Assurance Review – Phase 5

Urology services at University Hospitals of Morecambe Bay NHS Foundation Trust

Assurance summary

Recommendations for commissioners, NHS England, advisors and regulators

Final Report
June 2023

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Overview

This assurance review focusses on the actions that have been progressed and implemented in response to the recommendations made in the 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 an Index Case Report (issued in April 2021) and a full Independent Investigation Report (issued in November 2021).

This assurance summary presents our findings from a desktop review of documents provided by stakeholders as evidence of progression of the actions. Our report findings are structured into three core sections:

1. Recommendations for commissioners

Full Investigation Report (recommendations 53–58)

2. Recommendations for NHS England

Index Case Report (recommendations 32–34)

Full Investigation Report (recommendations 59–67)

3. Recommendations for advisors and regulators

Full Investigation Report (recommendations 68–72)

A separate report has been issued to the Trust which focusses on the progression of the recommendations for their organisation.

Assurance assessment

In the pages that follow, we have provided 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 table below). The assessment is designed to be useful and evaluative. We use a numerical grading system to support the representation of 'progress data' to help our clients focus on the steps they need to take to move between the stages of commenced, significantly progressed, completed, tested and sustained improvement. 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).

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

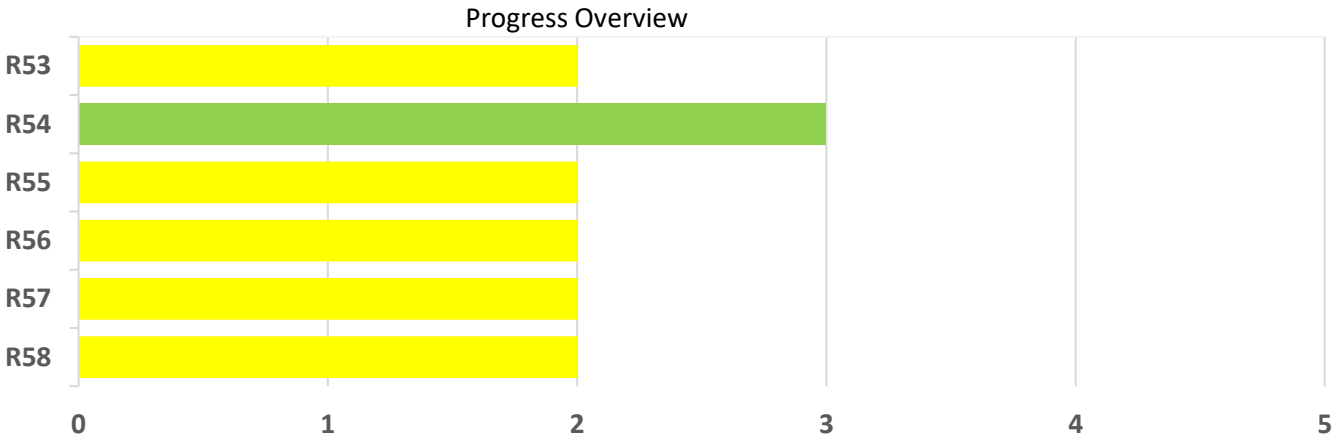
Assurance summary

Implementation of recommendations

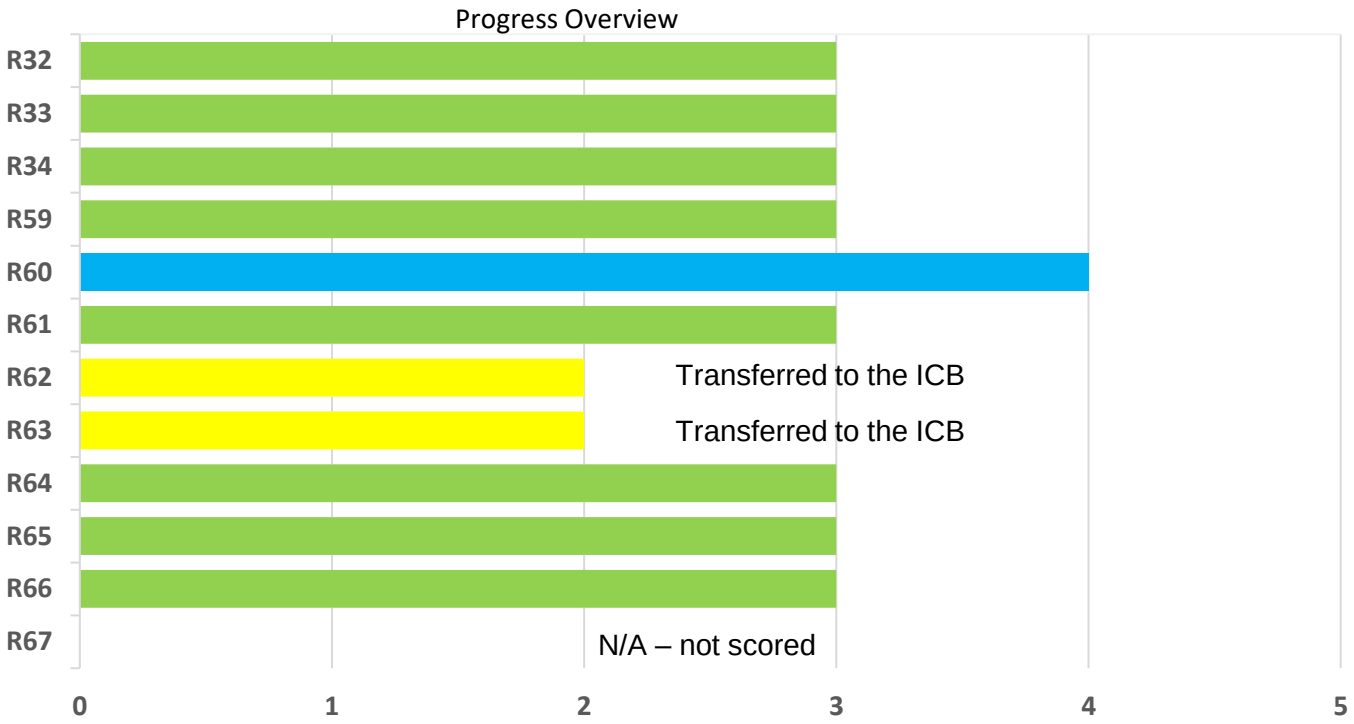
We have rated the progress of the actions which were agreed from the recommendations and learning points made. Our findings are summarised below:

Summary chart showing progress to date for each recommendation and organisation

Commissioner recommendations 53–58



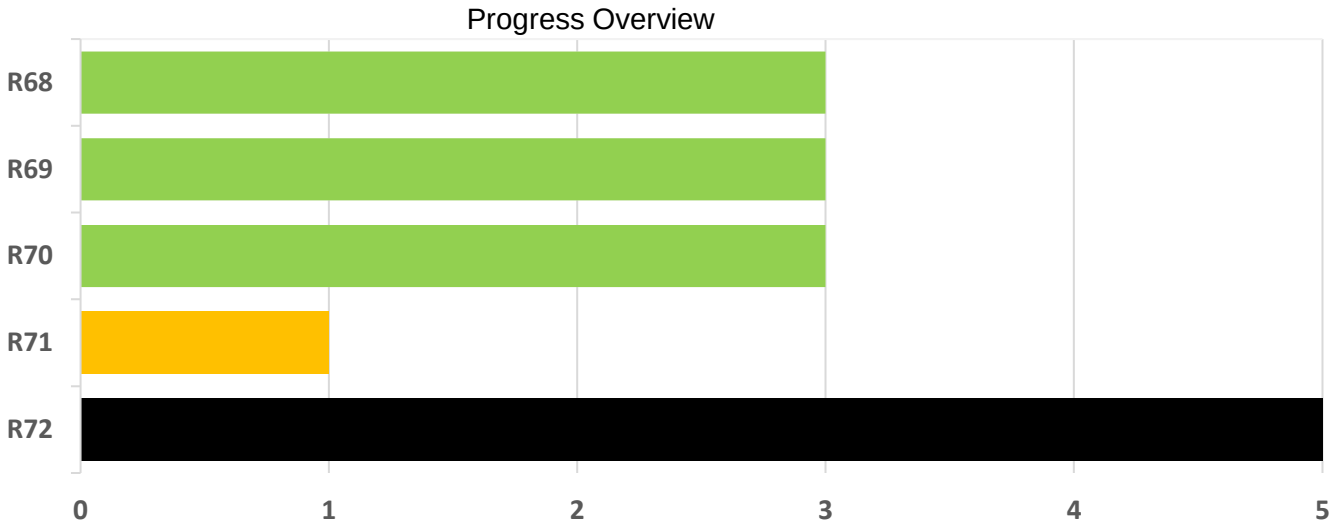
NHS England recommendations 32–34 and 59–67



Assurance summary

Summary chart showing progress to date for each recommendation and organisation (continued)

Advisors and regulators recommendations 68–72



Overall summary

Progress has been made in relation to all recommendations. Recommendation 67 has not been scored as it relates to the commissioning of this assurance review.

Recommendation 72, which relates to the testicular implant recall, has been fully implemented and no further incidents have been identified at the Trust.

Recommendation 60 has been completed and tested but the changes and required outcomes are not yet being consistently achieved.

A further twelve recommendations have been completed, but the changes made need to be tested through audits or routine monitoring to ensure they are having the required impact, are embedded in practice and the improvements are sustained going forward.

Seven recommendations have been significantly progressed but need to be completed and one recommendation has been commenced.

Headline commentary to support these ratings has been provided in the following pages.

It should be noted, however, that since the independent investigation was completed and published in November 2021, there have been considerable structural changes for commissioners and also NHS England. Integrated Care Boards (ICBs) replaced Clinical Commissioning Groups (CCGs) in July 2022 and NHS England and NHS Improvement merged into one organisation to become NHS England with regional teams. This has meant a change in personnel for both organisations and has resulted in delays in implementing some actions; although full handovers have now been achieved and momentum regained.

NHS England has also advised that the ICB have taken the lead responsibility for recommendations 62 and 63. We have therefore graded progress for these recommendations based on the evidence provided by the ICB.

Section 1: Recommendations for commissioners

Assurance summary

1. Recommendations for commissioners

Full Investigation Report (recommendations 53–58)

Recommendation 53

Commissioner oversight at specialty level

As part of the work underway to establish system governance, commissioners should agree shared mechanisms to enable proactive commissioning and visibility of the Trust's services at specialty/sub-specialty level.

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

The Integrated Care Board (ICB – previously the Clinical Commissioning Group (CCG)) has made good progress establishing the mechanisms to enable visibility of the performance of Trust services at a specialty level – the heat map for challenged services and the quality tracker are key tools for this purpose. However, the formal flow of information from place-based to system-level is not yet in place and reporting schedules need to clarify which groups should routinely receive and scrutinise the insight provided by these tools.

The revised governance arrangements under the ICB need to be formally documented as an ICB framework which incorporates the mechanisms used for specialty level assurance. ICB level arrangements will take time to embed, and commissioners must ensure specialty level insight remains a focus at the Commissioner Assuring Quality Group and place-based forums.

Recommendation 54

Mechanisms for specialty level scrutiny

Alternative mechanisms for specialty/sub-specialty level scrutiny as part of routine assurance processes should be examined, for example cyclical deep dives as part of an annual work plan led by commissioning managers for scrutiny by quality assurance forums. The heat map approach (as in Appendix 16) developed by the CCG provides a useful model for this purpose.

The CCG should add an analysis of complaints/concerns/incidents from GP practices at a specialty level on at least an annual basis as part of this scrutiny.

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

Commissioners have developed several mechanisms to collate insightful specialty level intelligence and thematic analysis. Soft intelligence reporting includes collation of incident reports and concerns from all healthcare providers including GP practices. The heat map approach is also helpful and is starting to become embedded; it is used to provide assurance over action plans in areas of concern. The quality tracker provides an early warning mechanism from soft intelligence and includes the recording of concerns from acute, community and primary care providers.

Combined with existing assurance mechanisms, such as the Safe Today Report, the ICB has a sound basis from which to build strong routine governance and insightful reporting at specialty level. The range of approaches and tools used do, however, need to be articulated in an updated Quality Improvement, Assurance and Accountability Framework. See also our observations for recommendations 53 and 55.

Assurance summary

1. Recommendations for commissioners (continued)

Recommendation 55	
Specialty level reporting A reporting template should be developed which brings together quality, activity and performance information at a specialty level. A programme of reporting at this level should be agreed with the Trust, with frequency of reporting for each specialty to reflect jointly agreed priorities. This should provide a single source of reporting to all relevant governance groups. The Safe Today Report provides a sound basis for development.	
Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**
The Urology heat map is being used effectively to understand the Trust's improvement plan progress against the Niche, CQC and Royal College of Surgeons' (RCS) report recommendations and is therefore a time limited reporting mechanism. For routine performance reporting, the Safe Today Report has been further developed to provide a more rounded view of the performance of the Urology service. More work is required so that this report includes the insight provided by the commissioner's heat map and soft intelligence reporting (including the quality tracker); this would provide greater insight on emerging areas of risk and how these are being managed.	

Recommendation 56	
Quality assurance reporting and escalation Terms of reference for all quality assurance forums should be explicit about specific areas of focus, reports to be considered and how issues should be monitored. Key Issues Reports should be used for escalation. An issues log should be maintained which identifies concerns with departments/specialties involved and this should be shared, populated and reviewed at key governance forums.	
Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**
The quality tracker is a comprehensive tool for the oversight of risks and emerging concerns and its use should be formalised to provide information to the Commissioner Assuring Quality Group, the ICB Oversight Group, the ICB Quality Committee and the Regional Quality Group, as appropriate. Terms of reference for the core ICB quality oversight groups need to be finalised and should be explicit on which reports are to be shared and how escalation is formalised (for example, through the use of key issues/highlight reports between groups/committees).	

Assurance summary

1. Recommendations for commissioners (continued)

Recommendation 57	
Audit of commissioner assurance processes Internal audit should test the efficacy of CCG assurance at a Trust specialty level as part of its annual work programme.	
Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**
Internal audit work covering the Niche recommendation requirements was planned to start in February 2023 with clear terms of reference agreed and final reporting due in March 2023. The ICB should consider the audit findings within the context of this assurance review.	

Recommendation 58	
Compliance with incident reporting requirements The CCG should ensure that its contractual requirements with the Trust relating to incident reporting, and as set out in the Quality Schedule to the latest contract (2021/22), are met.	
Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**
Effective governance forums for the oversight of serious incident reporting and compliance with contractual requirements are in place through the Serious Incident Group and the Commissioner Assuring Quality Group. Papers from these meetings show effective commissioner oversight of Trust serious incident reporting and significant scrutiny and proactive follow up to ensure contractual requirements are met. There is appropriate scrutiny by commissioners on each incident report, the quality of the investigation and associated action plan and closure of queries. We did not identify systematic reporting on Duty of Candour requirements to any of the governance groups, but the ICB has routinely received the Trust's quarterly incident report, which details Duty of Candour compliance. We note the Trust has stopped producing this report, pending transition to the Patient Safety Incident Response Framework (PSIRF) requirements. Revised reporting arrangements should be confirmed. Reporting on thematic reviews should be developed further with insight at specialty level. The ICB detailed incident tracker provides a sound basis for such analysis with opportunities for triangulation with Trust information on themes.	

Section 2: Recommendations for NHS England

Assurance summary

2. Recommendations for NHS England

Index Case Report (recommendations 32, 33, 34)

Recommendation 32

Coroner's statements

NHS England and NHS Improvement should develop guidance for Trusts and NHS organisations more widely in relation to the following aspects of recommendation 5 (R26) above:

- Statements to Coroners written in relation to whole episodes of care involving a team or a Trust service should be subject to validation and where a statement includes or implies failures in care all individuals named should be given a right of reply. This is distinct from an individual health care professional providing a witness statement solely in relation to their own input.
- Where failures in care are identified as a result of the production of a statement and a new incident is reported, the Coroner should be informed to determine if an investigation report will be required for any further proceedings.
- Trusts must assure themselves that their policies in relation to providing statements to the Coroner are being complied with. Statements should be based on fact rather than opinion and there should be a clear indication of how the statement has been compiled.

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

NHS England has considered the existing guidance available to Trusts and health care professionals. The Patient Safety Incident Response Framework (PSIRF) requires all medical practitioners to follow the Notification of Deaths regulations, and for NHS Trusts to liaise with the coroner and work collaboratively with all those involved in an investigation to ensure they are appropriately represented. Freedom to Speak Up (FTSU) arrangements provide an additional mechanism for concerns to be raised. Health Education England guidance on statements to coroners is about input by individuals; it does not cover the inclusion of references to other health care professionals but emphasises the need for statements of fact (rather than opinion or interpretation).

NHS England's regional Medical Director for System Improvement and Professional Standards discussed the recommendation with the regional Lead Medical Examiner in November 2022. The Medical Examiner requires statements from all qualifying attending practitioners who have concerns about the care provided when a case is referred to the coroner. This partly addresses the recommendation from the index case, as this would allow for the cross-validation of statements. There was no indication that the discussion specifically covered the right to reply for health care professionals named in statements. NHS England did not confirm whether they had considered processes for incident management of additional harm identified during a coroner process that had not previously been reported.

In February 2023, NHS England shared a draft letter to be issued to Integrated Care Boards (ICBs) across the North West, and subsequently to ICBs across all regions, to request that audits be undertaken of a sample of team/service coroner statements to ensure compliance with national guidance and Trust policies. The letter also requests that Trusts review their standard operating procedures to ensure compliance with the requirements of this recommendation for validation and the right to reply.

Assurance summary

2. Recommendations for NHS England (continued)

Recommendation 33	
Clinical practice NHS England and NHS Improvement should consider what relevant guidance could be developed for Trusts and NHS organisations more widely in relation to recommendations 1–8 made in this report and how these lessons might be shared. The learning from this report would be of benefit to the wider NHS community through an anonymised case study which will be developed from this case.	
Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**
NHS England has considered the need for additional guidance in consultation with an external expert (the Professor of Uro-Oncology from University College London Hospitals NHS Trust). The conclusion was that the recommendations made by Niche would be the expected standards required for a well-functioning pathway and that, while these are not included in clinical guidelines, they would be recognised by practitioners as best practice. The shared conclusion was that no further action was needed by NHS England in terms of additional guidance, but that the recommendations needed to be implemented by University Hospitals of Morecambe Bay NHS Foundation Trust (UHMBT). The Niche summary briefing was shared as a case study with executives from all NHS England regions via the Executive Quality Group in November 2022 (see Recommendation 65).	

Recommendation 34	
Clinical records and email communications NHS England and NHS Improvement should decide whether more guidance is needed in relation to the uses and retention of email correspondence (or other electronic communications) as part of health records and any regional or national implications of recommendation 9 above.	
Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**
NHS England's Head of Independent Investigations consulted on this recommendation with the regional NHS England Senior Information Governance Lead and the NHS England National Deputy Director of Patient Safety (Policy and Strategy) in November 2022. The discussion concluded that current national guidance in this area was sufficient. All Trusts should adhere to the NHS Records Management Code of Practice. The national code of practice was reviewed in 2021 and includes comprehensive direction on the management of email records. NHS England will request that UHMBT provide their relevant local procedural guidance (which has recently been updated by the Trust). NHS England will also require assurance that compliance with national guidance is tested through audit in 2023/24.	

Assurance summary

2. Recommendations for NHS England (continued)

Full Investigation Report (recommendations 59–67)

Recommendation 59

Protecting patient confidentiality

Examine ways in which confidential patient information is appropriately anonymised for the purposes of employment tribunal hearings. Guidelines should include:

- advice to healthcare professionals on the use of patient information in these proceedings in line with Good Medical Practice guidance and GMC guidance on the use of personal information;
- advice on the relevant GDPR and Data Protection regulations and the right to protect private information for both patients, their families and other individuals;
- information relating to circumstances where patients do consent to the use of their personal information being used; and
- the application of how Duty of Candour applies in such circumstances.

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

NHS England consider that the current guidance from the General Medical Council (GMC) on protecting patient confidentiality is clear and sufficient (Confidentiality: Good Practice in Handling Patient Information, 2018). On the Duty of Candour, NHS England has discussed the Care Quality Commission (CQC) guidance with legal advisors and it was also deemed sufficient. NHS England did not have any evidence of the issues in this case being experienced by other Trusts.

Recommendation 60

Never Event review

Revisit the Never Events cases highlighted in this review and ensure that the Trust applies rigour to all possible Never Events reporting.

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

A full recall programme of patients with a testicular implant was instigated and overseen in 2022. All patients affected were recalled and scanned as required. NHS England reviewed all the cases and concluded that no further action was required because clear guidance is now in place about the removal of needle guards on the products supplied.

As part of the work of the Urology Task and Finish Group for the testicular implant recall, NHS England has overseen a review of UHMBT's governance for reporting Never Events. The outputs and learning from the work undertaken were given in a detailed report to UHMBT's Quality Assurance Committee in September 2022. It sets out the governance processes for Never Events, which are reported as serious incidents on the Strategic Executive Information System and are subject to the Duty of Candour and a root cause analysis investigation.

Assurance summary

2. Recommendations for NHS England (continued)

Recommendation 61	
Learning from Deaths Consider a revision to the Learning from Deaths guidance to ensure that patient records on death are suitably managed in original form by professionals to reduce the risk of posthumous amendment.	
Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**
NHS England has confirmed that existing national guidance is sufficient, as set out in the Records Management Code of Practice and the GMC's guidance for medical practitioners. This guidance is clear on the safeguards and rigour required to protect patient records and prevent illegitimate access. The move towards electronic records across the NHS means that retrospective amendment to records should be less of a risk moving forwards and will be more easily identifiable if it does occur because a detailed audit trail will be available.	

Recommendation 62	
Networked support for team development NHS England and NHS Improvement and the CCG should seek stronger working relationships between the Trust and tertiary centres to support Consultants in facilitating the provision of sub-specialty services at the Trust.	
Summary of evidence and proposed NIAF rating	**Action significantly progressed – 2**
NHS England advised that the ICB have taken the lead on this recommendation (see also recommendation 63). They provided references to their strategy and national guidance to encourage ownership by ICBs of system improvement work including alignment of funding to ICBs and the establishment of an ICB Improvement Hub to coordinate service improvement work underway by the various networks involved. Following some reconfiguration of collaborative working groups, the Urology Clinical Network has been re-established and is providing a mechanism for all the Trusts across Lancashire and South Cumbria (LSC) to work together on the provision of specialist services. The Urology Clinical Network is attended by senior UHMBT representatives (including the Clinical Lead), the other acute Trusts across LSC and several representatives from the Cancer Alliance. The network is continuing the work of the former Urology Collaborative and is progressing the configuration of specialist services, including the review of demand/capacity/workforce, the move to single site services and sub-specialty plans. The Urology Collaborative previously identified the need for additional resource to enable this work. ICB representatives are not yet fully engaged with the network, but their involvement would further enable system support and oversight in this area.	

Assurance summary

2. Recommendations for NHS England (continued)

Recommendation 63

Development of safe services and specialist interests

A Urology strategy should be developed involving all key Urology medical staff and other relevant healthcare professionals to set the context for the following actions:

- The Trust should undertake an equipment stocktake for Urology and plan into the capital replacement programme the need for cystoscopes, bipolar diathermy and suction equipment both in the short term and over the medium term or consider lease options.
- Examine, with the Trust and CCG, the development of Urology sub-specialisms building on Andrology and stone services, the management of superficial bladder cancer, local anaesthetic transperineal biopsy work and paediatrics.
- Examine, through the provider collaborative network, the viability of Urology provision across two sites and its associated support services in the long term should be examined in respect of future provision at Furness General Hospital. Formal consideration of centralising inpatient and emergency Urology services on one site should be revisited. This should include options for dedicated ward-based facilities.

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

The ICB is taking the lead on this recommendation and commissioners have received UHMBT's equipment stocktake for Urology. This lists the date that equipment was purchased and also the contract end date if not purchased directly. A Urology Clinical Strategy is being developed and presentation slides from June 2022 include options for service delivery; although it is unclear which of these are being taken forward, how this is to be implemented and how this links into the work of the Urology Clinical Network. The presentation does, however, reference business cases which are being developed. These include urology scopes and bipolar diathermy suction equipment and give details of the stage of the approval process the business case is at.

The ICB has sought to engage with the Urology Collaborative about the strategy for Urology and service developments, although the ICB does not currently attend the reinstated Urology Clinical Network meetings. The network has discussed sub-specialty services and single site provision and requested that sub-speciality leads develop proposals for developments in their respective areas. NHS England has recommended the establishment of ICB Improvement Hubs to capture all quality improvement work underway under network arrangements.

Commissioners remain concerned about the effectiveness of arrangements for out-of-hours cover, workforce sustainability challenges and capacity for specialist services; a Cancer Plan is being developed to address these areas.

We note that the business case for a dedicated Urology Investigation Unit on the Royal Lancaster Infirmary (RLI) site has recently been approved and building work is due to begin.

Assurance summary

2. Recommendations for NHS England (continued)

Recommendation 64

Regulation and oversight of team dysfunction (Link to R65(E))

- NHS England and NHS Improvement should discuss the lessons learned from this review with the Care Quality Commission and share them with the National Quality Board or similar regulatory oversight group, in respect of the failings to resolve the long-standing dysfunction in this team.
- NHS England and NHS Improvement should provide clear guidance about what external support might be available to Trusts from the regional medical directors' teams and the advisory options when there is team dysfunction emerging.
- Regulatory activity should review the effective functioning of the Responsible Officer role in regard to managing concerns where team dysfunction may be apparent.
- Guidance should include ensuring Trusts are encouraged to seek early support where team dysfunction may put patient safety at risk.

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

NHS England provided evidence of discussion with all the North West Responsible Officers (ROs) on aspects of RO guidance detailed within the Niche report including team dysfunction, equality, diversity and inclusion, employment tribunals and confidentiality. Various actions were discussed including the need to use the Maintaining High Professional Standards Framework more effectively, to obtain support from the GMC Employer Liaison Advisors and the NHS England Human Resources team, for greater clarity on job planning and the line management of consultants and for access to additional education in this area.

A Task and Finish group met in February 2023 to determine what arrangements and guidance are already in place and whether there are any gaps which need to be addressed. Representatives from NHS England, the GMC, NHS Resolution, Health Education England and the NHS Leadership Academy informed the discussion. Actions taken forward included the need for more effective signposting to guidance, the potential development of a bespoke e-learning module for Medical Directors and Clinical Directors, updating the Maintaining High Professional Standards framework and consideration of broader leadership training for new consultants.

The CQC attended the North West Strategic Oversight Group (2021) where the lessons learned from this review were discussed. The Niche summary briefing of November 2021 was also shared at the national Executive Quality Group in November 2022. This highlighted the findings relating to team dysfunction and the weaknesses in holding consultants to account for their behaviour.

The current RO guidance on roles and responsibilities when doctors are involved in issues and incidents involving team dysfunction is clear about how NHS Trust ROs can access support. This guidance was also shared at the national Executive Quality Group.

Assurance summary

2. Recommendations for NHS England (continued)

Recommendation 65
Guidance and support to Responsible Officers from NHS England and NHS Improvement Regional Medical Directors • NHS England and NHS Improvement should ensure that guidance to ROs is up to date and a final version is in force to include the 2013 RO regulation amendments and learning since the role was introduced. • Regional Medical Directors should use this investigation as a case study to reinforce escalation processes for Responsible Officers who may be facing conduct difficulties within their medical workforce. • The North West Regional Medical Director should share this case study with other Regional Medical Directors to reinforce the importance of the RO role, appointment processes and the lessons learned from this investigation. • Good practice should be shared between Trusts to provide clarity on the best approaches for dealing with and escalating behavioural and conduct issues that are impacting on patient safety in line with Good Medical Practice. • The Trust Board should revisit its understanding of the role of the RO and assure itself that there is clarity of duties between the Medical Director (now as RO) and the wider team in exercising duties to meet the RO regulations.

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

NHS England advises that the need for revised guidance and education in this area will be considered by a task and finish group (see recommendation 64). The latest RO guidance was distributed to all ROs in November 2021. The Niche summary briefing was shared as a case study with executives from all NHS England regions via the Executive Quality Group in November 2022; there was no evidence of further dissemination to NHS Trusts for wider learning in this area.

The Trust has undertaken a comprehensive reassessment of the roles within the Chief Medical Officer (previously known as the Medical Director) team, considering national guidance and the expanding responsibilities of the Medical Director role. A revised structure with additional investment has been approved which seeks to address the weaknesses identified in the existing model. The roles of the Chief Medical Officer and the RO have been merged.

Assurance summary

2. Recommendations for NHS England (continued)

Recommendation 66	
Whistleblowing Guidance on setting up appropriate governance processes should be developed to support intractable whistleblowing cases. It should aim to provide resolution to concerns and facilitate learning in relation to patient safety.	
Summary of evidence and proposed NIAF rating	**Action completed but not yet tested – 3**
NHS England updated all its national guidance for Trusts on the FTSU during 2022. The guidance signposts readers to further support via NHS England and independent organisations for escalation if required. NHS England also produced a comprehensive evaluation and governance tool for NHS organisations for the review of their FTSU arrangements; this is a mechanism by which Trusts can address concerns and prevent whistleblowing cases from becoming intractable. NHS England advised that further progress on this action would be covered under recommendation 64. We note that their national FTSU team supported UHMBT to update its FTSU Policy in November 2022. The Trust is progressing a cultural transformation programme with reporting to the People Committee. This is a significant programme of work with a specific workstream focussing on FTSU and the establishment of a restorative and just learning culture. Progress includes the updated FTSU Policy, the identification of priority areas for improvement, benchmarking against exemplar sites, the clarification of Guardian and Champion roles, training relaunches and a new FTSU app for staff. It is anticipated that processes which enable staff to more easily raise concerns will help mitigate intractable whistleblowing cases.	

Recommendation 67	
Assurance review NHS England and NHS Improvement should commission a Phase 5 review (Autumn 2022) in line with the Terms of Reference to include assurance on key elements such as: • continuity of care; • named Consultant; • MDT [multidisciplinary team] management; • follow-up patient pathways; • the quality of incident reporting and investigations; • team development opportunities; and • mortality governance. to establish if implemented changes have become embedded and are sustainable.	
Summary of evidence and proposed NIAF rating	**Action completed and not subject to scoring – N/A**
NHS England North West commissioned the Phase 5 Niche assurance review which began in Autumn 2022 and will conclude with the publication of this report.	

Section 3: Recommendations for advisors and regulators

Assurance summary

3. Recommendations for advisors and regulators

Independent Investigation Report (recommendations 68–72)

Recommendation 68

Role of the GMC in relation to team dysfunction

The GMC should reflect on this investigation. They should:

- seek to understand how and if team dysfunction issues impact on fitness to practice investigations;
- determine whether the role of medical managers and their fitness to practice (in relation to their management function) have been sufficiently considered in this case;
- ensure that GMC guidance in relation to the Responsible Officer (RO) regulations is up to date and considers the 2013 amendments to the regulations and learning since the role was introduced;
- indicate to Trusts that the GMC Connect dashboard can be made accessible to Medical Directors as well as the RO team.

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

The General Medical Council (GMC) has provided a statement which evidences consideration of the investigation findings on the impact of team dysfunction on fitness to practise and the role of the Medical Director. They have confirmed that the review of the Good Medical Practice Guidance currently being undertaken provides an important opportunity for the GMC to strengthen expectations of doctors in relation to leadership, interprofessional behaviours and working effectively within multi-disciplinary teams. The GMC RO Referral Guidance was updated in December 2021 and there has been a communication to designated bodies that the GMC Connect dashboard can be accessed by those other than the RO.

Recommendation 69

Enforcement and follow up of actions from Royal College Invited Service Reviews

Invited Service Reviews should include:

- clear expectations for Royal College Invited Service Review Reports to be shared, in full, by the Trust with the relevant Trust Board;
- expectations for when Royal College Invited Service Review Reports should be shared, in full, by the Trust with regulators; and
- clarity about the implementation of action plans arising from Invited Service Reviews to enable the Royal College to be satisfied that recommendations have been fully addressed to end their active involvement.

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

The Royal College of Surgeons (RCS) has formally clarified its position to NHS England about its role in sharing its report findings from Invited Service Reviews. The RCS state that their independent reviews are advisory and do not have a regulatory status and that responsibility for sharing the report with relevant stakeholders sits with the organisation commissioning the review. Their recommendations may advise sharing the report findings with the relevant stakeholders where appropriate, but the RCS would only share findings with a regulator if they were not satisfied with the steps taken by an NHS Trust to address the recommendations made. The RCS clearly described their routine processes for the monitoring of the delivery of recommendations and the conclusion of their involvement with NHS trusts. NHS England are seeking further advice from the Academy of Medical Royal Colleges on the need for prompt sharing of RCS reports when a review is undertaken and there are concerns about a doctor's performance.

Assurance summary

3. Recommendations for advisors and regulators (continued)

Recommendation 70

Sharing of information between regulatory bodies

The effectiveness and intention of the Emerging Concerns Protocol https://www.cqc.org.uk/what-we-do/how-we-work-people/emerging-concerns-protocol should be revisited in the context of the findings of this case. The inclusion of additional signatories (e.g. Royal Colleges and NHS England) should be considered. This may be the most appropriate process to improve information sharing.

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

The GMC and Care Quality Commission (CQC) explained that the Emerging Concerns Protocol Working Group was established in July 2018, and therefore could not effectively be used in the Urology case to share insight on emerging concerns. The group included the Chief Executive Officers of the professional regulators and the system regulators for England, including the GMC and CQC. The RCS does not consider it necessary for the College to be a signatory to the Emerging Concerns Protocol, as it does not have a statutory role. The protocol is currently being reviewed to reflect changes to the signatories and any aspects of the Health and Care Bill 2022 which may affect its function. (Recommendation 69 describes the RCS's role in information sharing from Invited Service Reviews.)

There are also other ways in which the GMC and CQC share insight and intelligence; for example, working with the Nursing and Midwifery Council on data sharing projects and the GMC's Patient Safety Intelligence Forum.

Recommendation 71

Assessing the effective role of the Responsible Officer in Well-Led assessments

The role of the RO and its development since the introduction of this function in 2010 should form a regular and consistent part of examination as part of internal and external Well-Led and governance reviews.

Summary of evidence and proposed NIAF rating	Action commenced – 1

The CQC Single Assessment Framework follows the established NHS England Well-Led Framework key lines of enquiry for the effectiveness of leadership and governance, and for the roles and responsibilities of senior leaders. The supporting materials to the Well-Led Framework include an interview guide covering the RO role (dated 2017).

The Trust completed an internal Well-Led assessment in November 2022 and confirmed that the interview with the Chief Medical Officer covered the relevant aspects of their role as RO and Caldicott Guardian.

The CQC are currently developing their new regulatory approach for health and care providers, integrated care systems and local authorities. This includes the introduction of a new single assessment framework. As part of this work, the CQC are jointly reviewing, with NHS England, the approach to Well-Led reviews, including assessing how Trusts are supporting the RO in their role. A Trust-wide Well-led Working Group agenda has been provided as evidence of this Niche recommendation being considered in this process.

Assurance summary

3. Recommendations for advisors and regulators (continued)

Recommendation 72	
Testicular implant recall NHS England and NHS Improvement should share the findings from the testicular implant recall exercise with relevant bodies and agree the next steps at a local or national level.	
Summary of evidence and proposed NIAF rating	**Can demonstrate a sustained improvement – 5**

The testicular implant recall was promptly mobilised in August 2021 on receipt of draft report findings about the potential patient safety concerns that were escalated to NHS England. Specialist subject matter Urology expertise was engaged, manufacturers were contacted, and patients were recalled and scanned where required.

NHS England shared the Closure Report on the testicular implant recall, which was presented at the UHMBT's Quality Assurance Committee in September 2022. The report details the findings, lessons learned and actions taken to prevent reoccurrence. The findings were also discussed by the Director of Nursing (Clinical Quality) for NHS England North West and NHS England's National Patient Safety Lead for Never Events.

The Trust also provided details of an audit completed in June 2022 to review any incidents Trust-wide over the period from January 2016 to June 2022. No further incidents were found in Urology involving a retained needle guard.

Appendix 1: Glossary of terms used

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CCG	Clinical Commissioning Group	NIAF	Niche Investigation Assurance Framework
CQC	Care Quality Commission	PSIRF	Patient Safety Incident Response Framework
FTSU	Freedom to Speak Up	RCS	Royal College of Surgeons
GMC	General Medical Council	RLI	Royal Lancaster Infirmary
ICB	Integrated Care Board	RO	Responsible Officer
LSC	Lancashire and South Cumbria	UHMBT	University Hospitals of Morecambe Bay NHS Foundation Trust
MDT	multidisciplinary team		

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