Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Notice 27 RQIA of 2023

Date of Notice: 28th November 2023

Note: An addendum to this witness statement was received by the Inquiry on 16 Feb 2024 and is located at WIT-106891 to WIT-107046. A further addendum was received on 19 Feb 2024 and is located at WIT-107047 to WIT-107048.
Annotated by the Urology Services Inquiry.

Witness Statement of: Briege Donaghy

I, Briege Donaghy, will say as follows: -

Introduction

1. This statement is made on behalf of the Regulation and Quality Improvement Authority ("RQIA") in response to a request for evidence by the Inquiry Panel for the purposes of the Urology Public Inquiry.

2. I provide this statement in my role as Chief Executive Officer of RQIA, a position that I have held since July 2021 when I was appointed by the Authority, which I explain further below, with the approval of the Department of Health ("the Department"). I lead RQIA's Executive Management Team and I am responsible to the Authority for the general exercise of its functions.

3. This is my first statement to the Inquiry.

4. By letter of 28 November 2023, the Inquiry required RQIA to provide a statement to assist the Inquiry.

5. RQIA therefore provides this statement to inform the Inquiry in relation to the topics set out in the correspondence of 28 November 2023. I have been supported in providing this statement by current employees of RQIA, including RQIA's Director of Hospital Services, Independent Healthcare, Audit and Reviews (the Directorate within which sits our Inspection and Review Teams that focus on healthcare services). Where I provide information in this statement it is a product of my own knowledge or the product of information provided to me by colleagues who I understand are informed of the matters which are detailed.

136. In particular, RQIA will develop a 'safety culture' assessment tool to identify, encourage and support 'openness' and 'learning'. This will enable robust report back of findings in this area to HSC organisations to assist them in taking action to improve.

Conclusion

Under the current legislation and with constrained resources it is important that RQIA focus on key priorities. Here, reform of the legislation to enable a more efficient and effective intelligence driven and risk based approach, with a better balance of attention between the independent and the statutory sectors, and increased flexibility to address new ways of service delivery and new sectors of health and social care, is essential to improve the protection and safety of the public.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed:

Date: 15th January 2024

Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Notice 27 RQIA of 2023
Date of Notice: 28th November 2023

Second Witness Statement of: Briege Donaghy

I, Briege Donaghy, will say as follows: -

Introduction

1. This is my second statement to the Urology Services Inquiry, which is intended to address several discrete issues.

The RQIA board/Authority during Covid

2. At paragraphs 10 and 11 of my initial statement to the Inquiry I discuss the membership of RQIA. I wish to set out, in some further detail, the structure of RQIA and issues which it experienced in 2020.

3. The Chief Executive position in RQIA was held by Olive MacLeod from July 2016 up until the week commencing 23 March 2020; at which point she was redeployed to the Public Health Agency (PHA) and officially left RQIA on 31 August 2020. Mr Dermot Parsons became Interim Chief Executive from late March 2020 to 31 July 2020, before he had a period of sickness absence and then officially left RQIA on 31 December 2021. Dr Tony Stevens was appointed as Interim Chief Executive by the Authority with approval from the Department, from 1 September 2020 to 30 June 2021, before I was appointed to the role of Chief Executive, from 1 July 2021 until present.

4. Under paragraph 7 of Schedule 1 of the 2003 Order, the Chief Executive is an employee of and appointed by the Authority, and is responsibile to it for the general exercise of its functions in accordance with a scheme of delegation set out in the Authority's Standing Orders. This appointment is subject to the approval of the

care and treatment provided, does not lead to any clearly and publicly recorded outcome". By this comment, I mean that RQIA is concerned that there is no public record of achievement or outcome of inspections or reviews once submitted to the Department.

20. I would like to clarify paragraph 89 of my original statement regarding the Hospital Inspection Programme. My original statement comments *"None are outstanding insofar as recommendations are concerned"*. On reflection, the question was about any outstanding 'reports' of the Hospital Inspection Programme. Therefore, this sentence should read *"None are outstanding insofar as inspection reports are concerned"*. I apologise for any confusion on this point.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed:

Date: 16th February 2024

Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Notice 27 RQIA of 2023

Date of Notice: 28th November 2023

Third Witness Statement of: Briege Donaghy

I, Briege Donaghy, will say as follows: -

Introduction

1. This is my third statement to the Urology Services Inquiry, which is intended to address several discrete issues.

The Right Touch paper

2. At paragraphs 86 and 87 of my first statement to the Inquiry I referred to the Department's paper 'The Right Touch'. This document was received from the Inquiry via egress on **Friday 16th February 2024**. Within it, Annex A records a log of engagement activity and RQIA is referred to therein. On receipt of this information a further search was undertaken around the first date in the log, 3 May 2017, referring to a meeting with RQIA on this date. Email corresppndence has been located for 4 and 5 May 2017, indicating such a meeting was held on 3 May 2017. It was noted that the subject matter was referred to as 'Review of Regulation'. Previous searches had sought to locate information on 'The Right Touch' and had failed to locate this material. Further searches confirm RQIA received a Discusson Paper from the Department dated June 2017, this too is referred to in the Annex A log. In addition, an email dated 17 April 2018, also listed in the log, remarking 'update on progress sent to RQIA', was located with a progress document attached. The subject matter referred to as 'Review of the 2003 Order and policy'.

3. As a result of the above, I can now confirm that the information referred to in the Annex A of 'The Right Touch' is accurate in terms of engagement or communication with RQIA on this matter.

Urology Services Inquiry

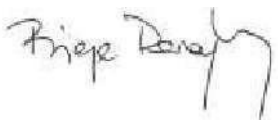
4. This information was not known to me prior to seeing 'The Right Touch' paper, despite searches for evidence of this in electronic archives. I had, in preparing my first statement to the Inquiry, spoken with Senior RQIA Executive Team colleagues, who had no knowledge on the matter. However, I have noted that the membership of the RQIA Executive Team during the time of this engagement, as per Annex A log, being late 2015 to early 2019, has entirely changed, with no previous EMT members currently members of the RQIA EMT. The Authority membership also changed in its entirely from June 2020. This points to challenges of retaining corporate memory during periods of organisational change.

5. Apologies to the Inquiry for the inaccuracy in my first statement regarding this matter and I trust this updated information is helpful in this regard.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed:



Date: 19th February 2024

extend the appointment of) an RQIA Interim Chief Executive without any communication with or involvement of the Authority; and

c. By excluding the Authority from involvement in any of these key decisions, the belief that the role of the Authority had been diluted and compromised.

9. On the day of the final Members' resignations, 18 June 2020, Christine Collins MBE was appointed as Interim Chair by the Minister, Robin Swann. An urgent Public Appointment process to enable the appointment of new Authority Members was then developed, agreed with the Office of the Commissioner for Public Appointments for Northern Ireland and put into effect. In the interim, two senior Department officials, whose roles were removed from those of the RQIA, so minimising any conflict of interest, were appointed as Temporary Authority Members from 14 August 2020 to enable the conduct of essential Authority business.

10. An Interim Six Member Authority, comprising individuals with legal, financial, medical, nursing, social work and administration/change management expertise, was appointed on 30th October 2020 for an initial term of 1 year. There was, therefore, a period of three months during the pandemic where the capacity of the Authority was diminished.

11. The Interim Authority appointed on 30 October 2020 was subsequently extended and continued in place until 31 January 2023, when it was replaced by a substantive 8 Member Authority following a Public Appointments process run in accordance with normal rules. The substantive Chair position was filled by Christine Collins MBE following a normal Public Appointments process, with effect from 1 October 2022.

12. As set out in the Nicholl Report, relations between the Authority (the RQIA Chair and Members), the RQIA Executive Management Team, and the Department had been dysfunctional for some time when the pandemic commenced. In this context, the resignation of the Acting Chair and Members, coupled with the other changes of senior personnel through redeployment, meant that RQIA did not have the full complement of strategic leadership and oversight required to effectively manage the organisation's "normal business" at that time (e.g. implementation of Internal Audit recommendations; financial control; oversight of performance management) and, clearly, a depleted Authority and senior management team will be affected by the impact and disruption

Department. The Chief Executive is also appointed by the Permanent Secretary of the Department as Accounting Officer for the RQIA and reports to the Permanent Secretary in respect of those functions.

5. In addition to Olive Macleod's redeployment in March 2020, RQIA experienced a loss of a number of other senior staff, either through temporary or permanent redeployment to places such as the Department or the PHA, following a request from the Department requiring RQIA to identify its clinical and social care staff. By this stage, the Department had also directed RQIA to suspend its inspections of registered services, as is referred to at paragraph 89 of my initial statement to the Inquiry. In April 2020, the then Interim Chief Executive developed and adopted, with the support of Assistant Directors, an Interim Management Structure.

6. RQIA is a relatively small organisation. The loss of experience of senior staff caused by these redeployments could not be replaced. Normal recruitment processes could not operate during the pandemic itself. Furthermore, the postholders retained their substantive posts on the understanding that they would return to these following redeployment. These redeployments had a material impact on the availability of senior management within RQIA, hence the need for an Interim Management Structure.

7. On 17 and 18 June 2020, the then-Acting Chair of RQIA, Mary McColgan and six Authority Members, resigned with immediate effect. Two other Members had resigned the previous week to take up other posts. These circumstances left the RQIA without an Authority and without any Members.

8. In their letters of resignation to the Minister, the ex-Members of the RQIA set out their reasons for stepping down. These reasons included the following (which are set out within the Nicholl Report):

    a. Concern at the lack of effort made by the Department to consult or engage with the Authority prior to making key decisions affecting the core purpose and statutory remit of the RQIA;

    b. Particular concern over the decision by the Department at the end of March 2020 to (1) redeploy the RQIA Chief Executive to the PHA and (2) appoint (and

The Regulation and Quality Improvement Authority

Review of Clinical and Social Care Governance arrangements in Health and Social Care Trusts in Northern Ireland

Overview Report 2008

informing and improving health and social care
www.rqia.org.uk

The Regulation and Quality Improvement Authority

Executive Summary

Introduction

The Health and Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 places a statutory duty of quality on HSC Boards and Trusts.

The Quality Standards for Health and Social Care, published in March 2006 underpin the duty of quality and provide a measure against which quality of services provided in health and social care can be assessed.

The five quality themes are:
- Corporate leadership and accountability of organisations
- Safe and effective care
- Accessible, flexible and responsive services
- Promoting, protecting and improving health and social well-being
- Effective communication and information.

This overview report provides a summary of clinical and social care governance reviews carried out by the RQIA of the six HSC Trusts, between March and April 2008.

Methodology

The reviews assessed the achievement of HSC Trusts against three themes of the quality standards
- theme 3 - Accessible, flexible and responsive services
- theme 4 - Promoting, protecting and improving health and social well-being
- theme 5 - Effective communication and information.

There are 38 criteria associated with these three themes and the RQIA decided to undertake detailed reviews focusing on seven criteria, which would best provide an assurance of the standard of service user and patient engagement.

A self-assessment proforma was sent to the six HSC Trusts which incorporated all 38 criteria as well as some in depth questions, to fully examine the Trust's position. The Trusts were also able to self assess their own performance using a five point scale where "1" represented "unlikely to be achieved" and "5" represented "fully achieved"

On receipt of the completed self assessment, an analysis was carried out by the RQIA and an analysis report forwarded to review team members.

The RQIA then carried out site visits to Trusts. These visits assessed each Trust's achievements against the quality standards, particularly emphasising the criteria to be explored in more detail.

Finally the RQIA produced a report for each Trust based on the Trust's self declaration, written submissions to the RQIA as well as input from members of the review teams.

8.3b The organisation has an effective information strategy and communication strategy, appropriate to the needs of the public, service users and carers, staff and the size, functions and complexity of the organisation.

8.3c The organisation has effective and integrated information technology and information systems which support and enhance the quality and safety of care and provision of services.

8.3d The organisation has systems and processes in place to ensure that urgent communications, safety alerts and notices, standards and good practice guidance are made available in a timely manner to relevant staff and partner organisations; these are monitored to ensure effectiveness.

Effective communication and information strategies are important to the smooth running of all organisations. There is an explicit commitment by Trusts to develop relevant strategies and all are at varying stages in this process in terms of draft documents and action plans.

All Trusts are developing, or already have in place a Safety Alert Broadcast System (SABS) and they also comply with guidance issued by the Northern Ireland Adverse Incident Centre. The Northern Trust uses a manual system for communication but is planning to introduce an electronic system in this current financial year.

Recommendation 14:

The RQIA recommends that HSC Trusts develop systems and strategies to promote effective communication and information sharing.

THE RIGHT TOUCH

A New Approach to Regulating Health and Social Care in Northern Ireland

June 2020

make them. **This paper concerns itself exclusively with *system regulation*.**

Strategic Context

1.7 This policy does not exist in a vacuum; it is only one of many policies and strategies linked to the Department's aim to improve the health and wellbeing of the people of Northern Ireland. As such it needs to support other initiatives which seek to deliver on this aim and the Executive's wider strategic goals contained in the *Outcomes Delivery Plan*[6].

1.8 The then Health Minister, Michelle O'Neill MLA, set out a vision for the future provision of health and social care[7] in which she stated that a stronger link needs to be made between regulation and quality improvement. This point has been echoed by service users/carers and providers during engagement events in the pre-drafting phase of this policy.

Background

1.9 In 2001, the Department produced a consultation paper entitled *Best Practice, Best Care*[8] in which it set out 3 key proposals to support the provision of a fast, effective and high quality health service. These were:

- Setting standards – improving services and practices
- Delivering services – ensuring local accountability; and
- Improving monitoring and regulation of the services.

1.10 This resulted in the establishment of arrangements for the independent monitoring of health and social care services; a wide range of minimum care standards and a patient-focused Service Frameworks Programme. All of which contributed to improvements in quality and standardisation of services across the HSC.

1.11 Underpinning these developments was the HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 (hereafter referred to as the 2003 Order). The Order also

[6] Outcomes Delivery Plan 2018-19, The Executive Office, June 2018
[7] Health and Wellbeing 2026 – Delivering Together, DoH, 2016
[8] Best Practice, Best Care – A framework for setting standards, delivering services and improving monitoring and regulation in the HPSS – A Consultation Paper, DHSSPS, April 2001.

introduced a statutory **duty of quality**, which was placed on all HSC bodies.

1.12 The 2003 Order also established Regulation and Quality Improvement Authority (RQIA) as the health and social care *systems* regulator for Northern Ireland. RQIA came into being in 2005 and has been operating as the Regulator ever since.

1.13 A further development to reinforce and strengthen the quality and safety agenda was the launch of the Department's quality strategy in 2011 called Quality 2020[9] (Q2020). It defined quality for health and social care in terms of three components:

- Safe
- Effective
- Person-centred

1.14 Q2020 is now embedded in the clinical and social care governance (CSCG) arrangements throughout the HSC and underpins all work undertaken to monitor and improve quality of health and social care services across the HSC.

1.15 The Department continues to be committed to improving the quality and safety of services and outcomes for patients through the co-production and co-design of services with service users/carers; the development of the HSC QI[10] initiative, and through ongoing work by the Regulator.

Policy Objective

1.16 The Regulation of services that may impact on the health and well-being of the population needs to be effective and appropriate in assuring the public that they are safe and of a high standard, and that providers continue to improve the quality of that service.

1.17 To measure the effectiveness of this policy a set of indicators will need to be developed. Views on what these indicators should be will form part of the consultation process for this policy.

[9] Quality 2020 - A 10 Year Strategy to Protect and Improve Quality in Health and Social Care in Northern Ireland, November 2011.
[10] https://qi.hscni.net/

SECTION 4 – WHAT DO WE NEED TO REGULATE?

4.1 It is important that to which services this policy applies to be clear and understood. The issue to define the scope of the policy was wrestled with during the pre-drafting phase. Was the policy simply to apply to those providers delivering a health and social care need? This would be convenient but would leave many services, treatments and interventions outside the scope of regulation.

Statutory Health and Social Care

4.2 Any policy aiming to provide assurances to the public of the safety and quality of health and social care should include the work of the statutory agencies e.g. the HSC Trusts, NI Blood Transfusion Service, HSC Board/Public Health Agency etc. These bodies are not currently regulated by RQIA.

Providers Currently Regulated

4.3 Those services and providers currently regulated by RQIA will continue to be covered within this policy. All provider types currently regulated provide a health and social care need and the public expectation is that they must provide a level of assurance that only regulation can satisfy. A list of providers currently regulated by RQIA is given at paragraph 2.7 above.

New and Emerging Treatments/Procedures

4.4 Since 2003, when the Order was made, there has been a significant increase in the range of services, treatments and procedures available to the general public. Many of these could not have been foreseen by those drafting the legislation, such as injecting dermal fillers or Botox® and the use of private paramedics and independent ambulances at sports or concert venues.

4.5 There has also been an increase in the availability of counselling and psychotherapy services and charitable organisations offering help and support to vulnerable people which may include medical interventions (e.g. for excessive alcohol or drug use).

5.11 ***Licensing*** schemes are regularly used in other industries/business sectors to allow organisations to trade or provide services while providing an assurance about quality and safety.

5.12 Another method of providing assurance involves ***Accreditation***. This allows providers of services to show how they meet certain standards which are either nationally or internationally recognised. For example, farmers producing food which is traceable, safe and farmed with care can apply for the Assured Food Standards accreditation and display their Red Tractor logo on their goods. Blue Flag beaches show that the beach is safe, water quality is good and certain amenities are present.

5.13 There are a number of such forms of accreditation which could apply to providers of health and social care services which are already established and have national recognition. It would be up to the Regulator to determine which accreditation schemes are appropriate for any given provider type.

5.14 ***Self-assessment*** might also provide acceptable assurance for services identified as posing a low level of risk.

5.15 The Regulator would be given the powers/authority to determine the levels of risk posed by providers and the appropriate level of assurance required to mitigate the identified risks.

Assessing the Risks

5.16 For Right Touch Regulation to be successful we need a system of risk assessment to ensure that the right level of regulation is put in place for each provider type. As the PSA puts it; "Describing regulation as risk-based in the absence of a proper evaluation of risk is, in our view, misleading and can undermine wider confidence and trust in regulation."[20]

5.17 And just to be clear…"**when we talk about risk, we mean the risk of harm to the public that the Regulator is there to reduce**".[20] It is important to take time to reflect that the Regulator's role is not to eliminate all risks – that is not feasible nor is it to provide safe care. The one with the primary responsibility to deliver a safe and effective service is the individual providing the service and, in

[20] Right Touch Regulation (revised), Professional Standards Authority, October 2015

turn, their employer who should be supporting the practitioner through the provision of appropriate facilities, tools/equipment and training.

5.18 By its very nature regulation can only provide a snap-shot of the standards of care or service provided at a point in time. While this can provide us with some level of assurance it does not provide us with a guarantee that the service is acceptable around the clock. The Regulator's focus ought to be on ensuring that the risk of harm is properly identified and that appropriate risk management is undertaken to deal with those risks.

5.19 It also needs to be said and noted that no health and social care intervention is risk-free. Our health and social care system features many checks and balances to mitigate the identified risks. Nevertheless, risk still exists and a full and proper assessment of the risks will need to be undertaken by the Regulator so that the public can be assured that the provision of services is as safe as can be expected.

5.20 The process of assessing the risks posed by each provider-type will be undertaken by RQIA after this policy has been agreed and adopted. The consequences of this decision could mean that rather than an inspection-based process of regulation, some provider-types currently regulated by RQIA will use another system – such as licensing or accreditation. Other providers, who are not currently regulated in Northern Ireland may come into the regulatory framework and will need to be registered and regulated by RQIA. These decisions will be taken in Phase 2 of the policy development after we have the principles and scope of the policy agreed. An example of the 'Decision Tree' used for Right Touch Regulation is included at **Appendix 3**.

5.21 A key component of assessing and managing risk is the collection of relevant, timely and accurate data. This intelligence gathering function requires a robust system to be in place which can validate the data and process it in a meaningful way so that the risks can then be quantified and qualified.

5.22 RQIA has, within the past few years, begun to develop their intelligence gathering and analysis capability. Data collected from several sources is now used to assist inspectors to identify

situations in care homes where their intervention might help and support the provider before a problem occurs. Further investment and development would be required to ensure that Right Touch Regulation is successful across all the provider types to be registered and regulated by RQIA.

5.23 The sharing of intelligence and information across HSC organisations, the independent sector, professional regulators and other government agencies with RQIA will need to be explored and where possible protocols put in place to allow the regulator to paint an accurate picture of a service or provider. Such protocols already exist between RQIA and some professional regulators. It would be envisaged that by sharing information and intelligence regulators will be able to intervene sooner and avoid duplication of effort – both for the regulator and for the providers. The principle we want to achieve here is "collect once, use often".

5.24 The Regulator would also use information gathered from service users/carers/public to assist in getting a more accurate picture of the care or service provided.

Quality Improvement

5.25 It is important that it is clear what is meant by the term 'quality improvement'. "There is no single definition but it is generally understood to be a systematic approach based on specific methodologies for improving care"[21]. Quality improvement is not a one-off fix but a continual process requiring a long-term commitment. It is driven from within the organisation's workforce rather than something "imposed" from above.

5.26 Brennan[22] warns that if not carefully done regulation can have the effect of stifling creativity and forces providers to concentrate too much effort on meeting outcome measurements imposed by the Regulator. There is a balance to be struck. Nevertheless, the consensus of opinion is that there is a role to be played by regulators in promoting quality improvement.

[21] Quality Improvement in mental health, The King's Fund, July 2017
[22] Brennan, Troyen A., The Role of Regulation in Quality Improvement. Milbank Quarterly, Vol. 76, P. 709, 1998

more strategic level. For example, on considering a Trust's fulfilment of its statutory duty of quality, using RQIA's functions under Article 35(1)(a). This provision states:

> *"the function of conducting reviews of, and making reports on, arrangements by statutory bodies for the purpose of monitoring and improving the quality of the health and social care for which they have responsibility".*

131. However, in the absence of additional resources, this activity would have to replace the current, operationally focussed Hospital Inspection Programme.

132. The Authority acknowledge that, if it were resourced appropriately, it could provide much more extensive examination of HSC Trust governance and strategic management arrangements. In the current instance, scrutiny and reporting on Trust governance arrangements might have identified issues.

133. In addition, a requirement for private medical (including surgical) practices to register with RQIA might have identified issues within the practice of this Doctor; such registration would have facilitated consideration of the need for any subsequent mitigation measures. Again, adequate resourcing is required to enable RQIA to carry out this role.

134. The Authority considers there is a pressing need for a more joined-up approach between regulators in Northern Ireland. RQIA are planning to commence an 'Emerging Concerns' protocol with service regulators, including GMC, from spring 2024. This is about working together to better optimise the use of intelligence, leading to improved identification of key issues, and enabling each organisation to take appropriate steps to explore and act on these through their different roles.

135. There is also need to encourage and support a culture of openness, focussed on patient safety. Staff must feel safe to 'speak up' when they are concerned about issues, without fear. Patients' and families' experiences must be heard; and regarded as a valuable and trusted source of, often early, insight into quality and safety issues. RQIA will play its part in this by facilitating discussion across HSC organisations about the shared responsibility to develop a culture that promotes and encourages 'speak up', being open, and encouraging action, learning and improvement. RQIA hosted an event involving patients and their families, senior leaders and clinicians from across the HSC in November 2023 to explore how the responsibility to do can be shared, and action taken forward. Further events on this theme are planned in coming months.