The Regulation and Quality Improvement Authority

Final Report on Findings in Respect of Term of Reference 1. RQIA Review of Southern HSC Trust Urology Services and Lookback Review

July 2023

Updated August 2024 with Trust response to Recommendations

Contents

The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) is the independent body responsible for regulating, inspecting and reviewing the quality and availability of health and social care services in Northern Ireland. RQIA's reviews identify best practice, highlight gaps or shortfalls in services requiring improvement and protect the public interest. Reviews are supported by a core team of staff and by independent assessors, who are either experienced practitioners or experts by experience. Our reports are submitted to the Minister for Health and are available on our website at www.rqia.org.uk.

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

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1. BACKGROUND

On 31 July 2020, the Southern Health and Social Care Trust (the Trust) submitted an Early Alert (Ref EA 182/20) to the Department of Health (DoH) Northern Ireland, in relation to urology services in the Trust. The basis for this Early Alert, was to describe early findings from scoping of records and identify any further work required to identify the scope and scale of any further look back.

The Early Alert advised that on 7 June 2020, the Trust had become aware of potential safety concerns related to delays in the treatment of surgical patients. These patients had been under the care of a consultant urologist, Mr Aidan O'Brien, who had been employed by the Trust from 6 July 1992 until his retirement on 17 July 2020.

The Early Alert described a lookback covering a 17-month period, (1 January 2019 - 31 May 2020) which had identified a number of concerns. The Trust became aware that:

- two out of 10 patients listed for surgery under the care of the consultant had not been recorded on the hospital's patient administration system at that time
- there were concerns with 46 patients who had had a procedure to insert a stent
- 120 of 334 elective inpatients patients with a delay in dictation of up to 41 weeks
- 36 patients with no case record on Northern Ireland Electronic Care Record.

A number of cases had subsequently been identified as meeting the threshold for investigation under the Serious Adverse Incident (SAI) procedure.

On 11 August 2022, the Chief Medical Officer wrote to RQIA requesting they undertake an independent review of the Trust's Urology Services and Lookback Review of patients previously under the care of Consultant A (Mr O'Brien) as a matter of urgency.

This is an interim report outlining findings in respect of Term of Reference 1 which requested we: *Undertake an assessment of the current Southern Health and Social Care*

Trust Urology Lookback Review process, to include arrangements for its delivery and oversight. Further Fieldwork is planned to explore the remaining terms of reference.

2. TERMS OF REFERENCE

The Terms of Reference for this review were developed within the context of the range of concerns raised by the Urology Services Inquiry (USI) to the Urology Assurance Group (UAG) within the Department of Health. The Department of Health sought to ensure the concerns raised were addressed in an appropriate and timely manner, whilst ensuring the Review did not infringe on the work of the USI.

Following discussion with the Department of Health, it was agreed that the Review would be undertaken in Two Phases. Phase I as detailed in this report focuses on Term of Reference item 1.

Term of Reference 1

Undertake an assessment of the current Southern Health and Social Care Trust Urology Lookback Review process, to include arrangements for its delivery and oversight.

To include:

1. Progress on the implementation of the recommendations made by the Southern Health and Social Care Trust's earlier investigation relating to the Urology Lookback Review and assess the robustness of the current Lookback Review.
2. Identify learning which can be applied to any further extension to the current Lookback Review.
3. Assess the extent to which Southern Health and Social Care Trust members of the Urology Assurance Group (UAG) have fulfilled requirements set out within the UAG Terms of Reference.

3. METHODOLOGY

Initiating Phase I, on 18 January 2023, RQIA shared its review questionnaire with the Trust, with a completed return requested for 8 February 2023. Following a request from the Trust, an extension to this date was granted to 22 February 2023.

On 14 February 2023, the Trust alerted RQIA that they would not be in a position to return the information requested. In follow up, on 10 March 2023, the Chief Executive of the Trust wrote to RQIA to advise that in preparing to respond to the questionnaire and provide the documentary evidence requested, as it had become evident that there was a significant overlap in detail contained in personal witness statements that Trust officers submitted to the Urology Services Inquiry (USI) under Section 21 of the Inquires Act 2005. The Trust had shared the terms of reference and review questionnaire with BSO's Department of Legal Services, Trust Counsel and the Urology Services Inquiry for advice. RQIA continues to await an updated position in respect of the Trust's legal advice, as of 22 June 2023 it has not received this. Given the potential patient safety concerns and acknowledging the further delay to the Trust questionnaire return, RQIA in order to support the requirement for independent assurance, adapted its planned methodology. RQIA informed the Trust it was committed to proceeding with the Review even in the absence of the questionnaire return.

Whilst unusual for the Expert Review Team (ERT) not to have the detailed responses to a review questionnaire and associated documentation in advance of the meeting, in an endeavour to progress with the Review, RQIA and its ERT attended the Trust Headquarters on the 22 of March 2023 to meet with the Director who was currently responsible for the Lookback Review and her team of admin and senior nurses. At this meeting a presentation was delivered.

At this short engagement, the Trust described the processes involved in the delivery of Lookback for Cohort 1 current Lookback Review and preparations to date being made to extend the Lookback to a second cohort.

After consideration of the information shared during the meeting with the Trust, a follow-up meeting was held with the Lookback Review Responsible Trust Director to explore progress made against the recommendations from the previous RQIA review of the Trust's Structured Clinical Record Review (SCRR) which had been undertaken in 2022. Documents that were requested and those received are listed in Appendix 1. RQIA have also undertaken further engagement with members of the Trust's Urology Lookback Steering Group and its Chair and a range of documents were requested by RQIA and provided by the project team.

Data sources which contributed to this report include:

- Review Questionnaire: Issued but not returned by SHSCT.
- Engagement Session: Two-hour engagement session with Accountable Director and Team delivering the Lookback Review which took place on 22 of March 2023.
- Documents requested and issued are detailed in Appendix 1
- Minutes from Urology Assurance Group Meetings: Supplied by the Department of Health.
- Follow-up engagement session with Lookback Review Responsible Director: One-hour meeting to explore progress made against the SCRR recommendations, which took place on 4 May 2023.
- Engagement session: With two external members of the Urology Lookback Steering Group.

4. FINDINGS

ASSESSMENT OF LOOKBACK REVIEW PROCESS

The Terms of Reference for this review required RQIA to consider the robustness of the Trust Lookback Review and to make recommendations for future phases. The ERT, having received a verbal account of the Lookback Review process and decision making stages directly from the clinical nurse specialists undertaking it and having examined the triage forms, were satisfied with the methodology described and how it had been described as deployed. The ERT considered that the process was likely to have correctly identified those patients who required further review and changes to their care and treatment.

The ERT were satisfied with the level of competence and knowledge of the Lookback Team which, at the time of our field work, consisted of:

- The leadership of a Responsible Director
- A separate Head of Service with operational responsibility for the process.
- An independent Consultant Urologist from England
- a Trust based Consultant Urologist
- Urology Clinical Nurse Specialists
- Senior Nurses who contribute on an 'as and when required' basis.
- Administrative support from a Project Manager; and an
- Administration Manager.

Overall, the Project Team undertaking the review demonstrated a good understanding of the management and oversight of the processes underway. Additionally, an options paper was provided which set out clear plans for the process to be applied on the assessment of future cohorts of patients and the ERT were very satisfied that there was a clear and rationale process for the proposals for undertaking this work.

INITIATION AND EARLY DECISION MAKING

The project team, who were not in place when the Lookback process commenced, described to the best of their knowledge the informal scoping phase which started in July 2020, and was formally initiated as a Lookback review procedure at this time. Key actions cited in the Early Alert issued in July 2020, included contact being made with the Royal College of Surgeons regarding an Invited Service Review and consideration of the potential scale and scope of any *future* lookback, the Early Alert was not specific in that this was the point of initiation of a formal Lookback in line with the earlier version of the Regional Guidance for Undertaking a Lookback. Within the meeting notes of the UAG, the first mention of formal Lookback as a defined subheading was May 2022, prior to this, the work was referred to as a record scoping exercise. There was discussion in May 2021, about the pending issue of the new Regional Lookback Guidance (which was subsequently formally issued as guidance across the Region in July 2021) and its relevance to the process the Trust was undertaking. There was an expectation expressed by a member of the Urology Assurance Group, and shared by the ERT, that the new regional guidance would have been already followed by the Trust because the document was widely available in draft form. Evidence was not found to support this had occurred, or when and how the new regional guidance for undertaking a lookback was formally adopted by the Trust as its reference point.

It was also noted that within Early Alerts issued in May and June 2022, almost a year later, the Trust was still in the process of writing to a number of patients in respect of notifying them about the Lookback Review. An Early Alert of 12 of May 2022 (EA 187) makes reference to changing management structure within the Trust and the resultant impact on internal stability. It also noted the significant impact of the pandemic coupled with preparations for the Urology Services Inquiry. The ERT considers these factors, and the resources and expertise available to the Trust, also had the potential to impact the progress of the Lookback Review.

The period of scoping, as documented, was complicated by multiple parallel learning exercises such as the Invited Case Record Review by the Royal College of Surgeons and the Serious Adverse Incident and Structured Case Record Reviews. The ERT considered the range of parallel activities had contributed to the protracted nature of the Lookback Review.

Within the pre-review questionnaire, RQIA sought information which would demonstrate good, planning, oversight and scrutiny of decision making within the Trust at the important early stages of the lookback process. The ERT had intended to review documentation describing the formation of the key early decision making structures, to benchmark these against the Lookback Review Policy (reissued in July/June 2021 and understood to be available in draft form in advance of this) and actions described in Early Alerts. This information was not provided by the Trust for reasons previously detailed.

It is noted that several significant processes were established by the Trust in parallel to the Look Back Review. These included the Royal College of Surgeons invited case record review and the Structured Clinical Case Review, a number of audits and reviews. Though these efforts to seek immediate early learning and system improvements are commended, the existence of multiple parallel learning exercises, in the early stages, had the potential to impact the degree of focus and resources available for the most critical task, to identify as quickly as possible all current patients that may be at risk or require recall.

APPROACH

A presentation provided by the Trust, described at a high level the approach used which identified 2,112 patients between January 2019 and July 2020.

This was developed through review of emergency elective patients, review of oncology outpatients, review of case backlogs, a regional audit on prescription of biclutamide, review of pathology results, review of Multi-Disciplinary Meeting outcomes and review of radiology results.

There was no opportunity for the ERT to sample completed Patient Review Forms, or directly access patient information to reach a view on the effective application of the process described by the project team. The documents provided, such as the Lookback Review End of Year Report (January 2023) did not contain sufficient details of the precise methodology used to identify the 2,112 patients or defined inclusion criteria for the first cohort. Subsequently, it was not clear to the ERT what specific inclusions, and whether any exclusions, had been applied or whether this number represented all identified patients of the Doctor during the specified time period or a select high risk group. The ERT considered that it was important for the Trust to be able to demonstrate the process used to enable assurance on who had been included in the cohort, i.e. new patients, patients who had been reviewed/ admitted, patients scheduled for review within or outside the time period, non-attenders or discharged patients. The ERT were not given a document to provide full details of all sources of data which were identified and searched and therefore all patients captured. The ERT considered that records of these early scoping stages and criteria used are critical for quality assurance of the process, as is the definitions used for inclusions in the cohort. In contrast, the project documentation for the next stage of the Lookback Review, Cohort two, provides greater detail on various criteria including inclusions and exclusions criteria to arrive at the proposed numbers.

Recommendation 1

For the previous Cohort, the Trust must provide the Urology Look Back Steering Group, the UAG and RQIA, with a document outlining the precise methodology used to identify the initial Cohort of 2112 patients, to include a clear set of inclusion and exclusion criteria, and a reproducible search methodology. In addition, this should be available for all future Cohorts.

Update August 2024: Summary paper on the identification of patients for Cohort 1 was received by RQIA on 21 September 2023 setting out the methodology. RQIA were satisfied with the methodology deployed.

The ERT sought to determine the chronology of the Lookback Review and identify exactly when a decision to formalise the process in line with the regional procedure was taken. Following our engagement meeting, the Trust provided an outline timeline of commencement and completion of the various stages.

The Lookback Review end of year report (January 2023) identified November 2021 as the formal initiation of the Lookback Review. However, the timeline provided by the project team indicated that the initial planning and preparation commenced in July 2020 and lasted nine months. Stage 2, the Review of Clinical Records, had commenced in March 2021 (not November 2021 as in the end of year report), suggesting that the process took 22 Months to complete. The triage of patient review forms had to date taken nine months and the recall of over 500 patients, had taken 25 Months and had not yet been completed. At the UAG meetings in the Autumn of 2020, reference is made to a record scoping exercise rather than Lookback Review. It was noted by the ERT that in the Lookback Review end of year report that the first outcomes are listed against September 2022 (18-19 months after initiation of scoping. No outcome reporting before September 2022 was identified and the point of initiation of outcome reporting and analysis was not clear.

The responsible Director explained that Activity Reports were presented regularly at several sub-group meetings. Initially a narrative report was presented to an Operational sub group in July 2022. In September 2022, the Director for Lookback Review established the official Activity Report template to be used to capture the progress going forward. These reports were not viewed by RQIA

It is therefore not possible to determine the timing of when the process became regarded by the Trust as formalised as a Lookback Review. It is the view of the ERT that the formalisation of the Lookback Review ought to have been clearly documented earlier and ideally in parallel with the issuing of the initial Early Alert, to ensure rapid mobilisation of

expertise to the Trust and, full oversight of the process in line with the developing new guidance, from that point forward.

Recommendation 2

The Trust should ensure, for previous and future cohorts of the Lookback Review, that end of cohort reports include clear dates of initiation of various stages of the Lookback review, to identify key decision points and milestones within the process in order to support effective oversight and scrutiny.

Update August 2024: The Trust confirmed to RQIA on 12 October 2023 that the actions had been taken as set out in the recommendation.

The Project Team described that the pace of the Lookback Review increased between July and November 2022, aligning with the mobilisation of resource and expertise and the appointment of a dedicated project team. During our engagement session it was noted that the Trust was focussed on completing the final stages of Cohort One. There were still a small number of patients (28 patients as of 7 March 2023, with the potential to increase to 38 patients when final Triage is complete) who were still awaiting their appointment. The ERT were assured that efforts were also being made to contact next of kin of deceased patients to inform them of the outcome of the review of their case.

The decision, in the initial phase of the Lookback Review, to take a comprehensive approach to case review of the cohort of 2,112 patients, rather than a stratified/targeted approach was a significant one, which impacted on the complexity of the work. This is likely to have contributed to the excessive time taken to complete these stages, particularly in view of the challenges in securing Urology consultant capacity which are well documented in the UAG meeting minutes. The ERT considered that had a decision instead been taken for early stratification, it would have had to be balanced against the risk of missed learning and opportunities to remedy treatment decisions across the whole mix of cases.

The documents that have been provided/ reviewed do not indicate if or when, consideration was given to alternative options for a stratified approach, rather than a sequential/linear/chronological one and how these decisions were reached or balanced. It is the view of the ERT that these complex decisions are those most likely to have benefited from the external critique or the perspective of an advisory or ethical panel such as the Trust Ethics Committee or the Department of Health's Ethical Forum.

The ERT strongly endorsed the approach suggested for subsequent phases of the Lookback Review using case stratification on the basis of risk, with the exclusion of deceased patients from future phases. Moving forward, the focus should remain on ensuring living patients are on correct treatment regimens, to minimise potential for harm, with an alternative process potentially being considered for deceased patients.

CAPACITY AND PLANNING

Another factor contributing to the elongated timescales for progressing the Lookback Review was adequacy of capacity and resource planning. The ERT considered that it is critical at the outset to dedicate and then ring fence resource for such an important piece of work, using expertise from external sources if not available internally. An example was when a single urology consultant had been undertaking recall appointments. The ERT considered that it was not appropriate to place such reliance on a single consultant, which aside from impact on core delivery of services, had reduced the opportunities for peer review and consistency checking and is likely to have resulted in competing demands between providing care to current patients and those recalled under the Lookback Review.

It was established that the Trust identified an external Consultant who undertook a review of the patient's case and completed a Patient Review Form to record this review. He returned the Patient Review Form to the Trust but he did not himself make a determination/ recommendation on whether a recall appointment was required.

The Urology Specialist Nurses to assessed / triaged the returned Patient Review Forms to identify which patients needed a recall appointment and with whom, a consultant or specialist nurse. The ERT considered there may have been merit in reversing this process with an initial review being undertaken by a Nurse Specialist and then final review on a subset of more complex cases to be completed by the consultant. This may have reduced the time taken to complete this stage of the review and reduced the overall workload for the consultant.

For cohort 2 an improved process has been agreed. The now electronic form will include a recommendation for recall and the consultant cannot return it until the requirement for a recall or other action is determined.

The Lookback Review Project Team confirmed that additional external support had recently been sourced through the South Eastern Health and Social Care Trust. In its report of 7th March 2023, over two years after commencement, the Trust indicated that 28 (with the potential to raise to 38) living patients were still awaiting a third level triage. The responsible Director reported that the team complied, at all times, with the Integrated Elective Access Protocol guidelines in managing and monitoring the appointments to attend the recall clinic, and that recall appointments were anticipated to be completed by April 2023.

Recommendation 3

For future cohorts, the Southern Health and Social Care Trust should give consideration to adopting a process for the triage of clinical records which requires a first review of cases by Clinical Nurse Specialists against defined criteria, and with clear guidance to identify those most likely to require, further recall and review by a consultant.

Update August 2024: The Trust notified RQIA in October 2023 that consideration had been given to this recommendation and it was considered not viable at that time due all patients requiring a review by a consultant, and that this step could not be bypassed, experience demonstrating that the role of the consultant in

determining the need for the patient to be recalled was required. RQIA were satisfied that the matter had been considered.

INFORMATION MANAGEMENT

Section 3.2 of the current Regional Guidance describes the requirement for a service user database, at initiation, to assist with the identification of patients at risk and this required the support of a robust information management system. This topic had been previously explored in detail within RQIA's previous Review of the Urology Structured Case Record Review. The ERT sought evidence of the Trust's response to RQIA's previous recommendations in relation to the system utilised during the early initiation stages of the Lookback Review. The Trust team described the transition in recent months from an original Excel spreadsheet to a more robust system based on Microsoft Access which was supporting systems of reporting. The new system was reported to be fully meeting the needs for the Lookback Review. The ERT were also assured that during the transition to the new system, there had been no risk of data loss or corruption and that robust information governance practices were in place around the use of this data. On reviewing the project plan for future phases of the Lookback Review, the ERT considered that there was clear evidence of the significant attention being given to the maintenance of this database and there were information management systems in place to aid the oversight, planning, delivery and reporting of the work.

OVERSIGHT

The updated Guidance for Implementing a Regional Lookback Review Process (Regional Guidance) was reissued in July 2021, after commencement of the record scoping phase of the Lookback Review. The Regional Guidance describes the role, purpose and membership of an internal Trust Lookback Review Steering Group.

This group should be established as part of Stage 1 activities, early in the Lookback process, to scrutinise regular Sit-Reps and oversee action plans. The ERT noted that the new updated guidance was published after the stage 1 had commenced and the date provided by the Trust for the establishment of its internal (Oversight) Steering Group was

September 2020, 3-4 months following the notification of the concerns within the Early Alert. During this time, the Department of Health the Health Social Care Board and The Public Health Agency, were participating in weekly meetings. Terms of reference for an initial SPPG-chaired Oversight and Co-ordination Group were approved on 19 of November 2020.

The last meeting of the HSCB Chaired co-ordination took place on 8 September 2022 to allow the establishment of the Trust's Urology Lookback Steering Group. Aligned to the closure of the Health and Social Care Board and the transfer of its functions to the new Strategic Planning and Performance Group as a function of the Department of Health, this change sought to streamline and clarify reporting and accountability arrangements.

The ERT was provided with a Draft Version of the Terms of Reference for the Trust's Urology Lookback Review Steering Group, but noted that on examination of these Terms of Reference its status was not clear (remains marked as draft). This is a critical document setting out the role of the Lookback Review Steering group in overseeing the programme of work and establishes lines of accountability and communication with other aligned groups under the umbrella of the Public Inquiry Programme Management Board. It references reporting outcomes to the Urology Services Inquiry and to the Trust's Public Inquiry Programme Board.

The Terms of Reference included:

- *Responsibility for the commissioning of appropriate groups and sub-groups to complete the Lookback Review in a way that is compassionate, timely and comprehensive.*
- *Oversee the undertaking and communication of all stages and phases of the Urology Lookback Review.*
- *Responsibility for the commissioning of appropriate groups and sub-groups to complete the Lookback Review in a way that is compassionate, timely and comprehensive.*

The first duty listed in the Lookback Review Steering Group Terms of Reference relates to ensuring discovery of all aspects of the Lookback Review to the Urology Service Inquiry; however, this is not in keeping with the primary purpose as described by the project team or in the view of the ERT. The Purpose of the Lookback Review was well described in the Standard Operating Procedure for Data Migration as follows:

> ***"The key objective of the Urology Lookback Review is to ensure that patients under the care of the Urology Consultant obtain appropriate treatment, support and care in an effective and timely way. The Review and Recall stages of the Lookback will evaluate the whole range of care provided to a patient; holistic care approaches, nuances of case management and the outcomes of interventions".***

This definition clearly delineates the role and purpose of the Lookback Review as separate from the Trust's legal duties to the Urology Services Inquiry and is better aligned to the description provided by the Trust during the engagement session. The prime focus of the Lookback Review must be the identification of individuals who may require changes to their treatment, and such a process would be required irrespective of the existence of The Urology Services Inquiry. During our meeting with project team members, they articulated overlapping and perhaps competing interests across both Lookback Review and Urology Services Inquiry Response processes.

However, they also noted that both will identify learning and opportunities for improvement which will require implementation with oversight being provided by both the Trust Executive Team and Trust Board.

The ERT considered the Terms of Reference for the Lookback Review Steering group which are still in draft, are not fully comprehensive when benchmarked against the updated Regional Guidance for Implementing a Lookback Review Process. They are not sufficiently detailed or clear on with whom and where authority for key decision making rests within the Trust's multi-layered structure.

The Regional Guidance for Implementing a Lookback Review Process indicates that a nominated Non-Executive Board Member should be part of the steering group; this would contribute to the assurance of the effectiveness of the group, but this is omitted from the current draft.

The ERT endorsed the external Critical Friend role as described by the project team. A critical friend is an individual who offers to provide honest and candid feedback in a supportive manner. These external, independent individuals who have been selected because of their significant health service experience are important but, the relationship between Critical Friend and the Steering Group was not outlined in the Terms of Reference. The Project documentation supporting the Lookback Review should be specific about the added value of the role of Critical Friends and how they engage with and support the Lookback Review Steering group.

The ERT welcomed the fact that the Draft Lookback Review Steering Group Terms of Reference, detail the need to ensure appropriate support is in place for service users and their families who may be impacted by the Lookback Review. However, there is not a Service user representative identified within the membership of the steering group, as outlined in the updated Regional Guidance for Implementing a Lookback Review Process. As identified in RQIA's previous review, the ERT considers that the Lookback Review Steering Group should ensure that the Trust meets its obligation to appropriately involve Service Users at key decision points in the lookback process. During our engagement session, the Trust project team described how it had accessed its local user group to seek their views on aspects of its work for example providing input and feedback to the drafting of letters to family and relatives. However, they confirmed that the benefit of this engagement had been limited; and that they were committed to strengthening Personal and Public Involvement throughout its programme of work and they would continue to seek service user input into the Lookback Review Steering Group, as it moves forward into future phases.

An opportunity exists, to strengthen the Terms of Reference for the Trust's Lookback Review Steering Group and bring them into closer alignment with the updated Regional

Guidance for Implementing a Lookback Review Process by clearly describing the mechanisms for Service User involvement.

Recommendation 4

The Trust should update the Lookback Review Steering Group Terms of Reference and Project Documentation to bring it fully in line with the Regional Guidance for Implementing a Lookback Review Process and reflect the prime focus of the Lookback Review. These should outline the arrangements for securing expertise in Communication, Information, Legal Advices, Ethics and Public Patient Involvement and the Input of Critical Friends. It should be formally approved by the Steering Group and kept updated with appropriate version control.

Update August 2024: The Trust confirmed to RQIA on 12 October 2023 that the actions had been taken as set out in the recommendation.

UROLOGY ASSURANCE GROUP (UAG)

The Terms of Reference for this Review include an exploration of how The Trust has fulfilled its requirements as set out in the UAG Terms of Reference. The establishment of the Urology Assurance Group was announced in a ministerial Statement issued on 27 October 2020. The first meeting of the UAG took place on 30 October 2020 and the group's Terms of Reference were approved on 6 November 2020 and updated in May 2022.

It is noted within the Terms of Reference that UAG will:

- *review the progress of the initial scoping exercise;*
- *consider emerging strategic issues;*
- *commission and direct further work as necessary;*
- *monitor the impact on urology and related services;*
- *ensure coordination with other associated reviews/investigations; and*
- *oversee communication across all stakeholder groups.*

The key expectation listed in the terms of reference for The Trust is as Follows.

"The UAG will receive updates from the Southern Urology Oversight Steering Group as appropriate. The Steering Group will continue to review the findings of the initial Lookback exercise and scope the potential need for a further Lookback exercise."

The Terms of Reference, minutes of the UAG and a sample of progress updates were reviewed by the ERT. Typically, the Trust provided a progress report under the following headings: Urology Services Inquiry, Urology Lookback Review, Lookback, Stage 1 – Cohort, Stage 2 – Review, Stage 3 – Recall, Cases Closed, Review Outcomes Report and a section on Finance.

The length of time taken by the Trust to complete the phases and provide data on the end outcomes of those patients recalled, had, in the ERT's view, the potential to concern the UAG in relation to the pace of progress. The Action Log associated with the UAG indicated timescales associated with actions remaining open for up to six months.

In November 2021, the UAG was advised that an Outcomes Report would be available by May 2022. In February 2022, the UAG was further advised that the Outcomes Report was to be developed after the conclusion of the current lookback review. In May 2022, it was noted it would be provided in June 2022 by the Trust to the Strategic Planning and Performance Group.

Subsequent progress reports received by the UAG contained quantitative information on the numbers of people progressing through the various stages of the review. An Early Draft of the Outcomes Report was noted to have been shared with DoH officers before the UAG meeting of November 2022. The final report "Lookback Review Summary and End of Year Position" is dated January 2023.

The Terms of Reference for the UAG clearly describe its role as providing assurance and external oversight for the Lookback Review.

During the engagement meetings with the Trust, the Responsible Director indicated that the UAG had not been overly directive, nor made decisions on behalf of the Trust but indicated that it had been helpful in endorsing Trust decisions.

Detailed and timely reporting to the UAG by the Trust, underpins its oversight and assurance functions and provides evidence to the DoH, of effective internal programme management, oversight and corporate governance within the Trust. The UAG relies therefore on sufficiently detailed evidence of robust decision making and internal scrutiny, to satisfy itself that the Trust is identifying and mitigating all key risks. As the Lookback Review proceeds, the ERT considers that the UAG could be more specific and directive within its terms of reference regarding the mechanisms, frequency and content of future reporting. This would support it in executing its important oversight role, thus setting clear expectations for the Trust in respect of compliance.

Recommendation 5

The Southern Health and Social Care Trust should expand its progress reporting template and agree with the UAG on the content, format and frequency of reports to be provided throughout future phases. This should mirror the content of internal reporting and include sufficient details on all material risks and their mitigations.

Update August 2024: The Trust confirmed to RQIA on 12 October 2023 that the actions had been taken as set out in the recommendation.

PROGRESS WITH THE IMPLEMENATION OF RECOMMENDATIONS FROM THE RQIA REVIEW OF THE TRUST STRUCTURED CASE RECORD REVIEW

The ERT assessed the extent to which Southern Health and Social Care Trust members of the Urology Assurance Group (UAG) and the wider Southern Health and Social Care Trust have implemented the Recommendations from the RQIA review of the Trust Structured Case Record Review Process.

During our engagement meeting, the ERT was provided with a progress update on the work to implement these recommendations. Appendix 3 in this report shows the tracking of the completion of 25 actions that span the 18 recommendations for improvement contained in the Structured Case Record Review Report. It shows 22 actions are substantially complete, 2 in progress and 1 outstanding.

Although this position provided some assurance for the ERT, due to limited time for discussion during the meeting with the Trust, the strength of evidence to support this position was further explored during a follow up meeting with the Chair of the Lookback Review Steering Group. The Chair provided more detailed explanations and examples to support the assurances provided in the progress update, including where appropriate that the Trust had elected to take alternative approaches to those recommended. It was confirmed that good progress had been made across the majority of recommendations including work to secure a clinician to undertake the thematic review of SCRR cases.

Further amendments were requested to the progress update for the recommendations, at the time of writing to strengthen the evidence and assurance provided these are still awaited. Sampling and further testing of the evidence underpinning these assurances is required may continue into Phase 2 of this review.

5. CONCLUSION

The ERT considers that the commitment and dedication of Trust staff should be commended at the end of this first stage of their Lookback Review. In particular, a significant burden of work has fallen to one consultant who was also responsible for raising initial concerns. The Lookback Review Policy (reissued in 2021) recommends that personnel directly involved in the event/hazard that triggered the Lookback Review, should not normally be involved in the composition of the Lookback Steer group, but it makes no suggestions on their inclusion in conducting the actual Lookback Review activities. Given the burden of work which has fallen upon a single individual, the Trust should assure itself that the size and composition of the team responsible for conducting the Lookback Review is sufficient to ensure the delivery of all the activities in a reasonable period of time.

The identification of the concerns in June 2020 leading to the decision to undertake the Royal College of Surgeons Record Review, followed by a number of SAI reviews and the Trust Structured Case Record Review and the subsequent recall of patients and formal Lookback Review, demonstrates the seriousness with which the Trust took its responsibility to identify all individuals at risk.

At the point of completion of Cohort One of the recall, 527 patients, from the cohort of 2112, will have been recalled. The ERT is mindful of the documented challenges faced by the Trust in undertaking the Lookback Review in respect of staffing, changing management structures and the pandemic. However, at almost three years following the first Early Alert, it is clear that it will still take a considerable amount of time to complete the recall of patients. Though Trust staff involved in the latter stages of the review process, have sustained momentum, gained significant experience and developed important skills and capability, the ERT considered that a greater mobilisation of resources and expertise was required much earlier, to produce a more rapid assessment

of risk and to define numbers to be recalled. Ring-fencing of these resources would likely have led to the Lookback Review being completed within a shorter timescale.

Attention must continue to be given by all concerned, to the effective internal and external scrutiny and oversight of the Lookback Review process, as well as its operational activities and outcomes. Attention to properly constituted operational and oversight groups, with appropriate authority and skills and resources, will deliver a disciplined approach, supporting the Trust to meet all its obligations. The role of and terms of reference for each of these groups should also be made absolutely clear and explicit. There was also an important opportunity to draw significant learning and experience from the planning and organisation of the Belfast Trust's recall of Neurology patients which may have occurred to some extent. Additionally, it is considered that significant learning as identified from this Lookback process and those in other Trusts, should be documented and shared widely for the benefit of those faced with undertaking such activities in future, and to inform future versions of the Lookback Review Regional Guidance.

Knowing the scale of the numbers involved and the limited resources available to the Trust, early stratification of high-risk groups, and limiting the size of the recall is likely to have been a defendable approach. Having completed a large recall, and examined the suboptimal care themes within audits, case record reviews, Structured Case Record Reviews and Serious Adverse Incident Investigations, the opportunity to implement this learning across all Trust services is expected to result in strengthened internal governance and patient safety. Through the remainder of this Review, the ERT will continue to seek evidence of the governance systems and processes in place to assure the safety of patients within the Urology Services and expects they will find evidence of this learning being applied.

6. SUMMARY OF FINAL RECOMMENDATIONS

The recommendations below have been updated with the Southern Health and Social Care Trust's response. These Trust updates having been added to this Report at August 2024.

Recommendation 1

For the previous Cohort, the Trust must provide the Urology Look Back Steering Group, the UAG and RQIA, with a document outlining the precise methodology used to identify the initial Cohort of 2112 patients, to include a clear set of inclusion and exclusion criteria, and a reproducible search methodology. In addition, this should be available for all future cohorts.

Update August 2024: Summary paper on the identification of patients for Cohort 1 was received by RQIA on 21 September 2023 setting out the methodology. RQIA were satisfied with the methodology deployed.

Recommendation 2

The Trust should ensure, for previous and future cohorts of the Lookback Review, that end of cohort reports include clear dates of initiation of various stages of the Lookback review, to identify key decision points and milestones within the process in order to support effective oversight and scrutiny.

Update August 2024: The Trust confirmed to RQIA on 12 October 2023 that the actions had been taken as set out in the recommendation.

Recommendation 3

For future cohorts, the Southern Health and Social Care Trust should give consideration to adopting a process for the triage of clinical records which requires a first review of cases by Clinical Nurse Specialists against defined

criteria, and with clear guidance to identify those most likely to require recall and review by a consultant.

Update August 2024: The Trust notified RQIA in October 2023 that consideration had been given to this recommendation and it was considered not viable at that time due all patients requiring a review by a consultant, and that this step could not be bypassed, experience demonstrating that the role of the consultant in determining the need for the patient to be recalled was required. RQIA were satisfied that the matter had been considered.

Recommendation 4

The Trust should update the Lookback Review Steering Group Terms of Reference and Project Documentation to bring it fully in line with the Regional Guidance for Implementing a Lookback Review Process and reflect the prime focus of the Lookback Review. These should outline the arrangements for securing expertise in Communication, Information, Legal Advices, Ethics and Public Patient Involvement and the Input of Critical Friends. It should be formally approved by the Steering Group and kept updated with appropriate version control.

Update August 2024: The Trust confirmed to RQIA on 12 October 2023 that the actions had been taken as set out in the recommendation.

Recommendation 5

The Southern Health and Social Care Trust should expand its progress reporting template and agree with the UAG the content, format and frequency of reports to be provided throughout future phases. This should mirror content of internal reporting and include sufficient details on all material risks and their mitigations.

Update August 2024: The Trust confirmed to RQIA on 12 October 2023 that the actions had been taken as set out in the recommendation.

Appendix 1: An Overview of the Documents Requested by RQIA and returned from SHSCT during Review Phase I

RQIA Requested (Described in letter 6 April 2023)	SHSCT Provided: Name of File, Link and Date Received	Document Title
A timeline (breakdown by month) which sets out key events for example: the date that each stage in Cohort One began and ended (if completed); the dates when key groups assigned with oversight/ assurance of the Lookback Review were established, first met; the date the first internal outcome report was provided to the Lookback Review Project Steering group and when key members of the lookback process jointed the Lookback Team.	1.Timeline Cohort 1.pdf *Received 07.04.2023* Staffing Changes for the Urology Lookback Review 20230505 Updated File: Staffing Changes for the Urology Lookback Review 20230505 *Received 09.05.2023*	UROLOGY LOOKBACK REVIEW GANTT CHART FOR COHORT 1 Staffing Changes for the Urology Lookback Review 20230505
Confirmation that the outcomes and appropriate data are shared through to Board Level within the Trust.	December 2022_ Trust Board Cover Sheet USI.pdf January 2023_Trust Board Cover Sheet USI.pdf March 2023_Trust Board Cover Sheet USI.pdf October 2022_ Trust Board Cover Sheet USI.pdf September 2022_ Trust Board Cover Sheet USI.pdf *Received 24.04.2023*	Update on Governance Concerns within Urology (Separate papers for respective dates)
A statement of purposed for the Access databased developed to store patent data involve in the Lookback Review (as per the presentation).	3. Statement of Purpose.pdf *Received 07.04.2023*	Standard Operating Procedure for Data Migration
Document titled - RQIA SCRR Review Recommendations Action Plan Summary.	4. RQIA SCRR Recommendation Action Plan Summary.pdf	RQIA SCRR Review Recommendations Action Plan Summary

RQIA Requested (Described in letter 6 April 2023)	SHSCT Provided: Name of File, Link and Date Received	Document Title
	Received 07.04.2023 *Updated Version Received 04052023*	Appendix Three
Documents titled - Urology Lookback Review Private Patients Pathway (Patients in receipt of private health services provided by Mr Aidan O'Brian) Final Draft 23rd January 2023.	5 and 7. LBR Private Patient Pathway v7 230120.pdf *Received 07.04.2023*	UROLOGY LOOKBACK REVIEW PRIVATE PATIENTS PATHWAY (PATIENTS IN RECEIPT OF PRIVATE HEALTH SERVICES PROVIDED BY MR AIDAN OBRIEN) FINAL DRAFT 23 JANUARY 2023
Document titled - Southern Health and Social Care Trust Urology Public Inquiry Programme. Report for Urology Assurance Group (UAG, 17th November, 2022.	6a. UAG Update for 17 Nov Meeting.pdf *Received 07.04.2023*	Southern Health & Social Care Trust Urology Public Inquiry Programme Update Report for Urology Assurance Group (UAG) 17 November 2022
	6b. Annex A LBR Activity Report 20221104.pdf *Received 07.04.2023*	Annex A ACTIVITY REPORT (Summary of Lookback Detail / Outcomes)
	6c. Annex A cont'd LBR Update Narrative Report to Support Data 20221104.pdf *Received 07.04.2023*	Annex A Cont'd Urology Lookback Review - Update Report Summary of Progress 07 November 2022
	6d. Annex B Sub-Optimal Care Analysis 25102022.pdf	Annex B SUMMARY OF SUB-OPTIMAL CARE REPORTED IN

RQIA Requested (Described in letter 6 April 2023)	SHSCT Provided: Name of File, Link and Date Received	Document Title
	Received 07.04.2023	PATIENT REVIEW FORMS1
Document titled - Urology Lookback Review Phase Two Options Paper as presented, 15 November 2022.	8. Options Paper for Urology Lookback Phase 2.pdf *Received 07.04.2023*	UROLOGY LOOKBACK REVIEW PHASE TWO OPTION'S PAPER 15 November 2022
Document tilted - Urology Lookback Review Cohort 2 – Project Plan, 23rd January 2022.	9. LBR Phase 2 - Project Plan v8.pdf *Received 07.04.2023*	Urology Lookback Review Cohort 2 - Project Plan 23 January 2022
Document titled - Southern Health and Social Care Trust Urology Public Inquiry Programme. Update report for Urology Assurance Group (UAG, 27th January, 2023.	10a. UAG Highlight Report - Activity Narrative for 27 Jan 2023 Meeting.pdf *Received 07.04.2023* 10b. LBR Summary - End of 2022 Year Position updated with 20 January activity.pdf *Received 07.04.2023*	Southern Health & Social Care Trust Urology Public Inquiry Programme Update Report for Urology Assurance Group (UAG) 27 January 2023 UROLOGY LOOKBACK REVIEW SUMMARY & END OF YEAR POSITION (DECEMBER 2022) 12 JANUARY 2023 (Updated 23 January 2023 in line with new activity figures)
Document titled - Urology Lookback Review Activity Update- Narrative, 8th March 2023.	11a. LBR Activity Report for Steering Group Meeting.pdf *Received 07.04.2023*	TABLE A - ACTIVITY REPORT (Summary of Lookback Detail / Outcomes)

RQIA Requested (Described in letter 6 April 2023)	SHSCT Provided: Name of File, Link and Date Received	Document Title
	11b. LBR Activity Report Narrative.pdf *Received 07.04.2023*	Urology Lookback Review Activity Update – Narrative 8 March 2023
The first progress update report provided to the UAG.	20201029_RE CONFIDENTIAL UAG papers (30 Oct 2020)_ATTACHMENT *Received 09.05.2023*	Report for Urology Assurance Group 30 October 2022
	LBR Update Narrative Report to Support Data 20221104.docx.pdf *Received 24.04.2023*	Urology Lookback Review - Update Report Summary of Progress 07 November 2022
	UAG 230522 - STATS TABLE.pdf	N/A
	UAG Highlight Report - Activity_Narrative_for 7 March 2023_Meeting.pdf *Received 24.04.2023*	HIGHLIGHT REPORT Urology Public Inquiry Programme Update Report for Urology Assurance Group (UAG) 7 March 2023
	UAG Update 20052022 .pdf *Received 24.04.2023* *Received 24.04.2023*	Urology Assurance Group Update 23rd May 2022 Southern Health & Social Care Trust Urology Public Inquiry Programme Update Report for Urology Assurance Group (UAG) 17 November 2022

RQIA Requested (Described in letter 6 April 2023)	SHSCT Provided: Name of File, Link and Date Received	Document Title
	UAG Update for 20 Sept Meeting.pdf *Received 24.04.2023* Urology Lookback Review Activity Report 12092022.pdf *Received 24.04.2023*	Update Report for Urology Assurance Group (UAG) 20 September 2022 ACTIVITY REPORT (Summary of Lookback Detail / Outcomes)
A copy of the communication strategy put in place for all patients of the Lookback review by the Lookback Review Lay Reference Group or, confirmation if not available.	*102020 FAQs for Review in Urology* Urology LBR Communications Engagement Plan v1 Urology LBR Phase 2 outline Comms Plan 20230424 *Received 26.04.2023*	FAQs Urology October 2020 SOUTHERN TRUST UROLOGY LOOKBACK REVIEW COMMUNICATIONS AND ENGAGEMENT PLAN Urology Lookback Review. Phase 2 Corporate Communications Strategy 2023
A copy of the template used to review / triage patients as part of the Lookback Review (as per image in presentation) .	14. Patient Review Form Triage Outcomes Form V2 (002).pdf *Received 07.04.2023*	Patient Review Form Triage Outcomes Pro-forma (version 3 as of April 2023)
A copy of the template used to review / triage patients as part of the Lookback Review (as per image in presentation) .	15. Revised Terms of Refefence Urology Assurance Group.pdf *Received 07.04.2023*	UROLOGY ASSURANCE GROUP TERMS OF REFERENCE
Urology Lookback Project Steer Group- Terms of reference.	16. Draft ToR Urology Lookback Steering Group.pdf *Received 07.04.2023*	TERMS OF REFERENCE LOOKBACK REVIEW (LBR) STEERING GROUP

RQIA Requested (Described in letter 6 April 2023)	SHSCT Provided: Name of File, Link and Date Received	Document Title
Urology Services Programme structures: Public Inquiry Structure; Lookback Review and Quality Assurance; Operational and accountability framework.	17. Programme structure.pptx *Received 07.04.2023*	Public Inquiry Programme Structure (Incorporating the Urology Lookback Review & Quality Assurance); and Urology Lookback Review Operational and Accountability Framework
Requested during 22 March 2022 Meeting – Copy of presentation on screen	22032023 RQIA Presentation.pdf *Received 24.03.2023*	Urology Lookback review RQIA Presentation
Outcomes and Data shared with Trust Board	*Trust Board Cover Sheet USI: October 2022, September 2022, December 2022, January 2023, March 2023* *Received 24.03.2023*	September 2022_ Trust Board Cover Sheet USI October 2022_ Trust Board Cover Sheet USI December 2022_ Trust Board Cover Sheet USI January 2023_Trust Board Cover Sheet USI March 2023_Trust Board Cover Sheet USI
Update Reports provided to UAG	*Update Report provided to UAG* *Received 24.04.2023*	20201029_RE CONFIDENTIAL UAG papers (30 Oct 2020) ATTACHMENT (Received 09.05.2023) LBR Update Narrative Report to Support Data 20221104.docx UAG 230522 - STATS TABLE

RQIA Requested (Described in letter 6 April 2023)	SHSCT Provided: Name of File, Link and Date Received	Document Title
		UAG Highlight Report - Activity Narrative for 7 March 2023 Meeting UAG Update 20052022 UAG Update for 17 Nov Meeting UAG Update for 20 Sept Meeting Urology Lookback Review Activity Report 12092022

Appendix 2. Further Evidence SHSCT may wish to share before Review End Proper

	Evidence type
1.	Documentation on methodology for identification of 2112 patients, where was this scrutinised endorsed and documented in Trust

Appendix 3. Southern Trust action plan against SCRR Review Recommendations Summary

Updated Version Received 04052023

Total Number of Trust Actions Required = 25

Date	RAG Rating	Number
24/10/22		8
		14
		3
18/11/22		9 ↑
		13 ↑
		3 =
16/12/22		18 ↑
		5 ↓
		2 ↓
03/02/23		18 =
		6 ↑
		1 ↓
20/03/23		20↑
		4↓
		1=
24/04/23		22↑
		2↓
		1=

RQIA SCRR REVIEW RECOMMENDATIONS IMPLEMENTATION PLAN

RECOMMENDATION 1				
1 (a) 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.				
Action Required to Deliver Recommendation(s)	**Responsible Officer[1]?**	**Update**	**Status RAG**	**Evidence pf Completion**
Update PID – with detail and purpose of SCRR,	LBR Project Manager (LE)	**20/10/22** – work commenced on this **18/11/22** - draft complete being reviewed prior to being finalised **16/12/22 -** Complete	Complete	Report
Draft a "stand-alone" summary of the background, purpose, objectives and process of SCRR	LBR Project Manager (LE)	**20/10/22** – work commenced **18/11/22** - draft complete being reviewed prior to being finalised **16/12/22 -** Complete	Complete	Report
1(b) 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.				
Add lay representation to the Urology Lookback Review steering and operational group.	Head of the Lookback Review (SW)	**20/10/22** – Lay representation sought via PPI team in Trust **18/11/22** - no further progress **16/12/22** – Two lay reps identified and joining Operational & Steering Groups	Complete	Emails confirming TOR
Patient / family information materials required for Phase 2 to be activity considered by Lay representatives and tested within other PPI forums either internal or external to Trust.	This is an action for the future – will be addressed and evidenced in phase 2			

[1] Responsibility for delivery this action plan sits with the SRO for the LBR who is chair of the LBR Steering Group (MOH)

RECOMMENDATION 2				
2(a) 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.				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Reorganise structures for the LBR process and reset role and function of steering group including membership	Chair of Steering Group (MOH)	**20/10/22** – complete	Closed	- Terms of Reference for Steering Group - Diagram of new structure
2(b) 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.				
Lookback Review in line with project management principles and processes. Draft PID to summaries the LBR process	Chair of Steering Group (MOH)	**20/10/22** – complete – new structure and process	Closed	- PID - New structure and process in place to include clarity on reporting and accountability

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.				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Appoint project manager to oversee the implementation of the Lookback Review in line with project management principles and processes	Chair of Steering Group (MOH)	**20/10/22** – complete LE in post from 1 September 2022 **27/02/2022** – LE completed PRINCE2 Foundation and Practitioner Training	Closed	- Staff in post - Certificate of P2 completion

RECOMMENDATION 4				
4(a) 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.				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence of Completion**
Same as per recommendation 1(a) above	See recommendation 1(a) above	**20/10/22** – work commenced **18/11/22** - draft complete being reviewed prior to being finalised **16/12/22 -** Complete	Complete	Report

RECOMMENDATION 5				
5(a) 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.				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence of Completion**
Draft options paper for extending the Urology Lookback Review and progress with option agreed by UAG.	Chair of Steering Group (MOH)	**20/10/22** – work commenced **18/11/22 –** Options paper shared with UAG on 17 November	Complete	Options paper
5(b) 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.				
RQIA to action not Trust				

RECOMMENDATION 6				
SHSCT should consider commissioning an independent body to undertake the SCRR process on its behalf.				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence of Completion**
RSC requested – not accepted SCRR process is currently outsourced to individual external urologists accessed via BAUS. Request to be made to RCP	Dep MD (DG)	**20/10/22** – unable to secure RCS to undertake this work, **18/11/22 –** IS (3FiveTwo) sourced – IS contract being urgently drawn up to commission this work **16/12/22 –** IS now being utilised	Complete	Emails from RSC Emails with BAUS First tranche (14 cases) passed to IS on 13 December

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				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence of Completion**
Sampling approach to case selection for SCRR to be included in the options paper on progressing with the SCRR process for consideration by UAG	Chair of Steering Group (MOH)	**20/10/22** – work commenced – **18/11/22** – to be further clarified when IS contract in place **16/12/22** – All of the outstanding cases (29) of the original 53 cases will be passed to IS. Consideration will be given to sampling the remaining 38 plus any new SCRRs added at screening in the NY **03/02/23** – Now 125 SCRR in total (potential for up to a further 9 which are planned for screening – which when	Closed	

		compete finishes screening for cohort 1. A paper to be drafted for UAG to consider sampling of the current outstanding 72 SCRR cases. **20/03/23 –** All original 53 index SCRR cases are now completed. Comparative review has been completed. Direction from UAG as of 13.02.23 is to move to a "targeted" approach to the remaining SCRR cases. LBR Team currently assessing those remaining cases for determination of issue and if this is a new theme.		

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.				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence of Completion**
Papers on SCRR and extending the Lookback Review to be shared with Trust ethic committee when complete	TBA	**20/10/22** - Not yet commenced – to discuss with new Medical Director when he takes up post **18/11/22 –** no update **16/12/22** – no update **03/02/23** – a seating of the ethic committee to be arranged to consider ethical considerations of Cohort 2 **24/04/23** – not considered necessary as both agreed by UAG.	Closed	Minutes of UAG from 7 March 2023

RECOMMENDATION 9				
SHSCT should engage with Trust legal representation to obtain a legal perspective on the arrangements for the SCRR.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Share SCRR related papers with DLS	Chair of Steering Group (MOH)	**20/10/22** - Current SCRR process arrangement shared with DLS. The options paper on the way forward re SCRR will be shared with DLS when complete and prior to discussion with UAG. **18/11/22** – to be further considered if SCRR to change when IS contract in place. **16/12/22** – unchanged **03/02/23** – paper referred to above under recommendation 7 to be shared with DLS when complete **23/3/23** – shared with DLS and USI	Completed & Closed	Email to DLS dated 23/3/23 & in document in USI discovery folder

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.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
As per recommendation 1(b) add Lay representation to the Urology Lookback Review steering and operational group. Provide information and bespoke induction of new Lay representatives to assist in contributing to the Lookback Review	Head of the Lookback Review (SW)	**20/10/22** – Lay representation sought via PPI team in Trust **18/11/22 –** no update while Head of LBR is unavailable **16/12/22** – Two lay reps identified and joining Operational & Steering Groups	Complete	Meeting with Head of LBR and 2 lay reps Information pack

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.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Share current process for communicating with patients / families re SCRR outcomes with DLS for feedback and advice.	Chair of Steering Group (MOH)	**20/10/22** – As per DLS advice for an individual patient –patients to be offered either report in full or summary from section 2.11. Letter also includes opportunity to discuss the finding with clinical team face to face and separately an offer of a clinical appointment with consultant urologist. Also includes an unreserved apology from the CX on behalf of the Trust	Completed & Closed	Email from DLS (21/7/22)

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.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Consider the above recommendation	Chair of Steering Group (MOH)	**20/10/22** – recommendation considered and decision taken not to change SCRR inter-process as calls into question the validity the work done previously.	Closed see below re next phase of LBR	
SCRR process to be reviewed - if being utilised for the extended cohort of patients. This recommendation to be applies at that time.	This is an action for the future – will be addressed and evidenced in phase 2			

RECOMMENDATION 13				
DoH should commission RQIA to undertake a Review of Governance Arrangements within Urology Services in Southern HSC Trust.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
DOH to action not Trust				

RECOMMENDATION 14				
14(a) 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.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Establish if RCP can facilitate the SCRR process	DMD (DG)	**20/10/22** – await feedback from RCP **18/11/22 –** no further feedback – response chased **16/12/22 –** Complete – IS contract in place	Complete	Contract Returned reports from IS
SCRR process to be reviewed - if being utilised for the extended cohort of patients. This recommendation to be applies at that time.	This is an action for the future – will be addressed and evidenced in phase 2			
14(b) 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.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Review the document that currently exists for the SCRR reviewers and update it in terms of good practice identified in RQIA review document as the basis for further review should SCRR continue to be utilised in the extended Lookback Review.	Project Manager (LE)	**20/10/22** – This work has commenced **18/11/22 –** Being prepared to support IS contract **16/12/22** – draft guideline shared with IS as part of contracting process	Closed	IS Contract Contract monitoring notes

14 (c) 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.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Consider this action	Chair of Steering Group (MOH)	**20/10/22** – recommendation considered – due to lack of SCRR reviewers it is not possible to undertake a second review of a sample of the returned SCRR reports. For this cohort of patients a comparative analysis of reasons for SCRR verse findings from SCRR has been undertaken and both align	Closed see below re next phase of LBR	SCRR theming analysis
SCRR process to be reviewed - if being utilised for the extended cohort of patients. This recommendation to be applied at that time.	This is an action for the future – will be addressed and evidenced in phase 2			

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.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Commission a "Thematic Review" undertaken when all 53 SCRR reports and complete.	Medical Director	**20/10/22** – an external urologist identified to complete this work when the report are returned. Currently on 24 of the 53 reports have been returned. **18/11/22 –** no further SCRR returned **16/11/22** – Meeting with Dr Sally Williams on 13/12 – Dr William agreed to coordinate a thematic Review when SCRR complete **03/02/23** – five outstand SCRR returns. Dr Williams to be contacted to start process for undertaking a thematic review **20/03/23-** Contract pending with Dr Sally Williams with support of the IS SME's who undertook the completion of the SCRR reports. **24/04/23** – DAC being drafted – delayed due to checking if an external urologist would complete negating need for a DAC	Ongoing	
Provide an analysis of the themes identified by Trust senior doctors through the internal "SCRR Screening" process and complete to themes identified external SCRR urologists	Head of the Lookback Review (SW)	**20/10/22** – Complete and will be kept up to date as reports are returned	Closed	Up to date report available

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.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Agree and document the process(s) for disseminating regional learning following the Lookback Review for consideration by UAG	Head of the Lookback Review (SW)	**20/10/22** – work commenced **18/11/22 –** no update to report **16/12/22** – no further progress **03/02/23** – no further progress as cohort 1 still to complete. **20/03/23 –** date agreed for Learning and Development Group this month. HOS will attend to disseminate from LBR Process. (Update from meeting will be reflected in next action plan update) **24/04/23** – learning to be shared following completion of Cohort 1 outcomes report.	Ongoing	
Update Communication plan to include this aspect of communication	Project Manager (LE)	**20/10/22** – cannot commence until above action completed **16/12/22** – no change **03/02/23** – no change **20/03/23** – no change **24/04/23** – no change – Outcomes report due end May for discussion and agreement at UAG on 7 June 23	Not started	

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.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Draft a "Statement of Purpose"	Project Manager (LE)	**20/10/22** – Copy in draft awaiting review and sign-off **18/11/22** – no update to report **16/12/22** – not signed off until cross-reference against template requested from BOH (via RQIA) – not yet received **03/02/22** – database developer completing – request made for draft to be shared **20/03/23** – Document Finalised	Complete	Statement of Purpose document

RECOMMENDATION 18				
18(a) SHSCT should urgently develop and implement a communication strategy specific to the Lookback Review and including the SCRR process				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Draft communications strategy including communication plan	Communications Manager (PT)	**20/10/22** – draft plan complete – awaiting review and sign-off **18/11/22 –** no update to report **16/11/22** – Phase 1 plan complete – will be revised for Phase 2	Complete and closed	PID including phase 1 comms plan
18(b) 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.				

Action(s) Required to Deliver Recommendation(s)	Responsible Officer?	Update	Status RAG	Evidence pf Completion
Consider above recommendation		**20/10/22** – channel of communication currently exists with GMC and USI. Communication with PSNI and / or coroner not warranted at this time – this will be established if required in the future.	Complete and Closed	Emails and documents shared with GMC and USI.

The Regulation and Quality Improvement Authority

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