An independent and external review to understand events that took place in the Adult Cardiac Surgery Department at Newcastle Upon Tyne Hospitals NHS Foundation Trust, between the period 1st January 2018 to 1st June 2021

[redacted]

On behalf of

Leeds Teaching Hospitals NHS Trust

Trust Headquarters

St James's University Hospital

Leeds LS9 7TF

Terms of reference

This report was commissioned by Dr A Vincent, Associate Medical Director for Quality & Patient Safety, on behalf of the Trust's Cardiothoracic Compliance and Assurance Executive Oversight Group.

Scope of the Review

An independent and external review to understand events that took place in the Adult Cardiac Surgery Department at Newcastle Upon Tyne Hospitals NHS Foundation Trust (NUTH), between the period 1st January 2018 to 1st June 2021, which relate to:

- [redacted]
- the process for dealing with those concerns; and
- the actions taken to respond and address those concerns.

Background

In May 2021, a series of [redacted] cases, [redacted] in which poor outcomes had occurred [redacted] was brought to the attention of the senior members of the Clinical Governance and Risk Department (CGARD) of NUTH.

[redacted]

Aims of Review

The independent review will look at what information was available within the organisation [redacted], and how the organisation responded to and acted upon such information between 2018 and 2021.

Specifically, the review will focus on:

- How concerns were raised [redacted]
- What action was taken, and whether the action taken was appropriate, sufficient and within the range of a reasonable response.

- What channels were used to raise such concerns and whether these were in line with Trust policies and procedures, normal informal and formal practices/governance, e.g. Datix, and if not, identify the reasons and establish if the diversion was a reasonable one.
- In line with a just and learning culture, identify any lessons learnt, and improvements to be made in either this department or elsewhere in the organisation in the future. The review is not intended to apportion blame to any individual or individuals.

Conduct of Review

The conduct of the review was set out as below by the Trust's senior management team.

1. The review will collect, collate and examine evidence in relation to concerns expressed [redacted] between 1st January 2018 to 1st June 2021.

This should include both general concerns [redacted]

This evidence should include those issues raised through established governance routes and in addition those raised through non-standard or informal communication and might include:

- E-mail or written correspondence.
- Minutes or specific recollections or records of meetings or conversations.
- Cases raised via the Datix system.
- Cases identified during Mortality and Morbidity meetings.
- Any other relevant documentary evidence.

2. The evidence will be collated and assessed to establish the facts to meet the aims of the review.

Structured interviews took place between October and December 2023 and were conducted either in person or by remote video conferencing. Staff interviewed

included cardiac surgeons, clinical directors, governance leads, medical directors and CGARD staff.

Output of Review

A written report detailing:

- Findings
- Conclusions in relation to the primary question as outlined in Aims of Review above.
- Recommendations for the organisation and department in relation to its alerting processes, policies, and mechanisms for raising concerns, and any learning for the wider organisation.

Clarification

A further clarification to the terms of reference was provided on 6 October 2023 to make it clear that records of conversations could only be used if they were made contemporaneously and agreed by those involved. Any documentary evidence to be discussed at meetings with staff should be disclosed prior to the meetings.

Acknowledgement

I would like to extend my thanks to staff at Newcastle Upon Tyne Hospitals NHS Foundation Trust for providing their availability for the purposes of this review. Staff were very generous with their time and genuinely keen to ensure that lessons were learned for the future. Staff members were also open and candid about their personal involvement and often reflective about how matters might have been dealt with differently, especially with the benefit of hindsight.

Summary of documents received with accompanying narrative

1. [redacted]

2. [redacted]

a) [redacted]

b) [redacted]

c) [redacted]

i) [redacted]

ii) [redacted]

iii) [redacted]

iv) [redacted]

v) [redacted]

vi) [redacted]

vii) [redacted]

viii) [redacted]

ix) [redacted]

x) [redacted]

xi) [redacted]

xii) [redacted]

d) [redacted]

[redacted]

e) [redacted]

f) An undated pdf document entitled ‘Thematic Analysis and Safety Recommendations’

g) A set of [redacted] serious incident reports, and associated action plans

3. An email from the Associate Medical Director for Quality and Patient Safety dated 18 May 2023 stating that the Trust was now in a position to commence the external review. A reply was sent to this correspondence on 25 May 2023 stating that the author would be available week commencing 26 June 2023 to visit the Trust and commence the review
4. An email from the Associate Medical Director for Quality and Patient Safety dated 19 June 2023 asking that the review be put on hold and enquiring about future availability
5. An email from the Associate Medical Director for Quality and Patient Safety dated 24 August 2023, asking that the author provide some dates to commence the review. A reply was sent offering dates in October 2023.
6. An email from the Associate Medical Director for Quality and Patient Safety dated 13 September 2023 with attachments including a letter of introduction and terms of reference.
7. An email from the Deputy Medical Director dated 27 September 2023, seeking confirmation that the author had no conflict of interest in undertaking the review
8. An email from the Deputy Medical Director dated 6 October 2023 with updated Terms of Reference (superseding the terms of reference sent on 13 September)
9. An email from the Deputy Medical Director dated 10 October 2023 with three attachments (Trust Quality Governance Structure, Trust Committee Structure 2018, PowerPoint slides of the Trust's Cardiothoracic Action Plan Oversight arrangements)
10. An email from the Associate Medical Director for Quality and Patient Safety dated 12 October 2023 with some suggested key lines of enquiry (KLOEs)
11. [redacted]
12. An email from the Deputy Medical Director dated 6 November 2023 with an outline of the PA allocation for various members of the Trust management structure

13. A further email from the Deputy Medical Director dated 10 December 2023 with a further clarification of PA allocation to named clinical and medical directors, and with an attachment of seven separate documents:

a) Trust structure flowchart (August 2018)

b) Capability Procedure to Address Concerns Regarding Competence of Medical and Dental Staff (version 7.5, effective 26 January 2017)

c) Dignity and Respect at Work policy (version 7.0, effective 22 January 2018)

d) Dignity and Respect at Work policy (version 7.1, effective 23 August 2018)

e) Disciplinary Policy and Procedure (version 10.5, effective 26 January 2017)

f) Disciplinary Policy and Procedure (version 11.1, effective 03 June 2020)

g) Disciplinary Policy and Procedure (version 11.0, effective 19 March 2019)

14. A flowchart was provided which highlights the committee structure and governance arrangements for cardiothoracic services at NUTH.

At clinical level, oversight is now provided by the Cardiothoracic Clinical Board at a regular Patient Safety and Quality oversight meeting. Oversight of this group is by the Cardiothoracic Clinical Board Assurance Group, which in turn reports to a monthly performance review meeting chaired by the Chief Operating Officer.

In parallel to this process, the minutes of the Cardiothoracic Clinical Board Patient Safety and Quality Oversight meeting are noted by the Cardiothoracic Compliance and Assurance Executive Oversight group, which is chaired by the Deputy Medical Director. Assurance is then provided to the Cardiac Oversight Group, and in turn the Trust Board.

[redacted]

a) A SCORE survey summary report for Theatres dated July 2019, for the Cardiothoracic Directorate at Freeman Hospital

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted].

ee) A copy of the Royal College of Surgeons external report dated 23 July 2021.

This report was issued in July 2021 following a request to the Royal College of Surgeons in February 2021 by the CMO to conduct an external review. Some key conclusions were:

i) The breakdown of relationships within the cardiac surgery department had impacted the ability of the unit to function in a cohesive and supportive way and had the potential to risk patient safety.

ii) There were serious team working difficulties which were not limited to adult cardiac surgery.

iii) Factions had developed within the department, with consequent effects on some staff members' health and wellbeing.

iv) There were reports that some cardiac consultants were not asking for assistance due to a breakdown in professional relationships.

v) MDTs were not working well, with insufficient time being allocated for mature case discussions. Attendance was variable, with some consultants choosing not to attend so as not to be associated with the poor practice in the recording of the decision making.

vi) Morbidity and mortality meetings were poorly attended and did not promote an environment conducive to learning and purposeful debate.

vii) The RCS concluded that a lack of intervention at executive level over time had led staff to lose confidence in the management to manage situations appropriately. Communication between management and clinicians regarding key decisions or actions had not always been consistent.

viii) The review team concluded that many staff lacked confidence in the Datix reporting system.

ix) The review team highlighted a number of concerns about the training programme in adult cardiac surgery.

x) The management, selection and distribution of cases did not appear to be equitable and there was a lack of collegiate working.

xi) A review of thirteen clinical records led the reviewers to conclude that there appeared to be a lack of ownership of cases and a lack of formal recording of MDT decision-making.

xii) The review team were concerned that continued divisions within the Unit had the potential to impact patient care and safety.

The key recommendations (that pertain to this report) were as follows:

i) Encourage learning and engagement to improve interpersonal relationships, with consideration of professional mediation

ii) Personnel changes and/or creation of new posts in order to improve the cultural behaviours within the unit.

iii) Improve the trainee programme.

iv) Ensure a robust reporting culture using Datix, including providing feedback and where necessary providing anonymity to the individual.

v) Improvements in aortic and transplant surgery, with appropriate support provided to team members.

vi) Provision of communication, coaching and mentoring training for individuals in positions of leadership or management.

vii) Formal documentation and a clear audit trail for any decisions or action points from the MDT and M&M meetings, including inter-departmental MDTs.

viii) Implementation of a dedicated MDT co-ordinator to ensure accurate recording and dissemination of minutes.

ix) Development of a formal code of conduct of expected behaviours at MDT and M&M meetings.

x) The Trust must put in place comprehensive systems to monitor quality, safety and operative outcomes, including early review and discussion of unexpected outcomes and surgical complications.

[redacted]

[redacted]

[redacted]

Key lines of enquiry

1. [redacted]

[redacted]

2 [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

3. How did the Morbidity and Mortality (M&M) meetings function between 2018 and 2021 and what happened when the cases subsequently found to be those of avoidable harm were discussed?

It was widely accepted that there were deficiencies in the departmental mortality review process between 2018 and 2021. [redacted]

[redacted]

[redacted]

4. [redacted]

5. [redacted]

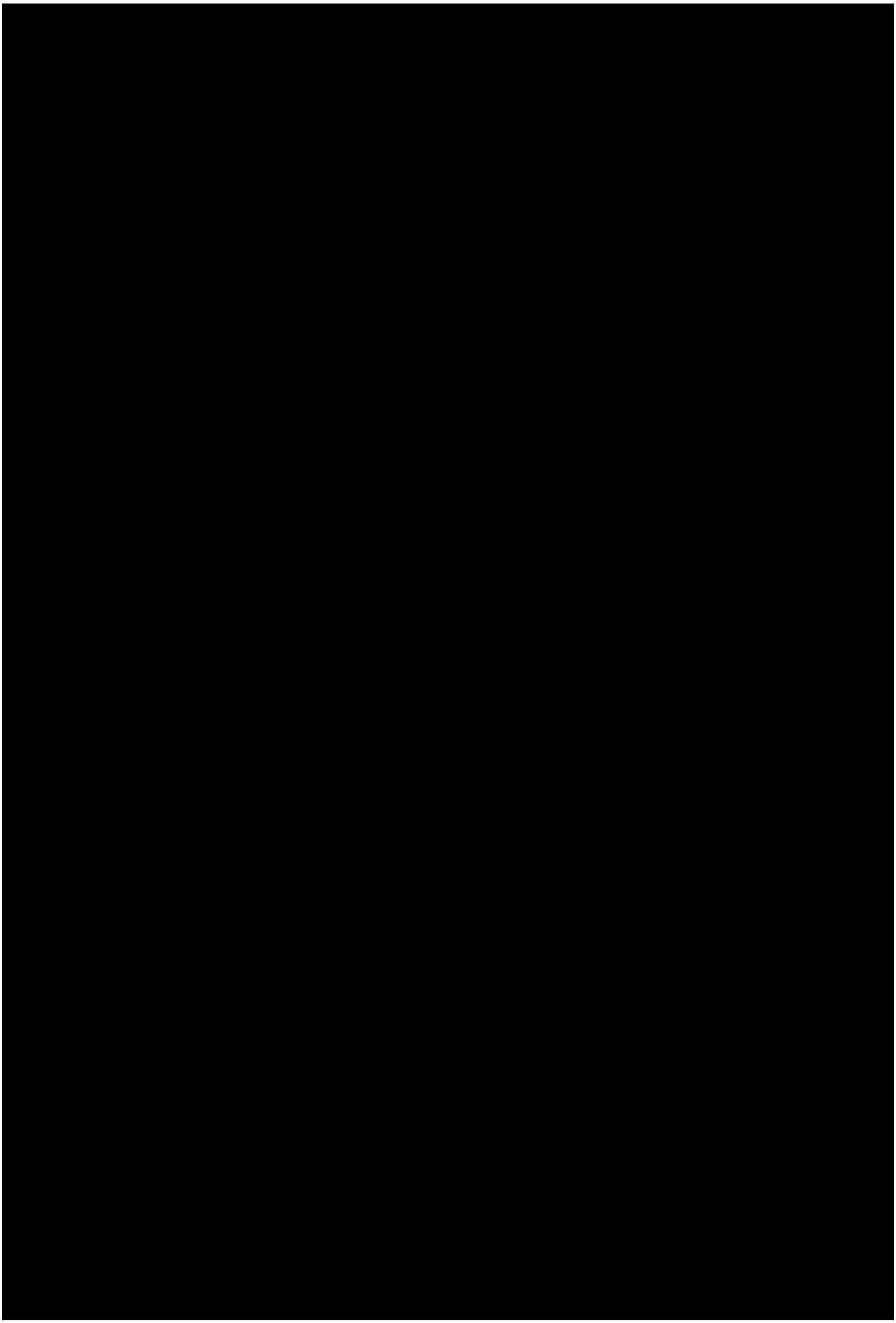
[redacted]

6. [redacted]

[redacted]

7. [redacted]

[redacted] It is worth stating that there is a relative paucity of written communication which raises three possibilities that I am unable to differentiate between. Firstly, that concerns were not in fact raised consistently between 2018 and 2021. Secondly, that concerns were raised verbally with an expectation that these would be dealt with in the same way as a written submission. Lastly, that written communication did occur, but these were not retained or possibly lost in the transition to nhs.net email.



[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

8. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

9. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

10. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

11. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

At the time, I understand that all patient safety incidents were escalated through Datix rather than a Potential Serious Incident notification being generated and escalated at directorate level. [redacted]

[redacted].

Although unexpected deaths were reported to the Coroner, this was done at individual clinician level with little in the way of corporate oversight. It is unlikely that an additional layer of scrutiny was provided by the team of Medical Examiners as they would not routinely review deaths referred to the Coroner.

In the wider Trust, CGARD appeared to function effectively with a direct reporting mechanism to the CMO and a number of separate but inter-dependent workstreams (patient safety investigations, mortality, risk compliance and assurance, quality assurance, clinical effectiveness). A weekly serious incident triage panel was held with wide medical and nursing representation, including the clinical directors for quality and patient safety. Both incidents reported on Datix and those flagged outside the normal reporting processes were discussed and a decision made about the appropriate route of investigation and external reporting to NHSE's StEIS (Strategic Executive Information System) portal. A monthly serious incident panel was held with the CMO and a number of other key individuals.

There did not appear to be a mechanism in place at the time whereby an overview of a directorate's metrics could be considered in one place. This was felt to make it harder to pick up signals of concern. This has now been addressed with the introduction of the new Trust structure, comprising eight clinical boards.

The 2017 peer review of the directorate identified concerns related to the functioning of the MDT and M&M meetings. It is not clear that the Trust then subsequently monitored the compliance and improvement actions to receive the necessary assurance that improvements had been made.

12. [redacted]

[redacted]

[redacted]

It should be noted that Covid dominated healthcare in 2020 and it is therefore reasonable to ask what impact this had on the situation. The consensus appears to be that cardiac surgery took bold steps to ensure the continuation of the service during the pandemic and levels of activity remained good [redacted] It does appear, however, that the mechanism to investigate serious incidents was somewhat diminished during Covid, with investigations often consisting of case note reviews, rather than the usual more detailed discussions with staff involved. This may have impacted the ability of individuals to highlight concerns.

13. How was CGARD involved with assessing the adult cardiac surgery department from 2018-21 using information from the peer review process, GMC and SCORE surveys, as well as data from Datix, mortality reviews and potential serious incident notifications?

As outlined above, a series of peer review exercises and staff surveys took place from 2017 onwards. Following each of these, a number of initiatives were put in place, with regular engagement pieces.

Cardiac surgery governance would be discussed at monthly meetings and any issues escalated to the regular head of department meetings. CGARD met with the

AMDs on a weekly basis. Regular Trust review panels took place, including quality committee, executive team meeting, serious incident panel and the clinical risk group.

Items discussed within the departmental governance meetings would be issues such as rotas or waiting list management. The agenda was often large, leaving little or no time to examine issues such as Datix reporting or duty of candour. There would be occasional discussion about theatre matters, but these would normally be discussed at audit type meetings with limited directorate oversight. Attendance was said to be variable. Overall, this meant there was limited opportunity for patient safety concerns to be formally brought to the attention of CGARD.

14. What could have been done differently at all levels within this organisation to recognise the patterns of concern earlier?

There was widespread agreement that, on the balance of probabilities, and with the benefit of hindsight, a different approach would have led to concerning signals being picked up earlier. Comments from staff included:

a) [redacted]

b) Focus within governance meetings was largely on finance and performance, with less emphasis on quality and safety. The overall governance structure was not robust enough to pick up signals of concern.

c) [redacted]

d) [redacted]

[redacted]

e) [redacted]

f) [redacted]

g) [redacted]

h) [redacted]

i) [redacted]

j) [redacted]

k) Lines of escalation were not always clear. There was limited opportunity for the clinical directors for quality and patient safety to scrutinise data such as mortality and morbidity meetings minutes in any detail. [redacted]

l) Ownership of data within the directorate was felt to be lacking at times, with no clear oversight of key metrics such as return to theatre rates etc.

m) [redacted]

n) [redacted]

o) [redacted]

p) [redacted]

Having considered all the relevant correspondence and individual testimony, I would make the following additional observations.

1. [redacted]

[redacted]

2. Of note, as a Foundation Trust, the consultant interview panel did not include an external college representative. [redacted]

3. [redacted]

[redacted]

[redacted]

[redacted]

4. [redacted]

[redacted]

[redacted]

[redacted]

5. Ensuring high-level clinical oversight of a busy teaching hospital NHS trust requires a significant amount of resource. [redacted]

Accepting that Leeds Teaching Hospitals NHS Trust is a slightly larger organisation, the difference in time allocated to senior management positions is significant. All Medical Director and Associate Medical Director roles in Leeds are given PA allocation, but with modest responsibility allowances. Within Risk Management and Corporate Governance, 11 PAs are distributed between three clinicians at MD and AMD level to carry out this work, with the expectation that at least one will always be able to attend key governance and oversight meetings. One of the Associate Medical Directors chairs the Trust's Mortality Improvement Group and reports directly to the Quality Assurance Committee and Trust Board. Clinical Directors for bed-holding

Clinical Service Units (CSUs) will typically receive a job planned PA allocation of 3-4 PAs.

It was reassuring that within the new NUTH structure, Clinical Board Chairs and Clinical Directors will receive a responsibility allowance and have PA allocation in their job plans.

6. [redacted]

It is extremely important for all parties that if concerns are raised, then a record of that meeting is made and held on file for future scrutiny. Concerns about a clinician's conduct or capability should be escalated to the Responsible Officer for discussion within a senior leadership forum including a representative from HR. A fact-finding exercise can then follow, with a subsequent decision made on whether a more formal investigation should take place. In all cases, support and regular follow-up should be provided, with minutes made of those conversations. Clinicians in positions of management responsibility must be clear that their role is to escalate concerns. This should be regarded as a neutral act to protect both themselves and the clinician.

The role of Freedom to Speak Up Guardians (FTSUGs) and the National Guardian were established in 2016 following the events at Mid-Staffordshire NHS Foundation Trust and recommendations from Sir Robert Francis' Freedom to Speak Up Inquiry. However, in many NHS organisations, awareness and trust in this role took some time to establish. I have not seen any evidence that the FTSUG was contacted between 2018 and 2021 regarding concerns about outcomes within the cardiac surgery department at Newcastle.

7. [redacted]

[redacted]

8. [redacted]

[redacted]

9. [redacted]

[redacted]

10. Although cardiac surgical deaths were reported to the Coroner, [redacted]

11. The Trust's Novel Interventions and Procedures Group (NIPG) gave approval for an innovative alternative technique for aortic valve replacement called an Ozaki procedure. The approval was for a specific patient cohort of children and young adults. [redacted]

10. [redacted]

[redacted]

11. [redacted]

12. [redacted]

In large teaching hospital trusts with devolved management structures, there is an inherent reliance on staff escalating concerns when they occur and individuals in positions of responsibility responding appropriately. [redacted]

[redacted] The introduction of the new Patient Safety Incident Response Framework (PSIRF) should assist with this culture shift. PSIRF replaces the current Serious Incident Framework (2015) and represents a significant change in the way the NHS responds to patient safety incidents. Its four key principles are compassionate engagement and involvement of those affected by patient safety incidents, a system-based approach to learning from patient safety incidents, considered and proportionate responses to patient safety incidents, and supportive oversight focused on strengthening response system functioning and improvement.

Recommendations

1. Ensure that the Royal College of Surgeons' 2021 review recommendations have been implemented in full, including:

a) A significant piece of engagement work to improve interpersonal relationships, with a recommendation for professional mediation

b) Ensure a robust reporting culture using Datix

c) Provision of communication, coaching and mentoring training for individuals in positions of leadership or management.

d) Formal documentation and a clear audit trail for any decisions or action points from the MDT and M&M meetings, including inter-departmental MDTs. This should include discussions about dual consultant operating and ensuring that surgeons of sufficient seniority are supporting more complex work. Any significant deviations from the agreed MDT plan must be brought back for further discussion and consensus.

e) Implementation of a dedicated MDT co-ordinator to ensure accurate recording and dissemination of minutes.

f) Development of a formal code of conduct of expected behaviours at MDT and M&M meetings.

g) Ensure there are comprehensive systems to monitor quality, safety and operative outcomes, including early review and discussion of unexpected outcomes and surgical complications.

2. The Trust should ensure there is process for robust and independent review of mortality with appropriate governance oversight to ensure that lessons are learnt. Emerging themes of concern must be shared with the Board at an early stage with a clear plan of action for investigation and review. CGARD should ensure that their team have consistent representation at the clinical board governance meetings, with full oversight of the key quality metrics such as mortality, complications and compliance with duty of candour.

Structured Judgement Reviews (SJRs) should be completed on a rolling basis with the outputs generated stored centrally to allow regular review and detection of

emerging themes. SJRs should be allocated by the Quality and Governance team to ensure independence and avoid selection bias, for the purpose of identifying shared learning and emerging themes. The SJR should include an assessment of whether the MDT planned operation was carried out and whether the operation was performed by the right time person at the right time. The review should also check the completeness of the referral to the Coroner.

3. Referrals to the Coroner should be in writing and contain clear details of the case, including any concerns regarding whether the death was avoidable. All referrals should be reviewed at AMD level in CGARD to ensure adequate oversight and to determine whether further investigation is required. It should also allow the detection of emerging themes of concern, such as a pattern of deaths for an individual surgeon or specialty area.

4. Morbidity and Mortality meetings should review all deaths for the purposes of shared learning and to determine whether a death was avoidable. All potentially avoidable deaths must be escalated immediately to CGARD with a potential patient safety incident notification. This should trigger a discussion with the treating clinician and a representative from the directorate or clinical board management team when determining the level of investigation. This decision should be shared with and ratified by the Chief Medical Officer and Chief Nurse. The Trust should review its approach to PSIIs with a view to determining whether utilising lead investigators from outside the clinical board or directorate will help ensure objectivity.

5. All patient safety incidents, including unexpected deaths and perioperative complications must be recorded on Datix contemporaneously with an appropriate level of harm allocated. CGARD must review all patient safety incidents of moderate harm or above in a weekly meeting to determine whether more information is required, or if a potential serious incident notification needs submitting. Where it is agreed that a moderate harm patient safety incident has occurred, the relevant directorate or clinical board must ensure that the first duty of candour letter is sent within ten days, unless there are very exceptional circumstances. CGARD must review duty of candour compliance on a rolling basis.

6. Where the clinical board or CGARD have identified emerging themes of concern (e.g. underdosing of low molecular weight heparin), these must be shared both

locally and at Trust-wide level. CGARD should work with the Trust's communications team to determine how best to reach staff at all levels to maximise impact.

7. Consider the value of a Royal College representative on all consultant interview panels to scrutinise the proposed job plan and ensure that appropriate mentorship of the newly appointed colleague has been discussed and agreed by all parties.

8. Ensure that all new consultant appointments have a dedicated consultant mentor and that a meeting with the interview panel's CMO representative takes place 3-6 months following successful appointment to check on progress and welfare.

9. [redacted]

10. Ensure there is adequate job-planned resource within CGARD and the Medical Directorate to allow detailed oversight of the Trust's large governance and oversight programme.

11. [redacted]

12. The Trust should ensure wide organisational awareness of the Freedom to Speak Up Guardian by means such as staff emails, departmental posters, local workshops and computer screensavers.

13. Further engagement is required to build layers of trust between the senior management and clinical teams, including adult cardiac surgery, to ensure that staff are confident to raise patient safety concerns without fear of consequence.

14. MDT meetings must be structured to allow adequate multidisciplinary representation. All cases must be discussed and then brought back to the meeting if a significant deviation from the agreed operative plan is subsequently deemed necessary. The level of the allocated surgeon's experience should be considered,

along with the need for dual consultant operating. The minutes from the meeting must be distributed and regularly scrutinised by the clinical board governance team.

15. The Trust must ensure proper oversight of novel procedures approved by the NIPG. Any deviations from the agreed proposals must be brought back for further consideration. A review of progress must take place at the specified time to ensure compliance with the agreed terms and to examine any outcomes of concern.

16. The new Patient Safety Incident Response Framework (PSIRF) must be introduced to the organisation as a priority as this will help to support the desired culture shift within the organisation.