Response	I was not aware of any Urology complaint being referred to the Ombudsman in my tenure. However, having reviewed the Trust systems there was one referral dating back to a complaint in 2010, running until 2014. I have attached all correspondence as appendix 40. Overall, looking back on the documents and not having been directly involved I am unaware as to whether this case was discussed at the governance meetings of the time. However, having reviewed the information I would be of the opinion that learning could certainly have been gained from this complaint.

Other Plan(s)

Q65	**65. In light of the current proposed plans to restructure management at the Trust, it would be helpful to have copies of:** **(a) the *Corporate plan* for 2017-2021/2022;** **(b) the *People Plan*, if available, and any previous versions;** **(c) the *Safety, Quality and Experience Plan*, if available, and any previous versions;** **(d) the *Patient and Client Experience Strategy*, if available, and any previous versions; and** **(e) the *Clinical Audit Strategy*, if available, and any previous versions.**
Response	(a) the *Corporate plan* for 2017-2021/2022; This is attached at Appendix 30a. (b) the *People Plan*, if available, and any previous versions; The People Plan is still in development. However, appendix 30b is a copy of slides that have been used to discuss the proposed purpose and content of the plan. (c) the *Safety, Quality and Experience Plan*, if available, and any previous versions; This is still in development. (d) the *Patient and Client Experience Strategy*, if available, and any previous versions; and This is attached at Appendix 6. (e) The *Clinical Audit Strategy*, if available, and any previous versions. The revised draft Clinical Audit Strategy is attached as appendix 30c.

Urology Services

Q66	**Please provide all notes and minutes of any meetings with the Trust Board, Trust Committees, any Trust or Departmental Staff or any third party or health body in which the problems with Urology Services were discussed.**
Response	I believe that all of the notes covered by this request have already been provided in response to Section 21 Notice 2a of 2021 In ease of the Inquiry, the minutes of meetings that I was party to have been attached as appendix 41.

Q67	**It appears from publicly available Annual Reports that, during your tenure, the Trust Board has had several Medical Directors: Dr Richard Wright (April 2018 – August 2018), Dr Ahmed Khan - Interim (April 2018 - December 2018), and Dr Maria O'Kane (December 2018 – present):**

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

	(i) What was the reason for this turn-over in personnel? **(ii) Did this turn-over in personnel impact on your ability to be properly appraised of clinical governance and patient care and safety oversight within Urology Services or more generally?** **(iii) Did the change in personnel impact on your role in any way?** **(iv) Do you consider that changes in personnel at both Senior Management and Board level contributed to difficulties in identifying and addressing problems?**
Response	*(i) What was the reason for this turn-over in personnel?* Dr Richard Wright Retired at in 2018 following a period of ill health. Dr Ahmed Khan undertook the Medical Director role on an interim basis whilst I established my new structures and got approval from the Permanent Secretary to fill my new Director posts. Dr Maria O'Kane was substantively appointed as Medical Director in December 2018. *(ii) Did this turn-over in personnel impact on your ability to be properly appraised of clinical governance and patient care and safety oversight within Urology Services or more generally?* As referenced in many places in this document, I have made considerable changes to governance processes and structures in my tenure. In my view, the need to make these changes was not as a result of staff turnover. However given my newness to the organisation, and with hindsight, I believe it would have been beneficial to have had a stable Medical Director role. Therefore, on reflection, director turnover may have impacted on my ability to be properly appraised of clinical governance and patient care and safety oversight within Urology Services. *(iii) Did the change in personnel impact on your role in any way?* At the time of the instability I would not have recognised the personal impact. With hindsight and on reflection, the newness of me to the role of Chief Executive coupled with an acting Medical Director, meant that I was not getting the same level of assurance as I am now getting with revised processes and an excellent Medical Director in Dr Maria O'Kane. *(iv) Do you consider that changes in personnel at both Senior Management and Board level contributed to difficulties in identifying and addressing problems?* Given that the Trust had a period of significant Chief Executive instability before I joined in March 2018 there is no doubt in my mind I had a lot to do to steady the ship. My main focus was twofold. First, to recruit a substantive Senior Management Team and, secondly, to created a strong governance environment. (I have described both of these elsewhere in this statement). Accepting the position I inherited, I would consider that during this process of creating steadiness it is likely that identification and addressing of problems was not optimal. In particular the review of clinical and social care governance and the subsequent implementation of improvement could only have started after I had steadied the role of Medical Director and therefore this review was in excess of one year after I was appointed. I would suggest that, if I had not needed to spend a year steadying the SMT, I would have started our governance improvement journey earlier in my tenure.

Q68	**Do you consider that the Board operated efficiently and effectively during your tenure? If not, please describe your experiences.**
Response	I consider, based on my experience and through audit, that the Board operated efficiently and effectively during my tenure. As can be seen through the Board effectiveness audits, carried out independently by BSO Internal Audit (appendix 36), the Board functioned in line with good governance and during my tenure, in all years, the Northern Ireland Audit Office reported to those charged with governance that our systems were sound.

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

	information relating to diagnosis. The Trust has just created a new role and appointed a new MDT Administrator as of the 4th January. The MDT Administrator will be pivotal in supporting the functions of the MDT meetings. The Trust have focused on our Cancer Nurse Specialists and have workshops starting 18th January to establish an audit framework specific to their role. The outcomes of this workshops will be shared regionally and will allow the Trust to benchmark against other Trusts with regards to performance and patient experience/ satisfaction. These workshops are also going to focus on nurse lead activity including Holistic Needs Assessment clinics.

Q75	***Can you explain from your perspective how you understood Urology Services was supposed to operate from a clinical governance and patient care and safety perspective compared to how it did in fact operate? If your understanding changed over time, please explain this within your answer.***
Q76	**Can you identify in what aspects you considered Urology Services to be operating adequately and in what respects it was failing to do so? If your understanding changed over time, please explain this within your answer.**
Q77	**Do you have an explanation as to what went wrong within Urology Services and why?**
Response	Given that questions 75, 76 and 77 are asking a very similar question in slightly different ways, I propose to answer all three in one composite answer. Based on my knowledge to date (recognising that it is unlikely to be full and complete) and acknowledging that it is the Inquiry that will determine the facts of what actually happened, I set out below my understanding and explanation of the issues raised in these closely related questions. From my perspective, Urology Services was supposed to operate in the same way as all other services, that is: 1. Services should be planned and commissioned in line with population need as identified through commissioning. 2. The Trust should respond to that commissioning intent with a plan to meet demand and be resourced in full. 3. Operational teams should be properly resourced and work together to deliver services in line patient and commissioner needs. In terms of Urology this should include across to other multi-disciplinary teams. 4. Management should set objectives and performance manage the team to meet those objectives 5. Patient outcomes should be monitored to ensure that patients are receiving the care that they need. 6. Governance should be monitored (clinical and social care governance), gaps should be identified and learning implemented. 7. Assurance reporting should occur through management lines up to Trust Board. In my opinion, based on my experience as Chief Executive in the Southern Trust and the historical knowledge I have gained with regards to the experience of Urology Services in the Southern Trust, the following are probable issues and failings that occurred: 1. Demand grew at a faster rate than resources. It is clear that the required activity volumes could not be achieved with the resources that were available to the team. This was a composite of two factors. First, the overall amount of money available from the commissioner was not enough for elective care to meet the demands. This factor has been recognised throughout the HSC and major investment is required. The second factor is that there are not enough Urologists in Northern Ireland to meet the demand, even if money was made available. 2. Given that so many elective specialties were struggling to meet demand and the Trust

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

Delivery Plan did not identify Urology as the only service not meeting its targets, there was no obvious focus on Urology performance.

3. Patient outcome and other safety indicators were not managed at a local level. For example, historically peer reviews were carried out yet there is little evidence of the action plans being delivered and little evidence of a clinical governance system identifying the lack of progress.
4. Despite attempts to manage Mr O'Brien, there was evidence that opportunities were missed to address his behaviours. For example, action plans that were agreed to be developed and implemented in 2016 were not fully carried through.
5. Mr O'Brien is reported to have behaved in a renegade manner and often excluded other members of the Multi-Disciplinary Team (MDT) to patient meetings.
6. The governance and management systems of the time were either not sensitive enough, or were deliberately evaded, so that issues of clinical or operational performance were not escalated. As a result, neither SMT nor Trust Board addressed the issues early enough as they remained invisible to them.

We, SMT, have attempted to address many of these issues over the last four years, although the issue of resourcing of elective care remains a considerable risk. Some of the action taken, and described elsewhere in this document, can be summarised as follows:

1. We have appointed a substantive and experienced Medical Director to take a lead on transforming our governance structures.
2. We have externally reviewed the Clinical and Social Care systems within the Trust and introduced the following improvements:
    a. Introduced new systems for managing CSCG on a weekly basis across all Directorates to enable a collective position and reporting to SMT and onward escalation to Trust Board if required.
    b. Strengthened the Directorate governance systems and now systematic processes out-turn strong controls and clear improvement.
    c. Introduction of a new system and process for managing Serious Adverse Incidents.
    d. Revision of the risk management processes, regular review of risks at SMT level, deep dives at Trust Board level and a satisfactory Internal Audit review of risk management in 2020/21.
3. We have introduced a Performance Committee of the Trust Board to interrogate performance and drive improvement.

I fully acknowledge that the work that we have started, with regards to improving Clinical and Social Care Governance (CSCG) within the Trust, still has a considerable journey to travel. The proposed new CSCG model of working (appendix 16) has yet to be imbedded and two major areas of improvement for 2022 are the introduction of the new clinical audit strategy and the implantation of improvements to the complaints process.

In conclusion, it is my view that it is clear that the governance systems did not highlight the risks that were being carried at an individual clinical level up to the Trust Board. The line of sight from the boardroom to the bedside, which should be clear in a high functioning system, was not so in the case of Urology. Poor performance was not highlighted or addressed at many levels and opportunities to address the issues were not taken.

Based on the work that has been undertaken by the SMT over the last four years I am assured that systems have improved and that the chance of failure has greatly reduced. However, as Chief Executive I am very sorry that the systems that were in place failed and that patients will have come to harm.

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

	now changed as the BT surgeon has left and there is no capacity to provide a centralised service. Currently this is being provided by both the Southern trust and the Western trust.

Other Concerns identified	Update
Out-sourced cancer diagnostics	There has been inaccurate reporting of MRI Prostates. This could place patients at risk as clinicians rely on these reports to inform decision making and counsel patients.
Job plan - MDT Clinical Lead	Dedicated time and support is required for the MDT Clinical Lead to fully undertake the role, including administration support.
Audits	There is a lack of resource to support the implementation of audits to inform quality improvement and service development.

May 2018

Received from Dr Dermot Hughes on 08/11/2022. Annotated by the Urology Services Inquiry.

Update on the concerns identified from the Urology MDT Peer review External Verification - October 2017

EV RAG rating – RED; % compliance 2017: 65%

Serious concerns **Update May 2018**

Serious concerns	Update May 2018
1. No cover in place for the clinical oncologist and the consultant radiologist	Clinical Oncology representation (core & cover) – provided through the regional Oncology Centre when possible but is not the same person each time and is still not consistent Consultant radiology representation – no cover for the radiologist though an expression of interest is being developed to recruit an additional radiologist with urology interest/expertise
2. 11% quoracy due to low clinical oncology and radiology attendance	Quoracy has decreased from previous year (25% down to 11%). Only 5 meetings were quorate throughout 2016 and it is perceived that this has decreased even further. Therefore more patients are not benefitting from the knowledge and expertise of a full multidisciplinary team when decisions are being made about diagnosis and care. This could lead to delays in the decision making processes and treatment.
3. Long waits for routine referrals	Due to increasing number of referrals, the service is concentrating resource on meeting red flags and urgent demand. Routine referrals waiting times have increased from 52 weeks to 128 weeks (present day). Referrals are triaged by consultants so there is the opportunity for routine referrals to be upgraded.
4. Nephron sparing surgery undertaken locally	This issue was resolved at the time of the external validation as Mr Haynes was providing support to undertake nephron sparing surgery at Belfast City Hospital. The situation has

Received from Dr Dermot Hughes on 08/11/2022. Annotated by the Urology Services Inquiry.

70.2 On the basis of the data available at that time and in the absence of concerns being raised about prescribing or the management of patients through the cancer pathways I did not have concerns raised with me at that time in relation to Mr O'Brien's clinical performance or patient safety, but was aware that his conduct was concerning. When it was discovered on 7th June 2020 that there was a discrepancy in waiting and surgical lists, this was fully explored and the Department of Health informed.

70.3 If I had known in January 2019 what I know now (i.e., since June 2020) I would have done a number of things differently.

i. As Medical Director, I would have advised the Directors' oversight of Mr O'Brien's MHPS case and the Chief Executive that a further restriction, if not exclusion, to his clinical practice be instigated. This should have been done while we undertook a review of all of his practice and not just the practice which had been highlighted as deficit at that point, namely in relation to triage, dictation, record access and private patients.

ii. As was the case throughout the MHPS investigation and throughout Dr Johnston's SAI, the system was blind to a part of itself, namely the uro-oncology aspects of care. On reflection, this was due to the fact that this part of the system in the Southern Trust is managed separately from Urology services, including the Cancer Nurse Specialists, and also because some of the consultants as part of the MDM were either absent or employed by a separate Trust (the Belfast Trust) or both.

iii. For example, there was lack of awareness during the SAI and MHPS processes that the Clinical Nurse Specialists had been excluded from the patients' care and, as such, they were not interviewed. Had they been included, this may have given us an indication at an earlier stage that there were difficulties with cancer pathways. It was not until Mr Haynes spotted the discrepancy in patient lists and explored this that we were able to identify the range of difficulties in Mr O'Brien's care of cancer patients. Dr Hughes' SAI process and the subsequent Structured

Received from Maria O'Kane on 02/09/22. Annotated by Urology Services Inquiry

6.0	FINDINGS

support from their GP and where hence referred to the Emergency Department which the review team agree was not the best place for them. The review team are of the opinion that access to a specialist nurse could have offered support for these families and provide direction to the appropriate services.

Governance / Leadership

- The review team considered the treatment and care of 9 patients who were treated under the care of Dr 1 Consultant Urologist. Individual reviews were conducted on each patient. The review team identified a number of recurrent themes following each review.
- The treatment provided to 8 out of 9 patients was contrary to the NICAN Urology Cancer Clinical Guidelines (2016). This Guidance was adopted by the Southern Health and Social Care Trust Urology Multidisciplinary Team and evidenced by them as their protocols for Cancer Peer review (2017). The Guidance was issued following Dr.1 & Chairmanship of the Northern Ireland Cancer Network Urology Cancer Clinical Reference Group.
- The Urology MDM made recommendations that were deemed appropriate in 8 of 9 cases and were made with contribution and knowledge of Dr.1. Many of the recommendations were not actioned or alternative therapies given. There was no system to track if recommendations were appropriately completed.
- The MDT guidelines indicate "all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner". None of the 9 patients had access to a Key Worker or Cancer Nurse Specialist. The use of a CNS is common for all other urologists in the SHSCT urology multidisciplinary team allowing any questions or concerns that patients' have to be addressed. This did not happen.
- The review team considered if this was endemic within the Multidisciplinary Team and concluded that it was not. Patients booked under other consultant urologists had access to a specialist nurse to assist them with their cancer journey.
- Statements to Urology Cancer Peer Review (2017) indicated that all patients had access to a Key worker / Urology Cancer Nurse Specialist. This was not the case and was known to be so.
- The Urology Cancer Nurse Specialist play an integral role of the MDT and should be facilitated on all the MDM to advocate on patient's best interest throughout the patient's journey. This should include independently referring and discussing patients at MDT.
- The Review Team regard absence of Specialist Nurse from care to be a clinical risk which was not fully understood by Senior Service Managers and the Professional Leads. The Review team have heard differing reports around escalation of this issue but are clear that patients suffered significant deficit because of non inclusion of nurses in their care. While this is the primary responsibility of the referring consultant, there is a responsibility on the SHSCT

6.0	FINDINGS

to know about the issue and address it.

- Assurance audits of patient pathways within the Urology Cancer Services were limited between 2017 and 2020. They could not have provided assurance about the care delivered.
- Because of resource, the MDM was very focused on first presentation at MDM and did not have a role in tracking subsequent actions if it lay outside 31 and 62 day targets. Tracking of patients was flawed by limitations within the MDM systems and the lack of Specialist Urology Nurses from their Key Worked role. Two of the three normal safety nets for patient pathway completion were,in essence absent. A collaborative approach did not appear to be actively encouraged within the MDT.
- Annual business meetings had an expressed role in identifying service deficits and drawing up an annual work plan to address them. Cancer Patient Pathway compliance audits were limited and did not identify the issues within this report.
- Governance of professionals within the MDT ran through their own directorates but there was no functioning process within Cancer Services to at least be aware of concerns - even if the responsibility for action lay elsewhere within the Southern Health and Social Care Trust. There was disconnect between the Urology MDT and Cancer Services Management. The MDT highlighted inaction by Cancer Services on Oncology and radiology attendance at MDM, but did not escalate other issues.
- The Review team found that issues around prescribing and the use of Clinical Nurse Specialists were of long standing. They were known internally and in the case of prescribing externally (Regional Oncology Services). The Northern Ireland Cancer Network drew up specific Guidance on Hormonal Therapy in Prostate Cancer in 2016 following concerns about this issue. The Guidance was not subject to audit within the Southern Health and Social Care Trust.
- The Review team were concerned that the leadership roles focused on service delivery while having a limited process to benchmark quality, identify deficiencies and escalate concerns as appropriate. Senior managers and clinical leaders in medicine and nursing were unaware of the issues detailed in this report.
- There had been a previous SAI signed off in May 2020 regarding adherence to Cancer Red Flag referral Pathways. The SAI process started in July 2016. The review team is concerned that, as part of early learning, assurances regarding other aspects of the cancer pathway were not sought. Clinical Leadership within Cancer Services were unaware of issues leading to the SAI in 2016.
- Patients in this review were not referred back appropriately to MDM as their diseased progressed. This meant there was no access to oncology and palliative care for many patients, when needed. Care needs within the community were unmet and patients left isolated.

7.0 CONCLUSIONS

The Review Team would like to thank the patients and their families for their contribution to the report and their willingness to share their experiences. The process was difficult and at times traumatic for them.The review team acknowledge that this report may cause distress to the patient and their families, however the team has endeavoured to produce a complete and transparent account of each patient's journey.

The Review of nine patients has detailed significant healthcare deficits while under the care of one individual in a system. The learning and recommendations are focused on improving systems of multidisciplinary care and it's governance. It is designed to deliver what was asked of the Review Team by patients and families -" *to ensure that this does not happen again or that another patient suffers".*

The Patients in this review received uni-professional care despite a multidisciplinary resource being available to all others. Best Practice Guidance was not followed and recommendations from MDM were frequently not implemented or alternative treatments chosen. There was knowledge of that prescribing practice varied from regional and national guidelines in the Southern Health and Social care Trust, as well as more widely across the Cancer Network. This was challenged locally and regionally, but not effectively, to provide safe care for all patients. Inappropriate non referral of patients to oncology and palliative care was unknown.

The primary duty of all doctors, nurses and healthcare professionals is for the care and safety of patients. Whatever their role, they must raise and act on concerns about patient safety. This did not happen over a period of years resulting in MDM recommendations not being actioned, off guidance therapy being given and patients not being appropriately referred to specialists for care. Patients were unaware that their care varied form recommendations and guidance. They could not and did not give informed consent to this.

The systems of governance within the Urology SHSCT Cancer Services were ineffective and did not provide assurance regarding the care and experience of the nine patients in the review. Assurance audits were limited, did not represent whole patient journey and did not focus on areas of known concern. Assurances given to Peer review were not based on systematic audit of care given by all.

While it is of little solace to the patients and families in this review, The Review team sought and received assurances that care provided to others adhered to recommendations on MDM and Regional / National Guidance.

Four of the nine patients suffered serious and significant deficits in their care. All patients had sub-optimal care that varied from regional and national guidelines.

As part of the Serious Adverse Incident process, the Review Team had requested input fromDr 1. This related to the timelines of care, for the nine patients involved in the SAI reviews and specifically formed part of the root cause analysis. This fell under professional requirements to contribute to and comply with systems to protect patients and to respond to risks to safety. To date a response has not been received.

9.0 RECOMMENDATIONS AND ACTION PLANNING
This will be achieved by - Ensuring all patients receive multidisciplinary, easily accessible information about the diagnosis and treatment pathway. This should be verbally and supported by documentation. Patients should understand all treatment options recommended by the MDM and be in a position to give fully informed consent. Timescale - Immediate and ongoing Assurance - Comprehensive Cancer Pathway audit and Patient experience. **Recommendation 3.** *TheSHSCT must promote and encourage a culture that allows all staff to raise concerns openly and safely.* This will be achieved by - Ensuring a culture primarily focused on patient safety and respect for the opinions of all members in a collatorative and equal culture. The SHSCT must take action if it thinks that patient safety, dignity or comfort is or may be compromised. Issues raised must be included in the Clinical Cancer Services oversight monthly agenda. There must be action on issues escalated. Timescale – Immediate and ongoing Assurance - Numbers of issues raised through Cancer Services, Datix Incidents identified, numbers of issues resolved, numbers of issues outstanding. **Recommendation 4.** *The Trust must ensure that patients are discussed appropriately at MDM and by the appropriate professionals.* This will be achieved by - All MDMs being quorate with professionals having appropriate time in job plans.This is not solely related to first diagnosis and treatment targets. Re-discussion of patients, as disease progresses is essential to facilitate best multidisciplinary decisions and onward referral (e.g. Oncology, Palliative care, Community Services). Timescale - 3 months and ongoing Assurance - Quorate meetings, sufficient radiology input to facilitate pre MDM QA of images - Cancer Patient pathway Audit - Audit of Recurrent MDM discussion - Onward referral audit of patients to Oncology / Palliative Care etc. **Recommendation 5.** *The Southern Health and Social Care Trust must ensure that MDM meetings are resourced to provide appropriate tracking of patients and to confirm agreed recommendations / actions are completed.* This will be achieved by - Appropriate resourcing of the MDM tracking team to encompass a new role comprising whole pathway tracking, pathway audit and pathway assurance. This should be supported by a safety mechanisms from laboratory services and Clinical Nurse Specialists as Key Workers. A report should

9.0 RECOMMENDATIONS AND ACTION PLANNING

be generated weekly and made available to the MDT. The role should reflect the enhanced need for ongoing audit / assurance. It is essential that current limited clinical resource is focused on patient care.

Timescale - 3 months

Assurance - Comprehensive Cancer care Pathway audit - Exception Reporting and escalation

Recommendation 6.

The Southern Health and Social Care Trust must ensure that there is an appropriate Governance Structure supporting cancer care based on patient need, patient experience and patient outcomes.

This will be achieved by - Developing a proactive governance structure based on comprehensive ongoing Quality Assurance Audits of care pathways and patient experience for all. It should be proactive and supported by adequate resources.This should have an exception reporting process with discussion and potential escalation of deficits. It must be multidisciplinary to reflect the nature of cancer and work with other directorates.

Timescale - 3 months

Assurance - Cancer Pathway Audit outcomes with exception discussion and escalation. Data should be declared externally to Cancer Peer Review

Recommendation 7.

The role of the Chair of the MDT should be described in a Job Description, funded appropriately and have an enhanced role in Multidisciplinary Care Governance.

Timescale - 3 months

Recommendation 8.

All patients should receive cancer care based on accepted best care Guidelines (NICAN Regional Guidance, NICE Guidance, Improving Outcome Guidance).

This will be achieved by - Ensuring the multi-disciplinary team meeting is the primary forum in which the relative merits of all appropriate treatment options for the management of their disease can be discussed. As such, a clinician should either defer to the opinion of his / her peers or justify any variation through the patient’s documented informed consent.

Timescale – Immediate and ongoing

Assurance - Variance from accepted Care Guidelines and MDM recommendations

should form part of Cancer Pathway audit. Exception reporting and escalation would only apply to cases without appropriate peer discussion.

The Trust has a Policy Scrutiny Committee. Stakeholders involved in the Committee indicated the challenges in maintaining oversight of review and renewal dates given the sheer volume and diversity of Trust Policies and Procedures. Another challenge is that on occasion the Trust Policy has reached the review date and there is a delay as new legislation or regional guidance is pending and/or a regional policy is being developed. In these instances the Trust should consider amending the Policy Procedure Checklist to indicate an extension to review/revision date due to external factors. Some policy authors advised the Reviewer of delay in time from submission to date of approval and dissemination of policies, especially when external deadlines were a factor. During the Review it was noted that version control was not always robust indicating the potential for staff to be working from a dated or draft version of a policy or procedural document. ***It is recommended that the Trust consider options for an electronic policy and procedure management system that is accessible, easy to navigate, contain a search facility and includes the capacity for email notification of new/changed policy and automates a review/revise reminder***.

4.14.2 Management of Standards and Guidelines

Each HSC Trust is accountable and responsible for ensuring that clinical standards and guidelines are effectively managed so that the required recommendations are embedded within local health and social care practice.

The Trust has a process for the management of standards and guidelines which is reliant on both Corporate and Directorate based systems. Standards and guidelines are logged onto the Trust's database system centrally by the Corporate Governance Team and then forwarded on a weekly basis to Directorate Governance Co-Ordinators, Pharmacy Governance and the Medical Directors Office. Each Directorate have developed their own processes for the management of Standards and Guidelines. During the Review stakeholders expressed concern that were there was evidence that Standards and Guidelines were disseminated, however, there was a lack of assurance that they were being implemented as subsequent audit of practice had not always taken place (see Section 4.15). This concern was reiterated by the Chairman and Non-Executive Directors, who identified that this was an area that required focus.

Internal Audit carried out an audit of the Management of Standards and Guidelines during May 2015 when 'Satisfactory' assurance was provided. They audited the process again in September 2018 and provided a Limited level of assurance identifying that although the Trust had good controls to record corporately the receipt and subsequent dissemination of Standards and Guidelines to the directorates there is no corporate overview and reporting of the Trust's overall compliance against Standards and Guidelines.

The Internal Audit also identified weaknesses in relation to the completeness of data held on the Trust's Standards and Guidelines Register and limited ongoing audit/follow up of compliance (as above).

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

Stakeholders described the challenges in managing the large volume of standards and guidelines that are received from external agencies. During 2017/18, a total of 230 guidelines were received from external agencies, 23 were not applicable to the Trust of the remaining 207 there were 39 that were not applicable to Acute Services. Senior stakeholders identified the challenges in managing standards and guidelines which have cross directorate applicability.

In April 2012, the Trust established a Corporate Standards and Guidelines Risk and Prioritisation group. The aim of this group was to provide a corporate forum to ensure that the Trust has in place a systematic and integrated approach for the implementation, monitoring and assurance of clinical standards and guidelines across all of its care directorates. The Reviewer understands that the Group was stood down in January 2017 to be replaced by monthly meetings between the Corporate Assistant Director Clinical and Social Care and Directorate Governance leads.

All of the Directorates have systems in place for the management of Standards and Guidelines. Acute Services have a robust system in place for the dissemination of Standards and Guidelines which represents a best practice model. The system was developed and is managed by a Patient Safety and Quality Manager (Standards & Guidelines) who is a NICE Scholar and a member of the Acute Services Clinical and Social Care Governance Team. The system includes a Standards and Guidelines Operational Procedures Manual, a reporting schedule, process maps including a process map for clinical change leads and an Accountability Reporting system for Acute Services. The downside of this system is that it is person dependent. The Patient Safety and Quality Manager also identified that the lack of clinical audit in providing assurance that standards and guidelines had been implemented was a systems issue.

Other challenges include identifying a clinical/managerial lead for guidelines – as there is an apprehension surrounding taking on the responsibility/accountability for change lead role.

Positive assurance statements go directly back to HSCB via the Corporate Clinical and Social Care Governance team. Previously they would have been approved by SMT prior to issue. ***It is recommended that a level of corporate oversight is reinstated (in line with the Assurance & Accountability framework S4.1).***

An 'Accountability Report' of the Trust's compliance with Standards and Guidelines had previously been reported to the Governance Committee on a twice yearly basis. ***It is recommended that the Accountability (Compliance) reporting arrangement is reinstated***.

The Trust will be required to comply with IHRD Recommendation 78 ~ *Implementation of clinical guidelines should be documented and routinely audited*. The challenges in respect of clinical audit are outlined in Section 4.15. It is anticipated that as part of the final stage of the IHRD Implementation Programme Assurance Framework HSC organisations will be required to provide independent

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

assurance of compliance with policies and procedures arising from the recommendations (see also Section 4.15 and 4.23).

The Trust, as a matter of urgency, should review the overarching corporate arrangements and resources to provide assurance regarding the effective management of Standards and Guidelines and to facilitate a risk based approach from the triangulation of data from incidents, complaints, claims, service reviews, Morbidity and Mortality reviews and Clinical Audit.

It is recommended that the Trust take the Standards and Guidelines model developed within Acute Services and provide a central management system within the Corporate Clinical and Social Care Team under the leadership of the Medical Director. The Reviewer understands that the IT system currently used within Acute Services may not have the capacity to deal with Trust-wide information.

4.15 Clinical Audit

The Trust's Clinical Audit Strategy was presented to the SMT on 20 June 2018 and was then presented to the Governance Committee on 6 September 2018. The Strategy defined clinical audit as 'a quality improvement cycle that involves the measurement of the effectiveness of healthcare against agreed and proven standards for high quality, and taking action to bring practice in line with these standards so as to improve the quality of care and health outcomes'. Clinical audit is an integral part of the good governance framework.

Senior stakeholders advised that Internal Audit had provided Clinical Audit with a 'Limited' assurance level. The Clinical Audit Strategy outlined the strategy and structure for overseeing clinical audit processes to provide an assurance to SMT and Trust Board that clinical audit activity would be appropriately managed and delivered. The paper clearly outlined the key issues and challenges for the organisation which include; ensuring that clinical audit is delivered consistently across all operational directorates, in line with national guidance and ensuring that there is a sufficient number of staff in the corporate clinical audit team and in the operational Directorates to support the delivery of the approved clinical audit programme. The Strategy also describes the prioritisation of clinical audit in line with Healthcare Quality Improvement Partnership (HQIP) proposals that clinical audit programmes are categorised into 4 distinct elements with 'external must do' audits being assigned the highest priority as Level 1 projects.

Clinical Audit will have an increasing and key function in providing corporate assurance that IHRD Recommendations have been implemented. Clinical Audit and the Morbidity and Mortality Process are intrinsically linked (see Section 4.16). Clinical Audit will be required to provide assurance that clinical standards and guidelines have been implemented (IHRD Recommendation 78 as outlined in Section 4.14). Also Recommendation 76 ~*Clinical standards of care, such as patients might reasonably expect should be published and made subject to regular audit*. Clinical audit will also be required to provide assurance of organisational compliance with clinical standards in IHRD Paediatric Clinical (Recommendations 10-30) for example, patient transfer, on-call rotas and clinical record keeping.

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

Stakeholders described the dilution of the clinical audit function over a period of time, this experience is similar to that of other HSC Trusts. The Clinical Audit Strategy 2018, identified that the current [administrative] staffing levels in the corporate Clinical Audit and M&M team and operational directorates as insufficient to support and deliver the clinical audit work programme. The Reviewer would concur with this statement and would add that the demand on this governance function is set to increase significantly as described above. This is covered in more detail in Section 4.23. Clinical and Social Care Governance Structures.

The Medical Director has also identified resource issues in the paper entitled 'Medical Leadership Review submitted to SMT in June 2019 (see Section 4.21). The appointment of a Clinical Standards and Audit Lead who will lead the coordination and monitoring of systems and processes to ensure maximum compliance with clinical standards as endorsed or mandated by regional or professional bodies is key.

Stakeholders advised that there was a need to demonstrate more robust linkages between clinical audit and quality improvement and the management of serious adverse incidents. ***It is recommended that the integration between quality improvement and the integrated governance function is reviewed to ensure optimum connectivity.***

The 2018 Clinical Audit Strategy and Action Plan should be reviewed and updated.

It is also recommended that the Clinical Audit Committee is reinstated and the reporting arrangements considered in the review of the Trust Board Committee Structure (Assurance & Accountability Framework Section 4.2.6 and Appendix 2.

Given the potential increase in focus and demand on clinical audit as outlined above ***it is recommended that the resource implications are reviewed, see Section 4.21 Medical Leadership and Section 4. 23.1 Corporate Clinical and Social Care Governance Department).***

4.16 Clinical Outcomes - Morbidity and Mortality (see also 4.21 Medical Leadership)

Morbidity and Mortality (M&M) reviews are primarily a tool for identifying opportunities for system level improvement. There was a focus during the IHRD Inquiry into the rationale and mechanics of M&M Review and the significant role this process has in improving outcomes through learning. In November 2016, the DoH issued guidance on a Regional Mortality and Morbidity Review (RM&MR) process. The aim of the guidance was to provide specific direction for M&M leads and a regional approach as to how M & M meetings should be established, structured managed and assured. RM&MR is hosted on the Northern Ireland Electronic Care Record (NIECR)

As part of the 2018/19 Annual Internal Audit plan, Internal Audit carried out an audit of M & M during October to December 2018. The SHSC Trust was one of four

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

Directorate of Acute Services
Directorate Risk Register - 31 May 2014

ID	Opened	Title	Des/Pot for Harm	Controls in place	Progress (Action Plan Summary)	Risk level (current)
3393	22/04/2013	Biochemistry CPA Accreditation	Laboratory has lost its biochemistry accreditation status and is now a non-accredited laboratory	The Lab continues to perform adequately in its external quality assurance and internal quality control.	13/5/14 - Application submitted 12/5/14 to UKAS for accreditation. Anticipated inspection Dec 2014. "April 2013 Action Plan to be formulated. 36 non-conformances to be addressed, several of which are critical, Working through non-conformances, however, waiting on new Standards ISO 15189; purchase order has been placed. 26/6/13 - standards have been received and a gap analysis has been completed. Staffing numbers has been sited as a critical non-conformance. additional staff have been recruited since inspection 26/6/13 - full manpower plan has been developed and Laboratory is seeking 5 additional staff to address the balance. Also working with regional group on bid for additional staff for 24/7 " Staffing levels - benchmarking to be undertaken. Anticipated total additionality is 11 staff, no funding identified.	HIGH
2594	16/04/2010	Insufficient capacity and resources to manage patients waiting for a review appointment in Acute Services	Potential of harm to the patient secondary to not having timely management of condition and/or disease-possible progression of disease/worsening status of condition. Risk of harm to patient by unmanaged progression or monitoring of condition in a timely manner secondary to SHSCT not having sustained capacity to provide review appointments, within the appointed time. Risk of harm to Medical and Nursing staff as addressing the patients needing review are all done as 'extra sessions'. Potential for exhaustion and escalation of sick leave. There has been inadequate Nursing resources recruited to support the increase work load. Risk of escalation of clinical risks as the Trust is under strict financial constraints, and does not have an obvious form of funding for this risk. Potential harm to patient family secondary to anxiety of not having a timely review. Potential of litigation against staff and Trust due to not providing treatment in a timely manner. Potential of harm to reputation of Trust due to potential lack of adequate patient management.	RVBL teams established to 'cleanse' the lists of patients waiting, ensuring no duplication or incorrect recording of activity. This group will also continue to meet and create effective strategy to manage this chronic gap in capacity. Monthly reports monitoring review waiting lists to give current position. Specialist Nurses working in Consultation with relevant Consultants to screen urgent, and patients waiting the longest length of time. Vacant Outpatient sessions have been backfilled with Review Backlog patients, when Consultant available. Heads of Service are meeting with Relevant Consultants and conveying current provision on a monthly basis.	12/5/14 - with respect to ATICS chronic pain service 9 patient waiting from 12/13 and a further 400 from 13/14. Monies acquired from HSCB, however, this only for consequence of additional new patients. Templates have been amended to meet and New and Review SBA. Further consideration needs to be given to role of Specialist Nurses within this service. 05.05.14 The Trust has received funding to address 700 patients in the Urology review backlog so additional clinics are being organised. 12.02.14 Acute Services continues to manage the review backlog within current resources which are accepted as being insufficient to see the number of review patients that have accrued as a result of additional waiting list clinics / activity required by HSCB to meet access standards. This has been raised to the Regional Commissioning Board but no funding has been made available for the review backlog in 12/13. 31.10.13 - General Surgery Total 2272, ENT Total 2413, T&O Total 369, Urology Total 3258. The Trust is currently seeking funding to re-establish RVBL clinics. 01.03.13: General surgery and Breast position at end of February 2013; no patients to be reviewed prior to 2012; total 1445 01.02.13 - Oral Surgery: 0 patients up to the end of January , Breast Surgery: 0 patients up to the end of January, Breast Family Hist: 53 - DHH 64 - CAH patients up to the end of January not booked or going through the partial booking process, General Surgery: 1189 patients up to the end of January across all sites not booked or going through the partial booking process.	HIGH

Received from SHSCT on 30/08/2022. Annotated by the Urology Services Inquiry.

ID	Opened	Title	Des/Pot for Harm	Controls in place	Progress (Action Plan Summary)	Risk level (current)
3529	05/02/2014	Non compliance to Standards and Guidelines issued to Southern Trust	Poor patient outcomes are a risk due to non compliance with Standards and guidelines issued from extenal agencies Staff are at risk if not practicing safe and effective care outlined in recommendations within standards and guidelines Currently there are 981 standards and guidelines on the Trust's register, due to volume and complexity of these guidelines it is a challenge for the trust to monitor and review the compliance status of all the standards and Guidelines received.	There is often a time lag between when the external agencies require the Trust to achieve full compliance and when this is actually achieved This may result in risks to the patient staff and organisation. the delay has potential to expose patient staff and organisation at risk	5/2/14 All newly issued S&G have been reviewed and managed through the new corporate process prior to sending to the nominated Lead Director and Change Lead for action AMD for Standards and Guidelines (Acute Services) in post. Establishment of six monthly performance/accountability reports for standards and guidelines. Standard item for discussion at SMT (monthly) and Governance Committee with submission of relevant reports / assurance statements Standard item for discussion at the Directorate Governance meetings with submission of relevant reports For those that are 'pharmacy' related a compliance report is also presented by the Trust's Medicines Governance Pharmacist to the Operational Directors and members of the Drug and Therapeutics Committee on a quarterly basis. Database established and system in place for logging and monitoring	LOW

Received from SHSCT on 30/08/2022. Annotated by the Urology Services Inquiry.

Acute Serices Directorate
Directorate Risk Register - March 2018

ID	Opened	Title	Form	A/D HOS Responsible	Risk	Updated
747	28/07/2008	CAH DSU, STH - DPU, DHH. No Backup Electrical supply	Yes	Ronan Carroll	HIGH	Mar-18
3829	13/09/2016	Absconding patients from all Wards & Department	Yes	Anne McVey, Kay Carroll	HIGH	Sep-17
773	29/07/2008	CAH Theatres Endoscope Decontamination room	Yes	Ronan Carroll, Sandra McLoughlin	HIGH	Mar-18
3528	05/02/2014	Pharmacy Aseptic Suite	Yes	Tracey Boyce	MOD	Oct-17
3729	01/09/2015	Lack of ability to recruit and retain senior decision makers in DHH ED (or inreach from Med or Surg) in OOH period	Yes	Anne McVey	MOD	Dec-16
3897	14/06/2017	Insufficient Consultant Radiologists to provide the necessary diagnostic reporting services for SHSST.	Yes	Heather Trouton, Jeanette Robinson	MOD	Mar-18
3663	29/04/2015	Single CT Scanner available on both CAH & DHH	Yes	Heather Trouton, Jeanette Robinson	MOD	Mar-18
2979	13/05/2011	Multiple records/charts per patient e.g. a patient may have STH, CAH, BPC & DHH medical notes	Yes	Anita Carroll, Helen Forde	MOD	Mar-18
3070	23/01/2012	Omitted and delayed medications within Acute Directorate Wards	Yes	Trudy Reid	MOD	Sep-17
3304	16/01/2013	Lone Workers in X-Ray after 12 midnight	Yes	Heather Trouton, Jeanette Robinson	MOD	Nov-17
3733	24/09/2015	Directorate's ability to recruit and retain nursing staff due to a regional and national shortage of qualified nursing staff.	Yes	Trudy Reid	MOD	Sep-17
3819	27/07/2016	Shortage of Qualified Midwives for recruitment	Yes	Barry Conway, Patricia McStay	MOD	Sep-17
3922	13/11/2017	Lack of funding to ensure compliance with NICE guidelines that have been regional endorsed by the DHSSPSNI.	Yes	Trudy Reid, Caroline Beattie	MOD	Nov-17
3529	05/02/2014	Non compliance to Standards and Guidelines issued to Southern Trust	Yes	Trudy Reid, Caroline Beattie	MOD	Dec-17
3515	14/11/2013	Ineffective Cardiac Monitoring System in certain Wards/Departments in CAH and DHH	Yes	Anne McVey, Kay Carroll	LOW	Nov-17
2422	13/10/2009	Multiple training schedules for staff at Trust Level. Lack of resources to facilitate staff to go to training.	Yes	Anne McVey, Kay Carroll, Mary Burke	LOW	Sep-17
3936	03/01/2018	Lone Worker in Laboratory	Yes	Geoff Kennedy	LOW	Mar-18
3929	12/12/2017	Declaratory Orders for patients who lack capacity	Yes	Trudy Reid	LOW	Mar-18
3875	21/02/2017	The transfer of patient data outside the EEA.	Yes	Heather Trouton, Jeanette Robinson	VLOW	Feb-17

ID	Opened	Principal objectives	Title	Des/Pot for Harm	Controls in place	Progress (Action Plan Summary)	Risk level (current)
3529	05/02/2014	Provide safe, high quality care	Non compliance to Standards and Guidelines issued to Southern Trust	There is often a time lag between when the external agencies require the Trust to achieve full compliance against the recommendations outlined within standards and guidelines and when this is actually achieved. Such non-compliance poses the following risks for the patient and the organisation: - Reduced ability to deliver quality patient care; - Compromised patient safety and wellbeing - Poor patient outcomes - mortality/morbity, delayed discharge, increased secondary complications. - Staff members are non-compliant with evidence based working practices, lack of standardised practice, vulnerable wrt registration - Organisational risk - complaints, incidents, litigation, Currently there are 1483 standards and guidelines on the Trust's register, with over 60% having an applicability to Acute Services Directorate. Due to volume and complexity of these guidelines it is a challenge for the Trust to monitor and review the compliance status of all the standards and guidelines that have been received. There is a corporate need to invest in a more fit for purpose information system that will effectively risk manage the process for managing standards and guidelines following receipt from the external agency. The Patient Safety & Quality Manager (Acute Services) has returned to work in October 2015 following a 2 year career break. During this absence there was limited dedicated back fill for the post and so the priority is to review the register, identify the backlog and prioritise those standards and guidelines that	Corporate governance have an Excel database in place for logging and monitoring S&G Standard item for discussion at the monthly Acute SMT Governance / Clinical Governance meetings with submission of relevant reports Patient Safety & Quality Manager (Acute Services) attends Acute Services SMT governance meetings on a quarterly basis Patients Safety & Quality Manager (Acute Services) attends divisional governance meetings on a monthly basis and presents tailored activity reports to determine progress at an operational level Patient Safety & Quality Manager (Acute Services) attends the bimonthly corporate S&G review group meetings. It is through this forum that all newly issued S&G are reviewed sent to the relevant Lead Director/s for nomination of appropriate Change Lead for action and full implementation. Terms of reference, procedural arrangements, process maps are in place. Establishment of six monthly performance/accountability reports for standards and guidelines. Standard item for discussion at SMT (monthly) and Governance Committee with submission of relevant reports / assurance statements. For those that are 'pharmacy' related a compliance	5.12.16 Information below remains current 19.7.16 - Decision needs to be made regarding the viability of re-appointing an AMD for Standards and Guidelines (Acute Services) - forms part of the current review of Acute Services structures. Administrative support for the Patient Safety & Quality Manager needs to be reviewed - there is currently no administrative support. Patient Safety & Quality Manager (Acute Services) has successfully achieved a one year NICE scholarship - project is to undertake a review of the directorate's process for implementing standards and guidelines - to be completed by 31/03/2017. Regionally the WHSCT is to undertake a pilot of Sharepoint to ascertain if this system would be fit for purpose for the development of a regional information system for the management of standards and guidelines. HSCB are involved in this process and funding to support this initiative is currently being sought. There continues to be an urgent need to put in place a more effective information system for the logging, dissemination and monitoring of standards and guidelines. Corporate governance is currently designing an inhouse system until an appropriate regional solution is agreed.	MOD
3515	14/11/2013	Provide safe, high quality care	Ineffective Cardiac Monitoring System in certain Wards/Departments in CAH and DHH	The current cardiac monitoring system is old and unable to monitor patients in various wards/departments in the hospital site given their physical location. Monitoring is not available for certain patients and patients then may be required to move to 1 North for monitoring unnecessarily.	Appropriate selection of patients for monitoring.	14.11.17 Waiting on decision to start work with the potential of relocating coronary care beds to the HDU in DHH. 1.12.16 No further update. 13.9.16 In relation to CAH telemetry, this has now been fully implemented in the main acute wards, cathlab, and delivery suite.DHH,is awaiting funding allocation. 27.05.16 - Work in CAH will be completed with 3 months time. Costing obtained in respect of DHH work and added to Capital Estates list for consideration. 1/3/16 Now in place residual witing being carried out. 14.07.15 - Replacement system purchased and installed. Estates undertaking wiring to ensure all acute areas are covered.	LOW
2422	13/10/2009	Provide safe, high quality care	Multiple training schedules for staff at Trust Level. Lack of resources to facilitate staff to go to training.	Staff unable to attend training due to multiple training schedules, therefore leaving ward short staff or staff not being updated. Mandatory requirements unable to be facilitated. With staff at training there is a potential risk of not providing safe high quality care to patients. It will deplete staff numbers at ward level therefore failure to meet the expected standards of care. This will apply pressure on colleagues who remain on the ward.	Ward Sister to manage off duty rotas and prioritise training needs/where there are high dependency levels responsibility of nurse in charge to assess situation and take decision on releasing staff for training/more flexible approaches to training eg delivered at ward level,e-learning etc.	23.9.17 - CMT remains challenging to achieve over 80% mainly due to 1- staffing challenges and 2 availability of training which is not 'online'. 1.12.16 No further update. 13.9.16 Awaiting update 27/5/16 - No change. 7/5/15 Ongoing issues remain with the number of training sessions being provided and the ability of ward Sisters to release staff to attend training due to workload and staffing pressures. The NEAT lead nurse team have commenced supporting nursing staff in medical and surgical wards providing essential written and verbal information and training to ensure patient care standards remain at a high level. With nurse revalidation commencing 15/16 it will become even more important to ensure that training is completed for all qualified nursing staff.	LOW

Received from SHSCT on 02/02/22. Annotated by the Urology Services Inquiry.

ID	Directorate	Opened	Principal objectives	Title	Des/Pot for Harm	Controls in place	Progress (Action Plan Summary)	Risk level (current)
3829	ACUTE	13/09/2016	Safe, High Quality and Effective Care	Absconding patients from all Wards & Department	Patients at risk of leaving the ward or department without investigations, diagnosis and management plan in place. Patient risk - Incomplete treatment for medical or mental health issues leading to physical and/or mental health deterioration Risk of self harm / death Staff risk- unable to deliver care to patients, risk of violence and aggression when trying to persuade patients to avail of assessment, treatment and care for their illness.	Level of absconding rates identified. Absconding patient protocol in place. Staff awareness raised. Datix reporting in place. Short life working group established to review access to wards and departs promoting pts and staff safety.	24.06.2019 Absconding policy available - any incidents submitted on Datix, reviewed and staff aware. 23/2/2018 - Additional measures have been introduced to access and egress from ED and AMU. Swipe card is required. Statistics need to be reviewed before consideration can be given to reducing the risk rating. Situation continually monitored.	HIGH
1220	ACUTE	18/08/2008	Provide safe, high quality careBe a great place to workMake the best use of resources	Breakdown of laundry equipment	Laundry equipment is outdate and requires replacement to avoid frequent breakdowns and disruptions to the laundry service. Potential risk to the supply of clean linen to wards and departments due to breakdown of essential laundry equipment. The aging laundry equipment needs to be replaced to avoid breakdowns and disruption to this core service. The risk affects the laundry service provided to not only Southern Trust facilities but also to Belfast City and Musgrave Park hospitals. Replacement parts for old and ageing equipment are now obsolete, causing delays in getting equipment repaired and back into operational use. The following pieces of equipment are required in the Laundry :- 1. Continuous Batch Tunnel Washer, Press and dryers - installed in 1992 (27yrs old) approx cost £760K 2. Ironer installed in 1975 (45 yrs old) approx cost £355K 3. Lint Extractor - requirement for fire safety - approx cost £70K 4. Pharmagg No 1 100kg barrier washer - installed in 2006 (14yrs old) approx cost £105K 5. Kent Dryer 100kg x4 - installed in 1987 (32 yrs old) approx cost £315K 6. Shrink Wrapper - installed in 2002 (17yrs old) approx cost £85K 7. Ironer installed in 1991 (28yrs old) approx cost £355K 8. Continuous Batch Tunnel Washer, Press and dryers - installed in 2001 (18yrs old) approx cost £760K Impact to service delivery - risk to the supply of clean bed linen to wards and departments in SHSCT and BHSCT. Risk of infection due to insufficient supply of linen for nursing staff to change / make up beds.	Estates has advised that it is becoming increasingly difficult to maintain the laundry equipment. They are unable to obtain replacement parts for the laundry equipment as the parts are now obsolete and it will ultimately come to a point when the machines will break down and remain out of operation. March 2019 - A new calander was installed and commissioned to replace one of the four calanders in the laundry. Two new 57kg washing machines were installed and commissioned to replace a 100kg washing machine that had been condemned. The frequent breakdowns also put a strain on the newly acquired equipment as they are being overused when other equipment is out of use. There is increased staff overtime due to equipment breakdowns and equipment running at reduced capacity. Additional shifts are needed to ensure provision of sufficient clean linen each day to wards and departments.	28/2/2020 £50,000 capital allocation approved to purchase a second hand calender to replace No 2 calender which was beyond repair and was condemned. 11/10/19 £82,300 capital allocation approved to purchase a replacement refurbished press for the Powertrans tunnel washer as the press was beyond repair and was condemned. 1/4/19 New calander and two new washing machines installed and commissioned. List of aging laundry equipment added to capital priority list. 19/12/18 Capital funding approved and tender process completed. New equipment due to be installed and commissioned by end of March 2019. 5.4.18 Business case was recosted Nov 17 and was approved by SMT March 18. 16.8.17 Business case is still with Finance for re-costing. 12.12.16 No further update. 21.11.16 An additional option has been included and is with Finance for re-costing. 17.8.16 Business case for replacement of calanders presented to SMT - not approved. SMT has asked for an additional option to be included in the case i.e. to outsource the laundry service from another provider. 23.02.16 Business case forwarded to Finance for costing	HIGH
773	ACUTE	29/07/2008	Safe, High Quality and Effective Care	CAH Theatres Endoscope Decontamination room	The interim Endoscope decontamination facilities at CAH theatres do not meet DHSSNI decontamination strategy. There are no transfer lobbies or staff gowning rooms. The process flow is severely compromised by the size of the extremely cramped unit. There is no room for expansion. The workload in the endoscope decontamination facility has increased considerably over the last number of years due to additional theatre and radiology sessions as well as additional clinics in ENT OPD and Thorndale Unit. There is inadequate space for holding the contaminated endoscopes for manual washing prior to the automated process in the endoscope washer disinfectors. This frequently creates a bottleneck and slows down the process flow and turnaround time. The endoscopes and transport trolleys have to be stored in the hospital corridor outside the endoscope decontamination room due to lack of space - increased risk of theft (trolley plus endoscopes). In the event of any prolonged endoscope washer disinfector downtime there would be significant disruption to endoscopic procedures in Theatres, Radiology, ICU or in ENT OPDand Thorndale Unit as there would be insufficient capacity to decontaminate the endoscopes on the Craigavon site. There would also be logistical issues and delays in turnaround times if the endoscopes had to be transported to another Trust site for decontamination ie Daisy Hill or South Tyrone. The endoscope washer disinfectors were installed in 2009 and have a working life of approximately 8 years. The Lancer endoscope washer disinfectors do not have the ability to perform channel patency tests to current DHSS guidance i.e. inability to perform partial blockage of the duodenal channel which is part of the quarterly channel patency testing regime. The EWD manufacturer has confirmed that they will support the FC 2/4 EWD models until 2022 for the electronics and until 2025 for mechanical parts.	Situation being monitored.	3.10.19 Replacement EWDs are included on the capital funding list. May 2019 SHSCT provided a summary report to DoH on strategic planning relating to the decontamination of reusable medical devices 24.06.19, 8.8.18, 12.6.18, 7.3.18 Risk remains unchanged 113.9.16 Head of Decontamination Services will work with Acute Planner to explore options for a modular unit adjacent to CAH CSSD to replace the existing the interim arrangement. Given that CSSD will form part of Phase 1 for the CAH Redevelopment, a modular solution will be considered as a further interim arrangement although it will need to address existing concerns. Indicative costs to be detailed in the paper and logged for consideration under capital allocations for 17/18. 23.2.16 Following discussion at Acute senior management team with Head of Acute Planning, the risk will be addressed in the first phase of the redevelopment of the Craigavon site. On this basis it was agreed that nothing further would be done at this stage. 5.1.16 Short paper highlighting the risks shared with Planning Dept and Director of Acute Services	HIGH
3951	ACUTE	10/04/2018	Provide safe, high quality care	Delays in isolation	Due to lack of side rooms/one to one nursing/lack of bed capacity in the service. Risk of spread of infection. Failure to isolate promptly can lead to outbreaks, close of bays, increased pressure on service. May lead to potential patient harm through the spread of potentially preventable infection or due to a lack of beds.	Trust can emphasise the importance of IPC issues at bed meetings and elsewhere. A recent teaching sessions was arranged to do this amidst the winter pressures. Side rooms are often occupied for reasons other than IPC reasons. IPC reasons for isolation are often of critical importance in that severe harm can be done to other patients and staff by failure to isolate promptly. This is often not the case for other reasons patients are in side rooms and side rooms should be prioritised to maximise patient safety. The Trust should also look to ways to enhance the capacity to isolate a patient when the hospital is full and a patient needs isolated urgently e.g. where a patient could be moved out of a room to facilitate critical IPC isolation.	Risk added to Directorate RR April 2018	HIGH

Received from SHSCT on 02/02/22. Annotated by the Urology Services Inquiry.

ID	Directorate	Opened	Principal objectives	Title	Des/Pot for Harm	Controls in place	Progress (Action Plan Summary)	Risk level (current)
3869	ACUTE	23/01/2017	Safe, High Quality and Effective Care	Limited Speech and Language Therapist Provision	Inability to provide adequate Speech and Language Therapy to acute based patients due to increased volume of referrals of complex patients over previous 10 years - situation escalated by inability to backfill 2 senior staff on maternity leave and complexity of patients requiring SLT assessment. Capacity to provide Dysphagia treatment significantly reduced. Delayed assessment of patients designated nil by mouth so rehabilitation potential reduced. Delayed review of patients on modified diet Delay in discharge as SLT unable to respond to request for assessment and intervention re: swallow management including information re: food/fluid textures to carers. Potential for SAIs. Patients discharged prior to assessment Limited rehabilitation to patients, hence longer length of stay in hospital. Complaints received re: service provision Inability to consistently meet professional standards Health and wellbeing of staff compromised Staff working outside levels of competency and under significant pressure. Inability to achieve regional PTL waiting time targets	Several requisitions for recruitment of suitably trained staff - unsuccessful Junior locum staff employed but not skilled enough to fully meet caseload demands All core staff offered additional hours Telephone referral system manned by administration staff Triage and prioritisation of referrals Waiting list for in patients Timetable constantly reviewed with staff managed & moved between the 2 sites to attend to priority demands Cancellation of VFS clinics which leads to distress of patients and families.	Dec 19 - deficits remain - recruitment to B7 and B6 posts have been unsuccessful. Retention of B5 locum into substantive post and potential to link B5 post to B6 Jan 2020 Jun19 The deficits in this service will now be major as there has been 2 resignations from B7 staff. 21.11.18 New post appointed Apr 18. However, capacity v demand compared with NHS benchmarking identifies approximately 50% deficit re staff required. Also Band 6 gap as member of staff left post. 22.1.18 Situation has deteriorated and continues to be monitored. 14.11.17 Secured SLT for AMU - recruitment in process, Capacity / Demand paper being revised, Prioritisation of demand continues. 6.6.17 Remains limited due to low investment in this service.	MOD
2979	ACUTE	13/05/2011	Provide safe, high quality care	Multiple records/charts per patient e.g. a patient may have STH, CAH, BPC & DHH medical notes	Patient is at risk due to information in multiple charts (no one chart may contain a full record of patient history and investigations). Trust from risk of litigation. Risk to patient of incomplete information being available at time of consultation, incorrect diagnosis due to incomplete information, delay in diagnosis, risk of injury and/or death. Reputation of Trust at risk.	Patient information is available electronically in Patient Centre, NIPACS, Labs, TOMCAT. Charts for CAH and DHH only now registered. All charts are made available if requested.	24.06.19 New system - one patient one chart for all new and recent patients. Ongoing update for older files for existing patients. 7.3.18 Risk remains unchanged 28.09.17 Further work is to take place with regard to registration of CAH and DHH charts and a move to 1 patient 1 chart. Initial discussions will take place in October with Health Records managers and the Booking Centre to identify issues relating to registration, and following this a proposal will be taken to Acute SMT for discussion and agreement. 28.12.16 - work ongoing with continuing to reduce number of charts per patient in circulation - robust weed and destruction of charts takes place every year and registration reduced. Risk reducing each year. 12.9.16 work still continuing on reducing the number of charts per patient - this is an ongoing exercise. A trial of going "paperlight" was conducted in June - Aug 16 which would reduce the amount of paperwork generated per patient however, until such time as a "write on" information system is available we cannot progress with paperlight / paperless clinics as information still needs to be recorded on the patient visit.	MOD
3529	ACUTE	05/02/2014	Provide safe, high quality care	Non compliance to Standards and Guidelines issued to Southern Trust	There is often a time lag between when the external agencies require the Trust to achieve full compliance against the recommendations outlined within standards and guidelines and when this is actually achieved. Such non-compliance poses the following risks for the patient and the organisation: - Reduced ability to deliver quality patient care; Compromised patient safety and wellbeing; Poor patient outcomes - mortality/morbity, delayed discharge, increased secondary complications; Staff members are non-compliant with evidence based working practices, lack of standardised practice, vulnerable wrt registration; Organisational risk - complaints, incidents, litigation, As of June 2019 there are 1836 standards and guidelines identified on the Trust's register. Due to volume and complexity of these guidelines it is a challenge for the Trust to monitor and review the compliance status of all the standards and guidelines that have been received. There is a corporate need to invest in a more fit for purpose information system . In 2017/18 BSO gave the WHSCT significant funding to support a pilot of a modified Sharepoint system that would in the first instance record and track the implementation of NICE guidelines and Technology Appraisals. The Regional NICE Managers forum acted as the project group and whilst the scope of the project was not embracive of all the types of standards and guidelines endorsed regionally it was at least a starting point. The ultimate vision was that upon completion this system would then be shared across the HSC (including the HSCB/DHSSPNIS) to provide a harmonised / standardised system that would provide effective monitoring and traceability of guidance implementation. Unfortunately this pilot has not yet yielded these desired outcomes and in the interim the SHSCT continues to use an excel spreadsheet whose functionality falls well short of service requirements. Given the number of standards and guidelines that are now held on this system there is risk of it collapsing. As a safe guard a system back up is saved on a weekly basis. There is also the added frustration that if any of the directorate governance teams are using the shared excel spreadsheet no-one else can use it. This can impact on staff not being able to carry out their administrative duties on the system at that point in time. This is inefficient and there is a risk of a	Provision of bi monthly assurance responses to the HSCB as part of the Trust's Positive Assurance response. Corporate governance have an Excel database in place for logging and monitoring S&G. Within Acute Services a directorate S&G forum has been established - inaugral meeting was held 19 January 2017. Terms of reference are in place and the forum is chaired by the Director and attended by the SMT. The forum meets twice a month to review all newly issued S&G so to ensure appointment of a clinical change lead is confirmed in a timely manner, thereby ensuring implemenation processes are put in place as early as possible. It also reviews and approves implementation plans requiring submission to the the relevant external agency. It approves any policy/procedures/guidance that has been developed as part of these implemenation plans. Standard item for discussion at the monthly Acute Clinical Governance meetings with submission of relevant reports Patients Safety & Quality Manager (Acute Services) attends all divisional governance meetings on a monthly basis and presents tailored activity reports to determine progress at an operational level Meeting schedule is in place to ensure meetings are held with the Heads of Service to review compliance against all S&G within their areas of responsibility A new Acute Services Lead Nurse, Midwifery & Radiology S&G forum - meetings held on a monthly basis Monthly summary report is issued out to Acute SMT to communicate to all staff what new regionally endorsed S&G have been issued. A copy is also shared with the M&M chairs so that they can review and share	02/06/2020 standards still difficult to achieve with limited funding, staffing and equipment 09.03.2020, 5.12.16 Information below remains current 19.7.16 - Decision needs to be made regarding the viability of re-appointing an AMD for Standards and Guidelines (Acute Services) - forms part of the current review of Acute Services structures. Administrative support for the Patient Safety & Quality Manager needs to be reviewed - there is currently no administrative support. Patient Safety & Quality Manager (Acute Services) has successfully achieved a one year NICE scholarship - project is to undertake a review of the directorate's process for implementing standards and guidelines - to be completed by 31/03/2017. There continues to be an urgent need to put in place a more effective information system for the logging, dissemination and monitoring of standards and guidelines. Corporate governance is currently designing an inhouse system until an appropriate regional solution is agreed. Due to ongoing work pressures Phase 1 (01/10/2015 to current date) and Phase 2 of the backlog review (all S&G issued from 01/04/2007 - 30/09/2015) will be undertaken from 01/01/2018 to 31/03/2018 has not been progressed as planned and will continue during 2019/20 workplan. Phase 1 (From 2017 to current date) has been completed. Phase 2 of the backlog (from April 2007 -Sept 2015) remains outstanding.	MOD
3070	ACUTE	23/01/2012	Safe, High Quality and Effective Care	Omitted and delayed medications within Acute Directorate Wards	Wards and departments not administering medications in a timely manner. Patients are receiving an inadequate quality of service with the potential risk for harm.	Staff nurse or ward based pharmacist where possible highlights all incidents via datix. Proforma is to be completed in conjunction with the Band 6 and the staff nurse responsible for the omission or delay to reinforce learning and improve standards. Staff nurse to escalate to Ward Sister if any delays or omissions at ward level.	06.09.17 Jilly and Trudy to discuss 1.12.16 No further update. 13.9.16 Audit completed. Report circulated for learning. Showing some improvement but NQI monitoring continuing. 27.05.16 - Yearly audit taking place May/June 2016. 23.02.16 - Ongoing NQI audits continue to highlight this problem area. 24.09.15 - Focus on the number of omitted and delayed medications in SEC continues supported by lead nurses, HoS and the NEAT project. Regular audits to monitor performance in this area and learning from medicines incidents group shared across the directorate.	MOD

	work. *Has the Board been made aware of any problems in this area and, if so, what has been done about it?* Trust Board is aware and have endorsed the improvement work that is ongoing regarding Clinical Governance and improvements towards managing risk, as detailed in question 11. Trust Governance Committee members have approved the redrafting of the corporate risk register to help the organisation record and understand risks in a more transparent fashion. *How is the Board assured that there is a continued focus on reflective learning from the things that go wrong and celebration of the things that go well?* Trust Governance Committee receive update papers from the Trust Learning from Experience forum. The governance system as a whole is a learning system. As detailed throughout this statement, and examples evidenced in question 23, the governance system identifies when things are working well, or where they have gone wrong, and implements plans to improve. The learning environment is further strengthened through the Lessons Learned Forum (Appendix 13a. Lessons Learned Terms of Reference)

Q19	**As CEO, what is your view of the efficacy of the quality and safety monitoring systems that are in place in the Trust and executed through your operational teams? Are there specific aspects of these systems that you find particularly helpful and are there parts of these systems that require improvement? What changes have you sought to put in place to augment the assurance that is in place, and what direct observations and conversations do you have with clinical staff on the ground to see for yourself what the issues and problems are and what services are providing excellence?**
Response	As I have stated elsewhere, and published in my annual governance statement (appendix 5), I am content that the systems that we have to monitor quality and safety are effective. However as with all systems there are opportunities for improvement. As referenced in question 11 the review that I commissioned (appendix 13) provided me with a clear view of what was working and what needed to be improved. With regards to the specific question about direct observation as can be seen in appendix 9, Chief Executive Visits, I have informal and formal meetings with clinical staff on a regular basis. The views that I have gathered from my interactions are always mixed and there is not one standard opinion about our safety monitoring systems.

Q20	**How much time do you spend talking to your Senior Management Team and the Trust Board about clinical governance issues generally? This might helpfully be expressed as a percentage of daily/weekly hours.**
Response	As clinical governance is at the core of our service delivery all of my discussions relate to this area either directly or by proxy, for example discussing obtaining additional funding for a new service improvement has a clinical governance improvement as its goal. Direct discussions regarding clinical governance at point of care is generally stratified by the role and responsibilities held by the member of my senior team.

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

	It identifies specific areas of focus for the given financial year but also seeks to set these within the context of the broader outcomes that the Department and the HSCB want to achieve as we work together to build a world-class health and social care service for the people of Northern Ireland. It also identifies a number of associated quality and performance indicators against which the HSC should monitor performance and take improvement action as required. The Direction is structured around four strategic aims linked to the vision set out for health in Health and Wellbeing 2026 'Delivering Together': • To improve the health of our population; • To improve quality and experience of care; • To ensure sustainability of the services delivered; • To support and empower the staff delivering health and social care services . The TDP provides a response to the regional commissioning priorities and decisions for the given year set by the Department of Health and the HSCB & PHA as well as priorities and decisions being taken forward at a local level by the Southern Local Commissioning Group. It also advises of the Trust's position in regards to each of the quality and performance indicators identified under each of the key themes. A key part of the TDP is the development of a financial plan which turns the actions from the TDP into a costed plan, which then becomes the basis of budgets. In respect of whether clinical risk, at a Trust level, is determinant of resource allocation, my view is that, in a commissioned system, clinical risk is only one of many aspects that determine the commissioners' view as to what they wish to buy from the Trust as a provider.

Q37	**During your tenure, is it your experience that Departments or specialities seek an increased budget allocation to reflect their specific risk and, if so, what has been your response? Please provide specific examples to explain your answer.**
Response	It has not been my experience that departments seek additional budget based on risk. Each directorate has its own dedicated accountant and financial team and, in partnership with the operational team, budget allocation is regularly reviewed to ensure that we can meet our objectives, which include patient safety. If items need to be escalated we, at SMT, would regularly review the balance between risk, benefits and costs of particular services and if we required additional resources we would discuss this with the commissioner (HSCB). This may result in conversations with the commissioners, through the Director of Planning, to develop new services or enhance existing ones. Any new changes to commissioned services will be introduced following the creation of an investment proposal (commonly referred to as an IPT). Appendix 31 provides an example of background information as to how budget allocation is constantly reviewed to ensure that resources are reallocated to meet the risk to services.

Q38	**Do you have any personal knowledge whether such a system, which permitted budgetary requests specific to risk management, existed before your time in post?**
Response	No, the Northern Ireland Health and Social Care funding model operates on a central commissioning basis as per question 36

Q39	**Are you aware of other Trusts or health care providers who take or apply this risk/budget allocation approach or model?**
Response	No, the Northern Ireland Health and Social Care funding model operates on a central commissioning basis as per question 36

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

Q40	**How, if at all, do you satisfy yourself that the approach taken to risk in allocating budgets is acceptable?**
Response	As per 36, the Northern Ireland Health and Social Care funding model operates on a central commissioning basis. This process provides a standardised approach that all Trusts apply. However, to ensure that we manage cost / benefit / risk on a regular basis there are a series of check and challenge loops to allow managers to make amendments during any given year so as to ensure the continued provision safe services. These include, but are not limited to, team meetings, directorate meetings, SMT, Governance Committee, Performance Committee, Audit Committee, Trust Board Meetings, Performance Meeting with the HSCB, Local Commissioning Groups. All of these meetings allow for discussions and critical challenge on whether costs, benefits and risk are in balance and provide me with an ongoing assurance that we are managing the resources entrusted to us to the best of our ability.

Q41	**Does the Trust Board ever raise the issue of budget allocation and the prioritisation of risk or seek to establish whether you, and they, are content that an acceptable risk prioritisation/budget allocation balance has been struck?**
Response	As per question 36 The Northern Ireland Health and Social Care funding model operates on a central commissioning basis rather than locally identified risks. The HSCB creates an annual commissioning plan which identifies the areas that they wish to commission. We, the Trust, submit a Trust delivery plan (TDP) to the HSCB which considers clinical risk and illustrates how the Trust plans to meet the set commissioned objectives. A key part of this process is the debate and approval of the Trust Delivery Plan (TDP) at the Trust Board (appendix 32 – Trust Board minutes). In addition, the Trust Board receives monthly updates on performance against the agreed budget and detailed updates on performance, against the TDP, at the performance committee. All of these reviews allow Trust Board the opportunity to challenge the allocation of budgeted resources. By way of example TDP 2019/20 (appendix 29) at pages 54,56 and 58 clearly identifies to the commissioner that the Trust is unable to meet the targets with regards to Urology Cancer performance, based on the resources available, however pages 85 and 98 go on to indicate that Clinical Nurse Specialists are being employed to help with the management of patients through their cancer journey.

Your Team and Governance

Q42	**Please explain the general method of working between you and senior management staff, to include an explanation of all lines of communication (formal and informal), frequency of contact and scheduled meetings, methods of evaluation and modes of record keeping.**
Response	As per my answers to questions 8 and 10: • The Trust Senior Management Team (SMT, Director level) is based on a single floor in Trust Headquarters with the exception of the Director of Acute Services (based in Craigavon Area Hospital on the same physical Trust site) and the Interim Director of Children's and Young Peoples services (based in Edenderry House, Portadown, 1.5 miles travel). • My leadership approach is to have an 'open door' policy where my senior team can, and do, speak with me informally as required or raise issues of concern directly in person. During the COVID-19 pandemic the ability has been curtailed however my team remain able to contact me via telephone or email on the same basis. • I also operate a SMT 'WhatsApp' group for directors to collectively share and update colleagues on a dynamic basis. This is supplementary to Trust email communications.

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

	call) I received a telephone call from the Permanent Secretary, Richard Pengelly, asking whether I was aware of 'Craigavon Urology Research and Education – CURE'. I was not aware and advised him of this. He proceeded to explain to me that it was a charity that had been created in 1997 by Mr O'Brien and that he understood Roberta Brownlee had been a director of the charity for 15 years up to 2012. Richard Pengelly asked me if Roberta had been declaring a conflict of interest in our Board meetings with regards to Mr O'Brien and Urology, which she had not. Richard Pengelly then instructed me to telephone the Chair and advise her of our conversation and request that she withdraw herself from any further Trust Board conversations on this topic. I subsequently phoned the Chair and advised her accordingly. It is my understanding that Roberta then telephoned Richard to discuss the issue. From that point forward Roberta excused herself from further Board meeting conversations on the topic. It is important to note that, even though our working relationship was less than optimal, I do not believe that this had any impact on the path that was followed with the Mr O'Brien Case and / or urology. All appropriate regard, to Mrs Brownlee as Trust Chair, was given from me. Our relationship did not alter my behaviours with regards to sharing information with the Chair and Board and I am of the view that the actions Mrs Brownlee chose to take were not affected by our relationship.

Q70	**Please explain how and in what circumstances you first became aware of possible concerns regarding Urology Services in the Trust.**
Response	As referenced in my answer to question 54 on the 6th September 2018 Dr Khan, acting Medical Director, made me aware that in his role as case officer for the Managing High Professional Standards case of Mr A O'Brien he was engaging with the GMC and the Trust HR function to start disciplinary procedures. (Reports included as appendix 18a and 18b) I had been made aware of this case by Vivienne Toal, Director or HR, in the previous months including that she had considerable concerns about the performance Mr O'Brien. At that time I had asked Vivienne for further information and I was advised of the incidents of 2016/17 whereby 783 untriaged letters were discovered in a drawer in Mr O'Brien's office as well as 307 sets of patient notes at his home address. In addition, a further 668 letters had no dictation outcomes and there were queries as to whether the management of private patients was in line with the agreed Trust processes. When the matter was raised to me in September 2018, I asked for an assurance from Esther Gishkori, then Director of Acute Services, and Dr Khan that the issues that had been identified two years previously (i.e., in 2016/17) had been addressed. I was advised that an SAI was being carried out to fully understand the learning, however in the interim control measures had been put in place. This involved monitoring by the service lead, Martina Corrigan, and the Assistant Director for Surgery, Ronan Carroll. This involved weekly monitoring of agreed actions. Following these conversations, I was assured that the existing issues were being dealt with. In the middle of June 2020 (I do not have a note in the diary of the exact date), Maria O'Kane, Medical Director, approached me in my office to raise her serious concerns about an issue that had come to her attention. She had been made aware by Mark Haynes, Associate Medical Director (Surgery), that an e-mail had been sent from Mr O'Brien to request that his patients that had not been added to the waiting list were to be considered for an urgent bookable list. When the Mr Haynes reviewed this further it was clear that there were other patients that required to be investigated. At that point Dr O'Kane had already commenced an administrative review and suggested that the offer for Mr O'Brien to return to work following his retirement should be withdrawn. I supported this proposal. Dr O'Kane and Melanie McClements (Director of Acute Services)

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

Initial call made to | CMO Office | (DoH) on | 31.07.2020 | DATE

Follow-up Pro-forma for Early Alert Communication:

Details of Person making Notification:

Name	Dr Maria O'Kane	Organisation	Southern Health and Social Care Trust
Position	Medical Director	Telephone	Personal Information redacted by the USI

Criteria (from paragraph 1.3) under which event is being notified (tick as appropriate)

1. ***Urgent regional action***
2. ***Contacting patients/clients about possible harm***
3. ***Press release about harm***
4. ***Regional media interest***
5. ***Police involvement in investigation***
6. ***Events involving children***
7. ***Suspension of staff or breach of statutory duty***

Brief summary of event being communicated: ****If this relates to a child please specify DOB, legal status, placement address if in RCC. If there have been previous events reported of a similar nature please state dates and reference number. In the event of the death or serious injury to a child - Looked After or on CPR - Please confirm report has been forwarded to Chair of Regional CPC.***

On 7th June 2020 the Trust became aware of potential concerns regarding delays of treatment of surgery patients who were under the care of a Trust employed Consultant Urologist. As a result of these potential patient safety concerns a lookback exercise of the Consultants work was conducted to ascertain if there were wider service impacts. The lookback which considered cases over a 17 month period (period 1st January 2019 - 31st May 2020), the following was found:

- The emergency lookback concentrated on whether the patients had a stent inserted during procedure and if this had been removed. 147 patients taken to theatre that was listed as being under the care of the Consultant during the lookback period with concerns identified in 46 of these cases.
- There were 334 elective-in patients reviewed where 120 of cases were found to have experienced a delay in dictation ranging from 2 weeks to 41 weeks, a further 36 patients who had no record of care noted on the regional NIECR system. To date one of the elective in-patient cases has been identified for screening for Serious Adverse Incident review.

In addition two recent cases managed by this consultant have been identified which are being screened as Serious Adverse Incidents involving two prostatic cancer patients that indicate potential deficiencies in care provided by the consultant in question where these deficiencies potentially had an impact on patient prognosis. The following actions have been taken:

- Discussions with the GMC employer liaison service have been conducted
- This case has been discussed with NHS Resolutions who have recommended restrictions of clinical practice including a request to the Consultant not to undertake private practice in his own home or other premises pending further exploration
- Restrictions have been placed by the Trust that they no longer to undertake clinical work and that they do not access or process patient information either in person or through others either in hard copy or electronically. A request has also been made they voluntarily undertake to refrain from seeing any private patients at their home or any other setting and confirm the same in writing.
- A preliminary discussion has been undertaken with the Royal College of Surgeons invited Review Service regarding the consultants practice and potential scope and scale of any lookback exercise

Appropriate contact within the organisation should further detail be required:

Name of appropriate contact: Stephen Wallace / Zoe Parks

Contact details:

Email address (work or home) zoe.parks Personal Information redacted by the USI ; stephen.wallace Personal Information redacted by the USI

Mobile (work or home) Telephone (work or home) Personal Information redacted by the USI

Forward pro-forma to the Department at: Personal Information redacted by the USI and the HSC Board at: Personal Information redacted by the USI

FOR COMPLETION BY DoH:

Early Alert Communication received by: ………………………………………....... Office: …………………….......……………..

Forwarded for consideration and appropriate action to: ……………………….......……… Date: …...............................

Detail of follow-up action (if applicable) ………………………………………...…………….

Working for a Healthier People

INVESTORS IN PEOPLE

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Reference: HSC (SQSD) 5/19

Date of Issue: 27th February 2019

EARLY ALERT SYSTEM

For Action:
Chief Executives of HSC Trusts
Chief Executive, HSCB and PHA for cascade to:

- *General Medical Practices*
- *Community Pharmacy Practices*
- *General Dental Practitioners*
- *Ophthalmic Practitioners*

Chief Executive NIAS
Chief Executive RQIA
Chief Executive NIBTS
Chief Executive NIMDTA
Chief Executive NIPEC
Chief Executive BSO

Related documents

HSC (SQSD) 10/10: Establishment of an Early Alert System

HSC (SQSD) 07/14: Proper use of the Early Alert System

Superseded documents:

HSC (SQSD) 64/16: Early Alert System

Implementation: Immediate

DoH Safety and Quality Circulars can be accessed on:
https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars

For Information:
Distribution as listed at the end of this Circular.

Issue

This Circular provides updated guidance on the operation of the Early Alert System which is designed to ensure that the Department of Health (DoH) is made aware in a timely fashion of significant events which may require the attention of the Minister, Chief Professional Officers or policy leads.

Action

Chief Executive, HSCB and PHA should:

- Disseminate this circular to all relevant HSCB/PHA staff for consideration through the normal HSCB/PHA processes for assuring implementation of safety and quality circulars.
- Disseminate this circular to Community Pharmacies, General Medical, General Dental and Ophthalmic Practitioners.

Received from SHSCT on 16/05/22. Annotated by the Urology Services Inquiry.

Chief Executives of HSC Trusts, NIAS, NIBTS, NIPEC and BSO should:

- Disseminate this circular to all relevant staff.

Chief Executive, RQIA should:

- Disseminate this circular to all relevant independent sector providers.

Chief Executive, NIMDTA should:

- Disseminate this circular to doctors and dentists in training in all relevant specialities.

Background

In June 2010, the process of reporting Early Alerts was introduced. The purpose of this circular is to re-issue revised guidance for the procedure to be followed if an Early Alert is appropriate.

This revised circular will also serve as a reminder to the HSC organisations to ensure that the Department (and thus the Minister) receive prompt and timely details of events (these may include potential serious adverse incidents), which may require urgent attention or possible action by the Department.

You are asked to ensure that this circular is communicated to relevant staff within your organisation.

Purpose of the Early Alert System

The Early Alert System provides a channel which enables Chief Executives and their senior staff (Director level or higher) in HSC organisations to notify the Department in a prompt and timely way of events or incidents which have occurred in the services provided or commissioned by their organisations, and which may require immediate attention by Minister, Chief Professional Officers or policy leads, and/or require urgent action by the Department.

Received from SHSCT on 16/05/22. Annotated by the Urology Services Inquiry.

Criteria for using the Early Alert System

The established communications protocol between the Department and HSC organisations emphasises the principle of ‘no surprises’, and an integrated approach to communications. Accordingly, HSC organisations should notify the Department promptly (within 48 hours of the event in question) of any event which has occurred within the services provided or commissioned by their organisation, or relating to Family Practitioner Services, and which meets one or more of the following criteria:

1. *Urgent regional action may be required by the Department, for example, where a risk has been identified which could potentially impact on the wider HSC service or systems;*

2. *The HSC organisation is going to contact a number of patients or clients about harm or possible harm that has occurred as a result of the care they received. Typically, this does not include contacting an individual patient or client unless one of the other criteria is also met;*

3. *The HSC organisation is going to issue a press release about harm or potential harm to patients or clients. This may relate to an individual patient or client;*

4. *The event may attract media interest;*

5. *The Police Service of Northern Ireland (PSNI) is involved in the investigation of a death or serious harm that has occurred in the HSC service, where there are concerns that a HSC service or practice issue (whether by omission or commission) may have contributed to or caused the death of a patient or client. This does not include any deaths routinely referred to the Coroner, unless:*

   i. *there has been an event which has caused harm to a patient or client and which has given rise to the Coroner’s investigation; or*
   ii. *evidence comes to light during the Coroner’s investigation or inquest which suggests possible harm was caused to a patient or client as a result of the treatment or care they received; or*
   iii. *the Coroner’s inquest is likely to attract media interest.*

6. *The following should always be notified:*

   i. *the death of, or significant harm to, a child, and abuse or neglect are known or suspected to be a factor;*
   ii. *the death of, or significant harm to, a Looked After Child or a child on the Child Protection Register;*
   iii. *allegations that a child accommodated in a children’s home has committed a serious offence; and*
   iv. *any serious complaint about a children’s home or persons working there.*

7. *There has been an immediate suspension of staff due to harm to patient/client or a serious breach of statutory duties has occurred.*

Received from SHSCT on 16/05/22. Annotated by the Urology Services Inquiry.

Family Practitioner Services should notify the HSC Board about events within the services they provide that meet one or more of these criteria. The HSC Board will then notify the Department.

Operational Arrangements

It is the responsibility of the reporting HSC organisation to ensure that a senior person from the organisation (at Director level or higher) communicates with a senior member of staff in the Department (i.e. the Permanent Secretary, Deputy Secretary, Chief Professional Officer, Assistant Secretary or professional equivalents) regarding the event, and also an equivalent senior executive in the HSC Board, and the Public Health Agency, as appropriate, and any other relevant bodies.

To assist HSC organisations in making contact with Departmental staff, **Annex A** attached provides the contact details of a range of senior Departmental staff together with an indication of their respective areas of responsibility. **The senior officers are not listed in order of contact. Should a senior officer with responsibility for an area associated with an event not be available, please proceed to contact any senior officer on the list.**

It is the responsibility of the reporting Family Practitioner Service practice to ensure that a senior person from the practice **speaks in person** to the Director of Integrated Care (or deputy) in the HSC Board regarding the event.

The next steps will be agreed during the call and appropriate follow-up action taken by the relevant parties. In **all** cases, however, the reporting organisation must arrange for the content of the initial contact to be recorded on the pro forma attached at **Annex B**, and forwarded, within **24 hours** of notification of the event, to the Department at earlyalert@health-ni.gov.uk and the HSC Board at earlyalert@hscni.net.

It is the responsibility of the reporting HSC organisation to comply with any other possible requirements to report or investigate the event they are reporting in line with any other relevant applicable guidance or protocols (e.g. Police Service for Northern Ireland (PSNI), Health and Safety Executive (HSE), Professional Regulatory Bodies, the Coroner etc.) **including compliance with GDPR requirements for information contained in the Early Alert pro forma and the mandatory requirement to notify the Information Commissioner's Office (ICO) about any reportable personal data breaches. The information contained in the pro forma should relate only to the key issue and it should not contain any personal data.**

Received from SHSCT on 16/05/22. Annotated by the Urology Services Inquiry.

There will be occasions when reporting organisations feel it is appropriate to provide updates on an Early Alert which has already been reported. Given that a passage of time may have elapsed and Ministerial changes, this is good practice. It may be appropriate, therefore, for a senior person from the organisation (at Director level or higher) to communicate with a senior member of staff in the Department (i.e. the Permanent Secretary, Deputy Secretary, Chief Professional Officer, or Assistant Secretary) regarding the update. This is not mandatory but reporting organisations will wish to exercise judgement as to whether there has been a substantive change in the position which would warrant a call.

Enquiries:

Any enquiries about the content of this circular should be addressed to:

Mr Brian Godfrey
Safety Strategy Unit
Department of Health
Castle Buildings
Stormont
BELFAST
BT4 3SQ
Tel: 028 9052 3714
qualityandsafety@health-ni.gov.uk

Yours sincerely

Dr Paddy Woods

Received from SHSCT on 16/05/22. Annotated by the Urology Services Inquiry.

3. **ANY OTHER BUSINESS**

i) SAI

Dr O'Kane brought to the Board's attention SAI investigations into concerns involving a recently retired Consultant Urologist. Members requested a written update for the next confidential Trust Board meeting.

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

Quality Care - for you, with you

Minutes of a Virtual Confidential Meeting of Trust Board held on, Thursday, 24th September 2020 at 9.15 a.m.

PRESENT

Mrs R Brownlee, Chair
Mr S Devlin, Chief Executive
Ms G Donaghy Non-Executive Director
Mrs P Leeson, Non-Executive Director
Mrs H McCartan, Non-Executive Director
Ms E Mullan, Non-Executive Director
Mr J Wilkinson, Non-Executive Director
Mr P Morgan, Director of Children and Young People's Services/Executive Director of Social Work
Mrs H Trouton, Executive Director of Nursing, Midwifery & Allied Health Professionals

IN ATTENDANCE

Mr B Beattie, Acting Director of Older People and Primary Care
Dr D Gormley, Deputy Medical Director (deputising for Dr O'Kane)
Mr B McNeany, Director of Mental Health and Disability Services
Mrs M McClements, Interim Director of Acute Services
Mrs J McConville, Assistant Director of Capital and Corporate Planning (deputising for Mrs A Magwood)
Mrs A Rutherford, Assistant Director of Finance (deputising for Ms O'Neill)
Mrs V Toal, Director of Human Resources and Organisational Development
Mrs J McKimm, Head of Communications
Mrs R Rogers, Head of Communications
Personal Information redacted by the USI Boardroom Apprentice
Personal Information redacted by the USI CPANI/QUB Mentee
Mrs S Judt, Board Assurance Manager (Minutes)

APOLOGIES

Mr M McDonald, Non-Executive Director
Ms H O'Neill, Director of Finance, Procurement and Estates
Dr M O'Kane, Medical Director
Mrs A Magwood, Director of Performance and Reform

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.

1. CHAIR'S WELCOME

The Chair welcomed everyone to the virtual meeting. She particularly welcomed Mr Personal Information redacted by the USI, Boardroom Apprentice 2020 and Mr Personal Information redacted by the USI – CPANI/QUB Mentoring Scheme.

2. DECLARATION OF INTERESTS

The Chair requested members to declare any potential conflicts of interest in relation to any matters on the agenda.

The Chair declared an interest in item 7) Urology and left the meeting for discussion on this item.

3. MINUTES OF PREVIOUS MEETING

The Minutes of the meetings held on 30th June 2020 and 27th August 2020 were agreed as accurate records and duly signed by the Chair.

4. MATTERS ARISING

i) Irrelevant information redacted by the USI

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.

The Chair left the meeting for the discussion on the next item.

Mrs Leeson took over as Chair.

7. **UROLOGY**

The Chief Executive set the context to this item by advising that there is likely to be significant media interest and reputational issues with this case.

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.

Dr Gormley stated that the situation remains fluid and he spoke to a paper which outlines a summary of the clinical concerns relating to Consultant A, the actions taken to review aspects of their practice and the development of appropriate management plans to minimise the risk of harm to patients. Mrs Leeson raised the previous SAIs from 2016 and asked about new SAIs to which Mrs McClements spoke of the potential for an additional 6 SAIs at this point. Dr Gormley advised that an External Chair has been appointed and Terms of Reference are in the process of being drafted. Mrs Leeson asked how far back the review process would go. Mrs McClements advised that the focus of the review has been on immediate concerns, but as the Trust has worked through these, other concerns have arisen, leading to further scrutiny. Ms Donaghy asked at which point was the Early Alert to the Department submitted. The Chief Executive undertook to clarify.

Action: Chief Executive

Mrs Toal referred members to the timeline included with the report. She advised that as the Consultant was no longer employed in the Trust, the Conduct Hearing under the MHPS process, cannot be concluded. The Grievance process remains ongoing with the Grievance Panel due to conclude by October 2020. Ms Donaghy asked about Consultant A's appraisals. Mrs Toal stated that there were issues relating to Consultant A's appraisals not being completed in a timely manner, Mrs McCartan asked about the timeline for this case to be in the public domain. The Chief Executive advised that the Minister is required to share details of this case with the Assembly and this is likely to be mid October 2020, subject to the outcomes of the review exercise.

In terms of future reporting to Trust Board, members asked that where there had been progress/actions taken by the Trust since the previous Board meeting, that the paper would be updated accordingly and presented to Trust Board.

The Chair returned to the meeting at this point.

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.

Quality care – for you, with you

BOARD REPORT SUMMARY SHEET

Meeting: Date:	Trust Board 24th September 2020
Title:	Clinical concerns within Urology
Lead Director:	Dr Maria O'Kane Medical Director
Purpose:	Confidential – For Information
Key strategic aims: Delivery of safe, high quality effective care	
Key issues/risks for discussion: This report outlines a summary of the clinical concerns relating to Consultant A, the actions taken to review aspects of his practice and the development of appropriate management plans to minimise risk or harm to patients. There is likely to be significant media interest in this case. Plans need to be put in place to respond to primary care colleagues and to establish a targeted help line for patient concerns. There is likely to be impact on other patients who are awaiting urological appointments/follow up. Consultant A is no longer employed as of 17th July 2020, having given his notice of his intention to retire from his substantive post as at 30th June 2020. The Trust declined his request to return given outstanding employment matters relating to a previous MHPS case commenced on 30th December 2016. Although Consultant A initially challenged this matter, following correspondence exchange between his solicitor (Tughan's) and DLS, he is no longer employed as of 17th July 2020. There has been no legal challenge in respect of this matter, to date.	

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.

Introduction

On 7th June 2020, Consultant A sent an email to the Scheduling administrative staff for Urology, which was copied to the Associate Medical Director (AMD) – Surgery, in which Consultant A explained that he had added 10 patients to the Trust's list for urgent admission. On the AMD's initial review of the list of patients in his capacity as AMD, he noted that 2 of the patients were stated to have been listed on 11th September 2019 and 11th February 2020, both requiring *"Removal/Replacement of Stent and Right Flexible Ureteroscopic Laser Lithotripsy".*

It appeared to the AMD that these patients had been assessed on the dates given by Consultant A (11th Sept 2019 and 11th Feb 2020), but the outcomes of these assessments did not appear to have been actioned by him as required i.e. to add the patients to the inpatient waiting list on the Trust's Patient Administration System at that time. These patients therefore appeared on the face of it to fall outside the Trust's systems with all the potentially very serious clinical risks attendant on that.

As a result of these potential patient safety concerns a review of Consultant A's work was conducted to ascertain if there were wider service impacts. The internal reviews, which considered cases over a 17 month period (period 1st January 2019 - 31st May 2020), identified the following:

- The first internal review concentrated on whether the patients who had been admitted as an emergency had had a stent inserted during procedure and if this had been removed. There were 147 emergency patients under the care of Consultant A listed as being taken to theatre. Of these, information was not available on NIECR for 46 patients. Following further review of inpatient notes, it was identified that 3 patients had not had their stent management plans enacted. Management has been subsequently arranged for these 3 patients.

- The second internal review was for 334 elective-in patients admitted under Consultant A's name during the same period. Out of the 334 patients reviewed there were 120 of cases who were found to have experienced a delay in dictation ranging from 2 weeks to 41 weeks, a further 36 patients who had no record of care noted on the regional NIECR system.

- To date five patient cases have been identified through screening for Serious Adverse Incident review - this screening has indicated potential deficiencies in the care provided by Consultant A. A further two cases, managed by Consultant A, have been identified and these are being screened as Serious Adverse Incidents. These seven patients' care is now being followed up by the Urology Team.

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.

Immediate actions following discovery of concerns in June 2020

- Advice sought from NHS Resolutions (formerly NCAS) who recommended restrictions of clinical practice.
- Referral of these concerns in respect of Consultant A was made to the GMC.
- Up until the date of termination, restrictions were placed by the Trust that Consultant A was to no longer undertake clinical work and that he did not access or process patient information either in person or through others either in hard copy or electronically. A request was also made that he voluntarily undertake to refrain from seeing any private patients at his home or any other setting and same was confirmed in writing via Consultant A's solicitor.
- Given that Consultant A is no longer employed, the handling of this case is now through the GMC, relevant solicitors and Trust.
- The Trust has set up a panel for the Serious Adverse Incident Reviews and this is being chaired by an independent Chair, with a Urology Consultant recommended by the Royal College of Surgeons as a Urology Subject Expert (from England).
- An Early Alert has been sent to the Department of Health advising them of the issues.
- Two separate weekly meetings have been established:
  - Internal oversight meeting - chaired jointly by Director of Acute Services and Medical Director;
  - External – Chaired jointly by Medical Director and Director of HSCB with representatives from Trust, PHA, HSCB and Department of Health.

The following are the areas that have been identified that immediately need to be concentrated on and actions being taken on these patients to mitigate against potentially preventable harm:

1. A concern identified in the SAIs is that a Cancer MDM treatment recommendation for a patient was not enacted. As a result, all notes for post MDM follow-up patients for Consultant A are being reviewed to ensure MDM treatment recommendations have been actioned. (This data is currently being collected as this is a manual exercise)
2. A further concern identified is patients have had diagnostic tests and the results have not been actioned or communicated to the patients, including results with significant findings. The diagnostic tests identified are Pathology and Radiology results. A total of 1711 results are currently being looked at by two of the Trust's Clinical Nurse Specialists. Where they identify that follow-up may not have been actioned, this is escalated for a Consultant Urologist to review and provide input.

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.

Where the reviewing consultant feels that there is a possible issue with care provided, a Datix will be completed by the Consultant Urologist.

3. A further review of inpatients who had stent procedures performed by Consultant A from January 2018 to December 2018 is being carried out to ascertain if any further patients require stent management plans.

In addition, a significant number of patients who are overdue follow up on Consultant A's Oncology Outpatient Review Waiting List (patients who are past their review date) are having their outpatient assessment provided by a recently retired Urologist who has been engaged by the Trust - 235 patients.

A preliminary discussion has been undertaken with the Royal College of Surgeons Invited Review Service regarding Consultant A's practice and potential scope and scale of any independent external review, if required.

Timescales

The above reviews and scoping exercises are either completed or under way so timescales still need to be clarified. The Department of Health is keen to manage the oversight of the review process. The Minister will be required to share details of this with the Assembly and this is likely to be mid- October, subject to the outcomes of the review exercises. A resource plan is in development to identify clinical capacity for communication, patient information and clinical assessment and management plans. This will present significant challenge given the current workforce issues within the Urology speciality.

Previous concerns relating to Consultant A

Previous concerns relating to Consultant A were being addressed since March 2016, and under Maintaining High Professional Standards from December 2016. The timeline for these previous concerns is detailed below:

March 2016

On 23 March 2016, Mr EM, the then Associate Medical Director (Consultant A's clinical manager) and Mrs HT, Assistant Director (Consultant A's operational manager) met with Consultant A to outline their concerns in respect of his clinical practice. In particular, they highlighted governance and patient safety concerns which they wished to address with him.

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.

but the review team is satisfied with Consultant A's account that he does not have these.

There were 66 clinics (668 patients) undictated and 68 with no outcome sheets, some going back a few years. Consultant A gave an explanation of doing a summary account of each episode at the end. He indicated patients were added to waiting lists at the point they should have been in any event.

Some of Consultant A's private patients were added to the HSC waiting list ahead of HSC patients without greater clinical need by these private patients.

27 November 2018

Consultant A submitted a lengthy and detailed grievance of 40 pages, with 49 Appendices. It was lodged along with a request for information. The grievance was held in abeyance pending completion of the information requests.

9 April 2019

Consultant A was advised by Dr AK, Case Manager that a GMC referral was to be submitted following a discussion regarding the case with the GMC Liaison Officer.

Timeline for grievance process – November 2018 to June 2020:

The requested information relating to the information request was provided to Consultant A in 2 returns – one on 21 December 2018 and one on 11 January 2019.

Consultant A wrote to the Trust again on 12 March 2019, and advised that he had sought the advice of the Medical Protection Society and also Legal Counsel, and that he was therefore submitting a request for further information. Consultant A advised that following its receipt, the Trust would be advised whether any further information was to be requested, and /or whether the Formal Grievance was to be amended.

HR Director wrote to Consultant A on 3 June 2019, seeking further clarity on information requested in his 12 March 2019 letter. The Trust advised him that the information request was extensive in nature and would require significant time and resources within the Trust to compile. The Trust advised him that all reasonable efforts were being made to gather the requested information, however within his request there were elements which were much too wide and not properly defined.

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.

	One weakness, from a personal reflection, is that during my early tenure the relationships between me and the Chair, Roberta Brownlee (whose tenure ended in November 2020, were not as strong as they could have been. Outside of public Trust Board meetings we had clashed a small number of times on the difference between the roles of a Chief Executive and a Chair. In my opinion, given the lack of consistency of personnel in the Chief Executive post prior to my tenure, the Chair had understandably become more involved in the operational delivery of the Trust. As the new Chief Executive, I found her approach 'overreaching' and in many cases unhelpful. On reflection, I know that this imperfect relationship may have had an impact on the functioning of the Board and I know, through discussion, some members of SMT found the relationship with the Chair difficult at times. I have provided further understanding of this issue in question 69 In some cases I felt undermined by the Chair as she often chose to interact directly with the members of SMT outside of my knowledge.

Q69	**Was the Board, individually and collectively, motivated to address concerns regarding governance and clinical and patient safety as they arose within Urology Services or more generally? Did they always follow up on concerns raised? Were meetings conducted in an open and transparent manner? What was your experience of the Boards appetite for identifying concerns and implementing lessons learned?**
Response	In this answer I can describe my experience from my tenure. As to the period before my tenure, previous Chief Executives and Directors would be better placed to respond. As you can see from the examples given in response to question 23, there is no doubt in my mind that, during my tenure, the Trust Board invariably were open, transparent and challenging with regards to identifying concerns and implementing lessons learned. Specifically with regards to Urology, during my tenure when items were brought to Trust Board I did not feel that the conversation was quite as open as with other topics. On reflection, I would question the total commitment of the Chair of the Trust to be totally open with regards to her willingness to criticise Urology and, specifically, Mr O'Brien. At the confidential meeting of the Trust Board on the 22 October 2020, we tabled the details of the case so far and strongly debated the concerns with regards to Mr O'Brien. I have included a section of the minutes below *"The Chair advised that Consultant A had written to herself in June 2020, the content of which she had shared with the Non Executive Directors in which Consultant A raised concerns at how the HR processes were being managed and requesting that his formal grievance and its included Appeal are addressed. The Chair was advised that this matter was being progressed through HR processes. The Chair also raised the fact that a number of different Urology Consultants had been in place over the years and asked why they had not raised concerns about Consultant A's practice and similarly, why had his PA not raised concerns regarding some delays in dictation of patient discharges. The Chair also asked should a GP not have recognised the prescribing of Bicalutamide as an issue?"* I was left with the strong impression during the meeting that the Chair was advocating on behalf of Mr O'Brien, a feeling which was shared and relayed to me by a number of SMT colleagues. It was common knowledge amongst the Trust Board and the SMT that the Chair had previously been a patient of Mr O'Brien and that she was a personal friend. I felt aggrieved that the Chair had not declared a conflict of interest in the conversation at the Board meeting. I discussed my concerns with members of SMT and was considering what I should do. A few days later (I cannot recall the exact date as I did not note the time and date of the

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

undermined by the Chair as she often chose to interact directly with the members of SMT outside of my knowledge."

Please comment on what Mr. Devlin states in this paragraph indicating in which respect(s) you agree or disagree with it, and why? Please provide examples and all relevant details.

I was shocked to read these comments by CX Shane Devlin. I was under the impression that I had a very good working relationship with Shane. I never once recall "clashing with him" as he refers. We had many meetings formally and informally. We walked the sites on occasions and had many cups of coffee together. We talked often of his children and their progress through university and school. Shane Devlin and his wife attended a formal Charity function as guests of mine. I strongly refute that I did not have a good working relationship with him. We agreed to differ on some occasions, but this was professionally and respectfully done.

If Shane believed our relationship to be a difficult one, it certainly was not made apparent on any occasion. We had many Board Development Days where we met to discuss the functioning of the Board and our relationships. I fostered an open, transparent and honest culture and wanted the environment to be one where members could discuss and resolve any issues between themselves.

As Shane rightly says, there had been some 'lack of consistency in personnel in the Chief Executive post' and associated instability. I felt that my position as a long-standing Chair provided much needed stability for the NEDs, and I had built very good professional relationships with them. This is what Shane was unsettled by.

I found Shane Devlin to be a strong confident CX and certainly would not have expected him to hold back in challenging me if he felt I was overarching or unhelpful. I append the 2018/2019 360 feedback form provided by Shane Devlin (Exhibit RB-05). You will note that his assessment of me in role as Chair was uniformly either 'very effective' or 'effective' – the two highest scores.

Received from Roberta Brownlee on 29/11/2022. Annotated by the Urology Services Inquiry

BOARD MEMBER'S ASSESSMENT OF THE CHAIR'S PERFORMANCE

Chair: ROBERTA BROWNLEE

Period of report: From 01/04/2018 To 31/03/2019

The following markings should be used to assess performance:

1 = Very effective 2 = Effective 3 = Partially Effective 4 = Not Effective

1. Attendance and commitment	
(a) Attendance at Board and other meetings	Marking: 1
2. Strategic leadership	
(b) Leads the Board effectively in setting the strategic direction of the Trust and ensuring the Trust's plans (and in particular, its statutory functions) are effectively delivered	Marking: 2
(c) Is visible within the Trust and is viewed as being accessible to Board Members and staff	Marking: 1
(d) Is alert to changes in the business needs of the Trust and ensures that these are communicated to Board Members and responded to, as appropriate	Marking: 1
(e) Leads the Board in holding management to account for performance through purposeful challenge and scrutiny, ensuring that good performance is recognised, and any under-performance is promptly addressed	Marking: 2

Received from Roberta Brownlee on 29/11/2022. Annotated by the Urology Services Inquiry

(f) Ensures that the principles of effective governance are known to, understood and practised by Board Members (NEDs & The Senior Management Team) individually and collectively	Marking: 1
(g) Ensures that the performance of the Board (and individual Committees) is reviewed regularly	Marking: 1
3. Builds effective relationships	
(h) Develops a mutually beneficial relationship with the Minister? and DoH Officials demonstrating a clear understanding of the Trust's and his/her responsibilities to both the Minister and Department	Marking: 1
(i) Develops an appropriate relationship with the Chief Executive and SMT (supportive yet challenging)	Marking: 2
(j) Promotes effective teamwork between Board Members and ensures that the Board operates as a cohesive team	Marking: 1
(k) Ensures that the Trust is well connected with its stakeholders and that any concerns or difficulties are addressed promptly and effectively	Marking: 1
4. Communication	
(l) Represents the Board and the Trust effectively with stakeholders	Marking: 1
(m) Has open and effective lines of communication (formal and informal) with Board Members and DoH and meets regularly with Chairs of Committees	Marking: 1

Received from Roberta Brownlee on 29/11/2022. Annotated by the Urology Services Inquiry

55.6

Date of discussions	Event	Detail of the content and nature of all discussions including meetings in which I was involved which considered concerns about Mr O'Brien	Name those present
10th December 2018	Meeting with Mrs Vivienne Toal Director HROD	On reviewing the MHPS information with the awareness that there had been patient safety concerns in relation to Mr O'Brien's administrative processes, I contacted Mrs Vivienne Toal Director for HROD on the 8th December 2018 and we met on the 10th December so that Mrs Toal could provide me with a brief outline of the history which led to the MHPS investigation.	Mrs Vivienne Toal

When and in what context did you first become aware of issues of concern regarding Mr. O'Brien?

Meeting with Chair of Trust during which Mr O'Brien's case was mentioned.

What were those issues of concern and when and by whom were they first raised with you?

Do you now know how long these issues were in existence before coming to your or anyone else's attention?

Mrs Brownlee volunteered to me that Mr O'Brien had saved her life, that she hoped I wouldn't raise concerns about Mr O'Brien as had been her experience previously with medical managers, that she thought he had been poorly treated through the MHPS process, and that he was an excellent surgeon.

Please provide any relevant documents

Date of discussions	Event	Detail of the content and nature of all discussions including meetings in which I was involved which considered concerns about Mr O'Brien	Name those present
11.01.2019	Meeting with Chair	As above. I spoke to Mr Devlin explaining that if there were concerns about any doctor I had a professional responsibility to pursue these concerns to assure patient safety. He agreed.	

Stinson, Emma M

From: Devlin, Shane
Sent: 21 October 2020 00:29
To: OKane, Maria
Cc: McClements, Melanie; McKimm, Jane; Toal, Vivienne
Subject: RE: TB Confidential item 7

Maria

Happy to discuss, although the chair has Not been a patient in recent years, she was a patient nearly 20yrs ago.

I think as chair she needs to be part of the conversation and the whole board need to be in the middle of this.

Catch up tomorrow

Shane

On 20 Oct 2020 23:54, "OKane, Maria" <Maria.OKane Personal Information redacted by the USI> wrote:
Shane my understanding from what the Chair has disclosed openly is that she has been a patient of this doctor in recent years. Given that we will be discussing the impact on patients potentially I am concerned. Maria

---

From: Devlin, Shane
Sent: 20 October 2020 10:52
To: OKane, Maria; McClements, Melanie; McKimm, Jane
Subject: FW: TB Confidential item 7

Please see below.

Can we have clear answers to the Chair's comments for the meeting

Thanks

Shane Devlin
Chief Executive
Southern HSC Trust
Trust Headquarters
Craigavon Area Hospital
68 Lurgan Road
Portadown
BT63 5QQ

Tel: Personal Information redacted by the USI

From: Brownlee, Roberta
Sent: 20 October 2020 10:48
To: Devlin, Shane
Cc: Judt, Sandra; Comac, Jennifer; Donaghy, Geraldine; Leeson, Pauline; McCartan, Hilary; McDonald, Martin; Mullan, Eileen; Wilkinson, John
Subject: TB Confidential item 7

Received from SHSCT on 21/12/2021. Annotated by the Urology Services Inquiry

Shane

I wish to confirm that I will be staying in for this item as Chair (item 7). This is an extremely serious matter for the Board and I need to be present. I have no conflict with this particular matter. My past personal illness I will try to overcome the emotions.

As mentioned when we last spoke of this at 1:1 will Dr Damian (as Dr Maria not coming to TB) be able to confirm that one Urologist Dr Mark (only) having reviewed files is adequate and acceptable under process. Just want to be sure we don't need other specialist opinions of assessment on patients conditions/notes etc on such serious matters (stents/medications). Also are we sure legally (and by DoH CMO) that AOB must not be informed of this all taking place to date and not until the morning of the press release??

We need to be assured that process is as perfect and robust as possible. I appreciate the Irrelevant information redacted by the USI legal information but was there any learning from it when he wasn't told to the morning of – any legal difficulties. Hope you understand where I am coming from – protecting patients is paramount and the Board too.

Roberta

Mrs Roberta Brownlee
Chair
Southern Health and Social Care Trust

Tel: Personal Information redacted by the USI **(External);** Personal Information redacted by the USI **(Internal)**
Email: roberta.brownlee Personal Information redacted by the USI
'You can follow us on Facebook and Twitter'

Received from SHSCT on 21/12/2021. Annotated by the Urology Services Inquiry

Irrelevant information redacted by the USI

7. UPDATE ON CLINICAL CONCERNS WITHIN UROLOGY

The Chief Executive informed members of discussions with the Department in relation to an intended statement by the Minister for Health to the NI Assembly. The Trust has advised that a public statement at this stage would be premature as the Trust has not completed a review of processes to the detail it requires. The Chief Executive therefore sought Trust Board approval to request a delay in the Ministerial announcement.

Members discussed the fact that there is likely to be significant media interest in this case with the potential for significant reputational risk to the Trust. Members emphasised the Trust's duty of care to patients and the importance of the Trust completing its investigative work to ensure that the information it provides is complete and accurate.

Dr Gormley spoke to a report which provides a summary of the clinical concerns relating to Consultant A, the actions taken to review aspects of his practice and the development of appropriate management plans. He reminded members that Early Alerts submitted to the Department of Health have been part of this process advising them of the professional performance and patient safety concerns. Dr Gormley advised that in relation to the SAI process, the Panel Chair has been appointed as well as a Subject Matter Expert.

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.

He informed members of an issue that has recently arisen regarding the Consultant's prescribing of the medication Bicalutamide which appears to be outside established NICE guidance. A review is underway to identify patients receiving this treatment.

The Chair advised that Consultant A had written to herself in June 2020, the content of which she had shared with the Non Executive Directors in which Consultant A raised concerns at how the HR processes were being managed and requesting that his formal grievance and its included Appeal are addressed. The Chair was advised that this matter was being progressed through HR processes. The Chair also raised the fact that a number of different Urology Consultants had been in place over the years and asked why they had not raised concerns about Consultant A's practice and similarly, why had his PA not raised concerns regarding some delays in dictation of patient discharges. The Chair also asked should a GP not have recognised the prescribing of Bicalutamide as an issue?

Dr Gormley stated that patients remained under this one Consultant's care and this will be examined under the SAI process. The Chair then asked about Consultant A's appraisals and asked if performance issues had been identified through this process and if so, were professional development and training needs then identified. Dr Gormley advised that Consultant A's appraisals were also part of the review process.

In terms of systems and processes, Mrs McClements spoke of the SAI process since 2016 when a robust action plan was put in place at that time to address such issues as triaging, communication etc. and the work since June 2020 to scope and review the patient records of Consultant A's cases. Mr Personal Information redacted by the USI noted that when performance issues were identified, additional measures were put in place and asked if these additional measures had not effected positive change, what further controls would need to be put in place should there be concerns raised about other Consultants. Mrs McClements referred to the query as to whether such clinical concerns could happen elsewhere and she advised that the Trust required more time to conduct its review and scoping exercises.

In response to a question from the Chair as to whether one Consultant Urologist reviewing the patient files was sufficient, Mrs

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.

McClements provided assurance that in addition to Mr Mark Haynes' involvement, there is some clinical nurse specialist input and the Head of Service is involved in reviewing systems and pathways. She referred to the multi-disciplinary aspect of this work as detailed in the paper. In addition, there has been Independent Sector Consultant sessions reviewing oncology patients and Subject Matter Experts engaged as part of SAI process.

Mr Wilkinson stated that this was a complex case with various strands. He advised that whilst he supported the Trust's request for a delay in a Ministerial announcement, it was important that this was not a prevaricated delay.

Ms Donaghy referred to this case coming into the public arena and asked about natural justice and Consultant A's right of reply. She raised her concern at the issues Consultant A had raised in his grievance around his appraisals, pressure of work etc. and she asked that these are addressed as part of any review. Mrs McCartan restated the importance of the Trust releasing information only when it is assured it is accurate. Mrs Leeson highlighted the importance of due process being followed with SAIs completed as a priority to ensure learning from this case for the benefits of patients.

Following discussion, the consensus view of Trust Board was to approve the Trust's request to seek a delay in the Ministerial announcement. Members emphasised the importance of a robust timeline to conclude the review processes. It was agreed that following the Trust Board meeting, the Chief Executive would informally advise the Department of Health of the Trust Board's decision followed by a formal letter.

Action: Chief Executive

8. **FINANCE REPORT**

Irrelevant information redacted by the USI

Received from SHSCT on 01/07/2022. Annotated by the Urology Services Inquiry.