222 researched drug therapies for postural hypotension and was told by Dr Watt, via a specialist nurse, that she could *"try something if I wanted to"*.
- (viii) No attempt was made to elicit and confirm the clinical signs that INI 222 was reporting. In particular, there was no check of pulse rate, blood pressure and no ECG was requested.
- (ix) INI 222, who suggested referral to cardiology, was subsequently medically investigated and it was alleged that significant abnormalities entirely in line with what she was reporting were discovered.

2.69 The gist of the complaint is set out at paragraph 17 of the letter of complaint:

His premature, incorrect diagnosis has forced me to endure 18 months of side effects from beta-interferon (including significant lymphocytopenia) not to mention the unnecessary expenditure incurred by my parents ... many of the problems relating to my care came down to poor listening of my problems by the neurology service, indeed even to the point of ignoring them. I felt that I was repeatedly dismissed and my genuine and serious symptoms trivialised, perhaps because they did not understand them.

2.70 Dr Gavin McDonnell, Consultant Neurologist, and a colleague of Dr Watt, who had not been in any way the subject of complaint, was asked about his involvement. In a letter to Mr Gerry Atkinson, Service Manager, of 5th July 2006, Dr McDonnell felt that this was a difficult and complex case with an unusual presentation. Dr McDonnell stated: *“Because of that, I feel that the criticisms levelled at Dr Watt are unfair. Clinical issues often become clearer, with benefits of hindsight and passage of time”*.

2.71 Dr Watt also answered the detailed letter from INI 222 in a letter of 18th July 2006 to Mr Atkinson. Dr Watt believed that INI 222 did have relapsing/remitting multiple sclerosis. He felt that the diagnosis was made on clinical grounds supported by the results of the investigations. Mr Atkinson felt that additional comments were needed from Dr Watt and there was a further delay in response.

2.72 On 4th October 2006, the then Clinical Director, Mr Stephen Cooke, emailed the recently appointed Medical Director, Dr Tony Stevens, as follows:

I had 5 emails regarding this yesterday, but prior to these I had already discussed these matters with Michael and Jim again. I have told him he is going to be in some difficulty if he does not complete the response, and get appraised, but he is adamant that he cannot do so as he still does not have a functional PC! I have suggested that he uses another one but I do not think he appreciates the potential outcome of his position.

The difficulty is that I don't think there is understanding amongst some medical staff of the need to comply with complaints/appraisal/other organisational procedures and they are seen as non-important. There is a need for us to toughen up our approach in such situations, and be seen to be firm, but as CD I really only have explanation/persuasion to use to resolve such problems.

Please advise on how to proceed further.

2.73 In response, Dr Stevens stated that if local resolution was not successful, the Trust was considering handling the complaint *“down a formal line”*. He went on to state: *“He [Dr Watt] needs to understand this and the implications”*.

2.74 By 18th October, Dr Stevens noted that Dr Watt had not responded satisfactorily and stated the following to Mr Adams, the then Divisional Director. He also included the Complaints Department in the email:

I have spoken to David. Dr Watt has not responded satisfactorily. Can I have a copy of report to date and Dr Watt's input. Can you advise whether he has set date for appraisal.?

- 2.75 Prior to this, Dr Watt had responded to Mr Atkinson's request for further matters to be addressed by stating in an email to Mr Atkinson on 11th October: *"I have answered what I can"*. There appears to be a limited understanding by Dr Watt of the Trust's role as his employer.
- 2.76 On 12th December 2006, Mr Adams wrote to Dr Watt stating:
- I understand that despite repeated reminders and requests you have failed to provide a response in relation to the enclosed.
- I must insist that this is provided no later than close of play on Friday 15th December. Given this is a further instance of your failure to comply with the complaint procedure I have copied this correspondence to Dr Stevens and will be discussing with him the action we should take.
- 2.77 A draft letter by Mr Atkinson had been prepared for some months. Eventually Dr Watt answered a number of additional questions, which had been highlighted in red.
- 2.78 On 18th December 2006, a meeting was arranged in Dr Stevens' office with INI 222 and her parents as well as Mrs Webb from the Complaints Office. The minutes of that meeting record the fact that there was some discussion about the diagnosis, but Dr Stevens had indicated that there *"may finally be a difference in medical opinion in the clinical aspects of this cases and that this may be difficult to resolve entirely through the complaint's process. He was however committed to resolving the issues as far as possible."* Dr Stevens felt that there was enough information to prepare a response to INI 222 and he committed to this being available by early January 2007. Dr Stevens also indicated that he would be reviewing the management of the complaints.
- 2.79 The Inquiry notes that on 20th December 2006, Dr Stevens met with Dr Watt and that, prior to the meeting, he had been briefed with a note from Mrs Webb regarding previous complaints. The note is set out below:

04.G.53 [INI 409]	In:	Out:	Response:
	26 Feb 04	16 April 04	33

Issues. Attitude – rude, 'superior', breakdown in communications.

No physical examination –

Wishes to attend another consultant.

Dr W **never replied** – Jim Morrow did so as he was the CD.

05.G.414 Jeffrey Donaldson	In:	Out:	Response:
obo [INI 406]	5 Oct 05	25 Nov 05	33

(She wrote to Dr W on 1/9/05)

Issues. Request for report for NI Compensation Agency.

05.G.533 [INI 407]	In:	Out:	Response:
	28 Nov 05	6 April 05	90

Issues. Report re: illness for Legal & General (forms posted 14/2/06).

06.GFL.035 [INI 411]	In:	Out:	Response:
	11.1.06	27.2.06	32

Issue – Doctor’s attitude & behaviour.

(To Division 30.1.06!!)

To PLO 21.2.06

06.G/Z.277 [INI 222]	In:	Out:	Open:
	9.6.06		

Issues. Diagnosis & Care.

Complaint management

(Info to Gerry A. 18.7.06)

06.G.454	[INI 87]	In:
		4 Sept 06

Clinical case – deceased son – [INI 87]

Patient of Dr W

S/B Dr Morrow (privately).

PM report to PLD 19.9.06

28.9.06 – Phone call from sec – this is not Dr W’s patient

Now pp of J Morrow

19.10.06 – email to D Adams from DW – not my pt. at the time of his death.

27.10.06 – reply from J Morrow.

31.10.06 – Another letter from family – very unhappy

8.11.06 - Another letter from family.

7.12.06 – Another letter from family

- 2.80 By early January, Dr Stevens had corresponded with Dr Gavin McDonnell regarding INI 222’s diagnosis. Dr McDonnell replied:

My dealings and discussions with [the patient] are clearly laid out in the relevant notes. As indicated in those notes, she appears to have had only one attack, she has only one lesion on MRI, no new lesions appeared on follow up MRI, she does not yet meet the criteria for definite MS and therefore DMT would not appear to apply. All of this is obviously a lot easier with hindsight and the follow up MRI.

2.81 Responding to this, on 3rd January 2007, Dr Stevens stated:

Gavin

Thanks for this. I am trying to reconcile the issues in this case to give you a cogent response that reflects the situation. It is difficult for me, as a non neurologist to weight the facts. What you seem to be saying is that with hindsight she does not have MS and that her view that she did not meet the criteria for B interferon has some merit. If this is the case then the trust will have to reflect this in its letter, albeit with the benefit of hindsight.

I recognise that the complaint is not directed at you, but your input is invaluable.

2.82 Arising out of his correspondence with Dr McDonnell, Dr Stevens then contacted Mrs Webb in Complaints on the same day:

Pauline

I am not sure where this leaves us. It may be wise to get some help in a final draft from a 3rd neurologist. What do you think about a meeting with Jim Gilmore?

This is getting into the realms of difference of medical opinion and has med legal overtones. Is it worth also a discussion with Peter Walby?

Can you check is Michael in this week. If so hassle him. If need be I will tell him to respond.

2.83 Earlier that day, Dr Watt had approved the proposed letter to INI 222 and gave a detailed response to Dr Stevens as follows:

I feel the reply is fine. The difference in medical opinion comes down to interpretation of the events after her initial presentation. I felt that she she [sic] had developed new problems which could not be explained by the evolution of the known spinal cord inflammation and could only be explained by a new lesion at a higher level and it was this that led me to conclude that she has MS. I would acknowledge that I believe that in patients who have MS the sooner they start disease modifying therapy the better, but I would not generally start someone on treatment after a single attack. I believed that in starting her on treatment when I did that she would have a better prognosis and that I was treating her as I would have wished myself or my family to be treated in similar circumstances. The fact that she has no [sic] gone on to have further attacks has led to doubt about the diagnosis but it could be argued that this has been due to the interferon treatment. There is ample evidence that treatment with interferon after a single episode of inflammatory demyelination prolongs the time to a further attack and avonex is now licensed for use in this situation, although not yet recommended by the ABN, and there is no evidence of long-term harm from treatment with beta-interferon.

- 2.84 The letter was eventually sent on 9th January 2007 and responded to each of the paragraphs in the original letter of complaint. The letter did refer to the difference in opinion and included Dr McDonnell's observation that it is easier with the benefit of hindsight and a follow up MRI to come to a more definitive view. The issue of whether INI 222 had been treated unnecessarily with Beta Interferon was not resolved and careful attention was paid to reflecting Dr Watt's own views of the case. At paragraph 17 of the response from Mrs Deirdre O'Brien, Acting Chief Executive, it is stated:

Dr Watt continues to feel that you have relapsing/remitting MS. The diagnosis was made on clinical grounds supported by the results of the investigations. Dr Watt feels that having the Beta-Interferon early in the course of your disease will leave you better off in the long run and, if you are right and you only had a single attack a case could be made for you having taken Interferon anyway as one of the products is now licensed for use after a single attack of inflammatory demyelination.

- 2.85 The response went on to outline the views of Dr McDonnell as follows:

Dr McDonnell, Consultant Neurologist, was also asked to comment on this case. In his clinical opinion you would appear to have had only one attack, you have only one lesion on MRI, no new lesions appeared on follow-up MRI, you do not yet meet the criteria for definite MS and therefore DMT would not appear to apply. This is clearly a lot easier with the benefit of hindsight and the follow-up MRI.

- 2.86 In evidence to the Inquiry Panel, it was clear that there had been reflection on this case. Dr Stevens, the then Medical Director, stated in response to a question from the Inquiry Chairman:

Mr Lockhart QC: But what I liked about the reflection that you initially gave us was that you got right to the heart of it, because right at the heart of this is the speed of diagnosis, the failure to carry out investigations, and the willingness to prescribe treatment before the criteria are met.

Dr Stevens: That's exactly correct. To my mind, in retrospect now, based on what we now know, that was probably the first example I'm aware of where that's expressed.

- 2.87 Dr Stevens had earlier in his evidence noted:

He was prepared to take the step to a diagnosis of multiple sclerosis ahead of the individual meeting criteria and without necessarily a full range of investigations and then proceed to treatment. Gavin McDonnell's almost last comments that, with the benefit of hindsight, didn't meet the criteria, diagnostic

criteria for MS, and therefore, probably didn't meet the criteria for treatment with disease-modifying drugs, but, at the same time, says but it's easy with the benefit of hindsight ...

... You can see that I was not terribly happy with the earliest drafts of the complaint response and was pushing Gavin and Michael very hard to say that, actually, look, we've got to answer her question about whether she was treated appropriately or inappropriately and insisted on the line that Gavin McDonnell gave us...that she didn't meet the criteria. Because I wanted her to know that I was trying very, very hard at that point to make sure that the complainant knew there was a difference in medical opinion...what I wasn't trying to do was identify that Michael might have been an aberrant doctor or that his decision making was seriously flawed.

- 2.88 Dr Michael McBride, Medical Director prior to Dr Stevens, also reviewed INI 222's complaint:

Knowing what I now know, this was a very important milestone and this is a very significant case in terms of subsequent events. I suppose, looking back on this now with the benefit of hindsight, one would have wanted to ask, perhaps, or now hope that one would've asked, "is this an isolated incident? Could there be other similar cases?"

- 2.89 The Inquiry Panel agrees with Dr McBride. It also notes that he was appointed Chief Medical Officer in September 2006, in the middle of the investigation, which was ultimately completed by Dr Stevens, the new Medical Director.

- 2.90 Dr Gavin McDonnell, in his evidence to the Inquiry Panel, was anxious to highlight that though he disagreed ultimately with the diagnosis of MS in this complaint, he could understand how it was made:

Not all MS attacks are associated with a visible new lesion on MRI, although this would usually be the case. Not all lesions are seen on MRI scans – they may be below the resolution of the scanner or the particular imaging sequences may not be sensitive enough to detect MS lesions. Lesions can also appear and resolve from MRI scans. Therefore, whilst I disagreed with Dr Watt in relation to the diagnosis, I could understand how Dr Watt got to the diagnosis when I was asked to review the case in 2006/7. I noted that the patient had not "yet met the criteria for definite MS.

- 2.91 This complaint was of interest because it involved a patient, who was also a qualified consultant, albeit in a different discipline, and who had a family member in a senior managerial role within the NI Healthcare system. In this respect, it is similar to the INI 5 case discussed below.

2.92 The fact is, however, that the method of dealing with complaints prevented this case from alerting those managing complaints that this was a part of a pattern. It may well be the case that there is in the medical history, a presentation on which reasonable neurologists could disagree in both diagnosis and treatment. This possibility is emphasised several times by Dr McDonnell, who, while clear in his own medical views, is sympathetic to the fact that at the time Dr Watt saw INI 222, the approach taken was not unreasonable. The Inquiry Panel, however, is critical of the fact that there is not an agreed systematic approach to dealing with questions of alleged clinical misdiagnosis and notes the following:

- (1) The focus of those seeking to resolve the complaint is to obtain from Dr Watt his response to the points made. While this was a critical and appropriate step, it should not have precluded obtaining an independent view or views. In this case, and somewhat unusually, Dr McDonnell was asked to give his views. He did disagree with the diagnosis and though he was sympathetic to Dr Watt's earlier predicament, this was a case where a further view might have been helpful as mooted by Dr Stevens in December 2006. The Inquiry Panel agrees with Dr Stevens.
- (2) Dr Stevens clearly had many of the right instincts, and subsequently took action against other doctors. He had a meeting with Dr Watt in December 2006, where he was properly briefed with a note from the Complaints Department about previous complaints. While the note was not especially detailed, there was sufficient information to raise further questions about other complaints, particularly because Dr Watt had not completed his appraisal, which was overdue. This exercise did not appear to have been undertaken although the Inquiry acknowledge that this may have been the first complaint involving an alleged misdiagnosis by Dr Watt
- (3) The points made by Mr Cooke in his email to Dr Stevens of 4th October 2006 at paragraph 67 appear apposite:
 - (i) Medical staff not seeing the need to comply or the importance of complaints (and appraisal).
 - (ii) The need for the Trust to toughen its approach.
 - (iii) What Mr Cooke considered to be the limitations of his role as Clinical Director.

2.93 At this juncture the Inquiry Panel noted that, despite proactivity by Dr Stevens, all the information on relevant complaints was not in front of him. The need to triangulate the available data and present to the Medical Director an accurate picture impeded the ability of the Trust to analyse the situation properly.

INI 87:

- 2.94 The parents of INI 87 wrote to the Belfast Trust on 4th September 2006 following the unexpected and sudden death of their son. The letter of 4th September 2006 was addressed to the Chief Executive of the Royal Group of Hospitals. The family sought clarification regarding a number of matters, including identifying who was responsible for reviewing and monitoring their son's medication and progress, the guidelines regarding levels of medication, particularly when drugs were used together and a number of other specific questions about monitoring a patient. The letter concluded:

We would be grateful if you could assist us with this and perhaps any other information you may find which would be of benefit to us in finding answers, which may help us come to terms with [INI 87's] death.

- 2.95 Dr Watt had seen INI 87 over a number of years and was contacted by the Medical Director's Office. After some delay, Dr Watt responded:

As [INI 87] wasn't my patient at the time of his death, although he had attended me on and off for quite a few years, I don't feel I should be commenting on something I was not responsible for.

- 2.96 Subsequently, the Medical Director's Office wrote to the Associate Medical Director, Mr Adams, and stated:

I have discussed this case with Mrs Webb. Dr Watt spoke with Pauline two weeks ago indicating that he felt this complaint was not his responsibility, but Dr Morrow's. Pauline explained that Dr Morrow saw [INI 87] once privately and that the questions relate to care, which was given under Dr Watt's management. It was agreed that he would speak with Dr Morrow, perhaps meet with the parents with Pauline in attendance. Dr Morrow, however, may not agree with this – if so, it lies solely with Dr Watt.

- 2.97 On 19th October 2006, an email from the Medical Director's Office to Dr Watt stated: *"Your response to this complaint was due on 6th October. Please forward or advise of delay. Thank you."*

- 2.98 This email was immediately followed by a connected email from Mr Adams stating: *"Michael please respond. David Adams."*

- 2.99 Dr Watt responded within 45 minutes and stated to Mr Adams:

He was not my patient at the time of his death. He had attended Dr Morrow at the UIC and he had arranged to review him in the BCH.

- 2.100 The following day, Mr Adams contacted Dr Morrow and asked him to liaise with Dr Watt and then respond.
- 2.101 On 27th October 2006, Dr Morrow provided a 5-page response to Mrs Webb concerning the complaint. That letter set out in precise detail Dr Morrow's dealings with INI 87. It transpired that Dr Morrow had seen INI 87 on 5th January 2006 when he attended privately at the Ulster Independent Clinic. Dr Morrow noted that INI 87 had been under the care of Dr Watt for some years. He had been referred to Dr Morrow for a review of his epilepsy and medication. A complex history was noted and Dr Morrow undertook to obtain all of the previous notes and review them before suggesting any change of therapy. Dr Morrow then obtained the notes and wrote to INI 87's GP, in some detail on 12th January 2006. Dr Morrow summarised his views as follows:

From the evidence within the notes, albeit that the notes are incomplete and that the early notes appear to be missing, it would appear that this man's original presentation was with psychiatric problems and the diagnosis of epilepsy, originally at least, seems to be based on abnormal ECG and odd behaviour. Certainly the description of attacks as conveyed from the letter from Mr Eldridge, Consultant Neurosurgeon in the Walton Hospital, is not at all typical of epilepsy and one wonders why this diagnosis was entertained in the first place. Subsequently there seemed to be compelling evidence that any attacks that had been noted by Dr Pang, who is an experienced epileptologist in the Walton centre for Neurology and Neurosurgery was that the attacks were non epileptic, behaviourally mediated. His subsequent presentation to myself is again very atypical of epilepsy in that he complains mainly of pain and numbness for which there does not appear to be any definite structural or anatomical cause

I feel therefore that the evidence tends to suggest that this young man's problems are certainly in the large part if not completely psychologically mediated. Whether he has an underlying tendency to epilepsy remains uncertain.

- 2.102 On 12th January 2006, an appointment was arranged for 30th January 2006 to discuss Dr Morrow's review of the records. INI 87 unfortunately passed away prior to the date of the subsequent appointment.
- 2.103 Dr Morrow stated in his correspondence of 27th October 2006 that:

To summarise my thoughts at that time, it was clear that [INI 87] had a long and complicated history, which was largely psychiatric in nature. He was felt to have depressive episodes, behavioural disturbances and addictive tendencies. He, however, had an abnormal EEG and was subsequently referred to Dr Watt, who diagnosed epilepsy. His EEG abnormality may have related to an

underlying arachnoid cyst, which was operated on (but I am unsure whether it was ever proven that any seizure activity emanated from this lesion) on the basis of continuing events which were felt to be epileptic.

Despite surgery, he continued to take events which as described to me in the clinic, very unusual [sic] and not at all typical of epilepsy.

On reviewing the notes it would appear that other Epileptologists including those at the Walton Centre for Neurology and Neurosurgery and Dr Pang Consultant Neurophysiologist and indeed, the Neuropsychiatrists that were reviewing [INI 87] also had all felt that most if not all [INI 87's] events were non epileptic in nature.

Following this review it was my intention to review [INI 87] to try to withdraw him from anti-epileptic medication and also to try to address the issue of his pain problems as once again there did not seem to be any structural cause for these complaints. Unfortunately circumstances supervened and [INI 87] died prior to his re-attendance ...

- 2.104 Dr Morrow then sought answers to the specific questions that were raised by INI 87's parents. He felt that Dr Watt was in a better position to address the issues raised and was disappointed that Dr Watt had declined to reply.
- 2.105 Following a letter from INI 87's father, complaining about the length of time to provide a written response, Mrs Webb wrote to INI 87's father and apologised for the delay. The letter indicated that a report had been received from Dr Morrow and that nothing had been received from Dr Watt. Mrs Webb further stated that the matter had been brought to the attention of the Acting Medical Director, Dr Stevens.
- 2.106 Despite efforts to obtain a response from Dr Watt, none was forthcoming. On 7th December 2006, INI 87's parents wrote to the Chief Executive, again concerned about the continuing delay.
- 2.107 On 12th December 2006, Dr Watt responded to Mr Atkinson, the Sub-Divisional Manager. His letter sought to answer the questions raised but was laconic and in sharp contrast to the detailed response from Dr Morrow. The salient extracts are set out below:
- (i) The review time is largely dictated by the frequency of attacks and recent changes to medication. The level of medication is not a factor in deciding when someone is reviewed.
 - (ii) [INI 87] had been attending Dr Watt about his epileptic attacks up until his discharge at his own request on 11th October 2005.

- (iii) The general practitioner is responsible for prescribing outside hospital, guided by the hospital consultants attended as an outpatient.
- (iv) Anti-convulsant levels are not routinely monitored in patients attending neurologists with doses being adjusted depending on the balance between benefits and adverse effects. Levels may be checked if there is doubt about compliance or suspicion of toxicity.
- (v) His treatment outside hospital is largely the responsibility of his GP shared to a degree by the specialists attended.

2.108 Dr Watt concluded his letter by stating that he was shocked and saddened by INI 87's passing and noted that he had a tendency to *"become dependent on analgesic medication"*, which his doctors were aware of and attempted to address.

2.109 Subsequent to Dr Watt's letter, a draft response to INI 87's parents was drawn up and circulated based largely on the comments provided by Dr Morrow. Dr Watt was asked to review the letter and stated in an email on 21st December 2006 to Mr Watson:

Pauline [sic]

I feel that it would be better to only answer what has been asked rather than adding details, which might only add to their concerns. I am aware that my reply was felt to be too short, but I did answer the questions and did not raise any other issues. Whether he did or did not have epilepsy has been visited many times over the years and never satisfactorily resolved. I could never persuade his mother that he might not have epilepsy and in the end I felt he had both epileptic and non-epileptic attacks.

Michael

2.110 He followed this up in an email to Mrs Webb of 3rd January 2007 regarding a proposed meeting between the Medical Director and INI 87's parents:

Pauline

I think it would be better if I attended the meeting and would be happier if the reply was closer to mine – all the stuff about the diagnosis makes it look as though we feel vulnerable in that area whereas we had been living with the uncertainty for years and managing his symptoms pragmatically.

Michael.

2.111 The initial draft of the letter, based on Dr Morrow's correspondence noted that INI 87's events were *"very unusual and not at all typical of epilepsy."* It went on to note the views of other medical professionals that *"most if not all [INI 87's] events were non*

epileptic in nature”. The initial draft of the letter concluded by stating as follows:

As stated earlier, Dr Morrow’s own review of the case suggested that the use of the drugs may have been somewhat inappropriate in [INI 87’s] case, given that the diagnosis of epilepsy was by no means secure and in fact when seen by those most competent in treating epilepsy vis a vis Mr Eldridge, Consultant Neurosurgeon and Dr Pan, Consultant Neurophysiologist, the suggestion was that most if not all of [INI87’s] attacks were non epileptic in nature.

2.112 In response to the initial draft, Dr Morrow emailed Mrs Webb, and copied in Mr Watson and Dr Watt, on 20th December 2006. Dr Morrow welcomed the opportunity to review the draft and suggested changes as *“there is, I feel a degree of think [sic] diagnostic uncertainty regarding [INI 87’s] attacks – but this is not what has been asked in his parents letter and I think to highlight these as graphically as you have is only to invite further criticism”*. There followed a series of amendments to the draft which had the effect of watering down the language of the initial draft and Dr Morrow’s views expressed in correspondence of 27th October 2006.

2.113 On 17th January 2007, a formal response, based on the advice of Dr Morrow and Dr Watt, was forwarded to INI 87’s parents. The letter, which recited extracts from the input of both Dr Morrow and Dr Watt, offered a meeting with INI 87’s parents and this was eventually arranged to take place on 1st February 2007 with Dr Stevens, Mrs Webb and Dr Morrow. The Inquiry Panel noted that in summarising the views of Dr Morrow the letter stated:

On reviewing the notes, it would appear that other specialists, including those at the Walton centre for Neurology and Neurosurgery, Dr Morrow, Dr Pang, Consultant Neurophysiologist at the Royal Victoria Hospital and the Neuropsychiatrists that were reviewing [INI 87], had felt that [INI 87’s] events **were not all attributable to epilepsy.**

Emphasis Added

2.114 This response included no reference to the potentially inappropriate prescription of drugs and the insecure nature of the epilepsy diagnosis as referred to in the initial draft.

2.115 The meeting with INI 87’s mother, Dr Morrow, Dr Stevens and Mrs Webb took place on 1st February 2007. From the notes of the meeting, it is apparent that the focus of INI 87’s parents was on delay in answering the questions raised and criticism also about Dr Watt’s attitude and communication and whether INI 87’s mediation was appropriate and had been monitored. Dr Morrow in the recorded summary of his view states:

Dr Morrow said [INI 87's] attacks look/sound what were epileptic attacks but that he also had pseudoseizures. **It was difficult to say how much was true epilepsy.**

Emphasis Added

2.116 At the same meeting Dr Stevens was noted as stating:

Dr Stevens indicated that Dr Watt's clinical skills were not causing concern and that the communication issue was being addressed.

2.117 Subsequent to the meeting on 1st February, Mrs Webb liaised with Mr Alphy Maginness from the Directorate of Legal Services. On 14th February, Dr Stevens called an urgent meeting regarding INI 87 at which he required the attendance of Mr Walby, Dr Morrow, Dr Watt and Mrs Webb. Before the meeting could take place, Dr Stevens was informed that the Coroner had instructed the PSNI to gather witness statements on his behalf, following which he would determine whether to hold an inquest. On 16th February, Mr Walby emailed Dr Stevens and indicated that Dr Watt should get his defence organisation to check his statement to the Coroner. The urgent meeting was then deferred by Dr Stevens when it became more apparent that an inquest was likely to take place. In an email of 16th February to Dr Walby, Dr Stevens stated:

As per my earlier email, I feel the likelihood of an inquest clarifies things in terms of how we respond to INI 87 parent. I will talk to Pauline about the phrasing of the letter and ask her to run it past you. I do not feel we need to meet to discuss. I completely agree that Michael (Dr watt) needs advice as proposed. He also needs to abide by action plan that arose from earlier meeting with him. I have written to David Adams on this point and will ask him to ensure the division follows this up.

2.118 Mrs Webb subsequently wrote to INI 87's parents on 27th February 2017, and made them aware that the Trust had been contacted by the Coroner regarding a possible inquest and assured them that the Trust would fully assist the Coroner with his investigations.

2.119 An Inquest did, in fact, take place and a detailed description of the events leading up to same are set out in the 2006-2007 chapter.

2.120 As with the INI 222 complaint, the temptation is to focus on the clinical details and determine whether there was substance to the complaint. That is not the task of the Inquiry. To what extent the diagnosis and treatment of INI 87 was reasonable is a question for others. The Inquiry Panel noted that the epilepsy diagnosis was not considered at the inquest. The Coroner concluded that INI 87 died of drug toxicity.

2.121 The issue of whether the clinical dimension of the INI 87 complaint should have been focused upon to a much greater degree was raised with Dr Tony Stevens when he gave evidence to the Inquiry. Dr Stevens felt that, as a non-neurologist, he was relying upon the view of Dr Jim Morrow, whom he felt had been more nuanced when he met with INI 87's parents on 1st February. Dr Stevens stated:

I, personally, don't think the clinical issue is a big one. And, anyway, Jim Morrow, who was very well sighted on him, was Clinical Director, I think, or at least Clinical Lead, at the time, raised no concerns and, in fact, stepped back at the family meetings, so I don't think I reasonably could have had any clinical concerns. And Michael [Watt] had been the one that had referred to the Walton clinic. His own statement made the point that he didn't think the family would ever accept that this wasn't epilepsy. So, he was probably managing a very complex situation.

2.122 Unfortunately, the Inquiry Panel was unable to hear from Dr Morrow because he was medically unfit to appear but would have liked to have explored with him as to why his views appeared much more nuanced when he met with INI 87's parents.

2.123 What was of interest to the Inquiry and which arose out of this complaint was the following:

- (i) The reaction of management to the delay and reticence by Dr Watt in addressing the issues.
- (ii) There was no consideration given to obtaining an independent view outside the Trust.
- (iii) There was an absence of any look back or review of earlier complaints.
- (iv) A concern that the clarity of Dr Morrow's⁵ view, as outlined in his letter to the GP regarding a diagnosis of epilepsy, was toned down when the joint letter to INI 87's parents was written on 17th January 2017 and when he met with INI 87's parents on 1st February.
- (v) Dr Stevens formed the view (which is later repeated in 2013⁶) at the meeting with INI 87's parents on 1st February that he was not concerned about Dr Watt's clinical ability. Arguably, however, there were questions to be addressed, as highlighted by Dr Morrow, which could have given rise to a more thorough

5 Dr Morrow was unable to attend before the Inquiry Panel because of a documented medical reason and has not had an opportunity to comment on these issues.

6 See email to Ken Fullerton dated 14th June 2013 with regards to the INI 348 complaint, and after initiating the informal stage of MHPS, which stated 'there is a pattern here that causes me some concern. While I would acknowledge Michael's clinical skills and commitment, there does seem to be an issue about administration and communication that has previously caused him difficulty'.

investigation as to why Dr Watt came to the view that INI 87 should have been treated with drugs based on the diagnosis that he was suffering from epilepsy.

- (vi) While the Coroner subsequently concluded that INI 87 died of drugs toxicity, this should not detract from the fact that the Trust had come across a related concern about possible misdiagnosis, which it could have investigated further.

Complaints with regards to Waiting Times at Clinics 2006 – 2007:

2.124 Several complaints dating from 30th November 2006 to May 2007 were disclosed, all of which related to the length of waiting times at Dr Watt's clinics at that time.⁷

2.125 All the complaints referred to followed a similar pattern. For example, in preparing a response to the INI 420 complaint, the Inquiry Panel noted a memorandum from Mr Paul Sharpe, Senior Manager in Health Records to Mrs Webb as follows:

Dr Watt's clinic is significantly overbooked. It was originally set up for four patients and he is seeing up to twenty-six. In addition the time slots for the clinics are set for four patients. Consequently patients are being asked to attend at the same times with the inevitable long waits for patients. I understand that Dr Watt has been making efforts within his Division to have his clinics changed to a more appropriate template.

Identical memorandums were prepared by Mr Sharpe with regards to other complaints at this time.

2.126 A response was produced such as that with regards to INI 422, signed by the Acting Chief Executive which indicated as follows:

We have recently introduced a new appointments system, which ensured that patients have an element of choice in selecting a suitable date to attend the hospital. This also helps to reduce the number of occasions when patients do not keep their appointments and contributes to shorter waiting times for appointments on the outpatient waiting list. Unfortunately the subsequent increase in the number of patients who attend also been significant and has led to the delay that you have experienced.

We are therefore reviewing the structure of Dr Watt's clinics. I apologise for any delay or inconvenience that you have experienced as a result of delays at the clinic. Our intention was to increase the efficiency of the clinics by improving attendance rates. However, we are obviously unhappy that achieving the aim has resulted in overbooked clinics where patients face unacceptable delays. We will revise Dr Watt's clinic configurations and achieve a netter balance between

⁷ INI 422, INI 420, INI 423, INI 424 INI 425, INI 426 INI 444, INI 427, INI 428, INI 429 and INI 445.

reducing the length of time that patients wait before receiving an appointment and the length of time that they wait at the clinic.

- 2.127 In response to a complaint from INI 444, the description of the clinic on 14th March 2007 was striking. There was also an alternative explanation regarding the number attending:

On that particular day, 36 patients were booked to be seen at the clinic within the allotted 2.5 hours hour clinic session. As is frequently the case due to the varying nature of clinic complaints the clinic did not run on time. All patients are seen in appointment time order and the consultation length may vary according to each patient. The reception and nursing staff have no control over the situation but endeavour to keep patients informed of any delays.

In order to fully utilise each clinic situation there is a degree of overbooking to counteract the 15% DNA rate (did not attend) patients who failed to turn up for scheduled appointment

- 2.128 What was apparent about the cluster of complaints set out above was: (i) the number received over a relatively short period of time; (ii) the identical response given by the Trust on each occasion; (iii) the lack of evidence that the complaints were evaluated by management or acted upon apart from expressing sympathy and concern.
- 2.129 In response to the complaint of INI 428, a reply signed by Dr Stevens, Medical Director, dated 31st May 2007 was a similar to many of the earlier complaints, save that the review promised appeared to have been completed by this time:

We have **since reviewed** the structure of Dr Watt's clinics. I apologise for the distress and inconvenience you have experienced. Our intention was to increase the efficiency of the clinics by improving attendance rates. However, we are obviously unhappy that achieving this aim has resulted in overbooked clinics where patients face unacceptable delays. **We are confident that the revisions to Dr Watt's clinic configurations** will achieve a better balance between reducing the length of time which patients will receive before receiving an appointment and the length of time they have to wait at the clinic.

Emphasis Added

- 2.130 In May 2007, INI 445 contacted the Trust helpline about delays at Dr Watt's clinic. On this occasion the letter of response from the Trust again from Valerie Jackson, Director of Older People, Medicine and Surgery on behalf of William McKee, the Chief Executive, reverted to the original wording of the earlier correspondence. "*We are currently reviewing ... We will revise Dr Watt's clinic configurations*". The inability of the Trust to distinguish between what had occurred or would occur suggested to the Inquiry Panel that the correspondence in response was not being reflected upon

in sufficient depth or there had been no communication with the Patient Liaison Office about the review of Dr Watt's practice template that appears to have been carried out and referred to by Dr Stevens in his response to INI 428.

- 2.131 On each occasion a complaint was referred to the relevant Service area, which was Neurology, the following advice was given to those charged with investigating the complaint:

The draft response should:

- Address all of the issues raised by the complainant
- Explain what happened and why it happened
- Detail any actions taken to prevent recurrence
- Where appropriate offer an apology

- 2.132 The Inquiry Panel noted that while apologies for patients' distress were handed out liberally in relation to waiting times, a pattern developed of setting out a narrative, which suggested analysis and action, but in truth bore little relationship to management concern.

INI 430:

- 2.133 This complaint, received on 21st June 2007, related to Dr Watt's attitude. Like other examples above, the complaint itself was not retained, but a response was obtained from Dr Watt, which stated:

Dr Watt regrets not letting you know the reason for his delay in getting back to complete the consultation with you. When he returned he did try to explain what had happened and attempted to apologise. At no time did he intend to upset you in any way. If he appeared abrupt, this was simply that he was anxious to keep the clinic moving as effectively as possible for the sake of all patients who were attending.

INI 421:

- 2.134 The complaint of INI 421 was received by the Trust on 25th October 2007, but a copy of the original complaint letter was not retained. The gist of the concern was that the complainant's husband had been waiting for the insertion of a pump but had been taken off the waiting list. The Patient Liaison Manager, Mrs Webb, wrote in December 2007 to let the patient know that Dr Gray would see them on 20th December 2007.

INI 446:

- 2.135 On 18th June 2008, INI 446 complained that she had attended an appointment with Dr Watt at the Ulster Independent Clinic in October 2007. Documentation relating to this complaint is was limited. A draft response to be signed by Patricia O’Callaghan, Director of Head & Skeletal Services, from July 2008 indicated that *“regrettably Dr Watt overlooked arranging an appointment for the MRI scan”*. The draft response noted that an appointment for a further MRI had been made for August 2008 but signposted the complainant to the private practice they attended if they had any further queries.

INI 417:

- 2.136 On 9th August 2010, INI 417 wrote to the Trust regarding a recommendation made by a Dr Bahra in London, who had proposed an epidural blood patch. INI 417 had previously been treated with Human Immunoglobulin treatment (“HIG”) and there was a delay in performing the proposed epidural blood patch. Attempts to arrange the procedure as a day-case were objected to by registrars due to their level of experience. There was also a divergence of medical opinion between Dr Bahra and Dr Watt, who wished to repeat the HIG treatment. On being asked for his comment Dr Watt stated:
- ... her parents seemed to be under the impression that I would follow the instructions from London to the letter and would in some way act as though I was a junior doctor under their direction.
- 2.137 Dr Watt subsequently approved a draft response sent by the Belfast Trust to INI 417, which addressed the allegation of delay on the basis that Dr Watt was on leave, but that he planned to carry out the epidural blood patch on his return and *“had the best interests of the patient at heart and it was not his intention to upset the patient”*. Apologies were proffered for any misunderstanding and a review appointment was organised. The difference in medical opinion was not addressed.
- 2.138 This case was included when an updated Datix search was carried out in 2018. It was classed under category “Y” as a Staff Attitude/Behaviour problem and Graded as – MEDIUM.
- 2.139 Dr Tony Stevens, Medical Director of the Belfast Trust at the time of the complaint, noted in his oral evidence on 3rd September 2019 that he did not believe that the complaint had reached his office and had been dealt with in the Neurosciences Department. The complaint does not appear in the copy of the Medical Director’s Office file disclosed to the Inquiry.

- 2.140 Having reflected, however, on the documentation surrounding the INI 417 complaint, Dr Stevens noted:

... the [INI 417] case, which, again, I believe, was probably a significant case, because, again, it showed some evidence that, although there was a third opinion in that case, he was tending to do – take his own path, do his own thing and also that he treated her with immunoglobulin at a time when, interestingly, there was a focus on the use of the human immunoglobulin. Having read the testimonies in this pack⁸, it was clear that other people saw him as an outlier in the use of immunoglobulin. No doubt, we'll come to that, but that was not something that, while I knew about the issue of overuse of immunoglobulin, it was not known corporately that he might be an outlier in that.

- 2.141 Dr Stevens further stated:

His attitude was dismissive at key times, ... Dr Bahra and I don't know whether Dr Bahra's advice was – I don't know the quality of it – but let's assume it was of good quality. Michael seemed to vary from it, including doing a treatment of immunoglobulin and a proposed second course of immunoglobulin until the family put an end to that based on the advice they got ... we were in the territory here if you look at joining up the dots.

- 2.142 It is noted that the response did not address the difference of opinion between Dr Watt and the view of Dr Bahra about the patient's treatment with HIG and the registrars' concern about performing an epidural blood patch. The issue of Dr Watt's use of HIG is commented upon further in the Prescribing chapter.

INI 418:

- 2.143 Following a diagnosis of multiple sclerosis on 6th August 2010, the complainant required a report confirming the diagnosis for critical illness cover to be put in place. On 26th November 2010, a complaint was made by telephone, concerning the length of time the report had taken. The absence of a report ensured that the patient was not able to receive the monthly payment due under the policy. Despite emails and telephone calls, no action was taken and after 4 months a complaint was made.
- 2.144 On 6th December 2010, Katrina Hughes, Assistant Services Manager in Neurosciences emailed a Complaints Officer, having spoken to the Clinical Director. Mr Cooke had confirmed that the completion of such forms was not a part of a consultant's NHS contract.

8 Dr Stevens was provided with a bundle of materials including various complaints prior to his appearance at the Inquiry.

- 2.145 On 7th December 2010, it was decided to treat the informal complaint as a formal complaint as the matter was not resolved quickly. In a letter of that date from Maura Quinn the Complaints Manager to INI 418's husband, a Form of Authorisation requiring the patient's signature and a leaflet describing the complaints procedure was forwarded.
- 2.146 On 20th December 2010, a Complaints Officer asked Katrina Hughes if there was any progress with this complaint and was informed that Dr Morrow, the Clinical Lead, had talked to Dr Watt and emphasised the importance of completing such forms.
- 2.147 On 22nd December 2010, Katrina Hughes emailed Dr Morrow, Clinical Lead, Mr Cooke, then Clinical Director, Mr Atkinson, Service Manager and the Complaints Department as follows:

All

I can't answer any more of this complaint but am **being plagued by complaints**.

I can advise complaints to advise the gentleman that this is outside NHS work however this still does not look good from a Trust perspective and Donna has let me know that there are **dozens of calls per week** in relation to this issue with other patients

I would be grateful for advice please

Thanks

Katrina

Emphasis Added

- 2.148 The fact that the Neurosciences Department recognised a pattern of dozens of complaints about the same issue raises the question as to why this was not picked up on by any other recipients of the email.
- 2.149 On 4th January 2011, Legal & General, the relevant insurer of INI 418's policy wrote directly to the Chief Executive of the Royal Victoria Hospital, Colm Donaghy, asking for help in obtaining the necessary information from Dr Watt. The forms eventually appear to have been completed on or about 7th January.
- 2.150 In a letter from the Complaints Department of 27th January 2011, Maura Quinn, Complaints Manager apologised for the inconvenience caused.
- 2.151 The confusion as to the obligations of a consultant in relation to the completion of such forms led to a plethora of complaints in relation to Dr Watt. Clearly, as Dr Morrow had pointed out, neurologists were expected to complete such forms,

whether there was a formal contractual obligation or not. The overriding impression is that, as Mr Cooke had remarked in his email of 4th October 2006 to Dr Stevens with regard to INI 222, there was no understanding among medical staff of the need to comply with complaints procedures. The Clinical Director felt he could only use explanation/persuasion to resolve problems with colleagues. This reality permeated the complaints process. Instead of management recognising that there was a problem with Dr Watt not filling in standard forms for patients and addressing the situation, if necessary by referring the matter to the GMC, the confusion persisted and those in the complaints department were left trying to make up creative excuses, pleading with doctors, or suggesting to complainants that it was a private matter between them and the consultant. The situation needed gripped and the behaviour addressed. In reality, the opposite occurred.

INI 419:

- 2.152 A case analogous to INI 418 was received by the Complaints Department on 15th December 2010. The complainant's driving licence had been revoked on 29th November 2010 and it was alleged that Dr Watt had failed to provide the necessary medical evidence to the Driving Vehicle Agency ("DVA"). The relevant forms had been provided to Dr Watt in August 2010 and the matter had been discussed further at an appointment with Dr Watt on 3rd November 2010. The complainant stated that she had contacted Dr Watt's secretary on numerous occasions in September, October and November. The complainant had written directly to Dr Watt on 28th November 2010 expressing disappointment that Dr Watt had not contacted the medical section of the DVA. In her letter to Dr Watt, the complainant stated:

... I have also arranged for the completed form to be collected by my sister at your earliest convenience, preferably today, so that she can drive it to the DVA in Ballymena. You will appreciate that I am technically banned from driving; otherwise I would collect it myself. My biggest concern is that I may have to apply for a new licence which means that I could be without transport for up to one month which is most inconvenience, especially for my work ...

- 2.153 On 15th December, the complainant wrote to the Complaints Department at the Belfast Trust. At that point, the complainant had been unable to drive for two weeks and had been informed by the DVA that any new application for a driving licence may take up to four weeks to process following receipt of relevant medical information. This letter of complaint was acknowledged by Maura Quinn, the Complaints Manager, on 16th December 2010. The letter of acknowledgement sought to reassure the complainant that the matter would be investigated.

- 2.154 In a subsequent letter of 14th January 2011, Ms Quinn explained that there had been a delay into the investigation for reasons, which were not explained.
- 2.155 On 20th January 2011, Ms Quinn indicated that Dr Watt's secretary had advised her that the forms had been completed and sent prior to Christmas.
- 2.156 Subsequently, an Officer in the Complaints Department telephoned the complainant and was informed that she required a formal response from the Trust as the length of time she had had to wait was unacceptable. This explanation was provided to the Neurology Services Manager, Mr Atkinson, on 24th January 2011.
- 2.157 On 26th January 2011, Mr Atkinson indicated to the Complaints Department that *"something like the following would suffice: 'I am sorry to hear that you have experienced some difficulties in relation to a private matter between yourself and Dr M Watt. I understand that the documentation you require has since been processed and I hope that this matter has been resolved to your satisfaction'."* Ms Quinn responded indicating that *"I am not sure this will suffice given that she had her licence revoked"*. On considering the same, Mr Atkinson indicated he had made a few amendments but *"I'm not sure that there is anything else to add. We have apologised for the delay and you have invited the complainant to contact you if required"*.
- 2.158 A formal response from the Director of Acute Services, Ms Patricia Donnelly, was sent to the complainant on 31st January 2011, which stated as follows:

Dear [INI 419]

Thank you for your letter of 16 December 2010 regarding your request for medical information from Dr M Watt, Consultant Neurologist, which was required for the completion of forms.

I am sorry to hear that you have experienced some difficulties in relation to what is a private matter between yourself and Dr M Watt. I am happy to note that the documentation you require has since been processed and I hope that this matter has been resolved to your satisfaction.

I apologise for all the inconvenience caused to you by this delay.

Should you require any further information, please contact Ms Maura Quinn, Complaints Manager on 028 90630025.

- 2.159 The complaint appears to have been forwarded to the Northern Ireland Ombudsman's Office in October 2011 but does not seem to have been the subject of any formal ruling or decision. This complaint was not on the January 2012 Datix entry but was one of the complaints sent to Dr Fullerton on 26th July 2013, when

he was reviewing the situation regarding Dr Watt's revalidation. The matter was included in the updated 2018 Datix and graded as "low" and classified as "other contracted service". It was noted that an apology was given, for what was "a private matter between complainant and consultant". The fact that Dr Watt had imposed upon him a 5-year warning by the GMC in 2007 does not appear to have been grasped or known about. If a doctor failed to fulfil a professional obligation, which may have been outside his strict contractual obligation then the matter could and should have been referred to the GMC.

- 2.160 In oral evidence, Ms Clare Lundy, the then Assistant Services Manager, stated to the Inquiry Panel on 21st January 2019:

... there's no other consultants that I'm aware of within neurology or even in the other specialties that I've worked in where there has been that number of reports being requested ...

- 2.161 In his evidence to the Inquiry Panel on 3rd September 2019 Dr Stevens reflected as follows:

... should we have fired some of those back to the GMC, there's an argument, ... a lot of these complaints were not getting up the line. They were being dealt with at a local level, and they weren't being triggered. They didn't trigger a Clinical Director or an Associate Medical Director to bring them to the doctors' and dentists' case review meetings, which started in 2009, which would've been an obvious place if they had concerns to bring them ...

... in retrospect, it would be reasonable to have flagged with the GMC that these were matters of concern, or these were issues that were causing us a problem: "Over to you". I think there are two reasons. One is I'm not sure anybody senior enough in the organisation was really being pestered with them and, therefore, it didn't become an issue. The second is it goes to the heart of the relationship with the GMC and ... whether the GMC would've acted on it ...

- 2.162 The Inquiry Panel noted that the GMC warning given in 2007 for a period of 5 years was still in force at the time of both the INI 418 and INI 419 complaints. This is further commented upon in the GMC chapter. Complaints like this one and the preceding one illustrate how a tardy approach to responding to requests for reports can lead to more time and resources being spent in an already stretched service area; the issue has real life consequences as patients are being delayed in claiming of insurance policies or clarifying their driving status; and ultimately it appears that, yet again, delay by Dr Watt was tolerated.

INI 5:

- 2.163 On 16th December 2010, a non-executive director of the Health & Social Care Board made a formal complaint about her diagnosis and treatment under the care of Dr Watt and more general complaints about her inpatient care. Following two consultations with Dr Watt, the patient had been prescribed a five-day course of oral steroids, which required the patient to be admitted for treatment in the Royal Victoria Hospital.
- 2.164 INI 5 met directly with the Chief Executive of the Belfast Trust, Mr Colm Donaghy, after which Mr Donaghy prepared and circulated a summary of the issues. On 23rd December 2010, Ms Maura Quinn wrote to INI 5 acknowledging the correspondence with Mr Donaghy.
- 2.165 Following receipt of the complaint, a draft response directly from Mr Donaghy was drawn up, which was more detailed than usual. This response received input from Dr Watt on 17th December 2010. He indicated that he had discussed the differential diagnosis with INI 5 and that psychosis was a recognised but infrequent complication of the steroids.
- 2.166 On 12th January 2011, Mr Donaghy wrote to INI 5 indicating that there had been a Trust investigation into the issues raised and stating that they would need some further time to complete their formal response. This was forwarded on 31st January 2011 and the Chief Executive offered to meet with the patient to discuss the issues arising.
- 2.167 In response to Mr Donaghy's letter of 31st January 2011, the patient replied on 8th February 2011, in detail, complaining in essence that the investigation and response from the Trust had not addressed the issues raised and was also full of inaccuracies. With regards to her diagnosis, INI 5 indicated as follows:

I spoke at length with you about the incorrect diagnosis made by Dr Watt and his unwillingness to Tegretol any alternative diagnosis even when questioned after seeing him briefly in his clinic on the day I was humiliated in his waiting room for an hour and 40 minutes. I suggested that nothing had gotten better with the steroids, that every symptom and more was multiplied by 100 in severity and I asked the question "What is it was something else?" As I now have been diagnosed (and now treated twice) for Lyme disease, I question how his reply could have been so certain "It's definitely an inflammation of the spinal cord." How could he be so wrong and not have cast his diagnostic mind wider after the negative MRI. He also knew the travel history as I gave it on the first visit. Additionally, I have been informed since that every so often the DoH sends

out reminders to doctors not to forget to consider Lyme Disease. As he is a consultant neurologist, I would have expected a more thorough and thoughtful approach. I am afraid he failed to listen to me. I think you will find that within your response this too is left unanswered.

2.168 In the concluding paragraphs of this correspondence, the patient stated:

... You conclude your response with a sincere apology for how I felt, rather than for the poor and inappropriate treatment I received. There is no admission of wrongdoing and no apparent lessons learned from my and others' experience on that ward or along the entire journey. You do realise that had I not had £700 to pay for an MRI, I would have still been waiting with neurological Lyme disease running rampant and who knows what else. Equally, I would have been psychologically distressed to say the least thinking I was dying of a brain tumour and all of the eventualities that coincide with that. How many patients are currently waiting for urgent tests like this that somehow become 'non-urgent'? How many people can't get through on the switchboard? How many people wait around for hours and at what cost to their employers? To the taxpayer? How many patients' urgent calls go unanswered and inadequately dealt with by staff? How many patients, at their most vulnerable, are mistreated and shouted at in the A&E department at the RVH? How many people are maltreated and have their human rights infringed in Ward F? And is this endemic? Have we lost all common sense from clinical care stretching to the investigative and complaints realm?

These questions are why a proper response would have been so important to me.

I felt extremely concerned for any complainants if this is the level/standard of investigation. I am so saddened that the Trust has not admitted to any wrongdoing and that there appears to be nothing learned. Even the Department of Health states in its guidance that it is better to be honest and admit where mistakes have been made and apologise.

My husband implored me to try and forget about it, saying that nothing will change no matter how I might like it to – that it's too big of a machine. Maybe he is right. But based on what I have seen so far including the unbelievably inaccurate and inappropriate response, I cannot help but respond further. I met you in my capacity as a non-executive director because I feel I have a duty and that includes being able to feel confident in the services we commission. That is why I came to meet you and I explained that in full. Based on the response I received, I am still not confident that things aren't just the same. I feel it would be remiss of me to let this go, even if it were only for patient safety reasons – the fact that Ward 2F is potentially extremely unsafe from my experience; but indeed there is so much more. I believe a more considered investigation and

answers to the questions outlined in my original complaint to you and here again is warranted. The answers to which have implications for the public and the services they use and rely on heavily.

Emphasis Added

2.169 As INI 5 was dissatisfied with the initial response by the Trust, Mr Donaghy offered a further meeting with himself and the Medical Director, Dr Stevens, in a letter to the patient of 16th February 2011.

2.170 In preparation for the meeting, Dr Stevens sought to meet with Dr Watt and Dr Sara Hedderwick, Infectious Disease Consultant employed by the Belfast Trust. Dr Hedderwick had considered a differential diagnosis of Lyme disease and concluded that it was unlikely. Dr Stevens had also received a summary of the steps taken by the Complaints Department to prepare a response. In an email of 22nd February 2011, Ms Maura Quinn informed Dr Stevens that the response had been composed from information received by the following staff:

Neuro – Gerry Atkinson
ED – Bernie Glover/Linda Linford/Brendan Sinnott
Outpatient wait – Lorna Mercer
2F – Siobhan Donald/Sr Irwin
Telecoms – Annemarie Perry

2.171 A meeting between the patient, Dr Stevens and Mr Donaghy was arranged for 28th March 2011. Dr Stevens met separately with Dr Watt, Dr Hedderwick and Sister Irwin.

2.172 Following the meeting on 28th March, Dr Stevens drew up an action plan to deal with matters arising. The actions were as follows:

ACTION	BY
Review success of introduction of clinical template	AS
Guidance on inpatients attending outpatient clinics to see a consultant	AS/BC
Use [INI 5's] experience to improve practice in 2F	BC
Feedback to Dr Watt	AS
Feedback to ED and 2F on [INI 5's] experience	AS/RC
Follow up on nurse who shouted [INI 5]	BC
Maintenance of call logs by secretaries	
[INI 5] involvement in patient experience	BC

2.173 On 3rd May 2011, Mr Donaghy wrote to the patient summarising the meeting that had taken place. Mr Donaghy indicated that the Trust was keen to maintain an ongoing dialogue with the patient *“to ensure that all matters are appropriately and*

finally dealt with". The patient had declined the opportunity to meet with Dr Watt, but Mr Donaghy was anxious that the patient would be involved in Trust initiatives on patient experience. The letter concluded:

... Can I repeat my wholehearted apology for the difficulties and distress you have experienced. Please accept my promise that we will make every effort to learn from your experiences. I look forward to further dialogue on these matters.

- 2.174 Dr Stevens met with Dr Watt on 17th June 2011 and followed this up with a letter dated 21st June 2011. In that correspondence, Dr Stevens stated:

I understand from our conversation that your clinics are now running effectively to the clinic template which is reducing waiting times, at the clinic, for patients.

Regarding communication with patients, particularly in respect of the differential diagnosis, I am pleased that you have reflected on [INI 5's] experience. I recognise that you have used this opportunity to consider how you communicate differential diagnosis to patients particularly where such diagnosis may cause alarm.

- 2.175 In his oral evidence to the Inquiry Panel on 3rd September 2019, Dr Stevens stated in relation to this complaint:

I have no note of it, but I have a clear memory of it, and I – or reasonably clear. I actually thought I would have spoken to John Craig, and I double-checked it with John, and he has no recall, so I went back and looked at who was the Clinical Lead, or Clinical Director, at the time, and it was Jim Morrow, and I concluded that I would have spoken to Jim. I definitely spoke to a neurologist ... I was given an assurance at the time that outpatient treatment of a large dose of steroids for a putative diagnosis of myelitis is reasonable ...

The challenge with [INI 5] was that she was extremely angry ... Misdiagnosis was not where she started in this. Her biggest concern had been around waiting for Michael Watt's clinic; the issue around the MRI; the issue around the diagnosis, which didn't include Lyme, but that he was suggesting it was a tumour or a syringomyelia or myelitis ... My concern about the Lyme disease issue and the breakdown in her relationship with Michael Watt was to ensure that she was being cared for appropriately by somebody she had confidence in. And my meeting with Michael and Sara, in a way, was to try and resolve some of the issues but also to make absolutely certain that we were all settled on who was going to care for her and where the care lay ...

On the issue which we're here today about, which is, "Was this a red flag about Michael's practice?", there were so many interplaying issues ...

2.176 INI 5 gave evidence to the Inquiry Panel at an early stage of evidence gathering. Significant time was taken to consider what a multi-layered complaint was. Occasionally the focus was on the question of diagnosis and whether, the patient had or had not suffered from Lyme disease or whether Dr Watt should have prescribed steroids when he did. While it is difficult to understand the context without averting in some measure to the medical details of this complaint, the Terms of Reference do not permit the Inquiry Panel to come up with conclusions on the medical treatment of particular individuals. This complaint is, however, of interest to the Inquiry for the following reasons:

- (1) INI 5 was a non-executive director of the Health & Social Care Board and within her own profession had a significant understanding of health and governance issues. The complaint lodged was taken extremely seriously by the Trust. The complainant secured two meetings with the Chief Executive, one of which included the Medical Director. The Trust was clearly anxious to resolve this complaint. In addition, the Medical Director, following his meeting with the patient and the Chief Executive, drew up an action plan, which included direct feedback to Dr Watt. While this approach was detailed and systematic, its effectiveness and the degree to which informal conversations were not noted and relied upon for reassurance, undermined the ability of the investigation to achieve any objective outcome. Any structured and ordered investigation needs a clarity about the issues raised and the methods used to determine whether concerns are justified.
- (2) This patient highlights in an articulate and insistent manner the problems she perceived with the responses that had been drawn up by the Complaints Department and the Medical Director. This case is a good example of the methods utilised by the Complaints Department, which could be summarised as follows:
 - (i) A careful attention paid to the history of dealings with the service within the Trust. When attended, treatment given, drugs prescribed, and other factual material collated into what in most cases amounted to a chronology of the patient's treatment.
 - (ii) A consistent theme of apology and recognition of distress for the complainant's perceptions without a commensurate evaluation of the extent to which complaints were objectively legitimate.
 - (iii) Liaison with the doctor, who was the subject matter of the complaint. Insofar as other medical practitioners were consulted, the discussions were often informal and not written down. In this case, the Medical Director appears to have reassured himself about

certain aspects of the treatment by talking informally to the Clinical Lead without any note or record being kept of that conversation, leaving it difficult to know exactly what was discussed and agreed.

- (iv) Significant reliance was placed on input from the relevant service area within the Trust. In most cases, a draft response to a complaint was drawn up by the Service Manager. Any response sought to collate the patient's interaction with Trust Services and a summary often included the comments of the clinician, who was the subject of the complaint. The Clinical Director may have been asked to sense check the response letter. Dr Craig, the Clinical Director since 2013, in his evidence to the Inquiry Panel on 6th February 2020, made it clear that he did not evaluate complaints or review the patients' medical records. The Service Manager is not a clinician. Their view of a complaint, which highlighted treatment and diagnosis concerns was of limited value and yet appear to be the person who was relied upon to give the necessary input. The system appeared to be so ingrained and longstanding, that it was difficult for those responsible for same to envisage an alternative.
 - (v) The absence of an appropriate investigation negated the possibility of any learning.
- (3) In her response to the detailed correspondence from Mr Donaghy, the patient trenchantly pointed out that the subject matter of the complaint had not been addressed and that the sincere apology was for how the patient felt *"rather than for the poor and inappropriate treatment I received"*. The patient's conclusion was that the level or standard of investigation was inadequate.

2.177 While this complaint was recalled in some detail by many of the people involved, including the Medical Director, the focus tended to remain on the merits and demerits of the patient's complaint about diagnosis, rather than about the methods utilised in order to get to a proper assessment of the complaint. The Inquiry Panel recognised that Dr Stevens had sought the advice of Dr Sarah Hedderwick, a specialist in infectious diseases specifically in relation to the query about Lyme Disease. Dr Stevens believed that Dr Hedderwick had provided an independent opinion but in her evidence to the Inquiry Panel on 9th April 2019, Dr Hedderwick stated:

Mr Lockhart QC: The substance of her complaint is that she was given high-dose steroids for the condition that he had — the differential diagnosis that he had made. To some extent, whether or not she ultimately had Lyme disease, the question is *"Was it reasonable to give a high dose of steroids on the presentation that he —?"*. That seems to be the critical question.

Dr Hedderwick: You're also taking to the wrong person about to answer that question, because, mostly I am a doctor for whom when I see steroids, its usually they were given at the for the wrong thing or they were given and now they've got an infection as a consequence of them. So, I'm very careful with steroids.

- 2.178 In the view of the Inquiry Panel, the reference to Dr Hedderwick, though helpful and appropriate was not the obtaining of an independent view on the critical issue of differential diagnosis and the prescription of steroids.

INI 431:

- 2.179 On 23rd September 2011, Gregory Campbell MP wrote to the Trust on behalf of his constituent, who had been a patient of Dr Watt. In order to substantiate INI 431's fitness to return to work, the DVA required a report from INI 431's treating physician. This had been outstanding for 3 months when Mr Campbell complained to the Chief Executive of the Belfast Trust.

- 2.180 The correspondence between the Public Liaison Service and the Service Manager within Neurology is instructive:

Josephine

The provision of a medical report is a private matter between Dr Watt and the Driver and Vehicle Agency. It is not part of Dr Watt's contract of employment with the Trust, however I have forwarded this correspondence to Dr Watt's attention and I hope this matter can be resolved soon.

Gerry

Hi Gerry

Thanks for this. Are you happy that I use this info as the basis of our response?

Josephine

Josephine

Yes that's OK. Medical reports are provided by consultants when requested. This is private work for which Dr Watt will receive a payment.

Gerry

- 2.181 The Inquiry noted that this complaint, as with the INI 418 and INI 419 complaints referred to above, was within the 5-year warning period imposed by the GMC in 2007 in respect of delays in preparing a report.

INI 447:

2.182 On 14th March 2012, INI 447 complained to the Trust about the delay in obtaining an MRI scan and an appointment. INI 447 was also concerned that he had not been prescribed the correct medication. Following a routine ENT operation, INI 447 developed neck spasms and he was advised by his GP and by Dr Primrose at the ENT clinic that he had developed dystonia⁹ for which he was prescribed medication. Frustrated by the lack of progress, INI 447 arranged a private appointment with Dr Watt at the Ulster Independent Clinic, who, after confirming the diagnosis of a form of dystonia, prescribed trihexyphenidyl and undertook to review INI 447 at the RVH at his NHS clinic.

2.183 According to the email complaint from his wife, INI 447 developed significant side-effects from the medication including extreme dizziness, hallucinations difficulty passing urine and memory lapse. The email asked for an early consultation, given the symptoms being manifested. In a draft response prepared by Mr Gerry Atkinson *"from a neurology perspective"*¹⁰ the position was summarised as follows:

I understand that an appointment with Dr Watt was arranged and your husband attended this on 29th March. Dr Watt felt that treatment with botulinum toxin would help your husband's symptoms and arrangements were made to progress this. Your husband next attended the RVH on 5th April when he was seen by Dr A Fulton and Dr S Kearney, consultant neurologists specialising in movement disorders. A CT scan of your husband's neck was undertaken at this time and it was decided that treatment with botulinum would not proceed at this stage. A further appointment at the Movement Disorder clinic at BCH was arranged for 11th April and botulinum toxin was administered.

2.184 The position summarised by Mr Atkinson above was reflected in the formal response of 23rd May 2012 from Mrs Patricia Donnelly, Director of Acute Services, sent on behalf of the Chief Executive, Colm Donaghy, to INI 447's wife.

2.185 Reflecting on this complaint, the following questions now seem obvious to the Inquiry Panel:

- (i) What steps were taken by the Trust to investigate if there were significant prescribing differences between Dr Watt and Dr Kearney and Dr Fulton?
- (ii) Noting that a CT scan was carried out, why did there not appear to have been tests carried out by Dr Watt?

⁹ Dystonia is a movement disorder in which your muscles contract involuntarily, causing repetitive or twisting movements.

¹⁰ Mr Atkinson was commenting "from a neurology perspective" because ENT, Imaging and ED were other service involved in responding to the complaint..

- (iii) Why was botulinum toxin administered when a week earlier it had been decided not to proceed with it?

The impression from the documentation is that it rarely seemed to have occurred to those summarising issues, collating a response or drafting a formal reply, that there was or may have been a clinical issue which needed to have been investigated.

INI 448:

- 2.186 On 3rd September 2012, INI 448's insurer complained that Dr Watt had failed to complete a medical report for an insurance company on critical illness. According to Legal & General, in an email of 5th December 2012, the information had been outstanding since 6th January 2012. The Complaints Manager eventually wrote to Legal & General on 14th January 2013 indicating that the report required had been completed. Although the documentation is incomplete, it appears that no one had questioned the fact that this was another example of delay in providing reports and that, while expired, Dr Watt had previously been given a 5-year warning by the GMC about not providing reports. The focus was on obtaining the report and closing the file. However, there was still a delay of several months from the complaint being made to the report being received.

INI 347:

- 2.187 This case arises out of a letter of complaint of 20th February 2013. The patient was referred to the TIA clinic in September 2007 and had been assessed by Dr Mark Magorrian, Consultant Geriatrician employed by the Belfast Trust and a colleague of Dr Watt, as having suffered a migraine. Dr Watt was present at the same clinic and was asked by Dr Magorrian to consider. Having gone through the same questions as Dr Magorrian, Dr Watt, according to the complaint submitted, had suggested as a precaution that they would do the same test as would be the case with a TIA *"to completely rule out any problems such as stroke, brain haemorrhage, TIA, brain injury/ tumour or heart problem"*.
- 2.188 The patient duly went for the relevant tests and heard nothing further. In 2010, an insurance policy with Scottish Provident was due for renewal and the patient discovered via her GP that Scottish Provident believed she had suffered a TIA based on a report prepared by Dr Watt of 2nd October 2007. The patient was indignant that no one had said that to her at the time.

- 2.189 It transpired that Dr Magorrian had, in fact, written to the patient's GP in October 2007. This letter was not seen by the patient at that time. Dr Magorrian stated:

I discussed this lady with Dr Watt today and Dr Watt also spoke with [INI 347]. On review of the symptoms the main feature is really a brief episode of right arm weakness. Clinically this would be in keeping with a transient ischaemic attack. The features wouldn't be convincing of migraine or seizures.

- 2.190 On 9th February 2012, the patient met with Dr Watt, who explained that their records could not be changed.

- 2.191 On 17th September 2012, the patient wrote to the Head & Skeletal Service Group in the Royal Victoria Hospital "*to contest the diagnosis of TIA*".

- 2.192 On 21st September 2012, the patient wrote to her GP confirming that she was contesting the report from the Royal Victoria Hospital dated 2nd October 2007. In her letter, the patient stated:

This is a case of principle and some sort of respect for the patient. To attend a routine procedure, be told that all tests are clear and nothing was found and then informed by an insurance company many years later that in actual fact you suffered a TIA is unacceptable and should never have happened. But more importantly it is a case of truth where a diagnosis has been made contrary to what the tests were carried out for, to *completely rule out* any issues including a TIA and of course the tests did that quite successfully.

- 2.193 On 20th February 2013, the patient then invoked the complaints procedure and set out chronologically the substance of her complaint, which reflected the gist of what had been given to her GP.

- 2.194 The patient's letter of complaint in 2013 concluded:

As expressed in my final letter to my GP, this is a case of principle and some sort of respect for the patient. To attend a routine procedure be told that all tests are clear and nothing was found and then informed over 4 years later that in actual fact you suffered a TIA is unacceptable and should never have happened. But more importantly it is a case of truth where a diagnosis has been made with nothing solid to back it up.

- 2.195 On 9th April 2013, a draft response was drawn up by Ms Lundy, the Assistant Services Manager. Ms Lundy had attempted to contact Dr Watt twice during March. The draft followed very much the template of apology for distress, a recitation of involvement with the service and a further concluding apology. The response was reviewed by Dr John Craig, newly appointed Clinical Director, who recommended the insertion of information relating to patients having a normal MRI scan following a TIA.

- 2.196 In this instance, however, while Dr Watt was not prepared to change his diagnosis, he had suggested a second opinion from another colleague in neurology. The formal letter of response was dated 30th April 2013 and was signed by Mrs Owens, then Interim Director of Unscheduled Care.
- 2.197 INI 347 wished to avail of such a second opinion. In consultation with Dr Watt, Ms Clare Lundy arranged for Dr Ailsa Fulton, Consultant Neurologist and, at that time, a colleague of Dr Watt, to see INI 347. Ms Lundy asked Dr Watt to *“avoid making reference to your clinical decision regarding [INI 347] experiencing a TIA”* and Dr Watt asked his secretary to remove references to the diagnosis accordingly.
- 2.198 A report of 4th June 2013 was drawn up by Dr Fulton and forwarded to Dr Watt after she had the opportunity to review the notes and examine INI 347. Dr Fulton took a different view based on the history given to her and stated:

On balance the bilateral arm symptoms, the bilateral eye pain and the preceding history of neck pain would be unlikely to be suggestive of a vascular/TIA event. Also the patient's lack of vascular risk factors and the lack of family history would be against a diagnosis of TIA. Following the clinic appointment I have reviewed [INI 347's] investigation results, her original GP referral letter and her original TIA clinic letter. There would appear to be discrepancies in the described clinical symptoms in the GP letter, the TIA clinic letter and now in the history I elicited today at clinic. I would be happy to discuss the case in further detail at any time. I have explained to [INI 347] today in clinic that my opinion is purely based on the information provided by her to me at clinic today.

- 2.199 The letter was sent to the patient and on 18th June, in an email to Ms Lundy, the patient sought clarification that the initial diagnosis was incorrect due to discrepancies in the described clinical symptoms, in the GP letter, the TIA clinic letter and the history received at the recent consultation with Dr Fulton. Dr Fulton responded by letter of 24th June 2013 as follows:

Further to your email correspondence with Mrs Claire Lundy in the Neurosciences office I am writing to clarify my opinion and diagnosis of your symptoms. The history and examination from your clinic attendance with me on 4th June 2013 are highly suggestive of cervical muscle spasm with associated nerve root irritation as a cause for your symptoms. I do not feel the history provided or examination was suggestive of a TIA given the bilateral symptoms and the lack of vascular risk factors. I hope this clarifies the information provided in my previous clinic letter. If you require any further details please do not hesitate to contact me.

- 2.200 On 19th February 2014, the patient again wrote to Ms Lundy seeking reimbursement of £455.40, being the additional premiums, which had to be paid as a result of the incorrect diagnosis. In her letter, the patient stated:

Further to the investigation by the Belfast Health & Social Care Trust which subsequently confirmed I did not suffer a TIA due to the bilateral symptoms, lack of vascular risk factors, lack of family history and the amount of discrepancies in the case history notes taken at the Royal Victoria Hospital I have now received confirmation from Scottish Provident that due to the new information and true account of my health has resulted in an honest premium of £24.52. I have since calculated the difference between what I have been paying over the years verses [sic] the true rate and now request reimbursement of the same.

Period (years)	Money Paid (£)	Difference (£)	x 12 months
April 2013 – April 2014	£36.95	£12.43	£149.16
April 2012 – April 2013	£35.33	£10.81	£129.72
April 2011 – April 2012	£33.49	£8.97	£107.64
April 2010 – April 2011	£31.26	£5.74	£68.88
			£455.40

- 2.201 The patient followed this up on 23rd April 2014 with a reminder letter noting that she had not received any reply. In particular, the patient wished to have it confirmed that *“the incorrect diagnosis of TIA had been removed from my personal records”*.

- 2.202 The complaint’s file was then recalled on 8th May 2014 and in a handwritten file note dated 22nd July 2014, Maura Quinn, Complaints Manager wrote:

Patient has since been reviewed by another neurologist, Dr Fulton. Clare [Lundy] will write to patient and copy letter to Complaints for file.

- 2.203 A suggested response was drawn up by Ms Lundy on 20th October 2014 and formalised on 28th October 2014 in a letter from Mrs Owens. The salient paragraphs of the response are set out below:

I understand that Mrs Lundy arranged an appointment with Dr Ailsa Fulton, Consultant Neurologist who then felt that on the balance of probability, you had not suffered a TIA.

Unfortunately I am unable to offer you any financial reimbursement in respect of premiums which you had paid to your private health care provider based on the information which had been initially provided by Dr Watt. As previously mentioned, this was Dr Watt’s clinical opinion and it had remained unchanged.

In your letter dated 23rd April 2014 you have asked for confirmation that “the incorrect diagnosis of TIA” has been removed from your personal records. Unfortunately I am unable to remove any medical records from your file. However, I would like to reassure you that Dr Fulton’s letter is also contained within your medical record which records her diagnosis following the explanation of symptoms you experienced on 6th September 2007. I understand from Mrs Lundy that you have a copy of this correspondence. If you would like a further copy, Mrs Lundy would be happy to arrange this for you.

2.204 On 4th November 2014, a Complaints Administrator indicated to Mr Atkinson and Ms Lundy that this patient’s complaints could now be closed off and that all of the investigation notes, statements from staff, etc should be forwarded for inclusion in the complaints file “*should this file be requested by the Trust Legal Department or the Commissioner for Complaints*”.

2.205 Despite the concern about the case being included in the complaints’ documentation, the complaint was not in the Medical Director’s pink file¹¹ nor does any summary appear to have been sent to the Health & Social Care Board. The Inquiry presumes that this case was one of those referred to at the DDCRM of 3rd June 2013. The file note stated:

Mrs Owens indicated that she had recently signed two complaints in relation to Dr Watt.

Although the patients’ names are not mentioned, these two complaints appear to refer to INI 334 and INI 347. This complaint was forwarded to Dr Ken Fullerton, the Associate Medical Director, by Mr Atkinson on 26th July 2013. Dr Fullerton had been asked by the Medical Director, Dr Stevens, to conduct a Finding of the Facts exercise, given the number of times that Dr Watt had been discussed at the DDCRM. Problems included the INI 45 complaint to the GMC, difficulties with completing appraisal and the complaints referred to by Mrs Owens on 3rd June 2013.

2.206 The Inquiry Panel noted that the matter was included in the updated Datix record of 2018. The complaint was correctly classified under clinical diagnosis and designated as a low risk or priority.

2.207 In oral evidence to the Inquiry Panel on 3rd September 2019, Dr Stevens, the Medical Director, gave evidence:

I have a more benign view of this case, for several reasons. The first is that she attended a joint TIA clinic ... there was a consensus between the two on the result ... My reading of all of it is that ... the lady’s symptoms changed and ... this falls, to some extent, within the acceptable difference between doctors.

¹¹ This was a file kept in relation to specific doctors who had been the subject of complaint.

- 2.208 Dr Fullerton, the Associate Medical Director, who had clinical experience of diagnosing TIAs, stated on 5th November 2019 to the Inquiry Panel:

Now, if I were a responsible clinician working in a TIA clinic and a patient turned up, and there was a reasonable chance that they may have a TIA, I have to then say, "What would a reasonable doctor do? If I do not treat this as a TIA, then the risk of the patient having a stroke is actually highest ... What happened at the clinic seems to me to be reasonable ...

... My criticism of Dr Watt in this case is that his attitude to the patient may not have been the same as mine, but, in terms of his treatment, again, it seemed to me it was within the realms of what might be considered reasonable.

- 2.209 The Inquiry Panel reviewed the same evidence from the vantage point of seeking to ensure that there was an effective process and the extent to which this complaint should have been highlighted or considered as part of a broader pattern. The Inquiry Panel noted the following:

- (1) When Dr Watt is recorded as having made clear to the patient in 2012, following a consultation, that his opinion remained unchanged, there is no written evidence, which either required or sought Dr Watt's views, in light of Dr Fulton's report. A phone call with Dr Watt was not sufficient. Dr Fulton had raised doubts about the diagnosis and this should have raised questions for those investigating.
- (2) It is correct to say that Dr Fulton emphasised that she was basing her view on the patient history as given to her in June 2013. There is some suggestion that this differed from the patient history as recorded back in 2007. There is also, however, concern about inaccuracies in the various contemporaneous notes and symptoms described in 2007, both in the GP report and the letter to the consultant. The investigation should have tried to reconcile the alleged varying accounts. What is clear is that the patient has been extremely proactive since discovering some years afterwards that she had been, in her view, incorrectly diagnosed.
- (3) While Ms Clare Lundy is to be commended for the manner in which she sought to address the contradiction, the template within which she was operating had limited scope. There is little expectation that the Trust would have come to its own view on a case based on the evidence collated. In circumstances where there is a stark and significant index case or where, as in this case, there was other evidence of a pattern of treatment and clinical approach then an independent view could be obtained from outside the Belfast Trust.

- (4) At that juncture, there was a focus by the Medical Director and by Dr Fullerton in assessing the revalidation status of Dr Watt. The Inquiry Panel has consistently stressed that it was essential that the Medical Director had the most accurate and up to date view of all relevant complaints. This applies even more acutely when the Medical Director is was being asked to provide details to the GMC as Regulator. This case is one of many instances where information was not collated properly.

INI 334:

- 2.210 On 15th February 2013, a patient complained that he had been misdiagnosed with epilepsy and prescribed medication when, in fact, he was suffering from chronic fatigue syndrome. In his letter to the Chief Executive, the patient stated:

I was diagnosed with epilepsy and was treated under the care of Mr Watt, Neurologist, at the Royal Victoria Hospital in Belfast. I was prescribed Tegretol by Mr Watt to treat my epilepsy.

It transpired that I did not have epilepsy and should never have been subscribed Tegretol. I have suffered from chronic fatigue syndrome and depression from taking same and my mental health has declined since.

- 2.211 The correspondence was acknowledged promptly on 18th February 2013. The letter from Ms Maura Quinn, Complaints Manager apologised that INI 334's experience of *"the service has been less than satisfactory"* and provided an assurance that *"the issues you have raised will be investigated under the Trust's complaints procedure"*.
- 2.212 A suggested response was drawn up by Ms Clare Lundy, Assistant Service Manager, and she indicated that this draft response had been reviewed by both Mr Gerry Atkinson and Dr John Craig¹². There is no evidence that Dr Craig suggested any amendments and emailed Ms Lundy on 22nd April, 2013 shortly after receiving the draft with the comment *"This is fine"*.
- 2.213 The draft went through several iterations and eventually on 31st May 2013 a letter from Mrs Owens, as Interim Director of Unscheduled Care, was forwarded to INI 334. The letter to INI 334 has been set out in full below because it is a good example of the manner in which complaints were addressed:

Thank you for your letter dated 7th February 2013. I would firstly like to

¹² On 22nd April 2013 Ms Lundy emailed Dr Craig as follows:

Can you please review the suggested response who suggests that Dr Watt mis-diagnosed him in 2022. You will note from the response that this gentleman DNS'd several OPD appointments. Dr Craig responded the same day as follows: "Thanks Clare. This is fine, however clearly if a patient fails to engage properly with the service they bear more than a degree of personal responsibility".

apologise for the time delay in responding to the concerns which you have raised. A senior manager with the Neurology Service at the Trust has investigated your concerns and we are now in a position to provide you with a response.

I understand that you were referred to the Neurology Department at the Royal Victoria Hospital on 29th January 2002 and that you attended your first appointment with Dr Watt, Consultant Neurologist, on 19th June 2002. At this appointment Dr Watt recorded the symptoms which you had expressed. It was his opinion at this time that the episodes you described were partial seizures and he prescribed Epilim 500mg daily. An MRI scan of the brain was suggested along with a review appointment which was arranged for 25th September 2002. Our records indicate that you did not attend the appointment on this date and arrangements were made for you to attend on 23rd April 2003. Regrettably, this appointment was cancelled as Dr Watt was on annual leave.

At a subsequent appointment on 23rd July 2003 Dr Watt reviewed your symptoms and suggested that the Epilim medication that you were taking should be changed to Tegretol 300mg. As you had not had an MRI scan, Dr Watt stated that he would request the MRI scan again. Dr Watt indicated that he would review you again in four months time. An appointment had been rescheduled for 11th August 2004 but was cancelled by our appointments office as Dr Watt was on annual leave. I apologise if this and the previous cancellation had caused you any undue anxiety, or if this was inconvenient for you.

Our investigation has shown that unfortunately the Imaging Department did not receive a request for you to have an MRI scan of the brain, and it is unclear from your medical records if the request was forwarded from Dr Watt's office to the Imaging Department.

I understand that further review appointments were then organised for you for 10th November 2004, 29th June 2005, 10th May 2006 and 24th January 2007, although our records indicate that you did not attend any of these appointments. As a result of your non-attendance at the clinic, Dr Watt was unable to review your clinical condition and assess the symptoms which you were experiencing in order to review his diagnosis and treatment plan. You were therefore discharged from Dr Watt's care and a letter in this regard was sent to your General Practitioner.

I am sorry if you feel that you have sustained personal injury, loss and damage as a result of an incorrect diagnosis. As previously mentioned, Dr Watt was not able to reassess your condition, symptoms and medication as you did not attend appointments which had been organised for you.

I understand that you recently attended Antrim Area Hospital under the care of Dr Esmonde, Consultant Neurologist. I am sorry to note from your

correspondence that you have suffered from chronic fatigue syndrome and depression. I sincerely hope that your condition has started to improve following your discharge from Antrim Area Hospital in November 2011.

In your correspondence you have requested a copy of all relevant notes and records pertaining to your care in the Belfast Trust. I understand that you have since been forwarded the relevant information to assist you in this request.

Once again, I would like to thank you for your letter and for drawing our attention to the care which you have received. If I can be of any further assistance, please do not hesitate to contact Ms Maura Quinn, Complaints Manager

- 2.214 The letter follows the traditional template of apologising for the person's distress followed by a comprehensive history of attendances and a further apology to the patient who is now suffering from chronic fatigue syndrome and depression. The response did not analyse or answer the question that had been asked. The patient believed he was wrongly diagnosed. A neurologist in a different Trust, on the face of it, appeared to agree with the patient that he was incorrectly diagnosed. The complaint would seem to have been investigated by an Assistant Service Manager (Ms Lundy), who had liaised at least in some part with Dr Watt. The fact that the letter of response was reviewed by the Service Manager, Mr Atkinson, and the Clinical Director, Dr Craig, as well as the Director of Unscheduled Care, Mrs Owens, provided no further enlightenment.
- 2.215 In his evidence to the Inquiry Panel, Dr Craig explained that he would often have been asked to "*sense check*" correspondence. He would have done this in the absence of the medical notes and records and would not have reviewed this as an independent evaluation of the substance of the complaint. The Inquiry Panel accepts that this was his view, though notes that other managers believed that they were getting a more considered view which could be relied upon. The Inquiry Panel takes the view that even a high-level review by Dr Craig would be able to spot an obvious pattern of clinical approach.
- 2.216 While it is the case that this patient's complaint was one of the cases referred to by Mrs Owens at the DDCRM meeting on 3rd June 2013 and appears to have been before the Associate Medical Director, Dr Fullerton, in his Finding of the Facts exercise in July 2013 prior to Dr Watt's revalidation, the problems of the initial investigation remained.
- 2.217 The Inquiry Panel took the view that the investigation of this complaint, both when it was made and by Dr Fullerton, was inadequate in the following respects:

- (1) Those investigating the complaint spoke only to Dr Watt. No effort was made to discuss the case with Dr Esmonde nor was the Clinical Director asked or advised to consider the clinical notes and records, not did the clinical director of his own initiative seek the notes or access the electronic care record.
- (2) The letter of response dated 31st May 2013 did not answer the simple question. The issue was whether it was reasonable for Dr Watt to have made the diagnosis of epilepsy and to have prescribed Epilim and then Tegretol.
- (3) The patient should have been asked why he did not attend review appointments and his medical notes and records reviewed to consider the ongoing prescription of Epilim and then Tegretol.
- (4) There was a difference of understanding about the extent to which Dr Craig was asked to provide an opinion, which was being relied upon by those in the Service Department and the Director who signed the letter. The confusion led to what in many instances was a superficial review of the draft response, which had limited benefit in the absence of the Clinical Director accessing the patient's medical notes and records. In this regard, the reference to the response being reviewed by the Clinical Director provided the misleading impression that the Clinical Director was satisfied with the diagnosis, which is the subject matter of complaint. All such a review can provide is a high-level overview, which may spot glaring errors.
- (5) Dr Fullerton's review was also problematic, although the Inquiry Panel accepts that he worked hard to collate information, which was incomplete when he commenced the process. He has not kept any notes of his assessment of the case and does not appear to have reviewed the patient's medical notes and records.

2.218 What is striking about this case is that, despite the complaint response being looked at by a range of individuals, and being reviewed by the Associate Medical Director, no one seems to have considered the basic question posed by the patient. The response given is entirely in keeping with the approach that was taken in most cases and the system in place can provide no reassurance in terms of patient safety or the identification of potential aberrant practice.

INI 348:

2.219 INI 348, whose husband was a senior official in a health organisation, initially wrote to Dr Tony Stevens, the Medical Director, following the patient being diagnosed with

a stroke in 2009 and issues with claiming under her critical illness cover which began in 2010. The patient attempted to contact Dr Watt without success. On 12th June 2013 she wrote to Dr Stevens explaining that she had attended the RVH Emergency Department in January 2009 with left arm weakness and eyesight disturbance. An emergency CT scan showed no abnormality, but the doctor on duty remained concerned about the patient having suffered a stroke and referred her to the TIA clinic where she was reviewed by Dr Watt. Further tests, including an MRI were arranged but Dr Watt stated that, in his opinion, she had *“definitely suffered a stroke”*.

- 2.220 A claim was subsequently lodged in respect of a critical illness policy. There was initially a significant delay. Dr Watt wrote to AXA Insurance stating that the patient had *“suffered in fact as no evidence??? of haemorrhage on imaging”*. In February 2010, AXA disputed evidence of stroke but agreed to review the situation if the consultant would clarify. Dr Watt, despite numerous telephone calls, did not clarify his views.
- 2.221 The patient was reviewed by Dr Watt in February 2012 as she had a separate episode of unusual facial and oral sensation which resolved within 24 hours. Dr Watt did not believe this was a stroke, but it was alleged by the patient that he was *“100% certain”* she had previously suffered a stroke and changed her medication. He also promised to write a further letter to AXA. This was subsequently not provided despite reminders being sent.
- 2.222 At a further review in September 2012, the patient complained again that Dr Watt had not provided a report as previously promised. The letter of complaint stated:

Despite further repeated phone calls from ourselves as well as the Ombudsman to Dr Watt’s secretary over the next 5 months, he still did not provide such a written statement and as a result the claim on my critical illness plan which the ombudsman agreed appeared to be very valid was delayed by a further significant period. Indeed it was only when the ombudsman played an audio recording of one of his brief conversations with Dr Watt that the insurance company eventually agreed a partial settlement of our claim which I accepted as I felt I could no longer continue with the stress and frustration of trying to pursue the issue with Dr Watt.

- 2.223 On a review of the complaint on 14th June 2013, Dr Stevens emailed Dr Fullerton, the Associate Medical Director and Dr Craig, the Clinical Director:

Ken/John

There is a pattern here that causes me some concern. While I would acknowledge Michael’s clinical skills and commitment, there does seem to be an issue about administration and communication that has previously caused him difficulty

This letter really needs to be managed as a complaint (I have also copied to [the complaints Dept]).

In parallel I would be grateful if you would consider any professional issues, taking account of previous concerns.

Regards

Tony

2.224 Responding on 17th June 2013, Dr Watt stated to Ms Clare Lundy:

I can only apologise for my failure to provide the reports to [INI 348's] insurers. I am aware that I have had problems providing reports over the years. I see a huge number of patients and as a result at times struggle to keep on top of the workload. I only get as far as doing reports when I am on top of other work, and this sometimes doesn't happen for months. Reports on patients who I have diagnosed as having a stroke despite normal imaging are a particular problem and often lead to repeated inquiries. These reports are not part of my job in the Royal and are not meant to be done in hours, and as it is not part of my employment my secretaries should not help me to prepare them.

2.225 Various iterations of the response were drawn up by the then Assistant Service Manager, Ms Clare Lundy and the reply was considered by, amongst others, Dr Stevens, Dr Craig, Dr Fullerton, who was at that time carrying out a Finding of the Facts review pursuant to the informal stage of the Maintaining High Professional Standard ("MHPS") process, and the Interim Director of Unscheduled Care, Mrs Bernie Owens.

2.226 Ms Lundy prepared a detailed draft outlining the history of appointments as gleaned from the medical notes and records. This draft recorded that Dr Watt's letter to INI 348's GP in 2009 stated a *"probable diagnosis of a minor stroke", a letter in February 2012 indicating that the diagnosis "once more lies between migraine and a further stroke with migraine appearing the more likely", and correspondence dated 9th October 2012 which, in Ms Lundy's assessment, did "not make reference to you suffering a stroke and states that your MRI scan did not identify anything of any significance"*.

2.227 On reviewing the complaint, Dr Fullerton indicated that he *"would be inclined not to put in so much clinical detail, as this is not material to the case"*. Ms Lundy, to her credit stated on 9th July 2013 that she was content with her draft as *"there is information there that suggests that maybe the symptoms were in relation to migraines"*. The clinical detail was subsequently omitted on the recommendation of Dr Fullerton. Dr Stevens, responding to Dr Fullerton's query as to whether the completion of such reports was a part of a consultant's contract, stated:

... I would make the point that this complaint reflects an aspect of practice that is still covered by revalidation and reflects earlier concerns regarding MW. I would expect that Dr Watt send a letter of apology.

- 2.228 The final draft of the letter was sent out on 19th June 2013, signed by Mrs Owens, and did not address the issue of the diagnosis raised by AXA in February 2010. Dealing with the contractual obligation point the letter stated:

Dr Watt has offered his sincere apologies for his failure to provide the necessary reports to you and AXA insurers regarding your critical illness cover claim and if you have incurred any subsequent financial loss as a direct result of this. While the provision of reports for insurance companies is not part of Dr Watt's contractual obligations with the Trust, I would nevertheless have expected Dr Watt to meet the commitments he gave to you verbally, by providing a suitable written report in a timely way.

I have asked that Dr Watt write to you separately with his apology. We will follow this matter up with Dr Watt as part of reflective practice.

- 2.229 The complaint, and associated correspondence, was collated and placed in the complaints file following a direct request from the Complaints Administrator. An apology to the patient was compiled on 22nd July 2013 and sent to Ms Lundy for onward transmission. The matter was also evaluated by Dr Fullerton as part of his review of Dr Watt's practice prior to revalidation.
- 2.230 This complaint happened to be received at a time when Dr Watt was being reviewed by the Associate Medical Director, Dr Ken Fullerton. The fact that the patient had contacted the Medical Director, Dr Stevens, appears to have given greater urgency to the importance of responding promptly and apologising directly.
- 2.231 A further feature of this complaint is that the original letter of complaint, when properly analysed, also raises a question of diagnosis. This was put to Dr Fullerton, who agreed with the Inquiry Panel on 5th November 2019 that there was a clinical component. Dr Fullerton, however, stated:

... but, again, the question is, "Is Dr Watt behaving reasonably?" Firstly, an MRI scan, particularly if it's not done in the early stages, does not necessarily exclude a stroke. Secondly – and I'm not sure – it's a particular MRI modality that needs to be applied ... a negative MRI a while after the symptoms does not exclude a stroke. It's still a clinical call.

- 2.232 When the complaint was analysed and the query raised by AXA considered, it was apparent that there was a clinical dimension, which should have been appropriately reviewed when Dr Fullerton was carrying out his Finding of the Facts exercise. As

with other complaints, it was not, in the view of the Inquiry Panel, appropriate for the person carrying out the review to rely solely on their own medical knowledge or to limit their investigation to those matters explicitly raised by the complainant. At a minimum, the medical notes and records should have been obtained, and the matter discussed with someone, who was independent of the reviewer.

- 2.233 A matter of concern was that although Dr Stevens highlighted a pattern, which caused him concern, there was no written evidence, which would allow a proper triangulation of all those instances where complaints focused on a failure to provide a report. Dr Stevens was of the view that those were obligations that all consultants would have had as a part of their role as a medical consultant. The issue tended to be viewed within the Neurosciences Service Department, however, as something, which was outwith the consultant's contract with the Trust. In reality, however, Dr Watt had already received a 5-year warning from the GMC regarding his failure to furnish reports and this failure became regular and persistent. At no point did there appear to have been appropriate management of what had become a chronic problem. There are clear clues in the papers, which suggest that Dr Watt's workload had become overburdened. In his email to Clare Lundy of 17th June 2013, Dr Watt stated:

I see a huge number of patients and as a result at times struggle to keep on top of the workload.

- 2.234 This admission does not seem to have alerted those in management to check whether Dr Watt was working to an appropriate clinic template or whether his job planning was up to date. For the avoidance of doubt, the Inquiry Panel accepts that it was the case that Dr Watt was greatly assisting the Trust by seeing a huge volume of patients. It is also recognised that a degree of pragmatism is required, and a purist approach can be unhelpful. Nevertheless, the role of the manager is to monitor the situation and be aware of the possible dimension of overworking. Frequent complaints specific to Dr Watt should have been a warning sign that needed to be investigated.
- 2.235 The views of Dr Watt expressed to Ms Lundy on 17th June 2013, principally that *"reports on patients who I have diagnosed as having a stroke despite normal imaging are a particular problem and often lead to repeated enquiries"*, could perhaps have led to the identification of broader issues. It is unreasonable to expect an Assistant Service Manager, relatively new to the post, to identify clinical issues of concern. A properly functioning complaints and management system could, however, have identified broader issues of concern arising out this and other contemporaneous complaints.

INI 449:

- 2.236 INI 449 also wrote to the Trust in June 2013 complaining that, following an outpatients' appointment with Dr Watt in April 2013, an urgent MRI request was drawn up, but not sent to the Radiology Department by Dr Watt. Eventually, INI 449 was admitted to Ward 4E and the MRI scan was completed. A clear apology was provided by the Trust on behalf of Dr Watt in a letter from Mrs Owens, then Director of Unscheduled and Acute Services, on 29th November 2013, which stated:

Dr Watt had completed the urgent MRI request form, but unfortunately he did not send this to the Radiology Department. Dr Watt states that he had a conversation with the Neurosciences Admission and Discharge Coordinator, Ms Vanessa Boyd, but unfortunately he did not follow through with this by providing Ms Boyd with the appropriate documentation, or with your mother's details. Dr Watt would like to offer his sincere apologies for the delay which ensued as a result of miscommunication and poor administration when dealing with the MRI request form, and the need for possible admission to hospital for further investigation and follow-up. Dr Watt would also like to apologise if this has caused your mother to suffer any further symptoms and for any undue anxiety and stress.

- 2.237 Given the candour of the response, the question arises as to what was being done to address the problem of miscommunication and poor administration by Dr Watt.

INI 349:

- 2.238 This complaint was forwarded to the Trust via the Patient Client Council and once again related to medical reports for two insurance companies regarding critical insurance cover. One of the reports had been outstanding for 14 months and had been the subject of continual complaint directly with Dr Watt on a monthly basis. The complaint was received in September 2013, just as Dr Fullerton had recommended Dr Watt for revalidation. It is noted that when the email was received from the Patient Client Council, it was logged by Ms Maura Quinn in Complaints as an 'inquiry,' not a 'complaint'. Given the context, this is surprising. The actual letter from the Patient Client Council stated:

The insurance companies are Scottish Provident and Bright Grey. In the case of the former the initial request was 14 mths [sic] ago. I understand that reminders are being sent to Dr Watt on a monthly basis; [INI 349] has also been in touch with his secretary on a number of occasions. One report for both will suffice.

The delay is causing [INI 349] some difficulty.

Is there anything that can be done to speed things up?

2.239 The complaint was initially forwarded to Dr Craig, the Clinical Director, and Mr Atkinson, the Service Manager.

2.240 In October 2013, Ms Lundy emailed Mr Atkinson to say that she had heard nothing back from Dr Watt, but that she thought Dr Fullerton was dealing with this.

2.241 On 11th October 2013, the patient personally filled in an online complaint notification, which stated as follows:

I have been awaiting my insurance forms to be completed for over year. I have asked Dr Watt on several occasions for the completion of the required forms. Further to this my wife wrote a letter to Dr Watt in April 2013. I ring Dr Watt's secretary every month for an update with no progress. The insurance company also write to Dr Watt monthly. The MS nurses have also intervened on my behalf and spoke to Dr Watt but with no success. The insurance company have also contacted me about the lack of progress and have said that they will close the claim if no further progress is made which means I would have to start the claim procedure all over again with the loss of month.

Please can you assist by speaking to Dr Watt and ask that he completes the forms the insurance company requires as soon as possible.

2.242 On 15th October 2013, Mr Atkinson contacted Dr Fullerton and Dr Craig offering to pursue the matter with Dr Watt "*mindful of previous complaints in a similar nature*". Dr Fullerton replied:

I thought this one had been resolved. When I met Michael he indicated that a previously outstanding report had been completed, and I took it to mean this one.

2.243 On the same date, Dr Fullerton emailed Dr Watt:

When we met, I was assured that there were no more reports outstanding.

Please respond to this one immediately, and advise me that you have done so. I can assure you that it is much quicker to respond to these requests at the time than a year after the event.

2.244 On 17th October 2013, Dr Watt responded:

Ken

As I told you at our meeting I have been paid for a report on [INI 349] – he must have another policy – I will complete it as soon as I can.

2.245 On 22nd October 2013, Mr Atkinson informed the Complaints Department that Dr Watt had advised Dr Fullerton that he had been paid for a report on INI 349. The email stated:

Dr Watt thinks [INI 349] must have another policy and he has assured Dr Fullerton that he will complete this as soon as he can.

2.246 By 5th November 2013, a complaints administrator contacted the Neurosciences Department, copying Dr Fullerton in, and stating as follows:

[INI 349] called yesterday seeking an update on his response. He advised 1 insurance company had received the consultant's reply but there was no date stated from when his MS was 6 months consistent, therefore he is losing out on 17 months, he asked if this could be resent with the date included. He also advised that Scottish Provident has not received any completed documentation.

2.247 The second report appears to have been forwarded by Dr Watt shortly before Christmas 2013.

2.248 Just as with the previous complaint, this patient's concern does not appear to have alerted those in management that there was a serious and chronic issue with Dr Watt's administration taking place in plain sight. These are not minor matters. The absence of a report to insurers can, in many cases, result in policies being paid out late or not at all. The Inquiry Panel again noted the following pattern:

- (1) The lack of any proper triangulation of the available data.
- (2) No hint that management believed that further action needed to be taken against Dr Watt for what had become a problem. This case is relevant because it is lodged just as Dr Watt has been revalidated in September 2013.
- (3) The reluctance by the Complaints Department to initially log it as a complaint implied a reticence to analyse the information that was being lodged with the Complaints Department. To refer to this situation as an '*inquiry*' failed to grasp the seriousness of what was being alleged.
- (4) Despite the urgency, Dr Watt, once again, took several months to deal with the substance of the complaint and provide the second report. His delay was met with continual requests and reminders that carried no threat of sanction or action. Consequently, the reminders had a negligible impact.

INI 350:

2.249 On 17th September 2013, the Complaints Department received a complaint from a patient, who had attended Dr Watt's clinic on 8th May 2013 and discussed the possibility of changing from his current medication to one of the more effective oral therapies. The patient indicated that he met the criteria and alleged that Dr Watt had

advised him that the new oral therapy would be a more effective treatment. In his letter the patient stated:

... Dr Watt assured me I met the criteria and advised that this would be a more effective treatment for me.

I asked the process and approx. time scales for this and all was well explained

1. Blood test
2. ECG
3. Request top up funding
4. Drugs available
5. Hospital bed request as a short stay is required

This could take from “a few weeks to a few months”

I had the bloods taken on 8th May at the MS Clinic and had an ECG that day too.

I had contacted the clinic on May 22nd and again on June 26th to try and get a progress update.

On both occasions I was told to keep going with the Copaxone until such times that the Gylenia was available.

On September 3rd I contacted the Clinic again to find out about progress.

On this occasion I was told that Dr Watt “had trouble getting a cardiologist to read the ECG” taken on 8th May.

I find this incredulous that it took 12 weeks for someone to approve a normal ECG. Considering as I had already been through Cardiology twice in the City for an ECG and a 24 hr Monitor on 28th May and 6th August respectively.

My complaint is that as of September 10th the top up funding has not even been applied for and the process of a “few weeks to a few months” has not even started, never mind arranging a short stay in Hospital ...

- 2.250 The response letter following investigation by Glen Cartmill a Senior MS Nurse, was completed on 19th December 2013 and signed by Mrs Owens. It was noted that funding approval had been obtained for the patient to commence the relevant treatment. In the interim, it transpired that the patient wished to travel to Spain and, after liaison with Dr Watt, it was decided to postpone commencement of the treatment and continue on the current medication. This complaint appears to have been dealt with comprehensively and is relevant only because it was received at or about the time Dr Fullerton was confirming revalidation. It appears that Dr Watt had considered and reflected on this complaint with Dr Fullerton. In the view of

the Inquiry Panel, the complaint illustrates the value of obtaining assistance from a specialist nurse, who appears to have been proactive in managing the response from the Multiple Sclerosis service.

INI 450:

- 2.251 On 27th January 2014, the husband of INI 450 complained that Dr Watt had carried out injections on his wife's back (which had not worked) and had left his wife in significant pain. At that time, INI 450 was informed that she was being placed on a waiting list for an MRI scan, but she was told that there was a long waiting list, despite the fact that she was "in extreme pain".
- 2.252 The issue of blood patching is dealt with in a separate chapter, but the Inquiry Panel noted that this was a patient complaining of extreme pain after several blood patch procedures carried out in 2014.
- 2.253 Ms Lundy identified a further complaint from INI 450 dated 9th April 2015 prior to her appearance before the Inquiry Panel on 25th May 2021. The complaint was a familiar one. The complainant indicated that his wife was under the care of Dr Watt and that, following surgery in March 2014, a claim had been submitted by the complainant's wife for disability cover. In November 2014, the insurance company wrote to Dr Watt asking him for a report on the complainant's wife. No response was forthcoming and eventually a complaint was lodged. In a typically effective and proactive way, Ms Lundy sought to resolve matters. She described the action she took in a written statement, which was submitted to the Inquiry Panel before she gave oral evidence. The relevant paragraphs are set out below:

34. [INI 450] and her husband had written to Dr Watt and requested a report on several occasions. I had dealt with a previous complaint by this patient in 2014 which related to delays in an MRI and treatment.

35. The patient complained by letter dated 8 April 2015. I escalated the matter to Gerry Atkinson, then Neurosciences Service Manager. Gerry's office was next to mine and I spoke to him about it. I told Gerry I was going to draft the report myself and ask Dr Watt to review it. I used the patient notes to complete the questions in the report request.

36. I recall I went to see Dr Watt on the ward with the report I had prepared. I recall Dr Watt went to sign the report without reading it, however, I suggested he should read it first. I had brought with me the letters within the patient's notes which I had used to compile the report. Dr Watt read the draft report and suggested one change. I made the change and brought it back for him to sign.

37. In preparing this statement I was discussing this instance with Mr Johnston and he was not familiar with it. It appears that the material relating to this complaint has not previously been provided to the Inquiry.

38. I checked with the Complaints Department as to why this complaint was not previously identified as relating to Dr Watt. I have been informed that unfortunately the complaint from this patient was not linked to Dr Watt on Datix. The Complaints Department has explained to me that the process for linking is not as robust as it is now, and I understand that the Belfast Trust is going to explain the position generally in response to a statutory notice from the Inquiry.

- 2.254 Notwithstanding Ms Lundy's efforts, the report was not received by the complainant until 3rd February 2016. No final response was issued as this complaint was deemed to have been locally resolved by Ms Lundy. Ms Lundy provided further information on the meaning and effect of local resolution in the same witness statement as follows:

Local resolution of a complaint is where direct engagement with the complaining patient results in an outcome to their satisfaction, and where, as a result, they do not require a formal written response. If it is appropriate to resolve a complaint in this way, then I will communicate that internally to the Complaints Department and update them on any agreed actions or plans put in place. I cannot say how the Complaints Department record or analyse complaints resolved in this way.

- 2.255 While Ms Lundy's efforts and motives are laudable, the Inquiry is concerned that the local resolution of complaints such as INI 450 created clear issues with regards to the recording of complaints and outcomes and impeded the identification of any potential trends. It is, however, of note that this complaint only came to the attention of the Inquiry Panel thanks to the efforts of Ms Lundy.

INI 434:

- 2.256 On 10th July 2014, a long and detailed complaint was submitted by INI 434 regarding the treatment and care received while a neurology inpatient and, the lack of care provided by a team, which included Dr Watt. Issues regarding the nature of communications with INI 434 and the fact that she alleged she was not physically examined were also raised.
- 2.257 The complaint was forwarded to Dr Watt on 15th July 2014 by Ms Clare Lundy asking Dr Watt to comment on each concern/question that the complainant had raised. This was to be completed by 22nd July 2014. Ms Lundy also felt that, given

the complications and the length of the complaint, the matter might be best resolved in a meeting with the complainant. The following day, Ms Maura Quinn from the Complaints Department agreed that a meeting would be the best way forward. It is noted that Dr Peter Short, a Consultant in Emergency Medicine, commented on the emergency department attendances in December 2013, May 2014 and June 2014 by the complainant. This response from Dr Short was completed within days of being received.

- 2.258 On 30th July 2014, the Complaints Manager offered to meet with the complainant. The complainant agreed to the proposal, and it was suggested that Dr Craig and Dr Watt would attend the meeting on behalf of the neurology team and Ms Lundy would also attend as Assistant Service Manager in the Neurosciences department. It is noted that, in a file note of 6th August 2014, the complainant had asked for a second opinion. Getting a date, which would suit all parties for a meeting proved difficult. After further delay, a meeting was arranged for 28th October 2014. A detailed agenda was drawn up for that meeting, which raised a series of 15 questions regarding the treatment received by the complainant and her request for a second opinion. The meeting proceeded and notes were drawn up by the Medical Director's Office following the meeting. Before these were forwarded to the complainant, Ms Quinn from the Complaints Department spoke at length with the complainant on 4th December 2014.
- 2.259 The notes of the meeting highlighted concerns, which focused on communication of results and confusion about the views of Dr Watt. The notes reflect the fact that most of the complainant's concerns had been answered and the complainant was distressed that she had had to go to such lengths to get answers, suggesting that things would have been much different if Dr Watt had taken the time to discuss her case with her in more detail. Dr John Craig, Clinical Director, was present at the meeting but, on being asked to address issues raised in further correspondence by the complainant, summarised his role as follows in emails of 6th November 2014 and 9th December 2014:

As I pointed out at the start of the meeting I was not present at the meeting to give any form of clinical opinion, rather I was there in a managerial role and also to demonstrate how seriously we take complaints. I will not be giving any form of summary response in regards to the clinical care that was received.

I was at the meeting as an observer. I do not think it would be appropriate for me to be giving an opinion based on differing opinions. I will reply to any letters from [INI 434], but will be making the above position clear.

- 2.260 A draft response to the initial letter of complaint was drawn up in December 2014, but despite a great deal of email correspondence, the formal response was not completed until 14th May 2015. The minutes of the meeting were also not forwarded for many months, and this was the subject of further complaint in April 2015. This was, in part, due to a failure by Dr Watt to forward necessary information despite pressure from Dr Craig, Mr Atkinson, Ms Lundy and Ms Quinn. On 13th March 2015, Dr Craig advised Dr Watt that: *“this is likely to get escalated to the Medical Director if not sorted in line with Trust Guidelines”*. Dr Watt eventually provided the requested information on 18th March 2015.
- 2.261 On 1st April 2015, notes of a telephone call from the complainant to the Complaints Department were shared. In response, Dr Craig queried as follows: *“can I ask that complaints provide comment on level of care provided to [INI 434]. It seems like an unusual request and outwith the complaints procedure”*. The Inquiry has seen no response to Dr Craig’s email.
- 2.262 On 8th May 2015, the complainant wrote to Dr Cathy Jack, the Medical Director. The complainant was concerned that she had still not received a formal answer from the Complaints Department nor the minutes of the meeting in October 2014. Following a detailed response of 14th May, and enclosure of the minutes of the meeting, the complainant responded to the author of the Trust correspondence, Mrs Owens, on 18th May 2015. The reply from the complainant took issue with what she believed were inaccuracies in the summary note of the meeting in October 2014 and she also queried many of the answers to the 15 questions that had been posed in the initial complaint. A draft response to this letter was commenced in July 2015. This draft required input from Dr Watt and the number of issues raised caused further significant internal emails to be generated. A second iteration of the draft response was drawn up in December 2015 and a further draft in March 2016. It is clear from the email correspondence that attempts were being made to deal with discrete aspects of the queries raised. In this case, Ms Anne Flynn, the Complaints Manager, spoke with the complainant on 19th May 2016. In an email to Mr Atkinson, Ms Flynn stated:

I spoke with [INI 434] today and she advised me that she wanted to close her complaint. She felt that the process had dragged on for far too long and she was tired of receiving holding letters. I did explain that I felt a response was imminent, but she was adamant that she wanted to draw a line in the sand.

- 2.263 On the following day, the Belfast Trust wrote to the complainant noting that she had withdrawn her complaint and apologising for the delay to the subsequent queries that had been raised.
- 2.264 What is conspicuous in the handling of this complaint is the concentrated efforts that were made by those leading the complaints process to try and get detailed answers to a significant number of questions. In some ways, the long delay between the correspondence from the complainant and a formal response is understandable, given the resource issues required from many parts of the health system within the Belfast Trust. It is further clear that the efforts made on behalf of complaints' staff were genuine and the complexity of the case almost overwhelming.
- 2.265 This was one of several complaints, which had been lodged by articulate and determined complainants. The number of questions raised made resolution of the complaint extremely difficult. It is the case that consultants are often required to expend significant time and effort in responding to a wide variety of complaints and the Inquiry Panel recognises that the investment required is often disproportionate to the outcome that can be achieved. Given the length of time it takes to see a neurology consultant, and the myriad of questions that can be included in a complaint, there is a case for an initial screening process, which would seek to discern whether there is a serious clinical issue before committing to a comprehensive process.
- 2.266 In written evidence provided to the Inquiry on 23rd May 2022, the Belfast Trust stated that, at present, they are bound by the regional complaints process. Paragraph 3.31 requires that:
- Where the complaint involves clinical/professional issues, the draft response must be shared with the relevant clinicians/professionals to ensure the factual accuracy and to ensure clinicians/professionals agree with and support the draft response.
- 2.267 The Department's regional guidance quoted above clearly instructs and requires Trusts to ensure that any response must be approved by the person who is the subject of the complaint. This may explain the pre-eminence that was given to obtaining the views of Dr Watt in respect of all of the complaints but it makes no sense that the approval must be obtained from the clinician who is the subject of the complaint. While natural justice would ensure that this clinician would be fully informed of the complaint and given an opportunity to respond, that response should not be determinative.

INI 130:

- 2.268 The complainant wrote to the Medical Director of the Belfast Trust, Dr Tony Stevens on 26th May 2014. The complaint was raised following a lack of response from Dr Watt and the gist of the complaint focused on the attitude of Dr Watt, delays in treatment and his alleged failure to give the complainant a diagnosis and advice regarding the use of Benzodiazepine. A further letter of complaint was written to the subsequent Medical Director, Dr Cathy Jack, on 10th September 2014, which related to the outstanding assessment of an alleged abnormal brain SPECT scan of 6th November 2013. The patient was concerned that her medical history of 27 years long term Benzodiazepine use had not been linked to the abnormal result in the brain scan. The patient stated:

No neurologist to date – has ever made any contact with my Benzodiazepine expert on my behalf at any time, or evidently, even looked into the extreme relevance of this Benzodiazepine subject. Clearly all relevant evidence and information has quite simply just been dismissed and ignored.

- 2.269 The complaints in total stretched to 11 pages of closely typed script, which raised a wide variety of concerns and allegations.
- 2.270 As with the previous complaint, Ms Lundy suggested that a meeting with the patient might be a better way forward. In this instance, however, the patient felt sufficiently unwell so as not to be able to attend a meeting. It is noted that the Medical Director, Dr Jack, encouraged resolution in October 2014 when she emailed Mrs Owens, Dr Fullerton (the then Associate Medical Director) and Dr Craig, the Clinical Director. On 7th October 2014, Ms Lundy, the Assistant Service Manager in Neurosciences, telephoned the complainant and, over three phone calls lasting nearly 2 hours on that day, sought to understand the complainant's main concerns.
- 2.271 Dr Craig met with Dr Watt in order to put in place a plan to respond to the complainant's concerns. Ms Lundy completed a timeline of appointments, investigations and admissions to hospital. Dr Watt was tasked to write a covering letter to the timeline. It is noted that on 8th October 2014, Dr Craig stated:

My biggest difficulty in trying to help deal with this woman's concerns is that I do not think that a neurologist should be giving an opinion on the chronic effects of benzodiazepine use and the effects of their withdrawal. In doing so they expose themselves and the Trust to unnecessary risks. Neither of these issues would be considered 'neurological' and I suspect that most practising neurologists would agree with this opinion. This is not to say that there are not facets of this woman's symptomatology that require consideration from a neurological perspective. I feel that Dr Watt should focus on these.

- 2.272 A draft response was first drawn up on 30th October 2014. This was revised in November 2014 and forwarded to the complainant on 25th November 2014. At the core of the complainant's concern was that her symptoms were related to the use of Benzodiazepines. It was noted that Dr Watt had spoken to Dr Lynch regarding the abnormalities in the SPECT scan. A further PET scan was carried out on 27th October 2014, which was entirely normal. The Trust also offered in this correspondence a second opinion with one of the leading neurology centres in England and offered to safely transfer the patient to the identified hospital with one other person.
- 2.273 The complainant responded on 20th January 2015. This letter consisted of 22 closely typed pages. Following a phone call on 27th March 2015, Ms Lundy suggested a meeting, which would include Dr Watt and Ms Lundy as well as members of the complainant's family. Ms Lundy asked the complainant if she would reconsider referral to England for a second opinion. This was declined because of the complainant's condition. A further letter was written by the complainant on 30th April 2015 to the Chief Executive of the Belfast Trust. The opening paragraph presents a useful summary of the essential complaint and concern:

This very serious matter of functional, metabolic and biochemical damage and deterioration, is still outstanding. To date my neurologist has failed to get any help or properly address my benzodiazepine condition, knowing that I suffer daily and increasing neurological functional brain damage. All due to, the addictive nature and physiological dependence, symptoms and effects, of long-term benzodiazepines; as verified in my abnormal SPECT scan and previously repeatedly recorded with my neurologists by my GP and particularly since 2008, by 2 world recognised benzodiazepine experts. Both experts repeatedly offered to speak and even meet with my neurologists and I also offered to come to RVH. My neurologists declined all offers of help.

To reiterate; it is most alarming, that for over 6 years, particularly since my completely paralysing seizure with extreme autonomic dysfunction etc, that a systematic cycle of serious and obvious neurological damage from the exact injury site – has been completely dismissed. Especially when since 2008, having the post benzodiazepine diagnosis and concerned input, of 2 world recognised benzodiazepine experts and then since 6th November 2013, also having a recognised functionally abnormal brain SPECT scan, identifying the damaging effects of long-term benzodiazepines.

- 2.274 There then followed a long sequence of internal emails, where efforts were made to try and set up a meeting with the complainant. A letter from the Complaints Manager on 3rd June 2016 apologised for the delay, but the problem of obtaining availability for Dr Watt to attend such a meeting proved to be challenging. At a meeting with Dr

Craig and Mr Young on 30th August 2016, it was noted that there was an outstanding request for Dr Watt to attend a meeting to discuss the ongoing complaint from the complainant. Although there had been a number of dates suggested by Dr Watt in March/April 2016, which had not proved to be possible for the complainant, numerous other requests by the Service Manager and the Complaints Department had not been addressed

- 2.275 Following the meeting on 30th August 2016, it was noted that Dr Watt was due to see the complainant at the Ulster Independent Clinic ("UIC") the following Wednesday and it was hoped that this would bring some degree of closure.
- 2.276 On 26th September 2016, Dr Watt informed the Service Manager, Mr Atkinson, who was following up on the outstanding issues involving Dr Watt that the complainant had undergone a blood patch procedure.
- 2.277 Despite the procedure, requests to arrange a meeting continued to no avail.
- 2.278 On 10th December 2016, the complainant wrote to Dr Watt following the blood patch procedure. The correspondence from the complainant indicated that the blood patch procedure had not resulted in any improvement and the correspondence focused on the ongoing problems the complainant believed had been caused by Benzodiazepine dependence. This correspondence then resulted in further intensive emails between Ms Lundy and Dr Watt. By way of example, on 20th December 2016, Ms Lundy wrote to the complainant stating:

I strongly believe that the best way of trying to resolve your ongoing concerns would be to have a meeting with you and Dr Watt. This would be facilitated by a member of the Complaints Department. Notes and action points would be produced. I understand that this has been difficult for you in the past when we have arranged meetings that unfortunately you were unable to attend ...

- 2.279 Unfortunately, despite efforts to convene the meeting, this did not occur. Further detailed correspondence was then forwarded by the complainant to the Chief Executive of the Belfast Trust, Martin Dillon on 22nd July 2017. This had been preceded by a detailed letter to Dr Watt of 24th June 2017.
- 2.280 On 28th July 2017, Ms Lundy summarised the ongoing management difficulties:

This is a longstanding complaint which goes back a few years. It has been very difficult to manage. I have started to gather information in relation to the difficulties experienced by many consultants and registrars when managing this lady's symptoms and admissions. Several meetings and consultations were arranged but cancelled by [INI 130]. There is a very long list of admission and

OPD DNAs and cancellations. [INI 130] has declined the offer of a referral to London for a 'second' opinion.

- 2.281 Various drafts were considered, in terms of the response to the complainant's letter to the Chief Executive. Eventually, the letter was approved by Mrs Owens, Director of Acute & Unscheduled Care, on 12th October 2017. In the concluding paragraphs of the correspondence, Mrs Owens stated:

... At this point, the Trust believes that all reasonable measures have been taken to offer you the care and support that you require. I appreciate that you have been unable to avail of some of the meetings or consultations which had been arranged for you due to your ongoing poor ill health. As previously stated, the Trust will continue to provide you with ongoing care and treatment as per your clinical requirements however; the Trust would now consider that local resolution into your complaint is now complete ...

- 2.282 In response to the correspondence, the complainant telephoned the Complaints Department indicating that she had wanted her SPECT scan reviewed as soon as possible. It was decided to arrange for an external review of the SPECT scan. In answer, the complainant, in her correspondence of 2nd April 2018, asked a number of questions, which are set out below:

1. I should be grateful if you please provide me with a copy of the proposed terms of reference for the review.
2. Can you confirm who will carry out the review and where they are from?
3. Will you confirm what kind of review this will be – a paper review alone or will the person undertaking the review be questioning staff. If so, will I also have the chance to speak to the person carrying out the review?
4. Why have I not been contacted about the adverse effects caused by Dr Watt's epidural blood patch September 2016, or about the talk with Dr Peukert in March 2017?
5. Who is the senior manager for Neurology services?

- 2.283 Following a further letter of reminder, Ms Lundy emailed Mrs Owens to say that the terms of reference had been drafted; that the images would be sent to the independent reviewer on that day (3rd May 2018) and that turnaround time was approximately 7-10 days.

- 2.284 Before a meeting could be arranged with the complainant to discuss the independent review, an email was received from the Litigation Management Office on 12th June 2018 indicating that allegations of clinical negligence were to be raised against

the Belfast Trust. Ordinarily, this would have closed the complaint because legal proceedings were pending. A letter, however, dealing with the review carried out by Dr Kevin Bradley was forwarded by Mrs Owens on 29th June 2018. The complainant also wished to know why she had not been included in the neurology recall and, by letter of 1st August 2018, Mrs Owens explained that as she had been discharged from the care of Dr Watt, she had not been included.

- 2.285 INI 130 gave evidence to the Inquiry Panel on 1st February 2019. It became increasingly apparent that this was a complex case in which genuine and substantive efforts had been made by the Trust to investigate the clinical issues. The Inquiry recognises that there are some complaints, which are so complex that they become almost impossible to manage within the complaints system. The present system is designed for resolution within 20 days. Where there are clinical issues of substance, however, days can stretch into months and sometimes years. Discerning at an early stage that a complaint should be handled differently or, in some cases, cannot be addressed fully because of resource issues, should also be a priority.

INI 435:

- 2.286 INI 435 attended an appointment with Dr Watt on 12th September 2013, who diagnosed her as suffering from Moyamoya Disease. It was believed that the patient might benefit from re-vascularisation surgery, and it was arranged for the patient to see a specialist in Addenbrooke's Hospital in England. There was a delay in funding because paperwork was not properly processed by Dr Watt. Approval was eventually given in January 2014.
- 2.287 On 17th September 2014, the patient wrote to Dr Watt. It was clear that part of the complaint related to her treatment in England. In respect of the delay caused by failure to properly process the forms for an extra contractual referral, Mrs Owens wrote on 22nd October 2014 to the complainant and apologised for the administrative mistake highlighting that *"unfortunately, the paperwork regarding the funding was not processed at the time and these omissions were not realised until January 2014"*. The referral to Addenbrooke's was followed by a consultation with Dr Watt on 2nd October 2014 and this provoked a further complaint dated 10th October 2014. In an email INI 435 stated:

... It was a very strange meeting. I had brought a list of questions to be answered regarding my condition and possible treatment. Dr Watt was unable to answer any questions on Moyamoya disease and at one stage, told me to look it up on the internet. I asked if he would be able to put me in touch with other Moyamoya

sufferers that had been through his office. There was a Japanese violinist, but he didn't know how to contact her. He suggested I log into a Japanese support group. I found his flippant attitude extremely disappointing. I left his office wishing I hadn't bothered attending. He was unhelpful and uninformative. I had to ask if I would be monitored. He will see me in a year, keep taking the aspirin and try not to get diabetes, high blood pressure or high cholesterol. Lose weight and keep fit ...

- 2.288 Dr Watt was asked on 4th November 2014 as to his commentary on the complaint. Dr Watt made a number of amendments to the proposed letter and the template that had been provided to Dr Watt, which then formed the basis of the formal response from the Trust on 20th November 2014. The letter stated:

... In your email, you have mentioned that Dr Watt was unable to answer any of your questions on Moyamoya disease and have described him as "unhelpful and uninformative". Dr Watt has commented that he had tried to answer your questions to the best of his ability, and that he felt he had given you time to raise any issues which you wanted to discuss with him. However, I extend sincere apologies that you were disappointed with the consultation and did not feel that your questions were adequately answered. Dr Watt has suggested a referral for a second opinion to another neurologist with a particular sub-specialty interest in vascular disease, such as Dr McCarron, Consultant Neurologist at Altnagelvin Area Hospital. I appreciate that this may be a longer journey than you would wish to travel, however if you feel this is a good idea, we can most certainly make arrangements for this ...

- 2.289 It is noted that when the complainant met with Dr McCarron, Consultant Neurologist employed by the Western Health & Social Care Trust, she called the Trust to advise that he had addressed her outstanding concerns.
- 2.290 Aspects of this complaint were clearly handled well. In particular, the Inquiry Panel noted that it was Dr Watt who suggested a second opinion and, as one would expect, on many occasions when a second opinion is obtained, a patient can be reassured.

INI 284:

- 2.291 On 29th December 2014, a friend of the patient wrote to the Belfast Trust. The letter was initially addressed to the patient's MP, Dr Alasdair McDonnell, and reached the Complaints Department on 29th January 2015. The letter of complaint was generic in nature and referred to concerns that the patient had not had successful treatment following a serious back injury at work and subsequent internal problems. The response to the complaint proved to be of much greater interest. The normal template

response was adopted; namely an initial apology, followed by a detailed review of the medical treatment received and a further apology. The Inquiry Panel noted the detail that was eventually formally included in a letter to the complainant, who had written to the Trust on behalf of the patient. The letter set out in some detail the treatment received and this is included below because of its broader relevance:

Our records indicate that [INI 284] was referred to Dr Michael Watt, Consultant Neurologist by Mr Gibson, Specialist Orthopaedic Registrar and was seen by Dr Watt on the 7th November 2012, where he performed an epidural blood patch on her. He then saw her again on the 14th November 2012, where he noted that the epidural blood patch was unfortunately unsuccessful in treating [INI 284's] on-going headaches and dizziness. Dr Watt then repeated the epidural blood patch treatment on the 11th December 2012 and noted there was still no improvement when he next saw her on the 18th December 2012.

... I understand that [INI 284] was then seen by Dr Seamus Kearney, Consultant Neurologist at Belfast City Hospital on the 13th May 2013. She had been referred to Dr Kearney by Mr Cooke, Consultant Orthopaedic Spinal Surgeon. At this appointment, Dr Kearney noted there were no objective abnormal neurological findings, therefore he arranged for [INI 284] to undergo MRI (magnetic resonance imaging) scanning of the head, which took place on the 20th June 2013. [INI 284] was then reviewed by Dr Kearney again on the 29th July 2013. Dr Kearney notes that MRI scanning showed no evidence of intracranial hypotension and arranged for [INI 284] to undergo a further MRI scan of the spine, which took place on the 21st August 2013. This showed no evidence of cerebrospinal fluid leak however did show degenerative changes and evidence of her previous spinal surgery.

Dr Kearney thought it was unlikely that [INI 284] was suffering from idiopathic intracranial hypotension, however referred [INI 284] to undergo a lumbar puncture. This took place on the 17th October 2013. [INI 284] was subsequently reviewed again by Dr Kearney on the 21st October 2013. He noted there was no evidence of intracranial hypotension or chronic infection to explain [INI 284's] ongoing symptoms. Dr Kearney noted he felt [INI 284] was possibly suffering from chronic migraine, as well as analgesic overuse headache. He also felt she had some symptoms suggestive of functional neurological symptoms and provided her with information with these. Dr Kearney planned to review [INI 284] again in 3 months' time. Dr Kearney subsequently referred [INI 284] to Dr Raeburn Forbes, Consultant Neurologist at Craigavon Area Hospital for a second opinion.

[INI 284] was subsequently reviewed at Dr Watt's outpatient clinic on the 4th March 2014. She was seen by Dr Watt and Dr Campbell, Specialist Registrar. Dr Campbell notes [INI 284's] neurological examination was entirely normal. However, he referred her to undergo a CT (computerised tomography)

venogram to exclude venus sinus thrombosis, though he felt it was unlikely this was the cause of her symptoms. This CT venogram was performed on the 3rd April 2014. [INI 284] then underwent a CT head scan on the 23rd April as well as a further MRI head scan and an MRV (magnetic resonance venography) cerebral veins scan on the 9th May 2014. She was then reviewed by Dr Watt again on the 24th June 2014, who noted that the CT venogram and the MRV showed evidence of chronic partly recanalised thrombus and thus suggested starting a course of Apixiban ...

- 2.292 This complaint raised a difference between the diagnoses of both Dr Watt and Dr Kearney. Efforts were made by the Inquiry to see whether Dr Kearney had been specifically approached, but the Trust, through its solicitor, responded that the management intern, Pearse Gibson, had checked his email and none were found to be communicating with a clinician. Mr Atkinson believed that the information would have been sourced from records held on the Northern Ireland Electronic Care Record.
- 2.293 The lack of evidence within the results from multiple tests performed by Dr Kearney is notable and has been documented clearly in the response. INI 284 is not just a case of alleged misdiagnosis, but the lack of objective evidence to support Dr Watt's diagnosis is laid out for all to see and does not appear to have been picked up on.
- 2.294 This complaint was also raised with Ms Lundy when she gave evidence to the Inquiry Panel on the second occasion on 25th May 2021. There does not seem to have been a means by which the person investigating the complaint, who has, correctly recorded the difference in diagnoses between Dr Watt and Dr Kearney, has highlighted the discrepancy to the Clinical Director or other clinicians. In this instance, it would have been both necessary and appropriate for the person investigating to seek the comments of Dr Kearney, both in relation to the number of blood patches that had apparently not worked, when carried out by Dr Watt, and to the record of Dr Kearney, where, in his view, he did not think the patient was suffering from spontaneous intracranial hypotension. Further, the complaint was not contained in the Medical Director's Office file, or on the updated Datix record in 2018.
- 2.295 The problem emerges that highly relevant evidence regarding blood-patching was uncovered and passed over without being remarked upon or evaluated. This is commented on in further detail in the Blood Patching chapter. This complaint was also being considered at an important time when, shortly thereafter, other issues came to light in respect of Dr Watt's practice and these matters are commented upon in more detail in the 2016 Missed Opportunity chapter.

INI 436:

2.296 In this instance, a Welfare Co-ordinator acting on behalf of the patient contacted the Complaints Department on 2nd February 2015. The letter of complaint had an initial paragraph, which, given the response in the previous complaint, should have raised concern. The letter stated:

... [INI 436] was referred to Neurology at the Royal Victoria Hospital where he was diagnosed as having orthostatic tremor due to spontaneous intracranial hypotension. His Consultant at the Royal Victoria Hospital, Dr Michael Watt, tried blood patches on 4 occasions (1 private and 4 through the NHS) to try and rectify the matter but to no avail ...

2.297 The Welfare Advice Co-ordinator went on to state in the letter:

... [INI 436's] complaint is 2 fold.

- (1) He feels that he should have been scheduled for an MRI and photo imaging at the outset of his treatment to allow his consultant to see exactly where the leak was, so that treatment could be concentrated in that area ...
- (2) He wishes to complain about the cancellation of his appointment on the 26th January 2015 as he urgently needs the MRI and treatment.

2.298 While the other aspect of the complaint was about the cancellation of the patient's appointment on 26th January 2015, the significant clinical question, which is similar to the previous complaint, is that a patient, who does not appear to have had an MRI scan, has undergone 4 or 5 blood patches without success. The focus of the investigation was on trying to deal with the question of the MRI scan being apparently cancelled. It transpired that the appointment for the MRI may well have only been a review appointment.

2.299 A further letter from Dr Watt to the patient's GP dated 2nd February 2015 is also of interest. Commenting on the blood patches, Dr Watt stated to a GP:

Each of the 4 lumbar epidural blood patches worked for only a few hours. He is having an MRI of brain and spine at the end of February and if this doesn't show anything particularly remarkable, we will then go ahead with a dynamic CT myelogram along with an image guided epidural blood patch if we can identify a leak and I will see him again once this has been done.

2.300 A formal response signed by Mrs Owens was issued on 11th March 2015. This response focused entirely on issues pertaining to the MRI scan and did not address, or refer to, epidural blood patch procedures.

- 2.301 This complaint had numerous clinical queries, which have not been picked up on by the Neurosciences Service Department. The fact that blood patches appear to have been carried out on numerous occasions with a question mark as to whether there was objective evidence to justify the diagnosis, could have raised a clinical red flag. The management intern, who was collating much of the information, was both proactive and assiduous in his approach. In the absence, however, of independent or other neurological input from a consultant, it is unlikely that the clinical issues that are now apparent, were going to be spotted. The focus, understandably, was on the immediate concern of a patient, whether that be a cancelled appointment or ongoing personal distress. This complaint is an example of a complaints system, which is not set up to discover potentially significant clinical issues.
- 2.302 The complaint was also lodged just as the incidence of blood patch procedures was increasing dramatically and was the subject of complaint from nursing staff because of the facilities and space required on the neurology ward. This is commented upon further in the Blood Patching chapter.

INI 437:

- 2.303 INI 437's complaint was received by the Trust on 30th March 2015. This complaint related to the difficulties in obtaining a response from Dr Watt when the complainant's condition deteriorated. The complainant had been attending Dr Watt since October 2014 and was informed that he should ring Dr Watt if his condition deteriorated. He subsequently felt worse, rang Dr Watt on 12th March 2015, wrote to him on 19th March and rang his secretary on 26th March to be informed that Dr Watt was not responsible for the TIA clinic.
- 2.304 This complaint was forwarded to Neurosciences on 5th May 2015 and Ms Lundy promptly forwarded it to Dr Watt and indicated that *"[INI 437] has requested the possibility of another consultant to review his case. What are your thoughts about this?"* Dr Craig emailed Dr Watt the following day and asked him to *"put something brief down and get it out ASAP to prevent this escalating"*.
- 2.305 On 6th May 2015, Ms Lundy asked Dr Craig which consultant neurologist this matter should be referred to. Dr Craig was clear that *"if TIA, patient should be referred to stroke service and not neurology"*. It appears from email correspondence that Ms Lundy successfully arranged a subsequent appointment with which INI 437 was "very happy".

- 2.306 The concern of the Inquiry Panel was that this complaint was not attributed anywhere to Dr Watt and was disclosed only after Dr Craig gave oral evidence about the complaint, which led, in turn, to a request by the Inquiry to the Trust. The answer to the complaint may well be correct, but there was an apparent breakdown in communication between patient and doctor and little attempt seems to have been made to rectify same.
- 2.307 This is one example of a complaint, which was ‘locally resolved’ with no formal response being issued. The complaint would have been logged and closed which raises a question about the efficacy of a governance system that has struggled to collate an accurate record of relevant complaints, including during the lifespan of this Inquiry.

INI 438:

- 2.308 INI 438 saw Dr Watt and was apparently informed that he would receive a further appointment within three months. In anticipation of this, the patient booked a private MRI scan so that this would be available for the next review. Subsequently, the complainant stated that he never received an appointment and was told by Dr Watt that he was booked up until the end of October 2015. A complaint was subsequently lodged with the Trust on 15th September 2015.
- 2.309 When the complaint was referred to the Neurosciences Service Department, the Service Manager tried to bring the appointment forward, but was informed by Dr Watt’s Secretary that all of Dr Watt’s clinics were overbooked. In her oral evidence to the Inquiry Panel, Ms Lundy indicated there was a clinic template for the number of patients to be seen and that whereas consultants may overbook to a certain extent, persistent overbooking should lead to a flag being raised.
- 2.310 While this complaint was resolved by the provision of an earlier appointment, the information that Dr Watt’s clinics were all significantly overbooked should have caused questions to be asked. This matter was again ‘locally resolved’ and no formal response issued, nor does there appear to have been any attempt to address the issues with regards to the numbers at Dr Watt’s clinics. This complaint did feature in the updated 2018 Datix record.

INI 441:

- 2.311 On 11th March 2015, INI 441 wrote to the Trust regarding an alleged failure to provide medical care. INI 441’s complaint consisted of three elements. Two

elements, which are outside the Inquiry's Terms of Reference, involved confusion about medical records and the obtaining of an MRI scan and the other part of the complaint concerned an incident on 21st December 2014 when the patient went into anaphylactic shock. The Inquiry was concerned with the neurological aspects of the complaint which stated as follows:

Roughly 14 years ago I had a stroke and was referred to Doctor Watt who also diagnosed me with epilepsy. The side effects of the treatment for the epilepsy made me very unstable and I came off all tablet [sic] in fear of what I would do to myself. I always told Dr Watt that I did not agree with his diagnoses and as a result he refused to ever see or treat me again. I now have letter from another doctor from the Royal stating that in his medical opinion I do not and have not ever had epilepsy.

- 2.312 An initial response which was sent to Mrs Owens, in an email of 21st May 2015, omitted any reference to the neurology component of the complaint, instead being based solely on a response from Immunology. This matter was flagged by Mrs Owens and returned to Neurosciences for their comments. The matter was then considered by a management intern, Pearce Gibson. In an email of 27th May 2015, he asked Mr Atkinson, Service Manager, and Ms Lundy, Assistant Service Manager:

Can I confirm that the only issue based in this complaint for neurology is the epilepsy diagnosis? I had asked Dr Watt to provide comment on this on the 25/03/2015 but his sec weren't able to get the notes from ICU until 14th April. I called up a few weeks later to get them as I thought we had to respond to the issues regarding the wrong address etc but wasn't able to find anything in the notes.

- 2.313 Later the same day, Ms Lundy commented:

Bernie is right about the letter. It does not address the concerns raised by this lady. The neuro aspect of this complaint is highlighted and requires a response. Pearce and myself will do this. When you break this complaint down, basically, the patient requires the following:

- MRI scan
- Neurology appt.
- Immunology appt.
- Apology regarding admin confusion with addresses (not sure how this happened) and also apology regarding wait for MRI scan.
- A basic plan of care for this patient.

ACTIONS:

- I phoned this lady this evening and advised of the immunology appt. and will organise the MRI and neurology appt (with Dr Kearney).
- I have given the lady my contact details and advised that I will phone her, at the latest next Tuesday (if not before this).

I am hopeful, that when all is sorted, this complaint will be resolved without the need for a long letter.

- 2.314 By 4th June, Ms Lundy was able to email the Complaints Department indicating that she had spoken to the patient and that the patient did not require a response because *"I have addressed all her concerns and the appropriate actions have been taken"*. These included the various steps identified by Ms Lundy in her earlier email of 27th May, with INI 441 being given an appointment for an MRI and, subsequently, an appointment with a consultant neurologist.
- 2.315 There was extensive evidence, both from her oral testimony to the Inquiry and the documents that were disclosed, which highlighted the fact that Ms Lundy took a proactive and pragmatic approach to complaints. She would often contact a patient who had lodged a complaint as soon as she received details from the Complaints Department. She looked for ways to resolve matters quickly and was often successful. Such an approach is to be commended, but when the focus is on obtaining hospital appointments and breaking through administrative impediments, sometimes clinical questions can get missed.
- 2.316 Unfortunately, that is what happened in this case. Dr Watt should have been spoken to. If the notes weren't available, as suggested by Pearce Gibson, they should have been obtained. The clinical questions in relation to the epilepsy diagnosis needed to be addressed and Dr Kearney, who had indicated to the patient that the complainant never had epilepsy, should have been spoken to. The Inquiry takes no view as to what would have happened as a result of the complaint about diagnosis, but the matter required to be investigated and, if necessary, by an independent consultant, if there was a continuing dispute between the neurologists and there was a clear pattern emerging.
- 2.317 Once again, this complaint evidences the fact that the focus within Complaints and the relevant Service Department was to resolve and address concerns raised. If a complainant does not further complain or indicate that a question has not been answered to his/her satisfaction, then there is no opportunity for learning to occur. Further, the method utilised inevitably fails to analyse the possibility of a pattern

of aberrant practice because there is little or no focus on the clinical questions that were being raised, save for a desire to get another consultant to see the patient or obtain tests that are outstanding.

- 2.318 The difficulties in trying to address clinical questions was the subject of detailed questioning by the Inquiry Panel. This is commented upon in the Conclusion section, but despite sincere efforts by people within the Neurosciences Service Department, the Inquiry Panel was not at all convinced that the clinical aspect of complaints was properly addressed in a manner, which would give real insight into the practice of a consultant. Ms Lundy gave evidence, for the second time, on 25th May 2021 and the following interaction took place with the Inquiry Chairman:

Mr Lockhart QC: Surely the decision about whether this was a misdiagnosis needs to be properly looked at, talk to Dr Watt, get the notes, potentially talk to another doctor and to say, 'was this reasonable?' It may well be that's right, and we all know that from looking at this ad nauseam for the last few years is there can be differing diagnoses, but that has to be a decision a neurologist would surely have to take?

Ms Lundy: Absolutely, and the patient was referred to see, I think it was Seamus Kearney saw the patient then.

Mr Lockhart QC: But the question hasn't been answered. Her question is *inter alia* or amongst other things, 'I was misdiagnosed with epilepsy'. Surely that has to be dealt with, that has to be considered?

Ms Lundy: Absolutely. Looking back now if this was a case that came in now, a complaint that came in now, then I would be doing the clinical record review, and I would be making sure the patient would see the consultant, and then I would be writing and explaining to the patient, or I would be inviting the patient up to meet to go through, but at this stage again this is whenever pseudomonas was around and I would say that I had fully intended to go back on this.

Mr Lockhart QC: The significance of it, to some extent, is when in 2016 they were considering -- and we are going to come into this as well -- what restrictions to impose, the only restriction was placed on blood patching. But if they had said to you, 'have there ever been any questions about diagnosis regarding epilepsy', you might have been able to say, 'I do remember a complaint and we will get that one looked as well'. It's not as if there isn't a possible consequence if you don't actually join the dots at the time, that's what I am saying, Clare.

Ms Lundy: Whenever the complaint comes to the Complaints Department they are supposed to log it in that way and it is supposed to be connected to a particular consultant with a particular issue. Obviously the system in this

case let us down in that it didn't actually link the consultant with the actual complaint itself.

Mr Lockhart QC: The system let you down at Complaints Department level because it wasn't logged. But then when it got to Neurology Service Department, the question wasn't answered. The question identified by Pearse is never answered. He is saying this is a question of an epilepsy diagnosis, and Bernie Owens is saying there's Neurology concerns here, and the answer is, 'let's get various appointments'. You have to answer the question surely was there -- there may well not have been for the very reason you are saying, but, 'let's talk to Dr Watt, let's get the records, let's look at somebody else's and ask them the question was it reasonable for Dr Watt to diagnose this patient with epilepsy in the absence of', and it may well have been fine.

Ms Lundy: In the same way you would expect if there was a patient going to see a consultant for another opinion, knowing that they had already seen somebody else that you would expect them to come back to you as well if there was an issue with a diagnosis.

INI 451:

- 2.319 On 12th March 2015, the husband of INI 451 wrote to the Trust Complaints Department regarding the waiting time at Dr Watt's clinic. In a draft response prepared by the Complaints Manager, the following is stated:

Our records confirm that your wife had an appointment with Dr Watt at his clinic on the 3rd March 2015 at 2.30pm. However in your e-mail you noted this was delayed by a further two hours. Unfortunately, due to the high volume of patients that attend Dr Watt's clinic, there can often be delays and I am sorry that your wife's appointment time had such a significant lapse. I can completely understand both of your frustrations with this lengthy wait and I am sorry that you and your wife have been inconvenienced by this delay.

- 2.320 Of interest to the Inquiry Panel was the perennial problem of overbooking at Dr Watt's clinic, which appears to have re-emerged. On this occasion, there is no question of reviewing the template. The draft letter of response is apologetic, but simply hopes that the next experience will be better. There is no evidence that the situation was being adequately managed or addressed.

INI 452:

- 2.321 On 1st October 2015, INI 452 telephoned the Complaints Department because he had had to wait for over 2 hours to see Dr Watt. The letter of response from Mrs

Owens of 9th March 2016 stated:

Regrettably, the Outpatient Clinic you attended is particularly busy due to the high volume of requests for appointments. Dr Watt regularly overbooks his clinics in order to provide patients with a more timely appointment and reduce the length of time they remain on the waiting list. Unfortunately, this can lead to delays at the clinic and patients often have to wait beyond their scheduled appointment time and on behalf of the Belfast Trust I apologise for this.

- 2.322 The fact that there was a further complaint about waiting times is unsurprising¹³. What was of interest to the Inquiry Panel in this letter is that the regular overbooking of clinics by Dr Watt was justified by the Trust on the basis that it reduced the waiting list. In one sense, that is understandable. Waiting lists in neurology have been problematic. Managers seeking to ensure that patients are seen, will anxiously attempt to do all that can be done to reduce the waiting list for patients. Unfortunately, however, there is a template for a reason and as Dr Watt's clinics were well outside the template guidance, then that is also an issue which needed to be considered and reflected upon. There is some evidence that this may have occurred at some point in 2007, but by 2015 there appears to be no question of reviewing the template. The difficulty is that this is not an issue that can be overlooked. If doctors' see too many patients in a fixed period of time, then axiomatically there is a greater likelihood of error.

INI 371:

- 2.323 On 10th February 2016, a further complaint was received regarding the failure by Dr Watt to complete insurance forms on behalf of INI 371. A request was sent on 1st October 2015 and followed up every 2 weeks. On 9th February 2016, the Complaints Department emailed INI 371 and stated:

I must also advise you that as completion of these forms are not part of their NHS contracts we are unable to log as a formal complaint.

- 2.324 The husband of INI 371 responded:

If completion of these forms is not part of the consultant's contracts, then can you tell me how we are supposed to get the information as all of the tests etc were done in the RVH under the NHS?

¹³ The problem of overbooking was a problem throughout Dr Watt's career. It was noted by the Inquiry that on 9th February 1999, reference 18.99G related to a patient, who was complaining about the failure by Dr Watt to provide a medical report and 00.O123 dated 5th April 2000 was a complaint about the waiting time at one of Dr Watt's clinics. Under the section entitled 'outcome' the legacy Datix system has recorded "Dr Watt always has overbooked clinics. If he had a no overbooking policy, it could delay serious diagnoses".

- 2.325 The forms were eventually provided in March 2016, but the point made in this case by the patient's husband was both obvious and compelling. The consultants who gave evidence to the Inquiry Panel all recognised that this was an obligation which should be fulfilled. The GMC certainly regarded it as part of a doctor's obligation. The GMC had already given Dr Watt a 5-year warning, which had expired in 2012, for not completing a report. At the very least, the Trust should have forwarded such complaints to the GMC if they were powerless to do anything more than try to persuade and cajole Dr Watt.
- 2.326 The Inquiry Panel noted that at this time, Dr Watt had been referred to the DDCRM and issues regarding Dr Watt's failure to respond within a reasonable time frame to requests from the Coroner and complete appraisals were escalated to the Medical Director's Office. As this case was resolved locally, with no formal response being issued, it could not be discussed at DDCRM or escalated to the Medical Director's Office as part of a pattern of delays in administration.

INI 439:

- 2.327 On 14th March 2016, an anonymous letter of concern from a fellow inpatient in Ward 4E was lodged regarding the treatment of a male patient on the same ward. The anonymous letter of complaint alleged that the answer given by Dr Watt to a query by the patient was *"insensitive, cruel, unethical, spiteful and totally unprofessional"*. It was alleged that Dr Watt had stated in answer to a question as to what happened if his present treatment did not work was *"we'll stick a tube in your stomach and throw you out"*.
- 2.328 When the letter was sent to the Neurosciences Service Department, the Complaints Department indicated that *"we can't investigate this as we have no details of the complainant however this is being passed to you for your information"*. Mr Atkinson wrote to Mr Young to enquire whether the Service Department should be doing anything, given that the letter was anonymous. The response of Mr Young to the complaint was set out in an email of 16th March 2016:
- As there's no name to this complaint it will be impossible to respond so investigating and drafting a response would be a complete waste of time. This should never even have come to us.
- 2.329 The Clinical Director, Dr Craig, asked for advice on what he should do about the complaint as he had taken a view that the content was serious. Dr Fullerton, then Associate Medical Director, referred the matter to Mr Peter Watson in the Medical

Director's Office indicating that it was for the Medical Director's file as it was not a complaint within the ambit of the Department of Health Guidance. Dr Fullerton also, however, suggested, while passing on the anonymous complaint, that Dr Watt should be added to the DDCRM to get a view on what needed to be done, given that Dr Fullerton was due to retire. Mr Watson sought legal advice from the Trust's legal adviser, on the specific issue and the then Medical Director, Dr Jack, emailed Mr Watson when she was informed of the complaint and stated:

Are there other recent complaints about Dr Watt? Should we treat this as a whistle blowing? I have copied to Claire [sic] to consider.

2.330 On 7th April 2016, following liaison with the Trust's legal adviser, Mr Watson emailed Dr Jack and agreed the way forward as follows:

- (1) If [the patient] is an actual patient, we should seek clinical advice (presumably in this context from the [Clinical Director]) in order to inform decision-making as to whether and how he is advised that he has been named in a complaint that has been received.
- (2) Dr Watt is entitled to see the complaint and should be advised that we will conduct preliminary enquiries (including of him and others) to see if there is substance to the concerns which may warrant informal or formal action within MHPS.
- (3) There should be a clear pathway for the management of concerns from anonymous sources – maybe there already is? We do not think it appropriate merely to discard just because we don't know the source; there is even more reason of course to investigate in a context where the alleged victim is apparently identified.

2.331 Mr Watson followed up this initial advice with Ms Gillian Atkinson, the Senior Manager for Data Protection within the Trust, who advised on information governance and who confirmed that the Trust had a duty to investigate anonymous concerns because it was in the public interest to do so.

2.332 As a result of this advice, Dr Craig, the Clinical Director, spoke with the patient. All of the clinical notes were reviewed, and Dr Craig concluded that there did not appear to be any concerns regarding any aspect of the patient's care. Dr Craig followed this up with a conversation with the patient's wife, who believed that they had an excellent relationship with Dr Watt. The approach taken by Dr Craig and the report that he compiled was comprehensive and adequately detailed.

2.333 This case was interesting to the Inquiry for a number of reasons. It demonstrated the difference in attitude between the Neurosciences Service Department and the

Complaints Department, where the anonymity itself was sufficient cause for the matter not to be investigated, and the Medical Director's Office, which took the matter seriously and, it is fair to say, directed that it be investigated thoroughly. The manner in which the Medical Director's Office approached the question of anonymity was appropriate, proportionate and comprehensive. In contrast, the attitude of Mr Atkinson and Mr Young suggested that the purpose of the complaints process, in the view of those who investigated complaints, was to respond to a complainant as opposed to considering whether there was, in fact, a potential problem, which needed to be investigated on the basis that it may raise concerns about a doctor's practice¹⁴.

INI 440:

- 2.334 On 9th May 2016, INI 440, who suffered from Moyamoya Disease, and believed that she had had a stroke, complained that Dr Watt had informed her that there was nothing they could do for her and that she was taking up a bed. Dr Watt was asked to comment on the specific complaint and when he failed to do so in a timely manner, the issue was raised in a meeting with Mr Young and Dr Craig on 9th August 2016. An initial response was given by Dr Watt on 31st August, but he had wished to review the notes. The notes were eventually obtained and reviewed by Dr Watt in October 2016. In an email of 22nd October 2016, Dr Watt stated to Mr Atkinson that he had reviewed the patient's chart and that this confirmed what he initially believed, which is that he had recommended that the patient stay in hospital, but that she insisted on going home. This was directly opposite to the gist of the complaint, which is that Dr Watt had sent the patient home.
- 2.335 The response was eventually provided on 11th January 2017 and the normal template of apology followed by a detailed description of clinical treatment concluding with a further apology. The discrepancy between the patient's complaint and Dr Watt's response was properly included in the letter as follows:

... I am extremely sorry that you also have concerns regarding your care and treatment with the Neurology team. I am sorry that you feel that Dr Watt did not find it necessary for you to remain on the ward. Dr Watt has commented that he recommended that you stay in hospital, but that you wanted to go home because your boyfriend was returning to the United States of America within the next few days. Dr Watt's view was that, apart from improving your blood sugar and blood pressure control, as you were already fully anti-coagulated

¹⁴ In fairness to Mr Atkinson, the matter was only provided to him for information purposes. He did escalate the matter appropriately asking senior management whether there was anything to be done by the Neurosciences Service. This is what ultimately led the matter to be brought to the Medical Director's Office.

with the correct dose of medication, there were no other treatments available while you waited for your surgery in Addenbrooke's at Cambridge. As your condition had improved, he was therefore content for you to go home with advice to return to hospital if you had any further symptoms ...

- 2.336 It is noted that this complaint was not initially provided to the Inquiry and raises again a question as to the effectiveness of the management of the complaints system. The matter only came to the Inquiry's attention because the Service Manager disclosed a note of the meeting between Dr Craig, Mr Young and Dr Watt on 30th August 2016 prior to his evidence to the Inquiry on 22nd January 2019.
- 2.337 The Inquiry Panel also notes that there does not appear to have been any investigation as to why there was a discrepancy between the response of Dr Watt and the complaint made. It appears that Dr Watt's response was treated as decisive, and no further investigation was required.

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- 2.338 This is the second complaint by or on behalf of this patient. The gist of the complaint, which was received on 23rd May 2016, was that the patient had been waiting since February 2016 for Dr Watt to complete an Extra Contractual Referral (ECR) form. This case was also discussed at Dr Watt's meeting with Mr Young and Dr Craig on 30th August 2016. Dr Watt had undertaken, following that meeting, to review his dictated referral letter, when his secretary returned from leave.
- 2.339 This was a further case, which was not initially identified by the Trust and forwarded to the Inquiry. The Inquiry became aware of the complaint following the disclosure by Mr Atkinson of the notes of the meeting of 30th August 2016 between Dr Watt, Dr Craig and Mr Young prior to his evidence to the Inquiry on 22nd January 2019.
- 2.340 A formal response to the complaint was eventually made on 2nd November 2016 and signed by Mrs Owens, the Director of Unscheduled & Acute Care. The response did include a full apology from Dr Watt for the delay and it was disclosed that Dr Watt had completed the ECR form on 8th September 2016. The matter had been referred to Queen Square in London on 19th September.
- 2.341 When the complainant went to London, it transpired that none of her scans had been sent and that the appointment was, in the view of the complainant, "*a waste of time*". The four outstanding reports were then sent to Queen Square in time for the revised appointment on 30th November 2016.

- 2.342 As far as the Complaints Department was concerned, the fact that the referral was made and the subsequent radiological reports, which were delayed, were then furnished, that was the end of the complaint. This was not the view of the complainant, who telephoned the Trust on 18th May 2018. The Complaints Department commented to the Service Department by email of 20th May 2018:

As briefly discussed on Friday, I took a call from the above lady (15:49pm) she stated that she previously spoke to you about the complaint made regarding Dr Watt and that she considers this still open. I had a look on Datix and cannot find an open case. She would like you to call her.

- 2.343 On 22nd May 2018, Mr Atkinson, the Service Manager, was informed that the patient wanted a written response explaining why there was a downfall in communication at the time.
- 2.344 A formal response to the complainant's various telephone calls was issued on 11th December 2018. It is correct to say that Dr Watt had already apologised for the delay, and this had been included in the original response. The outstanding query from the Inquiry Panel, however, was why Dr Watt did not appear to have been challenged about his continual administrative tardiness. If he was being overwhelmed at work, then this would have been an opportunity to address that problem. The difficulty is that such questions did not seem to occur to those who were investigating the complaint.

2007-2016 Consultant Neurologist Complaints:

- 2.345 On 15th April 2019, in response to a written request from the Inquiry, the Belfast Trust provided details of the number of complaints made against each Consultant Neurologist since 2007. The said details are set out in the following tables in respect of the consultant neurologists employed in the Trust at the time of disclosure along with those who were no longer employed by the Trust. The Inquiry has not reviewed the handling of complaints in respect of the other Consultant Neurologists. The Inquiry is mindful that the details were prepared at the request of the Inquiry and understands that such a table did not exist prior to the Inquiry's request.
- 2.346 From other evidence obtained by the Inquiry it became clear that the number of complaints recorded against Dr Watt in the table below was lower than it ought to have been although the Inquiry accepts that this was not an attempt to mislead (the correct figure in respect of Dr Watt's complaints as ascertained by the Inquiry has been added in brackets by the Inquiry). It may also be that there are other complaints

that haven't been accurately recorded against the other consultant neurologists (some of whom also worked in other Trusts) however the general picture of having no more than one or two complaints per year was consistent with their oral evidence. According to the tables, Dr Watt was regularly receiving multiple complaints per year whereas by contrast only one other Consultant Neurologist had more than one complaint in any year since 2007.

Current Consultant Staff	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Michael Watt	12 (14)	1 (2)	0 (1)	4 (1)	0 (3)	0 (2)	3 (6)	3 (6)	1 (6)	3 (6)
Stephen Hunt	0	0	0	0	0	1	1	1	1	1
Gavin McDonnell	0	0	0	0	1	0	0	0	1	2
John Craig	0	0	0	0	1	0	1	0	0	0
Paul McMonagle	0	0	0	0	1	0	0	0	1	0
Ellen Campbell	0	0	0	0	0	0	0	0	0	0
Seamus Kearney	0	0	0	0	0	0	0	0	0	1
Karen Doherty	0	0	0	0	0	0	0	0	0	0
Thomas Peukert	0	0	0	0	0	0	0	0	0	0
John McKinley	0	0	0	0	0	0	0	0	0	0
Aidan Droogan	0	0	0	0	0	0	0	0	0	0
Stella Hughes	0	0	0	0	0	0	0	0	0	0

Former Consultant Staff	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Ailsa Fulton	0	0	0	0	0	0	0	0	1	0
Victor Patterson	0	1	0	0	0	0	0	0	0	0
Jim Morrow	0	0	0	0	0	0	0	0	0	0
Stanley Hawkins	0	0	0	0	0	0	0	0	0	0
Tom Esmonde	0	0	0	0	0	0	0	0	0	0
Mark Gibson	0	0	0	0	0	0	0	0	0	0

Conclusions and Findings:

- 2.347 While the Belfast Trust has in more recent years augmented the Departmental Guidance and sought to address the problem of identifying the potential significance of a clinical complaint, the Inquiry Panel is not satisfied that there was, prior to 2016, sufficient understanding within neurosciences of what was trying to be achieved. Dr Craig's description of the exercise as, in his words, "*a sense check*" may have been a misdescription of what was expected, but the Inquiry Panel saw no evidence that the review by Clinical Directors was discussed, explained or that adequate training on the Guidance had been given. Ultimately, medical notes and records were not reviewed when a complaint response was forwarded to the Clinical Director and the checks made were superficial and could not be described as a proper review.
- 2.348 The evidence regarding the number of complaints in respect of each Consultant Neurologist set out at paragraph 347 makes clear that Dr Watt was an outlier. Notwithstanding that the information was prepared to assist the Inquiry and was not as accurate as it could have been, it illustrates the general picture that anyone dealing with complaints in neurology should have observed. Whilst Dr Watt being an outlier in respect of complaints would not in itself indicate aberrant practice it ought to have led to greater curiosity and further investigation to understand if there was a pattern of clinical complaints and reason for concern.
- 2.349 Dr Craig in his evidence and having viewed the relevant documentation concluded:
- Whenever I look back on that, there is no doubt that there were more than clues in those complaints. The very themes that are often raised were similar to the themes actually that Dr Colin Fitzpatrick [Discussed in detail in the Chapter on November 2016 - May 2018] was raising, and which we have seen time and again since.
- 2.350 The Inquiry Panel agrees with Dr Craig and believes that it is difficult to resist the conclusion that, had the information contained within the complaints system been properly and independently analysed by someone with the relevant expertise, a problem could have been identified at a much earlier stage.
- 2.351 The revised guidance in 2019 and the original '*Complaints in Health and Social Care: Standards and Guidelines for Resolution and Learning*', which were promulgated by the Department of Health in Northern Ireland, are both substantial documents of over 100 pages, which have detailed principles and a comprehensive framework. There was, however, a disconnect between the aim of promoting 'safety and quality' and the manner in which complaints were actually investigated and dealt with. To some

extent, the Department's focus on resolution and response times deflected those in Complaints Departments from properly considering patient safety issues. While guidance refers to minimising risk and identifying trends, there is a lack of detail on how this should be done. In a similar vein, while there was clear guidance on monitoring and recording, the systems in the Belfast Trust did not adequately and compendiously ensure that the key persons from a clinical perspective had a proper view in relation to all the relevant information about a doctor. This included when the Medical Director was investigating a concern about a doctor and the complaints relating to a particular doctor could contain extremely valuable information. This was demonstrated in the history of disclosure and by the fact that some complaints were not known about by the Medical Director's Office or, if they were aware of the existence of the complaint, the clinical issues had not been properly highlighted to the Office and noted for future reference. A system must support a Medical Director, who has a responsibility as the Responsible Officer, to be sighted, when necessary, on problems that have been identified elsewhere.

- 2.352 Paragraph 4.2 of the guidance in 2019 requires *"effective processes in place for identifying and minimising risk, identifying trends, improving quality and safety and ensuring lessons are learnt and shared"*. The reality is that the processes in place were almost wholly ineffective prior to November 2016 in identifying trends or ensuring lessons were learned.
- 2.353 Triangulation of data is perhaps an esoteric term, but it is a critical tool in any evaluation of a complaints process. Essentially it allows an investigator to collate all the relevant information to ensure that a decision-maker is fully sighted on the relevant material. There are many examples of where this did not occur such as:
- (i) Mr Peter Walby's summary of issues to the GMC in 2005, which missed any number of the now destroyed complaints and contemporaneous complaints regarding report writing.
 - (ii) Mrs Pauline Webb's summary report to the Medical Director in December 2006 omitted numerous relevant complaints.
 - (iii) In 2012 the Datix print off revealed only 5 complaints, which was used to inform the Trust's response to a GMC query regarding INI 45.
 - (iv) The failure to recognise potentially significant complaints referred to in DDCRM in June 2013.
 - (v) When Dr Ken Fullerton commenced his Finding of the Facts exercise, he was only given 6 complaints by the Neurosciences office.

- (vi) The DDCRM in 2016 was not informed of salient complaints.
- (vii) In 2018 when the Trust eventually asked for and looked for all complaints, a number of significant complaints were discovered for the first time.
- (viii) The absence of significant complaints from the pink file in the Medical Director's Office.
- (ix) The difficulties experienced in ascertaining the true number of relevant complaints as evidenced by the disclosure of 100 potentially relevant complaints over 3 years after the Inquiry commenced.

2.354 The present target of dealing with complaints is weighted towards 'resolution' of the problem within proscribed time limits, as set out in Regulation 14 of the Health & Social Care Complaints Procedure Directions (NI) 2009. The 20 working days for response is something which is measurable, and this has become a focus of review, despite the fact, that it was almost never achieved in relation to clinical complaints. The timeframe for clinical complaints is wholly unrealistic and needs to be changed. It is not surprising that the present emphasis within the Trust is on meeting the target time for a response as opposed to ensuring the quality of the answer given or any learning, which might be derived from the complaints. If staff are measured on response times, and that is the priority set by the Department of Health, then that is what they will concentrate on.

2.355 The storage and retention of complaint data must be an urgent priority for the Belfast Trust. In this regard, while the independent review into the destruction of relevant material in September 2018 was a welcome sign of a serious approach being taken by the Trust, the recommendations advanced by the review do not go far enough. The Inquiry Panel agrees with Dr Michael McBride that clinical complaint material should be retained throughout the career of a doctor to ensure patient safety. In this regard, the Inquiry sought a legal opinion from David Scofield QC (now Mr Justice Scofield) and Alistair Fletcher BL on the retention of complaints material in light of GDPR and other legal requirements. The opinion concluded:

It seems to us that, in principle, this information can be lawfully retained by a responsible officer as it concerns a matter that is intimately related to their role under the Regulations. There is a specific obligation to investigate concerns raised by patients or staff; and to record the details of what steps are taken. Our starting point is that any information raising legitimate concerns about patient safety is entitled to be retained for so long as it may be relevant to the protection of patient safety. In general terms, this is likely to be for so long as the relevant clinician remains in practice and treating patients.

- 2.356 The Inquiry Panel strongly agrees. If patient safety is to be paramount and trends are to be identified, then relevant clinical complaints' material should be retained throughout a doctor's career.
- 2.357 The Inquiry Panel noted the evidence of Mr Frank Young¹⁵ on 22nd April 2021, former Co-Director of the Neurosciences Division in relation to the overall issue of complaints. In his prepared statement, given in response to a number of questions posed in advance by the Inquiry Panel, and received by the Inquiry on 16th April 2021, Mr Young reflected:

The Department of Health and the Health and Social Care Board expect that all complaints verbal or written are responded to within 20 days of receipt. The focus of dealing with complaints was placed on time limits and answering complaints, not on assessing or analysing the content of complaints. Within my division on a daily basis an average of four Assembly or Parliamentary questions were forwarded by Corporate Communications and had to be responded to by close of play that day or within 48 hours ...

Historically each Directorate had its own dedicated complaints personnel but due to retirements, reorganisation and staff shortages, complaints had become centralised, and in doing so organisational memory and knowledge were irretrievably lost. In effect what this meant was that there was no one to see a problematic pattern emerge and pull senior management aside.

... getting responses turned around as soon as possible were seen as an overriding objective and analysis of the reasons a complaint had been made in the first place became secondary. There simply were not the resources to do both well and in hindsight this system was imperfect as it really failed to be timely or analytically useful.

- 2.358 Mr Young in his evidence to the Inquiry Panel on 22nd April 2021, augmented a number of his earlier prepared responses:

... the Service Manager got the patient's notes, looked at what was going on, and we put together a response. I would have reviewed that. Then it was topped and tailed by the Complaints Department. Then it had gone to the Director. If the Director looked at that and said, 'not happy about this,' or, 'I want more information,' that came back, it was clarified. Then once that was done, it went back to the Director, and then the response went out. We had a response time of 20 days, and for most complaints it's a nonsense ...

We didn't have a robust system around the management of complaints. It was more about turnaround.

¹⁵ Co-Director of Unscheduled & Acute Care.

I can remember speaking with Bernie Owens as the Director and saying, 'this isn't working.' The Complaints Department just ain't fit for purpose and we needed to have our own dedicated complaints manager within Unscheduled Care, because of the number and the complexity. I was told, 'no, it was being organised centrally.' It had been centralised and that was that, because if you appointed a complaints manager that probably would have been at an 8A or an 8B level and somebody was going to have to fund the budget.

- 2.359 While Mr Young was correct in his observation that the Complaints Department was not set up to investigate complaints, but to run a process, the Inquiry Panel does not share his view that a dedicated Complaints Manager within neurosciences would have made any difference. The fundamental problem was that the focus at all times remained on resolving the complaint rather than evaluating the clinical aspect of a complaint or recognising if there was a potential patient safety issue.
- 2.360 It is regrettable that the issues surrounding complaints were not appreciated or grasped by senior management despite the findings of the Lamey report in 2013¹⁶. The Inquiry Panel appreciates that there were budgetary constraints, but there is little evidence of evaluation or reflection on the system generally. The result was the delivery of a complaint service that contributed little to the critical process of identifying patterns of aberrant practice or improving patient safety generally.
- 2.361 The style of the response was often to describe the process by which the patient had been managed, sometimes to repeat the result of investigations, and to apologise profusely for the fact that the patient was in some way aggrieved. Whether or not the complaint was valid was usually not assessed or commented on and, therefore, no learning could conceivably be derived, or underlying trends identified.
- 2.362 What became a rigid response template was in contradistinction to the stated aim of the Trust as set out in the DOH guidance to inter alia: (i) address the concerns of the complainant; and (ii) to learn from complaints.
- 2.363 Unfortunately, the actual focus on ensuring an efficient and timely response undermined the more important aims of ensuring that:
- (a) All clinical complaints are adequately considered by the Clinical Director or someone of equivalent expertise and seniority. Such person examining should have access to the medical notes and records and provide a conclusion as to whether the clinical concern in the complaint is substantiated or not, as the case may be.

¹⁶ The Lamey Report was a non-statutory report chaired by Brian Fee QC, which considered the actions of the Trust in relation to the investigation of a dentist within the Belfast Trust.

- (b) If the Clinical Director or equivalent is for any reason unable to come to a view on the substance of the complaint, then the matter should be referred to an independent expert outside the Trust for an independent view.
 - (c) An investigation is carried out, or at least informed, by someone competent to address the complaint from a clinical standpoint.
 - (d) Complaints would be collated in such a manner as to enable effective interrogation by the Medical Director's Office to gain an accurate picture of the history of complaint as well as for review in the appraisal process.
 - (e) Patterns of certain types of behaviour or concern would be a specific focus of those investigating and evidence of similar complaints would be a trigger to more in-depth investigation.
 - (f) The outcome of all complaints should be retained and available for future reference and inquiry.
- 2.364 In those cases where efforts were made to address a clinical concern, it was felt sufficient to ask for the views of the clinician who was the subject matter of the complaint, rather than also seeking an informed view from another clinician in the same specialty. While the Clinical Director may have sometimes checked the response, he did not access or review the medical notes or records. Unsurprisingly, his comments were limited. It is obviously critical to obtain the views of the treating physician but if the answer given does not accept that there is any problem, little if anything will be learned without some form of independent review.
- 2.365 A further issue is that complaints tended to be generic and included a wide variety of concerns from car parking to catering. Discerning when a diffuse complaint had a clinical component or identifying a pattern of concern often required specialist expertise. Neurology complaints were sent to the Neurosciences Service Manager, who, in most circumstances, would not have been in a position to assess such a complaint in the absence of specialist advice. Too often the procedure followed was limited to obtaining a response from the physician, who was the subject matter of the complaint and developing a formal reply on that basis. This clearly led to many significant issues being missed.
- 2.366 The principal manner where a complaint was considered by a medical practitioner was through annual appraisal. This process, however, was primarily one of self-reflection by the appraisee, occurring months and often years after the treatment in question, and was not focused on identifying aberrant patterns of practice. This

is commented upon further in the Appraisal & Revalidation chapter. The evidence suggested that, in relation to Dr Watt's appraisals, when they did occur, complaints were not recorded consistently or, sometimes, at all. Unless the appraisee was alert to ensuring that all complaints were considered at appraisal, then, as the situation with Dr Watt's appraisal demonstrated, complaints which had not been properly or independently investigated in the first place ended up in a Datix system, which did not reveal the full extent of the complaint. This may have been because the complaint was categorised in a different way or not attributed to the relevant clinician(s).

2.367 What is clear, however, is that when required, the Medical Director's Office needs to have a clear overview of all complaints to ensure (i) that they have been reflected upon by doctors; (ii) that patterns of potentially aberrant behaviour are identified and (iii) that learning can occur. At present the Medical Director's Office will ask the Complaints Department to search the Datix system and provide a list of relevant complaints especially prior to revalidation. If that record is incorrect then the system is diminished in its effectiveness.

2.368 The Inquiry noted carefully that when the Independent Neurology Inquiry was announced in May 2018, the Belfast Telegraph published an article,¹⁷ which highlighted the views of the Trust regarding complaints:

On Wednesday, Dr Jack told the BBC: "We've reviewed our complaints over the last seven years and there is no red flag in relation to the complaints and in particular none around his diagnosis and treatments."

But last night the Belfast Trust said that no complaints made by patients regarding Dr Watt were seen as "red flag" issues.

"Most doctors receive complaints from time to time, some of which may be about diagnosis and treatment pathways," it said in a statement.

"We take every complaint very seriously and they are thoroughly and fully investigated through a robust complaints procedure." Dr Cathy Jack was completely accurate in her explanation." Any complaints received regarding Dr Watt (of which there were few) were fully investigated and did not raise any areas of concern."

2.369 The Inquiry carefully considered whether, in retrospect, there were any "red flag" issues, to what extent those complaints that were received were "thoroughly and fully investigated through a robust complaints procedure" and whether those complaints did not raise "areas of concern".

¹⁷ Belfast Telegraph 4th May 2018. Article entitled: *Belfast Trust patient recall: Northern Ireland mum reported concerns four years ago after frightening diagnosis put life on hold.*

- 2.370 Dr Jack provided a detailed statement to the Inquiry in September 2021, which sought to clarify several issues that had been raised earlier by the Inquiry about the statement to the BBC and the subsequent reporting in the Belfast Telegraph. The statement is reproduced at length as the issue requires detailed scrutiny:

During your attendance of 12th December 2019, a BBC News article dated 21st May 2018 (wherein it was indicated that the Trust had reviewed complaints for the preceding seven years and you are quoted as stating that there was “no red flag” in relation to the complaints. In evidence, you stated as follows:

Dr Jack: Within about half an hour, it was OK, and there was a conversation about, “What am I going to say about complaints?” and, basically, there’s no red flag – now I think there was a wee histogram or something or a table from complaints sent up, where a lot of them were communication or waits or delays. They’re only categorized into one element, so you look at that: you know, “There isn’t anything here, Cathy”. You go on and you say it. And now, you know, that statement’s going to haunt me, isn’t it? I would not have said it ... If you’d had two weeks, if you’d had the complaints file ...

Please consider the email chain into which you are copied on 24th April 2018, and wherein complaints data from DATIX is shared directly of complaints concerning Dr Watt was, therefore, held within the Medical Director’s Office from at least 24th April 2018.

Please provide any further comments you may have in respect of this issue in light of your previous evidence to the Inquiry.

Dr Jack Written Response.

This question relates to the interview I gave to the BBC, a small aspect of which was carried in the BBC news article of 21 May 2018 to which I was referred by the Inquiry. The BBC Newsline interview itself was at lunchtime on 2 May 2018. This was the day after the Belfast Trust announced the initial recall of approximately 2,500 patients. It was also the day I was to meet with hyponatremia families. It was to be the first meeting with the families since the hyponatraemia report was published. The meeting had to be cancelled on the morning of 2 May 2018, due to a bereavement occurring in one of the families. However, in the week prior to 2 May 2018, I had spent a substantial amount of time preparing for the meeting. This Inquiry will be aware that the main body of the Hyponatremia Inquiry report alone was more than 400 pages.

On the day of the recall itself the preparation included lengthy discussions with the Trust bereavement coordinator on the appropriate approach to take with these deeply distressed and heartbroken families.

The evening before, 1 May 2018, I was also involved with senior staff in the Belfast Trust dealing with an urgent communication from the Department of Health (DoH) about an upcoming Institute for Health Improvement Conference in Amsterdam. A DoH letter received at 17.00 required a response before 22.00. A substantive detailed reply left the Chief Executive's office at 19.45. At 10pm on 1st May 2018 Peter Watson left with me a 26-page timeline in relation to Dr Watt. The timeline did not have reference to any complaints. Even by the standards of the Belfast Trust, the 1 and 2 May 2018 were extremely busy and lengthy working days, and my focus was not on preparing for a media interview regarding Dr Watt that I did not know I had to give. I openly admitted to the Inquiry on 12 December 2019 (see internal page 9 of the transcript of 12 December 2019) that my reflection on the subject interview was that it would "haunt me". I had not expected to be doing the interview.

What I was trying to explain to the Inquiry during the session on the 12 December 2019 (I did not know the Inquiry was going to raise this issue with me; I had prepared to deal with matters from a much earlier period of time) was that I had not had the opportunity to prepare for it in the way that I would have liked. On the day of the interview, I was involved in discussions with the then Chief Executive, Martin Dillon, when the Trust's head of Corporate Communications came in and said one of us would have to do a television interview about the neurology recall. We discussed it, and, as it related to a doctor, we agreed it was appropriate that I, as Medical Director, should do it. We had a very short time to prepare what I was going to say. We discussed, amongst other things, the subject of previous complaints. I previously acknowledged before the Inquiry, that the Inquiry has a much fuller picture than we had at the time. The position, based on the information we had, was that there were "no red flags". My recollection is that the phrase "no red flags" was in fact one first suggested by Martin Dillon in our discussion, though it is my responsibility for having adopted it and used it during the interview. As I reflect on it now, it was not a useful phrase to use because the general public would not necessarily have understood what I meant by it as a Medical Director in the context of complaints relating to doctors.

The Inquiry has drawn my attention to an email that Rachel Maxwell sent to Peter Watson on 24 April 2018 at 11.30. It is clear from the email that the previous day Peter Watson had sought the known complaint history of Dr Watt. Ms Maxwell provided a 10-page summary table of the complaints known to her.

The Inquiry has asked me to accept that this communication from Ms Maxwell indicates that knowledge of complaints relating to Dr Watt was held within the Medical Director's office from at least 24 April 2018. I have no difficulty accepting this proposition, and do not believe I or others have ever suggested otherwise. It was always the case that I knew there had been complaints about Dr Watt. In fact, I believe I explained to the Inquiry that there was information

on some complaints relating to Dr Watt contained within the relevant pink file in the office of the Medical Director.

The point about the available information, as it was understood at the time, was (leaving aside the November/December 2016 concerns that prompted the restrictions) that none of it amounted to the type of concern that would have caused the Belfast Trust to consider that the medical practice of Dr Watt was putting the safety of patients at risk. That was the point I was trying to convey during my interview with the BBC. One of the key aspects of learning for myself, arising from this process, is about the information I based my answers on during the BBC interview. I answered on a mistaken belief that our complaints handling in the Belfast Trust was robust enough to identify a performance concern about a doctor.

- 2.371 The Inquiry Panel welcomes the clarity of Dr Jack's written response and agrees with her that complaint handling in the Belfast Trust was not robust enough to identify a performance concern. It is also fully accepted by the Inquiry Panel that Dr Jack was not in any way seeking to mislead and was at that time preoccupied with other matters of real gravity. Nevertheless, there are other aspects of the events at this time which raise further concerns not just about the complaints process, but the manner in which information is collated:
- (i) While a long list of complaints had been forwarded to the Medical Director's Office. The list was far from complete.
 - (ii) There was little or no focus on anything, but the events post December 2016 and the pervading sense that action had been taken following Dr Fitzpatrick's concern and the subsequent Royal College of Physicians review.
 - (iii) The dichotomy implicitly introduced by Dr Jack in her explanation to the Inquiry between "*a concern which was putting the safety of patients at risk*" and other complaints/concerns is unhelpful. The Inquiry believes that when matters emerged, a detailed evaluation of other concerns/complaints should have been carried out by the Medical Director's Office. Those in the Neurosciences Division should have been queried about and should have volunteered that there were previous concerns and This should have disclosed that, as recently as August 2016, Mrs Owens the Director of Acute Services had directed a conversation with Dr Watt about a range of matters of concern.
 - (iv) To rely on the robustness of the complaints system was misplaced. The complaints system was not fit for purpose, if one of the stated aims was to ensure that learning occurred.

2.372 The Inquiry Panel further noted that Brian Fee QC, who provided a report to the then Minister for Health in relation to the dental practice of Professor Lamey¹⁸, made a specific recommendation that all clinical complaints should be independently investigated.¹⁹ It is not clear to the Inquiry Panel that this recommendation was implemented by the Department or led to any substantive change to the extant guidance.

2.373 It is instructive to recite the following extracts from the Lamey report on the question of dealing with complaints and concerns:

4. A protocol is required in relation to the assignment of each complaint/concern to the SAI, MHPS or other process. This protocol would include documenting the considerations and deliberations which informed the rationale and the reasons for choosing which process to follow, together with details of the parties to the decision. It would be prudent to avail of the opinion of the Board, in particular, when making the decision, as sometimes happens at present. The decision, when taken, should not be considered as definitive. It should be subject to regular review (frequency to be determined) as investigations, such as look-back exercises, are progressed and be subject to escalation or de-escalation, as appropriate.

5. A template is required to record interactions, consultations, advices, deliberations, decisions, rationale and progress in relation to SAI and MHPS investigations.

6. The raising of an SAI/MHPS should result in the generation of a living document/dossier of all related material which would facilitate the ongoing investigation, reports and response to queries.

7. Risk assessments need to be conducted at intervals during the investigation process and as information emerges. Patient safety should always be the criterion for escalation irrespective of other considerations.

8. Commissioned reports, expert opinion, advices from regulatory bodies and NCAS should be used to inform and, if appropriate, alter the course of the investigations/look-backs. The institution, in its own right, has an obligation to uphold and foster patient safety and quality assurance on behalf of its patient cohort and to exercise a level of urgency in so doing.

9. It is necessary to ensure that those charged with conducting investigations, look-back exercises, etc are willing and able to devote the time necessary to bring

¹⁸ The Report was published by the then Minister for Health in 2013.

¹⁹ See Page 68 at [40]. "When a Trust receives a complaint concerning the clinical performance of a consultant level staff, an opinion from an appropriately qualified consultant independent of that Trust should be obtained on the merits of the complaint unless there are exceptional reasons for not so doing"

the exercise to a conclusion within a reasonable time frame. Regular review and evaluation should ensure that if expectations in this regard are proving difficult to meet, the matter is documented and brought to the attention of all bodies for resolution.

10. Human Resource concerns in respect of any employee need to be recorded and collated. This would include complaints; issues raised by the employee; differences in perception; expectations; compliance and non-compliance all of which should be documented and followed to conclusion through the use of a stepped protocol, which if it exists needs to be implemented and adhered to in all cases.

- 2.374 What is concerning to this Inquiry is that the current system relies on the proactivity of a small number of individuals, while others in the system are insufficiently aware of their governance responsibilities. This chapter has highlighted and commented above on the reasons that the current arrangements do not work effectively.
- 2.375 The Inquiry does recognise that under the leadership of Dr Jack, both as Medical Director and subsequently as Chief Executive, the issue of complaints has been highlighted as one of the main themes of emergent learning. Work has commenced²⁰ in relation to a structured case note review for complaints and the issues raised regarding complaints have been prioritised. It remains to be seen to what extent this addresses, what the Inquiry Panel believes was a fundamental problem.
- 2.376 In summary:
- (i) Information was kept by the Complaints Department, the Medical Director's Office and, in Dr Watt's case, the Neurosciences Directorate. Maintaining information within such silos ensured that no one person, and, in particular, the Medical Director, was able to take an overall view and numerous opportunities were missed with regard to Dr Watt's practice in being able to both identify concerning patterns of clinical diagnosis and adequate and independent investigation of relevant complaints.
 - (ii) There was no systematic way of collating clinical complaints and of looking at the information available. This difficulty was identified in the report of the Dental Hospital Inquiry chaired by Brian Fee QC. At Paragraph 8.1.2 the report stated:

It does not appear that these various concerns were contemporaneously collated into a single record or file. It may be that Trust management had

²⁰ Full details of the actions taken are set out in the footnote to para 22

anecdotal knowledge of all the concerns, however, the records obtained do not suggest a proper or adequate system for recording or collating concerns in respect of the quality of care or clinical performance delivered by Dr X.

- (iii) The Inquiry found that this concern had not been adequately addressed and that it was still difficult to construct an accurate and contemporaneous overview of a doctor's practice in a single record or file, notwithstanding the Datix system.
- (iv) The method of responding to complaints was inadequate and resulted in a system of response, which was artificial, patronising and ultimately inept from the point of view of investigation. It was only in recent years that the first steps were taken to obtain an independent view from a relevant specialist outside the Belfast Trust. While this is to be welcomed, there remained confusion about the role of the Complaints Department, the Service Department investigating and the resolution of complaints. Even the term '*resolution*' can lead to confusion. The absence of a system, which upholds, dismisses, or requires a complaint to be further investigated, ensured that clinical complaints were not adequately addressed. Apologising profusely for a patient's distress, in most cases at the beginning and end of every letter, tends towards the disingenuous and ultimately causes many people to either give up or develop a cynicism towards the Trust. For those few complainants, who had the patience to persist, they were offered nothing greater than more profuse apologies or greater clinical detail.
- (v) If the Complaints Department is performance-managed solely on response times, then that will become their primary focus as that is what they are measured against. If the Service Departments are reticent to go beyond the clinician, who has been the subject of complaint, and are unable to challenge a doctor, then the result will be a complaint that is responded to inadequately and without ever addressing the question that has been asked. Reciting long chronological histories of a patient's involvement with the Trust is only of value if this sets out the context in which the complaint is addressed or analysed.
- (vi) The evidence in relation to many complaints set out above would suggest that Service Managers and administrators are reluctant to challenge a doctor.
- (vii) There was, until recently, little evidence of the person investigating accessing a view form another suitably qualified clinician other than the clinician to whom the complaint related. The responses of the Trust were written in a

generic format, which apologised profusely for the distress of the complainant, recorded in minute detail the interactions of the patient with the Trust, but almost invariably failed to address the substance of the complaint.

(viii) A further failing of the system was that when complaints were being assessed or considered in light of ongoing concerns the person reviewing, if they were medical, would often deem that they were competent to assess the medical aspects of a complaint, even if the issue raised was outside their own specialism. While the Inquiry Panel recognises that it will not be every complaint that justifies obtaining an independent opinion, using relevant specialists outside the Belfast Trust, neither can it be appropriate to simply check with a doctor who is the subject of the complaint as to their view of what has occurred.

- 2.377 The Inquiry Panel is aware that, in some cases, the Neurosciences Directorate was faced with complaints, which were both complex and diffuse. On occasion, extraordinary efforts were made to both deal with the issues arising and resolve the complaint. The system lacked a filter or overview which would have given some relief to those, such as the Assistant Service Manager and Service Manager in Neurosciences, who often invested countless hours in seeking to come up with a detailed response that was sometimes immediately answered in the most exhaustive detail by the complainant. Obtaining detailed replies to a wide range of questions from numerous medical professionals, including consultants, often took months and sometimes years of delay. In the view of the Inquiry Panel, early analysis of the substance of the complaint, and an assessment of its clinical seriousness, could lead to a proper sifting of complaints, which would ultimately reduce the time taken with less serious complaints or complaints that are easily answered. The focus on providing extensive response in every case is not an efficient use of resources.
- 2.378 There needs to be a mechanism within the system, and as a part of the overarching Department of Health guidance, that allows for the Trust to give the best response they can (after appropriate investigation) and not be embroiled in years of fruitless correspondence. As ever, the driving force should be patient safety. There would be an obvious benefit in having another consultant review a complaint to discern: whether there is a clinical issue that needs to be investigated. The process may also help to discern whether a complaint is unjustified or even vexatious, at which point the Trust can adopt a more laconic response.
- 2.379 The complaints system was unfit for purpose and needs a radical overhaul to ensure that complaints are properly collated, stored and analysed in a way that will assist the Medical Director/Responsible Officer to have the most comprehensive picture

possible of a doctor's practice and have the opportunity to identify patterns of behaviour, which give rise to additional concern.

- 2.380 When Northern Ireland's largest patient recall was announced in May 2018, the Trust was placed under intense media scrutiny. One of the obvious questions that emerged was whether the issues surrounding Dr Watt's practice had been apparent to the Trust prior to November 2016 when Dr Fitzpatrick raised concerns directly with the Medical Director's Office. It is at this point that the various departments involved in such matters needed to co-ordinate carefully to ensure that accurate information was both collated and highlighted. Unfortunately, the public reassurances given by both the Medical Director and Chair of Division were unintentionally misleading. The fact is that there was information in various places, which should have alerted Trust managers to a pattern of potentially aberrant practice. Complaints that had apparently been investigated should have been reviewed and the Trust should have intensively focused on ensuring that the information available was properly triangulated.
- 2.381 To state, as Trust spokespersons did to the Belfast Telegraph in May 2018 that complaints were: (i) taken seriously; (ii) thoroughly and fully investigated; and (iii) considered through a robust complaint procedure, was manifestly wrong. In the view of the Inquiry Panel the complaints system was broken and contributed little to the essential process of identifying problems. Complaints were not adequately investigated and information was not properly collated or classified. The Medical Director's Office had only a partial view of the entire complaints picture and the investigations carried out within Neurosciences not only failed to identify clinical issues, but adopted an investigatory method that almost guaranteed an outcome that found nothing of substance or concern.
- 2.382 In a written submission sent to the Trust on 4th April 2022, full details of the initiatives taken by the Trust since the advent of this Inquiry in May 2018 are outlined.²¹ The Inquiry Panel welcomes the priority this matter has been given and, although not in a position to evaluate the actions that have been initiated, recognises that undertakings given to the Inquiry at an early stage have been taken seriously and implemented.

²¹ See paragraphs [21] to [23] *supra*.

CHAPTER 3 – LONE PRACTITIONER WORKING AND PRACTICE VISIBILITY

Introduction:

- 3.1 Paragraph B of the Terms of Reference requires the Inquiry to review the Trust's participation in processes to maintain standards of professional practice. The focus on examining lone working arose out of the evidence presented at an early stage of the Inquiry to the effect that Dr Watt's practice was relatively isolated from that of his colleagues.
- 3.2 The Inquiry heard that, initially, for the purposes of conducting ward rounds, there were 3 consultant teams within Neurology: 'A', 'B' and 'C'. Team A was comprised of 2 consultants and Teams B and C were each comprised of 5 consultants. Following the retirement of Dr Stanley Hawkins in 2012, the Belfast Trust Neurology Department had 2 teams comprising 5 consultants each (Teams B and C) and one 'team' with 1 consultant (Team A). From 2012 to 2017, Dr Watt was the sole remaining consultant practising in Team A. This imbalance was never addressed.
- 3.3 It is accepted that organising consultant teams for inpatient care is much more practicable than arranging a team for outpatient care. Inpatient care involves a relatively small number of patients who will be in hospital for a period of time. In contrast, outpatient care can involve a large number of patients, who may only be reviewed for a brief period of time by a consultant at a clinic. Dr Watt had several outpatient clinics where he would review many patients. While he was often assisted by a registrar and liaised closely with consultants from other sub- specialties in those clinics, the opportunity for the kind of team working seen in the inpatient context would have been more limited.
- 3.4 The views of all neurologists in respect of peer review and team working were sought. In addition, the Inquiry Panel sought explanations from management as to its view of extant practices. The concepts of peer review and multi-disciplinary team working were accepted by almost all the medical witnesses to the Inquiry¹ as being a positive and important working practice. As outlined below, many consultants also felt that team working offered the most effective safeguard against aberrant practice.

¹ The Inquiry does note that Dr Paul McMonagle, a Consultant Neurologist in Team C of the Belfast Trust Neurology Department, acknowledged that multi-disciplinary teams undoubtedly had a place for inpatient care and many outpatient disciplines, but was concerned that in some situations peer review teams could slow down progress, particularly where there was pressure on waiting lists. In his view, there were more multi-disciplinary structures at the Royal Victoria Hospital than in many other hospitals where he had worked.

- 3.5 The terminology is at times confusing and ‘multi-disciplinary team working’ and ‘peer review’ between colleagues are sometimes conflated and used interchangeably. There is, however, a distinct difference. In multi-disciplinary teams a patient is assessed collectively by a range of professionals across various disciplines, such as nursing, social work, medical, etc. Participants seek to integrate their contribution with the overall goal of improving the patient’s care. By contrast, consultant peer review, as operationalised within the Neurology Department in the Belfast Trust, is *intra*-disciplinary and tends to involve consultant colleagues in the same specialty liaising with each other and, on occasion, working together on the treatment of a patient. Although the focus is on collaboration, there will be, to some extent, an element of assessment or evaluation occurring.
- 3.6 Peer review, in this sense, covers more than just *intra*-disciplinary teams and there are a number of existing mechanisms through which a consultant may have the opportunity to either work alongside, or discuss cases, with peers. It is the case that the Neurosciences Grand Round, Morbidity and Mortality meetings for neurology and specific audits were part of an overall peer review system within the Belfast Trust. For instance, neurology consultants and registrars within the Trust will engage with specific Morbidity and Mortality (“M&M”) meetings for Neurology², where adverse outcomes are discussed between colleagues with a view to distilling learning and improving patient safety. Similarly, a weekly Neurosciences Grand Round meeting takes place, which is attended by a variety of colleagues from across the Neurosciences Division, e.g., neuroradiology, neurology, neurosurgery, and neuropathology. The Grand Round provides an opportunity for difficult or interesting cases to be presented and discussed and for learning to be shared. Typically, practitioners deliver presentations on a rotating basis. Dr Watt was reported to have attended many, if not most of these meetings. The Inquiry is aware that Dr Watt gave three presentations in the Grand Round meeting on cases of suggested spontaneous intracranial hypotension³.
- 3.7 In addition, various audits of procedures or other discrete aspects of neurology practice will, from time to time, be carried out. Clinical audit may, if specifically targeted, identify discrepancies in practice. Whilst the limitations of such audits are recognised, it is considered that they may, potentially, provide an opportunity for valuable insight into aspects of an individual’s practice which may not otherwise be readily visible.

² In his oral evidence on 2nd May 2019 Dr Jamie Campbell, now a Consultant Neurologist in the Southern Health and Social Care Trust explained that M&M meetings in Neurology did not occur when he was a registrar in the Belfast Trust which was from August 2011 up until January 2017.

³ This is discussed in more detail in the chapter on Epidural Blood Patching.

- 3.8 The more specific focus of the Inquiry, however, relates to opportunities for consultant peer review, particularly in *intra*-disciplinary teams, within the Neurology Department. The Inquiry was keen to explore how lone working came to be a feature of Dr Watt's practice and the view that was taken of this arrangement by those in Trust management.
- 3.9 In light of the above, the Inquiry Panel wished to consider: (i) the extent to which team working was considered beneficial by the medical professionals involved; (ii) how it developed that there was a 5:5:1 working arrangement in the 3 Neurology inpatient teams; (iii) to what extent this was commented or reflected upon by management, and (iv) the actions, if any, that were taken to redress the imbalance between the teams.

Advantages of Team Working:

- 3.10 The Inquiry canvassed with all Consultant Neurologists and registrars their view of team working and the extent to which they believed that such a method was a protection against the development of aberrant practice. There was a strong consensus that team working was not just advantageous, but essential and extracts from the evidence are set out below.
- 3.11 In oral evidence on 15th January 2019, Dr Ailsa Fulton spoke positively of her experience of working with her Consultant Neurologist colleagues, Dr Orla Gray and Dr John McConville, in the Neurology Department of the South Eastern Trust at the Ulster Hospital. Dr Fulton highlighted how *intra*-disciplinary teams can afford some opportunity for peer review:

With Orla Gray and John McConville. We grew up together as registrars ... we all know each other fairly well, and certainly, communication I think, between the three of us is very strong. We don't always agree completely. We go round together on a Friday as an MDT. On a Friday, we have ward consult sessions, and on a Friday, the three of us are all on the Ulster site, except Orla once a month is in Lagan Valley, but the rest of the time we're there. We go round together, and we really use that as an opportunity, so if one of us is seeing somebody who is a bit sick or we're not really sure what's happening or we've seen them and we think they need to be given something strong like maybe consider cyclophosphamide, rituximab, some of the very invasive therapies, we would use the Friday as an opportunity to say to the others, "What do you think of this case? Do you think this is a reasonable approach?" And it's really useful. And even in outpatients, you know, probably less than once a month, one of us might ask another to have a look at somebody and the patients will kind of cross paths.

- 3.12 In oral evidence on 28th March 2019, Dr Seamus Kearney, a Consultant Neurologist in Team B of the Belfast Trust Neurology Department, highlighted both the difference between multi-disciplinary and *intra*-disciplinary teams and the advantages of several consultants sitting down to talk about each other's patients:

My view is that there's a difference between multidisciplinary teams and multi-consultant teams. So, neurology is probably quite uncommon to have the current set-up for teams B and C, whereby you've got several consultants sitting down, talking about each other's patients and, you know, then going to see the patient collectively ... I think there are definite benefits in it ... I don't see any disadvantages to it.

- 3.13 In oral evidence on the 20th December 2018, Dr John Craig, Clinical Director for Neurosciences and part of Team B in the Neurology Department at the Belfast Trust, gave particularly clear evidence about the benefit of team meetings:

... whenever we have our team meeting, everything's presented. It's warts and all. So, you know, my cases will be presented in front of other neurologists, and these are often elective cases. So these are not necessarily people who've come through the doors of [the Emergency Department] and I just happened to inherit them because I was on call last night. These are people, for example, I'm bringing in who I think they've got a particular type of epilepsy. They might be a surgical candidate. Sometimes when it's being read out, what I'm doing — not what I'm doing, what I've brought them in for, it's, "Did I really think that?" But there's the opportunity for other people to question you and all the rest of it.

So, in a specialty like ours, where we spend most of our time in our rooms on our own, maybe with a nurse but often not with a nurse. When I do my [District General Hospital] clinic in Newry, I'm the only neurologist in Daisy Hill. I'm the only neurologist ever in Daisy Hill. So, there's nobody to look over my shoulder or question me. But, again, taking into account that we spend most of our time on our own, I think we really have to be clever in how we use the opportunities when we're together, and, clearly, team-based working and hearing what people are doing, there's a huge educational component to it. I'm far better at movement disorders now than I was two or three years ago, because I've got the other colleagues.

- 3.14 The Inquiry Panel recognises that neurology in Northern Ireland is a regional specialty, which entails a greater preponderance of outpatient attendance outside the Belfast Trust. As Dr John Craig explained, a number of Belfast Trust neurologists provide neurology clinics at District General Hospitals, where they are the only neurologists. The opportunities, therefore, for team working are more limited than within other sub-specialties. Further, the benefits of working as a team are also

clearly illustrated when neurologists deal with inpatient admissions in the Royal Victoria Hospital.

- 3.15 The advantages of team working were strongly endorsed by practising neurologists. The experience gained from seeing a large volume of patients is critical and, whilst the ability to always work in a team may be at times limited, the importance of receiving the advice and input of colleagues is heightened in the context of a specialty that deals with high numbers of cases, where diagnosis can often be complex or protracted.

History of Working Arrangements:

- 3.16 Given the benefits peer review and team working present, the Inquiry sought to understand the genesis of the working arrangements within the Belfast Trust and the impact upon the practice of neurology within the Trust during the relevant period. The history of how *intra*-disciplinary teams were constituted and maintained was discussed in oral evidence by a number of neurologists. Pressure initially seems to have originated from nursing staff to improve the efficiency of ward rounds. This was explained by Dr Aidan Droogan in his oral evidence on 10th April 2019. Dr Droogan is a Consultant Neurologist in Team C in the Belfast Trust Neurology Department:

When I was originally appointed, there were no consultants working in teams, apart from Tom Esmonde ... We were asked by the nursing staff would we make teams, so it was actually driven by the nurses. There wasn't sufficient nurses to do all the many, many ward rounds that would be going on in the unit throughout the week. They just didn't have the time, so they said, 'Would you mind bunching together and doing combined rounds?' and we said, 'Of course', so we sort of divided into groups.

- 3.17 Dr Stephen Hunt, Consultant Neurologist in Team B in the Belfast Trust Neurology Department, confirmed the genesis of the initiative in his oral evidence on 2nd May 2019:

It was sort of calculated on the back of an envelope and there was going to be 18 or 20 ward rounds now for nurses to attend; they couldn't do their job otherwise. So, it was more, sort of, to corral people into the same place at the same time to help facilitate other aspects around the ward.

- 3.18 An 'away day' was organised in 2002 and a facilitator duly appointed, to assist with organising consultants into teams. However, despite these efforts, Dr Hunt confirmed that initially agreement proved to be elusive:

My understanding is that in 2002, there was a meeting held ... and it took all day to try and get agreement for people to be in which particular team. And even at the end of that day, there wasn't agreement and the facilitator left because they just got fed up. Now, the purpose of arranging into teams wasn't to do with oversight of safety or quality, albeit you could say that would be a good idea. It was just physically because they were new appointees and there were going to be more ward rounds. So, the typical ward round comprises not just medical staff but nursing staff and, increasingly, other members of the multi-disciplinary team.

- 3.19 Eventually a loose team structure did emerge. Initially, team A comprised Dr Mark Gibson, Dr Stanley Hawkins and Dr Watt, but, with the untimely death of Dr Gibson in 2010 and the retirement of Dr Hawkins in 2012, Dr Watt remained the only member of Team A. In his oral evidence on 20th December 2018, Dr Craig explained the evolution of the teams:

So I think it went to three — at one point, it was three, six, three. And then obviously, unfortunately, there was some retiral and, you know, loss of a colleague. What happened after that was the teams then started to form more around people would retire and somebody would be replaced; the person that was replaced, say, was an epilepsy specialist, so then they joined the team that had the epilepsy doctor. So if you look at my team now, which is team B, there's three epilepsy specialists and three movement disorder specialists. Team C is a bit more disparate. There's two MS, one headache, one cognitive disorders. And then there was team A, which was Dr Watt.

- 3.20 Evidence was also received from registrars under Dr Watt who later became consultants and who had the opportunity to work alongside each of the teams. Dr Fulton (quoted above at paragraph 11) was in this category until she left the Belfast Trust to work for the South Eastern Trust. Her oral evidence on 15th January 2019 also helpfully explained the following:

When I arrived back [from working in Dublin], there were three consultant teams: team A was Stanley Hawkins, Mark Gibson and Michael Watt, and they had a ward round on a Monday morning, a combined ward round; team B, John Craig, Jim Morrow and Tom Esmonde, who had a ward round on a Monday afternoon and a Thursday afternoon; and Team C were Gavin McDonnell, Mark McCarron used to visit down from Altnagelvin and join that team, Aidan Droogan and Victor Patterson, and they had their ward round on a Tuesday afternoon. So, all very different personalities and a lot of consultants, where I'd been used to kind of working with one consultant at a time. And, I suppose really, from the start, the differences that I saw between Dublin and Belfast were the team system, and quite different personalities, and consultants who

had very different subspecialty interests in those teams. So, team A, to me, was always the least cohesive team, because of the personalities ...

... And, you know, kind of looking at time frames, I suppose in preparing for coming here, and thinking, "Well, why did it fall apart?", whenever Mark Gibson got sick, the first nine months were covered. John McConville did a bit of locum and then Dr [Inaudible] was a Polish locum who covered for a while, and then I took over as a locum for six months. But when I took over as a locum, instead of going into that Monday team, I had been asked to cover a Monday morning clinic in the City Hospital. So I was put into team B as a consultant. So, suddenly, it became four consultants and team A dropped to two consultants. Which was Stanley and Michael. And then it fell apart even further. Although those jobs were then filled permanently, Stephen Hunt and I kind of, I suppose, filled those roles, but nobody was ever put back into team A, so it was left as Michael and Stanley. But the other teams were unmanageable. They became unmanageable because there were so many consultants all wanting their say and having other commitments that they had to get to. No, but even it became — there was a detriment to the other teams, in that it was so unbalanced. So Michael was left as a lone practitioner. The other teams rapidly expanded, and trying to manage that number of consultants around a bedside, seeing patients —. I think it caused a difficulty ...

I think that the blame is being laid at his [Dr Watt's] feet without seeing how we, as a team, let him become a sole practitioner.

3.21 Dr Hunt also gave a useful insight into the actual workings of Team A in his oral evidence on 2nd May 2019:

At that time, Team A was Dr Watt, Dr Gibson and Dr Hawkins. So, the first ward round of the week was Monday morning, and the format was we all sat in a room and the various cases were discussed and then we went around and we physically saw the patients. Now, the conduct of that was slightly different from the conduct of other teams, laterally, OK, but that wasn't for any, sort of, particularly nefarious reasons.

... while they may have discussed the cases in the room together, they weren't necessarily in the practice of walking round the ward at the same time together.

So, depending on the availability of an SHO ... it could be the case that Dr Gibson would be away with me and Dr Watt might be walking round by himself. Now, more often than not, there would be another junior doctor with him, but he could be by himself. Once the ward round was finished, there was a session where Dr Gibson and Dr Watt and Dr Hawkins would teach, and that session used to be 10 to 11. It's now 11 to 12. But 10 to 11, you know, in trying to get anything done and red-up before 10, you know, first thing on a Monday

morning, was always a bit tight ... I can't remember at that stage – I don't think there was a formal second weekly ward round with the three of them together, but, as I say, Dr Hawkins would've been on the ward every day. He would've come and seen his patients. Dr Gibson would have come and seen his patients. He would've, again, insisted that, if you were physically present, you would go with him. He would indicate his displeasure if you weren't there. And he was a man of exacting standards, but he expected those of the people around him too ... Dr Watt was present in the talking bit. You know, in a meeting room like this – a lot smaller than this – but we discussed the cases and then we move on and you go and see the people.

- 3.22 Dr Hunt also explained to the Inquiry Panel how he had initially been assigned to Team A and had subsequently transferred to a different team:

Professor Mascie-Taylor: Could you just clear up why —? What was the situation over at team A and team B and C, and how it happened?

Dr Hunt: My initial appointment was as the locum.

Professor Mascie-Taylor: Of course, yes.

Dr Hunt: I cannot remember a conversation, but Dr Gibson was on team A, so, if I was notionally his successor or locum, then –

Professor Mascie-Taylor: You'd be on team A.

Dr Hunt: I'd be on team A. That was consistent with the timetabling of other sessions, outpatient sessions. So, I saw great value in continuing to work with colleagues that I had already been productive with. And one of the things that we were trying to aim for was to actually in Northern Ireland have a working, proper epilepsy service. Because, while the large majority of epilepsy management is medication-related, some of it's surgical-related, and that doesn't happen in Northern Ireland, and it still doesn't happen. We have been in discussions with colleagues in Dublin. And, you know, that actual, the progression of that – and this is of no criticism at all for the panel. But the progression of that has been stymied by the fact that all this is going on, and, you know, your time, your energy, everything else is totally consumed by it.

Professor Mascie-Taylor: Sure. Absolutely. Hugely. Huge distraction.

Dr Hunt: Yes. So, you know, it's like Brexit. There's no other – Nothing else happens except this. So, anyway, to go back to that point in time: I was then moving into a substantive post, thinking, you know, I'm going to be here for the rest of my days, potentially. Where do I want to be? And, you know, where I wanted to be was working along with these guys. They're busy people. You know, you wouldn't necessarily see them at other times in the week. And it

meant that that would be time where you could facilitate — you could say, “John, here, come with me, I want to talk about this now” — you know, which you wouldn’t have got otherwise. Plus, you know, if you ask about modelling yourself on —. You know, a lot of what I do is, sort of, the way that Jim Morrow does it, or did it. You know, so he’s somebody I respect enormously. And, you know, you sort of gravitate towards those persons.

- 3.23 The overriding impression from the evidence, in addition to the usefulness of *intra-disciplinary* teams and the protections they afforded was of the voluntary nature of the teams. They were organised at the request of the nursing staff and not management, and were arranged by consultants for consultants with little or no involvement by management. The Belfast Trust, in its written evidence of 16th December 2021, highlighted that management responsibility for the organisation, operation and oversight of teams of doctors is that of the relevant Clinical Lead and then the relevant Clinical Director.
- 3.24 The Inquiry Panel can only reflect that it saw little evidence that such clarity about first tier management responsibility for team working was effectively communicated by senior management within the Belfast Trust to the relevant Clinical Lead / Clinical Director within Neurology.

Nursing Staff:

- 3.25 Some of the most insightful evidence on the working practices of Dr Watt were given by those nurses who worked alongside him and who were also in a position to contrast and compare the practices of other neurology consultants.
- 3.26 In his oral evidence on 19th March 2019, Christopher McKee, Ward Manager in Neurology and a qualified nurse, noticed a difference with Dr Watt:

So, the Registrars went into different consultancy teams, but, obviously, Michael wasn’t part of one of those teams – Dr Watt. So, they would’ve been assigned to Dr Watt or you would’ve been assigned to the movement disorders, which was Seamus and John and all that.

He did his own [ward round]. So, Michael came in and Michael worked outside that. He didn’t – he wasn’t part of the sit-round-the-table ward rounds that the other two teams had. He worked alone.

I spoke to Vanessa about it and I spoke to Clare about it, and I was told that they tried – they’d looked at this and they tried but, because of Michael’s clinic commitments and how his clinics fell, he was not able to be part of that, which I

found a bit – a bit [short pause] dubious. Because, I think, if we – if there had've been a – a real emphasis put on, I think that could've been workable.

- 3.27 Evidence was also received from nursing staff in Ward 4E, who would have been familiar with the practices of the consultants in BHST who worked in Neurology. On 26th March 2019, Sister Sharon McConkey gave evidence of the situation that pertained after the retirement of Dr Hawkins in 2012:

Dr Watt continued on his own. I think that team became quite depleted really, and there were new consultants coming through, but nobody seemed to be appointed to the team to work with him ...

We kept thinking it was a bit strange ... I think there was a general -. He was-. He probably liked to work alone. I think that's his personality. I think that's the way it was. But I think that the other teams seemed to be expanding and he was still on his own and-. Well, it was commented on. Why is nobody else on to this team? You know, and -. But, you never would've got a straight answer from anybody. There was this perception: we all want to be on the A team, the best team in the house, you know. And, there was just personalities that got on very well together.

- 3.28 Sister McConkey highlighted the different dynamic between the various teams:

The Monday afternoon and the Tuesday afternoon teams definitely worked in different ways. Tuesday would've been a quieter team; Monday was a more vocal team. I think he was quite happy to work on his own, but I'm not saying that was the right way. I'd be happy to work on my own, but I have to work as part of a team.

He was working on his own, and I do believe that was -. It wasn't good for him, as much as anything, because he had no accountability, because he worked on his own there, then he went to his outpatient clinics, and, you know, and he was putting so many people through. And I know there were other people that worked there closely with him. But, you know, I never doubted his ability as a consultant.

- 3.29 Sister Vanessa Boyd gave similar evidence during her attendance at the Inquiry on 21st March 2019:

I would've said that there was an in-vogue team – the one to be in- and there were the ones, perhaps, that were a little bit subopt – not suboptimal in terms of not doing a good job but just that they weren't the 'A Team'. Do you know what I mean?

He always did his ward rounds with the registrar. He never – he unfailingly did those, but I don't think that he had the same access to peer review as other people did because he was on his own.

- 3.30 Nurses worked with Dr Watt at various clinics. They described how Dr Watt would make diagnoses and they would provide the aftercare. Several nurses who had experience in other locations or departments commented on how the culture within neurology did not enable them to challenge the consultants. They explained this by reference to the consultants being the primary decision-makers in a pyramidal hierarchy. The nurses also observed that Dr Watt did not have the same support from registrars as other consultants had. Some of the nurses commented on Dr Watt ordering fewer tests than his consultant colleagues. The nurses observed that Dr Watt did not work in a multi-consultant team like his colleagues and, as a result, did not have his decisions scrutinised and challenged like the other consultants. In addition to the oral evidence at paragraph 26 above, Nurse Manager Christopher McKee also told the Inquiry Panel how he had queried Dr Watt being in a team but was told by his own manager at the time, Ms Clare Lundy, that this could not be facilitated because of Dr Watt's clinical commitments. Nurse Manager McKee also raised these queries with Dr Craig, Clinical Director, but was told it was difficult because of the various clinics. Nurse Manager McKee agreed when it was put to him by Professor Mascie-Taylor that the response he got to his queries could be summarised as *"well, we've tried and we've failed."*

Dr Watt in Team A:

- 3.31 The Inquiry Panel thoroughly investigated the background to the extant arrangements and the reasons why, save for the exceptions detailed above, there seemed to be an overall lack of curiosity that Dr Watt was practising on his own in Team A. The Inquiry Panel was especially focused on the reaction of Dr Watt's consultant colleagues to Dr Watt's situation.

- 3.32 On 28th March 2019, Dr Seamus Kearney referred to the issue of covering Dr Watt when he was on holiday:

The only time that it would've come up would've been in terms of cover at the times of leave ...

I think, it wasn't of concern. It seemed --. Looking back now ... my recollection of it was, you know, that it was within that normal spectrum.

- 3.33 In his oral evidence on 1st February 2019, Dr Gavin McDonnell, Consultant Neurologist in Team C in the Belfast Trust and Clinical Lead for Neurology, highlighted how busy other neurologists were:

If I thought about it, I mustn't've thought about it for very long. The difficulty is

that we're all individually very busy, but extremely busy over the last number of years – a huge number of patients, working on so many different sites ... that my focus wouldn't have necessarily been on that. But when you look at it from the outside, yes, it does look odd. It doesn't look helpful. It can't be helpful for him. He's not getting other individuals to bounce ideas off. But it wasn't something that he was flagging up.

- 3.34 On 20th December 2018, Dr John Craig, the Clinical Director for Neurosciences and part of Team B in the Neurology Department at the Belfast Trust, candidly reflected that an opportunity to address the situation had been missed:

I mean, even at a purely operational level, it is an issue. So, for example, I've a ward round after this. If I'm late, I don't have to ring my colleagues. They're there. They will see my patients. I will discuss what the outcomes -. If there's anything left over, I will go and sort that out. So, even operationally, the way things developed were far from ideal. There was a good relationship, I suppose, if Dr Watt was going off on holiday and he'd a – we never really have any more than about six or eight inpatients ... but if you had two epilepsy patients, he would come and ask me, 'Can you look after my epilepsy patients?' And that's fine. There was a degree of teamworking there. But it should be more seamless than that. It should just happen."

"We probably asked it sometimes around, you know, if he was off on holiday, who's actually looking after his patients, as opposed to - ... You know, he never came to me and said, 'I should be -. I'm in a team, and I'm -', or 'I'm isolated. I should be with you, and I feel very -. And you guys don't have to-.'"

"So, again, you know, is that an opportunity missed? I think that was an opportunity missed."

- 3.35 In his oral evidence on 8th May 2019, Dr Michael Kinney, a locum consultant at the time of his attendance before the Inquiry Panel, and previously a registrar in the Belfast Trust, noted in relation to Dr Watt:

... even back in 2011 ... Dr Watt was working in isolation because the other consultants would meet at pre-specified times ... he was always on time for his ward rounds as such, but they never coincided with Dr Hawkins's ward rounds, even whenever they overlapped in their time together.

if you offered me a job in a hospital where I was the only person on the team, I wouldn't want to take the job.

- 3.36 On 14th May 2019, Dr Fiona Kennedy, a Registrar, who had been in London working as a Neurologist between 2009 and 2014, noted when she returned to Belfast that the *"striking difference"* with Dr Watt was that *"he worked a lot on his own"*.

- 3.37 Dr Aisling Carr, now a Consultant Neurologist in Queen Square in London, recognised the importance of the larger teams for new consultants in her oral evidence on 11th November 2019:

If you're a new consultant you want robust, challenging peers to help you, you know, maintain your education, and it was already obvious that you got better peer support in those larger groups.

Michael was a very instinctive neurologist. He was very well read. He was very, very knowledge ... that instinctiveness to his character allowed him, and all acknowledged this, to process clinical situations at a slightly different rate to others.

- 3.38 The benefits of team working, and *intra*-disciplinary practice were strongly endorsed by neurologists. This general positivity, however, needs to be juxtaposed alongside what could only be described as a lack of curiosity by neurology colleagues. Team working was not a mandatory requirement and there was clearly space for those like Dr Watt, who preferred working on their own.

Clinical Audit:

- 3.39 In assessing the opportunities for an employer or a manager to recognise problem signs in a doctor's practice, the Inquiry Panel recognises that merely working in an *intra*-disciplinary team in an inpatient ward setting is not, of itself, sufficient. The problem is, however, how one can see or assess what is going on in another consultant's practice. The system observed in neurology within the Belfast Trust provided limited opportunities for one consultant to know what was going on in another consultant's practice. This is, in part, inevitable, owing to the pressures that the NHS has been under. The practice ⁴appears, however, to have been hardwired into the mindset of individual consultants. The question is, how one affords periodic opportunity for the decisions of one consultant to be reviewed by their peers? This theme is expanded in the Recommendations section below, but one possible way is through the process of clinical audit and the case note review introduced by former Medical Director and now Chief Executive, Dr Cathy Jack.
- 3.40 Clinical audit is essentially an assessment tool with the prime purpose of measuring outcomes and identifying trends. It is not designed, nor intended as a means of strengthening patient safety, but in some instances, data collected in the course of such audits have the potential to identify patterns and reveal practice trends. In that

⁴ It may well be that there are other examples of departments in various Trusts across Northern Ireland, and beyond, where there are similarly limited opportunities for practice visibility.

regard, clinical audit can potentially lead to an opportunity for learning or assist in other processes. The Inquiry sought to review those audits which had taken place in neurology during the relevant period.

3.41 The Inquiry Panel sought all of the relevant documentation within the Trust on clinical audits carried out within the Neurology department between 2007-2019. A brief summary of the relevant audits is set out below:

(i) **Neurosciences Medical Records Audit 2014 (uncredited)**

The audit notes that clinical records should include details such as clinical findings, information given to patients, planned investigations, drugs and so forth. However, the audit criteria and results show that none of these were considered; rather, based on General Medical Council (“GMC”) guidelines, each record for time, signature, printed name, printed designation, GMC number and lead consultant was audited. Given what subsequently transpired regarding Dr Watt’s record keeping from the Gray/McConville reports, the Royal College of Physician’s (“RCP”) report, and the oral evidence taken by the Inquiry, it seems likely that an audit could have picked up serious issues with Dr Watt’s clinical record keeping. However, in this case, the results are only broken down into neurosurgery and neurology, so it is unlikely this would have been flagged in this instance.

(ii) **Neurologist adherence to guidelines when prescribing Plasma exchange**

This was an audit specifically aimed at assessing compliance by a neurologist with guidelines. Two particular points were of note to the Inquiry Panel:

- (a) There are two different sets of guidelines;
- (b) There is no breakdown of numbers by consultant. With an overall compliance rate of 88.7% (i.e. at least one guideline), it would be interesting to have known if those 12.3% of non-compliant cases were distributed pro rata amongst consultants or if there was an outlier.

(iii) **Audit of Prescribing Practice of Natalizumab (uncredited)**

The audit notes that all patients met NICE⁵ criteria to commence treatment. It only states that NIECR⁶ was used for data collection. The audit is of patients commencing Natalizumab ‘from April 2017’. It is not clear what time period the audit covers.

⁵ National Institute for Health and Care Excellence. NICE guidance comprises ‘evidence-based recommendations developed by independent committees, including professionals and lay members, and consulted on by stakeholders’. <<https://www.nice.org.uk/guidance>>

⁶ Northern Ireland Electronic Care Record.

- (iv) **Lumbar Puncture waiting List Quality Improvement Project (Aug – Oct 2018)**

- (v) **Audit of Natalizumab Prescribing in Northern Ireland (2011) (Hughes & McDonnell)**

Again, this audit showed relatively good adherence to NICE/ABN⁷ guidelines – 85% overall. However, again, it does not appear to go behind the initial diagnosis and there is no consultant breakdown to assess whether any individual is responsible for a disproportionate number of the non-compliant cases. It is only when a consultant breakdown is prepared that information could come to light, which would be likely to assist in identifying possible aberrant practice.

- (vi) **DMT Prescribing audit for Disease Modifying Treatment started Jan – Dec 2013**

- (vii) **Re-audit of natalizumab prescribing in NI (Stella Hughes, 2015)**

This audit was presented at a meeting of the Multiple Sclerosis Special Interest Group (“MS SIG”) on 10th February 2015. It shows that, in 2015, the prescribing criteria were met and reasons for starting was documented – no cause for concern was identified.

- (viii) **Managed Entry of Disease Modifying Therapies (Dec 2012, uncredited)**

This audit showed that 13% of cases involving disease modifying therapies did not meet NICE criteria; of the 87% that did, the requirement for a ‘disabling’ relapse was not clear in 67% of cases. Further, 4% did not meet at least one of the ABN criteria.

- 3.42 Consideration and comment on the governance around Dr Watt’s use of Human Immuno-Globulin (“HIG”) is contained in the Prescribing chapter. In respect of analysing clinical audit within neurology, the audits rarely compared individual clinicians. The opportunity, therefore, to discover aberrancy or whether a consultant was a clear outlier in terms of prescription, or the obtaining of tests, was quite limited. On the rare occasions when an audit was individualised, such as the use of HIG, there appears to have been no pressure to question or further interrogate the data on the part of those neurologists who were in attendance when that audit was presented by Dr Carr in 2007. It was the case that Dr Watt was, by some measure, the outlier in respect of the use of HIG. In her evidence to the Inquiry Panel on 11th November 2019, Dr Carr stated:

⁷ Association of British Neurologists.

Dr Carr: ... If you look at the human immunoglobulin usage per consultant and you look across the spectrum of all of the consultants, there was significantly larger volume of use by Dr Watt, and I presented that at an audit to the neurosciences group in 2006- 07.

You also look at how the usage per consultant – and it's divided up according to the Department of Health guidelines into red indications, which are first-line; blue, which is second-line; and grey, which is, "You're allowed to use it, but there really isn't the evidence" – and, if you look at the proportion of blues and reds to greys, it would appear that Dr Watt's proportions were - .

Professor Mascie-Taylor: Ratio was different, yes.

Dr Carr: Now, when we discussed that – and I say "we"; I was a very junior registrar – when that was discussed at the neurosciences meeting in 2007-ish, there were a broad range of consultants there, and that data was in front of everyone.

Now, at that time, there was the very recent discovery of antibodies which explained the autoimmune encephalitises. Essentially, these were a group of conditions where a patient would, really very suddenly – over days to weeks – become confused and in a coma and having epilepsy which was very refractory. Up until 2007-08, we didn't know the cause of this, and, essentially, those patients would've died. So, now – then, at that time, it was being discovered that these were actually autoimmune-based and, therefore, treatable, potentially treatable ...

Now, all neurologists everywhere were becoming very aware of these things, and, in that setting at that time, the discussion was, "Yes, we need to be behaving as per the commissioning guidelines. However, as clinicians, we cannot be allowed to be overpoliced in this setting, because medical understanding of these rare conditions is evolving and, if we have a patient in front of us, our clinical assessment should have enough power or weighting to allow access to these potentially life-saving treatments." So, the basis of the discussion at that time wasn't dismissive of policing or guidelines, but it was – everybody needed to, wished to acknowledge that our understanding of these rare conditions is changing and limitation on clinical practice from afar can be detrimental to the individual. So, in the context of purely the number of patients that Dr Watt saw through his high-turnover public or NHS practice, alongside his high- turnover private practice, the actual numbers of his HIG use was not deemed to be a very worrying outlier, if you know what I mean. That was if you look backwards, and interpret those numbers. Now, over time, commissioning of IVIg⁸ has become tighter and tighter and tighter.

8 Intravenous immunoglobulin.

Professor Mascie-Taylor: Indeed.

Dr Carr: Now, my naïve suggestion, as a very junior registrar at that time was, “Well, if we are using this product or this therapy to help in the diagnostic process – so, if we do a load of tests and we just don’t have the answer or they don’t tell us for definite – if we use it to see if the patient responds –”.

Professor Mascie-Taylor: Yes, therapeutic trial.

Dr Carr: Yes. “Should we be trying to make measurements of that?” That was my suggestion at the end of the audit. Now, that wasn’t taken up.

- 3.43 The Inquiry Panel fully accepts that one has got to put the matter into context. The lengthy extract from the evidence of Dr Carr reveals that at the time of the audit, there was, on the face of it, a potential explanation for the fact that Dr Watt was an outlier in respect of the prescription of HIG. What is disappointing, however, is that the results of the audit did not form an effective reference point whenever the issue of HIG prescribing and the process subsequently agreed upon was raised on subsequent occasions and, particularly, in early 2016. The impression given is that, if there is a perceived explanation for what could be viewed as a discrepancy, then that is the end of the matter. The Inquiry Panel further notes that Dr Carr’s suggestion regarding a therapeutic trial was not taken up or agreed upon by the body of consultants. Once again, an opportunity to further interrogate the data was missed. The subsequent difficulties are best described in the chapters on Prescribing and the Missed Opportunities in 2016.
- 3.44 The ineffectiveness of clinical audit as a means of identifying problems is also illustrated by the problems that Dr Watt had with record-keeping. The external reviews which were carried out, such as the report from the RCP, which was formally delivered in April 2018, and the draft Verita report, referenced the problem of Dr Watt’s record-keeping. In this regard, these reports linked the deficiency with the broader issue of accurately assessing the quality of care provided. At no point did any of the audits link a deficiency in record-keeping with a care quality or patient safety issue. The Inquiry Panel accepts that clinical audit is not the same as a detailed report from the RCP but may form the basis for further investigation and inquiry.
- 3.45 The perceived difficulties in relation to clinical audit within neurology were alluded to in the evidence of Dr Gavin McDonnell on 1st February 2019:

Dr McDonnell: I think it should do. I think a lot of the things that we audit — and you’ve probably heard the criticism before — you tend to audit things that you can measure.

Professor Mascie-Taylor: Absolutely. It's easier to do.

Dr McDonnell: So, it might be that there's a requirement that, you know, if you're on a particular drug, that you're getting your thyroid function test checked every three months. So, you think, "Well, we'll audit that because that's important and we can measure that very easily". But auditing the diagnosis of —

Professor Mascie-Taylor: It's more difficult.

Dr McDonnell: — is more difficult, and that might be more difficult if you perhaps don't have the expertise about to do that effectively. So, for instance, I suppose, maybe the epidural blood patches might be an example of that, because I don't think anybody else in Belfast would've considered themselves to be an expert on spontaneous intracranial hypotension.

- 3.46 While audit within neurology may present its own challenges, the Inquiry Panel was struck by what might be termed as a lack of curiosity within the consultant body. The almost complete absence of breakdown within an individual consultant's practice ensured that clinical audit played no appreciable role in identifying the problems that developed in Dr Watt's practice. This compares markedly with the approach taken by managers to measuring output by consultants. This was vividly described by Dr Ailsa Fulton in her evidence of 15th January 2019:

We started to get this generated email that came through, I think about three or four times a year, that showed the breakdown of the whole department and all of our clinics and what our waiting lists were like and the numbers of patients that we're seeing.

Michael was held up as a poster boy because he was seeing so many more patients than the rest of us.

- 3.47 Dr Michael Kinney, in his evidence of 8th May 2019 to the Inquiry Panel, highlighted the dearth of audits and his own ambition to see audits being utilised as a means of measuring progress:

Dr Kinney: Sure. I guess my thought on that is that audit would've been very sporadic, actually.

Professor Mascie-Taylor: Absolutely.

Dr Kinney: I can recall possibly a handful of audits presented in the five years that I was in the department. Now, in more recent times, just almost immediately prior to me leaving the Royal in 2017, there was, I believe, introduction of more kind of specific time for audit in our department. Although it was always a

hospital-wide audit day, clinics were cancelled, I don't recall there being any organised activity to actually audit things. Professor Mascie-Taylor: Just so I understand that. There was a hospital wide audit day, so were neurology clinics cancelled

Dr Kinney: Yes. I hope I am not wrong on that from a factual point of view but it was my ... recollection that you would come along to a clinic and find out that it had been cancelled because it was audit day across the site. I don't recall there being specific activities organised for us as a department in those areas until more recently – until probably the last year or two.

Professor Mascie-Taylor: But in most of the period you were a registrar the audit day, whilst it in some sense was an audit day i.e. clinics were cancelled in order to deal with it - in other sense it wasn't an audit day because no audit occurred.

Dr Kinney: That's correct, yes. Some consultants ran their clinics, so it wasn't that every single clinic was cancelled actually ... I mean, it's not an indicator of good practice, clearly. For me, as I start out on this path as a consultant, one of the big things I want to be able to do is measure things, to actually know what you're doing is good. I want to be able to prove that because I see that as being a method by which you can actually improve things and argue your case for getting more funding to improve things all the more. So, to not measure it and have no idea of disease burden and various things for prescribing practices seems almost unfathomable, actually. But I can understand why these things become difficult for consultants in practice because this takes time, and the systems for coding and various things are probably not set up ideally for this kind of work.

- 3.48 The Inquiry Panel agrees with Dr Kinney that the lack of any audit in Neurology on a hospital-wide audit day is not an indicator of good practice, nor does there appear to have been any concern raised in management that such action was problematic or explicable.
- 3.49 It is apparent from the documentation received by the Inquiry on the question of clinical audit, that audit records are held by individual consultants and registrars with the results being recorded in a red book. This is not ideal and points to the larger problem of audits not being individualised or strategically driven and centrally controlled.
- 3.50 In Dr John Craig's evidence to the Inquiry on 20th December 2018, he candidly considered how clinical audit might have been of assistance in relation to the dramatic rise in the diagnosis of spontaneous intracranial hypotension ("SIH"), which required blood patching. Dr Craig stated:

Dr Craig: Thinking about it, the way we might have got at it would've been to get an audit done. Audits always lag behind. They're usually six/12 months behind clinical practice, but, if we had done an audit and knowing what I know now, we would have realised that a lot of these patients that were getting blood patches had not had imaging done. We'd been told that imaging was a crucial part of the diagnostic process, but we —.

Mr Lockhart QC: So, at that lecture in 2014, at no stage were you given the impression that you could in fact diagnose without imaging or —.

Dr Craig: Well, I would — if I saw a case of this, I would be — as long as they didn't have a pacemaker or whatever — and I'd be asking for MR imaging of their brain and their spine 100% of the times, and, in fact, the diagnostic criteria rely very heavily on the MRI features. So, at our consultant meeting in 2015, if we had said at that time, "We have to have an audit of this. We haven't done this. We haven't gone back and looked at all those cases", but, you know, we might've found at that stage actually these people are having this done without imaging, and, clearly, that would've raised a question ... Yes, I mean, I certainly think that the way it was allowed to grow without proper balances and checks is certainly not something I think we'd be wanting to replicate in the future for anything.

- 3.51 The Inquiry Panel agrees with Dr Craig that clinical audit may have been especially useful in relation to blood patching. This is discussed further in the Blood Patching chapter but the lack of any clinical audit in this area was a clear opportunity missed.
- 3.52 The Inquiry Panel noted from the evidence of Dr Stanley Hawkins on 9th November 2018, that, when clinical audit was first started, it was meant to be a case note review and to occur on a monthly basis. In reality, this just did not happen as explained by Dr Hawkins:

Dr Hawkins: When clinical audit was first introduced there was a system of case note review. That was a long time ago. Then there was an audit department introduced in the hospital and it wanted to have control of clinical audit and they felt that case review was not sufficient. If there had been case note review over the last few years certain things might have come to light. Can I say that when a consultant's first appointed immediately that consultant would have a certain amount of autonomy.

Professor Mascie-Taylor: Indeed.

Dr Hawkins: One doesn't normally review someone else's case notes without a very good reason, and you would not normally systematically review case notes without a very good reason.

- 3.53 The Inquiry Panel agreed with Dr Hawkins' first observation about a case note review but was less impressed that review only normally occurred if there was "*a very good reason*". The Inquiry Panel considers that patient safety is the only reason needed, if it can be shown that regular case note review helps identify patterns of aberrant practice. The Inquiry Panel notes that a case note review initiative has now been taken up by Dr Jack in another specialty.
- 3.54 In her oral evidence of 28th February 2019, Dr Jack outlined a case note review process which had been implemented in Rheumatology:

Dr Jack: In the likes of rheumatology, what we're talking about with them is that, if they give a patient a – you are giving patients diagnoses and, if you give patients a life-changing diagnosis and you are about to start a biologic, you discuss it with a colleague and the two of you sign it off.

Professor Mascie-Taylor: And that's all that's required.

Mr Lockhart QC: And that is your answer to MDTs within outpatients.

Dr Jack: No. Then in MDTs as outpatients. You still need this, because you need to spot if somebody's doing an epidural blood patch, because it's not life-changing ... And those maybe that just have migraine headache, that are maybe being diagnosed with other conditions: you can either do a peer review, which is that you come once a year and pull a clinic, but my own feeling – and I've been talking to the lead in rheumatology – is that, once a month, a colleague randomly selects a case note from your clinic and looks at it, because then it is ongoing. Every month, one case is being reviewed independently. And so, if I look at your case, Brett, you'll look at Hugo's, Hugo will look at Mark's ... then you present it to the MDT.

- 3.55 From the evidence within neurology reviewed by the Inquiry Panel, clinical audit had a limited and negligible impact on the identification of aberrant practice. The failure in most audits to name individual consultants automatically limited the impact of the audit in identifying patterns or trends which might have given rise to further query or investigation. The impression of the Inquiry Panel is that a different approach to clinical audit could have a much greater potential in identifying possible aberrancy of practice.

Neurosciences Grand Round Meeting:

- 3.56 The Inquiry Panel took into account that a Grand Round meeting in respect of neurosciences had continued for many years throughout the relevant period and was undoubtedly helpful to individual consultants. The Inquiry Panel notes, for

instance, that colleagues working in hospitals such as Craigavon, Altnagelvin and the Ulster would attend the Grand Round meeting for neurosciences. This occurred on a weekly basis and provided an opportunity for specialists to discuss interesting cases and highlight clinical issues of common concern. The format was based on the idea of one consultant, often in collaboration with a registrar, introducing to the meeting a particular issue, which would then be discussed by colleagues. The Inquiry Panel formed the impression that consultants regarded the Grand Round meeting positively and both neurologists and neurosurgeons saw attendance as an important part of continuing professional development.

- 3.57 It was noticeable, however, that when the Inquiry specifically inquired with each neurologist, few doctors could recall being at the 3 separate meetings when Dr Watt gave presentations on spontaneous intracranial hypotension (“SIH”), even though there was sufficient evidence from enough doctors to confirm that the presentations had taken place. The issue of Dr Watt’s presentations is dealt with in the Blood Patching chapter but is mentioned in this section because there was no evidence before the Inquiry Panel that anything said by Dr Watt at any of the presentations caused concerns to be raised about the prevalence of SIH or the increase in blood patching. The Inquiry Panel concludes, therefore, that while the Neurosciences Grand Round has an importance in respect of training, it does not operate in a manner which would highlight potential problems or aberrancy.
- 3.58 In this regard, the Inquiry notes that, on the one occasion (of which the Inquiry is aware) that a Clinical Director (Mr Cooke) escalated a concern about a presentation by a neurosurgeon to the Medical Director, he was rebuked in writing by the then Clinical Lead, Dr Morrow. This is set out in greater detail in the 2006-2007 chapter. Dr Morrow’s reasoning was that the Grand Round meeting was not meant to be an opportunity where a concern about a specific colleague and his or her practice should be identified and acted upon. On 25th January 2008, Dr Morrow emailed colleagues when Mr Cooke had decided that, as Clinical Director, he should raise concern about a specific neurosurgeon’s competence with the Medical Director:

... never before have I heard the suggestion that following this meeting a colleague’s competence is called into question and that referral be made to the Medical Director.

I am afraid that if this is allowed to continue the Grand Round itself as a format for education will cease to function as we all start to practice defensive medicine. You therefore have my full support in questioning this decision of Steve’s.

- 3.59 Although Dr Morrow was not able to give evidence because of his medical condition, the Inquiry did receive a written statement from Mr Cooke on 26th November 2021 explaining the context to the emails. Mr Cooke stated that the presentation in question had not been attended by Dr Morrow and that he was not the only doctor present who was immediately concerned by his colleague's presentation. It appears that the doctor making the presentation which caused concern had subsequently corresponded with other members of the Grand Round explaining his position. It was that email which appears to have prompted Dr Morrow to respond as he did. Mr Cooke stated that when he explained the position to Dr Morrow and also gave a wider context that Dr Morrow understood and accepted Mr Cooke's position.
- 3.60 The Inquiry Panel understands that ordinarily a training meeting is not a forum, where one would expect issues of competence to arise. Nevertheless, when one does arise, a doctor and, especially, a Clinical Director, is required to act just as Dr Cooke acted.⁹ There must be no impediment to such escalation. Dr Morrow was a highly respected and senior neurologist who was also Clinical Lead. The concern is that his views on the matter may have carried real weight with colleagues and contributed to a culture where it became more difficult to raise concerns.

Mortality and Morbidity Meetings:

- 3.61 The Inquiry Panel also recognises that Morbidity and Mortality meetings began to take place within the Belfast Trust Neurosciences Department in the last number of years. The Inquiry Panel commend this as the meetings can often be an effective way of analysing the treatment and aetiology of a patient who has died and may often present, particularly in some sub-specialties, a learning opportunity. The Inquiry Panel notes that neurologists spoke positively about the usefulness of these meetings. However, given that they were not taking place during a significant part of the time period under consideration, the Inquiry is not well-placed to reach any conclusions about the extent to which such meetings may have presented an effective means by which problems with individual consultants could have been discovered within neurology.

Independent Sector:

- 3.62 The difficulties with consultants operating in the independent sector without oversight are commented upon in detail in the Independent Sector chapter. Much of

⁹ Section 25 (c) of the Good Medical Practice Guide states: "If you have concerns that a colleague may not be fit to practise and may be putting patients at risk, you must ask for advice from a colleague, your defence body or us. If you are still concerned you must report this, in line with our guidance and your workplace policy, and make a record of the steps you have taken".

Dr Watt's practice was carried out within the independent sector, where he would have been working on his own. Given the magnitude of his private practice, the Inquiry Panel believed that reference should also be made in this chapter on Lone Working and Practice Visibility to the link between Dr Watt's private practice and his NHS responsibilities. Many of the patients who were diagnosed with SIH, and advised to undergo a blood patch procedure, saw Dr Watt privately. Although there are at least three other Belfast Trust neurologists who carry out private work, the stark fact is that there is the barest of oversight. The Inquiry Panel noted that the difficulties with multi-disciplinary team ("MDT") working in the independent sector were commented upon in the Paterson report¹⁰, which made the following recommendation:

We recommend that Care Quality Commission, as a matter of urgency, should assure itself that all hospital providers are complying effectively with up-to-date national guidance on Multi-Disciplinary Team meetings, including in breast cancer care, and that patients are not at risk of harm due to non-compliance in this area.¹¹

- 3.63 The Inquiry Panel endorses that view. In the Paterson case, difficulties emerged, despite the fact there was both guidance and an established practice of MDT working in the independent sector. The difficulties arose in that the manner of MDT working was ineffective and decisions about surgery were often reached by one surgeon, without proper consultation with the other surgeons. In Northern Ireland, whilst there is a much smaller independent sector, there is a complete lack of guidance regarding MDT working in outpatient specialties such as neurology. The Inquiry Panel has concluded that, although there are difficulties, a form of peer review and MDT working in the independent sector needs to be the subject of guidelines, which are overseen by the RQIA. The fact is that the independent sector in Northern Ireland is increasingly commissioned to carry out NHS work by way of waiting list initiatives. Consequently, it is incumbent on those who both commission the care and provide the care to ensure that the same safety standards apply across both sectors.

Draft Verita Report:

- 3.64 Further to the Maintaining High Professional Standards ("MHPS") process, the Trust appointed Dr Seamus O'Reilly, the Medical Director in the Northern Health & Social Care Trust as the Case Manager for the MHPS investigation. Verita were

¹⁰ This was the Report of the Independent Inquiry of the issues raised by Paterson, a surgeon in the West Midlands who was convicted of harming patients in his care on a widespread scale. It was issued to the House of Commons on 4th February 2020.

¹¹ See page 219 of the Paterson report under the heading 'Recommendations'.

appointed as the case investigators and Dr Watt was interviewed by an investigation panel, consisting of Kieran Seale, an investigator at Verita, Dr Michael Marrinan, Medical Director at the Royal Hospital for Neuro-disability, and Dr Chris Clough, Consultant Neurologist at Kings College Hospital, who provided expert advice.

3.65 In a submission to the Inquiry of 31st January 2021 commenting on the Verita report, the Trust pointed out that the report was a draft report produced as part of an MHPS process, which was never finalised. The Trust advised that there were a number of factual mistakes and errors of understanding and submitted that the report should be treated with caution. It was explained that Dr O'Reilly, the case manager, had intended to make the draft report available to Dr Watt and the Belfast Trust for comment, but that, when it was possible to do this, Dr Watt was not in a position to participate in the process. Consequently, the MHPS investigation was effectively paused.

3.66 In respect of clinical teams, Dr John Craig, Clinical Director, told the Verita Panel that the original 'Team A' was comprised of neurologists:

... with a more traditional general neurology background". He further stated that "all three neurologists in that team trained at a time before the number of neurologists increased and neurology became so sub-specialised so they would all have tended to practise more independently than others in the sense that they would provide care for a wide range of conditions without referring as many patients to others.

3.67 Dr Craig explained that although Dr Watt was in a team of one:

... he never indicated to me that he wished to join another team, nor did anyone suggest to me that the teams should be reorganised ... Whilst it would have been possible to reorganise the teams it would have presented serious logistical difficulties because they were arranged around other clinics in multiple different hospitals and Trusts which would have been very difficult to change. There was therefore no momentum to change the teams.

3.68 The suggestion that it was incumbent on Dr Watt to state that he wished to join another team somewhat misses the point. As set out in the Part A section of the Verita report, Dr Watt did state on 9th June 2017, in a meeting with Dr Mark Mitchelson and Mrs Bernie Owens, the Director of Unscheduled and Acute Care, that he had difficulties because of lone working outside an established team. There is no evidence that he had raised the concern prior to that, as noted by Dr Craig. The point is, however, that it was also the responsibility of management to both identify and address the situation, given the clear and obvious benefits of team working and the dangers of a consultant working on his own.

- 3.69 In his response to the Verita investigation, Dr Watt referred to the team that he had been on, Team A, reducing to 1. In his oral evidence to the Verita Inquiry on 28th May 2019, Dr Watt stated in relation to this point as follows:

... Since then a couple of others – a friend of mine who works on the ward thought that Stephen Hunt worked with me for a time, but that may have been when he was sort of an acting consultant or locum consultant, so when he was made consultant he opted to go with, as I describe it, the “movers and shakers” team, which was John Craig and Jim [Morrow] at that time, so the guys that had a particular interest in epilepsy and Stephen -

52. Q: So they’re moving to specialism-based at that point?

53. A. A bit, but perhaps as much influence-based teams as – maybe also a team that was more of a work together team, so they maybe thought that they would get more support or maybe people that shared their own views; but for whatever reason, they were able to opt to work on a different team, rather than replacing someone who had left the team I was in. Then likewise, John McKinley I suppose could be viewed as a replacement for Mark Gibson, as he had expertise in movement disorders, and again, he ended up on the same large team, which I suppose even though none of them were professors had more of a professorial ward round feel.

54. Q : It sub-specialised, did it? You had teams around specialties, or not really?

55. A. The teams as they are now, John [Craig] and Stephen [Hunt] would be epilepsy, Seamus Kearney and John McKinley would be movement disorders. I’m not sure who else is in that team, there are about five or six of them

...

62. Q. You said something a few minutes ago, when these teams were forming a number of specialists said that they wanted to be in a team that shared their own views – that’s an impression – so, were you ever in a team that shared your views?

63. A. I was comfortable working with Mark Gibson and Stanley [Hawkins, probably more comfortable with Mark than Stanley, we had always got on well. Stanley was always hard to know what his thoughts were –

64. Q. Did you have a pal, did you consult with anybody –

65. A. Because Stephen Hunt had been a guy that maybe should have replaced Mark Gibson, even though he didn’t end up working with me, I still would have asked him to look after my patients when I was away, so that –

66. Q. In later years you were on your own –
67. A. Absolutely.
68. Q. So what was –
69. A. It was very difficult.
70. Q. You're going on holiday, what's the plan?
71. A. I had to ask Stephen [Hunt] if he would cover my patients.
72. Q. And the management didn't ensure that that had happened, or make an arrangement, or question it?
73. A. No
- ...
730. Q: You were talking about a guy from Bristol, Neil –
731. A. I probably got Neil wrong, it was a Professor in Cardiff, MS, talking about their MS MDT, and some of the other guys were also talking about it, maybe some of the ones from London, and they were saying that they had instituted an MDT to rein in some of their more maverick consultants or colleagues. I thought, why couldn't they have done that for me, or, if only they had done that for me, was my reaction to that.
732. Q. You wished you'd been part of an MDT –
733. A. Absolutely, or when this broke, rather than this being the consequence of it, it would have been –
734. Q. Did you raise that at all?
735. A. I did suggest that, in the course of the investigations in the Trust, before it got to this stage, but it would have been ideal if we had to have approval from an MDT for starting somebody – or if I had had to have approval, in fact, if we all had had to have approval equally, across the board, for starting somebody – MDTs for MS
- ...
740. Q. But there wasn't any mechanism in which you could tell people about –
741. A. No, that was coming - well, we had our monthly MS special interest group meeting which lasted an hour, and part of the reason for doing it was to bring along cases that you were wanting help with, with the diagnosis, but that didn't happen often, I didn't present anybody at that meeting. So there was a forum that you could potentially have done it, but it wasn't frequent enough and didn't last long enough.

3.70 On one view, the fact that Dr Watt raised his concerns about lone working for the first time in June 2017, suggests that he was not overly worried about the existing situation. The Inquiry Panel has not had the opportunity to hear from Dr Watt directly because of his medical condition, but the view of the Inquiry Panel is formed and shaped more by the evidence of the nurses, registrars and, to a limited extent, other consultants. Those who worked most closely with Dr Watt had the opportunity to contrast and compare his method of practice, as outlined above. The Inquiry Panel found that this was the most compelling evidence that Dr Watt working on his own for a number of years in Team A was unwise and liable to cause problems.

3.71 The Belfast Trust disagreed with the view of the MHPS case investigator. In its commentary, the Trust highlighted a number of matters. The Inquiry Panel has, in particular, taken note of the following points in the Trust's submission:

21. As Dr Watt himself explained, in-patient beds for neurology numbered less than 20. He had sometimes 10 patients, sometimes 2, sometimes no patients. The purpose of the in-patient neurology ward team structure appears to have been misunderstood and elevated to a level of importance that it does not bear. The in-patient ward team structure in neurology (neurology being predominantly an outpatient specialism, and with significant sub-specialisms) was not formed as some means to guard against the type of issues that have arisen in respect of Dr Watt, or any dangers associated with lone working. The structure was adopted in and around 2003 in response to the need to secure adequate nursing support for ward rounds, and in a way that fitted in with outpatient clinic schedules ...

23. The Belfast Trust was not asked about what it had to say on this issue before the comment was made by Verita. Had it been, or in response to seeing the comment in the report, the Belfast Trust would have made the following substantive points:

- a. Dr Watt was part of the Grand Ward Round each week and contributed to it;
- b. There is evidence that, when the situations arose, as they inevitably did, Dr Watt did work collaboratively with other consultants from different disciplines whose work intersected with that of the neurologist;
- c. The neurology in-patient team ward rounds were not a mechanism to manage risks;
- d. Had the neurology in patient ward rounds been a mechanism to manage risks, it is difficult to see how they would have identified any risks associated with Dr Watt.

3.72 The Inquiry Panel accepts that the genesis of the inpatient ward round and the designation of various neurologists into teams was not primarily as a result of pressure from neurologists but was a response to the need for adequate nursing support. Further, it is accepted that, particularly in the outpatient clinics, Dr Watt did work collaboratively with other consultants from different disciplines. The commentary later in this chapter in respect of the TIA clinic illustrates the point. Nevertheless, even taking all these matters into account, and viewing the question of isolation and lone working in a broader context, the Inquiry Panel believes that there were many signs of potential problems emerging, which went beyond just inclusion in the neurology inpatient joint ward round. The following salient factors have been identified by the Inquiry in this regard:

- (i) The Inquiry Panel struggles with the argument that the teams that were devised had a focus only on adequate nursing support. Evidence was received from Dr Hunt that before teams could be agreed, the neurologists had to attend an 'away day' and go through a mediative process because of the prior lack of agreement. When this meeting took place, Dr Hunt was a junior doctor and not a consultant. The Inquiry Panel can only conclude that the degree of contention was about far more than just adequate nursing support or the efficient running of clinics, but also included relationships between neurologists.
- (ii) The view of every consultant who appeared before the Neurology Inquiry was invariably that they were unaware of any significant problem with Dr Watt's clinical practice prior to November 2016. While there were a number of registrars who did raise concerns, these were not shared by the consultant body. At its height, the view would have been taken that Dr Watt was at one end of the spectrum of practice in terms of his approach to diagnosis and his reticence to accept that a patient was, for instance, suffering from a functional neurological disorder. Additionally, it was accepted that he would have been an outlier in terms of prescribing disease-modifying treatments ("DMTs") and would often wish to begin treatment in a more aggressive fashion than that of his peers. That analysis, however, did not lead to any degree of substantial concern on the part of his colleagues in their evidence to the Inquiry.
- (iii) When one then contrasts the views of Dr Watt's consultant colleagues with the evidence found by the RCP in its report, and the results of the recall process, it becomes apparent that a significant level of aberrant practice was taking place without the knowledge of his contemporaries. Either that means that consultants have not been forthcoming about their concerns or, alternatively, that they were so focused on their own patients and their own practice that they had limited interest or time to consider the work

of other consultants unless it directly impinged upon their own patients. The Inquiry Panel accepts the latter view on the evidence presented. In relation to Trust management, there needs to be a recognition that the extant systems in place failed to identify such a significant problem. The Inquiry Panel can only conclude that those systems did not operate properly. Dr Watt's problems did not emerge suddenly in late 2016. They were apparent throughout the relevant period, but despite referral to the DDCRM¹², the invoking of the informal MHPS procedure and a disproportionate number of complaints, there was little evidence that anyone realised that there was a significant clinical practice issue.

- (iv) Dr Watt had a prodigious workload and saw more patients than perhaps any other neurologist. Though this was to some extent self-induced, it led to a plethora of problems illustrated by complaints from patients about delay and a failure to carry out basic administrative obligations including responding to requests for reports. Any analysis of the complaints being received, including a GMC warning in 2007, should have caused the Trust to question why there were so many complaints against Dr Watt as compared with other doctors. Despite the existence of a Complaints Department, a system for storing complaints and a detailed process for responding to complaints, there seems to be little evidence that anyone asked the most basic of questions or queried whether Dr Watt's administrative difficulties might have something to do with the extent of his practice. This is set out in detail in the Complaints chapter. The Inquiry Panel believes, on the evidence presented and the documentation provided, that Dr Watt was regarded favourably by management because he played a critical role in helping manage the chronic problem of neurology waiting times.
- (v) While the Neurosciences Grand Round may have been a useful and necessary forum for the discussion of interesting cases, it was not, it appears, an opportunity for variations in practice to be analysed. On three occasions between 2014-2017, Dr Watt gave presentations in respect of diagnosing SIH and of the use of epidural blood patching. No significant issue appears to have been raised at the Grand Round and indeed few neurologists remembered even being there.

3.73 It is undoubtedly the case that inpatient ward round teams did not, and could not, of themselves, provide an answer to the problems of overwork and isolation. There was, however, something conspicuous about the fact that between 2012-2016, Dr Watt was effectively the only consultant in Team A following Dr Hawkins' retirement. That he was alone in Team A was clearly picked up on by his colleagues, but, once

¹² The DDCRM is a reference to the Belfast Trust Doctors and Dentists Case Review Meeting. A separate chapter comments on the evidence relating to Dr Watt's involvement with the DDCRM.

again, no one believed that any step needed to be taken to rearrange the existing teams or to change the personnel. Colleagues referred often to Dr Watt's '*different way of doing things*'. This came across to the Inquiry Panel as being an impression of idiosyncratic behaviour rather than anything which would give cause for concern. When the various strands of information are put together, it is, however, abundantly clear that it is not safe for patients or reasonable for Dr Watt to have been working in the manner that he was with the volume of patients that he cared for and the level of complaint that was apparent. There was no evidence given to the Inquiry Panel, which revealed that this potential problem with the team structure was ever sufficiently analysed or addressed.

- 3.74 The *status quo* in which Dr Watt was working from 2012 on his own in Team A, was accepted without challenge as the Trust strove to confront the problem of patients having to wait, often for years, before they could get an appointment with a neurologist in the NHS. The Inquiry Panel fully accepts the pressures on the existing system were, and are, intense and may, at times, be almost overwhelming. Nonetheless, there are steps that could have been taken, which, if properly implemented, would have led to an analysis being carried out in the higher echelons of Trust management and a recognition that Dr Watt was isolated in relation to working with inpatient admissions. That did not occur and the questions around lone working, and potential problems arising, were never asked at any level of management. In written evidence of 10th December 2021, Mrs Owens submitted that action could not be taken if matters were not brought to her attention. This is a consistent theme in the Trust's submissions, but the Inquiry Panel does not agree with the premise that a senior manager cannot be accountable unless they know about an issue. Dr Watt first raised a concern about workload and isolation on 9th June 2017 in a meeting with Dr Mitchelson and Mrs Owens:

Michael volunteered that he felt that his workload was pressurised and possibly out of control. He also stated that he felt isolated. He noted that he was not part of a team in terms of his ward rounds (previous colleagues no longer practising), and that in his clinics (bar the TIA clinic which he felt worked well), he was again the sole consultant. He made the following suggestions:-

- That another consultant, or team, practiced alongside him in clinics.
- That he was integrated into a ward team.

Michael voluntarily admitted that he "pushed the boundaries" of practice but did so in good faith. He admitted that he was sometimes quicker to make diagnoses than peers and more aggressive in starting treatments. He felt that colleagues were maybe too conservative and that he had concerns that delays in treatment had the potential to cause harm.

- 3.75 The issue of isolation was referred to in a subsequent letter from Dr Jack on 22nd June 2017 to Dr Watt:

I understand that when you met with Mrs Owens and Dr Mitchelson you indicated that you felt your workload was “pressurised and possibly out of control”, that you felt “isolated”, and that you “pushed the boundaries of good practice”. I understand that Dr Mitchelson arranged for you to be seen by the Trust Occupational Health Service, and I await a report from that consultation.

- 3.76 While reference to Occupational Health was clearly an appropriate step, the issue of lone working and isolation was not further analysed by the Trust. The Inquiry Panel notes with some alarm that in the Trust’s explanation, which was given to the Inquiry alongside the draft Verita report, there was little evidence that this issue had been adequately reflected upon.
- 3.77 There seems to have been little or no analysis of why it was that in June 2017, Dr Watt felt isolated and that his practice was pressurised and out of control. In contrast, some registrars who worked closely with Dr Watt could see clearly that Dr Watt working on his own was unwise and was something which, in hindsight, should have been addressed. It was also apparent to some of his nursing colleagues that he had a different method of working and was isolated.
- 3.78 The reality is, at the time, no one addressed it or even saw the need to focus on the situation, primarily because they believed it was for the consultants themselves to agree how the teams should be comprised. The fact is that alarm bells should have sounded earlier and the matter properly reflected upon. This does not seem to have occurred, either at that stage or subsequently. The Inquiry Panel accepts that it was also partly Dr Watt’s responsibility to raise the issue before he did in June 2017 when he was on the cusp of being fully restricted from clinical practice, but it is equally the case that management are not absolved in their responsibility simply because a consultant fails to raise a working practice, which is obvious and apparent.
- 3.79 In its written evidence of 16th December 2021, the Belfast Trust submitted that by June 2017, given Dr Watt’s impending full clinical restriction, there was nothing further at that point to analyse regarding Dr Watt and working in a ward team. The Belfast Trust points out that in 2019 it initiated a scoping exercise to identify small clinical teams and to assess what support arrangements were in place for those teams. A further survey was also due to be completed in January 2022.

The TIA¹³ Clinic:

- 3.80 Dr Watt was part of a weekly TIA clinic in which he did undoubtedly collaborate with other disciplines. It is noted that this factor is advanced by the Trust in its summary of 31st January 2021 (above) as evidence of team-working, at least in part. The Inquiry Panel did consider this but, while there was co-operation between various disciplines, the impression given by a number of witnesses, including registrars who participated in the clinic, was of Dr Watt being very much the ‘go-to’ person or central figure to whom other doctors deferred.
- 3.81 In her evidence of 11th December 2019, Dr Jack referred back to her own time as a geriatrician with an interest in stroke in the mid-2000s and recalled waiting outside Dr Watt’s room until he was free to discuss specific cases. Dr Jack stated:
- So, on the system [the patients] were all [Dr Watt’s] ... So, if you looked at my activity, they’d all be affiliated to him, even though I’d be there or Mark Magorrian would be there, but, actually, I’m responsible for those that I saw.
- ... if you had something that you needed to discuss, you’d just go and stand outside, and the next time he was free, you’d go in and talk, a bit like a reg would ... and you would see the new ones all ... He’d come in and he’d do reviews the whole time. We would see the new and then we’d start to pick off the review file.
- 3.82 Dr Mark Magorrian was a consultant in the care of the elderly with a special interest in stroke, which involved a TIA clinic once a week. In his evidence to the Inquiry Panel on 1st May 2019, Dr Magorrian explained:
- From 2006, that came to be, and I started doing the TIA clinic on a Thursday morning, and that was the clinic which Michael Watt had been the lead clinician at for years and had been there when I was a registrar in training. So, he was – he had been the main consultant at it.
- 3.83 Dr Cathy Patterson, who was also a consultant geriatrician with an interest in stroke, explained to the Inquiry Panel on 14th May 2019 that previously Dr Watt and, for a limited period of time, Dr Ailsa Fulton, had provided neurological input to the stroke clinic. She indicated that the clinic was now operating only with herself and Dr Magorrian and they would be presently seeing less than half the number of patients they would have done when Dr Watt had been a part of the clinic team.
- 3.84 Dr Karen McKnight, now a Consultant Neurologist in the Southern Health & Social Care Trust, was formerly a registrar working with Dr Watt in the TIA clinic and

¹³ TIA is an acronym for transient ischaemic attack.

highlighted in her evidence to the Inquiry Panel of 12th November 2019, just how busy the TIA clinic had been:

Initially, the TIA clinic was a very busy clinic, and probably the busiest clinic that I did. [Dr Watt] was supervising a lot of staff, so he had – there were stroke physicians, there were care-of-of-the elderly physicians there. I was there as a registrar. There was a nurse. So, there were a lot of doctors and quite a number of patients booked into each time slot, but then there were a lot of doctors to see them.

- 3.85 Dr Jamie Campbell, in his evidence to the Inquiry Panel on 9th January 2020, referred to his raising at a registrars' meeting of the busyness of the TIA clinic where Dr Watt was the lead consultant and the difficulties that that posed for training registrars. This meeting is discussed in the Concerns chapter, but in his evidence, Dr Campbell indicated that his colleagues would have discussed openly Dr Watt's clinics. Dr Campbell told the Inquiry Panel:

Dr Campbell: People would've said they disliked [the TIA clinics]. People would've said they, I think it's fair to say, hated those clinics – for various reasons ...

Mr Lockhart QC: Can you remember any of your colleagues using the word "hate"?

Dr Campbell: "I hate the TIA clinic" was common parlance. I must clarify not in any way the patients attending that clinic ... or the pathology being seen, but the running of that clinic. I think most of my colleagues – well, I would surmise that most of my colleagues would agree with that point.

Professor Mascie-Taylor: And had been party to that sort of discussion.

Dr Campbell: Yes ...

- 3.86 In the view of the Inquiry Panel, it is correct to point out that Dr Watt did co-operate and liaise closely with other consultants at the TIA clinic. The evidence, however, would suggest that Dr Watt was very much the lead consultant, to whom other physicians deferred on neurological matters. While Dr Ailsa Fulton was a fellow Consultant Neurologist who would have been present for part of the relevant period, Dr Watt was normally working as the only neurologist in the clinic. It is also significant that multiple witnesses gave evidence that Dr Watt tended to see the review patients whereas other consultants and registrars were seeing the new patients. This would have meant that the opportunity for colleagues to have sight of Dr Watt's practice as patients returned to the clinic over time would likely have been limited. The experience of the registrars suggests that the clinic was one that

they found particularly difficult because of its busyness. In that sense, therefore, Dr Watt's management of patients would not have been ordinarily challenged as one would expect in a peer review situation. The Inquiry Panel has, therefore, concluded that the fact that Dr Watt liaised with other consultants at the TIA clinic had limited relevance to the overarching problem of lone working and a lack of peer review.

Management Attitude:

- 3.87 In assessing the management attitude to lone working and the recognition of a particular problem in Dr Watt's practice, it is essential to begin with an understanding of the context which managers faced. The overarching concern of the Service Manager, Mr Gerry Atkinson, and the Co-Director, Mr Frank Young¹⁴, was to address not just budgetary constraints, but the intense pressures on the neurology waiting list. In a very real sense, their effectiveness was assessed by the number of patients that were seen and whether waiting lists could be reduced. This, of itself, is perfectly understandable.
- 3.88 The Inquiry Panel noted that Service Managers did not feel sufficiently confident to impose team working on consultants, despite its obvious benefits. The approach taken was that team working was desirable, but not necessary. The Service Manager would not have regarded his role as considering how doctors arranged their working practices within their own specialty. In his evidence to the Inquiry Panel, Mr Atkinson recognised the benefit of working in teams, but made it clear that it was not really something that was part of his responsibility. In his evidence of 22nd January 2019, he stated:

Professor Mascie-Taylor: One retired and one died, as far as I understand it, which left a team of one for quite some time. So, why was that permitted? Why did Michael Watt carry on in a team of one?

Mr Atkinson: I don't know is the answer to that. I was only aware of that sort of fairly recently about sort of the team structure. I mean, I've heard about the teams before, but I didn't appreciate that Michael wasn't part of a wider team and was actually working on a team on his own.

Mr Lockhart QC: If you'd known about that, Gerry, what would you have done? You know, what I'm concerned about here is that everyone who has spoken to us who has information – any of the neurologists would've indicated that that was an issue, and some of them have said various things about him, but it seems to us that it's a pretty obvious thing that, if one consultant is working

¹⁴ Co-Director of Unscheduled & Acute Care.

on his own, while the other two have got two teams of five, there's a danger of someone who has got particular views or particular practices suddenly just veering off.

Mr Atkinson: No, I would agree, and, like I said earlier, there are benefits to be had from working in a team ...

Professor Mascie-Taylor: You can just take two views. You can either say that, given what I think everyone accepts about lone practitioners, they are more at risk of varying from the norm, let's put it like that. Is it for the practitioner, is it for the consultant, to say, "Please can I join one of these teams?" i.e. the onus is with the consultant, or is it for the organisation to say, "Well, we believe that this is an effective way of working and, therefore, you are going to join one". Do you see the point of my question, which is –

Mr Atkinson: I do see the point of the question.

Professor Mascie Taylor: - where is the responsibility for that?

Mr Atkinson: I don't know whether the team structure is one that is imposed or suggested by the organisation or if that is a way that the consultant body decides to organise themselves, but as I say, clearly there are benefits in working in teams in that way ... I think he should've been part of a bigger team. He should've been part of a team. He wasn't part of a team at all, because you can't be in a team if you're on your own.

- 3.89 The Inquiry Panel accepts that Mr Atkinson, in good faith, believed that the issue of team structure was a matter for the consultants themselves. The Inquiry Panel considers that this was a misunderstanding of the management system that was in place, although the matter was primarily within the province of the Clinical Director.
- 3.90 This issue was also explored with Mrs Owens, the Director of Unscheduled and Acute Care. As an individual who was, at that time, just one level below the Trust Board and who reported directly to the Chief Executive of the Trust, she carried a wide array of responsibilities, some of which included ensuring patient safety. How was it then that Dr Watt was working in a team of one consultant, while others were in teams of five? In written evidence provided to the Inquiry on 10th December 2021, Mrs Owens highlighted two examples of her dealing with problems in a clinical team when the issue was raised with her. She pointed out in her evidence that she could not deal with an issue of which she was not aware (as explained at paragraph 73 above, the Inquiry Panel does not agree with this premise). Mrs Owens recognised that there were obvious dangers with lone working in her evidence to the Inquiry Panel of 6th December 2018:

Professor Mascie-Taylor: What do you make of that then given you have said about multi-disciplinary teams?

Mrs Owens: Yes. Obviously that would be, and hindsight and everything, there's always risks where individuals are working on their own.

Professor Mascie-Taylor: What I really don't understand is how we got to a situation where we have that split one, five, five. Why did that happen? What caused that situation and then what allowed it to continue?

Mrs Owens: Again my understanding has been that Michael Watt in terms of how he operated and functioned within that was a bit more -- the others were meeting at various times and there was a discipline and a rigour around that and Michael wasn't as, what's word I want to say, as organised probably to be there. He didn't always start on time. I think, to be fair, he had more of an out-patient workload and less in-patients is my understanding, maybe because he was just one, and the others found it difficult to link in with his practice.

Professor Mascie-Taylor: In retrospect I suppose the answer is obvious really. It is hard to see, I think, from where we sit how anyone might have thought that was a sensible thing to do. It's easier to see it wasn't sensible in retrospect. I absolutely see that. Given what we know about lone practitioners there's usually a reason why they are lone practitioners. I think you're hinting at some of the reasons you think he might be a lone practitioner. It often relates to the way they want to work and may also relate on some occasions to other people's perception and not wishing to work with them. Is that the case here?

Mrs Owens: I believe so. I think there's an issue around his wanting to work in a team and then how he was more, I think from my understanding, chaotic in his practice and in his organisation around that, and others found that more challenging. Yes, on hindsight and whatever, and I have been obviously having conversations with John in particular around this and the learning would be a flag should go up.

Professor Mascie-Taylor: Do you think anybody ever took him on over it? This may or may not be fair, but one has the impression, you used the word chaotic; he chose to work in a particular way, he chose not to be appraised, he chose this and he chose that. That all seems to somehow be accepted or tolerated perhaps is a fairer word than accepted. Do you think that's fair?

Mrs Owens: Yes, although I do know that John (Craig) as his clinical director was having conversations with him around his way of working in particular for his out-patients, as I said earlier. I think John would obviously be the best to answer exactly the level of challenge and whatever.

- 3.91 The Inquiry Panel believes that it is too easy to introduce an artificial dichotomy between the managerial responsibilities of those in the higher echelons of the Trust and those who are medical managers. Those at Co-Director and Director level, such as Mr Young and Mrs Owens, as well as the Service Manager, Mr Atkinson, have a responsibility to consider and ensure patient safety. That responsibility cannot simply be referred to the Clinical Director.
- 3.92 A Clinical Director may have had the opportunity to consider the importance of team working but, as the Inquiry Panel has already noted, Clinical Directors were often attempting to carry out a managerial role with limited hours and the burden of their own practices. The Inquiry Panel recognises that, in Neurology, there was little scope for reflection. There was a 3-year waiting list and the focus of managers was on reducing waiting lists and obtaining access for patients.
- 3.93 It again needs to be stated that the pressure on the neurology waiting lists was intense and the strong impression given from the evidence of the Service Manager and others within the Neurology Department was that Dr Watt had an extraordinary work ethic and saw a vast number of patients. As pointed out by Dr Fulton, and referred to above, Dr Watt was held up as *“the poster boy”* by management, because *“he was seeing so many more patients than the rest of us”*.
- 3.94 The Inquiry Panel has concluded that no one in management saw it as their responsibility to ensure that a consultant was not working on his own. In hindsight, and having regard to what subsequently transpired, the point seems obvious, but the reality at the time was that those in authority believed it was ultimately a matter for the consultants to arrange. This was, in the view of the Inquiry Panel, unacceptable and unsatisfactory.
- 3.95 The Inquiry has not been presented with any evidence to suggest that the dangers of lone working were considered at any stage. The Inquiry Panel considers that this was a major governance failure and came about because of a laissez-faire approach by management to the working arrangements agreed between consultants.
- 3.96 The Inquiry Panel noted, for instance, the evidence of Dr Ken Fullerton, Associate Medical Director on 20th November 2019, who gave a strong view on the working arrangements within neurology. Dr Fullerton indicated that he was unaware that Dr Watt was working on his own:

I would have been concerned about it and the first thing I would have done would have been to talk to John Craig, who was the Clinical Director, and ask was he aware of it and did he think this was a good idea and implied rather strongly that I didn't think it was a good idea.

- 3.97 In his oral evidence on 14th November 2019, Colm Donaghy, Former Chief Executive of the Belfast Trust¹⁵, noted:

There are some areas where it [multi-disciplinary team working] is a requirement within the NHS systems or, actually, it's culturally a requirement: it's now become such an accepted practice that not to do it would be extremely unusual and probably wouldn't be tolerated by the individual's peers.

- 3.98 Professor Ian Young, then Assistant Medical Director, recognised, in his oral evidence on 9th April 2019, that there were some specialties, where team working would not be possible because of the limited number of specialists working in Belfast, but was strongly supportive:

I think all clinicians should work as part of multi-member teams. I've no doubt about that at all. I think, occasionally, there are some micro-specialties where there might be challenges in achieving that. However, I think, in that case, individuals should work as part of a multi-member team with other professionals as close to their area of practice as possible.

- 3.99 Professor Young did recognise, however, that all consultants should work in teams. He noted that no doctor's practice is so specialised that it cannot at least be sense-checked:

There's a constant check and balance and if anybody's practice was out of sync, you would very rapidly discover that.

- 3.100 He further proposed that if every doctor shared patients at clinics and built in a system of random audits and three-monthly swapping of clinics, this would be of enormous benefit. Commenting on the possible reluctance of some consultants to participate, he said:

I would be extraordinarily disappointed if any doctor would decline the offer – indeed, it would immediately raise concerns in my mind about their practice.

- 3.101 In his oral evidence on 16th January 2019, Mr Ray Hannon, Consultant Vascular Surgeon and Associate Medical Director in the Belfast Trust, commented on what one might term as the 'norming effect' of colleagues challenging each other to ensure good decision-making:

These are all retrospective. In other words, something has happened that the system has caught after it happens or gets recorded. I think probably the best way to try and keep practice safe is, in advance of the surgeon doing the wrong operation, a multi-disciplinary team. The more working you have and the more

¹⁵ Mr Donaghy was Chief Executive from 2010-2014.

people to sort of say, 'You're gonna do what? No, you don't want to do that do you?' And then if that sort of decision making comes up frequently, somebody, you would hope, somebody senior in the team would say.

- 3.102 In his evidence on 1st May 2019, Dr Ferghal McVerry, Consultant Neurologist in the Western Trust, recognised the difficulties with solitary practice, but highlighted the importance of consultants being proactive in seeking out team working. The Inquiry Panel noted that Dr McVerry's job plan did not include team working, but, nevertheless, he gave evidence that the importance of working alongside colleagues was essential to ensure efficiency:

We should be aiming to work with multi-disciplinary teams to reduce, in your words, aberrant practice ... so the way to do that would be to work with oversight and to have mechanisms enshrined to allow that to occur. We do that currently because we're aware of the fact that working in solitary practice is something that you would want to avoid, but it's something that requires, in my experience, something proactive ... by the consultants. I never had an MDT in my job plan or whenever I started working as a consultant but it's something that I realised a while ago we should have to make our work practice more efficient for ourselves ... but that was something that required initiative on my part and Dr McCarron's part, who I worked with. So that's not something that was an assumption on any job description whenever I started as a consultant.

- 3.103 Beyond putting effective team working in place, the Trust requires appropriate processes and mechanisms to ensure that concerns can be raised and acted upon. The system in place during the relevant period was such that, as much as various managers may have thought that team working was valuable and effective, no one appeared to believe that it was their responsibility to take action. This was true at every level of management.

Job Planning:

- 3.104 Each consultant was required to agree a job plan with the Clinical Director. The extent to which Dr Watt perceived himself to be subject to this requirement as he continued on what was referred to as "*the old contract*" is unclear. The arrangement placed Dr Watt on less programmed-activity hours, but it did not absolve him from having a job planning meeting with the Clinical Director and Service Manager. The issue was raised in 2009 when the following written interaction took place between Dr Watt and Dr Morrow, the then Clinical Lead:

As I am still on the old contract I do not need a job planning meeting.

Michael Watt

3.105 Dr Morrow responded:

Michael

I think you do need a job planning meeting-but don't worry we have no control over you (it is a formality)

Jim

3.106 Given that in 2009 Dr Morrow was the Clinical Lead for Neurology and had responsibilities in relation to helping provide a safe and efficient neurology service, his attitude to job planning by Dr Watt was surprising. It is unfortunate that the Inquiry has not had the opportunity to hear from Dr Morrow because of a medical condition. On the basis of the documentation, the extract above suggests that Dr Morrow had a low view of the value of job planning and reinforces the perception that it was a matter of little importance compared to the more pressing challenges of providing for and seeing patients.

3.107 The Inquiry Panel also considered job planning with Mr Atkinson, the Service Manager:

Professor Mascie-Taylor: So, job planning: how did that work?

Mr Atkinson: Dr Craig and I would've sort of met with individual consultants.

Professor Mascie-Taylor: Right. So, the two of you did that together.

Mr Atkinson: We did that together.

Mr Atkinson: In my previous service manager post in dentistry, I wasn't involved in the meetings with individual consultants, nor with the previous Clinical Director in neurosciences, but it was something I did with Dr Craig. Whether I offered to help him with that or whether he asked me, I can't remember. But certainly, I was very happy to get involved in the job plan meetings.

Best practice is to do those on an annual basis. Now, we never really got there in terms of succeeding in meeting with every consultant over a 12 month period. And, for a time, we did have a programme in place, where we did have regular meetings. We gave over every Tuesday morning, or whenever it was, to job plans, or every other Tuesday. But then there's other pressures, and we're pulled in various directions, and other priorities so we always got a bit behind with the job planning.

Professor Mascie-Taylor: And how much did job plans change from year to year?

Mr Atkinson: Most of them would've changed.

Professor Mascie-Taylor: They would've done, yes.

- 3.108 Mr Atkinson confirmed that it had been some years since a job planning meeting had taken place with Dr Watt:

Mr Atkinson: The last job plan meeting with Michael, Dr Craig and myself was in 2014; I think June. And this was sort of different to the other consultant staff. He was part of the old consultant contract. So it was basically a sheet of paper with you know, there's the sort of diary for the week and it didn't change from year to year. So that was the difference there.

We did try and have another job planning meeting with him around the end of 2015 but the dates did not suit Michael and we never got around to actually doing it again _ Professor Mascie-Taylor: What was the implication of him being on the old contract?

Mr Atkinson: I don't know. I mean. I know there's very few consultants remaining in the Belfast Trust— they were given a choice to move on to the existing contract. I don't know what benefit was to be had for either of them but given that the vast majority of consultants moved to the new contract, I would've assumed that there was benefit in moving to that contract. So I don't know and I don't know whether he declared to anybody or understood why he wanted to remain with the old contract, but nevertheless he did_

Professor Mascie-Taylor: Do you think the Trust's attitude towards people on the old contract and the new contract were any different? What do you think more?

Mr Atkinson: Well it didn't make any difference to me He still had his clinic sessions, you know, his week carved out in such a way that we knew where he was for different parts of the day and each day of the week —

Professor Mascie-Taylor: Right, so in effect —.

Mr Atkinson: — and a process was in place to change that, you know, if he decided to change it. I mean, most of the changes to job plans would be in relation to one of the consultants taking on a new role, maybe they would take up educational supervisor, audit lead, whatever that was, and coming with that would've been additional PAs or parts of PA to account for that, but Michael didn't, you know — his didn't change.

Professor Mascie-Taylor: It didn't change in your view. The process was pretty much the same.

Mr Atkinson: No, it didn't change at all.

- 3.109 The Co-Director, Mr Young, was equally clear that the issue of job planning was a matter for the consultants, despite the fact that his own job description covered all aspects of management within the division. He told the Inquiry Panel on 22nd April 2021:

Mr Lockhart QC: Sure. Similar kind of questions about workload and job planning, he had no job plan since 2014. Were you aware of that?

Mr Young: No.

Mr Lockhart QC: Right. Should you not have been aware of that?

Mr Young: The job plans were agreed very much by the CD and the team themselves when they looked at the available slots that they had ...

Mr Lockhart QC: Do you not need to be kept informed of the fact that job plans are outstanding or somebody hasn't completed a job plan, because presumably they all have a template they are meant to work to. There's all sorts of concerns about who is going to the private sector. There were issues about over work, or concern like that. Is that not something that you would have been informed about on a regular basis?

Mr Young: No. Job plans isn't something that I would have been briefed on, on a regular basis, because, generally speaking, most of them worked very well.

Mr Lockhart QC: It is the whole idea again, I am sure Hugo will come in on this, but it is aware of being responsible for something and ensuring that a system is in place. Yet, here we find with Dr Watt there was no, it was very difficult to get him to do that, and yet you are responsible for it but nobody tells you about it.

Mr Young: Yes.

- 3.110 What is striking is the lack of job planning involving Dr Watt throughout his consultant career and during the relevant period between 2006-2018. There is also a dearth of documentation. In contrast, Dr Watt's work ethic was such that he was highly valued by those in management who were increasingly concerned about addressing huge waiting list pressures. In his evidence of 18th November 2020, the Service Manager, Mr Atkinson, stated:

Mr Lockhart QC: As I understand it, at no point, prior to Dr Watt going off in July '17, was there ever a discussion about the heaviness of his workload, or the fact he was doing too much?

Mr Atkinson: No.

Mr Lockhart QC: There was a discussion, at one stage, about his clinic and that was looked at, they brought him down to a, kind of, normal template, and he wanted to put it up again because he got bored.

Mr Atkinson: There was. That's right. Dr Craig and I met with him, or was it done through email, I can't remember. I do remember that his clinic template was reduced and he stopped seeing as many patients. I can't remember what

the background to that was, was it raised as a problem by him or by someone else, or what the issue was, but certainly, yes, that was done.

Mr Lockhart QC: Then it went up?

Mr Atkinson: Then it went up again, yes.

Mr Lockhart QC: It would be fair to say, you were personally never concerned, and I don't mean this in any way a pejorative sense.

Mr Atkinson: No.

Mr Lockhart QC: In some ways your stellar man?

Mr Atkinson: Salvation.

- 3.111 The issue of clinics that were overbooked was a periodic problem, which emerged at various relevant points between 2006-2016. It was the source of a significant number of complaints and, at certain points, efforts were made to try and impose a clinic template, which would have restricted the number of patients attending a particular clinic. Unfortunately, any efforts in this regard provided only a temporary fix. Dr Watt preferred to be busy and found the restrictions on the number attending reduced his sense of professional fulfilment, as explained by his secretary in her evidence to the Inquiry Panel of the 29th August 2019. It was Dr Watt who unilaterally increased the numbers attending his clinics following a reduction that had been agreed, although Dr Watt's secretary could not recall the precise date when this had occurred. The issue of Dr Watt exceeding agreed clinic templates was never properly addressed. Dr Watt appeared to lack insight although, in the days prior to his restriction in June 2017. He began to talk much more freely in formal meetings about the difficulties that he had encountered, the pressures he endured because of his workload and the number of patients who were seeing him at clinics.
- 3.112 Job planning is meant to be a way in which the obligations and responsibilities of the consultant can be planned in a manner which is efficient for the Trust and manageable for the doctor. In this regard, when taken seriously, there is much more a performance management dimension to the process than, for instance, appraisal. Dr Watt stayed on the old contract for whatever reason. He was reticent to attend job planning meetings and the Inquiry Panel notes that at no point does any individual within the management structure address this. As outlined above, Dr Morrow seems to have tolerated the situation. When Dr Watt did attend, the meeting, in the view of the Inquiry Panel, it appeared to be a formality and no job planning had taken place since 2014. There was, therefore, no appreciable benefit to the meetings, nor was there any real opportunity to discuss pressures of work or a concern that

Dr Watt was seeing too many patients at his clinics. In contrast, Dr Watt was clearly viewed as a real asset to the Neurosciences Division because of the huge number of patients he saw. This dynamic was prevalent throughout the relevant period and, in the view of the Inquiry Panel, contributed to the perception that certain contractual obligations for consultants were not mandatory.

Conclusions and Findings:

- 3.113 The consensus view among both neurologists and managers was that working in consultant peer review and multi-disciplinary teams had proved to be an effective and efficient method of working. The Inquiry Panel heard evidence of how teams B and C sat down together and discussed each other's patients before conducting a joint ward round.
- 3.114 Despite an apparent acknowledgement of the theoretical efficacy of team working, this does not appear to have been recognised as a professional obligation within the Neurology unit in the Belfast Trust. Although there was evidence that those at Associate Medical Director level would have been surprised if they had been aware that Dr Watt was working on his own, the Inquiry Panel is not satisfied that there was insufficient knowledge for Trust managers to act. If there was insufficient knowledge on the part of management, then the Inquiry Panel considers that this, in itself, was a basic failure to inquire and understand the team setup. On the basis of the evidence received, the Inquiry Panel is satisfied that a culture had evolved where the focus was almost entirely on managing patients and dealing with demand. In this context, there was little or no consideration at any management level of the dangers of lone working.
- 3.115 It is not, however, the case that those who were working alongside Dr Watt at a more junior level, failed to notice the problem of isolation. Evidence from registrars revealed that they were fully aware of the practice and there were numerous examples of registrars comparing the experience of working alongside consultants in Teams B and C, as compared with the experience of working alongside Dr Watt.
- 3.116 Although Dr Watt was respected for his acumen, his style was palpably different. This was recognised by a number of the nursing staff who commented on the unusual dynamic. The fact that registrars would tend to gravitate towards Teams B and C was also noticed and commented upon by nursing staff.
- 3.117 The Inquiry Panel concludes on the basis of the evidence that:
- (i) Peer review has a clear normalising effect.

- (ii) The sharing of opinions in real time contributes to improved diagnosis and management of patients.
- (iii) Peer review also contributes to learning and keeping practitioners up to date.
- (iv) Team working had an overall beneficial effect on patient safety.

- 3.118 The Service Manager, the Co-Director and the Director of Acute Services reflected in their evidence that the absence of team working in respect of Dr Watt was a problem, which needed to be addressed. They did not, however, consider that team working or indeed job planning were within their purview. At the same time, the Clinical Director, who would have had responsibility, together with the Service Manager, to discuss consultant job plans, had limited opportunity to alter existing working arrangements. The fact that there was no job planning meeting with Dr Watt since June 2014 illustrates the point. The practice which seemed to be, as far as Dr Watt was concerned, a “*formality*” appeared to have negligible value in his case. The communication between management and the Clinical Directors was focused on the ever-growing demand for neurology services as well as addressing budgetary constraints. In this regard, Dr Watt would have been perceived as a significant asset. He saw as many, if not more, patients than anyone else and helped alleviate the chronic problem of waiting lists. Little thought or reflection was given to the fact that he was working on his own in Team A, and that such an arrangement was unwise and, as it transpired, ultimately problematic. It would also have increased the opportunity for other health professionals to have observed Dr Watt’s practice.
- 3.119 Dr Watt clearly did not see value in job planning. At various points he believed that he was not required to carry out same. Nobody at any level of management ensured that he fulfilled what was a contractual obligation to the Trust. The seemingly optional nature of peer review working permits the endurance of a culture where lone working is still accepted without comment. The dangers of lone working were recognised by various witnesses and yet the Inquiry received little evidence that the existing arrangements within neurology were a matter of immediate concern to Trust managers.
- 3.120 Consultant neurologists, for the most part, were incurious and, although recognising that peer review and MDT working was helpful, saw little need or requirement to insist on same. The Inquiry Panel noted that Dr Hunt, although initially assigned to Team A, was quite free to transfer to another team on the basis that he preferred working with Team B. In that sense, consultants were somewhat autonomous and could decide unilaterally to change their team-working arrangements without

management interference. In this regard, consultants tended to perceive themselves as members of what might be better described as a voluntary coalition, rather than participating in an assigned team. Dr Hunt's experience illustrates this well.

- 3.121 A further difficulty was that, within Neurology, the Clinical Director or Clinical Lead did not view their role as managerial, or at least not in the sense that would be consistent with common conceptions of management within an employment structure. Relationships within Neurology still echoed earlier times, where the consultant's responsibility for a patient tended to occlude analysis and management. The fact that Dr Watt could continue working on his own in Team A for a period of 6 years is, of itself, evidence that there was a problem.
- 3.122 A dynamic existed in the relationship between general managers and clinicians that allowed a gap to develop between what managers were held to be responsible for and what happened in practice, as illustrated by the following exchange between Professor Mascie-Taylor, the Co-Panellist, and Mr Frank Young:

Professor Mascie-Taylor: Did you ever say to any of the doctor managers, 'I am a senior general manager and I am responsible for the safety of my patch, that is part of my job. I am looking to you to assure me that the consultant practice is safe'. Was that conversation ever had?

Mr Young: No.

- 3.123 Later in the interchange, Mr Young was asked about the way in which he was reassured about patient safety:

Professor Mascie-Taylor: The general manager has to make it explicit to that doctor manager that they are looking to them to reassure that manager about the safety of the practice, because that's where the gap appears to be. The general manager says, as you have said, 'I am frenetically busy. I am running around all the time. I am trying to look after the beds. I am trying to look after the staffing. I am trying to look after the budget. I am working 12 hours a day on a good day', and the doctors are saying 'well, we are not the managers'. So, somehow there is a hope, an optimistic hope that everything will be safe, which is not the sort of optimistic hope that you apply when you are thinking about beds or budgets ... But the same sort of rigour doesn't seem to apply to patient safety. Is that a fair analysis?

Mr Young: In hindsight, yes. It was a broken system. People were working extremely hard. People were doing the very best that they could in the time that they had, but, and I will say it again, I don't think there was enough protected dedicated time that these kind of things could be worked through, not just within my area, but for all of the clinical services where you have so many

consultants who are single handed or specialists, so that we can actually audit it properly ...

- 3.124 The fact is that the pressures on the system were such that a disconnect developed between a manager's formal responsibilities and what occurred on the ground. If the focus was on seeing patients and reducing waiting lists, then that was how a manager invested their time. The question of patient safety was to some extent taken on trust. In the majority of instances this may not have been problematic, but the absence of scrutiny made it difficult to identify aberrancy when it arose.
- 3.125 It is the case that establishing peer review in outpatient clinics, where most neurology patients are assessed is a much greater challenge than doing so in an inpatient setting. Where arrangements for shared clinics are put in place many of the advantages of peer review can be appropriated.
- 3.126 The Inquiry Panel understands that there was, and is, a particular focus on reducing waiting list times. It is unsurprising that doctors like Dr Watt, who demonstrated a remarkable work ethic, are applauded. There is a danger, however, that over-confidence in the ability or acuity of a Trust consultant can lead to obvious anomalies being overlooked or accepted without comment.
- 3.127 In the Belfast Trust Neurology Department, audit appears to have been sporadic and lacking structure. The picture which emerged from the evidence was one where clinicians audited areas of interest to them, rather than performing a structured audit as part of a coherent plan driven by safety and quality. During the course of the Inquiry, when sight of the neurology audits was requested, it was noted that they were not readily available within the Neurology Department, or indeed within the Trust centrally. If audit is going to be part of a consultant's job plan, then it should be carefully thought out and part of a joined-up team approach within departments.
- 3.128 The Inquiry Panel is required under the Terms of Reference to review "participation in processes to maintain standards of professional practice". After the retirement of Dr Hawkins in 2012, Dr Watt was essentially working on his own in Team A over a period of years. The teams that were devised were to assist nursing staff working in the neurology unit (Ward 4E) in the Royal Victoria Hospital. Over those years, there was no clinical audit, which was targeted or specific enough to identify any problem with Dr Watt's practice. Peer review was not a feature of neurology practice and though the Grand Round Meeting for Neurosciences had an important educational role, there appears to have been nothing that raised any concern about Dr Watt. While Dr Watt was co-operating with other consultant colleagues in the TIA Clinic, the evidence would suggest that he was being deferred to on any neurology matter.

- 3.129 The reality is that Dr Watt was working for a large part of the time on his own and this was not identified as a problem by management. The Inquiry Panel is satisfied that, had Dr Watt been working alongside his consultant colleagues, unusual practices could have been identified and discussed. Dr Watt had, himself, complained in June 2017, during his interview with Mrs Bernie Owens and Dr Mark Mitchelson that he was struggling because of lone working outside an established team. He repeated the observation in his November 2017 appraisal.

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Vivienne Toal advised the meeting that Heather Trouton had chaired the Sub-Groups on 8 November 2023. She explained that the meeting had been on a “virtual meeting”. She advised that 20 colleagues from across the membership of the four Sub Groups had attended the meeting. She added that Elaine Wilson the Director of Planning, Performance and Information had been also joined the meeting. At the outset of the meeting, Heather Trouton said she had shared information detailing the Programme of work undertaken by the External Reference Group (ERG) she had done this she said by taking the meeting through Presentation she had prepared. She said she had explained to the meeting that the purpose of the ERG is to fulfil the role of a “Critical Friend” by providing independent challenge and support to the Chief Executive and Directors who were leading the Southern Trust’s Improving Organisational Effectiveness Programme. She explained she had advised the Sub Groups representatives that the central aim of this Programme is to improve organisational health, maximise safety, quality and the experience for patients / service users and staff by identifying areas of concerns highlighted by the Inquiry into Urology services. Heather continued that she also explained to the meeting that the External Reference Group (ERG) had identified four themes which had led to the formation of the four Sub Group:

- Patient Safety and Quality, this Sub-Group led by Heather Trouton and Mary

Hinds

1 come to this in a moment:

2
3 "...the subgroup representatives that the central aim
4 of this programme is to improve organisational health,
5 maximise safety, quality, and the experience for 14:55
6 patients and service users and staff by identifying
7 areas of concerns highlighted by the Inquiry into
8 urology services. Heather continued that she also
9 explained to the meeting that the External Reference
10 Group had identified four themes which had led to the 14:56
11 formation of the four subgroups."

12
13 And they are set out there as the Patient Safety and
14 Quality Subgroup, the Governance Subgroup, Data
15 Analytics, and Culture and Leadership. 14:56
16

17 So just help us to better understand this. So the
18 External Reference Group, you've described it's
19 membership, come together at some point in 2023.

20 A. Yes. 14:56

21 161 Q. And have a series of meetings, and it's due to conclude
22 it's work this month. Is that right?

23 A. Yes.

24 162 Q. And we see, just scrolling back down, please, or back
25 up, we see that it's being described as leading the 14:57
26 Trust's Improving Organisational Effectiveness
27 Programme, and also assisting the, as part of that,
28 assisting the Trust to improve against the areas which
29 are the subject of this Inquiry. So is it - tell us

how it works and what is the, if you like, the end game for the External Reference Group? Is it, for example, going to produce a report of recommendations or is it not that kind of group?

A. It's not that kind of group. And what it does is, it has led - it has helped - it has led the thinking in relation to this rather than the doing, if you know what I mean? So it's there to stimulate us to think and to guide us towards improvement and to think how things might be done differently.

So in the spirit of all of this, and given that this started out with concerns about a blind spot, what we will do and, again, it's the end stages of development at the minute, is we - those of us from the Trust, and that's myself, the Director of Nursing, Heather Troughton; Director of Medicine, Stephen Austin; Vivienne Toal, who is the Director of HROD, and Elaine Wilson, we will - and Jane McKimm who leads out in the Inquiry; and Margaret Higgins, who is now Director for Transformation and Improvement - we are putting together a report on where, what our progress has been over the last year with the involvement of the External Reference Group to report back to them to say, you know, "These are the problems that we brought to you in terms of what concerned us in relation to the Inquiry and what you heard yourselves", given that Vervan does, you know, an update in relation to each of these hearings, "this is what we heard from you and now we're

1 reporting back to you to make sure that what we said,
 2 what we all heard actually aligns and that we've got
 3 this right". So they won't produce a report, we from
 4 the Trust are producing a report, and then we will
 5 sense check it with them to make sure that we're all on 14:59
 6 the same page and that we have, you know, heard their
 7 suggestions and guidance in relation to this and that
 8 they can see that we have taken that on board and are
 9 enacting it as best we can as a bigger group.

10 163 Q. So can you put that to an example? We can see, and 15:00
 11 maybe I'll bring it up now, it might be helpful to
 12 assist the discussion around this, Veryan Richards, one
 13 can see from the papers supplied that she's following
 14 very intently the questions I'm asking of witnesses and
 15 the answers that come back, and the questions that the 15:00
 16 Panel is asking and the answers that are coming back,
 17 and she has provided the External Reference Group with
 18 extracts from the transcript, and a series, if you
 19 like, provocative, "have you thought of this?", kind of
 20 question, isn't that right? 15:00

21 A. That's right, yes.

22 164 Q. And I'll show the Inquiry some examples of that. So if
 23 we go to TRU-303646. And this is a matter that was
 24 discussed at the External Reference Group meeting on
 25 the 29th September. And so, the aims, she said, I 15:01
 26 think she's referring to this exercise, is set out
 27 there, and then she does a transcript, notes and
 28 analysis, and if we scroll down the page she sets out
 29 the various themes that she's going to explore, or have

1 been explored in the Inquiry, and then over the page,
 2 we can see, and this was I think Day 42 of the
 3 Inquiry's work, so she records the questions and the
 4 answers, and then in blue she extracts, as I understand
 5 it, and you can correct me if I'm wrong, an issue which 15:02
 6 the Trust will have to grapple with, or she thinks
 7 might be wise to grapple with, arising out of the
 8 evidence that has been given. Is that a correct
 9 interpretation of her approach?

10 A. Yes. No, I mean as I understand it, Veryan listens 15:03
 11 very intently to all of this, and then I think, you
 12 know, given her perspective, and particularly her
 13 perspective as ethicist, she comes back to ask these
 14 questions, you know. But she's very clear that this is
 15 coming from her alone, it's not coming from the group, 15:03
 16 and it is to feed into a development of the group's
 17 thinking. But, yes, that tends to be the pattern of it
 18 in terms of how it is done.

19 165 Q. And if I could bring you to another document, because I
 20 think it originates from her, but maybe you can clarify 15:03
 21 it, if not today at some future point, TRU-304137. And
 22 here we have across eight areas, here's the first one,
 23 the Trust Board, and it goes into Senior Leadership
 24 Team, workforce, quality, patient safety, MHPS,
 25 communications, all of the sort of themes that the 15:04
 26 Inquiry is interested in, and on the right-hand side we
 27 have the Inquiry's Terms of Reference. So do you know,
 28 is this document something that has originated from
 29 her?

1 A. I think it has emerged from within that group and I
2 think it was developed across herself and some of the
3 other involved in the group, yes.

4 166 Q. Yes.

5 A. But I think it is bringing together some of the 15:04
6 questions that she has put to us, yeah.

7 167 Q. Yes. Yes.

8 A. Yeah.

9 168 Q. The Inquiry Panel will no doubt look at this in its own
10 time, but I think it sets out a series of questions 15:04
11 under each, if you like, each of the themes to be
12 extracted from the Inquiry's Terms of Reference. It
13 doesn't answer the questions but sets them out as, if
14 you like, issues to be thought about by the Trust. Is
15 that right? 15:05

16 A. Yes, that's correct. Yeah.

17 169 Q. So, that exercise having been performed by her, where
18 is that work going? What's the next stage of it?

19 A. So we have - we have - this is, in terms of the
20 collation of all of this, this is being done in 15:05
21 anticipation of the meeting on Friday, on the 15th. So
22 we have been down through this as a Senior Leadership
23 Team, you know, we've picked up the questions as we've
24 gone through the meetings, but as a Senior Leadership
25 Team now we've brought everybody together just to 15:05
26 revise this to get this into everybody's consciousness
27 again. And I think then as we go forward and we
28 continue to improve, because a lot of our focus and
29 activity has been about, you know, changing some of the

1 structures, you know driving up the quality of
 2 governance, you know, running the lookback review in
 3 relation to all of that, you know, against a whole
 4 backdrop of what was originally Covid, you know, the
 5 concerns about Daisy Hill Hospital, cytology, you know, 15:06
 6 the Caudrey Review, all of those things that have been
 7 going on in the background, sometimes involving the
 8 senior staff. So against the backdrop of that, I think
 9 this is now part of how we start to test our systems in
 10 terms of some of the changes that we've made, to say, 15:06
 11 "Actually, in terms of how we've put this together, is
 12 this representative?" So when I look at those
 13 questions, for example, in relation to Trust Board, you
 14 know, I will file down through all of the committees
 15 that are there, what actually gets discussed, and think 15:06
 16 to myself "Actually, have we addressed these?", and I
 17 can see areas where we need to improve and other areas
 18 there where I think "yes, we're nearly there or we've
 19 got there with them", and the same with each of these
 20 sections. I think this is a good way for us to 15:07
 21 challenge ourselves, you know, in terms of whether or
 22 not we've delivered.

23 170 Q. Yes. Yes. So again just for clarity purposes.

24 A. Mmm.

25 171 Q. You've described it I think quite well there. Before 15:07
 26 the External Reference Group came together, you had
 27 done a lot of work in terms of changing structures, a
 28 lot of focus on governance. This is related but a
 29 different strand or a different exercise that the Trust

1 is now pursuing?

2 A. I think - so this was part of the reflection to us in
3 terms of, you know, what we've done and what we need
4 do.

5 172 Q. Yes.

15:07

6 A. Right. And I think the next step in this process then
7 is the work that will be driven under the leadership of
8 the Director of Transformation and Improvement in terms
9 of taking the learning that we've got internally
10 obviously, you know, and this is anticipating what this 15:08
11 Inquiry will report on, because I, I completely accept
12 we may not have got this right. But what we're trying
13 to do is improve as much as we possibly can in the
14 interim, because we felt this was too important for us
15 to put to one side and wait, you know, part of this 15:08
16 will be for us to continually consider this to drive
17 the improvement within the organisation and to build on
18 it. So, you know, in relation to this to think if we
19 haven't got - if we're not answering these questions,
20 if they're the right questions, then are there other 15:08
21 things that we could do to try and improve in all of
22 this? And we will keep going with that and keep
23 reporting on it.

24 173 Q. Yes. Yes. So if we go - I just want to highlight some
25 issues or some developments that have emerged through 15:08
26 the external reference groups. If we go to the minutes
27 for the 29th September last year, TRU-306 - sorry,
28 303681. That is 303681. And Vivienne Toal is updating
29 the meeting, and she's explaining - if we just scroll

1 down - that - sorry, it's just down on over the page.
2 Just down a little further, please. Down to the next
3 page. Sorry, I've lost my place. Could you go back to
4 the bottom of page 81. So, Ms. Toal - I can't find it
5 on the page - but she's explaining to the Reference 15:10
6 Group that Elaine Wilson, as you've said Director of
7 Planning?

8 A. Mm-hmm.

9 174 Q. Has been asked to develop a new organisational vision?

10 A. Mm-hmm. 15:10

11 175 Q. And to be under-pinned by a new five-year strategic
12 plan. I hope if I can just take another look down a
13 page, she sets out - just keep going. Yes. So just
14 below that bullet point. Yes. Is that something that
15 has been agreed now that's being taken forward? 15:11

16 A. Yes, and the purpose in me presenting that to Trust
17 Board in September was to essentially get their
18 affirmation in relation to this, because we needed to
19 be absolutely sure that Trust Board was behind all of
20 this, you know, us as collective, in order to deliver. 15:11
21 So Elaine has started this week and essentially - and
22 we see the five-year vision as being, you know, the
23 vision for 2030 essentially, I know it's slightly
24 longer, but, you know, within all of that, you know,
25 she has - she and other members of the team have 15:11
26 consulted widely across the organisation with our
27 external stakeholders, she's working our way through
28 that, with our public, with patients and carers, and
29 service users, in relation to what they see we should

1 be delivering over that period of time, and then, you
 2 know, internally with any of us who are Trust Board
 3 members. So that's a work in progress at the minute.

4 176 Q. Is that, just to be clear, this work on vision and work
 5 on strategic plan, is that something that comes up in 15:12
 6 the calendar every five years and now is the time do
 7 it, or is this, if you like, new thinking borne out of
 8 the experiences of working through problems with the
 9 External Reference Group?

10 A. So naturally in the lifespan of any Trust there will be 15:12
 11 a refresh in some of these things, okay, but I suppose
 12 in recent times because we haven't had a Stormont
 13 assembly until recently there hasn't been a programme
 14 for government renewed, and usually the corporate plan
 15 and corporate strategy falls out of that and then each 15:12
 16 Trust then designs its own interpretation of that in
 17 terms of taking that forward. In the absence of -
 18 although we don't imagine it will be terribly
 19 different, but we will keep an eye to it - in the
 20 absence, before this started, of a programme for 15:12
 21 government and, you know, the usual steer from
 22 Stormont, we went on ahead and started this anyway,
 23 because whenever you look at, and again this was
 24 pre-pandemic but, you know, has been a theme and was a
 25 theme that came through in relation to the changes made 15:13
 26 in Daisy Hill. One of the things that was constantly
 27 said was "we don't have a vision in terms of where
 28 we're going", and that was one of the reasons that
 29 people felt at sea, which I completely agree with, I

1 think that wasn't clear. So built into all of this was
2 about us setting strategic direction so that, you know,
3 particularly staff and service users would understand,
4 you know, what it was we were trying to achieve. And
5 within that I think, and what we're modifying at the 15:13
6 minute are essentially the areas that we'll focus on.
7 So it's about quality and safety, about adding value
8 for money, and then about listening and acting
9 intentionally.

10 177 Q. Yes, and I'm trying to - I've been struggling to find 15:13
11 these key principles. I think they're just down the
12 page. Yes. And so Mrs. Toal is explaining that the
13 work to be taken forward in terms of the vision and the
14 strategy will be under-pinned by, or she hoped that
15 they would be under-pinned by these four principles as 15:14
16 you've outlined:

17
18 "safety and quality of care.

19 Investing our resources where they add most value.

20 A commitment to following through all actions that are 15:14
21 agreed, and all under-pinned by intelligent use of
22 data."

23
24 So has that work started?

25 A. Yeah. Well this was part of the consultation. So 15:14
26 based on what we learned in the process of the Inquiry,
27 you know, the staff cultural survey that had been done
28 at an earlier stage, and then some of the more recent
29 learning that had come out of our experiences with

1 Daisy Hill Hospital and, you know, the Covid review and
 2 all of that, these are the themes that kept emerging.
 3 So that shaped our vision in relation to that. And
 4 they have been refined in terms of, you know, with the
 5 presentations to the different groupings, you know, it 15:15
 6 has been through various iterations, but essentially
 7 this is getting close to what we will see the vision of
 8 the Trust being.

9 178 Q. And we can see, jumping ahead to the next meeting of
 10 the External Reference Group. If we go, for example, 15:15
 11 to TRU-303732. And Ms. Richards is explaining that
 12 it's essential that a protected resource is agreed to
 13 support the process and also that an updated narrative
 14 was developed on the Trust's website so that that could
 15 be shared with the staff. In terms of the senior 15:16
 16 leadership, and I include you in that obviously, and
 17 the Chair of the Trust Board, to what extent is it
 18 important to bring the workforce and, indeed, other
 19 stakeholders along with you in developing the strategy
 20 and the vision? 15:16

21 A. It's pointless do it without them because, you know, I
 22 can stand at the front and talk about what we might
 23 aspire do, but if the hearts and minds of, you know the
 24 patients and service users and the staff who work in
 25 the organisation aren't with us as well, then we won't 15:17
 26 deliver on it.

27 179 Q. There is talk within the External Reference Group
 28 papers, to the need for an engagement plan?

29 A. Yes.

1 180 Q. That is engagement with the staff, with external
2 stakeholders as well. Is that something that is being
3 developed?
4 A. Yes, and that's ongoing at the minute.
5 181 Q. Yes. 15:17
6 A. So through the work that Elaine leads, she and her team
7 lead in terms of these meetings with various groupings
8 and getting their feedback on all of this, you know
9 what they're doing is explaining the background to
10 this, you know, what we're proposing to do and, you 15:17
11 know, then modifying anything that they hear in there
12 in relation to that. So she will come back to present
13 - she gives us updates on that at the Senior Leadership
14 Team, but she will come back I think with a draft
15 proposal in relation to that over the next number of 15:18
16 weeks, you know. So that will happen reasonably
17 imminently.
18 182 Q. And the principles that I outlined there, we saw on the
19 page in front of us, patient safety and quality,
20 accountability and - sorry, I was reading from 15:18
21 something else. Sorry.
22 CHAIR: Resources.
23 A. The second one is adding value for money.
24 183 Q. MR. WOLFE: Yes. Sorry, I'll just get my note to get
25 it absolutely - I'm sorry, I'm causing confusion. 15:18
26 Bottom of the page. So why were those principles
27 selected? Do they, I suppose, give an indication as to
28 where you and your team see the need for development
29 and the need for clarity?

1 A. Yes, I think so. These came out, you know, they came
2 out of our experiences through the Public Inquiry, the
3 work that we undertook as I say in Daisy Hill and, you
4 know, some of the learning that came out of the Covid
5 experience, plus we had a big review to do in relation 15:20
6 to that at a point in time, and then the culture review
7 that was done 2016/2017 in relation to where the
8 organisation was and, you know, some of the feedback
9 we've had recently has resonated with that. So it came
10 out of that because - and then underpinned by - we've 15:20
11 two statutory duties in Northern Ireland; one is to
12 provide safe quality care and the other is to break
13 even and, you know, I think, you know, we also have to
14 be pragmatic in the midst of all of this and be
15 cognisant of the financial environment we're in, that 15:20
16 we cannot waste resource. So it is really important
17 that we do these, but not in an unrealistic way, and
18 that we realise that what we do must add value and we
19 must change what doesn't add value. Then I think, you
20 know, one of things - again, I was very struck by 15:20
21 whenever I arrived in the organisation but I think we
22 are getting better at is, you know, a commitment
23 basically to listen and to act intentionally, because I
24 think, you know, one of the things that was, you know,
25 I heard whenever I came into the organisation, and I 15:21
26 think led to that apathy around understanding the
27 impact of the loss of governance in all of that, was
28 this sense that, you know, "It doesn't matter what you
29 say, nothing changes", you know, it just felt all a bit

1 hopeless and, again, I think, you know, what has come
 2 through certainly in the consultations with
 3 particularly our, you know, the staff within the
 4 organisation, has been that we need to listen to what
 5 is being said and then we need to respond, and
 6 sometimes that response might be "I can't do anything
 7 about it at the minute", but people need to feel that
 8 they're being taken seriously. And then I think as
 9 well, it is again this intelligence use of data. How
 10 do we join the dots to actually make sense of all of
 11 this and try and reduce our tendency towards blind
 12 spots?

15:21

15:21

13 184 Q. Yes. There is another group that, as I understand it,
 14 has recently formed under Mrs. Toal's chairmanship, and
 15 that's the People and Culture Steering Group?

15:22

16 A. Yes.

17 185 Q. The Terms of Reference for that group are to be found
 18 at TRU-305063. And it's purpose is concisely described
 19 there at the top. And if we just scroll down. The key
 20 - just pause there. So the purpose of this group, it
 21 appears, is to provide support to the Strategy and
 22 Transformation Committee. Is that the Committee that
 23 Mrs. Wilson is leading to bring forward the strategy
 24 and vision or is that a different group?

15:22

25 A. So, the Trust Strategy and Transformation Committee is
 26 Chaired by Eileen Mullan as Chair of the Trust, okay,
 27 and that is again about bringing forward into the body
 28 of Trust Board by reporting, but also to hold within
 29 the organisation, you know, the strategic changes that

15:23

are being developed within all of this and any of the transformation that's made. So basically, I mean you've heard the quote, you know, "culture eats strategy for breakfast", and I mean we see at large all over the place. So it was really important that actually, you know, the people plan was developed last year along the lines of wellbeing belonging and growing, again completely evidenced based in terms of how that was pulled out as being the things that are really important in developing, you know, an excellent workforce that enjoys doing its job and does a good job. But in order to be able to do all of this, all of this needs to be aligned. So the people plan was developed and is developing, continues to develop alongside the strategic work that's going on, and these committees then report into this, or these steering groups report into this Committee that's chaired by the Chair of the Trust, to make sure it gets right to the heart of the organisation.

15:23

15:24

15:24

186 Q. Okay. So just so that we're clear. The job of bringing the strategy and the vision, it's being taken forward by Mrs. Wilson under the auspices of a Strategic Implementation Programme Board, is that right?

15:24

A. Yes. That's right, yes.

15:25

187 Q. It's going to report into Mrs. Mullan's Committee, is that right?

A. Yes. Yes.

188 Q. So that's the Strategy and Transformation Committee?

1 A. Yeah. Mm-hmm.

2 189 Q. But Mrs. Toal's group, it has an opportunity to connect
3 into those processes, is that right?

4 A. Oh, yes. Yes. And that works hand in glove, because,
5 you know, that's very much about how do we deliver what 15:25
6 we've promised through the people plan, you know,
7 strategically, in terms of making sure that staff are
8 aligned with what this vision is going to be and see it
9 as being worthwhile?

10 190 Q. Okay. So her committee, or her group, that is 15:25
11 Mrs. Toal's group, is the conduit to ensure that your
12 people, that is your workforce, are given an
13 opportunity to have a say on the development of the
14 strategy, the development of the vision?

15 A. It's the staff on the ground who are exploring all of 15:26
16 this with the various stakeholders come through the
17 Director of Planning's Directorate, their Directorate
18 of staff from there, but they're supported by Vivienne
19 Toal's HROD staff, okay. But both of them would say
20 that that is very much about, you know, helping to test 15:26
21 these concepts to understand if we are heading in the
22 right direction with it, and we think we are, the
23 iterations seem to be repetitively saying the same
24 thing, which is good, in and around. But in terms of
25 the delivery of this, this will be delivered out 15:26
26 through each of the directorates across the Trust,
27 because they can help shape it and describe it. But in
28 terms of the delivery it has to come into the lived
29 experience of staff every day, so that's the next bit

1 in terms of how do you make that transition so that
 2 this becomes the way we do business.

3 191 Q. Okay. So to summarise, the Trust is about to embark on
 4 a process where a five-year strategy and vision will be
 5 prepared. There are opportunities for staff and other 15:27
 6 stakeholders to contribute to the shaping of that?

7 A. Mm-hmm.

8 192 Q. And you have been supported in getting that project to
 9 the starting line by the expertise and experience of
 10 the External Reference Group, who have listened to your 15:27
 11 ideas, to your senior leadership team's ideas, and
 12 offered comment and advice?

13 A. Mm-hmm.

14 193 Q. How useful has been the engagement with the External
 15 Reference Group? 15:28

16 A. I think it has been enormously helpful because, you
 17 know, to have such ready access to so much expertise is
 18 rare and, you know, they come - the people involved
 19 externally I think come from a position of, you know,
 20 having had experience of some of these things 15:28

21 themselves in previous lives, but come with, you know -
 22 and the knowledge of other people going through some of
 23 these things, and I think can provide us with a lot of
 24 information, point us in the direction of finding
 25 things out, that I think have given us the confidence 15:28
 26 to function because, you know, I haven't been a Chief
 27 Executive very long, some of the other people on our
 28 senior leadership team haven't been directors very
 29 long. I think in terms of providing us with the

confidence, you know, to be able to deliver out on some of these things, that has been enormously important.

194 Q. And in terms of looking in the rear view mirror and seeing the potholes and the problems that you're hopefully leaving behind, at least in terms of governance, but perhaps more broadly than that, what is your ambition for the strategic plan and the vision in terms of where it will take the Southern Trust as an organisation and the people it employs?

15:29

A. Well, I mean, we are embedding governance. I think, you know, in terms of growing our workforce, you know, we know that that has been a very unstable system over a period of time. So over the last year/18 months, I mean we have employed 155 international nurses, we have recruited 72 internationally trained doctors, I mean a huge piece of work in terms of bringing stability into the system and, you know, educating people to, you know, work in the NHS. I mean super colleagues, you know, really enthusiastic and ambitious, and very enthusiastic about the work that we do, and that has really opened up lots of possibilities. So there's all of that stabilization piece that has gone on. You know, I think we have developed ourselves in terms of just understanding our own business much better, being a lot more strategic and planned and purposeful in what we do. We're trying to get away from being reactive but, you know, you're constantly hijacked by horrendous winter pressures and overcrowding in emergency departments, which everybody had, which can very often

15:29

15:30

15:30

15:30

1 take you away from the business. But again I think,
 2 you know, as we - and we've had, you know, the concerns
 3 about Daisy Hill, which we've managed to stabilise in
 4 the medium term, you know, the cytology review, which
 5 was well documented as well, again that has all been 15:31
 6 about, you know, really making sure that all of these
 7 governance processes that we have in place now, which
 8 are sensitive to operations, are working well for us so
 9 we can get through these problems. So bit by bit, and
 10 I think as we encounter these difficulties we are 15:31
 11 approaching them with more confidence, we now have the
 12 armament in place to actually deal with them
 13 expediently and get them over the line and get
 14 stability back the system. So I can see, I can see
 15 from a maturational point of view that we are slowly 15:31
 16 but surely working our way through there and, you know,
 17 our intention each time that we're hit with a
 18 difficulty - and there will always be difficulties in
 19 Trusts - is that we touch at once and we make sure that
 20 what we leave behind is sustainable so that we don't 15:31
 21 have to keep coming back in crisis mode.

22 MR. WOLFE: Chair, I know we've been going for an hour
 23 and a half. Should we take a short break and aim to
 24 come back or can we sit to say ten past or a quarter
 25 past four. 15:32

26 CHAIR: Okay. So let's take a 15-minute break then and
 27 come back and ten to and then sit for a maximum half an
 28 hour after that.

29 MR. WOLFE: Very well.



Quality Care - for you, with you

...Working Draft v3...

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**SOUTHERN TRUST EXTERNAL REFERENCE GROUP
(SOUTHERN TRUST ERG)**

CLOSE OF GROUP REPORT

<insert date>

1. PURPOSE OF THIS DOCUMENT

Trust External Reference Group (ERG), which was formed as a short-life group in November 2022 by the Chief Executive of the Southern HSC Trust to challenge and support the Senior Leadership Team (SLT) to maximise the learning in real time from the ongoing Statutory Public Inquiry, Urology Services Inquiry (USI), set up under the Inquiries Act 2005 on 24 November 2020 by the Health Minister, Robin Swann.

In addition to documentation of the outcomes of the work of Southern Trust ERG, this report will consider the process of using an “External Reference Group” approach to challenging and supporting a Trust during an intense and difficult period. As this method was not something the Southern Trust team was familiar with, it is important to capture and evaluate this experience and draw conclusions in relation to the value of this approach in supporting, challenging and learning from the experience in real time.

2. BACKGROUND & CONTEXTUAL INFORMATION

In June 2020, the Trust became aware of a potential issue regarding patients under the care of Mr Aidan O’Brien, Consultant Urologist. It appeared that a number of patients who required surgery to remove renal stenting, might not have been added to an inpatient / day case waiting list as expected. Whilst that in turn was not the case (the patients were on the waiting list), the process of establishing the facts uncovered other issues of significant concern with Mr O’Brien’s practice namely: delays or absence of reports and/or investigations; lack of / poor communication; incorrect treatment; and un-actioned outcomes following cancer multidisciplinary team meetings including for example, onward referrals and planned reviews.

Such was the concern regarding these findings, the Trust embarked on a formal Lookback Review to identify if patients had received optimal care from Mr O’Brien. Where the Lookback Review identified a patient who received care below the appropriate standard, the Trust took the necessary steps of recalling the patient to determine if a change to their treatment plan was required in order to ameliorate any harm that might have been caused.

Urology Lookback Review

The Lookback Review of Cohort 1 concluded in August 2023. The outcomes of this analysis pointed towards a need to extend the Lookback to a second cohort of patients focusing specifically on patients treated for a urology cancer and also for renal stone disease, back to 2010.

The Lookback Review for Cohort 2 is now complete. The outcomes report for this group of patients is in the progress of being drafted and will be shared with all stakeholders when finalised.

Whilst the Southern Trust ERG received updates on the progress of the Lookback Review, it did not get involved in the learning emanating from that process as its role was to focus on culture,

governance, quality and safety from an organisational perspective, issues which align more closely with the Terms of Reference of the USI.

Urology Services Inquiry

As referenced above, the USI, which remains ongoing, is a Statutory Public Inquiry chaired by Ms Christine Smith KC. The Terms of Reference for the Inquiry are:

- a) To review the Southern Health and Social Care Trust's (the Trust) handling of relevant complaints or concerns identified or received prior to May 2020 and its participation in processes to maintain standards of professional practice. The Inquiry shall determine whether there were any related concerns or circumstances which should have alerted the Southern Trust to instigate an earlier and more thorough investigation over and above the extant arrangements for raising concerns and making complaints;
- b) To evaluate the corporate and clinical governance procedures and arrangements within the Trust in relation to the circumstances which led to the Trust conducting a "lookback review" of patients seen by the urology consultant Mr Aidan O'Brien (for the period from January 2019 until May 2020). This includes the communication and escalation of the reporting of issues related to potential concerns about patient care and safety within and between the Trust, the Health and Social Care Board, Public Health Agency and the Department. It also includes any other areas which directly bear on patient care and safety and an assessment of the role of the Board of the Trust;
- c) To examine the clinical aspect of the cases identified by the date of commencement of the Inquiry as meeting the threshold for a Serious Adverse Incident (SAI) and any further cases which the Inquiry considers appropriate, in order to provide a comprehensive report of findings related to the governance of patient care and safety within the Trust's urology specialty;
- d) To afford those patients affected, and/or their immediate families, an opportunity to report their experiences to the Inquiry;
- e) To review the implementation of the Department of Health's "Maintaining High Professional Standards Policy" by the Trust in relation to the investigation related to Mr O'Brien. The Inquiry is asked to determine whether the application of this Policy by the Trust was effective and to make recommendations, if required, to strengthen the Policy;
- f) To identify any learning points and make appropriate recommendations as to whether the framework for clinical and social care governance and its application are fit for purpose;
- g) To examine and report on any other matters which the Chairman considers arise in connection with the Inquiry's investigations in fulfilment of these Terms of Reference.

Although it was the concerns identified in Mr O'Brien's practice which eventually led to the decision to undertake the USI, this Inquiry is primarily examining issues relating to systems and governance within the Southern Trust, as opposed to investigating the clinical practice of Mr O'Brien. An investigation into Mr O'Brien's practice is being undertaken by the General Medical Council (GMC) as a parallel, but separate, process.

At the outset of the Inquiry, the Trust recognised that there was (and still is) a unique opportunity to learn lessons and improve services in real time, particularly as the Inquiry team heard / hears evidence during the oral hearing phase of the Inquiry process, as opposed to waiting for the outworking / recommendations of the Inquiry. This "learning in real-time" approach is not to, in any way, second guess the role of the USI or attempt to predict its findings. Rather, its purpose is to engage with insights and information emerging from the Inquiry that might relate to weaknesses in culture, governance, quality and safety.

To support this approach, the Southern Trust ERG has been capturing and logging on an on-going basis the reflections, responses and experiences recounted by those who have attended to give evidence in person during the oral hearing phase of the USI.

This aspect of the Southern Trust ERG agenda has been taken forward by Mrs Vervan Richards, a member of the ERG whose lay focus is the patients / public perspective. Vervan brings an independent view of proceedings which ensures a strong service user perspective is an integral part of the on-going feedback.

3. SOUTHERN TRUST ERG TERMS OF REFERENCE

The core purpose of the Southern Trust ERG was to fulfil the role of an expert panel and "Critical Friend" providing independent challenge and support to the Chief Executive and Directors in their focus on improving organisational health and maximise safety, quality and experience for patients / service users and staff.

The intention was to take an "action learning" approach to its work, using independent members to question and challenge, thus promoting active reflection in order to draw out learning which would inform approaches going forward.

Using her networks, the Chief Executive secured input from expert colleagues from across the four UK regions who were completely independent to the Southern Trust. The independent members of Southern Trust ERG were:

Dr Tom Frawley (Chair)

Tom Frawley has a longstanding and distinguished career in public services in Northern Ireland starting in 1971 when he first joined the NHS as a management trainee. Notably in his career Tom was Chief Executive of the Western HSS Board continuing in that post until September 2000 when he was appointed Northern Ireland Ombudsman and Commissioner for Complaints retiring from

that post in April 2016. During the period that Tom was Ombudsman, he was elected Vice President of the World Board of the International Ombudsman Institute. Dr Frawley received an Honorary Fellowship from the Royal College of Nursing in 2014.

When he joined the Southern Trust ERG Tom had just completed a 4-year term as a member of the Northern Ireland Policing Board. He is also completing a second term as a member of the Professional Standards Authority, a position he was appointed to the Department of Health in January 2017. Tom took up the position of Chairman of the Western Health and Social Care Trust in May 2023.

Mrs Mary Hinds

Mary Hinds has more than 30 years of experience as a nursing leader. In her varied career Mary has held number of notable roles in Northern Ireland including the Director of Nursing at the Public Health Agency the role she retired from in September 2019. Mary also during her careers was the Director of the Royal College of Nursing in Northern Ireland and prior to that Director of Nursing in the Mater Hospital, Belfast.

In 2019, Mary was awarded the Mercy Medal by the Belfast Trust and Mater Hospital Trustees in recognition of her contribution to health care and in 2021, she was awarded a Fellowship of the Royal College of Nursing for her contributions to nursing in Northern Ireland. Mary is currently a Trustee for Marie Curie in Northern Ireland supporting “a better end of life care for all”.

Mrs Veryan Richards

Veryan Richards is an ethicist from University of Oxford. She is an Associate Lay Consultant member of the Royal College of Psychiatrists Invited Review Service team which carries out clinical service reviews at the invitation of an NHS Trust. She has experience of carrying out reviews in all 4 jurisdictions in the UK, including one in the Southern Trust Northern Ireland in 2019. She was a key contributor to embedding values-based practice and person-centred clinical care in the Royal College of Psychiatrists Revised Psychiatry Curriculum 2022 and the HEE Advanced Clinical Practice Core Capability Framework for Mental Health 2020. She is an author/co-author of several articles (including the Lancet Psychiatry) Royal College of Psychiatrists Reports, and documents. She was awarded the Royal College of Psychiatrists President’s Medal 2020.

As an Associate Lay Consultant, Veryan contributes by shaping the policy narrative in several areas of healthcare in the UK. She is particularly interested in the balance of evidence-based and values-based practice in the delivery of holistic person-centred healthcare. She has wide experience of representing the patient and public interest at strategic level in the areas of quality care, patient safety, and improving services.

Mr Robbie Pearson

Robbie Pearson is the Chief Executive at Healthcare Improvement Scotland and has held that position since 2016. Prior to that Robbie was Deputy Chief Executive/Director of Scrutiny and Assurance at Health Improvement Scotland.

Robbie has worked in the NHS for nearly thirty years and been a director in a territorial health board. Prior to joining Healthcare Improvement Scotland he served for two years as the Head of Healthcare Planning in the Scottish Government.

Dr Simon Watson

Simon Watson is the Medical Director in Health Improvement Scotland from April 2020. He is the professional lead for medical doctors, pharmacists and dentists and co-leads clinical and care governance with the Director of Nursing, Midwifery and Allied Health Professions. Prior to undertaking this role, Simon was part of NHS Lothian's Executive Leadership Team for four years as Chief Quality Officer and Executive Lead for Analytical Services.

Simon qualified as a medical doctor in 1996 and became a Consultant Nephrologist in 2007. He previously held various local and national leadership roles in clinical quality management. Simon continues to practice clinically in addition to his other duties for Health Improvement Scotland.

Mr Hugh McCaughey

Hugh McCaughey recently retired from his role as National Director of Improvement in NHS England which he undertook from April 2019, prior to which he was chief executive of South Eastern Health and Social Care Trust in Northern Ireland for approx. 10 years. He has strong links to the Institute for Healthcare Improvement and is a founding member of the Health Improvement Alliance Europe.

Hugh is well known and respected for his advocacy of equality, diversity and inclusion and his enduring commitment throughout his career has been to improving healthcare for all, using supportive methods and a relentless positivity and tireless focus on improvement and innovation.

The Trust members of the Southern Trust ERG were:

- Dr Maria O’Kane, Chief Executive;
- Dr Stephen Austin, Executive Medical Director;
- Heather Trouton, Executive Director of Nursing, Midwifery, AHPs and Functional Support Services;
- Vivienne Toal, Director of HR & OD;
- Jane McKimm, Public Inquiry Programme Director;
- Margaret O’Hagan, Director responsible for the Urology Lookback Review.

The purpose of Southern Trust ERG members was to:

- Provide constructive challenge to the Trust members of the ERG in order to strengthen and deepen the Trust's thinking and learning in respect of the Improving Organisational Effectiveness Programme;
- Keep up to date with all aspects of the Urology Services Inquiry and provide challenge and support to the Trust on issues arising from the Public Hearings to aid learning and improvement;
- Receive updates regarding the progress of Urology Lookback Review;
- Demonstrate curiosity and use constructive challenge to enhance the level of understanding and support to the Trust;
- Provide external advice and guidance when requested to support decision-making on all aspects of the programme; and
- Share personal and professional knowledge, information, expertise and experience to enhance organisational learning which will inform organisational reform and transformational change.

The first meeting of the Southern Trust ERG was on 28 November 2022. The group have met on seven occasions; 20 January 2023, 21 April 2023, 2 June 2023, 25 August 2023, 29 September 2023 and 10 November 2023. A final meeting of the group took place on 15 March 2024. Between these meetings, independent members joined agreed sub-groups where they provided bespoke advice and support.

Each of these meetings had an agreed agenda supported by set papers. The meetings were minuted to have a record of discussions, questions, analysis reflections and actions to take the agenda forward.

As part of the work of Southern Trust ERG four sub-groups, each was chaired by Trust ERG lead and supported by an independent ERG member, were created to progress work in the following areas:

- Patient Safety & Quality – Chair: Heather Trouton with support from Mary Hinds;
- Governance – Chair: Stephen Austin with support from Robbie Pearson;
- Data Analytics Analytics & Intelligence – Chair: Stephen Austin with support from Simon Watson;
- Culture and Leadership – Chair: Vivienne Toal with support from Hugh McCaughey.

The work of these four sub-groups was not specified in terms of how they were to do business or what outcomes were expected. It was an organic approach to finding and agreeing direction for the Trust to meet its terms of reference take in terms

In addition, Veryan Richards and Jane McKimm tracked the Public Inquiry hearings and provided feedback to evoke reflections that would inform learning for the Trust going forward.

4. SOUTHERN TRUST ERG OUTPUTS

The four Southern Trust ERG sub-groups had the freedom to develop their work plan and progress work in the direction their group members them. Below is a high level summary if the subgroups. Attached (Appendix 1) is summary of work the Trust has either completed, is in progress or has still to commence captured under the headings of the 4 four sub groups.

Patient Safety and Quality Sub-Group

This group was chaired Heather Trouton and supported by Mary Hinds. The members on their group represented all operational directorates and a number of professions and included a mix of Consultants, Directors and Assistant Directors.

The group met on a number of occasions. A number of issues were raised by this group regarding how they felt regarding the standards of patient safety and quality across the Trust, they had views on what was good and worked well and importantly what needed to be improved.

The next strand of the subgroup methodology was to hold a wider stakeholder engagement group session which involved 25 plus staff from all areas of the Trust, primarily at band 7/ 8a level. The 4 aspects of the HSC Values; Excellence, Working Together, Compassion and Openness and Honesty were adopted as a framework for capturing views. A facilitated discussion was held which was very interactive process in order to illicit the views of these staff members particularly in relation to their experience of how patient safety and quality is managed within the Trust. A summary of the detail that this discussion raised was drafted for the record.

The Patient Safety and Quality group paused any further engagement activities because in early November 2023, the Chairs of the four group met at the request of the Chair of the Southern Trust ERG and agreed to merge their work into one programme by coalescing into one process.

Governance Sub-Group

The Governance Group recognised previous work on Governance in the Trust (Champion Review). It was recognised that there was a need to strengthen connections between frontline staff / middle management and the senior leadership team in relation to governance and decision making. Whilst governance “machinery” is in existence, it needs more “oil” to promote development of live, real time governance.



Key areas needing development include

1. Development of real time governance and sensitivity to operations - Charles Vincent Framework Measuring and Monitoring for Safety (model capture above).
2. Safety Huddles – taking account of the improvement approach to safety huddles from Healthcare Improvement Scotland. Current safety huddles are patchy in implementation and quality, and thus need focus to develop reliability and consistency in approach
3. Systems to identify soft intelligence - “smoke signals” and triangulation of information/evidence
4. Greater cohesion in relation to organisational learning and knowledge sharing of information from complaints, adverse incident and clinical governance
5. Development of effective system of learning
6. Development of an empowered workforce to avoid sending communications up and down a hierarchical ‘chain of command’.
7. Development of sensitivity to different services across the Trust avoiding over-focus on acute services.
8. Greater and wider ownership of the Public Inquiry and its implications beyond urology
9. Avoid pre-disposition to silo working – focus on collaborative, collective approaches
10. Move from reassurance to assurance approaches

Reassurance		Assurance
“Is it okay because management says it is?”	“Is it okay because management have responded to questions from the board and this has given me confidence?”	“Is it okay because I have reviewed various reliable sources of information?”
Strong management personalities may dominate	Clear and logical explanations from board members	Independence of information source
Track record of success	What has happened; why it has happened and what is the response	Evidence of historic progress outcomes
Professional background or expertise	Management explanations are inconsistent	Triangulation with other information
No contradictory evidence		

Data Analytics and Intelligence Sub-Group

The Data Analytics and Intelligence Sub-Group met on a number of occasions to develop the elements of a future Data Analytics and intelligence strategy for the Trust. This was grounded in the issues emerging from historical events in Urology. Themes emerging from the wider work of the Southern Trust ERG were also incorporated into the Strategy, in particular they need for a strong, respectful and collaborative organisational culture to support the development and agreed for the Strategy.

The group made a number of recommendations to reflect all these considerations, the wider landscape of healthcare and future needs of the Trust and those it serves. The group recommended that the Trust commissions a formal strategic plan for Data Analytics and intelligence that includes consideration of five key ambitions to:

1. Support the continuous improvement in clinical and care processes;
2. Create a warning system to identify emerging clinical care or clinical governance concerns;
3. Empower patients through information sharing to support better self-care;
4. Deploy machine learning technologies to support business and clinical activity;
5. Create formal collaborations with strategic partners other sectors, notably academia.

As the sub-group reflected that there is never an ideal time to embark on a new Data Analytics and intelligence strategy. Nevertheless, the lessons emerging from the ongoing Public Inquiry demonstrated a need to develop culture, team-working, leadership and governance all of which require data and intelligence to inform action. Furthermore, the world is at a crossroads in the current information age and organisations that don't plan now may be potentially limiting their capacity to influence on the future. The sub-group concluded there are compelling reasons for the Trust to develop a Data Analytics and Intelligence Strategy.

The five key ambitions outlined in this document represent specific themes that have emerged in various discussions. They are not intended to be an instruction or requirement for the Trust. Its

focus are areas worthy of serious consideration as part of a new strategy. However it is hoped the analysis should prompt discussion in the wider consultations required in strategic planning and thus they can be supplemented, or replaced, by an alternative analysis or priority.

A key document shared with the Trust was the Analytical Framework (attached as Appendix 2) from the Scottish Sharing Health and Care Intelligence Network. The evidence base for this framework can be viewed on <https://www.emerald.com/insight/2059-4631.htm>. This framework has been and will continue to be used in the Trust to identify early warnings of emerging problems particularly in the areas of quality and safety of care.

Culture and Leadership Sub-Group

The Culture and Leadership Sub Group was co-chaired by Hugh McCaughey (ERG) and Vivienne Toal (Executive Lead/Sponsor). A range of leaders from the Trust accepted membership of the sub-group.

At the outset it was made clear that the sub-group was not established to ‘oversee’ cultural change in the Trust; this will take time, and will be a product of the leadership, priorities, strategies and behaviours within the organisation. Rather, members were invited to bring their wealth of knowledge, expertise and skills from their service, profession and vast experience, to help the Trust develop its route map for the journey of culture change, by aiding balanced discussions, providing constructive challenge and enabling access to learning from internal and external to the Trust.

In the context of culture change, a number of key outputs were identified at the outset:

- Identifying how to engage the organisation at all levels;
- Describing/defining current position;
- Describing what our people/organization aspires to as its culture;
- Describing what success looks like;
- Identifying the strategies that influence it;
- Identifying how the organisation functions and influences culture;
- Identifying how behaviours and actions aligned to the HSC values will help deliver the culture we want;
- Identifying how we will track progress.

Key areas of progress to date include:

1. New SHSCT Vision and Strategy development process underway;
2. Chief Executive compelling narrative delivered at Trust Board and Senior Leaders’ events;
3. Senior Leadership Team (SLT) Visibility – plan on a page;

4. Engagement Plan – development of Vision and Strategy. Presented to Trust Board – 26th October 2023. Covers our people – staff, community, population, carers, etc. – co-production approach;
5. The four Sub group meeting of ERG subgroups on 8 November 2023 – to review engagement plan, and agree that as all the group work to date was coalescing that future work not be in separate groups;
6. The first Trust Board workshop on development of vision and strategy (9th November 2023);
7. Engagement sessions ongoing from November 2023 to March 2024. Commenced with 2 Senior Leadership sessions – Divisional MDs, CDs, Assistant Directors, Heads of Service and Directors;
8. Reforming of the membership of 4 External Reference Subgroups to create an “Internal Reference Group to review feedback from engagement sessions and help SLT distill key themes

The progression of No1 above is the focus on the next steps as the Southern Trust ERG group steps back

USI Hearings

The Trust maintains a ‘live’ learning and observations log developed from the Oral Hearings at the Inquiry. These are independent reflections on what was heard at the Inquiry hearings, and are not in any way intended to pre-empt future recommendations or findings of the Inquiry Panel. The Trust recognises all evidence is personal to each participant, and any comments/learning are simply a recognition of that viewpoint, which will be considered by the Inquiry within the context of the entirety of the evidence.

However it is important that the experiences of patients and families, reflected in the early hearings, and the views and opinions of staff who have worked within the Urology service, and the wider Trust, are captured even at this early stage so it can guide the Trust’s improvement agenda going forward.

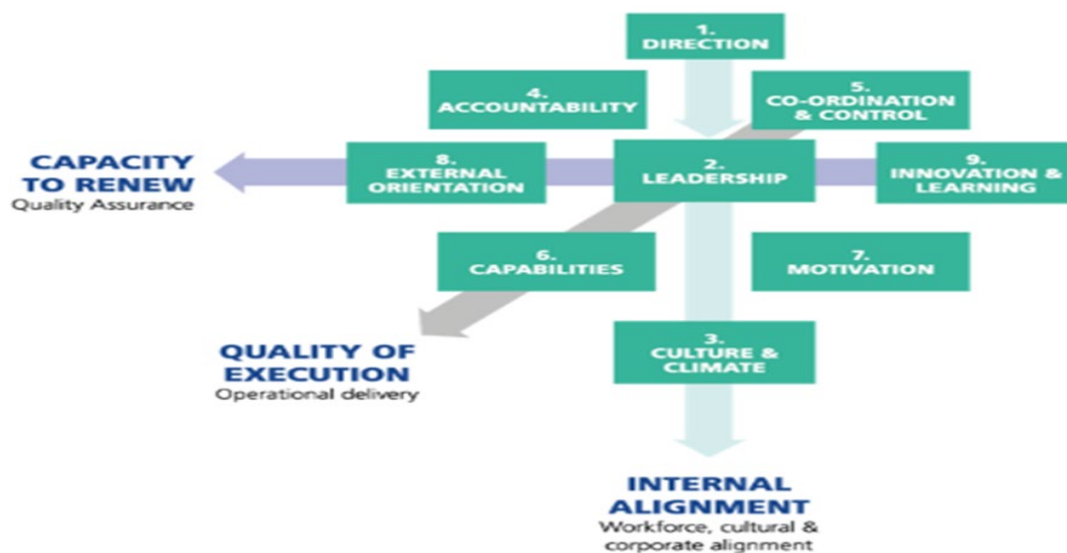
In relation to the Southern Trust ERG, Veryan Richard shared her reflections of the exchanges at the Hearings and posed rhetorical questions as a stimulus for the Trust Southern Trust ERG members to consider and reflect upon. To facilitate the Trust’s learning these reflections and observations were captured as questions which the Trust’s SLT use to consider learning from the Inquiry as it applies across all services and aspects of the organisation.

This document is attached (Appendix 3) for information. To note, this document remains a work in progress until the oral hearing aspect of the Public Inquiry concludes.

5. WHAT NEXT?

As referenced above the four sub-groups coalesced and the need for a definitive Vision and 5-year strategy underpinned by a Just Culture and robust Organisational Development Plan emerged as the agreed way forward for the Southern Trust at this time.

The Director of HR&OD is currently supporting Senior Leadership Team through monthly sessions on the development of the Organisational Development Plan which will sit alongside the already existing People Plan to support the implementation of the Trust's new vision and 5-year strategy. The framework being used is the McKinsey Organisational Health Model (below), which is helping SLT to initially work through how we need the organisation to function, and the work we need to do to improve leadership, capability, and coordination & control in particular, to help us execute high quality operational delivery.



The Director of HR & OD established the Trust's People & Culture Steering Group in November 2023, which oversees the implementation of the Trust's People Plan. The work of this Steering Group, along with the development of the Trust's Organisation Development Plan, will report in under the remit of the new Board level Strategy & Transformation Committee. A key part of this work will involve determining a robust progress tracking framework on our culture change journey.

6. REFLECTIONS ON "EXTERNAL REFERENCE GROUP" APPROACH TO SUPPORT & CHALLENGE

The use of an External Reference Group to support the Trust learn in real time while the USI, statutory public inquiry was ongoing is not an approach used alongside other Public Inquiries to date in Northern Ireland.

This section will be populated following the meeting of the Southern Trust ERG on 15 March as there will be an exercise during that meeting to capture reflections from all members.

Appendix 1

SUMMARY REPORT ON THE OUTPUTS FROM REAL-TIME LEARNING DURING THE UROLOGY SERVICES INQUIRY (USI)

The purpose of this document is to provide a summary of the work undertaken by officers in the Southern Trust which reflect real-time learning during the USI. It is set out under the themes of the sub groups which had been established for the Southern Trust External Reference Group (ERG).

The Southern Trust ERG sub-groups, were created to facilitate work in the following areas:

- Patient Safety & Quality Sub-Group – Chair: Heather Trouton; support by Mary Hinds;
- Governance Sub-Group – Chair: Stephen Austin; support by Robbie Pearson;
- Data Analytics & Intelligence Sub-Group – Chair: Stephen Austin; support by Simon Watson;
- Culture & Leadership Sub-Group – Chair: Vivienne Toal; support by Hugh McCaughey.

Set out below is examples of the work undertaken which have already been made, the work which is underway and that which is still to commence each of the work areas above¹.

PATIENT SAFETY & QUALITY ¹
Examples of Work Undertaken / Improvements Made
New de-brief form is produced following M&M meetings, highlighting additional information on SAIs and outcomes of discussion and sent to relevant M&M attendees and operational/governance colleagues
Application of the Shared Learning Policy and completion of template has begun following M&M meetings. A quarterly report is produced based on information obtained from regional reports showing areas and themes for learning
Structured Early Learning Tool used extensively in MHD and works well – roll out programme commenced
Robust structures in place to provide assurance on professional nursing standards including work to make public some key indicator data
Logging of and tracking of implementation of learning letters on Datix
Tracking of Implementation of NICE Guidance
Tracking of Implementation of Regional Guidance / Circulars / CMO-CNO-CPO Letters

¹ To note – some of the detail under the sub-group heading of Patient Quality & Safety and, Governance has been gleaned from work presented in and update report on Clinical & Social Care Governance

Work Underway / In Progress
Development of Executive Director Oversight Group as a process to oversee quality and safety issues / improvements – meetings have taken place,
Development of Trust SAI Policy and Procedure to assist in standardising processes – to be presented at SHSCT Policy Scrutiny meeting 28/03/2024 - implementation by April 2024
Development of Incident Management Awareness training package to be Corporate Mandatory Training for all staff across the organisation - go live by 1 st April 2024
SHSCT Safety Framework – Drafted and presented to SLT
Implementation of regular Safety Huddles/Briefings
Work Still to Commence
Strengthening of learning from patient/client experience needs to be strengthen
Establishing a process for triangulating potential learning but keeping it simple.
Find a way to identify linked trends between SAIs, incident, complaints within and across Directorates.
Further work to streamline / increase efficacy of M&M meetings and make them multi-disciplinary
Further develop the support to Patient Safety meetings to maximise feedback and learning
Further strengthening of Safety Huddles with more consistent application across the Trust.

GOVERNANCE¹
Work Undertaken / Improvements Made
Enhanced quarterly reporting from the governance teams to the Trust Board to Governance Committee
Introduction of a standalone Service User Feedback Report to Governance Committee
Weekly reporting / escalation of issues to SLT
Quarterly Reporting to Safety & Quality Steering Group and the Quarterly Reporting to Standards, Compliance and Regulation Steering Group
Introduction of Patient Safety Data & Improvement Team (M&M) Report to Safety & Quality Steering Group
Extended scope of Weekly Governance meeting agenda
Development of Datix system for recording, monitoring and reporting of SAI Recommendations and other “review” recommendations such as RQIA, Royal Colleges, GRIFT
Quarterly meetings with NIPSO and PCC to assist with progression, oversight and assurance
New de-brief form is produced following M&M meetings, highlighting additional information on SAIs and outcomes of discussion and sent to relevant M&M attendees and operational/governance colleagues
Family liaison role firmly embedded within MHD to support SAI processes and communication/interfaces with family/service users

MHD have a weekly live governance meeting mirroring the weekly governance meeting, which considers incidents, complaints, SAIs and divergence from governance controls which impact on patient safety
In MHD, involvement of a family member providing feedback to staff on their experience of care and areas for improvement following SAI processes.
Well described Governance Assurance Frameworks in some of the operational directorates
Performance Management of Medical Appraisal and Revalidation with Escalation Process if non-engagement
Complaints Analysis implemented (HCAT)
Incident / SAI Thematic Analysis
Clinical Audit system in operation focusing currently on national / regional audit programmes
Clinical Audit Reference Group (CARG) in operation overseeing Trust Clinical Audit work
Drafted and launch a “Working Well Together” strategy
Establishment of the following groups - Supporting Nurses and Midwives in Practice, Supporting AHP’s in practice, Supporting Social Workers in Practice , all of which oversee and support clinicians (outside of medicine which already exists) to practice safely
Work Underway / In Progress
Further implementation of actions / recommendations of the Champion Report
Development of Service User Feedback Awareness training package – Corporate Mandatory Training for all staff across the organisation, aiming to go live by 1 st April 2024
Service User Feedback Pilot in relation to early resolution – to commence April 2024
Completion of the “business partner model” approach to CSCG within Service Directorates
Full roll out of Governance Assurance Frameworks in all Directorates
Increased use of ‘Hot Debrief’/Rapid Review tools for Level 1 SAI reviews across the Trust to ensure learning is rapidly identified and shared
Clinical Audit planning in Divisions and Directorates commenced
Work Still to Commence
Audit evidence provided to support SAI recommendations which have been fully implemented
Inclusion of SAI recommendations in the triangulation of Governance activity information
Development of a Professional Governance Information System (PGIS) to further improve oversight and assurance of governance activity in relation to staff
Audit compliance with Corporate SAI Policy and Procedure
Development of standardised datasets for reporting of Complaints from Datix
Development of Risk Register module on Datix
Provide support to operational directorates to ensure that each directorate level risk register is dynamically populated and consistent with corporate requirements
Development of Live Governance framework (daily safety huddles/briefing, local weekly governance review, monthly strategic governance review)
Implementation of Charles Vincent Measuring for Safety Framework

DATA ANALYTICS & INTELLIGENCE
Work Undertaken / Improvements Made
Adoption of the Scottish Sharing Health and Care Intelligence Network Analytical Framework to use as a “heat map” to assess early signs of quality / safety issues. Used practically in MHD
Digital Steering Group commenced in Trust
Data Strategy in place in Trust
Work Underway / In Progress
Analytical Framework to be use as business as usual to identify early warning signs of emerging problems with the quality and safety of care / clinical governance concerns
Sharing of information with Patients (Shared Decision Making Nice Guidance 197) with patient empowerment
Work Still to Commence
Create formal collaborations with strategic partners other sectors, notably academia
Using the Encompass module when Encompass is introduced to empower patients through information sharing to support better self-care
Aim to develop forensic analytical systems to monitor core clinical and business activities to spot future signals of concern
Strategic Partnerships with other sectors, notably Universities (Ulster and QUB) in relation to Data Analytic Capability
Development of Machine Learning (AI) technologies to support clinical and business activities

CULTURE & LEADERSHIP
Work Undertaken / Improvements Made
All Director posts now filled with substantive appointments
Appointment of a Director for Transformation and Improvement to reflect this as a Trust priority for next 2 years
SLT agreement to use the McKinsey Organisational Health Model as the OD framework to support the implementation of the 5-year strategy
The establishment of the Trust’s People & Culture Steering Group in November 2023, which oversees the implementation of the Trust’s People Plan.
Senior Medical Leaders’ Group established in Trust to provide a collective medical leadership team across the Trust and resolved medical opinion / advice for the Medical Director and to provide enhanced communication across Divisions in the Trust
Work Underway / In Progress
Senior Leadership Team (SLT) Visibility – plan on a page
New SHSCT Vision and Strategy development process underway

Engagement Plan – development of Vision and Strategy. Presented to Trust Board – 26th October 2023. Covers our people – staff, community, population, carers, etc. – co-production approach
The first Trust Board workshop on development of vision and strategy
Engagement sessions ongoing from November 2023 to March 2024. Commenced with 2 Senior Leadership sessions – Divisional MDs, CDs, Assistant Directors, Heads of Service and Directors – help us to identify and understand the perspectives of staff
Embedding of Trust Values and Behaviours through the Trust
Alignment of policies and procedures with open, just and learning practices and principles – locally and regionally.
A range of HR & OD training and support clinics for managers ongoing – raising concerns, conflict, bullying and harassment, flexible working, supporting attendance, reasonable adjustments.
Ongoing roll out of Schwartz Rounds across the Trust monthly, enhancement of Psychology Staff Support service with manager support clinics.
Recognition and celebration of staff achievements by teams and SLT, Our People Awards, culture nights, cultural competency training, Cultural REaCH network.
Strengthening of Collective Leadership Teams across Divisions and Directorates
Development and Strengthening of Clinical Directors’ Forum to provide a collective cross Trust medical leadership forum
Development of CORE management skills programme leading to in house accreditation of managers
Work Still to Commence
Articulation of the 5-year strategy and implementation plan, along with supporting OD plan
Roll out of in person Corporate Welcome
New Leadership Development Framework

Appendix 2

Sharing Health and Care Intelligence Network Analytical Framework

Primary Cause		Warning Signs	
Breakdown in Health & Care Services or Provision	Leadership	- Lack of focus on quality and safety - Replacement/high turnover of senior manager(s) - Long standing vacancies at senior manager level	- Centralised decision making - No clear and effective performance management system - A failure to learn and share lessons
	Culture	Organisational Culture - A lack of value and support for frontline staff - A disconnect between staff and leadership - Inward looking closed culture/organisational introspection - Defensive or unresponsive to external assurance - Fear/blame culture & bullying behaviour - Lack of openness, transparency & candour - Low staff morale	Safety Culture - Limited capacity/capability to drive improvement - Failure to listen to/act on the views of staff, service users & stakeholders - Recurrent complaints from the same area on the same theme - Normalisation of deviant practices - Incidents, especially near misses, are not reported or acted upon adequately - Punitive approach to safety event reporting - Inadequate training and administrative support for safety
	Governance	Corporate Governance - Inadequate/poor strategic planning - Poor use of data to drive quality improvement - Continually failing to meet performance targets - Dysfunctional board and management team - Lack of board cohesion and inability to challenge - Red risks on Corporate Risk Register consistently unmitigated - Failure to identify and deal with issues - Failure to follow up internal audit - Significant sources of distraction – finance, large projects	Clinical Governance - Unclear roles & accountabilities at/below board level in relation to clinical governance - Insufficient resources, infrastructure and information systems for effective clinical governance - Normalisation and tolerance of deviance: errors, lapses, or mistakes to go unattended, unappreciated, or unresolved for an extended period of time - A communication and cultural disconnect between management and clinicians - Absence of/inadequate policies and procedures for dealing with poor clinical performance - Inadequate assessment and monitoring of the efficacy of Clinical Risk Management - Ineffective systems for reporting, investigating & learning from adverse events - Inadequate complaints management process and little evidence of complaints driving service improvement - Inadequate systems and processes for seeking and responding to staff and patient views
		Staff Governance - Absence of a comprehensive, long term workforce strategy - Low appraisal and revalidation rates for staff - Inadequate process for monitoring professional registration - Ineffective systems for the training and continued professional development of staff - Staff are not informed about the organisation and don't have access to communication channels which offer the opportunity to give and receive feedback - Staff are not engaged in decision making and accountability is not appropriately devolved - Inadequate support for the physical and emotional wellbeing of staff - Inadequate systems and processes for seeking and responding to staff and patient views	Educational Governance - Lack of adequate quality control of medical training by Boards - Multiple or persisting red flags on feedback surveys from trainees - Lack of action to address failure to meet GMC standards for postgrad medical training – triggering repeat QM visits - Escalation to GMC enhanced monitoring - Addition of conditions by GMC to enhanced monitoring cases - Lack of impact of Board educational governance in addressing poor medical training
	Financial Performance	- Lack of appropriate financial management & control - Significant budget overspend - Reliance on non-recurring savings - Scottish Government Brokerage	
	Workforce	- High vacancy rates - High sickness absence rates - High use of temporary/locum staff - High agency spend	
	Professional Engagement	- Ineffective teamwork and poor working relationships - Inadequate systems for record keeping and case management - Unrealistic workloads - Disconnect between clinicians and managers	
	Clinical & Care Performance	- Failure to meet national performance indicators - Unwarranted variations in outcomes, access, productivity, performance and patient flow - Non-compliance with standards - Poor inspection report/ratings	

*This framework was developed following a review of the reports from major inquiries into failures in the NHS over the previous 30 years. The review identified a number of recurrent key factors that were generally present in some combination (Primary Causes). A further review of the literature was undertaken to identify potential signals of emerging risks (Warning Signs).

Appendix 3

To be inserted

Foreword from General Sir Gordon Messenger

In October 2021, the Secretary of State asked me, alongside my now good friend Dame Linda Pollard, to examine the state of leadership and management in the health and social care sector. A daunting remit, but one which recognised the impact that good leadership at every level can make in a workforce which has been under incredible pressure in recent years and where the demands on its commitment and goodwill show no sign of slacking.

As an outsider with limited sectoral experience, it was with some trepidation that I set off on our listening and learning phase; a perhaps unwelcome interloper at a time when everyone was understandably focused on the pandemic and its consequences. Yet, throughout, I have encountered nothing but friendliness, candour, self-reflection, pragmatism and support from the impressive array of experts, front-line staff, academics, service users and leaders who willingly gave us their time to share their views. I have always held our health and social care workforce in the highest regard, yet my respect and admiration has deepened through witnessing their selflessness, professionalism and resilience first-hand. My thanks go to all those we spoke to, and my apologies to those we unwittingly missed.

Of the many telling observations we have heard, 2 stand out as almost universal; firstly, the very real difference that first-rate leadership can make in health and social care, with many outstanding examples contributing directly to better service, yet; secondly, that the development of quality leadership and management is not adequately embedded or institutionalised in our health and care communities. We have consequently focused our findings on areas which improve awareness of the impact that good leadership can have, and which instil it as an instinctive characteristic in everyone, not just those with the word in their job title.

Huge variety exists in the way primary, secondary and social care is structured and governed, so it has proved difficult to identify sensible interventions that have consistent relevance and impact across the board. The NHS is itself far from a homogenous unified organisation but rather a federated ecosystem where complex tribal and status dynamics continue to exist. Given the clear benefits of cross-boundary teamwork and collaborative behaviours, everything should be done to encourage greater parity of esteem, conditions and influence between sectors and, within secondary care, a re-balancing of the focus on acute trusts to the benefit of their community, mental health and ambulance trust counterparts. The vast majority of health and care delivery never touches the acute sector, and it is in the interests of all to keep it that way, so more equitable representation

and empowerment must be a key enabler to enhanced collaboration. Equally, the more that can be done to instil locally a culture of teamwork, understanding and shared objectives across the primary, secondary and social care communities, the better will be the nation's public health outcomes.

To those of our recommendations which require time and resource to implement, I predict a partially understandable reaction that the current pressures on the system preclude investment beyond the urgent. My response is that a well-led, motivated, valued, collaborative, inclusive, resilient workforce is 'the' key to better patient and health and care outcomes, and that investment in people must sit alongside other operational and political priorities. To do anything else risks inexorable decline.

I would like to thank the review team who have supported me so energetically and ably. Without their insight, industry and support, I would still be lost in the foothills of the challenge set me and will be forever grateful for their patience and commitment over the last few months. A special mention must go to my co-lead, Linda Pollard, who has contributed so much despite also holding down a crunchy day-job. Her wisdom, decency and forthrightness have shone through every day and, if this review achieves what it sets out to, the plaudits are hers.

Sir Gordon Messenger
8 June 2022

Executive summary

For a report like this to have the impact intended, it needs to speak to the community it affects. It must be supportive but honest. It must recognise the challenges and the context faced, but it cannot duck the difficult or uncomfortable. It should respect the everyday commitment, determination and goodwill of leaders and staff at every level to improve outcomes and experience for patients and service users yet also, through well-intentioned, constructive criticism, aim to provide a framework for improvement.

In that vein, we must confront the fact that there has developed over time an institutional inadequacy in the way that leadership and management is trained, developed and valued. Collaborative behaviours, which are the bedrock of effective system outcomes, are not always encouraged or

rewarded in a system which still relies heavily on siloed personal and organisational accountability. Very public external and internal pressures combine to generate stress in the workplace. The sense of constant demands from above, including from politicians, creates an institutional instinct, particularly in the healthcare sector, to look upwards to furnish the needs of the hierarchy rather than downwards to the needs of the service-user. These pressures inevitably have an impact on behaviours in the workplace, and we have encountered too many reports to ignore of poor behavioural cultures and incidences of discrimination, bullying, blame cultures and responsibility avoidance. We experienced very little dissent on this characterisation; indeed, most have encouraged us to call it out for what it is.

These symptoms are not, we would observe, necessarily the fault of historical or existing leadership teams or their staff. They are the result of a combination of factors over many years; some structural, some cultural, some emanating from behaviours at the top, including politicians, some born of complex inter-professional and status issues in the workplace. The important conclusion, however, is that they should not be tolerated as they directly affect care of the service-user as well as the staff, and that they can be tackled but only through determined cultural change from the top of the system to the front-line.

The recommendations of a one-off review cannot provide all the necessary ingredients for such a shift, but we do attempt to identify key interventions which we hope will deliver momentum and scale. We identify the point of entry as a critical opportunity to set cultural and behavioural expectations, and to emphasise that how one behaves is as much a component of professional acumen as what one does. We propose a locally delivered mid-career development event, designed to bring together professionals from all parts of health and social care around the triple lens of collaborative leadership, broader cross-sector awareness and understanding, and behavioural expectations. We encourage the medical profession to examine honestly their role in setting cultures, given their unique influence in the workplace dynamic. Most critically, we advocate a step-change in the way the principles of equality, diversity and inclusion (EDI) are embedded as the personal responsibility of every leader and every member of staff. Although good practice is by no means rare, there is widespread evidence of considerable inequity in experience and opportunity for those with protected characteristics, of which we would call out race and disability as the most starkly disadvantaged. The only way to tackle this effectively is to mainstream it as the responsibility of all, to demand from everyone awareness of its realities, and to sanction those that don't meet expectations. EDI should become a universal indicator of how the system respects and values its workforce, and the provision of an

inclusive and fair culture should become a key metric by which leadership at all levels is judged.

Beyond cultures and behaviours, we chose to focus on the current absence of accepted standards and structures for the managerial cohort within the NHS. With known exceptions, it has long been a profession that compares unfavourably to the clinical careers in the way it is trained, structured and perceived, and we received strong feedback from managers at all levels that greater professional status and more consistent, accredited training and development are required. This training must be aligned to professional skills required in the future, including digital and transformation, as well as core managerial delivery. We make recommendations to that end.

This approach to career management spills over into how individuals' particular skills and talents are encouraged and developed, and we heard frequently that managers do not always feel institutionally supported in their career choices. We did not find much evidence of a systemised career management function which exists to grow the right experience and talent and to place it where it is needed most. While there are many examples of world-class leadership in the NHS, we would observe that it often exists through the endeavours of an individual rather than as a consequence of proper talent management. The flip side of this opportunistic approach to succession planning is that it lacks equity and does not guarantee that the most deserving leaders reach the top. We would include non-executive director (NED) appointing in the same bracket. Despite the pivotal governance role of boards, the selection and development of NEDs is currently too localised and arbitrary to assure the right balance of skills, experience and background around the table.

It is clear that effective leadership can be an important, but by no means the only, component in addressing the thorny issue of geographical variation in the quality of care. We welcome the ongoing efforts by the current leadership to tackle this, and provide recommendations which seek to provide effective incentives for the right talent and teams to commit to these challenges, along with a package of support to give them the best chance of success.

The last section of the report is devoted to implementation, recognising that anyone can have great ideas but, if they don't lead to action, they are for nought.

Summary of recommendations

1. Targeted interventions on collaborative leadership and organisational values.

A new, national entry-level induction for all who join health and social care.

A new, national mid-career programme for managers across health and social care.

2. Positive equality, diversity and inclusion (EDI) action

Embed inclusive leadership practice as the responsibility of all leaders.

Commit to promoting equal opportunity and fairness standards.

More stringently enforce existing measures to improve equal opportunities and fairness.

Enhance CQC role in ensuring improvement in EDI outcomes.

3. Consistent management standards delivered through accredited training

A single set of unified, core leadership and management standards for managers.

Training and development bundles to meet these standards.

4. A simplified, standard appraisal system for the NHS

A more effective, consistent and behaviour-based appraisal system, of value to both the individual and the system.

5. A new career and talent management function for managers

Creation of a new career and talent management function at regional level, which oversees and provides structure to NHS management careers.

6. More effective recruitment and development of non-executive directors

Establishment of an expanded, specialist non-executive talent and appointments team.

7. Encouraging top talent into challenged parts of the system

Improve the package of support and incentives in place to enable the best leaders and managers to take on some of the most difficult roles.

1. Introduction

Effective leadership creates successful teams, and successful teams drive better outcomes. The best organisations are those which invest in their people to unlock their potential, and which build strong teams around a unifying purpose. The most successful are those which also foster leadership and accountability at every level, and where everyone is encouraged to become an agent for something bigger than themselves. This should be our goal.

There are many examples of inspirational leadership within the health and social care sector, delivered in the face of enormous pressure. From ward to board, from the manager in a care home to the receptionist in a GP surgery, great leadership and personal example are being exercised daily in pursuit of the best possible outcomes for patients and public health. But such qualities are not universal and nor are leadership and management skills engrained as the basic building blocks of organisational success, as they perhaps are in other sectors.

We need to recognise that the context for change is highly challenging. External pressures such as manifold performance metrics, stringent regulatory requirements, and short-term political demands, combine with internal pressures such as staff shortages, budget issues, sectoral disparity

and pandemic-induced backlogs to create a very difficult backdrop for compassionate leadership and collaborative, inclusive behaviour to thrive. These pressures can lead to 3 unwelcome outcomes:

- they drive a singular fixation on the task in hand, often to the detriment of nurturing the team and supporting its individuals. Over time this has certainly contributed to poorer experiences in the workplace and worsening outcomes; manifested by higher absence rates, deteriorating staff engagement and performance downturns
- they create an organisational instinct to prioritise the needs of the system and its hierarchy over a focus on the better patient and public health outcomes
- they can feed a sense of futility and helplessness in the workforce because individuals perceive they lack the tools or ability to rectify what they know is wrong

To reverse these trends requires a re-calibration towards building stronger teams and a renewed sense of respect and value amongst an empowered workforce, delivered through committed, compassionate leadership from bottom to top. The hard fact is that this must be prioritised alongside the pressing operational needs, and we should be ready to deploy the justification that spending time and resource on looking after the workforce will quickly repay the investment through improved support to patient and service users. Equally, the best way to root out inefficiency and waste is to encourage a collective accountability to tackle it, through empowerment and teamwork at all levels. In every way, investing in leadership and team-building makes economic sense.

Every opportunity must therefore be taken to embed such behaviours so that they become institutionally valued and instinctive to all. And right now we suggest a number of powerful factors combine to provide a generational opportunity to make the necessary cultural shift, owned and driven by the leadership at all levels of healthcare, social care and government:

- structurally, the introduction of the Health and Care Bill and the advent of integrated care systems (ICSs) provide greater opportunity to promote cross-sector collaborative and inclusive behaviours to deliver better system outcomes. The [integration white paper](#) further reinforces the value of close, inter-professional working at local level
- organisationally, the rationalisation over the coming months into a unitary NHS England (NHSE) provides the opportunity to align behind a core set of values and a common leadership culture, with the potential for spill-over benefits into both primary and social care.

Also, the emerging NHS operating model should provide the framework to align responsibilities, accountabilities and authorities

- internally, the [NHS People Plan](#), [People Promise](#) and [Our Leadership Way](#) provide the manifesto for change in the health sector; they deserve time to bed in and, if owned at every level and not perceived as merely more guidance from the top, have all the right components to motivate change
- culturally, a positive legacy of the pandemic is that it has changed the workplace dynamic across health and social care; driving accountability downwards, encouraging innovation, magnifying the value of teamwork including across sectoral boundaries, and strengthening a workforce sense of community through common experience and shared hardship. This sentiment should be capitalised upon

This introduction sets out both the opportunities and challenges which face our health and social care community. A one-off review like ours is unlikely to drive the deep cultural change needed – that must be the responsibility of existing leaders at all levels – but our hope is that our recommendations can provide the necessary frameworks and momentum to take the plunge.

Methodology

We kept our approach simple; form an inclusive and diverse team, consult as widely as possible, remain transparent throughout. Our excellent team, brought together at short notice, included representatives from the Department of Health and Social Care (DHSC), NHS England, Health Education England, NHSX and social care leaders, as well as clinicians, managers and academics – all bringing their own lived experience and personal knowledge of the health and care system. An early decision to ensure very strong EDI expertise in the core team proved consistently valuable.

Our ‘listen and learn’ phase was extensive, engaging with more than 1,000 stakeholders on over 400 different occasions, plus welcoming contribution from all via an open email address. We heard from all parts of the system and across the breadth of primary care, secondary care, local government, public health, social care, charity sector, patients and people who draw on care and support. We sought to avoid speaking only to the well-performing, better-known parts of the system, and actively encouraged constructive challenge and dissent throughout, including the establishment of a

challenge board which proved highly effective. COVID measures prevented us from visiting many places personally, yet the generosity of people at every level to give up their time was highly encouraging and indicative of their desire to drive positive change.

We have attempted to limit the number of recommendations to a digestible number, recognising that implementation on too broad a front can quickly dilute impact. Instead, we have invested in working closely with those who will need to own the recommendations if they are to take root. Where appropriate, we have tried to align with existing initiatives and to support the conclusions of previous reviews. This includes [Tom Kark's recommendations](#) regarding the fit and proper persons test for directors, which we feel are necessary alongside ours to ensure poor leadership is dealt with effectively. We have tried to avoid being over-specific in framing our findings, in the knowledge that subsequent co-creation is the best way both to ensure buy-in from the communities they affect and to minimise unforeseen disruption during inception.

Scope

Our terms of reference encouraged us to examine the nature of leadership across the entirety of health and adult social care, and from the top to the bottom of both. With a remit of this scale, we have necessarily focused in on a few key themes which we hope will yield the largest impact. One challenge we faced was the very different structures, governance and accountabilities that co-exist across sectors, and it quickly became clear that the more hierarchical secondary care sector has more identifiable levers of change than the flatter, dispersed, multi-provider structures of the wider health and care landscape, particularly in primary care and social care. This can have the effect of making it harder to enact universal change in the latter sectors, and can also heighten the risk that individuals find opportunities for development more difficult to access.

We have attempted, with some success, to avoid a disproportionate focus on secondary care in our thinking and many of our recommendations are of relevance across all sectors, particularly those which address cultural and behavioural development. But we reluctantly conclude that we have not done them full justice and would advise further work to identify how the impact of better leadership and management can be applied most effectively in our primary and social care communities. Specifically, we commend the focus on developing primary care leadership in the work that Dr Claire Fuller is leading on a stocktake of primary care within ICSs. This

will provide specific and practical advice to the ICS chief executives on how they can accelerate implementation of integrated primary care and prevention ambitions in the NHS Long Term Plan, which will include focusing on the importance of nurturing primary care leadership in their own systems. On social care, we have sensed a strong appetite amongst both local government and independent providers for collective, pan-sector leadership and management development, and strongly support the need for greater parity of investment in social care leadership.

2. Findings

This section sets out the key findings from our review which ranged both widely and deeply in health and social care. We encountered many examples of outstanding practice, including the difference that good, mature, collaborative working can make. Yet we also found areas where change and improvement are necessary to ensure leaders and managers are supported to deliver the best possible care. In that respect, while some of our observations may be perceived as critical or negative, they are by no means universal. But we heard them often enough to call them out.

Cultures and behaviours

In this area of cultures and behaviours, 2 broad themes emerged: the culture of collaboration and the culture of respect. Both themes emanate from and determine how people treat each other and service users; both affect the quality of care and outcomes for service users.

The culture of collaboration

We found that the current cultural environment tends to be unfriendly to the collaborative leadership needed to deliver health and social care in a changing and diverse environment. The system is undergoing a fundamental change from a competitive to a collaborative ethic, and behaviours need to reflect this. Decision-making too often relates to a narrow and limited set of accountabilities that do not allow, encourage or reward collaboration. We recognise that this is a direct result of how performance is currently measured, but strongly believe that a re-balancing towards collaborative, cross-boundary accountability is a pre-requisite to better outcomes.

We saw that the urgent tends to eclipse the important. Staff habitually respond to pressures inherent in the workplace by prioritising the task in hand rather than the team and individuals who together complete that task. This is unsustainable. Principal among the many agents that cause reactive rather than constructive behaviours are those pressures from above that force upward-looking rather than outward-looking responses. Some staff, for example, are presented with the responsibility to meet an external metric while lacking the ability or resource to meet it, while others operate freely without oversight in isolated areas. We saw accountability without authority, and vice versa.

Finally, we saw that leadership itself is undervalued as a way of setting the context for collaboration. Leadership is viewed as the responsibility only of those in specific line manager or senior leadership positions, rather than as a quality that runs instinctively through the entirety of the workforce. We found no consistent view of principles for collaborative or systems leadership; current models extol the virtue of certain behaviours but lack a structured framework.

The culture of respect

We heard too frequently that poor inter-personal behaviours and attitudes were experienced in the workplace. Although by no means everywhere, acceptance of discrimination, bullying, blame cultures and responsibility avoidance has almost become normalised in certain parts of the system, as evidenced by staff surveys and several publicised examples of poor practice. This exists at the micro-level, in individual workplaces, and across sectors, where the enduring lack of parity of esteem, conditions and status between healthcare and social care remains a blight on effective collaborative working.

How an organisation performs and behaves in relation to EDI is a clear indicator of its maturity and openness. Further, it will be a clear determinant of how an organisation fares in a rapidly changing social and work context. In this regard, we found that EDI, which is about respectful relationships and underpins a wider culture of respect, is partial, inconsistent and elective. In some places it is tokenistic.

Improving EDI is also a way of reframing career progression. The latter frequently depends on chance, contacts, regional variation, available time and budget. By training leaders to identify where such unfairness exists, access to opportunities will become allocated more fairly, and career progression will be determined more equitably.

In the NHS, we sensed a lack of psychological safety to speak up and listen, despite the excellent progress made since the [Francis Report](#). We would observe that the Freedom to Speak Up initiative can be narrowly perceived through the lens of whistleblowing rather than also organisational improvement, and we would encourage a broader perspective.

The improvement of organisational learning within health and social care deserves a deeper examination. Too often we encountered limits on the freedom to try without fear of failure, and a willingness to tolerate poor practice while expending energy on workarounds.

Implications of our findings

First, on collaboration. The NHS is a complex ecosystem where personal, professional and organisational accountabilities flow vertically through distinct silos. Similarly, social care is a complex landscape of overlapping public, private, and charity provision. The system needs mechanisms to build and reinforce horizontal, collaborative decision-making; within and between individual organisations, and across the full health and social care sector [see recommendations 1, 2, 3, and 4]. To deliver this, we identify 2 critical points of intervention in careers to embed the necessary behaviours and to align expectations: set culture and improve knowledge [see recommendation 1].

Second, shared greater awareness of the entirety of health and social care would lead to greater empathy and understanding. The system must improve mutual awareness and provide opportunities for staff to engage beyond their professional environment, to appreciate the totality of system, and to value diverse professional approaches. ICSs and integration at place provide excellent opportunities to test and prove the value of collaborative and inclusive leadership.

Third, we think that EDI must be embedded and mainstreamed as the responsibility of all regardless of role, and especially leaders and managers from front line to board. This must include the practice of zero tolerance of discrimination, but also greater awareness of the realities in the workplace for those with protected characteristics. Health and social care must work harder at EDI, recognising it is important in its own right, and key to how seriously an organisation treats the lived experience in the workforce and upholds practices that deliver equitable outcomes for all. Beyond mainstreaming, we also recognise the need for positive action [see recommendations 1, 2, 3, 4, 5, and 6]. We are not advocating for additional EDI professionals; indeed we would anticipate a reduction in numbers over time as leaders demonstrate that they are equipped with the

right skills to address inequality and create inclusive working cultures for all.

Standards and structures

The practice of management relies on both standards and structures; it emerged through our engagement that these are currently either insufficient or absent. Our observations cover the NHS specifically, but we recognise that many of these issues are equally relevant in wider health and social care. We recommend further work to investigate the levers to address common challenges, to ensure shared learning across health and social care can be applied with the most impact.

We found that management tends not to be perceived – formally or informally – as a professional activity. Management lacks the status enjoyed by the established professions in health and social care. We heard that this derives from the absence of acknowledged, universally applied standards to achieve agreed levels of behaviour and competence; and from inadequate, unstructured career support. Management can therefore appear as an under-valued career, rather than one at the very heart of great care.

We found inequity in how different managers are perceived; for example, the NHS Graduate Management Training Scheme (GMTS) is highly regarded, but it is unfair that participants are frequently treated as elite purely by virtue of having undertaken the scheme. Managers who do not join via GMTS, often equally talented, do not benefit from the same profile or opportunities. Lateral entrants are often inadequately inducted into leading and managing in context; and skills gained outside the sector, including those who have trained overseas, are not always fully valued. Clinicians who choose to take on leadership roles in addition to their clinical work told us they had little to no specific training to prepare them.

Management and leadership training, although excellent in some instances, is not based on any consistent or agreed universal standards, is an unhelpful mix of accredited and unaccredited courses and opportunities to access training are inequitably applied. Too much management and leadership training and development, and associated cultural transformation work, is piecemeal, partial and isolated. This whole landscape needs tidying.

There are excellent examples of talent management within organisations, but they are too widely scattered and are rarely completely inclusive. We consistently heard from managers that the lack of structure means career opportunities can appear to be linked more to who one knows and the network one is able to create, than to one's skills and experience. We saw that career management does not start early enough, and this leads to narrowing career paths to the detriment of wider experience. Career management needs to support those in their first role as much as those at mid and later career; too often individuals are recruited to jobs, rather than recruited to careers.

We found a lack of consistency with appraisals – and in some areas, these were absent altogether. Appraisals can range from a performance review and a development conversation to a simple tick-box of tasks completed. Development needs are either focused on individual wants with no relationship to organisational goals, or are neglected in favour of immediate pressures. It was rare to hear of appraisal linking individual, team, organisational and system goals effectively.

Finally, workforce data. Currently, data is not collated and exploited to the benefit of the individuals, teams, organisations, systems or regions as a whole. The result is that excellent talent remains invisible, career support remains opportunistic, talent-hoarding becomes the privileged domain of those that can, and the system struggles to deploy the best people to work where their skills are needed most.

Implications of our findings

There is a need for universal standards, covering practical, procedural and behavioural elements with the aim of ensuring a clearer set of expectations, and in turn equitable recognition and parity. Proper standards require consolidation and coordination; both are lacking in the current preference for multiple competency frameworks and lists of competencies of variable quality. These standards need to apply to and work for all, including those working part time or flexibly.

Consequently, there is a need to develop a formal training curriculum for managers, to deliver against these standards [see recommendation 3]. This requires larger-scale delivery of training to a pre-determined community, as opposed to the current system which is based on availability and opportunity. Completion of this training should be a pre-requisite to advancement to more senior roles, as current gateways can be arbitrary and inconsistently applied. The modules within this curriculum must allow for different career paths and preferences, but also be accredited to ensure high-quality consistency which is currently lacking. New accreditation could

provide alternatives to master's-level expectations stipulated in many Agenda for Change job descriptions currently and will need to take account of prior learning within the bench marking required for the NHS.

We heard that more can be done to support and guide individuals in how they make their career choices. While career and talent management should remain the responsibility of all line managers, organisations and systems, we can see real value in greater oversight at regional level. This new, regional function should have direct responsibilities as well as strategic oversight of managerial careers, working in close partnership with all parts of the system including the system chief people officers or equivalent and organisations' human resource directors [see recommendation 5]. This function becomes the focal point for the NHS human capital in the region with vital responsibility for the collection of data.

To be truly effective as a talent management function requires a more consistent and effective approach to appraisals, including better training for line managers in their delivery [see recommendation 4]. There is currently too much variability in the quality, effectiveness and outcomes [see recommendation 2].

Wider observations

As well as the findings outlined above, we have a number of other observations.

Regulation and oversight

We found that there is a positive view that the CQC can influence collaboration across the whole of health and social care through its inspections, and welcome its increasing focus on teams and systems. The well-led domain of CQC reports can develop its focus on culture and values rather than on managerial processes, and thereby reflect collaborative, compassionate and inclusive leadership in organisations. A judicious use of metrics and data can be a uniting and enabling agent, particularly if they are the basis for open and honest discussions; however, we also heard that over-emphasis on metrics can be burdensome and counter-productive. Where quality of care falls below what is required, the tone and outcome of regulatory visits can leave leaders feeling isolated and unsupported. With this in mind, we welcome the shift in emphasis from a punitive model to a remedial one.

Open, honest organisational learning here is priceless. We heard that good organisations have a positive relationship with regulators, while those performing less well often wait to be told what to improve. Transparency, and the ability to learn from mistakes and respond without blame, are all necessary for quality improvement; regulators can influence and promote both professional and organisational behavioural changes necessary. Readiness to seek help is a vital first step towards improvement and the route to external support must be clear, timely and stigma-free [see recommendation 7].

The role of the professional regulators (General Medical Council, Nursing and Midwifery Council and others) relates primarily to individuals but is increasingly important in assuring organisational quality. To ensure better read-across to professional standards, we would promote collaboration across all regulators in developing the management standards and the training materials for managers.

Clinical leadership

We found that the interaction between the clinical community and the rest of the workforce is a key element in setting the right cultures and behaviours. The authority and influence that doctors have both in society and within the NHS, means that the medical profession does have a unique responsibility for leading behavioural change where necessary and supporting a positive culture within their sector where all staff flourish.

Clinicians bring a perspective that spans patient interaction and wider population health needs. Done well, their knowledge and innate understanding of their 'clinical tribes' can be a huge force for good, but we have equally seen evidence that it can lead to entrenchment and loss of team ethos overall. We encountered the flawed assumption that simply acquiring seniority in a particular profession translates into leadership skills and knowledge; this both reduces the quality of leadership overall and can drive a sense of frustration for those individuals. Doctors are often co-opted for management roles, particularly early in their consultant career, for which they often feel inadequately prepared in comparison with their clinical training. An associated lack of fulfilment can set the tone for their approach to management later in careers.

We heard from allied health professionals that the lack of visibility of leaders from their professions on boards created a sense that careers in management would be limited. Senior nurses talked about 'going to the dark side' as a comment often made when they moved into senior management roles, although nurse postgraduate training does provide

elements of management learning. Again, the approach was felt to be ad-hoc and inconsistent.

Overall, even the most successful of clinical leaders reported that their career trajectories had been serendipitous, and that their knowledge was acquired in unstructured opportunities in comparison to their professional training.

We know the system will benefit from well trained, enthusiastic, supported clinical managers and leaders. Alongside the provision of national standards for NHS managers [see recommendation 3], education providers from undergraduate through to postgraduate education, working with professional regulators, have the opportunity to embed and align learning to prepare the clinical professions as future leaders.

The consistency of learning management and behavioural skills is often subsumed by clinical pressures. Extending access to the proposed management training bundles [see recommendation 3] provides an opportunity for a more structured and collective approach to management training for all clinicians. For the medical profession, this must include the trained medical workforce (that is, GPs, consultants and doctors in the staff and associate (SAS) grades). There are different challenges in primary care where we heard there is significant variation in leadership structures within and between GP practices, in their networks. We were told that it is unclear to a newly qualified GP which route provides the best leadership experience in comparison to the traditional clinical director to medical director pathway in hospitals. The new place partnership boards and integrated care boards should provide the outlets that are currently lacking for primary care and public health leaders. The same should be true for local social care leaders.

Leadership delivery in the future

We believe the current climate, including the move towards health and care integration and the work currently underway to merge the arms-length bodies and create a new NHSE, generates opportunity for a fresh approach to preparing leaders and managers in the future.

With regard to leadership development, it is entirely right that it is the role of the centre to demonstrate and drive the appropriate cultures and behaviours, around a set of unified values and purposes. We would observe that this is easier to achieve in the more unified structures of the NHS than in social care, and would encourage investment in setting common cultures and purposes across health and social care as a whole [see recommendation 1]. Further, as knowledge content changes with the

impact of digital health and other innovations, future leaders need access to a very different curriculum.

In the context of the NHS and social care, we heard that leadership development is currently uncoordinated and inconsistent, with a crowded landscape of different guidance, agencies and oversight. We believe that rationalisation and accreditation of training opportunities is required, at a greater scale that serves the entire system [see recommendation 3]. There are some excellent leadership development offers available, but they are offered on a 'pull' basis (that is, available but not expected), rather than a 'push' basis where there is expectation that prescribed cohorts will participate. We advocate a shift to the latter.

Collaborative action from the centre, the regions and at local level in healthcare will move the system from being an opportunistic, 'pull' model described above to one that sets broad, core curricula and manages accredited delivery, recognising that a strong local flavour needs to exist in the detail. The existing leadership delivery models, particularly in the NHS, require change to reflect this. Greater alignment of leadership training and development across health and social care sectors would yield immediate benefit.

3. Recommendations

We think some of the changes we recommend are gradual, subtle, and precise; we think others are immediate, radical, and wide-ranging; we think all are necessary. By driving improvement in leadership and management, we are confident that their implementation will have a positive outcome on both public health outcomes, productivity and efficiency.

1. Targeted interventions on collaborative leadership and organisational values

A new, national entry-level induction for all who join health and social care.

A new, national mid-career programme for managers across health and social care.

As the delivery of care transforms, a move to greater integration, different skills, and more collaborative behaviours is required. This includes a need

for improved, standardised training on equality, diversity and inclusion [see recommendation 2] as part of a new approach to the production of skilled managers. There are 2 critical waypoints where a significant impact can be made with new training interventions:

- at entry into a career in health and social care, by whatever route
- at mid-career where individuals often refine their ambitions and career trajectories

What is needed here does not currently exist: this is not about scaling any existing training programmes.

Entry level

The scope here is intentionally broad, capturing the breadth of those who enter a role in healthcare, social care, local government, and relevant voluntary and private sector organisations. In the NHS, [around 196,000](#) staff joined or took up new roles between September 2020 and September 2021; in social care [approximately 490,000](#) staff joined or took up new roles in the financial year (FY) 2020 to 2021. The potential for impact is significant, the requirement for scale imperative.

The aim of this programme is to introduce new starters to the culture and values that are expected within services and to foster a sense of belonging wider than the immediate organisation. The content of this programme should therefore be co-created by partners across health and social care, including NHS England, DHSC, Local Government Association, Skills for Care, staff networks and patient representatives. This programme should be for all new entrants including those entering formal programmes (such as the Graduate Management Training Scheme or the Assessed and Supported Year in Employment programme) and be used in combination with local inductions. The framework should be nationally set, with certain allowance for local variation, and made universally available to ensure consistency. There is scope to build on the Care Certificate standards, which already set out the introductory knowledge and skills that are important for those in non-regulated roles.

Mid-career

This programme is targeted at middle managers working in healthcare, social care, local government, and relevant voluntary and private sector organisations. We believe this needs to be 3 to 5 days and in person to get the full benefit, including ideally the creation of local alumni networks. It should work in harmony with the new national leadership programme outlined in the integration white paper. On implementation, the sectors

should work together to identify the cohort for this programme which could include, but is not limited to, GPs, mid-career clinicians, NHS middle managers, principal social workers, registered managers and so on. It is vital that the content is co-created if we are to realise the level of collaboration, system awareness and local delivery needed for the future. Again, the framework content should be nationally set to ensure consistency, with flexible and local delivery, either within ICSs or at place level across regions.

2. Positive equality, diversity and inclusion (EDI) action

Embed inclusive leadership practice as the responsibility of all leaders.

Commit to promoting equal opportunity and fairness standards.

More stringently enforce existing measures to improve equal opportunities and fairness.

Enhance CQC role in ensuring improvement in EDI outcomes.

It is the task of leaders at every level to cultivate the conditions for individuals to overcome entrenched and often unacknowledged disadvantage, by ensuring staff recognise and remove subtle exclusionary practices, and by working to remove the set of unspoken assumptions that favour certain groups in terms of career advancement [see recommendation 5]. Dedicated EDI professionals exist to enable this transition. We would anticipate the numbers of dedicated experts to reduce as they successfully instil such awareness in leadership at all levels.

If implemented effectively, we are hopeful that every one of our recommendations will improve equality opportunity. In addition, we believe the following specific measures are urgently needed to enable the necessary improvements on EDI outcomes across health and social care:

- educate leaders to ensure they understand their role in demonstrating and improving inclusive leadership. This must include a more central role for EDI in leadership training and development which, in turn, requires greater skills and understanding of the topic from those delivering the training. We would encourage the use of the Everyday Discrimination Scale as a useful, objective tool which supports leaders and teams to address this issue in the workplace
- agree and set uniform standards for equal opportunities and fairness across health and social care at entry-level and mid-career level [see

recommendations 1 and 3]. Use accredited training modules to set and maintain these standards [see recommendation 3]. Ensure organisational and individual accountability for delivery against these standards, including through appraisals [see recommendation 4]. Uniform standards should help leaders learn how to address discrimination at individual, team and systemic levels

- more stringently enforce existing measures to improve equal opportunities and fairness across all NHS functions. We would encourage similar universal targets in social care. Teams and organisations should set year-on-year goals for improvement, for example by increasing the representation of under-represented groups in training, in development opportunities, and in senior roles [see recommendation 5]
- to support such accountability, the CQC needs to reinforce the behavioural and cultural change necessary, as recommended in the [Inclusive Britain](#) policy paper. This includes ensuring that regulators take account of EDI data as part of their organisational assessments, and particularly the seriousness with which it is viewed by leaders

3. Consistent management standards delivered through accredited training

A single set of unified, core leadership and management standards for managers.

Training and development bundles to meet these standards.

While these recommendations are NHS specific, there is scope for the standards and core content of training and development bundles to be used more widely across health and social care, which should be explored in further detail. There is also good practice within social care from which the NHS can learn, such as principal social worker and registered manager standards.

The implementation next steps are as follows:

- development of the standards – the standards should be co-created, with input from across healthcare, including patient representatives, accounting for good practice that already exists, such as in the NHS People Plan. They should cover operational, strategic management and most importantly, the behavioural components and responsibilities for managers for inclusive leadership, as

- underpinned by all parts of this review. Once developed collaboratively, they should be nationally led and accessible to all
- development of the training bundles to meet the standards – single, standalone training intervention is unlikely to deliver the depth and breadth required, so we propose the co-creation of training and development bundles. These bundles should include a number of consistent training modules, on areas such as inclusive leadership [see recommendation 2] and core management skills and tools (such as how to conduct an effective appraisal [see recommendation 4]). This should build on existing good practice, such as the work of Proud2BOps in this area. We believe these bundles need a single accreditation process within the NHS to ensure consistency, high quality and portability. The bundles should also offer choice and flexibility to accommodate profession-specific requirements, local needs and individual career aspirations. Flexible components could include experiential learning, job shadowing, e-learning and skills-based projects
 - roll out – in the first instance, the bundles should be made available to non-clinical NHS managers at entry and at a prescribed mid-career point. This will underpin a more established career pathway and professional status for non-clinical managers; we believe that the qualification needs to be transferable, recognised across the NHS, and a pre-requisite for further advancement. Some flexibility will be required for lateral entry. Over time, this should be a mandatory requirement for NHS managers [see recommendation 5]
 - expansion – following roll out, there is opportunity to expand these bundles to all NHS clinical and non-clinical managers alike. This necessitates further work with educators, commissioners and regulators to develop the read-across to postgraduate clinical curricula where leadership and management skills are required

4. A simplified, standard appraisal system for the NHS

A more effective, consistent and behaviour-based appraisal system, of value to both the individual and the system.

While appraisals were paused during COVID, all staff in the NHS should have an annual appraisal. However, some express cynicism about effectiveness, as shown in [the latest NHS Staff Survey](#). Improvement is needed to the process and quality of appraisal, irrespective of whether individuals wish to progress to higher roles or not. The new system should be based on improvement methodology in 2 parts:

- performance in role including both technical and behavioural elements
- a career conversation around ambition and aspiration

This should enable individuals, organisations, and the system to clearly identify talented individuals and their development needs; and then link them to the wider system [see recommendation 5].

Commitment to a unified, simplified appraisal process demonstrates a move away from siloed processes, short-termism and the whims or biases of individual leaders and managers. It requires a shift from the current unwarranted variation in how performance and career aspirations are managed, to a process that is equitable and supportive for all – working at the pace of individual aspiration.

All NHS employees should be within scope for this recommendation, but this should start with a focus on non-clinical managers in the 2022 to 2023 financial year to ensure those most in need of structured career management are supported as a first priority.

The new process should assess the extent to which the individual has upheld the core values of the service and the extent to which they demonstrate a commitment to EDI and fair treatment, not just technical skill [see recommendation 2]. It should focus on how the individual has behaved, not just what they have done.

Appraisals will continue to be an annual performance and career conversation, with in-year follow up, based on a single set of documentation, which should be co-created, agreed nationally and made available to all organisations. It should be designed to sit alongside and complement documentation needed for professional revalidation. The new system should have latitude for team input, including more extensive use of 360 feedback where appropriate.

As the effectiveness of appraisal is as much to do with the appraiser as with process, the management bundles [see recommendation 3] include compulsory training for effective, fair and inclusive appraisal. It is necessary that the new appraisal system considers the appraisee's experience of their manager, in relation to their commitment to EDI and their inclusive practices [see recommendation 2]. Appraisal data, including completion, satisfaction and outcomes, should then form part of the evidence of a well-led organisation within CQC assessments.

5. A new career and talent management function for managers

Creation of a new career and talent management function at regional level, which oversees and provides structure to NHS management careers.

There is a need to create a more aggregated career management function to address 3 problems:

- the lack of clarity for career progression in management
- the failure of the system to utilise and encourage the diverse talent available [see recommendation 2]
- the shortage of people wanting to be managers in challenged parts of the system [see recommendation 7]

An effective career and talent management function could overcome these challenges, providing a compact between NHS managers and their organisations – both in support of the individual and to the benefit of the organisation and the system. The function should sit predominantly with NHS England at regional level; but forming part of a coordinated structure at organisation, place, system and where necessary national level. It should initially support and provide structure for non-clinical NHS management careers, with the potential to expand the remit rapidly to also cover clinical managers once established.

This needs to be inclusive, with sufficient scope, scale, and authority to perform the following functions:

- plan – give structure to succession planning wider than can be achieved in individual organisations or systems; including moving people with the right skills and experience to where they are needed most [see recommendation 7]
- support – provide individuals with career advice and support; encourage and signpost training and development opportunities; and provide clear routes to promotion for every individual, encouraging breadth of experience [see recommendation 2].
- hold and analyse data – responsibility for data collection and storage of data on all managers, categorised by profession, in each region. Such regional databases would supplement the national database of board level appointments which was recommended in Kark's Review
- manage talent – encourage and manage the talent within a geography to ensure better visibility, effective succession planning, and matching skills to role and need. Discourage talent-hoarding, where it exists

- oversee – oversee compliance with mandated managerial standards, associated training, and appraisals [see recommendations 1, 3 and 4]

6. Effective recruitment and development of non-executive directors (NEDs)

Establishment of an expanded, specialist non-executive talent and appointments team.

All boards have 3 roles: formulating strategy, ensuring accountability and shaping culture. NEDs and board chairs achieve this through bringing independent, external perspectives, skills and challenge. They make up over half of NHS board roles, yet their importance can be undervalued.

In the absence of sufficient central support, NHS organisations and latterly systems repeatedly fund private sector executive search firms at significant cost. Despite this, appointments lack the diversity and wider experience needed for this vital assurance role, sometimes presenting people already known in the system. We must improve this.

The current non-executive talent and appointments team within NHS England is highly regarded, yet too small to achieve the depth and reach needed. An expanded team could undertake a range of new and scaled up activities to support provider and system boards in close partnership with wider NHS England regional teams. These activities could include maximising attraction, setting standards and consistency in role descriptions, role preparation, induction and onboarding, management of talent pipelines and talent pools, central and regional databases and creating networks.

The team should have clear outcome measures and be accountable for evidencing a tangible shift year-on-year in diverse appointments [see recommendation 2]. [A report by NHS Confederation](#) shows the gains made in the early 2000s towards board diversity in the NHS have not been sustained, particularly in relation to women, people from black and minority ethnic communities and especially chairs and NEDs with disabilities. From the current position, we must break the mould and ensure a wider cross section of society see themselves fulfilling this vital role. In short, the NHS must achieve greater diversity so that NED and chair roles more closely reflect the communities they serve and the staff they govern.

Without greater penetration into other sectors, investment will not result in the change needed nor deliver the pipeline of diverse NEDs that can provide the skills and oversight needed. An intervention based on the roles of the individual, team, organisation and system will best shape the NED contribution in the future. Therefore, forging greater links within systems, with other governmental departments, other public sector organisations and commercial providers is vital.

7. Encouraging top talent into challenged parts of the system

Improve the package of support and incentives in place to enable the best leaders and managers to take on some of the most difficult roles.

There are currently little or no incentives for leaders and managers to move into leadership roles in organisations in challenging circumstances. This section builds on previous recommendations in [Sir Ron Kerr's Review](#) around a 'new deal' for leaders to make improvements through the creation of "an agreed package of incentives and support for leaders that take on 'difficult to recruit to' roles".

While there is good work already in train through NHS Intensive Support Teams, an improved and more widespread offer is needed as leaders have reflected to us that the reputational risk of failure remains too high. The package of support offered to leaders and managers should consist of the following functions:

- build team capability – strategically place talented managers and clinicians into organisations and reward them with upward career progression, as being selected should be role modelled and celebrated [see recommendation 5]. Support new recruits and executive teams with a regional taskforce, which includes experienced clinicians and managers, to co-produce a sustainable improvement plan
- provide holistic support and diversity – provide support networks for executives, clinicians and managers, such as peer mentoring, coaching, training and development, and positive action programmes [see recommendation 5]
- allow time and space for improvement – NHS England, CQC and others to reduce reputational risk and target pressures by bolstering support for leaders, championing progress, and accepting that failure is a normal component of service improvement and transformation, thus allowing leaders the psychological 'freedom to fail'

- ensure pragmatism – develop realistic improvement plans with appropriate structural support. These should be explicit and set out the expectations of the team, resource and support available - including funding to improve the quality of digital, estates, and equipment (as identified in Kerr's Review). The plan should be peer reviewed by provider chief executives to ensure it is pragmatic
- attract top talent – use flexibility in available terms and conditions to attract and deploy talented individuals at Very Senior Manager level, including relocation support where available and appropriate for staff moving to rural and coastal areas where unwarranted variation tends to be greatest

4. Implementation

We strongly believe our recommendations should transform health and social care leadership and management and drive the cultural and structural changes necessary to future-proof it. But we also recognise that previous reviews have reached equally sensible conclusions but failed to have the impact they deserve. To avoid a similar fate, we would highlight the following key components of successful implementation:

- Review Implementation Office (RIO): this group, comprised of multi NHS, social care and local government members, and with the highest agency, is essential to provide and drive the pace and scale of the implementation of this review. Its task is to deliver beyond anything that we have in the system at the moment; and to foster sector-wide co-creation to set achievable deadlines and apportion appropriate responsibility. This group should have direct mandate from the Secretary of State and support from the leadership in NHS and local government to deliver the review's recommendations
- ownership and accountability by example from all leaders: for any recommendation to have a chance of making an impact, the leadership must buy into its provenance and live by its virtues. Indeed, the NHS Leadership Compact – 'Our Leadership Way' could easily be used: it has resulted from deep and wide consultation and aligns with the NHS People Plan and People Promise. We get a strong impression from the new leadership at the top of the NHS and from local government that this is an agenda they are prepared to own, incentivise and live by. But buy-in and co-creation from those most affected is also key, and we would encourage a collaborative approach to implementation, drawing on experience and insight from

all leaders and the workforces they lead. There should be a strong local, frontline representation, and service users must be incorporated

- allocated time and resource: while we recognise the continuous pressure that the system will remain under, we strongly recommend a re-balancing of time and resource towards supporting and developing the workforce and argue that this will quickly repay the investment in the form of greater productivity, efficiency and quality
- data to support decision-making: workforce data is not yet sufficiently mature to support rapid implementation of some of our findings. While service-user data initiatives are clearly the priority for the time being, we would encourage resource being available to deliver the data necessary to facilitate workforce planning and support
- firm policy on participation: we believe our recommended training and development elements should be mandatory for selected cohorts. Making participation optional will effectively de-prioritise it and, while sensible flexibility will be necessary especially in the primary care and social care arenas, we would advise a firm policy on participation
- associated rationalisation: a common symptom of change in hard-pressed organisations is that new initiatives are bolted on to, rather than merged into, existing frameworks. This only adds to complexity and inefficiency and inevitably lessens impact. There is certainly scope for rationalisation in the current approach, and we would encourage a root and branch re-alignment of leadership and management development as part of the ongoing re-organisation, with as much integration between health and social care as is organisationally feasible

We recognise that change cannot happen overnight, and that resources and staff effort are necessary pre-requisites to reform programmes. To that end, we have offered the Department and NHSE a number of recommendations for a resourced FY 2022 to 2023 programme to set the conditions for a fully-funded and supported programme of leadership and management investment programme in FY 2023 to 2024. This includes the formation of multi-disciplinary implementation teams and a number of proposals for early wins.

5. Acknowledgments

The review team was made up of a plethora of health and social care sector subject matter experts, who were a great source of knowledge and guidance:

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Urology Services Inquiry

**Written Closing Submission of
The Southern Health and Social Care Trust
(Core Participant)**

31st May 2024

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Chapter 1

The Trust's Approach to this Inquiry

1.1 The Trust welcomes, and is grateful to the Inquiry for, the opportunity to make some closing submissions in writing to the Inquiry.

1.2 At the very outset of these submissions, the Trust wishes to repeat the detailed apology it provided in its oral opening on Day 8 of the Inquiry hearings, back on 10 November 2022. We will not repeat the apology verbatim (it can be found at TRA-00639 to TRA-00660) but would stress the following:

- a. The Trust apologises *to* -
 - i. affected patients and their families (because, fundamentally, it is patients whom each of the Trust and this Inquiry serves);
 - ii. the broader public; and
 - iii. its staff, many of whom do 'every day go beyond the call of duty'¹.
- b. The Trust apologises *for* -
 - i. the fact that the care given by it to a number of patients fell below what was acceptable and that, in some cases, this has caused or contributed to harm; and
 - ii. the fact that this sub-standard care was the result, not only of failings on the part of individuals for whom the Trust is responsible (such as Mr O'Brien), but also of broader failings of Trust systems, processes, and structures.

1.3 On 8 November 2022, the first public hearing day of the Inquiry, Mr Wolfe KC in his opening submissions made the following profound statement²:

¹ Per Mr Wolfe KC in his opening on Tuesday 8 November 2022 at TRA-00306 lines 5-8.

² TRA-00321, Day 6, p48, from line 14 .

... The conduct of a public inquiry such as this can act as a watershed moment. If those who are to participate are prepared to engage cooperatively, authentically, and in a spirit of openness, and if they actively reflect upon what they, as well as their colleagues, could have done differently, or better, there will be a genuine opportunity to change healthcare provision in Northern Ireland for the better.

1.4 In its oral opening submission on 10 November 2022 the Trust, as well as apologising, responded to Mr Wolfe's statement by publicly affirming its commitment to work with the Inquiry in an open and candid way so as to ensure that past mistakes are not repeated, either by it or by any other Trust.

1.5 The Trust hopes that it has lived up to this commitment and responded to the Inquiry's call.

1.6 In this regard, we observe that, as of late May 2024, the Trust has:

- a. disclosed in excess of 400,000 pages of potentially relevant documents to the Inquiry;
- b. provided, through witnesses whom the Trust legal team represents, 158 S.21 responses³;
- c. directly assisted, through the Trust legal team, 85 witnesses, 45 of whom were called to give oral evidence across approximately 60 of the Inquiry's 95 hearing days;

³ Including several provided promptly and dynamically in respect of discrete issues that arose during the hearing of other witnesses' evidence.

- d. assisted, through the provision of documents, a number of former Trust servants or agents who are not represented by the Trust legal team (such as Mrs Brownlee and Mrs Gishkori);
- e. assisted other staff who have been amongst the 200-plus nurses and registrars who received questionnaires⁴ from the Inquiry.

1.7 Looking beyond the headline statistics of cooperation to an even more important issue, the Trust has sought to adopt a positive approach to the issues raised by this Public Inquiry; a positive approach that has extended both before and beyond the parameters of the Inquiry.

1.8 What this means is that the Trust has actively approached both the issues examined by the Inquiry and the Inquiry process itself as opportunities rather than as challenges. In particular, the Trust has viewed the Inquiry and the events giving rise to it as:

- a. an opportunity to identify, reflect upon, and be candid about its failings;
- b. an opportunity to learn from its failings and improve; and
- c. an opportunity to change culture.

1.9 Examples of this include, but are not limited to, the following:

- a. Before any Public Inquiry was ever anticipated, indeed before all of the shortcomings related to or revealed through Mr O'Brien were even apparent, the Trust had recognised that there were shortcomings in its systems and had taken steps to address these. An exemplar of this is the commissioning of the Champion '*Clinical and Social Care Governance Review*'⁵

⁴ TRA-00322, Day 6, p49, lines 11-13

⁵ WIT-46954 to WIT-47014.

in 2019 by the (then) Chief Executive and Medical Director, each of whom was, at the time, relatively new to the Trust.

- b. In 2019 the Trust began, and has since developed⁶, its engagement with Mersey Care NHS Trust (a high-performing English Trust) to assist in developing a just and learning culture where staff, rather than feeling inhibited about ‘speaking up’ where they have concerns, are supported to do so⁷.
- c. In November 2022 the Trust set up an External Reference Group (‘ERG’), chaired and populated by experienced people from outside the Trust (along with some senior Trust personnel) to provide the role of ‘critical friend’ to the Chief Executive and Directors in their work to address the shortcomings which the issues giving rise to the Inquiry have exposed⁸.
- d. The Trust has already initiated multiple improvements in its systems and structures of management, training, corporate governance, and clinical and social care governance in order to address the shortcomings within the Trust which were revealed by the Aidan O’Brien issues⁹. It has not sat back and waited for the Inquiry to tell it what to do.

⁶ By way of very brief non-comprehensive overview, this engagement began in 2019, with them delivering to the Trust presentations on an Open and Just Culture and their learning around a Zero Suicide Approach. The Trust HROD Director then underwent training with them on Restorative Just Culture in 2021, leading to the revision of Trust various Trust policies (e.g., disciplinary, conflict, bullying and harassment, and so on). Prof Joe Rafferty (CEO of Mersey Care from 2012) was the external representative when Dr O’Kane was appointed CEX in 2022 and has been carrying out a mentorship role since that time. In early 2023, this role expanded to 1:1 meetings with each Trust Director followed by a workshop and presentation to the Trust on his findings. Since then, work has included engagement by the Performance Director to assist with the Trust’s strategy development work.

⁷ See, e.g., Maria O’Kane’s witness statement at WIT-45168 para 13 and WIT-45171 para 28 and her oral evidence at TRA-11652 Line 24 to TRA-11655 line 3, TRA-11669 lines 3-22, and TRA-11732 line 9 to TRA-11733 line 21. See also the evidence of Vivienne Toal at WIT-41009 para 1(iv) and TRA-03481 line 16 to TRA-03482 line 26.

⁸ See, e.g., the evidence of Maria O’Kane at TRA-11632 to TRA-11646. An insight into the clear challenge function performed by this group is clear from the documents relevant to it disclosed by the Trust – see TRU-303646 to TRU-304283

⁹ These are considered further in Chapters 4, 5, 6, and 7.

1.10 Finally in this regard, the Trust considers that it is important to acknowledge that all of the above has occurred in a particular context. One that includes, but is not limited to, challenges created by the following facts –

- a. the Trust is operating in a health service that has been recovering from an unprecedented global public health emergency;
- b. the Trust has had to face other significant challenges such as unprecedented pressures on its services at Daisy Hill Hospital due in no small part to regional difficulties in recruiting and retaining medical staff;
- c. the Trust is operating with ever more constrained public funding in a health environment where demand is increasing all the time;
- d. many of the Trust witnesses who have provided written and/or oral evidence to the Inquiry are serving doctors, nurses, managers, administrative staff, and Board members, all with very challenging ‘day jobs’.

The Trust acknowledges that, conscious of these important contextual factors, the Inquiry has dealt with the Trust and its witnesses in an understanding, patient, and fair manner.

Chapter 2

The Trust's Approach to Closing Submissions

2.1 It is important to set out at an early stage what this closing submission is not:

- a. it is not an attempt to summarise, or address the issues raised in, the evidence given by the 85 Trust witnesses from whom the Inquiry sought written and/or oral evidence;
- b. it is not an attempt to summarise, or address the issues raised in, evidence given by non-Trust witnesses from whom the Inquiry sought written and/or oral evidence;
- c. it is not an attempt to address every significant conflict of evidence or every significant issue that has arisen before the Inquiry;
- d. it is neither in the nature of a denial defence nor of a plea in mitigation; and (perhaps most importantly),
- e. it is most definitely not an attempt to write the Inquiry's report for it.

2.2 Rather, this submission is merely (in an attempt to adhere to the 'less is more' principle¹⁰) to do the following:

- a. to draw together some of the issues that have emerged from the voluminous evidence;
- b. to group those issues in a manner which might make it easier to understand them and the shortcomings on the part of the Trust that lay beneath or behind them;
- c. to identify some of the relevant shortcomings and, where applicable, some of their root causes;
- d. to highlight potentially relevant contextual factors;

¹⁰ Discussed, albeit in the context of Inquiry recommendations, in the evidence of Peter May in his questions and answers with Dr Swart and the Chair on Day 93, p100, line 13 to p101, line 27.

- e. to summarise where relevant changes have been, or are being, made which reduce the chance of the same shortcomings existing or persisting in the future.

2.3 Accordingly, we have grouped the issues under three broad heads, with a ‘chapter’ devoted to each. They are:

- a. the issues with Mr O’Brien’s practice which came to a head in 2016/2017;
- b. the issues with Mr O’Brien’s practice which came to a head in 2020; and
- c. other issues with Mr O’Brien’s practice.

This approach has been taken, not in an attempt to shift attention onto Mr O’Brien’s issues and away from the Trust¹¹, but because the issues that emerged in Mr O’Brien’s practice are the gateway through which the Trust’s various shortcomings have come to light and they are, in the circumstances, an appropriate lens through which to view those shortcomings.

2.4 In each chapter, we have adopted the following broad approach:

- a. we have summarised the main issues that arose in Mr O’Brien’s practice;
- b. we have analysed some of the Trust shortcomings that lay behind or were revealed by Mr O’Brien’s issues including, where applicable, both immediate / frontline deficits in the handling of the relevant issues as well as the root causes that lay behind those deficits;
- c. finally, we have summarised some of the improvements which have been (or are being) implemented in order to address those deficits, lessening the chance of reoccurrence and restoring public confidence.

2.5 Of course, none of the above is a substitute for the evidence itself, much of which the Inquiry has had the ample benefit of receiving orally, through forensic

¹¹ Which would be a foolish thing to do, not least because Mr O’Brien was part of ‘the Trust’ (or at least a significant servant or agent of it) at all material times.

questioning both by Counsel to the Inquiry and by the Inquiry Panel, and the Trust readily acknowledges that it is ultimately for the Inquiry to determine what failings there were, which of these were significant, and what their causes were. These submissions are advanced merely in an attempt to assist the Inquiry in performing those important tasks.

2.6 And in this regard the Trust also acknowledges the fact that the Inquiry is inquisitorial and subject to a duty of fairness¹² and that, regardless of the presence or absence of closing submissions, the Inquiry will consider all relevant evidence before reaching its conclusions and making its recommendations.

¹² See section 17 of the Inquiries Act 2005 and the exposition of the duty of fairness at chapter 9 of Beer, *Public Inquiries*, OUP, 2011.

Chapter 3

The Approach of the Public Inquiry

The Report of a Public Inquiry

3.1 Section 24 of the Inquiries Act 2005 mandates only two things in respect of a Public Inquiry's Report: that it set out the facts and that it set out the recommendations of the Panel.

24 (1) The chairman of an inquiry must deliver a report to the Minister setting out –

(a) the facts determined by the inquiry panel;

(b) the recommendations of the panel (where the terms of reference required it to make recommendations).

The report may also contain anything else that the panel considers to be relevant to the terms of reference (including any recommendations the panel sees fit to make despite not being required to do so by the terms of reference).

3.2 However, it does not restrict the Inquiry to these two functions. Indeed, it affords it a wide margin to address in its Report '*anything else that the panel considers to be relevant to the terms of reference*'.

The Purpose(s) of a Public Inquiry

3.3 A consideration of the purpose(s) of a public inquiry assists us in answering the question: what other matters an Inquiry Report might seek to address or include in its report. Such purposes are discussed in various places, including in Jason Beer KC's leading textbook, *Public Inquiries*,¹³ from 1.02 to 1.09.

¹³ Oxford University Press, 2011.

3.4 Amongst the purposes of a public inquiry identified by Beer the following, several of which are interlinked and overlapping, are of most relevance to the current Inquiry¹⁴:

- a. Establishing the facts;
- b. Accountability;
- c. Learning lessons (so as to avoid any repeat of past mistakes); and
- d. Restoring public confidence.

3.5 These were reflected by the Chair in her opening on Day 6 when she described the purpose of this Inquiry as being to establish *'if things went wrong, if so, why they did go wrong and what lessons can be learned so that mistakes are not repeated'*.¹⁵

(a) Establishing the facts

3.6 Clearly, it is necessary for the Inquiry to establish some facts. For example, without establishing facts relevant to 'what went wrong' it might otherwise struggle to identify and articulate the recommendations it will make in order to reduce or remove the risk of recurrence.

3.7 However, when an Inquiry's investigations and hearings range across decades and hundreds of thousands of documents (both of which are the case in this Inquiry), there is a very real practical constraint on the Inquiry's fact-finding ability. Put simply: to reach a reliable conclusion on the facts of every event or interaction that has featured in evidence, or to resolve every factual dispute, difference, or uncertainty, would simply take too long.

¹⁴ The other purposes identified by Beer, viz, catharsis, developing policy, and discharging investigative obligations under Article 2 or 3 of the ECHR seem to be of little or no relevance to a public inquiry of the current type.

¹⁵ TRA- 00277, Day 6, p4, lines 12-14

3.8 Thus, in practical terms an Inquiry will usually establish the facts necessary to enable it to achieve its purposes of accountability, learning lessons, and restoring public confidence.

(b) Accountability

3.9 The modern public inquiry has been described as '*a major instrument of accountability*' by the House of Commons Public Administration Select Committee in the first report of its 2004-5 session '*Government by Inquiry*'¹⁶.

3.10 This is undoubtedly accurate. And it is important to note that it applies to the entire public inquiry process. Accounting to the Inquiry (and to the public) for what one did or did not do is not a matter of choice. Witnesses are compelled to provide detailed answers to focused questions in s.21 notices, they are compelled to hand over copies of all potentially relevant documents that they hold or control, and they are compelled to answer forensic questions (sometimes across several days) in live-streamed, public hearings. In this regard, the process can be as important in terms of accountability as the ultimate outcome.

3.11 But there are significant limits to the accountability a public inquiry can lawfully hope to achieve in its Report. The Inquiry is expressly prohibited by s.2(1) of the 2005 Act from making findings in respect of any person's civil or criminal liability. Whilst s.2(2) of the Act acknowledges the risk of 'liability being inferred from facts that [the Inquiry] determines or recommendations that it makes', it would be wrong to interpret this as permitting or encouraging Inquiries to make findings of civil or criminal liability 'in all but name'. After all, a crucial distinction between a public inquiry on the one side and a criminal, civil, or professional misconduct case on the other side is that, in the latter, the subject of the proceeding faces precisely defined and pleaded allegations or

¹⁶ Page 7 - <https://publications.parliament.uk/pa/cm200405/cmselect/cmpubadm/51/51i.pdf>

charges and has the right to call all admissible evidence (including independent expert evidence) on his or her own behalf in respect of such allegations or charges. Neither of those features pertain in the realm of public inquiries.

(c) Learning lessons (so as to avoid any repeat of past mistakes)

3.12 This has, in the past, been identified as the primary or key purpose of a public inquiry. For example, the House of Commons Public Administration Select Committee ‘*Government by Inquiry*’ report (already referenced above), recorded that ‘*for the Government “the primary purpose of an inquiry is to prevent recurrence” and that it was also the government’s view that “the main aim is to learn lessons, not apportion blame”*¹⁷.

3.13 A notable feature of this Inquiry (which also sounds in respect of the next purpose of public inquiries, *viz*, restoring public confidence) is that it has, through its s.21 notices, its disclosure requests, and the oral evidence elicited in public hearings, focused extensively on the changes that have already occurred within the Trust (and beyond) so as to reduce or remove the risk of past mistakes in respect of the Trust’s Urology Service being repeated in the future.

3.14 This is undoubtedly the purpose of public inquiries which is most closely connected to the recommendations the Inquiry makes in its report. Put another way: it is (at least in part) through its recommendations (and their implementation) that this key purpose is achieved.

(d) Restoring public confidence

3.15 Restoring public confidence is an important purpose of a public inquiry, particularly when it concerns a key public service such as in this case. As with the accountability issue addressed above, it is clear that the Inquiry has already sought to achieve this particular aim through its work to date and its focus on

¹⁷ Page 8, para 10.

eliciting from the Trust and its witnesses evidence that lessons have been learned and that necessary changes have been made or are being made.

The Inquiry's Approach to its Findings

3.16 In her public opening remarks on Day 6 of the Inquiry hearings the Chair stated that¹⁸:

'it is the task of the Inquiry to find out what happened in relation to the care of patients within the Urology Department of the Southern Health and Social Care Trust; what were the systems that allowed that to happen? Did the systems in place to prevent it happening work? If not, why not? And to make recommendations to try to avoid it happening again.'

3.17 Such a focus on systems, rather than upon individuals, when it comes to the Inquiry's findings would be entirely appropriate in light of the analysis above¹⁹.

3.18 Such a focus would also be consistent with the following:

- a. The *Cabinet Office Guidance for Inquiry Chairs, Secretaries and Sponsor Departments* makes it clear, in the section providing guidance about the Inquiry Report,²⁰ that individuals need not always be named:

How to handle criticisms in the report. Some inquiries have simply stated criticisms where they occur and others have included a specific section drawing attention to findings. The Inquiry should consider whether the public interest requires that individuals should be named. (See pages 46-48 on Salmon and Maxwellisation procedures.)

¹⁸ TRA- 00277, Day 6, p4, lines 23-29.

¹⁹ Especially from paragraph 1.9 onwards.

²⁰ Page 39 - <https://www.parliament.uk/globalassets/documents/lords-committees/Inquiries-Act-2005/caboffguide.pdf>

Given the primacy of patients and their safety, the public interest is surely in respect of systems that were lacking (and the changes therefore required to prevent recurrence) rather than upon individuals.

- b. It has been recognised that there is a public interest generally in avoiding or reducing the risk of defensive practice amongst healthcare professionals. Thus, Stephen Sedley QC (as he then was), following involvement in several public inquiries concerning the childcare system, observed as follows in his Modern Law Review article, *Public Inquiries: A Cure or a Disease*²¹:

This negative product is not only related to individuals, though it is at its sharpest there. It can have a damaging effect on practice generally, for if a child care initiative goes disastrously wrong it may no longer be a matter of simply seeing what can be learnt from the mistake: there may be a public inquiry, public obloquy, public sacrifices. It is probable that, like the defensive medicine generated in the United States by endless malpractice suits, defensive social work is developing as a passive response to the proliferation of public inquiries.

- c. The need to encourage people to speak up has been widely recognised as an important public policy goal in health service settings²². In ‘*Freedom to Speak Up - An independent review into creating an open and honest reporting culture in the NHS*’²³, Sir Robert Francis QC identified a number of key principles including the following:

Principle 2 – Culture of raising concerns

²¹ (1989) MLR Vol. 52 p469 at p477/478.

²² See also the evidence of Vivienne Toal on this issue including her exchange with Dr Swart from TRA-03488 line 2 to TRA-03490 line 12 regarding the need for ‘freedom to speak up guardian’ roles in the NHS in Northern Ireland and developments in train on this front in the Trust.

²³ <http://freedomtospeakup.org.uk/the-report/>

Raising concerns should be part of the normal routine business of any well-led NHS organisation.

31 *Speaking up should be something that everyone does and is encouraged to do. There needs to be a shared belief at all levels of the organisation that raising concerns is a positive, not a troublesome activity, and a shared commitment to support and encourage all those who raise honestly held concerns about safety. This will sometimes require acceptance by staff that their own performance may be the subject of comment, and that this needs to be seen as an opportunity to learn rather than a source of criticism. I appreciate this is not always easy.*

There is clearly a public interest in ensuring that committed NHS employees (i) are not discouraged from speaking up about potentially serious concerns because of fears that much less significant concerns in respect of their own practices will be subjected to public criticism and (ii) continue to have the opportunity to deploy their skills for the public good. To return to the Sedley article quoted above, it is surely vital to avoid any perception of the type he alluded to amongst social workers following a number of childcare inquiries: *'The aftermath of more than one recent inquiry has generated the legitimate fear among local authority staff that any public inquiry may for them turn into a hanging party.'*²⁴

- d. An adverse practical consequence of making criticisms of multiple individuals is the need for multiple warning letters and the resulting potential for delay. This real, evidence-based risk was recognised by the House of Lords in its *Post-Legislative Scrutiny Report*²⁵ into the 2005 Act. For example:

'246. ... In evidence to us Mr Francis stated: "in practice I think my inquiry was extended by at least six months by having to undertake a rule 13 process." (Robert Francis QC of the Mid Staffordshire Inquiry)

²⁴ Page 478, first full paragraph.

²⁵ <https://publications.parliament.uk/pa/ld201314/ldselect/ldinquiries/143/143.pdf>

The Approach to Inquiry Recommendations

3.19 On one reasonable view, the recommendations produced by the Inquiry are, amongst all of its important work, of paramount importance.

3.20 The Institute for Government, in its report of December 2017 entitled *'How Public Inquiries Can Lead To Change'*²⁶, had the following to say about the importance of the publication of the Inquiry Report and the period thereafter²⁷:

Much of the most important work of inquiries is only just beginning when an inquiry report is published. As former inquiry chairs have put it:

"Implementation is – of course – everything."

Sir Robert Francis QC

"The main reason for most inquiries is to find out how we can avoid something like that happening again and what changes to systems, training and procedures would help to avoid that happening. Therefore, I think [inquiries are] absolutely about action."

Lord Michael Bichard

3.21 In terms of the nature of the recommendations it makes, CEDR's 2015 Guidance for Public Inquiry Chairs and Commissioning Bodies entitled, *'Setting Up and Running a Public Inquiry'*²⁸, offers a number of useful observations and pieces of advice regarding the recommendations a public inquiry makes:

²⁶ <https://www.instituteforgovernment.org.uk/publication/report/how-public-inquiries-can-lead-change>

²⁷ At page 27.

²⁸ https://www.cedr.com/wp-content/uploads/2019/10/CEDR_Setting_Up_and_Running_a_Public_Inquiry_-_Guidance_for_Chairs_and_Commissioning_Bodies.pdf

- a. It identified one of the 5 major points for reform as being– *‘Ensuring that the recommendations that are produced by the Inquiry are valid and workable and more likely to be implemented’*²⁹.
- b. It observed that, all too frequently, recommendations are not successfully translated into successful outcomes and that this constituted a failing that Inquiries should strive to avoid³⁰.
- c. It identified the importance of the report publication stage of the inquiry process and the need for recommendations to be workable³¹:

The most critical point of any Inquiry is necessarily the publication of its conclusions and recommendations. Whilst there are considerable benefits (as we have outlined above) of carrying out the processes of the Inquiry in terms of reference to victim recognition etc., the ultimate success or failure of an Inquiry will be determined from whether it has clearly produced an analysis of what happened and produced workable recommendations for review. Ultimately, if an Inquiry is to have any impact, its conclusions will need to be reasoned, comprehensive, real world aware, succinct and practical.

- d. It also stressed the importance of there being a mechanism for checking the implementation of the Inquiry recommendations³².

3.22 The Trust is confident that the Inquiry will endeavour to make workable recommendations. With this in mind, the Trust would offer a number of observations on the issue:

- a. The Trust would welcome recommendations which are rooted in the evidence received by the Inquiry about changes and improvements that have been

²⁹ Page, 10 Goal 4.

³⁰ Page 60.

³¹ Ibid.

³² Ibid.

implemented and borne fruit. For example, the Inquiry has heard evidence about how greater tracking and audit of MDM outcomes (funded 'at risk' by the Trust) has led to real improvements on the ground and a very significant reduction in the risk of MDM issues that had manifested themselves in respect of Mr O'Brien's practice being repeated in the future³³. The Trust would welcome recommendations endorsing steps like these, which it has taken proactively and at risk.

- b. As the Inquiry is well aware from the evidence it has received, the Trust is almost always engaged in the process of implementing recommendations from one Inquiry or Report or another (whether it be the HRDI or the 2020 Hughes SAIs or the INI or GIRFT). These recommendations are large in number. Where this Inquiry's conclusions about action that is required to prevent recurrence of harm coalesce with recommendations already made by a previous Inquiry or Report, the Inquiry should consider simply endorsing that prior recommendation rather than adding to overall numerical burden of recommendations.
- c. The Trust would welcome the Inquiry devising or suggesting a mechanism for checking the implementation of its recommendations³⁴.

3.23 In short, the above points probably distil to this: that the Trust wholeheartedly endorses the approach aired in the evidence of Peter May,

³³ See, e.g., the evidence of Maria O'Kane on this issue from TRA-11742 line 19 to TRA-11744 line 16. See also the evidence of Mark Haynes on Day 88 from TRA-11463 line 12 to TRA-11465 line 3 regarding improvements in monitoring cancer pathway patients and ensuring they have key workers. See also his evidence about the audit roles that now ensure both that Key Workers are involved (TRA- 11464-11465, Day 88, p94 line 26 to p95 line 3 and p104 line 8-27) and that MDM outcomes are implemented (TRA- 11461-11462, Day 88, p91 line 21 to p92 line 10 and TRA- 11476-11477 p106 line 3 to p107 line 27).

³⁴ By way of analogy, the Inquiry will be aware that the Chair of the RHI Inquiry secured the following assurance from the NIAO: '47 ... *The Inquiry has asked the Comptroller and Auditor General for Northern Ireland to monitor and, as necessary, pursue the effective implementation of this Inquiry's Recommendations. The Inquiry records that it is very grateful that the NIAO has agreed to undertake this task*' – see: *Chairman's statement at the RHI Inquiry Report launch, Friday 13th March 2020* - https://cain.ulster.ac.uk/issues/politics/docs/rhi/2020-03-13_RHI-Inquiry_Statement.pdf

when questioned by Dr Swart and the Chair at the end of Day 93 of the hearings³⁵:

DR. SWART: And just -- I started off with learning from inquiries. We will obviously be producing a report. You will have looked at lots of inquiry reports, you've got this group set up, what is most useful in terms of how these things are phrased? So, you know, just to start you off, it's probably not useful to have 300 recommendations that are very specific, if I was on the receiving end of it. But what is most useful? Is it more useful to do what Bill Kirkup did in East Kent, which is to say "Look here guys, I've written lots of inquiries and nobody implements them and it's all too complicated, so I'm going to phrase these recommendations differently", and really what he's doing is getting to the spirit, to use your words, what is most useful?

A. So for me, as I think I said in my earlier evidence, I'm conscious that you are coming to this after other inquiries have reached recommendations. So I suppose my -- what would be most useful to me is if, in looking at what you recommend, you try to build on what is already there and, as I said, put wind in the sails of what you think is going in the right direction and be clear about what different or additional is needed in order to address the challenges. You've heard lots of evidence. Because time has passed quite significantly, the world has also moved on. So part of the -- so for me this is -- I would encourage you to take a system view of this. What is it that's needed systemically in order to address things? There may be some specifics, of course, but as you've helpfully hinted, vast numbers of recommendations can be, you know, if you start chasing ticks in boxes rather than a focus on what really matters. So it might be just because of the positioning of this Inquiry in the context of other inquiries, it just takes a slightly different approach in order to land it, and then again, if the Panel were, or representatives of the Panel were willing to be engaged with afterwards to make sure we had understood properly, that would be extremely helpful as well.

DR. SWART: Yes. Thank you. That's all from me.

³⁵ From TRA- 12350-12351, Day 93, p100 line 13 to p101 line 27.

CHAIR: *Thank you, Dr. Swart. Well if it's any reassurance, I'm a great believer in less is more, Mr. May, so I don't think you'll be getting 300 recommendations from this Inquiry.*

Beware the 'benefit' of hindsight

3.24 Finally in this regard, the Trust would repeat the caution referenced in its oral opening when counsel quoted from the following part of Anthony Hidden QC's Report into the Clapham Railway Junction disaster in September 1989: *'there is almost no human action or decision that cannot be made to look more flawed and less sensible in the misleading light of hindsight. It is essential that the critic should keep himself constantly aware of that fact'.*

3.25 Put another way in the context of a concrete example: the Inquiry should be wary of the temptation (sometimes encouraged by Mr O'Brien in his representations to this Inquiry) to construe past omissions, such as the failure to pick up on, or interrogate, Mr O'Brien's alleged repeat assertion that he found triage impossible or the Trust's failure to follow up on the 23 March 2016 letter, as omissions *but for which* there would have been some significantly different outcome³⁶.

Chapter 4

³⁶ Another example is perhaps the suggestion that the information provided to Mr Haynes by BHSCT doctors in Spring 2019 ought to have triggered a wider concern about Mr O'Brien not implementing MDM recommendations or prescribing Bicalutamide in sub-optimal doses – see, in this regard, Mr Haynes' evidence on TRA- 11410-11417, Day 88 from p40 line 24 to p47 line 27.

Issues Which Came to a Head in 2016/2017

Issues

4.1 This chapter covers a number of issues in respect of Mr O'Brien's practice which came to a head in the period 2016-2017. Primarily, the issues were as follows:

- a. Failure to triage, in time or at all, referrals to urology;
- b. Taking patient notes to his home and retaining them there;
- c. Failing to dictate, in time or at all, following patient episodes;
- d. Advantaging some private patients.

4.2 Whilst these issues came to a head in 2016/2017, it is important to note that some of them were long standing and some were known about for some considerable time prior to 2016/2017.

4.3 It is also important to note that some of these issues were interrelated. For example, Mr O'Brien's failure to dictate in a timely way following patient encounters appears to have been one reason why he needed to bring patient records home and/or retain them there.

4.4 These issues engage a number of the Inquiry's Terms of Reference and in particular Terms (a), (b), (e) and (f).

(a) Triage

4.5 The Trust accepts that one key purpose, though by no means the sole purpose, of having consultant urologists triage referrals to urology from GPs and from other specialties is to ensure that the priority given to the case by the referring clinician is appropriate. In the event that a referral has been classified as 'routine' or 'urgent' when, in fact, it ought to have been classified as 'red flag', this misclassification

should be identified and remedied by the responsible consultant urologist at the referral triage stage.

4.6 In the case of Mr O'Brien, we know that there were times when he was responsible for triaging referrals to urology when he failed to complete triage, either in a timely way or at all.

4.7 A number of notable features of this problem have emerged from the evidence before the Inquiry:

- a. There is evidence of the problem in documents from as far back as December 2008³⁷ and these suggest that it was not a new problem at that point.
- b. Testimony from witnesses has been consistent with such documents in that it has confirmed that triage of referrals was a longstanding issue with Mr O'Brien's practice. Some of these witnesses suggested that the problem went back much further than 2008 – e.g., Katherine Robinson, who in her oral evidence expressed the belief that it dated back to the 1990s³⁸, and Mr Mackle, who in his witness statement recorded having to speak to Mr O'Brien about his triage in approximately 1996³⁹.
- c. The problem was known to both medical managers⁴⁰ and operational managers⁴¹.

³⁷ See, for example, an email chain beginning December 2008 at WIT-23742

³⁸ TRA-05179 line 28 to 05180 line 18.

³⁹ WIT-11815 para 210.

⁴⁰ Ibid.

⁴¹ See, for example, emails from different points during 2010 at TRU-281814 and TRU-259492-259493

- d. It was a recurring and fluctuating problem. In the words of Martina Corrigan:
*'... when the issue of triage was raised with Mr O'Brien, it would resolve for a short time before re-emerging and the cycle would repeat ...'*⁴².
- e. The extent of the problem was significant. For example, there is evidence that on multiple occasions the backlog of untriaged referral letters numbered in the hundreds⁴³.

4.8 Mr O'Brien has at times acknowledged that he was significantly in default of his triage obligations⁴⁴. However, he questions the precise extent of his default at certain points and he also seeks to place responsibility upon the Trust for his default.

4.9 In respect of the former issue, it is submitted that the Inquiry does not need to reach a concluded view regarding the precise extent of Mr O'Brien's triage default nor does it need to determine whose figures are correct in this regard. The inescapable reality is that Mr O'Brien was in default of his triage obligations to a significant extent on repeated occasions over a prolonged period of time.

4.10 In respect of the question of who bears responsibility for Mr O'Brien's default, his evidence can, in our submission, be distilled to the following core propositions:

- a. His triage methodology was an involved one, sometimes akin to a virtual consultation that included a telephone call to the referred patient.

⁴² WIT-26305 para 69.1 lines 4-5. Katherine Robinson described perhaps greater compliance by Mr O'Brien during Dr Rankin's tenure – see TRA-05177 lines 3-23. See also the evidence of Mr Mackle at WIT-11816 para 215.

⁴³ For example: TRU-281926 - April 2011 - 129 untriaged letters dating back to 1 February 2011, TRU-258498 - November 2015 - 277 letters dating back to October 2014, TRU-251446 – December 2016 – 318 letters dating back up to 78 weeks, and AOB-01399 – Dr Chada in her MHPS report refers to 783 referrals dating back to June 2015.

⁴⁴ See, for example, his email of 16.3.14 at AOB-70487 or his response to the MHPS Case Investigator's Report (AOB-01879 at AOB-01893, first para under 'Triage').

- b. It was not possible to perform triage duties within the limited time available and he conveyed this message to the Trust.
- c. He was aware that his colleagues triaged in a different, quicker way which he did not consider to be optimal.
- d. He sought direction from the Trust regarding how triage should be done (the implication being that if he was directed to perform it as his colleagues did he would comply), but no such direction was forthcoming⁴⁵.
- e. He continued to triage in what he considered to be the optimal manner and therefore repeatedly found himself to be significantly in default.

4.11 The Inquiry will have to decide whether it is necessary to determine where responsibility in respect of the triage issue rests: is it with Mr O'Brien or with the Trust or with both of them? Alternatively, the fact that the problem existed and persisted may be all that needs to be acknowledged. In the event that it is deemed necessary to determine the issue, then the Inquiry will have to consider –

- a. whether Mr O'Brien ought reasonably to have changed his approach to triage in light of the fact that his colleagues were able to perform triage timeously without any evidence of any significant risk or harm to patients⁴⁶;
- b. whether Mr O'Brien ought to have made it much clearer to the Trust the significant extent to which he was defaulting in his triage obligations; and

⁴⁵ See, e.g., Mr O'Brien's witness statement at WIT-82450 at para 143.

⁴⁶ Consider, for example, Mr O'Donoghue's approach and his opinion that Mr O'Brien 'overcomplicated triage' – from TRA-08465 line 3 to 17.

- c. whether the issuing of a direction by the Trust on this issue is likely to have made any positive difference in circumstances where we know that directions or protocols were issued on other matters⁴⁷ and not adhered to by Mr O'Brien.

4.12 Ultimately, the Inquiry might reasonably conclude that Mr O'Brien bore significant responsibility for the triage issues that arose in his practice.

(b) Patient Notes

4.13 The issue of patient notes is linked to the issue of dictation because it appears that one reason why Mr O'Brien brought patient notes to, and retained them at, his home is because he had not, whilst at work, dictated what he needed to dictate in respect of his clinical encounters with patients⁴⁸.

4.14 Notes would have been tracked out to Mr O'Brien or his secretary but be in neither person's office in the hospital.

4.15 The evidence to the Inquiry revealed a number of features, including:

- a. that finding charts tracked to Mr O'Brien was an issue⁴⁹ during the tenure of Katherine Robinson, Medical Records Manager in the Trust from 2000 to 2013⁵⁰.
- b. that the issue was escalated – e.g., in 2012 when Mr O'Brien was spoken to about it by Dr Rankin⁵¹ and in the autumn of 2013 when it was escalated to Heather Trouton and IR1s were completed in respect of it (all at WIT-61512 to 61511);

⁴⁷ E.g., in respect of IV antibiotics and IV fluids, in respect of the use of the DARO List, and in respect of the use of bipolar resection in saline vs/ monopolar resection in glycine.

⁴⁸ See, e.g., the evidence of his secretary at TRA-06208 line 9 to 23.

⁴⁹ TRA-05171 lines 15-26; echoed by Martina Corrigan at WIT-26264.

⁵⁰ TRA-05170 lines 3-5.

⁵¹ Recorded at TRU-251424, 2nd para.

- c. that, in spite of escalation and the completion of several IR1s, the issue continued to be a recurring problem throughout the period 2013-2016 (see Martina Corrigan at WIT-26264);
- d. that, by late 2016 / early 2017, Mr O'Brien had in excess of 300 sets of patient notes at home⁵².

4.16 There was evidence to the effect that the issue of individual charts (or small numbers of charts) which were tracked out to Mr O'Brien or his secretary being missing was known to various layers of more senior management⁵³ including clinical management⁵⁴.

4.17 It appears that, whilst the issue of charts at home was a longstanding, recurring, and known issue, the extent of the charts that were held by Mr O'Brien at home at any one time was not known, albeit that this information could have been obtained by the Trust⁵⁵. The true extent of the problem does not appear to have been appreciated until 2016/2017.

4.18 Whilst Mr O'Brien explained that some notes were at home because he had to transport them back from his clinic in SWAH (see, e.g., WIT-82554 para 435) it is also clear that this explanation did not account for the sheer volume of notes held by him nor the duration for which notes were held. Rather, the need to have access to notes in order to complete tasks such as dictation appears to be a key reason why Mr O'Brien retained so many patient notes at home.

⁵² For example, 30 December 2016 letter at TRU-251446 records 365 notes at 23 December 2016. Mrs Corrigan – at WIT-26150 para a – records that 307 charts were returned by Mr O'Brien at the end of December / start of January 2017.

⁵³ See, e.g., the evidence of Helen Forde at TRA-05073-05075 and the finding of Dr Chada in the MHPS Case Investigator's Report at TRU-00702 (final para).

⁵⁴ Such as Mr Mackle as AMD – see, e.g., WIT-11745

⁵⁵ For example, in a review backlog validation exercise of the type described by Mr Mackle at WIT-11819-11820 para 227.

4.19 Whilst it may be difficult to identify any examples of cases where the absence of patient notes in the hospital exposed a patient to harm⁵⁶, the practice clearly created a risk of a patient being exposed to such harm.

(c) Dictation

4.20 As referenced at para 4.13 above, the issue of undictated clinics appears to have been linked to the issue of patient notes⁵⁷.

4.21 Whereas the practice of other consultants was to dictate immediately after each patient was seen⁵⁸ or at the end of each clinic⁵⁹, Mr O'Brien did not do this but instead dictated at a later point (sometimes much, much later)⁶⁰. This ultimately led to a substantial backlog of undictated clinics.

4.22 The cause of this issue appears, at least in part, to have been Mr O'Brien's desire to perform the task in the way that he considered to be optimal (thereby echoing his approach to the referral triage issue mentioned above). In this regard, a number of witnesses gave evidence of Mr O'Brien's practice of writing very lengthy and detailed letters. For example, Mr O'Donoghue observed that 'when he did dictate he did exceedingly long letters which rarely got to the point'⁶¹.

4.23 It appears that, although this issue was not known to some relevant personnel (such as Katherine Robinson) until a relatively late stage⁶², it was apparent to

⁵⁶ See in this regard the evidence of Helen Forde at TRA-05127 line 23 to 05128 line 13.

⁵⁷ A point alluded to by the Inquiry on several occasions – e.g., Day 10 transcript at p76 lines 15-23.

⁵⁸ Mr Glackin described how he dictated 'immediately after I finish with the patient's consultation' TRA-08412 lines 12-22.

⁵⁹ Mr Haynes TRA-00856 last 3 lines; Mr Young, Day 74 TRA-09636 lines 4-6 and TRA-9644-9645 line 28 to p86 line 2 and lines 12-19.

⁶⁰ See, e.g., evidence of N Elliott at TRA-06124 lines 6-16 and TRA-06130 lines 18-23 and TRA-06135 lines 13-18 and TRA-06171 line 24 to TRA-06172 line 11 and TRA-06175 lines 3-22.

⁶¹ TRA-08576 lines 21-23.

⁶² TRA-05195 and WIT-60429 – Ms Robinson described how N Elliott alerted her in late 2016.

several of Mr O'Brien's colleagues⁶³ at much earlier stages. It is also evident from various contemporaneous documents⁶⁴.

4.24 It also appears that the dictation issue was one where, although the existence of the problem was appreciated by both clinical colleagues and a number of persons with clinical or operational management roles, the extent of the problem was not known⁶⁵. However, its extent could likely have been ascertained upon the making of appropriate enquiries – e.g., by and/or of Mr O'Brien's secretary⁶⁶.

4.25 There has been, and there appears to remain, a dispute about the extent of the problem at the point when it ultimately came to a head in 2016/2017. Whereas there has been repeated reference to 61 clinics' worth of non-dictation⁶⁷, this has been disputed by both Mr O'Brien and his former secretary⁶⁸. Nonetheless, there was undoubtedly a significant amount of undictated work outstanding from Mr O'Brien by the end of 2016 / start of 2017⁶⁹.

4.26 This created a real risk of harm - and potentially even caused some actual harm⁷⁰ – to patients.

(d) Private Patients

⁶³ At TRA-08150 line 25 Mr Glackin (who commenced in the Trust in August 2012) described how he encountered 'late dictation of letters, or letters not being present in the chart when I was seeing a patient'. At TRA-08151 line 29 to TRA-08152 line 2 he stated that 'I knew that he was having difficulty dictating his letters on time. That was widely known.' Issues known but extent not. Line 16-18. Mr O'Donoghue (who commenced in the Trust in August 2014) - at TRA-08573 lines 28 to TRA-08574 line 7 – described how he noticed within the first week of joining the unit (in 2014) that there were no letters in the patient notes. Mr Haynes (who commenced in the Trust in May 2014) gave similar evidence– see Day 10 transcript internal pages 51 line 19 to p51 line 10.

⁶⁴ Tru-258526-8 – August 2016 email exchange.

⁶⁵ E.g., see the evidence of Mr Glackin at TRA-08152 line 2 and lines 16-18. See also the evidence of Mr O'Brien's secretary at TRA-06136 lines 1-7.

⁶⁶ Or, according to his secretary, by interrogating the Data Quality Report – TRA-06192 lines 18-27..

⁶⁷ See the 15.12.16 email plus attachment from N Elliott at TRU-255968-to-255970; see also the 30.12.16 letter to Mr O'Brien – TRU-251446-to-251447.

⁶⁸ TRA-06184 lines 2-16.

⁶⁹ Even Mrs Elliott comes close to acknowledging this - TRA-06197 line 16 to TRA-06198 line 9.

⁷⁰ See in this regard the exchange between Inquiry Senior Counsel and N Elliott at TRA-06198 line 24 to TRA-06200 line 27.

4.27 The issue in respect of alleged advantaging of private patients can be summarised as follows: that some patients who had been seen privately by Mr O'Brien as outpatients, in due course had their substantive procedures performed within the NHS after a period that was significantly shorter than that for patients whose entire clinical journey had been within the NHS⁷¹.

4.28 The issue appears first to have been recorded in a number of emails from Mr Haynes, to Mr Young and Martina Corrigan, the first dated 27 May 2015 (WIT-54107) and the second dated 26 November 2015 (WIT-54106), each one referencing a different patient (or patients) and each one requesting that action be taken. The issue was raised again (with a further patient example) by Mr Haynes by email of 23 December 2016 (TRU-00071) against the backdrop of the (then) looming investigation into a number of issues in Mr O'Brien's practice.

4.29 In an email of 26 November 2015 Mr Young said he had spoken to the person concerned and would do so again. (TRU-270116). In his oral evidence Mr Young recalled speaking to Mr Haynes about the issue TRA-09653 and believed he had spoken to Mr O'Brien about it TRA-09657-TRA-09658. Mr O'Brien rejected the claim that he had been spoken to about this (TRA-04742) and denied that he had inappropriately prioritised any private patients.

4.30 Mr Haynes in his oral evidence spoke of how he identified the patients that gave rise to a cause for concern whilst Urologist of the Week TRA-00896-TRA-00897 AND TRA-00900, prompting both of his 2015 emails, but that he was not aware of any action being taken to address the issue in response TRA-00900-TRA-00901. He did suggest in his written evidence, however, that the practice that he believed existed ceased after the MHPS process⁷².

⁷¹ In potential breach of the relevant principles in 'A Guide to Paying Patients' – see TRU-267665 at TRU-267673 para 7.4.1.

⁷² WIT-53945 para 68.1. See also Mrs Corrigan's evidence at WIT-26280 para viii.a.

4.31 Mr Young's input into the MHPS process insofar as it related to private patients was addressed in his oral evidence TRA-09666. In short, any patient who underwent a procedure with Mr O'Brien in 2016 in respect of whom there was a short period of time between being added to a waiting list and their procedure being undertaken had their NIECR checked for a private patient letter⁷³. This yielded 11 cases which Mr Young was asked to consider and opine on the reasonableness or otherwise of the waiting time. His resulting opinions were tabulated by Mrs Corrigan⁷⁴. In short, he considered only 2 out of 11 of the waiting times to be reasonable. With the subsequent benefit of Mr O'Brien's responses to each case, and taking a 'generous' approach to some of Mr O'Brien's accounts⁷⁵, Mr Young in his oral evidence revised the reasonable cohort up from 2 to 6/7, leaving a number that remained unreasonably quick. Whilst he acknowledged that it was not in any sense a forensic analysis of the cases in question, he maintained that some of the time periods involved were quicker than he would, based on his experience, have expected, noting that 'some were within the month' (TRA 09674-09676).

Important Points to Acknowledge Regarding the 2016/2017 Issues

4.32 A number of points, reflective of failings on the part of the Trust and its systems, should be acknowledged in respect of the issues which came to a head in 2016/2017. In short, not only were many of the issues longstanding and known (such as his issues with referral triage, notes at home, and dictation), there had been a failure on the part of the Trust to address them effectively. Emphasis is placed upon the word 'effectively' because it is not the case that the Trust simply failed to act. Rather, it acted in a number of ways in response to a number of the above issues. However, many of its interventions were of limited effectiveness, as summarised in the examples below.

⁷³ See M Corrigan's description at TRU-283681.

⁷⁴ TRU-01069.

⁷⁵ TRA-09672 lines 2-4, plus TRA-09674, lines 1-14.

4.33 In respect of referral triage:

- a. Managers, particularly the Head of Service, engaged in a cycle of pursuing Mr O'Brien in respect of outstanding triage and securing improvement for periods of time, only for backlogs to appear again⁷⁶.
- b. The issue was escalated at various points to both operational and medical management⁷⁷ but the net result of this often appears to have been the tasking of the Head of Service to engage with Mr O'Brien to secure compliance.
- c. Trust staff often developed workarounds and accommodations to cope with Mr O'Brien's triage deficits rather than challenge him directly to secure meaningful change. For example:
 - i. Mr Young undertook Mr O'Brien's triage on a number of occasions⁷⁸.
 - ii. Mr O'Donoghue followed Mr O'Brien as Urologist of the Week on a Thursday and would have triaged several referrals (from the day before) which had been left undone by Mr O'Brien⁷⁹.
 - iii. The Referral Office kept a book which recorded referrals sent to Mr O'Brien so that he could be reminded and so that untriaged patients would not get lost⁸⁰.
- d. The Trust ultimately developed in about 2014 (what has been referred to in the Inquiry as) a 'Default System' in respect of referral triage⁸¹. The risk it was designed to guard against was that of a patient failing to be added to any

⁷⁶ See, e.g., Mrs Corrigan's evidence at wit-26305 para 69.1 regarding the ebb and flow of compliance by Mr O'Brien. See also her evidence from WIT-26275.

⁷⁷ See Mrs Corrigan's evidence at WIT-26294 para 63.2 and WIT-26294 para 63.3.

⁷⁸ WIT-26283 para 58.1.a.

⁷⁹ TRA-08578 line 21 to TRA-08581 line 10, and TRA-08584 lines 14-18.

⁸⁰ TRA-05180 lines 3-21. See also TRA-05125 line 12 to 05216 line 9.

⁸¹ See, e.g., WIT-26283 para 58.1.b; WIT-40949; or WIT-11784-WIT-11785 E Mackle mentioning D Burns introducing a new system in 2014.

waiting list whilst their letter awaited triage⁸². However, whilst the system removed this risk it failed to address another risk, *viz*, that a patient who had been classified at too low a priority would not get upgraded to the correct priority unless their referral was actually triaged⁸³.

4.34 In respect of patient notes at home, the pattern was similar in many respects to that in respect of referral triage. It arose repeatedly over the years, Mr O'Brien would have been contacted, and he would have brought in the missing notes⁸⁴. However, for a number of years records staff also submitted IR1s in respect of cases of missing notes tracked out to Mr O'Brien or his secretary⁸⁵. However, this formal escalation appears to have made little or no difference⁸⁶ and was eventually ceased⁸⁷. It is also unclear whether the Trust ever made the link between the notes at home issue and the issue of delayed or undone dictation by Mr O'Brien.

4.35 In respect of dictation, it appears that the other consultants (who started in the Trust in the period 2012 to 2014) were finding no patient letters in Mr O'Brien's patients' notes when they saw them and were having to do their best based on the available notes and what the patients said. Beyond this workaround, it is not clear that very much else was done.

4.36 Finally in this regard in respect of private patients, at most it appears that a conversation took place between Mr Young and Mr O'Brien (at least on the evidence of Mr Young). It appears that no attempt was made to address the issue formally – e.g., by initiating the 'retrospective audit' Mr Haynes had advocated in his May 2015 email about the issue.

Attempts to Grapple with these issues in 2016/2017

⁸² See, in this regard, the evidence of M Haynes at TRA-00880 at lines 13-23; and of K Robinson at TRA-05214 lines 19-28.

⁸³ See Mr O'Donoghue's evidence at TRA-08587 lines 1-10 in this vein.

⁸⁴ See H Forde at TRA-05112 to TRA-05113.

⁸⁵ See the evidence of H Forde at TRA-05088-05091 and the list of IR1s at WIT-61509.

⁸⁶ See evidence of H Forde at TRA-05092/3 on this issue.

⁸⁷ On the direction of Debbie Burns, according to Helen Forde – see TRA-05091.

4.37 It is clear that the Trust made more concerted attempts to address these issues in 2016/2017. These attempts included the letter of 23 March 2016 and the related meeting, the instigation of the MHPS process, and a number of SAIs. However, there remained several respects in which their attempts were sub-optimal.

4.38 Dealing first of all with the 23 March 2016 letter (TRU-274672) and meeting with Mr O'Brien on 30 March 2016 (at which he was handed the letter)⁸⁸:

- a. The issuing of a formal letter signed by senior clinical and operational managers was, on any reasonable view, an appropriate (albeit overdue) escalation of the issues.
- b. However, there is evidence (not least from Mr O'Brien) that the meeting of 30 March 2016 was relatively brief and that there was no discussion regarding how he might conceivably address the issues. Whilst it would be reasonable to observe that no discussion was needed in respect of the issues of triage, dictation, and notes at home⁸⁹, a discussion on the (then) 4th issue of the review backlog may have been reasonable.
- c. Following the meeting of 30 March 2016, it is clear than Mr O'Brien failed to revert with a plan for resolution of the issues, either immediately (as the letter in its final paragraph sought) or at all. Mrs Corrigan believed that he was told that a response was expected within 4 weeks⁹⁰. In spite of this, there appears to have been no follow-up by the Trust in respect of the letter.

⁸⁸ The meeting is summarised in Martina Corrigan's email of 28 April 2016 at TRU-274671.

⁸⁹ Indeed, as Dr Colin Fitzpatrick frankly observed in his evidence at TRA-04327 from line 5 onwards, some of these issues were not difficult to solve – 'you have a whole pile of charts sitting on your dining room table, you just put them in the boot of your car and bring them in'.

⁹⁰ Ibid.

- d. Thus, whilst the 23 March 2016 letter appears to have been a step in the right direction (and even perhaps to have triggered a reduction in the referral triage backlog⁹¹), it was not followed through.

4.39 Moving on to the MHPS process, a decision was made at an Oversight Group Meeting on 13 September 2016 to instigate an MHPS process in respect of Mr O'Brien⁹². However, there are multiple legitimate criticisms that can be made of that process. They include, but are by no means limited to, the following:

- a. The process had a stuttered and confused start. The decision having been made by the Medical Director, the Director of Acute Services, and the HROD Director in an Oversight Committee to commence the process in light of the 4 areas of concern outlined above (and a draft letter to Mr O'Brien prepared⁹³), a matter of days later (on 15 September 2016⁹⁴) the Director of Acute advised her 2 colleagues of her desire to press pause on the process and allow the Associate Medical Director and Assistant Director responsible for Mr O'Brien the opportunity to arrive at a local solution⁹⁵. Unfortunately, no such solution was in fact found and matters concerning Mr O'Brien progressed in any event due to the emergence of the SAI in respect of Patient 10 in or about November 2016⁹⁶. As a result, and in spite of the decision made in early September, an MHPS process did not, in fact, begin in respect of Mr O'Brien until the very end of 2016 / start of 2017.
- b. In spite of the preponderance of the evidence being to the effect that the timescales⁹⁷ laid down in respect of the MHPS process are unrealistically tight,

⁹¹ In terms of the triage backlog between March and August 2016 – TRU-274672 (the 23.3.16 letter) suggests 253 untriaged letters whereas TRU-274723 (17.8.16 email) suggests 174 letters.

⁹² TRU-00025-00026.

⁹³ TRU-251430; cover email at TRU-251429.

⁹⁴ See the Director's email at TRU-257642 plus responses at TRU-263683.

⁹⁵ Dr McAllister (then AMD responsible for Mr O'Brien) gave his view in his oral evidence that the Oversight Committee was deficient insofar as it did not involve him in its decision-making – see his questions and answers with Dr Swart on Day 24 from TRA-02815 line 11 to TRA-02816 line 20.

⁹⁶ See, e.g., Tracey Boyce's email of 9 November 2016 at AOB-01224.

⁹⁷ See WIT-18490 at WIT-18505 para 37 and TRU-83685 at TRU-83694 Appendix 2.

it seems clear that the MHPS process in the instant case took too long to complete (the Case Manager's Determination issuing in late September 2018). There appear to have been multiple reasons for this including:

- i. The fact that key roles within the process such as Case Investigator and Case Manager were performed by experienced, busy clinicians with limited capacity given their demanding 'day jobs'.
 - ii. The fact that the investigation necessitated the interviewing of a large number of witnesses, all of whom were also busy clinicians or managers.
 - iii. The fact that Mr O'Brien appeared to approach the process as being akin to a legal proceeding, such that he made repeated and enormously detailed demands for disclosure of allegedly relevant documents⁹⁸.
- c. It is clear that the process had to rely upon a number of persons performing important roles, such as the Designated Non-Executive Director ('NED') and Case Manager who, prior to their involvement in this process, had little or no MHPS experience.
- d. It is also clear that, in the final stages of the MHPS process, there was a significant lack of clarity regarding when roles such as that of the Designated NED and Case Manager actually ended.
- e. Following provision of the MHPS Case Manager's Determination, there was a failure on the part of the Trust to see through the 3 recommendations made by the Case Manager (action plan, conduct panel, and independent administrative review). In part, this was due to the grievance lodged by Mr O'Brien; in part it was due to the fact that an action plan already existed (and had been a driver

⁹⁸ See: AOB-01925. See also WIT-31934 to WIT-31945 Mr O'Brien to Dr Khan 30.7.17; and TRU-264105 to TRU-264108 Mr O'Brien to Dr Khan 12.11.18.

for some improvement on the part of Mr O'Brien since his return to work in early 2017); and in part the recommendation in respect of a review was overtaken by Dr O'Kane and Mr Devlin's Champion Review⁹⁹.

- f. On one reasonable view¹⁰⁰, the MHPS process provided a false sense of security in that, because of its focus on the 4 areas mentioned above, it provided a false reassurance that there were no issues in Mr O'Brien's clinical practice whereas, as became evident from the issues that came to a head in 2020 (with which Chapter 5 is concerned), such issues did exist.
- g. Finally in this regard, it is important to note that many of the structural problems with the MHPS system more broadly, as well as having been exposed in the corpus of evidence heard by the Inquiry between Day 20 and Day 39, had already been highlighted in consultation responses by the Trust (and by other Trusts) to the Department in each of 2011 and 2018¹⁰¹.

4.40 The Julian Johnson SAIs (in respect of Patients 11 to 15) were triggered by the SAI¹⁰² in respect of Patient 10 and the investigations carried out in late 2016 to ascertain if there were other cases like that of Patient 10. Whilst the Patient 10 SAI arose out of an IR1 in January 2016, was able to feed some of its learning back to the Trust to be factored into decision-making regarding Mr O'Brien in late 2016, and was completed by March 2017, the other 5 related SAIs took too long to be completed¹⁰³. That said, whether they ultimately added significantly to what was already known about (or being done to address) deficits associated with Mr O'Brien is debatable.

⁹⁹ WIT-46954; See the written evidence of Dr O'Kane at WIT-44995 para 8..

¹⁰⁰ Articulated, for example, by Maria O'Kane in her evidence at TRA-11620.

¹⁰¹ See WIT-42399 to WIT-42401, WIT-42998, WIT-43009 to WIT-43031, TRA-03410 from line 24, for some of the material on this.

¹⁰² PAT-000001 to PAT-000011.

¹⁰³ They were not signed off until 22 May 2020 – see TRU-161175.

Root Causes of Trust Failings

4.41 Identification of the above failings on the part of the Trust brings into sharp focus the question of what caused such failings. Put another way: why were issues that were, in large part, (i) longstanding and (ii) known to at least some clinical and operational managers, not addressed either adequately or at all?

4.42 There appear to be a multiple root causes in play here, several of which are addressed in the paragraphs which follow.

(a) Cultural Issues

4.43 It is apparent from the evidence of multiple witnesses that there were what might conveniently be described as ‘cultural issues’ that served as barriers to the effective resolution of the 2016/2017 issues. These issues appear to have been related to (i) Mr O’Brien’s standing, (ii) his attitude to challenge, and (iii) the size and location of the hospital. Taking each one in turn:

(i) Mr O’Brien’s Standing

4.44 Mr O’Brien started the urology unit in 1992, ran it as a sole consultant urologist for approximately 4 years¹⁰⁴, and played a significant role in expanding it, particularly in its early years. At all times between 1992 and his retirement in 2020 he was the senior consultant urologist in the unit.

4.45 Mr O’Brien had a substantial reputation and was well thought of by many patients and staff. A clear example of the latter can be found in the June 2011 Report of the Disciplinary Investigation¹⁰⁵ carried out by Robin Brown¹⁰⁶ into Mr

¹⁰⁴ July 1992 to January 1996; and again from December 1997 to May 1998.

¹⁰⁵ WIT-103538 at 103544.

¹⁰⁶ Then Clinical Director, General Surgery.

O'Brien's disposal of patient charts in a bin. Mr Brown concluded his report by observing:

*'Mr O'Brien says that he spends more time writing in and filing in charts than probably any other Consultant and from my own personal experience I can confirm that that is the case. Mr O'Brien has the utmost respect for patients, for their information and for the storage of records. This was an unusual behaviour ...
The motivation for the incident was honourable ... '*

In 2013, in the context of Mr Brown having had to speak to Mr O'Brien about the latter's triage deficits, Mr Brown once again reflected his high opinion of Mr O'Brien – *'Aidan is an excellent surgeon and I'd be more than happy to be his patient'*.

4.46 Mr O'Brien's legal connections, through his brother and later his son, were also well-known by staff who worked with him in the Trust. Several witnesses provided evidence of how awareness of these connections may have contributed to a reluctance to challenge him¹⁰⁷.

4.47 Similarly, it was well known by several people with whom Mr O'Brien worked in the Trust that he was a friend of the Chair of the Trust Board, Mrs Brownlee¹⁰⁸. Not only does it appear that Mr O'Brien mentioned their relationship on occasions but it is also the case that, on the day of Mr O'Brien's MHPS meeting with Mr Weir on 24 January 2017, Mrs Brownlee accompanied Mr O'Brien and his son a short distance within Trust headquarters to the room where the meeting was to take place and introduced him. The Inquiry has also received evidence about how Mrs Brownlee engaged with each of Esther Gishkori and John Wilkinson in a way that could be construed as advocating on behalf of Mr O'Brien. Vivienne Toal considered that knowledge of the friendship between Mr O'Brien and the Trust

¹⁰⁷ E.g., M Corrigan at WIT-26224 para 30.12. See also TRU-251964 email from Mr Haynes to S Gibson and Dr Khan and dealt with in S Gibson's evidence at TRA-02930 "Are you aware of this? Surely this behaviour (phone calls from wife and his son/legal adviser to Mr. Young, below with Mr. Weir) shouldn't happen? How can we (his colleagues) be protected."

¹⁰⁸ See, e.g., the evidence of M Corrigan at WIT-26300-26301 para 67.5.

Chair had a '*chilling effect*' on how issues with Mr O'Brien were addressed prior to 2016¹⁰⁹.

4.48 Given the above factors, it is perhaps not difficult to understand how there may have existed at least a perceived imbalance of power between Mr O'Brien and each of his more junior clinical colleagues and his operational managers (such as the Head of Service). It is likely that this imbalance will have made at least some staff more reluctant to challenge Mr O'Brien.

(ii) Mr O'Brien's Attitude to Challenge

4.49 Mr Haynes described Mr O'Brien as 'a challenge to challenge'¹¹⁰. His Head of Service echoed this evidence¹¹¹, describing how '*there was no backing down by him when he believed that he was correct and it was the system that was wrong*'¹¹² and how '*he always challenged back and he wore people down*'¹¹³.

4.50 The Inquiry is very familiar with Mr O'Brien's responses when reminded of the importance of using the DARO system¹¹⁴.

4.51 And we are familiar with his apparent failure to change his practice when sent an email by Dr Mitchell in 2014¹¹⁵ which the latter described as '*an email which I think if I'd received it, I'd have been quite shocked at, the forthrightness of the approach*'¹¹⁶.

¹⁰⁹ TRA-03500 from lines 21-27 in particular.

¹¹⁰ TRA-00842 lines 1-2; see also Mr Haynes TRA-11446 from line 1.

¹¹¹ WIT-26223-26224 paras 30.6 to 30.9.

¹¹² Ibid at para 30.8.

¹¹³ WIT-26300 para 67.2 line 2.

¹¹⁴ See the email chain at AOB-07574 to 07577 for the 2019 DARO exchange and an earlier similar email exchange between Mr O'Brien and Mrs Corrigan from 2011 about actioning results at TRU-276805 to 276808.

¹¹⁵ AOB-71990

¹¹⁶ TRA-07790 line 18 to TRA-07791 line 2.

4.52 We can also see, in Chapter 6, further examples of his general resistance to changing his practice in areas such as IV fluids and antibiotics and TURPs in glycine.

(iii) Size and Location of the Hospital

4.53 In many relevant ways, both the Trust and the community served by it are small. This is perhaps not surprising in a local hospital serving a largely rural community.

4.54 The urology unit itself has never been substantial. For example, it did not move beyond 3 consultant urologists until 2011/2012. In such a small unit, where a Head of Service works very closely with her consultants on a daily basis, there is an obvious tension between repeated challenge to a consultant in respect of his non-clinical work and the viability of a continued working relationship between them. Perhaps Mr Young encapsulated the point when he observed that, *'It's a small group. It's a small team. It's very important to get on to make the thing – to make the work gel, to make the whole as a unit gel.'*¹¹⁷

4.55 Looking beyond the urology unit to the Trust community and local community more broadly, the smallness and interconnectedness of them is undoubtedly a relevant feature. Staff largely lived in the locality where they worked. Thus, the Inquiry has encountered multiple connections beyond the professional. We have heard about how Mr O'Brien had been the Trust Board Chair's surgeon at a significant point in her past and how he treated a family member of a past Chief Executive¹¹⁸. We have seen how Mr Brown anticipated he might personally need to avail of Mr O'Brien's services in the future. And we have heard Mr Glackin's evidence of his family connection to Mr O'Brien and the latter's role as a mentor of sorts at an early stage in Mr Glackin's medical journey.

¹¹⁷ TRA-09054 lines22-25.

¹¹⁸ WIT-18567 para 1.7.

4.56 In this particular context, which might differ significantly from that of a large city hospital, it is possible that some managers were willing to exhibit greater tolerance of the ebb and flow of Mr O'Brien's compliance with expectations in respect of triage, patient notes and dictation, and that some colleagues were willing to either to work around him or, on occasions, to do his work for him¹¹⁹.

(b) Inadequate Appreciation of the Risk to Patients

4.57 The issues that came to a head in 2016/2017 (particularly those in respect of referral triage, notes at home, and dictation) have at times been described as 'administrative' failings.

4.58 Such a label risks obscuring the real risk to patient safety that is posed if, for example, a patient's referral letter is not triaged (and, where appropriate, its priority upgraded) or if their notes are unavailable when they arrive in A&E or if their GP is not advised by letter of their urological diagnosis and treatment path.

4.59 It appears that there may at times have been an inadequate appreciation of the risk to patient safety created by these (superficially) administrative failings. Indeed, this was a particular reflection offered by Mr Mackle in his evidence regarding triage¹²⁰. And the Inquiry has heard from witnesses who have stated that they appreciated the risks associated with failings¹²¹ as well as from those who have acknowledged that they did not¹²².

4.60 This inadequate appreciation of risk may also have played a role when the 'default system' in respect of triage was conceived. In her written evidence to the Inquiry¹²³, Mrs Trouton identified the two risks that accrued if triage remained undone:

¹¹⁹ As Mr Young did with Mr O'Brien's triage on more than one occasion.

¹²⁰ WIT-11817.

¹²¹ E.g., M Corrigan at WIT-26282 at para 57.1.

¹²² E.g., K Robinson at TRA-05171 lines 27 to TRA-05172 line 2.

¹²³ WIT-12135 at para 441.

441. Regarding the concerns of untimely triage in relation to patient safety, these were:-

- a. Patients not being afforded the expert opinion of a consultant Urologist as to their level of referral urgency (i.e., not having the opportunity to be upgraded from routine to urgent or red flag or from Urgent to red flag) and the potential to come to harm if not seen as quickly as their condition indicated.
- b. Patients not being added to the waiting list in a timely manner and therefore missing their rightful chronological management for a routine or urgent appointment.

4.61 As is clear from the evidence before the Inquiry and as already alluded to above, the 'default system' in respect of triage addressed only the second of the above risks (a referral patient not being added to the waiting list). It did nothing to address the risk (even if it was only a small risk) of untriaged referrals missing out on an upgrade in their priority status.

(c) Confusion or a Lack of Clarity Regarding Roles and Responsibilities

4.62 It is clear that there was, amongst staff at several within the levels within the Trust who could have assisted in grappling with the deficits in Mr O'Brien's practice, confusion or a lack of clarity about their roles and responsibilities. Two clear examples of this should suffice:

- a. We know, in respect of Mr O'Brien's delayed dictation problem, that his secretary was aware of it but did not raise the issue with anyone other than Mr O'Brien at least in part because she appears not to have considered it part of her role to do so¹²⁴. At the same time, staff¹²⁵ further up the management line from the secretary appear to have considered it to be the duty of the secretary

¹²⁴ See, as an example of her evidence in this regard, TRA-06165 lines 22-24 and TRA-06166 lines 1-5 and 11-16.

¹²⁵ E.g., K Robinson.

to tell others when the consultant was behind in dictation¹²⁶. Thus, there appears to have been at a material time a degree of confusion regarding the secretary's responsibilities, confusion which, if it had been avoided or removed, might have led to the extent of the O'Brien dictation problem coming to light at an earlier stage.

- b. On the clinical side, we know that there was confusion regarding Mr Young's role and responsibilities as Clinical Lead¹²⁷. He had no job description or job plan for the Clinical Lead role. He did not see himself as having any significantly greater clinical governance responsibility as Clinical Lead than as a consultant. He described his role as being 'the captain of the team'¹²⁸ and saw his responsibilities as lying more in respect of organisational matters such as rotas.

(d) Failure to deploy existing tools adequately or at all

4.63 It seems clear that there was a failure to deploy existing tools adequately or at all. There are several examples of this:

Escalation

- a. In respect of dictation, Mr O'Brien's secretary gave evidence about how she raised non-dictation with him repeatedly but never escalated the issue to anyone else until December 2016, as she thought management already knew¹²⁹.
- b. In respect of patient notes, there are multiple examples of the issue being drawn to the attention of a manager (such as, but not limited to, the Head of Service) but not being escalated further, potentially because every time it was raised the missing notes were returned.

¹²⁶ K Robinson evidence at TRA-05193 lines 3-7.

¹²⁷ See his evidence on this issue from Day 69, p72 line18 to p86.

¹²⁸ TRA-09044 line 24.

¹²⁹ TRA-06176 lines 24 to TRA-06177 line 23

- c. Similarly in respect of triage, there are numerous examples of the issue being drawn to the attention of a manager such as the Head of Service and of it sometimes being escalated further up the chain¹³⁰ but there is little evidence of it having been escalated to the Medical Director prior to 2016¹³¹. Not unreasonably, Mrs Corrigan reflected in her evidence that this issue ought to have been escalated to the Medical Director at an earlier stage¹³².

Use of Formal approaches

- a. There are examples of staff not availing of formal routes to address concerns about Mr O'Brien. Examples include:
- i. In respect of the recurring referral triage issue there appears to have been a reluctance to complete IR1s¹³³. Although Mr Haynes submitted the IR1 regarding Patient 10 in January 2016, he described the incident reporting system as being '*not the most user friendly*'¹³⁴ and provided evidence of his experience of no feedback being provided in respect of IR1s submitted nor input afforded to the IR1 'reporter'¹³⁵. He was of the view that this lack of feedback contributed to the failure of Trust systems (such as Datix) to identify and address concerns about Mr O'Brien at an earlier stage¹³⁶. He reflected that the absence of feedback could act as a deterrent to people reporting concerns¹³⁷.

¹³⁰ E.g., to the Assistant Director or Associate Medical Director - see 8 October 2013 H Trouton email to Mr O'Brien at AOB-06960 and also TRU-276904.

¹³¹ See, in this regard, the list of interventions in respect of triage between 2009 and 2016 set out by H Trouton in his witness statement at WIT-12135 para 443 to WIT-12137 para 444.

¹³² WIT-26307 para b.

¹³³ Note the exchange between Inquiry Senior Counsel and Mr Young on TRA-09084 regarding the fact that, prior to the 2016/2017 IR1s regarding Patients 10-15, it appeared that IR1s were not submitted regarding the triage issue.

¹³⁴ TRA- 876 lines 5-6.

¹³⁵ WIT-53915-53916 para 46.2.

¹³⁶ Ibid.

¹³⁷ TRA-00873 lines 8-24.

- ii. In respect of missing notes, although IR1s were completed for a time (already referenced above), staff appear to have ceased doing so, at least in part because it had failed permanently to resolve the issue.
- iii. When IR1s were submitted, it appears that on occasions, cases that might reasonably have been 'screened in' for SEA or SAI Review were simply not. For example, in the case of Patient 102 Mr Haynes saw him in October 2015 and noted that no letters had been dictated in respect of his previous clinical encounter in November 2014 and that the MDM recommendation (of referral for radical radiotherapy) appeared not yet to have been implemented. Although Mr Haynes completed an IR1¹³⁸ in respect of this patient, nothing further appears to have occurred. Neither Mr Haynes¹³⁹ nor Mr Cardwell¹⁴⁰ could explain this omission. Mr Haynes speculated that those involved in screening ought to have been *'more alert to potential [harm] and less focused on evidence of harm as the trigger for screening into an SEA or SAI'*¹⁴¹.
- iv. The potential to invoke or suggest invocation of the MHPS process may have been diminished by the fact that some staff who were aware of Mr O'Brien's deficits were unaware of the existence of the MHPS process. Prime examples of this are his Head of Service who was unaware of MHPS until 2016 or 2017¹⁴² and Mr O'Brien's Assistant Director for the period 2009-2016 who was not aware of MHPS at any point during her tenure and who only became aware of it during the lifetime of the Public Inquiry¹⁴³.

¹³⁸ WIT-54874 to WIT-54881.

¹³⁹ See WIT-53915 para 46.2 and TRA-00870- TRA-00875

¹⁴⁰ TRA-07629

¹⁴¹ TRA-00874

¹⁴² WIT-39881 at para 4.1.

¹⁴³ See H Trouton's evidence at WIT-14810 para 8.

- v. Similarly, the potential to involve NCAS appears similarly to have been reduced by reason of the fact that some were unaware of the potential assistance it could provide¹⁴⁴.
- vi. Risks caused by Mr O'Brien's various failings could have been, but were not, added to risk registers¹⁴⁵.

Use of Informal approaches

- a. Whilst it is clear that some informal methods were used (and used repeatedly), such as Mrs Corrigan speaking to or emailing Mr O'Brien to chase missing notes or undone triage, other informal methods appear not to have been used adequately. For example, whether because of a perception that Mr O'Brien was '*a challenge to challenge*' or because of cultural issues, it does not appear that a more structured meeting was ever arranged with Mr O'Brien to talk through the difficulties he was experiencing and the potential solutions to same. When a meeting was arranged in late March 2016, it was primarily to hand over the 23 March 2016 letter and some of the evidence about that meeting has already been described as creating an impression that it was a case of '*let's get this done and dusted and out of there as quickly as possible*'¹⁴⁶. The Inquiry may form the view that, at times at least, there was some degree of paralysis amongst managers in addressing the O'Brien issues, caused in part by a misapprehension that it was a binary choice for managers between informal prompts to Mr O'Brien (whether by Mrs Corrigan or Mr Brown) and the 'nuclear option' of an MHPS process¹⁴⁷. In this regard, Zoe Parks' evidence described how part of the motivation around the fresh MHPS guidance issued by the Trust in late 2017 was to ensure that the informal approach received appropriate emphasis as a management option¹⁴⁸.

¹⁴⁴ E.g., TRA-02513 line 7 to TRA-02514 line 4 - Dr Wright evidence.

¹⁴⁵ See, e.g., K Robinson's evidence at TRA-05205 lines 8-17.

¹⁴⁶ See the Chair's question of H Trouton on Day 22, p133, lines 8-11.

¹⁴⁷ In this particular regard, attention is drawn to the useful evidence given by Dr Colin Fitzpatrick on this issue in response to questions from Dr Swart between TRA-04372 line 22 and TRA-04375 line 24.

¹⁴⁸ TRA-05570 line 21 to TRA-05571 line 13. See also the evidence of Vivienne Toal on the importance of the informal element – TRA-03481 line 11 to TRA-03482 line 15.

(e) Problems with Existing Systems

4.64 Some existing Trust systems, which had the potential to identify and record (or even begin to address) some of the O'Brien issues, were not sufficiently sensitive to do so, even though it appears that it might have been possible with some additional effort to render them such. Furthermore, the potential governance role for such systems appeared to go unnoticed. For example:

- a. Backlog reports – These reports completed by consultants' secretaries (examples of which can be found at TRU-164942-3 and TRU-165082) did record 'clinics awaiting typing' but did not, at the relevant time, record 'clinics awaiting dictation'. Katherine Robinson acknowledged this in her evidence¹⁴⁹. Although Ms Robinson's evidence was to the effect that she would have expected a secretary to include in the report if there was a backlog of clinic dictation, the inclusion of such a column in the report would have ensured that this was done. Furthermore, although these reports could have performed this important function, their purpose was viewed as being solely in respect of secretarial workload management rather than governance¹⁵⁰.
- b. Appraisal – Mr Young carried out Mr O'Brien's appraisals for the period 2010-2015¹⁵¹. Although not conceived as a performance management tool¹⁵², appraisals had some potential to recognise concerns in a doctor's practice (and perhaps begin a process to escalate and/or address them)¹⁵³. Although an appraiser had access to complaints about the appraisee¹⁵⁴, the process appears, in the words of Mr Young, only to be '*as good as the information that is supplied*'¹⁵⁵. It did not, for example, have access to IR1s. It appears that known issues with

¹⁴⁹ From TRA-05188 line 23 – especially at TRA-05189 line 27 to 05190 line 24

¹⁵⁰ TRA-05190 line 25 to TRA-05191 line 17.

¹⁵¹ TRA-09716

¹⁵² TRA-09240 lines 19-21.

¹⁵³ Ibid TRA-09726, lines 17-29 to TRA-09727 line 3.

¹⁵⁴ Ibid TRA-9727 from line 21.

¹⁵⁵ TRA-09088 lines 11-12.

Mr O'Brien's performance, particularly in the areas of triage and patient notes, were not 'brought to the table' in his appraisals. This was acknowledged as a potential missed opportunity in evidence given to the Inquiry¹⁵⁶. Mr O'Brien does appear to have provided some information regarding triage in his 2015 appraisal (*'I triage red flag referrals when urologist of the week'*)¹⁵⁷ which, with the benefit of hindsight, might be construed as a warning sign requiring some probing. Of course, this appraisal appears only to have been completed in December 2016, by which point issues in respect of Mr O'Brien's triage were being actively addressed¹⁵⁸.

- c. Patient Records Logged Out – The system recorded that patient notes were logged out to a consultant or his/her secretary but not whether the consultant had then taken them home.

(f) Staff Churn and Staff Vacancies

4.65 In the period from 1992 to 2020, Mr O'Brien was a constant in the urology service and it appears that some of the deficits with which this chapter is concerned (e.g., in respect of referral triage) may have been present throughout much of the period (albeit at different intensities and with different potential consequences¹⁵⁹). In contrast, there was a significant turnover of both clinical colleagues and managers.

- a. For example, during his tenure he has had at least 11¹⁶⁰ substantive consultant urologist colleagues in addition to multiple locums. Only Mr Young has been a constant presence throughout most of Mr O'Brien's tenure.

¹⁵⁶ See Mr Young's exchange with Inquiry Senior Counsel at TRA-09717 from line 5.

¹⁵⁷ TRU-251310 at TRU-251312

¹⁵⁸ Mr O'Brien included a similar sentence in his 2016 appraisal [TRU-251320 at 251331], completed in November 2017, when his appraiser was Dr Scullion and when he was, in fact and by virtue of his return to work plan monitoring, actually performing more than red flag triage.

¹⁵⁹ E.g., the consequence of a failure to triage a referral and upgrade its urgency may have made little difference when the difference between the most and least urgent waiting lists was relatively small.

¹⁶⁰ Messrs, Baluch, Young, Akhtar, Glackin, Ho, Pahuja, Connolly, Suresh, Haynes, O'Donoghue, and Tyson.

- b. On the management side, there has been churn at almost all levels¹⁶¹. For example, on the clinical side in the decade between 2010 and 2020 alone he had 5 different Medical Directors¹⁶², 3 different AMDs¹⁶³, and 3 different CDs¹⁶⁴. On the operational side in the same period he had 4 different Directors of Acute Services¹⁶⁵ and 2 different Assistant Directors¹⁶⁶. Only Mrs Corrigan was a relatively¹⁶⁷ constant presence, albeit she has borne a large and increasing burden of managerial responsibility beyond the realm of Urology.

4.66 In addition to the churn of managers, there were a number of related sub-optimal features of the managerial landscape.

- a. For example, for the period of time when Robin Brown was his Clinical Director, Mr Brown was based primarily at Daisy Hill whereas Mr O'Brien was in Craigavon. This separation was of particular significance in the period from 2012 onwards when Mr Mackle (who had attempted to manage a number of issues with Mr O'Brien as AMD up to that point) took a step back from managing him due to an alleged complaint by Mr O'Brien against him.
- b. In addition to the above geographical issue, there were points when certain managerial roles were unfilled, such as between Mr McAllister ceasing to act as AMD and Mr Haynes taking up the role.

4.67 The timing of some managerial change was also, on reflection, unfortunate. A prime example of this is the loss of both Heather Trouton and Eamon Mackle in or

¹⁶¹ Including even at Chief Executive level, where for several years prior to the arrival of Shane Devlin in March 2018 there was a high degree of churn in this role. In the 3-4 years prior to S Devlin arriving the role was held by Mairead McAlinden, Paula Clarke, Francis Rice, and Stephen McNally. See, e.g., WIT-00026 at Q5 response, 3rd para where S Devlin reflects on this.

¹⁶² P Loughran, J Simpson, R Wright, A Khan, and M O'Kane.

¹⁶³ E Mackle, C McAllister, and M Haynes.

¹⁶⁴ R Brown, C Weir, and T McNaboe.

¹⁶⁵ G Rankin, D Burns, E Gishkori, and M McClements.

¹⁶⁶ H Trouton and R Carroll.

¹⁶⁷ She was absent for a prolonged period during 2018.

about April 2016, just after Mr O'Brien had been challenged (by them) for the first time in a formal way (i.e., through the letter of 23 March 2016 and subsequent 30 March 2016 meeting). It is quite likely that the movement on of these key managerial personnel at this key point in time was at least partly to blame for poor follow up to the 23 March 2016 letter.

4.68 It is perhaps not difficult to understand how, in such an environment, there was sometimes a lack of cohesion and a lack of follow-through when it came to managing the deficits in Mr O'Brien's practice. The fact that, on several occasions, there was no handover between successive occupants of certain managerial roles could only have compounded this problem.

(g) A failure prior to 2016 to adopt a more coordinated and less siloed approach to, and/or to 'stand back and look' at, Mr O'Brien's Practice

4.69 It is clear that the Trust could, prior to 2016, have taken a more coordinated approach to Mr O'Brien's practice and the deficits apparent in it. There are a number of aspects to this.

- a. First, they could have adopted a more coordinated approach to how they grappled with individual issues in Mr O'Brien's practice. If one considers the patient notes issue as an example, it appears that it was realised that notes were missing, a message then went out to Urology seeking the notes, (for a time at least) an IR1 was completed, the notes were (almost invariably) located and returned in time for the relevant patient encounter, and (if applicable) the IR1 was then closed. In one sense, each such event could be construed as a problem manifesting itself and then being solved. However, a more accurate view of the situation (and one that would be hard to resist for a manager 'standing back and looking' and coordinating the instances of the issue arising) might be of a continuing problem causing repeated 'near misses' necessitating a permanent solution.

- b. Second, instead of dealing with the issues (e.g., triage or notes) separately as they manifested themselves, they could have adopted a more coordinated approach. This might have been as simple as identifying that Mr O'Brien was deficient in more than one aspect of his practice and considering whether more substantial action and/or intervention and/or escalation was therefore necessary. Instead, however, it appears that Mr O'Brien's separate deficits were addressed separately prior to 2016. The Inquiry has in this regard multiple examples of separate chains of emails passing up and down between staff on separate issues of triage or patient notes but few examples of any coordination until 2016.

4.70 There were no doubt obstacles (albeit, given the process ultimately begun in 2016, not insurmountable obstacles) to taking such an approach but an added value of such an approach is that it would overcome such obstacles. For example:

- a. Silo working – The Trust is not alone (either amongst Health Trusts or large organisations more broadly) in sometimes conducting its operations in a siloed manner. There have been multiple examples of this in the evidence put before the Inquiry, one example of which was the evidence of Helen Forde who spoke about a siloed approach (in the context of the patient notes issue) to operational governance and clinical governance so that 'only medics could deal with medics'¹⁶⁸.
- b. Non-triangulation of information – No single person (other than Mr O'Brien) was sighted as to all of his issues, or at least as to the extent of all of his issues. So, whilst the Head of Service was periodically tasked to chase overdue triage or missing notes, she had much less knowledge regarding undone dictation (where the key information was in the hands of Mr O'Brien and his secretary).

¹⁶⁸ TRA-05096 lines 6 to TRA-05098 line 8.

4.71 Nonetheless, it is hard to avoid the conclusion that, if the Trust had ‘stood back and looked’ in a more coordinated way at the issues in Mr O’Brien’s practice that were known about in the years prior to 2016/2017, then:

- a. the extent of those issues would have been realised sooner; and
- b. more definitive action (either of the type initiated in 2016 and/or of a type including involvement of a body like NCAS) could have been taken at an earlier stage.

4.72 It is also important to acknowledge in this regard that, if the Trust had adopted such an approach, it might also reasonably have taken a broader look or a deeper dive into Mr O’Brien’s practice, a point that has been fairly acknowledged as a potential missed opportunity by several witnesses¹⁶⁹.

(h) Governance Deficits

4.73 Many of the above failings are themselves governance failings. However, sitting behind them were a number of broader or deeper governance deficits.

4.74 Shane Devlin in his witness statement has described how, within a short time of his arrival in 2018, he formed the view that the clinical and social care governance architecture of the Trust was inadequate¹⁷⁰:

... in 2019, I commissioned the HSC Leadership Centre to review the complete governance system within the Trust. I was concerned that the system was disjointed and that from my experience the system was not operating as I had experienced in other HSC organisations. I had a number of concerns based on my experiences;

¹⁶⁹ E.g., Mr Haynes at TRA-11421 from line 2.

¹⁷⁰ WIT-00037.

1. *The level of expenditure on the governance functions felt light. I was used to appropriately funded teams for areas such as SAI management, complaints, standards and guidelines.*
2. *There was little evidence of a systematic and dynamic flow of clinical and social care information to SMT on a regular basis. Clearly if there was an issue of concern there was evidence of items being raised. However my concern was that this was based on a 'push' system from the directorates, not from a regular systematic review process.*
3. *The level of data and statistical evidence being brought to the SMT, in respect of quality and safety, was lower than what I was used to in other organisations.*

4.75 Dr John Simpson, Medical Director between 2011 and 2015, gave evidence about how he had 'responsibility without power' for clinical governance and how he did not have a sufficient budget for it¹⁷¹. He described the impacts of 'austerity' and the tension between the resources needed for governance and the resources needed to meet targets¹⁷² and the 'relentless pressure to produce so-called ... efficiency savings'¹⁷³.

4.76 Tracey Boyce, Director of Pharmacy in the Trust at all material times, described the Acute Governance Team as being 'chronically under resourced for the size of the tasks expected of them'¹⁷⁴. This description was her considered reflection, based on substantial first-hand experience of the relevant governance structures. In particular, she described how, in October 2014, she was asked to manage the Acute Governance Team for a few weeks¹⁷⁵ but that she ended up performing the role (in addition to all of her other responsibilities

¹⁷¹ TRA-09215 line 6 to TRA-09217 line 2

¹⁷² WIT-25701 TRA-09218-TRA-09219

¹⁷³ TRA-09224 line 28-29

¹⁷⁴ WIT-87671 para 43.1.

¹⁷⁵ following the departure of Margaret Marshall to another role.

as Director of Pharmacy) until April 2016¹⁷⁶. She described how she only had capacity to devote a small portion of time to the role¹⁷⁷ and how, following the appointment of an Acute Governance Lead, in April 2016, Ms Boyce still had to retain a responsibility in this field¹⁷⁸ until mid-2019. Ms Boyce described how she had no job description or letter of appointment for either role and how governance in Acute was largely ‘reactive’¹⁷⁹ and that even this aspect was only done ‘to a certain level’¹⁸⁰. In this regard, she gave the example of hundreds of IR1s which, in late 2014, were discovered unopened and which then had to be considered (leading to approximately 20 SAIs)¹⁸¹. She described the reason for the under-resourcing of governance in Acute as being a financial one, linked to significant financial constraints on the Trust¹⁸², but reflected that this demonstrated an underappreciation of the importance of governance¹⁸³.

4.77 In answer to a s.21 Notice question¹⁸⁴ about ‘learning ... from a governance perspective’ arising from the events with which the Inquiry is concerned, Martina Corrigan has reflected that ‘*governance departments do not have enough human resources*’ and she went on to outline how operational managers, like herself, simply did not have the bandwidth to address complaints or ‘*to identify trends and patterns in areas such as complaints/SAI/queries ...*’¹⁸⁵.

4.78 Though perhaps of greater relevance to the issues around Mr O’Brien that emerged in 2020 or some of the other issues addressed in Chapter 5, it also appears to be the case that clinical audit within the Acute Directorate was inadequate¹⁸⁶.

¹⁷⁶ See her evidence from TRA-05831 line 16 to TRA-05835 end.

¹⁷⁷ TRA-05842 lines 22-24.

¹⁷⁸ TRA-05846 line3- 05848 line 29. She made it clear that the responsibility was properly that of the Director of Acute Services, then Esther Gishkori.

¹⁷⁹ TRA-05857 line 22.

¹⁸⁰ TRA-05837 line 8-9

¹⁸¹ WIT-87671 para 43.4 and TRA-05874 line 17 to TRA-05879 line 11.

¹⁸² TRA-05839 line 23 to 05842 line 11.

¹⁸³ Ibid.

¹⁸⁴ WIT-26301 Q68.

¹⁸⁵ WIT-26303 to 26304, all sub-para d.

¹⁸⁶ See, e.g., Tracey Boyce’s evidence at TRA-05860 from line 11 onwards.

4.79 If governance had been better resourced in the period prior to 2016/2017, when the Aidan O'Brien issues with which this chapter is concerned came to a head, it is reasonable to believe that this may have led to those issues being grappled with at an earlier stage. For example, greater governance scrutiny of the many IR1s that were submitted during 2013 and 2014 regarding missing notes, may have identified the risk of harm associated with this, the core unresolved issue, its link to the related dictation issue, and led to an SEA or SAI process. Given the role that the Patient 10 SAI played in bringing issues to a head and prompting MHPS action in late 2016, it is not unreasonable to believe that earlier SAIs regarding notes and/or dictation would have had similar potential to bring matters to a head. A similar point can reasonably be made in respect of Patient 102 and the failure to screen his IR1 (which involved both missing dictation and non-actioning of MDM outcomes) 'in' for an SEA or SAI in 2016.

(i) Issues at Trust Board Level

4.80 Perhaps the single most pertinent deficit at Board level in respect of the issues that came to a head in 2016/2017 is the following: the lack of curiosity and follow up by the Board once aware of the MHPS process underway in respect of Mr O'Brien in early 2017. This has been acknowledged (e.g., by Ms Mullan¹⁸⁷). It is not unreasonable to believe that greater curiosity and follow-up by the Board might have had the effect of ensuring that the MHPS process advanced with greater speed as well as ensuring that there was greater oversight of the implementation of the MHPS Case Manager's 3 recommendations.

4.81 In addition, greater curiosity and oversight by the Board on the MHPS issue might also have led the Board to identify that there was a significant governance

¹⁸⁷ Current Board Chair but, at the relevant time, a non-executive director.

deficit in the Acute Directorate given that, what the MHPS process undoubtedly revealed, was that the issues with Mr O'Brien had been of longstanding and had been known about by managers but had persisted without effective resolution for several years prior to the MHPS process.

Important Context

4.82 The Trust submits that it is essential, when considering the issues that came to a head in 2016/2017 and how the Trust did or did not address those issues (both before, and then from, 2016/2017), that the Inquiry does take account of the context in which events occurred, in particular, the points of context highlighted below.

(a) Resource Constraints

4.83 For much of the period with which we are concerned, in particular in the years after 2010, there have been significant constraints in respect of resources. The Inquiry has received substantial and wide-ranging evidence in respect of this issue. For example:

- a. John Simpson's evidence has already been described above. He contrasted how a safe system should run at 85% capacity rather than full capacity (as the Trust was doing) (day 71, p31-32) as it allows 'room to manoeuvre to run, running repairs, developments, reflection, deal with peak demand' (p31 line 29 p 32 line 1).
- b. Mairead McAlinden (Chief Executive from 2009-2015) described the 'challenges of securing funding for, and then recruiting, the workforce needed to ensure the Trust had sufficient capacity to meet the population demand'¹⁸⁸.

¹⁸⁸ WIT-18615 para 35.1, 3rd bullet.

- c. Richard Pengelly (Permanent Secretary in the Department of Health from 2014 to 2022) spoke about a 'resource constrained environment' and 'the paucity of resources that we have'¹⁸⁹.
- d. Sharon Gallagher (Chief Executive of HSCB up until March 2022 and thereafter Deputy Secretary in DoH responsible for the SPPG)¹⁹⁰ described how there still is not enough money in the health service here, how we are in a 'demand capacity deficit', how waiting lists in NI are longer than anywhere else in the UK, how from as far back as 2016 it was recognised that more money was required but how it has never arrived, and how it is '*a matter of public record that no service is currently achieving or receiving the funding that's required to meet the deficit*'¹⁹¹.

4.84 These resource constraints (which continue today¹⁹²) did have an impact upon some of the matters the Inquiry is investigating, as evidenced, for example, by the evidence of Tracey Boyce summarised above.

(b) Recruiting and Retaining Staff and the Capacity:Demand Mismatch

4.85 Related in part to the resource issue, it is clear that the Urology Service in the Trust has experienced significant staffing issues throughout most, if not all, of its existence. Against a backdrop of ever-increasing demand for urological services, particularly in an environment where the elderly comprise an ever-greater portion of our population, these staffing difficulties have contributed to what has been described by multiple witnesses as the 'capacity:demand mismatch'¹⁹³.

¹⁸⁹ TRA-10368 at lines 8 and 13

¹⁹⁰ WIT-66180 at para 1.

¹⁹¹ TRA-11015 lines 3-27.

¹⁹² <https://www.bbc.co.uk/news/uk-northern-ireland-68889278>

¹⁹³ Or, to use Inquiry Senior Counsel's more compelling description, 'skyrocketing waiting lists' in Urology – TRA-09231 line 22.

4.86 Detailed written and oral evidence has been provided by multiple witnesses regarding the difficulties the Trust has experienced in securing funding for, and then recruiting, sufficient Urology staff, whether it be Consultant Urologists or Clinical Nurse Specialists. In particular, Mr Young¹⁹⁴, Mr Haynes¹⁹⁵, and Mrs Corrigan¹⁹⁶ have all provided detailed evidence regarding these difficulties. In this regard it is clear that Mr Young and Mrs Corrigan¹⁹⁷ each agree that there have been staffing issues since the very outset of their respective careers in the Urology Service. Mr Haynes spoke of his frustration at the HSCB's director of commissioning implying that a solution to the problem was for the existing staff to work harder¹⁹⁸ and Mrs Corrigan described the 'soul destroying' process of recruiting (much needed) new staff, integrating them into the team, and then seeing them leave after a short time for an opportunity elsewhere¹⁹⁹. In this regard, it appears that, whilst there have been recruitment and retention issues in Urology (and, indeed, in other specialities) throughout Northern Ireland, they affect local hospitals like Craigavon more severely than regional Centres like Belfast City Hospital. Indeed, the Inquiry has received evidence from a number of consultant urologists²⁰⁰ who began their consultant career in Craigavon, only to move on to Belfast when a vacancy arose there.

4.87 The resourcing and staffing issues extend well beyond Urology. For example, Helen Forde provided detailed evidence²⁰¹ of the pressures resource constraints created in the field of patient records. Issues with oncology and radiology staffing are all well-known to the Inquiry in the context of the Urological Cancer MDM.

(c) Workloads

¹⁹⁴ WIT-51720 to WIT-51733, paras 15, 16 and 17.

¹⁹⁵ WIT-53877 to WIT-53879, para 13.

¹⁹⁶ WIT-26296 to WIT-26199.

¹⁹⁷ WIT-26199 at para 17.1.

¹⁹⁸ WIT-53880 at para 16.1.

¹⁹⁹ WIT-26200 para 18.2.

²⁰⁰ E.g., Mr Connolly.

²⁰¹ TRA-05128 to TRA-05133.

4.88 Related to both of the preceding issues, it is important to bear in mind the workload borne by many of the persons who worked closely with Mr O'Brien at key points in time. For example:

- a. In respect of Mr Haynes, the following extracts from his first day giving evidence are illustrative²⁰²:

Q. In terms then of the role of AMD, you were conducting that role in addition to a busy urological practice which had you both in Craigavon, and no doubt the satellite hospitals of the Southern Trust, and in Belfast once a week, you were Chair of NICaN and you had this AMD role. Thinking about it with some hindsight perhaps, was that a role that you were capable of performing effectively, given your other commitments?

A. I think, as I have included in my statement, I never felt I was in a position to give the time required to be Associate Medical Director, and part of that was driven by the waiting list, the length of time our patients are waiting for urological treatment, so I was always reluctant to pull back from any clinical work because of the direct impact that I could see on patients on a day-to-day basis. The inevitability of that was that I was not giving the time that would have been, I think, required to be AMD.

...

Q. At one point, it was October 2018, you indicated to the then Director of Acute, Ms. Gishkori, that you were minded to resign your position as Associate Medical Director, citing workload pressures and performing far in excess of what could be considered realistic or sustainable. Do you recall that?

A. Yes, I do.

The breakdown of his then working days at WIT-163344 is also striking.

²⁰² TRA-00834 from line 10 and TRA-00835 from line 27.

- b. In respect of Mrs Corrigan, her first witness statement²⁰³ contains a detailed account of the pressures of work she was under, including many working days that began between 7.00 and 8.00 am and ended more than 15 hours later.

4.89 This is important context for a number of reasons. First, pressure of work is likely to have had an impact upon the ability of other members of staff to manage Mr O'Brien and his issues or to adopt the type of coordinated approach to his issues that is considered at paragraphs 4.69 – 4.72 above. Second, it nonetheless shows (in the case of colleagues like Mr Haynes) that, in spite of pressures of work, it remained possible to perform duties in respect of matters like triage and dictation.

(d) Mr O'Brien

4.90 There are two points of context related to Mr O'Brien that the Trust submits should also be borne in mind in respect of the issues that came to a head in 2016/2016.

4.91 First, Mr O'Brien was in several ways an outlier. His deficits were not mirrored in the practices of the Trust's other consultant urologists. Stepping back and taking a broader view, the Trust itself did not have any known major issue in these areas. Indeed, in respect of some of these areas the Trust was a high performer. For example, in respect of patient notes Mrs Forde was able to describe how approximately 19,000 charts a month were being 'pulled' from Craigavon Hospital 'library' and how their average availability rate was 99.5%²⁰⁴, an achievement which the Inquiry itself acknowledged was impressive²⁰⁵.

²⁰³ From WIT-26310 to WIT-26313, para 70.2, in particular sub-paras a and b.

²⁰⁴ TRA-05083 lines 8-18.

²⁰⁵ See Dr Swart's observations at TRA-05160 lines 3-4. See also Katherine Robinson at TRA-05171 lines 9-14.

4.92 Second, following the intervention at the end of 2016 / start of 2017, Mr O'Brien did improve his performance in the 4 areas in question. Whilst his performance remained at times imperfect (e.g., in respect of notes and dictation and particularly when Mrs Corrigan was unavailable to monitor him), and whilst legitimate issues have been exposed in respect of the monitoring of his performance (in particular, the reliability of the data provided in respect of dictation²⁰⁶), his improvement does suggest that the intervention in question was at least partially effective at remedying the 4 issues that came to a head in 2016/2017.

Trust Actions to Improve / Restore Public Confidence / Protect Patients

4.93 Consistent with one of its key roles, the Inquiry has sought and received voluminous evidence (in the form of oral testimony, written statements, and disclosure) that speaks to how systems in the Trust have improved so as to reduce the risk of the shortcomings highlighted above recurring.

4.94 Focusing initially on the 4 issues that came to a head in 2016/2017, the following brief summary of some of relevant improvements is offered.

4.95 In respect of referral triage, this is monitored through a monthly 'dashboard' and an escalation process is in place²⁰⁷. There are also monthly meetings, attendance at which includes Mr Haynes in his Urology Improvement role, the Head of Service, and the Cancer Service Manager, where issues of triage performance, dictation, and results management are considered.

4.96 In respect of patient notes, with increasing use of electronic records (such as NIECR) there has been a reduced need for hard copy charts²⁰⁸. In addition, 'iFIT' is an improved system which will the Trust to charts being outside the

²⁰⁶ See the evidence of Mr Haynes in this regard.

²⁰⁷ See Mr Haynes' evidence, e.g., at TRA-11380 line 25 and also TRA-11484 line 22 to TRA-11486 line 21.

²⁰⁸ See Helen Forde's evidence at TRA-05059 at lines 1-12.

hospital²⁰⁹. Of course, the notes issue was linked to the dictation issue and the improvements in respect of dictation referenced below therefore also (albeit indirectly) reduce the chance of notes being removed from the hospital.

4.97 In respect of dictation, digital dictation has, at the very least, made it much easier to monitor what clinic has or has not been dictated²¹⁰. Backlog reports have also improved so that (a) they are now on a shared drive, visible to service administrator, and 'clinics not dictated' is now included as a column²¹¹; a new report on Patient Centre advises if a clinic has occurred and no dictation done²¹². There is also the monthly dashboard mentioned at paragraph 4.95 above (which also covers dictation), and better guidance has been given to secretarial teams on data they are to record and input to these systems²¹³.

4.98 In respect of each of the areas of triage and dictation (as well as in respect of results management), Mr Haynes described the positive 'self-policing' phenomenon that accrues from ensuring that there is regular data-sharing (regarding triage, dictation, and results) amongst a team of clinicians²¹⁴. In simple terms: no one wants to be the outlier. Thus, the development of sharing data within the team, even before the added layers of monitoring and escalation, in and of itself reduces the likelihood of deficits of the type experienced by Mr O'Brien from arising in the future.

4.99 Finally in this regard, in respect of private patients the risk of them being unfairly prioritised is much reduced by reason of audits of transfer forms and the fact that the urology waiting list is now pooled and controlled by a scheduler²¹⁵.

²⁰⁹ See Helen Forde's evidence at TRA-05163 line 19 to TRA-05164 line 14.

²¹⁰ See Noreen Elliott's evidence at TRA-06112 lines 6-8.

²¹¹ TRA-06112 lines 3-4.

²¹² See the evidence of K Robinson at TRA-05194 line 8 to 05195 line 2; see also TRA-05209 lines 18-28.

²¹³ See the evidence of Mr Haynes TRA-11485 line 25 to TRA-11486 line 21.

²¹⁴ Ibid TRA-11381 from line 7.

²¹⁵ Ibid TRA-11378 from line 23 – TRA-11379 line 20.

4.100 Adopting a broader focus, and cognisant of some of the root causes identified above for the Trust's failings in respect of the issues that came to a head in 2016/2017, the Trust has engaged in multiple improvement exercises across multiple areas. These are considered in part in Chapter 5 (where relevant to the issues that came to a head in 2020), are briefly summarised in Chapter 7, and have been a major theme of the written and oral evidence of multiple witnesses including, in particular, Shane Devlin, Maria O'Kane, Mark Haynes, Martina Corrigan, and Eileen Mullan. They have also featured in the evidence of other witnesses such as Vivienne Toal and Mr O'Brien's fellow urologists, Messrs Young, Glackin, Haynes, O'Donoghue, and Tyson.

4.101 These improvements cover multiple areas including, in particular, under the broad heading of 'clinical and social care governance': improvements in the areas of SAIs, clinical audit, complaints, morbidity and mortality / patient safety, whistleblowing, development of a 'being open' culture, MHPS, medical appraisal, revalidation, and job planning, as well as training and education. They extend from the 'coalface' right up to and including the Trust Board.

4.102 These improvements mean, selecting just some of the shortcomings identified above, that:

- a. Medical management has been strengthened significantly²¹⁶ with more²¹⁷ and better training and greater numbers of medical managers in key roles and with new oversight structures²¹⁸, making it less likely that problems of the type exhibited by Mr O'Brien in the fields of referral triage or patient notes would persist today without being effectively addressed by management.

²¹⁶ See Mr Wolfe KC's questioning of Maria O'Kane on the improvements in this sphere from TRA-11686 line 20 to TRA-11697 and in particular from TRA-11689 line 25 to TRA-11690 line 8. See also the March 2020 Medical Leadership Review discussed there which can be found beginning at WIT-79127.

²¹⁷ E.g., 'managing low level concerns' training – see TRU-305570 to 305573.

²¹⁸ Such as the Medical and Dental Oversight Group, ToR for which are at TRU-305992 to 305996.

- b. A doctor's appraisal now requires a greater focus on his or her shortcomings²¹⁹.
- c. In respect of adverse incidents and SAIs, DATIX (and the staff deployed to it) has been enhanced to ensure IR1s are followed through, information is triangulated, and trends are more easily identified, there is now a corporate SAI chair role, SAI information is included in the weekly governance reports, and there is an 'early learning template' to assist clinical teams in learning the lessons of adverse incidents and implementing change before any related SAI process is complete²²⁰.
- d. There is now better, more widely delivered training for MHPS²²¹;
- e. The Board is better sighted, and more curious in respect of, MHPS processes and the Trust has a much greater corporate and managerial awareness of the issues and themes arising through MHPS processes²²².

Conclusion

4.103 The Trust submits that all of this means that difficulties of the type that came to a head in 2016/2017, should they arise in any clinician's practice now or in the future, are much more likely to be identified, their potential implications recognised, and effective action taken to address them at an early stage.

²¹⁹ See, e.g., Mr Young's evidence on TRA-09718.

²²⁰ See, e.g., Maria O'Kane's evidence from TRA-11778 line 19 to TRA-11780 line 17. See also TRU-306245 to TRU-306250 for an overview of CSCG improvements in place or in progress as of March 2024.

²²¹ See, e.g., Vivienne Toal's addendum witness statement and her evidence at: TRA-03300 line 27 to TRA-03301 line 8; TRA-03412 line 24 to TRA-03414 line 18; TRA-03429 and TRA-03478 line 24 to TRA-03480 line 24.

²²² See, e.g., Maria O'Kane's evidence at TRA-11662 from line 13. See also examples of the levels of data and data analysis that now exists as part of the oversight of MHPS such as the MHPS 'Trend Analysis' report, the January 2024 version of which is at TRU-305574.

Chapter 5

Issues Which Came to a Head in 2020

Issues

5.1 This chapter covers a number of issues in respect of Mr O'Brien's practice and that of the Trust which came to a head in 2020. Nine patients were identified as potentially suffering harm and their treatment and care were the subject of Serious Adverse Incident ("SAI") review. The Trust has accepted the recommendations of the SAI reports. The Trust recognises the life changing and devastating consequences to the 9 families. The Trust offered an unequivocal apology to all the patients and their families in this review and accepted that the cancer care received was not the cancer care expected.

5.2 Primarily, the issues were as follows:

- a. Management with unlicensed anti-androgenic treatment – Bicalutamide;
- b. Failure to allocate a Key Worker;
- c. Failure to action MDM recommendations.

5.3 The issues identified also included:

- a. Informed consent;
- b. Follow-up;
- c. Actioning of reports;
- d. Delay in diagnosis.

5.4 Whilst these issues came to a head in 2020, it is important to note that, as with the issues that came to a head in 2016/2017, some of them were longstanding, with a number arising a considerable time prior to 2020. It is also important to note that,

as with the 2016/2017 issues, some may well be interrelated. For example, Mr. O'Brien's failure to action MDM recommendations, Mr. O'Brien's use of Bicalutamide, and informed consent.

5.5 It is also important to note that these issues arose in the context of multi-disciplinary working and referral.

5.6 These issues engage a number of the Inquiry's Terms of Reference and, in particular, Terms (a), (b), (c), (f), and (g).

(e) Management with unlicensed anti-androgenic treatment – Bicalutamide

5.7 The Trust accepts the review finding that Patient 1 was diagnosed with prostate cancer (Gleason 4+3) on 28 August 2019 and was subsequently started on an anti-androgen therapy as opposed to Androgen Deprivation Therapy (ADT). The Trust accepts that this did not adhere to the Northern Ireland Cancer Network (NICaN) Urology Cancer Guidelines 2016 and that Patient 1's management with unlicensed anti-androgenic treatment (Bicalutamide) delayed definitive treatment.

5.8 The Trust accepts the review finding that Patient 9 was diagnosed with prostate cancer and was commenced on Bicalutamide 50 mgs. The Trust accepts that Bicalutamide 50 mgs is currently only indicated as a preliminary anti-flare agent or in combination with an LHRH analogue and is only prescribed before definitive hormonal treatment.

5.9 In relation to Mr. O'Brien, we now know from the Bicalutamide Audit²²³ in relation to data provided for patients who received a prescription of Bicalutamide (any dose) between March and August 2020 that, in relation to Low Dose Bicalutamide Prescribing (50 mg), a total of 466 patients were identified from the Western, Northern, and Southern Local Commissioning Group areas as having received a

²²³ As referred to by Dr. O'Kane at WIT-20089 in response to Section 21 Notice 1a of 2022.

prescription for Bicalutamide 50mg. We now know that 34 of these patients were identified as being on the incorrect treatment as determined by the clinical indications used and that 2 patients had been commenced on the medication by services outside of NI Urology (1 by a GP and 1 in South Africa in 2005 and continued following their move to NI). We now know that, of the remaining 32 patients, 31 had been commenced on the low dose Bicalutamide by Mr O'Brien. We now know that 1 patient had been correctly commenced by Mr O'Brien on combined androgen blockade (LHRHa and 50mg bicalutamide) and had been switched to intermittent treatment by another Southern Trust Locum Consultant Urologist on review but that only the LHRHa (rather than both treatments) had been stopped at the time of this switch and that this patient has since been reviewed by the oncology team and the Bicalutamide discontinued. We now know that, from the remaining 31 patients, 2 were subjects of the 2020 SAIs – Patient 6 and Patient 4 - and that, of the 53 patients screened in for SCRR by 15 April 2022, 32 were on low dose Bicalutamide i.e., the same 32 patients.

5.10 In relation to the manner in which Mr. O'Brien prescribed Bicalutamide, Mr. O'Brien has informed the Inquiry that at no point during his years of clinical practice was a concern raised with him and that it was well known within the urology service and within the oncology service how Bicalutamide was being prescribed. Mr. O'Brien alleges that the first time a concern was raised was on 25th October 2020 when the Directorate of Legal Services wrote to his solicitors.²²⁴

5.11 The Inquiry will have to decide whether it is necessary to determine where responsibility in respect of patient management with unlicensed anti-androgenic treatment – Bicalutamide – rests. Is it with Mr. O'Brien or with the Trust or with both of them? In the event that it is deemed necessary to decide this issue, then the Inquiry will have to consider -

²²⁴ WIT-82585 at paragraph 544. Though see further in this regard some of the evidence considered from para 5.38 below.

- a. whether Mr. O'Brien ought reasonably to have changed his approach to Bicalutamide;
- b. whether Mr. O'Brien ought to have made it clear to the Trust how he used Bicalutamide;
- c. what did the Trust know in relation to Mr. O'Brien's use of Bicalutamide;
- d. what steps the Trust should have taken in relation to Mr. O'Brien's use of Bicalutamide.

(f) Failure to allocate a Key Worker

5.12 All 9 patients reviewed did not have a Key Worker allocated to their care.

5.13 The NICA N Urology Cancer Clinical Guidelines 2016 state²²⁵ that all patients should be assigned a key worker (usually a CNS) at the time of diagnosis, and appropriate arrangements should be in place to facilitate easy access to the key worker during working hours and an appropriate source of advice in his/her absence, as per National Cancer Peer Review standards.

5.14 The Trust's Urology Cancer MDT Operational Policy 2017²²⁶ states:

"The identification of the Key Worker(s) will be the responsibility of the designated MDT Core Nurse Member.

It is the joint responsibility of the MDT Clinical Lead and of the MDT Core Nurse Member to ensure that each Urology cancer patient has an identified Key Worker and that this is documented in the Record of Patient Management. In the majority of cases, the Key Worker will be a Urology Clinical Nurse Specialist (Band 7) or Practitioner (Band 6)...".

²²⁵ At WIT-85652.

²²⁶ At WIT-84545 at paragraph 3.1. As did the Trust's previous Operating Policy Urology Cancer Service April 2015 (updated September 2016) at AOB-77999 at paragraph 7.1.

The Trust's Operating Policy Urology Cancer Service April 2015²²⁷ states that the Responsibilities of the Core Nurse Member include:

"Acting as the key worker or be responsible for nominating the key workers for patients under care of the MDT, dealing with the team in line with the Trust Key Worker Policy."

5.15 Whilst the Review Team found there were no resources for a Urology Cancer Nurse Specialist to attend any outreach clinics, the Trust accepts that their contact numbers should have been provided to patients.

5.16 The Trust accepts that the allocation of a Urology Cancer Nurse Specialist as a Key Worker would support the patient on their journey as well as working collaboratively with the multi-disciplinary team to ensure key actions take place. The Inquiry has heard evidence from Kate O'Neill²²⁸ and from Mr. Gilbert²²⁹ that the purpose of the cancer nurse is 'continuity', which was not afforded to the 9 patients.

5.17 In relation to the allocation of a Key Worker, Mr. O'Brien has asserted that the first time he became aware of concerns in relation to an alleged failure to provide patients with access to CNSs was when he had sight of the SAI reports, that he was, for example, not the MDT Clinical Lead when Patient 1 received his diagnosis, and that it is untrue that he excluded all CNSs from the care of patients at clinics.²³⁰ Mr. O'Brien has asserted that Kate O'Neill ensured that all patients were reviewed by consultants following MDM discussion and that, as the MDT Core Nurse Member, Kate O'Neill was responsible for ensuring that all newly diagnosed cancer patients had access to a CNS.²³¹

²²⁷ Updated in September 2016 at AOB-77998 at paragraph 6.1

²²⁸ TRA-12104.

²²⁹ TRA-01168.

²³⁰ WIT-82583 at paragraph 537.

²³¹ WIT-82488 at paragraph 250.

5.18 The Inquiry will have to decide whether it is necessary to determine where responsibility in respect of the failure to allocate a Key Worker rests. Is it with Mr. O'Brien or with the Trust or with both of them? In the event that it is deemed necessary to decide this issue, then the Inquiry will have to consider –

- a. what was Mr. O'Brien's approach to the allocation of a Key Worker;
- b. did Mr. O'Brien exclude Cancer Nurse Specialists from the care of his patients at clinics;
- c. what was known, or ought to have been known, by the Trust regarding whether Mr. O'Brien's patients were being allocated a Key Worker;
- d. what steps the Trust should have taken in relation to ascertaining Mr. O'Brien's use of Key Workers.

(c) Failure to action MDM recommendations

5.19 The Trust accepts that recommendations made by the MDM were not actioned in the case of Patient 1. Patient 1 was discussed at MDM on 31 October 2019 and a recommendation to commence an LHRH analogue and to refer for an opinion from a clinical oncologist regarding EBRT was agreed. This was not actioned and Patient 1 was subsequently commenced on Bicalutamide 50 mgs once daily.

5.20 The Trust accepts that, in the case of Patient 4, the patient was discussed at MDM on 25 July 2019 when the recommendation to commence an LHRH analogue was made. Mr. O'Brien prescribed Bicalutamide (50 mgs once daily). The Trust accepts that the patient was started on an inadequate dose of a drug (Bicalutamide) which was not licensed for the treatment of prostate cancer and was contrary to the recommendations of the MDM. The Trust accepts that Patient 4 should have been referred to an oncologist to allow consideration of other treatment options. Patient 4's case was not brought back to MDM for re-discussion and multi-disciplinary input despite disease progression and the Trust accepts that, as a result, Patient 4's care was not co-ordinated with the palliative care team.

5.21 In the case of Patient 2, the Trust accepts that the patient was diagnosed with testicular cancer, that Patient 2's case was discussed at the Urology MDM on 25 July 2019 and that the recommendation was for Mr. O'Brien to review the patient and to refer him to the regional testicular cancer oncology service. The Trust accepts that the patient was reviewed on 23 August 2019 and the referral to oncology was made on 25 September 2019. The Trust accepts that a 2 month delay in referral to a medical oncologist complicated treatment choices.

5.22 The Trust accepts that, in the case of Patient 6, the patient presented with possible prostate cancer and was commenced on Bicalutamide 50 mgs. The Trust accepts that a diagnosis of prostate cancer was confirmed by biopsy in July 2019. The Trust accepts that Patient 6 was discussed at MDM on 8 August 2019 and that the plan was that Mr. O'Brien review the patient and discuss management with curative intent or surveillance. The Trust accepts that the Review Team found that, when Patient 6 was reviewed by a locum consultant in October 2020, Patient 6 did not recall any conversation about the options of external beam radiotherapy (EBRT) as a radical treatment and active surveillance.

5.23 The Review team found that in the case of Patient 7 an appropriate referral to the Regional Small Renal Mass MDM was omitted despite the MDM's recommendation on at least 2 occasions. The referral was not actioned by Mr. O'Brien.

5.24 In the case of Patient 3, who was diagnosed with penile cancer, the treatment provided was found by the Review Team to be contrary to the NCCN Urology Cancer Clinical Guidelines (2016) for Penile Cancer which state that local care is restricted to diagnosis and that all cases of penile cancer should be discussed by the supra-network MDT as soon as the diagnosis is confirmed by biopsy. However, a regional Penile Cancer Pathway was only agreed in January 2020 and Patient 3 was referred to the Regional Penile Cancer Service in February 2020.²³² The Review

²³² The Trust's Urology Cancer Services Operational Policy 2020 can be found at TRU-98103 and in particular at TRU-98113 in relation to penile cancer.

Team found that a referral to a specialist with appropriate experience should have been pursued. The patient was discussed at a number of MDMs between 18 April 2019 and 6 February 2020.

5.25 In relation to MDMs and their outcomes Mr. O'Brien has made a number of points in his witness statement²³³ including:

- a. the language used in expressing the agreed recommendation is of critical importance;
- b. that he considered MDMs to have been effective within the constraints placed upon them;
- c. the focus of MDMs was always on recommending the right approach for each patient;
- d. that he never felt that anyone felt inhibited from expressing their views;
- e. the decisions made at MDM were the agreed recommendations which would be considered and discussed with the patient at review;
- f. the agreed recommendations could not dictate the next steps in all cases;
- g. each consultant would have been responsible for considering, discussing, and informing the patients of the recommendations agreed following MDM discussion;
- h. other members were not subsequently informed of a deviation from an agreed recommendation as there was an understanding that the clinician and patient had the right, and indeed responsibility, to deviate from the agreed recommendation if the latter was declined by the patient, or if the recommendation was concluded by the clinician and patient to be inappropriate.

5.26 The Inquiry will have to decide whether it is necessary to determine where responsibility in respect of any failure to action MDM recommendations rests. Is it

²³³ WIT-82506 at paragraphs 307, 309, 310, 312 and 314.

with Mr. O'Brien or with the Trust or with both of them? In the event that it is deemed necessary to decide this issue, then the Inquiry will have to consider –

- a. whether there were any reasonable reasons for not actioning MDM recommendations;
- b. whether such reasons were discussed and recorded in patients' notes and records;
- c. whether such reasons ought to have been discussed and recorded in patients' notes and records;
- d. whether any failure to action MDM recommendations ought to have been brought back to MDM;
- e. whether any other reasons, such as disease progression ought to have resulted in patients being brought back to MDM.

(d) Informed Consent

5.27 The review team noted that there was no discussion with Patient 1 that the treatment given was at variance with regionally recommended practice and that there was no evidence of informed consent. Likewise, the review team noted that Patient 9 was unaware that his care was at variance with regionally recommended best practice and that there was no evidence of informed consent. In the case of Patient 4, the review team found that there was no evidence in the medical records or from speaking with the patient's family of informed consent.

5.28 The Inquiry will have to decide whether it is necessary to determine where responsibility in respect of any failure to obtain informed consent rests. Is it with Mr. O'Brien or with the Trust or with both of them? In the event that it is deemed necessary to decide this issue, then the Inquiry will have to consider –

- a. whether there is any evidence of informed consent;
- b. whether discussions in relation to consent ought to have been recorded in patients' notes and records;

- c. what would such recording of consent have entailed.

(e) Follow-up

5.29 Patient 9 was lost to follow-up after an appointment in July 2019. A routine review for September 2019 did not happen. Patient 5 had follow-up CT scans performed in June 2019 with a planned follow-up in July 2019. This did not happen. The Review team found that Patient 5 appeared to be lost to review. A repeat CT scan was arranged to be performed on 17 December 2019 with a plan for review in January 2020. This did not happen.

5.30 The Inquiry will have to decide whether it is necessary to determine where responsibility in respect of any failure to follow up rests. Is it with Mr. O'Brien or with the Trust or with both of them? In the event that it is deemed necessary to decide this issue, then the Inquiry will have to consider –

- a. were there any reasons why follow up reviews did not occur;
- b. were review backlogs known about;
- c. were there any alternatives to planned follow up such as DARO.

(f) Actioning of reports.

5.31 The Review team found that Patient 5 had a CT scan report available on 11 January 2020 which showed a possible sclerotic metastasis in a vertebral body which had not been present on previous CT scans and that this report was not actioned until July 2020 when a new consultant reviewed the patient's care. Patient 5 was subsequently diagnosed with metastatic prostate cancer.

5.32 The Review team found that in the case of Patient 7 a CT scan showed a further increase in the size of a lesion to 3.5 cm but no action was taken.

5.33 In the case of Patient 8, the patient underwent a TURP on 29 January 2020 and histology confirmed a prostatic adenocarcinoma. Mr. O'Brien planned to review the patient in April 2020 but the patient was not seen until August 2020 at an appointment arranged by another doctor when the histology was explained as an incidental finding that required continuing surveillance with an up to date serum PSA and a prostate MRI scan.

5.34 In relation to investigation results Mr. O'Brien has set out in his witness statement that he believes that there is a place for both monitoring and communication of results and reports by staff provided with the time to do so, and review of the patient as well as their pathology.²³⁴

5.35 The Inquiry will have to decide whether it is necessary to determine where responsibility in respect of any failure to action reports rests. Is it with Mr. O'Brien or with the Trust or with both of them? In the event that it is deemed necessary to decide this issue, then the Inquiry will have to consider –

- a. whether reports should be actioned in a timely basis;
- b. if so, by whom;
- c. whether it is reasonable not to action reports and to plan a review in the alternative;
- d. the history of this issue.

Important Points to Acknowledge Regarding the 2020 Issues

5.36 The following points, many of which are reflective of failings on the part of the Trust and its systems, need to be acknowledged in respect of the 2020 issues summarised above:

²³⁴ WIT-82540 at paragraph 398.

- a. Five out of the 9 patients in the review experienced significant delay in the diagnosis of their cancer.
- b. Three of the 9 patients were said to have met one of their 31/62 day targets:
 - a. Patient 8 was said to have met his diagnostic target for 31 days despite his tissue cancer diagnosis being missed and the patient suffering an 8 month delay;
 - b. Patient 3 was said to have met his 62 day target but was referred down a pathway that did not meet the NICaN Urology Cancer Guidelines 2016. (A regional Penile Cancer Pathway was only agreed in January 2020).
 - c. Patient 9 was said to have met his diagnostic target of 31 days despite having a delay from initial presentation of 15 months.
- c. The NICaN Urology Cancer Guidelines (2016) had been signed off by the SHSCT Urology Multi-Disciplinary Meeting (MDM) as its protocols for Cancer Peer Review in 2017.
- d. Mr O'Brien was Clinical Lead of the Urology Clinical Reference Group from January 2013 – January 2016.²³⁵
- e. Bicalutamide (50 mg) is currently only indicated before (as an anti-flare agent) or in combination with an LHRH analogue.
- f. The NICaN Urology Cancer Clinical Guidelines 2016 state that all patients should be assigned a key worker (usually a CNS) at the time of diagnosis.²³⁶
- g. The Trust's Urology Cancer MDT Operational Policy 2017 states that the identification of a Key Worker will be the responsibility of the designated MDT

²³⁵ TRU-99723

²³⁶ WIT-85652.

Core Nurse Member but that it is the joint responsibility of the MDT Clinical Lead and of the MDT Core Nurse Member to ensure that each Urology cancer patient has an identified Key Worker²³⁷.

- h. The SHSCT NICaN MDT Self-Assessment Report Proforma 2017²³⁸ stated:

“Progress is ongoing in relation to the full implementation of the Key Worker, Holistic Needs Assessments, Communication and ensuring all patients are offered a permanent record of Patient Management. With the appointment of two more nurses to the Thorndale Unit and clerical staff, all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner”.

- i. There were no resources for a Urology Nurse Specialist to attend outreach clinics.
- j. The use of a Cancer Nurse Specialist was common for all other urologists in the Trust’s Urology Multi-Disciplinary team.
- k. During MDM a quorum was not regularly achieved. For example, in the case of Patient 1 an oncologist had been absent.
- l. There was limited oncology presence within the Urology MDT. For example, on the date Patient 2 was discussed there was no oncologist present.
- m. The vast majority of Urology MDMs were not quorate due to the absence of an oncologist. For example, in 2019 the MDMs were 0% quorate.

²³⁷ WIT-84545 at paragraph 3.1 and at paragraph 5.14 herein.

²³⁸ WIT-84607.

- n. Whilst it was the primary responsibility of the consultant in charge to make the referral to oncology, a failsafe mechanism to ensure agreed actions took place such as an MDM administration tracker, was not in place.

(a) Longstanding Issues

5.37 Members of the MDT may not have been aware of, for example, MDM recommendations not being actioned in the case of Patient 1 but similar practice on the part of Mr O'Brien in prescribing an anti-androgen had been challenged or arisen before. For example:

- i. On 20th November 2014 Mr. Darren Mitchell at the BHSCCT e-mailed²³⁹ Mr. O'Brien indicating *inter alia* that:

"The NICAN hormone protocol (in process) would be useful in standardising our therapy across the region but Bicalutamide 50mg is not licensed for monotherapy use and will not be recommended in the protocol other than with the licensed context for the management of flare with LHRHa."

- ii. Prof. O'Sullivan indicated²⁴⁰ that he challenged Mr. O'Brien on a number of occasions in clinic letters (in respect of, he estimated, at least 3 patients), indicating something along the lines of '*the patient was receiving a sub-optimal dose of bicalutamide and I have now changed to the evidence based dose 150 mg daily or to another form of hormone therapy e.g. a Lutenising Hormone releasing hormone agonist*'.

(b) Known Issues

5.38 In relation to what the Trust knew about Mr. O'Brien's use of Bicalutamide and what steps the Trust should have taken in relation to Mr. O'Brien's use of

²³⁹ AOB-71990.

²⁴⁰ WIT-96648 at paragraph 1(iv).

Bicalutamide, the following are some examples in relation to what does or does not appear to have been known regarding the issue of Bicalutamide:

- a. Mr. Suresh indicated in his witness statement that he recalled a patient of Mr. O'Brien's being on unconventional treatment for prostate cancer – being treated with low dose Bicalutamide - and to adding this patient to the agenda of the next Urology MDM. Mr. Suresh indicated that the consensus was that treatment with long term low dose bicalutamide was unconventional and that Mr O'Brien was to review the patient and to discuss the appropriate options with the patient. Mr. Suresh could only recall that Mr. O'Brien was in attendance at the MDM and not the entire attendance²⁴¹.
- b. Mr. Suresh referred to the patient being discussed at MDM in his evidence on Day 66²⁴²:

“Q. And the Bicalutamide 50 monotherapy issue, do you remember if it was you that raised that?”

A. That's right. The reason for discussion, obviously, when it comes up suddenly, then, yeah, I did raise this issue. Yes.”

- c. Mr. Glackin commented on the issue of Bicalutamide being discussed at MDM in his evidence to the Inquiry on Day 63²⁴³. Mr. Glackin indicated that his only knowledge of Bicalutamide being discussed was at one MDT meeting when the discussion was that the patient needs to start ADT and to Mr. O'Brien nonchalantly saying “50mg?” and to those present saying, “I wouldn't do that, I would give him an LHRH analogue.” Mr. Glackin did not know for sure whether the event he referred to was the same event to which Mr. Suresh had referred. Mr. Glackin went on to make the following point:

²⁴¹ WIT-50363 at paragraphs 49.3 and 49.4.

²⁴² TRA- 08636-08641

²⁴³ TRA-08269-08270

"Now, the point that I would take away from that is, if you're in a meeting with your colleagues and they challenge you about the use of a particular medicine and they say that they would do something different, then I think you have to accept that perhaps what they're saying might be right, you have to reflect on what they've said to you, and you would then, you know, if it was me and it was a learning point, I'd go off and I'd read the documents and I'd reassure myself that what I was doing was correct or otherwise and I'd act accordingly. So, that's where -- that's the only time I recall that issue being discussed."

- d. Patient 139²⁴⁴, referred to in Mr. Glackin's evidence to the Inquiry on Day 63²⁴⁵, had been placed on low dose 50mg of Bicalutamide daily with Tamoxifen 10mg daily by Mr. O'Brien in 2010. Mr. Glackin saw this patient on review on 22 February 2016 aged 79.
- e. Mr. Haynes in his witness statement²⁴⁶ indicates that, in 2020, he started to become aware of a pattern of treatment with regard to prostate cancer with patients being on a low dose of Bicalutamide and to one patient during a week as Urologist of the Week in February 2020 which, at the time, he assumed was an error.
- f. Mr. Haynes was asked on Day 88²⁴⁷ about Dr. Mitchell²⁴⁸ saying that he had spoken to Mr. Haynes informally as he attended the regional urology MDM in 2019 and to having subsequently e-mailed Mr. Haynes about the off licence prescribing of Bicalutamide 50 in 2019 and 2020. Mr. Haynes indicated:

"I recall having a conversation with Dr. Mitchell about Bicalutamide. I can't remember the specifics of the date but it's recorded in Darren's email that we discussed on that date, and he followed that up with an email."

²⁴⁴ AOB-82836.

²⁴⁵ Commencing at TRA-08279

²⁴⁶ WIT-53934

²⁴⁷ TRA-11418

²⁴⁸ WIT-96668.

5.39 The Inquiry has received evidence, both oral and written in relation to the issue of Key Worker allocation, some of which has been conflicting at times. In relation to what the Trust knew or ought to have known in relation to the allocation of a Key Worker to Mr. O'Brien's patients the following are some examples in relation to what was or what was not known regarding this issue and when:

a. Kate O'Neill in her witness statement²⁴⁹ indicates:

- i. The first time she can recall being present with consultants during results consultations was when the Urology MDT was established in 2010.
- ii. As appointment to consultant roles increased over the years and as clinical activity increased her availability to every consultant clinic became limited.
- iii. One-stop clinics limited her availability further.
- iv. At the start of any results clinic it would have been her practice to inform the consultant of her availability.
- v. Where possible, she would be available during the Consultant/patient consultation and was present throughout the consultation. More often (though not always) she was invited in at the end of the encounter to provide information, support and a contact number. This was not unique to any single Consultant.
- vi. At no time was there an expectation that she would attend any satellite sites where cancer diagnosis may also have been discussed.
- vii. Consultants managed such challenges differently referring to Mr. Glackin, Mr. Haynes, and Mr. O'Brien.
- viii. At no stage did any of the nursing team within the Thorndale Unit recognise or raise a concern that CNSs were not invited to be present at uro-oncology consultations in general or by any particular Consultant.

²⁴⁹ WIT-80961 at paragraphs 50.3 to 50.5.

- b. Mr. Glackin indicated in his evidence to the Inquiry on Day 67 at TRA- 08737:

"So there wasn't any facility for us to bring our CNS team to Southwest Acute, largely because of staffing issues. Secondly, until very recently the CNS activity was all delivered in Craigavon. It wouldn't have followed consultants to Banbridge, for instance, or to Armagh, or South Tyrone for that matter. So, you know, we really only had CNS capability in Craigavon until very very recently."

- c. Kate O'Neill also indicates in her witness statement²⁵⁰ that:

- i. She never felt that Mr O'Brien prevented/obstructed CNS involvement in his clinic, nor did her colleague Jenny McMahon or Staff Nurse Dolores Campbell, who would both have deputised for her on occasions, ever raise this as an issue.
- ii. Her job plan meant that she was generally available for uro-oncology clinics with Mr Glackin, Mr O'Donoghue, and Mr Haynes but to a lesser extent with Mr O'Brien and Mr Young.
- iii. She does recall Mr O'Brien introducing her to patients to either plan prostate biopsy for them, engage or signpost to other services (such as Palliative Care Team), or for the provision of information, and that on those occasions she felt that she was able to offer information, support, and a contact number.
- iv. In her absence for whatever reason, in the majority of situations, a colleague would have been available to support the clinic where necessary to provide documentation/contact numbers and at no time did they ever raise a concern in relation to this activity.

- d. Kate O'Neill indicates in her witness statement²⁵¹ in relation to the specific issue of access to a CNS that:

²⁵⁰ WIT-80968 at paragraph 54.4.

²⁵¹ WIT-80970

- i. she was not aware of this issue until the report of the SAIs was made available in March 2021;
 - ii. she provided e-mail evidence dated 18 May 2015 entitled '*Involvement of Keyworker and provision of patient information*' and a further email dated 16 June 2017 entitled '*Issue raised at the Thorndale Unit Meeting today*', asking all Consultant colleagues that all patients who require the input of a keyworker would be offered the opportunity to meet with the appropriate member of staff on the day; and
 - iii. had she known that this was as issue, she would have engaged with the HoS, Consultants, and nursing colleagues in order to seek a solution, to ensure that a CNS, where possible, was allocated to every uro-oncology results clinic.
- e. The Inquiry has received notes of the meeting between Dr. Hughes, Martina Corrigan, and Patricia Kingsnorth dated 18th January 2021²⁵² which recorded that Martina Corrigan confirmed that Mr O'Brien never involved a specialist nurse which had always been the case from when she had started in the Trust and that Martina Corrigan confirmed that, during the time she had worked in the Trust, Mr O'Brien never recognised the role of the Clinical Nurse Specialists. Further, that Martina Corrigan confirmed that Mr. O'Brien never involved them in his oncology clinics and was then aware that some of the Clinical Nurse Specialists would have asked to be at the clinics but Mr O'Brien never included them. It was noted that Martina Corrigan advised that two of the Clinical Nurse Specialists did report that they did regularly challenge Mr O'Brien and asked him if he needed them to be in the clinic to assist with the follow-up of the patients but it got to the stage where staff were getting worn down by no action and they gave up asking as they knew that he wouldn't change.

²⁵² WIT-84355.

- f. Kate O'Neill indicated in her evidence to the Inquiry on Day 42²⁵³, when asked about the above notes of the meeting:

"Q...Do you recognise any of those complaints as coming from you in that paragraph.

A. That would not be the experience that I had."

- g. Kate O'Neill was asked about Martina Corrigan's reply to a Section 21 Notice²⁵⁴ in her evidence to the Inquiry on Day 42²⁵⁵. Kate O'Neill was taken to Martina Corrigan's response at paragraph 1.1, including where Mrs Corrigan indicated that it was her impression that Mr. O'Brien didn't recognise the potential value of having a nurse with him at clinics generally and that she personally felt that Mr. O'Brien didn't value the role that the CNSs held, which was an impression that had developed over time between approximately 2009 and 2015. Kate O'Neill indicated that her impression would be that Mr. O'Brien engaged with the two CNSs (as they were at that time) on a regular basis. Paragraph 1.4 of Martina Corrigan's Section 21 response was also read where Martina Corrigan emphasised that she did not ever recall during any of her conversations with nurses in the unit any specific mention of Oncology clinics or the cancer key worker role when they were mentioning Mr. O'Brien's non-use of nurses and that it was usually couched in much more general terms.
- h. Relevant parts of Martina Corrigan's oral evidence to the Inquiry can be found on Day 57²⁵⁶. Martina Corrigan was referred to the Key Worker issue, to her original Section 21 response²⁵⁷ concerning the timing of when she had been made aware of the allegation that Mr. O'Brien didn't allow access to Key Workers for oncology patients being in November 2020, to her interview by Dr. Hughes on 18th January 2021²⁵⁸, and to a subsequent Section 21 Notice to ask

²⁵³ TRA- 12076

²⁵⁴ WIT-94939

²⁵⁵ TRA- 12076-12081

²⁵⁶ TRA-07353-07369

²⁵⁷ At WIT-26267

²⁵⁸ At WIT-84355/6

for clarity and her explanation for some of the issues. Her statement in response to that Section 21 Notice was read from²⁵⁹ and paragraphs 1.2 to 1.5, 1.6, 2.1, 2.2, 2.4, 4.1, 4.2 , 6, 7, 8, 8.2 opened. Mrs Corrigan clarified her understanding or recollection of what was said at the meeting with Dr. Hughes. At paragraph 5.2.1 at WIT-94947, Martina Corrigan indicates as follows:

"I became specifically and acutely aware that Mr. O'Brien did not permit the Clinical Nurse Specialist to provide support as key worker to his oncology patients. I only became specifically and acutely aware of this from approximately Autumn 2020 from the investigations into the most recent SAI patients. I believe that this cancer key worker issue was never raised with me as a specific concern and as only oncology multidisciplinary meetings are part of the Head of Oncology Services remit, I was never involved in these. However, as mentioned in my response to Section 21 Notice No. 7 of 2023 at Question 1 thereof, the broad issue of Mr. O'Brien's non-use of nurses and Clinical Nurse Specialists was mentioned to me a number of times by nurses in the years prior to 2020 and I ought, upon reflection, to have appreciated the potential cancer key worker issue as a result."

- i. The Inquiry has received notes of the meeting between Dr. Hughes and the Acute Governance Urology MDM dated 18th February 2021²⁶⁰ which record that Mr. Glackin confirmed that nurses were excluded from Mr. O'Brien's practice and advised that management were aware of no nurses.
- j. Mr. Glackin indicated to the Inquiry on Day 67²⁶¹:

"So I'm not sure who used the word "excluded" first, whether it was him or me, but I think broadly knowing what we knew at that point in time in February,

²⁵⁹ WIT-94940

²⁶⁰ WIT-84347.

²⁶¹ TRA- 08751-08752

that it appeared that Mr. O'Brien was the only person who hadn't been using CNSs in a routine manner."

- k. Kate O'Neill indicated to the Inquiry on Day 42²⁶²:

"Q. And then the paragraph that we can see on the screen beginning "Dr. Hughes confirmed" just before that Mr Glackin advised he was chair of Urology MDM he took over from Mr. O'Brien. He confirmed nurses were excluded from Mr. O'Brien's practice.

"Was that the first time you had heard that from Mr. Glackin?"

A. Yes.

Q. And was that your experience?

A. That wasn't my experience."

- l. The Inquiry has received notes of the meeting between the Cancer Nurse Specialists Team and Dr. Hughes and Patricia Kingsnorth dated 22nd February 2021²⁶³ which recorded that Leanne McCourt didn't feel that Mr. O'Brien valued the Nurse Specialists and that she recalled him asking in the kitchen what the role of the Nurse Specialists was. The meeting notes recorded that Jenny McMahon advised that she was not sure why Mr. O'Brien didn't invite CNSs into the room and that Mr. O'Brien spoke very highly of CNSs and that Jenny McMahon made the point that Mr. O'Brien had review oncology on a Friday and that she wasn't asked to attend. It was noted that Jenny McMahon advised that nurse specialists were not invited to attend appointments (Mr. O'Brien's) but felt that Mr. O'Brien was very supportive of Nurse Specialists. Jason Young advised that he may not have been in the room but would have been introduced after.

- m. Leanne McCourt gave evidence to the Inquiry on Day 43²⁶⁴ and indicated that:

²⁶² TRA-12070

²⁶³ WIT-84357.

²⁶⁴ TRA-05461-05462

- i. she had no experience or knowledge of Mr. O'Brien not recognising or preventing the involvement of clinical nurse specialists or key workers;
 - ii. she felt supported by Mr. O'Brien;
 - iii. she did not recognise staff feeling worn down by no action to address Mr. O'Brien's issues;
 - iv. she didn't feel that challenging Mr. O'Brien regarding being available at clinics or having to make her presence felt was an issue;
 - v. she could not recall speaking to Martina Corrigan or Ronan Carroll about any issues regarding Mr. O'Brien;
 - vi. she did not express being frightened of Mr. O'Brien;
 - vii. she felt that she could approach Mr. O'Brien or confront him if the need arose.
- n. Leanne McCourt's evidence to the Inquiry on Day 43²⁶⁵, when asked '*what did you say and what message were you trying to impart to Dr. Hughes?*', was that she would have said (something) very similar to what she said in her Section 21, that Mr. O'Brien would have been very particular in his use of language and words, and that she thought it was just the "key worker" word that he didn't like. Leanne McCourt indicated that she didn't for one minute think that Mr. O'Brien didn't understand what a key worker was, or indeed what a CNS was and what her role was and that she believed that Mr. O'Brien did value that role.
- o. Mr. Glackin²⁶⁶ indicated that he became aware in 2020, through discussion with Kate O'Neill and Leanne McCourt, that they felt excluded from Mr. O'Brien's outpatient clinics and were not present to advocate on behalf of patients.

²⁶⁵ TRA-05468

²⁶⁶ WIT-42327 at paragraph 56.5 in response to Section 21 Notice No. 57 of 2022.

- p. Kate O'Neill indicated in her evidence to the Inquiry on Day 42²⁶⁷, when addressing paragraph 5.2²⁶⁸ of Martina Corrigan's Section 21 response referenced at sub-paragraph h above, that:
- i. between 2010, when MDTs started, right through to when the appointments were finally in place in 2020, the need for additional CNSs to perform the role of key worker and holistic needs were discussed at meetings with the Head of Service and the lead nurse on a repetitive and exhaustive manner;
 - ii. the standards set out in the operational policy couldn't be achieved without additional resources.;
 - iii. from about 2015 onwards (from peer review on) an A4 page would have been completed stating the information that was provided to the patient, the key worker name, and that the patient was provided with a contact number, which would have been put inside the patient's notes and that it would have required going to the patient's notes to see it;
 - iv. there was no audit process in place; and
 - v. after peer review, and following engagement with Mary Haughey, audit did occur in the autumn into winter of 2016, the findings were presented to the MDT team in March of 2017, and that there was agreement from that point forward that this should be completed at every key worker encounter.
- q. Patricia Thompson, having referred to Leanne McCourt, Jason Young, and Dolores Campbell, indicated in her evidence to the Inquiry on Day 60²⁶⁹, when questioned about whether she would have asked them whether Mr. O'Brien brought a nurse in or stopped them coming in, the following:

²⁶⁷ TRA-12088

²⁶⁸ WIT-94947

²⁶⁹ TRA-07726 lines 12-23.

- i. that she asked would Mr. O'Brien have brought nurses in but wouldn't have said 'did he stop nurses';
 - ii. that she would have asked did Mr. O'Brien bring nurses in or invite them in; and
 - iii. that they (Leanne, Jason, and Dolores) would have said that no, they wouldn't have been brought in to the consultation.
- r. A final piece in the contradictory and somewhat confused evidential jigsaw on the issue of use or non-use of Key Workers is the Chair's questioning of Leanne McCourt on Day 43²⁷⁰ where Leanne McCourt was asked about the potential tension between her witness statement to the effect that she was taken aback at Mr. O'Brien's condescending tone when he questioned her about the key worker role and her oral evidence to the effect that she rejected any suggestion that she had told Dr. Hughes that she felt that Mr. O'Brien didn't value nurse specialists.

5.40 In relation to the issue of failing to action MDM recommendations the following are some examples in relation to what was known regarding this issue:

- a. Patient 102 (who has been mentioned briefly in Chapter 4) was discussed at Urology MDM on 20 November 2014 and the recorded outcome was that the patient's re-staging MRI scan had shown organ confined prostate cancer and that the patient was for direct referral to Dr. H for radical radiotherapy. The patient was reviewed by Mr. O'Brien on 28 November 2014 and no correspondence was created from this appointment. A referral letter received from the patient's GP in October 2015 stated that the patient had not received any appointments from oncology. The IR1 form²⁷¹ and the related oral evidence of Mr Haynes and David Cardwell²⁷² suggests that screening was not performed to decide whether the incident should be an SAI or otherwise.

²⁷⁰ Commencing at TRA- 05504 and running to TRA- 05508.

²⁷¹ Which can be found at WIT-54874 – WIT-54881.

²⁷² Referred to in Chapter 4.

- b. Patient 137's case was one where the recommendation was to refer the patient for an endocrinology opinion or review. The incident report²⁷³ summarised matters as follows:

"Patient discussed at MDM 12th January. Outcome to be referred to endocrine MDM. Unfortunately this did not happen. Further GP referral - five months later, 12th May 2017 - brought this to my attention..." (Mr. Haynes).

- c. Mr. O'Donoghue indicates²⁷⁴ that he submitted an IR1 on 3rd October 2019 when he was chairing the Uro-oncology MDM in relation to a patient of Mr O'Brien who had not been referred for a kidney biopsy as per MDM advice dated 27th June 2019.

(c) Failure to Address Effectively or at all

5.41 The Inquiry may consider that there was a failure to recognise and address issues such as Bicalutamide, Key Worker allocation, and the actioning of MDM recommendations effectively or at all. In relation to the examples of what was and what was not known regarding the issues of Bicalutamide, Key Worker allocation, and the actioning of MDM recommendations the Trust would make the following points:

5.42 Bicalutamide:

- a. In relation to the patient which concerned Mr. Suresh regarding Bicalutamide 50mg as a monotherapy, Mr. Suresh's evidence on Day 66 was²⁷⁵, having been asked did people say, *"Well, I have done that", or "I've seen that", or "I've never heard of that", was there any discussion around that?:*

²⁷³ WIT-100386

²⁷⁴ WIT-50543 in Mr. O'Donoghue's response to Section 21 Notice No. 62 of 2022 at paragraph 49.1

²⁷⁵ TRA- 08638

"A. No, the discussion was mainly the indication like, as I told like with -- first question is whether "Is he on just purely on monotherapy, or are you sure that he is not on LHRH analogue injections as well?", and I said "No, that's why I am bringing up this issue". And they said "Oh, in that case the patient shouldn't be on", and then I told the patient wanted to see Mr. O'Brien to make the choice of different options, so they all agreed, yes, for to have the appointment with Mr. O'Brien for this patient to see in the clinic and to stop and then – yes".

- b. Discussing this issue, Mr. Glackin indicated in his evidence to the Inquiry on Day 63²⁷⁶ that, without knowing who was leading the MDT at the time as no date had been provided by Mr. Suresh, if he was the lead clinician he would have looked at this as a one-off, that he would have had no evidence to suggest otherwise, and that he had no particular reason to go digging around to find out if it was a repeat behaviour and that he just wouldn't have known that.
- c. Mr. Haynes, in his witness statement²⁷⁷, states:

"b. In June 2020, while in Daisy Hill Hospital for a theatre list, I reviewed Mr ----- and had immediate concerns regarding the care he had received. Amongst my concerns was that he had been treated with low dose (50mg) bicalutamide and this treatment was not the appropriate management for his prostate cancer. At a later date (I cannot recall the date of this conversation), in discussion with Dr Darren Mitchell, Consultant Clinical Oncologist and Urology MDM lead for Belfast Trust, I became aware that this had been raised directly with Mr O'Brien by the Oncology Team previously (although I am unaware of when this occurred)....

....I also advised the Medical Director of my concerns by email on 7th July 2020 regarding his and another patient's treatment (Mr -----). After completion of his staging scan, I arranged an outpatient consultation with me where I raised

²⁷⁶ TRA- 08273

²⁷⁷ WIT-53934 at paragraph 61.10 b.

my concerns regarding his previous care and assured the family that I would be reporting my concerns so that an investigation took place. Having informed them of my concern, I completed an IR1."

- d. Mr Haynes also states²⁷⁸ that, as there were then at least 2 patients who had been treated with low dose Bicalutamide, as a matter of urgency an audit of patients currently receiving Bicalutamide was conducted which identified a number of additional patients who were receiving low dose Bicalutamide.
- e. Mr. Haynes explained in his evidence to the Inquiry on Day 88²⁷⁹:

"Q. What you seem to be clear about is that this seems to have come to you as an isolated concern and you weren't provided with the history of concerns that were raised with Mr. O'Brien, prescriptions changed in 2014/'15 leading to the regional guidelines; that whole context which Dr. Mitchell has given to this Inquiry wasn't shared with you?

A. Well, it may have been in the discussion but we've got -- when we look at that patient, his management, the point in time he was initially treated was at that period in time. It wasn't a practice that was happening in 2019, this was a patient who was raised in 2019 as a possible problem but whose management by Mr. O'Brien and decision to not refer was back in 2014."

- f. Mr. Haynes further explained in his evidence to the Inquiry on Day 88²⁸⁰:

Q...But this e-mail to you in March 2019, I hope I'm correct in saying, was the first, if you like, externalisation of the problem. It was coming to you, wearing what would have been your Associate Medical Director's hat or your clinical director's hat; clearly wearing your management hat at that time. When

²⁷⁸ WIT-53939 at paragraph 62.12.

²⁷⁹ TRA- 11419

²⁸⁰ TRA- 11417

you think about it now, should have done more? Should have asked more questions, perhaps, of your colleagues in Belfast as to the nature of their concern?

A. I think if I look back now, you'd started with a preamble around missed opportunities, this is another missed opportunity. I can explain my thought process but in the context, as you highlighted, of issues raised before directly with Mr. O'Brien that I wouldn't have been aware of, in the context of the sort of wider concerns you've mentioned, the oncologist -- they may have been aware of additional patients that they just corrected or changed the treatment when they saw them. I should or could have initiated a wider investigation but I didn't have all of that information to hand at that point and so I didn't know that. So I guess my review and my decision that actually I couldn't see anything to spark a deeper investigation was one that I formed out of an attempt to be fair to the individual. I'd got a letter that said -- that gave a plausible reasoning for why that decision had been made."

- g. Mr. Haynes also indicated in his evidence to the Inquiry on Day 88²⁸¹ in relation to Patient 4:

"I can only presume I have assumed there has been an oversight rather than this representing his standard practice. Again, my degree of suspicion was too low."

and at Day 88²⁸²:

"In terms of that, if you like, reluctance to trigger investigation early, I think you have to recognise it is the first thing. I don't spend my emergency admission ward round conducting an analysis and critique of every patient's historic management. I've recognised there's an issue. I have not even -- I've managed him acutely, it is only later I've recognised that this fitted a pattern of behaviour. I've figured that it was an oversight, incorrectly. But as I've said,

²⁸¹ TRA- 11431

²⁸² TRA-11433

all patients who are going to start an LHRH analogue started on 50mg of Bicalutamide. I wouldn't be continuing it so I've assumed that there's an oversight; incorrectly."

- h. Mr. Glackin indicated in his evidence to the Inquiry on Day 63²⁸³ that, *"In some ways the Bicalutamide issue is a bit of a red herring. It's not quite seeing the wood for the trees. The bigger issue is not referring the patients to the oncologists for radiotherapy. That is the definitive treatment, and that is the thing that would be the key to managing the patient's disease."*

5.43 Key Worker allocation:

- a. In an e-mail dated 15th May 2015²⁸⁴ Kate O'Neill indicated that, in relation to a Key Worker, it was planned to keep a record of information provided to all patients diagnosed with a cancer and that at the point of diagnosis after seeing the consultant/with the consultant it was hoped to have a member of the nursing team available to meet with the patient/family.
- b. In a further e-mail dated 16th June 2017²⁸⁵ to all Consultant colleagues Kate O'Neill asked that all patients who require the input of a Key Worker would be offered the option to meet with the appropriate member of staff on the day.
- c. The 5 CNSs and their dates of appointment²⁸⁶ were as follows:
 - i. Jenny McMahon 04.07.2005;
 - ii. Kate O'Neill 04.07.2005;
 - iii. Leanne McCourt 01.03.2019;
 - iv. Patricia Thompson 03.08.2020; and
 - v. Jason Young 31.08.2020.

²⁸³ TRA- 08265

²⁸⁴ WIT-81161.

²⁸⁵ WIT-81166.

²⁸⁶ As set out in Ronan Carroll's witness statement at WIT-13110.

d. Jenny McMahon²⁸⁷ makes the point that she understood the absence of, or inadequate, CNS provision to be an inadequate resource issue, that in 2015 Kate O'Neill was the only urology CNS with a focus on cancer care, that she and Kate O'Neill were required to be available for one-stop clinics which limited the availability to provide key worker support at the times of oncology review clinics for all of the consultants, that the head of service and lead nurses were aware, and that the advice was that recruitment for further CNS posts was being pursued. As an interim measure, two Band 5 nurses were upgraded to Band 6 to help with the day to day running of clinics and would, at times, have provided key worker support.

e. Jenny McMahon also indicates²⁸⁸ that:

"...regarding the absence of or inadequate CNS provision, I believe this occurred as a result of insufficient CNS staff in post to provide support for patients during or following a breaking bad news encounter. This was further impacted by both Kate and I having other responsibilities including clinical activities scheduled at the same time as oncology clinics, having managerial duties for staff and the unit and being counted in the core clinical team numbers to fulfil other clinical duties required at the time."

f. Leanne McCourt²⁸⁹ indicates that, although she was employed as a clinical sister in Urology from April 2017 and then as a CNS from March 2019, she did experience issues around absence or inadequate CNS provision from 2017. She did still undertake a portion of Key Worker activity and attend the MDM but could not support the single cancer CNS as much as was previously expected as she had other responsibilities within her role. Leanne McCourt also indicates that she understood that Kate O'Neill and Jenny McMahon did raise this as a

²⁸⁷ WIT-81252 at paragraph 24.2.

²⁸⁸ WIT-81255 at paragraph 25.1.

²⁸⁹ WIT-85940 at paragraph 24.2.

concern with the HoS and that, when she was successful in her application and appointed to the role of Urology CNS in March 2019, this predicament did not really change until management duties were removed from the CNS team in March 2021.

5.44 Actioning MDM recommendations:

- a. In relation to Patient 102, David Cardwell was asked in his evidence to the Inquiry on Day 59²⁹⁰ why this incident was closed in the absence of a screening decision. He indicated:

A. Okay. At the beginning I would emphasise that I am extremely aware that the decision for closing of an incident rests with the operational team. In relation to this particular incident you will see on 17th June that I have went on and put in a final approve and a closed date. I can't explain why that has been done...

David Cardwell was asked whether it is likely that he would have sought an explanation as to why the incident was to be closed to which he indicated that it would have been his normal practice to have sought an explanation as to why it had been closed and that he would have been asking for some information in relation to the outcome of the investigation to include that on the Datix report form. When it was put to Mr. Cardwell that it is difficult to conceive of any good reason that he could have been given to have avoided a screening decision in a case like Patient 102, Mr. Cardwell accepted that was correct and that the incident should have been screened for an SAI and would have met the criteria. If this incident had been screened in for an SEA or an SAI review it is possible that it may have brought the issue of actioning MDM outcomes to a head earlier.

²⁹⁰ TRA-07629

- b. In relation to Patient 137, there was a letter to Mr. Young²⁹¹ in August 2018 which read:

"The review team concluded that following MDM any actions must be progressed by the consultants nominated as responsible for the action required as per the MDM outcome report. Referrals for specialist care need to be sent from consultant to consultant.

Can you provide reassurance that you have a process in place to ensure that MDT outcomes for patients under your care are actioned in a timely and appropriate manner?"

- c. Mr. Glackin indicated in his evidence to the Inquiry on Day 63²⁹² that, "...if you're going to vary from a MDM recommendation, you'd need very good grounds to do it, and you need to record that, you need the consent of the patient. And I think as we've said, you would bring it back to the meeting if there's a significant variation."

5.45 As mentioned above, some of the Mr. O'Brien issues were longstanding. Some of these issues had been known about for some time. There had been a failure to address the issues known about either effectively or at all. There was, for example regional knowledge in relation to Mr. O'Brien's use of Bicalutamide, albeit it appears that there was very limited sharing of it by BHSCCT clinicians with the Trust (other than directly with Mr O'Brien) prior to 2019. There was also, for example, some internal knowledge in the Trust in relation to Mr. O'Brien's use of Bicalutamide. Again, however, it was very limited and not focused in any single colleague of Mr O'Brien's. Whether such limited examples as referred to above concerning Mr. Suresh, Mr. Glackin, and Mr. Haynes as well as the context in which they arose should have triggered an investigation is an issue for the Inquiry.

Root Causes of Trust Failings

5.46 The identification above of various shortcomings on the part of the Trust begs the question of what the root causes were. In particular:

²⁹¹ WIT-100383

²⁹² TRA- 08300

- a. Why were some longstanding issues that were known about not addressed either adequately or at all?
- b. Why were other issues not known about?

5.47 Again there appears to be a number of root causes in play here which have been referred to in the evidence.

Bicalutamide

5.48 In relation to Bicalutamide 50 mg:

- a. Mr. Glackin indicated in his evidence to the Inquiry on Day 63²⁹³ that
"... I think we would all agree in our MDT that managing people long-term on Bicalutamide 50mg is inappropriate."

- b. Mr. Glackin explained on Day 63²⁹⁴ that:

"In Northern Ireland we provide essentially an advice note to the GP to prescribe these medicines. So, that goes out to the GP, the GP issues the equivalent of an FP10, and that goes to the local pharmacy and it's dispensed. I am aware that GPs in Northern Ireland get very detailed reports of their pharmacy prescribing, almost down to the tablet. So, the information about how these medicines are prescribed in Northern Ireland and dispensed was available. It was just never looked for until that audit."

- c. Later during his evidence on Day 63 Mr. Glackin indicated as follows²⁹⁵:

²⁹³ TRA-08266

²⁹⁴ TRA-08267

²⁹⁵ TRA-08269

"I suppose the other point is this: Many other medicines that are used in oncology within secondary care are prescribed and dispensed within secondary care. That's not true for these medicines. They're not on what's known as a red or amber list. There isn't a shared care protocol for these medicines between primary and secondary care. There are for lots of other medicines that would fall into these categories. So, you know, if these medicines had of been dispensed from secondary care and controlled from secondary care, our pharmacy departments in the Trust would have had oversight of that."

- d. Mr. Glackin in his evidence²⁹⁶ also addressed the question of how rotating MDT Chairpersons could have missed Mr. O'Brien's approach to hormone prescription if it had been started in advance of an MDT recommendation:

A. It probably wasn't starting in advance of the MDT, for the reason that most patients with prostate cancer come to the MDT when their histology is available, and then further after that when their staging scans are available, and it's usually at the point where their staging scans are available that the decision about treatment is made. So, following that, the patient would then be seen in an outpatient clinic, and it's at that point that the patient would receive the advice note for the GP to initiate the treatment. So, for my practice, that's how it works. The patient takes that note away and they get the GP to issue a prescription.

So, the MDT wouldn't necessarily have had sight of the advice note to the GP, and unless that patient was coming back to the MDT for some particular reason - and many of them wouldn't be - then we wouldn't be aware that they were on 50mg."

²⁹⁶ Day 63 at TRA-08274

- e. Vicki Graham explained the concept of 'first definitive treatment' and the role of the tracker in her evidence to the Inquiry on Day 42²⁹⁷:

"Q....Hormone treatments should count as first definitive treatment in two circumstances. 2. Where the treatment plan specifies that a second treatment modality should only be given after a planned interval. This may, for example, be the case in patients with locally advanced breast or prostate cancer where hormone therapy is given for a planned period with the aim of shrinking the tumour before the patient receives surgery or radiotherapy".

Is that a standard or definition that you work to?

A. Yes. Hormone therapy was a treatment.

Q. Yes. We'll come on to look at it in the context of the SAI review in a bit more detail later. When you saw that the patient had reached the point of first definitive treatment, was that the end of your role?

A. That was when our role, yes. That's when we would have ceased tracking.

Q. Yes. You wouldn't have tracked to see the outcome of that treatment?

A. Post first definitive, no, we wouldn't have been tracking that patient..."

Key Workers

5.49 In relation to the allocation of Key Workers:

- a. The 9 patients were not referred to Specialist Nurses and contact telephone numbers were not given.
- b. Kate O'Neill explained in her evidence to the Inquiry on Day 42²⁹⁸ that there was an emphasis on productivity in terms of meeting cancer targets and that the agreement with the Head of Service was that the

²⁹⁷ TRA-11961

²⁹⁸ TRA- 12043

CNS would not go out to any satellite clinics. The CNS focus was to be on the Craigavon site.

- c. Kate O'Neill explained the allocation of a Key Worker in practice in her evidence to the Inquiry on Day 42²⁹⁹:

A. So if it is appropriate to say now the operational policies, I understand were written at a time when there was an expectation that new appointments were imminent. They had been outstanding for a significant number of years at this stage, so the biggest challenges to me were still resourced based in terms of identifying a key worker. It could not be done at the MDT setting because we didn't know when next clinic review was occurring, so in the same way as holistic needs assessment wasn't being done formally it was being done in formally at that time due to resources. So what we managed as a team on daily basis then, was when the clinic was appointed as I said Mr Glackin's was on a Monday afternoon, well then someone I was able to be at that clinic or I delegated someone to be at it. It only became more complicated when there were parallel clinics going on, and it required the consultant to come out and get us when they were seeing patients, yeah."

- d. Kate O'Neill addressed what she knew in her evidence to the Inquiry on Day 42 at TRA-12053:

"Q. And just did you ever speak to Martina Corrigan to the effect that Mr. O'Brien doesn't allow us access or it's difficult or he is obstructive in any way?

A. No the issues would I have raised with Martina Corrigan would be more about over run of clinics or productivity within clinics I wasn't aware that anyone was being prevented from having access to a key worker in any role, no.

Q. Not using CNS when available?

A. Yes."

²⁹⁹ TRA-12049

- e. At the same time, Mr. Haynes indicated in his evidence to the Inquiry on Day 88³⁰⁰ in relation to the number of key workers available in 2018, 2019, and 2020, that the same shortage would have applied to him and his colleagues and that it didn't stop him from letting the team know whether a patient required key worker input.
- f. Mr. Glackin indicated in his evidence to the Inquiry on Day 67³⁰¹ in relation to the MDT Operational Policy:

"...The statement is there really to reinforce the fact that all the patients should have access to a cancer nurse specialist, and in order to have some oversight of that, that should be the responsibility of the MDT lead and the core nurse member. I think they're the two appropriate people for that responsibility. As the MDT clinical lead currently I have the overall responsibility, and clearly the core nurse member themselves being a CNS, would have, if you like, not line management responsibility, but a responsibility to ensure that the other CNSs are available to do this kind of work for the patients."

- g. Mr. Glackin went on³⁰²:

"So I had no awareness first of all that they didn't have a CNS, but if I had have had an awareness then it would have been up to me to address that with the CNSs and the core nurse member to say, to ask them, you know, were they aware that these patients hadn't been offered the opportunity of CNS input, and if they hadn't been offered it, why not, and you know, to dig into that a little bit and understand why it hadn't happened. So, you know, that's I think where my responsibility lies."

³⁰⁰ TRA-11472

³⁰¹ TRA-08739

³⁰² Also on Day 67 at TRA-08739:

I think there's an equal responsibility on the core nurse member to undertake that kind of questioning activity..."

- h. Mr. Glackin also indicated³⁰³ that the Key Worker's allocation wouldn't happen in practice at the time of the MDM meeting and that it happens afterwards.
- i. Finally in respect of Mr. Glackin, he indicated in evidence on Day 67³⁰⁴ that he was surprised that the 9 patients had not had a CNS involved in their care and that:

"...So I spoke informally to both Kate and Leanne and asked them what their experience was. Mr. O'Brien would not have had the CNS in the room at his clinics on every occasion, he may have invited them in for selected patients, and that was what I understood from those conversations.

I also -- Leanne also relayed to me the encounter that she had with Mr. O'Brien regarding the key worker discussion, and she outlined that discussion which took place -- from my recollection she described it taking place in the small kitchen in the Thorndale Unit. So that stuck in my mind as to a kind of important interaction that they had had on the key worker role."

- j. Patricia Thompson in her evidence on Day 60³⁰⁵ made the point:

"A. Yes, I felt that it was very much blaming Doctor 1. Whereas if you looked at some of the SAIs, there was events, there was times that a key worker could have been introduced by, maybe, another doctor or a registrar or another Nurse Specialist. And that's learning from the SAI that maybe there could be systems

³⁰³ Also on Day 67 at TRA-08741

³⁰⁴ TRA-08742

³⁰⁵ TRA- 07721

put in process for referral to key workers from other nurses or other doctors if a patient is presented through their journey."

MDM Outcomes

5.50 In relation to actioning MDM Outcomes:

- a. There was no mechanism to check MDM actions were implemented, including further investigations, staging, treatment and appropriate onward referral;
- b. NICA Regional Hormone Therapy Guidelines for Prostate Cancer 2016 were not followed. The Guidance was not subject to audit within the Trust.
- c. Issues around prescribing were long standing.
- d. MDMs operated in circumstances where the Urology MDM was under resourced and frequently not quorate due to a lack of professionals. This was often due to a lack of clinical oncology and medical oncology, both identified as regional issues .
- e. MDMs operated in circumstances where the Urology MDM was under resourced for appropriate patient pathway tracking. Patient tracking related only to diagnosis and first definitive treatment (31 and 62 day targets). There was never a whole pathway tracking process.
- f. When asked to reflect on why the Trust was at such a low level of performance with regard to its cancer MDMs, Dr. O'Kane gave the following evidence to the Inquiry (which is relevant, in part, to the MDM outcomes issue)³⁰⁶:

³⁰⁶ TRA-11744

“ Q. It appears at least on the papers to be a chalk and cheese situation. Can I ask you to reflect, because it's important that the Inquiry has your perspective on why this Trust was at such a low level of performance with regard to its cancer MDMs, not just Urology, it would appear to be short in critical respects across the cancer environment. So how do you account, or what's your perspective on why this organisation was so short that this extensive rebuilding exercise has had to take place?

A. Well, I think just to start with the MDM process to begin with. I mean there were concerns I think throughout raised about quoracy, but I think they didn't go beyond a certain level in the organisation. And then, you know, some of those who were involved from the Belfast Trust who raised concerns at points in time, I think, as I understood it, they had particular concerns in relation to some of the practices there and wrote to the consultant involved, but I think probably didn't know how to access our medical management structure, or we didn't make it explicit in terms of how that was actually done. So that kept all of those concerns at a certain level in the organisation and I think weren't addressed, and I think there was a kind of a hopelessness around it, which was, "well, this has been going on for a long time. It has never been sorted out. You know, we've complained about it before and it hasn't been dealt with", right, and I think that bred complacency.

Then I think what compounded all of this, because, you know, the other consultants who were working in that system, you know, they saw their patients through from start to finish, they kept a running score on where they were in the system, so that if they were concerned about them and, you know, if they needed CTs, MRIs, whatever, they got them followed through, they brought them back to their secretaries. They automatically followed through on any of the recommendations that came out of the MDM, and they made sure that all of their patients that they were worried about went into the MDM.

I think the difference in relation to Mr. O'Brien was, if he wasn't taking the patients to the MDM in the first place, then the MDM didn't know about them. And if the MDM was reporting on improvements or investigations to be done and he wasn't following through on those himself, then they weren't getting done.

So the enhancement in all of this - and that applies to all of those patients who were there on the cancer side. So the enhancement from the patient's point of view is that this does not solely rely on a consultant being aware. There is a safeguard in place now with the trackers. So they will pick this up and make sure that it goes back in. And the MDM itself is alive to the possibility that these patients need to go back into a system to be further investigated."

Governance Shortcomings

5.51 In relation to systems and governance and whether the systems of governance were ineffective:

a. Dr. O'Kane explained in her evidence to the Inquiry on Day 90³⁰⁷:

Q. And clearly you can't have a system dealing with this kind of medicine which is vulnerable to the behaviours of one clinician. The system needs to be arranged to pick that idiosyncratic practice up, challenge it and provide solutions.

So what is the explanation for that not, those basic systems not being there? What is the Inquiry to write into its report by way of an explanation for that low base?

A. I think there was a failure to recognise the complexity of the systems that we're dealing with, you know. These systems, I mean the level of referral into

³⁰⁷ TRA-11747

cancer services goes up. I think it's gone up by 50% in the last five years, so it's rising exponentially, and the spend around that hasn't increased in keeping with that, in terms of, you know, commissioning a service. But also, the complexity of the care has increased over time as well. You know, there are treatments available today that wouldn't have been available two or three years ago. So I mean that's constantly an evolution and it is incredibly dynamic.

So I think we failed as a system to appreciate the complexity of all of this, the fact that, you know, where there are many points of change in a process that they are always vulnerable to things going wrong. So every time you change a treatment, or you add something in or take something away, it's vulnerable to not being followed through, and we really need to heavily manage all of those stages. And, you know, to enable us to do that, the team needs to be robust and we need to have someone, other than the clinicians, basically managing all of that and doing that. So, you know, we're not perfect, but we're definitely stronger than we were in that regard."

- b. On Day 89³⁰⁸, Dr. O'Kane addressed the issues of Mr. O'Brien and the then state of governance within the Trust:

"Q. And on the issue of Mr. O'Brien and all that came with that, I think you were asked to reflect on the last occasion on the weaknesses within the Trust which caused or contributed to a situation where shortcomings in his practice, which from the Trust's perspective placed patients at risk, you were asked to reflect on what caused or contributed to that, and I suppose the headline from your answer was that the Trust and those who were charged with responsibilities in the governance area were unable to join the dots, and they were unable to join the dots and therefore unable to see what was, I suppose, hidden in plain sight, and that led to a situation where you and others, perhaps

³⁰⁸ TRA- 11606

not deliberately as you suggested, were given false assurance. Is that again a fair reflection of how you see it?

A. Yes. Yep.

Q. So, you have problems with the governance structures identified by you quite quickly, and then a whole raft of other areas emerging from what you saw in June 2020. Would you like to give the, I suppose, the Inquiry a summation of looking back at it from today's standpoint, bearing in mind all that you've heard in a yet uncompleted inquiry. What's your key reflections on the state of governance within the Trust, pick any date, 2019/2020, which you have had to go about trying to fix, what were the key problems?

A. Em, so I think in terms of my reflection of the stages of all of these, I think that it is, you know, for any of us who have been involved in this throughout that period of time, I think it would be fair to say that it is a source of regret to us that we didn't know in 2019 what we learned in June 2020. Okay. And hence the reason that, as you say, it has been a two-stage approach.

So in relation to governance, or in relation to the state of play and what I see as the fundamental challenges, it probably falls within the four areas of culture, governance - and within that I mean clinical and social care governance and corporate governance - how we've used data, and then the quality and safety within the organisation. And as I've mentioned in some of the previous submissions, we have brought on board an External Reference Group to help us with the thinking in relation to all of that, and I think, you know, in terms of those four main domains, then within all of that, if we apply, you know, a model for improvement such as, you know, the Vincent model, which looks at, you know, were we safe yesterday, are we safe today, will we be safe tomorrow, are our systems and processes sensitive enough to operations so that we understand that if things are going askew that we have the governance arrangements in there to pick that up at an early stage? And also the fifth leg of all of that, which is, then how do we drive improvement based on all of that? If I use that as the framework for thinking of this, this is my easiest way into it.

So in relation to where we were in relation to corporate governance. As you have pointed out, the June Champion review was undertaken across the summer of 2019 and, again, that was in response to my concerns about the lack of framework and structure around some of the patient safety and quality issues that we were dealing with. As you know, there were 48 recommendations in that report. We have filled out on the vast majority of them. The first 13 were to do with corporate governance at a point in time and, again, I think in fairness, Eileen, as Chair of the Trust, has really grasped those 13 now, but there was a period of time when that took a bit of debate for us to try and understand, and I think, you know, fair to say before Eileen arrived a realisation and acceptance that actually the corporate governance across the organisation needed to be strengthened, along with all of the other governance aspects that were there."

c. Dr. O'Kane further explained in her evidence on Day 89³⁰⁹:

"Q...So when we think about that, and this may not be an entirely straight line, if we bring it to what we know about the urology multi-disciplinary team, but it could be any service in the Trust estate, you have a practitioner, according to the SAI outcomes, who is not complying with NDT recommendations. So patients don't get the recommended treatment, they don't get referred down the road to oncology and what you have, but behind that it can't be spotted, it can't be identified, or it's going to be difficult to identify it because you don't have resources into audit or tracking, or whatever label we put on it, it's - is it as blunt as that in some respects?"

A. Yes, I think so, and I think, you know, if people had concerns in certain areas then they didn't readily have the tools available to them to help them understand what the problem was, you know. So if you were concerned about, you know, some of the clinical processes in relation to urology, it would have

³⁰⁹ TRA-11618

been very difficult to have had an audit project down around that because you didn't physically have the staff there do it for you."

d. Dr. O'Kane in her evidence further indicated³¹⁰:

"A. Yes, and I think, you know, there's an old adage which is "What gets measured gets done". Right. So at a point in time in the past what got measured was how much money you spent and how much activity you did. Right. There was less attention given to - and it's difficult to put a figure to it - quality and safety. So the two things that were easily measurable were done extremely well in relation to that. But then behind that, I believe that that was at a cost in terms of the clinical governance construction within the Trust.

Q. ...So when we go back to my question about how the senior leadership team - and maybe my premise is wrong? I said Senior Leadership Team standing in Craigavon Hospital June 2020, before Mr. Haynes and Mrs. Corrigan do their scoping work, you think all is well, obviously the June Champion Report freshly delivered late the previous year, and you have to work through some structural changes which are obviously very important, but it doesn't seem to me that you or your colleagues in the Senior Leadership Team had a sense of - and take the cancer services as our primary example, you didn't have a sense of how degraded the governance arrangements had become?

A. I think that's a fair reflection. And if you think back to the Maintaining High Professional Standards Investigation, right, which I think at this point in time was misleading, you know there was a suggestion that a wide range of people were consulted with at that point in time and that the feedback they gave was - I mean, one of the ultimate decisions that came out of that was that there weren't any concerns about Mr. O'Brien's clinical practice and, again, that was - and what was presented through the Maintaining High Professional Standards

³¹⁰ Also on Day 89 at TRA-11619

Report suggested that this was about administration and about professional, you know, management, but actually wasn't about - there weren't any clinical concerns. And I think that reassurance, and it was a reassurance, it wasn't an assurance, I think blinded us to the fact that actually what really hadn't been looked at in there was the cancer side of the house. So in normal circumstances, you know, if I were, for arguments sake, asking for a dermatologist or a psychiatrist, you know, to be investigated, you would assume that all of the activity would be within their department. I think what wasn't appreciated within that investigation was the fact that there was a part of his clinical activity sat without the people who were spoken to and that there was information in interest, and that I think came to light very forcibly then in June 2020.

Q. Mmm.

A. So that side of the house, the cancer side of the house was quiet until we got to June 2020, and then there was a realisation that actually all of this was going on in there. And, in fact, you know, the concerns about workload, waiting times, triage, all of those things were important but didn't completely map on to what we found then in relation to cancer."

Important Context

5.52 Against the backdrop of the Aidan O'Brien issues that came to the fore in 2020, particularly in the context of the Urological Cancer MDT, and the related failings on the part of the Trust these issues laid bare, it is nonetheless important to bear in mind (in addition to the contextual points referred to already in Chapter 4) the following specific contextual points:

- a. The MDM made appropriate recommendations for 8 out of the 9 patients.
- b. The Trust had invested in additional resource to provide a specialist nurse to all urology cancer patients by 2020.

- c. The role of Multidisciplinary Chair is now defined by a Job Description³¹¹ with specific reference to governance, safe care and quality care and resourced to provide needed oversight.

Trust Actions to Improve / Restore Public Confidence / Protect Patients

5.53 The Trust has accepted the recommendations of the Hughes and Gilbert SAI reports. The *'Update on the Action Plan in response to the Dermot Hughes SAI Recommendations Action Plan'* can be found at TRU-306489 – updated 8th March 2024.

5.54 Dr. O'Kane explained in her evidence to the Inquiry on Day 90³¹² that there were 68 recommendations which came out of the 9 SAIs, that there were overlaps in terms of the recommendations across the 9 reports, and that they were then streamlined into 11 areas with subtitles.

5.55 Dr. O'Kane in her evidence³¹³ also addressed the BSO Audit³¹⁴ and the updated position:

"Q..... As of November 2023, 65% or 17 of those 26 actions were deemed to be fully implemented by the Trust, and the remaining nine actions are deemed to be partially implemented, with work ongoing across the teams to ensure compliance. That was late last year, November. Is that the current position or have things moved on beyond that, in your view?"

A. I haven't counted them up in the latest report, but, no, that has moved on. Yep. Yep. So I mean overall I think nine out of the 11 recommendations, I think when they reviewed it they put green against it. How that measures up specifically about the action - in relation to the actions, I haven't counted that..."

³¹¹ TRU-403313 – TRU-403316.

³¹² TRA- 11739

³¹³ Day 90 at TRA-11748

³¹⁴ TRU-305875

5.56 By way of example the Action Plan Update referred to above records³¹⁵ - in relation to Recommendation 5, *viz*, that the Trust must ensure that MDM meetings are resourced to provide appropriate tracking of patients and to confirm agreed recommendations/actions are completed – that the following substantial progress (with potentially significant points highlighted in bold) had been achieved by 28 February 2024:

- *The Trust track patients from referral to first definitive treatment in line with what happens across all HSC Trusts in NI. The Trust is resourced to enable tracking to this scope and the CAPPs system can only support tracking from referral to first definitive treatment.*
- *Cancer Services monitor tracking monthly to ensure this is kept up to date to support escalation of any delays patients may experience on their cancer journey.*
- *The Trust has been commended by SPPG for keeping cancer tracking up to date, especially given the high and increasing trend in Red Flag Cancer referrals.*
- *All patients with a new cancer diagnosis discussed are discussed at a Cancer MDM.*
- *All patients will be allocated a Cancer Nurse Specialist as their Key Worker. A monthly report is produced by Cancer Services to evidence that patients are being allocated a Key Worker in line with the Cancer MDM Principles document (January 2023).*
- *Monthly snapshot reports are completed for all local Cancer MDMs to check that the plan agreed at MDM is implemented. These audits are completed by Cancer Services and issues flagged to Cancer Senior Management Team in line with an agreed escalation process.*
- *A pathology cross check mechanism has been established to check that all patients that are diagnosed with cancer via the laboratory are being brought to a Cancer MDT with monthly reports to evidence that this is happening.*
- *The Cancer Tracking Team are now resourced to cover all cancer MDMs.*
- *The team are fully staffed with no gaps currently and are up to date with tracking.*

³¹⁵ TRU-306502

- *Cancer Services received a monthly report to monitor tracking position.*
- *If cancer trackers identify any delays with patients on cancer pathways, they follow up on these issues with consultant secretaries and consultants as required. Cancer MDM chair may also be alerted to significant delays or issues. Cancer Senior management team and specialty Heads of Service / Assistant Directors will also be alerted to any significant issues*

5.57 Dr. O’Kane put the following flesh on the bones of the above summary during her evidence to the Inquiry on Day 90³¹⁶:

“We put additional funding against the MDM in relation to not just the job planning process but also increasing the number of CNSs who take part in all of that, making sure that there is medical presence there, and also then we invested in trackers, so that when a patient comes through this process now the tracker picks them up and makes sure that there is no gaps in terms of, you know, the outcome of the MDM being followed through...

...That is then audited on a regular basis, and they will take - out of samples of 38 they will take 5 cases and make sure, based on that sample size, which is, you know, in and around 12%, they'll do that on a regular basis to make sure that there aren't any patients falling through the gaps. Right.”

5.58 Dr. O’Kane in her evidence³¹⁷ in relation to Recommendation 1³¹⁸ – *the SHSCT must provide high quality Urological Cancer Care for all patients* - also explained the following:

“Q...And then a third stage, or a third portion of the work, there was data mapping for

³¹⁶ TRA-11742

³¹⁷ Also on Day 90 at TRA- 11751

³¹⁸ TRU-306490

each patient pathway or each condition pathway. One can see that that has a yellow rating. Some of the work in urology and I think in renal services isn't yet complete. We can see in the middle paragraph:

"The immediate work needed to be delivered in relation to Urology has been completed but the Trust is adopting an ongoing improvement focus across all cancer pathways supported by the cancer service improvement league."

So the RAG status for this sub-action is therefore yellow, it's ongoing work. A. Mm-hmm.

Q. Are you satisfied or are you in a position to be satisfied or assured that this aspect of the recommendation is in a good place, has been appropriately conducted and applied?

A. I think I would have liked it closed out, but I know that they are working on the aspects of this. To try - for the parts of this that haven't been delivered on yet, this will now - I mentioned yesterday about the External Reference Group and about how we're now moving the programme for improvement within the Trust completely, so that will be overseen by the Director of Transformation and Improvement in terms of ensuring and, you know, holding to account essentially the directorate in relation to making sure that these are delivered on over the next few months. So, I mean, we would all like it to be green, but I am confident that, you know, as this works gets underway that we will have this done."

5.59 Dr. O'Kane explained, when questioned in her evidence³¹⁹ in relation to Recommendation 2³²⁰ - *All patients receiving care from the SHSCT Urology Cancer Services should be appropriately supported and informed about their cancer care – this should meet the standards set out in Regional and National Guidance and meet the expectations of Cancer Peer Review – which was the only recommendation to have an amber RAG, the following:*

³¹⁹ Also on Day 90 at TRA- 11763

³²⁰ TRU-306493

"Q. It concerns the allocation of a key worker and the Trust is not currently in a position to stand over in every case that those allocations are taking place. It records here:

"As the new CaaPS functionality is not yet available which will allow monitoring of this and other KPIs, and given that sample audits have been undertaken for Urology, we have a level of assurance on this. However, we cannot fully sign the recommendation off as being green."

So there's that frailty in the system whereby you don't currently have a methodology to stand over appointments of key workers and compliance with their key performance indicators in every case, is that right?

A. We have - we do it manually, you know, in terms of trying to keep a running score to make sure that the patients are aligned and there's a monthly feedback in relation to that. But in terms of it being recorded on the system robustly and signed off by the CNSs, they're not able to do that. And CaaPS is one of a number of pieces of software, you know, that functions across the NHS at the minute that is awaiting the implementation of Encompass. That rollout of Encompass regionally started with the Southeastern Trust in November last year. The Southern Trust will get to this in April 2025. So this is going to take at least another year/18 months."

5.60 In her evidence³²¹ on Day 91, Dr. O'Kane also provided the following additional information in relation to the Key Worker issue:

"MR. WOLFE: Good morning. Good morning, Dr. O'Kane. Just going back to something I was asking you about yesterday. We were looking at the outworking of the recommendations following the Serious Adverse Incidents Reviews, and we were looking at the audits that were and have been carried out in respect of, for example, quoracy, in respect of cross-referencing from pathology, and then we came to nursing and we identified something of a gremlin in the works in the sense that CaaPS requires

³²¹ TRA- 11818

further work so that we can have an electronic record of the allocation of key workers to patients, and I was raising that with you as a concern because it's essentially a concern within the recommendation report that you have helpfully brought to our attention. You did say that there is nevertheless a paper check or a manual check that key workers are being allocated, and I just wanted, after that long introduction, to bring you and bring the Panel to some references for that.

If we go to TRU-304474. And we can see this dates back to November 2022. And Kate O'Neill, one of the nurse specialists, is writing to Wendy Clayton in response to a request for data outcomes, or audit outcomes I should say, and she sets out some information which helps to clarify that in the vast majority of cases key workers had been allocated, and gives explanations for the cases where allocation had not yet taken place. Any further comment you'd like to make on that?

A. I have seen more up-to-date information in the weeks that suggests that that has moved on but is still being, the information is still being collected in the same way, so we can provide the Inquiry with that.”³²²

5.61 In relation to the actioning of MDM outcomes, Dr. O’Kane explained³²³:

“Q. MR. HANBURY: Just another thing on the audits of the multi-disciplinary team working after Dr. Hughes's review of the nine SAIs - you've already answered one of them. In Recommendation 5, about the extended tracking, which you remember, the problem for a few patients, especially with prostate cancer, is that they were started on hormones and subsequently not referred for radiotherapy. Are you confident that that has been picked up with the new system of extended tracking?

A. Yes. And certainly in terms of the audits that are being done, you know the 5 out of 38 every week in relation to the patients described, it would suggest that they are being done. And that - again the trackers were specifically employed to undertake that function and to make sure all aspects of the treatment was actually happening, yes.”

³²² Please see TRU-409752 – TRU-409752

³²³ Also in her evidence to the Inquiry on Day 91 at TRA- 11895

5.62 And in respect of the prescribing of Bicalutamide 50 mg and the prevention thereof, Dr. O’Kane had the following to say³²⁴:

“Q. MR. HANBURY: So what's to prevent that happening now? What's to prevent that happening now?”

A. Well, all of those prescriptions should originate within the Urology Department. So they have a good programme in terms of, I think, being aware of all of this and making sure that everybody - I mean this is talked about a lot in terms of being compliant with all of this. Right. Our pharmacy processes at this point in time aren't robust enough to pick up, you know, if it's still being prescribed for the wrong reason, in terms of whether it's 150 or 50 milligrams of Bicalutamide. But certainly pharmacy is very aware of this and, you know, will appropriately challenge if they're concerned. But I think the ultimate solution to this will again be the implementation of Encompass next year. Now, I appreciate that's a year away. Because the Northern Ireland version of Encompass should bring together the different aspects of the clinical pathway, and the artificial intelligence that's built into the Encompass programme should try totally the prescription of Bicalutamide to the diagnosis and should be able to pick up that actually this is outwith what it should be in terms of, you know, the cancer disease process and metastasis. So that artificial intelligence that kind of guides the system and it should be helpful with that.”

5.63 In relation to picking up the use of medicines contrary to Guidelines and outside of licence, Mr. Haynes explained in his evidence³²⁵, when questioned by Dr. Swart, that the starting point for such a patient would be a recommendation from MDT for specific treatment and that the concern about Bicalutamide was the patient not receiving the appropriate prostate cancer treatment. Mr. Haynes explained that the audit process of the MDT outcomes would highlight the patient who has not had the recommended treatment which would in turn bring the patient back both to the consultant and to the MDT allowing for peer challenge. Mr Haynes further indicated that he would expect the MDT chair to bring that

³²⁴ Also on Day 91 at TRA-11899

³²⁵ Day 88 at TRA- 11520

patient to the medical line management – escalating the issue. Mr. Haynes also referred to support in terms of contact directly through the Deputy Medical Directors and the Medical Director and to those relationships and the regularity of meetings being such, that the issue would be able to be raised.

5.64 In respect of clinical audit, Dr. O’Kane explained in her evidence on Day 89³²⁶ that, at a point in time in the past in order to save money, the clinical audit team had been stood down and that now as part of the whole governance review it had been reinstated. On the same issue, asked whether there had been any identifiable change in respect of clinical audit in recent times, Mr Haynes described to the Inquiry how there had been a ‘huge change’ for the better³²⁷.

5.65 Dr. O’Kane also gave evidence on Day 89 in relation to the Champion report³²⁸, indicating that it gave her a framework in terms of improvement in relation to the overall corporate governance of the organisation and had been helpful in developing the operational governance within the Trust and that:

“...we have concentrated on completely reforming the way we undertake corporate governance and, again, that has taken a lot of engagement, reflection, discussion, and we now have a revised corporate governance structure in place that brings patient safety and the quality of care very much into the minds of staff within the organisation, and feeds into the Governance Committee and sits alongside the Risk and Assurance Committee - or, sorry, the Risk Assurance and Audit Committee - that basically then quality assures some of that work that comes in. And then the other committees that are developed, the other five committees that are alongside that then are to support the overall approach to corporate governance.”

5.66 Mr. Haynes commented on the actions taken as a result of the Task and Finish Group (taking forward the Hughes SAI recommendations) and assurance

³²⁶ TRA- 11617

³²⁷ TRA-11487 line 22 to TRa-11488 line 24.

³²⁸ TRA- 11609

processes surrounding the MDM in his evidence on Day 88³²⁹ when asked about a number of new support staff being brought into the MDT arena indicating that the roles are very much part of the assurance processes that surround the MDT, that the Cancer Information and Audit Officer was the individual who does a monthly audit of the outcomes recommended from MDT addressing the question are they being actioned and that he gets a report from that individual. Their role, according to Mr. Haynes, is the assurance process around MDT.

5.67 Mr. Haynes also gave evidence on Day 88³³⁰ addressing culture change in results sign-off. Mr. Haynes referred to the first step of the monitoring process being undertaken by himself and Wendy Clayton and to all of the consultants and nurse specialists within Urology using electronic sign-off for their results management. Mr Haynes referred to a red/amber/green table for each consultant's reporting and indicated that it tells him how long a result has been outstanding and awaiting action. Mr. Haynes referred to an escalation process indicating to the consultant that they have fallen into amber and a formal meeting to establish a way back to green if a consultant had fallen into red. Mr. Haynes suggested that the mere availability of an overview had helped to change the culture and that *"we all know how each other is doing, and no one wants to be bottom of the table. You don't want to be bottom of the class so it generates a culture whereby everyone keeps on top of things. If you get an e-mail that shows you as an outlier, it changes the way you behave"*.

5.68 Mr. Haynes gave evidence³³¹ in relation to Key Worker allocation and in relation to reports directed to the role of the Key Worker indicating that :

"A. Yes, to the best of my knowledge that is all implemented. I think there is an aspect to it that was required for the monitoring, for ease of monitoring, that required some regional input on the CAPP system, the cancer -- the computer system that's used for

³²⁹ At TRA- 11461. Further comment is at TRA-11463 to TRA-11465.

³³⁰ TRA-11466

³³¹ Also on Day 88 at TRA- 11474

recording the cancer patients. The actual, the physically doing it and auditing it and recording it is all being done."

5.69 In respect of the actioning of MDM outcomes, Mr. Haynes gave the following evidence³³²:

" A. So the audit is done on a monthly basis. Where there are, if you like, discrepancies, where there's an outcome or a query regarding the outcome, it is raised first-off with the clinician themselves. As I mentioned earlier, there may be a simple oversight or failure of the requesting process that means something hasn't been requested, or it may be that the clinician has forgotten to bring the patient back to MDT when they've changed it, so it allows for the clinician to actually look at it and bring it back if required. But if there's no action, then my understanding is that that is then escalated to the MDT Chair to bring it back to the MDT...

...A. So the commonest situation we've had - and from memory it has not been this process that brought the patient back to MDT, it has been the clinician who has brought the patient back to MDT - has been where the patient's wishes are different to those that have been put or recommended by the MDT. Where you have that consultation taking place with the clinician and the Clinical Nurse Specialist, and you have in that well-counselled patient they are making an effective decision to go with a different plan, it is very difficult to change a patient's decision when they've made a reasoned judgement themselves. We haven't had to challenge a clinician, saying I think we should do something different."

5.70 Mr. Glackin gave evidence on Day 63³³³ addressing the actioning of MDM outcomes, indicating that there is now in place a random audit of whether or not outcomes have been adhered to and that information is brought back to the MDT and shared with the MDT. Mr. Glackin indicated that he also receives that report as the lead clinician, and that if there are cases that don't appear to match what the

³³² Also on Day 88 at TRA-11476.

³³³ TRA- 08243

outcome was, then those cases are addressed on an individual basis. Mr. Glackin's evidence on Day 67³³⁴ addressing the audit of MDT outcomes included the following:

"A. So following the appointment of Mark Quinn, and under the direction of Angela Muldrew, we have a monthly audit process of outcomes from MDT to ensure that the outcomes are followed up and actioned. That report is provided to me, and it's also provided to the whole of the MDT, so that if there are any shortcomings or points that have not yet been actioned, they can be brought back to the meeting and discussed and actioned. So, that's been in place for almost a year. So that is working. We have a report from the Pathology Department that's run I think on a weekly basis to ensure that all pathology is brought to the meeting that should be. So they're at least two of the reports that are being supported by cancer services."

5.71 Kate O'Neill's evidence³³⁵ in relation to Key Worker allocation referred to a proforma³³⁶ allowing for improved auditing of Key Worker activity and explained that the Key Worker is named and that the system operates by way of a minimum data set and is audited.

5.72 Kate O'Neill also gave evidence³³⁷ addressing other improvements and Key Worker allocation including how increased resources 'have transformed [her] working life'. When asked about the potential for the issues around Key Worker allocation in the 9 SAIs to arise again, she offered the following evidence:

"A. I think we have eliminated that significantly. There is still improvements that I feel could be done and we'll work towards those. One of those would be more engagement with the ward-based patients, whether it could be considered or not going forward if we had sufficient resources to actually have a CNS on the ward round. You know, that provides a format for engagement with the ward staff and patients."

³³⁴ TRA-08725

³³⁵ Day 42 at TRA-12059

³³⁶ At WIT-81164.

³³⁷ Day 42 at TRA- 12106

5.73 Leanne McCourt gave evidence³³⁸ comparing the current system in relation to Key Worker allocation as compared to that at the time of the SAIs in the following terms:

“ A. I think, as I said, comparing the CNS role in terms of key worker then to now, absolutely. It's a more robust system, it's a more proactive system. There is now a person within Cancer Services that is in charge of audit, and they would send us a retrospective list at the end of every month of all the new diagnoses from that month. We appoint a CNS each month to cross-check that with the key worker activity so we can identify if indeed any patient doesn't have a key worker and rectify that.”

5.74 Also in her evidence on Day 43, Leanne McCourt discussed the system now and whole of pathway tracking as an idea for improvement³³⁹:

“Q. The system as it exists now in referral of patients, for example to Oncology, how confident can the Panel be that those referrals are being carried out and that there couldn't possibly be the situation that arose for this patient arising currently?

A. I can only speak for my role within this in that, now, patients who have a new diagnosis do have the key worker and are empowered to know what's happening. I think there have been discussions around the whole of pathway tracking that was alluded to in the testimonies yesterday but, to the best of my knowledge, that isn't currently in position at present.

Q. And do you think that would be a good idea?

A. Absolutely.”

5.75 The progress made is perhaps best summed up by Mr. Haynes when he gave evidence on Day 88, when he said³⁴⁰:

³³⁸ Day 43 at TRA-05479

³³⁹ TRA-05487

³⁴⁰ TRA-11478

“Q....Overall, taking into account your experience of working within this MDT before 2020 and knowing the environment now in light of these changes, how would you characterise the improvements? Has there been meaningful progress and is it a safer environment for your patients?”

A. I think there has been significant progress. It's a safer environment for patients. It's also an environment where we as clinicians feel safe. We know that there are processes to make sure that everything is happening as it should be.”

Conclusion

5.76 The issues in respect of Mr O'Brien's practice and that of the Trust which came to a head in 2020, and which were subject to SAI review led on to further patient scrutiny by the Trust in the Look Back Review and the SCRR process.

5.77 The Trust accepts that the cancer care received was not that which would have been expected.

5.78 Nonetheless, it is hoped that the Inquiry, patients and their families, and the public will be assured now by the steps taken by the Trust in relation to the issues identified to improve processes surrounding cancer care and the Urological Cancer MDT so that the risk of similar issues arising now or in the future has been significantly reduced.

Chapter 6

Resistance to Change

Issues

6.1 The Inquiry has heard and received much evidence regarding the almost exponential growth in demand for urology services over the last three decades. In the face of such rapid growth, the qualities of deftness and adaptability in respect of practice management and reacting to changing demands are essential attributes in the professionals providing urology services.

6.2 This chapter reflects on different aspects of Mr. O'Brien's practice which, viewed together, suggest that he was a professional who was often resistant to change and who seemed to be 'set in his ways'. We have already referenced in earlier chapters Mr Haynes' experience that Mr. O'Brien was 'a challenge to challenge', a view echoed by several other witnesses including his long-time Head of Service. The Inquiry will have to test this evidence against the corpus of other evidence it has amassed. When challenged with this characterisation of him, Mr O'Brien has been dismissive of it, describing it as 'gossip' and 'confetti': *"I don't buy into 'the challenge to challenge' gossip at all. I think we have listened to chill factors, legal connections, knowing Roberta Brownlee, and frankly I find it confetti really"* ³⁴¹.

6.3 This chapter will focus upon issues that arose in Mr. O'Brien's practice which might illustrate a resistance to change. In this regard, it is of course the case that some of the issues in Mr O'Brien's practice addressed in the two previous chapters evince a resistance to change: for example, his approach to referral triage and his approach to the prescription of Bicalutamide 50mg. In the circumstances, this

³⁴¹ TRA- 12210, Day 92, Pg.88, 18-24

chapter will attempt to focus primarily on other issues in his practice, not yet considered in previous chapters. These include the following:

- a. Admission for IV fluids and antibiotics;
- b. Cystectomies;
- c. Results and DARO;
- d. Pre-operative assessment;
- e. Monopolar in glycine *vs.* bipolar in saline resection in TURPs; and
- f. Issues already addressed in previous chapters.

6.4 These issues engage a number of the Inquiry's Terms of Reference and, in particular, Terms (a) and (b).

6.5 At the outset of this chapter, the Trust acknowledges that it has been guilty of a number of failings in this area. In some instances, there was a failure to recognise that Mr O'Brien had not changed his practice to conform with what the Trust considered to be best practice. On other instances, the Trust had such a knowledge but was deficient in how it acted on foot of this knowledge.

(a) Admission for IV fluids and antibiotics

6.6 Notes of a meeting held on 20 April 2009 referred to the Trust having identified a cohort of patients who were admitted as elective cases for IV antibiotics and IV fluids as prophylaxis for recurrent UTIs. Dr. Damani, Consultant Microbiologist, met with the urology team to agree guidelines. Following this it was agreed that, if a patient were to be admitted for IV fluids and antibiotics, a meeting had to be held with Dr Sloan and a microbiologist and that "this pre-requisite was non-negotiable".³⁴²

³⁴² TRU-281944, Eamon Mackle to Mr O'Brien 16.6.11

6.7 Notwithstanding this protocol, Mr O'Brien continued to admit patients over a number of years, apparently without microbiology notice or agreement. See, in this regard, examples from the years 2010 to 2013 inclusive at TRU-259410 to 259411, TRU-281944, TRU-259904, and TRU-276833.

6.8 Mr Wolfe KC questioned Mr O'Brien about whether he considered that he was obliged to comply with the Trust's antibiotic policy. Mr O'Brien did not concede that he was so obliged but attempted to justify his actions.³⁴³

6.9 Mr Young gave evidence acknowledging that he also admitted patients after the protocol had been agreed (albeit in much smaller numbers than Mr O'Brien³⁴⁴) but sought to differentiate himself from Mr O'Brien, highlighting that his patients would have been symptomatic³⁴⁵.

(b) Cystectomies

6.10 After March 2010 radical pelvic surgery, by direction of the Commissioner following the Drake report, was to be undertaken at the Belfast City Hospital. Mr O'Brien did not agree with this move, as was clear from his appraisal for 2011.³⁴⁶ However, he further conveyed his misgivings to his patients, prompting Dr Stevens of the Belfast Trust on 28 September 2010, to write to the Trust in the following terms regarding Mr O'Brien:

*"The lack of insight displayed by the surgeon, who then wrote letters suggesting that there was a callous disregard for patient welfare, is rightly unbelievable given the circumstances and the poor management decisions."*³⁴⁷

³⁴³ TRA- 12452, Day 94, Pg.74, Lines 5-13

³⁴⁴ See, for example, the lists of their respective patients at TRU-259410-259411 and TRU-281847-281852

³⁴⁵ See, for example, TRA- 09708 and TRA- 09710, Day 75, p32 and p34

³⁴⁶ TRU-251248, November 2011 Appraisal

³⁴⁷ WIT-99146 and TRA- 12445, Day 94, pg.87, Lines 23-28

6.11 Mr O'Brien did not accept that this had been drawn to his attention at the time. However, his evident reluctance to comply with the requirement to refer patients to Belfast City Hospital, notwithstanding the direction, highlights an intransigence and a reluctance to change his practice.

(c) Results and DARO

6.12 In 2011 the Head of Service wrote to all urological consultants relaying Mrs Trouton's direction that "*there is an expectation that investigative results and reports be reviewed as they become available and that one does not wait until patients' review appointments.*" Mr O'Brien wrote back to his Head of Service on 25 August 2011 in an email with 12 bullet points taking issue with the requirement³⁴⁸. A reasonable interpretation of this email was that Mr O'Brien would not be complying with the direction.

6.13 When asked about this resistance on Day 94 of the Inquiry Mr O'Brien claimed to be in agreement with the requirement in principle but qualified, "... The practicality of everything that we had to do, with inadequate time to do it, you know, you couldn't guarantee that you would be able to review all results."³⁴⁹

6.14 Mr. Wolfe KC also questioned Mr. O'Brien about his reluctance to use the DARO arrangement as a useful safety net³⁵⁰ in a context where Mr. O'Brien's practice was instead to arrange a review with the result of the investigation being considered at that time, thereby leading to potential delay. Mr O'Brien continued to voice his 'grave reservations' about DARO in evidence. Mr Wolfe KC was forced to press Mr O'Brien as follows before he would accept the usefulness of the system at all:

³⁴⁸ TRU-276805 to 276808 - email chain 25.7.11 to 25.8.11

³⁴⁹ TRA- 12468, Day 94, Page 110, Lines 16 - 19

³⁵⁰ TRA- 12489, Day 94, page 131, Lines 3-10

“Given your experience of missed results jeopardising the safety of patients, is it not remarkable that when the Trust constructs this kind of governance arrangement that you decide to isolate yourself and your colleagues and not use it?”³⁵¹

6.15 These same reservations, and his opposition to using DARO, were also illustrated by an exchange of emails in 2019³⁵². Collette McCaul emailed consultant secretaries on 30 January 2019 reminding them that DARO needed to be used and emphasising that, ‘there is no way of ensuring that the result is seen by the consultant if we do not do DARO, this is our fail safe so patients are not missed’. Mr O’Brien replied on 6 February 2019 expressing his great concerns about the process, leading both Mr Haynes and Mrs Robinson to reply to him the following day emphasising, between them, the need to comply with the process, the ‘safety net’ role it performs, the fact that it is a Trust-wide process, and that it has been in place since Dr Rankin was Director of Acute.

6.16 And the Inquiry is aware that the backdrop to all of the above was not some theoretical or hypothetical concern for patient safety. In fact, all of the above occurred against a backdrop of there having been a patient of Mr O’Brien’s where the failure to read and action a result did contribute to harm suffered by the patient, viz, the ‘never event’ in respect of Patient 95 when a surgical swab was retained post-surgery and not picked up due, in part, to a failure of Mr O’Brien to review and action results in a timely manner³⁵³.

(d) Pre-operative assessment

6.17 On Day 94 of the Inquiry Mr Wolfe KC asked Mr. O’Brien, was it not the case that every patient required a pre-operative assessment. Mr O’Brien did not accept this.³⁵⁴ He was referred to the cases of Patients 90 and 91 who missed out on the particular attention that a pre-operative assessment would have provided, which

³⁵¹ TRA- 12496, Day 94, Page 138, Lines 14-18

³⁵² AOB-07574 to 07577

³⁵³ See WIT-17471 SAI report Patient 95.

³⁵⁴ TRA- 12483, Day 94, Page 125, Lines 5-16

would likely have altered their treatment plans and he acknowledged that, if he had to do things over again, he might do things differently it. Nonetheless, he still appeared unwilling to shift in his view that pre-operative assessment was not necessary for every patient.

(e) Monopolar in glycine vs. bipolar in saline resection in TURPs

6.18 Mr O'Brien's reluctance to embrace change was amply illustrated by his response to the need for changes in urological and gynaecological practice announced by the Deputy Chief Medical Officer on 18 August 2015.³⁵⁵ Mr O'Brien engaged in testing of new equipment for bipolar resection in saline but on 7 February 2016 declared: *"I will not use or try bipolar resection again."*³⁵⁶

6.19 Mr O'Brien denied that he was required to "move over" to the new way of working answering:

*"I wasn't required to move over. I was certainly facilitated in continuing to use monopole resection using glycine with all of the precautions that I had been used to since my training days in Dublin..."*³⁵⁷

6.20 Mr O'Brien described that there was a precision to dissection with glycine and so it was his preferred median notwithstanding that by April 2018 there was a requirement that saline was to be used.

6.21 Whilst there is no evidence of any higher incidence of hyponatraemia or other issues arising for his patients due to the continued use of monopolar resection in glycine, Mr O'Brien's response to this change of practice again illustrates an unwillingness to change to bring his practice into line with what was expected of him by the Trust and the Deputy Chief Medical Officer.

³⁵⁵ WIT-54032

³⁵⁶ TRU-395978 and TRA- 12503, Day 95, Page 5, Lines 20-25

³⁵⁷ TRA- 12506, Day 95, Page 8, Lines 19-24

(f) Issues already addressed in previous chapters

6.22 Mr O'Brien's unwillingness to change his ways is, as acknowledged above, also evident from some of the issues addressed in previous chapters. Some notable features of those issues include the following.

6.23 In respect of the dictation issue, Mr Glackin was at something of a loss to understand Mr O'Brien's intransigence on the issue of dictating after each clinical encounter, describing it, in terms, as perverse³⁵⁸:

" It was raised with Mr O'Brien in the departmental meetings and ... Mr Haynes raised a particular issue ... the necessity to have a clinical letter dictated and available in the chart for every patient, and Mr O'Brien perversely expressed the view, perversely from my perspective, that it wasn't necessary to dictate on every patient, that he knew what was going on and he didn't have to write to the GP."

6.24 In respect of triage, the Chair broached the issue of whether, on reflection, Mr O'Brien ought to have moved from his Rolls Royce approach to triage (which, at times, included Mr O'Brien telephoning the patient and having a mini consultation) to the way everyone else did it. A careful series of questions³⁵⁹ culminated in the following: *'And I just wonder, having heard all that you've heard in the course of this Inquiry, do you reflect that maybe there was a better way for you to do it?'* Mr O'Brien gave a long answer³⁶⁰, expressing regret for people who missed out on an upgrade, alleging that the other consultants who got their triage done did it at the expense of patients, and bemoaning the fact that the Trust never gave them a clear understanding of what was expected from them in the form of triage.

³⁵⁸ TRA-08755, put to AOB on Day 92, pg. 75

³⁵⁹ TRA- 12655 – 12656, Day 95 from p157 line 29 to p158 line 27.

³⁶⁰ TRA- 12656 – 12657, Day 95 from p158 line 28 to p160 line 11.

But ultimately, he steadfastly declined to acknowledge that he ought, on reflection, to have adopted a different approach to triage, akin to that of his colleagues³⁶¹.

6.25 In respect of the Bicalutamide issue, Mr O'Brien's intransigence was also demonstrated in response to a question by Mr Wolfe KC on the last day of evidence to the Inquiry. Notwithstanding the breadth of evidence received in relation to the difficulties caused by prescribing too low a dose of Bicalutamide, Mr. O'Brien maintained that he was correct:

"Mr. Wolfe KC: 50mgs Bicalutamide has been said before this Inquiry not only to be unlicensed for the purposes for which you prescribed it but also suboptimal or ineffective in delivering the conditions preparatory for oncological intervention in the form of radiotherapy. The goal should be castration as opposed to seeking to control the PSA. So the primary object should be to prepare the patient for the radiotherapy intervention.

*Mr O'Brien: Well, with respect to those who made such claims, I disagree with them...."*³⁶²

Failings on the Part of the Trust

6.26 The clear failings on the part of the Trust in respect of the above issues are both obvious and familiar. They can be summarised as:

- a. failing effectively to grapple with some issues of which they were aware in a timely manner;
- b. failing to grapple with other issues of which they were aware at all; and
- c. failing even to be aware of further issues.

³⁶¹ The same refusal to accept that there was a better way than his way was evident in his response to Dr Chada's MHPS investigation – see, e.g., AOB-01893 2nd para under '1. Triage'.

³⁶² TRA- 12568, Day 95, Page 70

6.27 Category a. includes the issues of IV antibiotics and fluids and cystectomies, each of which were ultimately grappled with, albeit not as quickly as they might have been (in the case of IV).

6.28 Category b. includes DARO and results. The results issue was known about from as early as 2010 in the case of Patient 95 and the 2011 email exchange with Mr O'Brien. The DARO issue was also an issue that appears, based on the 2019 exchange of emails, to have been known about (at least in some quarters in the Trust beyond Mr O'Brien and his secretary) for some time.

6.29 Category c. includes the issue of continued use of monopolar resection in glycine after the bipolar resection equipment was available in the Trust³⁶³.

Root Causes of these Failings

6.30 The root causes of these failings also appear to include causes which are both obvious and familiar (and which have been discussed at length in previous chapters). They include:

- a. An inability or reluctance on the part of management fully to use both informal and formal tools to deal with Mr O'Brien, particularly when faced with what could be described as open defiance (as was the case in respect of DARO and results).
- b. A lack of clarity about who was responsible for escalating or addressing issues coupled with an over-reliance on persons such as the consultant's secretary to raise an alarm (e.g., in respect of DARO or results).

³⁶³ WIT- 103811 – 103812, S 21 No 20 of 2023- Mark Haynes Paragraph 1.18 *Consultants do not attend each other's operating lists and therefore I did not have an opportunity to identify that he was continuing to use monopolar resection. I do not have any specific recollection of being made aware by others that Mr O'Brien continued to use monopolar resection in glycine.*

- c. A lack of coordination of information by, or between, managers (possibly due to silos) and/or a lack of time to 'stand back and look' at his practice and make the necessary links between his resistance to change in multiple areas.
- d. Too high a level of deference towards and/or trust in Mr O'Brien, which is perhaps best encapsulated by Mr Haynes' evidence (given in the context of questions about Mr O'Brien's DARO email in early 2019 and an IR1 Mr Haynes submitted about Patient 92 shortly thereafter)³⁶⁴:

As I think I reflected about the 2017 concerns, I failed to recognise, broadly grouped together, the administrative concerns, the concerns that he wasn't actioning results, the concerns that he wasn't triaging; these issues. I failed to recognise that underneath these there was also an individual who wasn't managing patients in the way that they were supposed to be. I didn't have a high degree of suspicion at this time, and that's a failing on my part, that he was doing things in a different way. I wouldn't have imagined that an individual who had acted in the role I fill now as a Clinical Reference Group Chair for our cancer network group, who in sitting in that role had been instrumental in the development of guidelines in how to manage prostate cancer for Northern Ireland, had reviewed the NICE guidance as part of that; as part of that, as we've heard, that group had developed hormone treatment guidelines. I wouldn't have -- it didn't cross my mind as a suspicion that this individual, who seemingly has held positions that direct how things should be managed, is then in his own practice doing something completely differently."

- e. A lack of visibility into certain areas of his practice (e.g., in respect of his TURPs after bipolar resection equipment was available), perhaps in part as a result of deficiencies in clinical audit within the Trust.

Important Context

³⁶⁴ TRA- 11419 – 11422, Day 88, Page 49 line 25 to p52 line 24.

6.31 It is important to recognise, in addition to the important points of context already identified in chapters 4 and 5, a number of pieces of context discrete to the above issues such as the following:

- a. Mr O'Brien does appear to have conformed, albeit perhaps unwillingly, in respect of cystectomies and (more slowly) IV antibiotics and fluids. Mr Mackle, for one, considered that these were examples of issues in respect of Mr O'Brien ultimately being managed appropriately: *"Cystectomies, IV fluids, they were all Medical Director involvement and managing it, and perhaps that set the tone for how things should be managed after that."*³⁶⁵
- b. Mr O'Brien appears to have believed, based on his own experience, that the IV antibiotic and fluid practice worked. He went as far in this regard as to publish a detailed letter (co-authored by Mr Young and Mr Kho) in a respectable medical journal setting out his results and experiences on this issue³⁶⁶.
- c. There is no evidence that Mr O'Brien's continued use of monopolar resection in glycine led to any harm.
- d. There was a delay, related in part to the fact that capital expenditure demand always exceeded available capital (such that the Trust was always forced to deny or delay many requests for new equipment), in obtaining the bipolar equipment, such that, between testing the bipolar equipment and it arriving permanently, Mr O'Brien (like his colleagues) was reasonably able to continue using monopolar equipment.

Trust Actions to Improve / Restore Public Confidence / Protect Patients

³⁶⁵ TRA- 02272-02273, Day 21, Pages 72-73

³⁶⁶ WIT- 82743 - 82745

6.32 Many of the improvements initiated by the Trust in respect of the above issues have already been referenced in these submissions (and/or will be summarised in Chapter 7). For example:

- a. In respect of results, the substantial improvements in this sphere have been addressed in chapters 4 and 5 and include the e-sign off facility, better training and guidance to secretarial staff, and the monthly information dashboard (including information regarding their triage, dictation, and results) available to all consultants³⁶⁷.
- b. In respect of medical management, significant improvements on this front have been described in the written and oral evidence of Maria O’Kane and Mark Haynes³⁶⁸. Maria O’Kane summarised the remodelling of medical management as follows: *‘So, on the back of this report in 2020, what we did was revised - the job descriptions as Clinical Director and Associate Medical Director did not lend themselves to supporting the medical leadership that was needed. So we, you know, we undertook a complete revision of all of that, strengthened those roles, introduced an increased number of Clinical Directors and Divisional Medical Directors instead of Associate Medical Directors, increased - introduced Deputy Medical Directors and strengthened that function. All of the people who were selected were put through a fairly rigorous interview process and then have been given some support and training around that’*.³⁶⁹ In short, the improvements include both better training given to, as well as greater numbers of, medical managers.
- c. In the area of drugs Tracey Boyce³⁷⁰ in her evidence to the Inquiry explained the pitfalls that exist with a paper based prescribing system and the positive changes which will be brought about with the introduction of Encompass: *“Today, we still have a paper-based system until Encompass starts in the South Eastern*

³⁶⁷ See also Mark Haynes Transcript TRA- 11465 – 11468, Day 88, Page 95-98 and TRU-320269-Administrative and Clerical Standard Operating Procedure, Mark Haynes

³⁶⁸ See also the Medical Leadership Review March 2020 at WIT-79127.

³⁶⁹ TRA- 11689, Day 90, Page 17

³⁷⁰ TRA- 05908, Day 46, Page 83

Trust later this year. If you have a full electronic prescribing system administration, you can sort of set safety alerts and safety nets for your junior staff and your senior staff as well into the system. If someone tried to prescribe subtherapeutic gentamicin, it would either stop them or they would have to put in a reason why. It would allow you then to sit back in my role or my team's role to run reports and overviews. There is an antimicrobial monitoring team in Trust now; that would be very useful for them. At the minute they have to hand collect the data. There was no way of sitting back and having alarms ringing, shall we say, that there was something unusual happening.”³⁷¹

- d. And in terms of visibility of issues such as Mr O'Brien's continued use of monopolar resection, we have already touched in previous chapters upon significant improvements in the area of clinical audit. Mark Haynes summarised those improvements as follows: *“It's a huge change. So we have a member of staff from the audit team assigned to urology for audit purposes. She attends our Patient Safety meetings with us. She's constantly in communication with us with regard to the ongoing audit projects and, indeed, just yesterday was in contact with me about -- I think it's one of them on there or it's one that's on the current one. It's one of the ones through BAUS. It is there. It's the top one. So it's a much greater engagement and it's led to a massive improvement through the audit programme that we undertake in the team. As you say, what we have there is multiple levels of priority in terms of the department for audit, and they go down from "external must dos", down to "for interest", if you like, audit. The findings are presented at our Patient Safety meeting by our trainees. They have presented at our regional audit meeting for urology as well, and I know the trainees are looking at -- where appropriate, they're looking to put their projects in for presentation at national meetings as well.”³⁷²*
- e. And finally for present purposes, in respect of pre-operative assessment, Mr Haynes³⁷³ described in his evidence how different the approach to pre-operative assessment is now: *“The preoperative assessment team are engaged and*

³⁷¹ TRA- 05909, Day 46, Page 84

³⁷² TRA- 11488, Day 88 Page 118

³⁷³ TRA- 11484, Day 88, page 114

clinically led to try to improve that position. As I've said, within our service our theatre scheduling is done by our scheduler, so where patients haven't been through preoperative assessment, they are not added, or an active decision needs to be made and is made in communication between an anaesthetic team and a surgical team as to whether it is reasonable to proceed without it. Invariably the answer to that is no."

6.33 Thus, the panel can take comfort from the improvements implemented already by the Trust in this regard that the deeply unfortunate issues that arose with Patients 90 and 91 are unlikely to occur today.

Conclusion

6.34 As indicated above, the Trust accepts that it failed to take a sufficiently robust approach to managing Mr O'Brien's resistance to change / idiosyncratic practice across a number of areas and across a wide span of time. His unusual intransigence was undoubtedly a significant contributory factor in all of this and a feature that may well have posed significant challenges for any healthcare trust. Nonetheless, his unilateral, 'I know best' approach to aspects of his practice was permitted to continue for too long.

6.35 The Trust also recognises that some of the above failings may have exposed patients to the risk of harm, for which it apologises.

6.36 However, the Trust believes that the Inquiry and the public can be assured by the remedial measures it has subsequently taken that recurrence, now or in the future, of the issues that arose in the above areas is unlikely.

Chapter 7

Trust Improvement Work

7.1 Substantial improvement by the Trust in its systems of management and in its clinical and social care governance architecture are essential in order to help achieve the related goals of restoring public trust and confidence and reducing the risk of the events with which the Inquiry is concerned recurring.

7.2 The substantial improvements the Trust has carried out across multiple areas have already been considered at various points in previous chapters, in particular in chapters 4, 5, and 6 in the context of the specific issues that arose in Mr O'Brien's practice and the failings that those issues laid bare in respect of the Trust's systems of management and governance.

7.3 However, the depth and breadth of the improvement piece (coupled with the fact that it is, necessarily, always a work in progress) means that it would simply not be practicable to seek to enumerate in a submission of this nature every significant improvement undertaken by the Trust, particularly where the Inquiry has itself elicited and digested multiple witness statements, many thousands of pages of disclosure, and many hours of testimony on this important topic.

7.4 In the circumstances, all that this chapter does is to seek to supplement what has gone before in chapters 4, 5, and 6 by providing a guide to where some of the important evidence on the whole Trust improvement piece can be found. In doing so, it will approach the topic under the following headings:

- a. The Champion Review;
- b. Chief Executives' evidence;
- c. The Dr Hughes SAI Reviews;
- d. The Royal College of Surgeons Invited Review;
- e. The RQIA Report;

- f. GIRFT;
- g. Trust Board Reform.

(a) The Champion Review

7.5 Some of the backdrop to why the June Champion Review was considered necessary during 2019 can be found in the evidence³⁷⁴ of Shane Devlin, Trust Chief Executive from 2018 to 2022. In short, he had concerns that the ‘spend’ on governance seemed light, that he had a concern about the absence of regular flow of Clinical and Social Care Governance (‘CSCG’) information to the SMT, and he was concerned regarding the level of data on quality and safety coming to SMT. Similar evidence was given to the Inquiry by Maria O’Kane, who was Medical Director at the relevant time and who, together with Mr Devlin saw the need for clinical and social care governance reform within the Trust³⁷⁵.

7.6 The November 2019 June Champion ‘Clinical and Social Care Governance Review’³⁷⁶ made 48 recommendations (which are at WIT-47007 to 47012) covering everything from Board Governance to ‘being open’ to management of adverse incidents and SAIs to clinical audit to morbidity and mortality.

7.7 Since the publication of the report, the progress of the Trust implementation of Ms Champion’s recommendations can be charted by reference to a Trust spreadsheet which is updated as the recommendations are implemented. The version applicable when Dr O’Kane gave evidence in March 2024 can be found at TRU-306233 to 306243 and was up to date as at 05 March 2024. Of the 48 total recommendations, 34 had been completed and 14 were in progress.

7.8 Maria O’Kane put flesh on the bones of the report and the implementation spreadsheet by explaining in her oral evidence³⁷⁷ the impact of the Review and the

³⁷⁴ WIT-00036 bottom third of page to WIT-00038

³⁷⁵ TRA-11605 -11606

³⁷⁶ WIT-46954 to WIT-47012

³⁷⁷ TRA-11676 and TRA-11772

changes brought about under it, she explained some of the progress of its implementation and what it has led to including her Corporate Governance and CSCG Governance Functions and Structures Proposal³⁷⁸ as well as the restructuring of the Acute Directorate into two smaller, more manageable directorates³⁷⁹.

(b) Chief Executives' Evidence

7.9 Not only have the current Chief Executive and her predecessor been able to provide evidence about the backdrop to, and drivers for, initiatives like the Champion Review, they have been able to provide the Inquiry with other useful evidence regarding improvements in governance and other areas.

7.10 For example, Shane Devlin's evidence also provides details of reforms he initiated in respect of the senior management team structure³⁸⁰.

7.11 In a much broader sweep, Maria O'Kane has in her evidence been able to provide considerable detail of improvement and reform work undertaken during her tenure as both Chief Executive and Medical Director – i.e., from 2019 onwards. For example:

- a. In her statement no. 29 of 2022 (from WIT-44934) she summarises multiple governance improvements introduced during her tenure. For example:
 - i. From WIT-44973 to WIT-44977 (para 7.9) she details governance improvements in multiple areas including adverse incidents, SAIs, clinical audit, patient safety, complaints, medical oversight of litigation, M&M, learning from experience, whistleblowing, 'being open' culture, MHPS, medical appraisal, revalidation, job planning, private practice,

³⁷⁸ WIT-47270

³⁷⁹ TRA- 11772 to TRA-11778

³⁸⁰ WIT-00031-00033 at question 7

medical education, infection prevention and control, R&D, emergency planning, and business continuity.

- ii. From WIT-445014 to WIT45027 (para 21) she provides details of some of the above improvements under the headings of medical professional governance improvements, clinical and social care governance improvements, and strengthening of medical leadership (including, in particular, in Urology).
 - iii. Some further detail on the above changes is contained in the tables at para 36 (WIT-45041) and para 37 (WIT-45043) and, in more detail, in para 51 (WIT-45082) and the attachments referenced there. An overview is then provided at para 71.16 (WIT-45184 to WIT-45186).
- b. In her statement no. 3 of 2022 (from WIT-11149) she summarises improvements undertaken in response to the 2018 MHPS Determination and the Mr O'Brien SAI Reviews (at WIT-11161 to WIT-11172).
- c. In her oral evidence to the Inquiry in March 2024 (TRA-11525 to TRA-11944) and through more recent disclosure to the Inquiry (such as that running from TRU-305017 to 306518) she has been able to bring the Inquiry up to date in respect of the reforms outlined in the above witness statements.

(c) Dr Hughes' SAI Reports

7.12 The 9 SAI Review Reports and Over-arching Report were produced in the Spring of 2021 and can be found at DOH-00001 to DOH-00135.

7.13 A 'Task and Finish Group' was created to oversee the implementation of their recommendations, Terms of Reference for which are at WIT-11509 to 11510.

7.14 Mark Haynes addresses the 2020 SAIs in his oral evidence on Day 88.³⁸¹

³⁸¹ TRA- 11456- Transcript 22 February 2024 p86 line 107- p108 line 132 and at TRA- 11522 p152 line 4-line 22.

7.15 Maria O’Kane also addressed the progress of implementation of the recommendations in her evidence from TRA-11737 to 11754 and 11763 to 11766.

7.16 The BSO audit (TRU-305875 to 305886) of implementation of the recommendations has also been made available to the Inquiry and was considered in evidence at TRA-11748. It showed 65% implementation by November 2023.

7.17 A more up to date picture of the state of implementation (as of 8 March 2024) can be found in a tabular document at TRU-306489 to TRU-306514 and was addressed by Dr O’Kane in her evidence, the 68 SAI recommendations were ‘streamlined’ into 11 major recommendations with ‘subtitles’ beneath them. A simple overview of the table reveals that the overwhelming majority of the recommendations have been shaded green, meaning that they have been implemented.

(d) The Royal College of Surgeons Invited Review

7.18 This has been described in the previous chapter. In summary, within their report the Review Team identified 17 recommendations which fell into two categories, urgent recommendations to address patient safety risks, and recommendations for service improvement.

7.19 These recommendations were the subject of an implementation action plan within the Trust. The iteration of the action plan considered in evidence is dated 9th October 2023 and can be found at TRU-304948 to 304965. As with other such plans it use a ‘RAG’ rating and, of the recommendations in October 2023, 4 were red, 9 were amber, and 4 were green. Implemented steps include developments such as the implementation of a new consent police (recorded at TRU-304951). Of the recommendations where implementation had not commenced by late 2023, some of these related to issues beyond the control of the Trust. For example, recommendation 12 - *‘The Trust must ensure recognition amongst management and*

*clinicians that no patient should wait for longer than a pre-agreed period for surgery and follow up*³⁸². Commissioning and resource restraints evidently hinder the Trust's capacity to act on same. Recommendations 4 and 14, marked 'red', relate to recommendations for audits which capacity is awaited. It is submitted that, of the recommendations which have been completed or are in progress, the action plan contains a detailed timeline of steps taken to address the recommendations³⁸³, and it shows that significant improvements have been made.

7.20 In terms of oral evidence on the issue, Maria O'Kane gave evidence back on Day 15³⁸⁴ about the backdrop to inviting the RCS in to carry out the review and she was taken to a number of the above documents regarding implementation of their recommendations in her evidence on Day 90 from TRA-11766 onwards.

(e) RQIA

7.21 The RQIA produced a review report in respect of the Trust's SCRR process in September 2022³⁸⁵. It contained 18 recommendations which can be found from TRU-157770- TRU- 157773. Briege Donaghy of RQIA gave evidence on Day 86 of how these recommendations were accepted by the Trust³⁸⁶.

7.22 Evidence of the progression of implementation of these 18 recommendations (which were broken down into 25 separate required actions³⁸⁷) can be found in a number of places including, for example:

(a) TRU-181971- TRU-181981- This 11-page tabular document (in the familiar RAG-rated format) shows the state of play in respect of implementation in

³⁸² TRU-304960

³⁸³ TRU-304959- By way of example recommendation 11 which is now marked 'green' required the Trust to review waiting list processes, the specific steps taken to implement this recommendation are date stamped and include recruitment of a Scheduler, confirmation audits will be undertaken relating to private patients moving to the public sector and waiting list processes/prioritisation of patients, and exploration of pooled waiting lists ,

³⁸⁴ TRA-01572 Day 15, p161, line 19 to p162 line 15 and TRA- 01576 p165 line 19 to p166 line 3

³⁸⁵ TRU 157737-TRU157782

³⁸⁶ TRA-11217 Day 86, p56, lines 7-13.

³⁸⁷ i.e., some recommendations distilled to more than one action.

November 2022, very shortly after the RQIA report was issued. At that stage, 9 actions were rated green, 13 were amber, and 3 were red.

- (b) TRU-183363–TRU183377- This (now 15-page) version of the same document shows the state of play by April 2023, approximately 6-7 months post-publication of the report. By that stage, 22 actions were rated green, 2 were amber, and 1 was red. This remains the position and is related to the fact that the lookback has not yet concluded.

(f) Getting it Right First Time ('GIRFT')

7.23 The October 2023 *'Getting It Right First Time - Urology across Northern Ireland'* Report can be found at TRU-320188, and its general recommendations at TRU-320193 to 320195 and its Southern Trust specific recommendations at TRU-320218 to 320220.

7.24 The GIRFT report is enlightening because it gives the Inquiry some potential insight into how the Trust's Urology Service compares with others in Northern Ireland. As we have done in the other chapters, we highlight this as a potential important point of context. Of potential note in this regard are a number of features including:

- a. The recruitment issues that are apparent in the Trust compared to its comparators – see the table at TRU-320200;
- b. The impressive array of services performed by CNSs in the Trust compared to other NI Trusts – see the table at TRU-320201;
- c. The waiting time averages across the Trusts – see the table at TRU-320202;
- d. The breadth of stone services the Trust offers – see the table at TRU-320213.

7.25 In the family of reports and reviews yielding up recommendations to the Trust, GIRFT is a mere youth, having reported only in October 2023. Nonetheless, the Trust have been actively implementing the recommendations and, even at November 2023, it is clear that substantial progress had been made with 33% of recommendations ‘in the green’ – see in this regard the TRU-320313 to TRU-320331.

7.26 By 6 March 2024 the updated Action Plan updated (at TRU-306468) 39% of the recommendations had been implemented.

7.27 The impact of the GIRFT report was described in detailed terms by Mark Haynes in his evidence on Day 88³⁸⁸. He described how it was ‘broadly welcomed’³⁸⁹ that ‘it supported the direction of travel we wanted to go’³⁹⁰ and that GIRFT is led by clinicians and supported by the urology team in the Trust³⁹¹. Again, by way of potentially important context, and as fairly noted by Mr Wolfe KC in his questioning of Mr Haynes, the GIRFT report recognises the decade long deterioration of urology services in NI and how it is underrepresented in terms of urologists per head of population³⁹².

(g) Trust Board Reform

7.28 Eileen Mullan, who has been a non-executive director on the Trust Board from 2016 and Board Chair since December 2020 has provided quite a bit of written and oral evidence charting improvements at the level of the Trust Board and its committees. This can be found in her witness statement from WIT-100434 to WIT-100568 and in the transcript of her evidence on Days 77 and 78 from TRA-09938 to TRA-10190.

³⁸⁸ TRA-11493 Transcript page 123, TRA-11496 p 126, TRA-11500 p130 line 17 – p137 line 5

³⁸⁹ TRA-11501 Transcript p131 line 12

³⁹⁰ TRA-11504 Transcript p134 lines 23-24

³⁹¹ TRA-11505 Transcript p135 lines 11-14

³⁹² TRA-11505 Transcript p135 line 28 to p136 line 20

7.29 A non-exhaustive list of examples of improvements and reforms covered by Ms Mullan in her detailed witness statement include the following:

- a. Ms Mullan, who was still a NED when the Champion Review was commissioned has provided evidence on the outworkings of the Review at WIT-100462 to 100464.
- b. On the issue culture, she has described initiatives taken by her to encourage an 'open, honest and psychologically safe environment' (WIT-100466 at para 15.7).
- c. She has described improvements in reporting from committees to Trust Board which she has initiated (WIT-100475 para 18.8) and in developing a Trust Risk Appetite Statement (WIT-100479 para 21.5).

7.30 In her oral evidence on Day 77, Ms Mullan provided multiple examples of improvement at Board level. Some examples include the following:

- a. She was asked to look at the Terms of Reference of the Governance Committee and what she then knew about the evidence, and she indicated that the Governance Committee was not provided with the information in light of what we know now, through the Inquiry³⁹³. She went on to indicate that the Governance Committee's Terms of Reference would now be satisfied by the way in which information is brought to the committee. She referred to being at a changeover in relation to what comes to the Governance Committee and how it is coming. In particular, she referred to a requirement now that Committee Chairs in their reports to Trust Board detail escalation, meaning that the Committee Chair must take ownership of what the committee is escalating or not escalating³⁹⁴.

³⁹³ TRA- 09953- TRA 09954 Transcript Day 77 p16-17

³⁹⁴ TRA-09955- TRA09956 p18-19

- b. She referred to a layer of oversight now present which wasn't previously when asked about the Board or the Governance Committee having any involvement in the outworking of SAI recommendations and ensuring themes of governance that might emerge are dealt with, referring to an action plan being expected and follow up to the Board or the Committee in relation to progress³⁹⁵.
- c. She also addressed the Trust's new process of reporting from MHPS to the Governance Committee, referring to a synopsis of the issues and details of any out-workings and updates which now provides Board visibility into any MHPS processes underway in the Trust.³⁹⁶

7.31 In her evidence on Day 78, she provided further examples of improvement including:

- a. In relation to separate processes of MHPS, Appraisal, and SAI, and to the joining up of intelligence, she gave evidence about how different things are now.³⁹⁷
- b. She referred to improvements in reporting aspects of clinical and social care governance including the Champion Review, clinical audit, and unified governance leads.³⁹⁸
- c. She addressed the learning from a Board governance perspective at WIT-100557 and, in her evidence³⁹⁹, addressed the issue of culture and her efforts to demystify what the Board is, to take away any view that the Board is a secret place, and to open it up, given its importance to what happens in the hospital.

³⁹⁵ TRA-09975 p38

³⁹⁶ TRA-10060- TRA10061 p123-124

³⁹⁷ TRA-10106- TRA 10107 Transcript Day 78, p4-5

³⁹⁸ TRA- 10110 Day 78, page 8

³⁹⁹ From TRA- 10125, page 23

- d. She gave evidence about the positive changes made to the committees of the Trust Board.⁴⁰⁰
- e. She spoke about the challenge of, and her efforts in, trying to shift the culture of the leadership walk from one of inspection to one about getting a real sense and feel for what is going on in the unit and to bringing the Board closer to the teams.⁴⁰¹
- f. When asked by Dr. Swart what was the most significant improvement that she has been able to make and what she still thought needed to be done she responded as follows:

'I think it's making the Board a collective, responsible Board together. I think that has been achieved in the last three years. My worry list would include having the resources and capacity to deliver and what we need to do to really transform Health and Social Care for the Southern Trust but to effect the changes so that patient safety issues and concerns no longer exist'.⁴⁰²

- g. She was also asked by Dr. Swart about lessons learned, whether the right people go to meetings now, whether that is working, and whether she had got to the stage of presenting thematic learning to the full Board for the year and what had been changed. She answered:

'I'll take the last one first. We are not there yet, we are not there yet. The outworkings of the Champion review, the operation of governance layer that has been put in place, we are only starting there in terms of that feeding through. My aspiration is it will do just that, it will do just that. But I am hoping over the course of this incoming year we will see that bed in, the committee bedding it in and the teams then certainly being able to feed up what needs to be the focus of attention for the committee and the areas of

⁴⁰⁰ TRA- 10133, p31

⁴⁰¹ TRA-10157, p55

⁴⁰² TRA- 10162-TRA-10163, Transcript Day 78, p60-61

*concern and risk. I do get a sense, though, listening to our Directors, because they are a few months ahead of us in terms of their delivery of the operation, that they are being exposed to more than they have ever been exposed and they are unpacking things more than they unpacked before. I am getting a sense that there is a real visibility for them across a broader piece and they are joining dots.'*⁴⁰³

- h. She also, in answer to questions from the Chair about recommendations the Inquiry might make, gave evidence about the burden of work involved in implementing various extant Inquiry recommendations, the resource-consuming nature of that, and her desire to see Trusts supported to deliver that implementation rather than having to place the burden on existing employees with 'already very demanding and difficult jobs'.⁴⁰⁴

Conclusion

7.32 Then Trust hopes that the above overview and guide to some of the main improvement initiatives discussed in evidence before the Inquiry will assist the Inquiry in navigating the broad expanse of evidence that is now before it on the issue of improvements and reforms undertaken by the Trust which should significantly reduce the risk of the problems of the past recurring.

⁴⁰³ TRA-10164, p62

⁴⁰⁴ TRA-10184-TRA-10185 p82-83

Chapter 8

The Impact of Our Failings

8.1 Mr Wolfe KC rightly emphasised, at the very outset of the Inquiry's hearings, that, 'while the Inquiry will be anxious to learn of and understand the patients' clinical experience, it is not the function of this Inquiry to make findings about the clinical outcomes in individual cases'⁴⁰⁵.

8.2 The Inquiry has, of course, examined some individual cases very closely but this has primarily been in the realm of cases which were, or which ought to have been, SAIs and this examination has taken place, not so as to enable findings to be made about individual patient outcomes, but to enable the Inquiry to reach an informed decision about the governance of patient care and safety in the Trust's urology specialty (in discharge of its obligations under Terms of Reference (c)).

8.3 One outworking of this has been that the SAIs, in particular (but not exclusively) those in respect of Patients 10-15 and those undertaken by Dr Hughes, have received a substantial amount of attention and their facts are therefore well-known to the Inquiry.

8.4 Cognisant, however, of the Inquiry's important public role and, in particular, its purpose of restoring public confidence, the Trust considered it appropriate in this submission to point the Inquiry to some of the broader evidence, beyond the SAI Review Reports, that addresses the question of the impact upon patients of the issues which the Inquiry is investigating. In the circumstances, this chapter will briefly address the following issues:

- a. The Lookback Review (and related SCRR process) undertaken by the Trust in respect of Mr O'Brien's patients;

⁴⁰⁵ TRA-00011 lines 17-20.

- b. The Royal College of Surgeons Invited Review;
- c. The BCG Audit undertaken by Mr Haynes;
- d. The Bicalutamide Audit undertaken by Mr Haynes.

(a) Urology Lookback Review

8.5 Details of this Review and the related SCRR process can be found in a number of places in the evidence provided to the Inquiry to date including in:

- a. the amended Section 21 witness statements No.1 of 2022⁴⁰⁶ and No. 1A of 2022⁴⁰⁷ of Maria O’Kane, both of 13 May 2022; and
- b. in the *Urology Lookback Review Activity and Interim Outcomes Report Cohort 1* of 9 August 2023 ⁴⁰⁸.

8.6 The details of the Cohort 2 portion of the Review have not yet been put into a formal report. When they have been, the report will be promptly shared with the Inquiry. The details in respect of Cohort 2 that have been factored into the paragraphs below emanate from the current draft ‘*Southern Trust Urology Lookback Review Activity and Outcomes Report for Cohort 2*’ (which includes a summary of the Cohort 1 and Cohort 2 outcomes combined)⁴⁰⁹ and are included so as to provide, at the date of these submissions, the most up-to-date picture possible.

8.7 The first cohort of the Lookback covered the period 1 January 2019 to 30 June 2020 and involved all of Mr O’Brien’s patients during that time. It amounted to a total of 2112 patients.

8.8 The second cohort covered the periods 1 April 2010 to 31 December 2018 in respect of patients diagnosed with a urological cancer and 1 April 2013 to 31 December 2018 in respect of renal stone disease patients. These two groups of patients were

⁴⁰⁶ WIT-20070

⁴⁰⁷ WIT-20108

⁴⁰⁸ TRU-305965 to 305991

⁴⁰⁹ It is anticipated this will form part of the June upload of disclosure to the Inquiry.

identified because experience of the Trust with Cohort 1 was that certain patient groups were more likely to have the potential to require a change in their management plans. In addition to the above 2 groups, Cohort 2 also any patient who, at the time of its commencement in 2023, continued to have an “open episode” under the care of Mr O’Brien (i.e., was at that time on an outpatient review waiting list and / or on a waiting list for a procedure) and who was not already included in one of the above 2 groups. It was also open to any private patient of Mr O’Brien who had any concerns about their clinical management. Unlike Cohort 1, Cohort 2 covered only patients who were alive because the primary focus of the Lookback Review was to establish if patients were on a secure clinical pathway and, if not, to remedy that error.

8.9 Certain cases (albeit not all cases⁴¹⁰) in Cohort 1 that met the threshold for an SAI went on to be considered through the SCRR process.

8.10 Across Cohorts 1 and 2, the outcome can be summarised as follows:

- a. A total of 2302 patients (2112 in Cohort 1 and 190 in Cohort 2) have had their treatment and care reviewed. There are currently no remaining patients in either Cohort left to be reviewed.
- b. There were no concerns in respect of 1810 Patients.
- c. Concerns, both clinical and non-clinical, were identified in respect of 492 patients.
- d. 543 patients were seen in a recall clinic. The reason this number is larger than the 492 patients in respect of whom there were concerns is because it was

⁴¹⁰ From 7 March 2023 onwards, only case that met the SAI threshold and disclosed some new learning point (i.e., one not already raised in one or more of the cases already processed for SCRR) went on for SCRR.

decided that any 'no concerns' patient who had cancer would still be seen at a clinic. These no concern cancer patients numbered 51.

- e. 353 of the 543 patients required a change in their treatment at care. The categories of these changes were treatment, medication, referral, and diagnostics. Many of these changes were relatively minor. Only 1 of the 353 was in Cohort 2.
- f. However, 163 of the 543 patients met the SAI threshold. 141 were from Cohort 1 and 22 from Cohort 2.
- g. 78 of the 163 cases were considered in SCRR. The detailed outcomes are beyond the scope of this chapter but the themes (in terms of patient impact) and clinical learning can be themed as follows:
 - i. Delays or absence of reports/ investigations;
 - ii. Lack of / poor communication;
 - iii. Incorrect treatment;
 - iv. Un-actioned MDM outcomes including onward referrals and planned reviews;
 - v. Delays / omissions in triage;
 - vi. Not following up on / actioning outcomes of diagnostic scans;
 - vii. Prolonged use of intravenous antibiotics;
 - viii. Practice in relation to operative procedures, including the removal of stents and gaining consent;
 - ix. Prescription of unlicensed medication as an incorrect form of treatment;
 - x. Not utilising / referring to the Cancer Nurse Specialists for support and nurse-led interventions;
 - xi. Not providing patients with options and choice in relation to their treatment pathway (i.e., informed consent);
 - xii. Not following NICE guidelines.

8.11 The Cohort 2 Outcomes Report, referenced at para 8.6 above, is in draft and is being forwarded to the DOH-led Urology Assurance Group for consideration. The Trust hopes to publish this report, once finalised, by the end of June 2024.

8.12 The Trust is currently conducting a review of the deceased patients who were under the care of Mr O'Brien during the period 2010 – 2018 and who would have been included in Cohort 2 had they been alive (para 8.8 above refers). Once complete, the Trust intends to produce a composite report which will capture all of the clinical learning that has emerged from this entire lookback exercise.

(b) The Royal College of Surgeons Invited Review

8.13 On 9 November 2020, Dr O'Kane, then Medical Director of the Trust, asked the Chair of the RCS Invited Review Mechanism (IRM) to perform an invited clinical record review of some cases of Mr O'Brien's.

8.14 The review team were to consider 100 patients from the period January and December 2015. Their terms of reference asked them to consider the standard of care with specific reference to a number of (now familiar) issues including, for example, communication with patients (including patient consent), follow up action including onward referral, and completeness of patient records in respect of episodes of care. They were to identify if harm had occurred and any patients who may require follow up⁴¹¹.

8.15 The RCS Review Team began their work in April 2021 and reported on 29 September 2022⁴¹². In his opening speech to this Inquiry, Martin Wolfe KC stated that: *'The Inquiry may take the view that the Trust cannot be blamed for the delays on the part of the Royal College ... often thorough and comprehensive work is beset by unavoidable and unanticipated delays.'*⁴¹³

⁴¹¹ Section 2 of the Report.

⁴¹² TRU-345848-TRU-345965

⁴¹³ Day 7, Page 101, lines 16-26

8.16 The RCS team, for reasons they explain in their report, ultimately reviewed 96, rather than 100, patients' notes⁴¹⁴. Some of the points emerging from the review were as follows:

- a. The review team identified multiple areas for improvement.
- b. They identified concerns in multiple cases on issues such as investigations (e.g., failing or delaying in obtaining them and in acting upon them)⁴¹⁵, team working⁴¹⁶, follow-up action on patient care⁴¹⁷, completeness of patient notes⁴¹⁸.
- c. They identified significant concerns in several cases in areas such as assessment of patients⁴¹⁹, treatment (e.g., in respect of the prescription of Bicalutamide and delayed surgery)⁴²⁰, and communication (e.g., in respect of consent)⁴²¹.
- d. The review team did not consider there to be significant concerns arising in respect of patient harm in 90 of the 96 cases reviewed. Their view was that clinical management of these patients was acceptable and had led to no harm⁴²².
- e. In 3 cases the patients' care was deemed unacceptable and, as a consequence, these patients' standard of care was of concern⁴²³.

⁴¹⁴ Section 3.

⁴¹⁵ Section 3.2

⁴¹⁶ 3.6

⁴¹⁷ 3.7

⁴¹⁸ 3.9

⁴¹⁹ 3.1

⁴²⁰ 3.3

⁴²¹ 3.5

⁴²² 3.10

⁴²³ 3.10

- f. 7 out of 96 cases were identified as requiring clinical follow up to ensure patient safety (although the team acknowledged that some of these 7 may, by the time of the report, actually have been followed up)⁴²⁴.

8.17 The Inquiry may feel it can reasonably conclude that the RCS Invited Review provided important assurance to the Trust (and to the public) because it identified issues the Trust were aware of through their own identification of issues with Mr O'Brien's practice and Lookback Review. Many of the recommendations mirror recommendations in processes such as SAI Reviews relating to a number of cases. Maria O'Kane acknowledged this in her evidence⁴²⁵:

'I think one of the things that stands out for me is that the work that was undertaken by the Royal College of Surgeons, and they reported on 96 patients over a period of time, I think it was in and around 2010 to 2015, triangulates the findings that we had discovered in relation to our own lookback review in cohorts 1 and 2. So in terms of adding assurance to the robustness of our process, I thought that was helpful, because essentially they had similar findings, and I think there is certainly an overlap in terms of approach to the outworking's of, you know, what has come out of the nine Hughes's SAIs, you know, what we've learned in terms of our own internal lookback process and then what has resulted from the Royal College of Surgeons document.'

(c) BCG Audit

8.18 On 17 August 2022⁴²⁶ the Chair of the Public Inquiry wrote to the Trust identifying a patient safety issue arising from the Section 21 witness statement of Mr David Connolly (received by the Inquiry on 11 August) which the Chair asked the Trust to investigate. It arose out of the following portion of Mr Connolly's statement⁴²⁷: *"Similarly, he [Mr O'Brien] did not like using intravesical BCG therapy for high-risk non-muscle invasive bladder cancer and preferred Mitomycin therapy"*.

⁴²⁴ 3.12.

⁴²⁵ TRA-11767-TRA-11768

⁴²⁶ TRU-309777-TRU-209778

⁴²⁷ WIT-41996 para 70.3

8.19 On 30 August 2022⁴²⁸ the Chief Executive, Dr O’Kane, indicated that the Trust would carry out an audit, which was duly carried out by Mr Haynes.

8.20 In his report on the audit⁴²⁹, Mr Haynes describes how they investigated patients in the Lookback cohort plus patients first diagnosed with *high risk non muscle invasive bladder cancer* during the 2012-2013 and 2013-2014 financial years (as Mr Connolly worked in the Trust from September 2012 to March 2013). He also recorded an important point of context, viz, that there have been times in the past when the supply of BCG has been problematic and that this has, on occasions, had a bearing on the treatment available to patients.

8.21 While the data set for the twenty-seven 2012-2014 patients lacked some information in a few cases (e.g., clinical justifications were missing from some patient notes), Mr O’Brien was not deemed to be an outlier in any respect and Mr Haynes was able to conclude as follows:

From the data collected over this time period there is therefore no evidence that patients under the care of Mr O’Brien during this time period were less likely to be offered BCG in the management of their high risk non muscle invasive bladder cancer than patients under the care of the rest of the urology team.

(d) Bicalutamide Audit

8.22 In October 2020, Mark Haynes conducted a ‘rapid review’⁴³⁰ of patients receiving Bicalutamide in the management of their prostate cancer. The purpose of the review was to identify if those patients required change to their prostate cancer management, in light of the patient safety concerns raised relating to Mr O’Brien’s prescribing of 50mg Bicalutamide. In a letter to the GMC dated 21

⁴²⁸ TRU-309779 to TRU-309782.

⁴²⁹ TRU-320011 to 320015 plus attached documents from TRU-320016 to 320185.

⁴³⁰ TRU-346161

October 2022⁴³¹, Mr Haynes stated: *'The purpose of the review was simply to identify patients who required clinical review as a matter of urgency in order to consider their ongoing prostate cancer care.'* The review covered patients receiving both Bicalutamide 50mg and 150mg prescriptions during the period between March 2020 and August 2020, as this cohort of patients were most likely to be still receiving the treatment and potentially be in need of change. He describes reviewing 764 patients records on NIECR.⁴³²

8.23 Mr Haynes discussed the parameter of the review in evidence on Day 88:

*"What I've done is look at all 764 patients in them Trust areas which included all consultants in the Southern Trust and also included patients who were under the care of urologists in the Western Trust, so the Altnagelvin team; also included patients in the Northern Trust which covered some of the Altnagelvin team. So there were patients who were under the care of all Southern Trust consultants, under a number of consultants from other Trusts, and patients who were under the care of oncology teams. So that piece of work was not limited to Aidan O'Brien, but that was not the Lookback Review. That piece of work to identify patients who needed a change in their treatment."*⁴³³

8.24 The outcome of the review is detailed by Maria O'Kane⁴³⁴ and is referred to in detail at paragraph 5.9 above. In summation, a total of 466 patients were identified from the Western, Northern, and Southern Trust areas as having received a prescription for Bicalutamide 50mg. Of these, 34 were identified as not meeting the recognised indications and 31 of these patients had been commenced on Bicalutamide 50mg by Mr O'Brien.⁴³⁵ The management of the patients concerned was reviewed accordingly and corrected.

⁴³¹ TRU-346161

⁴³² TRU-346162

⁴³³ TRA-11400-TRA-11401

⁴³⁴ As referred to by Dr. O'Kane at WIT-20089 in response to Section 21 Notice 1a of 2022.

⁴³⁵ See above, paragraph 5.9 for detail relating to these patients and Transcript Day 88, Page 31, line 23-29, Page 32, lines 1-6

Conclusion

8.25 These different lookback exercises (save for the BCG Audit) demonstrate that shortcomings in the practice of Mr O'Brien and in the management and systems of the Trust have had an impact on many patients' care, albeit that, fortunately, the impact appears to have been of potential significance in only a small percentage of cases.

8.26 It is believed that all of these exercises should provide significant reassurance to the public, to the Inquiry, and to the Trust because, where issues need to be addressed, these exercises have identified them clearly, thereby enabling the Trust to address them.

Chapter 9

Conclusion

9.1 The Trust is very grateful to the Inquiry for having considered this written closing which has undoubtedly already gone on for longer than is optimal.

9.2 This closing chapter is not intended to rehearse or summarise all that has gone before. The Inquiry will, by this point, have considered not only the preceding pages but also the voluminous documentary evidence placed before it over the last 2-plus years.

9.3 More importantly, the Inquiry has had the enormous benefit of receiving detailed testimony from the many witnesses who were at the heart of the failures the Inquiry is considering and/or who have been involved in the substantial improvement efforts aimed at ensuring such failures never recur.

9.4 In this particular regard, and focusing (as these submissions must) on the current and former servants or agents of the Trust who have provided evidence to the Inquiry, we submit that the following points should not be controversial:

- a. These witnesses are or have been hardworking, diligent public servants.
- b. Many have been truly impressive.
- c. They have all demonstrated their desire to assist the Inquiry by putting large amounts of thought, care, time, and effort into their engagement with the Inquiry, whether that be in their written statements, in their consultations with Inquiry Counsel (and their preparation for same) or in their oral evidence (and their preparation for same), all of which can be very stressful. Many have been in the witness box for more than a day.

9.5 Almost every Trust witness has acknowledged that opportunities were missed by them and others or that mistakes were made. There was broad consensus that things could, and often should, have been done better across multiple areas and that many of the Trust's systems simply were not good enough.

9.6 When witnesses have acknowledged missed opportunities or mistakes, on their own part and/or in respect of others, it is important also to acknowledge that such shortcomings are almost never the result of the relevant person simply being careless in how they go about their work. Indeed, it is clear that many of the witnesses frequently went beyond the call of duty in the workplace (as Mr Wolfe KC very fairly acknowledged in his opening) and that many of them exist and operate at a level of concentration and precision in their work that may be foreign to many of us.

9.7 Looking back, and as the analysis in chapters 4 to 6 (as well as the various lookback and review exercises considered at chapter 8) hopefully shows, it is clear that the causes of the Trust's failings were multifactorial. They range from:

- a. cultural issues, e.g., in respect of a reluctance to challenge a consultant of Mr O'Brien's standing or in respect of an apparent paralysis in some managers, rooted in their perception that their remedial options were strictly binary: either a very informal prompt or a very formal MHPS process;

to

- b. systems failures in the Trust's clinical and social care governance structure, e.g., in the field of the reporting, coordinating, screening, and (if appropriate for SAI review) reviewing adverse incidents;

to

- c. management failings, e.g., in the coordination of information about the extent to which Mr O'Brien was deficient in multiple areas of his practice and the need to consider his practice more broadly;

to

- d. factors which, often to a large degree, are beyond the Trust's control, related to: resource constraints, increasing service demand, and the resulting capacity:demand mismatch (with the attendant impact upon the workload and busyness of clinicians, managers, administrative, and support staff).

9.8 Together, these failings created a situation where:

- a. known and unknown issues with a clinician grew and worsened; and
- b. colleagues and managers had either little or no time, and/or no obvious facility, to enable them to 'stand back and look' and assess the threat posed to patient safety by this doctor.

9.9 When referencing the opportunity for Core participants to file written closing submissions, the Chair rightly reminded those before the Inquiry of the importance of its Terms of Reference ('ToR'). Turning to them now, and recasting the Terms as questions, they perhaps reduce to the following relatively straightforward questions, with the following relatively straightforward answers (in light of all that has been said in the preceding chapters of this Submission):

- a. *ToR (a)* –

Q: Were there concerns or circumstances which should have alerted the Southern Trust to instigate an earlier and more thorough investigation into Mr O'Brien's practice at an earlier stage?

A: Yes.

b. *ToRs (b) and (c)* –

Q: Were the corporate and clinical governance procedures and arrangements within the Trust at the time adequate?

A: No.

c. *ToR (d)* –

Q: Were the experiences of patients what they ought to have been?

A: No.

d. *ToR (e)* –

Q: Was the MHPS process or its application an effective tool in addressing the issues with Mr O'Brien?

A: No.

9.10 Fortunately, the above distillation is not an end to the matters being considered by the Inquiry and it is hopefully clear to both the Inquiry and to the public that very substantial work⁴³⁶ has already been undertaken by the Trust to improve in all of the areas where it has been exposed as deficient, some of which was commenced before this public inquiry was announced.

9.11 Of course, securing and protecting patient safety must, in the world of health care, necessarily always be a journey rather than a destination. As the authors of the July 2019 NHS England *'Patient Safety Strategy - Safer Culture, Safer Systems, Safer Patients'*⁴³⁷, observe: *'Safety is not an absolute concept and has neither a single objective measure nor a defined end point'*. The Trust is acutely conscious of this and, from a very practical perspective relevant to the Inquiry, it necessarily means that the state of the Trust's improvement initiatives will be different now than it was when the last Trust witness (Dr O'Kane) gave oral evidence in March 2024, and it will be different again by the end of this year, and by the time the Inquiry is

⁴³⁶ Some of which improvement work has been addressed in chapters 4, 5, 6, and 7.

⁴³⁷ https://www.england.nhs.uk/wp-content/uploads/2020/08/190708_Patient_Safety_Strategy_for_website_v4.pdf

readying its Report for publication. Thus, there is a need for the Trust to continue to keep the Inquiry informed, in whatever manner the Inquiry would prefer, of the improvement journey, so that the Inquiry and the public can be assured that past mistakes are much less likely ever to be repeated, thereby restoring public confidence.

9.12 Finally, the Trust wishes to acknowledge and express its gratitude for the hard work, dedication, and patience of the Inquiry Panel, Counsel, Solicitors, and Staff. The Inquiry's close, forensic examination of working practices, procedures, and systems in the Trust has (as alluded to above) not always been a comfortable experience for those who have had to provide written and/or oral evidence, nor should it be. But it has necessarily provoked reflection and change within the Trust. The Trust recognises that the Inquiry has sought to be fair to all those from whom it has heard. No doubt the Inquiry will continue to exercise fairness to Core Participants and witnesses in the way it has done to date and, in the event that it is considering making any significant criticism of them, will afford them the opportunity to respond to such criticism before its report is finalised and published.

9.13 The Trust remains ready to assist the Inquiry in its important task and looks forward to the Report of the Inquiry in due course.

31st May 2024

Avril Frizell LL.B.

Emmet Fox LL.B.

Donal Lunny KC

Jonathan Park BL

Michael McGarvey BL

Elizabeth Ferguson BL

Samantha Madden BL

Alana Harty BL

1 THE INQUIRY RESUMED ON THURSDAY, 13TH JUNE 2024
2 AS FOLLOWS:

3
4 CHAIR: Good morning, everyone, it's a very full house
5 today, and welcome back, those of you who I haven't 10:02
6 seen for a while. Mr. Lunny, I've seen you.

7
8 CLOSING SUBMISSION BY MR. LUNNY:

9
10 MR. LUNNY: Good morning, Chair, good morning, 10:02
11 Dr. Swart, and good morning, Mr. Hanbury.

12
13 The Southern Health and Social Care Trust is very
14 grateful for the opportunity to make a short oral
15 closing, because we recognise, having regard to your 10:02
16 procedural protocol, that the making of any form of
17 closing is not something we have a right do.

18
19 As you're aware, the Trust, for whom I appear, is the
20 independent legal entity that came into existence on 10:03
21 1st April 2007 under the Southern Health and Social
22 Care Trust (Establishment) Order (Northern Ireland)
23 2006, but it is also its staff, because when the Trust
24 interacts with its patients, it does so through its
25 nurses, its doctors, its secretaries and its other 10:03
26 staff, and as Mr. Haynes put it on Day 14 of the
27 Inquiry's hearings, and I quote: "We are the Trust".

28
29 In terms of managing your expectations this morning,

1 and as we did at the start of our oral opening
2 statement, it's important that I outline to you what
3 this closing is not. It is not, you will be grateful
4 to hear, an attempt to summarise all the evidence heard
5 by you or all the evidence given by Trust witnesses or 10:04
6 even our written closing. You have all of those, and
7 you will undoubtedly assess them carefully,
8 comprehensively and fairly, and you'll reach your
9 conclusions in due course.

10
11 It is also not a Defence - with a capital D - nor an
12 attempt to shift blame or responsibility onto others
13 and it is not aimed at some other audience like the GMC
14 or the media. Rather, it is addressed to you, Chair
15 and Panel, and to those whom you represent through this 10:04
16 Inquiry, the public, and, it is an attempt to say or,
17 perhaps more accurately, to repeat, a small number of
18 things, things that the Trust considers to be
19 important, and those things are, in summary, first and
20 fundamentally, we are sorry. 10:05

21
22 Second, we believe that we have engaged cooperatively,
23 collaboratively and in the correct spirit with the
24 Inquiry.

25
26 Third, we have recognised and reflected upon our
27 failings and we have engaged meaningfully with the
28 issues being examined by the Inquiry, viewing them more
29 as a positive opportunity rather than a negative

1 challenge.

2
3 And fourth, finally, and perhaps most importantly of
4 all, we have improved.

5
6 I'll now deal with each one of those four topics
7 briefly and in turn.

8
9 So, first, we are sorry. The Trust, as you are aware,
10 apologised at the very outset of your public hearings. 10:05
11 We did not wait until the end of those hearings to do
12 so. We said, in quite some detail across what
13 ultimately became more than six pages of your
14 transcript, that we are sincerely sorry for our
15 failings and for the harm that has resulted. We did 10:06
16 not mince our words, we did not offer a pseudo-apology,
17 we did not use the passive voice or phrases like "it is
18 regrettable". Our apology, given at the outset of the
19 hearings, has been repeated and endorsed by several of
20 our witnesses, most notably by the Chief Executive of 10:06
21 the Trust, Dr. Maria O'Kane, on her very first day in
22 the witness box, on Day 15, and by the Chair of the
23 Trust Board, Eileen Mullan, on her first day in the
24 witness box on Day 77.

25
26 I don't propose to repeat verbatim the apology I gave
27 at the outset, but it can be found at TRA-00641 to
28 TRA-00647, but I will, if you will allow me, attempt to
29 distil it to its essence. 10:07

1
2 The Trust apologises to affected patients and their
3 families, because, ultimately, it is the patients whom
4 each of the Trust and this Inquiry serves; to the
5 broader public and to its staff, many of whom do, as 10:07
6 Mr. Wolfe KC very fairly acknowledged in his opening on
7 Day 6, "every day go beyond the call of duty".

8
9 The Trust apologises for the fact that the care given
10 by it to a number of patients fell below what was 10:08
11 acceptable and that, in some cases, this will have
12 caused or contributed to harm. The Trust also
13 apologises for the fact that this substandard care was
14 the result not only of failings on the part of
15 individuals for whom the Trust is responsible, but also 10:08
16 of broader, more fundamental failings in the Trust's
17 systems, The Trust's processes and its structures in
18 areas of management and clinical and social care
19 governance.

20 10:08
21 As was the case back on Day 8 when I offered the
22 detailed public apology, both Dr. O'Kane and
23 Mrs. Mullan were present, and they are here again in
24 the chamber today and, by their presence, they again
25 endorse the apology that I make. As you know, both 10:08
26 Dr. O'Kane and Mrs. Mullan have been present on other
27 days during the life of the Inquiry. They have both
28 provided evidence themselves and participated very
29 significantly in the Inquiry. Their written answers to

1 the questions posed by the Inquiry across a number of
2 Section 21 notices fill more than 500 pages, excluding
3 their exhibits, and, between them, they spent almost
4 six days in the witness box.

5
6 Finally, in relation to the 'we are sorry' theme, in
7 our opening I stated that the Trust's apology was
8 neither a token nor an empty apology. I acknowledged,
9 whilst the Chair had quite rightly highlighted that the
10 Inquiry cannot, because of Section 2 of the Inquiries 10:09
11 Act, determine the civil liability of the Trust in
12 respect of its treatment of any patient, the Trust,
13 nonetheless, wish to state openly, in respect of any
14 cases where harm had occurred that ought to have been
15 avoided, its clear commitment to meeting any resulting 10:10
16 claims in a timely way.

17
18 By way of an update and cognisant of that particular
19 commitment, I can confirm that, to date, 11 statements
20 of claim have been received and we have so far admitted 10:10
21 breach of duty in respect of most of them.

22
23 If I can turn now to the second point I identified, and
24 that's the question of our cooperation and
25 collaboration with the Inquiry. 10:10
26

27 Paragraph 44 of the Inquiry's procedural protocol of
28 October 2021 sets out in clear terms the Inquiry's
29 expectation that those engaging with it will adopt a

1 collaborative and cooperative approach. In your
2 opening of the Public Inquiry hearings on Day 6, Chair,
3 you made it clear what you expected in this regard.
4 You said at TRA-00293:

5
6 "It is our hope that all who were asked to help the
7 Inquiry in fulfilling its Terms of Reference, do so
8 frankly and openly and in a spirit of collaboration,
9 remembering that the entire raison d'etre for the
10 Inquiry is to help secure patient safety."

10:11

10:11

11
12 In our opening on Day 8, I indicated that the Trust
13 wished to reassure the Inquiry and the public of its
14 continued cooperation and, on the part of the Trust's
15 legal team, I assured the Inquiry of our commitment to
16 the two-way street of collaboration and cooperation
17 with the Inquiry's lawyers. We hope the Inquiry
18 considers that the Trust has lived up to those
19 commitments. In this regard, I can confirm that, as of
20 yesterday, 12th of June 2024, the Trust has disclosed
21 almost 415,000 pages of potentially relevant documents
22 to the Inquiry; it has provided, through witnesses whom
23 the Trust legal team represents, 158 Section 21
24 statements; the Trust has directly assisted, through
25 the legal team, 85 witnesses, 45 of whom were called to
26 give oral evidence across approximately 60 of the 92
27 days on which the Inquiry heard from witnesses; the
28 Trust has assisted, through the provision of documents,
29 a number of former Trust servants or agents who are not

10:11

10:12

10:12

1 represented by the Trust legal team, such as, for
2 example, Mrs. Gishkori; and the Trust has assisted
3 other staff who have been amongst the 200-plus nurses
4 and registrars who received questionnaires from the
5 Inquiry.

10:12

6
7 we also hope, Chair, that the Inquiry can see that the
8 Trust's witnesses have cooperated and collaborated
9 fully and, as I will come on to shortly in my third
10 topic, that they have attempted to meet the Chair's
11 expectation that witnesses would use the Inquiry as an
12 opportunity for reflection on what has occurred.

10:13

13
14 As you recognised, Chair, in your opening of the public
15 hearings on Day 6, engagement with a public inquiry can
16 be challenging for individuals. There are multiple
17 reasons for this, but, as lawyers who have acted in
18 different capacities in a number of public inquiries
19 over the years, there is always a risk that we will
20 overlook or underestimate those significant challenges
21 and stressors, and it's, therefore, if you will allow
22 me, important to remind ourselves and the public of
23 what some of those challenges and stressors are.

10:13

10:13

24
25 First, the context in which any public inquiry takes
26 place is usually an unhappy one. Some crisis or
27 catastrophe will have occurred, leading to an inquiry
28 being set up, and just as it is natural for people to
29 seek to avoid crisis and catastrophes, it is also

10:14

1 entirely natural to seek to avoid association with them
2 or to seek to avoid any reminders or reliving of them.

3
4 Second, a public inquiry inevitably means exposure to
5 forensic examination by lawyers, both in writing 10:14
6 through Section 21 notices and orally at hearings, as
7 well as focused questions from an eminent, experienced
8 and expert Chair and panel, interactions or events
9 that, at the time when they occurred, may have occupied
10 mere minutes during a hectic working day, can be the 10:15
11 subject of quite appropriate detailed questioning which
12 lasts exponentially longer than the interactions or
13 events themselves. Few, few of us welcome such levels
14 of scrutiny.

15 10:15
16 Third, a public inquiry's hearings take place in
17 public, and in the modern era, and in this jurisdiction
18 at least since the RHI Inquiry in 2017, this means that
19 a witness's oral evidence to an inquiry will be
20 live-streamed to as many members of the public as want 10:15
21 to watch it, with snippets being available for editors
22 to broadcast on the radio or TV news. Again, few
23 welcome such public exposure, but it is an entirely
24 necessary part of a modern public inquiry process and,
25 entirely separate from the Inquiry's ultimate report, 10:15
26 it does perform a vital role in discharging the
27 inquiry's accountability function.

28
29 Fourth, whilst those at the higher levels of any

1 organisation, such as directors, chief executives,
2 chairs of boards, may reasonably expect to have to
3 account publically for the organisation or for their
4 own actions or omissions, for example, before a public
5 meeting of a board or before a committee of the 10:16
6 Assembly, such an expectation does not attach to
7 employees like nurses and administrators, secretaries,
8 managers and doctors, and yet, most witnesses before an
9 inquiry like this one will be nurses, administrators,
10 secretaries, managers and doctors. 10:16

11
12 Fifth, a public inquiry may look into events that
13 occurred several years ago. For example, in this
14 Inquiry, we've spent quite significant portions of time
15 looking at issues relating to IV antibiotics and fluids 10:17
16 and cystectomies, all of which occurred between 10 and
17 15 years ago, and, of course, not every important human
18 interaction will be recorded in contemporaneous
19 documents. Even when such interactions are recorded,
20 the recording may be in summary form only, such as is 10:17
21 the case with minutes of meetings. So, public
22 inquiries can present significant memory challenges for
23 many witnesses.

24
25 Sixth and penultimately, many witnesses will have to 10:17
26 manage the challenges of a public inquiry whilst
27 holding down a demanding day job. This is particularly
28 true in respect of public inquiries in the healthcare
29 sector.

1
2 Seventh and finally, there is always the potential that
3 an inquiry will criticise a witness's actions or
4 omissions. Naturally, very few of us welcome
5 criticism, even less so the potential occupational or 10:18
6 professional consequences that might flow from it.
7 Many of the challenges I've just mentioned are
8 unavoidable. However, it's important that I
9 acknowledge that where it has been possible to
10 ameliorate them, the Inquiry has done so, whether that 10:18
11 be by way of granting extensions to witnesses in
12 respect of Section 21 statements or by attempting to
13 ensure that any potential hearing date suits a witness
14 or by affording clinician witnesses ample notice of
15 their hearing dates so that rotas could be managed to 10:18
16 ensure no patient was inconvenienced, or by getting
17 witness disclosure bundles issued earlier so as to
18 allow busy clinicians time to read them, or, finally,
19 by vacating a hearing date at short notice when tragic
20 events, in the form of a fatal road traffic accident, 10:19
21 affected some of those in the Urology service. For
22 these actions on the part of the Inquiry, the Trust
23 was, and remains, extremely grateful.

24
25 In spite of the various challenges, Trust witnesses 10:19
26 have engaged positively with the inquiry. In
27 particular, every single Trust witness from whom the
28 Inquiry has sought a Section 21 witness statement, has
29 provided one, indeed some have provided several

1 statements, and all have applied themselves to the task
2 of providing detailed, meaningful, considered answers
3 to the Inquiry's questions, and every single Trust
4 witness from whom the Inquiry wished to hear orally has
5 provided oral evidence to the Inquiry, even if it meant 10:20
6 returning, sometimes unexpectedly in the case of a few
7 of Mr. Wolfe's witnesses, for an additional day or days
8 in the witness box.

9
10 If I could move on then briefly to the third issue I 10:20
11 mentioned at the outset; namely, how the Trust and its
12 witnesses have recognised and reflected upon our
13 failings and engaged meaningfully with the issues being
14 examined by the Inquiry. This goes beyond the headline
15 statistics that I have just summarised of Trust 10:20
16 cooperation in terms of pages disclosed or statements
17 submitted or witnesses called, and relates really to
18 the quality and substance of the Trust and its
19 witnesses' engagement with the issues being
20 investigated by the Inquiry. 10:21

21
22 Again, on Day 6, in your opening of the public
23 hearings, Chair, you rightly encouraged those persons
24 and bodies with whom the Inquiry was engaging, to
25 reflect upon their relevant actions and omissions, and 10:21
26 the reference is TRA-00293. You said:

27
28 "We recognise that the Inquiry process is challenging
29 for everyone involved, but hope that those who are

1 involved see the Inquiry process in itself as an
2 opportunity for reflection on what has occurred and an
3 opportunity to correct mistakes that might have been
4 made."

10:21

6 We submit to you that our witnesses have been
7 appropriately reflective and they have been willing to
8 confront the spectre of their own shortcomings and
9 acknowledged them. There are numerous examples of this
10 throughout the evidence, throughout the landscape of
11 the written and oral evidence that lies before the
12 Inquiry, but by way of a few brief examples, we have
13 the following:

10:22

15 First, Mrs. Corrigan, who was Head of Service for
16 Urology, along with one, then two and then three other
17 specialities from 2009 to 2021, she recognised her
18 shortcomings in her very first witness statement to the
19 Inquiry, when she said:

10:22

21 "I will also acknowledge from the outset that there
22 have been failings on my part."

10:22

24 When, in her oral evidence on Day 57, she was asked by
25 Ms. McMahon KC:

10:22

27 "Do you feel that you made any mistakes?"

28
29 Mrs. Corrigan's characteristically frank response was:

1 "Oh, absolutely."

2
3 And you can find that at TRA-07406 from lines 4 to 6.

4
5 Second, we have Mr. Mackle, Associate Medical Director 10:23
6 with responsibility for Urology, in the period 2008 to
7 2016. He acknowledged his failure to view
8 Mr. O'Brien's repeated issue with triage as a serious
9 governance concern and acknowledged that a thorough
10 investigation ought to have been undertaken, and that's 10:23
11 at TRA-02176.

12
13 Third, Mr. Haynes, both in his Section 21 statement of
14 September 2022 and in his oral evidence on Day 10,
15 spoke of his personal regret that he didn't think that 10:23
16 a deeper look into Mr. O'Brien's practice was required
17 at the time of the MHPS investigation, and you can find
18 that both in his witness statement at paragraph 77.1
19 and his transcript from TRA-00853 onto 00854 and again
20 at 00862. 10:24

21
22 Finally, in this regard, Mr. Devlin, who was Chief
23 Executive of the Trust between 2018 and 2022, in the
24 context of the monitoring of Mr. O'Brien that went on
25 after the start of the MHPS process, Mr. Devlin 10:24
26 reflected on and apologised for the fact that they did
27 not poke, prod or probe Mr. O'Brien's practice further
28 and, therefore, failed to identify the issues that had
29 not been in plain sight but which came to a head in

1 2020. He acknowledged further the possibility that the
2 harm, or risk of harm, to the nine patients that became
3 SAIs under Dr. Hughes in 2020, may have been avoided
4 had this been done, and that's at TRA-01682.

5 These are but a handful of examples of many such 10:24
6 instances of sometimes difficult but entirely necessary
7 and appropriate and helpful self-reflection.

8
9 Looking beyond individual witnesses to the Trust
10 itself, you will recall that also on Day 6 of the 10:25
11 hearings, Mr. wolfe, in his opening statement to the
12 Inquiry, offered the following profound call or
13 challenge to all of those involved in the Inquiry:

14
15 "The conduct of a public inquiry such as this can act 10:25
16 as a watershed moment. If those who are to participate
17 are prepared to engage cooperatively, authentically and
18 in a spirit of openness and if they actively reflect
19 upon what they, as well as their colleagues, could have
20 done differently or better, there will be a genuine 10:25
21 opportunity to change healthcare provision in Northern
22 Ireland for the better."

23
24 At the very other end of the Inquiry, on Day 91,
25 superficially in answer to questions posed at that 10:26
26 point by Mr. wolfe but perhaps also in answer to the
27 broader call or challenge he laid down on Day 6,
28 Dr. O'Kane offered her reflection on the Trust's
29 Inquiry experience, and this is at TRA-11890, and I

1 preface this quote by giving you notice that I have
2 edited out of it, just for completeness' sake and for
3 clarity, I have edited out of it the verbal tick that
4 so many of us here suffer from, of filling pauses with
5 the phrase "you know". So, as I say, if you want to 10:26
6 read the full, unvarnished or unpolished transcript,
7 it's TRA-11890. And Dr. O'Kane said:

8
9 "But I honestly have to say that it has been helpful to
10 us in that, even though it has generated a huge amount 10:27
11 of work, I think it has made us think really carefully
12 about our business, about the work, the work that we do
13 and how we deliver it. I think it has helped us focus
14 on the importance of governance and what's located
15 within all of that. It has certainly given us the 10:27
16 opportunity, I think, to reach outside the organisation
17 in terms of really thinking about how things can be
18 done well, and certainly the colleagues from across the
19 rest of the UK have been hugely helpful in relation to
20 that and I think it probably has helped the 10:27
21 relationships within the Trust because we've had to
22 depend very heavily on each other and to really support
23 and understand the pressures that the clinical teams
24 have been under, particularly the Urology team, in
25 order to sustain this whole process. So, even though 10:27
26 it has taken effort and time and all of the usual
27 things, I do think, overall as a process, it has been
28 enormously helpful to us."
29

In response to a question about whether the Inquiry had, to date, led to clinicians adopting a defensive practice, Dr. O'Kane, at TRA-11892, replied as follows:

"I think we've tried to approach this as an opportunity for learning rather than defensiveness and hopefully that is borne out."

We certainly hope that it's apparent to the Inquiry, through all that it has seen and heard, and, in turn, that it is apparent, through the Inquiry to the public, that the Trust has actively approached both the issues examined by the Inquiry and the process itself more as opportunities than as challenges. In particular, in this regard, the Trust has viewed the Inquiry and the events giving rise to it as an opportunity to identify, reflect upon and be candid about its failings, an opportunity to learn from its failings and improve and an opportunity to change, in particular, culture. Some examples of this include, but are not limited to, the following three steps:

First, before any public inquiry was ever anticipated, indeed before all of the shortcomings, the Trust's shortcomings relating to or, perhaps more accurately, revealed through Mr. O'Brien, were even apparent, the Trust had recognised that there were significant shortcomings in its systems and had taken steps to address these. An exemplar of this is the

1 commissioning of the June Champion Clinical and Social
2 Care Governance Review in 2019, and that was
3 commissioned by the then-Chief Executive, Mr. Devlin,
4 and the then-Medical Director, Dr. O'Kane, each of whom
5 was, at that time, relatively new to the Trust. And I 10:30
6 will come on presently just to mention briefly some of
7 the reforms associated with that, that review, under
8 topic four.

9
10 Second, in 2019, the Trust began and has, during the 10:30
11 currency of the Inquiry, developed its engagement with
12 Mersey Care NHS Trust, which is a high-performing
13 English Trust, and this has been to assist in
14 developing what is known as a just and learning
15 culture, where staff, rather than feeling inhibited 10:30
16 about speaking up when they have concerns, are
17 supported to do so.

18
19 Third, in November 2022, the Trust set up an External
20 Reference Group, or ERG, chaired and populated by 10:30
21 experienced people from outside the Trust, along with
22 some senior Trust personnel, to assist the Chief
23 Executive and directors in their work to address the
24 shortcomings which the issues giving rise to the
25 Inquiry have exposed. The last of these, the External 10:31
26 Reference Group, may be considered to be of particular
27 note on the theme of critical self-reflection, because
28 it was entirely a Trust-initiated project at a time
29 when the Trust was already subject to a large amount of

scrutiny, not only by the Department, through The
Urology Assurance Group, but also by the Inquiry.

Mrs. Trouton explained the purpose of the ERG to
colleagues during 2023 as being:

10:31

"To fulfil the role of a critical friend by providing
independent challenge and support to the Chief
Executive and directors who were leading the Southern
Trust's improving organisational effectiveness
programme."

10:31

And the reference for that is TRU-303726.

Dr. O'Kane, in answer to questions from Mr. Wolfe,
described the ERG's origins and purpose in the
following terms at TRA-11629, and again I am editing
out the "you knows":

10:32

"I was particularly shocked by the fact that we'd had
this blind spot that we discovered in the summer of
2020 and I felt that the history in recent times in
relation to Mr. O'Brien and what had happened, was full
of blind spots and actually here was another one. And
I had been inadvertently complicit with it and that
troubled me, and I think that, on the basis of that, I
started to have conversations with people. I mean, it
resonated with some of the other members in SLT just in
relation to how we would take this forward. So, I

10:32

10:32

1 spoke broadly to trusted advisers around the system in
2 relation to, if you're faced with something like that,
3 how do you develop a reflective mirror for your own
4 organisation to spot things that you don't normally
5 see? Because there is a whole psychology of groupthink 10:33
6 and finding yourself repeating mistakes, and all of
7 that, inadvertently. So the advice I got back then was
8 to maybe think about bringing together a group of
9 experts, which I did."

10
11 And she then described the various external experts she
12 was able to secure to sit on the group.

13
14 She stated then at TRA-11632:

15
16 "That, I felt, gave us a really robust group of 10:33
17 experienced experts who wouldn't be frightened to
18 challenge us as a group in terms of some of our
19 thinking, had huge years of experience in the NHS and
20 understood it ultimately or intimately and had enough 10:33
21 distance from the system at this point in time to be
22 able to see us a bit more clearly than we could see
23 ourselves."

24
25 And the Inquiry has seen some of the outworkings of the 10:34
26 ERG in the evidence and in the documents, including the
27 documents periodically produced by the ethicist Vryan
28 Richards, who listened to our Inquiry hearings, who
29 identified themes under headings like leadership and

1 governance, quality and patient safety, culture and
2 behaviour, and then provided feedback and posed
3 challenging questions to the Trust, some of which
4 Dr. O'Kane, in her oral evidence, very frankly
5 described as being hard for the Trust to hear, and 10:34
6 again, the reference for that is TRA-11909.

7
8 One example of a positive change borne out of the ERG
9 through the involvement of colleagues from NHS
10 Improvement Scotland, has been the increasing use by 10:34
11 the Trust of the Scottish analytical framework, what I
12 think Dr. O'Kane, in her evidence, described as the
13 "Scottish heat map", and this has been used now across
14 all directorates in the Trust. This framework is used
15 to keep an eye out for early warning signs of 10:35
16 deterioration in systems and processes which may lead
17 to patient harm if not identified and remedied. In the
18 context of the sorts of issues the Inquiry has been
19 considering, this tool reduces the likelihood of there
20 being blind spots and it increases the ability of the 10:35
21 Trust to join the dots and, therefore, to intervene to
22 address issues at an earlier stage, and I am instructed
23 this has already been found to be helpful in both
24 mental health services and laboratory services.

25 10:35
26 So, in light of these and many other initiatives, we
27 submit that the Trust could not reasonably be accused
28 of sitting back and waiting for the Inquiry to tell it
29 what to do or how to change; rather, the Trust has

1 embraced the opportunity for self-improvement
2 identified in both the Chair and in Mr. Wolfe's opening
3 remarks.

4
5 This takes me on then to the fourth and final issue 10:36
6 identified at the outset: improvement. This is, very
7 obviously, an important topic in any public inquiry
8 because of the inquiry's key purposes of ensuring that
9 lessons have been learned so as to avoid any repeat of
10 any past mistakes and restoring public confidence in 10:36
11 the relevant institution - in this case, the Southern
12 Trust.

13
14 As we outlined in our written closing submission,
15 improvement in the context of healthcare is a perpetual 10:36
16 journey. Nonetheless, we suggest that, in the context
17 of the issues being considered by the Inquiry, the
18 Trust has travelled quite some distance in its
19 improvement journey over the last four to five years.
20 This journey has obviously been the subject of much 10:37
21 written and oral evidence received by the Inquiry;
22 for example, from witnesses like Dr. O'Kane,
23 Mr. Devlin, Eileen Mullan and Mr. Haynes. Some of it
24 has been summarised in our written closing, much of it
25 has been evidenced in our disclosure. In short, the 10:37
26 Trust has initiated multiple improvements in its
27 systems and structures of management, training,
28 corporate governance and clinical and social care
29 governance, in order to address the shortcomings within

1 the Trust which were revealed by the Mr. O'Brien
2 issues.

3
4 For present purposes, I seek only to illustrate how
5 things have been improved with a small number of
6 examples.

10:38

7
8 If we, first of all, consider improvement at the level
9 of the individual patient and through the lens of a
10 case with which the Inquiry is very familiar, and that
11 is Patient 1. We have seen his IR1, his SAI Review
12 Report and his relevant medical notes and we've heard
13 compelling oral evidence from his daughter, in the
14 presence of his widow, back on Day 5. We have also had
15 the unusual but substantial benefit of access to his
16 personal diary from the relevant time and we have also
17 heard expert oral evidence in respect of his treatment
18 pathway from Mr. Gilbert and from Mr. O'Brien's expert,
19 Professor Kirby. For present purposes, his case can be
20 summarised as follows:

10:38

10:38

10:39

21
22 On [REDACTED], Patient 1 was advised by
23 Mr. O'Brien of his diagnosis with Gleason 4 + 3
24 prostate cancer and commenced on Bicalutamide 150
25 initially, but then switched to 50 because of the
26 effects of that drug.

10:39

27
28 On 31st October 2019, he was considered at MDM, which
29 recommended commencing androgen deprivation therapy

(ADT) and referral for external beam radiotherapy (EBRT).

Personal Information redacted by the USI he was seen again by Mr. O'Brien, and then again on a number of occasions in 2020, in January and March and beyond. We know all of that from his medical notes. From his diary, we gain an insight into how he was feeling and how he deteriorated over that time. I will not open those entries today, but they run from PAT-001402 to 001414, and they are compelling.

what we can also see from his diary are two entries which relate to the issue of his referral to Oncology for EBRT. The first is at PAT-001379 and it's on Personal Information redacted by the USI the day he was advised of his diagnosis. He has recorded:

"Not a good day really, intermediate risk cancer, referred for radiotherapy and hormone replacement."

Then, on Personal Information redacted by the USI, at PAT-001400, a date when he saw Mr. O'Brien, he appears to have noted what he understood to have happened:

"Referred to oncologist at City Hosp."

However, in spite of the MDM recommendation of October 2019 and in spite of what had been recorded in

1 Patient 1's diary in [Personal Information redacted by the USI] and [Personal Information redacted by the USI]
2 he wasn't referred to Clinical Oncology for EBRT until
3 June 2020, when he was seen by Mr. Haynes. He sadly
4 passed away [Personal Information redacted by the USI].

5
6 Two of the key deficits identified by the SAI review
7 were the failure to action the MDM recommendation and
8 the failure to ensure he had a key worker.

9
10 Mr. Gilbert is very clear in his opinion that the MDM 10:41
11 recommendation, in particular the referral to Oncology
12 for EBRT, ought to have been implemented straight away.
13 Mr. O'Brien disagrees with that. And it is, of course,
14 important to note in this regard that whether either
15 deficit made any difference to Patient 1's ultimate 10:42
16 outcome, is properly a matter for civil proceedings
17 and, if necessary, a civil court, not for the Inquiry.
18 Quite correctly Mr. Gilbert, for his part, was clear in
19 his oral evidence to avoid expressing any opinion on
20 whether earlier referral to Oncology for EBRT would 10:42
21 have made any difference.

22
23 Nonetheless, from the Inquiry and the public's
24 perspective, key concerns arising from this case are
25 that an MDM recommendation went unactioned and no key 10:42
26 worker was allocated and, whatever the reason for these
27 omissions, the Trust appears to have been unaware of
28 both of them.
29

1 Because of the Trust's improvement work since that
2 time, we can now provide reassurance that these
3 deficits are much less likely to arise now. In this
4 regard, Mr. Haynes described in some detail to you, in
5 his evidence on Day 88, how there are now monthly
6 snapshot audits of the implementation of the
7 recommendations of all local cancer MDMS to identify
8 any failures of implementation. This development is
9 also recorded in the RAG-rated SAI Action Plan, which
10 the Inquiry has seen, which charts the implementation
11 of all of the Dr. Hughes' SAI recommendations, and I
12 shall return briefly to it in a moment, but for your
13 note, the most recent iteration of it, provided this
14 week in disclosure, is at TRU-309818.

10:43

10:43

15
16 We also, in relation to the deficits I have just
17 mentioned, know from witnesses like Martina Corrigan
18 and the various clinical nurse specialists, that there
19 is now a full complement of clinical nurse specialists
20 able to undertake the role of key worker and, from the
21 SAI Action Plan, we know that the name of the key
22 worker assigned to a patient is now recorded on CaaPS,
23 either during or soon after their cancer MDT meeting,
24 and that pending an enhancement to the CaaPS system
25 that is related to the Encompass rollout, a BOXI -
26 B-O-X-I - report is now run monthly from CaaPS to
27 ensure that all patients are allocated a key worker.
28 Both of these changes form part, and I stress only
29 part, of what Mr. Haynes, in answers to questions from

10:44

10:44

10:44

1 the Chair at the end of Day 88, considered to be the
2 most important change in the Trust in recent years;
3 namely, much greater visibility into individual
4 clinicians' practices and how they work, and this is
5 gained, for example, through audit and through data 10:45
6 collection and data reporting. Mr. Haynes emphasised
7 that, without such visibility, there is a risk of a
8 clinician practicing in isolation, something which
9 Mr. Haynes recognised could be "dangerous for the
10 individual clinician as much as it is for the patient. 10:45
11 With the benefit of such data, this risk is
12 significantly reduced."
13

14 And Mr. Haynes' overall verdict on the current state of
15 the Urology cancer MDT, in light of the above and other 10:45
16 improvements, was as follows, and the reference for
17 this is TRA-11478:
18

19 "I think there has been significant progress. It's a
20 safer environment for patients. It's also an 10:46
21 environment where we, as clinicians, feel safe. We
22 know that there are processes to make sure that
23 everything is happening as it should be."
24

25 To finish this issue, the Inquiry has seen the evidence 10:46
26 of how implementation of all of the Hughes SAI
27 recommendations has been tracked and monitored through
28 the RAG-rated SAI Action Plan I mentioned a moment ago.
29 You've heard how, for example, by November 2023, 65% of

1 the recommendations had been implemented in full, with
2 the remaining 35% being partially implemented, with
3 work ongoing.

4
5 As of June 2024, the position is that 86% have been 10:46
6 fully implemented, with the remaining 14% partially
7 implemented, with work ongoing. And I'm instructed
8 that some of the partially implemented issues are
9 beyond Trust control.

10 10:47
11 Moving beyond the example of improvement viewed through
12 the prism of an individual patient to broader
13 structural change across the Trust, we have the
14 Champion Review, and again, for your note, that report
15 can be found at WIT-46954. 10:47

16
17 As the Inquiry is aware, the Champion Review of
18 Clinical and Social Care Governance in the Trust was
19 commissioned in the spring of 2019 and it reported near
20 the end of that year. Its origins lay on a realisation 10:47
21 on the part of both Mr. Devlin, then Chief Executive,
22 and Dr. O'Kane, then Medical Director, both of whom
23 were relatively new to the Trust, that Trust government
24 systems were inadequate.

25 10:47
26 Dr. O'Kane, in her witness statement, number 29 of
27 2022, spoke of her perception that some of the key
28 functions that were required to assure governance
29 supporting patient safety, were rudimentary and some

1 were not fit for purpose, and you can find that in her
2 answer at paragraph 71.16 in that statement, and she
3 elaborated on this in her oral evidence on Day 15 at
4 TRA-01419 and Day 89 at TRA-11608.

5
6 Shane Devlin, for his part, in his witness statement,
7 in answer to question 29, explained that the review in
8 respect of the Cawdery murders was a major catalyst for
9 him to commission the governance review so as, in part,
10 to improve the SAI process.

11
12 As you know, the Champion Review made recommendations
13 for significant change across a large number of areas.
14 I won't list them all, but they include Board
15 governance, the Being Open Framework, controls
16 assurance, management of adverse incidents, including
17 SAIs, complaints and litigation management, clinical
18 audit, morbidity and mortality, governance information
19 management systems such as Datix, corporate and
20 clinical social care governance structures and the
21 interface between corporate and directorate clinical
22 and social care governance.

23
24 In her evidence on Day 15 at TRA-01419, Dr. O'Kane
25 described how the Trust has been working its way
26 through the 48 recommendations that Ms. Champion
27 produced and how they had significantly invested in the
28 related improvements and how she believed that, even by
29 that point, in December 2022, the Trust was "in a very

1 different place to where it had been previously".
2 And both Maria O'Kane and Eileen Mullan gave evidence
3 about how, at Trust Board and Trust Board committee,
4 governance structures have significantly improved with,
5 for example, a much better flow of relevant information 10:50
6 up to and, if appropriate, on through the Board's
7 Governance Committee.

8
9 The state of implementation of the Champion
10 recommendations has moved on since Dr. O'Kane gave her 10:50
11 evidence in March of this year, with the up-to-date
12 position being that 35-and-a-half of the
13 recommendations have been fully implemented, while
14 12-and-a-half are in the process of implementation. Of
15 the recommendations that are in the process of 10:50
16 implementation, a few are outside the control of the
17 Trust, many are well under way, some are parts of
18 longer-term pieces of work and some have been delayed
19 pending regional work; for example, work in relation to
20 the SAI framework. 10:51

21
22 Improvement work in the Trust is clearly ongoing. Work
23 remains to be done to implement fully the SAI
24 recommendations and the GIRFT recommendations, but much
25 progress has been made, and its continuing, and I've 10:51
26 given you the update in relation to the SAIs and the
27 Champion Review. I haven't given you the update in
28 relation to GIRFT, which, as you know, is an October
29 2023 report.

1
2 Having been at 33% green in November 2023 and then 39%
3 green when Dr. O'Kane gave evidence to you in March of
4 this year, we are now at 56% green, 33% amber, i.e. in
5 progress, and 11% red, and I am instructed that the two 10:51
6 red recommendations are regional recommendations that
7 require implementation across the entire region, and
8 you can see all of that in the document at TRU-309783.
9

10 So, we submit that both the Inquiry and the public can, 10:52
11 therefore, be reassured by the very substantial
12 improvements that have been made, and that are
13 continuing to be made, by the Trust across the Board.
14

15 All of these improvements significantly reduce the 10:52
16 chances of the problems that manifested themselves in
17 or through Mr. O'Brien's practice recurring. Of
18 course, it is an inescapable fact that these
19 improvements have occurred and must continue to occur
20 in a Health Service that exists in an ever more 10:52
21 challenging financial landscape. One only need look at
22 any of the newspapers here in the last week to see what
23 our health minister has been saying about the
24 inadequacy of what has been allocated to his department
25 in the most recent budget and the potential serious 10:53
26 consequences that could flow from that. This,
27 undoubtedly, represents a very significant challenge to
28 our Trust and to all of the other Trusts in Northern
29 Ireland. It also, we submit, brings into sharp focus

1 the need to identify improvements that do not consume
2 more resources, what was described as "working
3 differently" during exchanges between Mr. Wolfe and
4 Mr. Haynes on Day 88 of the hearings.

5
6 In this particular regard, we heard Mr. Haynes'
7 evidence about the need to make better use of existing
8 resources, whether that be in terms of being more
9 efficient about who needs a review appointment or
10 utilising virtual reviews for some patients or

10:53

11 expanding the range of clinicians who can perform
12 procedures on a patient and, on the last of these, the
13 Inquiry has received evidence about how the Southern
14 Trust is a leader in terms of ensuring that its highly
15 skilled clinical nurse specialists are trained and
16 equipped to perform ever-greater numbers of procedures,
17 thereby freeing up the relatively scarce consultant
18 urologist resource for procedures that only a
19 consultant surgeon can perform, and there is a good
20 example or a good summary of all of that in the GIRFT
21 report, as to where the Southern Trust sits with
22 clinical nurse specialists relative to other Trusts.

10:53

23 We submit that the current financial climate also
24 highlights the importance of initiatives like GIRFT and
25 the implementation of the recommendations, not just by
26 the Southern Trust but regionally and by all Trusts.
27 Mark Haynes perhaps provided the best explanation of
28 the importance of GIRFT in today's stretched NHS
29 environment, in his evidence on Day 88 at TRA-11502.

10:54

10:54

10:54

1 He said:

2
3 "I think effectively the aim of the GIRFT document is
4 about what things outside of more resource can be done
5 to deliver care more effectively. It encourages, as 10:55
6 you see within that recommendation that is in front,
7 the use of advanced nurse practitioners and physicians'
8 associates to deliver care which would have previously
9 been delivered by doctors. It encourages the
10 developments of high volume, low complexity surgical 10:55
11 centres. It encourages network working for a service
12 to support and maintain the service, in the case of
13 kidney cancer services in the recommendations here. It
14 encourages the development of specialist centres, so
15 you make, if you like, the non-specialist centres 10:55
16 attractive to recruitment. It aims to address all the
17 things outside of more resource being put in that can
18 improve the service for patients but also for the staff
19 delivering that care."

20 10:56
21 All of that said, greater efficiency can only ever
22 deliver so much. It can only ever be one part of a
23 bigger jigsaw, and it obviously remains essential to
24 the running of a safe Urology service and a safe
25 hospital and a safe Health and Social Care Trust that 10:56
26 they are properly funded by government to do their
27 essential work.

28
29 Finally, on the topic of improvement, and as

1 improvement is always, as I've said, a journey rather
2 than a destination, over the months ahead the Trust
3 will continue to implement the improvements that are
4 relevant to the Inquiry's work, whether it be in
5 respect of the Champion Review or the Hughes SAI
6 recommendations or GIRFT. The Trust is keen to keep
7 the Inquiry and, through it, the public, updated as to
8 this progress and hopes, therefore, that the Inquiry
9 will remain open to continuing to accept disclosure
10 updates from the Trust on this topic.

10:56

10:57

11
12 So, to conclude these brief oral closing remarks, I
13 want to do three things: first, to sound a note of
14 caution; second, to summarise; and third, to express
15 gratitude.

10:57

16
17 So, by way of caution, we would caution the Inquiry to
18 beware of the benefit of hindsight. As we reminded the
19 Inquiry in both our opening and in our written closing,
20 there is almost no human action or decision that cannot
21 be made to look more flawed or less sensible in the
22 misleading light of hindsight.

10:57

23
24 In the particular context of this Inquiry, we say be
25 wary of the temptation, sometimes encouraged by
26 Mr. O'Brien in his representations, to construe past
27 omissions, such as the Trust's failure to give
28 direction to consultants about what was expected in
29 terms of triage, as omissions but for which there would

10:58

1 have been some significantly different outcome.
2 we would also caution the Inquiry not to be distracted
3 from the important points by minor issues.
4

5 In the particular context of this Inquiry, much ink has 10:58
6 been spilt and many words uttered on Patients 104 and
7 105, and the Trust's -- the mistake that the Trust
8 appears to have made in early June 2020 in believing
9 that neither patient was on the Trust PAS. It looks
10 like the Trust was wrong about this and, that being the 10:59
11 case, an inaccurate reference to those patients was
12 included in documents when it ought not to have been,
13 but to focus on that, on that error, would be to risk
14 missing the real point. The chain of events set in
15 train by the belief that neither patient was on PAS, 10:59
16 led to the uncovering of significant other issues with
17 other patients. It was a stepping-stone to both a
18 rapid lookback and to the Dr. Hughes' SAIs. If it was
19 an error, and the preponderance of the evidence very
20 much suggests that it was, then it was a fortunate 10:59
21 error.
22

23 Finally, by way of caution, we would caution the
24 Inquiry not to ignore the context, and there are
25 multiple aspects to this, but just by way of example, 10:59
26 we've heard a lot of evidence about the capacity demand
27 mismatch and its consequences. Do not lose sight of
28 the impact the resulting workloads may have had on the
29 ability or capacity of doctors and managers to connect

1 the dots or to stand back and look at Mr. O'Brien's
2 issues. Equally, do not lose sight of the impact the
3 mismatch had in terms of the risk to patient safety
4 posed by some of Mr. O'Brien's deficits or how it
5 increased the importance of a task like triage.

11:00

6 Contrast, for example, the minimal risk of harm to a
7 patient whose urgent referral goes untriaged and,
8 therefore, not upgraded to red flag, in an environment
9 where the difference between a red flag and an urgent
10 waiting list is a matter of weeks, with a much greater
11 risk of harm in such a situation when the difference
12 between an urgent and a red flag waiting list is many
13 months, and, we submit, do not be myopic when
14 considering the context. Do take account of

11:00

15 Mr. O'Brien's point about the heavy workload placed
16 upon clinicians like himself as a result of the
17 capacity demand mismatch, but don't forget that his
18 colleagues managed do their triage and their dictation,
19 or that, in spite of his workload, he managed to
20 maintain a private practice.

11:01

11:01

21
22 So, to return to where we started and to summarise, we
23 are sorry. We have co-operated wholeheartedly with the
24 Inquiry. We have reflected and viewed this entire
25 process as an opportunity for learning and positive
26 change rather than as an attack, and we have changed
27 things for the better so that the public can be
28 reassured that lessons have been learned and that past
29 mistakes are much less likely to recur.

11:01

1 And finally, expressing our gratitude. The Trust
 2 wishes to acknowledge and express its sincere gratitude
 3 for the hard work, dedication and patience of the
 4 Inquiry Panel, its counsel, its solicitors and staff.
 5 The Inquiry's close forensic examination of working 11:02
 6 practices, procedures and systems in the Trust has
 7 certainly not always been a comfortable experience for
 8 the Trust or for those who have had to provide written
 9 or oral evidence, nor should it be, but, as I have
 10 said, it has necessarily provoked reflection and 11:02
 11 positive change.

12
 13 The Trust also recognises that the Inquiry has sought
 14 to be fair to all those from whom it has heard. No
 15 doubt the Inquiry will continue to exercise that 11:03
 16 fairness to Core Participants and to witnesses in the
 17 way it has done to date and, in the event that it's
 18 considering making any significant criticism of them,
 19 will afford them a reasonable opportunity to respond to
 20 that before the report is finalised and published. 11:03

21
 22 That's all I propose to say, you will be relieved.
 23 CHAIR: Thank you very much, Mr. Lunny. The Inquiry
 24 has heard, from the evidence and from your helpful
 25 submissions, both written and orally today, about the 11:03
 26 work the Trust has undertaken to improve its systems of
 27 governance, and we've heard, for example, that you've
 28 gone at risk in some instances to do so. But the
 29 Inquiry is interested to know what further support does

1 the Trust require from either the Department or
2 elsewhere to deliver these improvements?

3 MR. LUNNY: well, I will say that's obviously an
4 important question and a very good question and I hope
5 it's also a question the Panel will raise with the
6 Department later this morning --

11:04

7 CHAIR: Don't worry.

8 MR. LUNNY: -- if that's not throwing a grenade at my
9 learned friend, Mr Reid.

11:04

10
11 There are a number of aspects, I suppose, to the answer
12 I can give.

13
14 First, there is more the Department maybe can do and
15 there is more that can be done at a regional level.

11:04

16 Some of the examples of governance, important
17 governance changes we have made at risk include some of
18 the clinical audit resource that you've heard evidence
19 about and also some of the resource that's now deployed
20 on the tracking or snapshot audits of MDM

11:05

21 recommendations. Now, there maybe a time lag in the
22 Department seeing the benefits of investment like that,
23 and that, in turn, is perhaps related or tied in with
24 the fact that we haven't had more than a one-year
25 budget in health, or anywhere, for some time. It seems
26 obvious, Chair, that whilst there might be a time lag
27 associated with the financial benefits that accrue from
28 governance steps like that, there undoubtedly is a
29 benefit. The Department spending money and giving

11:05

1 Trusts money to spend on governance, will ultimately,
2 in the medium to longer term, save more money than it
3 will cost.

4
5 Resources spent in governance will usually help to 11:06
6 identify and resolve problems before they become
7 serious, and we know that serious and entrenched
8 problems not only can have serious consequences which
9 cost more to treat, but consequences in terms of
10 clinical negligence litigation as well. 11:06

11
12 So it might, in one sense, be better if posts like that
13 were promoted to the Department, not under the heading
14 of governance, but as posts that, in the medium to
15 longer term, will save money. But I do say that 11:06
16 they -- being able to front-load funding in
17 anticipation of medium to long-term benefit, is
18 something that appears to be very closely tied up with
19 the budget, and it would appear to be much easier to do
20 if three- or five-year budgets for health are set, 11:07
21 rather than annual budgets.

22
23 But it is -- I suppose the other aspect to it, and it
24 ties in with evidence, I think, that Mr. May gave, is
25 that Trusts are given money; it isn't necessarily 11:07
26 ring-fenced for anything in particular. Perhaps there
27 should be a ring-fenced portion of the budget for
28 governance. And it probably also ties in with what
29 Mr. Pengelly said in some of his evidence, that there

1 is maybe a lack of understanding sometimes amongst
2 politicians and the public, that administrators, as
3 they are sometimes known in the NHS, actually perform a
4 very valuable function, and you've heard a lot of
5 evidence about regional challenges in terms of 11:08
6 recruiting and retaining clinicians like nurses or
7 consultant urologists. A huge and important difference
8 with a resource like tracking and some audit resource
9 is that you don't need to recruit those people from the
10 clinician class; you can recruit people without 11:08
11 professional qualifications to perform those tasks. So
12 an obstacle that exists in other parts of the Trust and
13 other parts of the Health Service in this region,
14 doesn't exist in relation to those, those important
15 roles. So I hope that's an answer, at least in part. 11:08

16 CHAIR: It certainly is. Thank you very much,
17 Mr. Lunny.

18
19 we are going to take a short break, ladies and
20 gentlemen, before we hear then from Mr Boyle. Sorry, I 11:09
21 should have said 15 minutes.

22
23 THE INQUIRY RESUMED AFTER A SHORT BREAK AS FOLLOWS:

24
25 CHAIR: Thank you, everyone. Mr Boyle. 11:23

26
27 CLOSING SUBMISSION BY MR. BOYLE:

28
29 MR. BOYLE: Thank you, Chair, Dr. Swart, Mr. Hanbury.