Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Notice 67 of 2022

Date of Notice: 5 August 2022

An addendum to this witness statement was received by the Inquiry on 01/02/24 and can be found at WIT-106837 to WIT-106874. Annotated by the Urology Services Inquiry.

Witness Statement of: Aidan Dawson, Chief Executive, Public Health Agency

I, Aidan Dawson, will say as follows:-

1	*Having regard to the Terms of Reference of the Urology Services Inquiry, please provide a narrative account of your involvement in or knowledge of all matters falling within the scope of sub-paragraphs (a), (b) and (c) of those Terms of Reference. In particular you are required to address the circumstances in which the Public Health Agency ("the PHA") became aware of the issues relating to potential concerns about patient care and safety within the Southern Health and Social Care Trust ("the Trust"), and the engagement which subsequently took place between the Trust, the PHA and/or others and the processes and decision making which followed. You are asked to explain the PHA's role and input, if any, in the process which led to the Trust conducting a 'Lookback Review' and adopting a 'Structured Clinical Record Review' ("SCRR") process. You are also required to explain the processes which led to the decision to establish this public inquiry, and the reasons for that decision. Your narrative account should include an explanation of your role, responsibilities and duties, and you should provide a detailed description of any issues raised, meetings attended and actions or decisions taken by you, the PHA and others to address any concerns. It would greatly assist the inquiry if you would provide this narrative in numbered paragraphs and in chronological order using the form provided.* **Introduction** 1 On behalf of the Public Health Agency can I begin by thanking the members of the Urology Services Inquiry for the very important work that they are undertaking. The Agency regrets that patients have suffered as a result of the care provided in the SHSCT by Mr O'Brien and we are fully committed to supporting the work of the Inquiry. 2 The Agency welcomes the opportunity to provide an account of our involvement and knowledge of all matters falling within the scope of the Inquiry's Terms of Reference and we have set this out in the following paragraphs to the best of our corporate memory informed by discoverable documentation. Can I also assure the Inquiry panel that the Agency is cognisant of its responsibilities as the

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	date and the outcome of the Invited Service Review by the Royal College of Surgeons / BAUS which was received by the SHSCT at the beginning of October 2022 and was shared with PHA on 20th October 2022. 290 When PHA was originally notified of the 2017 SAI (see response to Q 15) and raised queries with SHSCT re triage of urology referrals from general practice, PHA accepted at face value the responses received from the SHSCT at that time that the problem related to a single doctor whose practice had been restricted and would be dealt with under the MHPS procedures. PHA does not have access to original notes and is reliant on all information being disclosed in the SAI report and subsequent clarifications provided. 291 The 2007 Lookback guidance was updated in 2021 and the update provides a more structured approach to managing lookbacks with step wise progression on actions to follow when investigating problems associated with a single service or single practitioner. 292 The timeliness of undertaking and sharing of SAI reports remains problematic and together with the RQIA review of SAIs published in 2022 demonstrates the need for an overhaul of the SAI process is required. 293 The recommendations of the Independent Inquiry into Neurology (June 2022) are relevant and an action plan for implementation of its findings needs to be agreed regionally and applied to all specialities.
48	*Any other evidence or documents within the PHA's custody or control, including emails, letters, notes, minutes, memoranda, file notes, diary entries or otherwise, whether in electronic or hard copy, which relate to any matter relevant to the work of the Urology Service Inquiry or which might be relevant to the work of the Urology Services Inquiry (see note below).* 294 Documents have been scoped in answers to the above questions. Also searches of Email systems have been conducted across the PHA and are referenced in the documentation return.

Statement of Truth

I believ[redacted] this witness statement are true.

Personal Information redacted by the USI

Signed [redacted]

Aidan Dawson,
HMFPH PHA Chief Executive

Date: 24 October 2022

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UROLOGY SERVICES INQUIRY

USI Ref: Notice 67 of 2022

Date of Notice: 5 August 2022 **Witness Statement of: Aidan Dawson, Chief Executive, Public Health Agency**

I Aidan Dawson will say as follows:

1. This is my second written statement to the Urology Services Inquiry. I make this statement as a supplement to my substantive statement of 24 October 2022. I am grateful to the Inquiry for this opportunity to elaborate on my previous evidence and do so in order to offer clarity on the PHA's role in the Serious Adverse Incident process and the ongoing review thereinto.

2. The procedure for the reporting and follow up of Serious Adverse Incidents (2016) outlines the purpose of this process as;

- To provide a mechanism to effectively share learning in a meaningful way with a focus on safety and quality ultimately leading to service improvement for service users, and;
- To ensure the process works simultaneously with all other statutory and regulatory organisations that may require to be notified of the incident.

3. The SAI procedure (when incidents are notified and when reports are received by SPPG/PHA) is anonymised and therefore is not a mechanism for identifying staff involved in incidents. The SAI procedure is not replacement for, or an alternative version of, disciplinary processes which may arise separately in relation to such incidents.

4. The Department of Health is currently leading on a review of the SAI process following the RQIA Review of the Systems and Processes for Learning from Serious Adverse Incidents in Northern Ireland (June 2022). The PHA is represented on this review by the Director of Nursing and the Director of Public Health on the oversight board. The Assistant Director and Nurse Consultant for Safety, Quality and Innovation are also closely involved in this work. The intention is to move way from the use of "Serious Adverse Incidents" and to identify "Patient Safety Events (PSE)" for Learning and Improvement. This work is ongoing and is expected to be completed in 2024, but agreed changes are being introduced incrementally throughout the process, to manage the transition and to expedite changes where possible.

5. It is the intention that the new process will allow for a more flexible, system-focused approach to learning and improvement framed within a culture which prioritises safety, openness and compassion for all those involved in a Patient Safety Event.

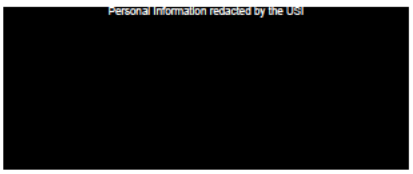
6. Identification of learning from SAIs is ongoing throughout the process. Once a SAI is notified it is reviewed by the Safety and Quality team for any immediate actions, then is reviewed by the incident review group again to identify if there is any immediate learning. Once the report is received it is listed for the appropriate professional group where it will be reviewed in a collective multidisciplinary group to identify if any regional learning should be issued. The PHA are constantly reviewing the methods of learning we utilise in order to disseminate regional learning and are about to start a second ECHO programme for learning from SAIs which engages our service colleagues in the learning. The first programme was very well evaluated. We can on occasion issue letters but going forward these will largely be issued for urgent learning where prompt assurances of compliance are required. The method of learning that the PHA is responsible for issuing is Learning Matters/ Learning From newsletters. These are reminders based on learning from SAIs. I take leave to exhibit sample Learning Matters publications to this statement.

7. PHA hosted a series of Regional SAI Learning Events. These were co-ordinated by what was the Safety Forum (now HSCQI) and brought together speakers from all of the Trusts to present on some of their incidents in order to learn together. They usually had keynote speakers in both morning and afternoon and then a variety of breakout rooms where attendees could go to learn from areas pertinent to their practice. These events took place up until 2019 but were stood down due to the Covid-19 pandemic. I refer to a sample of the programmes for these Learning Events for the Inquiry's information.

8. These Learning Events have not recommenced since emergence from Covid-19 and, although restarting them has not been ruled out, they have to some extent been superseded by the ECHO (Extension of Community Healthcare Outcomes) programme which allows more people to take part in regional learning. This programme commenced in 2022/23 and has been well-received among HSC colleagues. I exhibit an evaluation document on an ECHO on learning from Serious Adverse Incidents and, specifically, the deteriorating patient.

Statement of Truth

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

Signed: 

Aidan Dawson, HMFPH

PHA Chief Executive

Dated 30 January 2024

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	19 The Agency's IT service provider, the Business Services Organisation (BSO),has been asked to search the digital archives of those individuals who have retired or left PHA and whose duties may have included work on urology within the Terms of Reference. Any additional relevant documentation found as a result of that search will be provided when the search has been concluded.
3	*Unless you have specifically addressed the issues in your reply to Question 1 above, answer the remaining questions in this Notice. If you rely on your answer to Question 1 in answering any of these questions, specify precisely which paragraphs of your narrative you rely on. Alternatively, you may incorporate the answers to the remaining questions into your narrative and simply refer us to the relevant paragraphs. The key is to address all questions posed. If there are questions that you do not know the answer to, or where someone else is better placed to answer, please explain and provide the name and role of that other person. If you rely on the assistance of others to complete this Notice then we would be grateful if they could be identified in your response by way of their name and role within the PHA.* 20 PHA staff involved in the completion of this notice have included: Dr. Joanne McClean – Director of Public Health Dr. Brid Farrell – Deputy Director of Public Health Dr. Diane Corrigan – Consultant in Public Health Medicine Mr. Rodney Morton – Director of Nursing, Midwifery and Allied Health Professionals. (NMAHP) Mrs. Denise Boulter – Assistant Director (NMAHP) Mr. Stephen Wilson – Director of Operations (Interim) Ms. Karen Braithwaite – Senior Operations Manager (Delivery)
4	*Summarise your qualifications and occupational history, to include all positions held up to your current position and the dates you held each role, setting out your duties and responsibilities in each post.* 21 <u>Qualifications</u> Sept 1985 - June 87, Student, A Level Study [redacted] Personal Information redacted by the USI 1987-1990 - Under Graduate Student, Degree in Economics, [redacted] Personal Information redacted by the USI 22 <u>Employment History</u> Belfast Health and Social Care Trust Period: 20.02.2017 – 30 June 2021 Position: Director Specialist Hospitals and Women's Health and Mental Health 23 I was responsible and accountable to the Chief Executive for the Strategic, Operational and Financial management of the Specialist Hospitals and Women's Health and Mental Health Directorate of the BHSCT. I was responsible for the service delivery, the quality of services, data management and financial

40 **1) Statutory Framework**
The Public Health Agency is a statutory body, which came into existence on 1 April 2009. The Headquarters of the Agency is at 12-22 Linenhall Street, Belfast, BT2 8BS.

41 The Agency is governed by Statutory Instruments: HPSS (NI) Order 1972 (SI 1972/1265 NI14), the HPSS (NI) Order 1991 (SI 1991/194 NI1), the Audit and Accountability (NI) Order 2003 and the Health and Social Care (Reform) Act (Northern Ireland) 2009.

42 As a statutory body, the Agency has specific powers to act as a regulator, to contract in its own name and to act as a corporate trustee. In the latter role it is accountable to the Charity Commission for those funds deemed to be charitable as well as to the Minister responsible for Health.

43 **2) Functions of the Agency**
The PHA incorporates and builds on the work previously carried out by the Health Promotion Agency, the former Health and Social Services Boards and the Research and Development office of the former Central Services Agency. Its primary functions can be summarised under three headings:

• **Improvement in health and social well-being** – with the aim of influencing wider service commissioning, securing the provision of specific programmes and supporting research and development initiatives designed to secure the improvement of the health and social well-being of, and reduce health inequalities between, people in Northern Ireland;

• **Health protection** – with the aim of protecting the community (or any part of the community) against communicable disease and other dangers to health and social well-being, including dangers arising on environmental or public health grounds or arising out of emergencies;

• **Service development** – working with the Health and Social Care Board (now SPPG) with the aim of providing professional input to the commissioning of health and social care services that meet established safety and quality standards and support innovation.

44 Working with the HSCB, the PHA has an important role to play in providing professional leadership to the HSC. The PHA also aims to improve the early detection and treatment of illness through provision of a range of screening programmes.

45 In exercise of these functions, the PHA also has a general responsibility for promoting improved partnership between the HSC sector and local government, other public sector organisations and the voluntary and community sectors to bring about improvements in public health and social well-being and for anticipating the new opportunities offered by community planning.

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II. Benign Cystectomies;

III. Prescription of Bicalutamide; and

III. Any other trends identified or data collected with regard to Urology Services within the Trust, whether positive or adverse,

Address the following questions:

A. Provide a copy of any data available to the PHA;
B. Outline the source of any data available to the PHA;
C. Outline what, if any, analysis was conducted on any data collected;
D. Outline what, if any, trends were identified as a result of any analysis conducted;
E. What, if any, concerns were identified as a result.
F. Outline what, if any, action was taken to obtain any explanation or clarification of any trends identified or address any concerns which arose.

88 I. **IV Fluids and antibiotics**

A. Provide a copy of any data available to the PHA
No data are held by the PHA.

89 **B. Outline the source of any data available to the PHA**
Data on patient activity in respect of IV fluids and antibiotics (IVT) may be held by the Trust or by SPPG but are not available to the PHA.

90 **C. Outline what, if any, analysis was conducted on any data collected** There was no analysis of data, however, there is correspondence between Dr Diane Corrigan, PHA Consultant in Public Health Medicine, and senior Trust staff, including the Medical Director, Dr P Loughran, and the Clinical Director of Surgery/Associate Medical Director, Mr E Mackle, between April 2009 and July 2011.

91 **D. Outline what, if any, trends were identified as a result of any analysis conducted**
This issue did not relate to trends in activity. The correspondence demonstrates that management and clinical staff within the Trust had identified a treatment pathway within the specialty of urology that appeared at odds with usual practice. Following a discussion with Dr Corrigan in April 2009, the Trust's Medical Director sought independent expert advice from a consultant urologist and a consultant microbiologist from GB on this matter. On 24th April 2009 Dr Corrigan emailed Dr Loughran with the contact details of a consultant urologist who had provided expert advice to the DoH Review of Urology in 2008, as a potential source of independent advice to the Trust (Attachment 18).

92 **E. What, if any, concerns were identified as a result**

In April 2009, the initial concern expressed by the Trust Medical Director was that the procedure did not have a published evidence base and was potentially wasteful of resources, as it required a patient to be admitted to receive IV fluids via a peripheral venous line, along with IV antibiotics, instead of having oral antibiotics as an outpatient. A draft report from Dr Loughran, including the views of the independent experts, was shared with Dr Corrigan in January 2010 as it referred to her by name (Attachment 19). The draft report was not supportive of the practice. Dr Corrigan provided some suggested wording amendments.
These included "*I have discussed the above with Dr D Corrigan, the PHA adviser to the HSCB Southern office. On the basis of the information provided, she has advised that it would not be appropriate for SHSCT to continue to provide a treatment for which there is neither a published evidence base, nor a supporting consensus of professional opinion outwith the Trust. If SHSCT urologists feel strongly that this treatment is of value they should participate in a recognised clinical trial, with ethical committee approval. For those patients already on this treatment regimen an orderly process should be agreed and implemented to move them onto alternative treatment regimes, with the support of medical microbiology. It will be important that the reasoning behind this decision is sensitively communicated to this cohort of patients."* The final report was not shared with Dr Corrigan; she assumed that the Trust would now complete the process to bring the treatment to an end.

93 However, Dr Corrigan became aware at a meeting in July 2010 with the Trust, in respect of implementation of the Regional Review of Urology, that the practice of admission for IV fluids and antibiotics had not completely stopped, and that 2 patients may by then have been receiving IV fluids via a central line. Placement of a central line can result in significant short or longer-term complications. If a central line was not required as part of an accepted clinical pathway this raised a safety concern.

94 In reviewing earlier correspondence on the issue, Dr Corrigan re-read the draft report received in January 2010 and noted a comment in an Appendix stating that some of the patients having this treatment had had a cystectomy (removal of bladder) and an ileal conduit (creation of a new tube from a piece of small bowel into which both kidneys drain via the ureters, and from which urine is diverted through a stoma on the surface of the abdomen). One sentence 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 the new concern about persisting use of the IV fluid treatment regime within the urology specialty, despite an understanding that this had been phased out by the Trust, Dr Corrigan decided to seek data on the numbers of patients having cystectomy operations in NI hospitals for a 5 year period from April 2005 to March 2010 to explore if practice in Southern Trust was in line with that elsewhere in NI. This information was obtained from the HSCB information team within the HSCB Performance management and Service Improvement Directorate (PMSID).

95 **F. Outline what, if any, action was taken to obtain any explanation or clarification of any trends identified or address any concerns which arose** Dr Corrigan emailed Mr Eamon Mackle, Clinical Director of Surgery in the Trust, on 9th August 2010 (within Attachment 20) indicating concern that IVT was ongoing and that some patients were receiving this via a central line. She suggested the Trust should establish a multidisciplinary team to address the issue. This email also stated that she planned to seek information on trends regionally in cystectomy operations.

Correspondence between Dr Corrigan and the Medical Director of the Trust on 1st September 2010 (Attachment 25), copied to the Trust's Director of Acute Services Dr Gillian Rankin, and Mr Eamon Mackle Clinical Director of Surgery, sought an assurance that the practice of admitting patients for IV fluids and antibiotics (IVT) was being brought to an orderly end. Further actions were requested in respect of benign cystectomy in the same correspondence which are set out in the next section.

96 **II. Benign Cystectomies**

A. Provide a copy of any data available to the PHA
Three Excel spreadsheets, provided to Dr Corrigan by the HSCB Performance Management and Information Directorate in August 2010, are provided as attachments in (Attachment 20, 21 & 22). The first two show annual numbers of cystectomy and ileal conduit procedures in NI, by hospital and consultant. The second is a refinement of the first with different search criteria. The third spreadsheet shows Craigavon Hospital data only.

97 **B. Outline the source of any data available to the PHA**
The data available to the PHA was sourced from the HSCB Performance Management and Information Directorate and is extracted from coded inpatient episodes held on Trust Patient Administration Systems (PAS). The quality of this information, and any conclusions drawn from it, relies upon the completeness and accuracy of coding within Trusts.

98 **C. Outline what, if any, analysis was conducted on any data collected**
Dr Corrigan reviewed the data. Once cystectomy operations done for malignancy or for complex neurological conditions were excluded, the remaining numbers were small and varied from year to year. Over the time period complex cancer surgery had been expected to move towards centralisation in Belfast, and this appeared to be reflected in the data. Of the small number of cystectomy procedures done for benign reasons, there appeared to be a slightly higher proportion done in Craigavon Area Hospital than expected compared to other hospitals.

99 **D. Outline what, if any, trends were identified as a result of any analysis conducted**
The response to the previous question covers this point.

100 **E. What, if any, concerns were identified as a result**
Dr Corrigan shared a summary of the issues to date, including the link to IV fluids and antibiotics and the data collected, with the Director of Public Health, Dr Carolyn Harper (the DPH), and Dr Corrigan's line manager, Dr Janet Little, Assistant Director for Service Development and Screening (AD). She sought their advice on potential next steps (emails of 19th 23rd and 25th August 2010, (Attachment 20, 23 & 24), in light of the information to date.

101 **F. Outline what, if any, action was taken to obtain any explanation or clarification of any trends identified or address any concerns which arose** Dr Corrigan's email to the DPH and AD explained that she could not be sure if the data demonstrated a significant clinical issue in respect of benign cystectomy, but suggested sharing the data with the Trust, asking that they reviewed the data and undertook their own investigation based on the greater clinical detail available to the Trust in patient records. In the DPH's absence on annual leave, Dr Little agreed with this approach (email of 25th August 2010, (Attachment 24). Dr Corrigan wrote to the Medical Director of the Trust on 1st September 2010, copied to the Trust's Director of Acute Services Dr Gillian Rankin, and Mr Eamon Mackle Clinical Director of Surgery (Attachment 25). This letter

- shared the cystectomy and ileal conduit data described under B above;
- asked the Trust to check the accuracy of the data and depending on the outcome consider seeking expert independent advice;
- asked for an assurance that all patients requiring radical pelvic surgery were now being referred to the regional centre (in Belfast);
- asked the Trust to provide a report detailing steps on manage ongoing risks associated with IVT, including the timeframe for this to cease.

102 On the same date Dr Corrigan emailed Beth Malloy, HSCB Assistant Director for Elective Care, who led on both cancer services commissioning and managed implementation of the 2008 Regional Review of Urology, and Caroline Cullen, Senior Contracts Manager, HSCB Southern Locality Commissioning Group (SLCG) to check the commissioning position in respect of an expectation that benign cystectomy procedures should be done in Belfast (Attachment 26).

103 Dr Corrigan emailed Mrs Lyn Donnelly, HSCB Assistant Director of Commissioning for the Southern Locality Commissioning Group (SLCG) on 3rd September 2010 (Attachment 27), copying the correspondence that had been sent to the Trust, to inform her of the issues. Mrs Donnelly in an email dated 8th September (Attachment 28) stated that she had informed the HSCB Director of Commissioning, Mr Dean Sullivan.

104 Dr Corrigan also forwarded email (Attachment 27) to Mrs Pat Cullen, Assistant Director of Nursing, Quality and Safety on 7th September 2010. The same email was later shared on 2nd December 2010 with the HSCB Director of Performance Management and Service Improvement, Ms Louise McMahon, who was leading implementation of the Urology Review, to provide context for a discussion on cystectomy which had taken place at a regional meeting.

105 The Trust Medical Director, Dr P Loughran, emailed a response to Dr Corrigan's letter of 1st September 2010 on 16th September (Attachment 29). This confirmed that:

- IVT had not ceased, but plans to do so, including a weekly report on progress to him, were now agreed;
- a remit had been agreed for a review of the cystectomy operations for benign disease over the previous 10 years, led by Mr E Mackle;
- that there were definite arrangements to ensure no further radical pelvic surgery cases would be done in the Trust.

Dr Loughran's email was forwarded to Dr J Little and Mrs L Donnelly on 20th September 2010 for information.

106 On 11 March 2011 Dr P Loughran's office forwarded a letter to Dr Corrigan providing an updated position and resolution of clinical matters within the Trust urology service. This stated that

- None of the original cohort of patients on IVT remained on this treatment
- An internal, clinically-led, review had taken place of benign cystectomy cases over a 3 year period (13 cases).
- The Trust had engaged an external specialist urologist as independent assessor who was expected to visit the Trust at the end of March 2011.

This letter was forwarded to Lyn Donnelly, AD, SLCG on 29th March 2011 (email and letter , (Attachment 30)
In a final email dated 28th July 2011 from Dr Loughran to Dr Corrigan (Attachment 31) he stated that the external review by Mr Marcus Drake from Bristol was almost complete, and that having seen the interim report there were no gross errors or faults and that overall he expected the final report would be supportive/indeterminate. He reiterated that this surgery was no longer being undertaken in the Southern Trust.

107 **III. Prescription of Bicalutamide**

Prior to receiving the early alert and subsequent meetings, the PHA was not aware of prescribing issues.

108 **IV. Any other trends identified or data collected with regard to Urology Services within the Trust, whether positive or adverse**

In the early 2000s Urology would have been one of many specialties within Southern Trust where the SHSSB would have been in regular contact with the Trust in relation to waiting lists, waiting times, the implementation of new models of care, requests for new funding and contract adjustments. Professional staff who subsequently became employees of the PHA would have attended many of these meetings. The master copies of agendas, minutes, business cases and performance management data are held by the HSCB as successors of the SHSSB and are not currently available to the PHA. The PHA document search includes a small number of emails and copies of these documents which were held in individual PHA staff personal files.

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	114 When a report is submitted by the HSCT for a SAI to HSCB Governance it is forwarded to the DRO/ Professional group for consideration of the robustness of the report and any regional learning. Once the DRO/ Group are content with the report and have or have not indicated any regional learning the report will be closed via email from the SPPG serious incidents inbox. 115 If regional learning is identified this will be taken forward by the relevant DRO/ Professional group in the form of a learning letter, reminder of best practice letter or a Learning Matters newsletter article. 116 The policy decision for the transfer of the procedure is a matter for the Department of Health. 117 The oversight of the Procedure for the Reporting and Follow up of Serious Adverse Incidents is overseen by HSCB/SPPG and they are best placed to explain any updates or amendments to the procedure.
14	*In the period prior to 2016 was the PHA made aware of any SAI and/or complaint (whether formal or informal) involving the care provided by, or the conduct of Mr Aidan O'Brien. If so, provide full details.* 118 The computerised system (Datix) for SAI management is managed by the SPPG, previously HSCB. Some, but not all DROs within PHA have "read only" access to Datix: the data held is owned by SPPG. PHA staff who contribute to the HSCB/SPPG SAI process may have emails and documents relating to individual SAIs or copies of minutes of meetings and action logs issued by the SPPG or HSCB, but these personally-held records are incomplete. 119 The PHA is aware of an additional SAI [Personal Information redacted by the USI], involving the specialty of urology in CAH prior to 2016. As is the case in all Trust RCA reports, individual staff members are not identified. This incident occurred on 7th July 2010 and was notified to HSCB on 3rd September 2010. The incident was reported as a retained swab after major urological cancer surgery. The DRO, Dr Diane Corrigan, Consultant in Public Health Medicine, identified that the incident also involved a problem in respect of management of a radiology result. The emails and reports which are held by PHA are included in the response to question 48. Additional information may be held by the SPPG on the Datix system or elsewhere. 120 **Detail on** [Personal Information redacted by the USI] **A. Identify the Governance Lead and outline all actions taken by them** The HSCB lead this process. 121 **B. Identify the DRO and outline all actions taken by them** Dr Diane Corrigan, Consultant in Public Health Medicine, PHA. The HSCB position report (Attachment 37) states that Dr Corrigan was forwarded the SAI Report (Attachment 32) on 7 January 2011. On 7th April 2011 Dr Corrigan emailed Dr C McAllister, lead investigator for the SAI seeking advice (Attachment

33). The HSCB position report states on 4th May 2011 that Dr Corrigan was intending to meet the Trust about open SAIs that month to clarify outstanding issues. On 14th November 2011 Dr Corrigan wrote to Mrs Debbie Burns, Assistant Director Clinical and Social Care Governance in SHSCT (Attachment 34). The detail of subsequent correspondence is set out in sections F, G and H below.

122 **C. Outline when and in what circumstances the PHA became aware of each SAI**

The HSCB position report states that the SAI was notified on 3rd September 2010.

123 **D. If there was any delay in reporting the SAI on behalf of the Trust, outline what if any steps were taken by PHA to address same**

HSCB manages the timelines for submission of notifications.

124 **E. If there was any delay in preparing the investigation or review report on behalf of the Trust, outline what, if any, actions or steps were taken by PHA to address same**

The HSCB manages the process to seek reports from Trusts. The HSCB position statement (Attachment 37) indicates that the Trust sought an extension for submission of the RCA report.

125 **F. Upon receipt of the investigation or review reports, what action was taken by the DRO to quality assure the adequacy of the investigation and to reduce the risk of recurrence**

The DRO felt that the SAI report, while comprehensive in respect of the issue of a revised process to avoid recurrence of a retained swab, had not addressed a more important issue. The patient was to have a CT scan some months after their operation, and then to be reviewed at outpatients a short time later. The scan was done and the report indicated an abnormal finding. The differential diagnosis included a potential cancer recurrence; in fact, this abnormality was the retained swab. However, the result was filed, the patient was not reviewed as planned, and the problem only came to light following hospital admission many months later. If the abnormality had been a cancer recurrence the patient could have come to even greater harm. The DRO wrote to the Trust on 14th November 2011 asking that the issue of filing results without them being seen by a clinician was addressed (Attachment 34).

126 **G. Outline what if any learning was identified by the DRO**

The DRO also suggested on 14 November 2011 that there was additional action that could be taken by the Trust to avoid a similar incident. In particular, that the Trust could develop a formal Trust policy for all specialties, so that results of investigations were not filed in patient charts before they had been seen by a doctor.

127 **H. How was any learning identified by the DRO shared or communicated with the Trust or any other relevant person or body**

The emails and letters between Dr Corrigan and the Trust's Assistant Director for Clinical & Social Care Governance, Medical Director and Governance Manager (Documents (Attachments 34, 35, 36, 38) indicate that her suggestion was not considered easy to implement. Alternative protocols were shared with HSCB but none appeared to address the underlying issue. However, it was confirmed on 17th December 2014 (Attachment 39) that the process was as follows:

'Secretaries have confirmed that they do not file results without them first being viewed by the consultant; Consultants mostly sign these and some then dictate a letter.'

128 Dr Corrigan accepted this statement on 29 October 2015 (in e-mail string, (Attachment 40). As she did not know if there had been similar SAIs reported she shared the Trust email with Ms Lynne Charlton, PHA Head of Nursing (Quality, Safety and Patient Experience) who asked HSCB to run a Datix query in respect of SAIs filed away without action (Attachment 40). It was reported by HSCB staff on 16th January 2017 that it was not possible to undertake this search as this category of incident was not coded on Datix (in e-mail string (Attachment 42).

129 **Outline the nature of the discussion at the HSCB/PHA SAI Review Group and address if any trends were identified or problematic issues discussed. Provide any relevant documentation relating to any such discussions or follow up**

Emails show that there was a further request to see a copy of the CAH laboratory protocol (in HSCB position report, (Attachment 41). This was provided. The SAI was closed by email to the Trust on 30th November 2017 (Attachment 43). This email stated that 'learning issues raised within this SAI have been taken forward within the Delayed Diagnosis Exercise and the Newsletter article 'Accurate Communication of actions and results', published in edition 6 of the Learning Matters Newsletter'.

130 **I. Outline if any of the issues, trends or concerns arising from the SAI review were attributed to the practice of Mr O'Brien**

The report did not identify the clinicians involved.

131 **J. Outline what, if any discussions took place with the Trust with regard to any issues, trends or concerns arising from the SAI whether these were attributed to the practice of Mr O'Brien or otherwise**

Email correspondence took place between Dr Corrigan, the HSCB governance team, and Trust officers as described in answers F, G and H and provided to the Inquiry.

132 **K. What if any action was taken by the PHA to ensure the recommendations from the SAI were implemented and the issues addressed.**

All the recommendations in the Trust RCA Report were for action within the Trust. As stated in section 8.0, page 27, of the *Procedure for the Reporting and Follow up of Serious Adverse Incidents*, Trusts are expected to have mechanisms in place to cascade local learning from adverse incidents and SAIs. Implementation of local recommendations are therefore not followed up by HSCB or PHA. The correspondence to the Trust from HSCB on closing this SAI on 30 November 2017 (Document 23) stated "In line with the HSCB Procedure for the Reporting and Follow up of SAIs (Nov 2016), please note that it is the responsibility of the Trust to take forward any local recommendations or further actions identified and monitor these through the Trust's own governance arrangements. This is an essential element in reassuring the public that lessons learned, where appropriate, have been embedded in practice."

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25	*Did the PHA reach any view concerning the appropriateness, quality and timeliness of the steps taken by the Trust to communicate and escalate the reporting of issues of concern within the Trust to the Department, the PHA or any other relevant body? If so, fully outline the view which has been reached and set out the reasons for the view which has been reached. If the PHA has not evaluated this issue, please explain why and provide such a view.* 217 Actions of the SHSCT following issuing of the Early Alert Dr Farrell phoned the Medical Director to get additional information (see response to question 1). The Medical Director described the problems they had uncovered including: delays in putting patients onto the waiting list, delays in patients being followed up after hospital discharge, non communication of management plans for patients and not acting on results of investigation. In response to the issues identified SHSCT were in discussions with the Royal College of Surgeons (RCS) and British Association of Urological Surgeons (BAUS) about an invited service review (ISR) to look at a sample of records of records for the previous 5 years and organising an Independent chair for the Serious Adverse Incident reviews. They had already started a case note review and were trying to find additional capacity in the Independent sector for patients to be reviewed. Dr Farrell advised that the Chief Medical Officer needed to be informed if patients were being contacted following case note review. 218 The PHA's priority after the Early Alert was to ensure that measures were taken to ensure patients were on the correct treatment pathway and patients with a delayed review were seen in a timely manner. PHA also clarified that Aidan O Brien was not seeing patients and that the appropriate regulatory authorities e.g. GMC and RQIA were involved. As more patient reviews were completed new issues emerged e.g.suboptimal prescribing. 219 The PHA subsequently attended the meetings with SHSCT where updates were provided. PHA did express concerns (19/11/20, 04/03/21, 03/03/22) at these meetings that more cases will need to be reviewed when the initial case note review of cases between the 01/01/19 and the 30/06/20 is completed. PHA also raised the issue that more support was needed to be given to the clinician who was doing these reviews and that a more structured approach was needed for extracting information from case notes (see e mail to from Dr Farrell to Paul Cavanagh of 3rd December 2020 advising that minutes did not reflect discussion on need for structured proforma for extracting information from casenotes and reviewing the outcome of patient reviews) 220 Actions of the SHSCT following receipt of the Overarching SAI report When the overarching SAI report was received, Dr Farrell emailed the medical director in SHSCT (4/03/21) and the Director of Commissioning in HSCB/SPPG giving a general comment about the report and raised concerns about the commentary relating to how urology cancer multidisciplinary teams (MDTs) operated and whether this way of working was happening in other cancer MDTs

	in the SHSCT. Following this a meeting was arranged with the SHSCT and NICAN representatives to explore further and seek assurances that they were operating as effective MDM. 221 The PHA experience is that compared to the Neurology Lookback exercise, a lot of the work being undertaken by the SHSCT following the issuing of the early alert had been completed by the BHSCT before the PHA / HSCB became involved. When the public announcement was made of the Neurology lookback Belfast Trust already had capacity secured for everyone to be reviewed and patients were able to book their appointment to be reviewed by a neurologist after they received a letter from the BHSCT advising them of the neurology lookback. In the neurology lookback the invited service review had been completed and because of the result of the invited service review all neurology patients in a certain time period were invited to be reviewed and high risk patients would be seen early in the recall. 222 Urology as a speciality is not comparable to Neurology but the processes to be followed when clinical concerns emerge about a single doctor should be similar. When patients need to be reviewed in a lookback ideally this needs to be expedited as quickly as is practicable. However, SHSCT experienced difficulty securing additional urology capacity and already had significant waiting lists. New issues also emerged during the casenote review which needed to be addressed eg prescribing. 223 The new Lookback Guidance is much clearer on what needs to be done when there are concerns about the practice of an individual.
26	*Did the PHA reach any view concerning the effectiveness of the corporate and clinical governance procedures and arrangements within the Trust in the context of the matters which gave rise to the need to issue an Early Alert? If so, fully outline the view which was reached and set out the reasons for the view which had been reached. If the PHA did not evaluate this issue, please explain why and provide such a view.* 224 The PHA has not made an assessment of corporate and clinical governance procedures in SHSCT. 225 As described in the responses to question 1 and question 25 the PHA's priority after the Early Alert was to ensure that patients were on the correct treatment pathway and patients with a delayed review were seen in a timely manner. PHA also clarified that AOB was not seeing patients and that the appropriate regulatory authorities e.g. GMC and RQIA were involved. 226 Several of the recommendations of the Neurology Independent Inquiry (June 2022) are relevant to this question. Recommendations 27, 46, 47 and 48 of the Inquiry report concern actions to follow when there are issues with one aspect of practice eg triaging of letters do you need to review other aspects of practice at the same time? How do Trusts ensure regional guidelines are followed? How do Trust identify variations or changes in practice in a timely way?

	271 The PHA has not sought assurances from any of the people/organisations listed and does not consider it appropriate for more than one organisation to be contacting Mr O Brien.
42	*If assurances have been sought and provided in respect of Mr O'Brien's private patients, how has the PHA tested the effectiveness of these assurances? Is the PHA satisfied by the assurances provided? If not, what are the PHA proposed next steps, if any, regarding Mr O'Brien's private patients?* 272 Please see answer to question 41.
43	*Has the PHA reached any view concerning the appropriateness, quality and timeliness of the steps taken by the Trust to address the issues of concern and ensure patient safety? If so, fully outline the view which has been reached and set out the reasons for the view which has been reached. If the PHA has not evaluated this issue, please explain why*. 273 The PHA does not have access to patient information and is acting in an advisory role in the lookback process. At the regular meeting between the SHSCT and HSCB/PHA clarification was regularly sought on a range of issues. 274 Ongoing assurance that patients are being reviewed in a timely way was being provided through this group and the Department of Health led oversight group.
44	*From the information available to the PHA to date, what does it consider went wrong within the Trust's urology services and with regard to Trust governance procedures and arrangements? Has the PHA reached any view on how such issues may be prevented from recurring? Has the PHA taken any steps with a view to preventing the recurrence of such issues?* 275 All HSC organisations are expected to meet extant DoH requirements as set out in the relevant Circulars such as those on complaints, early alerts and lookback reviews. Trusts are also expected to adhere to HSCB/SPPG guidance on the management of SAIs. Individual Trusts have flexibility in establishing internal structures within certain parameters to manage clinical governance issues. They are also responsible for managing individual clinician performance issues. The PHA does not have an oversight role in this regard. Although senior PHA staff have participated in the HSCB and DoH groups established to oversee the process from 2020 onwards, PHA had no regular engagement with the Trust between January 2017 and the issuing of the Early Alert. 276 It follows that the PHA does not have a final view on this question, but the following issues appear relevant. 277 The SAI process, although not designed to identify or manage failings in individual clinical practice, did on this occasion flag a problem in 2016 within urology and when asked the Trust stated this was in relation to one clinician. The HSCB/PHA process sought and received assurances from the Trust that the issue had been resolved (primarily by the introduction of an e-triage system). The SAI system relies upon trust in communication between HSCB/PHA and Trusts. It is not resourced to test the veracity of Trust assurances.

	278	The PHA is now aware that the Trust had been trying to address issues in Mr O'Brien's practice from 2016. The MHPS process was prolonged and unfortunately did not resolve the situation. It is noted that the majority of the issues identified appear to relate not to the clinician's technical competence as a surgeon, but instead to appropriate and timely triage of referrals, ordering of diagnostic tests, action on results and MDT teamwork. It appears possible that governance systems are more focussed on failings in clinicians' technical competence and are less capable of managing poor practice in areas of 'patient administration'. The latter are equally capable of causing patient harm and need to be given equal weight.
	279	There needs to be a systematic approach within Trusts to identify and flag clinical or administrative issues meriting further exploration. In the Submission from Mr Paul Cavanagh, HSCB Director of Commissioning to Mrs Sharon Gallagher, HSCB Chief Executive in May 2021 it was noted that data infrastructure in the HSC makes routine audit of care across all pathways very challenging. However, recommendations 5, 6, 8, and 9 in the Submission address issues in cancer pathways which should prevent recurrence in this high risk field of practice. These recommendations are supported by the PHA.
	280	In addition, all measures described in Q 40 need to be working effectively and efficiently to detect suboptimal practice and there needs to be single oversight of all of these within a Trust.
45		*Does the PHA consider that it did anything wrong or could have done anything differently which could have prevented or mitigated the governance failings of the Trust?*
	281	The PHA regrets that patients have suffered as a result of the care provided in the SHSCT by Mr O'Brien. As set out in the response to Q43, the PHA is not fully sighted on the internal processes which took place within the Southern Trust between 2016 and notification of the early alert in 2020. However, it is noted that the SAI process, although primarily designed to identify regional learning, and not to identify or manage individual clinician failings, did allow the Trust to flag that there was a problem and that action was needed to address a risk to patients. It was reported to HSCB/PHA that actions were being taken; it is not yet clear why that did not resolve the issues. In this context PHA staff working within the SAI process were not in a position to prevent or mitigate Trust failings.
	282	To prevent or minimise the risk of this happening in the future requires a significant system and culture change within Trusts to ensure that all approaches listed in response to Q40 operate efficiently and effectively and are considered as a whole.
	283	The recommendations of the Neurology Inquiry are also relevant to what happened in Urology in the SHSCT.
46		*From the PHA'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 PHA? Whether your answer is yes or no, please explain.*