The Regulation and Quality Improvement Authority

RQIA Review of the Urology Structured Case Record Review Southern Health and Social Care Trust

May 2023

The Regulation and Quality Improvement Authority

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- Is care effective?
- Is care compassionate?
- Is the service well-led?

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Section 1 Introduction

1.1 Background and Context

On 31 July 2020, the Southern Health and Social Care Trust (SHSCT) contacted the Department of Health (DoH) to report an early alert concerning the clinical practice of a Urology Consultant (referred to in this report as Consultant A).

An initial review, which considered cases over an 18-month period of the consultant's work in SHSCT from 1 January 2019 to 30 June 2020, focussed on whether patients had had a stent inserted during a particular procedure and if the stent had been removed within the clinically recommended time frame. The initial review identified concerns with 46 cases out of a total of 147 patients who had the procedure and were listed as being under the care of the consultant during the period addressed by the initial look-back exercise[i]. The findings were significant and led the Minister for Health, Robin Swann MLA, to announce on 24 November 2020 that a statutory public inquiry would be established under the Inquiries Act 2005.

The Urology Services Inquiry, which is currently ongoing, is chaired by Ms Christine Smith QC has been charged with: (a) reviewing SHCT's handling of relevant complaints or concerns identified or received prior to May 2020 and its participation in processes to maintain standards of professional practice; (b) evaluating the corporate and clinical governance procedures and arrangements within the Trust in relation to the circumstances which led to the Trust conducting a "lookback review" of patients (c) examining the clinical aspect of the cases identified by the date of commencement of the Inquiry as meeting the threshold for a Serious Adverse Incident (SAI) and any further cases which the Inquiry considers appropriate; (d) afford those patients affected, and/or their immediate families, an opportunity to report their experiences to the Inquiry; (e) To review the implementation of the Department of Health's "Maintaining High Professional Standards Policy" by the Trust in relation to the investigation related to Mr O'Brien; (f) To identify any learning points and make appropriate recommendations as to whether the framework for clinical and social care governance and its application are fit for purpose and (g) examine and report on any other matters which the Chairman considers arise in connection with the Inquiry's investigations.

In parallel, yet entirely separate, to the work of the Urology Services Inquiry, SHSCT subsequently established a review group to assess the further findings of the initial review exercise and to explore the need for a further look-back review in the context of additional concerns.

Areas of concern were identified relating to:

- Elective and emergency activity;
- Radiology;
- Pathology and cytology results;
- Patients whose cases were considered in multidisciplinary team meetings;
- Oncology; and

[i] Ministerial Statement by Health Minister to the Northern Ireland Assembly, 24th November 2020

- The safe prescribing of an anti-androgen drug outside established NICE guidance in the management of prostate cancer.

Nine cases were identified that met the threshold for a Serious Adverse Incident (SAI) review. Following the completion of these initial nine SAI reviews in 2021, the Trust was advised by DoH that the SAI process should not be used to review subsequent potential issues in care identified by the lookback process.

As a result, SHSCT developed a Structured Case Record Review (SCRR) process based on the Structured Judgement Review methodology as developed by the Royal College of Physicians. The aim of the SCRR process was to identify any areas of learning where patient safety could be improved.

In March 2022 SHSCT asked RQIA to undertake:

- A review of the choice of Structured Judgement Review methodology to underpin their SCRR process.
- A review of the Trust SCRR process in relation to its effectiveness in identifying learning.

It was further agreed that, in the event that the SCRR process was not considered to be appropriate the Trust would like RQIA to suggest an alternative approach.

1.2 Terms of Reference

Although RQIA was requested to review the suitability of the Trust's SCRR process, we considered that the scope of the review should be wider. It would not be appropriate to only assess the tools involved but we should also assess the surrounding process within which the SCRR operates. Therefore, the following Terms of Reference were agreed with SHSCT.

1. To assess the suitability of the Structured Judgement Review methodology as the basis for the Trust SCRR process.

2. To assess the specific Trust SCRR methodology in relation to its effectiveness in identifying learning.

3. To assess the overall trust process/framework for conduct of its record review.

4. To make recommendations in relation to the overall process and if the SCRR process is not considered to be appropriate suggest an alternative approach.

1.3 Review Methodology

RQIA used a PRINCE project management approach to underpin this review. The review utilised a range of methodologies to obtain supporting information to inform our assessment:

- We undertook a review of the literature around the use of the Structured Judgement Review Method to help identify key themes and areas of focus.

- We designed and issued structured questionnaires to the Southern Health and Social Care Trust.
- We analysed information returned to us and used this to develop Key Lines of Enquiry for meetings with the Trust.
- Our Expert Review Team (ERT) conducted focus groups and meetings with the independent panel of reviewers, senior staff and other relevant staff from the Trust.
- We analysed the information gathered through our structured pre review questionnaires, meetings, focus groups and staff questionnaire responses in order to determine our key findings and recommendations.

Section 2 Findings

In assessing the effectiveness of all aspects of the SCRR process we considered the overall process in respect of a number of component parts.

2.1 OVERALL TRUST PROCESS AND FRAMEWORK FOR SCRR

2.1.1 Background to the Structured Case Record Review

The provision of background and contextual information is vital to the understanding of the rationale and purpose of the Structured Clinical Records Review process. This information was provided by SHSCT, in conjunction with a Structured Case Review proposal document and was explored further by the Expert Review Team during fieldwork sessions with Trust representatives.

During fieldwork, the Expert Review Team heard the Urology Services Inquiry was announced unexpectedly in November 2020 during what was a difficult time for SHSCT, when it was grappling not just with the emerging issues within Urology Services but also with the COVID-19 pandemic and its associated pressures for service; this contextual information provided the Expert Review Team with a valuable insight into the challenges faced. At the point of announcement of the Inquiry Terms of Reference (see Appendix 1) SHSCT had already commenced a Lookback Review and through this had identified a significant number of patients meeting the threshold for an SAI review under the regional SAI procedure[1].

Due to the volume of patients identified, the time and resource required to progress SAI reviews, and the limited additional value of repeatedly reviewing the same type of incident via the SAI process, it was suggested that an alternative methodology is used to derive learning from these cases. The decision to use the SCRR approach, as an alternative to SAI methodology, was taken in conjunction with SPPG and DoH's Urology Assurance Group. The Expert Review Team considers that this decision was the correct one, and that Structured Judgement Reviews methodology, such as that developed by the Royal College of Physicians, is a robust method of assessing the quality of care and treatment of individual cases, when applied as intended. As such, the Expert Review Team endorses the decision to adopt an alternative approach to undertaking repeated SAI reviews in such circumstances.

Although the decision to proceed with the SCRR was taken prior to the announcement of the Urology Services Inquiry, the Expert Review Team noted that SHSCT continually referenced the SCRR process within the context of their broader work to meet the requirements of the Inquiry. However, the Expert Review Team understands that the Inquiry and the SCRR are separate processes and that these references to the Inquiry were likely to give rise to confusion.

The Urology Services Inquiry is an independent statutory process, supported by underpinning legislation, to deliver on its Terms of Reference; whereas the SCRR is a Trust and DoH-initiated process to establish themes of learning with a view to improving Trust systems to reduce the likelihood of similar incidents happening in the future. Whilst running in parallel to the Inquiry, the SCRR is an entirely separate process and is intended to derive learning and implement the necessary improvement to protect current patients.

During fieldwork, Trust representatives accurately described this distinction between the differing roles and purposes of the Urology Services Inquiry and SCRR, the relationship between the differing processes and the arrangements for sharing information with the Inquiry Team. However, upon reviewing Trust documentation, although the rationale for the SCRR is clearly stated, the Expert Review Team identified a lack of clarity in the documentation explaining the role, purpose and remit of the SCRR and, in particular, reinforcing that it is an entirely separate process to the Urology Services Inquiry.

Similarly, SHSCT SCRR documentation does not make clear whether the cases selected for SCRR are being reviewed on behalf of the Urology Services Inquiry.

This lack of clarity has potential to cause confusion since the Urology Services Inquiry Terms of Reference (ToR) include:

> (c) To examine the clinical aspect of the cases identified by the date of commencement of the Inquiry as meeting the threshold for a Serious Adverse Incident (SAI) and any further cases which the Inquiry considers appropriate, in order to provide a comprehensive report of findings related to the governance of patient care and safety within SHSCT's urology specialty.

The Expert Review Team considered that, although Trust representatives demonstrated a good understanding of the distinction between these two processes, the patient / family information materials and Trust documentation were not clear. In the current format, the versions provided to the Expert Review Team do not adequately inform patients and families of the clear distinction between the Urology Services Inquiry and SCCR process, thus, have the potential to inadvertently cause confusion and compound anxiety and distress.

We were informed that SHSCT, in light of recent criticism regarding factually inaccurate information contained in patient letters, regarding the Urology Services Inquiry's purpose, has sought to improve the clarity and accuracy of documentation. The Expert Review Team was provided with a copy of a "Patient Letters Investigation" report which outline a thorough investigation undertaken by an experienced Director independent from the SHSCT and is accompanied by a number of sensible

recommendations. The Expert Review Team commends this report and welcomes these improvement efforts. In addition to these, the Expert Review Team is of the view that SHSCT would benefit from improving their systems for developing and quality assuring patient / family information or indeed any documentation that is publicly accessible or likely to enter the public domain. Such arrangements should include the involvement of a lay person / service user representative and those with communications expertise within SHSCT. Where there is a pending or ongoing Public Inquiry, legal input could be considered to avoid confusion in interpretation of roles and remits.

Recommendation 1

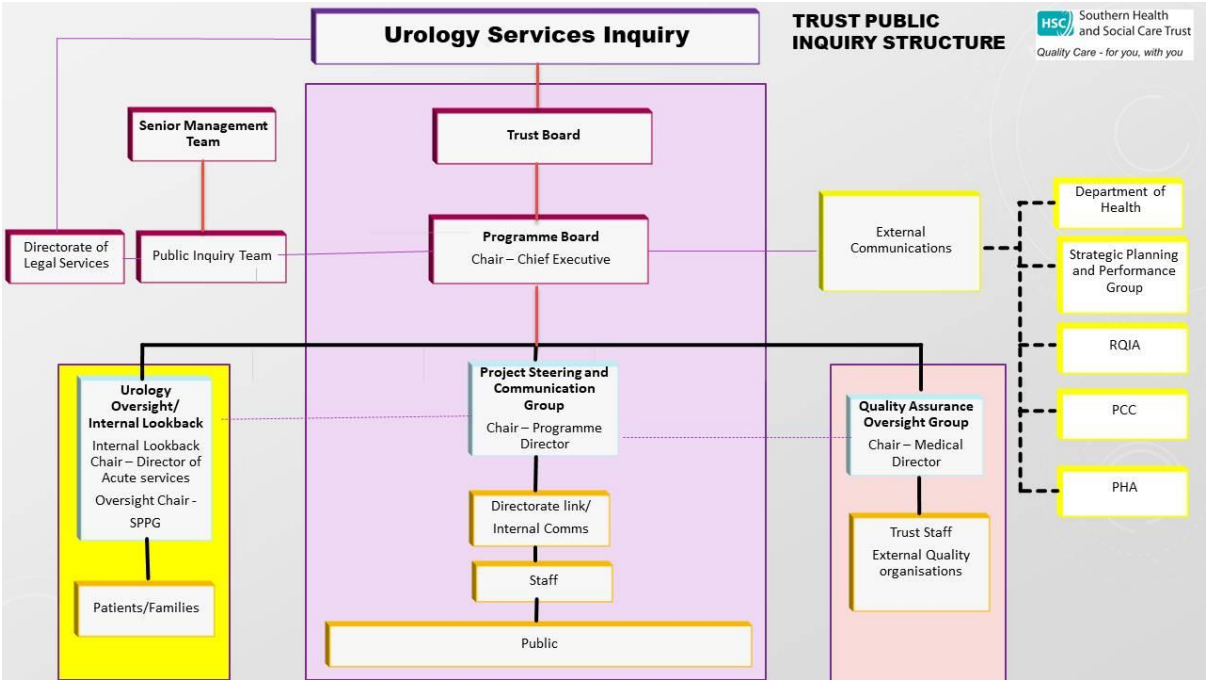
SHSCT should urgently update all relevant documentation to ensure that there is clarity regarding the SCRR including a description of the SCRR purpose, remit and process; explicitly stating that it is a separate process to any parallel Inquiries or investigations.

SHSCT should review their arrangements for developing and quality assuring patient / family information materials and publicly accessible information to ensure there is adequate lay / service user involvement, communications expertise and, where beneficial, legal input.

2.1.2 Review Structure

Robust structures are essential for ensuring effective delivery, assurance and accountability. SHSCT provided details of the Review Structure and advised that the SCRR process sits within its current Trust governance structures.

Figure 1. Current Review Structure



We were informed that the Review Structure is presently overseen by SHSCT Internal Urology Lookback Group. SHSCT Public Inquiry Programme Board is chaired by the Chief Executive. The Programme Board members act on behalf of SHSCT Board to oversee the work of the:

- Public Inquiry Response and Communications Group;
- Public Inquiry Urology Oversight / Lookback Steering Group; and
- Quality Assurance and Improvement Oversight Group

The Lookback Review is included on the Corporate and Acute Services Risk Registers. External oversight of the process is provided by the fortnightly Service

Planning and Performance Group (SPPG) Meeting and Department of Health led Urology Oversight Group.

ToR were provided for the Urology Services Inquiry Programme Board, Trust Internal Urology Lookback Group and Health and Social Care Board[ii] (HSCB) Urology Group. The Expert Review Team noted the broad remit of oversight and co-ordination groups and considered that some of the committees were very large, with overlapping membership. The Expert Review Team noted that the composition of the Lookback Review Steering Group (referred to as the Urology Oversight / Internal Lookback Group) does not reflect the Regional Guidance for Implementing a Lookback Review Process (July 2021)[2] which suggests inclusion of:

> "a Non-Executive Director, the Director of service/speciality concerned, relevant professional Executive Director(s), Risk and Governance representative, Head of Communications, Information Technology manager, Medical Records manager and senior service, representatives with expertise Public Health Agency (PHA) representative and an Health and Social Care Board (HSCB) representative (in the case where the Lookback Review has been identified as an SAI, the role on the Steering Group will be clearly identified to ensure that the independence of the PHA/ HSCB is not jeopardised). The organisation may also wish to consider a member of a relevant service user representative/advocacy group is included as a member of the Steering Group."

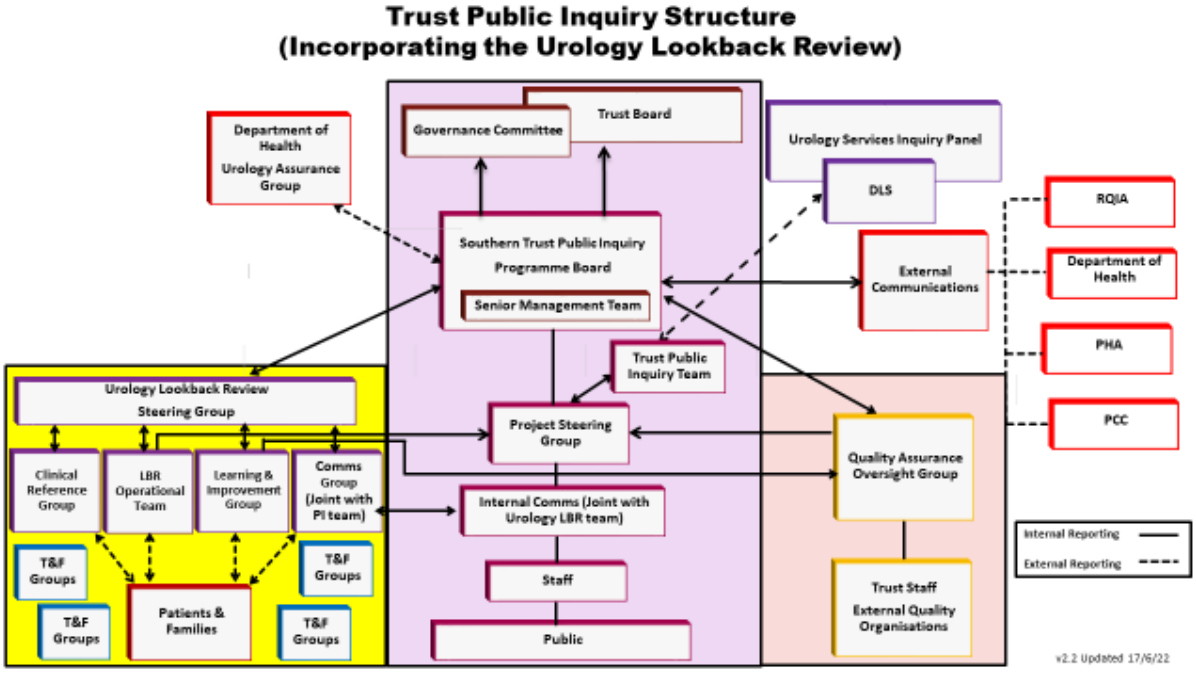
The Expert Review Team acknowledged the challenges and sensitivities of including a service user / advocacy representative who has been impacted by or has a vested interest in the matter of concern. However, the inclusion of a lay member, not impacted by SHSCT Urology concerns, but nonetheless with previous experience of representing the interests of service users / the public on similar pieces of work, can be hugely valuable and should be considered by SHSCT. The benefits include enhanced public confidence in the process, improved adherence to the statutory duty of Personal Public Involvement (PPI), provision of advice on patient / family / public messaging and on the fulfilment of a duty of candour.

The Expert Review Team considered that there was a lack of clarity surrounding leadership / responsibility and arrangements for accountability and reporting. During fieldwork, we were advised that the Chief Executive has ultimate accountability for the SCRR and that recent work had been undertaken to improve oversight, reporting and ensure clear lines of accountability. This resulted in a proposed new structure for oversight of the SCRR process. The Expert Review Team is of the view that any new structure should also be designed to support SHSCT to fulfil its responsibilities in respect of all Urology work, to deliver on SCRR objectives and should avoid creating unnecessary duplication or complexity.

The Expert Review Team was informed that the new structure exists in shadow form at present with the Operational Team being chaired by the seconded Director in a holding position until the new Director responsible for surgery takes up post.

Figure 2. Proposed New Review Structure (draft document at the time of the Review)

[ii]The Health and Social Care Board was replaced by the Service Planning and Performance Group (SPPG) April 2022.



Although the Expert Review Team welcomes improvements to the overarching review structure, it is of the view that, given the sizeable undertaking and complexity of the work, the operational arrangements for management and co-ordination of the SCRR and potentially the Lookback Review itself, would benefit from the establishment of a dedicated project team. It was noted that one individual was seconded from another Trust to support SHSCT with its work and this was a welcome development; however, no other Trust representative attending the fieldwork sessions reported having experience of conducting Lookback Reviews. This represents a considerable lack of skill and experience, which can occur when there has been recent turnover or change within the management structures of an organisation. In light of this shortfall, the dedicated project team should include people with previous experience in undertaking similar work, who can draw upon a wide network of 'critical friends' to provide support, advice and guidance.

Recommendation 2

SHSCT should consider reviewing the composition of Lookback Review steering group to reflect that which is stated within Regional Guidance for Implementing a Lookback Review Process; in particular, consideration should be given to the inclusion of a lay representative.

SHSCT should establish a dedicated project team for the management and co-ordination of SCRR. SHSCT should recruit people with the skills and experience who, if required, can seek the advice and guidance of experts from across the region.

2.1.3 Project Management

Effective project management is crucial in ensuring a well-co-ordinated delivery of objectives within acceptable timescales; this is best implemented with the support of a project manager accredited in using validated project management methodology such as PRINCE / PRINCE 2.

SHSCT SCRR project is currently managed as a sub-workstream of SHSCT corporate lookback process rather than by an individual with project management expertise supported by dedicated project team. Furthermore, the process does not use a specific project management methodology and has followed an iterative approach in terms of its design, signoff and deployment.

To ensure identified project actions are undertaken, minutes are kept of screening and lookback meetings and these are carried forward into future meetings. Individual case records for SCRR are tracked to the relevant Expert Reviewer; ensuring updates can be sought on progress.

The Expert Review Team considered that, whilst these arrangements might suffice for small numbers of cases, they are not sufficiently robust for managing a large volume of work. The Expert Review Team is of the view that a dedicated project team for the co-ordination and management of the Lookback Review and SCRR process, should include a Project Manager; ideally such an individual should have previous experience in managing a Lookback Review or, in the absence of previous experience, should have an understanding of the process and should be supported by a network of people who have the requisite skills and expertise.

The Expert Review Team was advised that a proposal paper outlining an updated Lookback Review structure, process and accountability has been submitted to SHSCT Programme Board. In this paper it states that the Urology Lookback Review is a project and should be constructed as such in terms of purpose, ToRs, reporting lines, risk register etc., including the identification of / clarity on who is the Senior Reporting Officer (SRO) for the project; suggesting this should sit at Director level.

SHSCT further advised that this includes a review of the associated Project Management arrangements in order to ensure that the project progresses swiftly and with clear accountability. The Expert Review Team welcomes this approach.

Recommendation 3

Considering the need for dedicated co-ordination and management of the Lookback Review and the SCRR process; SHSCT should prioritise the appointment of a suitably qualified Project Manager.

2.1.4 Terms of Reference / Objectives of the SCRR

A clear Terms of Reference (ToR) or, in lieu of a ToR, a set of specific objectives serves to focus the minds of those undertaking the Structured Clinical Record Review process on the purpose, remit and what needs to be achieved during the course of the

process. Providing a framework for monitoring progress and accountability for delivery, it is also helpful in communicating the scope of work in a clear, open and transparent way; a Terms of Reference can also assist in conveying information about the process to interested parties, such as DoH, SPPG / PHA, Health and Social Care (HSC) Trusts, patients / families / carers and the public.

Unfortunately, there were no ToR / Objectives provided by SHSCT relating to the SCRR process itself. The Expert Review Team considers that a ToR should be drafted and agreed as soon as possible. Trust representatives were keen that this should adequately convey the clinical elements of the SCRR.

In light of this, a possible ToR could include:

1. To assess the quality of care and treatment provided by Consultant A, using Structured Judgement Review methodology which gives specific consideration to the following:

- Triage;
- Initial assessment;
- Diagnostic investigations;
- Outpatient care;
- Inpatient care;
- Perioperative care;
- Care during any medical or surgical procedure (excluding IV cannulation);
- Communication with colleagues, MDT and primary care;
- Communication with patient and families; and
- Discharge plan and follow-up arrangements.

2. To review the findings of the individual Structured Judgement Reviews and produce a thematic analysis report.

3. To identify learning and make recommendations for improvement.

The Expert Review Team also considered that it would helpful for SHSCT to explicitly state the purpose of the SCRR. It is referenced within the Review Methodology Section of the proposal document provided by SHSCT that “the objective of the SJR method is to look for strengths and weaknesses in the caring process, to provide information about what can be learnt about the hospital systems where care goes well and to identify points where there may be gaps, problems or difficulty in the care process”. This is closely aligned to the purpose of the SCRR, which is ultimately for SHSCT to define, but may best be described as serving “to assess the quality of care and treatment, in order to identify learning and implement improvement”.

Recommendation 4

SHSCT should define and explicitly state the purpose of the SCRR process. Furthermore, a clear Terms of Reference / set of objectives should be agreed and referenced within the relevant Trust documentation.

2.1.5 Time period for inclusion of cases for SCRR

All cases reviewed as part of the current Lookback Review undergo screening for consideration for inclusion in the SCRR process; those meeting the SAI threshold are 'screened in'. The scope of the Lookback Review pertains to all patients that were under the care of Consultant A during the time period 1 January 2019 – 30 June 2020. The Expert Review Team explored the rationale for this time period with Trust representatives. When concerns first came to light, this period was chosen as it was believed that this was when patients were most at risk from aberrant clinical practice.

The Expert Review Team acknowledges that no lookback exercise can review all cases at once, that there has to be a starting point, and that a phased approach is preferable in order to expedite learning and facilitate reflection; furthermore, to start with those patients identified as being most at risk is sensible, justified and in keeping with regional guidance. However, the Expert Review Team was informed that since then, it has been identified, by examination of historical care through the Patient Casenote Review process, that patients treated by Consultant A prior to 2019 may also have received substandard care. This is unsurprising; it is the Expert Review Team's experience that problems with a clinician's practice tend to be longstanding and not restricted to a particular period of time. We were advised that in light of this finding, the Royal College of Surgeons (RCS) is currently undertaking a review of a sample of 100 cases from 2015 in order to identify whether there were problems present at this stage

The Expert Review Team is of the view that if there is already enough evidence to inform a risk assessment that patient groups receiving treatment prior to 2019 are at risk of harm, SHSCT should not wait for the RCS work to conclude and should proceed as a matter of urgency to extend their Lookback Review to identify and recall at risk patients under the care of Consultant A prior to 2019. This can be done using a phased, risk-stratified approach based on the learning gathered to date. It can then be extended and scaled up further, following receipt of the RCS findings, should this be required. However, regardless of the approach adopted, given the risk posed to live patients, it is imperative that a further phase of the Lookback is commenced as a matter of priority.

Since this is likely to be a considerable undertaking, requiring suitable expertise to offer advice and guidance, it is vital that SHSCT is adequately supported by its partners across the HSC system, including DoH/ Urology Assurance Group / SPPG and PHA. As this work is scaled up, an independent assessment of the current Urology Lookback Review arrangements would serve to provide assurance regarding its effectiveness and identify any areas that need strengthened; this assessment could be undertaken by RQIA as a 'Part 2' to this review of the SCRR. Assurance of the current lookback arrangements would serve to strengthen the foundations in place for extending the time period and scaling up to include additional patient subgroups.

Recommendation 5

SHSCT should give urgent consideration to extending their Lookback Review to identify and recall further groups of patients. DoH / Urology Assurance Group / SPPG, PHA and RQIA should work together to support SHSCT with the Lookback Review.

RQIA should consider undertaking an independent assessment of Trust arrangements for the Urology Lookback Review in order to provide assurance on its effectiveness and identify any areas for improvement.

As there is a need to prioritise the Lookback Review, to ensure that patients at risk are promptly reviewed and that ongoing care and treatment is arranged, it may be preferable for an external body, such as the Royal College of Physicians, to undertake the SCRR on behalf of SHSCT. Not only would this allow Trust teams to focus on the Lookback Review whilst maintaining a safe level of care provision for its current and new patients, it would mean that the SCRR is conducted by an independent organisation that has the requisite expertise, governance structures, well tested processes and quality assurance mechanisms in place to support this type of work; consequently, the output may be more expedient and performed to a higher standard. However, the Expert Review Team acknowledges that commissioning an independent body may not be possible either due to a lack of agreement, resources or time, in which case the recommendations outlined in this report should support SHSCT itself to facilitate the SCRR.

Recommendation 6

SHSCT should consider commissioning an independent body to undertake the SCRR process on its behalf.

2.1.6 Case selection

Appropriate case selection is important to ensure effective use of time and resources, which should be prioritised towards cases where there is likely to be learning.

During fieldwork, Trust representatives outlined the process for case selection. All service users who were under the care of Consultant A between January 2019 and June 2020 were reviewed using a 10-question Patient Review form either internally by SHSCT or an external consultant urologist commissioned for this purpose. This 10-question Patient Review Form explored current as well as historical care. At a point in time, this list of questions was shortened to 4 questions which explored current care, following discussions with SPPG (formerly HSCB) who were keen that it mirror the approach used by the Belfast HSC Trust Neurology recall. It reverted back to 10 questions at the request of the Trust (and with agreement by SPPG) with all relevant case notes being assessed retrospectively to ensure consistency.

Where concerns regarding the quality of care are identified, these cases are then considered at a screening meeting, attended by the Trust's acute directorate governance and clinical staff, to establish if the concerns meet the threshold set out in

the regional SAI procedure. Where the case meets the criteria for an SAI, it is progressed as an SCRR.

The Expert Review Team considered that if the aim is to identify all cases where there is likely to be learning, the use of SAI thresholds may not be the most effective method. This was explored with Trust representatives who were in agreement. We were advised that cases considered for inclusion in the SCRR included the following:

1. SAI threshold met; concerns around the care and treatment in keeping with a theme already identified
2. SAI threshold met; concerns around the care and treatment in keeping with an emerging theme, not previously identified
3. SAI threshold not met; nonetheless, learning identified
4. SAI threshold not met; care and treatment "reasonable"

The Expert Review Team is of the view that it is acceptable to include cases from Group 3. Although a case may not meet the criteria for an SAI review, it may still contain valuable learning from a patient experience or service quality perspective.

To date, 53 cases have been identified that meet the criteria for SCRR. This number is likely to increase further, particularly if the care and treatment of additional patient groups is going to be subject to an extension of the Lookback Review; a total in excess of 90 cases is expected to be identified from this phase alone.

During fieldwork the Expert Review Team heard that of the 53 SCRRs passed to the external SCRR urologists between February and May this year only 20 have been returned to date. This prolonged process poses challenges for the Trust as they are keen to establish the full extent of learning in relation to these cases.

Given time constraints and limited availability of expert reviewers, the Expert Review Team was keen to explore whether a sampling approach had been considered by SHSCT. Such an approach would seek to maximise learning within the constraints of available resources and may lead to improvements being implemented at an earlier stage.

During fieldwork, Trust representatives remarked on the similarity of themes across the cases that have already been reviewed. We were informed that there was very similar learning arising from 19 out of 20 cases reviewed to date. This supports an argument that a point of saturation might be reached and there may be limited additional benefit to reviewing all cases, as was initially intended.

The Expert Review Team recognises that a pragmatic approach to sampling would mark a departure from the original intention and direction of the SCRR. It would be the Expert Review Team's view that such a departure requires a clear rationale to be agreed by the DoH; this would require the purpose, scope and Terms of Reference for the SCRR review to be clearly articulated and defined. DoH should ensure that such an approach is justified when taking into consideration the wider context, including the planned work and emergent findings of the Urology Services Inquiry. The Expert Review Team's view is that a sampling approach would expedite learning and would allow an opportunity for earlier improvement to be implemented. However, there are

ethical considerations and SHSCT should take steps to ensure that the sampling framework is robust and should be open and honest with patients and families about the approach and its rationale.

Understanding that some patients and families may be disappointed that their case is no longer going to be reviewed, SHSCT may wish to include an option for patients and families to request inclusion in the SCRR. If it is not feasible or reasonable to grant such a request, then the patient or family should be informed of the additional routes available to them, such as submitting a concern to the SHSCT Complaints Department, GMC, PSNI or any redress scheme. They should additionally be informed about the Urology Services Inquiry and directed to it's website for further information.

Recommendation 7

SHSCT should consider implementing a sampling approach to case selection for SCRR. Such an approach should be agreed with DoH / Urology Assurance Group / SPPG. SHSCT should be clear on the rationale, its benefits and limitations and ensure that there is openness and transparency in communication with patients, families and the public. SHSCT should engage the Clinical Ethics Committee to consider any ethical issues arising from such an approach which can then be addressed and mitigated by SHSCT.

2.1.7 Ethical Considerations

The application of ethical principles when conducting reviews of a complex and sensitive nature is invaluable to guide decision-making and ensure that the review is conducted in an open, transparent, fair and sensitive way. It can be helpful in ensuring a rigorous approach, adherence to a duty of candour, respect for confidentiality but also autonomy (i.e. right not to know) and in ensuring that specific patient groups are not inadvertently disadvantaged. It is also helpful when considering specific ethical issues that may arise from the process of reviewing patient cases, such as circumstances where previously undiagnosed or undisclosed hereditary conditions are identified.

SHSCT advised that no Clinical Ethics issues were identified for discussion with SHSCT Clinical Ethics Committee. The Expert Review Team is of the firm view that given the scale and sensitivity of the work involved, and the potential for inadvertent harm to be caused by the process, SHSCT would benefit from giving due consideration to the application of Ethical Principles. Advice from SHSCT Clinical Ethics Committee should be urgently sought and, if deemed necessary, this could be assisted by the HSC Regional Clinical Ethics Committee.

We refer SHSCT to a recently issued Ethical Framework[3], developed specifically for RQIA's Expert Review of Deceased Patients of Dr Watt, which contains overarching themes that are applicable to any lookback or review of this nature:

1. Respect for Persons (which includes Privacy, Confidentiality and Data Protection, and the Right to Know and the Right Not to Know)
2. Transparency and Candour

3. Fairness
4. Responsibility

It was RQIA's experience that the process of discussing ethical principles and deliberating the potential for ethical issues is as valuable as the end product of any framework or ethical paper. In the context of the Expert Review of Deceased Patients of Dr Watt, it had wider benefits beyond ensuring that the methodology and the approach were ethically rigorous, and greatly assisted with the drafting of correspondence to families, and in the interactions with families by the RQIA Family Liaison Team.

Recommendation 8

SHSCT should request SHSCT Clinical Ethics Committee to review both current and proposed arrangements for the Lookback Review and SCRR. Where ethical issues are identified, SHSCT should give this due consideration and, where required, adapt the methodology and approach for the review.

2.1.8 Legal Considerations

A legal perspective on review proposals and arrangements is prudent when undertaking work of this nature.

The Expert Review Team's experience is that it can be helpful across a number of areas including:

- Identifying previously unconsidered pitfalls in relation to correspondence with interested parties, proposed review methodology and approach;
- Ensuring there is appropriate indemnity for reviewers undertaking the SCRR;
- Managing data protection issues;
- Managing legal challenges from solicitors acting on behalf of patients / relatives;
- Managing legal challenges from Consultant A's legal team; and
- Requesting clinical records of patients reviewed by Consultant A in a private a capacity

Trust representatives advised that the Directorate of Legal Services (DLS) is supporting SHSCT with the Urology Services Inquiry and that an opinion could be sought if required. However, SHSCT advised that legal advice had not been sought as the SCRR is being utilised as an alternative of SAI to establish learning from the situation. The Expert Review Team considered that legal input would be required in order to make this determination and also to consider the potential for future legal ramifications.

It is the Expert Review Team's view that given the significance and scale of concerns, the likelihood of negligence and that this is a departure from the regional SAI process, a legal perspective should be sought in relation to the arrangements for SCRR.

Recommendation 9

SHSCT should engage with Trust legal representation to obtain a legal perspective on the arrangements for the SCRR.

2.2 METHODOLOGY AND IDENTIFICATION OF LEARNING

2.2.1 Patient and Family Engagement

There is a statutory duty of Personal Public Involvement as set out in the Health and Social Care (Reform) Act (Northern Ireland) 2009[4]. Best practice in involvement is to seek the input of service users and families to help shape the review process, particularly around sensitive person-centred communication, the provision of support and a mechanism for sharing concerns. There may be additional valuable information from affected service users / families that will not be evident in the clinical documentation of the clinician under investigation; information from families and carers is particularly vital in those cases where a patient has sadly deceased. Importantly, effective patient and family engagement is crucial in order to adhere to the principles of candour and 'being open'.

The regional SAI procedure stipulates the requirements for patient and family engagement. On 7 July 2022, the report of the RQIA Review of the Systems and Processes for Learning from Serious Adverse Incidents in Northern Ireland[5] was published; this has relevant findings on effective engagement and involvement of families and recommendations for strengthening the regional approach and procedure. Furthermore, a draft 'Statement of Rights' as an output of the O'Hara Inquiry may be helpful in focussing HSC Trusts on the importance of appropriate and sensitive interaction with patients and their families.

Although the SCRR is not an SAI process, the Expert Review Team is of the view that, as a minimum, patients and families should be informed of the purpose of the SCRR, and that those affected should have an opportunity to provide additional information about their care and treatment. SHSCT outlined their process for engaging and involving families. The Expert Review Team is impressed with and commends the significant efforts SHSCT has made in contacting all impacted families, which, given the scale, is a huge undertaking. However, we note recent issues arising regarding the quality of patient information and consider that the arrangements for patient and family involvement in both shaping the process and sharing concerns require improvement.

The Expert Review Team considers that SHSCT PPI team and those external to SHSCT, such as the PHA and Patient Client Council, have been underutilised in ensuring that there are robust arrangements for PPI as part of the Lookback Review and SCRR.

Recommendation 10

SHSCT should review their arrangements for the involvement of patients and families to ensure that it fulfils its statutory duty of Personal Public Involvement. SHSCT should consider engaging those with Personal Public Involvement expertise and external

partners such as the PHA who have PPI training resources for staff and the PCC who could provide advice and support in the involvement of patients and families as part of the Lookback Review and SCRR.

SHSCT outlined its arrangements for following up and sharing the findings of the SCRR with patients and family members. Although there is a Family Liaison Officer (FLO) available to support patients and families, the findings are primarily shared through postal correspondence. Whilst this may be the preference of a large number of families, many may require additional support to understand and emotionally cope with the findings.

The Expert Review Team consider the following to represent good practice[6,7,8]:

- As far as possible, reports should be quality assured, checked for factual accuracy, and should be written in easy to understand lay language;
- Patients / families should be provided with a range of options on how they wish to receive the report; one option should be a face to face meeting. They also have a right "not to know" the findings;
- The Family Liaison Officer should be accompanied by a medical doctor in relaying the findings of the report;
- Psychological support should be made available to those impacted by the process and findings of the SCRR;
- If further medical follow-up is required by patients or relatives, there should be Trust arrangements in place to facilitate this in a timely manner; and
- There should be opportunities for the FLO to debrief with colleagues and timely access to psychological support for the FLO and any others involved in family engagement.
- Independent advocacy should be considered for patients or families, particularly when cases are complex. The PCC have extensive experience in this area through previous work on SAIs and other Inquiries.

During fieldwork, the Expert Review Team explored the support available for those staff members involved in the review and, in particular, the patient and family engagement. SHSCT described effective provision of support including: senior and peer support, psychological support and access to Inspire Wellbeing Counselling service. The Expert Review Team is content that the arrangements for support appear sufficient but cautions that a substantial proportion of the work appears to be undertaken by one FLO. Given the large number of cases identified, it may be beneficial to increase the capacity of the Family Liaison Team to provide support to those impacted by the Lookback Review and SCRR.

Recommendation 11

SHSCT should review their arrangements for sharing SCRR findings with patients and families giving consideration to good practice as outlined by the Expert Review Team in this report.

2.2.2 Methodology & Tool

Structured Judgement Review methodology is a reliable, well validated tool that has been developed by the Royal College of Physicians. It allows for the blending of traditional, clinical-judgement based, review methods with a standard format. The approach requires reviewers to make safety and quality judgements on particulars of care, to make explicit written comments, and to assign a score for the quality of care at each phase. This produces a rich set of information about each case in a form that can be aggregated to produce knowledge about clinical services and systems.
SHSCT discussed the use of this tool with the Royal College of Physicians and opted for this methodology to underpin the SCRR process.

The Structured Judgement Review methodology was adapted for the SCRR in order to take into consideration the relevant phases of care. The phases of care assessed are:

- Triage;
- Initial assessment or review;
- Review of Diagnostics;
- Ongoing Outpatient Care;
- Admission and Initial Management;
- Ongoing Inpatient Care;
- Care during a procedure (excluding IV cannulation);
- Perioperative care; and
- Discharge plan of care.

The Expert Review Team is not privy to all the specific clinical concerns therefore cannot be certain that the tool adequately scrutinises all relevant aspects of care. With this caveat in mind, the SCRR tool generally appears reasonable. However, the Expert Review Team did note some areas that SHSCT may wish to address. There is some divergence from the RCP methodology in terms of the data collection instrument. There is no section to assess:

- Quality of documentation in the records;
- Communication between Consultant A and the patient / carer / family; and
- Communication between colleagues, MDT and primary care.

Whilst we were advised that deceased patients are included in the review, there are no sections outlining a review of the death certification or whether a referral to the coroner's service was required.

Of particular value in relation to deceased patients, but of great value for all cases, is the consideration of patient and family concerns. In general, there is a lack of patient

and family input into the SCRR process. Patients and families were not engaged with in order to shape the review. Equally, there is no consistent mechanism to proactively seek the concerns of patients and families for consideration as part of the individual SCRR. This marks a considerable deficit in the information available to formulate findings. The experience of the Expert Review Team is that, where concerns from patients and families are taken into account, this greatly enhances the learning process and provides information and context that is often not present in the notes. RCP has successfully incorporated patient / family concerns into its review process by asking expert reviewers to review the notes firstly without knowledge of the patient / family concerns and then a second time taking the patient / family concerns into consideration. The complaint can then be judged to be 'upheld', 'partially upheld' or 'not upheld'.

RQIA's experience from the Expert Review of Deceased Patients of Dr Watt is that there is a close correlation between the views of family members and the judgement of the structured judgement tool (SJR), strengthening the argument that there is great benefit in attaining patient and family input. Where there is little or no correlation between the patient / family story and the clinical picture documented in the records, the Review Panel may determine that the family concern is 'not upheld'; of note, this only occurred for two (out of 44) patients included in Phase 2 of the Expert Review of Deceased Patients of Dr Watt.

Recommendation 12

SHSCT should liaise with RCP and consider amending the Structured Clinical Record Review tool to include an assessment of the quality of documentation and an assessment of the documented communication with patients and families; the clinical team, MDT and primary care. SHSCT should consider facilitating the consideration of patient / family concerns as part of the SCRR to mirror the approach undertaken by RCP.

Whilst Structured Judgement Tools provide an objective assessment of the care and treatment documented within the clinical records, it can only allow for a partial systems perspective. For example, it may tell a story of care and treatment according to the national standards of the time, of the standard and quality of documentation, multidisciplinary involvement, communication between colleagues and communication with family members. Of direct relevance, it will not examine factors such as caseload, working relationships and peer review.

Furthermore, it will not tell us about the governance systems within Urology Services or within SHSCT as a whole. It will not examine the role of external bodies and the wider system in providing oversight and assurance of quality and safety of care.
With this in mind, DoH or SHSCT Board may wish to commission RQIA to undertake a Review of Governance within Urology in Southern Health and Social Care Trust. This would provide an opportunity to identify and remedy any deficits, and to share learning within SHSCT and across the system so that governance systems may be strengthened and future harm prevented.

Recommendation 13

DoH should commission RQIA to undertake a Review of Governance Arrangements within Urology Services in Southern HSC Trust.

2.2.3 Expert Reviewers

Each case is reviewed independently by a 'Subject Matter Expert' (or Expert Reviewer) utilising the SCRR methodology. SHSCT provided details of Expert Reviewers, including a description of the job role and a copy of the guidance provided to reviewers at the outset of the work. The Expert Reviewers are nominated via the British Association of Urological Surgeons (BAUS) for their subject matter expertise. SHSCT ensures that each reviewer is appropriately registered and of good standing with their professional regulator, the General Medical Council (GMC). The Expert Review Team is content that reviewers appeared suitably independent and qualified.

In total, SHSCT approached 13 reviewers of which four Expert Reviewers have been recruited to support this work. Given the difficulty recruiting Consultant Urologists and the time consuming nature of the SCRR process, the Expert Review Team considered whether specialist nurse reviewers or urologists in training could be used instead. A clearly defined protocol with consultant oversight of the process would facilitate this. It was considered that a hierarchical culture within HSC, associated with perceptions amongst the Northern Ireland public that attaches particular significance to reviews undertaken by a consultant, may be a barrier to implementing a non-consultant review process. Therefore, if the work cannot be supported by specialist nurses or trainee urologists, consideration should be given to the use of doctors working outside the specialty of urology.

The Expert Review Team noted that no training was provided to Expert Reviewers, who instead were stated to be familiar with SJR tool methodology. In addition, there was no specific manual provided to reviewers; albeit the following guidance was provided:

- Using the Structured Judgement Review method - A guide for reviewers; National Mortality Case Record Review Programme 2019[9]; and
- Structured Judgement Review - Frequently Asked Questions 2019.

Additionally, the process had not been piloted and there was no method of calibration between reviewers to ensure inter-reviewer reliability and consistency. Importantly there is no mechanism for quality assuring the work of reviewers, either by assigning two reviewers to each case or by second-reviewing a sample of the cases.

The Expert Review Team notes that 20 SCRRs had been completed at the time of fieldwork; and while we understand the challenges in delivering quality assurance of reviews within the current limited pool of reviewers it may be beneficial to conduct an independent review by a second expert reviewer to ascertain the degree of reliability and consistency in assessing the quality of care. A panel should then be convened to discuss any significant discrepancies in judgement, to gain consensus and provide expert reviewers with an opportunity to standardise their approach.

Even in the absence of discrepancies, it can be helpful for clinical reviewers to have a forum to discuss cases, debrief and avail of emotional or psychological support. Although it was reported that each reviewer can contact SHSCT Deputy Medical Director for Quality and Safety if issues arise, the Expert Review Team is of the view that SHSCT is missing an opportunity to proactively support reviewers, seek feedback on the process and seek reviewers' views on the learning arising.

Recommendation 14

SHSCT should not be limited to consultant urologists when recruiting clinical reviewers to undertake the SCRR process. All Expert Reviewers should be provided with guidance and support, including an opportunity to debrief, feedback and avail of emotional / psychological support if required.

A document should be drafted specific to this particular piece of work to guide reviewers through the process of conducting the SCRR; this should include a defined protocol for the assessment of the quality of care and treatment.

A sample of cases already reviewed using the SCRR methodology should undergo a second review to ensure inter-reviewer reliability and consistency. Consideration should be given to quality assurance of a defined sample of cases for the remainder of the SCRR.

2.2.4 Review Panel

Good practice dictates that in undertaking a review, an expert panel to deliberate findings and attain consensus on recommendations is preferable to the judgement of one individual expert. A forum for discussion between panel members allows for a sharing of expertise and perspective, brings a deeper and broader understanding of issues, mitigates bias and derives learning more effectively.

SHSCT stated that there is no specific review panel for the SCRR; however, the Trust Lookback Group oversees the overall lookback process that includes the SCRR. On completion of the initial batch of SCRRs, an independent Consultant Urologist will develop a thematic report on the findings.

The Expert Review Team considered that, as SHSCT has rightly identified that a key outcome of the SCRR is a thematic analysis in order to identify learning and inform system improvements, the process would benefit from a dedicated review panel rather than relying on the professional judgement of one individual to collate findings, identify themes and make recommendations. This was explored with Trust representatives during fieldwork, who advised that the RCS and BAUS had both been approached to undertake an independent quality assurance of the SCRR but SHSCT had not been able to secure agreement from either of these bodies. Subsequently SHSCT considered convening a multidisciplinary panel comprising eight individuals but due to limited resource and availability of staff this had not progressed. The Expert Review Team considers that a smaller panel, including urology, governance and lay expertise would suffice; encouragingly, Trust representatives were amenable to this model.

The Expert Review Team is of the view that any learning and evidence-based recommendations made by the review panel would require a commitment from SHSCT to implement a clear prioritised action plan within acceptable timescales.

Recommendation 15

A review panel should be constituted, for the specific purposes of identifying learning and determining recommendations arising from the SCRR process. This panel should include individuals with expertise in urology and governance, and include a lay member.

2.2.5 Identification and Dissemination of Learning

Dissemination of learning is crucial in order to improve systems for delivery of care both within SHSCT and across the region. Any strategy for the dissemination of lessons learned should be supported by DoH / SPPG / PHA and should incorporate an action log of the system improvements required, along with timescales for follow up and review.

SHSCT stated that each SCRR report will be reviewed by a Trust clinician who will identify if there is any previously unidentified learning. The thematic analysis report will also be considered by SHSCT in respect of broader system issues.

SHSCT advised that returned SCRRs are reviewed by a Trust clinician who will decide on the appropriateness of sharing learning more widely; this includes learning that should be shared beyond Trust boundaries. Mechanisms for sharing learning were stated to include:

- Using SHSCT local shared learning template;
- Regional shared learning template;
- Morbidity and Mortality Meetings (Patient Safety Meetings);
- Acute Governance Meetings (Directorate wide); and
- Urology and Cancer Services team meetings.

The Expert Review Team considered that the arrangements for identifying, implementing and disseminating learning required strengthening. The reliance on the professional judgement of one clinician to undertake a thematic analysis, in the absence of a mechanism for the reviewers to discuss and feedback, compounded by the lack of quality assurance of individual reports, risks that important system issues may go unidentified. Similarly, the reliance on a Trust clinician to determine whether learning should be shared wider, lacks independence, and runs the risk that one person acts as a gatekeeper to the implementation of improvement and dissemination of lessons learned.

As stated previously, a review panel with representation from urology, governance and a lay member would serve to ensure that there is a robust mechanism for deriving, implementing and making determinations on the dissemination of learning. Where learning is derived, the Expert Review Team would expect that recommendations are made and clear prioritised time-specific action plans are put in place with arrangements for monitoring and accountability. A follow-up review, with defined

parameters for assessment around implementation, would provide assurance around the implementation of sustainable improvements.

The information provided by SHSCT indicates that the consideration of dissemination of learning is confined to within Trust boundaries; although a regional shared learning template is referenced, it is not clear whether this in itself would be sufficiently robust to disseminate learning to the relevant stakeholders across the system. SHSCT representatives were of the view that the previous HSCB process for sharing learning from SAIs needs to be adapted or replicated for the SCRR process but that this had not yet commenced. The Expert Review Team is of the view that the mechanisms for sharing learning should be discussed urgently with DoH / SPPG / Urology Assurance Group. Recipients should include Urology Services Inquiry, SHSCT Board, Urology Assurance Group, DoH / SPPG, PHA, and RQIA; under duty of candour principles, it should be considered whether there is an onus to share learning with the public. In any case, an effective strategy for communication with stakeholders would serve to underpin arrangements for the effective dissemination of learning.

Recommendation 16

SHSCT should work with DoH / SPPG / PHA to develop an effective dissemination strategy for the Lookback Review and SCRR so that learning is shared regionally with all relevant stakeholders and the public is effectively informed under duty of candour principles.

2.3 GOVERNANCE OF THE SCRR

2.3.1 Risk Management

Effective risk management relies on the identification, assessment, mitigation and monitoring of risk. All projects incur risks, such as risks associated with timescales, available expertise, budgetary constraints and data protection vulnerabilities. However, projects of this nature can carry considerable additional risk, such as the risk of causing harm to patients / families / public and reputational risk to the health service. It is vital that the structures, systems and processes in place support effective recognition and management of such risk.

The Expert Review Team was advised that the project does not keep a formal risk log; however, risks are recorded and discussed through meetings. At the time of review, there were three risks identified with mitigation actions identified for each.

When the Expert Review Team explored the issue of risk it was advised that the risks associated with the SCRR had progressed to both the directorate risk register for Acute Services and to the Corporate Risk Register.

The Regional Guidance for Implementing a Lookback Review Process (July 2021) states that:

> "When scoping the nature, extent and complexity of the Lookback Review Process (Section 2.6 – 2.7) the Steering Group should evaluate and escalate the risk in line with the organisation's Risk Management Strategy. This will

ensure that the risk(s) identified will be included in either, the organisation's Board Assurance Framework, Corporate Risk Register or Directorate Risk Register and managed in line with the Risk Management Strategy."

The Expert Review Team was further advised that SHSCT is currently transitioning to a revised organisational structure, designed to fully support SHSCT to fulfil its function in respect of the SCRR objectives; this is currently operating in in shadow form. As a consequence, the project will operate under more robust governance structures with a live risk register maintained specifically for the Lookback Review. Issues of risk will also be included in the ToR for the new Urology Lookback Review Steering Group and SHSCT Public Inquiry Programme Board (note these are working titles which may change when the new structure is finalised). The Expert Review Team welcomed these improvements which will serve to strengthen the current arrangements for risk management.

2.3.2 Records Management

Effective management of clinical records requires protocols for retrieving, scanning and sharing records, underpinned by strong governance arrangements. SHSCT described robust arrangements for accessing and sharing of clinical records, which was in keeping with good information governance.

A list of patient names and health and care numbers of those cases identified for SCRR is shared with a dedicated administrator. When a decision is made to proceed with SCRR, the relevant patient records are obtained through normal hospital processes by request of hardcopy notes via the medical records team. Notes in patient charts which are not available on NIECR are copied, scanned and uploaded to Egress Secure Workspace, an electronic platform, for sharing with expert reviewers. Expert reviewers also have secure access to NIECR.

There is a dedicated member of the clinical governance team assigned to support the SCRR process, who is responsible for obtaining the charts, extracting the records for scanning and who also uploads to Egress Secure workplace and notifies and liaises with the external expert reviewers. The Expert Review Team considered this approach to be acceptable.

2.3.3 Data Considerations

SHSCT outlined their arrangements for data protection. Document transfer is managed via SHSCT Egress document sharing platform and also via secure VPN access to NIECR records. Each Expert Reviewer is required to complete a Trust confidentiality agreement and Data protection agreement prior to accessing records.

The Expert Review Team identified a potential General Data Protection Regulation (GDPR) issue with the arrangements for contacting families. SHSCT would benefit from further consideration of information governance, and in particular, data protection issues in relation to SCRR.

Given the sizeable number of patients involved, a database is beneficial to track progress of the Lookback Review / SCRR, to analyse demographic and clinical

information, and to monitor outcomes. SHSCT is presently developing a new database to store and analyse information in relation to the selected cases. Unlike the previous database which relied on manual population, the new database allows for automatic population, reducing the risk of input error. The Expert Review Team welcomes this development and advises that a statement of purpose should be drafted for the new database, outlining the rationale for transferring data; a copy of the old redundant file should be retained in case it needs to be examined at a later stage. If deemed to be helpful, SHSCT could be signposted to regional experts who recently developed a database as part of the neurology live patient recall.

Recommendation 17

SHSCT should draft a statement of purpose for the new database, outlining the rationale for transferring data and should retain a copy of the redundant file on record.

2.3.4 Communication with Stakeholders

Effective communication with stakeholders ensures that there is clear, consistent messaging on the purpose, remit, progress and findings of any review. It also facilitates liaison and co-operation regarding specific aspects of the work where external input is required in order to achieve a particular outcome. The need for robust stakeholder communication is referenced within the Regional Guidance for Implementation of a Lookback Review which highlights that the principle of 'no surprises' should be adopted and outlines that there should be:

- An agreed communication plan/liaison plan for other HSC organisations or independent/private providers which might be affected;
- An agreed media/communications management plan if required, that aims to be proactive in disclosure to the general public and considers responses to media enquiries; and
- Engagement with PSNI and coroner's service in line with standard procedures.

In addition to the above stakeholders, there should also be a channel of communication established with the GMC via the HSC Trust's Responsible Officer. All these elements are best considered as part of a comprehensive Communications Strategy developed for the specific Lookback Review.

SHSCT advised that when completed, the SCRRs are planned to be shared with the Urology Services Inquiry along with the thematic review of cases. Additionally, DoH will be provided with updates on the process via the Urology Assurance Group. SHSCT advised that the Coroner will be notified if there is a potential issue identified via the SCRR processes which has not previously been identified via Trust processes.

The Expert Review Team considers that there is an absence of an overall communication and stakeholder engagement strategy. It is also noted that there is no channel of communication established between SHSCT and PSNI or GMC. The GMC is likely to be interested in the findings, which will be relevant to the Fitness to Practice (FTP) investigation of the consultant concerned. In addition, there is a possibility that the harm found could be of PSNI interest in terms of possible assault, gross negligence, or in extreme cases, manslaughter. The Expert Review Team considers

that a Communications Strategy should be developed and examples from recent lookback exercises or similar review work across the region may assist SHSCT in expediting this.

Recommendation 18

SHSCT should urgently develop and implement a communication strategy specific to the Lookback Review and including the SCRR process.

A channel of communication specific to Urology work streams should be established between SHSCT, PSNI, GMC and Coroner's office; SHSCT should ascertain the thresholds for referral in respect of specific concerns arising out of cases reviewed as part of the SCRR.

Section 3 Conclusion and Recommendations

3.1 Conclusion

RQIA acknowledges the commitment of SHSCT to ensuring that this work is undertaken a manner that is robust and effective in deriving learning and informing improvements. This was evident, not only by the fact that SHSCT approached RQIA to request this review, with the aim of providing assurance, but also in the Expert Review Team's engagement with Trust representatives and staff during fieldwork. We acknowledge the amount of time and effort that SHSCT staff have given to this piece of work and commend their openness, candour and willingness to learn from the expertise of the Expert Review Team. This positive engagement and 'buy in' will assist SHSCT in implementing the necessary improvements.

RQIA was initially approached to provide independent assurance of the SCRR methodology. During preliminary discussions with SHSCT, we determined that this assurance should be broadened to include the wider process, governance and framework surrounding the SCRR process. This was felt to be particularly important given that the SCRR arose as a result of a significant number of SAIs which were identified through SHSCT Lookback Review, at which point the decision was made to adopt alternative methodology to the SAI process. The Expert Review Team endorses this decision. Structured Judgement Methodology, when applied appropriately, is a reliable, validated methodology which offers an effective means of deriving learning and implementing improvements.

However, when examining the SCRR process within the context of the Lookback Review, it was apparent to the Expert Review Team, that the Lookback in itself is not only a significant undertaking for SHSCT but its progression is a matter of urgent priority. An assessment of the historical care of patients, whose cases had undergone the screening process for SCRR, identified deficits in care and treatment prior to 2019. SHSCT is presently conducting a risk assessment and has commissioned RCS to undertake a review of cases relating to 2015 which should assist SHSCT in determining the future scope and scale of their Lookback. The Expert Review Team is of the firm view that SHSCT should not wait until this work concludes, and based on the evidence SHSCT has gathered to date should proceed to review and recall further groups of patients which it has identified to be at risk of harm.

Understanding that this is a considerable undertaking and that issues have already been identified regarding the availability of expertise and resource to support the Lookback Review, SHSCT will require significant support from the wider HSC system: DoH, SPPG, PHA and RQIA. A dedicated, appropriately resourced and experienced project team should be established as soon as possible to support this work. This may require secondment of additional individuals with the relevant skills and experience to SHSCT. RQIA recognises the efforts SHSCT has already undertaken to improve its lookback arrangements and is keen to support SHSCT with further improvements. As RQIA is best placed to provide assurance on the current arrangements to ensure strong foundations for scaling up and extending the Lookback time period, we recommend that RQIA undertakes a follow-up piece of assurance work looking specifically at the Lookback Review. Going forward, in order to allow SHSCT to focus on the Lookback Review, ideally the SCRR should be undertaken by an independent

body. The Expert Review Team understands that SHSCT may not be able to secure the support of an external organisation; therefore, we make a number of recommendations to strengthen the existing SCRR process and arrangements.

SHSCT should explicitly state the purpose of the SCRR and draft a Terms of Reference as soon as possible. Caveated with the fact the Expert Review Team is not privy to all specific clinical concerns, the tool itself appears reasonable, but it does deviate from the tool used by RCP and leaves a number of areas unexamined such as quality of documentation. In addition, given that a proportion of patients are deceased, it would be judicious to update the tool to take into consideration death certification and the need for coronial referral. The Expert Review Team advises that SHSCT liaise with RCP to ensure the tool is appropriately aligned and that SHSCT mirrors RCP's approach to considering patient and family concerns as part of the SCRR process.

The arrangements for patient and family involvement require significant strengthening. Inclusion of lay membership on the relevant project groups would ensure SHSCT meets its statutory duty of patient and public involvement. The Expert Review Team also provides advice on best practice in involving, listening to and supporting patients and families through processes such as these in a way that reduces the potential for further harm and serves to restore faith in the health service. Given the scale, complexity and sensitivity of the work involved, due consideration should be given to seeking an ethical perspective on arrangements through SHSCT Clinical Ethics Committee.

RQIA notes the large number of cases that have been identified for SCRR and the difficulty this poses in terms of conducting SCRRs within reasonable timescales, compounded by the limited number of expert reviewers. A sampling approach is pragmatic and effective in deriving learning within the constraints of time and resource. However, this requires a clear purpose; ToR; agreement with DoH / Urology Assurance Group; due consideration of ethical considerations; and considered and sensitive engagement with patients and families. Importantly, where cases are selected for review, this should be done to a high standard.

A document should be developed to guide reviewers through the SCRR process and there should be a mechanism for calibration between reviewers to ensure consistency and inter-reviewer reliability. Additionally, a sample of the cases should be subject to second review for quality assurance. Understanding that this is challenging to achieve within reasonable timescales with a limited number of reviewers, the Expert Review Team recommends that SHSCT considers recruiting non-urology consultants to review the cases, guided by a defined protocol and with appropriate expert oversight.

Whilst the outcome of individual case reviews will be valuable to patients and families in terms of understanding what went wrong and why, it is the overall learning derived from the SCRR process that will assist SHSCT and the region in improving its systems. Therefore, it is vitally important that SHSCT strengthens its arrangements for identification and dissemination of learning. A review panel comprising members with expertise in urology and governance, and a lay representative should be established to deliberate findings, derive learning and make evidence-based recommendations. Equally, the mechanisms for sharing learning require an effective dissemination

strategy to be agreed with DoH / SPPG and PHA. Underpinning this, communication with stakeholders including GMC, Coroner's Service and PSNI requires to be underpinned by a Communication Strategy and established channels of communication. Furthermore, the arrangements for sharing information with the public under a duty of candour and for developing patient and family information require considerable strengthening. Encouragingly this is already being explored by SHSCT in light of concerns surrounding factual accuracy of previously issued patient correspondence.

On the whole, the challenges facing SHSCT are considerable, complex and require a concerted effort with appropriate involvement of a number of organisations; DoH / SPPG, PHA and RQIA. Retaining the focus on patient safety, the Lookback Review requires urgent support and upscaling. Whilst SCRR will be valuable in establishing deficits within the care and treatment of this patient population, it is limited in terms of deriving systems and governance learning. As such, RQIA advises that a Review of Governance of Urology Services would be crucial in terms of providing assurance around the current service. RQIA is committed to providing both independent assurance and improvement support to SHSCT as it continues its efforts to urgently address deficits in care whilst improving the quality and safety of SHSCT urology services.

3.2 Summary of Recommendations

Recommendation 1

SHSCT should urgently update all relevant documentation to ensure that there is clarity regarding the SCRR including a description of the SCRR purpose, remit and process; explicitly stating that it is a separate process to any parallel Inquiries or investigations.

SHSCT should review their arrangements for developing and quality assuring patient / family information materials and publicly accessible information to ensure there is adequate lay / service user involvement, communications expertise and, where beneficial, legal input.

Recommendation 2

SHSCT should consider reviewing the composition of Lookback Review steering group to reflect that which is stated within Regional Guidance for Implementing a Lookback Review Process; in particular, consideration should be given to the inclusion of a lay representative.

SHSCT should establish a dedicated project team for the management and co-ordination of SCRR. SHSCT should recruit people with the skills and experience who, if required, can seek the advice and guidance of experts from across the region.

Recommendation 3

Considering the need for dedicated co-ordination and management of the Lookback Review and the SCRR process; SHSCT should prioritise the appointment of a suitably qualified Project Manager.

Recommendation 4

SHSCT should define and explicitly state the purpose of the SCRR process. Furthermore, a clear Terms of Reference / set of objectives should be agreed and referenced within the relevant Trust documentation.

Recommendation 5

SHSCT should give urgent consideration to extending their Lookback Review to identify and recall further groups of patients. DoH / Urology Assurance Group / SPPG, PHA and RQIA should work together to support SHSCT with the Lookback Review.

RQIA should consider undertaking an independent assessment of Trust arrangements for the Urology Lookback Review in order to provide assurance on its effectiveness and identify any areas for improvement.

Recommendation 6

SHSCT should consider commissioning an independent body to undertake the SCRR process on its behalf.

Recommendation 7

SHSCT should consider implementing a sampling approach to case selection for SCRR. Such an approach should be agreed with DoH / Urology Assurance Group / SPPG. SHSCT should be clear on the rationale, its benefits and limitations and ensure that there is openness and transparency in communication with patients, families and the public. SHSCT should engage the Clinical Ethics Committee to consider any ethical issues arising from such an approach which can then be addressed and mitigated by SHSCT.

Recommendation 8

SHSCT should request SHSCT Clinical Ethics Committee to review both current and proposed arrangements for the Lookback Review and SCRR. Where ethical issues are identified, SHSCT should give this due consideration and, where required, adapt the methodology and approach for the review.

Recommendation 9

SHSCT should engage with Trust legal representation to obtain a legal perspective on the arrangements for the SCRR.

Recommendation 10

SHSCT should review their arrangements for the involvement of patients and families to ensure that it fulfils its statutory duty of Personal Public Involvement. SHSCT should consider engaging those with Personal Public Involvement expertise and external partners such as the PHA who have PPI training resources for staff and the PCC who could provide advice and support in the involvement of patients and families as part of the Lookback Review and SCRR.

Recommendation 11

SHSCT should review their arrangements for sharing SCRR findings with patients and families giving consideration to good practice as outlined by the Expert Review Team in this report.

Recommendation 12

SHSCT should liaise with RCP and consider amending the Structured Clinical Record Review tool to include an assessment of the quality of documentation and an assessment of the documented communication with patients and families; the clinical team, MDT and primary care. SHSCT should consider facilitating the consideration of patient / family concerns as part of the SCRR to mirror the approach undertaken by RCP.

Recommendation 13

DoH should commission RQIA to undertake a Review of Governance Arrangements within Urology Services in Southern HSC Trust.

Recommendation 14

SHSCT should not be limited to consultant urologists when recruiting clinical reviewers to undertake the SCRR process. All Expert Reviewers should be provided with guidance and support, including an opportunity to debrief, feedback and avail of emotional / psychological support if required.

A document should be drafted specific to this particular piece of work to guide reviewers through the process of conducting the SCRR; this should include a defined protocol for the assessment of the quality of care and treatment.

A sample of cases already reviewed using the SCRR methodology should undergo a second review to ensure inter-reviewer reliability and consistency. Consideration should be given to quality assurance of a defined sample of cases for the remainder of the SCRR.

Recommendation 15

A review panel should be constituted, for the specific purposes of identifying learning and determining recommendations arising from the SCRR process. This panel should include individuals with expertise in urology and governance, and include a lay member.

Recommendation 16

SHSCT should work with DoH / SPPG / PHA to develop an effective dissemination strategy for the Lookback Review and SCRR so that learning is shared regionally with all relevant stakeholders and the public is effectively informed under duty of candour principles.

Recommendation 17

SHSCT should draft a statement of purpose for the new database, outlining the rationale for transferring data and should retain a copy of the redundant file on record.

Recommendation 18

SHSCT should urgently develop and implement a communication strategy specific to the Lookback Review and including the SCRR process.

A channel of communication specific to Urology work streams should be established between SHSCT, PSNI, GMC and Coroner's office; SHSCT should ascertain the thresholds for referral in respect of specific concerns arising out of cases reviewed as part of the SCRR.

Appendix 1: Terms of Reference for the Statutory Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust

(a) To review the Southern Health and Social Care Trust's (the Trust) handling of relevant complaints or concerns identified or received prior to May 2020 and its participation in processes to maintain standards of professional practice. The Inquiry shall determine whether there were any related concerns or circumstances which should have alerted the Southern Trust to instigate an earlier and more thorough investigation over and above the extant arrangements for raising concerns and making complaints.

(b) To evaluate the corporate and clinical governance procedures and arrangements within the Trust in relation to the circumstances which led to the Trust conducting a "lookback review" of patients seen by the urology consultant Mr Aidan O'Brien (for the period from January 2019 until May 2020). This includes the communication and escalation of the reporting of issues related to potential concerns about patient care and safety within and between the Trust, the Health and Social Care Board, Public Health Agency and the Department. It also includes any other areas which directly bear on patient care and safety and an assessment of the role of the Board of the Trust.

(c) To examine the clinical aspect of the cases identified by the date of commencement of the Inquiry as meeting the threshold for a Serious Adverse Incident (SAI) and any further cases which the Inquiry considers appropriate, in order to provide a comprehensive report of findings related to the governance of patient care and safety within the Trust's urology specialty.

(d) To afford those patients affected, and/or their immediate families, an opportunity to report their experiences to the Inquiry.

(e) To review the implementation of the Department of Health's "Maintaining High Professional Standards Policy" by the Trust in relation to the investigation related to Mr O'Brien. The Inquiry is asked to determine whether the application of this Policy by the Trust was effective and to make recommendations, if required, to strengthen the Policy.

(f) To identify any learning points and make appropriate recommendations as to whether the framework for clinical and social care governance and its application are fit for purpose.

(g) To examine and report on any other matters which the Chairman considers arise in connection with the Inquiry's investigations in fulfilment of these Terms of Reference.

The clinical practice of Mr O'Brien is being investigated by the General Medical Council (GMC) and it would, therefore, be inappropriate for the Inquiry to encroach on the GMC's remit. The Inquiry shall submit a report as soon as practicable to the Minister for Health. Should the Inquiry as part of its investigation establish any issue of concern which it believes needs to be brought to the Minister's immediate attention, then this will be done.

Appendix 2: Structured Judgement Review[10]

Case note review remains a prime means of retrospectively assessing quality of patient care. Implicit review is based on clinical judgement and is judged to be effective in identifying and recording the detail and nuance of care (both unsatisfactory and good).

Unstructured implicit review was criticised for low inter-rater reliability (high variability) and for potential reviewer bias. Structured implicit review methods require reviewers to use a judgement based structured explicit scale to rate quality of care from very poor to excellent. However, this form of review only provides a scale based quantitative result giving no indication of why a reviewer made a particular judgement. This means that it is useful for large scale monitoring or epidemiological studies of adverse events but is less effective for more detailed review at ward or hospital level of why an event occurred.

To increase the value of structured review in reviewing the whole spectrum of care quality, rather than focussing only on adverse event rates, a methodology was developed where reviewers were required to provide implicit clinical judgements and to write explicit comments to support judgement based quality of care scores: this forms the basis of Structured Judgement Review.

Structured Judgement Review requires reviewers to make safety and quality judgements over phases of care, to make written comments about care for each phase and to score care for each phase.

The objective of this review method is to look for strengths and weaknesses in the caring process, to provide information about what can be learnt about hospital systems where care goes well and to identify areas where there may be gaps, problems or difficulties with the care process. It can be used for a wide range of hospital based safety and quality reviews across services and specialties and not only for those cases where patients die in hospital. The quality and safety of care may be judged and recorded whatever the outcome of the case and good care is judged and recorded in the same detail as care that may have been problematic.

There are two stages to the review process.

Stage One

Carried out by ‘front line’ reviewers who are trained in the method and who undertake reviews within their own services, for example in Morbidity and Mortality Reviews.

Phases of care – the ‘structure’ part of the process.

Phases of care are shown below but may be varied depending on the type of care or service being reviewed:

- Admission and initial care – first 24 hours
- Ongoing care
- Care during a procedure

- Perioperative/procedure care
- End of life care (or discharge care)
- Overall assessment of care

Explicit Judgement Comments

Explicit judgement commentaries provide:

- The means for the reviewer to concisely describe how and why they assess the safety and quality of care provided.
- A commentary that other health professionals can really understand if they subsequently look at the completed review.

Phase of Care Scores

Care scores are recorded after judgement comments have been written and the score is itself an overall judgement of the reviewer. Scores range from excellent to very poor.

1. Very poor care
2. Poor care
3. Adequate care
4. Good care
5. Excellent care

Judging the quality of recording in the case notes.

As part of the overall assessment, the reviewer is also asked to record their judgement on the quality and legibility of the records again using a score of 1-5.

Second Stage Review

A score of 1 or 2 is given when the reviewer assesses that care has been poor or very poor. A score at this level should trigger a second stage review through the hospital governance process.

A second stage review also uses the structured judgement method and takes place if a patient has died. If the second stage reviewer broadly agrees with the initial case review a decision may be taken to carry out a further assessment concerning the potential avoidability of the patient's death.

The judgement is framed by a 6 point scale. A score of 1,2 or 3 on the avoidability scale would indicate a governance 'cause for concern'.

1. Definitely avoidable
2. Strong evidence of avoidability
3. Probably avoidable (more then 50:50)
4. Possibly avoidable, but not very likely (less than 50:50)
5. Slight evidence of avoidability
6. Definitely not avoidable.

Structured Judgement Review can produce learning at two levels:

- The detail captured can identify both poor practice and good practice of individual clinicians.
- When multiple reviews are undertaken within a clinical area or a hospital, a thematic analysis can be performed that may highlight systemic issues in a system.

Quantitative data identify very poor to excellent care in a number of care phases. Qualitative data from explicit judgements may be analysed, for example using word detection software, to identify recurrent themes.

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