Good medical practice

Working with doctors Working for patients

General Medical Council

The duties of a doctor registered with the GMC

Patients must be able to trust doctors with their lives and health. To justify that trust you must show respect for human life and make sure your practice meets the standards expected of you in four domains.

Knowledge, skills and performance

- Make the care of your patient your first concern.
- Provide a good standard of practice and care.
  - Keep your professional knowledge and skills up to date.
  - Recognise and work within the limits of your competence.

Safety and quality

- Take prompt action if you think that patient safety, dignity or comfort is being compromised.
- Protect and promote the health of patients and the public.

Communication, partnership and teamwork

- Treat patients as individuals and respect their dignity.
  - Treat patients politely and considerately.
  - Respect patients' right to confidentiality.
- Work in partnership with patients.
  - Listen to, and respond to, their concerns and preferences.
  - Give patients the information they want or need in a way they can understand.
  - Respect patients' right to reach decisions with you about their treatment and care.
  - Support patients in caring for themselves to improve and maintain their health.
- Work with colleagues in the ways that best serve patients' interests.

Maintaining trust

- Be honest and open and act with integrity.
- Never discriminate unfairly against patients or colleagues.
- Never abuse your patients' trust in you or the public's trust in the profession.

You are personally accountable for your professional practice and must always be prepared to justify your decisions and actions.

Good medical practice

This guidance has been edited for plain English.

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This guidance was updated on 29 April 2014 to include paragraph 14.1 on doctors' knowledge of the English language. It was further updated on 29 April 2019 to remove the sub-heading 'honesty' from immediately before paragraph 65.

You can find the latest version of this guidance on our website at **www.gmc-uk.org/guidance**.

For the full website addresses of references in this guidance, please see the online version on our website.

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About this guidance

Good medical practice includes references to explanatory guidance. A complete list of explanatory guidance is at the end of the booklet.

All our guidance is available on our website, along with:

- learning materials, including interactive case studies which bring to life the principles in the guidance and show how they might apply in practice

- cases heard by medical practitioners tribunals, which provide examples of where a failure to follow the guidance has put a doctor's registration at risk.

Professionalism in action

1 Patients need good doctors. Good doctors make the care of their patients their first concern: they are competent, keep their knowledge and skills up to date, establish and maintain good relationships with patients and colleagues,[1] are honest and trustworthy, and act with integrity and within the law.

2 Good doctors work in partnership with patients and respect their rights to privacy and dignity. They treat each patient as an individual. They do their best to make sure all patients receive good care and treatment that will support them to live as well as possible, whatever their illness or disability.

3 *Good medical practice* describes what is expected of all doctors registered with the General Medical Council (GMC). It is your responsibility to be familiar with *Good medical practice* and the explanatory guidance[2] which supports it, and to follow the guidance they contain.

4 You must use your judgement in applying the principles to the various situations you will face as a doctor, whether or not you hold a licence to practise, whatever field of medicine you work in, and whether or not you routinely see patients. You must be prepared to explain and justify your decisions and actions.

5 In *Good medical practice*, we use the terms 'you must' and 'you should' in the following ways.

- 'You must' is used for an overriding duty or principle.
- 'You should' is used when we are providing an explanation of how you will meet the overriding duty.
- 'You should' is also used where the duty or principle will not apply in all situations or circumstances, or where there are factors outside your control that affect whether or how you can follow the guidance.

6 To maintain your licence to practise, you must demonstrate, through the revalidation process, that you work in line with the principles and values set out in this guidance. Only serious or persistent failure to follow our guidance that poses a risk to patient safety or public trust in doctors will put your registration at risk.

Domain 1: Knowledge, skills and performance

Develop and maintain your professional performance

7 You must be competent in all aspects of your work, including management, research and teaching.[3, 4, 5]

8 You must keep your professional knowledge and skills up to date.

9 You must regularly take part in activities that maintain and develop your competence and performance.[6]

10 You should be willing to find and take part in structured support opportunities offered by your employer or contracting body (for example, mentoring). You should do this when you join an organisation and whenever your role changes significantly throughout your career.

11 You must be familiar with guidelines and developments that affect your work.

12 You must keep up to date with, and follow, the law, our guidance and other regulations relevant to your work.

13 You must take steps to monitor and improve the quality of your work.

Apply knowledge and experience to practice

14 You must recognise and work within the limits of your competence.

14.1 You must have the necessary knowledge of the English language to provide a good standard of practice and care in the UK.[7]

15 You must provide a good standard of practice and care. If you assess, diagnose or treat patients, you must:

a adequately assess the patient's conditions, taking account of their history (including the symptoms and psychological, spiritual, social and cultural factors), their views and values; where necessary, examine the patient

b promptly provide or arrange suitable advice, investigations or treatment where necessary

c refer a patient to another practitioner when this serves the patient's needs.[8]

16 In providing clinical care you must:

- **a** prescribe drugs or treatment, including repeat prescriptions, only when you have adequate knowledge of the patient's health and are satisfied that the drugs or treatment serve the patient's needs[9]
- **b** provide effective treatments based on the best available evidence
- **c** take all possible steps to alleviate pain and distress whether or not a cure may be possible[10]
- **d** consult colleagues where appropriate
- **e** respect the patient's right to seek a second opinion
- **f** check that the care or treatment you provide for each patient is compatible with any other treatments the patient is receiving, including (where possible) self-prescribed over-the-counter medications
- **g** wherever possible, avoid providing medical care to yourself or anyone with whom you have a close personal relationship.[9]

17 You must be satisfied that you have consent or other valid authority before you carry out any examination or investigation, provide treatment or involve patients or volunteers in teaching or research.[4, 11, 12]

18 You must make good use of the resources available to you.[3]

Record your work clearly, accurately and legibly

19 Documents you make (including clinical records) to formally record your work must be clear, accurate and legible. You should make records at the same time as the events you are recording or as soon as possible afterwards.

20 You must keep records that contain personal information about patients, colleagues or others securely, and in line with any data protection law requirements.[14]

21 Clinical records should include:

- **a** relevant clinical findings
- **b** the decisions made and actions agreed, and who is making the decisions and agreeing the actions
- **c** the information given to patients
- **d** any drugs prescribed or other investigation or treatment
- **e** who is making the record and when.

Domain 2: Safety and quality

Contribute to and comply with systems to protect patients

22 You must take part in systems of quality assurance and quality improvement to promote patient safety. This includes:

- **a** taking part in regular reviews and audits of your work and that of your team, responding constructively to the outcomes, taking steps to address any problems and carrying out further training where necessary
- **b** regularly reflecting on your standards of practice and the care you provide
- **c** reviewing patient feedback where it is available.

23 To help keep patients safe you must:

- **a** contribute to confidential inquiries
- **b** contribute to adverse event recognition
- **c** report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another person, at risk
- **d** report suspected adverse drug reactions
- **e** respond to requests from organisations monitoring public health.

When providing information for these purposes you should still respect patients' confidentiality.[14]

Respond to risks to safety

24 You must promote and encourage a culture that allows all staff to raise concerns openly and safely.[3, 15]

25 You must take prompt action if you think that patient safety, dignity or comfort is or may be seriously compromised.

a If a patient is not receiving basic care to meet their needs, you must immediately tell someone who is in a position to act straight away.

b If patients are at risk because of inadequate premises, equipment[13] or other resources, policies or systems, you should put the matter right if that is possible. You must raise your concern in line with our guidance[15] and your workplace policy. You should also make a record of the steps you have taken.

c 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.[14, 16]

26 You must offer help if emergencies arise in clinical settings or in the community, taking account of your own safety, your competence and the availability of other options for care.

27 Whether or not you have vulnerable[17] adults or children and young people as patients, you should consider their needs and welfare and offer them help if you think their rights have been abused or denied.[18, 19]

Risks posed by your health

28 If you know or suspect that you have a serious condition that you could pass on to patients, or if your judgement or performance could be affected by a condition or its treatment, you must consult a suitably qualified colleague. You must follow their advice about any changes to your practice they consider necessary. You must not rely on your own assessment of the risk to patients.

29 You should be immunised against common serious communicable diseases (unless otherwise contraindicated).

30 You should be registered with a general practitioner outside your family.

Domain 3: Communication, partnership and teamwork

Communicate effectively

31 You must listen to patients, take account of their views, and respond honestly to their questions.

32 You must give patients[20] the information they want or need to know in a way they can understand. You should make sure that arrangements are made, wherever possible, to meet patients' language and communication needs.[21]

33 You must be considerate to those close to the patient and be sensitive and responsive in giving them information and support.

34 When you are on duty you must be readily accessible to patients and colleagues seeking information, advice or support.

Working collaboratively with colleagues

35 You must work collaboratively with colleagues, respecting their skills and contributions.[3]

36 You must treat colleagues fairly and with respect.

37 You must be aware of how your behaviour may influence others within and outside the team.

38 Patient safety may be affected if there is not enough medical cover. So you must take up any post you have formally accepted, and work your contractual notice period before leaving a job, unless the employer has reasonable time to make other arrangements.

Teaching, training, supporting and assessing

39 You should be prepared to contribute to teaching and training doctors and students.

40 You must make sure that all staff you manage have appropriate supervision.

41 You must be honest and objective when writing references, and when appraising or assessing the performance of colleagues, including locums and students. References must include all information relevant to your colleagues' competence, performance and conduct.[22]

42 You should be willing to take on a mentoring role for more junior doctors and other healthcare professionals.[3]

43 You must support colleagues who have problems with their performance or health. But you must put patient safety first at all times.[3]

Continuity and coordination of care

44 You must contribute to the safe transfer of patients between healthcare providers and between health and social care providers. This means you must:

a share all relevant information with colleagues involved in your patients' care within and outside the team, including when you hand over care as you go off duty, and when you delegate care or refer patients to other health or social care providers[8, 14]

b check, where practical, that a named clinician or team has taken over responsibility when your role in providing a patient's care has ended. This may be particularly important for patients with impaired capacity or who are vulnerable for other reasons.

45 When you do not provide your patients' care yourself, for example when you are off duty, or you delegate the care of a patient to a colleague, you must be satisfied that the person providing care has the appropriate qualifications, skills and experience to provide safe care for the patient.[8]

Establish and maintain partnerships with patients

46 You must be polite and considerate.

47 You must treat patients as individuals and respect their dignity and privacy.[16]

48 You must treat patients fairly and with respect whatever their life choices and beliefs.

49 You must work in partnership with patients, sharing with them the information they will need to make decisions about their care,[21] including:

- **a** their condition, its likely progression and the options for treatment, including associated risks and uncertainties
- **b** the progress of their care, and your role and responsibilities in the team
- **c** who is responsible for each aspect of patient care, and how information is shared within teams and among those who will be providing their care

d any other information patients need if they are asked to agree to be involved in teaching or research.[12]

50 You must treat information about patients as confidential. This includes after a patient has died.[14]

51 You must support patients in caring for themselves to empower them to improve and maintain their health. This may, for example, include:

a advising patients on the effects of their life choices and lifestyle on their health and well-being

b supporting patients to make lifestyle changes where appropriate.

52 You must explain to patients if you have a conscientious objection to a particular procedure. You must tell them about their right to see another doctor and make sure they have enough information to exercise that right. In providing this information you must not imply or express disapproval of the patient's lifestyle, choices or beliefs. If it is not practical for a patient to arrange to see another doctor, you must make sure that arrangements are made for another suitably qualified colleague to take over your role.[23]

Domain 4: Maintaining trust

Show respect for patients

53 You must not use your professional position to pursue a sexual or improper emotional relationship with a patient or someone close to them.[16]

54 You must not express your personal beliefs (including political, religious and moral beliefs) to patients in ways that exploit their vulnerability or are likely to cause them distress.[23]

55 You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should:

- **a** put matters right (if that is possible)
- **b** offer an apology
- **c** explain fully and promptly what has happened and the likely short-term and long-term effects.

Treat patients and colleagues fairly and without discrimination

56 You must give priority to patients on the basis of their clinical need if these decisions are within your power. If inadequate resources, policies or systems prevent you from doing this, and patient safety, dignity or comfort may be seriously compromised, you must follow the guidance in paragraph 25b (see section *Domain 2: Safety and quality*).

57 The investigations or treatment you provide or arrange must be based on the assessment you and your patient make of their needs and priorities, and on your clinical judgement about the likely effectiveness of the treatment options. You must not refuse or delay treatment because you believe that a patient's actions or lifestyle have contributed to their condition.

58 You must not deny treatment to patients because their medical condition may put you at risk. If a patient poses a risk to your health or safety, you should take all available steps to minimise the risk before providing treatment or making other suitable alternative arrangements for providing treatment.

59 You must not unfairly discriminate against patients or colleagues by allowing your personal views[24] to affect your professional relationships or the treatment you provide or arrange. You should challenge colleagues if their behaviour does not comply with this guidance, and follow the guidance in paragraph 25c (see section *Domain 2: Safety and quality*) if the behaviour amounts to abuse or denial of a patient's or colleague's rights.

60 You must consider and respond to the needs of disabled patients and should make reasonable adjustments[25] to your practice so they can receive care to meet their needs.

61 You must respond promptly, fully and honestly to complaints and apologise when appropriate. You must not allow a patient's complaint to adversely affect the care or treatment you provide or arrange.

62 You should end a professional relationship with a patient only when the breakdown of trust between you and the patient means you cannot provide good clinical care to the patient.[26]

63 You must make sure you have adequate insurance or indemnity cover so that your patients will not be disadvantaged if they make a claim about the clinical care you have provided in the UK.

64 If someone you have contact with in your professional role asks for your registered name and/or GMC reference number, you must give this information to them.

Act with honesty and integrity

65 You must make sure that your conduct justifies your patients' trust in you and the public's trust in the profession.

66 You must always be honest about your experience, qualifications and current role.

67 You must act with honesty and integrity when designing, organising or carrying out research, and follow national research governance guidelines and our guidance.[4]

Communicating information

68 You must be honest and trustworthy in all your communication with patients and colleagues. This means you must make clear the limits of your knowledge and make reasonable checks to make sure any information you give is accurate.

69 When communicating publicly, including speaking to or writing in the media, you must maintain patient confidentiality. You should remember when using social media that communications intended for friends or family may become more widely available.[14, 27]

70 When advertising your services, you must make sure the information you publish is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge.

71 You must be honest and trustworthy when writing reports, and when completing or signing forms, reports and other documents.[22] You must make sure that any documents you write or sign are not false or misleading.

a You must take reasonable steps to check the information is correct.

b You must not deliberately leave out relevant information.

Openness and legal or disciplinary proceedings

72 You must be honest and trustworthy when giving evidence to courts or tribunals.[28] You must make sure that any evidence you give or documents you write or sign are not false or misleading.

- **a** You must take reasonable steps to check the information is correct.
- **b** You must not deliberately leave out relevant information.

73 You must cooperate with formal inquiries and complaints procedures and must offer all relevant information while following the guidance in *Confidentiality*.

74 You must make clear the limits of your competence and knowledge when giving evidence or acting as a witness.[28]

75 You must tell us without delay if, anywhere in the world:

- **a** you have accepted a caution from the police or been criticised by an official inquiry
- **b** you have been charged with or found guilty of a criminal offence
- **c** another professional body has made a finding against your registration as a result of fitness to practise procedures.[29]

76 If you are suspended by an organisation from a medical post, or have restrictions placed on your practice, you must, without delay, inform any other organisations you carry out medical work for and any patients you see independently.

Honesty in financial dealings

77 You must be honest in financial and commercial dealings with patients, employers, insurers and other organisations or individuals.[30]

78 You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients.

79 If you are faced with a conflict of interest, you must be open about the conflict, declaring your interest formally, and you should be prepared to exclude yourself from decision making.

80 You must not ask for or accept – from patients, colleagues or others – any inducement, gift or hospitality that may affect or be seen to affect the way you prescribe for, treat or refer patients or commission services for patients. You must not offer these inducements.

Endnotes

1 Colleagues include anyone a doctor works with, whether or not they are also doctors.

2 You can find all the explanatory guidance on our website.

3 *Leadership and management for all doctors* (2012) GMC, London

4 *Good practice in research* (2010) GMC, London

5 *Developing teachers and trainers in undergraduate medical education* (2011) GMC, London

6 *Continuing professional development: guidance for all doctors* (2012) GMC, London

7 This paragraph was added on 29 April 2014. Section 35C(2)(da) of the *Medical Act 1983*, inserted by the *Medical Act 1983 (Amendment) (Knowledge of English) Order 2014*.

8 *Delegation and referral* (2013) GMC, London

9 *Good practice in prescribing and managing medicines and devices* (2013) GMC, London

10 *Treatment and care towards the end of life: good practice in decision-making* (2010), GMC, London

11 *Making and using visual and audio recordings of patients* (2011) GMC, London

12 *Consent to research* (2013) GMC, London

13 Follow the guidance in paragraph 23c if the risk arises from an adverse incident involving a medical device.

14 *Confidentiality: good practice in handling patient information* (2017) GMC, London

15 *Raising and acting on concerns about patient safety* (2012) GMC, London

16 Maintaining boundaries (2013) GMC, London

- *Intimate examinations and chaperones* (paragraphs 47, 25c)
- *Maintaining a professional boundary between you and your patient* (paragraph 53)
- *Sexual behaviour and your duty to report* (paragraphs 53, 25c)

17 Some patients are likely to be more vulnerable than others because of their illness, disability or frailty or because of their current circumstances, such as bereavement or redundancy. You should treat children and young people under 18 years as vulnerable. Vulnerability can be temporary or permanent.

18 *0–18 years: guidance for all doctors* (2007) GMC, London

19 *Protecting children and young people: the responsibilities of all doctors* (2012) GMC, London

20 Patients here includes those people with the legal authority to make healthcare decisions on a patient's behalf.

21 *Decision making and consent* (2020) GMC, London

22 *Writing references* (2012) GMC, London

23 *Personal beliefs and medical practice* (2013) GMC, London

24 This includes your views about a patient's or colleague's lifestyle, culture or their social or economic status, as well as the characteristics protected by legislation: age, disability, gender reassignment, race, marriage and civil partnership, pregnancy and maternity, religion or belief, sex and sexual orientation.

25 'Reasonable adjustments' does not only mean changes to the physical environment. It can include, for example. Being flexible about appointment time or length, and making arrangements for those with communication difficulties such as impaired hearing. For more information see the EHRC website.

26 *Ending your professional relationship with a patient* (2013) GMC, London

27 *Doctors' use of social media* (2013) GMC, London

28 *Acting as a witness in legal proceedings* (2013) GMC, London

29 *Reporting criminal and regulatory proceedings within and outside the UK* (2013) GMC, London

30 *Financial and commercial arrangements and conflicts of interest* (2013) GMC, London

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Email: **gmc@gmc-uk.org**
Website: **www.gmc-uk.org**
Telephone: **0161 923 6602**

General Medical Council, 3 Hardman Street, Manchester M3 3AW

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General Medical Council

General Medical Council

Professional standards

In effect: 25 April 2017

Confidentiality: good practice in handling patient information

Summary

This guidance sets out eight principles of confidentiality that you should apply to your practice. It provides a framework to help you decide when you can share information. And helps you to think about why you are sharing the information. It also has a handy flowchart which you can use to help you decide whether to share the information.

The guidance includes a section on managing and protecting information. This has helpful advice on doctors' personal responsibilities for protecting patient information. It also gives advice on when you can share information after a patient has died.

General Medical Council

Confidentiality: good practice in handling patient information

Professional standards: More detailed guidance

This guidance came into effect 25 April 2017

This guidance was last updated on 13 December 2024

You can find the latest version of all our professional standards at www.gmc-uk.org/guidance.

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Confidentiality is an important legal and ethical duty but it is not absolute.

This guidance sets out eight principles that you should apply to your practice. It provides a framework to help you decide when you can share information. And helps you to think about why you are sharing the information. This may be for the direct care or protection of the patient, to protect others or for another reason.

The guidance includes a section on managing and protecting information. This has helpful advice on the personal responsibilities of doctors, physician associates and anaesthesia associates for protecting patient information. It also gives advice on when you can share information after a patient has died.

It was updated on 25 May 2018 to reflect the requirements of the General Data Protection Regulation and Data Protection Act 2018 and on 13 December 2024 when regulation of physician associates and anaesthesia associates by the GMC came into effect.

We also have six pieces of shorter guidance which explain how to apply the principles of Confidentiality to situations we know can be difficult in practice. These are:

- Confidentiality: disclosing information for education and training purposes
- Confidentiality: disclosing information for employment, insurance and similar purposes
- Confidentiality: disclosing information about serious communicable diseases
- Confidentiality: patients' fitness to drive and reporting concerns to the DVLA or DVA
- Confidentiality: Reporting gunshot and knife wounds
- Confidentiality: responding to criticism in the media

About our Confidentiality guidance

Our core guidance, *Good medical practice*, makes clear that patients have a right to expect that their personal information will be treated as confidential. This guidance, which forms part of the professional standards, sets out the principles of confidentiality and respect for patients' privacy that you are expected to understand and follow.

This guidance outlines the framework for considering when to disclose patients' personal information and then applies that framework to:

a. disclosures to support the direct care of an individual patient
b. disclosures for the protection of patients and others
c. disclosures for all other purposes.

This guidance also sets out the responsibilities of all doctors, physician associates and anaesthesia associates for managing and protecting patient information.

In this guidance, we use the terms 'you must' and 'you should' in the following ways.

- 'You must' is used for a legal or ethical duty you're expected to meet (or be able to justify why you didn't).
- 'You should' is used for duties or principles that either:
  - may not apply to you or to the situation you're currently in, or
  - you may not be able to comply with because of factors outside your control.

The standards of good practice apply to doctors, physician associates and anaesthesia associates (collectively referred to as medical professionals and whom we address directly as 'you' throughout the guidance). As with all our professional standards, this guidance applies to all our registrants to the extent it is relevant to the individual's practice.The professional standards describe good practice, and not every departure from them will be considered serious. You must use your professional judgement to apply the standards to your day-to-day practice. If you do this, act in good faith and in the interests of patients, you will be able to explain and justify your decisions and actions. We say more about professional judgement, and how the professional standards relate to our fitness to practise processes, appraisals and revalidation, at the beginning of *Good medical practice*.

If in doubt, you should seek the advice of an experienced colleague, a Caldicott or data guardian[1] or equivalent, a data protection officer, your defence body or professional association, or seek independent legal advice.

Other materials available

Further guidance is available on our website explaining how these principles apply in situations we know can be difficult in practice. At the time of publishing this guidance, we are also publishing guidance on:

a. patients' fitness to drive and reporting concerns to the DVLA or DVA
b. disclosing information about serious communicable diseases
c. disclosing information for employment, insurance and similar purposes
d. disclosing information for education and training purposes
e. reporting gunshot and knife wounds
f. responding to criticism in the media.

Ethical and legal duties of confidentiality

1. Trust is an essential part of the relationship between patients and medicalprofessionals and confidentiality is central to this. Patients may avoid seeking medical help, or may under-report symptoms, if they think their personal information will be disclosed[2] without consent, or without the chance to have some control over the timing or amount of information shared.

2. Medical professionals are under both ethical and legal duties to protect patients' personal information from improper disclosure. But appropriate information sharing is an essential part of the provision of safe and effective care. Patients may be put at risk if those who are providing their care do not have access to relevant, accurate and up-to-date information about them.

3. There are also important uses of patient information for purposes other than direct care. Some of these are indirectly related to patient care in that they enable health services to function efficiently and safely. For example, large volumes of patient information are used for purposes such as medical research, service planning and financial audit. Other uses are not directly related to the provision of healthcare but serve wider public interests, such as disclosures for public protection reasons.

4. Healthcare is continuing to evolve and change. It is likely to be more challenging to make sure there is a legal and ethical basis for using patient information in a complex health and social care environment than in the context of a professional relationship with an individual patient.

   In this guidance, we aim to support medical professionals to meet their responsibilities while working within these complex systems.

Acting within the law

5. Medical professionals, like everyone else, must comply with the law when using, accessing or disclosing personal information. The law governing the use and disclosure of personal information is complex, however, and varies across the four countries of the UK.

6. In the legal annex to this guidance, we summarise some key elements of the relevant law, including the requirements of the common law, data protection law and human rights law. In the main body of the guidance, we give advice on how to apply ethical and legal principles in practice, but we do not refer to specific pieces of law unless it is necessary to do so.

7. If you are not sure how the law applies in a particular situation, you should consult a Caldicott or data guardian, a data protection officer, your defence body or professional association, or seek independent legal advice.

The main principles of this guidance

8. The advice in this guidance is underpinned by the following eight principles.[3]

    a. **Use the minimum necessary personal information.** Use anonymised information if it is practicable to do so and if it will serve the purpose.
    b. **Manage and protect information.** Make sure any personal information you hold or control is effectively protected at all times against improper access, disclosure or loss.
    c. **Be aware of your responsibilities.** Develop and maintain an understanding of information governance that is appropriate to your role.
    d. **Comply with the law.** Be satisfied that you are handling personal information lawfully.
    e. **Share relevant information for direct care** in line with the principles in this guidance unless the patient has objected.
    f. **Ask for explicit consent** to disclose identifiable information about patients for purposes other than their care or local clinical audit, unless the disclosure is required by law or can be justified in the public interest.
    g. **Tell patients** about disclosures of personal information you make that they would not reasonably expect, or check they have received information about such disclosures, unless that is not practicable or would undermine the purpose of the disclosure. Keep a record of your decisions to disclose, or not to disclose, information.
    h. **Support patients to access their information.** Respect, and help patients exercise, their legal rights to be informed about how their information will be used and to have access to, or copies of, their health records.

Disclosing patients' personal information: a framework

When you can disclose personal information

9. Confidentiality is an important ethical and legal duty but it is not absolute. You may disclose personal information without breaching duties of confidentiality when any of the following circumstances applies.

a. The patient consents, whether implicitly or explicitly for the sake of their own care or for local clinical audit, or explicitly for other purposes (see paragraphs 13 - 15).
b. The patient has given their explicit consent to disclosure for other purposes (see paragraphs 13 - 15).
c. The disclosure is of overall benefit[4] to a patient who lacks the capacity to consent and the disclosure is made in line with the relevant capacity legislation (see paragraphs 41 -49)
d. The disclosure is required by law (see paragraphs 17 - 19), or the disclosure is permitted or has been approved under a statutory process that sets aside the common law duty of confidentiality (see paragraphs 20 - 21).
e. The disclosure can be justified in the public interest (see paragraphs 22 - 23).

10. When disclosing information about a patient you must:

a. use anonymised information if it is practicable to do so and if it will serve the purpose
b. be satisfied the patient:
    i. has ready access to information explaining how their personal information will be used for their own care or local clinical audit, and that they have the right to object
    ii. has not objected
c. get the patient's explicit consent if identifiable information is to be disclosed for purposes other than their own care or local clinical audit, unless the disclosure is required by law or can be justified in the public interest
d. keep disclosures to the minimum necessary for the purpose
e. follow all relevant legal requirements, including the common law and data protection law.[5]

11. When you are satisfied that information should be disclosed, you should act promptly to disclose all relevant information. You should keep a record of your decision and actions.

12. You should tell patients about disclosures you make that they would not reasonably expect, or check they have received information about such disclosures, unless that is not practicable or would undermine the purpose of the disclosure – for example, by prejudicing the prevention, detection or prosecution of serious crime.

Disclosing information with a patient's consent

13. Asking for a patient's consent to disclose information shows respect, and is part of good communication between medical professionals and patients. Under the common law duty of confidentiality, consent may be explicit or implied.[6]

a. Explicit (also known as express) consent is given when a patient actively agrees, either orally or in writing, to the use or disclosure of information.
b. Implied consent refers to circumstances in which it would be reasonable to infer that the patient agrees to the use of the information, even though this has not been directly expressed.

14. You may disclose information on the basis of implied consent for direct care when the conditions in paragraphs 28 and 29 are met, and for local clinical audit when the conditions in paragraph 96 are met. In other cases, you should ask for explicit consent to disclose personal information unless it is not appropriate or practicable to do so.

    For example, this might be because:

a. the disclosure is required by law (see paragraphs 17 - 19)
b. you are satisfied that informed consent has already been obtained by a suitable person[7]
c. the patient does not have capacity to make the decision. In such a case, you should follow the guidance on disclosures about patients who lack capacity to consent (see paragraphs 41 - 49)
d. you have reason to believe that seeking consent would put you or others at risk of serious harm
e. seeking consent would be likely to undermine the purpose of the disclosure, for example by prejudicing the prevention, detection or prosecution of a serious crime
f. action must be taken quickly, for example in the detection or control of outbreaks of some communicable diseases where there is insufficient time to contact the patient
g. seeking consent is not feasible given the number or age of records, or the likely traceability of patients.
h. you have already decided to disclose information in the public interest (see paragraphs 63 - 70).

15. If you disclose personal information without consent, you must be satisfied that there is a legal basis for breaching confidentiality (see paragraph 9). You must also be satisfied that the other relevant requirements for disclosing information are met (see paragraph 10).

Disclosing information when a patient lacks the capacity to consent

16. You may disclose relevant personal information about a patient who lacks the capacity to consent if it is of overall benefit to the patient and the disclosure is made in line with the relevant capacity legislation. You can find more guidance on this in paragraphs 41 - 49.

Disclosures required or permitted by law

17. You must disclose information if it is required by statute, or if you are ordered to do so by a judge or presiding officer of a court (see paragraphs 87 - 94).

18. You should satisfy yourself that the disclosure is required by law and you should only disclose information that is relevant to the request. Wherever practicable, you should tell patients about such disclosures, unless that would undermine the purpose, for example by prejudicing the prevention, detection or prosecution of serious crime.

19. Laws and regulations sometimes permit, but do not require, the disclosure of personal information.[8] If a disclosure is permitted but not required by law, you must be satisfied that there is a legal basis for breaching confidentiality (see paragraph 9). You must also be satisfied that the other relevant requirements for disclosing information are met (see paragraph 10).

Disclosures approved under a legal process

20. You may disclose personal information without consent if the disclosure is permitted or has been approved under section 251 of the *National Health Service Act 2006* (which applies in England and Wales) or the *Health and Social Care (Control of Data Processing) Act (Northern Ireland) 2016*. These pieces of law allow the common law duty of confidentiality to be set aside for defined purposes where it is not possible to use anonymised information and where seeking consent is not practicable. There is no comparable legal framework in Scotland.

21. If you know that a patient has objected to information being disclosed for purposes other than their own care, you should not usually disclose the information unless it is required under the regulations. You can find more guidance on disclosures with specific statutory support in paragraphs 103 - 105.

Disclosures in the public interest

22. Confidential medical care is recognised in law as being in the public interest. The fact that people are encouraged to seek advice and treatment benefits society as a whole as well as the individual. But there can be a public interest in disclosing information if the benefits to an individual or society outweigh both the public and the patient's interest in keeping the information confidential. For example, disclosure may be justified to protect individuals or society from risks of serious harm, such as from serious communicable diseases or serious crime. You can find guidance on disclosing information in the public interest to prevent death or serious harm in paragraphs 63 - 70.

23. There may also be circumstances in which disclosing personal information without consent is justified in the public interest for important public benefits, other than to prevent death or serious harm, if there is no reasonably practicable alternative to using personal information. The circumstances in which the public interest would justify such disclosures are uncertain, however, so you should seek the advice of a Caldicott or data guardian or a legal adviser who is not directly connected with the use for which the disclosure is being considered before making the disclosure. You can find further guidance in paragraphs 106 - 112.

Disclosures prohibited by law

24. Health professionals are required by certain laws to restrict the disclosure of some types of information. You can find examples of disclosures prohibited by law in the legal annex.

Data protection law

25. This guidance focuses on medical professionals' ethical and legal duties of confidentiality. But the processing of personal data must also satisfy the requirements of data protection law, which imposes various duties on data controllers. Individual professionals can be data controllers in their own right (for instance if they are partners in general practice, or hold data about patients whom they treat privately), but in many cases the data controller will be the medical professional's employer. This guidance aims to be consistent with data protection law, but it is not guidance on the law. You can however find an overview of data protection law and its relationship with the common law duty of confidence in the legal annex.

Using and disclosing patient information for direct care

Sharing information for direct care

26. Appropriate information sharing is an essential part of the provision of safe and effective care. Patients may be put at risk if those who provide their care do not have access to relevant, accurate and up-to-date information about them.[9] Multidisciplinary and multi-agency teamwork is also placing increasing emphasis on integrated care and partnership working, and information sharing is central to this, but information must be shared within the framework provided by law and ethics.

Implied consent and sharing information for direct care

27. Most patients understand and expect that relevant information must be shared within the direct care team to provide their care.[19] You should share relevant information with those who provide or support direct care to a patient, unless the patient has objected (see paragraphs 30 and 31).[11]

28. The usual basis for sharing information for a patient's own care is the patient's consent, whether that is explicit or implied (see paragraph 13 for definitions). You may rely on implied consent to access relevant information about the patient or to share it with those who provide (or support the provision of) direct care to the patient if all of the following are met.

    a. You are accessing the information to provide or support the individual patient's direct care, or are satisfied that the person you are sharing the information with is accessing or receiving it for this purpose.
    b. Information is readily available to patients, explaining how their information will be used and that they have the right to object. This can be provided in leaflets and posters, on websites, and face to face. It should be tailored to patients' identified communication requirements as far as practicable.
    c. You have no reason to believe the patient has objected.
    d. You are satisfied that anyone you disclose personal information to understands that you are giving it to them in confidence, which they must respect.

29. If you suspect a patient would be surprised to learn about how you are accessing or disclosing their personal information, you should ask for explicit consent unless it is not practicable to do so (see paragraph 14). For example, a patient may not expect you to have access to information from another healthcare provider or agency on a shared record.

Patient objections to sharing information for their own care

30. If a patient objects to particular personal information being shared for their own care, you should not disclose the information unless it would be justified in the public interest,[12] or is of overall benefit to a patient who lacks the capacity to make the decision. You can find further guidance on disclosures of information about adults who lack capacity to consent in paragraphs 41 - 49.

31. You should explain to the patient the potential consequences of a decision not to allow personal information to be shared with others who are providing their care. You should also consider with the patient whether any compromise can be reached. If, after discussion, a patient who has capacity to make the decision still objects to the disclosure of personal information that you are convinced is essential to provide safe care, you should explain that you cannot refer them or otherwise arrange for their treatment without also disclosing that information.

If a patient cannot be informed

32. Circumstances may arise in which a patient cannot be informed about the disclosure of personal information, for example in a medical emergency. In such cases, you should pass relevant information promptly to those providing the patient's care.

33. If the patient regains the capacity to understand, you should inform them how their personal information was disclosed if it was in a way they would not reasonably expect.

Sharing information with those close to the patient

34. You must be considerate to those close to the patient and be sensitive and responsive in giving them information and support, while respecting the patient's right to confidentiality.

Establishing what the patient wants

35. The people close to a patient can play a significant role in supporting, or caring for, the patient and they may want or need information about the patient's diagnosis, treatment or care. Early discussions about the patient's wishes can help to avoid disclosures they might object to.

    Such discussions can also help avoid misunderstandings with, or causing offence or distress to, anyone the patient would want information to be shared with.

36. You should establish with the patient what information they want you to share, with whom, and in what circumstances. This will be particularly important if the patient has fluctuating or

diminished capacity or is likely to lose capacity, even temporarily. You should document the patient's wishes in their records.

Abiding by the patient's wishes

37. If a patient who has capacity to make the decision refuses permission for information to be shared with a particular person or group of people, it may be appropriate to encourage the patient to reconsider that decision if sharing the information may be beneficial to the patient's care and support. You must, however, abide by the patient's wishes, unless disclosure would be justified in the public interest (see paragraphs 63 - 70).

38. If a patient lacks capacity to make the decision, it is reasonable to assume the patient would want those closest to them to be kept informed of their general condition and prognosis, unless they indicate (or have previously indicated) otherwise. You can find detailed advice on considering disclosures about patients who lack capacity to consent in paragraphs 41 - 49.

Listening to those close to the patient

39. In most cases, discussions with those close to the patient will take place with the patient's knowledge and consent. But if someone close to the patient wants to discuss their concerns about the patient's health without involving the patient, you should not refuse to listen to their views or concerns on the grounds of confidentiality. The information they give you might be helpful in your care of the patient.

40. You should, however, consider whether your patient would consider you listening to the views or concerns of others to be a breach of trust, particularly if they have asked you not to listen to specific people. You should also make clear that, while it is not a breach of confidentiality to listen to their concerns, you might need to tell the patient about information you have received from others – for example, if it has influenced your assessment and treatment of the patient.[13] You should also take care not to disclose personal information unintentionally – for example, by confirming or denying the person's perceptions about the patient's health.

Disclosures about patients who lack capacity to consent

41. You must work on the presumption that every adult patient has the capacity to make decisions about the disclosure of their personal information. You must not assume a patient lacks capacity to make a decision solely because of their age, disability, appearance, behaviour, medical condition (including mental illness), beliefs, apparent inability to communicate, or because they make a decision you disagree with.

42. You must assess a patient's capacity to make a particular decision at the time it needs to be made, recognising that fluctuations in a patient's condition may affect their ability to understand, retain or weigh up information, or communicate their wishes.

43. We give detailed advice on assessing a patient's mental capacity in our guidance *Decision making and consent*. Practical guidance is also given in the *Adults with Incapacity (Scotland) Act 2000* and *Mental Capacity Act 2005* codes of practice.[14]

Considering the disclosure

44. You may disclose personal information if it is of overall benefit to a patient who lacks the capacity to consent. When making the decision about whether to disclose information about a patient who lacks capacity to consent, you must:

    a. make the care of the patient your first concern
    b. respect the patient's dignity and privacy
    c. support and encourage the patient to be involved, as far as they want and are able, in decisions about disclosure of their personal information.

45. You must also consider:

    a. whether the patient's lack of capacity is permanent or temporary and, if temporary, whether the decision to disclose could reasonably wait until they regain capacity
    b. any evidence of the patient's previously expressed preferences
    c. the views of anyone the patient asks you to consult, or who has legal authority to make a decision on their behalf, or has been appointed to represent them
    d. the views of people close to the patient on the patient's preferences, feelings, beliefs and values, and whether they consider the proposed disclosure to be of overall benefit to the patient
    e. what you and the rest of the healthcare team know about the patient's wishes, feelings, beliefs and values.

46. You might need to share personal information with a patient's relatives, friends or carers to enable you to assess the overall benefit to the patient. But that does not mean they have a general right of access to the patient's records or to be given irrelevant information about, for example, the patient's past healthcare.

47. You must share relevant information with anyone who is authorised to make health and welfare decisions on behalf of, or who is appointed to support and represent, a patient who lacks capacity to give consent. This might be a welfare attorney, a court-appointed deputy or

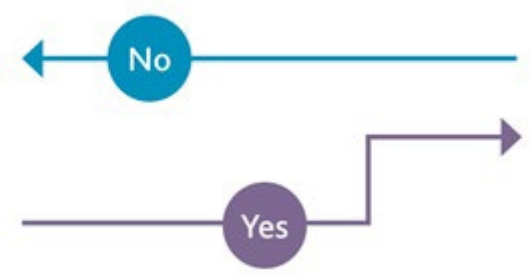
guardian, or an independent mental capacity advocate. You should also share information with independent mental health advocates in some circumstances.[15]

If a patient who lacks capacity asks you not to disclose

48. If a patient asks you not to disclose personal information about their condition or treatment, and you believe they lack capacity to make that decision, you should try to persuade them to allow an appropriate person to be given relevant information about their care. In some cases, disclosing information will be required or necessary, for example under the provisions of mental health and mental capacity laws (see paragraph 47).

49. If the patient still does not want you to disclose information, but you consider that it would be of overall benefit to the patient and you believe they lack capacity to make that decision, you may disclose relevant information to an appropriate person or authority. In such cases, you should tell the patient before disclosing the information and, if appropriate, seek and carefully consider the views of an advocate or carer. You must document in the patient's records your discussions and the reasons for deciding to disclose the information.[14]

Decision tool



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Disclosures for the protection of patients and others

Disclosing information to protect patients

50. All patients have the right to a confidential medical service. Challenging situations can however arise when confidentiality rights must be balanced against duties to protect and promote the health and welfare of patients who may be unable to protect themselves.

Disclosing information about children who may be at risk of harm

51. For specific guidance on confidentiality in the context of child protection, see our guidance *Protecting children and young people*.[16] For general advice on confidentiality when using, accessing or disclosing information about children and young people, see our guidance *0–18 years*.[17]

Disclosing information about adults who may be at risk of harm

52. As a rule, you should make decisions about how best to support and protect adult patients in partnership with them, and should focus on empowering patients to make decisions in their own interests. You must support and encourage patients to be involved, as far as they want and are able, in decisions about disclosing their personal information.

Legal requirements to disclose information about adults at risk

53. There are various legal requirements to disclose information about adults who are known or considered to be at risk of, or to have suffered, abuse or neglect.[18] You must disclose information if it is required by law.

You should:

a. satisfy yourself that the disclosure is required by law
b. only disclose information that is relevant to the request, and only in the way required by the law
c. tell patients about such disclosures whenever practicable, unless it would undermine the purpose of the disclosure to do so.

54. You can find advice about disclosures that are permitted but not required by law in paragraphs 17 - 19.

Disclosing information to protect adults who lack capacity

55. You must disclose personal information about an adult who may be at risk of serious harm if it is required by law (see paragraph 53). Even if there is no legal requirement to do so, you must give information promptly to an appropriate responsible person or authority if you believe a patient who lacks capacity to consent is experiencing, or at risk of, neglect or physical, sexual or emotional abuse, or any other kind of serious harm, unless it is not of overall benefit to the patient to do so.

56. If you believe it is not of overall benefit to the patient to disclose their personal information (and it is not required by law), you should discuss the issues with an experienced colleague. If you decide not to disclose information, you must document in the patient's records your discussions and the reasons for deciding not to disclose. You must be able to justify your decision.

The rights of adults with capacity to make their own decisions

57. As a principle, adults who have capacity are entitled to make decisions in their own interests, even if others consider those decisions to be irrational or unwise. You should usually ask for consent before disclosing personal information about a patient if disclosure is not required by law, and it is practicable to do so. You can find examples of when it might not be practicable to ask for consent in paragraph 14.

58. If an adult patient who has capacity to make the decision refuses to consent to information being disclosed that you consider necessary for their protection, you should explore their reasons for this. It may be appropriate to encourage the patient to consent to the disclosure and to warn them of the risks of refusing to consent.

59. You should, however, usually abide by the patient's refusal to consent to disclosure, even if their decision leaves them (but no one else) at risk of death or serious harm.[19, 20] You should do your best to give the patient the information and support they need to make decisions in their own interests – for example, by arranging contact with agencies to support people who experience domestic violence.[21] Adults who initially refuse offers of assistance may change their decision over time.

Disclosing information to protect others

60. Medical professionals owe a duty of confidentiality to their patients, but they also have a wider duty to protect and promote the health of patients and the public.[22]

Legal requirements to disclose information for public protection purposes

61. Some laws require disclosure of patient information for purposes such as the notification of infectious diseases and the prevention of terrorism. You must disclose information if it is required by law, including by the courts (see paragraphs 87 - 94).

Disclosing information with consent

62. You should ask for a patient's consent to disclose information for the protection of others unless the information is required by law or it is not safe, appropriate or practicable to do so (see paragraph 14), or the information is required by law. You should consider any reasons given for refusal.

Disclosing information in the public interest

63. Confidential medical care is recognised in law as being in the public interest. The fact that people are encouraged to seek advice and treatment benefits society as a whole as well as the individual. But there can be a public interest in disclosing information to protect individuals or society from risks of serious harm, such as from serious communicable diseases or serious crime.[23]

64. If it is not practicable or appropriate to seek consent, and in exceptional cases where a patient has refused consent, disclosing personal information may be justified in the public interest if failure to do so may expose others to a risk of death or serious harm. The benefits to an individual or to society of the disclosure must outweigh both the patient's and the public interest in keeping the information confidential.

65. Such a situation might arise, for example, if a disclosure would be likely to be necessary for the prevention, detection or prosecution of serious crime, especially crimes against the person. When victims of violence refuse police assistance, disclosure may still be justified if others remain at risk, for example from someone who is prepared to use weapons, or from domestic violence when children or others may be at risk.

66. Other examples of situations in which failure to disclose information may expose others to a risk of death or serious harm include when a patient is not fit to drive,[24] or has been diagnosed with a serious communicable disease,[25] or poses a serious risk to others through being unfit for work.[26]

67. Before deciding whether disclosure would be justified in the public interest you should consider whether it is practicable or appropriate to seek consent (see paragraph 14). You

should not ask for consent if you have already decided to disclose information in the public interest but you should tell the patient about your intention to disclose personal information, unless it is not safe or practicable to do so. If the patient objects to the disclosure you should consider any reasons they give for objecting.

68. When deciding whether the public interest in disclosing information outweighs the patient's and the public interest in keeping the information confidential, you must consider:

    a. the potential harm or distress to the patient arising from the disclosure – for example, in terms of their future engagement with treatment and their overall health
    b. the potential harm to trust in medical professionals generally – for example, if it is widely perceived that doctors, physician associates or anaesthesia associates will readily disclose information about patients without consent
    c. the potential harm to others (whether to a specific person or people, or to the public more broadly) if the information is not disclosed
    d. the potential benefits to an individual or to society arising from the release of the information
    e. the nature of the information to be disclosed, and any views expressed by the patient
    f. whether the harms can be avoided or benefits gained without breaching the patient's privacy or, if not, what is the minimum intrusion.

If you consider that failure to disclose the information would leave individuals or society exposed to a risk so serious that it outweighs the patient's and the public interest in maintaining confidentiality, you should disclose relevant information promptly to an appropriate person or authority.

69. You must document in the patient's record your reasons for disclosing information with or without consent. You must also document any steps you have taken to seek the patient's consent, to inform them about the disclosure, or your reasons for not doing so.

70. Decisions about whether or not disclosure without consent can be justified in the public interest can be complex. Where practicable, you should seek advice from a Caldicott or data guardian or similar expert adviser who is not directly connected with the use for which disclosure is being considered. If possible, you should do this without revealing the identity of the patient.

Responding to requests for information

71. You must consider seriously all requests for relevant information about patients who may pose a risk of serious harm to others. For example, you must participate in procedures set up to protect the public from violent and sex offenders, such as multi-agency public protection

arrangements (MAPPA) in England, Wales and Scotland and public protection arrangements in Northern Ireland (PPANI).[27] You must also consider seriously all requests for information needed for formal reviews (such as inquests and inquiries, serious or significant case reviews, case management reviews, and domestic homicide reviews) that are established to learn lessons and to improve systems and services.

72. If you disclose personal information without consent, you must be satisfied that there is a legal basis for breaching confidentiality (see paragraph 9). You must also be satisfied that the other relevant requirements for disclosing information are met (see paragraph 10).

Disclosing genetic and other shared information

73. Genetic and some other information about your patient might also be information about others with whom the patient shares genetic or other links. The diagnosis of a patient's illness might, for example, point to the certainty or likelihood of the same illness in a blood relative.

74. Most patients will readily share information about their own health with their children and other relatives, particularly if they are told it might help those relatives to:

    a. get prophylaxis or other preventative treatments or interventions
    b. make use of increased surveillance or other investigations
    c. prepare for potential health problems.[28]

75. If a patient refuses to consent to information being disclosed that would benefit others, disclosure might still be justified in the public interest if failure to disclose the information leaves others at risk of death or serious harm (see paragraphs 63 - 70). If a patient refuses consent to disclosure, you will need to balance your duty to make the care of your patient your first concern against your duty to help protect the other person from serious harm.

76. If practicable, you should not disclose the patient's identity in contacting and advising others about the risks they face.

Using and disclosing patient information for secondary purposes

77. Many important uses of patient information contribute to the overall delivery of health and social care. Examples include health services management, research, epidemiology, public health surveillance, and education and training. Without information about patients the health and social care system would be unable to plan, develop, innovate, conduct research or be publicly accountable for the services it provides.

78. There are also important uses of patient information that are not connected to the delivery of health or social care, but which serve wider purposes. These include disclosures for the administration of justice, and for purposes such as financial audit and insurance or benefits claims.

79. Anonymised information will usually be sufficient for purposes other than the direct care of the patient and you must use it in preference to identifiable information wherever possible. If you disclose identifiable information, you must be satisfied that there is a legal basis for breaching confidentiality.

80. You may disclose personal information without breaching duties of confidentiality when any of the following circumstances apply.

    a. The disclosure is required by law, including by the courts (see paragraphs 87 - 94).
    b. The patient has given explicit consent (see paragraph 95).
    c. The disclosure is approved through a statutory process that sets aside the common law duty of confidentiality (see paragraphs 103 - 105).
    d. The disclosure can, exceptionally, be justified in the public interest (see paragraphs 106 - 112).

    You must also be satisfied that the other relevant requirements for disclosing information are met (see paragraph 10).

Anonymised information

81. The Information Commissioner's Office anonymisation code of practice (ICO code) considers data to be anonymised if it does not itself identify any individual, and if it is unlikely to allow any individual to be identified through its combination with other data.[29] Simply removing the patient's name, age, address or other personal identifiers is unlikely to be enough to anonymise information to this standard.[30]

82. The ICO code also makes clear that different types of anonymised data pose different levels of re-identification risk. For example, data sets with small numbers may present a higher risk of re-identification than large data sets. The risk of re-identification will also vary according to the environment in which the information is held. For example, an anonymised data set disclosed into a secure and controlled environment could remain anonymous even though the same data set could not be made publically available because of the likelihood of individuals being identified.

83. You should follow the ICO code, or guidance that is consistent with the ICO code, or seek expert advice, if you have a role in anonymising information or disclosing anonymised information.

The process of anonymising information

84. Information may be anonymised by a member of the direct care team who has the knowledge, skills and experience to carry out the anonymisation competently, or will be adequately supervised.

85. If it is not practicable for the information to be anonymised within the direct care team, it may be anonymised by a data processor under contract, as long as there is a legal basis for any breach of confidentiality (see paragraph 80), the requirements of data protection law are met (see the legal annex) and appropriate controls are in place to protect the information (see paragraph 86).

Disclosing anonymised information

86. If you decide to disclose anonymised information, you must be satisfied that appropriate controls are in place to minimise the risk of individual patients being identified. The controls that are needed will depend on the risk of re-identification, and might include signed contracts or agreements that contain controls on how the information will be used, kept and destroyed, as well as restrictions to prevent individuals being identified. You should refer to specialist advice or guidance when assessing risk, or considering what level of control is appropriate.[31]

Disclosures required by statutes or the courts

Disclosure required by statute

87. There are a large number of laws that require disclosure of patient information – for purposes as diverse as the notification of infectious diseases, the provision of health and social care services, the prevention of terrorism and the investigation of road accidents.

88. You must disclose information if it is required by law. You should:

    a. satisfy yourself that personal information is needed, and the disclosure is required by law
    b. only disclose information relevant to the request, and only in the way required by the law

c. tell patients about such disclosures whenever practicable, unless it would undermine the purpose of the disclosure to do so
d. abide by patient objections where there is provision to do so.[32]

89. You can find advice about disclosures that are permitted but not required by law in paragraph 19.

Disclosing information to the courts, or to obtain legal advice

90. The courts, both civil and criminal, have powers to order disclosure of information in various circumstances. You must disclose information if ordered to do so by a judge or presiding officer of a court.

91. You should only disclose information that is required by the court. You should object to the judge or the presiding officer if attempts are made to compel you to disclose what appears to you to be irrelevant information, such as information about a patient's relative who is not involved in the proceedings. You should also tell the judge or the presiding officer if you think disclosing the information might put someone at risk of harm.

92. If disclosure is ordered, and you do not understand the basis for this, you should ask the court or a legal adviser to explain it to you. You should also tell the patient whose information the court has asked for what information you will disclose in response to the order, unless that is not practicable or would undermine the purpose for which disclosure is sought.

93. You must not disclose personal information to a third party such as a solicitor, police officer or officer of a court without the patient's explicit consent, unless it is required by law, or ordered by a court, or can be justified in the public interest. You may disclose information without consent to your own legal adviser to get their advice.

94. In Scotland under the process of precognition disclosure, if you receive a precognition request, in some cases you will have a legal duty to share information, and in other cases disclosure would be voluntary and subject to the guidance at paragraph 9.[33]

Consent

95. You should ask for consent to disclose personal information for purposes other than direct care[34] or local clinical audit unless the information is required by law, or it is not appropriate or practicable to obtain consent (see paragraph 14 for examples of when this might be the case).

Disclosures for health and social care secondary purposes

Clinical audit

96. All medical professionals in clinical practice have a duty to participate in clinical audit[35] and to contribute to clinical outcome review programmes.[36] If an audit is to be carried out by the team that provided care, or those working to support them, such as clinical audit staff, you may disclose personal information on the basis of implied consent, as long as you are satisfied that it is not practicable to use anonymised information and that the patient:

    a. has ready access to information that explains that their personal information may be disclosed for local clinical audit, and they have the right to object
    b. has not objected.

97. If a patient does object to personal information about them being included in a local clinical audit related to their care, you should explain why the information is needed and how this may benefit their current and future care. If the patient still objects, you should remove them from the audit if practicable. If that is not practicable, you should make sure this is explained to the patient, along with any options open to them.
98. If a clinical audit is to be carried out, but not by the team that provided care or those working to support them, the information should be anonymised. If this is not practicable, or if personal information is essential to the audit, you should disclose the information only if you have the patient's explicit consent or if there is another legal basis for breaching confidentiality (see paragraph 80). You must also be satisfied that the other relevant requirements for disclosing information are met (see paragraph 10).

Disclosures for financial or administrative purposes

99. If you are asked to disclose information about patients for financial or administrative purposes, you should give it in an anonymised form, if that is practicable and will serve the purpose. If identifiable information is needed, you must be satisfied that there is a legal basis for breaching confidentiality (see paragraph 80).[37] You must also be satisfied that the other relevant requirements for disclosing information are met (see paragraph 10).

The professional duty of candour and confidentiality

100. All medical professionals have a duty of candour – a professional responsibility to be honest with patients when things go wrong. As part of this duty, they must tell the patient when something has gone wrong, and explain the short- and long-term effects of what has happened.[38]

101. If the patient has died, or is unlikely to regain consciousness or capacity, it may be appropriate to speak to those close to the patient. When providing information for these purposes, you should still respect the patient's confidentiality. If a patient has previously asked you not to share personal information about their condition or treatment with those close to them, you should abide by their wishes. You must still do your best to be considerate, sensitive and responsive to those close to the patient, giving them as much information as you can.

Openness and learning from adverse incidents and near misses

102. A number of reporting systems and schemes exist around the UK for reporting adverse incidents and near misses. Organisations also have policies for reporting and responding to adverse incidents and near misses and in some cases organisational duties of candour have been written into law.[39] If the law requires personal information to be disclosed for these purposes, you should follow the guidance in paragraph 87. If the law does not require it, you should ask for consent to disclose personal information unless it is not appropriate or practicable to do so (see paragraph 14). In exceptional cases, disclosure may be justified without consent in the public interest (see paragraphs 106 - 112).

Disclosures with specific statutory support

103. In England, Wales and Northern Ireland, statutory arrangements are in place for considering whether disclosing personal information without consent for health and social care purposes would benefit patients or the public sufficiently to outweigh patients' right to privacy. Examples of these purposes include medical research, and the management of health or social care services. There is no comparable statutory framework in Scotland.

104. Section 251 of the *National Health Service Act 2006* (which applies in England and Wales) and the *Health and Social Care (Control of Data Processing) Act (Northern Ireland) 2016* allow the common law duty of confidentiality to be set aside for defined purposes where it is not possible to use anonymised information and where seeking consent is not practicable. You can find more detail about these statutory arrangements in the legal annex.

105. You may disclose personal information without consent if the disclosure is permitted or has been approved under regulations made under section 251 of the *National Health Service Act 2006* or under the *Health and Social Care (Control of Data Processing) Act (Northern Ireland) 2016*. If you know that a patient has objected to information being disclosed for purposes other than direct care, you should not usually disclose the information unless it is required under the regulations.[40]

Public interest disclosures for health and social care purposes

106. In exceptional circumstances, there may be an overriding public interest in disclosing personal information without consent for important health and social care purposes if there is no reasonably practicable alternative to using personal information and it is not practicable to seek consent. The benefits to society arising from the disclosure must outweigh the patient's and public interest in keeping the information confidential.

107. You should not disclose personal information without consent in the public interest if the disclosure falls within the scope of any of the regulations described in paragraphs 103 - 105, and the disclosure is not permitted, or has not been approved, under those regulations.

108. If the regulations described in paragraphs 103 - 105 do not apply, you may need to make your own decision about whether disclosure of personal information without consent is justified. The circumstances in which the public interest would justify such disclosures are uncertain, however, so you should seek the advice of a Caldicott or data guardian or a legal adviser who is not directly connected with the use for which the disclosure is being considered before making the disclosure.[41]

109. Before considering whether disclosing personal information without consent may be justified in the public interest, you must satisfy yourself that it is either necessary to use identifiable information or not reasonably practicable to anonymise the information. In either case, you must be satisfied that it is not reasonably practicable to seek consent.[42]

110. When considering whether disclosing personal information without consent may be justified in the public interest, you must take account of the factors set out in paragraph 67. You must also be satisfied that:

    a. the disclosure would comply with the requirements of data protection law and would not breach any other legislation that prevents the disclosure of information about patients (see the legal annex for examples)
    b. the disclosure is the minimum necessary for the purpose
    c. the information will be processed in a secure and controlled environment that has the capabilities and is otherwise suitable to process the information (see paragraph 86)
    d. information is readily available to patients about any data that has been disclosed without consent, who it has been disclosed to, and the purpose of the disclosure.

111. If you know that a patient has objected to information being disclosed for purposes other than their own care, you should not disclose information in the public interest unless failure to do so would leave others at risk of death or serious harm (see paragraphs 63 - 70).

112.You must keep a record of what information you disclosed, your reasons, and any advice you sought.

Ethical approval for research

113.You should only disclose personal information for research if there is a legal basis for the disclosure and the research has been approved by a research ethics committee.

114.If you are applying for ethical approval for research, you should let the research ethics committee know if personal information will be disclosed without consent and tell them the legal basis for the disclosure.

Requests from employers, insurers and other third parties

115.Third parties, such as a patient's insurer or employer, or a government department, or an agency assessing a claimant's entitlement to benefits, may ask you for personal information about a patient, either following an examination or from existing records. In these cases, you should:

a. be satisfied that the patient has sufficient information about the scope, purpose and likely consequences of the examination and disclosure, and the fact that relevant information cannot be concealed or withheld
b. obtain or have seen written consent to the disclosure from the patient or a person properly authorised to act on the patient's behalf. You may accept an assurance from an officer of a government department or agency, or a registered health professional acting on their behalf, that the patient or a person properly authorised to act on their behalf has consented
c. only disclose factual information you can substantiate, presented in an unbiased manner, which is relevant to the request. You should not usually disclose the whole record,[43] although it may be relevant to some benefits paid by government departments and to other assessments of a patient's entitlement to pensions or other health-related benefits
d. offer to show your patient, or give them a copy of, any report you write about them for employment or insurance purposes before it is sent, unless:
    i. they have already indicated they do not wish to see it
    ii. disclosure would be likely to cause serious harm to the patient or anyone else

iii. disclosure would be likely to reveal information about another person who does not consent.[44, 45]

116. If a patient refuses or withdraws consent, or if it is not practicable to get their consent, you may still disclose information if it can be justified in the public interest (see paragraphs 63 - 70). You must disclose information if it is required by law (see paragraphs 87 - 94).

Managing and protecting personal information

Improper access and disclosure

117. Health and care records can include a wide range of material, including but not limited to:

a. handwritten notes
b. electronic records
c. correspondence between health professionals
d. visual and audio recordings
e. laboratory reports
f. communications with patients (including texts and emails).

118. Many improper disclosures of patient information are unintentional. Conversations in reception areas, at a patient's bedside and in public places may be overheard. Notes and records may be seen by other patients, unauthorised staff, or the public if they are not managed securely. Patient details can be lost if handover lists are misplaced, or when patient notes are in transit.

119. You must make sure any personal information about patients that you hold or control is effectively protected at all times against improper access, disclosure or loss. You should not leave patients' records, or other notes you make about patients, either on paper or on screen, unattended. You should not share passwords.

120. You must not access a patient's personal information unless you have a legitimate reason to view it.

121. You should not share personal information about patients where you can be overheard, for example in a public place or in an internet chat forum.[46] While there are some practice environments in which it may be difficult to avoid conversations with (or about) patients being overheard by others, you should try to minimise breaches of confidentiality and privacy as far as it is possible to do so.

Knowledge of information governance and raising concerns

122. You must develop and maintain an understanding of information governance that is appropriate to your role.

123. You should be satisfied that any members of staff you manage are trained and understand their information governance responsibilities. If you are responsible for employment contracts, you must make sure they contain obligations to protect confidentiality and to process information in line with data protection law.

124. Unless you have a role in commissioning or managing systems, you are not expected to assess the security standards of large-scale computer systems provided for your use in the NHS or in other managed healthcare environments. If, however, you are concerned about the security of personal information in premises or systems provided for your use, or the adequacy of staff training on information governance, you should follow our advice in *Raising and acting on concerns about patient safety*.[47]

Processing information in line with the data protection law

125. The *General Data Protection Regulation* read with the *Data Protection Act 2018* sets out the responsibilities of data controllers[48] when processing personal data, as well as a number of rights for individuals (known as data subjects). Detailed guidance is available on the website of the Information Commissioner's Office (ICO).[49] You can find a summary of the data protection principles in the legal annex to this guidance.

126. If you are a data controller, you must understand and meet your obligations under data protection law. This includes responsibilities to make sure patients' personal information that you hold is handled in ways that are transparent and in ways that patients would reasonably expect, and appropriate technical and organisational measures are in place to guard against data loss. You must also make sure information is readily available to patients that explains how their information is processed, including:

    a. who has access to information you hold that might identify them and for what purposes
    b. their options for restricting access to some or all of their records
    c. their rights to complain about how their information is processed, and how to make a complaint.

When deciding how to provide this information, you should take into account the ICO's guidance on fair processing or privacy notices.[50]

127. Whether or not you are a data controller, you must be familiar with, and follow, the confidentiality, data protection and record management policies and procedures where you work and know where to get advice on these issues. This includes policies on the use of laptops and mobile devices.

Records management and retention

128. If you are responsible for managing patient records or other patient information, you must make sure the records you are responsible for are made, stored, transferred, protected and disposed of in line with data protection law and other relevant laws. You should make use of professional expertise when selecting and developing systems to record, access and send electronic data.[51]

129. You must make sure any other records you are responsible for, including financial, management or human resources records, or records relating to complaints, are kept securely and are clear, accurate and up to date.[52] You should make sure administrative information, such as names and addresses, can be accessed separately from clinical information so that sensitive information is not displayed automatically.

130. The UK health departments publish guidance on how long health records should be kept and how they should be disposed of. You should follow the guidance, even if you do not work in the NHS.[53]

The rights of patients to access their own records

131. Patients have a right to access their own health records, subject to certain safeguards.[54] You should respect, and help patients to exercise, their legal rights to have access to, or copies of, their health records. The ICO gives guidance on what fees you may charge.

Communicating with patients

132. Wherever possible, you should communicate with patients in a format that suits them. For example, electronic communications – such as email or text messaging – can be convenient and can support effective communication between doctors and patients, with appropriate safeguards.[55]

133. Most communication methods pose some risk of interception – for example, messages left on answering machines can be heard by others and emails can be insecure. You should take reasonable steps to make sure the communication methods you use are secure.

Disclosing information after a patient has died

134. Your duty of confidentiality continues after a patient has died.[56]

135. There are circumstances in which you must disclose relevant information about a patient who has died. For example:

- when disclosure is required by law
- to help a coroner, procurator fiscal or other similar officer with an inquest or fatal accident inquiry[57]
- on death certificates, which doctors must complete honestly and fully
- when a person has a right of access to records under the *Access to Health Records Act 1990* or the *Access to Health Records (Northern Ireland) Order 1993*, unless an exemption applies
- when disclosure is necessary to meet a statutory duty of candour.[58]

136. In other circumstances, whether and what personal information may be disclosed after a patient's death will depend on the facts of the case. If the patient had asked for information to remain confidential, you should usually abide by their wishes. If you are unaware of any instructions from the patient, when you are considering requests for information you should take into account:

a. whether disclosing information is likely to cause distress to, or be of benefit to, the patient's partner or family[59]
b. whether the disclosure will also disclose information about the patient's family or anyone else
c. whether the information is already public knowledge or can be anonymised or de-identified
d. the purpose of the disclosure.

137. Circumstances in which you should usually disclose relevant information about a patient who has died include:

- the disclosure is permitted or has been approved under a statutory process that sets aside the common law duty of confidentiality, unless you know the patient has objected (see paragraphs 103 - 105)

- when disclosure is justified in the public interest to protect others from a risk of death or serious harm
- for public health surveillance, in which case the information should be anonymised, unless that would defeat the purpose
- when a parent asks for information about the circumstances and causes of a child's death
- when someone close to an adult patient asks for information about the circumstances of that patient's death, and you have no reason to believe the patient would have objected to such a disclosure
- when disclosure is necessary to meet a professional duty of candour (see paragraphs 100 - 101)
- when it is necessary to support the reporting or investigation of adverse incidents, or complaints, for local clinical audit, or for clinical outcome review programmes.[60]

138. Archived records relating to deceased patients remain subject to a duty of confidentiality, although the potential for disclosing information about, or causing distress to, surviving relatives or damaging the public's trust will diminish over time.[61]

Legal annex

There is no overarching law that governs the disclosure of confidential information. The common law and other laws that require or permit the disclosure of patient information interact in complex ways and it is not possible to decide whether a use or disclosure of patient information would be lawful by considering any aspect of the law in isolation.

This section sets out some of the key elements of the law that are relevant to the use and disclosure of patient information, but it is not comprehensive. It is also not intended to be a substitute for independent, up-to-date legal advice. If you are unsure about the legal basis for a request for information, you should ask for clarification from the person making the request and, if necessary, seek independent legal advice.

We have also published a more detailed factsheet, *Confidentiality: key legislation*, which you can find on our confidentiality guidance on our website.

Sources of law on confidentiality, data protection and privacy

The common law

Information acquired by medical professionals in their professional capacity will generally be confidential under the common law. This duty is derived from a series of court judgments, which have established the principle that information given or obtained in confidence should not be used or disclosed further except in certain circumstances. This means a medical professional must not disclose confidential information, unless there is a legal basis for doing so.

It is generally accepted that the common law allows disclosure of confidential information if:

a. the patient consents
b. it is required by law, or in response to a court order
c. it is justified in the public interest.

But the common law cannot be considered in isolation. Even if a disclosure of confidential information is permitted under the common law, the disclosure must still satisfy the requirements of data protection law.

Data protection law (UK)

The *General Data Protection Regulation* (GDPR), supplemented by the *Data Protection Act 2018*, regulates the processing of personal data about living individuals in the UK. It sets out the responsibilities of data controllers when processing personal data as well as a number of rights for individuals, including rights of access to their information. The Information Commissioner's Office (ICO) is the authority responsible for upholding information rights in the UK. Detailed guidance on complying with the data protection law is available on the ICO website: www.ico.org.uk.

The GDPR defines personal data as:

'any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person'

The GDPR defines a data controller as 'the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data'. Individuals can be data controllers in their own right (for example, if

they are partners in general practice, or hold data in relation to patients whom they treat privately) but in many cases the data controller will be the medical professional's employer.

The GDPR is based around six data protection principles, and provides a range of rights for individuals. The principles state that personal data must:

- be processed lawfully, fairly and in a transparent manner
- be processed for specified, explicit and legitimate purposes and not in any manner incompatible with those purposes
- be adequate, relevant and limited to what is necessary in relation to the purposes
- be accurate and up to date
- not be kept for longer than is necessary
- be secure

The first principle of the GDPR states that data must be processed lawfully and fairly. This means:

a. patients' information must not be processed in a way that breaches either statute or common law. For example, if disclosing information would be a breach of the common law duty of confidentiality, it would also be unlawful under the data protection law
b. patients' personal information must be handled in ways that are transparent and in ways they would reasonably expect.

One or more of the conditions for processing in Article 6 (for all personal data) and Article 9 (for special category data', which includes health data) to the GDPR must also be met for the processing to be fair and lawful.

In all cases where personal data is processed, at least one of the conditions set out in Schedule 2 must be met. The conditions most likely to be relevant in medical practice are that:

- the data subject has given consent (Article 6(1)(a))
- the processing is necessary for the performance of a contract (Article 6(1)(b))
- the processing is necessary because of a legal obligation that applies to the data controller (except an obligation imposed by a contract) (Article 6(1)(c))
- the processing is necessary to protect the vital interests of the data subject (Article 6(1)(d))
- the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority (Article 6 (1)(e))
- the processing is necessary for the purposes of legitimate interests pursued by the data controller or a third party (Article 6 (1)(f)).

Where special category data are being used, at least one of the conditions in Article 9 must also be met. Information on a patient's health record is likely to be special category data for the purposes of the GDPR. The conditions most likely to be relevant in medical practice are that:

- the data subject has given explicit consent (Article 9(2)(a))
- the processing is necessary to protect the vital interests of the data subject or another person in a case where the data subject is physically or legally incapable of giving consent (Article 9(2)(c))
- the processing is necessary for reasons of substantial public interest Article 9(2)(g))
- the processing is necessary for medical purposes where the processing is undertaken by a health professional or someone else who owes an equivalent duty of confidentiality (Article 9 (2)(h))
- the processing is necessary for reasons of public interest in the area of public health (Article 9(2)(i))
- the processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes (Article 9(2)(j)).

The *Data Protection Act 2018* sets out more specific requirements which must also be met when a data controller is relying on the public interest and health conditions in Article 9. In some circumstances a data controller is required under the *Data Protection Act 2018* to produce an 'appropriate policy document' which sets out the compliance measures in place to protect the data. This requirement does not apply if the disclosure of sensitive personal data uses the health-related conditions for processing, but it does apply if an employment related condition is relied on. The interactions between the GDPR and *Data Protection Act 2018* are complex and data controllers should seek specialist advice where appropriate.

Consent under the GDPR

The standard of consent under the GDPR is higher than under the common law of confidentiality. The GDPR defines consent as:

'any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.'

The GDPR also sets out a number of other conditions for consent.

- The controller must be able to demonstrate that the data subject has consented to the processing of personal data.

- Consent can be withdrawn at any time (this doesn't affect lawfulness of processing before withdrawal). Prior to giving consent, data subjects must be informed of their right to withdraw. It must be as easy to withdraw consent as to give it.
- Consent should not be regarded as freely given if the data subject has no genuine or free choice or is unable to refuse or withdraw consent without detriment.

It will not always be appropriate for data controllers to rely on consent under GDPR as a condition for processing health data. For example, implied consent is an accepted concept under the law of confidentiality, but it is unlikely to be a sufficient basis for sharing personal data based on consent under Article 6(1)(a) of the GDPR, and will not be sufficient for sharing 'special category data' based on explicit consent under Article 9(2)(a) of the GDPR. However, the GDPR does provide alternative conditions for processing data which are likely to be more appropriate in a health context.

This means that an individual professional who is a data controller may be relying on different legal justifications for disclosing information under the common law duty of confidence and under the GDPR. It also means that medical professionals can continue to share information on the basis of implied consent if the conditions set out in paragraphs 28 and 29 (for direct care) and 96 (for local clinical audit) of this guidance are met.

Other requirements imposed by the GDPR

The GDPR imposes a number of other requirements on data controllers, and confers various rights on data subjects. A full summary of the GDPR is outside the scope of this guidance, but detailed guidance is provided by the Information Commissioner's Office.

Human Rights Act 1998 UK

The Human Rights Act 1998 incorporates the European Convention on Human Rights (ECHR) into UK law. A person's right to have their privacy respected is protected by Article 8 of the ECHR. This right is not absolute, and may be interfered with where the law permits and where it is *'necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.'*

Any interference with a person's right to privacy must be a necessary and proportionate response to the situation. This means there must be a fair balancing of competing interests. These include:

- the potential damage caused to the individual whose privacy will be breached
- society's interest in the provision of a confidential health service

- the public interest that will be achieved through breaching the individual's privacy.

Relevant factors to take into account when considering a disclosure in the public interest are given in paragraphs 63 - 70, and 106 - 112 of this guidance.

Other ECHR rights that may be relevant to considerations about whether disclosing a patient's personal information is necessary and proportionate include Article 2 (which protects the right to life), Article 3 (which prohibits torture or inhumane or degrading treatment or punishment) and potentially others. Such considerations are complex and you should seek legal advice if necessary.

Freedom of Information Acts across the UK

The Freedom of Information Act 2000 (England, Northern Ireland and Wales) and Freedom of Information (Scotland) Act 2002 give public access to information held by public authorities. Public authorities include government departments, local authorities, the NHS, state schools and police forces. The Acts do not give people access to their own personal information such as their health records. If a member of the public wants to see information that a public authority holds about them, they should make a subject access request under the *Data Protection Act 1998*. You can find guidance about the Freedom of Information Act 2000 on the ICO website. Guidance about the *Freedom of Information (Scotland) Act 2002* is available on the website of the Scottish Information Commissioner.

Computer Misuse Act 1990 UK

It is an offence under this Act to gain unauthorised access to computer material. This would include using another person's ID and password without authority to use, alter or delete data.

Regulation of healthcare providers and professionals

Various bodies regulating healthcare providers and professionals have legal powers to require information to be disclosed, including personal information about patients. The following sets out only a selection of these bodies, and gives a summary of their most relevant powers and refers to the codes of practice they publish about how they use their powers.

The **Care Quality Commission** (CQC) in England has powers of inspection and entry and to require documents and information under the *Health and Social Care Act 2008*. Sections 76 to 79 govern the CQC's use and disclosure of confidential personal information. Section 80 requires it to consult on and publish a code of practice on how it obtains, handles, uses and discloses confidential personal information. You can find the code of practice on the CQC's website.

Healthcare Inspectorate Wales has powers under the *Health and Social Care (Community Health and Standards) Act 2003* to access a patient's personal information.

Healthcare Improvement Scotland has similar powers in relation to registered independent healthcare providers under the *Public Services Reform (Scotland) Act 2010*.

The **Regulation and Quality Improvement Authority** in Northern Ireland has powers under sections 41 and 42 of the *Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003* to enter establishments, agencies and health and social services bodies or providers' premises and inspect and take copies of records, subject to the protection of confidential information provided for in section 43.

The NHS Counter Fraud Authority has powers under the *National Health Service Act 2006* and the *National Health Service (Wales) Act 2006* to require the production of documents to prevent, detect and prosecute fraud in the NHS. The Department of Health (England) and the Welsh Assembly Government have published codes of practice for the use of these powers. There are no comparable specific powers to require the production of documents for these purposes in Scotland or Northern Ireland.

The *General Medical Council* has powers under section 35A of the *Medical Act 1983* (as amended) and under schedule 3, paragraph 7(4) of the Anaesthesia Associates and Physician Associates Order 2024 to require disclosure of information and documentation relevant to the discharge of our fitness to practise functions, provided such disclosure is not prohibited by other laws. Other professional regulators have similar powers. For example, the **Nursing and Midwifery Council** has powers to require disclosure of patient information for the purpose of carrying out its fitness to practise functions in some circumstances under section 25 of the *Nursing and Midwifery Order 2001*.

The **Parliamentary and Health Service Ombudsman**, the **Northern Ireland Public Services Ombudsman**, the **Public Services Ombudsman for Wales** and the **Scottish Public Services Ombudsman** have legal powers similar to the High Court or Court of Session to require the production of documents and the attendance and examination of witnesses for the purposes of investigations about the health bodies that fall within their remits.

Laws on disclosure for health and social care purposes

Health and Social Care Act 2012 (England)

Section 259 gives the Health and Social Care Information Centre (known as NHS Digital) the power to require providers of health and social care in England to send it confidential data in limited circumstances, including when directed to do so by the UK Secretary of State for Health or NHS England. Patient consent is not needed, but patient objections will be handled in line with

the pledges set out in the *NHS Constitution for England* and directions given to NHS Digital by the Secretary of State.

Health and Social Care (Safety and Quality) Act 2015 (England)

This Act places a duty on providers and commissioners of health and social care in England to share information when it is considered likely to facilitate the provision of health or social care to an individual and when it is in the individual's best interests. The duty will not apply where an individual objects (or would be likely to object), or where the information is connected with the provision of care by 'an anonymous access provider' (such as a sexual health service) or where the duty cannot be reasonably complied with for other reasons. The duty does not override duties under the common law or the Data Protection Act 1998. The Information Governance Alliance has published guides to the Health and Social Care (Safety and Quality) Act 2015 on its website.

Health and Social Care (Control of Data Processing) Act (Northern Ireland) 2016

This Act requires the Department of Health in Northern Ireland to make regulations that permit or require the processing of confidential information for defined health and social care purposes. The Act allows the common law duty of confidentiality to be set aside where seeking individuals' consent is not practicable, where it is not possible to use anonymised information and where the committee established under the Act has authorised the processing. The Act does not set aside the *Data Protection Act 1998* or the *Human Rights Act 1998* and any use of information must continue to comply with the requirements of these two pieces of legislation.

No regulations have yet been made under the Act. Until such regulations are made the Privacy Advisory Committee will continue to advise health and social care bodies about the use of information relating to patients and clients. You can find out more about the committee on its website.

Section 251 of the NHS Act 2006 (England and Wales)

Section 251 of this Act allows the Secretary of State for Health to make regulations to set aside the common law duty of confidentiality for defined medical purposes. In practice, this means the person responsible for the information can disclose confidential patient information without consent to an applicant without being in breach of the common law duty of confidentiality, as long as the requirements of the regulations are met. The person responsible for the information must still comply with all other relevant legal obligations such as the *Data Protection Act 1998* and the *Human Rights Act 1998*.

The regulations that enable this power are called the *Health Service (Control of Patient Information) Regulations 2002*. Any references to 'section 251 support or approval' actually refer to approval given under the authority of the regulations. These powers can only be used where it is not practical to obtain consent and anonymised information cannot be used, having regard to the cost and available technology. They cannot be used to permit information to be disclosed solely or principally for the direct care of individual patients. The regulations only apply in England and Wales.

The regulations provide different kinds of support.

- Regulation 2 provides specific support for cancer registries to receive and process identifiable data on patients referred for the diagnosis or treatment of cancer for the medical purposes set out in the regulation.
- Regulation 3 provides specific support for identifiable patient information to be disclosed to, and processed by, the persons or bodies listed in paragraph 3 of Regulation 3 when processing is intended to diagnose, control or prevent, or recognise trends in, communicable diseases and other risks to public health.
- Regulation 5 can be used to permit processing for a range of medical purposes, broadly defined to include 'preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of health and social care services'. Any person wishing to obtain support under Regulation 5 will submit an application to the Confidentiality Advisory Group of the Health Research Authority. The Confidentiality Advisory Group will then give advice to the relevant decision maker, which is currently the Health Research Authority for research applications and the Secretary of State for Health for non-research applications.

  > The Confidentiality Advisory Group will not usually authorise disclosures under Regulation 5 to which the patient has objected. The Health Research Authority may not give an approval unless a research ethics committee has approved the medical research concerned.

You can find more information about section 251 of the *NHS Act 2006* and the role of the Confidentiality Advisory Group on the website of the Health Research Authority.

Statutory restrictions on disclosing information about patients

Gender Recognition Act 2004 (UK)

Section 22 of the Act makes it an offence to disclose 'protected information' when that information is acquired in an official capacity. 'Protected information' is defined as information

about a person's application for gender recognition and a person's gender history after that person has changed gender under the Act. Section 22 also sets out a series of exceptions where disclosure is considered to be justified. These are further expanded and clarified by *The Gender Recognition (Disclosure of Information) (England, Wales and Northern Ireland) Order 2005* and *The Gender Recognition (Disclosure of Information) (Scotland) Order 2005*.

Human Fertilisation and Embryology Act 1990 (UK)

Section 33A protects the confidentiality of information kept by clinics and the Human Fertilisation and Embryology Authority. Information may be accessed or disclosed only in the specific circumstances set out in the Act. Disclosing information that identifies the patient in other circumstances without the patient's prior consent is a criminal offence.

The National Health Service (Venereal Diseases) Regulations 1974 (Wales) and the NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000 (England)

These regulations provide that any information capable of identifying an individual who is examined or treated for any sexually transmitted disease, including HIV, shall not be disclosed, other than to a medical practitioner in connection with the treatment of the individual in relation to that disease or for the prevention of the spread of the disease.

Endnotes

1. Caldicott or data guardians are senior people in the NHS, local authority social care services, and partner organisations, who are responsible for protecting the confidentiality of patient information and enabling appropriate information sharing. Data protection officers have a statutory function under the General Data Protection Regulation to monitor a data controller's compliance with the GDPR.

2. In this guidance, 'personal information' means information from which individuals can be identified either in itself or in combination with other available information. 'Disclosure' means the provision or passing of information about a patient to anyone other than the patient, regardless of the purpose. Sharing information within healthcare teams is a form of disclosure, as is providing access to patients' records.

3. These principles are aligned with the Caldicott principles for information governance within health and social care.

4. We use the term 'overall benefit' to describe the ethical basis on which decisions are made about treatment and care for adult patients who lack capacity to decide. Our guidance on overall benefit is consistent with the legal requirement to consider whether treatment 'benefits' a patient (as the term is used in the *Adults with Incapacity (Scotland) Act 2000*), or is in the patient's 'best interests' (as the term is used in the *Mental Capacity Act 2005* in England and Wales, and in the common law in Northern Ireland). The use of the term is also consistent with the legal requirement to apply the other principles set out in the *Mental Capacity Act 2005* and *Adults with Incapacity (Scotland) Act 2000*.

5. Medical professionals working in a managed environment will do this largely by understanding and following this guidance and corporate information governance and confidentiality policies. If you are a data controller, you are personally responsible for understanding and meeting your responsibilities under the data protection law. See the legal annex to this guidance for more information.

6. Implied consent is not likely to be sufficient to share personal data under Article 6 of the GDPR and is not sufficient to share 'special category data' such as health data under Article 9 of the GDPR. However, other conditions for processing health data are likely to apply. See the legal annex for more detail.

7. See paragraph 115 of this guidance and our guidance *Delegation and referral* (2024). You can find all GMC guidance on professional standards and ethics available on our website.

8. An example is the *Crime and Disorder Act 1998*. Section 115 permits disclosure to organisations such as the police, local authorities, or probation services but does not create a legal obligation to do so.

9. In 2013, the Caldicott principles were updated to include a new principle: '*the duty to share information can be as important as the duty to protect patient confidentiality*.'

10. In this guidance, 'direct care' refers to activities that directly contribute to the diagnosis, care and treatment of an individual. The direct care team is made up of those health and social care professionals who provide direct care to the patient, and others, such as administrative staff, who directly support that care.

11. In England the *Health and Social Care (Safety and Quality) Act 2015* created a duty to share information for direct care except in certain circumstances. See the legal annex to this guidance for more information.

12. For example, if staff providing treatment may be at risk of serious harm which cannot be managed through the use of universal precautions. See our guidance *Disclosing information about serious communicable diseases*. You can find all GMC guidance on professional standards and ethics at www.gmc-uk.org/guidance.

13. Patients are also entitled to access their health records under the data protection law. See endnote 54.

14. The main provisions of the *Mental Capacity Act (Northern Ireland) 2016* have not yet come into force. The common law duty to act in the best interests of a patient who lacks capacity to consent therefore continues until the Act is commenced. In Scotland, under the *Adults with Incapacity (Scotland) Act 2000* (the 2000 Act), you will have legal authority to make decisions about treatment if you are the treating medical practitioner with lead responsibility for the patient's treatment and care, subject to issuing a certificate of incapacity. In this context 'medical practitioner' is taken to mean 'doctor' given its use in The Medical Act 1983. It should be noted that this legal authority is not restricted to doctors in Scotland as section 47(1A) of the 2000 Act states that in addition to medical practitioners, dental practitioners, ophthalmic opticians, registered nurses and any individual who falls within such description of persons as may be prescribed by the Scottish Ministers also has this authority. This list does not include physician associates or anaesthsia associates so on this basis physician associates and anaesthesia associates do not have this legal authority.

15. Independent mental health advocates should also be given the information listed in section 130B of the *Mental Health Act 1983*. Guidance on the roles of independent mental health advocates is given in the *Mental Health Act 1983 Code of Practice 2015*.

16. *Protecting children and young people* (General Medical Council, 2012). You can find all GMC guidance on professional standards available on our website.

17. *0–18 years:* (General Medical Council, 2007). You can find all GMC guidance on professional standards and ethics available on our website.

18. The requirements of the relevant Acts – the *Adult Support and Protection (Scotland) Act 2007*, the *Social Services and Well-being (Wales) Act 2014* and the *Care Act 2014* – are summarised in the *Confidentiality: key legislation factsheet.*

19. In very exceptional circumstances, disclosure without consent may be justified in the public interest to prevent a serious crime such as murder, manslaughter or serious assault even where no one other than the patient is at risk. This is only likely to be justifiable where there is clear evidence of an imminent risk of serious harm to the individual, and where there are

no alternative (and less intrusive) methods of preventing that harm. This is an uncertain area of law and, if practicable, you should seek independent legal advice before making such a disclosure without consent.

20. The Department of Health in England has published *Information sharing and suicide prevention: consensus statement* (2014), which is consistent with the principles in this guidance.

21. Safelives has published guidance on disclosing information to multi-agency risk assessment conferences (MARACs), which are local meetings established to discuss how to help individuals who are at high risk of murder or serious harm. The guidance is available on the Safelives website. Personal information may be disclosed to a MARAC with consent, or if the disclosure can be justified in the public interest (see paragraphs 63–70 in this guidance).

22. See 'The duties of medical professionals registered with the General Medical Council' at the front of this guidance.

23 There is no agreed definition of 'serious crime'. *The Confidentiality: NHS Code of Practice Supplementary Guidance: Public Interest Disclosures* (Department of Health, 2003) gives some examples of serious crime. These include crimes that cause serious physical or psychological harm to individuals (such as murder, manslaughter, rape and child abuse); and crimes that cause serious harm to the security of the state and public order; and 'crimes that involve substantial financial gain or loss' are also mentioned in the same category. It also gives examples of crimes that are not usually serious enough to warrant disclosure without consent (including theft, fraud, and damage to property where loss or damage is less substantial). NHS Protect has published *Not part of the job* (NHS Protect, 2012), which gives guidance to NHS staff on reporting assaults and violent incidents at work.

24. We give specific advice on reporting concerns about patients' fitness to drive in our guidance *Confidentiality: Patients' fitness to drive and reporting concerns to the DVLA or DVA.* That guidance deals specifically with drivers on the roads, but the same principles apply to drivers and pilots of other kinds of regulated transport, including by rail, water and air. You can find all GMC guidance on professional standards and ethics on our website.

25. See our guidance *Confidentiality: disclosing information about serious communicable diseases.*

26. See our guidance *Confidentiality: disclosing information for employment, insurance and similar purposes.*

27. You should consider the assessment of risk posed by patients made by other professionals and by groups established for that purpose, but you must make your own assessment and decision as to whether disclosure is justified. Your assessment of risk is a matter of

professional judgement in which an offender's past behaviour will be a factor. The Royal College of Psychiatrists publishes guidance for psychiatrists about sharing information in the context of public protection, including participation in multi-agency public protection arrangements (MAPPA) and panels. You can find this in *Good Psychiatric Practice: Confidentiality and Information Sharing* (Royal College of Psychiatrists, second edition, 2010).

28. For more information, see *Consent and confidentiality in clinical genetic practice: Guidance on genetic testing and sharing genetic information – A report of the Joint Committee on Medical Genetics* (Royal College of Physicians, second edition, 2011).

29. You can find the Information Commissioner's Office (ICO) *Anonymisation: managing data protection risk code of practice* (2012) on the ICO website.

30. Other potential identifiers include the patient's initials, postcode, NHS or CHC number, local identifiers (such as hospital numbers), national insurance number, and key dates (such as birthdate, date of diagnosis or date of death).

31. See endnote 29 for the reference to ICO guidance.

32. The NHS Constitution for England and NHS Scotland's *The Charter of Patient Rights and Responsibilities* both set out the rights of a patient to object to how their information is used. Under data protection law, a data subject has a right to object to processing if it causes unwarranted and substantial damage or distress. For more information, see the *Guide to Data Protection* on the ICO website.

33. Please see our legal factsheet for further information about precognition..

34. See endnote 10 for the definition of 'direct care' in this guidance. Guidance on sharing information for direct care purposes is given in paragraphs 26–33.

35. In this guidance 'clinical audit' means the evaluation of clinical performance against standards or through comparative analysis, to inform the management of services.

36. See *Good medical practice* (2024), paragraph 13b. Formerly known as national confidential inquiries, clinical outcome review programmes are systematic reviews that are carried out with the aim of supporting changes that can help improve the quality and safety of healthcare delivery. You can find more information on the website of the Healthcare Quality Improvement Partnership. You can find all GMC guidance on professional standards and ethics, available on our website.

37. Commissioners have limited rights to request personal information held by general practices for defined purposes, although they should usually respect patients' objections. See the directions on confidentiality and disclosure of information and the code of practice for the relevant country for more information. *Confidentiality and Disclosure of Information (General Medical Services, Personal Medical Services, Alternative Provider Medical Services) Directions*

2013 and Code of Practice (Department of Health, 2013); Confidentiality and Disclosure of Information: General Medical Services and Alternative Provider Medical Services Directions (Northern Ireland) 2006 and Code of Practice (Department of Health, Social Services and Public Safety, 2006); Confidentiality and Disclosure of Information: General Medical Services (GMS), Section 17c Agreements, and Health Board Primary Medical Services (HBPMS) Code of Practice and Directions; Confidentiality and Disclosure of Information: General Medical Services and Alternative Provider Medical Services Directions 2006 and Code of Practice (Welsh Assembly Government, 2005).

38. We give guidance on professional and organisational duties of candour in *Openness and honesty when things go wrong: the professional duty of candour* (General Medical Council and Nursing and Midwifery Council, 2015). You can find all GMC guidance on professional standards and ethics, available on our website.

39. The obligations associated with the statutory duty of candour in England are contained in regulation 20 of the *Health and Social Care Act 2008 (Regulated Activities) Regulations 2014*. In Scotland they are contained in section 22 of the *Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016*.

40. Disclosures permitted under regulations 2 and 3 of the *Health Service (Control of Patient Information) Regulations 2002* may, in some circumstances, be required rather than permitted. The Confidentiality Advisory Group of the Health Research Authority will not usually authorise disclosures under regulation 5 to which the patient has objected. See the legal annex to this guidance for more detail on the regulations.

41. In Scotland, the Public Benefit and Privacy Panel for Health and Social Care scrutinises requests for access to some (but not all) NHS Scotland originated data. You may disclose personal information if the disclosure has been approved by the Public Benefit and Privacy Panel for Health and Social Care.

42. The Confidentiality Advisory Group (CAG) of the Health Research Authority publishes a range of guidance for CAG applicants, which you may find helpful. It is available at www.hra.nhs.uk.

43. Disclosure of the whole record may breach the principles of data protection law, as the full record may contain information that is excessive and not relevant for the purpose.

44. If any of the exceptions set out in paragraph 115(d) of this guidance apply, you should still disclose as much of the report as you can. The Department for Work and Pensions publishes advice about reports for benefits purposes.

45. In some circumstances, patients are entitled to see a report that has been written about them under the provisions of the *Access to Medical Reports Act 1988*. For more details see the *Confidentiality: key legislation* factsheet which you can find on the our confidentiality guidance page, available on our website.

46. See also our guidance *Using social media as a medical professional* (General Medical Council, 2024). You can find all GMC guidance on professional standards and ethics, available on our website.

47. *Raising and acting on concerns about patient safety* (General Medical Council, 2012). See endnote 46 for the web address.

48. The GDPR defines a 'data controller' as: 'the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data'. Key definitions of terms in the General Data Protection Regulation are available on the website of the Information Commissioner's Office.

49. The *Guide to data protection* is available on the website of the Information Commissioner's Office.

50. This is contained in the *Guide to data protection*; see endnote 49.

51. The Information Commissioner's Office publishes technical guidance. NHS Digital formerly known as Health and Social Care Information Centre in England publishes good practice guidelines on technology-specific areas of information security and information governance. It also publishes the Information Governance Toolkit for NHS organisations, which is an online system that allows NHS organisations and partners to assess themselves against Department of Health Information Governance policies and standards. In Scotland, guidance and information governance standards are collected on the Knowledge Network. In Wales, organisations are expected to use the online Caldicott-Principles Into Practice (C-PIP) assessment to measure their compliance with components of information security. GPs can check their compliance using the Welsh GMP Toolkit.

52. You can find guidance on the retention and destruction of these kinds of records in *Information Management Policy – Retention and Destruction* (Department of Health, July 2015).

53. Schedules of minimum retention periods for different types of records are given in *The Records Management Code of Practice 2021: A guide to the management of health and care records (NHSX, 2021)*; Records Management: NHS Code of Practice (Scotland)(Scottish Government, 2008); Welsh Health Circular (2000) 71: For The Record (The National Assembly for Wales, 2000) and Good Management, Good Records (Department of Health, Social Services and Public Safety, 2005). You should also consider any legal requirement of specialty-specific guidance that affects the period for which you should keep records. You should not keep records for longer than necessary.

54. Article 15 of the *General Data Protection Regulation* gives patients the right to access their personal information, although exemptions apply in certain circumstances. Most exemptions are contained in the *Data Protection Act 2018*. For example, an exemption applies if

providing subject access to information about an individual's physical or mental health or condition would be likely to cause serious harm to them or to another person's physical or mental health or condition. You also do not have to supply a patient with information about another person or that identifies another person as the source of the information, unless that other person consents or it is reasonable in the circumstances to supply the information without their consent. See the Information Commissioner's Office technical guidance, *Dealing with subject access requests involving other people's information* (Information Commissioner's Office, 2014).

55. The Scottish Government and NHS Scotland have published *Using email in NHS Scotland: A Good Practice Guide* (2014). The Professional Record Standards Body and the Health and Social Care Information Centre have published *Faster, better, safer communications: Using email in health and social care (in England)* (2015).

56. There is an obvious ethical obligation. There may also be a legal obligation: see *Lewis v. Secretary of State for Health [2008]* EWHC 2196. Section 38 of the *Freedom of Information (Scotland) Act 2002* includes a deceased person's medical records within the definition of personal information, which is exempt from the general entitlement to information.

57. See paragraph 98 of *Good medical practice* (General Medical Council, 2024) and paragraph 32 of our guidance *Providing witness statements or expert evidence as part of legal proceedings* (General Medical Council, 2024). You can find all our guidance on professional standards and ethics, available on our website.

58. See endnote 39 for references to statutory duties of candour.

59. The permission of a surviving relative or next of kin is not required for, and does not authorise, disclosure of confidential information, although the views of those who were close to the patient may help you decide if disclosure is appropriate.

60. See endnote 36 for a description of clinical outcome review programmes.

61. You should contact your organisation's approved place of deposit or The National Archives, the Public Record Office of Northern Ireland or the National Archives of Scotland for further advice about storage of, and access to, archives of records of ongoing research or historical value. Health records of deceased patients are exempt from the *Freedom of Information (Scotland) Act 2002*.

Email: **gmc@gmc-uk.org**
Website: **gmc-uk.org**
Telephone: **0161 923 6602**

General Medical Council, 3 Hardman Street, Manchester M3 3AW

Textphone: **please dial the prefix 18001** then **0161 923 6602** to use the Text Relay service.

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You are welcome to contact us in Welsh. We will respond in Welsh, without this causing additional delay.

Mae croeso i chi gysylltu â ni yn Gymraeg. Byddwn yn ymateb yn Gymraeg, heb i hyn achosi oedi ychwanegol.

Code: GMC/CON/1224

A. Of course. Of course.
346 Q. Did you tell anyone?
A. Yes, you can tell -- we did tell people. I mean, when I founded or set up CURE with Roberta Brownlee, we had four or five SPRs who did higher degrees, I mean I was very, very research-orientated, and I believe in a thing called clinical research, which clinicians should be doing, rather than laboratory research. 16:39
347 Q. Yes.
A. And I think that audit-generated research is so valuable because it closes the loop and all of that. But there is a limit to what you can do in addition to swimming against the tide of an inadequate service. 16:39
348 Q. I'm not suggesting that all clinicians should do this. I'm merely suggesting did you ask the question? Do you agree it's an important question? 16:39
A. Oh, absolutely yes.
349 Q. And you've talked about speaking to patients about the risks of various treatments and their choice.
A. Hmm. 16:39
350 Q. Did you document all of those risks in the notes and in letters to patients, for example?
A. No.
351 Q. Why didn't you?
A. Because -- because I'm not very good at writing and talking at the same time. So, you know, it's -- I did it. 16:40
352 Q. Mm-hmm.
A. And I think it's -- I mean that relationship between

doctor and patient is so important, and it's so important that patients are fully informed of that.

353 Q. I'm bringing that up as really a measure of patient-centred care.

A. Yeah. 16:40

354 Q. It's, you know, have they had the right information? Is it in writing?

A. Yeah.

355 Q. Because they do need to have something to refer to?

A. Yeah. 16:40

356 Q. And what is the ethos in the Trust? What's the spirit of that and what is done to assist you in these matters? Because the patient experience of that particular consultation I think is very important.

A. Hmm. 16:40

357 Q. You know, the post-MDT one where they are having that conversation with their treating clinician, trying to understand what's going on. So if you take that as an example of patient-centred care, was there an ethos of understanding the importance of that? 16:41

A. Well, there were some audits done of patient satisfaction and so forth, but I think there were --

358 Q. I'm going a bit further than that.

A. I think they were rather rudimentary, yeah. And in case I gave the wrong impression, it's not that I 16:41 didn't record it in the chart. I mean I wrote out all of the risks and benefits for the patient and gave it to them, in addition to the information booklets and so forth.

359 Q. But it's not in the notes, is it?
A. But not in the notes. Yeah.
360 Q. Hmm. And looking back on that, do you think you could have just photocopied it and put it in the notes, couldn't it? 16:41
A. Yes. I could have done, yes.
361 Q. Okay.
A. If I'd known actually I was going to be asked that question at a public inquiry I would certainly have insured it at the time, yes. 16:41
362 Q. Serious incidents. Lots of talk about that. If you look at serious incidents generally across the whole of the UK, if you look public inquiries generally, going back years and years, there are similar lessons everywhere, and learning from these things appears to 16:42 be problematic. Why is that, do you think?
A. Well, it's a hobbyhorse of mine. I don't know whether you will agree? I think the term "Serious Adverse Incident" is one that should be possibly done away with it. I prefer the one, Serious Adverse Experience, 16:42 because it's not patient-centred. I think, you know, I've sat at Patient Safety meetings at Directorate level, and at plenary session, and regionally for years, and you tend to have this incident, and the -- the discussion, and in fact some of the SAI reports are 16:42 rather circumscribed around an incident. Whereas, you know, I think actually a more holistic and more longitudinal look at the patient experience, you know, we listened to the son of a person who is deceased, who

please set out in full the nature of the concern, who, if anyone, you spoke to about it and what, if anything, happened next. You should include details of all meetings, contacts and outcomes. Was the concern resolved to your satisfaction? Please explain in full.

26.1 Yes. I raised a concern that related to "triage in urology," as set out in my response to Question 24 at 24.2., after it was brought to my attention by a member of the Acute Governance team on 9th November 2016. Please see my response to Question 27 27.10 to 27.18 for further details about this concern.

27. Did you have concerns regarding the practice of any practitioner in urology? If so, did you speak to anyone and what was the outcome? Please explain your answer in full, providing documentation as relevant. If you were aware of concerns but did not report them, please explain why not.

27.1 Yes. I had two concerns regarding Mr Aidan O'Brien during my employment in the Trust.

27.2 The first concern involved the prescribing and administration of gentamicin to urology patients. One of the experienced clinical pharmacists, who was based on the Craigavon Area Hospital (CAH) surgical wards, asked to speak to me about a clinical concern that she had not been able to resolve herself. She was aware of a number of patients who had been admitted for five or more days to receive an infusion of gentamicin, at Mr Aidan O'Brien's request.

27.3 Gentamicin is an aminoglycoside antibiotic used to treat serious infections, such as sepsis and acute pyelonephritis. It has a number of serious side effects including ototoxicity and nephrotoxicity.

27.4 The pharmacist's concerns were that the dose of gentamicin being prescribed was subtherapeutic and that she could not find any record or sig that

must be wrong as well, Dr. Boyce. Your response to that?

A. Well, I mean, I was in the room when that phone call was received. Now, to be fair to Mrs. Brownlee, I didn't hear what she said to Esther; I only was aware of what Esther told me afterwards. But I do recall it, definitely. As I say, it stuck in my mind and it was something when I was asked was there anything else I should disclose, in the interests of being open it was something I witnessed during my time in that role. 12:23 12:24

174 Q. Yes. Very well. Thank you for that. You have indicated within your witness statement that you had two concerns, or two concerns concerning Mr. O'Brien came across your desk metaphorically during your time within the Trust. The first issue I want to explore with you is a concern was drawn to your attention about his prescription or use of an antibiotic known as gentamicin? 12:24

A. Gentamicin, yes.

175 Q. Let's look at how this came to your attention. If we go to WIT-87655. If we pick up at 27.2, you have said that one of the experienced clinical pharmacists who is based in Craigavon Area Hospital surgical wards asked to speak to you about a clinical concern she had not been able to resolve herself. She was aware of a number of patients who had been admitted for five or more days to receive an infusion of gentamicin at Mr. O'Brien's request. 12:24 12:25

Doing the best, can you recall who this experienced clinical pharmacist was?

A. I am 90% certain it was a pharmacist called Claire Ward.

176 Q. Claire Ward? 12:25

A. Yes. She was based on the surgical wards at the time. We didn't have a pharmacist for every surgical ward, we just had one, and another pharmacist who would have worked more on gynae surgery and so on who would have covered. I would be 99% certain it was Claire Ward. 12:26

177 Q. You described her as experience?

A. She was an excellent pharmacist, clinical pharmacist.

178 Q. Her account to you was specifically in relation to Mr. O'Brien's conduct; is that right?

A. That's correct. 12:26

179 Q. No other clinician or consultant was reported to you?

A. Not that I was aware of at the time.

180 Q. Did you subsequently gain an understanding that, in terms of this practice, Mr. O'Brien and Mr. Michael Young were engaged in it? 12:26

A. Yes. Obviously in the bundle of papers I received and I have read, obviously I now understand that Mr. Young may have been, or was, also admitting patients for gentamicin.

181 Q. She says that, you recall -- if it was Mrs. Ward? 12:27

A. Yes.

182 Q. Hadn't been able to resolve the issue herself. Do you recall what actions, if any, she may have taken to try and resolve it?

A. Well, experienced pharmacists like herself based on the ward would have addressed it directly with the admitting consultant and their team. Obviously she could see that the patients weren't ill at the time of their admission, they had no underlying infection, and they were also receiving subtherapeutic doses of gentamicin. Obviously, that's a big risk from all sorts of angles in terms of promoting future resistance to that antibiotic, which, if the patient did admit get admitted with a life-threatening infection or so on, the antibiotic mightn't have worked at that moment they needed it. Even though the patients weren't being harmed at the time, they were being at risk. 12:27 12:27

Also having read the bundle, I understand some of the antibiotics were being given by central lines as well which I had no awareness at the time. Again, I don't understand why a central line would have been needed. Again, that's a big risk. But obviously that wasn't part of my understanding at the time. 12:28 12:28

183 Q. Yes. Were you told that she tried to address it or sought to address it with Mr. O'Brien but it wasn't resolved? Was that your expectation of what she would have done?

A. My expectation, and also that's why she was coming to me, because that was our sort of escalation. If a pharmacist was concerned about a clinical issue, they were expected to deal with it directly themselves with the consultant because that's where the relationship 12:28

was, they are part of the clinical team on the ward. If something that was concerning them persisted, then they escalated it to myself to try and address on their behalf.

184 Q. Tell me a little about gentamicin. Is this a regularly used antibiotic; is it particularly potent or toxic; what's the concerns around it? 12:29

A. It's quite an older antibiotic but it's still in use. It's an aminoglycoside antibiotic. It can have particularly nasty side effects in higher doses or prolonged doses. It can cause deafness, kidney damage. When we use it to treat an active infection, we actually monitor the blood level of gentamicin to make sure that it doesn't creep up, or the patient is not retaining it so it doesn't become toxic. It's in common use. It would be held as a stock item on most of the surgical wards. 12:29 12:29

So, the way the front pharmacy works - or certainly in our hospital works - was all the wards had a basic level of stock that they kept in their medicines cupboards. We would have had experience in pharmacy, we knew what a general surgical ward needed every week. Rather than the nursing team having to order every item they needed on a daily basis up and down to pharmacy, we would have held -- stocked the cupboards on the ward for them. If they needed to start a gentamicin infusion, they didn't need to contact pharmacy, they had it available in the cupboard. Once a week then the 12:30 12:30

pharmacy technical team would have gone up and, as it is called, topped up their stock. They had an agreed level they would have held every week. My team would have gone up, saw what they used and replaced it, basically. Gentamicin would have been a stock item on a surgical ward. 12:30

185 Q. Yes. If we just scroll down a little. I think in 27.3 you say in short form what you have just said. At 27.4 you outline the pharmacist's concerns. You say that: 12:31

"The dose was subtherapeutic. There was no sign of infection with the patient who was being treated with it. Patients appeared clinically well. She had spoken to staff and understood that the dose was to be used as specified by Mr. O'Brien." 12:31

What does subtherapeutic mean in that context?

A. Obviously based on patient's -- an adult patient, their weight and so on, there is a dose that you would start at to make sure you don't overdose, but you also don't want to underdose, to make the antibiotic work. There would be a therapeutic dose in gentamicin that you would initiate with a patient. As I say, you would have done what's called a trough blood level so many hours later to see how that individual patient was managing the gentamicin so that the next dose could be tweaked if necessary to make it higher or lower. But these were below. From memory, and I can't remember exactly but from memory, they were well below what you 12:31 12:32

would start gentamicin at in an average patient.

186 Q. Now, I don't think we need to delve too much into the rights or wrongs of this, but the Trust clearly took a view, and we understand that Mr. O'Brien took a different view and continues to take a different view, as to the efficacy of this practice. In terms of his rationale, as we understand it, the claim is that this intravenous therapy can be beneficial for a carefully selected patient with recurrent UTI. 12:32

12:33

In your experience, had you seen the drug gentamicin used in this way at that time?

A. No. No. This was the first time I became aware that that was happening. Certainly I wasn't aware of any evidence base to support its use, you know, in terms of published evidence. As pharmacists, obviously that's what we would look for in terms of the evidence base to support a practice such as that. 12:33

187 Q. If we scroll down, you said that, in your view, the pharmacist concerned were valid, and you set out your thinking - patients were being exposed to side effects unnecessarily, being cannulated for no reason, and being put at risk of acquiring an infection during hospital stay. There was also the risk of antimicrobial resistance could develop as a risk, as you saw it? 12:33 12:34

A. Yes, I think so.

188 Q. There was also the issue of, unnecessarily as you put it, using hospital resources.

To the best of your knowledge, did you come across any suspicion that patients who had been subject to this treatment had suffered antibiotic resistance, or are you just outlining risks here? 12:35

A. It was more the risk because obviously that would be in the future. I mean, resistance to gentamicin in certain parts of the world can be as high as 40%. Obviously, we need to preserve the antibiotic stock that we have in the world. Basically because there 12:35 aren't many new antibiotics coming on line, it's really important that we don't abuse them so that they are there for patients in the future if they really need it.

189 Q. If we scroll down to the action that you took. You 12:35 escalated this to the then Medical Director, Dr. Loughran, and you did so verbally?

A. Yes. At one of my one-to-ones with him.

190 Q. You cannot say when this stuff was done but you give a date range, January 2008-December 2010. You didn't 12:35 make any record of this?

A. No, unfortunately I didn't. My meetings with Dr. Loughran were very much him assisting me, facilitating. As we talked earlier about the one-to-ones being a supportive meeting in terms of 12:36 discussing issues and so on. It was a verbal discussion; I brought the issue to him and basically he said, okay, that sounds important, leave it with me.

191 Q. Given your concern about the issue, its implications,

it being out with conventional practice, as you saw it, is this not a matter that ought to have been dealt with more formally such as by raising an incident report, or do you consider that raising it directly and verbally with the Medical Director was the appropriate course? 12:36

A. I mean, looking back, yes, it should have been reported formally. I think at the time I wasn't aware of any harm having come to the patients. Yes, it wasn't appropriate but like I certainly wasn't aware of any of them succumbing to a line infection or anything like 12:37 that. I think, trying to think back, that was probably my thinking, that nobody has come to any harm but it's not right. It's a practice that needed to be investigated further to see. Maybe there was evidence but certainly I wasn't aware of any. I suppose that 12:37 was the sort of context that I took it to the Medical Director as the sort of almost like the line manager for the consultants in terms of.

Also, Dr. Loughran would have chaired the Drugs and 12:37 Therapeutics Committee at the time, and I would have been sort of like a secretary to the committee. Obviously that was starting to fall into our remit in terms of drugs and therapeutics, in terms of the use of the drug in that way. 12:38

192 Q. Yes. Then at 27.8 you record that a few weeks later, Dr. Loughran gave you an update about the actions he had taken, in informal conversation again. You have no record of it?

A. No.

193 Q. But you recall him telling you that he had spoken to Mr. O'Brien and told him that his practice of prescribing an infusion of gentamicin to patients was to cease immediately. He also advised you that he had spoken to ward managers to make them aware that Mr. O'Brien was no longer allowed to admit patients for this purpose. So, the message you got back was your concerns and the concerns of your pharmacist were shared and that the Trust had responded? 12:38

A. Yeah.

194 Q. Were there any consequences for the patients that you were aware of?

A. In terms of consequences clinically, not that I am aware of. I do know from obviously Dr. Loughran telling me the feature that there was a big patient backlash. The patients weren't happy that the treatment had been stopped, that they were no longer to be admitted. I do remember that. In terms of harm, future harm to the patients, not that I am aware of. 12:39

195 Q. Yes. I suppose I should have asked the question more carefully. In terms of withdrawing this treatment from patients, did you apprehend any adverse consequences for patients in removing them from this regime?

A. No. Not that I was aware of, no. 12:39

196 Q. Now, your statement doesn't suggest that you were told that there was a process in train, led by Dr. Loughran but engaging a number of both external and internal professionals in the examination of this issue. We

know, the Inquiry knows, for example, that the Trust had sought advice from a urologist based in Great Britain called Mr. Fordham; a microbiologist based in GB called Dr. O'Driscoll that Mr. O'Brien was met with and Mr. Young was met with in September 2010, and that a confidential paper in relation to this was brought up to the Board in September 2010 and again in November. Was any of that drawn to your attention? 12:40

A. Not at all. I only became aware that other people already maybe knew - I don't know if they knew before me or after me - when I read the documents that had been included in the bundle that I received. Certainly Dr. Loughran, he hadn't mentioned that to me at all at the time. 12:41

197 Q. Indeed, a protocol appears to have been developed? 12:41

A. I see that.

198 Q. If we just bring that up on the screen. It's a document that I think the Inquiry has considered previously. It's TRU-251143. It sets out the steps required as part of a process to review all cases of patients currently and intermittently receiving IV fluids and antibiotics. It goes through a number of steps, and I assume you have familiarised with that. But again, not something that was drawn to your attention at the time? 12:41 12:42

A. No.

199 Q. You were not a junior member of staff?

A. No.

200 Q. You were at Assistant Director level?

A. Mm hmm.
201 Q. This was an issue that you had escalated?
A. Mm hmm.
202 Q. It was clearly a parallel process that was taking practical steps to address. It was drawn to the attention of the Board. Can you think of any good reason why you wouldn't have been told that this is an issue that had come into the Trust separately through the Commissioner? 12:42
A. No. I mean, unless maybe I raised it and then after I raised it, because obviously I can't remember exactly when I first said. The only thing I could think of is maybe it came afterwards, but then you would have thought maybe I would have been updated in the future. It's a shame because obviously the pharmacists on the ward are a resource to keep an eye out to make sure it had stopped. I don't know why I was not updated or included at that point in terms of -- nor why Dr. Corrigan had become aware of it somehow as well. 12:42 12:43
203 Q. Could I ask you just a systems issue, a systems question? 12:43
A. Mm hmm.
204 Q. You described gentamicin as a stock medicine. This is surgical wards, so the stock would be there, without the need for a prescription? 12:43
A. No.
205 Q. Is it written into the Cardex?
A. Yes, a prescription on the ward is made into what we call the Cardex. It is the inpatient prescription.

So, one of Mr. O'Brien's team or one of the surgical junior doctors would have written the prescription according to Mr. O'Brien's instruction on the Cardex, and then that leaves the nursing staff to administer the medicine in accordance with that instruction. 12:44

206 Q. Yes. It seems to have been somewhat accidental, albeit you're an experienced pharmacist who clearly became alert to the problem. Would you agree with the analysis that this practice appeared to have been in place for some years and it was in a sense stumbled upon? 12:44

A. My staff stumbled upon it?

207 Q. Yes.

A. Yes. I think because back in that time we really only had one surgical pharmacist for three -- I think were there four surgical wards? Maybe three anyway. Obviously Claire was spread very thinly in terms of her role on the role. The pharmacist's role is, as best they can, to review all new prescriptions and make sure they are correct and appropriate, and obviously take 12:44 12:45 the patient's medication history as well to make sure that, if they have come through ED, the history that was taken from the patient about what their existing medication is has been correctly translated onto that inpatient Cardex and reviewed. Obviously with only one 12:45 pharmacist for three wards, that obviously didn't always happen, so Claire obviously wouldn't have seen any patient admitted for therapy, but she saw enough of them over a period of time that it became a concern for

her, which then came to my attention at that point. Nowadays we have a pharmacist for every ward so it would be much tighter surveillance.

208 Q. Again, the system for spotting what the Trust has called irregular prescribing, is it down to the alert pharmacist on the ward spotting the problem or is there a more sensitive way that these kinds of issues could be spotted if they were to occur again? 12:46

A. Unfortunately, at the minute it is still down to alert staff, whether it is the pharmacist or obviously the nursing staff or other medical staff. Our prescribing system in Northern Ireland based on wards and medicines administration system is paper-based, so there is no way of sitting back and having an overview. Now, I'm sure you have maybe heard already from other witnesses about Encompass that is coming. It's unfortunate. Back in 2015, I was sitting on a working group. They were going to introduce electronic prescribing and medicines administration system to all Trusts back, I think, 2015. In 2015/2016 that work was stood down because they thought at that point Encompass was going to come quite quickly and there was no point in investing in a standalone system when a bigger system was going to knock it out, you know, knock its position. So, that work was stood down. 12:46 12:47 12:47

Today, we still have a paper-based system until Encompass starts in the South Eastern 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. 12:47 12:48

209 Q. Let me come back to that in the context of the Bicalutamide issue in just a second or two. Just to finish off the gentamicin issue, could I bring up AOB-10091. I said before I don't wish to delve into the merits or the demerits of the use of gentamicin in these particular cases. You have expressed your view as to its propriety or conventionality, and you remain of the view, is that right -- 12:48 12:49

A. That's correct.

210 Q. -- that it's not something you would endorse?

A. No.

211 Q. Mr. O'Brien, for his part at the top of the page, this is an extract from his contribution to the MHPS investigation. He's responding here to what Mr. Mackle said in his statement, but it neatly encapsulates his view of the propriety of using the practice. He said: 12:49

"This issue related to the practice of both Mr. Young and I electively re-admitting patients who regularly suffered from recurring urosepsis for intravenous hydration and antibiotic therapy in order to minimise frequency and severity of infection." 12:50

You accept that it was both him and Mr. Young?

A. I understand now, yes.

212 Q. What you are dealing with is what came to your attention, and it was simply Mr. O'Brien. 12:50

He goes on to say that:

"This practice was disapproved by the Trust. However, our experience was subsequently published, having 12:50 proven to be successful in its purpose and without emerging antibiotic resistance."

He draws attention to the fact that it was published. If we could just briefly look at that, bring it onto 12:50 the screen. WIT-82743, a thesis published in 2011 in the journal Inspection. It runs to, if you scroll down -- scroll down, please, to the next page. Published in the names of Vincent Good, Michael Young, Aidan O'Brien, 16th August 2011, just after these 12:51 issues had been addressed the Trust. Just scroll up slightly. They record:

"From our preliminary results, we conclude that IVT is

beneficial for carefully selected patient with recurring UTI, and their treatment should be individually tailored. We do not claim to know the optimal duration of treatment."

12:52

Scroll right down to the next page, please:

"And regularity of IVT regime but suggest that it should be adapted to patient's condition."

12:52

Did you appreciate the rationale for the treatment when you reported in?

A. In terms of the rationale for the infusion?

213 Q. Yes.

A. No, because, I mean, it was well accepted that if someone maybe had recurring urinary tract infections, the oral route would have been the prophylactic route. Providing antibiotics, either low dose, even that wasn't really advised. Having patients at home with a supply of antibiotics, that if they started to get the early symptom of urinary tract infection, they could self-start. Certainly I wasn't aware of any research that supported the approach being taken with a low dose gentamicin infusion.

12:53

12:53

214 Q. Reflecting on all of this now from a governance perspective, do you think the systems of governance worked well or otherwise when addressing this issue?

12:53

A. I suppose in terms of how we identified it, it didn't work well because we were relying on that paper-based

system to spot unusual practice. In terms of afterwards, certainly from what I was told, it was addressed by Dr. Loughran, and then was fed back to me that the practice was stopped. I was asked if the pharmacist saw any more patients, I had to let him know, which they didn't.

In terms of my reflection on it, as far as I was concerned it had been dealt with, but I now know obviously there was maybe some other stuff going on in the background that I wasn't party to that maybe wasn't as straightforward as Dr. Loughran led me to believe at the time and what I was told at the time in terms of addressing it.

215 Q. Yes. Could I briefly deal with the issue, if I could, and perhaps a little out of sequence. 12:54

A. Okay.

216 Q. It is convenient to address it in light of what you have just recently said about systems. If we go to WIT-87665. At paragraph 8.1 at the bottom of the page, you say that you are aware that Mr. O'Brien was recommending the prescription of subtherapeutic doses of Bicalutamide for men diagnosed with prostate cancer. You became aware of this when Mark Haynes, Associate Medical Director, asked you for Trust Pharmacy help in auditing these prescription recommendations. 12:54 12:55

Over the page, please. You said, in summary, that you weren't able to assist Mr. Haynes --

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LETTER TO THE EDITOR

Preliminary assessment of regular short-term intravenous fluids and antibiotic therapy in recurrent UTI

Dear Sir,

We read with interest on the article by Falagas et al., concerning antibiotic treatment in women with uncomplicated cystitis.[1] In this context, the management of recurrent urinary tract infection (rUTI) remains a therapeutic challenge. Within our department, we have identified a cohort of patients with rUTI, who have had multiple emergency admissions for severe rUTI episodes requiring intravenous fluid and antibiotic therapy. For years, these patients have been treated appropriately with multiple oral antibiotics treatment and prophylactic antibiotic courses by their GP, but with little success since their symptoms, in particular nausea and generally unwell being, have prevented compliance to oral antibiotic therapy and adequate oral rehydration. As a consequence, their condition deteriorates and inevitably leading to the need for emergency hospital admission.

Over their multiple emergency admissions, we have evolved our treatment strategy to electively administer a combination of short-term intravenous fluids and antibiotics therapy (IVT) regularly to this cohort. The duration of admission for treatment varied dependent on the patient's treatment response and usually ranges between 3 and 5 days. In this select cohort, their nausea symptoms have prevented adequate oral rehydration and hence about 1–2 L per day of intravenous fluid were administered during admission. The antibiotic choice used during IVT is dependent on the most recent MSSU culture sensitivity. When IVT is completed, further oral antibiotics are not given. The rationale for this strategy is to adequately treat any underlying UTI completely prior becoming symptomatically severe and therapeutically difficult to manage. This cohort of rUTI patient usually became symptomatic about 3 months after their emergency admission for severe UTI. The frequency and duration regime is not fixed, but rather flexibly adapted according to patient's symptoms. The intention is to gradually prolong the regularity of this regime, for example every 3 monthly, then 6 monthly and gradually yearly. The ultimate aim is help these rUTI patients achieve independence from IVT and yet maintain a reasonably good quality of life. We report our experience with regular short-term intravenous fluids and antibiotic therapy (IVT) as an adjunctive treatment.

A retrospective cohort analysis was done on 16 patients with rUTI on IVT, and was followed up for an average of 100 months. There were 11 female and 5 male patients with the mean age of 41.2 (SD $\pm$ 15.9) years. Five patients have ileal conduit/urostomy, 2 patients had long-term suprapubic catheter, 4 patients perform ISC, 1 patient has a Mitrofanoff formation and the remaining patient without significant comorbidity. In all patients, extensive and comprehensive investigations have been performed to exclude any urologically treatable conditions that predispose to rUTI. Comparative assessments included emergency admission, urinary culture, antibiotic usage, SF-36 and FACIT-TS quality of life questionnaires, between the period before and during IVT.

There were a total of 206 of IVT admission episodes contributing to a total of 934 days and a mean duration of hospital stay per admission of 4.7 days. The mean duration between each IVT admission was 2.9 months. The number of emergency admission (88 vs 16, $p = 0.001$, X_2) and outpatient clinic reviews (216 vs 5, $p = 0.001$, X_2) have decreased significantly. The IVT for elective admissions predominantly utilised Gentamicin, followed by Co-amoxiclav as shown in Table 1. Similarly in the emergency admissions, intravenous Gentamicin and Co-amoxiclav were the antibiotic of choice. In the outpatient or GP practice setting, the predominant oral antibiotics used were Trimethoprim followed by Ciproxin and Cefelexin. A total of 1050 MSSU culture and direct microscopic results were obtained. Majority of MSSU are obtained at GP setting as shown in Table 2. The most common cultured uropathogen was coliforms, followed by mixed growth, Enterococcus faecalis, Proteus and Pseudomonas. There was significantly more mixed growth culture results obtained during the IVT period comparatively (14.8% vs 4.2%). There was a decreased in ESBL cultures during IVT treatment. Otherwise, the IVT did not significantly change the proportion of the colonising uropathogen type cultured.

There was a complete response rate of 100% to the SF-36 QoL and FACIT-TS questionnaire. The overall negative impact of rUTI on the QoL confirmed the debilitating nature of the disease. There are statistically significant

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Table 1 Frequency and type of antibiotic usage.

Antibiotic therapy	IVT admission	Emergency admission	OPD & GP
Intravenous			
Gentamicin	45.5%	40.5%	–
Co-amoxiclav	36.8%	38.1%	–
Ciprofloxacin	6.4%	4.8%	–
Cefuroxime	6.4%	9.5%	–
Meropenem	2.3%	2.4%	–
Cefutaxime	1.8%	0	–
Teicoplanin	0.05%	2.4	–
Vancomycin	0.05%	0	–
Netilmicin	0	2.4%	
Oral			
Trimethoprim	–	–	43.9%
Ciprofloxacin	–	–	35.2%
Cefelexin	–	–	10.9%
Co-Amoxiclav	–	–	5.5%
Nitrofurantoin	–	–	3.3%
Ampicillin	–	–	1.1%

improvements after being on the IV regimen in six of the SF-36 domains including the physical functioning (52.3 vs 35.4, $p = 0.05$), social functioning (51.6 vs 27.3, $p = 0.01$), physical role limitation (37.5 vs 4.7, $p = 0.01$), emotional role limitation (58.3 vs 24.9, $p = 0.04$), bodily pain (53.6 vs 30.5, $p = 0.03$) and vitality (42,5 vs 21.9, $p = 0.002$). The FACIT-TS showed an overall treatment satisfaction score of 81.5% and a treatment recommendation score of 95%. There were 3 recurring themes of commentaries from patients via FACIT-TS, and they were: i) IVT is effective, more so than oral antibiotics ii) IVT has significantly improved their quality of life and reduced the rate of emergency hospital admissions iii) IVT would be much better if given in a non-hospital admission setting.

Because the major cost burden was incurred from inpatient hospital stay, one alternative solution is to develop IVT into an outpatient treatment, also known as Outpatient Parenteral Antibiotic Therapy (OPAT) or to develop a home intravenous antibiotic treatment.[2,3] OPAT and home intravenous antibiotic in various infectious conditions has been shown to be clinically efficacious and cost-effective in the United Kingdom National Health Service setting and the Australian healthcare system respectively. Administration of IVT through OPAT represents a potential economically viable option. Further, the carefully selected rUTI patients undergoing IVT are relatively well and require minimal clinical observation.

From our preliminary results, we conclude that IVT is beneficial for a carefully selected patient with rUTI and their treatment should be individually tailored. We do not claim to know the optimal duration of treatment and

Table 2 Admission and urinary culture data.

	Before IVT	During IVT	*p*-value
Mean duration of follow-up (months)	67.1	32.9	–
No. of emergency admission episodes	86	18	0.001, X_2
Mean duration of emergency episode (days)	5.6	5.8	NS
No. of OPD episodes	208	5	0.001, X_2
MSSU culture			
Not significant $<10^4$	219 (40%)	186 (37.0%)	–
No growth	73 (13.3%)	54 (10.7%)	–
Coliforms	145 (26.5%)	80 (15.9%)	–
Mixed growth	23 (4.2%)	74 (14.8%)	–
Enterococcus faecalis	40 (7.3%)	34 (6.8%)	–
Proteus	6 (1.1%)	29 (5.8%)	–
Pseudomonas	11 (2.0%)	16 (3.2%)	–
Escherichia Coli	5 (0.9%)	15 (2.9%)	–
Klebsiella	7 (1.3%)	4 (0.8%)	–
ESBL	8 (1.5%)	2 (0.4%)	–
Enterococcus faecium	2 (0.4%)	4 (0.8%)	–
Enterococci spp.	2 (0.4%)	1 (0.2%)	–
Staphalococcus aureus	2 (0.4%)	2 (0.4%)	–
Candida albicans	2 (0.4%)	0	–
MRSA	0	1 (0.2%)	–
Streptococcus Group A	2 (0.4%)	0	–
Streptococcus Group B	0	1 (0.2%)	–
MSSU origins			
Elective	–	213 (42.3%)	–
Emergency	109 (19.9%)	22 (4.4%)	–
OPD	86 (15.7%)	0	–
GP	352 (64.4%)	268 (53.3%)	–

NS – not statistically significant.

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regularity of IVT regime, but suggest that it should be adapted to patient's condition. It is hoped that this report will serve as a pilot assessment of its efficacy and proof of concept to allow for future randomised trials.

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Competing interest statement

None declared.

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Vincent Koo*
Michael Young
Aidan O'Brien
Department of Urology, Craigavon Area Hospital, 68 Lurgan Road, Portadown BT63 5QQ, Northern Ireland, United Kingdom
E-mail address: Personal Information redacted by USI

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* Corresponding author. Tel.: Personal Information redacted by USI fax: +44 Personal Information redacted by USI

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by the development of a vaccine against the three most common infecting organisms which have left people like this, and this is work that has been done in England, and which was started off licence in private practice. So sometimes, you know, developments do occur when they're not mainstream and when you're forced into a particular situation.

92 Q. But can I just bring you back to 2009?

A. Yes.

93 Q. Can I ask you from, I suppose, your understanding of the limits of a professional practice such as yours. You are no doubt conscious that there is nothing in the literature at that time to support this practice. There is the use of Trust resources in bringing these patients into the hospital. How can you do that without resort to permission from the management side of urology, whose resources, whose need to control the resources is important from the perspective of other patients and their needs?

A. Well we didn't -- Michael Young and I didn't do so, because there would have been no difficulty in the same organisation, the same urology management accommodating these people for a longer period of time. You asked the question from the perspective: How could you justify admitting these people when there was no evidence base for it, even though we had accumulated our own experiential evidence base, that by doing so we prevented them coming in and using the same resources for a longer period of time.

11:57 11:57 11:58 11:58 11:59

IN THE MATTER OF A PUBLIC INQUIRYUNDER THE INQUIRIES ACT 2005

THE UROLOGY SERVICES INQUIRY

CLOSING SUBMISSIONS ON BEHALF OF MR AIDAN O'BRIEN

1. These are the closing written submissions on behalf of Mr Aidan O'Brien. The panel is invited to consider these written submissions alongside Mr O'Brien's original Section 21 response dated 2nd November 2022[1] (and the chronologies which accompanied it), the addendum statement dated 31st August 2023[2] and his further addendum statement[3] submitted prior to Mr O'Brien's return to give evidence to the Inquiry for a second time in April 2024. The panel also has Mr O'Brien's respondent statements to the investigation conducted by Dr Chada[4], his subsequent comments relating to the respondent statement/interview conducted by Dr Chada thereon[5] and the grievance he lodged[6] with his employer, the Southern Health and Social Care Trust ("the Trust").

2. The panel is also invited to consider the very detailed oral evidence that Mr O'Brien gave to it on 19th[7], 20th[8] and 21st[9] April 2023 and on 8th[10], 10th[11] and 12th[12] April 2024.

3. A good deal of oral evidence has been heard and documentation submitted to the Inquiry which touches upon the clinical practice of Mr O'Brien.

4. In relation to Mr O'Brien's clinical practice, the Inquiry's Terms of Reference ("TOR") specifically provide as follows:

[1] WIT-82373 to WIT-82657
[2] WIT-98807 to WIT-98808
[3] WIT-107564
[4] TRU-00821; TRU00830
[5] AOB-01792
[6] AOB-15001 -15316 & AOB-02561 - 02572
[7] TRA-04619-04746
[8] TRA-04747-04883
[9] TRA-04884-05014
[10] TRA-12123-12250
[11] TRA-12359 - 12498
[12] TRA-12499 - 12664

> "(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;
>
> ….
>
> The clinical practice of Mr O'Brien is being investigated by the General Medical Council (GMC) and it would, therefore, be inappropriate for the Inquiry to encroach on the GMC's remit."

5. Mr O'Brien has noted and has relied upon the observations made by the Chair[13] and Counsel to the Inquiry[14] ("CTI") on the extent to which the Inquiry is minded to consider and make findings relating to his clinical practice, decision making and issues of causation in individual patient cases. For that reason, it is not the intention of these submissions to venture into the particularity of Mr O'Brien's management of individual patients save to the extent that it is necessary for him to do so in order to advance submissions which are consistent with the TOR. As the panel will also know, Mr O'Brien has expressed his grave concern about his ability to respond to issues raised about his clinical practice given that the complete, up to date, medical records relating to the majority of patients on the cipher list have not formed part of the disclosure provided to him.

6. It is unusual for a medical practitioner to find himself in a position where suggestions are made that there are concerns regarding his clinical practice, which it is said may give rise to governance issues, if the reality may well be that the concerns are misplaced so that no governance issues are in fact engaged. Without access to the complete and up to date clinical and administrative records for his scrutiny, it has not been possible for Mr O'Brien to rebut, dispute or accept any such concerns. Be that as it may, Mr O'Brien has endeavoured to strike an appropriate balance in the submissions which follow. If there are any further issues upon which the panel would benefit from additional evidence or submissions, Mr O'Brien is content to co-operate in any way that he can.

The essential context to Mr O'Brien's practice

[13] TRA-09933 - 09934
[14] TRA-09377 & TRA-12388

7. The panel is invited to consider fully and reflect in its report the essential context in which Mr O'Brien practised as a consultant urologist in the Trust.

8. Mr O'Brien singlehandedly set up the urology service in the legacy Craigavon Area Hospital Group Health and Social Care Trust, taking up his appointment as a consultant on 6th July 1992[15]. Thereafter he devoted his entire professional life to the service of the many patients he attended to and cared for over the following 28 years.

9. From the inception of the Trust's urology service until Mr O'Brien's employment ended in July 2020, the Department of Health ("the Department"), the Health & Social Care Board, Craigavon Area Hospital Group Trust and the Southern Health and Social Care Trust have presided over a grossly inadequate and unsafe urology service, causing patients to suffer and come to harm. It was disheartening in the extreme to hear from the Department's permanent secretary, Mr May that, if anything, the situation will continue to deteriorate before there might be some improvement in urology services provision[16].

10. Immediately prior to Mr O'Brien beginning his tenure as a consultant urologist, the consultant urologist/population ratio in Northern Ireland was 1:300,000 compared to 1:180,000 in Great Britain. Notwithstanding this self-evident inadequacy and the increasing need for urological services, the then Director of Public Health of the Southern Health & Social Services Board took a period of eight months to be convinced of the actual need of the Board's then resident population of almost 270,000 for a specialist urology service. This early reluctance to acknowledge the need for a specialist urology service is indicative of an enduring inadequacy in commissioning, staffing, and resourcing which has plagued the service ever since[17].

    As a consequence of these shortcomings, Mr O'Brien found himself having to provide singlehandedly a continuous, acute urological service until a second consultant urologist, Mr Baluch, took up his post in January 1996, in addition to the provision of an elective service until that date. He again had to do so from January 1998 following the departure of Mr Baluch until Mr Young replaced him in May 1998.

[15] See AOB01879 to AOB01886; AOB03498 to AOB03503 for background to development of the Urology Services at the Trust
[16] TRA-12330
[17] See Mr Connolly's email AOB-06264 expressing concern re General Surgeons displacing Urology cases and evidence at TRA-09490 - 09497 Connolly on 4th December 2023

11. Mr O'Brien documented the likelihood of ever-increasing inadequacy and its consequences in his paper of March 1997: 'The Future of Urological Services'[18]. These very early expressions of concerns demonstrate beyond doubt that there can be no suggestion that Mr O'Brien has only invoked the inadequacy of the Trust's urology service as a way of defending alleged inadequacies in his practice or for the purposes of this Inquiry. At the time of the 1997 paper, demand was increasing, and capacity was lacking. There were then 451 patients waiting up to 43 months for inpatient admission. Mr O'Brien anticipated that the Trust would seek to appoint a third consultant in addition to himself and Mr Young in 1998. Yet, almost ten years after advising that "by currently accepted standards, the population of the Southern Area requires a urological service provided by 4 Consultant Urologists" a third consultant had not been appointed. There was an enduring shortfall, the brutal reality of which was that Mr O'Brien and others were required to treat as many patients as they could over time. As a result, Mr O'Brien and Mr Young shared a 1:2 rota for years[19], meaning that on the rare occasions when either of them took some time away, the other continued to provide an acute, emergency service in addition to using vacated theatre sessions to provide an elective service that was not reduced or only minimally so.

12. The McClinton Review in 2004[20], seven years after Mr O'Brien's paper, made a host of recommendations to try and improve the service. It stated: "At the core of an excellent Urological service there must be sufficient Consultant Urologists with access to an adequate number of beds and operating sessions together with the support of appropriate numbers of properly trained nurses and theatre staff"[21].

13. Mr Young's written response to the Trust following the McClinton recommendations is telling: "We do most sincerely hope that this external review now acts as a catalyst for development, as similar recommendations were put to the Trust in the past'[22]. Mr Young had written to the Trust's Medical Director on several occasions expressing concern about the excessive workload and the excessive consultant working time[23].

[18] AOB-00027 to AOB-00035
[19] Young's evidence TRA-08992
[20] WIT-52121 to WIT-52140
[21] WIT-52126
[22] WIT-52148
[23] WIT-51720; WIT-52068-52069

14. The panel is particularly reminded to review the letter which Mr Young wrote to Mr Templeton, Chief Executive of Craigavon Area Hospital Group Trust, on 17 September 2003 as much of its content is as relevant 20 years later as it was then.[24] Mr Young and Mr O'Brien had decided to discontinue the practice of having consultants and registrars conducting two outreach outpatient clinics simultaneously as they both had cause for concern regarding the safety of inpatients at Craigavon Area Hospital while medical staff were off site. The letter reflects the insistence on the reinstatement of the clinics, which the urologists indicate "will be acted upon".

15. The letter expressed concerns at that time regarding the safety of inpatients and of those patients acutely admitted while staff were off site. It also expressed disappointment that "you would give serious consideration to the continued viability of the urology services" before going on to observe "our figures from the recent recovery plan were exceptionally favourable and we have made many suggestions to improve the situation and the service but unfortunately they have not been acted upon." It referred to the decision to have an external review conducted in response to having a third consultant appointed whereas no such review would be considered necessary if any other speciality requested the appointment of an additional consultant. It referred to the demand/capacity mismatch. It referred to the lack of satisfactory job plans and the lack of resources to enable the service to provide safe care to those patients in most need of it. It referred to the consultants having taken on extra lists "on their own volition, without any form of recompense but did so for the enhancement of the service – this is not the best way forward when the service relies on a significant amount of goodwill".

16. Mr Young continued that "unfortunately, this has all been very negative and extremely disillusioning for the personnel in a unit, who have a fabulous capacity and willingness to stride forward despite the enormous challenges to do so." The panel, charged with providing a "comprehensive report of findings related to the governance of patient care and safety within the Trust's urology speciality", may wish to reflect upon why clinicians became disillusioned and disenfranchised from management. Mr Young's letter of 20 years ago provided the answer which was as relevant 20 years later as it may be now.

17. The McClinton review paper observed that two consultant urological surgeons working a 1:2 rota often with no middle grade staff was a situation which was "unacceptable

[24] WIT-52092

and unsustainable"[25] and referred to the inadequacy of the service's capacity in terms of beds and theatre sessions coupled with observations about how "extremely hard" the then "2-man unit" was working and which was "well beyond expected levels"[26].

18. In short, none of this was new; it simply had not been adequately addressed and it still has not been adequately addressed. Is this not one of the most significant governance issues for the panel to fully address?

19. With ever increasing demand clearly outstripping capacity, the working "well beyond expected levels" simply continued for the remainder of Mr O'Brien's tenure as a consultant urologist[27].

20. The year 2009 was a significant inflexion point in time with respect to the inadequate progress being made to expand the inadequate and unsafe urology service. On the one hand, 2009 saw the introduction into legislation of the Health and Social Care (Reform) Act (Northern Ireland) 2009 ("the 2009 Act"), which remains in force. The general duties of the Department are detailed in section 2 of the Act. In particular, section 2 stipulated, inter alia, that the Department must develop policies to secure the improvement of the health and social well-being of, and to reduce health inequalities between, people in Northern Ireland, must allocate financial resources available for health and social care, having regard to the need to use such resources in the most economic, efficient and effective way, and it must hold to account the Regional Agency, RBSO and HSC trusts in the discharge of their functions.

21. The 2009 Act also stipulated in section 21 that it is the duty of a HSC trust to exercise its functions with the aim of improving the health and social well-being of, and reducing health inequalities between, those for whom it provides, or may provide, health and social care.

22. The reconfiguration of inpatient wards in Craigavon Area Hospital was announced in 2009. This was a project, ironically called the "Acute Quality Care Project", led by Mr Simon Gibson with Mr Mackle as its clinical lead. The reconfiguration resulted in the loss of the urology inpatient ward, 2 South. Patients were to be admitted to general surgical wards, staffed by nurses with little or no urological expertise. This

[25] WIT-52127
[26] WIT-52130
[27] Notwithstanding the demands he was given a Clinical Excellence Award in 2009 AOB-00121

was a negative, retrogressive measure inflicted by the Trust upon the urology service.

23. Concerns were raised as long ago as January 2010 in relation to the ward reconfiguration and to the loss of radical pelvic surgery, which was then presciently considered to also have the potential to compromise patient care and safety, and with the concomitant impact the same would have on the status of the department and thus the ability to recruit to the department[28]. It is self-evident that if the services a department can offer are not only totally overwhelmed but also limited or limiting then recruitment to such a department will be more challenging.

24. It should be noted that the concern which Mr O'Brien had regarding the loss of radical pelvic surgery having the potential to compromise patient care and safety, related to his fear that the inadequate service capacity of the Department of Urology at Belfast City Hospital could result in older or comorbid patients not being offered potentially curative, radical cystectomy for bladder cancer[29].

25. The Implementation Plan following the 2009 Review of Urology Services in Northern Ireland set objectives which were rightly described in evidence as "grandiose"[30]. The objectives had not been met by the time Mr O'Brien left the service in 2020 (11 years later). This was notwithstanding the hard work of all of the staff in the service.

26. There clearly were difficulties in what have been described as the "Monday meetings" and engagement with Dr Rankin and Mr Mackle. Mr O'Brien felt the meetings were very difficult[31]. Kathryn Robinson in her evidence described meetings with Dr Rankin on a Tuesday where Dr Rankin "would have went (sic) nuts" and that "everybody would have been quite nervous going to this meeting[32]", how they were "stressful meetings"[33] and she questioned in retrospect whether that was a "good environment for people to be working in"[34].

[28] AOB-00138
[29] WIT-82445 at paragraph 124
[30] TRA-12146 - 12147 Mr O'Brien am of 8th April
[31] TRA-05006
[32] TRA-05177-05178
[33] TRA-05184
[34] TRA-05185

27. Mr O'Brien was not alone in expressing concerns about how the urology service was being mismanaged in 2009-2010. See Mr Young's letter to Heather Trouton in November 2009[35]. In terms of engaging with Dr Rankin, high level concerns were also expressed by Mr Young[36] (letter dated 27th October 2010). Some of the suggestions being made by non-urologists about how to run the urology department were being advanced on an out-dated BAUS model, with Mr Young bringing the draft revision to management's attention. In his oral evidence, Mr Young described how he felt that Dr Rankin was not taking on board the consultants' suggestions for the good of the urology service[37]. This echoes the concerns expressed by Mr Young in his letter to Mr Templeton seven years previously. Mr Akhtar also raised concerns and rejected the suggestion being made by Mr Mackle of resistance and obstruction. He felt on the contrary, there was a lack of communication from management[38]. It would be quite wrong in the circumstances to suggest or conclude that Mr O'Brien was an incalcitrant outlier. He was not.

28. In the job planning facilitation process in 2011, Mr O'Brien could not have been clearer about the inadequacy of what management was suggesting, which related directly to "the provision of an effective, efficient and safe service"[39].

29. Mr Mackle suggested he had been accused of bullying or harassing Mr O'Brien and that he brought this to the attention of Dr John Simpson, then Medical Director. In fact, Mr O'Brien had not complained that Mr Mackle was bullying or harassing him. Dr Simpson in his evidence denied that Mr Mackle had raised this with him, going so far as to say that if Mr Mackle had done so he would have directed him to record it and the matter would have been investigated[40]. Zoe Parks, who was pivotal in resolving an issue relating to pay, did not view the issue as bullying or harassment. Nor was she ever made aware that any such complaint had been made[41]. There was a genuine concern in relation to Personal Information redacted by USI (triggered by Mr Mackle) which was resolved in Mr O'Brien's favour. As the panel knows, Mr O'Brien did not progress with his grievance in relation to this matter.

[35] AOB-00134
[36] WIT-52049 to WIT52051
[37] TRA-09060 Young 8th Nov 2023 just after lunch
[38] TRA-08385 - 08386 Akhtar 10th Oct 2023
[39] AOB-00308
[40] TRA-09279 - 09280 Dr John Simpson
[41] TRA-05544 Zoe Parks 18th May 2023

30. When Mr Glackin returned in 2012, he observed that it was clear to him that "there was and remains a persisting problem with excessive waiting times for new appointments, review appointments and surgical procedures",[42] which was in stark contrast to his experience in the West Midlands. He recalled in his oral evidence how Mr O'Brien raised concerns on many occasions about the capacity of the urology service in meetings with Trust management present. Mr Glackin said the response did not amount to much[43]. Self-evidently other Trusts managed to run efficient, well-resourced urology services. The Southern Trust has never done so. Given the obvious and inevitable patient safety issues, this represents an obvious failure in governance that has been present in the Trust and persisted for decades.

31. In his 2012/13 appraisal, Mr O'Brien summarised the nature and extent of the work he was providing, including the time required in preparation for and timely communication after the MDMs which he was chairing[44]. He was raising the compromise to the care of his patients:

> "The main issues compromising the care of my patients are my personal workload and priority given to new patients at the expense of previous patients. With regard to workload, I provide at least 9 clinical sessions per week, Monday to Friday. Almost all inpatient care and administrative work, arising from those sessions, has to be conducted outside of those sessions. Secondly, the increasing backlog of patients awaiting review, particularly those with cancer, is on ongoing cause for concern.[45]"

32. The pressures of time and the inability to implement agreed actions were known to the Trust. See the email from Ms Trouton to the consultants stating: "...as Aidan quite rightly states we often agree actions but often never get to implement due to many competing demands on our time"[46].

33. Mr O'Brien also continued to put forward constructive suggestions to try to find solutions to the mismatch between demand and capacity whilst observing that it "has been most difficult to impress upon authority the notion that those who provide the

[42] WIT-42298
[43] TRA-08118 - 08119 Glackin 21st Sept 2023
[44] AOB-22323
[45] AOB-22325
[46] AOB-06748

service may also be those best equipped to know what is required."[47]. The panel might find echoes here of the attempts made by Mr Young to persuade Dr Rankin of the same, and the consternation expressed by Mr Young and Mr O'Brien about the closure of Ward 2 South. See also Mr O'Brien's suggestions on the Stock Take of the Regional Review in 2014[48] and his positive suggestions in relation to implementing changes to try to reduce the number of incoming referrals[49]. Mr O'Brien's attempts to bring about change also included his email of 17th August 2014 and his proposals such as advanced/enhanced triage, the conduct of triage by nurse specialists rather than consultants and suggesting that as much as could be done in primary care was done before referral into the Trust. These constructive suggestions and proposals were advanced with a view to improving the efficiency of working practices. As Mr O'Brien observed in his email, "the first and overriding priority of every clinician of the week is the provision of round the clock emergency care. It is therefore impossible to provide emergency care if you have a fixed commitment elsewhere."[50]

34. A decade after the McClinton Review, the need for Mr O'Brien and others to work beyond expected or sustainable levels continued. In the period between 2013-2016, Mr O'Brien undertook additional operating sessions in an attempt to reduce patient waiting times. He undertook some 122 additional operating sessions over that period[51] which, when coupled with the preparation and administrative time associated with the same, is likely to have given rise to a conservative total of an additional 730 hours of work[52]. He was, as he put it, "running to stand still"[53].

35. In his attempts to flag the issue of waiting times and risks to patient safety, Mr O'Brien emailed in response to notification of the 62-day pathway breachers that he was "increasingly aware of the cost paid by the non-cancer patients"[54]. He emailed, at close to 1.40am on 28th June 2016, his concern around delays to patients noting, "we cannot continue like this"[55]. He had 275 patients on his operative waiting list, and he had equated red flag patients, cancer patients with no red flag status, those with indwelling stents for up to two years, those with indwelling catheters for over two years, whilst

[47] TRU-01534
[48] AOB-03808 to AOB-0381
[49] AOB-03820 to AOB-03822
[50] AOB-00781
[51] AOB-15274
[52] WIT-82417 paragraph 53
[53] TRA-04637 Mr O'Brien 19th April 2023
[54] AOB-75851
[55] AOB-77568

trying to accommodate other long waiters. This email was sent just days before the departure of Ms Hunter[56] in July 2016 who had emailed in 2015 her concerns about the lack of safety on the ward[57]. Ms Hunter's July departure email was in turn days before Mr O'Brien emailed Ms Andrea Cunningham about the increase in patients being allocated to his clinics[58]. The response to inadequacy was simply to require the practitioners to do more.

36. Between January 2016 and November 2016, before going on Personal Information leave, Mr O'Brien conducted over 83 elective inpatient operating sessions as against a contracted job plan of 58 sessions[59]. The additional, necessary perioperative care and associated administrative time equated to more than 35 sessions. He undertook this additional work in order to minimise the numbers of patients suffering harm and at risk of coming to harm. By doing so, he had reduced the number of patients awaiting inpatient admission from 275 to 232 by the time he went on Personal Information redacted leave in November 2016[60]. As he observed when meeting with Dr Wright at the end of December 2016, there were just not enough hours in the day to be faultless; that he had tried it without sleeping, without food and the reality was he simply had to try and allocate the inadequacy to the area that was least likely to have consequences for patients[61].

37. Mr Young comments on the period in his statement where he says[62] :

> "Undoubtedly, the times of shortfall in the consultant number have had a significant impact and the burden of the backlog has never been adequately addressed (either by the Trust or the DoH, in my opinion)."

38. The risks to patients inherent in patients waiting extraordinarily long periods of time for treatment should have been self-evident to the Trust and the Department. The risks were in any event repeatedly brought to the Trust's attention. Mr O'Brien was not the only practitioner to raise them. See in particular the email from Mr Haynes[63] to Esther Gishkori in May 2018 which begins and ends in the starkest and clearest of terms:

[56] AOB-77594
[57] AOB-75761
[58] AOB-77631
[59] AOB-23225
[60] WIT-82417 at paragraph 53
[61] AOB-56013 to AOB-56014
[62] WIT-51732
[63] AOB-01811 to AOB-01812

> "I write to express serious patient safety concerns of the urology department regarding the current status of our Inpatient theatre waiting lists and the significant risk that is posed to these patients …
>
> Unless immediate action is taken by the Trust to improve the waiting times for urological surgery we are concerned that another potentially avoidable death may occur."

39. The email from Mr Haynes of 8th June 2018[64] included a table showing the disparity in relation to the waiting times urology patients were being exposed to compared to the waiting times for other specialties. This disparity has endured and is reflective of the Trust's mentality from inception that somehow the urology service was undeserving of proper prioritisation. See also the email from Ms Corrigan in January 2019 on the comparative red flag first appointment longest waits. It was urology by a considerable distance[65]. There can be no doubt that these disparities were in contravention of the statutory duty of the Trust as stipulated the 2009 Act. Still, by mid-2019 there was over-booking of Mr O'Brien's clinic to try and ensure patients were seen[66]. This is hardly surprising as by then urology had the majority of breaches of the 62-day pathway and the longest routine wait at some 269 weeks i.e. over 5 years[67].

40. Surely the single greatest governance issue facing the Trust's urology service is that Ms Mullan, the Non-Executive Chair of the Trust, acknowledged when giving evidence to the Inquiry that the focus was on targets and that she could not say that patient safety was the first and foremost concern[68].

41. Dr O'Kane wrote in her witness statement that, during her tenure as Medical Director from 1st December 2018 to 30th April 2022, the difficulties with waiting lists were compounded by staffing shortages which were brought to her attention by various staff via informal mechanisms. However, "none being raised as specific patient safety issues"[69]. Surely such a lack of professional insight and corporate ignorance of the

[64] AOB-01814
[65] AOB-07451
[66] AOB-08341; AOB-08415; AOB-08448
[67] WIT-100492
[68] TRA-09968 Mrs Mullan 10th January am
[69] WIT-45007

risks to the safety of hundreds of patients waiting on long waiting lists for years for treatment should be a governance issue of the highest order.

42. The Trust management response to the situation facing its urology service has always been inadequate. Even when the number of consultant urologists was increased, there was not an associated increase in theatre time or bed space. In his statement Mr Carroll stated[70]:

> "Concerning the excessively long waiting times for all Urology Services the staffing resources available were insufficient to meet the demand on the Urology Services. These inadequate resources applied to Consultants and supporting middle grade medical staff, CNS's and operating time. Operating time per consultant was 1 all day in-patients list and 1 day case list weekly both of which were inadequate to meet the demand. However, it should be noted that the physical theatre capacity available would not have been able to accommodate more Urology operating sessions.
>
> For 3 South the nursing workforce compliment was sufficient for the commissioned 31 beds. The challenge for 3 south was the number of vacant nursing positions unfilled resulting in an over reliance on nursing agencies providing the nursing staff, both trained and untrained.
>
> …It was apparent that demand for urology was unabating and exceeding the capacity available."

43. Occasional, but invariably inadequate, steps were taken in an attempt to improve the situation. There was an inadequate increase of theatre sessions by only 0.5 sessions, from 10.5 per week to 11 per week for all consultant urologists in December 2018. The most startling example of an inadequate response was a HSCB funded validation exercise which was an administrative exercise to remove patients from the waiting list without a consultation with their doctor[71]. Even when there was a meagre and wholly inadequate increase in theatre capacity of 0.5 sessions per week for all the consultant urologists, that too was reversed, after one month[72]. Such concerns raised by Mr

[70] WIT-13105
[71] AOB-09482 to AOB09500
[72] AOB-81889

O'Brien and his colleagues should have been addressed by the Trust as governance issues, but they were not.

44. In late 2019, Mr Haynes sent a letter to Dr McCarthy which stated[73]:

> "…At our recent group meeting we had in depth discussions on the current challenges with regards demand vs capacity for urological surgery in Northern Ireland with particular reference to waiting times for urological cancer surgery.
>
> The current position is placing the urological cancer surgeons in a position of not being able to consistently offer surgery within expected timescales for cancer treatments. This places surgeons in a difficult position, where there is an increasing expectation placed on clinicians to risk assess patients awaiting cancer treatment to determine priority on the list and the risks associated with this expectation. In practice this means inevitably delaying some patient's cancer treatments in order to expedite another patient's treatment. …
>
> There is concern that these 'low risk' patients may subsequently being (sic) found to have higher risk disease or disease progression when they have their definitive treatment. ...
>
> However, there are limitations, as many urological patients are also at significant risk from benign disease and delivery of these treatments cannot be deferred without harm coming to this group of patients. Effectively, as you are aware, routine inpatient urological surgery is not being delivered at present. You will also be aware of the direct link between increasing waiting times and demand for community/primary care/emergency department/unscheduled care which also consequently can impact on our ability to deliver inpatient treatments."

While Mr Haynes was correct in asserting that by 2019 routine inpatient urological surgery was effectively not undertaken, it should be appreciated that, by then, there were patients awaiting elective admission for urgent urological surgery since 2014.

[73] WIT-54708

45. By November 2019, the longest wait for any patient referred as a Red Flag referral within the Southern Trust was for patients with or suspected of prostate cancer, 'Urology (Prostate),' which had spiralled to 103 days[74].

46. Moreover, by 2018 some 60% of the breaches of the 62-day targets for all red flag referrals to the Trust were urological red flag referrals[75]. Such data reflected the disproportionate and disparate inadequacy of the Trust's urological cancer service, even though the latter was the priority component of the entire urological service. It also undoubtedly contravened the statutory duty of the Trust.

47. In an email headed "Urology Triage" in September 2019, Alana Coleman, referring to the booking time for red flag (RF) patients noted[76] "RF are booking no less than 6 weeks at present," She posed the question "…should we just ask the consultants if they are willing for their clinics to be over-booked to accommodate?".

    Mr Glackin replied[77] :

    > "...If the trust cannot deliver this then there is an issue of demand outstripping supply. Simply relying on me or any other clinician to overbook a clinic will not solve this supply issue and I am not willing to do this work unpaid or to the detriment of my existing workload."

48. This is a classic expression of the invidious choices practitioners were and are having to make in a situation of demand/capacity mismatch which had endured for decades and which left clinicians and those who support them to do their best, sometimes going beyond what is healthy, to try to meet demand while knowing that despite their best efforts more people will be kept waiting for longer[78].

49. In the early part of 2020, notwithstanding the ever-increasing numbers of patients waiting for surgery, there was still a considerable shortfall in the amount of operating time being afforded to the urology department. In February 2020, Mr Haynes calculated he required some 59 hours of operating time but was allocated just 24 hours, less than

[74] AOB-09871
[75] WIT-82431 (and references referred to therein) at paragraph 81
[76] TRU-258588
[77] TRU-258587
[78] TRA-05628 Sharon Glenny 18th May 2023

half of the operating time required[79]. This was notwithstanding articles in the Belfast Telegraph distributed by the Trust's Medical Director on 22nd January 2020 showing that patients referred for a routine urology appointment faced a wait of 141 weeks in September 2018, which had increased to 196 weeks (just over 3 ¾ years) by November 2019. The Trust is recorded as having apologised and said that it "prioritised patients by urgency and in line with guidance"[80].

50. Notwithstanding the pressures the Trust's urology service was under and at the height of the Covid pandemic in June 2020, the Trust refused to allow Mr O'Brien to return to part time employment following his notice of retirement from full time employment and refused to accept his revocation of retirement, without having a replacement for him.

51. Mr Glackin's evidence painted a disheartening picture where the capacity issues have been flagged and known about for years and that there has been no substantial change for over a decade[81].

52. As the panel is aware, the dire situation in the urology service has persisted. Recent data have revealed that there were 4,458 patients awaiting first outpatient appointments on 30 September 2023. Of these, 2,733 (61%) were waiting in excess of one year and 541 patients were waiting in excess of 5 years. Of the total, 1,063 (24%) were awaiting urgent outpatient consultations. In addition, 1,341 patients were awaiting admission for treatment, either as inpatient or day cases[82].

Mr O'Brien's commitment and work ethic

53. To try to mitigate the enduring inadequacies of the Trust's urology service, Mr O'Brien worked incredibly hard. Any alleged or perceived deficiencies or shortcomings in Mr O'Brien's practice cannot be stated to be as a result of any lack of commitment, application, or hard work on his part. He has never been idle.

54. There is a significant amount of evidence before the Inquiry as to Mr O'Brien's level of commitment and work ethic over many years[83].

[79] WIT-34356
[80] AOB-04585 to AOB-04591
[81] TRA-08208 Glackin 21st Sept 2023
[82] TRU-411759
[83] TRA-02104 - 02105 Mr Mackle 26th Jan 2023 early morning

55. The following extract from the statement of Dr Charles McAllister[84] is just part of the chorus of evidence which speaks to the incredibly dedicated and hard-working practitioner Mr O'Brien was throughout his career:

> "Mr O'Brien was generally considered to be extremely hard working, if not the hardest working Surgeon in the Trust, was regarded as technically excellent in Theatre with the most demanding of major urological surgery, and just as importantly excellent in direct pre-op and post-op care.
>
> Personally, although I have anaesthetised for Mr O'Brien I more frequently have looked after his patients in the Intensive Care Unit. What I saw was as good as any surgeon and better than most. He saw his patients in ICU twice a day during the week and at least once a day at the weekend whenever he had a patient there. He was always available for consultation/advice/action on any patient who was admitted to ICU with or who developed urological issues whether they were his patient or not. I never heard any colleague criticise or complain about his clinical work and anaesthetists seem to enjoy working with him. He was one of the very few Consultants I would regularly see in the hospital at night and he was frequently in at weekend. Whenever a patient of his did not have what he thought was an optimal outcome he would present this himself (and not a trainee as most Consultants did) at the monthly Morbidity and Mortality meeting in painstaking or even excruciating detail".

56. There is yet further evidence from nurses, of particular resonance due to the concerns expressed about Mr O'Brien's engagement with CNSs/Key Workers. In her statement Leanne McCourt[85] says this:

> "If I needed advice from him, he was professional and forthcoming. When I was a junior staff nurse, he would have taken time to explain things and help me to learn. He was very dedicated to care of his patients, and I would describe him as "kind and caring" to his patients in clinic. I recall one such time where I was present when a life-changing diagnosis was given to a young man. Mr O'Brien

[84] WIT-14871 to WIT-14872
[85] WIT-85917

offered to drive him to the oncology appointment he had arranged for him later that day as he was concerned the young man was distressed and shaken."

57. Patricia Thompson also confirmed in her evidence to the Inquiry that Mr O'Brien was always professional and engaged with other staff members' opinions without any difficulty[86].

58. Mr O'Brien's work with the charity CURE is further evidence of his commitment and dedication.

59. Mr O'Brien's preparation for, participation in, and steps taken following MDMs is also beyond question. In her statement to the Inquiry, Vicki Graham[87] said:

> "All that I can recall is that while Mr O'Brien was chair of the Urology MDM that he was so committed and dedicated to this role. Prior to Mr O'Brien taking on this role I, as Cancer Tracker, had to compile the clinical summary for each patient that was to be discussed. Mr O'Brien changed this so that each Clinician provided a more comprehensive clinical history[88]…"

60. In addition to his direct, patient-focussed work, Mr O'Brien was also highly regarded as a teacher and a colleague to whom more junior consultants could, and did, turn for advice and assistance. Mr David Connolly[89] said:

> "In my time working with Mr O'Brien, I found him to be very similar to other older Consultants that I had worked with during my training. He had a wealth of experience and was technically a very good surgeon. He was a good teacher and was very patient with trainees. His patients were very fond of him, even to the point where they preferred to see Mr O'Brien personally instead of other Consultants or trainees and they respected his opinion above all others."

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[86] TRA-07709 Thompson 14th Sept 2023 am before break
[87] WIT-60915; See also her evidence on Mr O'Brien's work following MDM TRA-11986 - 11988 16th May 2023
[88] WIT-82503; Mr O'Brien was in fact unsuccessful in his endeavour to have his colleagues compile and submit a clinical summary to the Cancer Tracker when referring a patient for MDM discussion as they declined to do so in addition to, or instead of, dictating a letter addressed to the patient's GP, even though they were advised that it was not the responsibility of, or appropriate for, the Cancer Tracker to compile a clinical summary.
[89] WIT-41995; See also TRA-09512 – 09514 Connolly 7th June 2022; See also Mr Pahuja's statement at WIT-59685

61. Any suggestion that Mr O'Brien was in some way aloof, distant or unapproachable is simply not borne out by the preponderance of the evidence the Inquiry has received[90]. To draw any inference as to Mr O'Brien's character as a practitioner for almost 30 years from a single incident where he reprimanded Mr O'Donoghue for starting an MDM discussion prematurely would be most unfair when the Inquiry has not, so far as one is aware, sought statements from the many anaesthetists and theatre staff who worked incredibly closely with him in theatres for many years in the most stressful of circumstances.

62. As the panel is aware, Mr O'Brien was appointed Lead Clinician of the Trust's Urological Multidisciplinary Team (MDT) and Chair of the Urological Cancer MDM in April 2012. He volunteered for that role following the departure of Mr Akhtar in March 2012. Mr Young had other commitments and both he and Mr O'Brien were of the view that it was unfair to expect the newly appointed Mr Glackin to undertake it[91]. He remained as Lead Clinician until December 2016. He was sole chair of the MDM until the introduction of Urologist of the Week in November 2014 and remained as a rotating chair thereafter until December 2019.

63. In January 2013, he was appointed Clinical Lead and Chair of the Northern Ireland Cancer Network (NICaN) Clinical Reference Group in Urology, a post he held until January 2016. He was approached by the previous incumbent and the secretariat to take it on. In the end he felt he had to take it on as no one else had stepped forward[92]. This was a Northern Ireland wide appointment, and it was part of his additional responsibilities to ensure clinical management guidelines were drafted for the first ever national peer review of all Urology MDTs in Northern Ireland in June 2015.

64. The panel is also aware that during 2016, Mr O'Brien put his commitment to the patients and the Trust ahead of his health by delaying his personal medical treatment to ensure there remained sufficient support in place for Mr Suresh[93].

65. The panel also knows that Mr O'Brien, aware of and open about the backlog in relation to his administration, volunteered to address the same while he was on Personal Information redacted by leave

[90] See also the evidence of Matthew Tyson TRA-08808 - 08809 7th Nov 2023; Mr Robin Brown TRA-09124 14th Nov 2023; Mr Suresh TRA-08668 17th Oct 2023
[91] TRA-12174 lines 10-25
[92] TRA-12174 lines 1-8
[93] AOB-22956

following his own surgery in November 2016. There was little governance intervention then to encourage and support him to rest and recuperate. It was an offer that could have been gracefully declined, but it was not[94]. The Trust thereby permitted and condoned Mr O'Brien having patient records at home to work on them.

66. If anything, as indicated by this experience, Mr O'Brien was trying to do too much. In his addendum statement, Mr O'Brien has endeavoured to assist the Inquiry by drawing attention to the time that had historically been allocated in proposed job plans for administration, compared to that which Mr Haynes found to be necessary in 2018, as well as that since allocated to his former colleagues, in addition to time allocated for their fulfilling those roles that had been undertaken by Mr O'Brien and for which no time had been allocated[95].

67. Yet, one has a sense when something did go wrong, the Trust looked not to the painfully obvious demand/capacity mismatch but instead placed the responsibility upon the shoulders of the clinicians themselves. This complete transfer of all responsibility from the Trust to the clinicians was exemplified by the case of the retained swab addressed by Mr O'Brien in his addendum statement[96] The Root Cause Analysis recommendations included that outpatient backlog reviews should be cleared (the patient had waited 12 months post-operatively for review). Dr Diane Corrigan of the Public Health Agency stated[97] that the

> "…recommendation relating to this issue was that outpatient backlog reviews should be cleared. This recommendation is reasonable, albeit not necessarily easy for the Trust to implement given the resources required to do so."

Dr Corrigan suggested that the Trust consider

> "…whether there is a need for a formal Trust policy, such as review of all test results by medical staff before filing, whether or not the patient is awaiting outpatient review"

Thus, while the reasonable recommendation that the Trust clear outpatient backlog reviews would not be easy, given the resources required to do so, the responsibility

[94] AOB-01226 to AOB-01225
[95] WIT-107613 at paragraphs 153 to 158
[96] WIT-107564 to WIT-107568
[97] PHA-00632

could be transferred to clinicians to review all results for all patients without any consideration of any additional resources or time required to enable them to do so.

68. Throughout his entire career, Mr O'Brien worked far beyond his contractual obligations, he worked when on leave[98] it being noted that he was "working even harder during holidays"[99] and even when on Personal Information redacted leave. He did additionality whenever it was offered, whether paid or unpaid, including longer days of operating and operating lists on Saturdays[100].

69. The panel is invited to reflect upon the evidence Mr O'Brien gave in April 2024:-[101]

> "One has to make choices with regard to actually reading or being able to deal with all of the emails that you receive each day, which is the more important things to do as you walk into the hospital each morning? Is it go to deal with the in-patients? Is it to sit down and read your emails? You know, I think that when you look at the differing practices that evolved, whether it's Mark Haynes getting up at 5:00 o'clock in the morning to do all of his administration, and spending some 15 hours a week in doing so, or whether it's me doing it until 3:00 o'clock in the morning, or whether actually increasingly it's people saying "actually I'm not prepared do either and I walk away from it". In fact, I have been reading recently some interesting literature talking about the impact of what's called discrepant services on individual clinicians when issues like compassion and empathy and support that they're able to give to patients during their caring for them is squeezed out because of the priorities that the employer or management would have. So, there are serious issues indeed. So, yep, there is no doubt about it, I agree entirely with Mark Haynes. This is the -- he described it very appropriately as the unmeetable expectation arising from that mismatch between demand and capacity."

70. The impact of the system was, as suggested to him, compelling him to make choices and, as he put it himself, "trade offs"[102] in terms of how to try and cause the least suffering. This was the invidious position he referred to in his witness statement. He made essentially the same point in his grievance document, i.e. it was the time he was

[98] AOB-82710;
[99] AOB-71498
[100] AOB-05688
[101] TRA-12169 line 9 to TRA-12170 line 5
[102] TRA-12170 lines 6-9

taking to reduce an ever-increasing backlog that had caused him to fall behind in his administrative work[103].

71. Mr O'Brien did not feel that he could so easily compartmentalise resource issues and agree that the waiting list problem was a "Trust issue". The panel will recall his description of the 'third leg' of that stool and how ultimately a waiting list problem is by far and away and, most importantly, a problem for the patient. The patients will be the ones who continue to suffer until they receive their treatment. Thus, he felt compelled to take on the additionality whenever he could[104]. As he observed[105]:

> "I just found that ethically and compassionately, if you are reading and trying to respond to cries of desperation every day, I couldn't pass up the opportunity to operate on two or three more patients. I think I'm correct in saying -- I was reading some of my own notes in recent days where I think I did something like 26 additional operating sessions during 2019, and yet my urgent in-patient waiting list is longer than ever..."

72. Given the inadequacies of the system within which he worked, Mr O'Brien was required to make decisions in terms of what aspects of his practice should be prioritised. It was suggested to him that the counterbalance in relation to shortcomings was that he was delivering what some might consider "an excessively high standard of service" to some patients and whether the "balance tilted too far on occasions", which he accepted was possibly the case[106]. However, he has been in no doubt that many more patients benefited as a consequence of his prioritising, removing them from harm's way, in the context of the Trust's failure to do so.

73. It is also fair to observe that the Trust was aware of the 'trade offs' Mr O'Brien was making between the different aspects of his clinical practice. The Trust knew he was hard working, but also knew there were aspects of his clinical practice that were suffering. In his witness statement, Mr O'Brien set out at length and cross-referenced to numerous email evidence showing that the Trust knew there were elements of his

[103] AOB-02029
[104] TRA-12171 lines 10-24
[105] TRA-12172 lines 5-13
[106] TRA-12183 lines 20-28

practice with which he was struggling, the introduction of the 'default' system in relation to triage being the most obvious example of all.

74. However, it must be emphasised that the primary reason for Mr O'Brien being unable to complete all administrative aspects of his practice was that he did not ignore the suffering of patients waiting years for admission for treatment, or the risks of patients coming to serious harm due to their waiting for years for admission for treatment, including delayed diagnoses of and deterioration in significant pathology. Conversely, if the Department of Health had met its statutory duty by directing a service sufficiently adequate as to be safe, and if the Health & Social Care Board had commissioned such a service, it would then have been possible for Mr O'Brien, and his colleagues, to have fulfilled all of their ethical and moral obligations to their patients.

75. As he related in his primary witness statement[107], Mr O'Brien's motivation throughout his career has only ever been, to the very best of his ability, to provide the best care that he could possibly give to the maximum number of patients whom he considered were in most need of it at any particular time. He regarded it as a vocation and a privilege to do so. He worked beyond any contractual obligations, as has been acknowledged. He worked when on leave. He worked when on Personal Information redacted by leave. He alleviated suffering and reduced the numbers of patients coming to harm. However, he found it impossible to achieve that for all patients whose suffering required to be alleviated and impossible to eliminate the risk of all patients coming to harm. It is only fair to observe that there has never been any element of bad faith or malign intent in relation to his treatment of patients and rightly none has been suggested.

76. The panel should recognise and take into account in its consideration of other issues just how committed and hardworking Mr O'Brien was. The Trust was well aware of this. Of course, it suited the Trust's needs to have Mr O'Brien (and others) working late into the night, at weekends and on annual leave in their selfless attempts to mitigate the risk of harm resulting from the Trust's urology patients being on the longest urology waiting lists in Western Europe.

General observations on Mr O'Brien's character

[107] WIT-82435 paragraph 95

77. The Inquiry has received quite a lot of evidence about Mr O'Brien's character and personality, much of it ill-informed and it is hoped that the panel will not attach any weight or significance to such evidence.

78. The panel is encouraged not to be swayed by evidence of 'impression' formed or expressed by those who did not know the facts, did not work with Mr O'Brien, were not treated by him as a patient or, indeed, had never met him - as in the case of Dr O'Kane. Contrast Dr O'Kane's evidence in particular with that of Mr Mackle who, despite his differences with Mr O'Brien, observed that Mr O'Brien was "extremely polite … pleasant … a gentleman" and who was held in high regard"[108]. Ms Trouton described him as very polite and a gentleman[109]. Kathryn Robinson described him as an "absolute gentleman"[110]. Mrs Corrigan's description of Mr O'Brien's behaviour was also rejected by Mr Akthar. It was never "his way or no way"[111]. In his witness statement to Dr Chada in 2017, Mr Young stated, referring to Mr O'Brien, that "we have always had a good relationship and speak openly about a wide variety of things. We have had only two cross words in the 20 years we've worked together".[112] He also stated that he "had absolutely no concern about Mr O'Brien's clinical competence" and that he and his family "would go to him personally if needed[113]".

79. Nor should the panel reach conclusions based on throw away remarks such as causing "havoc in theatres" when there is no direct evidence that Mr O'Brien did so in terms of listing of surgery (the one case Ms Gishkori relied upon was not in fact as a result of Mr O'Brien listing the patient[114]), nor any evidence from those who worked with him in theatres or analysis done in terms of his scheduling or time taken in theatre. On the contrary, Mr Suresh, with whom Mr O'Brien did work in theatre, described Mr O'Brien as being meticulous, with excellent communication skills in theatre and experienced no sense of 'havoc' at all[115].

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[108] TRA-02199 & 02210 Mackle 31st January 2023
[109] See also TRA-02326 Ms Trouton 31st Jan 2023 am he was 'very polite' and 'a gentleman'
[110] TRA-05222 K Robinson 27th April 2020 after morning break
[111] TRA-08403 Mr Akhtar 10th Oct 2023
[112] TRU-00754
[113] TRU-00755
[114] Ms Gishkori also wrongly assumed that Mr O'Brien had deliberately and coincidentally absented himself on Personal [redacted] in the Autumn of 2016 which the panel know was incorrect. TRA-06821 Gishkori 14th June 2023 am. That was a classic example of how ill-informed assumption, unless checked, can lead to adverse and unfair perceptions.
[115] TRA-08699 – 08700 Suresh 17th oct 2023

80. There are other examples of such ill-informed and mistaken views, such as Mr O'Donoghue being under the impression Mr O'Brien had "hidden away" records which was simply not the case[116] and his assertions that Mr O'Brien's triage "went on certainly for a couple of weeks after he finished on-call" and that "he dictated letters on a few of his patients which were four pages long[117]" with no paragraphs. The Inquiry has not put to Mr O'Brien an example of a referral triaged by him two weeks following completion of Urologist of the Week, or an example of one letter, four pages long, with or without paragraphs, dictated upon triage. It is these kind of baseless stereotypes for which there is no corroborative evidence that should give the panel pause for thought in terms of making findings of fact without cogent, reliable evidence.

81. Exaggerated and uncorroborated allegations such as these have been used to characterise Mr O'Brien as a clinician who has provided an unnecessarily high standard of care to some patients to the detriment of others. In addition, they have been used to portray Mr O'Brien as a clinician who has been inefficient in his practice, with the implication that such inefficiency prevented him from achieving more in the time allocated, if any, even if the time allocated was demonstrated by Mr Haynes in 2018 to be a fraction of that which was required.

82. As indicated above, many of the stereotypical characterisations of Mr O'Brien have been proffered to the Inquiry by witnesses, some of whom had never met him, based entirely upon impressions. Their impressions have been contradicted by other witnesses who had worked with Mr O'Brien for years. The Inquiry is familiar with such characterisations of Mr O'Brien by Mrs Corrigan and Mr Carroll who, with Mr Haynes, were the main sources of information, or impressions with which Dr O'Kane formed her own sense and impressions of Mr O'Brien. She certainly formed and gave witness to these impressionistic characterisations without having met with Mr O'Brien or sought his views in order to ascertain their reliability.

83. From the interactions Dr O'Kane had with these medical and professional managers, she had the *sense* that "they did and do work well together with the exception of the working relationship with Mr O'Brien"[118]. Her *impression* was that "the remaining staff had the greatest respect for each other regardless of discipline and were very professional in their interactions with their patients and each other. They appeared to

[116] TRA-08577 - 08578 O'Donoghue 11th Oct 2023 am
[117] TRA-08466
[118] TRA-01480

work well together outside the challenges of having to manage and work with Mr O'Brien". Another *impression* was "that over the years Mr O'Brien's colleagues had developed ways of not confronting him for fear of having to deal with unpleasantness…"[119]

84. Almost two years after the event, Dr O'Kane persisted in reporting in her witness statement of 23rd August 2022 that the long waiting lists "hid in plain sight the issue that was uncovered on 7th June 2020 when Mr O'Brien emailed Mr Haynes re placing patients on surgical waiting lists. This revealed that patients had not been placed on waiting lists at all following their initial consultation or following investigations or a cancer MDM". As the Inquiry is aware, this assertion was completely incorrect.

85. In a similar vein, Dr O'Kane included in her list of "difficulties" with Mr O'Brien in the past the "prescribing of IV antibiotics and opiates". Difficulties with the prescribing of opiates has not been raised before.

86. She proceeded to state that he was also described as spending long hours on the wards at times when he was neither required or expected to be there and then was asking for additional payment recognition for this. It is not the case that he requested additional payment recognition for this.

87. Moreover, she claimed that Mr O'Brien only signed off his job plan or plans before he retired to allow his pension to be finalised. This allegation was also unfounded.

88. Dr O'Kane's characterisation of Mr O'Brien reached its apotheosis in paragraph 55.36 of her witness statement of 23rd August 2022 when she embarked upon an appraisal based upon impressions, appearances and beliefs. It should be a matter of concern that any Medical Director and Responsible Officer, since Chief Executive, of a Health Trust should characterise a clinician in such a manner without considering the necessity to meet with the clinician, discuss any concerns or issues as to their character and allow them an opportunity to respond before arriving at a proper appreciation of the character of that clinician.

89. Concern has also been expressed about a supposed "chill" factor or a supposed inability to challenge Mr O'Brien. A rather meaningless expression was used by Mr

[119] TRA-01481

Haynes suggesting that he was a "challenge to challenge"[120]. If someone challenges an individual and they happen to disagree or have their own views and are capable of expressing them clearly either orally or in writing, they could be said to be a 'challenge to challenge.' However, the views of the person challenged may in fact prove to be right and prevail. Any suggestion that it may have been Mr O'Brien's position as the most senior urologist in the Trust that made him a 'challenge to challenge' does not sit easily with the relative lack of challenge that emanated from the Belfast Trust's oncologists in relation to Mr O'Brien's use of Bicalutamide. Professor O'Sullivan and Dr Mitchell are senior clinicians working in a different Trust. Why did they not challenge Mr O'Brien in rather more direct terms? This cannot be explained on the basis of any fear of Mr O'Brien or "chill factor".

90. If there was a "chill" factor surrounding Mr O'Brien, this is not something Mr O'Brien created, fostered, encouraged or contributed to. One element of this was the fact that he had family members who were lawyers[121]. He cannot help that fact. If others had a perception that because he had family members who were lawyers, and that consequently they were in some way inhibited from questioning him or managing him, it speaks more to them and the robustness of the Trust's governance arrangements than it does about Mr O'Brien. Further, individuals are entitled to have a lawyer present in the MHPS process and are entitled to take legal advice, just as they are entitled to challenge management when errors have been made about their pay. The reality, as opposed to unsubstantiated mythical perception, is that at no stage in his career did Mr O'Brien actually bring legal proceedings against the Trust or any fellow employee.

91. Equally, if Mr O'Brien was afforded a degree of deference based on his experience, or the high regard he was held in by practitioners and patients alike, he had no control over this. As Mr Devlin observed, patient safety issues could have been brought to the attention of the Chief Executive, formally or informally, regardless of the views anyone had of Mr O'Brien.

92. During the course of the Inquiry, was alleged that the Chair of the Trust Board had advocated on behalf of Mr O'Brien who was asked whether he had ever solicited her to do so. He resolutely refuted any suggestion that he had done so, or even considered

[120] TRA-00842
[121] Accepted by Dr Chada as nor more than a personal impression see TRA-04120 - 04121 Chada 29th March 2023

doing so[122]. The Chair of the Trust likewise denied that Mr O'Brien had ever asked her to do so and there is no evidence that he in fact did.

93. In a similar vein, and more seriously, it was suggested during the course of the Inquiry that Mr O'Brien may have commissioned his former secretary to procure for him letters relating to Patient 139, or whether she had provided him with said letters without his requesting her to do so.[123] Mr O'Brien robustly refuted that either of these serious suggestions had occurred, there being no evidence that either had.[124]

94. For all of the above reasons, it is submitted that the Inquiry panel should exercise caution in arriving at conclusive findings concerning Mr O'Brien's character.

Evidence of Mr Hagan

95. The panel is invited to treat the evidence of Mr Hagan with considerable caution. It is historic and the clinical and administrative records of the individual to whom he referred have not been disclosed to enable Mr O'Brien to comment upon them. One partial exception to that is a ureteric stone case where Mr Hagan suggested (a) that there were energy sources available other than EHL, and (b) that when he had a complication through use of EHL, he was being directly supervised in theatre during the procedure by Mr O'Brien who had to take over. The incomplete records disclosed undermine both of those claims[125].

96. This example also underscores Mr O'Brien's more broadly held concern about the panel reaching conclusions as to matters of fact in clinical cases where the patient records have not been disclosed and subjected to forensic interrogation. But for the fact that these incomplete records materialised, the panel may have been invited to comment adversely in relation to Mr O'Brien, which obviously would have been unfair and unjust.

97. Mr Hagan says he spoke to Mr Young to raise concerns, but Mr Young has no recollection of him doing so[126].

[122] TRA-04844 – 04845 Mr O'Brien 20th April 2023
[123] TRU-320464
[124] TRA-12602
[125] WIT-107586 at paragraph 64(ii) to (iii)
[126] TRA-09686 and WIT-103605

98. In his witness statement, Mr Hagan also claimed to have received a telephone call from Dr McAllister about TUR surgery. Dr McAllister not only had absolutely no recollection of any such telephone conversation, which it was suggested he had initiated, but went so far as to observe it was not possible for him to have made such a call and said he had no memory of it because he believed it did not happen[127].

99. Mr O'Brien has set out his response to the Hagan concerns in his addendum witness statement[128] and the panel is invited to prefer his evidence.

Intravenous fluids and antibiotic therapy

100. Mr O'Brien addressed the issue of intravenous fluids and antibiotics in his original Section 21 statement;[129] which was submitted prior to disclosure of records from the Public Health Agency to the Inquiry[130]. The Inquiry will note at PHA-00440 that there is a record of a call with Mr O'Brien on 22nd April 2009 in which it is recorded that Mr O'Brien wanted "an in depth look at the cohort … not just telephone contact with specialists". This is indicative of Mr O'Brien positively inviting scrutiny of the practice so that the decision making could be properly informed. This of course flies in the face of the assertion that he was a "challenge to challenge" (whatever that may mean). The kind of investigation he invited did not take place.

101. What followed is described in Mr O'Brien's addendum statement and not repeated here[131]. As Mr O'Brien explained in his oral evidence to the Inquiry, this practice of elective admission of patients was for a relatively small number of patients for whom oral antibiotics, whether prescribed therapeutically or prophylactically, had been unsuccessful and who became repeatedly and acutely unwell, to a severe and life-threatening extent in some cases, requiring acute re-admission, and its aim was to try to prevent this cycle repeating itself[132]. These characteristics were clearly reported

[127] WIT-102756 at paragraphs 2.02 to 2.03
[128] WIT-107578 to WIT-107593
[129] WIT-82547 at paragraphs 417 to 424
[130] PHA-00430 to PHA-00553
[131] WIT-107569 at paragraphs 17 to 23
[132] TRA-12398 – 10th April early am

in the letter to the editor of the Journal of Infection, co-authored by Mr Young and Mr O'Brien[133].

102. The management of this issue remains a concern for Mr O'Brien.

103. The properly rigorous investigation requested by Mr O'Brien should have entailed a detailed analysis of the data to be published and should have entailed a multidisciplinary review of individual patients, including the participation of their caring clinicians. Most importantly, it should have been conducted by persons wholly independent of the Department of Health and of its arms-length bodies in Northern Ireland. It would have been most beneficial if there had been such a wholly independent body to which clinicians could have referred an issue such as this for investigation. It remains a matter of regret for Mr O'Brien that he did not insist that such a proper investigation be conducted.

104. Instead, the outcome of the management of this issue has been framed as an example of clinicians not being compliant with a Trust policy. Mr O'Brien recalled in his evidence to the Inquiry that, in one instance, he was responding to a general practitioner's request for the acute admission of a patient from the patient's home. This example highlights the difficulty that may arise for both primary and secondary care clinicians, and the danger for patients, when compliance with protocol conflicts with clinical reality, as the need for the patient's acute admission would have been avoided if compliance with the policy and protocol had not been required.

Cystectomies

105. Mr O'Brien addressed the issue of simple cystectomies performed for benign, non-malignant pathology and Professor Drake's review in his original Section 21 statement[134] and further in his addendum statement[135].

106. With regard to the provision of radical cystectomy for bladder cancer, there was consternation on the part of both Mr O'Brien and Mr Akhtar regarding the late notice given for the transfer of patients to Belfast, patients who were understandably dreading yet further delay in their treatment. Perhaps the more significant issue from a

[133] WIT-82743
[134] WIT-82550 paragraphs 425 to 429
[135] WIT-107570

governance perspective is that Mr Hagan's view that patients had been poorly managed was not raised with the treating clinicians, even though Mr Hagan advised that this was the substantive issue. The only issue Mr O'Brien was made aware of was the content of contemporaneous correspondence. Once again, without access to or the provision of complete clinical records, Mr O'Brien has been disabled from assisting the Inquiry regarding these patients.

107. Mr O'Brien addressed the case of Patient 127, who had a bladder tumour resection in February 2016, and the consequent correspondence sent to the Trust, in his addendum statement[136]. Mr O'Brien emphasised in his addendum statement that the concern expressed in relation to the delay in referral of this patient due to her having a bone scan was indeed subsequently discussed at MDM. He also accepted in his evidence to the Inquiry that a response to the Belfast Trust should have been provided[137], confirming that the Southern Trust MDT had taken on board that bone scanning was not indicated in the staging of bladder cancer.

108. Mr O'Brien also explained in his addendum statement that a reason he was able to recall this case having been discussed at MDM was the MDT noting that it would probably have made little, if any, difference concerning decisions regarding the patient's further management if there had been no delay in the patient's referral. This patient was one of a number of patients considered by Southern Trust clinicians to be fit for radical cystectomy only to be considered unfit by Belfast Trust clinicians. This was an issue addressed with the Regional MDT on individual occasions previously, and since, to no avail. Nevertheless, Mr O'Brien regrets that he did not avail of the opportunity provided by this case to advocate for this patient, as he had done previously, by responding to the Belfast Trust, raising this governance issue.

Glycine

109. Mr O'Brien was entirely open about his ongoing use of glycine and the patient safety issues he had encountered when he performed bipolar, as opposed to monopolar[138], resection of the prostate. Again, it would be unfair to criticise Mr O'Brien

[136] WIT-107591 paragraphs 83 to 89
[137] TRA-12458 - 12459 10th April
[138] TRU-395975

for continuing to use a method of resection that was certainly facilitated by the Trust, in the absence of a formal direction to stop doing so, and where he had made the Trust aware of the patient safety concerns he experienced when trialling the new system. As he told the Inquiry, he was at all times vigilant in relation to biochemical derangement[139] and there is no evidence of any adverse outcomes from his continued practice of using glycine as an irrigating fluid during endoscopic resection.

Formal (MHPS) Investigation

110. Mr O'Brien was called to a meeting on 30th December 2016, whilst on [Personal information redacted] leave recovering from surgery, at which he was informed he was to be excluded from the workplace. The panel has heard about the traumatic impact this draconian action had upon him[140] and the lack of support on a human level for him as a long serving Trust employee. It is understood the MHPS process remains subject to review, and it is hoped that the review will reflect on the impact a decision to exclude can have on the individual practitioner and recommend a robust system to ensure the safety and wellbeing of those who are subject to such a step.

111. Nevertheless, the Inquiry will be aware of a presentation prepared by Ms Zoe Parks, Head of Medical HR, in advance of a Workshop in 2023, notably entitled 'Handling a Concern about a doctor or dentist to Maintain High Professional Standards'[141]. In the 'Overview of MHPS', Ms Parks records that MHPS was introduced by DHSSPS Circular, that it became effective from 1st December 2005, that a formal departmental direction requires all Trusts to comply with MHPS and that MHPS is incorporated into contracts of employment of individual doctors.

112. It is worthy of note that DHSSPS communicated with all Trusts in Northern Ireland on 30th November 2005 requesting that all Trusts advise the Department of their implementation of MHPS by 31st January 2006. In her witness statement of 26th September 2022, Dr O'Kane advised that she in turn had been informed by Ms Parks that neither the Southern Trust nor the Department of Health held any records confirming that the Trust had notified the Department of its implementation of MHPS[142].

[139] TRA-12507 Mr O'Brien morning of 12th April 2024
[140]TRA-04833 Mr O'Brien 20th April 2023 after lunch
[141] TRU-411613
[142] WIT-57941

It is doubtful if the Trust did ever advise the Department of its arrangements for implementation, and there is no record of MHPS having been incorporated into his contract of employment of individual doctors. Mr O'Brien certainly did not receive any communication from the Trust to that effect. Indeed, he had never heard of MHPS until he met with Dr Wright and Ms Hainey on 30 December 2016.

113. The emphasis of Ms Parks' presentation in 2023 was "ensuring that people are properly trained and competent to carry out their roles"[143]. Yet when Dr O'Kane provided in her witness statement of 26 September 2022, a record of the training received by those who decided at the meeting of the Oversight Group on 22 December 2016 to commence a Formal Investigation in accordance with the Trust Policy of 2010, none attending had received formal training in the MHPS framework[144]. While there was no record of Dr Wright having been formally trained, Dr O'Kane could recall that he had attended training with her when they were both Assistant Medical Directors in the Belfast Trust in or around 2014[145]. Remarkably, while Ms Vivienne Toal herself had not received any formal training in MHPS, she had been involved in training others in the Trust Guidelines of 2010[146]. While Dr O'Kane recorded that Mr Simon Gibson had received training on an unspecified date in August 2016, it would appear that this was through "formal and informal discussions, updates and assurances" provided by the Medical Director, by the Operational Director who had not received any training, and by the Director of HROD who had not received any training[147].

114. The presentation for the Workshop in 2023 emphasised that it was "imperative that exclusion is not misused or seen as the only course of action"[148]. The presentation related that the subject is much debated in case law, citing the case of Kamath v Blackpool Teaching Hospital 2021 in which it was stated that *'an act of [exclusion] by an employer can constitute a breach of the implied term where, by in combination with other acts or omissions it (i) destroys or seriously damages the relationship of trust and confidence and (ii) is without reasonable and proper cause'.* The Inquiry is invited to find that this exactly summarises the consequences of Mr O'Brien's exclusion.

[143] TRU-411618
[144] WIT-57959
[145] WIT-57959
[146] WIT-57961
[147] WIT-57962
[148] TRU-411621

115. Mr O'Brien commented on the MHPS process in his Section 21 statement[149] and in his Response to Report of Formal Investigation[150] which, together with all of the appendices attached thereto, is commended to the panel in its entirety. In combination with the above comments, it is Mr O'Brien's position that the concerns which the Trust raised with Mr O'Brien by letter in March 2016 were not managed at all as they should have been and were then managed by a formal investigation from December 2016 until October 2018, with exclusion until 26 January 2017, when they could have been managed informally. The panel is also invited to consider the negative impact which the period of exclusion had upon the arranged management and review of patients, all of which was cancelled and for which Dr Wright reassured Mr O'Brien he would take responsibility, but evidently did not do so.

116. The panel is also reminded of the grievance[151] submitted on Mr O'Brien's behalf. From a governance perspective, Mr O'Brien's concerns are set out in his Section 21 statement and in the grievance and so are not repeated herein. The time taken to complete the underlying investigation and then resolve the consequent grievance was unacceptable. By his contract of employment, the grievance process required to be completed in 20 working days of its presentation on 28 November 2018. His grievance had yet to reach a hearing by the time the Trust ended his employment 20 months later, in July 2020. This speaks volumes about the robustness of the Trust's governance policies and procedures. The time taken to complete the underlying investigation and to then resolve the consequent grievance was not only utterly unreasonable but, in breach of his contract of employment, entirely unacceptable. In addition, Mr O'Brien had this process hanging over him from 30th December 2016 until his employment was ended by the Trust in July 2020. The process was not concluded until months later.

117. The panel is equally reminded of the fact that Mr O'Brien's grievance of November 2018 clearly included an appeal of the Case Manager's Determination that he should be referred to a Conduct Hearing. This appeal was not considered or heard prior to termination of his employment in July 2020.

[149] WIT-82517 to WIT-82620
[150] AOB-10585
[151] AOB-15001 -15316 & AOB-02561 -02572

118. Most importantly, the grievance disclosed grave concerns of public interest. These were not considered or addressed by the Trust prior to termination of Mr O'Brien's employment in July 2020. However, Ms Shirley Young, Chair of the Grievance Panel, drew attention to this disclosure that could have been regarded as whistleblowing on 15 July 2020[152], two days prior to his last day in the employment of the Trust.

119. The panel will have noted the failure of the Trust to comply with the Case Manager's Final Conclusions/Recommendations regarding the systemic failures on the part of the Trust that were identified by the investigation report:

> "The investigation report also highlights issues regarding systemic failures by managers at all levels, both clinical and operational, within the Acute Services Directorate. The report identifies there were missed opportunities by managers to fully assess and address the deficiencies in practice of Mr O'Brien. No-one formally assessed the extent of the issues or properly identified the potential risks to patients.
>
> …
>
> In order for the Trust to understand fully the failings in this case, I recommend the Trust to carry out an independent review of the relevant administrative processes with clarity on roles and responsibilities at all levels within the Acute Directorate and appropriate escalation processes. The review should look at the full system wide problems to understand and learn from the findings."[153]

120. Pauline Leeson, who has been a Non-Executive Director of the Board since 2017, was only provided with Mr Khan's report which called for an independent review shortly before she gave evidence to the Inquiry in January 2024. The report had not been shared with the Trust Board. Mr Pengelly confirmed it had not been shared with the Department[154]. In short, the evidence suggests that the above recommendations critical of the Trust were ignored.

121. It also resonates with the Trust likewise failing to correct the false allegation that "2 out of 10" patients had not been added to the waiting list for readmission when

[152] TRU-292396
[153] TRU-158356 – TRU-158357
[154] TRA-10419 - 10421 Pengelly 16th Jan 2024

they should have been. The fact that this allegation was false had not been brought to the attention of the Board by January 2024. These failings are indicative of a Trust that is content for individual clinicians to shoulder personal responsibility for shortcomings without addressing the broader picture when systemic failings have been identified and brought to its attention.

122. Nevertheless, Mr O'Brien applied himself to the best of his ability to address the issue of triage, one of the concerns that gave rise to the Formal Investigation initiated in December 2016. He did this at considerable cost, foregoing one day's annual leave following each UOW, and so that the priorities of UOW were not compromised by triage.

123. Mr O'Brien was unaware that Mr Haynes had been escalating such a breach of the Return-to-Work plan concerning triage to Dr O'Kane in March 2019 until the escalation by email was disclosed by the Inquiry.[155] Mr Haynes reported that there were still 79 referrals awaiting triage on 31st March 2019, including 16 red flag referrals, four days following competition of Mr O'Brien's UOW. He included a screen shot of seven patients awaiting triage since 26th March 2019. He advised Dr O'Kane that he was unaware of the reporting and escalating that may have occurred following Mr O'Brien's return to work.

124. This contrasts with the screen shots of referrals awaiting triage by Mr Haynes, by Mr Young and by Mr O'Donoghue on 7th June 2020.[156] Mr Haynes had urgent referrals awaiting his triage dating back to 20th April 2020, almost seven weeks previously, and at least one red flag referral awaiting his triage since 13th May 2020, over three weeks previously. It is not known if there has been any reporting or escalation or governance related action in relation to these referrals awaiting triage over these periods.

125. Mr O'Brien has acknowledged that he struggled to dictate letters on all patients on the days when they attended his outpatient clinics, as he was increasingly unable to remain in the hospital in the evenings to do so, due to having increased caring commitments within his family, as was acknowledged in September 2019. However,

[155] TRU-251571 – TRU-251573
[156] WIT-83408

he endeavoured to promptly dictate letters regarding those patients whose management required to be progressed in a timely manner.

126. Mr O'Brien has refuted the allegation that he had prioritised the admissions of patients who had attended privately, and which was first raised by Mr Haynes in his email to Mr Young and Mrs Corrigan in May 2015[157]. Mr O'Brien has always rigorously endeavoured to arrange the management of all patients, including their admissions for treatment, in order of their clinical priority rather than in the chronological order of their position on waiting lists, as these have been crudely insensitive to clinical need and priority. His practice did not change in that regard during or following completion of the Formal Investigation.

Key Workers

127. In his Section 21 statement[158] Mr O'Brien reflected upon the significant contribution made by the CNSs over time including Kate O'Neill, Jenny McMahon and Leanne McCourt. It had been his understanding that the urological medical and nursing staff had worked well together, enjoyed good relations and "were supportive of each other in endeavouring to provide the best care they could to those most in need of it". In her evidence, Kate O'Neill confirmed that they had an excellent working relationship with Mr O'Brien[159].

128. As Mr O'Brien observed in his addendum statement,[160] the allegation that he did not value the role of specialist nurses has probably caused him more hurt than any other. Through the work of CURE, he contributed significantly to a process that enabled urology nurses to gain valuable knowledge, expertise and experience[161]. The suggestion that he would then take steps to positively exclude them from providing assistance is as illogical and profoundly offensive as it is highly unlikely. Kate O'Neill in her evidence said this did not happen[162]. Leanne McCourt said she was in fact the

[157] TRU-274504
[158] WIT-82488 at paragraphs 248 to 251
[159] TRA-12043 16th May 2023
[160] WIT-107605 at paragraph 127
[161] WIT-107605 at paragraph 128
[162] TRA-12069 - 12070 16th May 2023

key worker for a number of Mr O'Brien's patients[163]. The panel will recall Ms McCourt took exception to the suggestion she had said Mr O'Brien did not understand the role of key worker/CNS and felt that she had been misrepresented. She said Mr O'Brien absolutely did understand and value the role[164].

129. In his original Section 21 statement,[165] Mr O'Brien set out the terms of the Trust Urology Cancer MDT's Operational Policy of 1st September 2017[166] which states that it is the joint responsibility of the MDT Lead Clinician and the MDT Core Nurse Member to ensure that all newly diagnosed cancer patients have a key worker allocated. Mr O'Brien was first aware that there was any issue or criticism of patients not having had a key worker allocated upon sight of the SAIs. No one had raised this issue with him beforehand.

130. Mr O'Brien has also set out in detail in his addendum statement how concerned he is as to how the narrative around this particular issue developed during the course of the SAI review. The panel is invited to consider his observations in some detail. Kate O'Neill expressed concerns in her evidence to the panel,[167]as did Patricia Thompson[168].

131. Kate O'Neill also flatly denied suggestions put to her based on the evidence of Mrs Corrigan and Mr Carroll who, she said, had "no understanding" of their working relationship with Mr O'Brien, and "never witnessed it".[169] Patricia Thompson also rejected the evidence of Mr Carroll that they were afraid of Mr O'Brien. That was not something she had ever heard or ever said[170].

132. In 2015, the Northern Ireland Cancer Patient Experience Survey 2015 showed that in the Southern Trust only 68% of patients were given the name of the CNS in charge of their care[171]. This was a Trust-wide inadequacy. There were clearly systemic issues at play, which is reinforced by the evidence of the nursing staff themselves.

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[163] TRA-05453 Leanne McCourt 17th May 2023
[164] TRA-05468 Leanne McCourt as above
[165] WIT-82582 at paragraphs 536 to 537
[166] AOB-03859
[167] TRA-12068 - 12070 16th May 2023
[168] TRA-07713 - 07718 14th Sept 2023 post am break; Professor O'Sullivan also had to correct a note of a discussion with Mr Hughes which had failed to accurately reflect his evidence – see TRA-08006 – 08007
[169] TRA-12094 - 12095 16th May 2023
[170] TRA-07726 - 07727 14th Sept 2023
[171] WIT-98668

133. In her statement, Kate O'Neill observed as follows[172] :

> "I do not consider that the role and functions of the CNS were resourced properly from the outset. The absence of a unit manager, lack of dedicated clerical support and being counted within core nursing staff for all clinical activity severely restricted my ability to progress, advance and develop my role in providing independent nurse led services and to provide adequate keyworker input. The prolonged process to appoint additional CNS members contributed further to delays in further service development.
>
> As service development progress was delayed, the impact upon patient care would have been most evident in the inability to provide keyworker input for every patient with a cancer diagnosis."

134. See also the witness statement of Leanne McCourt[173] where she states:

> "My view of why there was an absence of or inadequate CNS provision is there was a chronic, longstanding underfunding of this area of the workforce…"

Mr O'Brien reminded the Inquiry in his addendum statement of the terms of the MDM Operational Policy, where the responsibility for the allocation of a key worker is set out. It would be quite wrong, therefore, to conclude that Mr O'Brien bore responsibility for their allocation, and, equally, the panel will want to consider how it could have remained the case that patients may not have had a key worker allocated as and when they had further clinical input for which Mr O'Brien was not responsible[174]. In her evidence to the Inquiry, Patricia Thompson referred to the fact that there were other points in the patients' pathways where other practitioners were involved and when nurses could have been allocated as key workers. She was of the view that the SAI findings might better have represented those points rather than blaming Mr O'Brien as the only individual[175]. There were clearly systemic issues involved.

Bicalutamide

[172] WIT-80935
[173] WIT-85941
[174] WIT-107611 at paragraphs 146 to 150
[175] TRA-07721 Thompson 14th Sept 2023

135. Mr O'Brien addressed the issue of Bicalutamide in relation to individual patient cases in his original s21 statement[176]. He also provided a very brief synopsis of the historical development of the anti-androgen, Bicalutamide, and of its use in the management of prostate cancer in his addendum statement of March 2024[177]. The panel is invited to consider the same. The panel also has the benefit of the expert reports and oral testimony of Prof Kirby where he expressed supportive views on Bicalutamide use by Mr O'Brien. In his primary witness statement of November 2022, Mr O'Brien reported in good faith that he had never been challenged for using Bicalutamide 50mg. However, in his addendum statement of July 2023 he reported that he had since discovered an email sent by Dr Mitchell, Consultant Oncologist at the Cancer Centre at Belfast City Hospital, in November 2014 requesting that Mr O'Brien look into the circumstances that gave rise to a patient having been initially prescribed Bicalutamide 50 mg daily for high risk, organ confined, prostate cancer in 2012, before having the dose increased to 150 mg daily one year later and on which he remained until his referral for radiotherapy in 2014[178].

136. Mr O'Brien regrets that he is unable to recall whether he was aware of Dr Mitchell's email, whether he replied to it in writing rather than by email, though he is unable to locate the latter. He remains keen to address the issues surrounding this patient, for which he would require the complete, up-to-date, clinical records.

MDT/MDM

137. The suggestion that Mr O'Brien was practising in a 'uni-professional' manner or found the MDT process difficult to embrace as it required him to 'surrender his autonomy' as a practitioner, is simply not borne out by the evidence. His commitment to the MDT process is beyond question. He was its lead for years, prepared for MDMs assiduously and attended meetings regularly, which is more than can be said for colleagues from other specialties. As he described in his evidence, he made every effort to make the meetings as comprehensive as possible[179]. As stated previously, preparation for MDM was rendered all the more time consuming due to his colleagues

[176] WIT-82631 to WIT-82641
[177] WIT-107571
[178] AOB-71990
[179] TRA-12517 - 12518 Mr O'Brien morning of 12th April 2024

refusing to provide a clinical summary or updates as required, instead of or in addition to providing a copy of a dictated letter to the patient's GP.

138. Whilst there is reference in the lookback exercise to some cases not being recorded as having been discussed at MDM, in the absence of a detailed examination of the patient records and the systems extant at the time for recording MDM discussion (one of which reviews discussed in evidence did not even include the year when it may have happened[180]), it would be wrong to conclude that it was Mr O'Brien's culture or practice not to refer patients to MDM. That is simply not the case. There has been no evidence led from people who actually attended MDMs that Mr O'Brien's cases were not routinely discussed. In fact, there is clear evidence to the contrary. See the evidence of Vicki Graham[181], including her rebuttal of the claim made by it seems, Mr Carroll, that staff avoided challenge at MDM.

139. An element of this arises from the SAI review process where Dr Hughes produced a note of a discussion with Professor O'Sullivan in which he had recorded Professor O'Sullivan as having said that Mr O'Brien "did not engage" with the MDM process. Professor O'Sullivan told the Inquiry that he definitely did not say that Mr O'Brien "did not engage"[182]. See also the email from Mr O'Brien to Dr Mitchell in March 2015 expressing the frustration of the Trust's clinicians that the Belfast Trust's radiologists did not remain for discussion of cases in the Regional MDM[183].

140. In his evidence to the Inquiry, Mr O'Brien expressed his grave concern at the claim by Dr Hughes that patients entered a contract with the MDT to have their management directed or dictated by the MDT, and that the MDT required to be informed and to sign off any divergence from its decisions. While he acknowledges that Dr Hughes resiled from use of the term "contract" when challenged, Mr O'Brien nevertheless maintained that he has been unaware of any patient being informed of or being asked to consent to his/her management being determined by a MDT. Moreover, it would be wholly improper for that to be the case as it would be tantamount to asking a patient to surrender their own bodily autonomy.

[180] TRU-309747
[181] TRA-11988 16th May 2023
[182] TRA-08003 Prof Sullivan 20th Sept 2023
[183] AOB-72888

141. However, there possibly remains a subtle suggestion that the decisions concluded at MDM to be recommended to the patient carry a weight consequent upon their being agreed by a MDT, that the patient's right to disagree with the recommendation is less rational, and to the extent that their right to their own autonomy is compromised. But their right to autonomy is inalienable. This was eloquently articulated by Sir Brian Langstaff in delivering his Final Report of the Infected Blood Inquiry on Monday 20 May 2024 when he said:

> "Respecting people's right to control what happens to their own body has always been an ethical cornerstone of medicine, always. A booklet produced by the Medical Defence Union in or around 1953 explained that consent had to be quote "genuine consent, a real expressed willingness by the patient to undergo the treatment after its nature, its risks and its objective have been clearly explained". In 1980, the British Medical Association's handbook on medical ethics said "consent is freely given if the patient understands the nature and consequences of what is proposed" and the next year they added, quote "doctors offer advice but it is the patient who decides whether or not to accept the advice".[184]

142. This is a wholly different matter from that of the responsible clinician providing the patient with the recommendations of MDT at subsequent review, and of systems in place to ensure that has been done. Mr O'Brien has been explicit in his primary witness statement and in evidence to the Inquiry that he always took the time to ensure that each patient had a complete understanding of all the management options available to him/her, the benefits and risks associated with each, including those recommended by MDT, and the reasons for the recommendations. He asserted how those recommendations may have had to be modified in view of factors, such as comorbidities, not wholly known to MDT on arriving at its recommendations. He advised of his practice of ensuring that patients were afforded the time to arrive at their own decisions. It would have been beneficial if a key worker had been appointed and available to attend consultations with each patient, or alternatively had contacted the patient subsequently to ensure that their understanding was complete, as a component of their holistic needs assessment.

[184] https://www.youtube.com/watch?v=x3c_zZAh4TE

143. As the panel has heard, there was no general practice or mechanism to bring patients back to the MDM where different treatment was required[185] or the patient may have chosen different treatment[186] from that recommended by the MDM. Professor O'Sullivan gave evidence about how often the recommendation from MDM may not be overly-prescriptive in terms of the type of hormone therapy and referred to how one might "ideally" re-discuss at MDM[187]. Professor Kirby used the same phraseology[188]. There was no hard and fast rule about the situations in which a clinician was required to bring patients back to MDM, and no formal process in place to do so. It is nevertheless clear that the circumstances at the Trust were not ideal circumstances in which to re-consider significant numbers of cases given how busy clinicians and the MDM was trying to address new patient cases.

Pre-operative Assessment

144. The issue of pre-operative assessment was highlighted by the case of Patient 90 who sadly died following bilateral ureterolysis. He did not have a formal pre-operative assessment performed during the period that had elapsed since being placed on Mr O'Brien's waiting list on 7th June 2017 for urgent readmission and his elective admission on 9th May 2018 being arranged on 3rd May 2018 as documented in the report of the Root Cause Analysis of the subsequent SAI investigation[189].

145. An appointment was arranged for Patient 90 to attend for pre-operative assessment on the afternoon of 4th May 2018, but he did not attend. The patient had been deemed fit to proceed but Mr O'Brien did not appreciate that he had not had a pre-operative assessment until the SAI investigation was conducted. It is regrettable that he did not have, as even a preliminary assessment may have raised concerns with regard to proceeding with surgery within days.

146. Mr O'Brien wrote of his regret that he had not noted pre-operatively the reported findings of CT scanning indicative of cardiac disease when previously under the care of physicians, as he would have referred Patient 90 for further cardiac assessment prior

[185] See email from Patricia Kingsnorth at TRU-09830
[186] TRA-12532 - 12533 Mr O'Brien morning of 12th April 2024
[187] TRA-08020 - 08021 Prof Sullivan 20th Sept 2023
[188] TRA-09366 Prof Kirby
[189] TRU-255064

to surgery. He has since expressed his regret that he did not additionally refer him for a haematological assessment in view of the history of myelodysplasia. Mr O'Brien acknowledged his responsibilities and failings in optimising the condition of Patient 90 for surgery. In his evidence to the Inquiry, Mr Glackin reported that Mr O'Brien personally presented this case of mortality as an SEA and that he reflected upon it openly[190]. Mr O'Brien very much regrets the outcome.

Results, Reports and DARO

147. The principle that clinicians should carry a responsibility for reviewing and acting appropriately upon the results and reports of investigations which they have requested for their patients is common sensical. It can also be complicated by various scenarios, such as consultant clinicians being expected to carry the responsibility for investigations requested by their junior clinical staff or the need for other clinicians to take responsibility when the requesting clinician is on leave.

148. Mr O'Brien related in his primary witness statement the evolving context that gave rise to the expectation that clinicians would review and act upon the results and reports of investigations[191]. By 2010, as in all aspects of the urology service provided by the Trust, there was an increasing disparity between the numbers of patients requiring outpatient review and the capacity to do so. The risks arising from the diverging capacity to review patients with the reports of requested investigations was highlighted by the case of Patient 95.

149. Mr O'Brien has related in detail in his addendum statement of March 2024 how the response to the recommendations in the report of the SAI investigation resulted in an expectation by the Trust that all results and reports of investigations would be reviewed and acted upon by the requesting clinicians[192]. Mr O'Brien raised his concerns regarding the practicalities, reliability and capacity of clinicians and secretarial staff to accept this additional responsibility[193]. He also referred to his concern regarding the time which would be required to undertake the responsibility, a quantum of time which had yet to be quantified, in preparation for a facilitation meeting concerning job planning

[190] TRA-08193 Glackin 21st Sept 2023
[191] WIT-82414
[192] WIT-107564
[193] TRU-276805

in September 2011[194]. The outcome of facilitation was a reduction in time for administration in Mr O'Brien's job plan rather than an increase to undertake the additional responsibility[195].

150. The Trust expectation that all results and reports would be reviewed and acted upon was formalised as Discharge Awaiting Result-Outpatients (DARO). Though deprived of any time to undertake the review of results and reports, Mr O'Brien certainly did review results and reports, but simply did not have the time to review all of them. When pressed by Counsel to the Inquiry about what he did with his own practice Mr O'Brien's response was telling: "I tried to do more of all of it"[196].

151. Mr O'Brien has explained that he did use DARO on the misunderstanding that the DARO was applied to those patients whose definitive discharge from review was anticipated, but pending a final investigation being reported to be normal. It was not until February 2019 that he learned that DARO was applied to every outpatient who had an investigation requested and that none of these patients were to be placed on any waiting list of any kind until the result or report was reviewed and acted upon. This interpretation of its application was a misinterpretation of the original intent that DARO was only to be applied when the patient's further management could not be determined until the result or report of the investigation was reviewed.

152. The Inquiry is familiar with Mr O'Brien's expressed concerns[197]. Mr O'Brien's concerns were amplified by the discovery later in 2019 that DARO was also being applied to all patients referred and who had any investigation requested upon triage. These patients were to be discharged before they ever had an outpatient appointment. It was further alarming to discover that Mr Young had expressed concerns about the same action in 2015[198].

153. The Inquiry is aware that the Trust met in January 2020 to consider the issue of the dictation of letters following review of patients and following review of results and reports. The Trust acknowledged that there were no written standards in relation to what was considered reasonable for dictation of results and letters after dictation. The

[194] AOB-00308
[195] AOB-00326
[196] TRA-12473 10th April pm
[197] WIT-22785
[198] TRU-274539

Trust had never stated a standard (even though one had been imposed upon Mr O'Brien in 2017) and the Trust was unaware of any standard set externally by Royal Colleges or other organisations[199].

154. Mr O'Brien regrets that he had not had the time to review all results and reports of all investigations over the years, despite trying "to do more of it all". He very much regrets that he had not reviewed the report of the CT scan of Patient 95 in 2010, and that of Patient 92 in 2018.

Structured Clinical Record Reviews (SCRR)

155. Mr O'Brien is in considerable difficulty being able to comment upon the SCRR process given the relative lack of information in relation to the cases, including the criteria for selection. He is equally in difficulty in relation to SAIs.

156. Mr O'Brien has not had an opportunity of scrutinising the records of the patients and their care, with a view to disputing or accepting the findings and particularly whether the findings are accurate reflections of their care. As a core participant in the Inquiry, it has deprived Mr O'Brien of contributing to its mandate to provide comprehensive recommendations concerning governance of patient care and safety in the urology service at the Southern Trust.

Termination of Employment

157. In February 2020, Mr O'Brien decided that it was time to reduce his working hours and move to part time employment. It is a common practice for consultants to end full time employment, draw down their pension and return part time, particularly in view of the desperate need for doctors to meet the ever-expanding health care needs of patients. Mr O'Brien proposed that he would cease full time employment at the end of June 2020, take July 2020 off and return in August 2020 to work part time.

158. On the 8th June 2020, Mr Haynes advised Mr O'Brien by telephone that he would not be permitted to return to work after 30th June 2020. It was suggested that

[199] TRU-251814 – see under 'Expectation re compliance'

there was a practice in the Trust that employees who have outstanding HR processes are not allowed to return to work. This was another example of the harm caused to Mr O'Brien by the Trust's failure to deal with his grievance, which had been outstanding for 20 months, and any disciplinary hearing that may still have to have taken place following the conclusion of the grievance. These are real material consequences of the Trust's mishandling of the MHPS investigation, failures in governance and the damage done to the relationship between the Trust and Mr O'Brien.

Recommendations

159. This Inquiry has been precipitated by concerns raised about and has revolved around the 'clinical practice' of Mr O'Brien. The Inquiry has heard of Mr O'Brien's inability to compartmentalise his 'clinical practice', unable to ignore the plight of patients suffering on long waiting lists for first outpatient appointments when it came to triage, or on even longer waiting lists awaiting admission for treatment. What are the perimeters of 'clinical practice'? Is it the case that it can ethically be confined to a distinct zone of activity, legitimately and defensively disregarding or transferring the audible plight of those beyond the perimeter? It would be of great service to current and future clinicians for the Inquiry to consider recommendations concerning the confines or boundaries of clinical practice, if there are any.

160. Healthcare professionals should be encouraged to report their concerns regarding the adequacy and safety of services commissioned and provided to their patients to bodies such as the Regulation and Quality Improvement Authority and the General Medical Council, wholly independent of the Department of Health, the commissioning body and the employing Trust.

161. Serious Adverse Incidents (SAIs) may legitimately be precipitated by 'incidents' but often do not adequately address the patient's experience in a longitudinal manner. SAIs have been 'incident centred' rather than 'patient centred' for too long. The Inquiry could consider recommending that SAI be renamed as Serious Adverse Experience (SAE) which of course does not exclude the investigation of an incident.

162. The Inquiry is requested to advise that it be mandatory for all doctors and dentists to have formal and regular training in their employers' policies for Managing

Concerns and in the MHPS Framework (or any successor) so that all are fully acquainted with them.

Summary

163. It is indisputably the case that the urology service directed by the Department of Health, commissioned by the Health & Social Care Board and provided by Craigavon Area Hospital Group Trust and by the Southern Health & Social Care Trust has been disproportionately inadequate over a period of 30 years, to the extent that it has caused very many patients to suffer for prolonged periods of time, during which they remained at increasing risk of coming to increasingly severe harm. It has been regrettable that has been the case.

164. Mr O'Brien and his colleagues have done their utmost to bring the plight of these patients to the attention of all those ultimately responsible for their care. Mr O'Brien and his colleagues have worked relentlessly for many years, endeavouring to reduce suffering and the risk of harm.

165. Mr O'Brien repeats his regret[200] that he could not have done more that would have made a positive difference. Most importantly, Mr O'Brien regrets any suffering or harm that patients may have experienced due to any decisions, actions or failings on his part.

31 May 2024

G Boyle KC, R Millar, and Tughans

[200] TRA-12664

HSC Public Health Agency

South Office
Tower Hill
ARMAGH
Co Armagh
BT61 9DR

Tel : Personal Information redacted by the USI
Fax :
Web Site : www.publichealth.hscni.net

Dr P Loughran
Medical Director
Southern Trust HQs
College of Nursing
68 Lurgan Road
PORTADOWN
BT63 5QQ

CONFIDENTIAL

1 September 2010

Dear Dr Loughran

In the context of the Urology Review implementation process, I was present at a recent meeting with Trust staff to discuss progress. I had already noted from the written submission that there appeared to be a high proportion of elective urology episodes at CAH which did not have an operative procedure. This is being explored further, but in a brief discussion with the Clinical Director for Surgery it appeared that the practice of some urologists of admitting patients for intravenous fluids and antibiotics as a treatment for chronic urinary tract infections has not ceased. If I understood the position correctly, some patients may now be receiving this treatment via central lines. I would be very concerned if this was the case. I forwarded to Mr Mackle the email correspondence to your secretary which set out my opinion on this practice back in January. I had assumed steps were being taken to bring this to an end.

Following the recent meeting I re-read the external expert reports relating to the use of IV therapies at CAH (Appendices of the draft document I was asked to comment on last January). There was one sentence which read "Whether these patients have been well served by the major bladder surgery they have undergone is difficult to say as the records do not include the original letters leading up to the surgery." In the context of my unease at the ongoing use of a treatment at CAH which had not been supported

by external experts, I informed Mr Mackle that I intended to seek NI-wide information on the numbers of cystectomies and ileal conduit procedures carried out by Unit and consultant across NI. I was seeking assurance that the use of operative intervention in patients with chronic cystitis at CAH was in keeping with that in other units.

I enclose data from 2005/06 to 2009/10 from all hospitals in NI, including CAH. The search criteria selected elective admissions of patients who had either cystectomy or ileal conduit formation recorded as the primary procedure code. The primary diagnosis is shown alongside. The information has been checked to exclude duplicate patients. These data have to be interpreted with caution as they are dependent on coding quality and the total numbers are very small. I have considered the possibility that patients who had had these procedures done in the past and who were admitted for another purpose might have been recorded incorrectly as having the procedures a second time, thus inflating the total numbers, but the check for duplicate cases would have been expected to minimise this possibility. If this is primarily a coding error then this would indicate a need to review coding practice in the Trust.

From this information it appears that cystectomy and conduit creation is done in the great majority of cases in NI for malignant disease. There appear to be small numbers done for other reasons, though in some cases the diagnostic coding is too vague to be sure what the true underlying diagnosis might have been, e.g. when recorded as 'peritonitis, faecal incontinence, mycobacterial infection or attention to openings of urinary tract'. The role of the regional centre seems to have become more prominent over the five year period, with cessation of cystectomy work at Altnagelvin and the Mater Hospitals. The specialist role in treating patients with spinal problems/neuropathic bladders is reflected in the BCH data.

There is no clear pattern throughout the five-year period in relation to cystectomies done for cystitis, though perhaps the first two years of that period would indicate higher proportions than expected at CAH. In 2005/06 and 2006/07 the cystectomy and/or ileal conduit creation operations recorded across NI were 32 and 41 respectively. The numbers done for reasons other than malignant disease (as per the ICD coding) were 9 and 7 respectively. Four of the 9 done in 2005/06 were for cystitis, of

whom 3 of the four had their operation at CAH. In 2006/07 three of the seven non-malignant patients operated on in NI were coded as having a primary diagnosis of cystitis, all three of whom had their operation at CAH.

From 2007 onwards the number of procedures done for non-malignant indications at CAH fell to 2, 2 and 4. In that group of 8 cases, one was for UTI unspecified and one for mycobacterial infection but none specifically for cystitis.

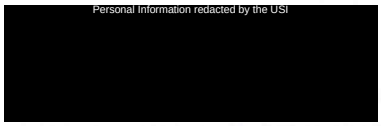
I have asked for information for the five years preceding 2005 and will forward that to you when it becomes available. In the meantime, I would be grateful if the Trust would review this information with a view to checking its accuracy, i.e. that the coding of these cases is correct. Your information department may wish to re-run the data but if they wish to cross-check this version by casenote number the latter can be made available.

Until the data have been verified it may be premature to take any further steps, however depending on the outcome the Trust might wish to consider whether it would be appropriate to seek additional advice from the GB experts who provided the earlier reports.

Following the Urology Review decision, as of March 2010 radical pelvic urology surgery for malignant disease should no longer be being done in SHSCT. This would include cystectomy. Trust staff discussed the process for cancer cases recently at a meeting chaired by Beth Malloy from PMSI Directorate of the HSCB. The rationale for this policy decision, which is in line with IOG guidance, was to concentrate the relatively small number of such cases in the hands of a small number of surgeons who could maintain specialist skills. No specific reference was made in the Urology Review to radical pelvic surgery for non-malignant disease. It was perhaps assumed to be implicit that the even smaller volume of this type of work would also be centralised. I would be grateful for an assurance that the urology team at CAH is now referring on all patients being considered for radical pelvic surgery regardless of the underlying diagnosis.

Lastly, I would be grateful for a report from the Trust detailing what steps are being taken to manage the ongoing risks associated with delivering IV therapies to the original cohort of patients. As a first step, it would be helpful to have an assurance that none are receiving this treatment via a central line. It would also be helpful to have a position statement detailing how many patients are still on this form of treatment and the expected timeframe for this to cease.

Yours sincerely



Dr D Corrigan
Consultant in PHM

Enc

cc Dr G Rankin, Director of Acute Services, SHSCT
Mr E Mackle, Clinical Director of Surgical Services

I am not aware of any further instances of violation of the protocol after this. *Document located in Relevant to PIT, Evidence Added or Renamed 19 01 2022, Evidence No 77, No 77 – Eamon Mackle, 20111218 Email IV Fluids and antibiotics in urological patients.*

Benign Cystectomies

203. Dr Diane Corrigan, Consultant in Public Health Medicine, on 1 September 2010 wrote to Paddy Loughran and copied in Gillian Rankin and myself, noting that, when she read the review of the IV Fluid and IV antibiotic therapies, that there was a comment re major bladder surgery. She had recently informed me that she was going to conduct an N.I.-wide audit of the number of procedures being performed. This she reported as showing a higher than expected number of cystectomy and/or ileal conduit procedures for benign disease than would be expected. *Document located in Relevant to PIT, Evidence Added or Renamed 19 01 2022, Evidence No 77, No 77 – Eamon Mackle, 20100901 – email urology.*

204. On 9 September 2010, at a meeting held by Gillian Rankin and myself and attended by Aidan O'Brien and Michael Young, a statement regarding the screening process the Trust was planning to undertake was tabled. Aidan O'Brien at this point said that, if Mark Fordham was appointed to carry out a review, then under no circumstances was he prepared to meet with him. *Document located in Relevant to PIT, Evidence Added or Renamed 19 01 2022, Evidence No 77, No 77 – Eamon Mackle, 20100910-email urgent.*

205. On instruction the most recent 12 cystectomies for benign disease, dating back to 2006, were collated with the assistance of Martina Corrigan and reviewed by myself. I was unable to reassure the Trust on at least 6 of the cases. A decision was made by the Trust that an independent reviewer should be sought. I therefore drove to Aldergrove Airport hotel one evening to meet with Mark Fordham who was staying there for the night prior to a flight early the next morning, following a visit to NI in respect of the Urology Review. He advised on how he thought any review should be performed and said he would get back to me with a suggested expert. On 9 February 2011 I wrote to

Mr Marcus Drake, Consultant Urologist at the Bristol Urological Institute, and asked him to conduct the review. *Document located in Relevant to PIT, Evidence Added or Renamed 19 01 2022, Evidence No 77, No 77 – Eamon Mackle, 20110210 Email Governance Issue.*

206. Mr Drake attended the Trust on 25 March 2011 and I supplied him with my summary of the cases and the available hospital notes for his review. On 3 May 2011 we received a draft report from Mr Drake. *Document located in Relevant to PIT, Evidence Added or Renamed 19 01 2022, Evidence No 77, No 77 – Eamon Mackle*, *20110503-email NI SouthenTrust review of cystectomy cases*. In it he concluded as follows: (i) That the majority of cases appear to have been managed with compassion and consideration; (ii) The cases in general appear to have supportable clinical grounds; (iii) He did, however, feel the documentation was insufficiently comprehensive and felt that there should have been a clear description of severe pathology, substantive functional impairment and impact on quality of life, attempts to undertake conservative measures and discussion of risks involved; (iv) He did request a check to see if any more notes were available; (v) He was critical of a lack of a plan for one patient receiving botulinum injections; and (vi) He recommended the process that the trust had already instituted re management of infection.

207. A check was made to see if any of the further information he requested was available and, when it wasn't, the draft report was accepted. Paddy Loughran wrote to Dr Corrigan on 28 July 2011 summarising the above and assured her that there would be no further cystectomies performed in the Trust. *Document located in Relevant to PIT, Evidence Added or Renamed 19 01 2022, Evidence No 77, No 77 – Eamon Mackle, 20110728, Email Urology Review.* I sent Dr Corrigan a copy of the conclusions on 5 August 2011. *Document located in Relevant to PIT, Evidence Added or Renamed 19 01 2022, Evidence No 77, No 77 – Eamon Mackle 20110805 Email Cystectomies in the Southern Trust.*

208. On 7 September 2011 Gillian Rankin wrote to the three urologists informing them that no elective cystectomies were to be performed in the Southern Trust. Martina Corrigan, as Head of Service, monitored the in-patient admissions and theatre lists to ensure that no further elective cystectomies were performed. *Document located in Relevant to PIT, Evidence Added or Renamed 19 01 2022, Evidence No 77, No 77 – Eamon Mackle, 20110907 Email for Comment Correspondence to Urologists.*

Triage

209. Triage was an issue which was raised with me at various times.

210. When I was Lead Clinician for Out-patients, Mr O'Brien had a folder in his office with referral letters in it. The issue was raised with me by Mrs Hazel Neill, Nurse Manager for Out-patients, at a regular meeting we had. I spoke to Mr O'Brien at the time (I can't recall when exactly, but it was approximately 1996) pointing out that this practice was not acceptable. He informed me that he had checked the letters and had selected any high risk ("Red flag") letters to be seen quickly. He did however assure me that he would clear the backlog. I also informed the CD, Mr Osmond Mulligan, of the practice and of my actions, as well as the General Manager of the Trust Mr John Templeton. My recollection is that Hazel Neill informed me that the triaging was then completed. Prior to the booking centre, my recollection is that the out-patient staff were responsible for booking appointments and kept a check on the return of letters sent for triage.

211. During the period 2007 to 2009 my recollection is that on (I think) 2 occasions I was asked to speak to Aidan O'Brien to complete the triaging process. I can't recall who asked me to do so.

212. On 30 March 2010 Heather Trouton wrote to Aidan O'Brien and Michael Young pointing out that there were 60 referrals untriaged. *Document located in Relevant to PIT, Evidence Added or Renamed 19 01 2022, Evidence No 77, No 77 – Eamon Mackle, 20100310 Email Triage*. It turned out that the delay was with Aidan O'Brien's referrals. On (again, I think) 19th

CYSTECTOMY CASES UNDERTAKEN FOR BENIGN URINARY CONDITIONS, SOUTHERN TRUST OF NORTHERN IRELAND.

MARCUS DRAKE, SENIOR LECTURER, UNIVERSITY OF BRISTOL

I am currently practicing as a Consultant Surgeon at the Bristol Urological Institute, Southmead Hospital, Bristol, UK. I subspecialise in Female and Reconstructive Urology, Neurourology and Urodynamics. I am Senior Lecturer in Urology at the University of Bristol, and Visiting Professor in Health and Applied Sciences at the University of the West of England. I am Chairman of the International Continence Society Standardisation Committee and of the Urogenital Specialty Group in the UK's Comprehensive Clinical Research Network. I am Editor of the BJU International Website, and a member of several journal Editorial Boards. I undertook my medical training at the Universities of Cambridge and Oxford and was awarded my Doctorate Thesis by the University of Oxford, studying the physiological effects of spinal cord injury on the human bladder. I have written several publications in peer-reviewed journals.

A brief review of medical records was undertaken to ascertain the key issues relating to the decision processes leading up to cystectomy. This should not be taken as a comprehensive evaluation, in view of the limited time available to me. Below are presented the key features derived from the notes and my opinion relating to management of the patients on whom I was asked to comment

PATIENT Personal Information redacted by the USI

Cystectomy Date: Personal Information redacted by the USI

KEY FEATURES FROM NOTES

Personal Information redacted by the USI

25th March 2011

Personal Information redacted by the USI

OPINION

1.1 The uncertainty in this lady's case relates to the fact she had seen surgeon in the presence of another patient who previously had had a cystectomy for a somewhat similar presentation. Similar symptoms were described and described as achieving consensus "relating to similarity of symptoms."

1.2 Nonetheless, suitable steps were taken in evaluating her; specifically, she was found to have an abnormal response to bladder distension under anaesthetic, oedema and chronic inflammation were found pathologically, and she had undergone review by a mental health professional. These findings do point to a genuine indication for cystectomy in this lady.

1.3 Information that I would like to see to finalise a conclusion would be the histology from her cystectomy, a frequency volume chart, and the original trace of the urodynamics. A frequency volume chart would help ascertain whether functional bladder capacity is markedly impaired. Ideally, a pain score should be evaluated in patients of this type.

Personal Information redacted by USI

KEY FEATURES FROM NOTES

Personal Information redacted by the USI

[redacted]

OPINION

2.1 It is not clear why she had her colostomy and urostomy in the first place – the procedure was done at a different hospital, and the initial indication has yet to be determined.

2.2 It is uncertain whether she had a rectal stump– if so an inflamed residual rectal stump could cause suprapubic pain. Assessment of this would have been suitable prior to cystectomy, if applicable. Nonetheless, secondary cystectomy for pain after diversion is necessary in some patients.

2.3 Clear documentation that the patient was warned that pain could subsequently persist despite cystectomy would have been appropriate.

Personal information redacted by USI

KEY FEATURES FROM NOTES

Personal Information redacted by the USI

OPINION

3.1 The urodynamic studies had not reproduced the incontinence symptom and the mechanism was uncertain. It was therefore imperative that some alternative demonstration of urinary incontinence was undertaken such as a pad test. It would have been appropriate to consider repeat urodynamics.

3.2 Confirmation of mechanism of leakage and cataloguing of failure of directed therapy (such as high-dose antimuscarinics and self-catheterisation, or botulinum injections into the bladder with self-catheterisation) was needed. Without knowledge of mechanism, we cannot be certain that all measures short of cystectomy were considered.

3.3 It is unclear whether she would have been a candidate for learning to self-catheterise intermittently (many patients are unable to do so, and this is relevant in patients with function limited by neurological disease). The need for a suprapubic catheter suggests that maybe she would not have been able to self-catheterise.

3.4 An alternative option to cystectomy would have been a bladder neck closure with suprapubic catheter. Thus, documentation of problems related to the suprapubic catheter would have been appropriate to justify the larger procedure of urinary diversion.

Personal Information redacted by USI

Cystectomy: Personal Information redacted by

KEY FEATURES FROM NOTES

Personal Information redacted by the USI

OPINION

4.1 There are no issues relating to this case as far as I can see. Severity of problem and alternative options were discussed. The patient elected to proceed with the operation.

Personal Information redacted by USI

KEY FEATURES FROM NOTES

Personal Information redacted by the USI

OPINION

5.1 She appears to receive botulinum injections prior to training in CISC, which subsequently proved fruitless.

5.2 She expressed unwillingness to face the prospect of indwelling catheterisation (including suprapubic catheter). This statement is supported by a letter from Mr Ho, registrar, in a letter dated 6 November 2008. Personal Information redacted by the USI was against any notion of long term urethral or suprapubic catheter.

5.3 Botulinum injections into the bladder can have a paralysing effect on ability to pass urine. Consequently, 20% (range 10-40%) of people will need to have alternative means of bladder drainage- either self-catheterising or indwelling catheter.

5.4 Using botulinum in a patient who is statedly averse to indwelling catheterisation and has not been shown able to self catheterise is open to criticism.

5.5 It will be essential to see documentation as to how the bladder drainage issues were discussed for this lady before finally concluding whether her management was appropriate.

Personal Information redacted by USI

Cystectomy: Personal Information redacted by the USI

KEY FEATURES FROM NOTES

Personal Information redacted by the USI

Personal Information redacted by the USI

OPINION

6.1 Severe inflammation was demonstrated; this is compatible with a situation for which cystectomy could be warranted.

6.2 I have not seen documentation of pain scores or frequency volume charts. This would help support conclusion 1.

Personal Information redacted by USI

Underwent cystectomy on Personal Information redacted by the USI.

KEY FEATURES FROM NOTES

Personal Information redacted by the USI

OPINION

7.1 I was able to undertake only a very brief review of notes

7.2 There seems to be a substantial degree of dependence; she continues to require hospitalisation for management of symptoms, which are being dealt with by intravenous antibiotics. This does raise the question of whether an additional psychological or psychiatric element or a dependency state should be considered.

7.3 The protocol for admissions for intravenous antibiotics should be reviewed. The evidence base in such patients is weak, and for a urologist to undertake such management mandates consultation with suitable multidisciplinary support. Consultant microbiology expertise should be included in managing this sort of scenario.

Personal Information redacted by USI

OPINION

I was unable to undertake a sufficient review of this lady's notes.

8.1 Diagnosis of interstitial cystitis needs to have some objective confirmation to describe pain scores, reduced functional bladder capacity (i.e., low maximum void volume on frequency volume chart), and endoscopic procedure in which the bladder was distended to ascertain its maximum anaesthetic bladder capacity- including visualisation to observe the emergence of an ulcer or post-distention glomerulation.

CONCLUSIONS

9.1 The majority of cases appear to have been managed with compassion and consideration

9.2 The cases in general appear to have been supportable clinical grounds.

9.3 The documentation is insufficiently comprehensive, and in order to warrant proceeding to cystectomy, clear description of the following is needed; severe pathology, substantial functional impairment and impact on quality of life, attempts to undertake conservative measures, discussion of risks involved.

9.4 More comprehensive review of notes may identify documentation addressing some of the points in 9.3

9.5 An issue that stands out is failure to plan for possible voiding dysfunction in a lady receiving bladder botulinum injections who was averse to catheterisation.

9.6 Inpatient management of infection as seen in one of the cases should be undertaken in the context of specialist input from a multidisciplinary team including microbiology

Personal Information redacted by USI

Mr Marcus Drake, MA (Cantab), BA, BM, BCh, DM (Oxon), FRCS (Urol).

Consultant Urological Surgeon, Bristol Urological Institute

HEFCE Senior Lecturer in Urology, University of Bristol

Visiting Professor, University of West of England.

20 December 2008

Ms. Catherine Mc Nicholl
Service Delivery Unit
Templeton House
411 Holywood Road
Belfast
BT4 2LP

Dear Catherine,

I have reflected at length upon the direction of the Regional Review of Urological Services since attending the meeting at the Park Avenue Hotel on the 9th October 2008. I appreciated the opportunity afforded to me to share some of my concerns with you and with Mark Fordham when we last met at the same venue on 4th December 2008. I confess that it had been some years since I had once scanned 'Improving Outcomes in Urological Cancers'. I have since digested it twice. I have also had an opportunity to read and discuss the 'Models for Future Delivery' document. After all of that, I still do have genuine and grave concerns regarding the future of urological services, particularly those outside of Belfast.

In your introductory remarks on 9th October 2008, you expressed the view and desire that the Review was not about the past, or even about the present, but about the future. Whilst I understand the conceptual rationale, I believe that there is every probability that the mistakes of the past may be repeated, if not reviewed. More importantly, without a complete appreciation of the precarious journey from past to present, and the tenuous nature of the present, its simplistic replacement by the future carries with it risk of profoundly negative consequences. I am entirely honest in stating that I have not heard from anyone involved in the review to date, any sense of appreciation of how difficult it has been to achieve the present status, and how negatively the Review may impact upon it.

In 1990, there still remained a single, specialist urological department in Northern Ireland, at Belfast City Hospital, with five consultant urologists. Like many other singular specialist departments located in Belfast, it called itself the Regional Urology Service. Behind that title worked a mindset, which I often heard expressed, that they were singular out of necessity because of their specialist nature, and more significantly, that their specialist nature could only be optimally preserved if they remained singular. Moreover, that mindset completely superceded, for decades, any other considerations regarding need, demand or capacity throughout Northern Ireland. The claim to have, or the perception of the presence of, a 'first class' or 'world class' singular, specialist department, and worthy of the Regional title, blinded all to any inadequacy anywhere.

On 30 June 1991, Mr. Graham, a consultant general surgeon at Craigavon Area Hospital, and who had developed an interest in urology, retired. He did so leaving a waiting list which included 77 patients requiring TURP. On 30 June 1991, I completed higher professional training in Dublin. Surgeons at Craigavon Area Hospital learned that I had a 2 month hiatus before taking up a fellowship in paediatric urology in Bristol. I was asked if I would come to Craigavon to do some of those on the waiting list. I did all 77 in July and August 1991. By then, it was apparent to the Chief Executive and to all surgeons that there was undoubtedly a need to appoint a urologist. I was advised by them that this would entail a long and difficult battle, and I was asked to promise that I would apply if they won that battle. I was entirely unable to understand then, or since, how there could possibly be such a battle.

The battle lasted nine months, and it was very difficult. The late Mr. J. Kennedy, then senior Consultant Urologist, wrote that it was impossible to appoint a urologist at Craigavon Area Hospital as he or she would 'need special equipment'. The Board's Director of Public Health was most concerned that there would be adequate need or demand for one urologist, from a resident population of 290,000. Relentless pressure was placed upon the Board that the only safe and effective way of providing urological services at Craigavon Area Hospital was by a consultant jointly appointed by Craigavon Area and Belfast City Hospitals. However, in April 1992, the Chief Executive and surgeons at Craigavon Area Hospital gained the Board's agreement to appoint a urologist independently.

Meanwhile, I had fallen in love with paediatric urology and with Bristol, and the West Country. I had by then been offered a further year in Great Ormond Street, with the prospect of returning to Bristol as a consultant paediatric urologist. Everyone in Bristol thought that I was mad to decline that offer to return to a place in Northern Ireland, of which they had never heard. I was concerned about taking my family to Northern Ireland at that time. Even though I was born in Lurgan Hospital, the decision to honour my commitment to apply caused me great concern. I must be honest in confessing that the dominant reason I did, was to return home. I took up the post in July 1992.

This was the first appointment of a consultant urologist or urological surgeon in Northern Ireland outside of Belfast. I find it impossible to completely understand the origins or justifications of such forceful opposition to development in the face of such overwhelming need. The consultant : population ratio for Northern Ireland then was 1:260,000. If Northern Ireland was then a sovereign state, it would have had the worst or least adequate urological services in the EU or OECD countries.

I tried to tempt Colin Mulholland to come to Craigavon in 1993 as a second consultant urologist, but he preferred Altnagelvin Area Hospital, and precisely for the same reason that I had returned to Craigavon. He was returning home. All the better as there were now two fledgling departments outside of Belfast.

We appointed Mr. Wahid Baluch in 1996. Trained in Dublin and delighted to be appointed a consultant, Craigavon (in rural Northern Ireland) did not meet his aspirations. He left in 1998 for Dorchester. We offered his post to Mr. Michael Young in 1998. He did not accept until he was interviewed four days later for a consultant post in Belfast City Hospital, a post he expected to be offered and which he intended

to accept. The post at Belfast City Hospital was offered to Mr. Thomas Lynch instead, enabling Mr. Young to accept our offer. In 2004, we offered a third consultant post to Mr. Tariq Sami, who ultimately preferred to remain in his post at Birmingham City Hospital, rather than return to Craigavon. Mr. Richard Batstone withdrew in 2007 because he and his family felt isolated in rural, mid Ulster. Mr. Akhtar was appointed to that third post at Craigavon in 2007. His wife and children remain in Cambridge. It has taken 15 years for us to increase our consultant complement to three, for a resident population now approx. 320,000, and there is no guarantee that the third will remain. This has been our experience in the Southern Area. With respect, it is not an experience of anyone in SDU, or elsewhere in the Department, or NICE, or even in our own Southern Board. It has been my experience, of 16 years duration, and Mr. Young's during these last 10 years, and the greatest burden is the daily struggle to compensate for the inadequacy.

Similarly, Mr. G. Lennon was appointed a consultant at Altnagelvin Area Hospital in 1997. He left three years later for the richer pastures of Dublin. Mr. Schattka was appointed in his place, and remains in post.

Mr. Robert Kernohan, Consultant Urologist at Belfast City Hospital, developed a presence in Coleraine during the nineties. He transferred to Coleraine full time, when the new Causeway Hospital opened, including a substantial investment in urological services. Mr. Paul Downey was appointed to a second consultant post in Coleraine. Mr. Downey left a consultant post in endo-urology, at the University Hospital of South Manchester, as his wife severely wanted to return home to Northern Ireland. Mr. Kapasi was appointed to a third consultant post in Coleraine earlier this year, and concurrent with the resignation of Mr. Kernohan. His resignation is the loss of one of the most talented, skilful, urological surgeons in Northern Ireland, and that loss is suffered by rural Northern Ireland in particular. I believe that there should be no doubt in anyone's mind that his resignation is the first negative consequence of the changes which have already taken place, and those considered to be imminent.

I would never have imagined in 1991 or 1992 that it would be such a painful, frustrating, disappointing and disillusioning experience to see urological services throughout Northern Ireland reach adequacy, at least for the demand, if not the need. In 1996, BAUS recommended a consultant : population ratio of 1:80,000. This was accepted by the Department of Health at Westminster, in 1997, as the standard to be aimed for in England and Wales. I participated in a Review in Northern Ireland in 1998, and chaired by Dr. Hall, then Principal Medical Officer. Due to Northern Ireland having a younger age profile than England and Wales, the Department insisted that it would aim instead for a ratio of 1:100,000, and to have reached that standard by 2008! It would appear from 'Models of Future Delivery' that the BAUS recommendation of 1996 may now be considered an appropriate hallmark of consultant numbers in Northern Ireland, as a whole. Meanwhile, in 1999, the Urological Manpower Committee of the European Board of Urology reported that the mean ratio in the 33 member, associated and affiliated countries was 1:54,000. That calculation excluded all office urologists. That ratio has since fallen to 1:45,000 by 2005.

I really do regret this long narrative, but do believe it essential to ensure that you have a certain and complete grasp of the status quo, particularly that outside of Belfast. For me, the huge elephant in the room has always been service inadequacy, in recent times referred to as 'capacity issues'. When a region is served by a singular specialist department, service inadequacy in a sense does not exist, as it is invisible, as the specialists do not work in the locations where it is visible. And so for years, it is entirely possible to have a 'first class' but grossly inadequate service. This centralising force can be powerful and influential, tempting but deceptive. The alternative attempt to proceed towards adequate capacity by establishing specialist services in locations where none have previously existed, and enhancing those which do exist, may be resisted and frustrated by several 'interests', from general surgeons with an interest in urology, to Medical Directors and Chief Executives, to Trust Boards and Health Boards, to the Department of Health, and with urologists with their own vested interests scattered along the way. It would appear that the pursuit of quality and that of quantity are perceived to be in endless conflict. The first casualty of limited resources has always been quantity, and those who have made those 'difficult decisions' to sacrifice quantity always assuaged by the reassurances given that they have ensured that the limited services provided are 'first class', 'world class', 'gold standard'.

However, the need for the long narrative has little to do with the conflicting demands of quality and quantity, of which you are entirely au fait. I believe that it is vitally important that you fully appreciate that the dominant factor in the development of specialist services outside of Belfast, ab initio to date, has been the existence of a few trainees preferring to be appointed to consultant posts outside of Belfast. I did not apply for a post at Craigavon Area Hospital in 1992 because it was advertised. In fact, the post would never have materialised without my commitment to apply. Similarly, the post at Altnagelvin Area Hospital was advertised in the rare belief that a highly desirable appointee actually wanted to be appointed there, and to stay there. Indeed, when Mr. Kernohan began services in Coleraine, there was not even a post to go to. The development of services in all three locations has been chiefly frustrated by the preference of the overwhelming majority of potential applicants to be appointed to posts in Belfast or other cities in UK and Ireland.

It had been intended that centralisation of complexity would have been facilitated by the introduction of a two-tier training, producing consultant urologists after three years of training, and consultant urological surgeons after six years. Thankfully, in my view, it took only a short time for those committed to this concept, to realise and acknowledge that the concept was flawed. Now, we have reverted to a five year training programme, and with the option of applying for one additional year in a fellowship. Future training will be substantially similar to that of previous years, and possibly structurally better. I would expect that the overwhelming majority of competitive, ambitious, future trainees will complete fellowships, either in UK or elsewhere. I believe that urological departments in hospitals in rural Northern Ireland will face the same difficulties in recruitment and retention of consultants in future years as in past years. If those departments are to become deskilled, I fear that those difficulties will become impossibilities.

I have been advised that the number of trainees in UK is expected to significantly exceed the number of available posts for some years to come, and thus reassured that the prospect of unemployment on completion of training should ensure that all posts will be filled. If so, I fear once again that Colchester will come before Craigavon. I believe that there is a significant risk that the future status of urological service provision outside of Belfast will be so relegated.

It is for all of these reasons that I believe that the Regional Review of Urological Services should not arrive at any conclusions that put at risk the gains which have taken so long to achieve.

It may come as a surprise to read that I found much in 'Improving Outcomes in Urological Cancers' of merit. However, I do have grave concerns regarding the weakness of the evidence, particularly that upon which empirical recommendations are made regarding institutionalised work load. I am profoundly concerned that the authors saw fit to do so, even though they had reported that 'little direct research has been carried out on the organisation and delivery of services…Research designs which might be regarded as of relatively poor quality for evaluating a clinical intervention, may therefore be the most reliable available for assessing the organisational issues'. I would strongly recommend that you read 'Volume-outcome relationship in surgical urology: myth or reality?' by Erik K. Mayer et al., in the British Journal of Medical and Surgical Urology, Volume 1, Issue 2, September 2008. The authors report that the 'methodological quality of volume-outcome research does not appear to have vastly improved…with the implication that, at best, existing study design is only modest. This potentially limits the transferability of existing studies' reported correlations to clinical practice, and also raises the question whether much of the volume-outcome relationship will be voided by more methodologically robust research'. In particular, there are strong justifications for dissociating volume-outcome relationships pertaining to individual surgeons from the volume-outcome relationships pertaining to the institutions in which they work. In fact, more recent awareness of the multitude of factors contributing to institutional outcomes would question the legitimacy of that association in the first instance. Yet, the chief recommendation pertaining to complex pelvic surgery relates to the institution rather that the surgeon! I believe that the selective referral hypothesis is the determinant of individual volumes and outcomes in Northern Ireland, and should remain so.

Similarly, and with particular relevance to Northern Ireland, I do not believe that there is robust evidence to combine radical prostatectomy with radical cystectomy in institutionalised complex pelvic surgery. Apart from the fact that they both involve viscera in the anatomical pelvis, and that radical cystectomy includes removal of the prostate when performed in the male, they have little else in common. They are performed for radically different pathologies, with different urgencies, in very different patient cohorts (for whom geographical access have relatively different import), with entirely different complication and adverse risks, and requiring entirely different surgical experience and expertise. Cystectomy performed for bladder cancer may not always necessitate being radical, may be sexuality-preserving, and followed by orthotopic bladder replacement or by continent diversion. I do therefore find it somewhat alarming and deeply worrying that urological cancer service provision in Northern Ireland would be compelled to be compliant with Guidelines which give precedence to institutional volumes of two different operations for different

pathologies in different patient cohorts, without any justifying evidence, while relegating the experience (volume) of individual surgeons to a secondary status of transitional import, and their expertise to that of hypothetical aspiration. As there is no statutory or similarly binding obligation to be compliant, I would indeed agree that one should be pragmatic and sensible in the application of the Guidelines.

For all of these reasons, I would ask that the following recommendations be considered:

That any surgeon performing radical prostatectomies should perform a minimum of 10 per year

That any surgeon performing cystectomies for bladder cancer (usually radical) should perform a minimum of 10 per year

That radical prostatectomies be performed only at Altnagelvin Area and Belfast City Hospitals.

That radical cystectomies be performed only at Belfast City and Craigavon Area Hospitals.

I believe that the above configuration would largely preserve the current skill status at Altnagelvin Area and Craigavon Area Hospitals, without compromising the future enhancement of Belfast City Hospital. I do also believe that it would enhance the rationale for the Three Team Model of Regional Service Delivery.

Whilst I believe that the Three Team Model will probably become the preferred model, it does remain my view that urological need at Antrim Area Hospital will not be adequately met by providing outreach services of an outpatient, diagnostic and day surgery nature alone. If a presence is to be provided 7 days per week, the only point of so additionally doing is to be able to provide emergency and urgent care. Such will inevitably require inpatient surgery. It is my view that such surgery should be provided at Antrim Area Hospital, and that it would not be appropriate to have to transfer such patients to Belfast City Hospital. Therefore, it is my view that two or three consultants should be appointed to Antrim Area Hospital, irrespective of the Model option chosen. If part of Team East, those appointments may be of greater immediate priority than the next two appointments at Belfast City Hospital.

While all of the contents, views and recommendations contained in this letter are mine and mine alone, I can advise you that I have discussed my views with my two colleagues at Craigavon Area Hospital, and that they are supportive of my recommendations. In seeking your consideration of them, I do earnestly believe that these recommendations, and any others, should be submitted to another meeting of all consultant urologists early in the New Year. I therefore formally request that the above recommendations be so,

Yours most sincerely,

Aidan O'Brien,
Consultant Urological Surgeon.

Department of Urology,
Craigavon Area Hospital,
Craigavon,
BT63 5QQ.

27 September 2010.

Dr. Gillian Rankin,
Interim Director of Acute Services,
Administration Floor,
Craigavon Area Hospital.

Dear Dr. Rankin,

I reply to your letter of 14 September 2010. I do genuinely apologise for the delay.

As your letter relates to compliance with the Regional Review, I read again my written submission of December 2008 to Ms. Catherine McNicholl, who chaired / facilitated the Regional Review. Apologetic for its length, I have taken the liberty of enclosing a copy. Reading it again, I appreciate how naïve I was to believe that it was worthwhile, that it may have some influence. I did not appreciate how predetermined the outcomes were to be. In particular, I did not appreciate that the imposition of guidelines would take precedence over any and all other considerations. While I had cause to be shocked by the expressed indifference of decision makers to the wishes and preferences, consent or lack of it, concerns and anxieties of patients, or the difficulties and challenges facing them, or even whether change could impact negatively upon their clinical outcomes, I had no idea until last week how callously, cruelly and totally indifferent they could be.

On reading again my submission, I appreciate how prescient my concerns were for the future of our department / urological services from this hospital, and for the future of urological services in Northern Ireland as a whole, but particularly for the population outside of Belfast. In fact, I recall being restrained in expressing my concerns, as I had some doubt that I may not be right. I need not have been. The progressive implementation of the Review, coupled with the negative impact of the ward reconfiguration last year, and the relentless decommissioning efforts of the Commissioner this year, will I now fear lead to the complete destruction of our department, in so far as it still exists. I believe that the current levels of demoralisation and stress suffered by staff, exacerbated by the distress of our patients, will lead to the departure of key members of staff, provided any opportunity at all. I fear that recruitment will be impossible. I certainly would not advise anyone to apply for or accept any post here, in the current and foreseen circumstances.

When I recommended that radical prostatectomy be provided at Altnagelvin Area and Belfast City Hospitals, I did so as Mr. Mulholland had been repeatedly reported to be the best radical prostatectomist in Northern Ireland. However, I did so in December 2008 before fully appreciating how impressive Mr. Akhtar would be in performing that operation, and before the Northern Ireland Cancer Registry reported in 2009 that it had found the rate of incontinence one year after radical prostatectomy

in Northern Ireland to be 24%! Whilst I have not checked, this rate has to be the highest ever recorded or reported, anywhere in the world. When we audited some years ago, our radical prostatectomies performed at Craigavon Area Hospital, we had an incontinence rate of approximately 7%. The mean incontinence rates internationally are 10 – 12%. Has the Commissioner addressed this issue? Has the Commissioner launched an investigation into how reported incontinence rates in Belfast should be so high? Was the patient whose radical prostatectomy was scheduled to be performed by Mr. Akhtar last week, and which was cancelled without his consent, informed that, so far as is independently known, his risk of incontinence may have increased 3-fold? Will future patients be so informed? If not, why not? As I now know from the events of last week, clinical performance and outcomes are not an issue. Certainly, the expressed concern of the patient about their clinical management or outcome, is not a consideration. Improving clinical outcomes is not a consideration. All that matters is the imposition of Improving Outcomes Guidelines, irrespective of the detriment suffered by anyone!

I found the events of last week profoundly shocking and traumatic. I could never have imagined that such decisions could be made by some who had once qualified as doctors. I believe that it was appalling to cancel the admissions of those who urgently needed their surgery. [redacted] was in such symptomatic distress from a bladder full of tumour that he required acute admission to hospital. The cancellation of his planned elective admission caused him such additional mental distress as to have him cry, to express suicidal intent, wanting to go home to die! I could go on, but won't, as it is as pointless as it was before! Suffice to say that last week changed everything for me, and my colleagues. It completely removed any remnant of the veneer of clinical validity from the thrust of the Review.

For all of the above reasons, and regarding the contents of your letter, I wish to avail of this opportunity to highlight the fact that I believe bound, first and foremost, and to best of my ability, by the Hippocratic Oath that I professed in 1978. I believe that my duty is to provide the best possible care to the maximum number of those in most need of it. I did not need NICE or BAUS to tell me so, or guide me to that conclusion. I do not agree with the imposed application of Improving Outcome Guidelines in the manner proposed in the Regional Review. There has not even been an assessment of clinical outcomes following radical cystectomy in Northern Ireland in order to determine how best to improve outcomes. Even when that has been conducted as in the case of radical prostatectomy, centralisation may be directed to the centre with the worse outcomes!

As I have indicated previously, I have found that the mean duration of consultation at my clinics has been approximately 18 minutes. I have found that the duration is not influenced by new to review ratios. On Tuesday 21 September 2010, it took 190 minutes for me to review 10 patients, and that did not include time required to dictate letters. I cannot agree to comply with BAUS guidance regarding outpatient templates. My inability has absolutely nothing to do with the fact that I believe that the guidance is both ridiculous and obsolete, or that I have no association with BAUS whatsoever, or that I do not feel any obligation to be compliant with anything emanating from BAUS. My inability is simply due to my being unable to do what is for me impossible!

I have found your letter deeply worrying, and a cause of further stress and distress. I find it remarkable that a clinician should be required to 'see' new patients within 20 minute 'slots' and review patients within 10 minute 'slots'. So doing is to compromise or jeopardise the completion of a 'consultation', thereby once again, jeopardising clinical outcome. You have referred to these as 'clinical guidelines'. I believe that there is absolutely nothing clinical regarding the duration of a consultation. In fact, I believe that the guidelines risk being counter-clinical.

Being constructive, I do believe that all clinics can be four hours long: morning clinics running from 9am to 1pm, afternoon clinics from 1.30pm to 5.30pm. I will only agree to appointing patients in 20 minutes slots, with 12 appointments per doctor, whether new or review. Indeed this will be the minimum required, due to the further intent or requirement to enter and update data on all cancer patients on Capps. I will not accept the imposition of templates with more than 12 patients per doctor in attendance.

Regarding the triaging of letters, I do indeed aspire to be able to complete the triaging of all letters within one week. In particular, I would like to have all referrals triaged in a manner so that they are dispersed to their various destinations at 9am each Monday morning. All 'red flag' referrals are currently triaged by me on a daily basis. I undertake to have all referrals, irrespective of urgency, triaged within one week of referral, as above, by 1 November 2010. That undertaking is conditional upon maintenance of the current cohort of three consultants, and could not necessarily be maintained if our numbers were to decrease,

Personal Information redacted by the USI

Aidan O'Brien,
Consultant Urological Surgeon.

positively. Were you reluctant to transfer patients?

A. No, not at all. What we were -- what we didn't want to have happen, and which subsequently did happen, we asked for notification, let's say it were on the 19th or the following day, if we had been told that from the 14:04
1st October Belfast City Hospital is now prepared and is able to accommodate the transfer of radical pelvic operations to it, that's what we requested so that we would have a transition period to prepare patients for transfer. 14:04

137 Q. Then if we could look at TRU-259513, and just at the bottom of the page, please? So it's 17th September, about a month after Mrs. Trouton has sat down with Mr. Young, and she is writing to Beth Molloy explaining that there are two patients who require a cystectomy 14:05
due to malignancy and she's asking what's to be done about this in terms. And if we scroll up to Beth Molloy's response. There we are. And she is -- just scroll down. I thought we had Beth Molloy's response? Maybe not. Just go on up then, please. So Heather is 14:06
being told by Diane Corrigan, a colleague of Beth Molloy, Dr. Corrigan, in the Commissioner's Office:

"The patients need to be referred as soon as possible to the Belfast City Hospital Service. I would 14:06
suggest..."

- and then she provides contact arrangements for that. And then up the page, please? On up the page. Okay.

mind to have a catheter draining it, and he -- we had decided to keep him over the weekend so that I would operate on him the following week, and he was particularly distressed by the prospect that relief of his painfully distended bladder could be delayed. And I was very, very grateful to Mr. Hagan for actually taking him with first priority and, in fact, he cancelled cases that he had arranged to do the following week in order to facilitate that patient. So I recall clearly that day leaving a patient that evening, a patient in tearful distress at the prospect of having his surgery deferred. So even though Mr. Hagan subsequently expressed some concern about the unnecessary readmission of that patient in the months since his first diagnosis in July, and now it's September, two months later, thankfully he proceeded to have his surgery done the following week and I continued to review him for the next 10 years, because his surgery was curative, and the only reason I was reviewing him was because he was affected by recurrent urinary tract infection for which we did not need to use elective admission for IV fluids and antibiotics.

14:13 14:14 14:14 14:15 14:15

144 Q. But getting back to...

A. And getting back to the....

145 Q. The premise of my question was these were inappropriate correspondence on the part of you.

A. Well -- yes.

146 Q. You should not have been, as Mr. Hagan would have it, writing to the patients in the way that you were,

suggesting management decisions, or the appropriateness of management decisions that he may not be able to deliver, and putting him under pressure using words like "dread" to make a decision consonant with your own management decision for the patient? 14:15

A. Yes.

147 Q. Inappropriate he thought.

A. Yeah, I understand how he came to that conclusion and felt in that way. And when you look at it retrospectively in the cold light of day, it would -- I 14:16 can understand how anybody would agree with that. However, the context is equally important. Because if we had had that one month notice period in order to transfer people in an orderly fashion, such communications would not have been made to GP, to Chris 14:16 Hagan, or to any patient, and I cannot emphasise that adequately. Whether that excuses, in your view, the language that was used. But patients were dreading the prospect that they would have their surgery or management deferred by this precipitous decision that 14:16 took place on a Wednesday.

148 Q. Yes. We know from the materials that have been made available to the Inquiry, and I'm sure you've seen it and indeed remember it, your actions in writing these letters in that way was the subject of criticism from 14:17 Dr. Rankin.

A. Mm-hmm.

149 Q. The correspondence AOB-00191 was sent to you on the 27th September 2010, and it is expressed in terms of

being great concern that you've indicated to a patient in advance of a care pathway being agreed your preferred management of the case.

"I believe this puts inappropriate pressure on the receiving team and is regrettable." 14:17

That's something, looking back on it now you see the sense of, that being a fair comment, albeit that you were working in, you would call, extreme circumstances? 14:18

A. Yeah. It is most regrettable that this transfer at that time took place in the manner in which it did.

150 Q. Yes?

A. And I appreciate that the Inquiry is also familiar with the other aspects of the communications between 14:18 Mr. Hagan and Dr. Diane Corrigan subsequently about their lack of preparedness for such a precipitous decision. So I think actually that there was a lot of exasperation, and frustration, and concern for patients at that time that led to that kind of language being 14:18 used.

151 Q. Could I bring you to internal correspondence between Mr. Hagan and his colleague Dr. Stephens, the then Medical Director at the Belfast Trust. And if we start at WIT-99146, and this is correspondence written the 14:19 day after, this is 28th September, the day after you received your letter which we've just looked at from Dr. Rankin. He says at the top of the page:

Clinical History of Service User / Patient B

Introduction

The following clinical history has been compiled from information contained in copies of the patient's Craigavon Area Hospital (CAH) records and from information from the Northern Ireland Electronic Care Record (NIECR) provided by the Southern Health & Social Care Trust (SHSCT) in February 2021.

Clinical History

Service User B (SUB) was born on [redacted]. He had a history of chronic obstructive pulmonary disease related to smoking, peptic ulceration, systemic lupus erythematosus, osteopenia and degenerative disease affecting his cervical and lumbar spine. He was a 69 year old man when he presented to the Emergency Department at Craigavon Area Hospital on 01 May 2019 in acute urinary retention requiring urethral catheterisation. Acute urinary retention had been preceded by symptoms of bladder outlet obstruction. He subsequently had a trial removal of an indwelling urethral catheter, but was unable to pass urine. He was again catheterised.

On receiving his referral, I noted that his serum PSA was elevated at 9.16ng in April 2019, and that it had increased to 11.19ng/ml at the time of urinary retention on 01 May 2019, prior to decreasing again to 9.45ng/ml by 03 May 2019. Even though these serum PSA levels may have been entirely related to an enlarged, benign prostate gland causing increasing bladder outlet obstruction resulting in urinary retention requiring catheterisation, I was concerned that they may have been indicative of prostatic carcinoma. I was also concerned by the long periods of time such patients waited for first outpatient consultations at that time. Patients suspected of having prostate cancer were waiting up to 15 weeks for first outpatient consultations in 2019. Therefore, I arranged an appointment for SUB at my oncology review clinic on [redacted] to avoid the risk of such delay. Otherwise, he may not have had an outpatient appointment until August 2019.

I found SUB to be keeping well when I met him on [redacted], bothered only by the indwelling catheter. He confirmed that he had lower urinary tract symptoms prior to the onset of acute urinary retention. I noted that he had normal renal function. On clinical examination, it was my impression that he had a small, malignant prostate gland, and that the malignancy may have been locally advanced.

I advised SUB that he would be best served by having an endoscopic resection of his prostate gland (TURP) performed in order to relieve him of bladder outlet obstruction which had become so severe as to result in complete inability to pass urine, requiring an indwelling urethral catheter. Cognisant of the clinical impression that his small prostate gland was probably malignant, I did expect that maximal, endoscopic resection of his small, prostate gland performed with the intent of ensuring relief of bladder outlet obstruction would have additionally harvested adequate tissue for the detection of prostatic adenocarcinoma, if present. I arranged his elective admission on [redacted]. In anticipation that histopathological examination of resected prostatic tissue would confirm a diagnosis of prostatic carcinoma, I initiated androgen deprivation by prescribing

Bicalutamide 50 mg daily. I chose to prescribe Bicalutamide 50 mg daily in the first instance to prevent progression of the presumed malignancy, while avoiding the adverse toxicity associated with a higher dose while awaiting diagnostic confirmation and further treatment options, dependent upon the diagnosis and staging of the carcinoma, if confirmed, while also bearing in mind that the clinical impression of prostatic carcinoma may have been erroneous.

On endoscopic assessment of his lower urinary tract performed under spinal anaesthesia on [redacted], there was an area of pale, ulcerated mucosa on the ventral aspect of the membranous urethra. The prostate gland did not appear to be enlarged or obstructive. I found him to have severe hypertrophy of the bladder neck and a trabeculated bladder. The global endoscopic impression was that of bladder outlet obstruction due to bladder neck hypertrophy rather than prostatic enlargement. I maximally resected the bladder neck and the prostate gland to its pseudocapsule. SUB was able to pass urine satisfactorily following removal of an indwelling urethral catheter on [redacted], and was discharged on [redacted]. He was advised to continue to take Bicalutamide 50 mg daily upon discharge and while awaiting review.

At review on [redacted], I found that there had been no evidence of carcinoma on histopathological examination of tissue resected on [redacted]. Even though SUB continued to be able to pass urine, he reported that he was more severely symptomatic than he had been prior to the onset of acute urinary retention. He reported hesitancy of micturition, a variable urinary flow and a sensation of unsatisfactory voiding following micturition. However, these voiding symptoms were relatively mild compared to his storage symptoms, which included severe nocturia, having to rise four or five times each night to pass urine, though he attributed this nocturia to some significant degree to being a poor sleeper. He also reported pain on passing urine.

I was very mindful of my initial impression of SUB probably having a malignant prostate when considering further investigative options at review on [redacted]. I was reassured to some degree by the absence of any evidence of carcinoma on histopathological examination of resected prostatic tissue, as I had maximally resected prostatic tissue, though I was additionally concerned that such a small volume of tissue had been sent for histopathological examination. Nevertheless, I was aware that it was possible that he may still have had carcinoma present in unresected, peripheral prostatic tissue. I was also cognisant of the risk that the oncology review backlog could jeopardise his intended review and further investigation. However, at that time, I was firstly concerned that he may have ongoing urinary infection which would have been associated with an increased risk of urosepsis complicating prostatic biopsies. I therefore chose the option of having urinary microscopy and culture performed that day, of repeating a serum PSA level, of prescribing an antibiotic for presumed urinary infection, of requesting ultrasound scanning of his urinary tract and with a view to reviewing him in September 2019. I requested his GP to prescribe Ciprofloxacin 250 mg twice daily for a period of two weeks.

SUB was found to have pyuria on urinary microscopy. There was no evidence of significant infection on urinary culture. His serum PSA level was 1.8ng/ml. I was aware of these results when I dictated a letter to the GP and which was typed on [redacted]. I requested the GP to facilitate SUB having his serum PSA level repeated during the first week of August 2019. I explained the rationale of having SUB remain on Bicalutamide 50 mg daily, in that he should be presumed to have prostatic carcinoma until proven otherwise, particularly if his serum PSA level increased

despite continued androgen blockade. I also wrote to SUB advising him of his serum PSA level of 1.8ng/ml on [redacted] and requesting him to arrange an appointment with the GP practice nurse to have his serum PSA level repeated during early August 2019 as I hoped to be able to review him later in August 2019 with the result and the report of the ultrasound scan which had been requested. He was placed on the waiting list on the Trust's Patient Administration System for review at my urological oncology review clinic in August 2019. I ~~had~~ hoped to be able to review SUB on [redacted], with the intent of requesting prostatic MRI scanning prior to prostatic biopsies followed by MDM discussion in September 2019, and provided that there was no evident of infection present.

Performing prostatic MRI scanning prior to prostatic biopsies has been considered to be best practice for some years, for several reasons. Scanning prior to biopsies has facilitated targeted biopsies of regions of the prostate gland considered to be suspicious of malignancy on scanning. Those regions considered to be most suspicious of malignancy are more likely to be the regions harbouring the more aggressive and clinically significant cancers. Secondly, targeting suspicious regions also facilitates reducing the total number of biopsies taken from the prostate, reducing the risk of adverse consequences of having biopsies performed. Thirdly, when MRI scanning is performed following prostatic biopsies, the anatomy of the prostate may be distorted by having had biopsies performed, the distortion persisting for varying periods of time thereafter. The risk and severity of such distortion is all the greater following prostatic resection, and would be further exacerbated by prostatic infection. In compliance with such best practice, it had been the practice of our MDT to defer MRI imaging for a period of six weeks following prostatic biopsies, and for a period of two to three months following prostatic resection. It was for these reasons that I intended to have SUB return for review on 23 August 2019 with the intent of arranging prostatic MRI scanning in September 2019, prior to having biopsies performed.

I had a urological oncology clinic scheduled each Friday morning at Craigavon Area Hospital, each Friday afternoon scheduled for supporting professional activities (SPA). The urological cancer clinic each Friday morning ran in parallel with a clinic for patients attending for urodynamic studies, with or without flexible cystoscopies. These latter patients often included patients with prostatic carcinoma undergoing urodynamic and endoscopic assessment of lower urinary tract dysfunctional symptoms. I performed the flexible cystoscopies if the clinical nurse specialists conducting the urodynamic studies were not qualified to perform flexible cystoscopies. I would review these patients following completion of urodynamic studies, with or without flexible cystoscopy, to plan their further management with them.

In appointing patients to the urological oncology clinic, priority was given to patients following MDM discussion of their diagnosis and management. If the number to be reviewed following MDM exceeded the available appointment slots, I would then prioritise those to be reviewed at the next available clinic, deferring others to later. In addition, I would on occasion also give priority to those new patients whose red flag referrals I had triaged, in order to expedite their assessment and management, if it was evident that they had, or probably had, an advanced carcinoma, and in view of the increasingly long periods of time such patients would otherwise have awaited first appointments. If there were appointment slots available after all patients had appointments arranged following MDM, and any newly referred patients had been appointed, I would then identify other patients for review, attempting to do so by clinical priority, without having adequate

time to do so comprehensively. All appointments were arranged and confirmed by my secretary by telephone with all patients attending for review at the clinic.
I had been on annual leave on Friday 02 August 2019 and on Friday 09 August 2019. I was able to arrange for ten oncology patients to attend on Friday 16 August 2019 in addition to three patients attending for urodynamic studies and two patients attending for urodynamic studies and flexible cystoscopy. I was able to arrange for ten oncology patients to attend on Friday 23 August 2019 in addition to four patients attending for flexible cystoscopy and urodynamic studies. The pressure for appointments on these dates was also exacerbated by the lack of an outpatient clinic at South West Acute Hospital in Enniskillen on Monday 26 August 2019 as it was a Public Holiday, and where I reviewed many oncology patients from County Fermanagh.

SUB was certainly a patient of clinical priority. At his review on [redacted], I had initially intended to review him in early September 2019. When I wrote to his GP on [redacted], my view of his clinical priority was reflected in my hoping to review him on Friday [redacted], rather than early September 2019. However, his review was not accommodated on that date, due to competing clinical priorities.

In real time, there was continued pressure to appoint patients to subsequent clinics, with every attempt made to accommodate patients most deserving in accordance with clinical priority, within limited time available. Twelve patients attended for oncology review on Friday 30 August 2019 in addition to three oncology patients attending for flexible cystoscopies, two of whom additionally had urodynamic studies performed. By then, SUB's review had receded into the large cohort of patients awaiting oncology review.

I did not have the opportunity of reviewing SUB prior to speaking to him by telephone on [redacted] 2020, following an attendance by him at the Emergency Department in acute urinary retention on [redacted]. He advised that the lower urinary tract symptoms which he had at review in July 2019 had subsequently completely resolved. As they had done so, and as he had been reassured by the decrease in his serum PSA level to 1.8ng/ml in July 2019, he informed me that he had then discontinued taking Bicalutamide. He remained asymptomatic until April 2020 when he began to experience recurrence of similar urinary symptoms accompanied by tenesmus. I noted that ultrasound scanning of his urinary tract had been normal in August 2019 with a normal prostatic volume of 22 ml and satisfactory bladder voiding reflected in a residual urine volume of 74 ml only. Due to symptoms worsening, he attended the Emergency Department at Craigavon Area Hospital on [redacted]. He was assessed by a Registrar in Urology. He was considered to be in urinary retention and to have a locally advanced malignancy of his prostate gland. Urethral catheterisation had resulted in complete relief of urinary symptoms and of tenesmus. However, when I spoke with him on [redacted], he reported that he had again experienced tenesmus, and had found the indwelling urethral catheter to be uncomfortable.

I noted that his serum PSA level had been found to be 9.4ng/ml when he attended the Emergency Department on [redacted]. I therefore contacted his GP by telephone on 12 May 2019 to request that SUB be prescribed Bicalutamide 50 mg daily once again, in addition to Tamsulosin 400 mcg daily, the latter to enhance the prospect of a successful, further trial of removal of the indwelling catheter. His GP agreed to have the catheter removed on the morning of [redacted] and prior to SUB attending the hospital later that day for assessment. At the request of the GP, I confirmed the above requests by email to avoid delay, followed by a dictated letter in the usual

fashion. I arranged for SUB to be tested for Covid 19 two days prior to his attendance, advising him that he would only be permitted to attend if he tested negative for Covid 19. Lastly, I dictated a letter addressed to SUB to confirm these arrangements.

SUB was assessed by a Registrar in Urology when he attended during the afternoon of [redacted]. He reported that he had been unable to pass urine following removal of the catheter that morning, since when he had become uncomfortable. He was again catheterised, and had 500 ml of urine drained from his bladder. A prostatic MRI scan was requested. As SUB additionally reported having had rectal bleeding in addition to tenesmus, he was also referred to a consultant colorectal surgeon for assessment.

Prostatic MRI scanning was performed on [redacted]. He was again reported to have a normal prostatic volume of 22ml. The rectal wall was reported to be markedly thickened and the sigmoid colon was dilated. He was reported to have colonic diverticulosis. The anterior rectal wall and the prostate gland were reported to be inseparable. Reduced T2 signal change affected the thickened rectal wall and the posterior prostate gland from its apex to its base, with the possibility that the presumed malignancy may have involved the right seminal vesicle. The presumed malignancy was reported to extend to both levator ani muscles. There appeared to be a track of gas extending anteriorly from the rectum to the posterior aspect of the prostate gland. It was also reported that more inferiorly, a further larger gaseous track extended to the urethra. There was no evidence of pelvic lymphadenopathy or of skeletal metastatic disease. It was considered that he probably had a rectal tumour infiltrating the prostate gland and complicated by recto-urethral fistulae.

On obtaining the report of the MRI scan, the Registrar again wrote to the consultant colorectal surgeon on [redacted] to inform him of the report. There was no evidence of metastatic disease on CT scanning of his chest, abdomen and pelvis, performed on [redacted]. He had the lesion examined endoscopically by the colorectal surgeon on [redacted]. He was found to have an ulcerated, lower rectal lesion with features considered characteristic of a rectal carcinoma. However, histopathological examination of biopies of the lesion found it to be a high grade, Gleason 9 or 10, prostatic adenocarcinoma. The consultant colorectal surgeon then requested that SUB's further assessment and management be discussed at Urology MDM.

When discussed at the Urology MDM on [redacted], it was concluded that SUB had at least locally advanced prostatic carcinoma. It was recommended that SUB be reviewed, that he have androgen deprivation therapy (ADT) commenced, even though he already had Bicalutamide prescribed in May 2020, and that a bone scan be arranged prior to further MDM discussion with a view to considering referral to Clinical Oncology. He was reviewed by a Consultant Urological Surgeon (name redacted) on [redacted], when he was advised of the histopathological diagnosis of prostate cancer which was then considered to probably be locally advanced, pending the findings of bone scanning which was requested.

In his letter of [redacted] addressed to the GP, the Consultant Urologist reported that SUB advised him that he had stopped taking Bicalutamide in May 2020. This was a contradiction of his advice to me in May 2020 when he informed me that he had discontinued taking Bicalutamide in 2019, as a consequence of which I had requested that he be prescribed Bicalutamide once again. The Registrar in Urology had related on [redacted] that he had been unable to pass urine following catheter removal even though he had been taking both Bicalutamide and Tamsulosin.

Even if SUB had continued to be prescribed and had continued to take Bicalutamide since 2019, it is unlikely that he would have discontinued taking it in May 2020, even though it had been prescribed for him once again.

In any case, the Consultant Urologist who reviewed SUB on [redacted] requested the GP to prescribe Bicalutamide 50 mg daily once again, and to prescribe the LHRH agonist, Decapeptyl SR 11.25 mg, once every three months. He advised that the first injection of Decapeptyl SR be administered one week following resumption of Bicalutamide which should then be discontinued three weeks later, and '*not given again*'. There was no evidence contained in the information provided of any engagement with a Urology Cancer CNS at this consultation on [redacted].

SUB had the indwelling urethral catheter replaced in the community on [redacted]. Despite drinking as much as possible following its replacement, there was little drainage of urine by way of the catheter. The urine in the catheter drainage bag was considered to contain faeculent material. SUB additionally reported passing urine per rectum. He attended Craigavon Area Hospital later that day. An attempted replacement of the indwelling urethral catheter was unsuccessful. He was therefore admitted and had an open suprapubic catheterisation performed under general anaesthesia on [redacted]. He was advised postoperatively that he would additionally require a defunctioning colostomy, and that it would have been optimal to have this performed as soon as was possible, and preferably during his current inpatient stay. However, SUB preferred to go home for a period of recuperation before undergoing any further surgery. He was discharged on [redacted]. He remained on Bicalutamide 50 mg daily and Tamsulosin 400 mcg daily, in addition to Co-Amoxiclav, on discharge.

Bone scanning had been performed on [redacted] when there was no evidence of skeletal metastatic disease. His current status and further management were discussed at MDM on [redacted] prior to his elective readmission for defunctioning colostomy. It was recommended that he continue treatment with ADT and that he be considered for palliative radiotherapy subsequent to having a defunctioning colostomy performed.

SUB presented to the Emergency Department once again on [redacted] as urine was bypassing around the suprapubic catheter while faeculent material was draining from his bladder by way of the catheter. He was admitted from the Emergency Department on [redacted]. A defunctioning colostomy was performed under general anaesthesia later that day. The stoma was sited in the left lower abdominal wall. He was planned for discharge on [redacted].

He was next reviewed by the Continence Service on [redacted] when he had the indwelling suprapubic catheter replaced. The letter of [redacted] indicated that an appointment would be arranged to have the catheter replaced again eight weeks later. He was also reviewed by the Stoma Nurse Specialist on [redacted] when the sigmoid colonic stoma appeared to be satisfactory. He was then reviewed by a Consultant Rheumatologist on [redacted] when he was advised to resume taking Hydroxychloroquine 200 mg daily for his systemic lupus erythematosus. SUB was reluctant to do so. However, his GP was requested to prescribe it if the patient was agreeable. It was prescribed on [redacted].

SUB was reviewed by a Consultant Urological Surgeon (name redacted) on [redacted]. In the letter which the Consultant Urological Surgeon dictated that day, he reported that SUB had not

had a very good weekend, and that he had intermittent episodes of diarrhoea and penile discomfort. He recorded that SUB was being treated with Decapeptyl SR 22.5 mg administered every six months, even though the GP had been requested in July 2020 to prescribe the three monthly preparation of 11.25 mg of Decapeptyl SR. He also reported that SUB's serum PSA level had increased from 9.4ng/ml on [redacted] to 17.3ng/ml by [redacted]. This increase would have been reliably indicative of rapid disease progression, with a PSA doubling time of six months, even in the absence of ADT. Assuming that he had been prescribed and administered Decapeptyl 11.25 mg in July 2020, this increase in serum PSA levels was all the more significant. There is no evidence that SUB had a serum testosterone assay performed that day to determine whether he was castrate. Even though there had been such an increase in serum PSA levels, the Consultant Urological Surgeon decided not to add Bicalutamide, but considered that it would have to be added to the patient's treatment if his serum PSA levels were to increase further.

In addition, the Consultant Urological Surgeon considered that SUB would benefit from palliative radiotherapy, for which he referred him to the Cancer Centre at Belfast City Hospital. There is no evidence of an intended or planned, further urological review. There is no evidence of participation of a Urology Cancer CNS in his review on [redacted]. There is no evidence of engagement with or referral to Palliative Care Services.

SUB attended the Cancer Centre as an outpatient on [redacted] when it was recorded that he was suffering constant, severe, pelvic pain radiating to his penis and perineum, even though he was taking Co-codamol 30/500 four times daily. He was reported to have lost weight and to have no energy. It was recorded that ADT had been initiated in July 2020 when he had the six monthly dose of Decapeptyl SR prescribed. It was recorded that the suprapubic catheter was due replacement in a couple of weeks hence *'as it has been there for a good few months at this stage'* even though it had been replaced in September 2020. SUB was advised that it appeared that he had an aggressive, locally advanced, prostate cancer that was not going to be curable, in view of the appearances of the malignancy on imaging and in view of the serum PSA kinetics. He was advised that optimising his quality of life was the current priority, and that optimising pain relief was the top priority.

He was given a prescription for Oromorph to be taken when required, in addition to Morphine Sulphate tablets to be taken twice daily. He also had Bicalutamide 50 mg daily and Dexamethasone 2 mg daily prescribed. The CNS in attendance made a referral to the local Palliative Care Service. It was agreed that SUB proceed with a course of palliative radiotherapy, 20 Gy being delivered in 5 fractions, from Tuesday [redacted] until [redacted] 2020. Radiotherapy Planning CT scanning was performed on 05 November 2020 to enable him to proceed with radiotherapy on 10 November 2020. It was intended to review him six weeks later, and he was advised to contact the CNS at the Cancer Centre or the local palliative care team in the interim should the need arise.

SUB was brought by ambulance to the Emergency Department at Craigavon Area Hospital on [redacted] as he was unwell. He awoke that day, acutely short of breath, and had groin pain. The Encounter History made reference to him having radiotherapy for pain management. A chest XRay on [redacted] was normal. The initial diagnostic impression was that of sepsis. He was admitted from the Emergency Department on [redacted] and was discharged on [redacted] The Encounter History indicated that the definitive diagnosis was an upper

respiratory tract infection. A Discharge Notification or discharge letter pertaining to this admission has not been included in the information provided. It is not possible to determine whether a review was intended or planned.

The information provided does not clarify whether SUB had attended for radiotherapy prior to his acute admission to Craigavon Area Hospital on [redacted], whether he completed the intended course of radiotherapy and whether he attended the Cancer Centre for review as intended.

SUB came under the care of the Acute Care at Home Team (ACAHT) on [redacted] following a new onset of confusion. The Discharge Summary of [redacted] recorded that he had been eating and drinking well, but that he was off his feet and had fallen out of bed on two occasions. He was suffering from orthopnoea and paroxysmal nocturnal dyspnoea. He had had a rigor and the suprapubic catheter drained foul urine. The catheter had been replaced on [redacted]. He was found to have bilateral lower limb oedema.

His global renal function was minimally impaired with an estimated GFR of 58 ml/min. His proBNP level was elevated at 861pg/ml, indicating of a degree of heart failure. He was found to be iron deficient. He was also found to have a coliform urinary infection on urinary culture. The infection was treated with Gentamicin, even though the infecting organism was resistant to Gentamicin. The suprapubic catheter was replaced on [redacted] and SUB was discharged from the care of the ACAHT on [redacted]. During his management at home, he expressed the view that he did not wish to have any further admissions to hospital.

There was no evidence in the information provided in February 2021 of SUB having had a serum PSA level assayed since October 2020. Similarly, there was no evidence of him having a serum testosterone level assayed to assess his castrate status since prescription of a LHRH agonist in July 2020. There was no record in the ECR Medications Summary Form of [redacted] of SUB having been prescribed a LHRH agonist during the previous six months. The Summary Form did indicate that he continued to be prescribed Bicalutamide 50 mg daily.

However, in further information contained in Mr Dawson's report of [redacted], Mr MH, Consultant Urologist, wrote to SUB's GP on 06 February 2021 following a consultation which he had by telephone with SUB and with his wife. In that letter, Mr MH makes reference to SUB remaining on Dexamethasone 2 mg daily in addition to maximal androgen blockade, and to him having had some palliative radiotherapy in November 2020.

No further information was provided since February 2021.

However, I believe that SUB died on [redacted].

Aidan O'Brien

outpatients, as they could eat and drink. I did not encounter this approach in any other urological unit I worked in before or since.

II. **Cystectomy and Orthotopic neobladder formation.** Amongst the patients coming in for antibiotic therapy and IV fluids was a patient who had had a cystectomy (a major operation to remove the bladder that would generally take between 4 and 5 hours) and neobladder (creation of a new bladder) to treat recurrent urinary tract infections (UTIs). There was a young woman, in her early 20s, who had this procedure before I arrived to do my rotation at CAH, but who then had subsequent admissions for fluids and antibiotics during the time I was in CAH. I am not absolutely certain of the correct name of the patient at this remove, but my legal representative will provide the USI with the name that is in in my memory. The USI may wish to look at the particular case. The young woman made a lasting impression on me as she was really miserable, especially as she was continuing to have UTIs notwithstanding the major operation she had been put through. The predominant indication for cystectomy and neobladder is for treatment of bladder cancer and I was disturbed that this major procedure had been undertaken for recurrent UTIs in a young woman. I could find no evidence base in the literature for this. At the end of a ward round, where I had accompanied Mr. O'Brien, I challenged him as to why he had carried out such a radical and life changing operation on this young woman in the context of recurrent UTIs. He remarked that someone else had said that to him, and he justified it to me by telling me he had specifically discussed this case with a Urologist in the United States of America (USA) who agreed it had been a reasonable course of action. I felt, as a second-year surgical trainee, inevitably anxious about challenging an experienced consultant, that I had expressed my view and Mr. O'Brien had provided an explanation that was hard to dispute at the time. I think this was the only case of this type that I myself saw during my rotation, but I cannot say if there were others with whom this approach was taken. I did speak to Mr. Young during my rotation about various concerns I had about Mr. O'Brien, but I cannot now say whether this was one of the matters that I spoke to Mr. Young about. I may have, but I cannot say that I did. Looking back on this now, with 17 years' experience as a Consultant Urological Cancer Surgeon, I can see no justification for the operation.

during that on a number of occasions during the development of the presentation to the Director of Commissioning in late 2014, and on a number of occasions at Departmental meetings and general discussions between each of us.

83 Q. Is it fair to say that across the Urology team, there were a range of different views about the purpose and, perhaps, the efficacy of dealing with Triage as part of these duties and, in fact, in your observations to Dr. Chada's investigation, I think you described Triage, did you use the word pointless that context?

A. I think it's nonsense, actually.

84 Q. Nonsense. What did that reflect from your perspective?

A. I think within the text, Dr. Johnston has reflected this thought process. In a process like referral in to Secondary Care, any process works best if the first decision is likely to be right almost all the time. The best process would be a process, as I mentioned earlier as an example, if you are over the age of 45 and you've got blood that you can see in the urine, there shouldn't be any mechanism by which you can be referred on anything other than a Red Flag basis. Using technology available to us and electronic referral forms, then the ideal situation would be that that actually the referral category is right and I don't need to double-check it. What Triage is doing, or one of the things Triage is doing is it's utilising Clinical time in a Service that hasn't got enough Clinical time to check that the referral category is

right, rather than using technology and mandated fields to make sure that it's right at the outset. That is where I say I think Triage is nonsense. If we are having to check and you are getting a significant percentage are referred at the wrong category, and that carries a patient risk at the back of it, then surely a better process is one that ensures that it isn't wrong. At various points we would have discussed if any changes could be made to the electronic referral system. We would have used analogies of booking flights. If you were booking a holiday and there was a 5% chance that you booked a flight to the wrong destination it wouldn't be a very effective booking system. The same principle can be applied to referrals. 12:06 12:06 12:07

85 Q. Yes. You, in some sense, shared Mr. O'Brien's frustrations in respect of the process of triaging that confronted you as a busy Clinician. Where you parted with him was that you felt able to comply with the rules as regards Routine and Urgent referrals, whereas he couldn't find the time to do it as part of his duties as Urologist of the Week? 12:07

A. Yeah. While I had a view personally about whether alternative systems could be adopted that made the requirement for this less of an issue, I didn't abandon it as a duty to carry it out, and I carried it out. I also, as I described, adopted strategies to streamline patients' contact with the Department by a form of Advance Triage that was as efficient in use 12:07

of my time as I could make it.

86 Q. If we scroll just to the bottom of the document, conclusions. Let me just see. Keep going, please. Sorry, I don't have a page number for this. Keep going, please. 12:09

In what is a wide-ranging response to the draft SAI review, Mr. O'Brien reaches the following conclusions. He says that he does agree with the recommendations contained in the report with a number of caveats. He 12:09
says he does believe that it is crucially important that recommendation be amended to ensure that the Trust developer a clear, agreed written policy of its expectations -- something you deal with in part of your review. He goes on to say in the next paragraph: 12:09

"I believe that no Consultant Urologist should be expected to concern him or herself with reviewing their conduct of Triage to align themselves with his or her colleagues, especially when the colleagues claim to be 12:10
conducting Triage in a similar manner. That proposal will be replaced, in my view, by a clear, agreed, written policy of what the Trust", to paraphrase, should expect. 12:10

That seems to be a riposte to the recommendation contained in draft to him that he should seek to align himself to how his colleagues, you and perhaps others, were dealing with Triage. You presumably saw that

the blood test or in the X-ray, that needed to be -- should be expedited, then that action is taken. So you had to review the test result and that seemed appropriate.

84 Q. Did you have a system in place, perhaps using your secretary, in terms of when you would read the result and how would that be draw your attention? 12:42

A. Okay. Going back before the ECR system kicked in well that it was all done on the computer, it was all done by paper. I mentioned before about my black box. That was an A4 box in my office that my secretary would put all the printed X-ray results and bloods into. She would put the important ones to the top. The black box also took at the time any referral letters from other consultants or admin that didn't go via the booking office all went into this box. And those test results that she screened that were exceptionally important she put on my chair so, you know, those were done first. 12:42 12:43

The administration of that, again might have been a wee bit like the triage we talked about before, are they done on a daily basis, are they done at 72 hours or is it done on a weekly basis? But certainly I like to clear my box at least once a week. 12:43

85 Q. I just want to take your views on DARO. If we just scroll up, please. You'll see Mr. O'Brien coming back on this 6th February. He is greatly concerned, alarmed, "to learn of the directive which has been shared with me", presumably by his secretary, about a 12:43

I don't think that any consultant clinician should be expected, by their employer, to sacrifice so much of their time to meet the expectations of the employer.

Now, to answer your question more directly, what should have been the response in 2017, '18, '19? Could we have, as a group of clinicians, sat down in a room and somehow succeeded in getting management to engage with us to at least attempt to understand what those expectations meant for us, the amount of time that was required to undertake them, and what trade-offs that we could all agree to would be made? But, I mean, I did make a genuine and serious attempt to have those issues that I highlighted, from I would say actually early 2015, when I appreciated, and when I made it very clear that it was impossible for me to complete triage whilst Urologist of the Week, but then more formally in January '17, and again in 2018, to have that real substantive discussion with senior management to address these issues in a sustainable manner, but I didn't succeed. 16:01 16:01 16:01 16:02

131 Q. Yes. One of the supports on one view that is available to the clinician is the process of appraisal.

A. Mmm.

132 Q. And certainly we've heard evidence that when it was introduced in conjunction with the revalidation process, it was an instrument very much geared towards assisting the professional, the clinician, in their developmental needs, and I think we'll start with that 16:02

certain of what they say were shortcomings in the practise of Mr. O'Brien, triage, failure to dictate, keeping patients' charts at home, just to stick with the items that were scrutinised as part of the MHPS investigation. Those matters were known about for, in some cases, many years, triage, for example, and yet your analysis is nothing went wrong, the Trust spotted it and dealt with it. 15:59

A. Yes. Well, with regard to the triage issue, it was only in the last three weeks I discovered because -- from reading the witness bundles, the triage issue was in 2009, 2011, the one we're talking about. So I wasn't aware there were triage issues, although I suppose I did notice when I was on-call, because I followed him, that there was always triage waiting for me as well from his week that I ended up doing. 16:00

So I suppose it was a bigger problem than I realised when I was -- the triage I was thinking of was the large set of triage that was discovered in his office whilst he was ill. So that's the first point. 16:00

284 Q. So in summary, when you wrote this last summer you were unsighted on the extent of the knowledge --

A. -- on the triage issue. It was just the one triage issue. As I said, it was only in the last three weeks I discovered there were other problems. 16:01

The dictation, that was something I was aware of and I had noticed that within the first week of joining

Craigavon because I did Mr. O'Brien's theatre list, because I had no patients of my own, and I noticed there were no letters in the notes. And it took a long time to work out why they were on the theatre list, so I was quite frustrated. So that's the first inkling I had that there was something going on with regard to dictation.

285 Q. That would have been in 2015, perhaps?

A. As in August, my first week, first, second week.

286 Q. Oh, right, back in 2014. 16:02

A. '14, because I did his lists. Patients were coming to theatre with no letters.

287 Q. Yes?

A. So that's probably the first point I became aware there was some issue. I think I was new in the job, so it wasn't something I was really going to action, although I didn't... 16:02

288 Q. We will look at those in a bit more forensic detail in a moment. Then there were the 2020 issues that emerged, I suppose off the back of the Serious Adverse Incidents Reviews. 16:02

A. Yes.

289 Q. They related to conduct in association with the multi-disciplinary team and the care pathways in association with oncological patients. 16:02

In asking this question and to foreshorten it, can I assume that you know some of the themes that emerged from those SAIs?

that he had told Mrs. Corrigan. I thought -- again, I may have been told, but I didn't remember that she went to the office and found these. But that's obviously incorrect.

300 Q. Yes. I think the impression, or the correct position in fairness to everybody, Mr. O'Brien and Mrs. Corrigan, is that she accepts that she was told that these letters would be found in a particular place, in perhaps a filing cabinet, I forget, but within his office? 16:09 16:10

A. And that's what I sort of realised in the last few weeks.

301 Q. Yes. As I think you've acknowledged already, you did have a degree of knowledge prior to this January 2017 meeting, that triage and Mr. O'Brien were uncomfortable bedfellows. 16:10

A. Yes.

302 Q. At least in terms of the triage of routine and urgent cases; is that right?

A. In that it landed on me, because I followed him. 16:10

303 Q. I think we touched upon this briefly this morning, how did you arrive at the view that he was having difficulty, or at least there was a difficulty in completing what was expected of him by the conclusion of his Urologist of the Week period? 16:11

A. This was before he was given -- this was a way before he got the following Friday in which to complete his triage. So it would have been, really, from when I started. So the triage was kept in Thorndale in an

inbox, in a tray, and it was always waiting, sitting there, when I started on the Thursday.

304 Q. So you should come in to an empty box?

A. Yes.

305 Q. Is that right? 16:11

A. Yes.

306 Q. But what you were finding was referrals that hadn't been completed by Mr. O'Brien?

A. Yes.

307 Q. Did they fall into all categories or were they predominately urgent and routine? 16:12

A. I can't remember. I assume they were urgent and routine, but I actually don't know.

308 Q. Yes. And was this a --

A. I can't remember. 16:12

309 Q. Was this a weekly occurrence with few exceptions or was it --

A. It seemed to be a recurrent issue because I was always following him on-call and I found it quite irritating.

310 Q. You found it irritating because -- 16:12

A. Because it was --

311 Q. -- it was a bad start to the week for you, you were picking up --

A. Yes, I had referrals, his triage, plus all the stuff that was coming in for me. 16:12

312 Q. Yes. Did that irritation trigger conversations with either Mr. O'Brien or, for example, Mr. Young?

A. I can't swear. I possibly had informal conversations with people. Who, in particular, I had those informal

conversations, I can't remember. But I obviously did moan to people because of the irritation it caused me. I probably didn't say it to Mr. O'Brien. No, I wouldn't have said it to Mr. O'Brien, I think.

313 Q. Why was that? Why would you not think to say to the person apparently creating the problem? 16:13

A. Perhaps I should have, but I just didn't. Perhaps I dodged the issue and sort of did them most of the time. I think I might have left a few for him. Maybe I did direct them, I can't remember whether I directed him to some of them. My patience was probably wearing somewhat. 16:14

314 Q. Is it possible that this is a case of new consultant on the block, against experienced consultant, and there's an element of deference in avoiding confrontation? 16:14

A. I probably had respect for him because he was a senior consultant. I didn't know all these triage issues had gone on previously. Perhaps I avoid confrontation at times and I thought "I'll get on with it". But my patience was wearing thin after a while. 16:14

315 Q. Is it possible that what was left for you to attend to had come down quite late on the Wednesday evening so that he wouldn't have seen them. Is that an explanation?

A. It could be for some of them, but I doubt for a lot of them because it was more than a little pile. There seemed to be a reasonable number at times. 16:15

316 Q. If you're correct and Mrs. Corrigan's evidence is I think uncontroversial in terms of her finding

a significant number of untriaged referrals in Mr. O'Brien's office, having been pointed in that direction by Mr. O'Brien, the situation would appear to be: He is doing precious few urgent or routines by his own admission and they are being placed in his office. 16:15
You are doing some of the urgent and routines that have come in on the Wednesday, presumably?

A. Yes.

317 Q. Is that your --

A. Probably definitely on the Wednesday. 16:16

318 Q. It's clear, and the Inquiry has seen the correspondence and heard about the conversations between Mr. Young, for example, and Mrs. Corrigan, that the difficulties around triage were a regular topic of correspondence and discussion for quite a period of time before you 16:16
joined up --

A. Yes.

319 Q. -- and subsequent to that. Were you not, whether as an individual or a team member attending the weekly or monthly Departmental meetings, were you not privy to 16:16
discussions around what Mr. O'Brien was and wasn't doing in triage?

A. As far as I remember I wasn't aware of the extent of the problem with triage that had been going back ten years before I joined. But at the same time I may have 16:17
mentioned it at the meetings, I don't know whether I did or not, about the triage. I probably did moan about it because I did find it very irritating. So I doubt very much I would have kept it to myself.

320 Q. I suppose, in addition to that, do you recall any attempts on behalf of the team, on the part of the team, I should say, or on part of the Team Leader, if I can call Mr. Young that, to try to interrogate the reasons for the difficulty, which I think was perceived on the part of Mr. Young as being a slowness in delivery of triage, whether or not he understood that there was a failure of triage. We can ask him? 16:17

A. You mean a slowness of Mr. O'Brien triaging or slowness of -- 16:18

321 Q. I mean there is different strings to the evidence this Inquiry has received. Some people have said and will say, I understand that we assume that Mr. O'Brien was just slow in getting it back, whereas the clear picture is that, in fact far from being slow, he was simply not doing it in terms of urgent and routine. 16:18

So my question to you is, I suppose, whatever the problem was being regarded as, whether slowness or not doing it, why was that not, and perhaps it was, was that a topic of conversation amongst you as a team with Mr. O'Brien? 16:18

A. I don't think it was. I think probably part of the problem with regard to me was I was doing them, so they weren't lying around. I think the issues came to a head and I sort of things came out. Those triage were found in his office and he was given the Friday afternoon afterwards, after on-call, to enable him to do that triage. I think part of the problem was the depth he 16:19

tried to do the triage.

As I said earlier today, I mean I've seen some of the letters he dictated whilst on-call and they were four-pages long of no paragraphs, just continuous narrative. I think if you tried to do that kind of long letters, I don't know how many hundred come in a week, it's impossible. I don't think of any benefit because nobody can read those letters. They're just too long, too unfocused. 16:19 16:20

322 Q. I'm keeping my finger on, if you like, the state of knowledge and what was done with that knowledge just for the moment. So you had a discrete piece of knowledge that he wasn't doing the Wednesday, if I can describe it in those terms, because you were left having to do them. 16:20

You are not giving us any indication of recollecting that Urology Consultants as a team at meetings attended by Mr. Young and Mrs. Corrigan were an opportunity used to address Mr. O'Brien's shortcomings, whether to provide support or challenge, but to at least address the issue? 16:20

A. Yes, because I'm not -- well I don't know, I may have said it casually rather than formally. So I don't think it was discussed at the meeting as an actual problem where there could be a solution to it. But I'm trying to remember back and it's not something I expected to have to reproduce, so I can't remember 16:21

exactly, but...

323 Q. Given your understanding of the Patient Safety implications for not looking at urgent and routines, the whole point of the exercise being to see whether the general practitioner has got it right, because lurking in there could be a real risk for a patient who is being referred as routine, but in fact the proper categorisation is red flag and what have you. 16:21

Given that risk, do you find it surprising that you certainly had no memory of any stand-out discussions around this which might have been used to either support or challenge Mr. O'Brien? 16:22

A. Yes, I think in hindsight -- well, one is I obviously did the ones that were lying, so they weren't an issue, so I triaged them. But I think in hindsight I probably should have made more of a formal complaint, I mean particularly knowing now what had happened. 16:22

324 Q. You have said in your statement, if we go to WIT-50551 at 69.1. You were asked whether there was a failure to engage fully with the problems within Urology Services. You have chosen to answer that question by reference to Mr. O'Brien and you say: 16:23

"Yes, I think there was a failure to engage with Mr. O'Brien with Urology Services. Mr. O'Brien failed to triage urology referrals and he failed to refer a patient from the uro-oncology MDM to another patient (sic). 16:23

necessitated approaches that maximised the efficient use of our time, and certainly that's the way I approached work.

85 Q. In terms of Patient Safety then, what you are proposing maintains a safe approach? 15:40

A. Yes.

86 Q. In terms of the second element of what I have just read out, which is if you can't deal with the demands of the job, then it's your obligation to raise that with management, with the employer. It would appear, and 15:40 we'll develop this later perhaps, that Mr. O'Brien's, let's call it inability, or to be neutral, to deal with Triage in the way that he was expected to deal with it, was known to the employer for some time. How that was articulated in terms of his ability, or willingness, is 15:41 perhaps a debate for another day, but in terms of your experience of working with him and knowing how management within the Trust operated, was it a case often of, we know his concerns but we are not prepared to listen or not prepared to assist? 15:41

A. I think all members of the Urology team would have expressed at various points that there was essentially too much work to do, and Triage was part of that. As you say, there were points in time where it had been identified previously where he'd not been doing Triage, 15:42 and that had been found rather than raised as I'm not doing this, is my understanding. I don't think it was so much a, we know he's an issue that he can't do it, it's every one of us has an issue that we have got

a lot of work. I think what was challenging was my colleagues knew, for instance, how I did Triage, which was trying to be as efficient as possible. Mr. O'Brien had taken a view that he would phone all of these patients, which inevitably meant that the patients, when they got phoned, got a very good service because they got essentially a consultation, but it also inevitably took even more time than was required, and so he'd made a choice to do it in a way that took longer than was necessary, and he wasn't willing to change the way that he did it to take less time and, therefore, enable him to keep on top of it. 15:43 15:43

87 Q. His consideration was that it was necessary to do it in this way because of the demands posed by the waiting lists, if I don't Triage in a deeper, more meaningful way with this patient, he will be flung on to the, as you said, routine waiting list and unlikely to be seen for an age? 15:43

A. I mean, ultimately, Triage, as I've reflected earlier, in a system which is not able to meet demand means that those with routine conditions on the information available to you at Triage, wait many years to be seen. That is inevitable. But to take that mismatch in capacity and demand and turn it into a full telephone consultation for every referral during a week to mitigate that risk overloads an individual and creates an impossible to deliver workload. At no point had anyone suggested that that was the way it should be done. 15:44 15:44

Trust and it is, of course, partly all of you. Was that the case, did you feel you couldn't agree and you needed some help with it? Was that the case? Because it wasn't really clear where that was going to go.

A. Yes. The vast majority of us knew what -- had interpreted what triage was involving. And Mr. O'Brien was making it too complex in that it was taking too long. 16:15

192 Q. So other than -- so that was the problem. Did you then go and talk to your Clinical Director or anyone else to say look, we can't sort this out. Clearly we're the urologists, we need to sort it out because we know about this, but we are having his difficulty, can you recommend how we deal with it. Did you do that conversation-wise or formally? 16:16

A. Well, our conversations were with the Acute Service Director level who was running the admin and the --

193 Q. But this is a clinical issue really, isn't it?

A. Yes, I suppose it is. It had been going on so long we assumed that everybody knew about it, and that the likes of the CD and the AMD level -- we were aware that -- 16:16

194 Q. You didn't have a a mediation meeting to sort it out or anything like that?

A. No. 16:17

195 Q. Okay. One of the things you said today was around as clinical lead you can't know everything, which is clearly true. You only know what people tell you or what data you are provided with. What is difficult to

triage, so on the waiting list as routine. If it had been triaged, it would have been a red flag upgrade, because the PSA was 34 and 30 on repeat."

Do you agree with that as an analysis? 10:12

A. Yes, I do.

25 Q. Yeah:

"Saw Mr. Weir for leg pain and CT showed metastatic disease from the prostate primary. Referred to us and 10:12 seen yesterday. As a result of no triage delay in treatment of 3.5 months. Wouldn't change outcome. SAI?"

If that case had come across your desk in that way -- 10:12

A. At which stage, referral or...

26 Q. Well, at the stage of Mr. Haynes writing this. I'm seeing this case coming back, it occurs to me that it hadn't been triaged, it should have been triaged, and if it had have been triaged, I would have red flagged 10:13 it. Is that --

A. Yeah. So I agree I would have red flagged it. I also think it warrants an IR1.

27 Q. Yes. And scrolling up, we can see how it was batted around. It comes to Mrs. Corrigan, she wants to 10:13 discuss it with Mr. Carroll, the assistant director. Mr. Carroll, if we go up the page, throws it over to the assistant medical director, Dr. McAllister. Dr. McAllister - scrolling up please - decides that the

I managed my time, I think, reasonably well. I mean, triage I usually did later in the day when the other activities had all been completed, so when patients had been taken to theatre, when the ward round had been done and more urgent things had been dealt with. So if I needed to stay in the evening, I stayed in the evening and did it. So, you know, I could be triaging, 8, 9, 10 o'clock at nighttime but I completed it on the day, it was done every day. It wasn't at the expense of other activities, it was a lot of work but I don't think other activities suffered. 10:10 10:10

3 Q. Maybe another way of looking at it is that the emphasis on triage diminished the time that you could and would otherwise might have liked to give to the other duties associated with UOW? 10:11

A. No, again, I think I spent enough, the amount of time needed on the other activities, I spent on those activities. Triaging was something that didn't need to be done immediately and so it was dealt with when I had time to do it. So I didn't sort of cut corners in other activities or do less in the other activities at the expense of triage. 10:11

4 Q. One of the things you spoke about on the last occasion was the ward round when, I suppose Thursday morning, if my recollection is right -- 10:12

A. That's right.

5 Q. It had been built into the model, at least originally, that the person ending his UOW week would hand over to the incoming consultant. I think you explained to us

that's what --

142 Q. So when you refer to common practice, you are referring to the box that was used to transfer the notes between offsite locations but still Trust property and back to Craigavon records, that's what you are referring to? 14:06

A. Yes.

143 Q. You mentioned also in your answer, when you met your secretary you discussed triage. Now I know that the red flag system come in at the end of 2009, early 2010, so you preceded that and also postdated that system. 14:07 What was your system for triaging during your tenure at Craigavon?

A. My tenure at Craigavon, when I came in at that time there wasn't any red flag system. It was only just an urgent and something like routine type of thing. What 14:07 I used to go through the notes, the letter which is sent to me and pick up the salient feature, and if I feel that there is a suspicious sign of a cancer, which is quite obvious, like a patient with a hematuria, a patient with HYPSA, so I ask my secretary 14:07 to see them within a period of time which is quite soon, urgent-urgent.

But then later on came in a red flag, so we used to have a red flag to put it on the investigation, triage. 14:07 It was quite a practice at the time that an on-call surgeon or an on-call urologist will be looking at their triage and sort them out within a timely fashion.

144 Q. Now, when you were consultant of the week, when

you were completing your triage duties at that time, did you find that you had the capacity to adequately do the triage that was allocated to you while you were on that on-call that week?

A. First of all, when I was there the system was slightly different. There wasn't any consultant of the week. We used to do the on-call on a daily basis, I believe. So I did have my on-call day and I used to do some extra work out-of-hours sometimes to complete my triaging. But I must say that the time was a little constrained to do so much work. But as I didn't have my family with me, so I usually used to stay after work to complete the work, if needed to be. 14:08 14:09

145 Q. I think I meant to say "surgeon on-call", rather than "consultant of the week". I think that preceded, my mistake. 14:09

A. Not at all.

146 Q. But during that week, just to give us a general feel, did you ever have to raise it as an issue that you weren't able to fulfil your triage duties or were you aware of anyone else, including Mr. O'Brien, not being able to fulfil his duties in relation to triage? 14:09

A. It was actually, yes, I always did mine within a reasonable time. As I said, a reasonable time for me was within the same week. Like if I have been informed about the triaging on a Wednesday, I will try to finish it by Thursday or Friday. A couple of occasions, it was not raised as an issue, issue, that it is ongoing, but it was said that, oh, due to leave or that 14:09

of the clinic, without falling behind?

A. Oh, it was just part of your clinic time is that you had time built into that so that you would be able to do your dictation as part of seeing the patient. It was considered part of your allocated four hours, is that you had that time to see the patient and dictate on them and book whatever investigations or procedures they needed.

58 Q. And at the time that you were there in 2012, was triage part of your role? 11:31

A. It was.

59 Q. And what way was it carried out when you started your post at Craigavon?

A. So you would've got paper triage letters from GPs or from A&E or from other consultants and that would've went to a central appointments and they would've then date stamped it and sent it to individual consultants for triage. Because there were five of us, it would've been split between the five of us. I don't remember how that they chose, I assumed it was just, you know, evenly sort of given to all of the consultants. Like, I don't honestly know how it happened, but I knew that every day I would get a folder that had a number of triage letters in it and then it was my job to triage those. 11:31

60 Q. And again, was that something that you ever weren't able to do because of your other commitments, or was it something, a bit like your dictation, you just factored into your working day?

A. You generally would've done it around what else you had done. So, you know, you can't do it at clinic, because clinics are busy and there's patients there all the time, but, for example, in theatre it would've been fairly common that you bring your triage down to theatre and, therefore, when you were waiting for a patient to be put to sleep, that you would have 10/15 minutes and you would be able to triage some of the letters. And then if you didn't have time to do that, then you may have done it at the end of your working day. And it would've been not uncommon that I would've stayed on late to finish off admin tasks that I didn't want to leave behind. 11:31 11:31

61 Q. Do you have any recollection of Ms. Elliott or anyone else having to chase you up for dictation or triage or for the location of notes? Did any of those things happen when you were there? 11:31

A. As I said, I was just started. I was trying to make an impression.

62 Q. Best behaviour, you were on your best behaviour? 11:31

A. You know, I didn't want to sort of, like, fall behind. So it was never an issue. But as I said, like, you never had enough time for admin. And I still don't have enough time for admin and I regularly stay on at the end of a working day in order to make sure that it's all done. But, you know, the admin roles you have are very important, so I would make sure that I did what was allocated to me. 11:31

63 Q. I just want to read into the record your comments on

but I want to see the CT report, and then, if needed, to upgrade, yes.

18 Q. And was that the way triage was done when you arrived at Craigavon, or was that a system that was introduced while you were there? 10:13

A. As I told, initially we were just doing normal triaging, like marking as routine or urgent. We would not be investigating. But I think the advanced triaging started a bit later.

19 Q. And was that something that all the consultants -- was there a view taken that all the consultants would approach it that way, or was it really up to each individual clinician as to what approach they took? 10:13

A. I think this was the policy we agreed within the Department. So I presume every consultant was doing it . 10:13

20 Q. And do you know when that policy came in?

A. I'm sorry not exactly when.

21 Q. But your recollection is that there was a view taken that that is the way in which triage should be carried out? 10:14

A. I felt that it's the better way like, you know patients, rather than waiting for months and months to have a clinic visit, and then to ask for an investigation. So I think this advanced triaging speeded up the process of investigations. 10:14

22 Q. I suppose I am trying to get to -- there's two issues really. The first is what you did as a clinician, and you have explained that. And the second issue is

trying to establish if advanced triage, as it's referred to, was a policy, or a conscious decision made by the Trust at some point. So I think I understand your position at the moment to be that you considered advanced triage to be the most appropriate way for you to assess patients for prioritisation, but the second element of that I just want to make sure your evidence is clear, was there a decision collectively made that advanced triage was to take place in the way you have described? 10:14 10:15

A. Yes.

23 Q. There was?

A. Yes, as I remember, yes, it was.

24 Q. And you can't recollect when that conscious decision was made? 10:15

A. That's I can't recollect. One of the -- during the Department meeting it was discussed and it was all agreed.

25 Q. Was it the case that doing advanced triage in this way took up more time? 10:15

A. It was. Certainly.

26 Q. And was there any suggestion, when this decision was made, that there would be facilitation in the job plan for the time that it took to do this?

A. I'm not sure that the issue of job plan or timing came up, no. As far as I am, no, it didn't come up. 10:15

27 Q. Given that you had to look at the letter and then order the different tests and follow up the results and then revisit the categorisation dependant on the results, as

I understand it, did that take more time for triage to be completed?

A. I mean personally for the clinician this was taking more time, certainly. But for the patient I think it was beneficial in the sense it was speeding up the process.

28 Q. And was this something that the consultants agreed among themselves, or was it something that came from the clinical lead, or the medical director or anyone else, where they said this is how we want triage done. Do you recall? 10:16

A. I don't particularly recall how it came up, but it's all after discussion in the departmental meeting.

29 Q. Now when you undertook this form of advanced triage did that ever result in you falling behind in the triage that was allocated to you at any point? 10:16

A. Not particularly. It was taking more time, but there was no backlog or anything from my point.

30 Q. And were you aware of any of the other consultants having difficulty completing triage under this particular process? 10:17

A. Not until now the Inquiry came up.

31 Q. And we'll just go to your statement where you discuss triage. It's WIT-50372, at paragraph 66.1. I'll just let you find your way to that, Mr. Suresh? 10:17

A. 372. Yes, I'm on that page, please. Yeah.

32 Q. It's paragraph 66.1. Do you have that in front of you?

A. Yes, I've got it, yes. Yeah.

33 Q. Now the question we asked was:

read, obviously, there's other potential goings-on is obviously a bit upsetting in that perspective, I would say.

26 Q. Well, if I can take one of the examples that has been well ventilated before the Inquiry, the issue of triage, was that something that you were involved in as a registrar? 10:45

A. No.

27 Q. And, in 2019, when you came back as a consultant, did you have any -- you obviously were involved in triage at that point? 10:46

A. Yes.

28 Q. What was your view of how effective that was in 2019, the process that you were undertaking as a consultant?

A. So, in 2019, we undertook what's known as advanced triage. So during your consultant on call week, you would triage the electronic referrals, as well as the paper referrals in a timely manner, which meant that by the end of the week you had a clean ship and everything was done. And anyone who you thought was going to come to immediate harm, you brought them in there and then or to a Hot Clinic so you could see them during your week on call. And it was important to have the triage done for two reasons: One was for patient safety and governance, but also so that your colleague coming on, you don't leave them with a back foot before they're about to start an on-call week. 10:46 10:46

29 Q. If I could just take you to your statement at WIT-42199 at paragraph 9.2 -- so we're asking about triage:

demand?

A. Well, there was a report which I read recently, and I'm sure I read at the time, but it wasn't brought to my attention --

266 Q. It wasn't on your radar? 13:05

A. Not that I remember. Perhaps it was and I don't remember. I don't remember.

267 Q. So the waiting list initiatives, it's hard to understand why somebody with not enough time still has lots of waiting list initiatives. Is that done, do you 13:05 think, in a properly controlled way in terms of ensuring that the doctor is not putting themselves at risk with additional hours and ensuring that other things don't fall by the wayside? Do you think that is sufficiently well monitored? 13:05

A. I'm not sure it was.

268 Q. Just the last one from me. There's a lot of talk about triage, lots of different things have been brought into that and, on the one hand, there has been a sort of suggestion that management must decide how triage 13:05 should be done. Clearly triage is really a clinician activity. What is your view? Who should be deciding how triage is done in a department. Whose job is that?

A. The consultant's.

CHAIR: Thank you, Dr. Swart. 13:06

A few questions from me, Mr. Brown.

269 Q. You mentioned that you had received training in MHPS --

A. Yes.

take the requirement to triage off you permanently, but was a short-term fix, one might call it. But assistance comes in a variety of ways. When you reflect upon it now, your approach to triage, and dictation, and those kinds of things, should you have talked it out with your colleagues in a manner which might have led to them better understanding your position and being in a position to offer you advice and guidance? 12:43

A. Well I think there's evidence that we did have those discussions. 12:43

76 Q. Well I know you had those discussions, but what I'm asking you is, could you have approached it in a better manner?

A. Possibly. I would still go back to for me what was the fundamental issue. The fundamental issue with regard to triage was for myself, with my colleagues sitting down with, for example, the Medical Director and the Director of Acute Services, to work out exactly what it was that was required of us. That's what I wanted. That's what I asked for. That's what did not happen. I don't know if it even has yet happened? So, ehm... 12:43 12:44

77 Q. But is that not, with all due respect, something of an elaboration, in the sense that I hear you repeatedly, and I see it in writing from you, and you've brought it to the meeting with your fellow consultants, "Give us direction on how do triage", was the request to management. But everybody else was doing triage in accordance with -- and I hope I'm not oversimplifying 12:44

Corrigan, Martina

From: Haynes, Mark <[redacted]>
Sent: 21 June 2016 09:09
To: Weir, Colin
Subject: FW: Memo from Dr Wright re DUTY OF CARE

FYI as he's one of yours!

From: Wright, Richard
Sent: 20 June 2016 17:22
To: O'Brien, Aidan
Cc: Haynes, Mark
Subject: Re: Memo from Dr Wright re DUTY OF CARE

Hi Aidan
We live in a new world. what has been suggested is in line with GMC best practice and I would expect that like everyone else you should comply.
I suspect if you don't you may find more of your patients will be disadvantaged.
regards Richard

Sent from my iPad

On 2 Jun 2016, at 22:41, O'Brien, Aidan <[redacted]> wrote:

> Dear Richard,
>
> Thank you for your memo concerning Duty of Care.
> I do entirely agree that no one should expect another to assume responsibility for the result of a test without explicit agreement.
> This could, and probably should, be extended to the discharge of patients from review in secondary care with stated advice for or expectation of ongoing review in primary care without the prior agreement of the primary care physician.
> We are currently discussing this very issue with Macmillan and with primary care in relation to the ongoing review of patients with prostate cancer.
> Such issues have significant implications for both secondary and primary care.
>
> However, neither of these issues should be confused with another scenario which occurs just as frequently and which impacts upon the efficient management of patients.
> This is where we write to a GP requesting that a PSA be performed by the practice nurse one week prior to the patient's stated review on a specific date so that the result will be available on the date of review, rendering that review all the more meaningful.
> That is something we urologists have done frequently for years.
> Or to request that urinary culture is performed one week prior to a procedure, such as urodynamic studies, to ensure that it is safe to do so, or to prescribe appropriate antibiotic therapy beforehand, or to choose to defer, and replace with another patient instead.
> Even when there has been absolutely no doubt whatsoever that there is no expectation placed upon primary care for the interpretation of results, we are now having primary care practices refusing to facilitate these tests as a consequence of this Agreement concerning Duty of Care.
> Recently, a patient of mine was refused a PSA, requested of GP and of the patient, by me in writing prior to review, by a Practice Manager, because of the 'new regulations'.
>
> I believe that such a lack of cooperation between primary and secondary care equally unacceptable.
> I find it a new low in collaboration between primary and secondary care for the good of the patient.

It should be stressed that it has only been a minority of practices who have done so to date.
Some believe that the agreement concerning Duty of Care is being cynically and opportunistically exploited by some in Primary Care.
I believe this issues needs addressing.

Meanwhile, I personally have no intention of sending out to patients a completed biochemistry request form and labels when there was no need before,

Aidan.

From: White, Laura
Sent: 02 June 2016 15:56
To: Acheson, Janet; Adams, Dr Beverley; Adrian East; Ahmad, Munir; ahsanalam[redacted]; Aljarad, Bassam; Anderson, Tracy; Arava, Shiva; Armstrong, Matt; Bennett, Tim; Best, Stephen; Boggs, Edgar; Boyd, Kathryn; Bradley, Una; Brazil, Dr R; Brown, Jeffrey; Brown, Martin; Browne, Gail; Bunn, Jonathon; Bunting, Helen; Campbell, Clarke; Campbell, John; Carson, Anne; Cassidy, Lisheen; Chada, Neta; Clarke, Chris; Clarke, Rosemary; Coghlin, Caroline; Conlan, Enda; Convery, Rory; Corkey, Chris; Cotter, Paul; Coulter, Paul, G; Craig, David; Cullen, Aidan; Cunningham, Marietta; Currie, Aoife; Daly, Cathy; Damani, Nizam; DeCourcyWheeler, Richard; Dedic, Karel; Donnelly, Brian; Doyle, Timothy; Duffin, Donal; Eedy, David J; Epanomeritakis, Manos; Ervine, Aaron; Eswedi, Hakim; Farnan, Turlough; Ferguson, Andrew; Flannery, Daniel; Forbes, Raeburn; Ford, Ruth; gavinmbriggs[redacted]; Gibbons, Michael; Gilpin, David; Glackin, Anthony; Gormley, Damian; Gracey, David; Graham, David; Grier, David; Gudyma, Jaroslaw; Gupta, Nidhi; Hall, Sam; Hamilton, Beverley; Hampton, Gareth; Hanna, Heather; Harty, John; Hayes, Elaine; Haynes, Mark; Hewitt, Gareth; Hillemand, Christophe; Khwaja, Salman; Lewis, JulieZ; McConville, Conal; Moore, Michael; nizdaman[redacted]; smcosgrove[redacted]; Ahmed, Gamal; Chinnadurai, Anitha; [redacted]; Hogan, Martina; Holmes, Erskine; Hughes, James; Hull, Don; Iqbal, Nauman; James, Barry; John, Alexander; Johnston, Dr Linda; Jones, Claire; Kamath, Meeta; kearney, Angela; Kerr, Paul P; Khan, Ahmed; Knox, Andrew; Korda, Marian; Kumar, Devendra; Lewis, Alastair; Leyden, Peter; Lichnovsky, Erik; Liggett, Nathaniel; Loane, Katharine; Lowry, Darrell; Macauley, Mark; Mackle, Eamon; Magee, Glynis; Maguire, Peter; Maiden, Nicola; Mangan, Brian; Martin, Laure; Mathers, Helen; Mathers, Rachel; McAllister, Charlie; McArdle, Gerarde; McCaffrey, Patricia; McCaul, David; McClean, Gareth; McClelland, Anthony; McConaghy, Paul; McConnell, Mae; McConville, Richard; McCormick, Michael; McCormick, Tim; McCracken, Geoff; McEneaney, David; McGalie, Clare; McGarry, Paul; McGivern, Sarah; McGleenon, Bronagh; McGovern, Anna; McGucken, Paul; McGuinness, Dr Joan; McKay, Damian; McKee, Raymond; McKeown, Ronan; McKeveney, Paul; McKinney, Karen; McKnight, Karen; McLoughlin, Caroline; McMahon, Dr; McMurray, David; McNaboe, Ted; McNeilly, Thomas; McVeigh, Gerry; Menown, Ian; Merjavy, Peter; Millar, Gerry; Millar, Sarinda; Milligan, Aaron; Mills, Heather; Minay, Joanne; Moan, Shane; Monaghan, Clare; Morgan, Neal; Morrow, Michael; Osmonde Morris; Patton, David; Ahmed, Suliman; artohagan[redacted]; Bhat, Shivaram; claireshevlin[redacted]; Funston, Lesley Ann; Henderson, Nicola-Ann; Kadhim, Hasan; Khan, Muhammad; Marks, John; McCambridge, Orlagh; McFadden, Matthew; McGarry, Philip; McKeown, Gillian; McParland, Michael; McSherry, Pauleen; Mulroe, Teresa; Murdock, Andrew; Murnaghan, Mark; Murphy, Philip; Murphy, Seamus; Neill, Adrian; Nelson, Elaine; Nicholl, Hilda; Nicholson, Michael; Noble, Edward; O'Brien, Aidan; OConnor, Kieran; ODonoghue, JohnP; ONeill, Judith; OReilly, Seamus; Orr, Des; O'Toole, Conor; Parks, Lorraine; Patel, Dimple; Pathiraja, Melanie; Patton, Sean; Polley, Liam; Porter, Simon; Quinn, Ciara S; Quinn, Phil; Rafferty, Claire; Rajkumar, Shan; Rea, Margaret; Reddy, Ekambar; Rice, Paul; Roberts, Mark; Rutherford-Jones, Neville; Savage, Eimear; Scullion, Damian; Shah, Rajeev; Shah, Shilpa; Shahid, Sara; Sharpe, Peter; Sidhu, Harmini; Sim, David; Smith, Mike; Sobocinski, Dr Jacek; Spedding, Ruth; Stewart, Adriel; Subramanian, Arun; Suresh, Ram; Tariq, S; Thompson, Sam; Thorpe, Robbie; Walker, Stephanie; Watson, Bruce; Weir, Colin; Williams, Marc; Williams, Marian; Wilson, Lynn; Winter, Colin; Wright, Richard; Yarr, Julie; Young, Michael; Young, Thomas; Yousaf, Muhammad
Subject: Memo from Dr Wright re DUTY OF CARE

Dear Colleagues

Please find attached memo from Dr Wright in relation to Duty of Care for your attention.

Regards, Laura

Laura White
PA to Medical Director
Dr Richard Wright
Southern Health & Social Care Trust
Trust Heqdquarters
College of Nursing
68 Lurgan Road
BT63 5QQ

<image001.png> *Direct Line:* Personal Information redacted by the USI
<image002.png>**Laura.White** Personal Information redacted by the USI

Please consider the environment before printing this email

<image003.png>

<20160601_Memo_DutyOfCare_RWpblw.doc>

observation before signing off on the final report. What do you make of that?

A. I mean, essentially you are presented with a Clinician who, the reason the SAIs had happened is because he had not been able to do the Triage of a significant number of referrals, and had not done it and had not alerted anyone that he hadn't done it. What he's saying there, in my interpretation, is, even though that's the case, I'm not willing to change the way I do it to try and meet the time scales the way that my colleagues do until someone tells me exactly what's expected of me. 12:11

87 Q. If we scroll down, finally, to -- just a little.

This Review Report, as I have indicated earlier is delivered finally on 22nd May 2020, a period of some four or five years after the failures of Triage had occurred, and anything between two and a half and three years after some of the Datixes were raised. Within your statement to the Inquiry, you indicate that the Trust is aware of the risk of delay attendant in investigating some of these SAI cases. By any stretch of the imagination, this is a grossly delayed report. Would you agree? 12:12

A. As I have reflected in my statement, the process of an SAI report takes too long, and indeed this one took, as you highlight there, two and a half years. There are often multiple factors into why an SAI report can take so long. Some of them relate to challenges in bringing, often, panel members together for meetings 12:13

And I think the preface to that discussion might well have included a paper prepared by Mr. O'Brien in September of that year. So having put all of that information in front of you, what it seems to speak of in 2018 and then again in an SAI review published in the summer of 2020, is that the team, the Urology Service, is crying out for guidance by way of a policy or whatever, in terms of how triage is to be done, what's expected. And, secondly, a need to assess whether it's feasible to continue doing urologist of the week with triage within those responsibilities. Is that still the position? Is it still a concern?

A. It is still a concern. So I think I did write this document. It's not dated, and that's my fault that it is not dated. There are also handwritten notes which I think the Inquiry have access to. They're in my handwriting. And in this, as in all the sections of this document, what I'm trying to reflect is the nature of the discussion and the views expressed by the members of the team. They're not my personal views. As best as I could capture them, they are the views of the team.

So there was a variance of opinion as to how we should be dealing with is this. Mr. Haynes had one particular view, that we were responsible for sorting this out ourselves and that "we were the Trust", I think was the phrase he used. I think that that might have been

captured in a recording, which you may have the transcript to. Mr. O'Brien, Mr. Young and I didn't share Mr. Haynes view. We felt that it was incumbent on the Trust to provide a policy to clearly outline how this activity would be delivered, and we were therefore at variance with Mr. Haynes in that regard.

195 Q. So, I don't want to spend an awful lot of time on this, for obvious reasons, but just drilling down a little deeper. We have the debate as to whose responsibility it is to sort it out, but in terms of the team members, was there a divergence of view in terms of the doability of triage during the urologist of the week period? 14:24

A. Yes. Mr. O'Brien expressed the view at this meeting, and at other meetings, that he was struggling to do this activity in the time given. He also described how he was doing this activity in his own time. Whereas others, myself included, were able to deliver this activity within the allotted time. 14:24

196 Q. And is that, as I think you've alluded to already, is that divergence of views a reflection of a deeper divergence in terms of the approach to be taken to triage? In other words the time to be spent and the activity. You described it as a quasi clinic approach or words to that effect? 14:25

A. Yeah. So certainly I was not taking the approach that each patient needed a telephone consultation to work out what we were going to do. Mr. O'Brien expressed the view that he did that, that he spoke to lots of

Corrigan, Martina

From: Glackin, Anthony [redacted]
Sent: 29 March 2022 16:03
To: Stinson, Emma M
Cc: Corrigan, Martina
Subject: Document for USI
Attachments: 20180924 Urology service development meeting.pdf

Please find attached minutes, hand written notes and copies of documents shared for consideration by team members at the Urology Service development meeting of 24 September 2018.

Anthony J Glackin MD FRCSI(Urol)
Consultant Urologist
SHSCT
[redacted]

Secretary: Elizabeth Troughton
Telephone [redacted]
[redacted]

Minutes of Urology Service Development Day

Consultants Meeting

In attendance: Mr Young,
Mr O'Brien,
Mr Haynes,
Mr Glackin,
(Mr O'Donoghue joined later).

1.1 Urologist of the week working model.

This topic was discussed extensively with each consultant able to contribute to the discussion. The consensus was that the inpatient ward round was of prime importance requiring consultant presence. The structure for referral and advice provided needs to be improved. Where possible definitive care should be delivered during the current inpatient stay.

1.2 Triage of new referrals.

The Trust needs to provide a plan detailing what exactly it expects the consultants to do in terms of triage. This must include recognition of the time constraints and time commitment required to complete triage including time spent speaking to patients, booking scans, reviewing results and mitigating risk for patients on the curent long outpatient waiting list. Consideration was given to decoupling the triage activity from that of the Urologist of the week.

1.3 Annual leave.

The team is define the number of consultants and other members of middle grade staff who can be away at any one time. Discussion of Christmas and Summer holidays should be well in advance of holiday time to permit good planning. A process for agreeing leave should be developed and adhered to.

Other business:

Mr O'Brien tabled a written document setting out his issues of concern for discussion at the meeting. Similarly Mr Young provided an email listing topics for discussion. It was suggested that those items not discussed should be given time at the weekly departmental meetings.

- First Out Patient Consultation Waiting Times
- Development of care pathways (bladder cancer, LUTS/BOO)
- Outreach clinics
- Specialty Doctor Clinics
- Consultant Job Planning

- Care of Benign Urology Patient
- Cancer MDT
- Theatre allocation and usage
- Waiting List Management
- Winter pressure planning
- Technology & Equipment

Meeting of consultants and senior nursing staff

In attendance:

Sr Caddell,
Sr McElvanna,
Sr Magill,
Sr Lockhart,
Sr Magee,
Sr O'Neill
Sr McMahon,
Sr McCourt,
Charge Nurse Young,
Mr Young,
Mr O'Brien,
Mr Haynes,
Mr Glackin,
Mr O'Donoghue

2.1 Ward issues:

1. Outlying of urology patients to facilitate medical inpatients.
2. Staff retention and vacancies.
3. Staff education program for Urology inpatient care.
4. Lack of medical support for medical inpatients on ward 3 South due to locum staff and a lack of continuity.
5. Interruptions to ward rounds.

2.2 Thorndale issues:

1. Too few cystoscopes.
2. Clinics overrunning.
3. Requests for inpatient flexible cystoscopy.
4. Introduction of endoscopy check list.
5. New patient clinic running problems due to time keeping and case mix.
6. Provision of intravesical chemotherapy service.

Sr Leanne McCourt tabled a prostate cancer option grid to be piloted within the Department.

Sr Jenny McMahon tabled the Southern Health and Social Care Trust endoscopy safety checklist.

ISSUES OF CONCERN FOR DISCUSSION
At
DEPARTMENTAL MEETING
On
24 SEPTEMBER 2018

The main issues of concern which I would wish to have discussed at the Meeting of 24 September 2018 relate to the practice of 'Urologist of the Week' (UOW), triage of referrals, the waiting times for a first outpatient consultation, the waiting times for elective admission for surgery, and the various relationships and influences between all of these.

I am honest in asserting that I have struggled to know how best to have these issues discussed, as I believe that they will be contentious, with all of us having very differing perspectives of that which is expected of us as individuals. I hope that we can express our views without confrontation and without causing offence. I hope that we can listen to each other respectfully. Above all, I do hope that we will be able to agree standards of practice to be submitted, perhaps in optional form, to senior Trust management, so that we will have a written clarification of expected practices.

UROLOGIST OF THE WEEK

From the outset in 2014, I found the discussions regarding the introduction of UOW to be frustrating and incomprehensible. I simply could not understand how it could not be a good thing to have a system where all inpatient care, whether acute or elective, would be undertaken by a consultant urologist with the assistance of junior staff (in training). I could not understand how it was considered that the Trust would not support and fund UOW without offering to undertake other duties when UOW, as it would not take all one's time to look after inpatients. At one time, it was even proposed that the UOW would be able to do an afternoon clinic! Regrettably, in my view, we did agree to include triage in the duties of UOW. In due course, I came to believe that there was a range of perspectives of the concept of UOW, from that which I expected it to be, to being 'Urologist on Call', and variations in between.

It had been my understanding that my week as UOW would begin with a Handover Ward Round at 09.00 am on a Thursday morning. The Handover would be from the consultant urologist whose week was ending, to me whose week was beginning. The Ward Round would continue until all inpatients were reviewed, their care being handed over. It would not be replaced by any other duty or practice by either consultant, with the exception of one or the other having to operate in emergency theatre. It would not be curtailed by attending departmental or other meetings, with the possible exception of the monthly scheduling meeting. The priorities of that first day would be to get to know the inpatients under my care for the next week, to meet them, to know their history, examine them, plan their further management, including definitive operative management when possible. As we all have experienced, I believe that we would also have a duty of care to those patients elsewhere, about whom advice and assessment is sought, and who may become inpatients under our care.

It had been my understanding that each of the seven days of that UOW week would be the same, including Saturdays and Sundays. It has been my experience that the most common conflict has

been when operating made it impossible to undertake ward rounds. When that has occurred on consecutive days, clinical inpatient care has been undertaken by registrars, often with different registrars on different days, with obvious risk to continuity of care. The other main concern that I have experienced when UOW has been that registrars are dealing with many calls for advice from elsewhere, without input from the UOW, resulting in the default outcome of having the patient referred to the department, to be triaged by another UOW one or two weeks later. The week would end with my handing over to the next UOW with a ward round commencing at 09.00 am the following Thursday morning, and ending when all inpatient care has been handed over.

It has been of increasing concern to me to observe an increasing divergence from the practice which I had understood UOW to require. It has increasingly become a common occurrence for no ward round to be undertaken by the UOW over a weekend, including three day, bank holiday weekends. It has been reported that one whole week went by in recent months without one ward round being conducted by the UOW. As often as not, I have begun my UOW week without handover from the previous UOW, and ended it without the next UOW being present. A recent handover took place with neither UOW being present. It had been my understanding that no activity other than emergency operating was to replace or usurp inpatient management when UOW. I did not consider that operating elsewhere, conducting Stone MDM / Clinic, urodynamic studies (I have been guilty), or getting documentation in file for (successful) appraisal, never mind triage, were to replace the primacy of inpatient management. I believe that there has been an increasing practice of 'letting them get on with it', referring to the registrars, both with inpatient management at ward level, and in some instances, operating, with I believe, suboptimal outcomes as a consequence, on occasion.

But I may have been wrong, and if the consensus is that I have been wrong, and if the Trust will underwrite that consensus, I will abide by it, even though it has been my definite experience that inpatient outcomes have been compromised, and will be again.

TRIAGE

I found it impossible to complete triage while being UOW, and I still do. Since returning to work in 2017, I spend the weekend following my UOW completing triage. In doing so, I have requested scans, initiated treatments, dictated letters to GPs, informed patients by telephone or dictated letters to them. I have done so for 45 to 66 patients referred, the equivalent of five to seven, virtual new clinics, without time allocated to doing so, never mind remuneration. Then the reports return! I find it such an anomaly that we have been allocated four hours of total administration time per week, and at least six hours of SPA time in our job plans!

I do believe that we need to consider the complexities of triage. The Red Flag referrals are relatively straight forward, though I was unable to obtain consensus regarding advanced triage of Red Flag referrals in 2015, even though they comprise a minority of the all referrals. I believe the remaining majority are the issue, particularly in the context of the waiting times for first consultation for urgent and routine referrals. If a man is referred with LUTS this month, should he wait until September 2019 before having an ultrasound scan performed, to find that he has a bladder tumour in addition to an enlarged prostate gland? Should he similarly wait until then before having a PSA, or having Tamsulosin prescribed for presumed BPH? Should these be preconditions to referral in the first instance? Should a woman referred with recurrent urinary

infection wait more than one year before she too would have an ultrasound scan performed, or have antibiotic prophylaxis prescribed? Should a man with erectile dysfunction wait even longer before he has treatment initiated? Could one with a scrotal swelling not have an ultrasound scan performed prior to referral, precluding referral in most cases?

In many instances, I find the most egregious referrals are those consequent upon consultation with our registrars. I have triaged referrals for red flag flexible cystoscopy following discharge of patients from our own department! Why was it not organised by those doing the discharging? Why does a registrar advise referral of a patient for a TROC, rather than arranging it at the time? Why does a registrar advise referral of a patient with a small stone at the lower end of the left ureter, instead of arranging the review?

I have requested several times from the Trust its stated Policy and Procedure on Triage, without acknowledgement. I can only conclude that it does not have one. I advised the Director of Acute Services in January 2017 that the issue of triage, its relation to UOW and to waiting times for first consultation, be addressed. There has been no response.

Once again, I would like us to embark upon a discussion of triage in all its complexity, and I expect that the Trust will be engaged in that process, resulting in a clear, written understanding of our obligations, so that we are not to be held liable.

WAITING TIMES FOR ELECTIVE INPATIENT SURGERY

This issue hardly needs further comment. We are all aware of the interspecialty disparity in waiting times, as of June 2018. I believe that the disparity is both scandalous and indefensible. I also believe that the lack of any substantive response from the Trust is equally so. I believe that we must collectively bring our concerns to the Trust Executive, and to the Trust Board which I understand to be unaware of the disparity, and unaware of any substantive attempt to remedy the situation.I also do believe that we should look at disparities between our own waiting lists, especially with a view to making every attempt on our part to minimise risk of serious morbidity or mortality.

In January 2015, I placed on my waiting list a pretty fit, 90 year old man for resection of his prostate gland which had regrown since it had previously been resected in 2006, and which had been the source of haematuria in 2015. He was admitted to the Cardiology Ward in August 2017 with coliform urosepsis resulting in a type II, myocardial infarct. He was readmitted again in August 2018, again with urosepsis. Since discharge, he has had visible haematuria, exacerbating a chronic anaemia. A CT Urogram has been normal. There was no evidence of urothelial pathology on flexible cystoscopy which was done during his recent inpatient stay. Yesterday, I arranged his admission on 17 October for TURP, keeping him on antibiotic prophylaxis until then.

I feel a sense of shame when dealing with such a patient. Whether it is disparity within our own specialty, or between specialties, it is unacceptable that such a man should have to wait almost four years, at risk of such morbidity, while an urgent gynaecological case would not have to wait more than three months.

Since I was appointed 26 years ago, the solution to any urological inadequacy has always been regarded as a requirement for additionality, which could either not be afforded, or there was no space for more beds, or staff could not be recruited, or whatever. I do believe that the first solution should be to cause displeasure to those specialties which do not have such a critical situation as we do have. How many gynaecological operating sessions are there per month in the Southern Trust? Why not allocate half of them to Urology?

Lastly, I often think that if I had a tumour of my left kidney, it would have to be removed within 62 days, or thereabouts. If I have a staghorn calculus in the remaining kidney, it does not receive the same clinical priority. I may just develop renal failure, requiring dialysis, a recognised complication!

SUMMARY

I hope I may be forgiven for expressing my views, frustrations and concerns, but I believe that it is time to do so. I have equally committed to listening to those of my colleagues. From doing so, I hope that we can collectively arrive at a clear understanding of our individual and collective obligations, and above all, that we have a clear, written memorandum of understanding, or agreement, or covenant, maybe even a Policy and Procedure, from the Trust of our practice obligations.

AIDAN O'BRIEN
24 SEPTEMBER 2018.

Davis, Anita

From: Clayton, Wendy
Sent: 16 December 2021 12:05
To: Davis, Anita
Subject: FW: Away day draft minutes
Attachments: Away day draft minutes.docx

Follow Up Flag: Follow up
Flag Status: Completed

Sharepoint

From: McMahon, Jenny
Sent: 16 December 2021 12:04
To: Clayton, Wendy
Subject: FW: Away day draft minutes

From: Glackin, Anthony
Sent: 27 November 2018 16:11
To: Corrigan, Martina; Caddell, Caroline; ONeill, Kate; McMahon, Jenny; McCourt, Leanne; Young, Jason; Haynes, Mark; Hennessey, Derek; Jacob, Thomas; O'Brien, Aidan; ODonoghue, JohnP; Young, Michael
Subject: Away day draft minutes

Please forward any corrections to me.

Thanks
Tony

with each consultant. *Relevant document located at Relevant to Acute, Evidence Added or Renamed 19 01 2022, Acute, Retired Staff, Dr Gillian Rankin, 20101206 Uro Issues re Long Wait Pts*

28.3 Specific meetings not held on a regular basis included the following:

a. 1 December 2009 meetings re range of governance issues chaired by the Chief Executive, with the Medical Director, AMD, AD, Acting Director of Performance and Reform, AD of Performance, Interim Director of Acute Services. The range of issues on the agenda included:
    i Demand and capacity and the need to optimise the use of clinical sessions;
    ii Quality and safety - Medical Director to discuss with Mr Fordham seeking an urgent professional opinion on:
        A The appropriateness and safety of the current practice of IV antibiotics;
        B Triage of referrals and 1 consultant refusing to meet the current standard of triaging within 72 hours;
        C Red flag requirements and 1 consultant refusing to adopt the regional standard that all potential standards require a red flag and are tracked separately;
        D Chronological management of theatre lists for theatre with 1 consultant keeping patients' details locked in the desk.
    iii Action agreed that if there was no compliance, correspondence would be sent regarding the implications of a referral to NCAS if appropriate clinical action was not taken. *The relevant document can be located in S21 No 8 of 2022, 58. 20091201 Uro Service Mtg Notes.*

b. 7 December follow up meeting with Mr Young, Consultant Urologist after 1 December meeting. Key points of discussion are set out. *Document located in Relevant to HR, reference no 35, 20091207 Ref35 - Meeting re Urology Service*

was a potential for delays with patients' treatment plans around triage". That's at your statement, for note WIT-60389, paragraph 30.1.

You clearly could see, standing back even from the clinical perspective of that system, that triage played an important role in making sure people got medical treatment on time? 11:34

A. Yeah.

186 Q. Would it have been your view that the system of triage that didn't operate to properly assess people actually increased the potential for risk and patient harm? 11:35

A. Yes.

187 Q. In 2015, and you have referred to this in your statement - again for note, WIT-60376 at paragraph 13.6 - you have referenced a report by what was the old Health and Social Care Board. 11:35

A. Mm-hmm.

188 Q. Where they say that the referral booking centre process is robust, but they actually reference Mr. O'Brien and they recommended that the GP prioritisation be used. 11:35

Did you see that as an endorsement of the default system that was put in place, that you were using the GP prioritisation rather than waiting on the consultant to triage? 11:36

A. Yes and no. I think what was meant by that was, look, if you are in dire straits, use the GP default. I don't think it was meant to be, look, you have

a problem with this particular consultant, use this all the time. I don't think it was meant for that.

189 Q. But what's clear from that reference in that report is that the Board knew about the issue?

A. Yes. 11:36

190 Q. In 2015?

A. Yes.

191 Q. Did they ever, or anyone from the Board ever come back and ask is there a patient risk involved; is there a risk assessment being done; is this impacting on the 11:36 services that they have commissioned? Any information like that ever sought from you to be fed back to the Health and Social Care Board?

A. I can't recall.

192 Q. In 2017, e-triage was introduced. First of all, did it 11:37 help? If it did, how did it help?

A. Well, it was great from the booking centre's point of view because we no longer had to keep photocopying or scanning referrals because they were electronic. Therefore everybody could see, especially the rest of 11:37 the whole of the consultants could see if Mr. O'Brien hadn't triaged on his week or whatever. It was all very visible. So yeah, it is good.

193 Q. Was it good just as indicating the extent of the problem rather than fixing it? 11:37

A. Yes.

194 Q. Is that the same situation at the moment with e-triage?

A. Yes.

195 Q. So, if triage wasn't being completed again, what we are

agenda for this kind of meeting?

A. Yes.

139 Q. And so we have the SAIs, they're discussed -- approved or not, as the case may be. And then scrolling down, we can see then that there's a complaints opportunity to deal with complaints; incident management position; and you can see the rest. Again, is this a standing agenda, essentially? 11:18

A. Yeah, the items in bold were the standing items. So Risk Registers, Acute Medical Audit Committee, Standards and Guidelines, those were all monthly standing items. This was to bring this forward into this senior forum to get that discussed. 11:19

140 Q. We know that -- we'll go and on and look at triage as a specific issue as we go on today -- 11:19

A. Yeah.

141 Q. -- that, without descending into the minutiae of it --

A. No.

142 Q. -- that a system was implemented. You appear not to have own about the system that was implemented, but is that the kind of thing that should have come on to an agenda such as this to be discussed or to be ratified or not? 11:19

A. So I guess we're opening a Pandora's box with this one. So we say or it is repeatedly said there was a default system. The default system on -- of February 2014 that came out from an AD across and was to be discussed with clinicians in the e-mail was actually a mirror of IEAP, which was the standards and guidelines of the time. So 11:20

did it need to come through here for reapproval? No, because it was an implementation of the already standing systems and processes. Things that are new to the system -- for example, at point 6, Regional NEWS Trigger Reset Guidance. So this had come out of -- like, there was regional learning letters and the use of the MEWS and NEWS system and there was changes to be made. So that was across the region, so we were going to talk about how we were going to do that. But that actual process -- and I know I say I don't recall that, I can see I'm included in two e-mails, but I was on annual leave at that time -- 11:20 11:21

143 Q. Yes, we will come back to deal with that --

A. No, because it was an IEAP reiteration.

144 Q. Yes, okay. So this is a meeting that anything radical or new should come before this? 11:21

A. Yeah, and also -- yes, and regional and issues that we had. So the AMD is to identify the top ten priority audits for their division. What are you doing? What are you auditing in your division, and why? And tell your colleagues and your peers why you're doing it and bring the results forward so we can discuss how well we're doing. Incident management is an internal thing, so internal things could come, but SAIs go out as well. So it was both internal broad management, but that was a system and process reiteration. 11:21 11:22

145 Q. Yes. I'm interested in hearing more in terms of how SAI process in general was used as a tool --

A. Yes.

respect for the consultant body. I've worked with them for many years. They all work extremely hard and their work is significant and they take decisions every day in terms of people's care and treatment. So, people I work with in health, I have a great respect for, so I was not going to humiliate Mr. O'Brien by saying, you know, "You just can't -- you're not performing this." So, we talked over how busy he was with other things, what he was committed to. In my view, everyone else, in the main -- although we have an episode of ophthalmology not triaging either -- in the main, everyone else was keeping up. So, was he too -- too busy -- no, I would have said not. Did I want to absolutely push that home to him? No, I just needed the outcome that he wasn't going to triage, and to try and get him to continue to work with us 10:11 10:11 10:12

3 Q. Thank you. That's clear. You mention pharmacy -- sorry, opht --

A. Ophthalmology, yes!

4 Q. Yes, it's a word I can never quite say from a young age! "Ophthalmics" is easier for me. You mention that ophthalmics had a problem with triage? 10:12

A. Yeah.

5 Q. And I want to explore with you now how the system of the default triage, as it's been called, and I understand from you that's a troublesome descriptor and we'll look at the IEAP and you can explain why you think the term "default" in this context is somewhat troubling. But I think your primary position is that 10:13

what the Inquiry understands as having happened, in circumstances where triage isn't being done in Urology, a practice grew up whereby patients were placed on a waiting list in accordance with the general practitioner or the referrer's classification and we understand - and this is routine emergence, not red flag - we understand that, in the main, those referrals were not followed up. In other words, the triager - and here we can say Mr. O'Brien, largely - was not then pushed to do the triage and, so, the referrals sat. You knew nothing about that? 10:13 10:14

A. No, but I don't agree with just how you've described it there because I think some of the evidence shows that the process, the reminder to triage and the process for triaging, which is commonly known as the default, which came out from Anita Carroll, was my understanding from reading the evidence is that - and her e-mails - is that was applied to all specialties. So there's no mention of that. And, anyway, as you say, when you read her flow chart, it is just implementing IEAP anyway for slow triage, however. So, first of all, I think it was for all specialties, from what I can see. Secondly, in the SAI that you talked about yesterday, the one that was the lady was referred in October '14, in that SAI there actually is evidence of tracking of triage and that it didn't come back on two subsequent follow-up e-mails to different people to get it back. So, I think some efforts may have been being made to get referrals back, but not in line with the flow chart 10:14 10:15 10:15

that was produced in February.

6 Q. Okay. The primary point of the question, I think, and thank you for clarifying what you think was going on in some of the cases --

A. Yeah. 10:16

7 Q. The primary question was in terms of not following up on --

A. Yes.

8 Q. -- urology referrals that hadn't been triaged as part of the process, or the omission to follow them up, that 10:16 aspect was unknown to you?

A. Unknown to me.

9 Q. Yes. And let me just take you through the ophthalmics issue, first of all, and we can see where that sits in in terms of your understanding of what was going on in 10:16 Urology.

So, if we go to WIT-98402 and, on 13th February, if we go to the bottom of the page, please -- well, the 12th February. So you're being copied into an e-mail. It 10:17 just happens to be the week before you're speaking to Mr. O'Brien about taking him off triage. So there's various e-mails around this ophthalmics issue and this is a convenient place to start. So there's obviously conversations going on about a problem within 10:17 ophthalmics and you're being told about it:

"Catherine is going to run an indepth report. There are 238 patients currently not triaged, of which 153

are over two weeks and 85 are waiting less than two weeks. The longest waiter for triage is 20 weeks."

And just scroll up, please. This is really of, I suppose -- the substance of it is not terribly important for the Inquiry; it's the fact that where it is to lead to that becomes important. So you say this must be escalated to Belfast as soon as possible. Can you help us a little bit, just having said that it's not terribly important -- 10:18

A. Yeah.

10 Q. But, in essence, what's going on here, can you remember, with ophthalmics?

A. Ophthalmology was what we would have called a visiting service, so, it was -- we had possibly, maybe, one or two, or maybe not, ophthalmologists employed by the Trust, but it was a visiting service provided by Belfast, but it was a full service so we did day surgery as well. And so that's why I would have said immediately escalate to Belfast, because that clinical management line, you know, equivalent to CD/MD/Lead Clinician would have been in Belfast. So, it was immediate to get why they aren't triaging -- why is somebody waiting 20 weeks not triaged and what are we going to do about it? So, that was the basis of that. 10:18 10:19 10:19

11 Q. Okay. And so there's this -- these e-mails are essentially "Let's get the facts straight, let's run a report --

A. See where we are first.

12 Q. -- let's establish what's going on."
A. Yeah.
13 Q. A couple of days later, we get to a description of a process that needs to be, if you like, implemented so that the waiting list problem around these patients is cured. 10:19

So, if we go to WIT-98404 and Anita Carroll is writing to a number of people. You're one of the recipients of this e-mail. I understand you're on leave that day. 10:20
A. That's right.
14 Q. -- and for a couple of days after that. And what she's saying is -- and, again, this is in the context of the ophthalmics issue, is that your understanding?
A. That is definitely my understanding. When you read the range of e-mails about ophthalmology, you can see that people were quite surprised that we had this 283 backlog and it came as a bit of a we mightn't have our eye on that ball thing. And I actually think there's an e-mail before that from, maybe, the 15th from Anita to someone else - to Heather, maybe - about, you know, "Here's what we originally reminded clinicians about triage, but in light of our discussions maybe we should amend that" and then she goes on in this one: 10:20 10:20 10:21

"I attach a draft process. I suggested to Heather that we should move to the position of accepting the GP categorisation on referrals. If these have not been returned..."

-- so I think what they were trying to do there is devise a system to make the triage times much more visible.

15 Q. And if we scroll down the page then, this is the process. Now, the referral is received into the Booking Centre, sent to the consultant and I understand the IEAP time limit is -- is it 72 hours? 10:21

A. Yes.

16 Q. But, here, this process is saying if the patient hasn't been -- sorry, if the patient has been triaged within a week, then obviously you appoint. But what happens in circumstances where triage hasn't happened? And this is a process of escalation here. So, if the answer is "No", we follow the right-hand pathway and it goes to the secretary to remind the consultant, etc., and then it goes back to the service administrator if it's still "No". And then if the service administrator has received a response within a week, it's an appoint. But, if not, it goes up the line to the OSL. If the patient has been triaged within four weeks - again, appoint - and, if not, it goes up the line to the RBC supervisor and the service administrator, etc. 10:22 10:22 10:23

So, at what point, if at all, does this system deal with the situation where the answer remains "No"? Does the patient make it on to a waiting list? 10:23

A. So, when the -- it doesn't -- it hasn't said there "appoint". But did it go -- up at the top, did it say

appoint to if no -- no, it doesn't say "If they're not appointed, appoint a GP." But the IEAP advises that. So the 2008 guidance from the Department advises that. I think the bottom box is important because it is the confirmation of the IEAP which is -- the very bottom box is Katherine Robinson is the Booking Centre Manager and Head of Service; and the Assistant Director, it goes to the Assistant Director as well, so that's obviously an escalation for an assistant director to take an action, their functional services. 10:24

17 Q. Yes, if we can take a look at the IEAP -- it was a protocol introduced in 2008?

A. '08.

18 Q. TRU-00840. [Short pause] So, that's what I call the Executive Summary then of it, and let me bring you to the process for dealing with referrals. So if we go down five pages to 00845 and this is the management of Outpatient services and I think the points that are of interest are 3.4 and 3.5. So: 10:26 10:27

"All referrals should be received at HRO and registered within one working day of receipt, enabled to be tracked through the system. GP priority must be recorded at registration. All outpatient referrals will be prioritised and returned to the HRO within three working days." 10:27

So that sentence is a description of triage.

A. Yeah.

19 Q. "Following prioritisation, referrals must be actioned on and pass an appropriate correspondence issued to patients within a working day."

10:27

3.5 then:

"Where clinics take place, referrals can be viewed less frequently than weekly. A process must be put in place and agreed with clinicians whereby GP prioritisation is accepted in order to proceed with booking urgent patients."

10:28

So, that's the important point. If triage is delayed for any reason, go ahead and accept the GP prioritisation in order to book the patient.

10:28

A. I think there's another bit in it --

20 Q. Okay.

A. It's either an appendix or there's another bit where it actually describes maybe a bit more about delay in triage. I could be wrong, I could be making that up, but I think not. Does anybody...

10:28

21 Q. I'm not sure.

A. Maybe further on does it discuss it with delay or -- there is another part which -- I mean, it's basically saying the same thing, but it's saying that in a nine -- this was developed when the Department was aiming for a nine-week outpatient booking. You have to give three weeks' notice to a patient for a reasonable

10:29

offer. And, so, that brings you to six. And then you're back up against it because you're booking six weeks in advance for your clinic leave. So, that was why and we were working at around about the 14, we were working to 15 weeks. So the actual waiting time was short and you didn't have much time to book the three-week appointment in advance, so you had to go ahead and book. 10:29

22 Q. Yes. And maybe this isn't --

A. I think there's another point. 10:29

23 Q. -- we can maybe try and find that.

A. Yeah.

24 Q. I think we all understand what the protocol -- I think maybe this isn't quite the text that you had in mind. But the point of the -- the avenue the protocol allows Trusts to go down is where the referral comes in and triage or "prioritisation" is the word used here -- 10:30

A. Yes.

25 Q. -- doesn't take place within the expected timeframe, it is nevertheless important to allow the patient to find his or her way into the system to get on board for treatment purposes. And, so, you can, in that circumstance, use the GP categorisation; is that your understanding? 10:30

A. That's my understanding, but that will prove an issue if your waiting time goes out for all waiting lists. So, if you're urgent and you're routine and everything goes out, then your patient will still be on the waiting list, but they could be on the wrong waiting 10:31

list, which I think then occurred. But when we were working to a short waiting time, you needed this because you had to book three weeks ahead and six weeks in advance of the clinic. So you had to do this.

26 Q. Yes. And in circumstances where you have this elongated waiting list, it becomes extremely important to get the triage -- 10:31

A. Exactly.

27 Q. -- done?

A. And back. Even though your patient -- it's delayed, even though your triage is delayed, it still needs to be chased and come back because it could alter which waiting list your patient is waiting on, which would then alter their time. But at least at the time when you're waiting to get it back, it's placed. But you have to chase, like it said in their process. 10:31 10:32

28 Q. Yes. And, as we know, in the referrals that went to Mr. O'Brien, the problem, as the MHPS investigation discovered, was the absence of the chase. Now, you have quibbled with that somewhat and you pointed to Patient 10's case and said, well, there is evidence that there was some follow-up to try and get the triage back in that case, and I don't argue with you on that. But as we can see -- 10:32

A. Not enough. 10:32

29 Q. -- not enough. It didn't come back?

A. No. It didn't follow their process. It didn't follow the flow chart. It didn't escalate or it didn't say it escalated to the Assistant Director.

30 Q. Yes. Just before we move on to what your understanding of that was and whether you had an understanding that that was what was happening in Urology, I want to take you back to an e-mail you wish to draw our attention to. It was issued in September 2013 -- 10:33

A. Yeah.

31 Q. And it's TRU-278624. Just to orientate the Panel, we started this sequence by looking at the problem in ophthalmics around 13th February or so, and, at that time, Anita Carroll is writing to you to say this had been the earlier version -- 10:33

A. Yeah.

32 Q.

"...but in light of discussion, I will amend."

10:34

So, she's referring to the e-mail below on 13th September when it appears that a general message is sent out, perhaps acknowledging broader triage issues. It may not have been an ophthalmic issue at that point, but there's a general concern to ensure that triage is being managed appropriately. So, this comes out across management. I think your name is -- 10:34

A. It is, and it goes to clinicians as well, it goes to AMDs.

33 Q. Yeah. So maybe we should have taken it in that order. What was happening in September and how did it connect in to February? 10:34

A. I don't know.

34 Q. Okay.

A. I've no recollection and I couldn't find anything. So, I'm not sure, to be honest. However, when she writes back and says to Heather on 13th February and says -- this is after discussion -- "maybe we should amend this", I guess that's when 17th February came out. 10:35

35 Q. Yes. Okay. So, I've described the problem in urology?

A. Yeah.

36 Q. Mr. O'Brien is Urologist of the Week, or he takes his turn to be Urologist of the Week at various points after the autumn of 2014. One of the responsibilities 10:35 of that role is to triage. He triages the red flags. The urgents and routine cannot be done, in his view. That is known to the Booking Centre and while, for the sake of argument, there might have been some chase on that, ultimately, the service was left with a 10:36 significant number of urgent and routine referrals un-triaged. So, that was the issue which was explored as part of the MHPS investigation. And if I can turn to that now, if we go to TRU-00675 and the penultimate paragraph, bottom of the page, please. So, Dr. Chada 10:37 writes that:

"During the course of the investigation, it became clear that a number of people within the Trust were aware of problems in respect of Mr. O'Brien's adherence 10:37 to the triage process. The Referral & Booking Centre were not receiving referrals back within the agreed targets from Mr. O'Brien when he was Consultant of the Week. In order to manage this, a decision was taken

during 2015 to introduce a default process whereby all patients were placed on the waiting list according to the GP categorisation of urgency, if the referral was not received back from the consultant urologist. This default process was adopted and agreed by the Director of Acute Services at the time, Ms. Debbie Burns, and number of other senior Trust staff, according to some witness interviewed. The rationale for this decision was to put in place a safety net to ensure patients were added to the waiting list. The reasons underpinning this decision will be dealt with later in the report." 10:37 10:38

And if I can go on just for completeness:

"As a consequence of the concern identified in respect of Patient 10 and the subsequent investigation referred to in Section 2, a lookback was undertaken to determine if there were any other un-triaged referrals that same week. It was discovered that there were others un-triaged and this, in turn, led to a review of all referrals. A large number of un-triaged referrals were subsequently located in an office drawer in Mr. O'Brien's office by Mrs. Martina Corrigan." 10:38 10:39

Then, over the page, the figure put on that is:

"In total, it was found that there were 783 un-triaged referrals dating back to June 2015."

So, I suppose the charge there, Mrs. Burns, is that you not only knew of this, but had approved of that as a process. And we can see within the report and the appended statements that Martina Corrigan, Anita Carroll, Katherine Robinson, Eamon Mackle and Heather Trouton all speak to you having -- the descriptions may vary to some extent, but they all speak to you having at least a knowledge, if not an approving hand in the development of this approach to meet the mystery of triage not being done. 10:39 10:40

First of all, were you asked to speak to Dr. Chada as part of this investigation?

A. No. I had left the Trust at that time. I guess the other thing to say is, Dr. Chada saying there it's 2015 -- if we're referring to the February, 17th February 2014 process, that was obviously 2014. If that's what she's referring to. It's not clear what she's referring to because it continues to chase the triage. I've read everybody's witness statement. As you say, they all vary a little bit. I think possibly in her interview with Julian Johnston, Martina Corrigan stated that it was developed between her and maybe possibly Anita and Katherine in a room by themselves. 10:40 10:40 10:41

37 Q. Would you like me to take you -- maybe it would be helpful to go to that?

A. It's just to demonstrate that -- I think everybody's recollection may be different but --

38 Q. Let me take you to that, in fairness to the point you wish to make. It's WIT-98395 and it would appear that, like you, Dr. Johnston interviewed a number of witnesses or a number of personnel, perhaps, is the best way to put it -- 10:41

A. Yes.

39 Q. -- for the purposes of his SAI investigation?

A. Yes.

40 Q. This isn't what I wanted to bring you to. Just scroll up to see the page number again... Yes, sorry, if we 10:42 can go to WIT-98517? That's it. So he's interviewing Martina Corrigan. Sorry, he's interviewing Martina Corrigan with Trudy Reid present. Can you just scroll through to the next page? There's a background set out in terms of the triage issue and down to where 10:42 it's highlighted in yellow, I think -- yes. So, if I can pick up just before that on what Dr. Johnston has recorded, I think you would say that, if he's got it right, Mrs. Corrigan has got it wrong?

A. Yeah. 10:43

41 Q.

"During Mrs. Burns' time as Interim Director of Acute Services, the un-triaged letters built up again. Mrs. Burns met with Mr. O'Brien and Martina Corrigan and very firmly told him to triage." 10:43

We've seen your e-mail of 21st February essentially excusing Mr. O'Brien from triage --

A. Yeah.

42 Q. -- and putting it in the hands of Mr. Young to sort out?

A. Yeah.

43 Q. And Mr. Young took it on. So, highlighted in yellow, Dr. Johnston picks up on the point: 10:43

"According to the Debbie Burns interview, she told Mr. O'Brien to stop triaging."

It would appear, on the face of that note, that 10:43 Mrs. Corrigan was inaccurate in rehearsing the history of February 2014. But it's the next point, I think, you wanted to make:

"Mrs. Carroll, Mrs. Robinson and Martina Corrigan met. 10:44 Mrs. Carroll considered what are we going to do - if Mr. O'Brien is not triaging patients, then they were not going on to any waiting list, urgent/routine. They were the only people in the room. While the process of putting people on the waiting list without triage meant 10:44 that people did not get missed, which was good to be on a list, it meant that there was no way of picking up who was triaged or what was the extent of the non-triage."

10:44

So, you're pointing to this note --

A. This is one example of others where there seems to be some confusion about the process, who devised it and when it was devised. There is another note from Anita

O'Brien -- or, sorry, Anita Carroll. I think it's in her witness statement or it's in Dr. Chadah's report where she confirms that Anita Carroll confirmed the process in I think it was November 2015. So unless there was a second process, I'm unaware. The point there at the end of that which says there was no way the triage -- or the extent of the non-triage -- that's not correct because the process, you can monitor the triage and whether you get it back or not and there was people assigned to do that and to escalate. So, everybody's recollection seems different. 10:45 10:45

44 Q. Yes. So what you take from this note, as I understand your position, is that here is Mrs. Corrigan explaining how she and two others, Mrs. Carroll and Mrs. Robinson, got together -- they were the only people in the room -- and grappled with "What are we going to do with Mr. O'Brien's non-triage?", and you would say that that suggests that they came up with -- 10:45

A. I'm not sure because I wonder is that a later process in November? Yes, it's either they came up with it or it's another process that they devised later when they knew he was still continuing to triage when I had left and they decided in November 2015 to do something else. 10:46

And the other point that I just wanted to make, if it's okay to make it now, is that if they assign 17th February to me in their statements, actually that's probably -- I mean, I was on leave, the e-mail went out, it didn't come from my office -- but it's okay, 10:46

because it's actually the IEAP rules. It was correct if it had have been implemented. It would have been okay.

45 Q. Yes.

A. So, after getting over the shock of everybody's like assigned it to me when I didn't know, when you look at it, it's an okay process, that one. 10:46

46 Q. Yes. So what I understand you to be saying is that this 17th February e-mail in the context of ophthalmics, if it was announcing to the world that: "Where we have a problem with non-triage, it's okay to follow the IEAP procedure" -- 10:47

A. Yes.

47 Q. You've no difficulty with that?

A. No. And the other -- 10:47

48 Q. But the part of the equation that you think, the important part of the equation that was missing from what was done in urology was the failure to pursue to get the triage done in a context where you certainly have a risk -- 10:47

A. Yes.

49 Q. -- of the need to upgrade patients?

A. Yes.

50 Q. Again, in a context where the waiting list pressures puts upgraded patients in jeopardy, if they're not upgraded? 10:48

A. Yes. And I've had another thought. I wanted to say as well that the process came out on 17th February. I was going to meet Aidan to stop him triaging on 20th

February. Therefore, I did not need this process for urology because I was addressing urology and the individual in a separate way. So, this process seems to have got attached to urology. I am 100% sure, I think -- well, that's not -- I'm fairly certain that the 17th process was for all specialties, and it wasn't going to be needed for urology because I was going to stop Aidan on the 20th.

51 Q. Can I bring you to something that Mrs. Corrigan says in -- 10:48 10:49

A. Yeah.

52 Q. -- in her witness statement to the Inquiry? I haven't brought you and I don't think I need to bring you to what each individual says --

A. No. 10:49

53 Q. -- in their statements to Dr. Chada. You would accept the broad proposition --

A. Yes.

54 Q. -- that while there's differences between them --

A. There's differences. 10:49

55 Q. -- they're essentially saying that you had knowledge of this process and its application to urology, and you disagree.

Mrs. Corrigan, at WIT-26271, if we scroll down the page please, she's being asked about -- just scroll down further, please. Yes, that's fine, just before that. She's being asked to account for her attendance at various meetings, or her recollection of attendance at 10:49

various meetings. And so she can remember, she says, for example, attending a meeting -- an exception where Mr. O'Brien was in attendance, but she can remember attending with you and Mr. O'Brien in your office and the discussion was triage and he was asked how he could be assisted. And: 10:50

"There were no formal notes of that meeting, but Mrs. Burns sent an e-mail to Mr. Young the next day advising him of the discussions and asking him for his help." 10:51

So, that was the meeting of 20th February 2014.

If we go down the page then, she says: 10:51

"These meetings were informal and they were to discuss how we could ensure that..."

-- sorry, referring to Mrs. Burns, Mrs. Carroll, Mrs. Trouton. So these are another set of meetings. 10:51

A. Okay.

56 Q. And she's saying:

"These meetings were informal and were to discuss how we could ensure that patients who Mr. O'Brien was failing to triage were not disadvantaged and it was at these meetings that a work-around was agreed that patients would be added to the Outpatient list 10:51

according to the clinical priority the GP had assigned to them. And when the letter was returned following triage, if this clinical priority then changed, a similar change would accordingly be made on the waiting list. It was also from these meetings that Mrs. Trouton and Mrs. Carroll developed the escalation for triage." 10:52

So, it's non-specific. The Inquiry may note it. It appears to be a different recollection than the recollection that was given to Dr. Johnston. Again, do you recall sitting down with - just scroll back, please - Anita Carroll, Mrs. Trouton, Mrs. Corrigan to discuss a process of this kind in the context of Mr. O'Brien? 10:52

A. No, I have no recollection of that and I just have to go by my documentary e-mail evidence. But just to say 55.5 doesn't agree -- it contradicts the paragraph above where we stop him triaging, because you don't need a triage process then to manage him, you've stopped it. 10:52 10:53

57 Q. Yeah. Could I bring you to the e-mail that you received from Fiona Reddick?

A. Yeah.

58 Q. It's at WIT-98509. And maybe if you'd just go down a little just to get the context, down two pages, please, to 11. So, it's August -- it starts off in June. There were -- it records, and you're not in the chain at this stage, but it records that: 10:53

"Referrals are not coming back."

I think the total -- eight referrals are not coming back and Mr. O'Brien is the responsible clinician.

And from August then, if you scroll back up the page to -- there's an escalation process and, if we go on up to '09 in the sequence, and so Fiona Reddick is writing to you --

A. Yeah. 10:54

59 Q. It's 2nd July and she's explaining that she wants to give you the heads-up. It says:

"Rang Aidan to get an update as to where the red flag referrals are. Some of them are now sitting at day 8 and we have no account of what is happening. This is the escalation process within Cancer services. Aidan is aware of this from previous conversations. He is dealing with them and processing investigations as he triages, but he just needs to let us know and keep informed so that we can track accordingly. He is bringing them in shortly but is very cross at this process and tells me that he is coming to speak to you. The escalation process worked well across all other areas." 10:55

So, I suppose, Mrs. Burns, you have been at pains to tell us that one of the reasons why it feels strange to you that other people were talking about the need to

for the late triage and he would have always -- sorry, for triage that was late, and he would have always done that. But that was the actual then ultimate problem, was he actually didn't triage.

15 Q. I know you listened into Mrs. Burns' evidence in relation to the default position. Her understanding seemed to have been that although the default was in place to allow people to go on to the list according to the GP's prioritisation, that there was -- it was anticipated that they would ultimately be triaged by a consultant and, if they needed recategorised, then that would take effect on the list, dependent on what the consultant's view was about the clinical priority. Was that your understanding or was it your understanding that the GP's default was where someone sat on the list? 10:10 10:11 10:11

A. I think, because I do recall the meeting where this was discussed -- it's obviously part of the IEAP, which was the reason why it was brought up that the -- what happened sort of before that, and I hope I'm right with this, but what happened before that is when a GP sent in a referral, they weren't added to the waiting list until they were triaged. So, what happened was I'd got a letter -- somebody's referred me in and one of the consultants has triaged me, so I go on the list according to my priority. Somebody comes in, a letter comes in under Mr. O'Brien and it doesn't go on to a waiting list because it hasn't been triaged. So then they come to pick patients for the clinic. So because 10:11 10:12

I'm on the waiting list, I'm picked, but the patient that hasn't been triaged hasn't. So I think it was more a move to make sure that everybody was on a waiting list and to make sure they're on the waiting list that the GP priority was what was agreed, which is what is in the IEAP anyway. 10:12

16 Q. Just to go back to the essence of the question, really, which was: Was it your understanding that the GP categorisation would be the priority the patient was set at or was it -- 10:12

A. Yes.

17 Q. Sorry --

A. Yes.

18 Q. Yes. And so it wasn't anticipated that that would subsequently be triaged again by you at that point? 10:12

A. No, sorry, when the letter came in, if it said it was urgent or new -- or, sorry, urgent or routine, it would go on the waiting list with that priority. For all -- and Mrs. Burns was right yesterday, that was for -- it doesn't matter whether it was Ophthalmology or ENT or General Surgery or Urology, it went on on that priority. But once the consultant would have triaged, they either upgraded it or downgraded it and then that priority would have been changed then on the waiting list. 10:13

19 Q. So, your understanding was the same as Mrs. Burns'?

A. It was, yes.

20 Q. And for the Panel's note, Mrs. Corrigan refers to this in her Section 21 at WIT-26271 at paragraph 55.5. And

what that paragraph does is suggests that Mrs. Burns and you were involved in that collectively around an understanding of the triage position?

A. Yes.

21 Q. You don't disagree with Mrs. Burns' evidence at all? 10:14

A. The one thing I do disagree with, I think it's the timeline. I think everybody is getting a wee bit confused about the timeline when all the decisions were made. Because what happened was this all came to a head in November 2013 -- I think, yesterday, you 10:14 brought me to an e-mail of February 2013 where Mrs. Trouton was trying to address it. It came to a head again in November '13 and she actually asked for Mr. Young and Mr. Brown to help out with the issue. Mr. Young, at that stage, had sort of given an 10:14 indication that he would help out with triage -- that was in November -- now, remember this is before we met with Mr. O'Brien -- but then he came back at the beginning of December to say that, no, that wasn't what he was suggesting. So there was a number of meetings 10:15 in December time and it came to a head that the letters still weren't being triaged.

So, in or around January, I do recall the meeting -- it was with Heather, Mrs. Trouton; Mrs. Anita Carroll; 10:15 Mrs. Robinson, and myself, and they were basically asking what we were going to do about the whole thing about Mr. O'Brien's triage. Now, Mrs. Burns was not present at that meeting at that time and Anita had

suggested the GP prioritisation, that we would move to that.

What happened then was I sent down to, as we used to call it, the corner office, down to Mrs. Burns and asked her to come up and join the meeting. It was a heated discussion, it was a heated debate, and that's where the escalation policy came out of -- but really was to do with Mr. O'Brien at that stage, but then it ultimately moved that there was an Ophthalmology problem and it was then for all specialties. So, I suppose, that's where the difference is. It ultimately started out with Mr. O'Brien, but this was pre -- before Mrs. Burns and I met with him, because it wasn't being resolved. And in between times, Mrs. Carroll and Mrs. Trouton were doing the escalation, which is the e-mail that you spoke about there, the flow chart. 10:15 10:16 10:16

22 Q. It was brought in before Mrs. Burns was aware, the default, is that what you're saying?

A. No, I think what I'm saying is it was discussed before Mrs. Burns and I met with Mr. O'Brien, and I think that's where the confusion is because she was saying that everything happened in or around the same time. But there had been discussions right through sort of December/January, with regards to what resolution we would come up with to try and make sure that these patients were put on a waiting list of some description -- or, sorry, for their priority. 10:16 10:17

23 Q. And I think Mr. Wolfe took the Panel and Mrs. Burns to

the note of your interview with Dr. Johnston?

A. Mm-hmm.

24 Q. And where you said that the process was developed by you, Anita Carroll and Katherine Robinson, with no one else in the room, and that this would enable you not to have to monitor triage because it was being done. Is that an accurate reflection, given that you've said that there was still an expectation that, even though the default process was in place, that triage would ultimately be done and a recategorisation applied, as necessary? 10:17 10:17

A. It's not a reflection. I went back to look about those notes. Those notes are still in draft form. The interview happened in February 2017 with Mr. Johnston or Dr. Johnston, and I wasn't shared the notes until the following January. It's totally inaccurate. The part where it says there was only two of us in the room, that's actually referring to the meeting that Mrs. Burns and I had with Mr. O'Brien, because Dr. Johnston asked us was there anybody else in the room whenever -- because I had said, I think, that there was no notes of the meeting and he said "Was there nobody else there?" And I had said, "No, there was just the two us." But when you read the notes, it looks like it was just the two of us, just us in the room with regards to Anita, Katherine -- and Debbie, Mrs. Burns was definitely not in the room when we discussed it, but I went and got her and brought her back into the room. It was in our office on admin 10:18 10:18 10:18

floor.

So, the notes don't reflect what happened at all, because the notes actually say I have told Mr. O'Brien to triage, which doesn't match up with anything, you know, any of the evidence or anything that I've ever said or understood.

25 Q. And when did you get those notes?

A. January 2018.

26 Q. And did you correct them or send back in and say "These are not accurate --

A. I couldn't find where I had corrected them or sent them back, but -- because I've only started to look for them yesterday after Mrs. Burns' evidence. But I definitely would have corrected them things if I had of had them. And I've never seen a final draft either.

27 Q. You understand that one of the focuses for the Panel is the governance system and processes that allow decision-making, I suppose, to be tracked back to origin. This seems to have been a fairly relatively important discussion that was going to slightly change the route by which triage was going to be approached, and certainly there's some contested evidence now around what was expected to be done. Do you feel that decisions like that should be minuted and documented and circulated to the individuals, both who are in charge and whom it's going to affect?

A. Absolutely, because I know from the meeting with Mrs. Burns, I did put it in writing with regards to the

plan with Mr. O'Brien not triaging. But I have looked back and I have never actually shared information with regards to the GP, the default of the GP prioritisation, which is now, you know, a regret. But then again, I don't think it was, you know, for me to do it because it wasn't my decision. It was a decision made by two assistant directors in discussion with a director, so I absolutely agree, we should have had minutes from that meeting, albeit even if it was an e-mail note. 10:20 10:21

28 Q. You say it was Anita Carroll, Heather Trouton and Debbie Burns --

A. -- who ultimately made the decision, yes.

29 Q. Around the default?

A. Yes. I suppose it's -- one of the things is everybody sort of feels that there was no escalation after that. But, on checking, there was escalation of it definitely up until November '14 -- or November '15, but after that it just seems to stop, we don't get the same escalation. And, I suppose, the only reason I ended up knowing about the actual escalation, because, you're right, I wasn't copied into it, was I was getting e-mails from Mrs. Carroll asking me to chase Mr. O'Brien for un-triaged letters and I did go back to Mrs. Robinson and I said to her "Why am I getting e-mails direct from Mrs. Carroll?" and she said "It's to do with the new escalation" and it was actually Katherine that shared that with me because, up until that, I hadn't been copied in. I just think maybe it 10:21 10:21 10:21

was an omission.

30 Q. What you've described seems to be quite a piecemeal way of communicating that everyone knows a bit of the picture, but nobody seems to have an overall view, would that be fair? 10:22

A. That's very fair, yes.

31 Q. Having heard Mrs. Burns and the other evidence so far, is there anything else you want to say about the triage or the default triage process, or do you think you've covered your understanding of it? 10:22

A. I think I've covered my understanding of it, unless there's any other questions for me.

32 Q. I just want to ask you a couple of questions about the non-dictation issue. Generally, you have covered that in your statement at WIT-26264 and, if we could go to 10:22 WIT-26265 at paragraph 54.14, I just want to read this paragraph out -- just go back. So you say -- the paragraphs:

"Not dictating on patients after clinics or day 10:23 procedures"

-- you say:

"This first came to my attention in 2014 when the 10:23 consultants, Mr. Haynes, Mr. Glackin and Mr. O'Donoghue, were doing some extra sessions to help reduce the review backlogs. Whilst doing this exercise they raised informally that there appeared to be a

Issues and Themes of concern include:

- In May 2014, there was an informal process was implemented to monitor/manage Urology letters which had not been returned with management advice (not triaged). It appears that this process was created in an effort to limit risk of harm to the patient. The presence of this process implies that it was accepted that triage non-compliance was to be expected by a minority of consultants within the Urology specialty. On 6 November 2015, an email from the AD of Functional Service formally implementing this process. The Review Panel are anxious that the current process does not have a clear escalation plan which evidences inclusion of the Consultant involved. In addition, this process has not been effective in addressing triage non-compliance. From 28 July 2015 until 5 October 2016, there are 318 patient letters which were not triaged. Currently the Trust cannot provide assurance that the Urology non-triaged patient cohort are not being exposed to harm while waiting 74 weeks for a Routine appointment or 37 weeks for an urgent appointment.

- During the manual look-back exercise on 14 November 2016, Patient 99 [redacted]s patient chart could not be found on Trust premises. Patient 99 [redacted]'s chart did appear in the Acute Governance office the week commencing 28 November 2016. After informal queries, it is understood that patient notes are not transported via Trust vehicles to or from Dr 6's outlying clinics (inc SWAH). This could compound efforts to establish any chart location or outstanding dictation. The Review panel acknowledge that processes should not be drafted to address one issue with one specialist team. On balance, the Review team agree there is sufficient cause for concern that Trust documentation may be leaving Trust facilities and the process of record transportation for this Specialty does need urgently addressed.

- There is clear evidence that this patient Patient 99 [redacted]s letter was not triaged by week ending 30 October 2014. Patient 99 [redacted]was seen in SWAH by Dr 6 in January 2015. The outpatient letter was dictated 11 November 2016 and typed 15 November 2016. The Review panel have grave concerns that there are other Urology patient letters not being dictated in a timely manner. Upon further investigation, the Panel have found that the Trust does monitor the number charts needing audio-typing of dictation but there does not appear to be a robust process to monitor if post-consultation patient dictation has been completed. This has the potential to be compounded if patient charts are leaving the Trust facilities. The SAI Panel are anxious that assurance is sought that there is reasonable compliance in relation to the timely dictation letters by Dr 6.

[69] Having had the opportunity to reflect, do you have an explanation as to what went wrong within urology services and why?

69.1 On reflection, and setting out the range and number of issues in urology services, I believe that the following is clear:

a. The service was under considerable pressure due to increasing referrals; and was insufficiently resourced to meet the catchment population needs. The long term absence of the ICATS urology doctor (contracted for 7 sessions per week), contributed to the consultant pressures as they had to see all referrals in outpatients.

b. There was also additional pressure due to the consultant clinical behaviour of Mr O'Brien which meant that smaller numbers of patients were seen in each outpatient clinic and more patients were reviewed than consultant peers would review. There was also little appetite in the service to agree protocols with primary care to review certain cohorts of patients.

c. There was poor professional practice which had been longstanding. It proved to be difficult to get agreement with Mr O'Brien to change this behaviour. When change in his behaviour was agreed, the specific behaviour was not always sustained and he would revert to previous poor practice. An example of this was when Mr O'Brien agreed to triage referrals within the required time standards; it became apparent subsequently that this change in behaviour was not sustained and required regular checking.

[70] What do you consider the learning to have been from a governance perspective regarding the issues of concern within urology services and the unit, and regarding the concerns involving Mr. O'Brien in particular?

[71] Do you think there was a failure to engage fully with the problems within urology services? If so, please identify who you consider may have failed to engage, what they failed to do, and what they may have done differently. If your answer is no, please explain in your view how the problems which arose were properly addressed and by whom.

71.1 I believe that there was a failure to engage fully in the following ways:

71.2 There was resistance to change in clinical behaviour. Resistance to change was the general sense in the urology service. However, when change was required in order to implement improvements for patients, two consultants did make these changes in their personal behaviour. Examples of changed behaviour are changing clinic templates and the new to review ratios to reflect BAUS guidance; setting up the local MDM (Multidisciplinary meeting) in preparation for the regional MDM; agreeing new patient pathways such as 1-stop clinics. These 2 consultants also undertook additional work, such as triaging on behalf of Mr O'Brien when he failed to cooperate in undertaking this process in the required time standards. Mr O'Brien tested the new clinic templates and his clinics regularly overran by 2 hours. He therefore was unable to, or chose not to, amend his behaviour in outpatient clinics.

71.3 It is difficult to state what could have been done differently within the Trust, and without reference to outside professional bodies, to change the behaviour of a single consultant who was resistant to change and refused to acknowledge that there was a requirement to work within a clinical system where the DoH, the Commissioner (HSCB), and the Trust had set out the parameters. Examples of such requirements are the time standards set out in the DoH IEAP, the HSCB requirements to use BAUS guidance for outpatient clinic templates and numbers of review appointments, and the challenge made to the referral of the initial cohort of patients to Belfast for radical pelvic surgery. However, perhaps earlier action may have been appropriate in seeking an external assessment of competence to practice.

71.4 In terms of other issues in the service, there was full support to obtain agreement and funding for both in-house additional theatre lists (where the consultants

"I will speak with him again today and then let Robin follow up on this. One of the things that was said to me before is that he is not the only consultant who brings a chart home, but I suppose with Aidan it is more the amount he brings home and the length of time he keeps them for. I will let you now how I get on".

We will obviously hear from Mrs. Corrigan in relation to that. There were several emails of discussion or intended discussion with you to ask you to return patient notes, whether individual notes or what you might have at home. Do you recall being told, essentially, you shouldn't be keeping notes at home? 16:24 16:25

A. I think, yes, maybe once or twice in terms of the generality, whereas much more frequently - I think someone quoted 60-odd emails requesting 60-odd charts individually. I think someone has said that -- has testified to the fact that I always returned them and returned them expeditiously and so forth. If that answers your question. 16:25 16:26

230 Q. I think one is right. If one were to do a survey on the emails on triage, I think that would be at the top of the list. I can take you through them individually if required, but there's certainly indications of conversations with you asking you to get charts back. 16:26

A. Yes.

231 Q. Were you aware of what was the position on 12th February 2014, that the Trust was creating incident reports when charts which were clearly in your

position weren't to hand within the hospital when another clinician may have required them?

A. No. I'm only smiling because I had never heard tell of incident report forms until a few years after that, when someone said to me that they had filled in an incident report. I thought it was something to do with the Inland Revenue and went and Googled it. I have never filled out myself. No, I didn't know about that.

232 Q. Again, a pattern is noted in how you deal with patient charts. If we bring up on the screen TRU-277892. In October 2014 -- just scroll between a little, please. Heather Trouton is asking Martina Corrigan: 16:27

"Are you aware that this issue of notes with Aidan O'Brien is still a problem? Has it improved at all". Up the page. "It had improved but I feel it may be slipping again and I will talk to Aidan again". 16:28

Was there, again, a pattern, rather like triage but perhaps for different reasons, of you complying with the request to get notes back and then falling into the difficulty for whatever reason of not getting them back or not getting them back quickly enough? 16:28

A. That wouldn't be my recall of it at all. I'm not denying that Martina may have spoken to me. I don't have any recall of any word with me about charts at home following any documented intent to do so. I don't recall it and I don't deny it. I just don't have any recall of it. 16:29

method by which this issue could be managed, other than waiting for further development of the functionality of the radiology system.

72.4 Whilst remaining vigilant across the range of issues and weekly monitoring for many of them, the overriding issue was that of entrenched clinical behaviour by the consultant which was made more difficult to manage as often a change in behaviour towards improvement was not sustained permanently, despite it being agreed by Mr O'Brien. On reflection, this type of behaviour should have been recognised for what it was, and identified and discussed by me with SMT colleagues when more formal action could have been considered. Formal action could have been considered with the Medical Director and the Director of HR and Organisational Development. In conclusion, I did not fully utilise the arrangements which were available at the time in order to address the continuing clinical behaviour which did not meet the standards required.

[73] Do you think, overall, the governance arrangements were fit for purpose? Did you have concerns about the governance arrangements and did you raise those concerns with anyone? If yes, what were those concerns and with whom did you raise them and what, if anything, was done? If not, please explain why.

73.1 The governance arrangements were reviewed in 2010 through the Review of Clinical and Social Care Governance. This resulted in organisational change resulting in the following:

a. The developing culture of openness and learning from mistakes;
b. Clear lines of accountability and reporting through the Chief Executive to Trust Board for both operational and professional lines of accountability;
c. Embedding of deeper systems of governance and staff training in these, e.g., Datix completing to report on clinical incidents;
d. Easier recognition of SAIs and processes to investigate and learn from them;

Documents attached namely;

337. 20191101 - Email [redacted] RIP

338. 201912015 - email complaint [redacted]

339. 20190929 - email complaint [redacted] RIP

340. 20190319 [redacted] complaint

341. 20140922 - [redacted] enquiries

342. 20190716 – complaint [redacted]

343. 20151201 - email query AC

and can be located in folder - Martina Corrigan - no 24 of 2022 - attachments

55. Please detail all discussions (including meetings) in which you were involved which considered concerns about Mr. O'Brien, whether with Mr. O'Brien or with others (please name). You should set out in detail the content and nature of those discussions, when those discussions were held, and who else was involved in those discussions at any stage.

55.1 During my tenure I can confirm that I was involved in numerous discussions regarding the concerns about Mr O'Brien. I can also advise that the majority of these discussions were verbal and took place with the below staff either individually or collectively.

2009 - 2013

Mr Mackle, Mrs Trouton, Dr Rankin

55.2 Issues discussed were non-conforming with triage, not adhering to the process for scheduling patients, not pooling patients, not complying with performance targets (such as waiting lists and patient flow 4-hour and 12-hour targets), benign cystectomies, and IV antibiotics and Fluids. These meetings would have taken place in Dr Rankin's office, Mrs Trouton's office or in the Associate Medical Director's office, all on the Admin Floor in Craigavon Area Hospital (CAH). There were also telephone conversations

with the lessons highlighted in Dr Dermot Hughes' overarching Serious Adverse Incident report as follows:

a. The Trust must promote and encourage a culture that allows all staff to raise concerns openly and safely.
b. Ensuring a culture primarily focused on patient safety and respect for the opinions of all members in a collaborative and equal culture.
c. The Trust must take action if it thinks that patient safety, dignity or comfort is or may be compromised and mechanisms should be put in place to allow this to happen.
d. The Trust have commenced strengthening its governance structure and there has been a lot of work on improvement being developed and led by our previous Medical Director, Dr O'Kane, and this needs to continue into all Directorates and Divisions within the Trust.

68.2 In my opinion, there has also been the following learning from a governance perspective:

a. A key learning for me is the failure of staff to formally raise concerns that they had about Mr O'Brien's practice. So, whilst we were aware of non-conformance with triage, patient notes at home, IV antibiotics and cystectomies, I think that there were a lot of missed opportunities to become aware of issues such as medication practice (bicalutamide), not having a key worker present with him during oncology consultations, not acting on results, and not being available for the morning ward rounds. Whilst I could monitor the aspects of his job that I was aware of, I do believe that, if others had raised these other concerns, we would have been in a position to address these much sooner than when they came to the fore in 2020.

codes associated with Mr O'Brien. Then, using this information I would have arranged a thorough search of his office and his secretary's office to validate which charts were actually in the offices. This would have produced a list of charts that were tracked out to Mr O'Brien but that were not actually in their tracked location. This would have given a clear picture of the extent of charts not in his office. However, I failed to do this, mainly because I felt that if I asked my staff to do this piece of work, which would take them some time, nothing would have been done, and nothing would change. I based this belief on the fact that although I raised the issue many times, and it was escalated through the service, and I could demonstrate that there were charts at Mr O'Brien's house that were required for admissions or clinics that no-one did anything. I had been told to stop completing Datixs by the Director of Acute Services, Debbie Burns, I had escalated the issue, my Assistant Director Anita Carroll had asked if it should be placed as a risk on the Risk Register – all of this and nothing was done. I felt it would have been wrong to ask my staff to do additional work when I did believe that there would be no change. Having reflected this is not a good enough reason not to have done this, but that was what I believed.

42.2 I believe that everyone is so busy with the day to day work and providing a service in difficult circumstances that important issues like governance can slip and loose its momentum.

42.3 There needs to be more of a focus on governance and the importance of it in the day to day running of the service.

42.4 I feel that the Head of Service, and Assistant Director did make a mistake in not addressing the chart issue – Datix was used to highlight the problem but nothing changed and I received no feedback as to what action was taken. There is nothing I could have done differently as I raised the concerns through the Trust's Datix system until I was told to stop by the Director of Acute Services, Debbie Burns. I also raised my concerns via conversation and email to the Head of Service, Martina Corrigan. I raised my

the accuracy of it, and people may have different views, you are being told there are currently 253 un-triaged letters dating back some 18 months. Therefore, it is being spelled out for you, lack of triage means we do not know whether the patients are red flag, urgent or routine. 15:24

The next line is, presumably, new information to you as well. What can we do in that situation? We put them on the list using the default system, as it became known, with no record to urgency. 15:24

A. I do accept your point. When you put the four together it does paint a problem picture. And, as I said in my statement, I do regret I never actioned it but I'm trying to provide context for why I didn't do it. But I do, and I think I said in my statement, myself and either, because we didn't have a CD or AMD, but when Dr. McAllister and Mr. Weir came onboard, we should have acted sooner. 15:25

230 Q. Is it fair to say that you didn't see any patient risk issues in the four matters that were outlined? Or put it another way, you didn't see patient risk issues at such a level of gravity to encourage an immediate response from you? 15:25

A. I think that would be fair to say, yes. 15:26

231 Q. Even though you knew that there was to be a, at least there was an expectation of a four-week turnaround from Mr. O'Brien, you didn't diary this with a view to following it up if he breached that expectation?

A. No, I didn't.
232 Q. When you think about it now, what should you have done with this letter?
A. Well, I should have acted on it. I should have gone to see Mr. O'Brien in person and said, and asked him: 15:26
You've got this letter; sorry, I probably would have went with a senior doctor and we would have met with Mr. O'Brien, sat him down, spoke to him, asked him, you got the letter. Somewhere along the way the four-week time limit was introduced, and then ask him what he had 15:27
done, if he hadn't done anything, what he was hoping to do and see whether or not we could move forward on it.
233 Q. Was there any sense that, you'd given him explanations upon reflection about your inaction, is there any sense that Mr. O'Brien was untouchable in that from your 15:27
perspective as an operational manager, 'I can't really go there. This man is too senior, too experienced, and even if I went there I wouldn't be listened to'?
A. I think that's always the possibility you face when a non-clinician speaks to a senior clinician, that they 15:28
would -- I wouldn't say disregard you but, in my experience, it is much more beneficial and powerful if a CD, a Clinical Director or AMD speaks to him.
234 Q. You received, as you mentioned earlier, an email from Dr. McAllister on 9th May. If you could just briefly 15:29
look at that. WIT-14875. By this stage the Inquiry is very familiar with this. You can see scrolling down quite a list of issues. Item 6 addresses urology. Not all of these issues, as you know, are Mr. O'Brien

dashboard detail of triage and time scales for triage. There is a data limitation within how that's obtained, which means that the time scales applied can be complicated by factors like a patient needing registration or the referral going to another Trust first before being redirected, because the time scale is from the point at which the GP presses refer, not the point at which it is passed to the consultant for triage. So there is a limitation in that but it is monitored and there is an escalation process. 15:30 15:31

I neglected to mention earlier when we talked about results but it applies to the dictation and the triage as well. We also have an in-person interface meeting where myself, the head of service, our manager for our admin and support team, and our Cancer Services manager meet on a monthly basis and run through the performance across the team looking at triage, looking at dictations, looking at results management, and if any other things need to be brought up. You mentioned earlier is it fair for a secretary to be the one who contacts the consultant first. It is not only the secretary that does it, it would come to that meeting as well. 15:31 15:31

137 Q. You spoke on the last occasion, and indeed in real time you were speaking to Dr. O'Kane about the shortcomings of the backlog reports that were being utilised to monitor Mr. O'Brien. In general, I think you expressed the view that they would perhaps give the uneducated 15:31

Southern Health and Social Care Trust

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: [redacted]
Personal Information redacted by the USI

Date of Incident/Event: Multiple dates

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: Male Age:

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN)

Report Author: The Review Team

Date report signed off: 26 February 2021

Date submitted to HSCB: 1 March 2021

1.0 EXECUTIVE SUMMARY

The purpose of the review is to consider the quality of treatment and the care provided by Doctor 1 to the patients identified and to understand if actual or potential harm occurred. The review findings will be used to promote learning, to understand system wide strengths and weaknesses and to improve the quality and safety of care and treatment provided. Nine patients have been identified as potentially suffering harm. This review will examine the timelines of each individual case and analyse if any deficits in treatment or care has occurred. As part of the review the cancer pathways will be used to determine where learning can be extracted.

The SHSCT recognise the life changing and devastating consequences to the 9 families. It wishes to offer an unequivocal apology to all the patients and their families involved in this review. This was not the cancer care they expected and should not have been the cancer care they received.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair former Chair of the NICAN. Former Medical Director Western Health and Social Care Trust.
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (Formally from SET / recently SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical Governance Coordinator (SHSCT)

3.0 SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this review are to:

- To carry out a systematic multidisciplinary review of the process used in the diagnosis, multidisciplinary team decision making and subsequent follow up and treatment provided for each patient identified, using a Root Cause Analysis (RCA) Methodology.
- To review individually the quality of treatment and care provided to each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.
- To engage with patients / families to ensure where possible questions presented to the review team or concerns are addressed within the review.
- To develop recommendations to establish what lessons are to be learned and how our systems can be strengthened regarding the delivery of safe, high

3.0 SAI REVIEW TERMS OF REFERENCE

quality care.

- Examine any areas of good practice and opportunities for sharing learning from the incidents.
- To share the report with the Director of Acute Services/ Medical Director of SHSCT/ HSCB/ Patients and families involved/ Staff involved.

4.0 REVIEW METHODOLOGY

The review will follow a review methodology as per the Regional Serious Adverse Incident Framework (2016) and will be cognisant of the rights of all involved to privacy and confidentiality and will follow fair procedures. The review will commence in October 2020 and will be expected to last for a period of 4 months approximately, provided unforeseen circumstances do not arise. Following completion of the review, an anonymised draft report will be prepared by the review team outlining the chronology, findings and recommendations. All who participated in the review will have an opportunity to provide input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

Prior to finalising the report, the Lead Reviewer will ensure that the Review Team apply Trust quality assurance processes to ensure compliance of the review process with regional guidance prior to delivery of the final report to the Review Commissioner. The Review Commissioner will seek assurance that the quality assurance process has been completed.

5.0 DESCRIPTION OF INCIDENT/CASE

The review team conducted individual reviews on 9 patients on their treatment and care. A summary of each case is discussed within this report.

Causal deficits in their care and contributory factors were identified.

Service User A

Service User A was diagnosed with prostate cancer and was started on an anti-androgen therapy as opposed to Androgen Deprivation Therapy (ADT). This did not adhere to the Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016). These Guidelines had been signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-Disciplinary Meeting (MDM), as their protocols for Cancer Peer Review (2017). This guidance was issued when Dr 1 was the regional chair of the Urology Tumour Speciality Group and should have had full knowledge of its contents. Following discussion with the families, the review team noted that there was no discussion with Service User A that the treatment given was at variance with regionally recommended practice. There was no evidence of informed consent to this alternative care pathway.

The review team have identified that during the MDM that a quorum had not been met. This was due to the absence of an oncologist from these meetings. Even so, the recommendations made by the MDM were not actioned by Dr 1. Members of the MDT may not have been aware of this, but similar practice in prescribing an anti-androgen had been challenged. Any challenges made regarding the appropriateness of treatment options were not minuted nor was the issue escalated.

The Review Team suggested that the initial assessment of Service User A was satisfactory although rather prolonged, the subsequent management with unlicensed anti-androgenic treatment (Bicalutamide) at best delayed definitive treatment. Bicalutamide (50mg) is currently only indicated before (as an anti-flare agent) or in combination with a LHRH analogue (Complete Androgen Blockade) Bicalutamide monotherapy (150mg) is not recommended for use as a continuing treatment for intermediate risk localised prostate cancer (reference is EAU guidelines), and further it decreases overall survival. Treatment for prostate cancer is based on achieving biochemical castration (Testosterone <1.7 nmol/l), which is best accomplished by the use of a LHRH analogue, by an LHRH antagonist or by bilateral subcapsular orchidectomy.

Service User A did not have Urology Cancer Nurse Specialist allocated to his care. The review team questioned this and it was established that whilst there were no resources for a Urology Cancer Nurse Specialist to attend any outreach clinics, their contact numbers should have been provided to the patient.

The Review Team conclude that Service User A received unconventional and inadequate treatment. The expected multi-professional involvement in his care was omitted. Service User A's disease progressed whilst being inadequately treated. The opportunity to offer him radical treatment with curative intent was lost.

5.0 DESCRIPTION OF INCIDENT/CASE

Service User B

Service User B was diagnosed clinically and biochemically with prostate cancer, and was commenced on bicalutamide 50mgs. Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent (or in combination with a LHRH analogue) and is only prescribed before definitive hormonal (LHRH analogue) treatment. The review team note that this treatment was not in adherence with the Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016), which was signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-disciplinary Meeting, as their protocols for Cancer Peer Review (2017). This guidance was issued when Doctor 1 was the chair of this group and had full knowledge of its contents. The review team note that, following discussion with Service User B, he was unaware that his care given was at variance with regionally recommended best practice. There was no evidence of informed consent to this alternative care pathway.

A biopsy result taken at the time of transurethral resection of prostate (TURP) showed benign disease (low volume sample 2g from central area of prostate). There were no further investigations to explore the clinical suspicion of prostate cancer.

The possibility of localised prostate cancer was considered from the time of presentation because the PSA was elevated; however, there was no record in the medical notes of any digital rectal examination (DRE) findings. During the operation further signs might have been elicited and appropriate biopsies could have been performed. TURP is not an adequate way to biopsy the prostate gland for suspected prostate cancer. The Review Team conclude that sufficient evidence of localised prostate cancer was apparent from the time of presentation. A correct course of action would have been to arrange appropriate staging scans and biopsies. Service User B should have undergone investigation with a MRI scan of the prostate and pelvis and a bone scan should have been considered. A transrectal biopsy performed either at the time of the TURP or separately, would have secured the diagnosis.

Arrangement could then have been made to start conventional Androgen Deprivation Therapy (a LHRH analogue) with referral on to an oncologist for consideration of external beam radiotherapy (EBRT) potentially with radical intent. However, the patient was apparently lost to follow up after his appointment in July 2019.

Service User C

Service User C was referred to urology service following a visit to ED in December 2018. He was reviewed promptly by Dr 1 in January 2019. Investigations were arranged and a diagnosis of a large right-sided renal carcinoma was made. He was counselled regarding the risks and benefits of surgical intervention and chose to proceed with the high-risk surgery.

On 6 March 2019 Service User C was admitted for an elective radical nephrectomy. The procedure was undertaken as planned and he was transferred to the intensive care unit (ICU) to support his blood pressure. He was later transferred to the ward. He developed a bacteraemia (infection) which was successfully managed with the advice of the microbiology team. Follow up CT scans were performed in June with a planned follow up in July 2019. This did not happen. Service User C was admitted to Ward 3 North following an ED admission. He was reviewed again via telephone in November

5.0 DESCRIPTION OF INCIDENT/CASE

2019 by Dr 1 who arranged for a repeat CT scan to be performed on 17 December 2019 with a plan for review in January 2020. This did not happen.

The CT scan report was available on 11 January 2020 which showed a possible sclerotic metastasis in a vertebral body which had not been present on the previous CT scans. This report was not actioned until July 2020 when a new consultant reviewed the care. Service User C was subsequently diagnosed with prostate cancer.

The Review Team find that the treatment and care in relation to management of the renal tumour was of a high standard. High-risk surgery was performed successfully following informed consent as to the risks and benefits of the surgery. A urology review was planned for July 2019 following the CT scan report in June but this didn't happen. Service User C appeared to be lost to review. The scan performed in December 2019 with a plan to review in January was not actioned and the plan for review did not happen. This resulted in a delay of 6 months in diagnosis of a prostate cancer from the scan result. This would be approximately a delay of 18 months from his first presentation in ED in November 2018.

Service User D

Service User D attended ED on 24 December 2018 with retention of urine. A urinary catheter was inserted, and a urology consultant review was planned to coincide with a trial removal of catheter with a specialist nurse. Service User D was placed on the waiting list for a TURP. A normal PSA result (2.79 ng/l) was noted.

On 19 June 2019 Service User D underwent a TURP. The procedure notes describe the prostate tissue as having "endoscopic appearances of prostatic carcinoma". Histology confirmed adenocarcinoma (Gleason score 5+5) in 90% of the resected tissue. His case was discussed at MDM on 25 July 2019 who noted there was no evidence of metastases on a CT abdomen and pelvis. It recommended a CT scan of chest and a bone scan to check for spread outside the prostate. Further, a LHRH agonist as ADT should be commenced. In August 2019 a bone scan and CT scan were requested together with an ultrasound scan of the urinary tract to assess bladder emptying. Doctor 1 prescribed Bicalutamide (50mgs once daily), in order to 'assess its tolerability in a generally frail man' and in the 'light of the low presenting PSA'.

The Review Team could not locate any record in the medical notes of a digital rectal examination being performed at any point during this patient's medical treatment. This may well have provided evidence to support the malignant nature of the prostate gland prompting a swifter biopsy.

The patient was discussed at MDM on 25 July 2019 when the recommendation for ADT (a LHRH analogue) was made. He should have been started on this hormonal therapy to achieve "castration testosterone levels" as soon as the diagnosis of poorly differentiated prostate cancer was made. Instead he 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 at MDM. This therapy was not in adherence with the Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guidelines (2016) which were signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-disciplinary Team, as their standard of care for Cancer Peer Review (2017). This guidance was issued when Dr 1 was the regional

5.0 DESCRIPTION OF INCIDENT/CASE

chair of the Urology Tumour Speciality Group and should have had full knowledge of its contents. There was no evidence in the medical notes or from speaking with Service User D's family of informed consent to this alternative care pathway.

Service User D should have been referred to an oncologist to at least allow consideration of other treatment options. His care was not coordinated with the palliative care team. The diagnosis of possible metastasis which would not have changed best practice was nevertheless pursued in a dilatory fashion. The Review Team suggested that when the patient developed anaemia consideration should have been given to the possibility of this being due to malignant involvement of the bone marrow, rather than an effect of severe chronic disease.

The Review Team noted that Service User D's case was not brought back to MDM for rediscussion and multi-disciplinary input despite disease progression.

Service User E

Service User E was diagnosed with testicular cancer. His case was discussed at MDM.He attended for CT chest, abdomen and pelvis on 9 July 2019 which indicated no evidence of metastases (cancer spread). The following day the patient had a left inguinal orchidectomy (removal of left testicle and full spermatic cord) carried out. Pathology of the resection specimen found that the tumour was a classical seminoma measuring 2.6cm across. Although the tumour was confined to the testes, it did involve the rete testis (exit tubules from the testis) and , in addition, intratubular germ cell neoplasia was seen. These findings indicate an increased risk of spread. Service User E's case was discussed at the Urology MDM on 25 July 2019. The plan was for Doctor 1 to review the patient in outpatients and refer him to oncology.

The patient was reviewed on 23 August 2019 and it was noted that Servicer User E had an uncomplicated recovery and his operative wound had healed satisfactorily. It was agreed that he would be reviewed in SWAH again in February 2020 by Doctor 1 to determine if the patient wished to have a testicular prosthesis implanted. The referral to oncology was made on 25 September 2019.

Although, this presentation was unusual, the progress of the patient's investigation and treatment up to the orchidectomy was of a high standard. However, the 2 month delay in his referral to a Medical Oncologist complicated treatment choices. Whether this will compromise the long-term outcome is uncertain as this treatment is recommended to be given within 6 weeks as per the designated protocol.[1,2,3]

The Review Team acknowledge that there is limited oncology presence within the Urology MDT and the date when the patient's case was discussed there was no oncologist present.

The vast majority of the Urology MDMs within the Southern Trust are non-quorate due to the absence of an oncologist and does not meet the existing guidelines. (0% quorate for 2019).

Whilst it was the primary responsibility for the consultant in charge to make the referral to oncology a failsafe mechanism to ensure agreed actions took place, such

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as an MDM administration tracker, was not in place.

Alternatively, the allocation of a Urology Cancer Specialist Nurse as a Key Worker would have supported the patient on his journey as well as having ensured key actions had taken place. Service User E was not referred to a Urology Cancer Nurse Specialist nor was any contact details provided to him. The MDM guidelines indicate "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"[(4)]. This did not happen. A Key Worker/ Urology Cancer Nurse Specialist would have prompted the oncology referral sooner.

Service User F

Service User F presented with possible prostate cancer and was commenced on bicalutamide 50mgs indefinitely or until biopsy results were available. The diagnosis of prostate cancer was confirmed by biopsy in July 2019. The patient was discussed at the MDM on 8 August 2020. The diagnosis of intermediate-risk organ confined prostate cancer was agreed. The plan was that Doctor 1 should review the patient and discuss management by surveillance or by active treatment with curative intent.

When Service User F was reviewed by a locum consultant in October 2020 the patient did not recall any conversation about the options of external beam radiotherapy (EBRT) as a radical treatment and Active Surveillance. A Urology Cancer Nurse Specialist was appointed as the Key Worker at this review, not having one at time of diagnosis.

Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH analogue) treatment. Bicalutamide monotherapy (150mg) is not recommended for use as a continuing treatment for intermediate risk localised prostate cancer.

The presence of a Urology Cancer Nurse Specialist would support the patient on his journey as well as working collaboratively with the multidisaplinary team to ensure key actions had taken place. Service User F was not referred to a Cancer Nurse Specialist. This is in contrast to declaration for Cancer Peer Review 2017 "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" [(4)]. This did not happen.

Service User G

Service User G was diagnosed in June 2016 with a renal mass measuring 2.5 cms in diameter on the anteromedial cortex of the lower pole of the left kidney. The case was presented to MDM in July 2016, and the recommendation was for active surveillance with interval CT scans. These were carried out at the scheduled times.

On 23 August 2018 his case was discussed at MDM. The July 2018 scan was reviewed and now showed the lesion to measure 3.0cm. The MDM recommended to review and discuss with the patient the options of continuing active surveillance or

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open partial nephrectomy. The case was to be discussed at the Regional Small Masses MDM.

On 28 March 2019 at MDM the renal mass was noted to be enlarging. A further recommendation for Dr 1 to discuss the options of laparoscopic radical nephrectomy versus continued surveillance with its attendant risks was made.

On 29 March 2019 the patient was reviewed by a Locum Consultant Urologist. It was noted that the patient had a 3.1cms left sided kidney mass since July 2018 and this mass was increasing slowly in size. It was noted that the CT would be repeated in November 2019.

On 13 November 2019 a CT scan was performed which showed a further increase in size of lesion to 3.5 cms. No action was taken.

The overall progress of this patient's management was, on balance, acceptable even though the result of the November 2019 CT scan was not acted on.

The Regional Small Renal Mass MDM was developed to oversee the management of this group of patients. An appropriate referral to this group was omitted, despite the MDM's recommendation on at least two occasions.

The patient was reviewed in 29 March 2019 by locum consultant who appears not to have had an update from the MDM held on 28 March 2019.

The patient underwent laparoscopic radical nephrectomy on 25 November 2020 and was discharged on 27 November 2020 with a planned follow up. On 15 January 2021 Dr. 5 reviewed Service User G. He was noted to be doing well. Histopathology confirmed the left kidney mass was pT1a grade 3 papillary carcinoma (mixed oncocytic and type 2) kidney cancer. A plan for CT chest abdomen and pelvis in 12 month was agreed.

Service User H

Service User H was diagnosed with penile cancer. The pathology confirmed squamous cell carcinoma of the prepuce. There was both lymphovascular invasion and perineural infiltration, both of which are associated with an increased risk of metastatic disease, at presentation and subsequently.

The MDM was a virtual meeting conducted by a single urologist. Its plan was that Doctor 2 would review the patient and arrange for a CT scan of the Service User's chest, abdomen and pelvis to complete staging. The CT scan (26 July 2019) showed a single enlarged, left inguinal lymph node measuring 1.3cms in its short axis. Otherwise, there was no evidence of metastatic disease.

At the MDM of 12 September 2019 it was agreed that the Service User H should undergo a left inguinal lymphadenectomy. There does not appear to have been any discussion regarding the referral of Service User H to a supra-regional penile cancer MDT.

The Review Team found that the MDM recommendations did not follow NICE

5.0 DESCRIPTION OF INCIDENT/CASE

guidance for the management of penile cancer [6,7,8] and that there was an opportunity at each meeting to intervene and question Service User H's management.

The treatment provided to this patient was contrary to the NICAN Urology Cancer Clinical Guidelines (2016) for Penile Cancer where it states that local care is restricted to diagnosis. This Guidance was adopted by the SHSCT Urology MDT and evidenced by them as their protocols for cancer peer review 2017. Dr 1 was chair of the NICAN Urology Tumour Speciality Group when the guidance was issued.

The initial clinical assessment of Service User H would have benefited from staging imaging either before or immediately after the original circumcision. All cases of penile cancer should be discussed by the supra-network MDT as soon as the diagnosis is confirmed by biopsy.

The clinical stage G2 pT1 should have led to a consideration of surgical staging with either a bilateral inguinal lymph node dissection (ILND) or sentinel node biopsy (SNB). This omission reduced the likelihood of Service User H's 5 year survival from 90% to less than 40%. The left ILND yielded only 5 nodes, which might be considered at the lower limit of that expected in experienced hands.

The consent form signed by the surgeon and patient is inadequate as it does not state the rationale for the procedure nor the potential complications. The timings between the steps in treatment and management were unduly long and failed to the show the urgency needed to manage penile cancer.

Service User I

Service User I was seen on 27 October 2014 with lower urinary tract symptoms that continued despite medical treatment. Doctor 1 discussed options with Service User I and he decided to proceed to surgery (TURP).

A letter dated 11 November 2016 Service User I's General Practitioner asked for Service User I TURP to be expedited.

The Patient underwent TURP on 29 January 20 and histology confirmed prostatic adenocarcinoma.

Collation of Multidisciplinary meetings should have a fail-safe whereby lists of all urological cancers by site and SNOMED code are generated weekly. This system was not in place.

Although Doctor 1 planned to review the patient in April 2020, he was not seen until August 2020 at an appointment arranged by another doctor who has continued care. The patient had done well following his TURP. The histology was explained as an incidental finding that required continuing surveillance with an up to date serum PSA level and a prostate MRI scan.

Service User I was informed on 9 September 2020 that the serum PSA level was within the normal range and that the MRI scan did not show any features of prostate cancer. The prostate cancer was considered unlikely to represent a threat during the patient's life expectancy and would not be anticipated to require any treatment other

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than surveillance with PSA monitoring.

6.0 FINDINGS

Diagnosis and Staging

- 5 of the 9 patients in this review experienced significant delay in diagnosis of their cancer. This was related to patients with prostate cancer and reflected variable adherence to regionally agreed prostate cancer diagnostic pathways, NIACN Urology Cancer Clinical Guidelines (2016).
- Service User B had a delay of over 15 months from presentation.
- The review team could not find evidence of a Digital Rectal Examination in the notes of Service User D - potentially missing an opportunity to detect his high grade cancer earlier in his pathway.
- Service User F had a slow initial diagnostic pathway which was outside expected cancer care time-frames.
- Service User C had a delayed diagnosis of a metastatic prostate cancer following successful treatment of Renal Cancer. This was due to non-action on a follow-up CT scan report.
- Patient I had a delayed diagnosis of Prostate cancer due to non-action on a histopathology report at TURP.
- Patient H with penile cancer had a 5 week wait between referral and first appointment. Subsequent time to diagnosis and MDM were appropriate. He had a 17 week wait for a CT scan for staging.
- Service User G was on a renal mass surveillance programme - a recommendation at MDM to discuss his case with the regional small renal lesion team was not actioned and it is not known if they would have suggested earlier intervention.

Targets

- Three of the nine patients were said to have met one of their 31 / 62 day targets.
- Service User I 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.
- Service User H was said to have met his 62 day (1st treatment) target but had been referred down a pathway that did not meet the NICAN Urology Cancer Guidelines 2016. A regional Penile Cancer Pathway was agreed in January 2020.
- Service User B was said to have met his diagnostic target of 31 days despite having a delay from initial presentation of 15 months.

6.0 FINDINGS

Multidisciplinary Meeting

- The MDM made appropriate recommendations for 8 of the 9 patients but there was no mechanism to check actions were implemented - this included, further investigations, staging, treatment and appropriate onward referral.
- Dr 1 was present for the discussions and party to the recommendations, 8 of which were compliant with National and Regional Guidelines.
- In the case of the 5 patients with Prostate cancer, 5 patients were referred to the Multidisciplinary Meeting and had appropriate MDM recommendations.
- Service User A and Service User D to start Androgen Deprivation Therapy with LHRHa while Service User F was advised to have active surveillance or curative intent radiotherapy. None of these recommendations were implemented.
- NICAN Regional Hormone Therapy Guidelines for Prostate cancer 2016 were not followed.
- Service User B had a delayed diagnosis of prostate cancer and was belatedly seen at the Urology MDM 15 months after his first presentation. The recommendations from this MDM were correct but not implemented. Regional NICAN Hormone Therapy Guidelines for Prostate Cancer 2016 were not followed
- Service User I had an unexpected diagnosis of cancer at TURP. His diagnosis on pathology report was not actioned and he was discussed at MDM 8 months after his surgery and pathological diagnosis of cancer. His subsequent MDM recommendations were correct.
- Two patients had renal cancer. Service User C was initially appropriately discussed at MDM with action on recommendations. However a routine CT scan in December 2019 was not actioned, leading to a delayed re-presentation to MDM with a second primary diagnosis of metastatic prostate cancer.
- Service User G was on a surveillance pathway for a small renal lesion he was appropriately discussed at MDM. The meetings were not always quorate but a radiologist was present on 4 out of 5 occasions. An MDM recommendation to seek input from the regional small lesion group was not actioned.
- Service User E had a testicular tumour and was appropriately discussed at MDM with the recommendation onward referral to the regional testicular oncology team. This recommendation was time critical but did not happen.
- Service User H was appropriately discussed at the local MDM at diagnostic stage. Unfortunately his treatments and further discussions were restricted to local level and did not meet the NICAN Urology Cancer Guidelines 2016. Patient H should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 and, although a Regional Penile Cancer Pathway was only agreed in January 2020, referral to a specialist with appropriate experience should have been pursued.
- Collation of MDM lists did not include a fail-safe list from histopathology. This would ensure all tissue diagnoses of cancer were cross checked against clinician declared cases. This would capture unexpected cases of cancer as in case I or as in case B where a delayed diagnosis presented to the GI surgeons

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for initial biopsy.

- The patient's care was through a Multidisciplinary Team process but unfortunately they did not benefit from it. The Multidisciplinary Meeting failed in its primary purpose to ensure patients received best care as defined by Regional and National Guidelines.
- The Urology MDM was under resourced and frequently non quorate due to lack of professionals. The MDM had quorate rates of 11% in 2017, 22% in 2018 0% in 2019 and 5% in 2020. This was usually due to lack of clinical oncology and medical oncology. Radiology had only one Urology Cancer Specialist Radiologist impacting on attendance but critically meaning there was no independent Quality Assurance of images by a second radiologist prior to MDM.
- The Urology MDM was under resourced for appropriate patient pathway tracking. The Review Team found that patient tracking related only to diagnosis and first treatment (that is 31 and 62 day targets). It did not function as a whole system and whole pathway tacking process. This resulted in preventable delays and deficits in care.
- Safe cancer patient care and pathway tracking is usually delivered by a three pronged approach of MDT tracking, Consultants and their Secretaries and Urology Specialist Nurses, in a Key Worker role. The Review found that these 9 patients were not referred to Specialist Nurses and contact telephone numbers were not given. Therefore the CNS were not given the opportunity to provide support and discharge duties to the 9 patients who suffered as as consequence. The MDM tracking system was limited. The consultant / secretary led process was variable and resulted in deficits. The weakness of the latter component was known from previous review.
- As patients were not re-discussed at MDM and Urology Cancer Nurse Specialist were not involved in care, non implementation of these MDM recommendations was unknown to others in the MDM. One patient D presented as an emergency and his care was changed to the MDM recommendation by another consultant.

Multidisciplinary working and referral

- The review team noted repeated failure to appropriately refer patients
- Service User A should have been referred to oncology initially and then to palliative care as his disease progressed.
- Service User B should have had an earlier diagnosis and referral to oncology.
- Service User D should have been referred to oncology and palliative care.
- Service User E should have been referred to oncology for time critical care.
- Service User F should have been referred to oncology.
- Service User G should have been referred to the Small Renal Mass Team.
- Patient H should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 but a

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Regnional Penile Cancer Pathway was only agreed in January 2020. Patient H should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 and, although a Regional Penile Cancer Pathway was only agreed in January 2020, referral to a specialist with appropriate experience should have been pursued.

- Patients were not aware that the care given varied from Regional Standards and MDM recommendations. They could not have given informed consent to this.
- All patients were not referred to Urology Cancer Nurse Specialists despite this resource being increased by the Southern Health and Social Care Trust. Peer Review 2017 was informed that this resource was available to all. Their contact numbers were not made available.
- As patients were not re-discussed at MDM and Urology Cancer Nurse Specialist were not involved in care, non referral was an unknown to others within the MDM.

Patient Support and Experience

All patients or families reported a positive experience with their treating consultant initially.

All patients and families were unaware of the additional support available to other patients.

Where patients had disease progression, they expressed concern at the disjointed nature of service provision and the inability to access supportive care. As they were unaware of the normal support mechanisms they believed this to be the normal standard of care or a standard that had been compromised by Covid 19 Pandemic.

All patients and their families were shocked by the fact that their care was not supported and that the care did not follow MDM recommendations. This was especially true when appropriate care should have entailed onward referral to oncology or palliative care.

Affects of Covid

- Some patient's planned review appointments did not go ahead but were rescheduled virtually. Some of the patients did not have their planned review in March / April 2020.

- The review team after speaking with the families and hearing their stories learned that for many of these patients they could not access services in their locality due to the covid restrictions. At the time two families described having difficulty accessing district nursing services for intravenous antibiotics in the community as services were stood down. One family expressed dismay at having difficulties visiting their loved one prior to his passing in hospital due to the covid restrictions and the emotional impact this has had on their grieving process. Others described how when catheters blocked they could not access

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support from their GP and where hence referred to the Emergency Department which the review team agree was not the best place for them. The review team are of the opinion that access to a specialist nurse could have offered support for these families and provide direction to the appropriate services.

Governance / Leadership

- The review team considered the treatment and care of 9 patients who were treated under the care of Dr 1 Consultant Urologist. Individual reviews were conducted on each patient. The review team identified a number of recurrent themes following each review.
- The treatment provided to 8 out of 9 patients was contrary to the NICAN Urology Cancer Clinical Guidelines (2016). This Guidance was adopted by the Southern Health and Social Care Trust Urology Multidisciplinary Team and evidenced by them as their protocols for Cancer Peer review (2017). The Guidance was issued following Dr.1 & Chairmanship of the Northern Ireland Cancer Network Urology Cancer Clinical Reference Group.
- The Urology MDM made recommendations that were deemed appropriate in 8 of 9 cases and were made with contribution and knowledge of Dr.1. Many of the recommendations were not actioned or alternative therapies given. There was no system to track if recommendations were appropriately completed.
- The MDT guidelines indicate “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”. None of the 9 patients had access to a Key Worker or Cancer Nurse Specialist. The use of a CNS is common for all other urologists in the SHSCT urology multidisciplinary team allowing any questions or concerns that patients’ have to be addressed. This did not happen.
- The review team considered if this was endemic within the Multidisciplinary Team and concluded that it was not. Patients booked under other consultant urologists had access to a specialist nurse to assist them with their cancer journey.
- Statements to Urology Cancer Peer Review (2017) indicated that all patients had access to a Key worker / Urology Cancer Nurse Specialist. This was not the case and was known to be so.
- The Urology Cancer Nurse Specialist play an integral role of the MDT and should be facilitated on all the MDM to advocate on patient’s best interest throughout the patient’s journey. This should include independently referring and discussing patients at MDT.
- The Review Team regard absence of Specialist Nurse from care to be a clinical risk which was not fully understood by Senior Service Managers and the Professional Leads. The Review team have heard differing reports around escalation of this issue but are clear that patients suffered significant deficit because of non inclusion of nurses in their care. While this is the primary responsibility of the referring consultant, there is a responsibility on the SHSCT

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to know about the issue and address it.

- Assurance audits of patient pathways within the Urology Cancer Services were limited between 2017 and 2020. They could not have provided assurance about the care delivered.
- Because of resource, the MDM was very focused on first presentation at MDM and did not have a role in tracking subsequent actions if it lay outside 31 and 62 day targets. Tracking of patients was flawed by limitations within the MDM systems and the lack of Specialist Urology Nurses from their Key Worked role. Two of the three normal safety nets for patient pathway completion were,in essence absent. A collaborative approach did not appear to be actively encouraged within the MDT.
- Annual business meetings had an expressed role in identifying service deficits and drawing up an annual work plan to address them. Cancer Patient Pathway compliance audits were limited and did not identify the issues within this report.
- Governance of professionals within the MDT ran through their own directorates but there was no functioning process within Cancer Services to at least be aware of concerns - even if the responsibility for action lay elsewhere within the Southern Health and Social Care Trust. There was disconnect between the Urology MDT and Cancer Services Management. The MDT highlighted inaction by Cancer Services on Oncology and radiology attendance at MDM, but did not escalate other issues.
- The Review team found that issues around prescribing and the use of Clinical Nurse Specialists were of long standing. They were known internally and in the case of prescribing externally (Regional Oncology Services). The Northern Ireland Cancer Network drew up specific Guidance on Hormonal Therapy in Prostate Cancer in 2016 following concerns about this issue. The Guidance was not subject to audit within the Southern Health and Social Care Trust.
- The Review team were concerned that the leadership roles focused on service delivery while having a limited process to benchmark quality, identify deficiencies and escalate concerns as appropriate. Senior managers and clinical leaders in medicine and nursing were unaware of the issues detailed in this report.
- There had been a previous SAI signed off in May 2020 regarding adherence to Cancer Red Flag referral Pathways. The SAI process started in July 2016. The review team is concerned that, as part of early learning, assurances regarding other aspects of the cancer pathway were not sought. Clinical Leadership within Cancer Services were unaware of issues leading to the SAI in 2016.
- Patients in this review were not referred back appropriately to MDM as their diseased progressed. This meant there was no access to oncology and palliative care for many patients, when needed. Care needs within the community were unmet and patients left isolated.

7.0 CONCLUSIONS

The Review Team would like to thank the patients and their families for their contribution to the report and their willingness to share their experiences. The process was difficult and at times traumatic for them.The review team acknowledge that this report may cause distress to the patient and their families, however the team has endeavoured to produce a complete and transparent account of each patient's journey.

The Review of nine patients has detailed significant healthcare deficits while under the care of one individual in a system. The learning and recommendations are focused on improving systems of multidisciplinary care and it's governance. It is designed to deliver what was asked of the Review Team by patients and families -" *to ensure that this does not happen again or that another patient suffers".*

The Patients in this review received uni-professional care despite a multidisciplinary resource being available to all others. Best Practice Guidance was not followed and recommendations from MDM were frequently not implemented or alternative treatments chosen. There was knowledge of that prescribing practice varied from regional and national guidelines in the Southern Health and Social care Trust, as well as more widely across the Cancer Network. This was challenged locally and regionally, but not effectively, to provide safe care for all patients. Inappropriate non referral of patients to oncology and palliative care was unknown.

The primary duty of all doctors, nurses and healthcare professionals is for the care and safety of patients. Whatever their role, they must raise and act on concerns about patient safety. This did not happen over a period of years resulting in MDM recommendations not being actioned, off guidance therapy being given and patients not being appropriately referred to specialists for care. Patients were unaware that their care varied form recommendations and guidance. They could not and did not give informed consent to this.

The systems of governance within the Urology SHSCT Cancer Services were ineffective and did not provide assurance regarding the care and experience of the nine patients in the review. Assurance audits were limited, did not represent whole patient journey and did not focus on areas of known concern. Assurances given to Peer review were not based on systematic audit of care given by all.

While it is of little solace to the patients and families in this review, The Review team sought and received assurances that care provided to others adhered to recommendations on MDM and Regional / National Guidance.

Four of the nine patients suffered serious and significant deficits in their care. All patients had sub-optimal care that varied from regional and national guidelines.

As part of the Serious Adverse Incident process, the Review Team had requested input fromDr 1. This related to the timelines of care, for the nine patients involved in the SAI reviews and specifically formed part of the root cause analysis. This fell under professional requirements to contribute to and comply with systems to protect patients and to respond to risks to safety. To date a response has not been received.

8.0 LESSONS LEARNED

The review identified Cancer Care given by Dr 1 that did not follow agreed MDM recommendations nor follow regional or national best practice guidance. It was care given without other input from Cancer Specialist Nurses, Oncology and palliative care. It was inappropriate, did not meet patient need and was the antithesis of quality multidisciplinary cancer care.

Ensure all patients receive appropriately supported high quality cancer care irrespective of the professional delivering care.

Ensure all cancer care is multidisciplinary and centred on patients physical and emotional need.

Have processes in place to provide assurances to patients and public that care meets these requirements.

That the role of the Multidisciplinary Meeting Chair is defined by a Job Description with specific reference to Governance, Safe Care and Quality Care. It should be resourced to provide this needed oversight.

9.0 RECOMMENDATIONS AND ACTION PLANNING

The recommendations represent an enhanced level of assurance. They are in response to findings from nine patients where Dr 1 did not adhere to agreed recommendations, varied from best practice guidance and did not involve other specialist appropriately in care. They are to address what was asked of the Review by families - "that this does not happen again".

Recommendation 1.

The Southern Health and Social Care Trust must provide high quality urological cancer care for all patients.

This will be achieved by - Urology Cancer Care delivered through a co-operative multi-disciplinary team, which collectively and inter-dependently ensures the support of all patients and their families through, diagnosis, treatment planning and completion and survivorship.

Timescale – Immediate and ongoing

Assurance - Comprehensive Pathway audit of all patients care and experience. This should be externally benchmarked within a year by Cancer Peer Review / External Service Review by Royal College.

Recommendation 2.

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 expectation of Cancer Peer Review.

9.0 RECOMMENDATIONS AND ACTION PLANNING

This will be achieved by - Ensuring all patients receive multidisciplinary, easily accessible information about the diagnosis and treatment pathway. This should be verbally and supported by documentation. Patients should understand all treatment options recommended by the MDM and be in a position to give fully informed consent.

Timescale - Immediate and ongoing

Assurance - Comprehensive Cancer Pathway audit and Patient experience.

Recommendation 3.

TheSHSCT must promote and encourage a culture that allows all staff to raise concerns openly and safely.

This will be achieved by - Ensuring a culture primarily focused on patient safety and respect for the opinions of all members in a collatorative and equal culture. The SHSCT must take action if it thinks that patient safety, dignity or comfort is or may be compromised. Issues raised must be included in the Clinical Cancer Services oversight monthly agenda. There must be action on issues escalated.

Timescale – Immediate and ongoing

Assurance - Numbers of issues raised through Cancer Services, Datix Incidents identified, numbers of issues resolved, numbers of issues outstanding.

Recommendation 4.

The Trust must ensure that patients are discussed appropriately at MDM and by the appropriate professionals.

This will be achieved by - All MDMs being quorate with professionals having appropriate time in job plans.This is not solely related to first diagnosis and treatment targets. Re-discussion of patients, as disease progresses is essential to facilitate best multidisciplinary decisions and onward referral (e.g. Oncology, Palliative care, Community Services).

Timescale - 3 months and ongoing

Assurance - Quorate meetings, sufficient radiology input to facilitate pre MDM QA of images - Cancer Patient pathway Audit - Audit of Recurrent MDM discussion - Onward referral audit of patients to Oncology / Palliative Care etc.

Recommendation 5.

The Southern Health and Social Care Trust must ensure that MDM meetings are resourced to provide appropriate tracking of patients and to confirm agreed recommendations / actions are completed.

This will be achieved by - Appropriate resourcing of the MDM tracking team to encompass a new role comprising whole pathway tracking, pathway audit and pathway assurance. This should be supported by a safety mechanisms from laboratory services and Clinical Nurse Specialists as Key Workers. A report should

9.0 RECOMMENDATIONS AND ACTION PLANNING

be generated weekly and made available to the MDT. The role should reflect the enhanced need for ongoing audit / assurance. It is essential that current limited clinical resource is focused on patient care.

Timescale - 3 months

Assurance - Comprehensive Cancer care Pathway audit - Exception Reporting and escalation

Recommendation 6.

The Southern Health and Social Care Trust must ensure that there is an appropriate Governance Structure supporting cancer care based on patient need, patient experience and patient outcomes.

This will be achieved by - Developing a proactive governance structure based on comprehensive ongoing Quality Assurance Audits of care pathways and patient experience for all. It should be proactive and supported by adequate resources.This should have an exception reporting process with discussion and potential escalation of deficits. It must be multidisciplinary to reflect the nature of cancer and work with other directorates.

Timescale - 3 months

Assurance - Cancer Pathway Audit outcomes with exception discussion and escalation. Data should be declared externally to Cancer Peer Review

Recommendation 7.

The role of the Chair of the MDT should be described in a Job Description, funded appropriately and have an enhanced role in Multidisciplinary Care Governance.

Timescale - 3 months

Recommendation 8.

All patients should receive cancer care based on accepted best care Guidelines (NICAN Regional Guidance, NICE Guidance, Improving Outcome Guidance).

This will be achieved by - Ensuring the multi-disciplinary team meeting is the primary forum in which the relative merits of all appropriate treatment options for the management of their disease can be discussed. As such, a clinician should either defer to the opinion of his / her peers or justify any variation through the patient's documented informed consent.

Timescale – Immediate and ongoing

Assurance - Variance from accepted Care Guidelines and MDM recommendations

should form part of Cancer Pathway audit. Exception reporting and escalation would only apply to cases without appropriate peer discussion.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 9.

The roles of the Clinical Lead Cancer Services and Associate Medical Director Cancer Services should be reviewed. The SHSCT must consider how these roles can redress Governance and Quality Assurance deficits identified within the report.

Timescale - 3 months

Recommendation 10.

The families working as "Experts by Experience" have agreed to support implementation of the recommendations by receiving updates on assurances at 3, 6 and 12 monthly intervals.

Recommendation 11

The Southern Health and Social Care Trust should consider if assurance mechanisms detailed above, should be applied to patients or a subset of patients retrospectively.

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4. Peer review Self-Assessment report for NICaN 2017

5. Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016)

6. EAU guidelines for penile cancer: section 6.2.1 (2019)

7. NICE improving outcomes in urological cancer (2002)

8. NICAN Urology Cancer Clinical Guidelines (March 2016), Penile Cancer treatment Section 9.3 (3).

9.0	RECOMMENDATIONS AND ACTION PLANNING

10.0	DISTRIBUTION LIST

Mr Shane Devlin – Chief Executive SHSCT

Mrs Melanie McClements – Director of Acute Services SHSCT

Dr Maria O'Kane – Medical Director SHSCT

Mrs Heather Trouton Executive Director of Nursing, Midwifery and AMPs

PHA

HSCB

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:	Personal Information redacted by the USI	**HSCB ref Number:**	Personal Information redacted by the USI

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	x	**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI?	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
Please select as appropriate (✓)	**a)** No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**	x	**NO**	
	If **YES**, insert date informed: **all informed 26 October 2020**			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed (***if you select this option please also complete 'l' below***)			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

Continued overleaf	**d)** No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

Received from DoH on 08/09/2021. Annotated by the Urology Services Inquiry.

LEVEL 1 – SIGNIFICANT EVENT AUDIT INCLUDING LEARNING SUMMARY REPORT AND SERVICE USER/FAMILY/CARER ENGAGEMENT CHECKLIST

SECTION 1

1. ORGANISATION: SHSCT	**2. UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE:** Irrelevant redacted by the USI
3. HSCB UNIQUE IDENTIFICATION NO. / REFERENCE: S Irrelevant redacted by the USI	**4. DATE OF INCIDENT/ EVENT: 17 July 2018**
5. PLEASE INDICATE IF THIS SAI IS INTERFACE RELATED WITH OTHER EXTERNAL ORGANISATIONS: No	**6. IF 'YES' TO 5. PLEASE PROVDE DETAILS:**

7. DATE OF SEA MEETING / INCIDENT DEBRIEF: 07 August 2019

8. SUMMARY OF EVENT:

Patient 92 was referred to Craigavon Area Hospital Emergency Department on 2 November 2017 by her GP for a productive cough, lethargy, sweats and back pain for 2 months. Patie nt 92 was admitted to the ward and treated for a urinary tract infection (UTI) and poor diabetic control. Patie nt 92 was discharged home the following day with a plan for an outpatient renal tract ultrasound scan (USS). Patie nt 92 had her USS on 16 November 2017 which reported further investigation was required to exclude renal malignancy.

Patie nt 92 had a follow up CT renal abdominal scan on the 28 November 2017. The CT scan reported that appearances most likely represented areas of renal inflammation, and likely infected renal cysts with probable abscess formation and that the appearances were not typical for underlying malignancy (cancer).

Patie nt 92 was contacted and advised to attend CAH ED for treatment of same. Patie nt 92 attended CAH ED and was admitted to the ward for treatment of an infected renal cyst. Prior to her discharge a follow up outpatient urology review appointment was arranged for 6 weeks and a repeat CT renal abdominal scan in 3 months' time.

Patie nt 92 never received a follow up urology outpatient review appointment. Patie nt 92 had a repeat CT scan on 13 March 2018 which reported a solid nodule suspicious of renal cell carcinoma. There was no follow up following CT report.

Patie nt 92 attended her GP on the 10 July 2018 complaining of right sided abdominal pain. Patie nt 92's GP noted the overlooked CT report and immediately forwarded a red flag urology referral to Craigavon Area Hospital.

SECTION 2

9. SEA FACILITATOR / LEAD OFFICER: Dr D Gormley, Consultant Physician	**10. TEAM MEMBERS PRESENT:** Ms W Clayton, Head of Service Mrs K Robinson, Booking & Contact Centre Manager Mrs C Connolly, Clinical Governance Manager

Diane Corrigan, Consultant in Public Health Medicine, then conducted a province-wide review of the practice and this showed a higher than expected number were performed in Craigavon Area Hospital. I was instructed to review the last 12 cases performed. As a general surgeon I found myself unable to reassure the Trust re the indication for half of them. An Independent review was then conducted by Marcus Drake, Consultant Urologist in Bristol. We were unable to obtain all the information he required to produce a final report but, essentially, he felt that there were no gross errors or faults. However, a recommendation of the urology review had been that all major pelvic surgery was to be conducted in Belfast. In September 2011 the urologists were informed that no further elective cystectomies were to be performed in the trust.

21. The Benign cystectomies issue is also discussed in more detail below, in particular in my responses to Questions 54-57.

Disposal of Patient Records

22. In June 2011 I was made aware that an auxiliary nurse in the urology ward had found a bundle of papers in one of the bins. The bundle consisted of fluid balance charts, TPN Fluid prescription forms, MEWs Charts and Prescription records belonging to 2 patients' charts. Human Resources were involved, and an investigation was undertaken. Aidan O'Brien accepted that he was wrong to have disposed of the records and he was issued with an informal warning in August 2011.

23. This issue is discussed in further detail below, in particular in my answers to Questions 54-57 & 61.

Review of Results of Investigations

24. In 2009 a "never event" occurred whereby a swab was post-operatively left in a patient and was only discovered a year later when the patient was admitted as an emergency. A CT scan had been reported as abnormal three months later, but an investigation revealed that Aidan O'Brien had a policy of not reviewing results until patients attended out-patients. Aidan O'Brien raised

multiple objections when it was suggested that he should be reviewing all results therefore an instruction was issued to all consultants informing that it was their responsibility to review all the results of investigations on their patients once they are available.

25. This issue is addressed in more detail below, in particular in my answers to Questions 54-57.

Patient Outcomes and Charts at Home

26. In 2013 Medical Records complained that an ongoing problem with Aidan O'Brien was patient hospital charts in his house and he was advised that this was not permitted. Following the expansion of the urology service to become Team South, outpatient clinics were provided in Enniskillen and patient records therefore needed to be transported to the clinic and back to Craigavon afterwards. The Trust transport was used for all other peripheral surgical clinics but for this service it had been arranged that, after the clinic, the consultant would bring the charts back to the Craigavon. Following dictation of the letter to the GP the outcome for the patient would be recorded (e.g., put on waiting list for surgery, discharged, or review arranged). Aidan O'Brien, however, was bringing the charts to his house after the clinic but not completing the dictation which also meant patient outcomes were not recorded. The Trust became aware in late 2015 of it as a problem but only discovered the extent of the problem, when following Heather Trouton's and my letter in March 2016, he returned the charts.

27. This issue is addressed in more detail below, in particular in my answers to Questions 58-61.

Bullying and Harassment

28. In 2012 I was informed that Aidan O'Brien had spoken to Roberta Brownlee, then Chair of the Trust Board, complaining that I had been bullying and harassing him. I consider this to have been a false accusation and, on reflection, I believe it may have been malicious. Prior to 2012, I had acted as a major challenge to Aidan O'Brien' opinions and views regarding

the Directorate did review results of investigations on a regular basis, we could not be certain they all complied.

225. Following further discussions with Gillian Rankin my recollection is that an instruction was then issued to all the consultants in the Directorate reminding / informing them that it was their responsibility to review the results of investigations on their patients once they are available. Secretaries were informed that results of investigations were not to be filed in the chart unless they had been reviewed and signed / initialled by a consultant.

Patient Outcomes

226. My recollection is that at the end of 2015 we started to become increasingly aware of an issue regarding patient centre letters and outcomes. Some of the urologists were undertaking waiting list work / validation and found that, in many of Aidan O'Brien's patients, their clinic outcomes and letters were not recorded and there was no record in the chart. It was also noted that many of the hospital charts were not available for clinics.

Charts at Home

227. A recurring issue since I came to the trust was consultants at times taking charts home. On request from Medical records they would be returned to the hospital. Aidan O'Brien was not unique in this respect and from time to time all consultants would be reminded not to bring them home. In September 2013 Helen Forde, Head of Health Records flagged the issue with Heather Trouton and Anita Carroll and through Anita Carroll to Debbie Burns. *Document located in Section 21 4 of 2022, 20130905 E re Charts to Consultants Home.* Debbie Burns identified it as a governance issue and Robin Brown was instructed to discuss with Aidan O'Brien and if not did it need escalated. 22 September 2013 Robin Brown emailed to say he would deal with it. *Document located in Section 21 4 of 2022, 20130922 E re Datix Incident Report*. I do not recall the issue of charts at home being discussed with me until the end of 2015. At the end of 2015 / early 2016 as part of an overall investigation Heather Trouton made me aware that it had started to

Corrigan, Martina

From: Corrigan, Martina [redacted]
Sent: 25 August 2011 16:23
To: 'aidanpobrien [redacted]
Subject: RE: Results and Reports of Investigations

Aidan,

Many thanks for your response – I will forward this to Eamon for assistance in addressing your queries and I will come back to you on this as soon as possible.

Regards

Martina

Martina Corrigan
Head of ENT and Urology
Craigavon Area Hospital

Tel: [redacted]
Mobile: [redacted]
Email: martina.corrigan [redacted]

From: aidanpobrien [redacted]
Sent: 25 August 2011 15:37
To: Corrigan, Martina
Subject: Re: Results and Reports of Investigations

Martina,

I write in response to email informing us that there is an expectation that investigative results and reports to be reviewed as soon as they become available, and that one does not wait until patients' review appointments. I presume that this relates to outpatients, and arises as a consequence of patients not being reviewed when intended. I am concerned for several reasons:

- Is the consultant to review all results and reports relating to patients under his / her care, irrespective of who requested the investigation(s), or only those requested by the consultant?
- Are all results or reports to be reviewed, irrespective of their normality or abnormality?
- Are they results or reports to be presented to the reviewer in paper or digital form?
- Who is responsible for presentation of results and reports for review?
- Will reports and results be presented with patients' charts for review?
- How much time will the exercise of presentation take?
- Are there other resource implications to presentation of results and reports for review?
- Is the consultant to report / communicate / inform following review of results and reports?
- What actions are to be taken in cases of abnormality?
- How much time will review take?
- Are there legal implications to this proposed action?

I believe that all of these issues need to be addressed,

Aidan.

Willis, Lisa

From: Mackle, Eamon
Sent: 16 November 2011 18:07
To: Trouton, Heather
Subject: Fw: Results and Reports of Investigations

Follow Up Flag: Follow up
Flag Status: Flagged

From: Rankin, Gillian
To: Mackle, Eamon
Cc: Corrigan, Martina; Trouton, Heather
Sent: Thu Sep 08 07:29:02 2011
Subject: RE: Results and Reports of Investigations

Dear all,

I am concerned that we have not been able to sort this one out yet despite trying to have a conversation with Mr O'Brien.

Heather I wonder if when you are meeting the 3 surgeons regarding speciality interests this whole area of how results are read when they arrive rather than waiting for review apt could be discussed.
The secretaries need to be given a brief as to what is expected of them and tis would need discussed and agreed.
Perhaps a protocol for secretaries is needed when there is not currently a system in place which I hope is not more widespread.
Can I leave it with you until ~I return?
Thanks,
Gillian

From: Mackle, Eamon
Sent: 26 August 2011 16:37
To: Rankin, Gillian
Cc: Corrigan, Martina
Subject: FW: Results and Reports of Investigations

Gillian

I have been forwarded this email by Martina and I think it raises a Governance issue as to what happen to the results of tests performed on Aidan's patients. It appears that at present he does not review the results until the patient appears back in OPD.

Eamon

From: Corrigan, Martina
Sent: 25 August 2011 16:22
To: Mackle, Eamon
Cc: Trouton, Heather
Subject: FW: Results and Reports of Investigations

Eamon,

I will need assistance when replying to this email.

Thanks

Martina

Martina Corrigan
Head of ENT and Urology
Craigavon Area Hospital

Tel: Personal Information redacted by USI (Direct Dial)
Mobile: Personal Information redacted by USI
Email: Personal Information redacted by USI

From: aidanpobrien Personal Information [mailto: Personal Information redacted by the USI]
Sent: 25 August 2011 15:37
To: Corrigan, Martina
Subject: Re: Results and Reports of Investigations

Martina,

I write in response to email informing us that there is an expectation that investigative results and reports to be reviewed as soon as they become available, and that one does not wait until patients' review appointments. I presume that this relates to outpatients, and arises as a consequence of patients not being reviewed when intended. I am concerned for several reasons:

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- How much time will review take?
- Are there legal implications to this proposed action?

I believe that all of these issues need to be addressed,

Aidan.

-----Original Message-----
From: Corrigan, Martina < Personal Information redacted by USI >
To: Aidanpobrien Personal Information redacted by the USI ; my Personal Information redacted by USI >; Akhtar, Mehmood Personal Information redacted by USI >; O'Brien, Aidan < Personal Information redacted by USI >; Young, Michael < Personal Information redacted by USI >
CC: Dignam, Paulette < Personal Information redacted by USI >; Hanvey, Leanne < Personal Information redacted by USI >; McCorry, Monica < Personal Information redacted by USI >; Troughton, Elizabeth Personal Information redacted by USI >
Sent: Wed, 27 Jul 2011 5:30
Subject: FW: Results
Dear all

The Regulation and Quality Improvement Authority

An Independent Review of Reporting Arrangements for Radiological Investigations

Phase 1 Overview Report, March 2011

informing and improving health and social care
www.rqia.org.uk

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Appendix A

Standards and recommendations for the reporting and interpretation of imaging investigations by non-radiologist medically qualified practitioners and teleradiologists (Royal College of Radiologist March 2011)

Section 1: Introduction

1.1 The Regulation and Quality Improvement Authority (RQIA)

RQIA is a non departmental public body responsible for monitoring and inspecting the quality, safety and availability of health and social care services across Northern Ireland. It also has the responsibility of encouraging improvements in those services. The functions of RQIA are derived from The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003.

RQIA operates within a value system that supports the belief that learning is at the heart of improvement. To ensure a clear focus on improvement, organisations need to have effective systems which can identify performance standards and support the learning necessary for improvement.

RQIA's main functions are:

- To inspect the quality of services provided by Health and Social Care (HSC) bodies in Northern Ireland through reviews of clinical and social care governance arrangements within these bodies.
- To regulate (register and inspect) a wide range of services delivered by HSC bodies and by the independent sector. The regulation of services is based on minimum care standards to ensure that service users know what quality of services they can expect to receive, and service providers have a benchmark against which to measure their quality.
- To undertake a range of responsibilities for people with mental ill health and those with a learning disability, following the transfer of duties of the Mental Health Commission to RQIA under the Health and Social Care (Reform) Act (NI) 2009.
- To carry out monitoring, inspection and enforcement of legislative measures for the protection of individuals against dangers of ionising radiation in relation to medical exposure set out in The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 (IR(ME)R). RQIA became responsible for functions in relation to IR(ME)R on 15 March 2010.

1.2 Context for the Review

On 15 February 2011, Michael McGimpsey, MLA, Minister for Health, Social Services and Public Safety, commissioned RQIA to undertake an independent review of the handling and reporting arrangements for plain x-ray radiological investigations across Northern Ireland.

The request for the review followed delays in the reporting of plain x-ray radiological examinations at Altnagelvin Hospital, Londonderry (Western Health and Social Care Trust) and Craigavon Hospital, Craigavon (Southern Health and Social Care Trust).

On 18 February 2011, RQIA agreed to undertake this commissioned review in two phases, as set out in the terms of reference, taking into account the following framework documents and advice issued from the Department of Health, Social Services and Public Safety (DHSSPS) in respect of their application to the service in Northern Ireland:

- Standards for the Reporting and Interpretation of Imaging Investigations (Royal College of Radiologists), January 2006
- National Patient Safety Agency (NPSA) Safer Practice Notice 16; Early identification of failure to act on radiological imaging reports, February 2007
- Standards for the Communication of Critical, Urgent and Unexpected Significant Radiological Findings (Royal College of Radiologists), 2008
- Priorities for Action (PfA) 2010

1.3 Terms of Reference

Phase 1

1. To describe the systems in place for handling and reporting on plain x-rays across the five HSC trusts.

2. To examine the governance arrangements in place across the five HSC trusts to assure patient safety and protection with regard to handling and reporting on radiological investigations.

3. To examine the arrangements for communication of the reports of x-rays to patients and practitioners.

4. To make recommendations for action to manage any identified current issues in relation to the handling and reporting of x-rays.

Phase 2

Following publication of the report of Phase 1 of the review, the terms of reference for Phase 2 will be reviewed in the light of the findings of Phase 1.

5. To describe the circumstances leading to any significant delays in the handling and reporting of radiological investigations in the last two years and how those delays have been managed by the five HSC trusts and the HSC Board.
6. To identify any factors which contributed to delays in handling and reporting radiological investigations across Northern Ireland during the past two years and make recommendations to avoid these happening in the future.

7. To consider the impact of identified delays on service users.

8. To examine any other relevant matters emerging during the course of the review.

1.4 The Review Team

The team includes the following membership for Phase 1 of the review:

- Dr Nicola Strickland, Registrar of the College and Registrar of the Faculty of Clinical Radiology, Royal College of Radiologists (RCR)
- Sally MacLachlan, Senior Clinical Officer, Medical Exposure Department, Health Protection Agency (HPA)
- Jon Billings, Director of Healthcare Quality, Health Information and Quality Authority (HIQA)
- Dr David Stewart, Director of Service Improvement and Medical Director, RQIA
- Hall Graham, Head of Primary Care and Clinical and Social Care Governance Review and Independent Health Care Regulation, RQIA

supported by:

- Helen Hamilton, Project Manager, RQIA

1.5 Methodology Used to Collect Evidence in Phase 1

a. RQIA asked all HSC trusts to provide the following written material in relation to radiology services within the trust:

- completion of a questionnaire at trust level on radiology services and systems
- completion of a short questionnaire in relation to each radiology department within the trust
- provision of a specified list of supplementary information and documentation

b. The members of the review team met with representatives of managerial and clinical staff responsible for the provision of radiology services in each trust, to gain further clarification in relation to the written material provided. These meetings took place between 10 and 14 March 2011.

RQIA is grateful to the staff across all trusts who were involved in the provision of written material, at short notice, to inform the review process and who met with the review team to provide clarification on the delivery of radiology services within the trusts.

1.6 Reporting of Findings

The RQIA review team has prepared individual Phase 1 reports for each trust. These reports describe the arrangements for the provision of plain x-ray imaging and the findings and conclusions of the review team after visits to each trust. The trust reports include recommendations for actions at trust level.

This report presents an overview of the findings of the review team across Northern Ireland. The recommendations included in this report relate to actions to be taken at Northern Ireland level.

1.7 Standards and Guidelines

A. Standards for the Reporting and Interpretation of Imaging Investigations (Royal College of Radiologists), January 2006

The Royal College of Radiologists (RCR) standards for the reporting and interpretation of imaging were established to define the aspects of radiological services and care which promote the provision of a high quality service to patients. The standards define what is required in an imaging report, whoever issues that report. 14 standards are defined.

- Robust clinical governance procedures must be in place and be applied to imaging investigations and reports, wherever they may originate.
- Non-radiologists who interpret imaging should work in teams with ready access to radiologists for advice.
- The type of investigation most likely to be suitable for interpretation by those without medical training is that which involves a single organ, with a single suspected pathology and a yes/no answer.
- Radiologists and Trusts have a duty of care to the patient to ensure that no individual who reports imaging investigations is expected to work beyond their level of knowledge and competence.
- An individual who reports an investigation must understand the explicit and implied information on the request form.
- An individual who reports an investigation must have sufficient technical knowledge to assess image quality and know the limitations of the investigation in a particular patient.
- An individual who reports an investigation must have been trained in radiological observation and analytical skills.
- Medical training is required when imaging findings are correlated with clinical details and the results of laboratory tests to make a clinical diagnosis.
- Further investigations should only be suggested if they are medically indicated and will contribute to patient management.
- The professional status of an individual who reports an investigation should be clear on all written reports.

- The wording of the report should be clear and take into account the professional background of the referrer.
- There must be a reliable method for the referrer to discuss difficult cases in more detail with the individual who reports the investigation.
- An individual who reports an investigation must recognise when the findings constitute a medical emergency and comply with local mechanisms to alert referrers in urgent cases.
- All communications with the patient must adhere to professional guidance.

B. National Patient Safety Agency (NPSA) Safer Practice Notice 16; Early Identification of Failure to Act on Radiological Imaging Reports, February 2007

On 5 February 2007, NPSA published a safer practice notice to advise health care organisations to review their systems to ensure that radiology imaging results are communicated and acted on appropriately. NPSA had received 22 reports from across the United Kingdom between November 2003 and May 2006 where failure to follow up radiological imaging reports led to patient safety incidents, most of which involved fatalities or significant long-term harm. The NPSA safer practice notice recommended that all health care organisations providing or commissioning radiological imaging services should:

- ensure that the radiological imaging reports of all patients are communicated to, and received by, the appropriate registered health professional and, where necessary, action is taken in a manner appropriate to their clinical urgency;
- ensure registered heath professionals design "safety net" procedures for their specialty;
- make it clear to patients how and when they should expect to receive the results of a diagnostic test;
- review relevant policies and procedures in line with the safer practice recommendations outlined in the safer practice notice.

On 16 July 2007, the Director of Safety Quality and Standards at DHSSPS wrote to all HSC organisations to ask them to work towards compliance with the safer practice notice and to bring the notice to the attention of staff.

C. Standards for the Communication of Critical, Urgent and Unexpected Significant Radiological Findings (Royal College of Radiologists), 2008

In 2008, RCR developed and issued standards in relation to the communication of critical, urgent and unexpected significant radiological findings following the publication of NPSA Safer Practice Notice 16.

The standards were set in the context of a changing working environment for radiology services. With the roll-out of picture archiving and communication systems (PACS) and digital reporting systems, previous paper based alert systems were becoming obsolete. The standards provide outline definitions of three categories of findings requiring action.

- **Critical findings**. Where emergency action is required as soon as possible
- **Urgent findings**. Where medical evaluation is required within 24 hours.
- **Significant unexpected findings**. Cases where the reporting radiologist has concerns that the findings are significant for the patient and will be unexpected.

Standards for the communication of urgent reports are described:

- Every department should define and develop policies for the communication of critical, urgent and unexpected significant findings as outlined by Safer Practice Notice 16, unless they are confident that their processes are sufficiently robust to make this unnecessary. This will not replace the essential requirement for each referrer to be responsible for reading the result of every investigation they generate but should be aimed at providing a safety net for the highlighting of significant findings.
- The processes involved should be auditable, transparent and represent a clear trust policy agreed between the radiology department and requesting clinicians.
- Trusts should develop and provide the appropriate IT support and resource required to achieve compliance with Safer Practice Notice 16 by reliable electronic means. This is most effectively achieved with a system of automatic electronic feedback of results to the referring clinician with availability to other designated members of the relevant clinical team.
- As IT links and communication within trusts and the NHS as a whole continue to develop, systems will require regular review and updating.

In November 2008, the Chief Medical Officer of Northern Ireland wrote to HSC organisations and relevant independent sector establishments strongly commending the guidance set out by the RCR in the standards publication.

D. Priorities for Action

Priorities for Action (PfA) sets out minimum standards of performance for trusts in Northern Ireland. These standards are subject to monitoring by the HSC Board.

In PfA 2008-09, a target was introduced for diagnostic services for the first time. The target was that, from April 2009, no patient should wait longer than nine weeks for a diagnostic test. This was applied to a specified list of 16 diagnostic tests. Within radiology services the target was applied to magnetic resonance imaging (MRI), computed tomography (CT), ultrasound investigations, barium studies, DEXA scans and radio-nuclide imaging. The list did not include plain x-

ray imaging as it was not possible to monitor waiting times centrally for plain x-rays until the introduction of RIS/PACS across Northern Ireland.

PfA target definition guidance issued by the HSC Board in April 2009 advised trusts that extension of monitoring to include plain x-ray imaging would be commenced on implementation of PACS. This is planned to start formally in April 2011. A period of testing reporting arrangements with trusts has been taking place in 2010-11.

E. Standards and Recommendations for the Reporting and Interpretation of Imaging Investigations by Medically Qualified Non-Radiologists and Teleradiologists (Royal College of Radiologists) March 2011 (Appendix A)

RCR has recently developed a new publication, for application across the United Kingdom, which defines standards for radiologists, regulatory authorities, hospital managers and individual doctors regarding medically qualified non radiologists who wish to interpret imaging investigations. The publication also provides standards for consideration when imaging investigations are outsourced to teleradiologists employed by off-site teleradiology companies.

The RQIA review team recognises that these standards have not yet been formally issued across Northern Ireland but considers that they are helpful in informing the recommendations of this review. The standards are intended as supplementary to the 2006 standards described above which still apply. Eleven standards are defined within the document.

1. Every imaging investigation must be reported within an agreed time by an individual qualified to interpret that particular investigation.

2. All imaging investigations must be accompanied by a formal permanently recorded written report.

3. All imaging investigations are best reported by a radiologist.

4. Health boards, commissioners of health care and hospital trusts must provide the resource, in terms of numbers of radiologists, IT provision and infrastructure to achieve the above standards.

RCR recognises that, with the current level of consultant radiology staffing, many organisations in the UK will not be able to achieve the best practice standards at present. In this context standards have been defined for medically qualified non radiologists as follows.

5. When image interpretation is delegated to non-radiologist medically qualified practitioners, hospitals, their medical directors and clinical radiology directors are responsible for ensuring the expertise of the practitioner and obtaining their agreement that they will provide a written record of the result of each investigation they interpret.

6. All practitioners who interpret imaging investigations must identify their name, status and position when making a written record of an imaging investigation.

7. There should be regular audit (at least once a year) of unreported imaging investigations.

8. Radiologists must be available to provide definitive reports on urgent imaging at all times. Similarly consultant radiologists should be available to provide their expert opinion on imaging investigations at all times.

Standards on the use of teleradiology are defined as:

9. Where reporting of imaging investigations is outsourced to off-site radiologists not working in the health care facility where the imaging investigations are performed, the health care facility management, medical director and radiologists must ensure that the previously published RCR standards on teleradiology[1] are met.

10. Patients or their carers/advocates must be aware when imaging investigations are to be interpreted off-site by an outsourced provider and assurances obtained that this is acceptable. The use of teleradiology services should be clearly signposted by notices in the department, with leaflets providing further information, especially in waiting areas, so patients, carers and advocates can query the reason, or voice any concerns to the radiographic staff at the time of the investigation.

11. Where reporting of imaging investigations is outsourced to off-site radiologists not working in the health care facility where the imaging investigations are performed, the health care facility management, medical director and radiologists must ensure the reporting teleradiologists fulfil the GMC requirements to practice medicine in the UK.

The RCR document makes two recommendations for consideration by providers and commissioners of radiology services.

1. The RCR recommends that future commissioners of health care promote the development and use of local imaging networks which involve local hospital clusters and integrated IT and teleradiology solutions.

1. The Royal College of Radiologists. *Standards for the provision of teleradiology within the United Kingdom*. London: The Royal College of Radiologists, 2010. http://www.rcr.ac.uk/docs/radiology/pdf/BFCR(10)7_Stand_telerad.pdf

2. All future PACS procurements should ensure functionality is provided for efficient inter-hospital transfer of x-rays and reports- fully utilising common data sharing protocols and standards such as XDSi (cross platform document for sharing imaging, as defined by Integrating the Healthcare Enterprise) and DICOM (digital image and communications in medicine standard).

1.8 Requirements under the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)

The responsibility for assessing compliance with and enforcing The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 known as IR(ME)R transferred from the DHSSPS to the Regulation and Quality Improvement Authority (RQIA) on 15 March 2010 under The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010.

The regulations are intended to:

- Protect patients from unintended excessive or incorrect exposure to radiation and ensure that, in each case, the risk from exposure is assessed against the clinical benefit
- Ensure that patients receive no more exposure than is necessary to achieve the desired benefit within the limits of current technology
- Protect volunteers in medical or biomedical, diagnostic or therapeutic research programmes and those undergoing medico-legal exposures
- Ensure that all medical exposures have a documented clinical evaluation

Section 2: Findings of the Review Team

2.1 Description of the Systems for Handling and Reporting of Plain X-rays in Northern Ireland

2.1.1 The organisation of radiology services across Northern Ireland varies by trust and reflects local patterns of hospital provision and trust policies on service design.

- The Belfast Health and Social Care Trust (Belfast Trust) has four radiology departments These include radiology departments at the Royal Hospitals (Royal Victoria Hospital, Royal Belfast Hospital for Sick Children, Royal Jubilee Maternity Hospital and the School of Dentistry), Belfast City Hospital, Mater Hospital and Musgrave Park Hospital.
- The Northern Health and Social Care Trust (Northern Trust) has a single integrated trust wide radiology service with shared plain x-ray reporting lists.
- The South Eastern Health and Social Care Trust (South Eastern Trust) has three radiology departments. Ulster Hospital reports on plain x-rays from Ulster, Ards and Bangor hospitals and there are also departments at Lagan Valley and Downe hospitals.
- The Southern Health and Social Care Trust (Southern Trust) has four radiology departments based at Craigavon, Daisy Hill, South Tyrone and Armagh Community hospitals
- The Western Health and Social Care Trust (Western Trust) has two radiology departments reporting on plain x-rays based at Altnagelvin Hospital (which also reports on Roe Valley Hospital) and at Erne/Tyrone County hospitals.

2.1.2 The review team were advised of two contracts in place with independent sector providers in Great Britain for the reporting of plain x-rays.

2.1.3 The Western Trust established a contract in 2010 for radiology reporting as part of an action plan to tackle a delay in reporting. The contract is still in place and can be called upon as part of the trust escalation arrangements to prevent future delays.

2.1.4 In 2011, the Southern Trust agreed a contract with an independent sector provider to report on 4,000 to 5,000 plain x-rays to eliminate a delay in reporting. The trust has assessed that it has a capacity gap on reporting of just fewer than 2,700 plain x-rays per month, based on the current reporting policy. A short-term contract for around 1000 x-rays per month is being secured with the independent sector provider to take effect from the end of April 2011. The remaining shortfall will be met

through the use of additional programmed activities and waiting list initiative sessions.

Staffing

2.1.5 Trusts advised the review team of a total of 13.8 whole time equivalent (WTE) consultant radiologist vacancies across Northern Ireland out of their funded establishments. There were 106.3 WTE consultants and 4.6 WTE locum consultants in post at the time of the review.

2.1.6 Trusts described different experiences in relation to recruitment to vacant consultant posts. The Southern and Western Trusts have experienced considerable difficulty in recruiting consultants. The Belfast Trust has experienced difficulty in recruiting consultants with specific areas of expertise, in particular neuro-radiology. The South Eastern Trust advised that it had had several applicants for an advertised post and the Northern Trust had all funded posts filled at the time of the review visit.

2.1.7 All trusts described capacity gaps, within their funded establishment, in their ability to report on plain x-rays in relation to the current volumes of plain x-rays. Different trusts were addressing this shortfall in a combination of different ways. Some trusts contract for additional reporting sessions from their own consultants in seeking to close this gap; others have implemented protocols for plain x-rays to be reported by other clinicians; and some trusts are contracting with the private sector.

2.1.8 In 2008, a review of consultant radiologist staffing carried out by DHSSPS projected a requirement of 180 WTE consultant posts by 2018 across Northern Ireland. It was estimated that 108 consultant vacancies would occur during the 10 year period taking account of 10 vacancies in 2008, 24 likely retirements and a projected growth of 88 posts.

2.1.9 All trusts have on-call arrangements in place for consultant radiologists to provide opinions and report on urgent x-rays. The Northern Trust has a trust wide on-call rota and the Belfast Trust is considering implementing an across site on-call system.

Picture Archiving and Communication System (PACS) and Radiology Information System (RIS)

2.1.10 PACS, in conjunction with RIS, is an electronic system which enables radiology departments to store, rapidly retrieve and share digital x-rays, and their reports, within and between hospitals. Development of PACS has revolutionised the way in which radiology departments work. PACS enables the electronic storage and organisation of x-rays, removing the

need to retain large numbers of hard copy plain x-ray films. PACS can enable new systems of reporting to be put in place and new arrangements to monitor the timeliness of reporting.

2.1.11 In Northern Ireland the implementation of an integrated solution to the provision of RIS/PACS has been taking place (NIPACS) to enable x-rays and reports to be viewed by appropriate health professionals across the health care network. NIPACS has been designed to integrate the functions of reporting, archiving and communicating x-rays (PACS) with radiology information systems (RIS) and inputting reports through voice recognition software (VR).

2.1.12 NIPACS has been rolled out across trusts in a planned programme of implementation.

- South Eastern Trust went live in October 2009
- Northern Trust went live in December 2009
- Southern Trust went live in March 2010
- Western Trust went live in May 2010
- Belfast Trust went live at Mater, Musgrave Park and Royal Belfast Sick Children's hospitals in December 2010

2.1.13 Belfast City Hospital and Royal Victoria Hospital Imaging Centre in Belfast Trust each have a different and separate PACS in place. It is planned that they will be integrated with NIPACS later in 2011. All HSC hospitals in Northern Ireland will then be part of an integrated PACS network with the ability to share and read x-rays across the system.

2.1.14 Reporting of x-rays into NIPACS and the PACS at the Belfast City and Royal hospitals can be carried out using voice recognition software. The review team were advised that in all trusts voice recognition is now the only or most common method of inputting radiology reports into RIS at radiology reporting workstations in hospitals.

2.1.15 Consultants using NIPACS can have access to x-rays using web technology from home when on call. At present there is no facility to use voice recognition in this situation but reports can be typed and uploaded onto RIS.

Booking Arrangements

2.1.16 Across all trusts, there is good access for patients referred by GPs or in hospital to plain x-ray imaging. Many hospitals operate on an open access basis for plain x-rays. An appointment system is in place at some hospitals for non-urgent referrals.

Reporting Arrangements for Plain X-rays

2.1.17 The review team found that the trust arrangements where some plain x-rays are not routinely reported by radiologists but are devolved for reporting by other clinicians have been locally determined. There are some differences between trusts as to reporting policy in relation to chest x-rays and x-ray referrals from orthopaedics and fractures.

2.1.18 In all trusts there are arrangements in place for a radiologist to provide a second opinion on request on any x-ray where these are routinely reported by other clinicians.

2.1.19 There are arrangements in place in some trusts for defined lists of x-rays to be reported by trained reporting radiographers and these are subject to audit.

2.1.20 In relation to chest x-rays:

- In Belfast Trust all chest x-rays are reported by radiologists, apart from portable x-rays taken in intensive care, cardiology and cardio-thoracic surgery where x-rays are evaluated by consultants or specialist registrars in the relevant specialty. There are weekly meetings held between radiologists and consultants in intensive care to discuss x-rays.
- In the Northern, Southern and Western Trusts all chest x-rays are reported by radiologists.
- In South Eastern Trust all chest x-rays are reported by radiologists except for the second (or subsequent) portable chest x-rays taken on patients in coronary care at Ulster Hospital.

2.1.21 In relation to orthopaedic and fracture x-rays:

- In Belfast Trust, orthopaedic and fracture plain x-rays are evaluated by consultants or senior registrars in orthopaedics and fractures, and are not reported by radiologists except on request.
- In Northern Trust, orthopaedic plain x-rays are evaluated by clinicians from the Musgrave Park Regional Orthopaedic Service (MPROS) who provide a visiting outpatient service at clinics in the trust. Initial x-rays of fractures are reported by consultant radiologists. Follow up fracture x-rays are evaluated by clinicians at fracture clinics.
- In Southern Trust, all orthopaedic plain x-rays (including MPROS clinic x-rays at Daisy Hill Hospital) are reported by radiologists apart from post operative inpatients. A&E x-rays are not reported by radiologists apart from chest x-rays and under 16 year olds. Reporting radiographers working in A&E and Minor Injury Units report on skeletal x-rays.
- In South Eastern Trust, inpatient orthopaedic x-rays are reported by radiologists. MPROS clinic x-rays are evaluated by consultants or

specialist registrars in orthopaedics. Initial A&E fracture x-rays are always reported by radiologists. Follow up fracture x-rays are evaluated by clinicians at the fracture clinics.

- In Western Trust, all orthopaedic x-ray are reported by radiologists. For fracture x-rays, initial x-rays and first follow up x-rays are always reported by radiologists. Second or subsequent x-rays are evaluated by clinicians at the fracture clinic.

2.1.22 In relation to x-rays requested from general dental practitioners and orthodontists, all trusts advised the review team that these are not routinely reported by radiologists and are evaluated by dentists and orthodontists.

2.1.23 When x-rays are reported by clinicians, other than radiologists or reporting radiographers, all trusts advised the review team that it is not normal practice for a report to be placed on the trust RIS/PACS. The written evaluation of these x-rays is expected to be recorded in the patients' clinical records.

2.1.24 Belfast Trust has recently carried out audits of recording of plain x-rays evaluations in orthopaedics and fractures and reported high compliance with a record of the x-ray in the notes. Southern Trust has carried out checks that there are written records of x-ray evaluations in patient records in A&E. There have been no formal audits in other trusts as to whether there is compliance with recording in notes.

Delays in reporting

2.1.25 The review team asked all trusts to provide information on any significant delays in the reporting of plain x-rays which occurred over the period from 1 January 2009 until the time of the review.

2.1.26 Belfast Trust advised that there had been no significant reporting delays at Belfast City or Royal hospitals. At the Mater Hospital there had been some delay in the typing (but not reporting) of radiological reports prior to NIPACS going live in December 2010 and actions had been taken to mitigate any risk. Reporting times had increased at Musgrave Park Hospital as the new arrangements were established for NIPACS. The trust advised that there were no current delays at the time of the review visit.

2.1.27 Northern Trust advised that, prior to the introduction of NIPACS in November 2009, there was a delay of up to six weeks in the reporting of plain x-rays. Actions to address this included additional sessions of reporting time and a new arrangement for a Northern Trust Radiologist of the Day. There have been no significant delays since the implementation of NIPACS.

2.1.28 South Eastern Trust informed the review team that no significant reporting delays occurred in 2009 or 2010. There was no delay at the time of the review visit.

2.1.29 Southern Trust advised the review team that a delay had arisen in 2010 in plain x-ray reporting. A major factor leading to the delay was a shortfall in the amount of consultant radiology time available. In April 2010, the trust took a decision, based on clinical concerns, to report on all chest-rays at the time of implementation of NIPACS. This, together with a decision to report on all orthopaedic x-rays at clinics in Daisy Hill, increased the number of x-rays to be reported. To address the delay, the trust employed additional sessions of consultant reporting time and, in 2011, contracted with an independent sector provider to report on x-rays. At the time of the review visit the trust advised that the delay had been addressed but that the reporting capacity gap remains. The trust has a short term contract for 1,000 x-rays per month to be reported by the independent sector provider until there is sufficient internal reporting capacity.

2.1.30 Western Trust advised the review team that a significant delay in plain x-ray reporting took place at Altnagelvin Hospital during the period from 2008 to 2010. The major factor contributing to the delay had been a shortfall in consultant radiologists. In December 2009, there were 7 WTE consultants in post out of an establishment of 13.5 WTE. The trust put in place a programme of actions to tackle the delay, including additional reporting time of trust radiologists and a contract with an independent sector provider. The trust informed the review team that there were no delays in reporting at the time of the visit and an escalation plan is in place to take action to avoid the risk of any future delay occurring.

2.2 Governance Arrangements to Assure Patient Safety and Protection with Regard to Handling and Reporting on Radiological Investigations

2.2.1 The review team found that all trusts have established governance structures for radiological services within their overall trust governance frameworks. There are clear professional lines of responsibility.

2.2.2 There are arrangements in place for reporting incidents relating to radiological services both internally, in line with trusts' systems and externally, in line with statutory and non-statutory reporting arrangements including IR(ME)R to RQIA and Serious Adverse Incident (SAI) reporting to HSC Board.

2.2.3 There are risk management processes in place including local radiological department (or division) and corporate risk registers.

2.2.4 In each trust there are local arrangements for meetings at which risks and incidents relating to radiological services are discussed.

2.2.5 All radiology services hold meetings to discuss discrepancies in reporting in line with RCR guidance. These are usually held on an anonymous basis. The invitation list to meetings varies between trusts with regard to specialist registrars and reporting radiographers. Meetings are minuted and attendance recorded.

2.2.6 All trusts described processes for monitoring of reporting times for plain x-rays. Trusts advised that the introduction of NIPACS has greatly enhanced monitoring processes as it is now possible to see, on a daily basis, work lists of all x-rays for which reports are outstanding.

2.2.7 In all trusts radiologists participate in multidisciplinary meetings on a regular basis sometimes using video-conferencing facilities, depending on location.

2.2.8 Trusts described arrangements for involvement in clinical audit. Examples of recent audits include:

- Belfast Trust has carried out audits of the roles of radiographers in reporting x-rays and on compliance with documentation in orthopaedics and fractures.
- Northern Trust has audited reporting turnaround times, red flag reporting for cancer patients and radiographer reporting.
- South Eastern Trust clinical audits include x-ray quality in paediatric chest x-rays and an audit of justification for X-ray requests.
- Southern Trust, through a trust wide Radiology Clinical Network, has carried out an audit of the appropriateness of classification of urgency status by GPs on referral forms.
- Western Trust has carried out audits of chest x-rays and hip x-rays in children.

2.2.9 All trusts have set out their arrangements for the delegation of responsibility for the evaluation of plain x-rays by non-radiologists within their employers' procedures (Procedure J) as required by IR(ME)R.

2.2.10 The review team asked for details as to whether there were written agreements with clinical departments, or with individual clinicians other than radiologists, for them undertaking the role of evaluation of, and providing a written report on, plain x-rays. Trusts advised that there had been agreements in the past but recent written agreements were not in place.

2.3 Arrangements for Communication of the Reports of X-rays to Patients and Practitioners

2.3.1 Trusts advised the review team that patients are informed verbally when attending radiology departments as to how and when they will receive the results of their x-ray examination. The Northern Trust has developed a leaflet “Waiting on the results of an X-ray scan?” to give to patients, explaining the process. The South Eastern Trust is standardising appointment letters to contain information as to how patients should access test results. The Southern Trust has developed written guidelines for radiology staff on informing patients about results. Posters are displayed in Southern Trust departments which are updated weekly as to the current timeframe for receiving results.

2.3.2 For all radiology departments linked to NIPACS there is the capacity to send results electronically to GPs and this is now the main method of distribution of results. In the Belfast Trust GPs are currently being contacted to confirm agreement to electronic only reporting. At the Belfast City Hospital reports are only sent in paper form but the trust is working with the Business Services Organisation (BSO) to introduce electronic reporting.

2.3.3 Trusts advised the review team that, although the results of radiological investigations can now be accessed on PACS at ward level across all hospitals, the most common method of distributing routine results is still to print paper copies and to send them through the internal mail to the referring clinician.

2.3.4 A number of clinicians, in some hospitals, now access their results on-line by local agreement. They can have their own individual work lists set up to facilitate this approach.

2.3.5 Trusts described their local systems for taking action if a radiologist identifies a suspected cancer or other unexpected finding when reporting on a plain x-ray. There are some variations in these systems and in how the facilities on NIPACS are being utilised to support them. Suspected cancers are subject to red flag systems with local arrangements for follow up including sending messages electronically, or by fax or telephone, to cancer trackers.

2.3.6 All trusts put steps in place to take forward the implementation of NPSA Safer Practice Notice 16 on Early Identification of Failure to Act on Radiology Reports. The notice was circulated and actioned in advance of the roll out of NIPACS which has created the potential to build in further safeguarding mechanisms.

2.3.7 Trusts advised the review team that in relation to the RCR publication Standards for the Communication of Critical, Urgent and Unexpected Findings (August 2008), there are arrangements in place for the

reporting radiologists to inform the referrer. This can include direct contact by telephone or email. At present NIPACS does not receive a feedback record that such reports have been read by an appropriate clinician. South Eastern Trust drew attention to the need to implement a results acknowledgement system to enhance assurance that reports have been read and to facilitate audit of this process.

Section 3: Conclusions and Recommendations

3.1 Conclusions

3.1.1 The focus of Phase 1 of this review, in keeping with the terms of reference, has been on the current systems and arrangements in trusts for the handling and reporting of plain x-rays. At the time of the review visits, the RQIA review team was advised by trusts that there were no significant delays in the reporting of plain x-rays. The review team found no evidence of issues requiring immediate action to protect patient safety.

3.1.2 Having considered the information provided by all trusts, the review team recommends that the focus of Phase 2 of this review should include an assessment of the circumstances leading to delays in the reporting of x-rays in the Southern Trust and Western Trust and the actions taken to address those delays.

3.1.3 The review team found that all trusts have established governance systems for radiology services within their corporate governance frameworks. There are arrangements in place for incident reporting, risk management, clinical audit and consideration of discrepancies in x-ray reporting.

3.1.4 The review team has been advised by trusts that there is a capacity gap in available radiological consultant staffing to report on all plain x-rays in keeping with RCR best practice guidance. Trusts are taking a range of actions to address this gap, including funding additional sessions of trust radiology staff and using independent sector providers. Some trusts have experienced great difficulty in recruitment to vacant consultant radiologist posts. Against this background, the review team recommends that a new workforce strategy for radiology should be developed for Northern Ireland.

3.1.5 All trusts have arrangements in place for the reporting of plain x-rays by non-radiologists in defined areas. The nature and level of this reporting does differ between trusts. The RCR has recently developed a set of standards which apply to this situation (Appendix A). The review team recommends that the DHSSPS review these standards to consider adopting them for application across Northern Ireland.

3.1.6 The review team has been advised by trusts that there are no recent written agreements with non-radiological clinical departments or individual clinicians in relation to the delegation of responsibility for reporting on plain x-rays. The review team recommends that these should be put in place and that audit programmes are established to

provide assurance that there are written records of evaluations of these x-rays, which is a requirement under IR(ME)R.

3.1.7 The review team was informed of differences in reporting arrangements for orthopaedic and fracture services across Northern Ireland. The reporting arrangements in relation to the MPROS service were based on the previous model of radiology provision through which x-rays were taken at peripheral hospitals and then the hard copy films were physically taken back by clinicians from MPROS to Musgrave Park. With the development of NIPACS, all MPROS x-rays are now available electronically at all sites. As this service involves several trusts, the review team recommends that a regional agreement is put in place as to reporting arrangements. Possible options for recording a report on these x-rays on NIPACS should be explored.

3.1.8 During visits to trusts it was clear to the review team that the implementation of NIPACS is having a major positive impact on the provision of radiological services across Northern Ireland. Following the full integration of the PACS at Belfast City and Royal Victoria hospitals with NIPACS, all clinicians will be able to access x-rays and reports from across Northern Ireland in a seamless way. The review team recommends that a firm date is set for the integration of PACS at the Belfast City and Royal Victoria hospitals with NIPACS.

3.1.9 The development of NIPACS provides the opportunity to develop new approaches to radiology provision. The Northern Trust has already moved to having a single integrated radiology service with shared reporting of plain x-rays across the trust. The Southern Trust has also introduced communal reporting lists for plain x-rays. The review team recommends that other trusts should consider moving to communal working lists for plain x-rays across their trusts.

3.1.10 The review team considers that there would be additional benefits in moving to Northern Ireland wide (across trust) reporting lists for plain x-rays. This approach would utilise the major advantages in Northern Ireland of having both NIPACS and a single Unique Patient and Client Identifier. The arguments in favour of introducing communal work lists for unreported x-rays include:

- optimal utilisation of available radiologist reporting time across hospitals in the current situation where there have been identified capacity gaps
- ensuring equity in plain x-ray reporting times across hospitals and trusts

3.1.11 When considering the introduction of trust-wide or Northern Ireland-wide communal reporting lists for plain x-rays the review team suggests that three lists on RIS/PACS are created for unreported x-rays to enhance

prioritisation arrangements for reporting by radiologists or reporting radiographers:

- unreported chest x-rays which should be prioritised for urgent timely reporting
- trauma (A & E) x-rays of the appendicular skeleton[2] which can be reported by radiographers trained to do so – as agreed and audited within their local hospital or by radiologists
- all other unreported x-rays of those which have been designated to receive a report by a radiologist

3.1.12 The review team considers that further benefits of NIPACS could be achieved by taking a Northern Ireland-wide approach to areas such as shared escalation arrangements to avoid delays, provision of specialist opinion and having common approaches to red flagging of urgent reports. The review team recommends that all relevant HSC organisations should consider the establishment of a Northern Ireland-wide Managed Clinical Network for Radiology to agree how to maximise the benefits of an integrated system for radiology.

3.1.13 To realise the full benefits of NIPACS it will be necessary to engage clinicians effectively across different specialities. For example the introduction of paperless reporting is a significant change from current working practices. Implementation will require engagement from clinicians across hospitals to ensure they have confidence in any new arrangements. Clinicians will require training and assistance from PACS administrators on using NIPACS. The review team recommends that all trusts should review their arrangements for engaging and training clinicians across hospitals in taking forward NIPACS.

3.1.14 The review team were advised that, at present there are not arrangements in place to have an electronic feedback of results system within hospitals in Northern Ireland. Such systems can provide a robust, auditable user-friendly means of clinicians receiving the results on the imaging examinations they have requested on their patients. They can have a built-in alert system for the presence of any results to be read, an alert to presence of urgent results, and a means of segregating out, and retaining electronically, the result on patients which need further action. This can remove the need to print any paper reports. The review team understands that it is possible to implement such a system without having a full Electronic Patient Record in place. The review team recommends that the potential for implement electronic feedback of results systems is explored to enhance the functionality of NIPACS across hospitals in Northern Ireland and to facilitate the introduction of paperless reporting.

[2] The appendicular skeleton includes the limbs, collar bones, shoulder blades and the pelvis. The rest of the bones of the body are called the axial skeleton which includes the skull, spinal column, sternum and ribs.

3.1.15 This review is focusing on the handling and reporting of plain x-rays. The overall provision of radiology services is continuing to develop at a rapid pace with new types of complex imaging emerging (which is time-consuming to report) and overall demand for imaging rising. The review team considers that it would be an opportune time for a new strategy for imaging services to be developed for Northern Ireland to ensure a planned approach to service development in a situation where there are major opportunities to capitalise on previous investments made in PACS technology.

3.1.16 The review team found differences in the approaches across trusts to advising patients as to how and when they will receive the results of their x-ray examination. The review team recommends that a common leaflet across Northern Ireland setting out these arrangements would be useful as patients do travel to hospitals outside their home trust for imaging investigations.

3.2 Recommendations

1. DHSSPS should develop a strategy for the future provision of imaging services in Northern Ireland which incorporates a new workforce plan for radiology.

2. All relevant HSC organisations should consider the establishment of a Northern Ireland Managed Clinical Network for radiology.

3. DHSSPS should review, and consider for adoption in Northern Ireland, the new standards from the Royal College of Radiologists for the reporting and interpretation of imaging investigations by medically qualified non-radiologists and teleradiologists (Appendix A).

4. There should be a common framework for evaluating and recording reports on plain x-rays within orthopaedic services across Northern Ireland.

5. All relevant HSC organisations should exploit the full potential of the integrated provision of RIS/PACS across Northern Ireland, including trust-wide (or Northern-Ireland wide) reporting lists for plain x-rays where these are not already in place.

6. A firm date should be agreed for the integration of PACS at the Belfast City and Royal Victoria hospitals with NIPACS.

7. The review team recommends that all trusts should review their arrangements for engaging and training clinicians across hospitals in taking forward NIPACS.

8. All trusts should put in place written agreements with clinical departments in which there are arrangements for the reporting of plain x-rays by non-radiologists or reporting radiographers. There should be signed agreements with each individual clinician in relation to this function.

9. All trusts should establish a programme of planned audits to provide assurance that there are written evaluations of any x-ray examinations, which do not have a report recorded on the trust RIS/PACS.

10. Trusts should establish written escalation procedures (where these are not in place) to reduce the risk of delays in plain x-ray reporting, setting out triggers and actions to be taken at clinician, departmental and organisational level.

11. A common leaflet should be available across Northern Ireland for patients setting out arrangements as to how and when they will receive the results of their x-ray examinations.

12. The review team recommends that the focus of Phase 2 of this review should include an assessment of the circumstances leading to delays in the reporting of x-rays in the Southern Trust during the period from 2010 to early 2011, and in the Western Trust from 2008 to 2010 and the actions taken to address those delays.

Appendix A

Standards and recommendations for the reporting and interpretation of imaging investigations by non-radiologist medically qualified practitioners and teleradiologists

Board of the Faculty of Clinical Radiology
The Royal College of Radiologists

Foreword

Previous standards for the reporting and interpretation of imaging investigations published by The Royal College of Radiologists (RCR) have provided standards for medically qualified doctors who are trained and accredited in radiology and for non-medically qualified role extended practitioners to whom the reporting of specified imaging investigations has been delegated by a radiologist.[1,2]

This publication defines standards and best practice for radiologists, regulatory authorities, hospital managers and individual doctors regarding medically qualified non-radiologists who wish to interpret imaging investigations or who consider 'working impressions' of the same in acute situations. The publication also provides standards that should be considered when imaging investigations are outsourced to teleradiologists employed by off-site teleradiology companies.

The RCR would like to thank its Faculty Board and Patients' Liaison Group for considering these Standards, its Professional Support and Standards Board for developing them and Drs Mark Callaway, Rob Manns, Clive Kay, Paul Allan and Jane Adam for their energy, good advice and major contributions to the project.

These standards apply to all UK countries.

Dr Tony Nicholson
Dean of the Faculty of Clinical Radiology
The Royal College of Radiologists

Introduction

In 2006, The Royal College of Radiologists (RCR) published *Standards for the Reporting and Interpretation of Imaging Investigations*.[1] This provides a useful background and explanation of the relevant issues and should be read in conjunction with this document. The standards set in that publication still apply and though subject to periodic review are likely to do so for many years.

In 2010, the RCR published *Medical image interpretation by radiographers: Guidance for radiologists and healthcare providers*,[2] which explained further the principles of image interpretation and the role of non-medically qualified role extended practitioners in the reporting of imaging investigations.

Neither of these documents dealt specifically with medically qualified doctors who have not trained as radiologists and their role in image interpretation. Communications between the RCR, other disciplines, professional organisations, hospital trusts, regulatory authorities and health departments in all four UK countries, strongly suggests that this lack of clarity must be addressed.

Where imaging investigations require the use of ionising radiation, these standards are informed by *The Ionising Radiation (Medical Exposure) Regulations 2000* (IR(ME)R).[3] The principles underpinning these standards also apply to non-ionising radiation-based imaging investigations.

The General Medical Council's (GMC) position is clear about doctors who wish to practise medicine in the UK.[4] When outsourcing to remote teleradiologists, these standards draw on such GMC statements, and the previous RCR teleradiology publication.[5]

Standards

Standard 1. Every imaging investigation must be reported within an agreed time by an individual qualified to interpret that particular investigation.

When imaging investigations are requested, they are justified on the basis that the result will aid diagnosis and influence patient management. It follows that in all cases the resulting image is reviewed by an individual qualified to do so in a timely manner so that appropriate medical management is undertaken and delayed diagnosis and treatment avoided. The English National Imaging Board has set best practice guidelines for reporting times[6] to which the RCR has given qualified support.[7]

Standard 2. All imaging investigations must be accompanied by a formal permanently recorded written report.

The report forms the permanent record of the interpretation of that imaging investigation on which management decisions are made and must be available as part of the permanent medical record of the relevant individual. It is best practice that this written report is displayed alongside the relevant image on a picture archiving and communications system (PACS) rather than being stored or recorded separately elsewhere. The content of this report should adhere to the standards laid out in *Standards for the Reporting and Interpretation of Imaging Investigations*.[1]

Standard 3. All imaging investigations are best reported by a radiologist.

Radiologists are medically qualified, have undergone a two-year minimum period in postgraduate medicine and surgery and have undergone a further minimum period of five years' postgraduate training in imaging science, theory and interpretation. They are, therefore, the best qualified to provide clinically relevant radiological reports. Other professional groups do not share this depth and breadth of experience and training in clinical imaging. The National Patient Safety Agency has highlighted the need for an integrated system of reporting, centred on radiology and not a fragmented unstructured system relying on variable individual competencies and diligence.[8]

Standard 4. Health boards, commissioners of healthcare and hospital trusts must provide the resource, in terms of numbers of radiologists, IT provision and infrastructure to achieve the above standards.

This follows logically from Standards 1,2 and 3.

The role of medically qualified non-radiologists in image interpretation

UK radiology departments should strive to achieve the above standards. However, while the number of UK radiologists per head of population has increased since 2001, it is recognised that currently there are still fewer UK consultant radiologists than in many other comparable European nations.[9,10] The actual figure varies from centre to centre and from nation to nation but averages 43 per million. As a result, in many healthcare organisations, these standards cannot be achieved at present.

In this setting, the RCR considers that the most appropriate solution is the provision of additional resources or service improvement measures to provide patients with timely reporting or reporting supervision of all imaging investigations by radiologists.

In the interim, IR(MER) 2000[3] provides for medically qualified non-radiologists to interpret imaging investigations relating to their field of expertise, as long as the training of these individuals has included relevant image interpretation, and as long as such individuals agree to make a written record of each investigation which contains their name and status. Such practitioners must work in an environment where

they have access to high-quality image display monitors that allow accurate reporting as per the radiology department reporting environment

The responsibility for ensuring such individuals are sufficiently expert to interpret imaging investigations and agree to record the results of their interpretation rests with the hospital's management and radiology leadership.

Standard 5. Where image interpretation is delegated to non-radiologist medically qualified practitioners, hospitals (through their medical directors) and clinical radiology directors are jointly responsible for ensuring the expertise of the practitioner and obtaining their agreement that they will provide a written record of the result of each investigation they interpret.

Standard 6: All practitioners who interpret imaging investigations must identify their name, status and position when making a written record of an imaging investigation.

In most UK healthcare organisations, PACS is not linked to radiology information systems (RIS) outside radiology departments. Therefore, Standard 2 cannot be complied with where medically qualified non-radiologists have agreed to undertake the task of image interpretation. The recording of results in clinical notes or letters is acceptable under IR(ME)R 2000[3] and is an alternative to RIS–PACS reporting. However, this option makes auditing compliance and discrepancy very expensive and labour intensive. If no audits are carried out, experience has shown that situations develop within organisations where non-radiologists fail to provide a written report**. It** may appear therefore that an imaging investigation has not been viewed if there is no record. Furthermore, when such imaging investigations contain significant findings, there may be very expensive and damaging medico-legal and patient care consequences.

Recommendation 1
To achieve Standard 2, where image interpretation has been delegated to medically qualified non-radiologists, information systems used for report recording outside radiology departments must interface with the hospital's RIS to allow linking of the report and image(s) to support patient care and audit.

Standard 7. There should be regular audit (at least once a year) of unreported imaging investigations.

This must form part of best practice within all radiology departments as an element of a patient safety programme. Such audit will determine whose responsibility it was to record a report for each unreported image and institute appropriate action to minimise the number of unreported examinations. Similarly, if there are delays in reporting of images, this must be remedied.

Interim reports by doctors in training and other non-radiologist consultants

When a patient is seen in outpatients or acutely on the ward or in the emergency department, imaging investigations are often initially seen and interpreted by non-radiologist doctors in training or consultants whose interpretive expertise does not lie specifically in the imaging they have requested. Although radiologists must always be available to give an urgent opinion when required clinically, there will be occasions when others will provide interim reports and a definitive radiologist report may be issued after an interval.[6]

Specialist trainee doctors undergo examination and assessment of skills at regular intervals in their training. This will include elementary but escalating training in relevant image interpretation. It is for the relevant medical Royal Colleges to accredit their trainees and for their employing healthcare organisations to agree their right to consider diagnoses in emergency situations based on imaging and to what level. Such considerations do not constitute the final or authorised report but are a 'working impression' of the examination, which will subsequently be reviewed by a suitably qualified individual who will provide a formal report.

It is for the same healthcare organisations to make sure there are enough consultant radiologists to provide a timely expert written report and for radiology departments to make sure that this can be delivered at all times.

Standard 8. Radiologists must be available to provide definitive reports on urgent imaging at all times. Similarly consultant radiologists should be available to provide their expert opinion on imaging investigations at all times.

Previous RCR standards publications[1,2] have explained the role of non-medically qualified role extended practitioners in this regard. Where radiologists have delegated image interpretation to this group, the same radiologists are responsible for the supervision and regular independent audit of reporting and recording.

Use of teleradiology

To comply with Standards 1 to 3, healthcare organisations may choose to send imaging investigations to an outside facility for interpretation by radiologists off-site and employed by private teleradiology companies. The RCR does not consider this best practice but understands the pressures many UK radiology departments are working under in delivering a timely reporting service.

Where training departments outsource imaging in this way, the impact that outsourcing will have on training and teaching of trainee radiologists must be considered and assessed. If there is any doubt about the impact on training, they should contact the RCR Department of Specialty Training (Clinical Radiology) for advice.

The RCR has previously published *Standards for the provision of teleradiology within the United Kingdom*.[5] It cannot be overemphasised that in the interests of patient care and safety, when such decisions to outsource are made, hospitals, their medical directors and radiologists must ensure that the hospital employs reporting teleradiologists who have medico-legal responsibility for their image interpretations and written reports and can be held to account in the UK for the quality of their work. Specifically, the RCR considers that such teleradiologists must be individually identifiable, licensed and revalidated by the GMC. The GMC Medical Register states that, 'Doctors must be registered with a licence to practise with the General Medical Council (GMC) to practise medicine in the UK' **(sic)** and 'Doctors work in many different environments. Those who treat patients must be registered with a licence to practise. This applies to all doctors irrespective of whether they practise full time, part time, as a locum, privately or in the NHS, or whether they are employed or self-employed.'[4]

Furthermore, if teleradiologists are not on the GMC Specialist Register, the outsourcing trust will effectively employ doctors who practise medicine on patients in their hospital who cannot be regulated by the Responsible Officer unlike every other doctor employed by the hospital.

Standard 9. Where reporting of imaging investigations is outsourced to off-site radiologists not working in the healthcare facility where the imaging investigations are performed, the healthcare facility management, medical director and radiologists must ensure that the previously published RCR standards[5] are met.

Standard 10. Where reporting of imaging investigations is outsourced to off-site radiologists not working in the healthcare facility where the imaging investigations are performed, the healthcare facility management, medical director and radiologists must ensure the reporting teleradiologists fulfil the GMC requirements to practise medicine in the UK.

In addition, outsourcing radiology departments should make sure that patients know who their imaging investigation will be interpreted by and obtain their agreement that their image can be outsourced. The use of teleradiology services must also be clearly signposted by notices in the department, with leaflets providing further information, especially in waiting areas, so that patients, carers and advocates can query the reason, or voice any concerns to the radiographic staff at the time of the investigation.

Standard 11. Patients or their carers/advocates must be made aware when images are to be interpreted off-site by an outsourced provider and assurances obtained that this is acceptable

Further recommendations

The RCR recommends that future commissioners of healthcare promote the development and use of local imaging networks which involve local hospital clusters and integrated IT and teleradiology solutions. This may involve partnership with teleradiology companies. In this way, larger groups of specialist radiologists with established effective working relationships with their local hospitals can be created and utilised to provide improved and sustainable specialist radiology reporting services across several hospitals. Education and training of future specialist radiologists would be best served in this way.

Recommendation 2
All future PACS procurements should ensure functionality is provided for efficient interhospital transfer of images and reports – fully utilising common data sharing protocols and standards such as XDSi and DICOM.

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The Regulation and Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
BELFAST
BT1 3BT

Tel: (028) 9051 7500
Fax: (028) 9051 7501
Email: info@rqia.org.uk
Web: www.rqia.org.uk