Assurance Review – Phase 5

Urology services at University Hospitals of Morecambe Bay NHS Foundation Trust

Assurance summary

Trust recommendations

Final Report April 2023

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Assurance summary

Overview

This assurance review focusses on the actions that have been progressed and implemented in response to the recommendations made in a range of interim and final reports produced by Niche as part of the previous phases of the independent investigation into concerns and issues raised relating to Urology services at University Hospitals of Morecambe Bay NHS Foundation Trust (UHMBT or 'the Trust'). These included a Current Controls Report (issued in October 2020), a Current Case Review (issued in December 2020), an Index Case Report (final draft issued in April 2021) and a Final Independent Investigation Report (published in November 2021).

This assurance summary presents our findings from a desktop review of documents provided by the Trust, interviews and an on-site visit in January 2023 to evidence progression of the actions. We also undertook a follow-up Current Case Review in October 2022. We reviewed the case notes of 111 patients who had been seen by the Urology service as inpatients and/or outpatients up to and including August 2022. The approach used for the Current Case Review was to consider 18 of the recommendations from our published report – namely recommendations 10, 12, 14–20, 22–25, 36, 40–42, 44.

We also reviewed all Urology inpatient deaths subject to a case review from September 2021 to September 2022; there were nine cases. This review looked at the quality and consistency of Mortality Case Reviews specific to recommendations 10, 15 and 26. Findings from this have formed part of our summary findings about the progress that has been made on these recommendations.

Our report findings are structured into four sections as follows:

1. **Recommendations from the Current Controls Report**
   Recommendations 1–13
2. **Recommendations from the Current Case Review**
   Recommendations 14–21
3. **Recommendations from the Index Case Report**
   Recommendations 22–31
4. **Recommendations from the Final Investigation Report**
   Recommendations 35–52

A separate report has been issued to the Integrated Care Board (ICB) and NHS England, which focusses on the progression of the recommendations identified for these organisations alongside other regulators including the General Medical Council (GMC), the Royal College of Surgeons and the Care Quality Commission (CQC).

Assurance assessment

In the pages that follow, we provide our independent assessment of the progress made against each of the recommendations and their associated actions. This is followed by a numerical scoring assessment that rates the progress using the Niche Investigation Assurance Framework (NIAF) scoring system (see tables overleaf). The assessment is designed to be evaluative. We use a numerical grading system to support the representation of 'progress data' to help focus on the steps that need to be taken to move between the stages of commenced, significantly progressed, completed, tested and sustained improvement. A 3 is regarded as a good score because it means the actions have been completed. Scores of 4 and 5 are harder to achieve due to the cycle of testing needed to demonstrate that sustained improvements have been achieved (for at least 12 months).

Assurance summary

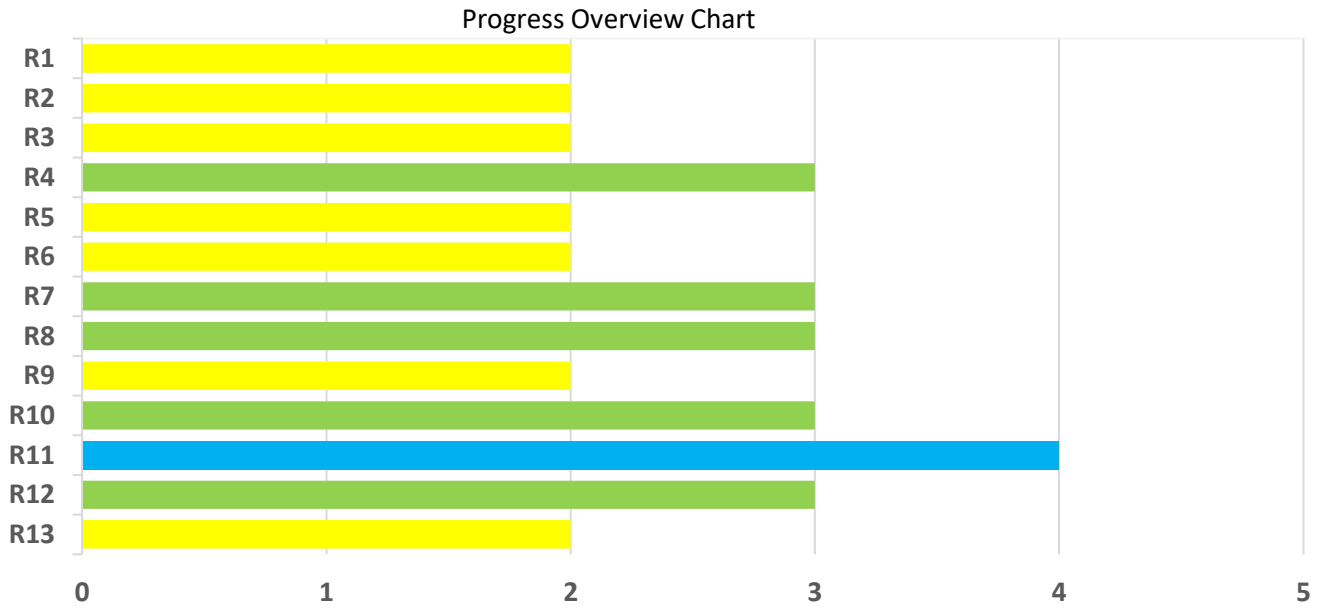
Implementation of recommendations

Score	Assessment category
0	Insufficient evidence to support action progress/action incomplete/not yet commenced
1	Action commenced
2	Action significantly progressed
3	Action completed but not yet tested
4	Action completed, tested, but not yet embedded
5	Can demonstrate a sustained improvement

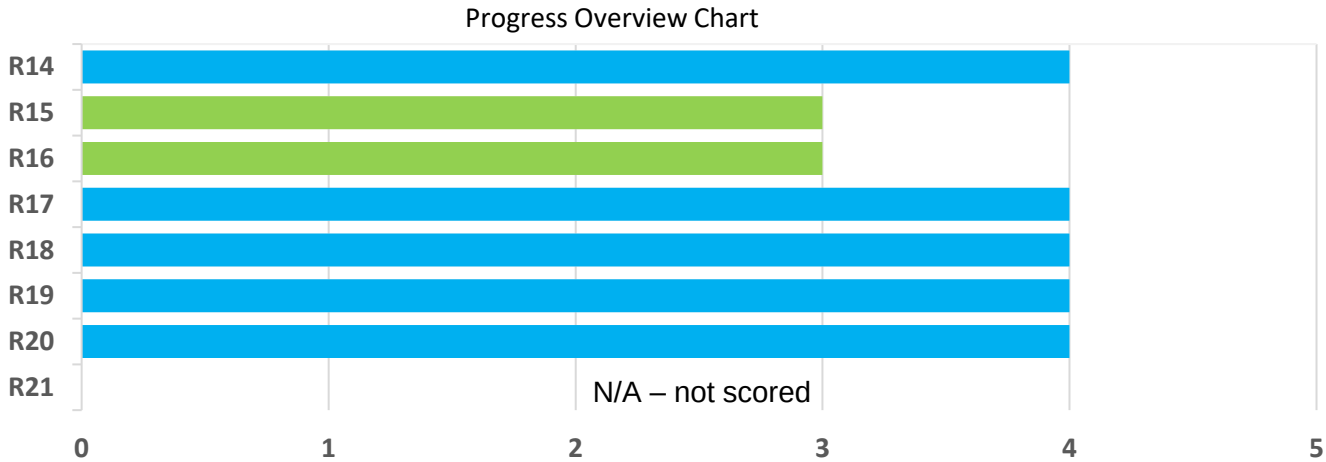
We have rated the progress of the actions which were agreed from the recommendations made. Our findings are summarised below:

Summary charts showing progress to date for each recommendation

Current Controls Report: recommendations 1–13

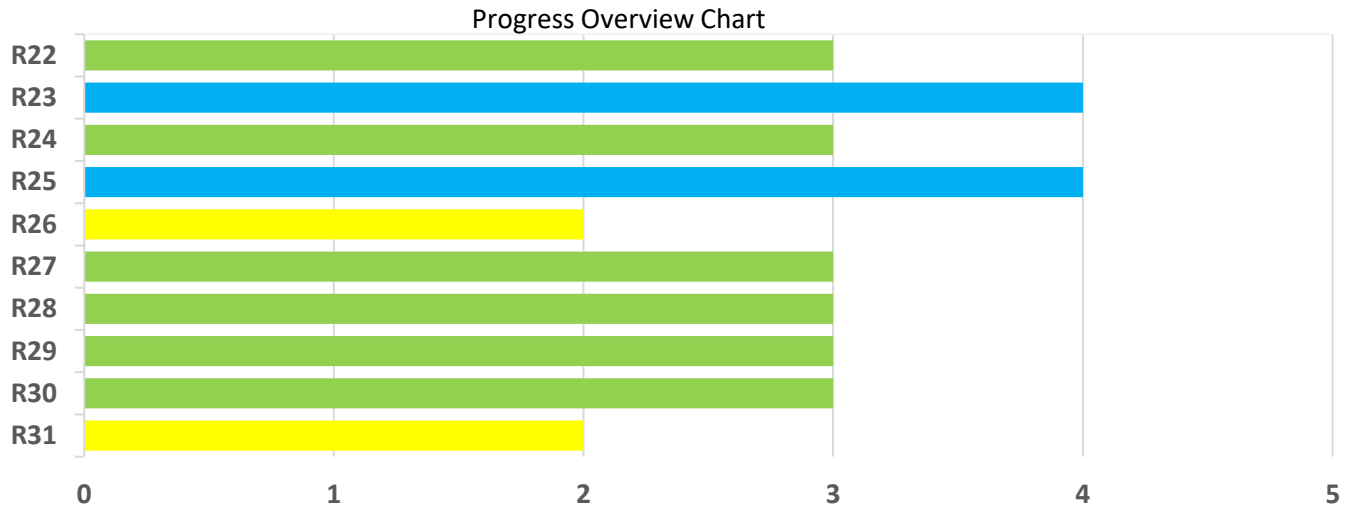


Current Case Review: recommendations 14–21

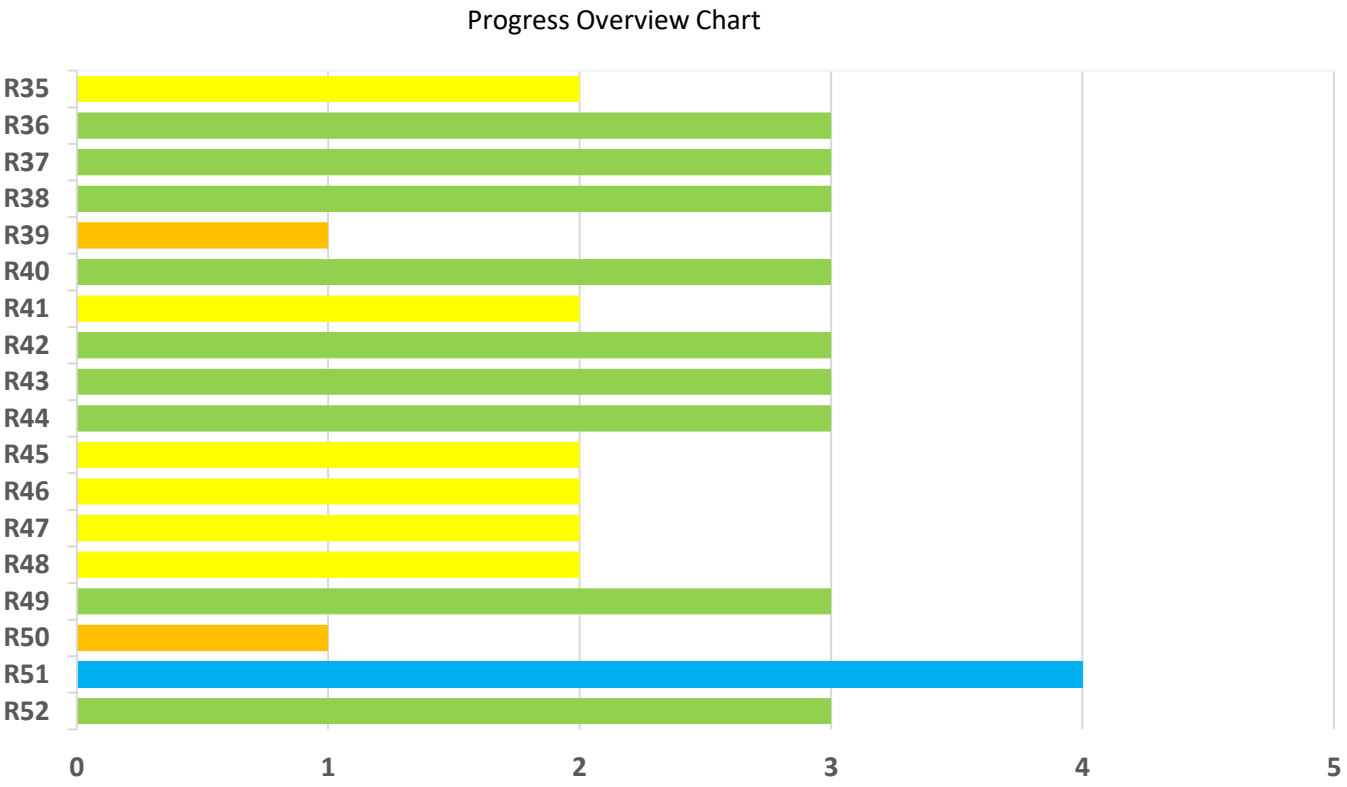


Assurance summary

Index Case Report: recommendations 22–31



Final Investigation Report: recommendations 35–52



Assurance summary

Overall summary

Progress has been made in relation to all recommendations, but particularly in key clinical areas that presented patient safety risks, e.g. professional relationships within the Urology department, stent management, fluid balance monitoring and recording, application of the Mental Capacity Act, consenting practices, physiological observations and escalation (through the National Early Warning Score (NEWS2)). At a departmental level, the Urology team should be congratulated on progress to date; momentum must now be maintained, although this is not the sole responsibility of the clinical team.

Of the 48 recommendations that were made for the Trust, 17 have yet to be fully implemented. This includes 15 which have been significantly progressed and two where evidence of progression is more limited. Another 22 have been completed, but the changes made need to be tested through audits, patient and staff feedback, or other forms of routine monitoring to ensure they are having the required impact, are embedded in practice and improvements are sustained. Nine recommendations which have been completed and tested need repeat cycles of testing or ongoing monitoring to ensure the required outcomes are consistently achieved.

A master action plan (shared in March 2023) assigned Executive Director ownership to recommendations with designated owners for action implementation and progress updates to the Urology department or care group if required. The plan was, however, limited to achieving a score of 3 (action completed but not yet tested) and did not clearly articulate the aspiration to secure assurance about the impact of changes being made. It is evident that until recently there had been some gaps in Executive Director understanding and ownership of the detail and relevance of some of the actions and recommendations and their importance; this could be due to the turnover of staff at executive level at and after November 2021.

This may also have contributed to the relatively late implementation of a number of the recommendations given the deadline requirements of this assurance review. We found that there has been concerted activity and policy development in the last five months (November 2022 to March 2023). although essential components of corporate and quality governance and escalation flows do not yet provide an adequate line of sight from ward to Board. Continued focus, central oversight and robust monitoring needs to be maintained to ensure that recommendations are fully embedded, that required outcomes are achieved and improvements sustained. There is a (shared) need at executive level for further ownership so that the recommendations achieve the desired impact with a more rounded view of the implementation of change between the department, care group and corporate teams.

We also note that since our prior reviews, there have been department management changes in Urology. The role of the Clinical Lead is paramount in ensuring improvements continue for the benefit of the local population. This means providing and responding to key information and driving change across the team in a transformational manner. The new Urology Investigations Unit in Lancaster Royal Infirmary is eagerly anticipated and may well assist in driving some of the transformation required; work has now started on this much anticipated development.

Headline commentary to support these ratings is provided in the following pages. It should be noted that we have added a new action to recommendation 50 (the role of governors and escalation mechanisms) in response to additional issues that were raised during our on-site Current Case Review in January 2023.

Section 1: Recommendations for the Trust

1a: Recommendations 1-13 from the Current Controls Report (October 2020)

Section 1a: Recommendations from the Current Controls Report

Recommendation 1

Oversight of Urology through Trust governance structures

Reporting lines need to be clearly articulated in the terms of reference for each of the groups and committees which have been established for oversight of the Urology service and depicted in an organogram. Links to the Urology department, care group, committee and Board governance structure should also be confirmed.

Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**

The Trust has taken several steps to clarify reporting lines and illustrate the oversight mechanism for Urology. A new Trust-wide Quality Governance and Accountability Framework (QGAF) was launched in August 2022, which is designed to show how assurance flows "*from the point-of-care to the Board*". The QGAF includes standardised templates for agendas, minutes and terms of reference (ToR). It also sets out the core meetings that each specialty and care group should have in place.

We found that there is still significant work to do to apply the expectations of the QGAF to Urology and the Surgical and Critical Care (S&CC) Group; it was recognised by interviewees that further work is needed to ensure that the QGAF is implemented in practice. For example, ToR for key meetings at both specialty and care group level continue to use different formats and headings, and vary significantly in terms of content and detail. The way in which some specialty-level meetings connect to Trust-wide meetings is not always clearly stated, which undermines the extent to which the Trust can be confident that key issues are identified, escalated and responded to. A key example is the Mortality Triangulation Group (Trust-wide) and the Urology Audit and Governance Meeting (specialty level). The embryonic nature of the QGAF was evidenced by the high number of ToR that were reviewed and approved in the last three months.

Recommendation 2

Quality and safety data in the Integrated Performance Report

The quality and safety data in the Integrated Quality and Performance Report (IQPR) should be expanded to include trend and thematic analysis. Key quality and safety metrics should be included in a new upfront performance dashboard and hotspot reporting should include more detailed analysis on key risks.

Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**

Work has been undertaken to improve the content and presentation of the IQPR and the Trust has incorporated guidance on performance reporting from NHS England. Interviewees shared the view that exception reporting has improved and it now better enables the reader to understand the context of key risks; an example cited by a number of interviewees was Fractured Neck of Femur reporting. The increased use of statistical process control methodology is also a notable improvement and is being utilised to better effect across the Trust to identify data trends. This is supported by the narrative boxes at the bottom of each exception page. A scorecard has been introduced to the report which triangulates performance across quality and safety, colleague wellbeing, financial standards, restoration and recovery targets.

However, the IQPR still does not include sufficient thematic analysis, which is a material weakness in its ability to provide assurance to the Board. There are some isolated examples of themes being noted in the report, however this is done on an inconsistent basis. We have been told that this is a key priority in the next phase of the development of the document, followed by rolling out the IQPR format to care group performance review packs. Also see commentary in Recommendation 9.

Section 1a: Recommendations from the Current Controls Report

Recommendation 3	
Performance framework for Urology Introduce a performance and accountability framework which clearly sets out the approach to corporate and care group scrutiny of Urology and, where necessary, support from the Enhanced Support Programme (ESP)	
Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**

In Autumn 2022, the Trust launched its Performance Accountability Framework (PAF) which is designed to enable the Executive team "*to monitor performance by the care groups, Support Services, corporate teams and provide guidance, support and intervention where needed."* The PAF defines the role of each tier of governance in the Trust (such as Board of Directors, Executive Team, care groups and so on) in the oversight of performance.

In developing the PAF, the Trust has decided to absorb the role of the Enhanced Support Programme into its overarching approach to performance monitoring. The framework has been designed according to both the CQC's five domains and the NHS England Single Oversight Framework (SOF). The framework states that each care group will be allocated a segment or rating which will dictate the level of autonomy it has and support required.

Under each CQC domain in the PAF, the Trust has set out a series of 'triggers' which influence the overall rating; these triggers are subjective and are not 'SMART' which raises the risk that an underperforming service and/or care group is not identified. For example, a trigger under the 'Safe' domain is "*concerns arising from quality indicators*" but the nature of concerns is not quantified.

Each care group has a monthly performance review meeting with a standardised agenda and reporting structure; sub-specialty discussions remain limited although risks are discussed. This meeting is followed by a formal letter from the Executive team which sets out the care group's SOF segment and rationale for the decision.

The content of the reporting pack varies in quality. We understand the Trust intends to introduce the new IPR format to care groups during 2023, and this will include a revised approach to risk-based reporting. The current reporting pack does not clearly distil key trends or highlight the most material movements in performance. For example, the S&CC pack for December 2022 notes that "*the system is expected to consistently fail the target*" in relation to the 18-week referral to treatment (RTT) standard; however, it does not state how this will be mitigated, nor what the impact of this mitigation is expected to be. There is an over-reliance on care groups to proactively highlight and escalate key risks, including those that are specialty-based. Whilst we have been told that support has been provided to care groups to ensure that key risks and issues are highlighted in a consistent manner, further work is required to more clearly define the reporting and escalation link between specialties and care groups. This is particularly important given the breadth of care group service portfolios, the existence of a number of challenged services within the S&CC care group, the embryonic nature of IPR reporting at a care group level, and the fact that the PAF was only introduced towards the end of 2022.

Section 1a: Recommendations from the Current Controls Report

Recommendation 4	
Urology audit The newly appointed Urology Audit Lead should have dedicated and experienced support to provide best practice guidance on conducting audit and governance meetings. The terms of reference and agendas for the audit meeting should be drawn from best practice in other Urology services.	
Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**
The new Urology Audit Lead has received dedicated support in the form of training in conducting formal meetings and there is now improved administrative capacity. The ToR and agendas for audit meetings were revised and redesigned in September 2022, based on meetings held by other Urology services; this means the membership of the audit and governance meeting is now more aligned to best practice. The minuting and attendance at audit meetings have significantly improved and they now use a relevant agenda which is fed by mortality review, patient safety issues, opportunities for learning and the sharing of incidents. However, the agendas are full and the Chair has to ensure there is time for discussion and debate where required and time to focus on the improvement loop and thematic analysis, so that the themes are identified, addressed, retested and the learning is embedded in practice.	

Section 1a: Recommendations from the Current Controls Report

Recommendation 5	
Safe Today Report The Safe Today Report should be received at department and care group level before presentation to UT&FG [Urology Task and Finish Group] and UQOC [Urology Quality Oversight Committee]. It should also be developed further to provide more appropriate measures of assurance with: inclusion of an overarching scorecard to enable the reader to understand performance 'at a glance'; a reduction in the narrative analysis throughout the report; greater emphasis on prospective performance through the use of early warning indicators and forecasting in order to allow timely identification of deteriorating performance; more same causal factor analysis of complaints, litigation, incidents and Patient Advice and Liaison Service (PALS) feedback; an expansion of the quantitative and qualitative data relating to patient and staff experience, including patient feedback in the form of real time and retrospective data collection, staff pulse surveys and a wider range of workforce metrics (e.g. turnover, appraisals, training, use of agency staff, staff sickness, as well as concerns raised by staff).	
Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**
Progress has been made to strengthen the Safe Today Report, which now includes a scorecard to provide an 'at a glance' picture of performance. There is also a dashboard which presents data relating to quality and safety, people, performance and finance. The Trust has been supported by its internal Making Data Count team and has also had input from NHS England with positive feedback received on the development of the report. There remain a number of material aspects of the report that need to be strengthened in order for the report to provide a robust picture of the safety of the service in our view. For example, the usefulness of the report is currently limited by the number of targets without completed trend data or targets/thresholds. The impact of the report would be significantly enhanced by the use of early warning indicators, clear summaries of the impact of actions taken to date and any remaining gaps. The report still needs to introduce some causal factor analysis across the quality governance agenda; inclusion of this will facilitate greater understanding of the quality and safety risk profile. There is also a lack of qualitative workforce information, such as staff concerns and experience data, and analysis of staff sickness; we understand that work is still ongoing to address this area, namely via development of the people and culture dashboard (see recommendation 46) .	

Section 1a: Recommendations from the Current Controls Report

Recommendation 6	
Meeting administration Meeting administration must be improved. This should include: a review of the ToR for all meetings at departmental and care group level to ensure they are in date, aligned to the objectives required of the meeting, and also other key meetings, with agendas planned to reflect these; the introduction of standardised templates for agendas, minutes, and action logs; and the provision of training for individuals with minute-writing responsibilities and all minutes should be reviewed by the relevant Chair before distribution.	
Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**
The Trust has taken several steps to improve meeting administration, including the review and approval of the ToR for most key meetings, and the introduction of standardised templates for agendas and minutes. The majority of this activity took place between September and December 2022. There are some meetings for which ToR have not yet been formally approved and, as outlined earlier, we found some examples of ToR that do not clearly link a meeting with the rest of the Trust's governance structure as outlined in its QGAF e.g. the Mortality Steering Group. Minute-taking training for individuals with minute-taking responsibilities began in December 2022.	

Section 1a: Recommendations from the Current Controls Report

Recommendation 7

Risk registers at service, care group and Trust level

The challenges currently being faced by the Urology service should be reviewed to determine whether the risks are sufficient to warrant inclusion on the service, care group or Corporate Risk Register (CRR) or the Board Assurance Framework (BAF); this includes the difficulties with on call cover at Furness General Hospital (FGH) and continuing fractured relationships as a patient safety risk. Departmental and care group meetings should include risk as a standing agenda item and the risk profile of the service should be reviewed at least quarterly.

Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**

The Trust has made some steps towards strengthening its overall approach to risk management, including launching a new risk management policy and strategy in early 2022.

The Trust's internal auditors published a report outlining their findings in relation to risk in May 2022; this concluded that "*the Trust has made significant progress to improve its Risk Management approach and systems*".

Although no evidence that there has been a holistic review of the risk profile of Urology, individual risks have been reviewed and in most cases either moderated through additional controls or closed where the risk is no longer evident (for example, 2990 world-wide supply of bladder cancer treatment). There are four live risks on the Urology (and care group) risk register, with one included on the Corporate Risk Register in line with the risk it presents. These are shown in the table below:

Risk	Description	Score	On BAF?	On CRR?
2182	Indicative review date (IRD) backlog linked to issues identified through clinical incidents	12	No	Yes
310	62-day cancer compliance due to lack of capacity	9	No	No
2743	No dedicated National Confidential Enquiry into Patient Outcome and Death (NCEPOD) list	9	No	No
3158	UHMBT referral pathway for cystectomy patients are referred out of the Trust to East Lancashire Hospital Trust.	6	No	No

The Surgical Governance and Assurance Group (SGAG) terms of reference state a monthly review of risks; this is limited to new risks or risks for closure with a more detailed quarterly update of all risk. More frequent scrutiny of specialty risks would improve controls.

Section 1a: Recommendations from the Current Controls Report

Recommendation 8

Quality of investigations in Urology services

All reported incidents and complaints received in relation to Urology services should, for a period of at least 12 months, be investigated by a dedicated independent team outside the department which has access to independent Urology advice. This would remove pressure on the existing team to investigate each other and provide room to work on relationship development. It would also help to set a standard for future high-quality investigations.
[This recommendation related to incidents and complaints requiring investigation, not all cases].

Summary of evidence and proposed NIAF rating	Action completed but not yet tested – 3

In line with this recommendation, all reported incidents and complaints received in relation to Urology services were investigated by a dedicated independent team for 10 months after the findings of our Current Controls Report were shared with the Trust. A programme of training was started to ensure that relevant core staff have the required skills to carry out investigations internally. Investigations were handed back to the Urology team in 2021, but with greater oversight from the Corporate team, including from the weekly Patient Safety Summit meetings. We have reviewed five of the last Urology serious incident investigations and have noted a significant improvement in the quality of written reports. Action plans are more detailed and these are supported by more thorough chronologies and a better analysis of events.

Recommendation 9

Thematic review

Quality performance reporting should include thematic and same causal factor analysis of complaints, litigation, incidents, and PALS information to ensure that lessons can be learned, and actions taken to prevent recurrence of the same. Themes should be discussed at departmental, care group, and committee level with a clear focus on actioning improvement.

Summary of evidence and proposed NIAF rating	Actions significantly progressed – 2

This recommendation has only been progressed recently, although an example of a themed review template was provided that had been obtained from another Trust in mid-2022.

On 15 December 2022, a multidisciplinary Task and Finish Group was established to support the Trust's ambition to move forward with the learning to improve agenda and to introduce a new learning lessons framework for the organisation with a first meeting on 6 January 2023. Timescales for delivery of the framework, which includes establishment of a Learn to Improve meeting, policy and the issue of regular bulletins going forward, are for the end of March 2023. We have been told the Trust are on track for delivery but have yet to see the policy or meeting terms of reference.

'Learn From Events' quarterly reports have, however, been presented to the Quality Assurance Committee in December 2022 and February 2023, and also to subsequent Patient Safety Group meetings. These remain a work in progress; while some common themes and learning were identified for incidents, complaints and claims, there is no reference to PALS or other patient experience information (see recommendation 39) and limited commentary about actions being taken to address any causal factors other than for falls and pressure ulcers.

Complaints, incidents, Never Events and deaths are discussed in the Urology audit meeting, but the volume of information covered in the meetings has sometimes resulted in these discussions being curtailed. We have also been told that feedback from the care group to the department on trends, themes and causal factor analysis is limited'.

Section 1a: Recommendations from the Current Controls Report

Recommendation 10	
Mortality review (Link to R15 and R26) Every inpatient Urology death must have a case review conducted by Consultant Urologists with external support in using structured judgement review (SJR) methodology (Royal College of Physicians) or other recognised case note review methodology and be subject to Trust level scrutiny (as per Trust Policy). Every death must then be presented without exception to a Urology mortality meeting. These should be separate from audit and multidisciplinary team (MDT) meetings until such time that mortality review becomes an accepted and business as usual activity.	
Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**

To assess this recommendation, we examined Urology Mortality Case Reviews (using SJR methodology) undertaken in the last 12 months; there were nine. These were conducted between 16 to 83 days after death. They were completed by four different reviewers, with some being reviewed by the Urologist leading on mortality.

All cases had been scrutinised by a Medical Examiner, which we confirmed with the Medical Examiner's Office following our site visit. They were all completed promptly (seven were within two days of death). It is of note that in five of the nine cases, the Medical Examiner recommended an SJR. There was potential for learning in a further case. Of the nine cases, one did not have the potential for further learning identified by the Medical Examiner, a need for an SJR or a referral to the Coroner.

All cases had been presented to the Urology mortality meeting, although presentations rely on high-quality SJRs. We have raised the need for improvements in the level of curiosity required to inform robust assessments.

Of the nine cases, eight were considered as 'definitely not preventable' by the Trust reviewers. Our review would indicate, on balance, that these assessments tended towards being overly positive. This was a similar theme arising in an additional external review by NHS England, although there is the recognition that reviewer judgements have an expected element of variability. There was a tendency to consider care as 'good', with limited evidence of the basis for this recorded in the assessment.

Overall, this is a significantly improved process with efforts at all levels to improve the identification of Urology cases through automation.

It is evident that case reviews (SJRs) are now being undertaken (although not all by Consultant Urologists) and that Urology inpatient deaths are being identified more appropriately and reliably. However, during our on-site visit in October 2022 we escalated concerns about the quality of two case reviews where we considered that insufficient attention had been paid to potential causal issues post-operatively (venous thromboembolism (VTE) and white cell count). We recommended they undergo further review and that the need for Duty of Candour be considered.

We also had queries regarding the consistency of the death summary on the medical certificate of cause of death (MCCD). However, further assessment of the Medical Examiner process provided reassurance that there was scrutiny across all nine cases.

SJRs need further improvement to ensure that there is detailed assessment, in particular those that are also requested by the Medical Examiner's Office. This will help to extract learning about the patient experience because mortality review is not solely about cause of death but is an opportunity to consider overall care provision.

Section 1a: Recommendations from the Current Controls Report

Recommendation 11	
Professional relationships Intelligence from the InterBe meeting in August 2020 should be used to assess the severity of concerns associated with relationships between senior clinical staff to determine whether issues can be resolved or if other remedial action needs to be taken.	
Summary of evidence and proposed NIAF rating	**Actions completed, tested, but not yet embedded – 4**
The InterBe Cultural Development Programme was introduced in April 2020. At the beginning it found substantial concerns expressed by the Urology team about a working culture that needed fundamental change. Following the delivery of a 12-month programme of group and individual meetings and coaching sessions, feedback in a meeting on April 2021 showed there had been significant improvements in working relationships. This programme has been further progressed in conjunction with other internal organisational development initiatives, but with conversations about how to enable the Urology team to function independently without the need for this type of facilitation. Improvements continue to be referenced, although frustrations still exist between the clinical and senior management teams, with some (Consultants) feeling that actions are not always implemented in response to concerns raised. Monthly drop-in sessions with members of the Executive team were introduced in December 2022 to address this issue and further support the Urology team, but it is too early to understand the impact they are having.	

Section 1a: Recommendations from the Current Controls Report

Recommendation 12

Pooled model of patient care

- There is an urgent need to review the pooling of patient referrals and the way in which patients are allocated to, and reviewed by, clinicians in Urology to ensure that continuity of care is optimised.
- There should be clear procedures for allocating patients against specific pathways (including in line with Cancer MDT guidance). Any subsequent changes to management plans should be agreed with the Named Consultant/an appropriate clinician especially if there are clinic cancellations or delays to treatment.

Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**

The approach of the pooled model of patient care has been reviewed Trust-wide and a standard operating procedure (SOP) agreed within S&CC for patients requiring elective surgery. The Urology team, in conjunction with the Cancer Alliance, has also approved a number of clinical pathways, including for prostate and other cancers, stent insertion and removal. These processes have, however, only recently been introduced and there are still concerns about the continuity of care that patients are receiving. Concerns have been highlighted through complaints and internal audits and were evidenced in our on-site review in October 2022, although improvements have been noted in recent survey feedback and Urology quality service reviews since this time.

There have been several attempts to introduce the named Consultant to improve the continuity of care; these attempts have been revisited. A Urology Named Responsible Consultant SOP was ratified in November 2022 with further revisions approved in March 2023. Contingencies for short notice absence and emergencies have been considered, and the procedure now includes that changes to management plans should be agreed with the named Consultant/an appropriate clinician and how this will work in practice.

There has also been a decision that the MDT should be attended by the whole Urology Consultant team to facilitate better communication about, and management of patients through the named Consultant approach although attendance still needs to improve (see Recommendation 41).

Commissioners have maintained oversight of the implementation of the revised procedure for the pooled model of care by attending the Niche Support and Review Panel meetings and through the Safe Today Report presented to the Trust's Quality Committee. Challenges to the implementation of this approach have been noted, including workforce pressures.

The model of care and attendance at MDT meetings needs to be monitored to ensure fully functional and embedded in practice.

Section 1a: Recommendations from the Current Controls Report

Recommendation 13

Monitoring of additional activity sessions (AASs)

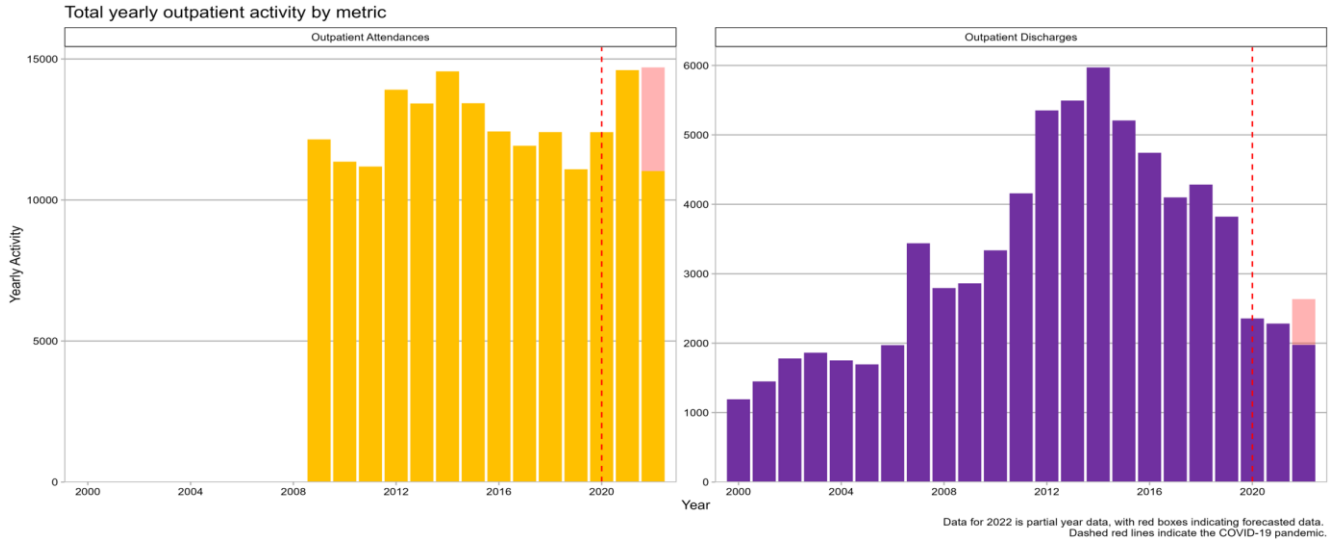
Introduce a robust policy and controls to retrospectively and prospectively review AAS activity in the Urology department, including a quarterly analysis of the number, value, and justification for AASs undertaken on a clinician-by-clinician basis.

Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**

Progress has been made to ensure the Trust has a more robust approach to the financial sign off of AASs. The Controlling and Monitoring AAS Policy was approved in July 2022 and it sets out the need for AASs to be approved by each Associate Director of Operations (ADoP) and is ultimately overseen by the Chief Operating Officer. A SOP has also been developed (Controls for AAS) and was ratified in December 2022. The SOP states that AASs will be monitored quarterly at Know Your Business meetings for each Clinical Business Unit. We note that the actual value of AASs approved versus planned is now included in the Safe Today Report

There is, however, no evidence that the clinical rationale for AASs is reviewed or has been challenged, nor is there any analysis of the number and value of AASs undertaken on a clinician-by-clinician basis. Interviewees corroborated this and stated that they were unaware of any analysis or challenge applied to AASs; the only change that they were aware of was the requirement for AASs to receive financial sign off by the ADoP.

We note from the Niche quantitative analysis (see graphs below) that outpatient discharges have dropped further in the last two years and a lack of management of the active discharge of patients may be driving an unnecessary demand for follow-up appointments paid for through AASs.



It remains that there appears to be an acceptance that high numbers of regular AAS are the only way to provide a service in perpetuity. Consideration should be given to mechanisms by which AASs might be reduced (eliminated) by redesigning patient flows, up skilling nurses or employing additional consultants if clinical demand requires.

1b: Recommendations 14-21 from the Current Case Review (December 2020)

Section 1b: Recommendations from Current Case Review

Recommendation 14	
Fluid balance monitoring Fluid balance practice should be audited and a programme of high-quality recording put in place for Urology patients.	
Summary of evidence and proposed NIAF rating	**Action completed, tested, but not yet embedded – 4**
The Trust has ensured a focus on key aspects of care such as nutrition and hydration through several initiatives including Fundamentals of Care, the Deteriorating Patient Group, the Nutrition and Hydration Group, improvements to the identification and management of acute kidney injury, the introduction of dining companions, and using family members to support nutritional and fluid intake. Training has also been provided to all Urology medical and nursing staff on fluid balance recording. A Clinical Service Review that was undertaken in April 2022 by senior Trust and Clinical Commissioning Group (CCG now ICB) staff found examples of good practice recording and they also saw information about this subject on ward education boards. Our Current Case Review in October 2022 found that fluid balance recording was good for short-stay and day case procedures, and we noted practice which is in line with required standards for longer-term patients, although some improvements in documentation were required. The Trust also undertakes a range of audits and reviews which assess compliance with practice; however, results vary and there is an acknowledgement by the Trust that further action is required.	

Section 1b: Recommendations from Current Case Review

Recommendation 15

Mortality review (Link to R10 and R26)

- Following on from our recommendation on mortality review in our Draft Current Controls Assessment Report, the Trust must develop a robust mechanism for identifying deaths by speciality using both admission and treatment function codes and other identifiers. This should include deaths up to 30 days post-discharge.
- The HOGAN and National Confidential Enquiry into Patient Outcome and Death (NCEPOD) scoring arising from mortality reviews must be subject to audit and further scrutiny within the Trust.
- All NCEPOD or HOGAN scores of 2 or above should give rise to further review by the Trust, investigation where appropriate and the potential need for Duty of Candour processes.

Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**

The Trust has an improved and more reliable process for identifying Urology deaths than previously. There is, however, a recognition that Urology intervention can sometimes be a contributory input for patients who have been admitted to other specialties, and that deaths may therefore (appropriately) not be designated as a Urology inpatient death. Cases that relate to other specialties are more reliably identified, although this still requires manual oversight.

The HOGAN (a standardised score given following a retrospective case review on a 1–6 scale to assess preventability) and NCEPOD scores are being used consistently, although the scores given appear to be overly positive on occasion and there is no evidence of the Trust Mortality Group reviewing the scores as an improvement focus. One case was considered ‘preventable’, and the remaining cases were deemed ‘definitely not preventable’ using the HOGAN rating by Trust reviewers. The NCEPOD scoring suggested that there was room for improvement in only one case. We escalated cases on our site visit in October 2022 as our review was not consistent with this assessment.

The Medical Examiners identified potential for learning or a need for SJR in at least six cases and two cases were with the Coroner – both of which had learning and potential room for improvement. There remains a risk that, even though the process has improved considerably, the opportunities for learning from deaths is limited because case reviews are not sufficiently robust.

The Trust mortality dashboard uses treatment function codes and includes data on deaths up to 30 days post-discharge. It is important to note that the development of this dashboard is in a second phase and is yet to be released. However, the Business Intelligence team came across to us as diligent, engaged, receptive and passionate about getting accurate data so they could secure the buy-in needed to use the phase 2 dashboard when it is released. The main difficulty is the identification of cases where Urology has important input but is not the main specialty. They responded to our suggestions and have a detailed understanding of the data and its sources. There is a good opportunity for this to provide an overview of learning opportunities if the Trust supports the engagement across specialties and there is ownership and understanding of this important tool at executive level.

Section 1b: Recommendations from Current Case Review

Recommendation 16

Named Consultants

- Named Consultants, for complex patients, should be introduced in Urology. This should include non-cancer patients. Complex cases without a diagnosis should be discussed at MDT or Radiology meetings.
- Clinicians should be allocated clinical responsibility for the oversight of pathways including by cancer type to develop greater ownership and to drive improvements in services.

Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**

The Urology department initially launched the named responsible Consultant model of care in early 2021; however, a number of internal audits and reviews identified that it had not been effectively progressed.

With additional focus and support from the Trust, and as mentioned in recommendation 12, the Urology Named Responsible Consultant SOP was agreed and ratified in November 2022 to coincide with new job planning rotas. Further revisions have been made to clarify the process for decision making, and feedback (including through audit) has indicated that the operating model is beginning to work more effectively for elective patients. The impact on patients who are admitted as an emergency has yet to be fully assessed.

Attendance at MDTs is also improving, with a requirement for all Urologists to attend and also present their own cases where possible; however, a review of registers indicate that further improvements in attendance are required (see Recommendation 41).

Commissioners have maintained oversight of the implementation of the revised procedure for the named responsible Consultant by attending the Niche Support and Review Panel meetings and through the heat map and Safe Today Reports. Continuity of care audits have recently been shared with the ICB and discussions on this model of care are continuing, including within the Urology department.

The model of care and attendance at MDT meetings needs to be monitored to ensure fully functional and embedded in practice.

Section 1b: Recommendations from Current Case Review

Recommendation 17	
Capacity and best interests: applying the Mental Capacity Act 2005 • Capacity assessment and best interest decision-making should be improved through audit, training, and best practice examples. • An enhanced focus should be given to people presenting with dementia or confusion and those with a learning disability. • A thematic review examining the pathway, management and replacement of suprapubic catheters should be undertaken.	
Summary of evidence and proposed NIAF rating	**Action completed, tested, but not yet embedded – 4**

There is evidence of considerable focus by the Trust on the Mental Capacity Act and ensuring that care is given in line with the best interests of patients who do not have the mental capacity to make decisions for themselves, including those with dementia or learning disabilities. This is reflected in local policies but also the Safeguarding Strategy that was approved in 2020. Information and updates on current guidance have been provided to staff through presentations and e-learning and a safeguarding resource file is also available to them, which includes associated information for relatives and/or carers.

Reports, audits and inspections which have been undertaken in 2021–2022 reflect improvements that have been made in relation to consenting practice, Deprivation of Liberty Safeguards and other aspects of the Mental Capacity Act, and with monitoring and reporting to the Board; although results remain varied in some cases.

Our Current Case Review site visit in October 2022 saw clear evidence of the use of appropriate capacity assessments; capacity assessments completed were relevant to the situation and repeated as necessary. There has clearly been enhanced focus on improving practice in this area of documentation. Safeguarding paperwork alongside the capacity assessments was also clear in a range of cases, including for elderly people and children, and was appropriately applied in the cases we reviewed.

In relation to the management of suprapubic catheters, an audit into associated bowel perforations was undertaken in 2021–2022. It was noted that ultrasound was only recorded in 11/162 insertions and harms resulted in 13 cases. These included two bowel perforations (confirmed by the Trust to be within the expected risk range referenced by The British Association of Urological Surgeons (BAUS) in their insertion of a suprapubic catheter guidance), four post insertion sepsis cases, three site infections/cellulitis and four other. No action was taken as a result of this audit and there is no reference to a re-audit to facilitate improvements despite an 8% harm rate being identified. We are waiting confirmation that the post procedural complications and harms were reported as incidents.

Section 1b: Recommendations from Current Case Review

Recommendation 18	
Consent • Consent for operations must be completed on every occasion. Any consent not completed correctly must be reported and investigated to improve practice. • Consenting practice should be subject to audit and should include whether the patient dated the consent and the practice of confirmation of consent where the operating surgeon is different from the consenting surgeon. • Theatre staff should be alerted to our concerns regarding consenting practice and be authorised to report all incidents where consent is not compliant with expected practice.	
Summary of evidence and proposed NIAF rating	**Action completed, tested, but not yet embedded – 4**
Consenting practice has been reviewed by the Trust. Policies and procedures have been updated in line with best practice guidance and methods for recording consent revisited to ensure that risks have been documented and conversations with patients and/or their families are appropriately retained in the electronic record. This has resulted in the adoption of e-consenting which is being trialled across the Trust and, more recently, by some of the Urology Consultants. It is anticipated that full roll-out will increase compliance with consenting requirements and that future audit results will improve because paper consent forms will no longer be required. The software also prevents the clinician proceeding with consent until they have declared a capacity assessment has taken place and/or the correct capacity process has been followed. During our review, we saw evidence of good consenting processes in most cases.	

Section 1b: Recommendations from Current Case Review

Recommendation 19	
Lorenzo • All scan and clinical results should be acknowledged by the requester. Clinicians should be trained on the use of Lorenzo to ensure that they are aware of how to complete this activity. • It should be made clear to all staff in which part of Lorenzo key documentation should be filed to reduce the amount of time spent finding key clinical information. • A record of stent register status should be clearly marked and visible.	
Summary of evidence and proposed NIAF rating	**Action completed, tested, but not yet embedded – 4**
There have clearly been developments with Lorenzo in the last two years. This electronic patient record system and associated training packages have been modified in conjunction with clinical staff and the Monthly Task and Finish Group for Improvement in Lorenzo Documentation has endeavoured to ensure oversight and monitoring of the changes being made. The addition of the stent register is a key improvement and this tool is being appropriately used in the majority of cases, with very few patients now having delayed stent changes. Additional safety netting measures were also introduced in January 2023 and include that the patient will be retained on the clinician's awaiting results access plan until the stent is either removed or changed. Similarly, test results are now typically seen and acknowledged within appropriate time frames (although the system does not enable the acknowledgement of all results) through implementation of the Results Acknowledgement Project Plan. However, although the training provided to staff is clear, there are still inconsistencies in the filing of clinical documents. This was seen during our site visit in October 2022, when we found significant variances in practice. We understand the Trust is looking to procure a new electronic patient record system which will improve efficiency while also being compatible with other local Trust systems.	

Section 1b: Recommendations from Current Case Review

Recommendation 20

Recording of ethnicity

- The sample provided does not include information on ethnicity other than White or Unknown/Mixed. The Trust should examine whether it is recording ethnicity in its records in line with expected practice.

Summary of evidence and proposed NIAF rating	Action completed, tested, but not yet embedded – 4

Ethnicity recording is a key data field that should be recorded (with a patient's consent) to facilitate analysis of information by ethnicity for a range of purposes, including patient safety and cultural adaptations. However, this data has not been captured consistently for all patients; this is reflected in audit results and also our on-site Current Case Review.

Recognising the need to improve, the Trust has introduced further guidance and crib sheets for front-facing administration/clinical staff and a Recording Patient Ethnicity Procedure SOP is due to be published in February 2023. These documents provide clear directions to staff on the information required, the opportunities for capturing this information (such as face-to-face interactions and a new texting initiative) and the categories available for recording (including 'not known' if staff are unable to determine or ask about a patients ethnicity).

Recommendation 21

Case note review

There should be a repeat case note review (100 cases) in 12 months (Autumn 2022) to assess if improvements have been sustained and embedded.

Summary of evidence and proposed NIAF rating	Action completed but not applicable for scoring – N/A

Niche was commissioned to undertake the Current Case Review, and this was completed in October 2022. Of the sample provided, a total of 111 case notes were reviewed (34 outpatient cases, 62 inpatient cases – either as overnight stays or day cases – and 15 transfers from FGH to Royal Lancaster Infirmary (RLI)). The approach used to review case notes was to begin consideration 18 of the recommendations from our published investigation report, namely recommendations 10, 12, 14–20, 22–25, 36, 40–42, 44.

We found that progress had been made in relation to 11 recommendations; however, there were also three recommendations where evidence to support progression was more limited and four that we were unable to assess from this method of testing. Where appropriate, we provided examples of further assurance that was required to demonstrate actions are complete, tested, embedded and/or sustained as appropriate.

1c: Recommendations 22-31 from the Index Case Report (April 2021)

Section 1c: Recommendations from the Index Case Report

Recommendation 22

Improving the pathway for bladder cancer diagnosis

- Where appropriate, conducting a flexible cystoscopy on the day of attending the One Stop Clinic would make this a truly one-stop service.
- Patients meeting the two-week wait criteria with visible haematuria and normal estimated glomerular filtration rate (eGFR) should be triaged to have a CT Urogram prior to attending clinic to streamline the service.
- Patients requiring ongoing monitoring following chemotherapy/radiotherapy should be referred back via the MDT to a named Consultant at the Trust, on completing their therapy, who is then responsible for coordinating ongoing care (e.g. in this case, being clear about the rationale for examination under anaesthetic (EUA), biopsy, cystoscopy and stenting). The MDT will need to ensure there is a clear management plan and processes put in place to ensure Urology actions are implemented. This will also allow time to plan dates for surgery to meet required timescales.
- Lancashire and South Cumbria Cancer Alliance follow up protocols should be agreed and followed.
- All patients should be listed on the stent register. If they are transferred to another Trust with the expectation that the stent is removed, this should be explicitly stated; if patients are transferred into the Trust with a stent in situ, they should be added to the Trust's stent register.

Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**

The One Stop Clinic remains an invaluable resource for the Urology team and is a continued area of strength. We saw evidence through our Current Case Review of a very responsive service, which has endeavoured to ensure a one-stop experience for new patients. As a supportive measure, patients meeting the two-week wait criteria (including those with visible haematuria) are now triaged by the on-call Consultant at FGH and patients are selected for a CT Urogram (used to examine the kidneys, ureters and bladder) prior to attending clinic – although the efficacy and impact of this has not yet been assessed. Where this has not been possible, diagnostics and other interventions have been arranged within short time frames. It is evident that Radiology services continue to work well to support timely investigations. Further improvements in service delivery are anticipated through the recent approval of a business case for a dedicated Urology Investigations Unit on the RLI site; for which building work is due to commence.

Pathways and SOPs are being developed for a range of urological conditions through task and finish groups, process mapping events and consultation with other MDT members. The Cancer Alliance Protocols for the Management of Patients with Urological Malignancy have been approved and shared within the Urology department in October 2022. These include guidance on the management of bladder, kidney, prostate, testicular and penile cancers, and the processes for referrals, grading, notifications to the network MDT Coordinator for inclusion on specialist MDT meeting agendas, risk stratification and follow-up procedures.

The addition of the stent register to Lorenzo is a material improvement, with patients experiencing more timely reviews, removals or replacements as required; protocols have also been agreed for out-of-area patients coming into and out of the service. This system is working well.

During our site visit and Current Case Review we saw no significant issues with ongoing care and the long-term surveillance of patients with urological cancers, although there was recognition that there are still delays on some occasions. Patients are discussed at the local MDT and plans agreed, although the named Consultant model of care is not yet fully operational. We saw evidence of referrals back to the MDT following chemo/radiotherapy in addition to referrals to the network meeting.

Section 1c: Recommendations from the Index Case Report

Recommendation 23

Clinical monitoring

The Trust should continue to embed good practice and use of:

- Venous thromboembolism (VTE) assessment.
- Nutrition, hydration and associated food/fluid balance monitoring must be enforced as fundamental standards. Use of the Malnutrition Universal Screening Tool (MUST) should be audited at specified intervals to ensure scoring and onward actions are appropriate.
- Total Parenteral Nutrition (TPN) guidelines should be reviewed and monitored to ensure that this option is considered early for all patients who are at risk of malnutrition.
- The Trust should monitor the recent implementation of the electronic NEWS2 charts to ensure that the new system is successful in identifying and responding to deteriorating patients.
- Access to formal on call microbiology advice out-of-hours should be provided.

Summary of evidence and proposed NIAF rating	**Action completed, tested, but not yet embedded – 4**

The Trust has focussed on key elements of clinical monitoring using a range of improvement mechanisms and working groups such as the Fundamentals of Care Group, the Deteriorating Patient Group and more recently the Sepsis, AKI [acute kidney injury] and VTE Steering Group, with oversight from SGAG, the Quality Committee and through the Integrated Performance Report to the Board.

Policies have been updated to ensure they are in line with national best practice guidance. This includes Guidelines for the Escalation of Acutely Unwell Patients and also the Nutrition Policy for Adult Inpatients when it was recognised that information on TPN was limited and a separate policy was required. Microbiology advice is also now available seven days a week, in and out of hours, and guidelines/contact details are communicated to staff.

It was not possible to comment on all aspects of this recommendation during our on-site Current Case Review in October 2022, as we saw no cases where TPN, food charts or out-of-hours microbiology advice were an aspect of care. But our review did find that VTE assessments were inconsistently completed despite a good proforma being available. MUST recording was generally good for patients with a longer length of stay and we saw evidence of the NEWS2 score being effectively employed to escalate concerns to the medical team. These findings are reflected in Trust audits which found:

- although improving, the Trust is not achieving the 95% standard for VTE assessments;
- 92% compliance with first MUST assessments and 87% for subsequent assessments; and
- 92.9–97.2% compliance with NEWS2 e-observations over the last six months.

Further improvement plans are being progressed to improve compliance in all cases.

Section 1c: Recommendations from the Index Case Report

Recommendation 24

Standard operating policies and procedures

The Trust must ensure the following are up-to-date and subject to regular audit:

- the identification and management of Urosepsis and obstructed kidneys;
- the identification and management of sepsis and the deteriorating patient;
- the management and registration of stents;
- handover of patients between on call Consultants;
- consenting guidelines, including actions to be taken when patients cannot consent and when emergency surgery is required;
- interspecialty referral processes; and
- recording decisions made when a patient is referred to Intensive Treatment Unit (ITU), the escalation of capacity issues and a clear protocol regarding options when ITU is full.

Summary of evidence and proposed NIAF rating | **Action completed but not yet tested – 3**

The policies referenced within this recommendation have been updated in line with national best practice guidance although ratification of the Emergency Management of the Infected Obstructed Kidney SOP is ongoing. This has now been cross-referenced with the Trust wide Sepsis Management in Adults Policy to ensure consistency of terminology and is due to be presented to the Urology Audit and Governance meeting in March 2023, with a view to Care Group and Trust approval in April 2023. While training requirements are specified (where required), mechanisms for monitoring compliance with the policies are not cited in all cases; a revised template has been introduced which may support completion by authors of new or updated policies going forward.

There have been a number of audits in relation to the management of sepsis, the management and registration of stents, the deteriorating patient, and consenting. We have seen no specific Urology review of the effectiveness of interspecialty referrals although this aspect of care is included in other audits such as for the Urology Interventional Radiology In and Out of Hour Pathway and emergency transfers from FGH to RLI.

The process for recording of decisions when a patient is transferred to the ITU, or the escalation and management of the patient when the ITU is full is detailed in the Critical Care Admission, Discharge and Operational Policy (v4 drafted in November 2022). An Adult Critical Care Peer Review Report (July 2022) identified that the decision to admit was not always documented and that an audit of documentation would assist the unit to evidence compliance with the four hour admission standard. Bed occupancy and delays in accessing beds are monitored but we can see no evidence of the audit that was recommended having been progressed.

Policy/SOP	Date	Audited
Emergency Management of the Infected Obstructed Kidney	2023	Yes
Sepsis Management in Adults	2023	Yes
Stent management (various)	2022	Yes
Handover (Urology Handbook)	2022	Yes
Consent to Examination or Treatment	2021	Yes
Interspecialty referrals (Urology Handbook)	2022	Partial
Critical Care Admission, Discharge and Operational Policy	2022	Partial

(continued overleaf)

Section 1c: Recommendations from the Index Case Report

Recommendation 24

Summary of evidence (continued)

During our on-site Current Case Review in October 2022, there were not enough patients in the sample to comment in any depth about the management of obstructed kidneys and urosepsis. However, for six out of the nine patients, sepsis screening tools were used effectively, and subsequent responses were in line with expected guidelines. The introduction, effective use and monitoring of the stent register has also helped significantly to ensure that stents are removed or replaced within agreed time frames. Consenting and handover processes have improved and are covered in recommendations 18 and 44 respectively. We could not comment on other aspects of this recommendation as the sample of patient case notes did not include these areas of care although we noted some good examples of effective interspecialty working between the medical/surgical teams.

Recommendation 25

Nephrostomy service

- The Trust and Clinical Commissioning Groups (CCGs) should review arrangements for out-of-hours nephrostomy provision, including over bank holidays and emergency cover.
- The arrangements that have been put in place should be assessed to ensure that standards for accessing nephrostomy provision out of hours and for returning patients to the Trust are appropriate, agreed, and form part of a standard operating procedure that is audited to confirm compliance.

Summary of evidence and proposed NIAF rating	**Action completed, tested, but not yet embedded – 4**

Out-of-hours nephrostomy provision has been reviewed by the Trust and the ICB through the Lancashire and South Cumbria Interventional Radiology Working Group. Guidelines for in- and out-of-hours care have been approved, and these are supported by a flow chart which clearly depicts the steps to be taken and the process for reporting incidents if required. Where stenting is not possible for a patient at the Trust, they may need to be transferred to the Royal Preston Hospital for insertion of a nephrostomy. There is, however, no service level agreement for this and some of the staff we interviewed felt that this would strengthen the arrangements that have been agreed and ensure this backup service is in place when required. An agreement for repatriating the patient also needs to be in place so that patients are promptly returned to the Trust's care.

The nephrostomy pathway was subject to an audit in December 2022 to assess compliance. This resulted in modifications being made that clarified the referral and monitoring requirements of the process.

During our Current Case Review we noted one patient who required nephrostomy insertion. The patient was transferred from FGH to RLI before then being transferred to the Royal Preston Hospital. It is unclear why the patient could not have gone directly from FGH to Preston to avoid an unnecessary transfer.

There is evidence of review of the existing guidelines for nephrostomy in the action tracker to the Niche Support and Review Panel, which is attended by commissioners. The audit work on nephrostomy is not, however, referenced on the Urology audit plan.

Section 1c: Recommendations from the Index Case Report

Recommendation 26

Mortality review (Link to R10 and R15)

- Any post-operative death should be subject to rigorous and contemporaneous case review and monitored at Trust level. This would also help support accurate reports to the Coroner if required to be written some months post-death.
- Death summaries and sudden death reports to the Coroner should be audited for quality/accuracy.
- Every inpatient death within the Surgical and Critical Care Group (S&CC) should be reported and subject to case review, this review should be shared within the department and at Trust level.
- Every inpatient death in Urology services and other surgical specialties should be discussed in departmental meetings.
- Every inquest involving the Trust must include consideration of whether an incident might have occurred that requires investigation and to prepare statements/reports in an adequate timeframe.
- Statements to Coroners written in relation to whole episodes of care involving a team or a Trust service should be subject to validation by legal or corporate services to ensure that all parties have a right of reply (where needed) and that statements made are accurate. This is distinct from an individual health care professional providing a witness statement solely in relation to their own input.
- Failures in care identified as a result of producing a Coroner's statement must be reported as an incident and any named individuals given a right of reply.
- The Trust's Providing Statements to the Coroner Standard Operating Procedure should be revised to include the above.
- The Trust must assure themselves that the Providing Statements to the Coroner Standard Operating Procedure is being complied with. Statements should differentiate between fact and opinion. In addition, there should be a clear indication of how the statement has been compiled.
- The Trust should ensure that records are retained post-death and copies made for the purposes of review and investigation to mitigate the risk of retrospective entry.
- [The Medical Examiner role was introduced in the Trust in April 2020; this function should be assessed against the above recommendations].

Summary of evidence and proposed NIAF rating	**Action significantly progressed - 2**

Also see recommendations 10 and 15 for bullet points 1–4 of the recommendation above. This rating focuses on the remaining points 5-11.

We were provided with a list of 12 Urology related structured judgement reviews (SJRs) and the evidence that eight had an associated incident. It is not possible to tell if this was incidental or was a result of the SJR. There is no prompt in the SJR proforma to report an incident.

A full and comprehensive audit of 2021 death summaries was completed of 17 cases in or involving Urology. The audit set a high standard for assessment against seven standards. It concluded that there was no Trust policy for the completion of death summaries and that death summaries should be completed within 48 hours. Results from the audit showed:

- 94/100 death summaries were completed and 82/100 causes of death were completed.
- 29/100 family discussions were recorded and 47/100 had an accurate diagnosis.
- 88/100 had documented Coroner referrals and 82/100 included post-mortem information.

A re-audit was recommended and a February 2022 discussion of the results of the death summary audit within the Urology Audit meeting showed the desire to achieve 100% on the next audit although we have seen no evidence of this being included on a forward audit plan. The audit confirmed the need to improve the quality and thoroughness of SJRs but we can see no evidence of the actions from the audit informing improvement plans.

(continued overleaf)

Section 1c: Recommendations from the Index Case Report

Recommendation 26 (continued)

Summary of evidence (continued)

As part of our review of SJRs, we were able to speak with the Medical Examiner Offices and the Regional Medical Examiner. Our review evidenced a prompt and comprehensive service in relation to the nine Urology cases that we considered.

There is clear guidance on writing statements in the Trust's Providing Statements and Confirming Attendance at Inquests to the Coroner SOP and in national guidance, although there remains the issue that Coroner statements are necessarily written by an individual about their personal input. The Trust has added the following into the current SOP, "*consider whether the statement raises any issues that require input from other staff to confirm accuracy or present an alternative point of view. If so, this should be notified to an appropriate senior clinician and governance representative and further statements requested as required*". This goes some way to addressing the issue, by putting the onus on the individual. We have been told that draft statements are subject to independent review by the Legal Services Team to confirm they are clear and comprehensive but we are not convinced this would prevent a similar situation from reoccurring (i.e. one member of the team submitting an unvalidated view of clinical care that could imply criticism of the practice of others without a right to reply).

The revised SOP was shared with staff in 'Weekly News' via a link to the 'Documents uploaded in the last 30 days'; however, it is the responsibility of the author (or dissemination lead identified in Section 10 of the document template) to ensure that the requirements of the procedural document are communicated to relevant staff. Changes have now been communicated to all Trust staff via a 'Friday Round Up' global email and on the Legal Services internal web page in March 2023.

Evidence has been supplied to support incidents having been raised following inquests and the submission of statements for the Coroner.

The Providing Statements and Confirming Attendance at Inquests to the Coroner SOP requires audits to be undertaken each quarter, with the first due at the end of March 2023. In the interim, the Trust has audited 12 randomly selected files, three for each Legal Services Officer, to confirm the statements have been appropriately reviewed in line with the monitoring section of the SOP and required outcomes. This audit is incomplete with seven cases not yet having received the statements that had been requested.

Section 1c: Recommendations from the Index Case Report

Recommendation 27

Managing complaints and compound family questions

- The Trust's Management Procedure for the Investigation and Resolution of Complaints should be reviewed to ensure advice is clear on the handling of persistent/compound complaints that are not vexatious.
- Repeated approaches/compound questions from a family in relation to concerns in care, including the death of a loved one, should be formally logged as a complaint.
- These cases should be allocated an appropriate single point of contact or family liaison officer to manage the process and support the family. These cases should also be flagged and carefully monitored as they have potential for extended resolution timescales.
- Any case involving an inquest or complaint from a family should also be reviewed to determine whether it should be recorded as an incident(s). Any subsequent investigation and complaints processes should be managed in a coordinated fashion.
- Compound complaints often arise once medical records are provided as these may be incomplete (due to archiving and multiple patient record systems). The Trust should ensure that full sets of medical records are provided at the outset of the request in line with existing Freedom of Information Act (FOIA), Subject Access Requests (SAR) and Access to Health Records Policies.
- Clear guidance on sharing the medical records of deceased patients with families should be set out to ensure that relatives are provided with requested information promptly and in line with the appropriate legislation.
- When FOIA or SAR include requests for email-based information, all searches should be formally logged and centrally managed so that the Trust has a full record of searches available to them.

Summary of evidence and proposed NIAF rating	**Action completed but not yet tested - 3**

The Investigation, Resolution and Learning from Complaints Policy has been revised with ratification of v11 and v11.1 by the Procedural Document Group Chair's Action in January 2023. A training and awareness programme is being developed to ensure a consistent Trust-wide approach to complaints management, alongside an audit programme to support continued improvements and compliance.

The revised policy includes that a Case Officer will be assigned to the complaint and will remain the single point of contact for the complainant/family for the duration of the complaint. It also details the process for 'unresolved' or 'persistent' complaints and states that repeated approaches/compound questions from a family about concerns in care, including the death of a loved one, will be formally logged as a complaint and/or dealt with according to criteria and a process which is described.

The policy directs staff to log an incident if it becomes apparent, either upon receipt of a complaint or during the investigation, that a serious incident requiring investigation has, or may have, occurred. While the policy states that complaints identifying low harm do not require incident reporting, a process has been introduced to review all new complaints at the Trust-wide Daily Triage Meeting with incidents reported if required.

The Trust also has a Managing Access to Health Records and Images Request SOP (September 2021). This includes time frames for the sharing of clinical records. A recently revised version (v5.1, undated) now covers requests for information held outside of the health record (for example, email correspondence) and a requirement to complete weekly audits to ensure that access to health records requests are appropriately responded to, although we have not seen evidence of these being completed. These changes are very recent and it will be important to ensure robust engagement with the medical records, information governance and subject access request teams to ensure compliance and testing going forward.

(continued overleaf)

Section 1c: Recommendations from the Index Case Report

Recommendation 27

Summary of evidence (continued)

While the Freedom of Information SOP (July 2021) covers all recorded information (for example, drafts, emails, notes, recordings of telephone conversations) and the requirement to register new requests, we can see no requirement to log all searches. The process for dealing with requests for deceased patients is described.

The Trust is tracking compound complaints (through re-visits) and has developed a complaints dashboard which flags the status of complaints for each of the care groups.

As an indicator of the risk of compound complaints, during 2021/2022 the Trust received and formally responded to 337 complaints; 75 (22%) of these complainants requested the to Trust revisit their case following receipt of the formal response. This is a rise of 5% from 2019/20 when the number received was 438 with 17% requesting a further response; however, the reduction in the number of formal complaints is noted. The Trust was involved in 10 preliminary Parliamentary and Health Service Ombudsman (PHSO) investigations during 2021/22, with no cases requiring further progression.

Recommendation 28

Consultant relationships

- The Trust should pay particular attention to any grievance raised by a Consultant or senior medical member of staff about another peer. Prompt and diligent investigations should be undertaken to ensure that the basis of concerns is fully understood and properly actioned to resolve peer-to-peer difficulties and concerns in a transparent and effective manner.
- The Board should be made aware at an early stage of any specialty where relationships may be failing as this is a key patient safety marker. The Board should monitor actions to achieve improvement. This should be undertaken via the Employee Relations Report.
- The Medical Director should be informed of any concerns about Consultant relationships (as Responsible Officer).

Summary of evidence and proposed NIAF rating — **Action completed but not yet tested – 3**

A Professional Standards Group was established in February 2022. However, meetings have been hampered by operational challenges; the most recent meeting was held in September 2022, when they met to discuss the intended role of the group and to review its ToR. When fully established, this will allow senior clinical and non-clinical staff to advise, support and action where performance concerns or complaints have been raised either in relation to individuals or groups of staff and will clearly describe routes of escalation (for example, to the Medical Director, the Executive Director Group, the People Committee and the Board, including through Employee Relations Reports with exceptions arising from this report taken to the private sessions of the Board of Directors' meetings). The ToR appear to ensure appropriate membership and methods for reporting. A 'clinician concern management flow chart', drafted in October 2022, supports this process and clearly depicts the steps that a medical practitioner can take when raising concerns about a peer.

In addition, the Medical Director has monthly meetings with representatives from the Human Resources department to discuss appraisals, revalidation, grievances and GMC cases. They also attend, and have supported presentations to, the Regional Responsible Officer Network, which has been looking at clinical dispute resolution to further improve early identification and resolution of team dysfunction.

We have been told that the Maintaining High Professional Standards (MHPS) Policy is under review and that agreed actions and escalation routes will be described within a flow chart that will be incorporated into the revision. This document has not been shared with us.

Section 1c: Recommendations from the Index Case Report

Recommendation 29	
Triggers for external investigations • Terms of reference for all externally commissioned investigations should be scoped individually and quality assured to ensure that patient/family questions are included and that specific Trust concerns are addressed. (This principle should be followed for all root cause analysis (RCA) and serious incident (SI) reports undertaken internally in line with good practice). • The Trust should develop a set of triggers for external investigations to be undertaken including when departmental dysfunction is apparent. • The Trust should revisit its tolerance for requesting external support in investigations.	
Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**
A Commissioning, Managing & Reviewing on Internal and External Service Reviews procedure was revised in November 2022 with defined triggers for both internal and external reviews. These include consideration of indicators that might suggest team dysfunction. The procedure also includes a requirement for terms of reference to be scoped individually and quality assured to ensure that patient/family questions are included and specific Trust concerns addressed. There is a standing agenda item on the weekly Executive Directors Group for discussion of organisational 'hot spots' which might need further scrutiny and review. Potential triggers for internal and external investigations are then presented for further discussion at Integrated Performance Review meetings for each of the care groups and we have seen evidence of this happening in practice. When interviewed, the ICB also demonstrated awareness of the work undertaken by the Trust to document a methodology for the triggering of internal/external investigations that incorporates the consideration of team dysfunction.	

Section 1c: Recommendations from the Index Case Report

Recommendation 30

Clinical records in the form of emails (Link to R34(E))

- The Trust should add all Consultant staff email accounts to their Very Important Persons (VIP) list for a period of seven years once employment is ended.
- The Trust should revisit its record-keeping policy as regards the use of email communications between clinicians containing clinical information. This should include:
  - clarification of what is an acceptable use of email in sharing patient specific clinical information, both internally and externally, to the Trust (including in clinical networks);
  - ensuring that where patient specific clinical information is shared by email (if appropriate) that these communications are retained as part of the clinical record;
  - revisiting the Trust email archiving policy, in light of the above, to ensure that emails can be retrieved where necessary (for example for SAR purposes); and
  - that all professionals should record the fact that an onward communication has been made within the clinical record.

Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**

The Clinical Records Management Policy includes a retention schedule that details a minimum retention period for each type of health record, including emails. The VIP Policy has also been revised to confirm that VIP accounts include Board members, Consultants and Matrons and that these will be flagged to indicate they should be retained for seven years (CEO for 20 years).

The Trust's Acceptable Use Policy for Information Communication and Technology Systems and Equipment confirms that emails may be disclosed under the Data Protection or FOIA, including deleted items, and that these can be used in legal/disciplinary proceedings. Revised record-keeping guidelines support this policy and clearly state the expectations of email use when the email contains patient identifiable information. This aligns with the use of encryption when sending external emails.

Section 1c: Recommendations from the Index Case Report

Recommendation 31

Clinical dispute resolution

The Trust should introduce a mechanism of escalation, separate to the existing grievance and Freedom to Speak Up processes, whereby clinical disputes (in MDTs, between individuals or within departments) are formally mediated and resolved. The responsibilities for professionals involved in the event to engage in this mechanism of escalation should be made clear. This should be supported by a formal policy and should detail timescales for reporting, arbitration, resolution, and the trigger for the involvement of independent clinical adjudicators. Processes to report into other forums (such as Clinical Governance, Mortality Review, Ethics Committee and Revalidation) should be made clear within this policy.

Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**

This recommendation was aimed at providing a non-adversarial mechanism that can deal with a range of situations where a senior medical professional can seek clinical support or escalate concerns about decisions within a team where the presenting challenge sits outside normal escalation processes. During our investigation we identified cases of clinical disagreement as well as lone decision making that did not have a pathway through which to go and therefore fell through the gap of existing processes.

The Trust does have an Early Resolution Policy (Behaviours at Work) that was ratified in 2019. This is aimed at finding constructive and lasting solutions to workplace disagreements, conflicts and complaints about behaviours at work. It includes a process for requesting resolution support through, for example, formal mediation, individual/team learning and organisational development intervention. This policy has not been reviewed since 2019, but is due for review in May 2023. The revised policy will need to ensure all aspects of this recommendation and dispute resolution are covered; in particular where mediation or other forms of resolution between clinical team members is required on either a clinical decision or relationship difficulties.

A Professional Standards Group has been set up to advise on the management of performance concerns or complaints about senior clinicians and ensure all concerns are managed in accordance with relevant policies, including MHPS. The group intends to meet monthly, however, this has been hampered by the operational pressures faced by the Trust and wider NHS during winter 2022/23. The most recent meeting was held in September 2022 when they met to discuss the intended role of the group and to review its ToR. The Trust also intends to review and revise its MHPS Policy in early 2023. We understand that a revised ToR will be considered at the April 2023 meeting.

Steps have also been taken to clarify the process by which a Consultant or senior clinician would raise concerns; and a Clinical Concern flow chart was developed in October 2022. This is a stand-alone document but we note that it is not aligned with other policies for ease of reference for staff. The flow chart sets out who should initially be alerted to a concern, how a concern should be escalated, and what the role of key leaders is.

The Executive Director Group meetings include a standing agenda item titled ‘Hot Spots’ under which it receives the Employee Relations Report. We have been told that there have been no concerns raised in relation to Urology during 2022. In December 2022, an internally announced Quality Service Review was carried out across the Urology service to consider culture and relationships. The draft report notes that there are “*improved professional relationships*” and staff morale.

We are still not yet assured that if similar issues arose there is a mechanism (albeit rare) that would be suitable for resolution. This has been discussed by the Trust at the Regional Responsible Officer’s Meeting and also the National Executive Quality Group in an attempt to seek support in addressing the recommendation. Regional teams have agreed that further guidance would be welcomed and the national team will be working on a solution to ensure a unified approach going forward.

Section 1c: Recommendations from the Index Case Report

Recommendation 31 (continued)

Summary of evidence (continued)

The Trust has recognised that further work is required in this area and have agreed the following actions and timelines for delivery:

Action	How will we demonstrate completion	Deadline for completion
Describe a mechanism for resolving lone decision making/clinical disagreement. National work on this topic to issue guidance to Trusts is ongoing in this area which will support the development of this policy. The national work needs to conclude and the associated guidance published before the policy can be developed and introduced.	Development of a policy on lone decision making/clinical disagreement.	Within 3 months of national recommendation being available
Review of the Trust Early Resolution Policy to ensure all aspects of the Trust's approach to mediation or other forms of resolution between clinical team members is referenced.	Ratification of a refreshed Trust Early Resolution Policy.	June 2023
Ensure the Professional Standards Group meets regularly.	Records of meetings and attendance.	June 2023
Alignment of the Clinical Concern flow chart with other Trust policies on the escalation of concerns to enable ease of reference for staff.	Introduction of a revised Clinical Concern flow chart that is aligned with other Trust policies on raising concerns.	June 2023

1d: Recommendations 35-52 from the Independent Investigation Report (November 2021)

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 35	
Review Niche patient case studies The Trust should review all Niche case studies in priority order to contact patients in respect of Duty of Candour or ensure appropriate investigations have been completed to a high standard and actions have been implemented.	
Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**

During the initial Niche investigation, the Trust reviewed patient cases as they were identified to assess whether Duty of Candour was required. A further review of the patient list provided by Niche was undertaken in July 2022 with discussion at the weekly Support and Review Panel meetings (these were established in July 2022 to '*monitor the actions identified to address the recommendations made within the Niche Independent Investigation into Urology Services (Final Report November 2021) and any subsequent recommendations from enquiries received*').

A further in-depth analysis of the case studies commenced in November 2022 with a paper provided to the Quality Committee on 16 January 2023, outlining the progress to date. This included that during November and December 2022, the Governance Team had carried out a review looking at the 14 prioritised cases that were highlighted in the November 2021 Full Investigation Report, and identified the next steps for each case.

An update paper to the Quality Committee presented on 23 February 2023 confirmed that all 573 Niche case studies had been reviewed in priority order:

- For the high-priority cases (graded 6–9) this resulted in the initiation of seven 72-hour reviews, three claim reviews and two mortality reviews (these latter reviews have been completed).
- A thorough analysis was undertaken for the lower-priority cases (graded 1–5). The review ensured triangulation of incidents, complaints, claims and any other correspondence. In most cases (176) no further action was deemed necessary because no or low harm had been caused, because actions had been completed since 2019, because there was evidence of Duty of Candour being enacted and/or there was evidence of completed Niche recommendations that addressed the actions and learning from the patient incident, complaint or claim. 34 cases require further action, which is currently being progressed against the themes identified.

There is now a better understanding of the cases, some of which have been addressed or actions assigned. Progress against this recommendation is being shared monthly at the Quality Assurance Committee until all actions are complete.

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 36

Urology pathway priority management

- There is a need to redesign follow-up pathways for Urology patients to match capacity and demand to prevent backlogs and balance this with the faster response for new referrals. Clear protocols for long-term active surveillance which ensures cases are appropriately seen at the right intervals are required.
- Advance booking for long-term surveillance procedures should be introduced (including stent replacement and cystoscopy) and audited to ensure delays are minimised.

Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**

The Urology service has introduced a number of patient initiated follow-up pathways for better capacity and demand management. They allow patients and their carers the flexibility to arrange their follow-up appointments as and when they need them. Information leaflets, which include contact details for the Urology team, are provided to support this process. Nurse-led clinics are also being increased to offer extra support.

The department has refreshed a number of pathways and policy documents, including for prostate cancer and stent management, to more clearly describe the administration and booking of follow-ups. Staff reported in the December Service Review by senior Trust and ICB staff, that they did not feel there was enough engagement on the prostate cancer pathway and that it did not take account of local challenges. However, staff also advised that they have provided feedback on pathways as part of the monthly audit meeting and work is underway to look at how pathways can work more effectively.

This is important as the Trust is under significant pressure, with a large backlog of patients who require follow-up appointments. Our Current Case Review in October 2022 (of cases up to August 2022) found that some patients were being followed up unnecessarily and could instead have been contacted by letter. We also found some cases where follow-ups were delayed, although the position appears to be better than it was in 2020. Our data analysis similarly found an increase in follow-up outpatient attendance for the financial year 2020/21, where the ratio jumped from 1.4 (2019/2020) to 2.2 (2020/2021). However, the ratio has now decreased and the current figure for the partial year of 2022/2023 is 1.3, which is the lowest ratio for the past 15 financial years.

The Urology team has submitted a business case for a dedicated Urology Investigations Unit, which will help them provide outpatient services more effectively. Approval for the unit has now been received.

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 37

Capacity and demand modelling in Urology

The Trust should undertake a capacity and demand modelling exercise (including the use of [Patient Level Information and Costing System] PLICS information) to provide an up to date baseline for the service and to support job planning. This should include:

- Medical staffing levels
- Junior staffing resources
- Administrative resource
- Nursing skills and a clinical nurse specialist role review

Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**

A modelling exercise was completed in September 2021, to inform the clinical operating model in Urology using an activity and capacity modelling framework. The baseline and potentials for outpatients and theatres have been described, with opportunities for nurse-led and other pathways (including for vasectomy, prostate biopsy, flexible cystoscopy, and contribution to clinics, including the One Stop Clinic). A quantified potential has been summarised through capacity requirements, workforce implications, priorities and delivery options. However, it is not clear about the involvement of key clinical Urology staff in the modelling exercise and whether they are aware of the modelling that has been undertaken.

The Remedial Action Plan for Urology captures the weekly demand and capacity gap. This was red rated in September 2022 (with a backlog of approximately 1,000 cases); we do not have more up-to-date information to understand whether this is an improving or deteriorating situation. Remedial actions are described, although we can see no evidence of progress updates on the plan that has been shared with us.

A business case has been recently approved for a dedicated Urological Investigations Unit. Urology outpatient services are currently delivered across five sites and it is anticipated that establishment of this unit will improve efficiency through the use of enhanced facilities which are equipped and staffed to offer a comprehensive range of Urology diagnostic and treatment interventions. Managing the balance between inpatient, day case and outpatient care has been identified by the team as an opportunity to streamline services and offer a better patient experience; it is anticipated that more patients can be diagnosed without needing to be admitted and that pressures on hospital facilities will be reduced.

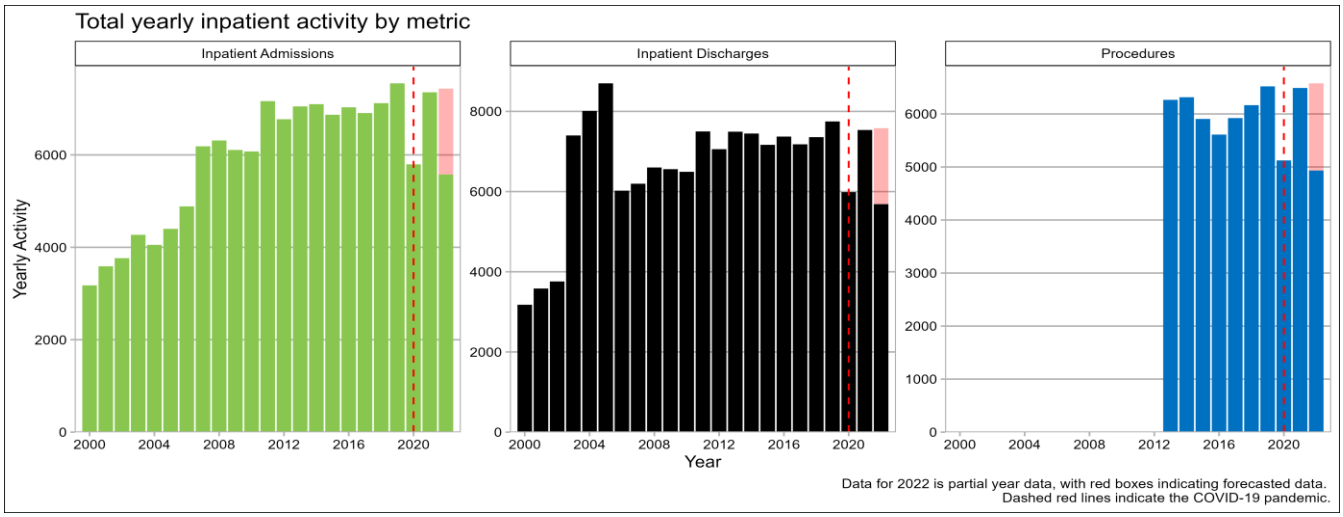
Our quantitative analysis shows that Urology demand has remained relatively static since our prior reports in 2021 (see graphs overleaf). It is important for new ways of working and skills mix to be part of future planning and training. The historical reaction to the lack of capacity has been additional clinics and this in turn has led to regular (reliable) AASs, which are costly and are often provided without understanding whether core clinical sessions are appropriately utilised (see recommendation 13).

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 37 (continued)

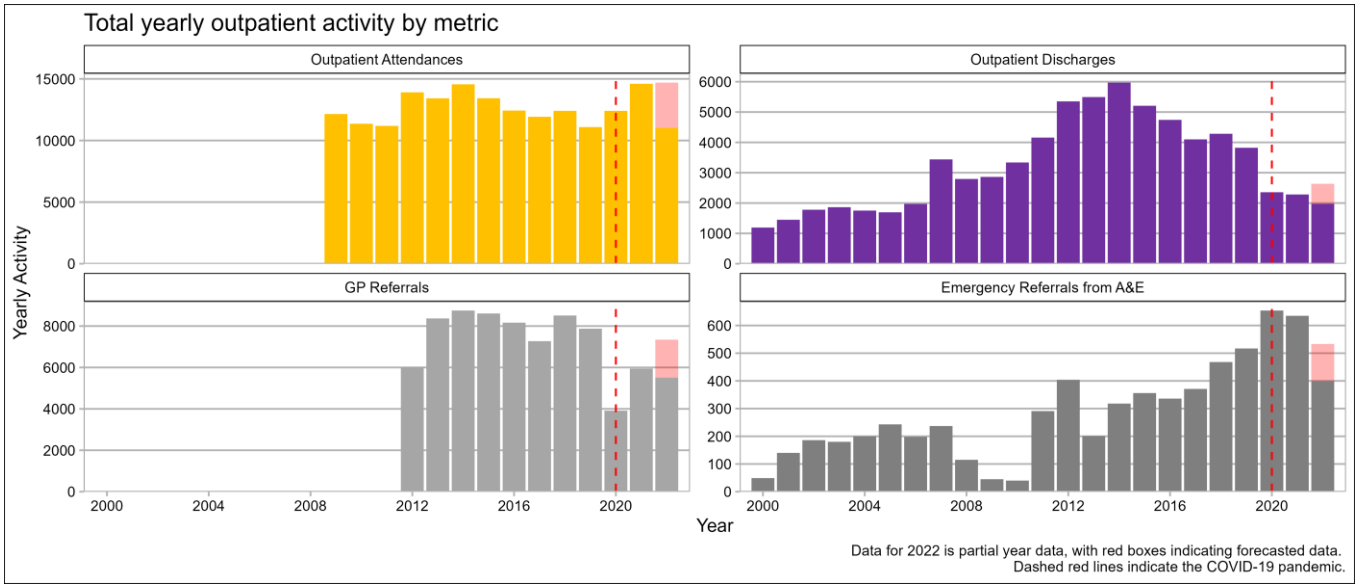
Summary of evidence (continued)

NB: pink sections show forecasted activity. Our data analysis has shown that over the last two decades there has been an overall increase in inpatient admissions. Although a dip can be seen since the COVID-19 pandemic, the admission rate appears to have returned to pre-pandemic levels. Prior to the pandemic, inpatient discharges had remained static since 2011. Other than in 2020, no significant fluctuations in the number of procedures can be seen.



Outpatient attendance remained broadly **static** before 2020, with a slight **increase** being seen since the COVID-19 pandemic. Outpatient discharges have **decreased significantly** over the last decade, with the biggest decrease in 2020.

GP referrals **decreased significantly** in 2020 and have not yet returned to pre-pandemic levels (although 2022 is a partial year). Emergency referrals from A&E have **increased** over the last decade. Although a decrease may occur in 2022, but this cannot be said with certainty due to there being only partial data for the year.



Section 1c: Recommendations from the Independent Investigation Report

Recommendation 38

Revisit and align all reporting policies

The Trust should revisit and recommunicate the following policies to ensure that the purpose is clear, that they are aligned to each other and that they are workable for staff to readily follow and apply when escalation is required. This should include a flow diagram so staff can see which policy to follow in which situation.

- Incident reporting
- Raising Concerns
- Grievance management
- Whistleblowing
- Freedom to Speak Up

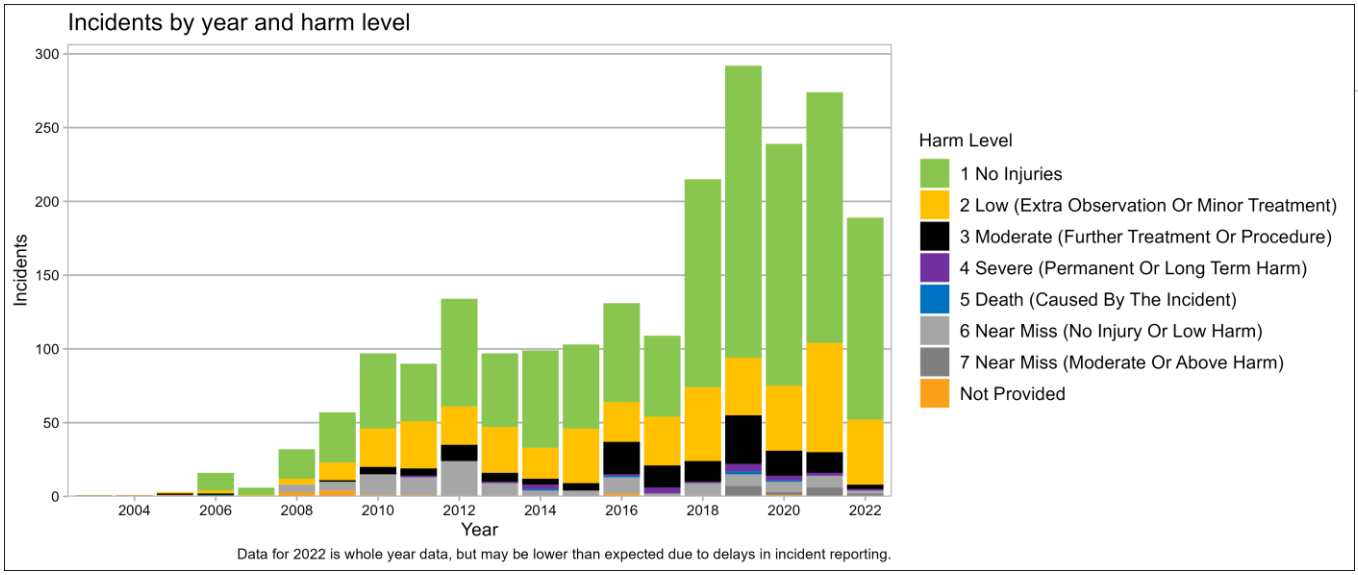
Summary of evidence and proposed NIAF rating | **Action completed but not yet tested – 3**

The policies referenced within this recommendation have been refreshed to ensure alignment with each other and to national best practice guidance. A 'raising concerns at a glance' infographic has also been approved, which describes what issues can be raised under which policy; although this has yet to be fully communicated and displayed in each clinical and non-clinical department to ensure it is used.

The triggers for internal and external investigation have been described (see recommendation 29) and the introduction of the Trust-wide Triangulation Group in combination with the introduction of thematic reporting (see recommendation 9) will help the early identification of 'hot spots' that will be escalated to the Executive team and the Board as required.

That said, the Board, care group and Urology service should be mindful of the trends in incident reporting. Our quantitative analysis indicates some reduced reporting, in particular among Consultant Urologists (who have reported minimal incidents) and for near misses. This needs to be understood to ensure that medical leadership and all staff are appropriately reporting patient safety incidents.

The graph below shows the latest status on incident reporting in Urology.



Section 1d: Recommendations from the Independent Investigation Report

Recommendation 39

A specialty focus

The Trust should identify key specialty metrics that enable focus on harms to be triangulated in sub-specialties of the Surgical and Critical Care Group (S&CC). This should include:

- A single monthly report on claims, incidents, Parliamentary and Health Service Ombudsman (PHSO), Never Events and complaints with a cumulative analysis of themes arising.
- At least biannual thematic reviews (regardless of whether complaints or claims are upheld) to understand any concerns being raised at the earliest possible opportunity.
- An annual reconciliation of claims and complaints and their conversion to incident reports should be undertaken to ensure all patient safety concerns are logged through the incident reporting process for learning.
- Learning and sharing relevant patient safety issues arising from MHPS investigations (which should be logged as incidents where appropriate).
- Use of the annual GMC National Trainee Survey results to ensure information on junior doctors' experience is considered as part of these metrics.

Summary of evidence and proposed NIAF rating | **Action commenced– 1**

A Patient Relations Annual Report (1 April 2021 – 31 March 2022) was presented to the Quality Assurance Committee in October 2022. This included information at a care group level on complaints, claims, PALS and referrals to the Parliamentary Health Service Ombudsman. Themes for each were described and some individual learning points but this does not include specialty hotspots, same causal factors are not described across all feedback groups or actions required to prevent recurrence of the same. We have not seen an annual reconciliation of claims and complaints and their conversion to incidents to ensure all patient safety concerns are logged through incident reporting processes for learning.

The Trust is in the early stages of developing and publishing a learning booklet with a specialty focus. This will summarise the latest learning from sources such as the British Medical Journal's best practice reviews, National Institute for Clinical Excellence (NICE) guidance, and Healthcare Safety Investigation Branch publications, alongside learning identified internally. We have seen an example from Maternity, published in November 2022; while this included the learning from one internal incident, significant progress needs to be made to ensure learning across all incidents, events, complaints, patient and staff feedback, is analysed and disseminated through the learning booklets.

The Trust has not fully progressed the action relating to thematic reviews. As referenced in recommendation 9, two Learn From Events Report have been presented to the Patient Safety Group and Quality Assurance Committee in 2023, and the establishment of an MDT Task and Finish Group are further supporting the development of these reports. We note that while some common themes and learning were identified, there was no reference to PALS (or other patient experience feedback such as Never Events and PHSO data) and there was little commentary about actions being taken to address any common causal factors. We understand that this is a priority for early 2023 with the Trust having identified one of its key patient relations priorities for 2022/23 as being "continue to focus on the early identification of themes and trends to ensure focussed improvements".

The Trust has established a Professional Standards Group, which will facilitate a consistent review of new and ongoing MHPS cases. This process has not progressed to the point of being able to share learning or links to incident information. The Trust has also not yet introduced the annual GMC National Trainee Survey results into the process; currently this sits with the Education Team, the Guardian of Safe working and the Care Groups.

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 39 (continued)

Summary of evidence (continued)

The Trust has recognised that further work is required in this area and have agreed the following actions and timelines for delivery:

Action	How will we demonstrate completion	Deadline for completion
Development of a mechanism for the annual reconciliation of claims and complaints which demonstrates their conversion to incidents and provides organisational oversight of all patient safety concerns, ensuring they are logged through incident reporting processes to facilitate learning.	• Presentation of the 2022/2023 annual reconciliation at the July 2023 Quality Assurance Committee (QAC). • Inclusion of the annual reconciliation in the QAC annual workplan.	1 July 2023
Review of the mechanism for the production of speciality learning booklets to ensure the process facilitates the capture of learning opportunities from all incidents, events, complaints, patient and staff feedback.	• Continued publication of the monthly 'Learning To Improve' Newsletters (March 2023 published, April 2023 edition prepared). • Inclusion of lessons learnt from the breadth of the areas listed in the action section in the May 2023 newsletters. The product will continue to develop in terms of content over 2023/24.	May 2023
Development of a revised approach to the production of Learning to Improve Newsletters to ensure it includes reference to themes arising from patient experience feedback and data and actions being undertaken to address common causal factors identified via thematic reviews.	• Presence of a section in the Learning to Improve Newsletters highlighting improvement themes identified from patient feedback and the Trust's Patient Safety Partners. • Presence of a section in the Learning to Improve Newsletters addressing common cause factors and associated actions being undertaken.	May 2023
Process to be established to demonstrate how the annual GMC National Trainee Survey results will be reviewed by the Trusts Professional Standards Group.	• Inclusion of reference of oversight of the GMC National Trainee Survey results in the ToR for the Professional Standards Group. • Inclusion of the GMC National Trainee Survey results in the Group's annual workplan. • Confirmation of the first review date of the GMC National Trainee Survey results by the Professional Standards Group.	May 2023

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 40

Implement clinical audit programme (Link to R4, R9, R14, R18, R25, R41, R47)

A standard should be set for each of the following against which a clinical audit programme should be implemented:

- Handover quality
- Emergency surgery including access to and use of theatres out of hours
- Emergency transfers from FGH to RLI
- Stent register compliance
- Results review and acknowledgement
- MDT referrals, implementation of actions, attendance and quality of behaviours
- Out-of-hours support from junior doctors
- Ward round management
- Consenting practice
- Continuity of care
- Harms as a result of delayed follow ups and IRDs
- Application of National Institute for Clinical Excellence (NICE) guidance

Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**

This summary needs to be read in conjunction with the recommendations listed above and also recommendations 12, 16, 19, 24, 43 and 44.

The Trust has policies or SOPs for all the items listed within this recommendation. We have also seen evidence of the 2023-24 Urology Forward Audit Plan (dated September 2022), which lists a range of level 1 to 4 audits, external and internal must dos and divisional priorities. These include "*Niche recommendation 40*" audits marked as "*external must do*". Each includes the standards for audit, which are aligned with local and national guidance. All audits have been completed with largely positive outcomes. Planned re-audits and PDSA cycles will help to assure that improvements are sustained going forward.

It was not possible during our on-site Current Case Review to comment on all aspects of this recommendation. We could not see sufficient evidence of the required practice for handovers, emergency surgery and access to theatres out of hours, out-of-hours support for junior doctors (although in three cases this was available either in person by a Consultant or via telephone advice), harm as a result of delayed follow-ups, and application of NICE guidance.

However, our review aligned with results from the Trust audits which evidenced improvements in relation to transfers from FGH to RLI, consenting practice, MDT referrals and implementation of actions (see recommendation 41), stent register compliance, results review and acknowledgement (see recommendation 19).

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 41

Cancer MDT management

The Trust, with the Cancer Alliance, should:

- Agree and implement new Standards of Care (SoC) in line with the advice of the Streamlining MDT Meetings guidance.
- Clarify the expectations of core members at both local and network MDTs and the expectation for named Consultant Urologists to present their cases. A deputy role for the chair of the local MDT should be put in place.
- Ensure that all core members attend the MDT as agreed above.
- Audit the new processes to ensure alignment with the introduction of the named Consultant.
- Ensure responsibility for actioning decisions made at the local MDT is maintained within the Trust.
- Ensure there is clarity for responsibility for actioning decisions made at the network MDT.
- Ensure that professional behaviours are demonstrated at both local and network MDTs and confirmed through observation and transparent feedback on a regular basis for all attendees.

Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**

A Cancer MDT SOP was adopted in March 2022, and lists the roles and responsibilities of MDT members and also the required actions and communications which need to result from the meetings.

The Trust uses the Somerset Cancer Register for recording MDT meetings; documentation and governance have improved since our 2020 review and as confirmed through observations by the Cancer Quality Improvement Lead for the Cancer Alliance, but streamlining has yet to occur.

Recordings of the Urology MDT meetings for 2022 have been shared with us and behaviours appear to have improved significantly. Team members were asked to give their views on areas where specialist expertise was required and all attendees listened fully to the advice given. In relation to attendance, the lead Urologist gave a brief summary of the case when available; however, this is not possible in all cases (see commentary on the named Consultant in recommendations 12 and 16).

We were informed that all Urology Consultants are expected to attend MDTs as a way of implementing good communication and ensuring continuity of care/supporting the named Consultant model; this is a positive move and one which was enacted when the new rota commenced in November 2022. All Consultants are now timetabled to attend the MDT unless they are on-call. Although improved, individual attendance for 12 meetings between 1 December 2022 and February 2023 still varied from 33.35% to 83.3%.

The Quality Improvement Lead for the ICB and Cancer Alliance gave a presentation to the Urology team on streamlining Urology MDT meetings (date unknown). This described their observations of the current MDT meetings, which were largely positive (including verbal collective agreement on outcomes) apart from fitness and social information not always being readily available and this leading to frustrations within the team. The requirements for the governance and implementation of SoC were described. This resulted in a number of recommendations being made, including '*the development of the relevant standards with sign off by the clinical lead for that tumour site in collaboration with the Cancer Alliance Tumour Board; and a process for triage agreed at Trust-level with roles and responsibilities set out for referring clinicians, those involved in reviewing cases and the MDT Chair (this may require adaptation of job plans*)'.

(continued overleaf)

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 41

Summary of evidence (continued)

While we have not seen evidence of an action plan being progressed or monitored for these recommendations, we are aware that a number of pathway SoC have been agreed locally (for example, the Perfect Prostate Pathway) and by the Cancer Alliance (Protocols for the Management of Patients with Urological Malignancy). We were told during our interviews that streamlining has yet to occur. There have been some delays in the development of Standards of Care, as there was a recruitment process going on for a new Trust Cancer Lead. A Consultant Surgeon has now been appointed to this role and it is hoped that this will now be further progressed.

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 42

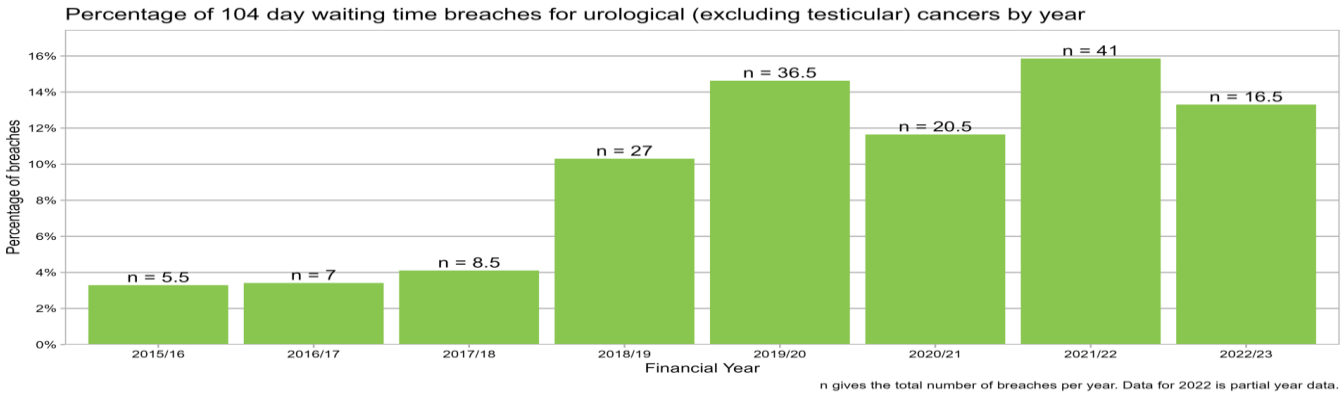
104 day cancer breach root cause analysis

- Ensure all 104 day cancer waiting time breaches are subject to a root cause analysis (RCA) and thematic reviews are acted upon to ensure pathway problems are properly identified and improved.
- The Trust should follow the newly released (October 2021) North West Guideline: Managing Long Waiting Cancer Patients.

Summary of evidence and proposed NIAF rating | **Action completed but not yet tested – 3**

The Trust's Reporting and Management of Incidents including the Serious Incidents Procedure, sets out the arrangements for reporting and managing all incidents. Some incidents have an agreed process to follow once an incident report has been submitted; this includes the 104 Day Delays in Cancer Treatment Incidents Process, which require a specific questionnaire to be completed for all reported delays, instead of a RCA. The questionnaire concludes with a harm rating (physical and psychological) and incorporates contributory factors and lessons learned.

104 day breaches are reported at the S&CC Governance and Assurance Group, the Quality Committee and the Board. Our quantitative data analysis can be seen below:



Quarterly thematic reporting is being carried out in line with the North West Guidelines: Managing Long Waiting Cancer Patients. In October 2022 the report identified the total number of breaches (13, seven of which were for Urology), overdue reviews (two, one of which was for Urology) and an analysis of themes by specialty with some actions described. Cross-specialty themes were not described. Supplementary audits are taking place to ensure that actions are being implemented to prevent delays or are responded to appropriately once breaches have occurred.

A Trust Cancer Board has been established with draft ToR, agreed in December 2022. Members will – among a range of other tasks – advise on and challenge plans to improve the delivery of cancer services across all tumour sites as identified within the cancer strategy; and advise on overarching themes from monthly performance analysis, including breach report analysis, harm reviews and action plans. The effectiveness of this meeting has yet to be determined.

Commissioners have routine oversight of 104 day breaches through the Safe Today Report and the Trust's Integrated Performance Report. Positive feedback has been received from the Cancer Alliance on the implementation of the North West guideline. However, in November 2022 the ICB reported through their Assurance Review Plan some continuing weaknesses in assurance, including not receiving investigation reports where the threshold is below Strategic Executive Information System reporting, and limited evidence of the impact of actions taken as a result of these incidents.

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 43

Emergency theatre access

- The Trust should monitor the use of emergency theatres out of hours in Urology (building on the analysis provided in this report) to establish whether the existing Standard Operating Procedure (Theatre Access) is effective in changing the pattern of practice highlighted by this report.
- This should be examined in the context of whether some emergency theatre demand could be reduced through the provision of ward based facilities.

Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**

The Trust has a range of policies and procedural documents which support the appropriate listing of patients for elective or non-elective surgery. Theatre start times and the use of vacant theatres have been reviewed with options for improvements submitted to the S&CC Group for approval. A risk has also been added to the risk register to reflect the absence of a dedicated NCEPOD list for surgery. This states that "*In-hours Urology patients need to be operated upon on a dedicated general surgery list requiring negotiation with general surgeons, which can result in delays in managing emergency Urology patients, such as infected obstructed kidneys for stenting*". However, our quantitative analysis indicates that less emergency surgery is being conducted out of hours than previously (see graph overleaf).

A business case was submitted and recently approved for a dedicated Urological Investigations Unit. It is anticipated that this will facilitate the more effective delivery of Urology outpatient services through a comprehensive range of diagnostic and treatment interventions. It is anticipated that this will also help to reduce the need for theatre time because some procedures can take place in the unit instead of needing theatre space, although it is recognised that it will take some time to open and operationalise.

That said, our assurance review data analysis found that the total number of emergency operations by Urology at the Trust decreased from 2016/17 onwards (see graph overleaf). This is mainly due to a decrease in the number of out-of-hours operations, with the most significant decrease in 2021/22. Between 2013/14 and 2020/21, 62% of operations occurred out of hours, whereas between 2021/22 and 2022/23 this dropped to 48% with an overall reduction in emergency surgical cases. However, out-of-hours emergency surgery appears to fall to a small number of Consultants.

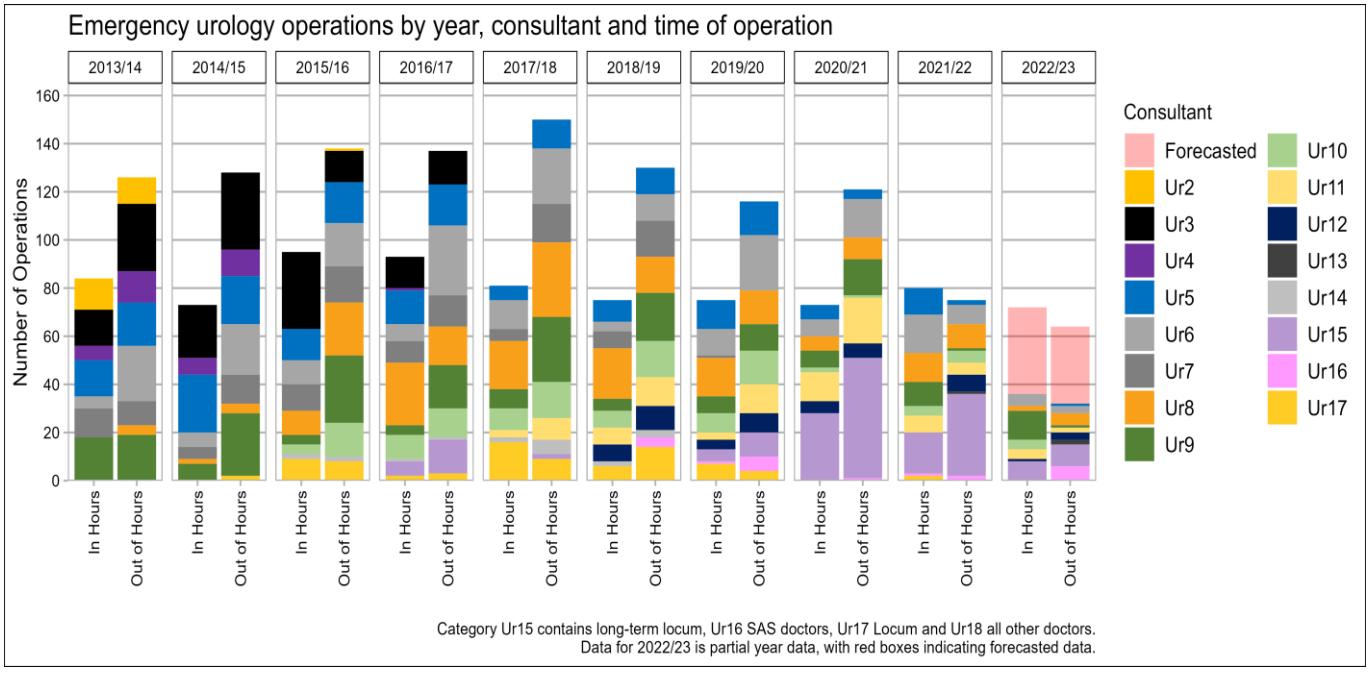
We note that the December 2022 audit meeting action tracker includes an item from 16 June 2022: "*Emergency Access to Theatre - To audit and compare against the new SOP for emergency access in the last 12 months in and out of hours. To review which clinicians are carrying out surgery out of hours*".

This was due in August 2022 and was marked as complete, but the minutes state that the findings will be presented in January 2023. These audit results have not been shared with us.

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 43 (continued)

Summary of evidence (continued)



Recommendation 44

Patient handover

Handover of patients between Consultants should include:

- A formal handover arrangement between Consultants for out of hours cover.
- A handover for patients who are transferred between Consultants.

Summary of evidence and proposed NIAF rating	Action completed but not yet tested – 3

Guidance is available to medical staff (including in the Urology Handbook) on the requirements for the handover of patients to colleagues and to other departments or specialties as required.

Our review has confirmed that in Urology a handover is conducted via MS Teams every morning and evening between the incoming and outgoing medical team, in line with the revised policy. In October 2022 we heard examples of these virtual face-to-face meetings working well, and that those involved felt supported and valued the opportunity to discuss care with their colleagues. This feedback was also reflected in the Quality Service Review by the Trust in December 2022.

However, the Urology Handbook states that there should be a joint 'in person' ward round on Friday and Monday mornings to ensure safe handover with the Consultant on call, but we saw little evidence of this happening in practice during our Current Case Review and some staff that we interviewed said that although time is allocated to this process, in reality it does not always occur. So there is inconsistency between policy and practice.

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 45

Managing team dysfunction

A uniform approach should be applied to team dysfunction. This should include:

- Clear communication from the Trust re the service strategy, goals and objectives - particularly around behavioural standards
- Holding to account against professional standards in Good Medical Practice
- Sustained visible leadership and "sponsorship" from the Board
- Intelligent review of patient outcomes and harms
- Follow-up, monitoring and review to ensure that behavioural improvements are sustained.

Summary of evidence and proposed NIAF rating	Action significantly progressed – 2

The Trust's Putting Patients First Strategy for UHMBT 2022–2027 was launched in June 2022. This incorporates a strategic priority to "*Create the culture and conditions for our colleagues to be the very best they can be".* This is being delivered through a range of mechanisms, including culture transformation work, which is being undertaken in relation to Freedom to Speak Up, leadership development, inclusion and engagement initiatives and events. The Values and Behavioural Framework has also been refreshed in conjunction with staff, and was relaunched in September 2022 through a variety of communication methods.

Staff that we spoke with were largely positive about these initiatives, although they recognise that cultural change takes time to embed and that further work is required to ensure optimal team cohesion and staff wellbeing going forward.

In support of the Medical Director and the performance management/support for medical staff, a Professional Standards Group (PSG) was established in February 2022. Members have an in-depth knowledge of medical and dental performance and provide advice on handling individual concerns and cases that are presented. The group intended to meet monthly, however, this has been hampered by the operational pressures faced by the Trust and wider NHS during winter 2022/23. The most recent meeting was held in September 2022 when they met to discuss the intended role of the group and to review its ToR; these are due to be presented at the PSG in April 2023, and also at the People Committee within their cycle of business, with final ratification through the Trust Procedural Documents Group. The Medical Director also has monthly meetings with representatives from the Human Resources department to discuss appraisals, revalidation, grievances and GMC cases.

The Trust also has a 2019 Early Resolution Policy (Behaviours at Work) that is due for review in May 2023. As mentioned in Recommendation 31, this will need to clarify when mediation or other forms of resolution are required for clinical decision disputes or relationship difficulties.

Board members are also trying to increase their collective and individual profiles through buddying arrangements with the care groups, through requests for clinical teams to present at various corporate meetings, development of a Clinical Strategy and an away day for all Consultant and SAS doctors (October 2022); some of these initiatives are only recent or have yet to realise their required impact (see recommendation 48).

As mentioned in recommendations 2 and 9, there have been some improvements in reporting with initial thematic analysis of patient outcomes and harms, although further developments are required.

In Urology, the InterBe programme (see recommendation 11) has been completed and has led to demonstrable improvements in the dynamics of the Urology team, although ongoing support from the Organisational Development team is still required. Support is also being offered to the team through monthly 'drop in' meetings with members of the Board which were initiated in December 2022.

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 46	
Duty to monitor staff wellbeing The Trust has a duty to monitor staff stress levels and wellbeing and to intervene to support and understand the underlying issues before burn out affects patient care. The Trust should develop a cultural dashboard to identify key metrics that can provide early warning of team stress e.g. Occupational Health referral, employee relations concerns, engagement scores.	
Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**
A people and culture dashboard has been launched, which includes data on staff sickness levels, numbers and types of occupational health referrals, appraisal completion, and national staff survey response rate. A heatmap also includes the top 10 areas of the Trust with less than 85% staff availability, which enables the reader to immediately identify potential staffing hotspots. The dashboard is not yet presented in a way that enables triangulation between topics; but we understand that there is the intention to triangulate between staffing data and feedback from exit interviews, as well as occupational health referrals. Further work is required to develop the dashboard into a tool that aids the identification of teams under stress. The Trust established a health and wellbeing website during 2022, which is linked to the national Health and Wellbeing Framework. An Improving Together newsletter has also been developed and four editions have been published over the last year. The main purpose of the newsletter is to provide information to staff on the Trust's Improvement Plan, which includes mechanisms to both support staff and enable them to speak up when they have a concern.	

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 47

Appraisals for medical staff (Link to R40)

- Appraisals may identify colleagues who are having difficulties and a protocol should be put in place to safeguard staff when concerns are apparent.
- The Responsible Officer should explicitly monitor appraisals which may demonstrate team dysfunction as a means of early warning and to instigate remedial interventions.
- Specialty interests with key outcome measures at unit level should be agreed. Individual Consultants should be given lead responsibility for specialist areas with outcomes linked to the clinical audit programme and fixed into appraisal processes.

Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**

The NHS England: Information Flows to Support Medical Governance and Responsible Officer Statutory Function Guidance Paper (August 2016) is out of date (due for review five years after publication) but clearly shows, through narrative and flow chart diagrams, how and when information of note or concern that is discussed in an appraisal can or should be shared. This guidance is available to all medical staff. The Trust has also informed us that all doctors have an obligation under the GMC's Good Medical Practice guide to declare any situation that may impact patient safety to their own manager, and to the Responsible Officer if necessary. This may be the case, however, a precipitating reason for our independent investigation stemmed from a failure to identify team dysfunction or act appropriately which was a key responsibility of the Responsible Officer.

Medical appraisers have been trained and feedback about the appraisal process for doctors at the Trust has been largely positive, although audits have identified a lack of challenge in some cases. In December 2022, the Trust approved their internal process for actions to be taken following completion of Consultant appraisals. This includes that appraisers will submit the appraisal documentation to the Medical Appraisal and Revalidation Coordinator/Delegate Responsible Officer who will read every appraisal to check compliance with the policy. The Trust has evidenced that every medical appraisal is checked by the appraisal team before being signed off. The process includes that the Associate Medical Director of Appraisal and Revalidation/Fitness to Practise will contact both the Appraisee and Appraiser if concerns are raised that might impact patient safety and will escalate any unresolved issues to the Responsible Officer or Deputy Medical Director (Professional Standards) for onward action, whilst maintaining the confidentiality of the appraisal process; we have not been provided with examples of this happening in practice. We also note that the appraisal team will not interfere with issues faced within their care groups including, for example, rota problems and behaviours. It is unclear why this would be the case if concerns have been raised through appropriate channels but not responded to, particularly as these types of concerns may indicate team dysfunction.

We have been told that most specialities within the Trust have sub-speciality leads with required and agreed job planning allocation and that specific objectives are agreed during job planning processes; however, we have seen no evidence of specialty interests (linked to key outcome measures and the clinical audit programme) being agreed, including at Urology service level, and fixed into appraisal processes.

Functions of the RO remain a delegated process in the Trust. Although the Medical Director has monthly meetings with representatives from the Human Resources department to discuss appraisals, revalidation, grievances and GMC cases, we are not yet clear if there have been any material changes in regards to the robustness of monitoring team dysfunction through the Medical Directorate.

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 48

Engagement with Consultant body

- Engagement by executive and non-executive members of the Board with the Consultant body should be examined and options provided to facilitate increased opportunities for interaction.
- This should include a clear programme of engagement at sub-specialty level over a rolling programme. This should be in addition to existing Medical Advisory Committee meetings.

Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**

The Trust has introduced a weekly Executive Chief Nurse walkabout with senior nurses and matrons across Trust sites, which give colleagues working in clinical areas an opportunity to raise concerns, share their experiences, and give feedback to these team members. A Harm Free Care Panel has also been established; this meets weekly and allows for patient safety issues to be raised. The launch document states that "*clinical data is explored to identify any issues and appropriate action is taken*". The Urology wards at RLI have been visited as part of this approach.

In 2014, the Trust established an Executive/Non-Executive Director (NED) buddying arrangement, in which each care group is allocated one Executive and one NED. The position of NED buddy for S&CC has been vacant; however, we understand that this has been filled by an incoming NED who started at the Trust in March 2023. The Urology Consultants were invited to attend the Quality Committee in December 2022, which allowed for some engagement about their service with NEDs present; this was described as a useful session.

Also in December 2022, the Executive Director's Group started a rolling programme of drop-in meetings with the Urology team on a monthly basis. The purpose of these sessions is to increase the opportunities for interaction between members of the Executive Team (and more recently the Lead Governor and Non-Executive Directors) and Urology staff but it is disappointing that it has taken until this late date to establish this forum.

There have also been other engagement activities with the wider Trust Consultant body through, for example, development of the Clinical Strategy, but targeted engagement with the Urology Consultants has been limited.

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 49

Trust Management of Royal College reports

- The Trust should inform regulators (CQC and NHS England and NHS Improvement) and commissioners of any plans for external reviews for quality and safety concerns, including Royal College Invited Service Reviews as soon as they are confirmed. This will ensure that regulators and commissioners can take this into account in their assurance activity in real time.
- Advisory reports from the Royal Colleges should be shared, in full or in summary where appropriate, by the Trust with the Trust Board.
- The Trust should formally inform the regional or local NHS England and NHS Improvement team, the Care Quality Commission and relevant fitness to practise investigations conducted by the GMC and commissioners of relevant Royal College reports and share these where appropriate.
- Transparent action plans arising from all Royal College reports should be developed by the Trust, shared with the Trust Board and formally monitored through the Trust Quality Committee.

Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**

The Trust has introduced a new clinical audit proposal form for an additional audits procedure developed in November 2022. This seeks to clarify the process by which additional audits (including Royal College reviews) are identified and facilitated.

The existing Management of External Agency Visits, Inspections and Accreditations Policy has also been updated to include greater specificity about who is responsible for managing external reports, including those from the Royal Colleges and Fitness to Practise Reports, alongside their associated action plans. The policy states that the Compliance and Assurance Office will hold a database of all external agency visits, inspections and accreditations, which will be kept updated and monitored so that the Board and/or relevant committees are aware of reports, progress with action plans and risks associated with their implementation. The role of the Quality Committee in this has also been outlined and the Executive Chief Nurse and the Director of Governance are designated as the staff responsible for informing the regulators (CQC, NHS England) and commissioners of any plans for external reviews of quality and safety concerns; this will be managed through the monthly CQC engagement meetings where possible.

We have not been provided with any evidence to confirm that this process is fully understood in practice or has been followed for any recent external reviews.

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 50

Clarify role of governors and escalation mechanisms

- Governor training and induction programmes should be revisited to confirm that methods for escalating concerns are clearly set out and understood.
- Procedures for escalation should include processes for resolution where governors remain dissatisfied with responses to issues raised.

Summary of evidence and proposed NIAF rating	Action commenced – 1

The Trust has established a Raising Concerns Protocol, which includes information on the different routes that can be used when raising concerns, such as the role of the Freedom to Speak Up Guardian, the Company Secretary, the Chair, and the Senior Independent Director. The protocol was included in the most recent induction slide pack for governors in October 2022 and was also published via the Governors Microsoft Teams channel in August 2022.

We held a focus group attended by 14 governors in January 2023. With the exception of one governor present, there was a unanimously held view that the process for escalating and resolving concerns remained unclear. Key points raised by those present were:

- There were technical glitches that made the session challenging. New governors had no recollection of the Raising Concerns Protocol being covered during their induction and they could not confirm whether it was in the information pack they had received.
- Governor training sessions are held regularly, but the Raising Concerns Protocol has not been included so far.
- Particularly criticism about the approach to managing concerns that have not been adequately resolved or responded to, we note that this is not clearly set out in the Raising Concerns Protocol.

It is impossible to disaggregate the issue of effectively responding to governor concerns, with the extent to which the role of the governors is defined and understood. We understand that governors received NHS Providers' training on their statutory role with discussion about how concerns are raised (most recently in June 2022). We have also been told by the Trust that revised induction materials were shared with all governors for their feedback but that no comments were received on the Raising Concerns Protocol and that during induction there is always a focus on escalation.

Yet it was clear that this issue is unresolved for most of those present at the focus group. The nature of concerns raised by governors, and their expected response, is grounded in a clear and shared understanding of what the purpose of the governors is. The appropriateness of using the role of the Lead Governor as a conduit to escalate concerns was also called into question by some present.

It was abundantly clear throughout the focus group that the relationship between the Trust and the governors remains hampered for some by a legacy of distrust stemming from the Kirkup review; high-profile staff tribunals; and issues in Urology, Trauma and Orthopaedics. It was also evident that there were factions in the governor group. There is continuing disruption in the governor group with differing perspectives and too much time spent on dealing with perceived past wrong doings that the Trust at Board level has attempted to address and resolve. There remains a lack of acceptance amongst some governors to use the processes that are in place. Significant email traffic on repeat issues is a significant distraction for Trust staff.

Recommendation 50a: An intensive programme of externally facilitated development is required to: rebuild trust between the Trust and the governors; establish clear expectations for the role of governors on an individual and a collective basis; ensure there is clarity about how to raise concerns and what to do when governors remain dissatisfied; and to explore the effectiveness of existing governance structures to support the function of the Council of Governors, including the role of Lead Governor.

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 50 (continued)

Summary of evidence (continued)

The Trust has recognised that further work is required in this area and have agreed the following actions and timelines for delivery:

Action	How will we demonstrate completion	Deadline for completion
Session to be held with the Council of Governors to debrief them on the report content and additional recommendation and consult on the next steps to be taken.	Notes and actions of the meeting.	30 May 2023
Chair of the Council to speak with the Chair of the ICB and NHS England Regional Team to discuss the outcomes of action 1 above and consider the support offers available. This may include a historical review to enable a better joint understanding of the cause of the difficulties, together with a programme of development to support a well- functioning relationship.	Written confirmation from the ICB and NHS England of the support options available for development work.	30 May 2023
Consideration of support options paper by the Council of Governors and agreement of support to be deployed.	Written agreement from the Council of Governors confirming which elements of the support available will be utilised and within what time frames.	30 May 2023
Support programme implemented.	Evidence of support forums/mechanisms deployed.	June 2023

Section 1d: Recommendations from the Independent Investigation Report

Recommendation 51	
Institutional memory Formal handover procedures should be in place for all incoming and outgoing Board members (including postholders with committee chair roles). These handovers should include employee relations issues and sub-specialty summaries	
Summary of evidence and proposed NIAF rating	**Action completed and tested, but not yet embedded – 4**
The Trust has developed a documented Executive Director handover process which applies to all posts at Band 8D and above. The process includes the completion of an executive handover document by the outgoing postholder; document sections include prompts such as 'ongoing Committee actions', 'risks', and 'employee relations issues', as well as space to include sub-specialty issues where appropriate. The handover process and document were approved in October 2022, and have been used twice to date. Interview feedback indicates that the process and supporting handover document have helped to enable a more structured and planned approach to changes in senior personnel.	

Recommendation 52	
Media articles Revise advice and guidance on dealing with media articles that name individuals and provide support to ensure an appropriate right of reply is sought (also in line with GMC guidance on responding to criticism in the media).	
Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**
The Trust has developed a new Media Policy which was approved in April 2022. It seeks to "*ensure that all colleagues know what to do if they are contacted by a media representative in their capacity as a Trust employee or wish to share news via the media".* The policy includes guidance on colleagues' right of reply. The policy has also been informed by the latest GMC guidance on responding to criticism in the media. We understand that Executive Directors received media training during 2022.	

Appendix 1: Glossary of terms used

Appendix 2: Glossary of terms used

AAS	Additional activity sessions	NIAF	Niche Investigation Assurance Framework
ADoP	Associate Director of Operations	NICE	National Institute for Clinical Excellence
AKI	Acute kidney injury	PALS	Patient Advice and Liaison Service
BAF	Board Assurance Framework	PHSO	Parliamentary and Health Service Ombudsman
CCG	Clinical Commissioning Group	PLICS	Patient Level Information and Costing System
CQC	Care Quality Commission	PSIRF	Patient Safety Incident Response Framework
CRR	Corporate Risk Register	QGAF	Quality Governance and Accountability Framework
eGFR	Glomerular filtration rate	RCA	Root cause analysis
ESP	Enhanced Support Programme	RLI	Royal Lancaster Infirmary
EUA	Examination under anaesthetic	S&CC	Surgical and Critical Care
FGH	Furness General Hospital	SAR	Subject Access Requests
FOIA	Freedom of Information Act	SGAG	Surgical Governance and Assurance Group
GMC	General Medical Council	SJR	Structured judgement review
ICB	Integrated Care Board	SoC	Standards of Care
IQPR	Integrated Quality and Performance Report	SOF	Single Oversight Framework
IRD	Indicative review date	SOP	Standard operating procedure
ITU	Intensive Treatment Unit	ToR	Terms of reference
MCCD	Medical certificate of cause of death	TPN	Total Parental Nutrition
MDT	Multidisciplinary team	UHMBT	University Hospitals of Morecambe Bay NHS Foundation Trust
MHPS	Maintaining High Professional Standards	UQOC	Urology Quality Oversight Committee
MUST	Malnutrition Universal Screening Tool	UT&FG	Urology Task and Finish Group
NCEPOD	National Confidential Enquiry into Patient Outcome and Death	VIP	Very Important Person
NED	Non-Executive Director	VTE	Venous thromboembolism
NEWS	National Early Warning Score		

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