Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Notice 50 of 2022

Date of Notice: 4 May 2022

Witness Statement of: Peter May, Permanent Secretary

Statement of Truth

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

Signed: __ Peter May ______________________________

Date: ___18/08/22_____________________

Received from Peter May on 19/08/2022. Annotated by the Urology Services Inquiry.

(a). review of longer term exclusions (see table on pages 19-20, and paragraphs 30 and 31 on page 19, of MHPS);

(b). the recruitment and selection of appeals panels in clinical performance cases (see Annex A of MHPS on page 35); and

(c). provision of process advice to smaller HPSS (now Health and Social Care) organisations, where necessary (pages 41-42 of MHPS).

197. While there has been significant interaction between the two organisations since the issues involved were first brought to the Department's attention, the limited role of the Department with respect to its involvement in individual MHPS processes, coupled with the clear responsibility placed upon the Chief Executive of an organisation with respect to ensuring MHPS procedures are followed, mean that Departmental officials do not have a sufficiently detailed knowledge of the process in this individual case. No-one in the Department, myself included, would feel confident in any assessment we would make of the effectiveness of how MHPS was implemented and applied in this particular case. Further, the Department would not wish to pre-empt or influence the consideration of the Panel in this important aspect of the Inquiry.

198. I have detailed above my belief that a substantive review, in general terms, of the MHPS policy should be undertaken by the Department as a matter of priority. That will be put as an option to the Minister for very early consideration. I am committed to sharing further information emerging from any review with the Inquiry as it progresses, should that assist your deliberations.

Received from Peter May on 19/08/2022. Annotated by the Urology Services Inquiry.

DEPARTMENT OF HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY

FRAMEWORK DOCUMENT

Received from DOH on 08/12/2021. Annotated by the Urology Services Inquiry

iv HSC Trusts;

v Special Agencies (i.e. Northern Ireland Blood Transfusion Service, Northern Ireland Medical and Dental Training Agency and Northern Ireland Guardian ad Litem Agency);

vi Patient and Client Council; and

vii Regulation and Quality Improvement Authority

1.7. The focus of the Framework Document is the health and social care system in Northern Ireland and, although not covered by the Reform Act, the Northern Ireland Practice and Education Council and the Northern Ireland Social Care Council are included in the document for completeness. The Northern Ireland Fire and Rescue Service is outside the scope of the Framework Document.

1.8. All of the HSC bodies referred to above remain ultimately accountable to the Department for the discharge of the functions set out in their founding legislation. The changes introduced by the Reform Act augment, but do not detract from, that fundamental accountability.

1.9. Independent family practitioners also play a significant role in the delivery of health and social care. Health and social care objectives can only be achieved with the engagement of a high quality primary care sector that is accessible, accountable and focused on the needs of patients, clients and carers.

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(Northern Ireland) 2009, has a range of functions that can be summarised under three broad headings.

2.6. **Commissioning** – this is the process of securing the provision of health and social care and other related interventions that is organised around a "commissioning cycle" from assessment of need, strategic planning, priority setting and resource acquisition, to addressing need by agreeing with providers the delivery of appropriate services, monitoring delivery to ensure that it meets established safety and quality standards, and evaluating the impact and feeding back into a new baseline position in terms of how needs have changed. The discharge of this function and the HSCB"s relationship with the PHA are set out in sections three and four.

2.7. **Performance management and service improvement** – this is a process of developing a culture of continuous improvement in the interests of patients, clients and carers by monitoring health and social care performance against relevant objectives, targets and standards, promptly and effectively addressing poor performance through appropriate interventions, service development and, where necessary, the application of sanctions and identifying and promulgating best practice. Working with the PHA, the HSCB has an important role to play in providing professional leadership to the HSC.

2.8. **Resource management** – this is a process of ensuring the best possible use of the resources of the health and social care system, both in terms of quality accessible services for users and value for money for the taxpayer.

2.9. The HSCB is required by the Reform Act to establish five committees, known as Local Commissioning Groups (LCGs), each focusing on the planning and resourcing of health and social care services to meet the needs of its local population. LCGs are co-terminus with the five HSC Trusts.

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2.16. The six HSC Trusts are established to provide goods and services for the purposes of health and social care and, with the exception of the Ambulance Trust, are also responsible for exercising on behalf of the HSCB certain statutory functions which are delegated to them by virtue of authorisations made under the Health and Personal Social Services (Northern Ireland) Order 1994. Each HSC Trust also has a statutory obligation to put and keep in place arrangements for monitoring and improving the quality of health and social care which it provides to individuals and the environment in which it provides them (Health and Personal Social Services (Quality, Improvement and Regulation) (NI) Order 2003).

2.17. Section 21 of the Reform Act places a specific duty on each Trust to exercise its functions with the aim of improving the health and social wellbeing of, and reducing the health inequalities between, those for whom it provides, or may provide, health and social care.

Business Services Organisation

2.18. The BSO, which is established as the Regional Business Services Organisation under Section 14 (1) of the Health & Social Care (Reform) Act (Northern Ireland) 2009, contributes to health and social care in Northern Ireland by taking responsibility for the provision of a range of business support and specialist professional services to other health and social care bodies, as directed by the Department in accordance with Section 15 of the Reform Act.

2.19. The BSO incorporates the majority of services previously provided by Central Services Agency. The BSO, however, provides a broader range of support functions for the health and social care service, bringing together services which are common to bodies or persons engaged in providing health or social care. These include: administrative support, advice and assistance; financial services; human resource, personnel and corporate services; training; estates; information technology and

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include:

i Keeping the Department informed about the provision, availability and quality of health and social care services;

ii Promoting improvement in the quality of health and social car services by, for example, disseminating advice on good practice and standards;

iii Reviewing and reporting on clinical and social care governance in the HSC - the RQIA also undertakes a programme of planned thematic and governance reviews across a range of subject areas, reporting to the Department and the Health and Social Care and making recommendations to take account of good practice and service improvements. Such reviews may be instigated by RQIA or commissioned by the Department;

iv Regulating (registering and inspecting) a wide range of health and social care services. Inspections are based on a new set of minimum care standards which ensures that both the public and service providers know what quality of services is expected. Establishments and agencies regulated by the RQIA include nursing and residential care homes; children's homes; independent hospitals; clinics; nursing agencies; day care settings for adults; residential family centres; adult placement agencies and voluntary adoption agencies. The Reform Act also transferred the functions of the former Mental Health Commission to the RQIA with effect from 1 April 2009. The RQIA now has a specific responsibility for keeping under review the care and treatment of patients and clients with a mental disorder or learning disability.

2.22. The RQIA is also the enforcement authority under the Ionising Radiation and Medical Exposure (Amendment) Regulations (N.I.) 2010 [IRMER] and is one of the four designated National Preventive Mechanisms under the United Nations Optional Protocol for the Convention against Torture [OPCAT] with a responsibility to visit individuals in places of detention and to prevent inhumane or degrading treatment. RQIA also conducts a rolling programme of hygiene inspections in HSC hospitals.

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assure itself that it is clear, well understood and operates in the interests of patients.

143. Departmental officials will recommend to the Minister that this INI recommendation should be progressed by the Department as a priority.

The role of the Regulation and Quality Authority, and a planned fundamental review of regulation

144. The RQIA was established under Article 3 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 (“The Order”). The Order created the enabling legal framework for RQIA to have overall responsibility for monitoring and regulating the quality of health and care services delivered in Northern Ireland; The Order gives responsibility for and powers to regulate a wide range of care services including many services delivered by the HSC as well as services delivered by the independent sector

145. The Order makes provision for the duties and responsibilities of the RQIA. These can be summarised as 3 main aims:

(a). Keeping the Department informed about the overall state and provision of health and social care services, and in particular, about their availability and their quality.

(b). Encouraging improvement in the quality of services by conducting reviews of health and social care organisations' clinical and social care governance arrangements against quality standards; and thematic and service reviews; and specific investigations as directed by the Department.

(c). Regulation of the following establishments and agencies:

(i). children’s home;

(ii). a day care setting;

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149. RQIA's Hospitals Programme Team had planned to undertake a series of inspections to outpatient departments during 2021/22 as part of follow up of the RQIA review of Governance Arrangement in the Belfast Trust. Being mindful of the significant and escalating service pressures across HSC hospitals and in particular the phased plans for Rebuilding Health and Social Care Services, this work has not yet commenced.

150. The HIP is not the only presence RQIA have in hospitals. RQIA conducts rolling programmes of hygiene inspections and inspections of augmented care services. These inspections focus on specific elements of care and are centred on meeting the standards associated with the delivery of that care. These inspections include examination of clinical and social care governance.

151. Hospitals are not regulated in Northern Ireland. RQIA can however issue Improvement Notices where they find non-compliance with the 2006 Quality Standards. Where RQIA have serious concerns they may suggest that the Department introduce special measures to a hospital or Trust but the decision as to whether to accept RQIA's recommendation rests with the Department. Another function is RQIA Reviews, which seek to provide assurance to the public about the quality, safety and availability of health and social care services in Northern Ireland. The reviews aim to encourage continuous improvements in health and social care services and ensure the rights of service users are safeguarded. Of relevance to this Inquiry may be the review of Consultant Medical Appraisal Across HSC Trusts September 2008, which is provided to the Inquiry at Appendix 38.

152. In terms of governance reviews, RQIA has published its reviews of clinical and social care governance arrangements in health and social care boards, Trusts and agencies across Northern Ireland. The findings from its reviews demonstrate how the concepts and practicalities of clinical and social care governance and risk management are being taken forward in health social care organisations across Northern Ireland. A list of relevant governance reviews is provided to the Inquiry at Appendix 39 to this statement.

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153. The preceding paragraphs are a means of providing the context for a forthcoming fundamental review of regulation, to be led by the Department. A draft consultation document on such a review had been completed in 2020 but was not published owing to the Covid pandemic. That draft is currently being updated to take account of lessons learned from the pandemic, as well as from the findings of the INI and indeed the preparation of this statement. It is the Minister's intention that this fundamental review will be taken forward during the current mandate of the Assembly. A copy of the draft, unpublished consultation document 'The Right Touch: A New Approach to Regulating Health and Social Care in Northern Ireland' is provided to the Inquiry at Appendix 40 to this statement. An analysis of issues 'The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 – Gaps and Issues' is provided to the Inquiry at Appendix 41.

Mr Aidan O'Brien - Urology Concerns Timeline

154. The Department first became aware of concerns relating to Urology Services in the Southern Trust on 31 July 2020 when the Trust submitted Early Alert pro forma (ref EA 182/20) [DOH-19704] to the Department on the basis of the likelihood of the Trust needing to contact patients about possible harm.

155. In accordance with the Early Alert protocol, the Trust also notified the Department in advance of submitting the pro forma via a telephone call from the Trust Medical Director to the Office of the Chief Medical Officer (CMO). The proforma was copied to the HSCB, also in line with the Department's Early Alert protocol.

156. Policy guidance on the Establishment of an Early Alert System was issued by the Department to the HSC on 28 May 2010 as Circular HSC (SQSD) 10/2010 (a copy is provided to the Inquiry at Appendix 42). The Early Alert System became operational on 1 June 2010 as a means of complementing, not replacing, existing formal and informal channels of communication. It provides a channel to enable HSC organisations to notify the Department in a prompt and timely way of events or incidents which have occurred in the services

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will share its experience and learn from others to put the best possible system in place in Northern Ireland.

All work by the Department of Health in Northern Ireland on candour and openness will focus on patient safety and an ongoing commitment to ensuring that individuals and organisations are provided with the support they need to fulfil their responsibilities.

The Department is committed to this cultural change, but recognises that it will not happen overnight. The Being Open Framework will allow organisations to put in place the support and systems required to ensure that individuals will be fully empowered to exercise their individual duty of candour.

Agreeing on a Being Open Framework and implementing its principles will ensure that the public can have confidence that individuals within the health service will have the support and protection of their organisations and legislation to be open and candid in all that they do.

Another significant recommendation from the IHRD Report is the introduction of an Independent Medical Examiner office to scrutinise those hospital deaths not referred to the Coroner.

A non-statutory prototype Independent Medical Examiner service is now operating across all five Health and Social Care Trusts. This means that when a doctor completes a Medical Certificate of Cause of Death, an Independent Medical

Examiner reviews the certificate together with the patient's clinical record and has a discussion with the certifying doctor about the circumstances of the death.

This helps to ensure that deaths occurring in hospital are appropriately reported to the Coroner when there is a need to do so. It also assures the family that the death certificate is reasonable and accurate and that if any safety or governance issues are identified, these are brought to the attention of the relevant Trust in order that immediate action can be taken if this is required.

In the coming months, the prototype non-statutory Independent Medical Examiner office will consider the most appropriate way in which a statutory service might interact with bereaved families, and how such an IME system can include reviews of those deaths occurring in community settings which are usually certified by GPs.

The IME prototype will provide all the required information to inform the development of a statutory Independent Medical Examiner service for Northern Ireland.

The IHRD report also makes ten recommendations regarding Serious Adverse Incident (SAI) reviews, which take place when death or serious harm occurs. The report on the RQIA Review of the Systems and Processes for Learning from Serious Adverse Incidents was published on the 7th July 2022 and is available on the Department for Health Website (RQIA Review of Systems and processes | Department of Health). The report makes five recommendations and clearly highlights the need to co-design a new evidence-based, regional procedure, which

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Health & Social Care Trusts

8. The Department of Health delegates its operational responsibilities to its sixteen ALBs. Six of these bodies are Northern Ireland's Health and Social Care Trusts (the five regional Trusts plus the Northern Ireland Ambulance Service). Each ALB is a legal entity in its own right, employing its own staff and operating at arm's length from the Department.

9. The Department sets the framework, budget, priorities and targets within which the Trusts must operate. Each Trust has a Board consisting of a non-executive Board Chair and Executive and non-Executive members. The Board of each Trust is responsible for holding the Chief Executive to account for the management of the organisation and the delivery of agreed plans and outcomes. Responsibility for the operation of Departmental policy within Trusts is the responsibility of the Trust Boards.

10. Alongside the delegation of operational responsibilities, as principal Accounting Officer I also delegate the Accounting Officer role to the most senior officer of each of the Departments ALBs, e.g. within each Trust to each Chief Executive.

11. From 2003/2004, the Department utilised Controls Assurance Standards (CAS) as a means of ALB Boards providing evidence and assurance that they were doing their 'reasonable best' to manage themselves in meeting their objectives and protect stakeholders against risk.

12. From 1 April 2018, a revised approach of proportionate assurance was introduced were-by ALBs provide assurance to policy leads in the Department with respect to their compliance with Departmental policy.

13. Each Chief Executive, as an additional Accounting Officer, is accountable, through the Permanent Secretary, to the Minister and Assembly in terms of performance and expenditure of resources. They are responsible for the sound management of funds allocated to them and for managing their organisation within agreed arrangements with the Sponsor Department.

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the two (2011 and 2018) reviews of the policy which began and did not complete.

109. Turning to the future action to strengthen the MHPS policy, it is my view that a rapid but fundamental review of MHPS must be started – and, most importantly, completed – as soon as possible and as a matter of priority.

110. I consider that such a review should be commissioned by the Department but conducted by persons external to the Department. Options for such a review will be put to the Minister for consideration and selection of a preferred option. The Department's Workforce Policy Directorate, working with the Chief Medical Officer Group, will take responsibility for the commissioning of the review.

111. The Inquiry will note that the 'Independent Neurology Inquiry: Report June 2022. Volume 1, page 31, (INI) report, published on 21 June 2022, made three specific recommendations (recommendation 16-18) to the Department in relation to MHPS, and those recommendations will be fully considered within the review. Excerpt is provided to the Inquiry at Appendix 36. The recommendations are that:

- Recommendation 16: The NI Department of Health should ensure that the confidentiality dimension of the MHPS process is always subordinate to patient safety considerations;

- Recommendation 17: The NI Department of Health should review paragraph 39 of MHPS and issue guidance on the appropriate balance between confidentiality for the clinician and safety for the patients;

- Recommendation 18: The NI Department of Health should oversee the establishment of a group to consider the balance between the fair treatment of clinicians and the safety of patients under MHPS. The group should focus on reducing the complexity of processes and re-evaluating the degree of confidentially. The group would benefit from input from appropriate experts to include Human Resource expertise and Medical Directors.

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USI Ref: Notice 65 of 2022

Date of Notice:

Witness Statement of: Ryan Wilson, Director of Secondary Care, Department of Health

I, Ryan Wilson, will say as follows:-

1. On 3 August 2020 I took up post as Acting Director of Secondary Care, a Directorate within the Healthcare Policy Group in the Northern Ireland Department of Health ("the Department" or "DoH"). I have held various policy roles in the Department since 2005, including roles within Healthcare Policy Group since 2013, prior to taking up my current role, to which I was permanently appointed in August 2021.

2. In this statement I have set out a description of the events and issues relevant to the questions in Notice 65 of 2022 ("Notice 65") which I or my Directorate have first-hand knowledge of or responsibility for. Where events and issues relate to the responsibilities of other business areas within the Department, or those of external organisations, I have set out a description of these to the best of my knowledge and outlined where those responsibilities sit within the structure of the Department and/or the Health and Social Care ("HSC") system.

3. Before providing a narrative of my involvement in or knowledge of matters falling within the scope of sub-paragraph (b) of the Inquiry's Terms of Reference, and responding to any of the remaining specific questions at paragraphs 4-31 of Notice 65, this statement describes my role, that of Secondary Care Directorate, the statutory basis of the Department's relationship with its Arm's Length Bodies, and

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the policy and commissioning context within which HSC urology services are provided. This includes the last comprehensive review of adult urology services in Northern Ireland which was completed in 2009, the prioritisation status of urology services in the context of the Department's overall health service transformation agenda under its current 10-year transformation strategy "Delivering Together", and the impact of the COVID-19 pandemic on the delivery of this transformation agenda.

My role

4. The Director of Secondary Care is an Assistant Secretary and the Department's senior advisor to the Minister of Health on secondary healthcare policy, with responsibility for developing and reviewing Departmental policies which underpin the delivery of healthcare mainly within hospital settings, and the clinical specialties through which these services are delivered. This includes hospital urology services, which were last reviewed between 2008-2009 (see further details at paragraphs 21-33 below).

5. Departmental policy in relation to healthcare in Northern Ireland is generally guided by the relevant legislation and by clinical and professional guidelines, e.g. those published by the National Institute for Health and Care Excellence ("NICE") and endorsed by the Department for implementation in Northern Ireland (further detail about NICE guidelines is set out at paragraphs 13-17 below), and professional bodies such as the Royal Colleges. The Department's policy position in relation to urology services is summarised at paragraphs 11-12 below.

6. Secondary Care Directorate also plays a key role in supporting the Health Minister by regularly providing policy briefing for Assembly business (including Oral and Written Assembly Questions, as well as correspondence and briefing requests from the Assembly's Health Committee) and Ministerial engagements, as well as preparing responses to correspondence received by the Minister or by the Department from service users and their elected representatives.

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7. Where correspondence is received by the Department in relation to operational matters, including an enquiry or a complaint relating to the treatment or care of an individual patient, this is generally referred to the appropriate Arm's Length Body ("ALB"), which is usually the relevant HSC Trust responsible for the care of the patient or the delivery of the service in question. It would be inappropriate for the Department to investigate or advise on any individual patient's clinical care. The ALB is generally asked by the Department to investigate the matter in question and to provide a response to the correspondent's enquiry or complaint. Any complaint is processed by the ALB in accordance with the Health and Social Care Complaints Procedure.

8. In the performance of these functions, the Secondary Care Directorate works closely with many of the Department's ALBs, including the six HSC Trusts which are responsible for the operational delivery of secondary healthcare services, as well as commissioners from the joint commissioning functions provided by the Public Health Agency ("PHA") and the Department's Strategic Planning and Performance Group ("SPPG", formerly the Health and Social Care Board or "HSCB").

9. Paragraphs 8-15 of the Witness Statement of Peter May, Permanent Secretary of the Department of Health, sets out the relationship between the Department and HSC Trusts, outlining that DoH delegates its operational responsibilities to ALBs, including the six HSC Trusts.

10. Paragraphs 16-19 of Peter May's Statement set out the role of HSC Trusts in the employment and management of doctors within the HSC.

Departmental Policy in relation to HSC Urology Services

11. A Departmental document titled "Standard Policy Brief – Urology (reviewed Sept 2019)" has been provided to the Inquiry [DOH-12114 - DOH 12118]. This is one of a number of internal standard briefing documents held within the Secondary Care Directorate for the purposes of providing officials with accessible, factual, high

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level information about the relevant clinical specialty (in this case urology), including the location of services, clinical guidelines, legislation, waiting lists, relevant issues, and date of the most recent service review.

12. The Urology Policy Brief document notes that:

- There is no single Departmental policy for urology services, as this clinical specialty covers diseases, trauma and congenital abnormalities of the kidney, bladder, genitalia and urinary tract as well as male sexual and reproductive health, the management of many non-surgical problems, such as urinary infections, and surgical problems such as the correction of incontinence, prostate problems and the treatment of cancer. It notes that urology is closely linked with cancer services, due to the related areas of prostate and bladder cancer, as well as gynaecology and genito-urinary medicine and sexual health specialties.

- A wide range of NICE clinical guidance is available on a range of urology related conditions, which is available on the NICE website.

- In common with HSC services generally, the principal legislation underpinning the delivery of urology services in Northern Ireland is the Health and Social Care (Reform) Act (NI) 2009 (“the Reform Act”). Further detail about the Reform Act is set out under “Commissioning and Funding of Trust Healthcare Services” at paragraphs 18-20.

- A regional review of urology services was completed in March 2009 by the HSCB; and,

- the date suggested by the Secondary Care Directorate for the next policy review of urology services was 2019. This reflected the time that had passed since the previous review, however it should be noted that the commencement of any major policy or service review would be subject to other Departmental priorities and the availability of Departmental and HSC resources to lead and

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support this work. A further review has not been completed since the Policy Brief document was revised in September 2019. Further detail about the 2009 Review is set out at paragraphs 21-38 below. Detail about the Department's consideration and prioritisation of a review of urology services within a wider programme of high priority reviews, both in 2016, and in 2020 in the context of the COVID-19 pandemic, is set out at paragraphs 39-53 below.

NICE Guidelines

13. NICE is an independent organisation tasked with producing national guidance on good clinical practice and the cost-effective use of NHS resources in England. NICE provides a very robust and rigorous approach to its consideration of available evidence and provides expert guidance. The Institute publishes a range of guidance and their Clinical Guidelines relate to the management of broad conditions and groups of patients.

14. As NICE guidance is designed and developed for the NHS in England, it does not automatically apply in Northern Ireland. On 1 July 2006, the Department established links with NICE whereby all guidance published by the Institute from that date is locally reviewed for applicability to Northern Ireland and, where appropriate, is endorsed for implementation in the HSC.

15. Departmental policy underpinning these links with NICE, and the process for reviewing, endorsing and implementing NICE guidelines, is the responsibility of the Chief Pharmaceutical Officer (currently Cathy Harrison).

16. NICE guidelines can be complex and may require significant change to the existing service provision and additional investment. Therefore implementation of NICE guidelines, once they are endorsed by the Department, may take place over several years and is subject to the availability of additional recurrent funding.

17. Responsibility for implementing NICE guidelines, once endorsed and funded, sits with healthcare delivery organisations (mainly HSC Trusts), and is overseen by the

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Functions such as financial planning, financial policy and financial management (including the allocation of budgets to SPPG and to some ALBs, and the in-year monitoring of expenditure) in respect of the overall Departmental budget allocated by the NI Executive, are the responsibility of the Departmental Director of Finance (currently Brigitte Worth). The equivalent functions in respect of the SPPG budget, which includes the commissioning of services from HSC Trusts, have transferred from the HSCB to the Department from 1 April 2022 and are the responsibility of the SPPG Director of Finance (currently Tracey McCaig).

2008/09 Review of Urology Services

21. In 2008, the Department's former Service Delivery Unit ("SDU") initiated a Regional Review of HSC Adult Urology Services. The Department has thus far been unable to locate any records preceding the initiation of the Review (though further checks of registered files in storage are taking place), including any policy advice recommending that it should be progressed at that time, however a submission subsequent to the completion of the Review from Secondary Care Directorate to the then Health Minister, Michael McGimpsey, dated 23 April 2009, outlined that the rationale for the Review proceeding was as follows: *"this was in response to concerns regarding the ability of HSC urology services to manage growing demand, meet cancer and elective waiting times, maintain quality standards and provide high quality elective and emergency services."* A copy of the submission of 23 April 2009 is provided to the Inquiry at Appendix 3.

22. A copy of a letter issued on 2 June 2008 by Hugh Mullen, the then Director of Performance and Provider Development, SDU, and Chair of the Regional Urology Steering Group, advising HSC Trusts that the review had been initiated, is provided to the Inquiry at Appendix 4.

23. The first meeting of the Regional Urology Steering Group was held on 17 September 2008. A list of members of the Regional Urology Steering Group is provided to the Inquiry at Appendix 5 and a copy of the Review's agreed Terms of Reference is provided to the Inquiry at Appendix 6. A copy of the final Review

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Report, titled *"Review of Adult Urology Services in Northern Ireland - A modernisation and investment plan"*, which was published in March 2009 by the HSCB, is provided to the Inquiry at Appendix 7.

24. The Terms of Reference set the overall purpose of the Review as follows: "*To develop a modern, fit for purpose in the 21st century, reformed service model for Adult Urology Services which takes account of relevant guidelines (NICE, Good Practice, Royal College, British Association of Urological Surgeons, British Association of Urological Nurses). The future model should ensure quality services are provided in the right place, at the right time by the most appropriate clinician through the entire pathway from primary care to intermediate to secondary and tertiary care."*

25. The context for the Review, as noted in the Review Report, was the evolution of the field of urology from being *"the province of the General Surgeon"* into a separate surgical specialty, and the growth in the number of urologist appointments in NI hospitals from 10 in 1999 to 17 in 2008/09.

26. The Review was completed in March 2009. The Review Report, published by the HSCB in March 2009, as referenced above, contained 26 recommendations aimed at improving capacity and sustainability of urology services. Some key elements of a proposed service expansion and redesign included:

    - An increase in the number of consultant urologists from 17 to 23;
    - All radical pelvic surgery should be undertaken at a single site;
    - At least 5 clinical nurse specialists should be employed;
    - Increase the proportion of elective operations undertaken as day cases;
    - Urology services to be configured into a 3 team model covering Northern, Southern and Eastern areas respectively.

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had recommended that the Minister endorse all the recommendations. A copy of this submission is provided to the Inquiry at Appendices 9a and 9b.

32. The Health Minister agreed the recommendations should be taken forward but had asked that the Department to seek confirmation of clinician support for the recommendations. Clinicians' support was subsequently received and a further submission confirming this was sent by Secondary Care Directorate to the Minister on 18 March 2010. This submission also sought the Minister's approval to endorse the Regional Review recommendations, to announce this by way of a press release, and to agree that the HSCB should arrange to implement the recommendations as soon as possible. The Health Minister agreed and asked for a press release to issue on 30 March 2010. A copy of an email dated 29 March 2010 containing the Health Minister's approval is provided to the Inquiry at Appendices 10a and 10b.

33. Dr Miriam McCarthy, the then Director of Secondary Care in the Department, wrote to Hugh Mullen, HSCB, on 2 April 2010 to communicate this decision and to request that the HSCB implement the recommendations as soon as possible. A copy of Dr McCarthy's letter is provided to the Inquiry at Appendix 11.

Implementation of the 2009 Urology Review Recommendations

34. In response to Written Assembly Question AQW 133/2011 [DOH-21093 – DOH-21096] (issued on 22 September 2010), asking how many of the Review's 26 recommendations had been implemented by each HSC Trust, Minister Michael McGimpsey advised as follows, based on input received from the HSCB: *"The Review of Adult Urology Services in Northern Ireland contained 26 recommendations, of which four have been fully implemented and a further 12 are well progressed towards implementation. The timescale of full implementation is being guided by the Health and Social Care Board, and is subject to the approval of implementation plans by commissioners to fully deliver all of the recommendations. Trusts have submitted a draft implementation plan, which sets*

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38. On 23 January 2019, officials from the Secondary Care Directorate, Department of Health, wrote to the HSCB Chief Executive, Valerie Watts, to formally request an update and evaluation on the implementation of the Review recommendations, and for completion of a Post Project Evaluation on the 2009 Review of Urology Services [DOH-12120 – DOH-12128]. A response was requested by March 2019, however, the Department does not hold any record of a response from the HSCB.

Urology Services in the context of the Bengoa Report, Delivering Together and the Department's Programme of Priority Service Reviews

39. In October 2016 the former Health Minister, Michelle O'Neill MLA, launched "Health and Wellbeing 2026: Delivering Together" (referred to as "Delivering Together"), a ten-year strategy to reform the way health and social care services are designed and delivered in NI, with a focus on person-centred care, rather than on buildings and structures. A copy of the strategy is provided to the Inquiry at Appendix 19. Delivering Together was based on the 2016 report "Systems not Structures: Changing Health and Social Care" following a review by an expert panel which was led by Professor Rafael Bengoa (referred to as "the Bengoa Report"). A copy of the Bengoa Report is provided to the Inquiry at Appendix 20.

40. The Bengoa Report recognised the increasing demand for hospital based services influenced by demographic changes, particularly a growing, ageing population with more chronic health problems and complex health needs. It also recognised that demand for care has been outstripping the ability of the system to meet it for many years, and that this trend will increase in the years ahead and will only be addressed by action to increase capacity, promote healthier lifestyles and tackle health inequalities.

41. The Bengoa Report set out a rationale and a proposed criteria for reviewing services, and proposed a number of "Priority 1" individual services which should be prioritised by the Department for review. These were: emergency and urgent care, stroke, primary care including GP out of hours, general surgery, pathology,

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and vascular services. It proposed that urology services should be among a number of “Priority 2” services for review.

42. Following the publication of Delivering Together in October 2016, the Department established the “Transformation Implementation Group” (“TIG”), chaired by the Permanent Secretary, and comprising senior officials from the Department and Chief Executives from the HSCB, PHA and the six HSC Trusts, to oversee planning and implementation of prioritised service reviews. TIG continued to provide this function during the period in which the NI Assembly was suspended (January 2017 – January 2020), providing strategic direction and endorsing the direction of travel across individual review projects during this period, in order to be in a position to develop and provide policy recommendations for decision by an incoming Health Minister once the Assembly was restored.

Impact of COVID-19 on the Department’s Programme of Priority Service Reviews

43. From February 2020, work on the programme of service transformation reviews, including the TIG oversight structure, was paused indefinitely as the Department entered what became a prolonged phase of business continuity operation requiring resources to be wholly diverted to managing the HSC response to the COVID-19 pandemic.

44. On 9 June 2020, following the first wave of the COVID-19, and in order to begin to address its impact on the health service and on patients awaiting care, the Health Minister, Robin Swann MLA, published a “Strategic Framework for Rebuilding Health and Social Care Services”. A copy is provided to the Inquiry at Appendix 21.

45. The Strategic Framework acknowledged the pressures that faced the health service prior to COVID-19, and the prevailing threat of further COVID-19 waves at that time.

other high priority service reviews and transformation initiatives are ongoing, including in stroke, neurology, pathology and orthopaedic services. It is currently envisaged that work on Priority 2 service reviews will only progress when sufficient capacity becomes available within the Department and its Arm's Length Bodies, through the release of resources once ongoing priority reviews are completed, or through further investment to increase resources and capacity, or both. The Department is currently not in a position to estimate a timescale for this given ongoing staff and budgetary constraints.

USI Notice 65 of 2022

54. Turning to the information requested within Notice 65 of 2022, I note that this was issued prior to the Inquiry's receipt of the witness statement of the Permanent Secretary (provided in response to Notice 50 of 2022), and therefore my response in the following sections may bear some degree of overlap with that statement. Where this is the case I have cross-referenced the Permanent Secretary's statement and provided additional detail where appropriate/available. I have stated either where I am responding on the basis of my direct knowledge, involvement, or responsibility as Director or Secondary Care, or otherwise where responsibility sits elsewhere within the structure of the Department and/or the HSC system.

The Department's Awareness of and Response to Urology Concerns within the Southern HSC Trust

55. The following paragraphs set out my response to paragraph 1 of Notice 65 by providing a narrative account of my involvement in or knowledge of all matters falling within the scope of sub-paragraph (b) of the Inquiry's Terms of Reference, including the circumstances in which the Department became aware of the issues relating to potential concerns about patient care and safety within the Southern HSC Trust ("the Trust"), and the Department's role in the process leading to the Trust conducting a Lookback Review and adopting a "Structured Clinical Record Review ("SCRR") process, and an explanation of the processes and reasons which led to the decision to establish this public inquiry. My response relates to

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and overlaps with some of the information provided paragraphs 154-193 of the Permanent Secretary's statement under the section titled *"Mr Aidan O'Brien - Urology Concerns Timeline"*, however in the interests of completeness I have recounted events from my perspective in full.

56. My response will show that:
    - the Trust-led Lookback Review was already under way when the Department became aware of concerns relating to urology services in the Southern Trust, after which the Trust's progress with the Lookback Review was guided by ongoing discussion with the Department, HSCB and PHA, both prior to and subsequent to the establishment of a Department-led Urology Oversight Group in October 2020;
    - the adoption and development by the Trust of a SCRR process arose following discussions between the Trust and the Royal College of Physicians and subsequent discussion within the Urology Oversight Group;
    - the decision to establish a public inquiry arose following the establishment of the Urology Assurance Group and discussion with the Chair of the Independent Neurology Inquiry, with the decision taken by the Health Minister in light of the seriousness and extent of the concerns which were emerging from the ongoing scoping work by the Southern Trust in relation to the practice of Aidan O'Brien, and to ensure that the full extent of the concerns could be identified and pursued in a transparent and independent way.

<u>Early Alert EA 182/20</u>

57. The Department first became aware of the issues relating to potential concerns about patient care and safety relating to Urology Services within the Southern Trust on Friday 31 July 2020, when the Trust notified the Department of an Early Alert on the basis of the Trust potentially needing to contact patients about possible harm.

58. Prior to 31 July 2020 there was no awareness within the Department of concerns relating specifically to Aidan O'Brien or the issues referred to in the Early Alert

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at that time comprised approximately 230 patients who may have received sub-optimal care, and that the full scope of the consultant's practice (i.e. work potentially carried out in other Trusts, in cross-border or in private healthcare settings) was not currently known.

71. On Thursday 13 August 2020 an email from the Minister's Private Office, responding to the notification received from the Office of the CMO on 31 July 2020, confirmed that the Minister had noted Early Alert EA 182/20 [DOH-00664 – DOH-00666]. A further email from Private Office on 24 September 2020 confirmed that the Minister had noted my submission of 6 August 2020 (SUB-1740-2020). Copies of both emails are provided to the Inquiry at Appendices 37a and 37b.

Events and Departmental Actions following the immediate response to EA 182/20

72. On 18 August 2020, SHSCT submitted an update to the Chief Medical Officer via email [DOH-00667 – DOH-00670]. This update advised that:
    - the doctor had retired and that the Trust was in contact with him through his legal representative;
    - on advice of NHS Resolutions and the General Medical Council he had agreed not to see private patients;
    - the SHSCT did not have an oversight of his previous private patients;
    - to the best of the SHSCT's knowledge he was not working for another Trust and was not registered with the Medical Council of Ireland;
    - the SHSCT was liaising with GMC regarding professional matters;
    - the SHSCT was continuing to consider any potential quality of care issues;
    - the SHSCT was liaising with the Royal College of Surgeons to engage with the British Association of Urological Surgeons to consider the import and extent of its findings and to access subject matter experts in relation to Serious Adverse Incidents (SAIs);
    - the SHSCT was minded to make a decision on the requirement for a formal lookback exercise and what the nature and scope of such a process would look

Shane Devlin, Trust Chief Executive; Maria O'Kane, Medical Director, and Melanie McClements, Director of Acute Services), led these meetings by providing updates on the progress with the lookback exercise, including support that was being received from other urology consultants from other HSC Trusts and the independent sector in the review of patient records.

76. Weekly update calls hosted by the Trust took place via Zoom on 10 September 2020, 17 September 2020, 24 September 2020, 1 October 2020, 8 October 2020, 15 October 2020, 22 October 2020 and 29 October 2020, prior to the formal establishment of the Urology Assurance Group from 30 October 2020 (further details on this are provided below). The Department does not hold a formal record of these calls and I am therefore unable to confirm exactly who attended from which organisation on which date. I attended these meetings as Director of Secondary Care. The Department was also represented at each meeting by some or all of the following senior officials: Michael O'Neill, Acting Director of General Healthcare Policy; Jackie Johnston, Deputy Secretary Healthcare Policy Group; David Gordon, Director of Communications; Richard Pengelly, Permanent Secretary; Professor Sir Michael McBride, CMO; Dr Lourda Geoghegan and Dr Naresh Chada, Deputy CMOs.

77. The HSCB and PHA, as joint commissioners of services with joint responsibility for the SAI process, were generally represented at these meetings by Paul Cavanagh, then Acting Director of Commissioning in HSCB, Olive MacLeod, Acting Chief Executive of the PHA, and Dr Brid Farrell, senior public health lead in the PHA.

78. Over the course of these weekly calls, a clearer picture evolved of the full scope of issues needing to be investigated and the number of patients within different cohorts about whom the Trust had identified concerns and potential SAI cases. The Trust advised that it was developing a comprehensive communications plan for the purposes of handling communications and call-backs with any patients impacted, their families, GPs, elected representatives and the media. Discussions took place over the course of these calls regarding the relative merits of making a

Department's ability to fully deliver on the full range of its policy priorities and commitments. The effect of this is often that policy may be developed but the ability of the Department and the HSC to implement it may remain subject to the confirmation of available funding.

173. Without prejudice to the work of this Inquiry, and distinct from the policy responses which have been recognised above, the Department considers that its response to the emerging issues as they were being reported from 31 July 2020 onward, in the context of the ongoing pandemic response, has been appropriate. Oversight structures have been developed and refined commensurate with the emerging scale and scope of concerns, and these continue to provide a means of supporting and drawing assurance from the Southern Trust. Notwithstanding this, any further learning which may emerge from the Inquiry or any of the ongoing processes in relation to the Department's responsibilities will be considered and taken forward as appropriate.

174. Paragraph 31 of Notice 65 asks *"From the Department's perspective, what lessons have been learned from the issues of concern which have emerged from urology services within the Trust? Has this learning informed or resulted in new practices or processes for the Department? Whether you answer is yes or no, please explain."* I refer the Inquiry to my responses to paragraphs 29 and 30 of Notice 65 (paragraphs 168-174 above refer), which outline emerging lessons to date and associated actions identified or under way.

Statement of Truth

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

Signed: ___ ______________________________

Date: ____01/09/2022____________________

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