# Thematic Analysis
# And
# Safety Recommendations

**Background**

The Trust is one of the largest teaching NHS foundation trusts, with a catchment population of 1.7 million including Northumberland, Tyne & Wear, North Cumbria and North Durham/Sunderland. The department provides tertiary cardiac services including transplantation to a larger catchment area, including Scotland. The Trust also runs a speciality service at a satellite clinic in Carlisle once a week.

The department currently comprises nine adult cardiac surgeons of which six cover both Transplant and cardiac surgery; the three recent cardiac surgeon appointments all have one of the senior cardiac surgeons named and on-call with them overnight as support. Hence, the senior cardiac surgeons work on a 1 in 3 rota. All surgeons take part in the acute aortic dissection service. The congenital rota is separate and is on a 1 in 2 basis with one surgeon providing holiday relief. Thoracic services have five consultants and cover is on a 1 in 5 basis.

[redacted]

We worked through three phases during the review: inquiry and analysis; development of themes; and recommendations for the future. These will then be shared with the department to co-design a list of priorities and an action plan. A new governance lead has already been appointed during the time of this investigation.

[redacted]

**Investigation process and methodology**

We used a standard process for the investigation based on the Healthcare Safety Investigation Branch (HSIB) model:

• Gathered all relevant evidence

• Established the factual circumstances surrounding each event

• Analysed the evidence

• Identified the most significant safety factors and safety issues that contributed to the event being investigated

• Formulated findings and safety recommendations

This process was supported by the following:

**Review of medical records**

Records accessed included hospital records (paper and electronic) and GP records. All relevant trust policies, procedures and practices were reviewed. This may have included a review of post-mortem findings and medical reports for Coroner, waiting list records, records of acuity levels and staff duty rosters.

**Subject matter review panels**

The panels during this investigation were attended by an experienced subject matter advisor in cardiac surgery, who provided advice and guidance. This guidance included signposting to evidence, national guidance and current best practice. In addition, further subject matter advisors were consulted where necessary e.g., for thoraco-abdominal cases.

**Staff interviews**

Face to face or virtual interviews were conducted with key participants, who provided a depth of information in addition to the medical records. We also requested interviews with other members of the Trust who provided further background information to support the investigation. Where individuals were able to provide small pieces of information relevant to the investigation, investigators conducted telephone or email enquiries.

[redacted]

**Analysis**

The basis of human factors as a science is to understand that humans have limitations, and these limitations are both physical and cognitive. Our process allows us to look at wider systems within healthcare as well as how individuals behave within it. We used a range of analysis tools to review the evidence collected during the investigation process. These included Systems Engineering Initiative for Patient Safety (SEIPS) (Holden et al., 2013). This supported investigators to incorporate evidence from a range of sources, with the emphasis on how people interact with the tools, systems, and situations they encounter. A safety-II approach (Hollnagel et al., 2015) was used to compare how ‘work as prescribed/imagined’ compared with ‘work as done’.

Once analysis was complete, we formed findings and safety recommendations based on the relevant factors of the cases, aimed at reducing the chance of reoccurrence and optimising learning for all members of trust staff. The findings are included in individual reports however, this report contains an overarching view of emergent themes to support broader, directorate-wide systems-based learning with related safety recommendations.

## 1. Psychological safety

### Confidence and trust within the department

The panel learnt that previously, clinical concerns in the department and subsequent suspensions, were handled by the Trust in what was perceived to be a draconian manner. [redacted] The situation escalated rapidly, involving senior management, leading to anxiety and mistrust. We learnt that relations within the consultant group fractured, and this may have impacted on how and when help was sought in a number of cases.

Some of the people we spoke to were uncomfortable giving names or information to us relating to incidents despite the confidential nature of the interviews. The datix system is poorly understood and largely utilised for low level incidents only, with missed opportunities for shared learning. [redacted]

### Confidence and trust between the department and senior management

We learnt that there was a perception from some staff that their safety concerns had previously been dismissed and that they had had to fight to bring the cases back to the attention of senior management. This may be in part due to the lack of robust governance structures, reporting and data collection within the department to use as supporting evidence. This atmosphere of mistrust appeared to be further compounded by the findings of a recent external review. We learnt that some staff were unhappy with the way the findings of the review were communicated, and whilst details needed to remain confidential, this led to gossip and a lack of trust within the team. Nonetheless, creating trust and a safe environment for sharing concerns in the future is key for Clinical Governance and Risk Department (CGARD) to support the directorate effectively through the learning and change process that is now required.

**Safety recommendation**

**The directorate, with support from senior management, to create a psychologically safe climate for individuals to share experiences or concerns and for others to listen without reacting. The investigation considers that that external expert (independent) help will be required to support the required cultural change.**

## 2. Service organisation

### Mentoring new consultants

The investigation heard there are concerns in the department around supporting and mentoring new consultants until they mature in their senior role. We heard conflicting reports about mentorship arrangements and we consider a more formal process is required to ensure clarity of role and a consistent approach across the department.

**Safety recommendations**

**Any new appointments are made with the directorate manager, Head of Department and Clinical Director having prior insight into the nature for the practice of the departing surgeon and a clear plan to manage any outstanding cases. If the leaving surgeon has a sub-specialty interest the plans for that service going forward must be articulated prior to a new appointment.**

**A formal, documented, mentoring program for all new consultants, formally agreed on acceptance of the post with named mentors for sub-specialism where applicable (e.g., mitral, aortic) as well as rota cover for transplantation.**

**The directorate to consider use of proleptic appointments, ensuring agreed and robust governance where these are made.**

## The aortic service

[redacted] None of the other surgeons had an interest in aortic work. We learnt that this also created difficulties for the vascular team if they needed advice about a patient and the surgeon with an interest was not available.

We have identified several serious incidents amongst aortic cases. We noted that the team as a whole are inexperienced in this type of work. [redacted] We heard that the anaesthetic and perfusion teams also have concerns about their exposure to and experience with this type of work.

Very few organisations in the UK have a sizeable thoracic-abdominal practice (30-40 cases per annum) and the investigation considers that consideration should be given to the viability of such a service on a regional basis.

**Safety recommendations**

**The Trust to ensure appropriate mentoring and support for surgeons undertaking complex aortic surgery, including external preceptors on site if necessary.**

**The directorate to ensure input from an experienced aortic surgeon with a clear pre-op strategy planned for more complex aortic cases (e.g., previous type B repair, previous carotid surgery).**

**The Trust to consider whether all thoraco-abdominal surgery might be better undertaken at a recognised UK site with significant collective experience of the procedure.**

## The mitral service

We heard that there were a group of surgeons that were identified as mitral surgeons and that this group undertook all mitral valve repairs, the informal policy in the department was that any surgeon could undertake mitral valve replacement.

A number of the reviewed cases involved patients with significant mitral valve calcification rendering them unsuitable for repair but carrying considerable technical challenges in handling the mitral valve and carrying a higher mortality risk. There was variable support for these cases, the operability of one was disputed but not documented, and when there was more than one consultant involved it was not always clear that either had significant mitral experience. The technical challenges of this group can be considerable and should be undertaken by surgeons with experience in this field, ideally with documented MDT input recognising the risk. If they were to go through a Dual Consulting Operating (DCO) process, it would also be expected that at least one of the surgeons has a specific mitral interest and experience.

**Safety Recommendation**

**The directorate to clarify the role of mitral surgeons in complex mitral replacement surgery.**

## Multi-Disciplinary Team meetings (MDT)

The investigation was unable to establish a coherent picture of the MDT process, however, it was clear was that many complex patients did not pass through the MDT, and others were discussed after listing for surgery. This meant that opportunities for optimal care plans were not taken and may have impacted on the outcome for these patients. We heard that attendance at the meetings was poor and that the consultant listing the case for discussion would not necessarily attend.

The more conventional format for MDTs would be that cases are brought to the relevant MDT by the referring cardiologist, discussed at a quorate forum and then if the decision is for surgical intervention the case is then allocated to the surgeon who is best skilled to undertake this surgery. This decision made with openness and transparency and with clear documentation of the MDT outcome including any subtleties relevant to the nature of the surgery articulated. This would also enable sharing of information about complex cases which require review in more than one speciality MDT, supporting a full appraisal of all the possible treatment options and subsequent decision-making. Due to a lack of a functioning MDT, we also heard that anaesthetic concerns after pre-assessment were not escalated. This also needs addressed.

The surgical pathway for “unstable” patients was not clearly defined and there appeared to be a lack of ownership of these patients e.g., patients being seen daily on wards with the comment “awaiting surgery” being documented continually whilst their named consultant was on leave.

**Safety recommendations**

**The directorate to establish robust MDT meetings that are fit for purpose across all specialities. This should include a clear SOP identifying the membership of the group, inclusion and exclusion criteria for cases for discussion and a clearly documented surgical plan following MDT review,**

**including specifying the type of procedure to be undertaken and consideration of the optimal surgical team for complex cases. This may involve colleagues from other units where necessary.**

**The directorate to require documentation of all decisions not to offer surgery, ideally with a second opinion and clearly identify ownership of these patients and a method to ensure a subsequent management plan for them.**

**The directorate to ensure a mechanism whereby concerns from pre-assessment are fed back to the MDT for further consideration and/or the opportunity for pre-operative planning meetings with the wider clinical team in advance of a planned operation.**

**The directorate to ensure that unstable patients have a clearly defined pathway for review by a senior decision maker. This should include the line of responsibility when their named consultant is on leave.**

## Dual Consultant Operating (DCO)

The principle of DCO was introduced nationally to address the possibility of risk averse behaviour with high-risk cases, as the outcome of cases thus allocated pre-operatively would be measured at unit rather than individual surgeon level. There are a number of principles within the policy (available at https://scts.org/professionals/surgical_sub_specialities/cardiac/unit_and_outcome_data.aspx) but in essence for a case to fulfil DCO practice, it should be discussed at an MDT where the decision for DCO is made and documented, the surgeons are identified, have a clear operative plan and are both present for the majority of cases and there is a clear audit trail both in the notes and for subsequent audit. It is not applicable for mentoring or the introduction of new techniques.

On occasion we heard that there was a reluctance within the department to call for help and/or offer it when relationships deteriorated. Although we heard that surgeons regularly scrubbed together, assisting one another, and in a number of the cases reviewed there was more than one surgeon scrubbed, the formal process of DCO it is not embedded within the department.

A number of the cases reviewed were high risk, atypical procedures and although often had more than one surgeon present, the lack of documentation of MDT decision and operative strategy suggests that they represent cases where the principles of DCO could have been very fruitfully applied.

Some units in the UK have adopted a Star Chamber approach for complex cases and this may be something the directorate wish to consider.

**Safety recommendations**

**The directorate to consider the implementation of the national DCO policy, with documented MDT discussions in notes, clear allocation of surgeons and full audit trail.**

## Waiting list management/identification of long waits

[redacted] We were

told that each consultant manages their waiting list with their secretary. We learnt that lists are not shared openly and there was uncertainty as to what was on lists. We were unable to find any evidence of any failsafe mechanism in the waiting list system. We were told that patients needing aortic surgery in 2017/2018 were sent to Liverpool; there was no evidence of referrals or transfers to Liverpool.

**Safety recommendations**

**The directorate to ensure transparency of lists and timely waiting list reviews, with delays and reasons flagged within Trust.**

**The directorate to agree robust oversight processes and what failsafe mechanisms required to ensure safe and timely processes.**

**The directorate to develop a process to ensure any deaths occurring whilst a patient is on the waiting list, are documented at M&M meetings with any reasons for delay identified and shared.**

## 3. Governance, policies and assurance processes

### New Interventions Procedure Group (NIPG)

The panel learnt that an application was made to NIPG in January 2018 to introduce a new procedure for aortic valve reconstruction, namely the Ozaki procedure. The application proposed this was predominantly for paediatric and young adult patients and was approved by the Clinical Director and Directorate Manager at the time of submission. NIPG recommended approval with the requirement to present an update of patient outcomes; this was finally approved at Clinical Governance and Quality Committee. We learnt that sometime after this approval, an additional adult aortic surgeon was invited, by the initial surgeon and at the request of the Clinical Director and senior congenital cardiac consultant, to participate in the programme following the necessary training and proctorship. We were told the initial consultant had presented this plan to expand the Ozaki programme at one of the surgeon's meetings; the other surgeons could not recall this taking place. A further application to extend the remit of Ozaki procedures to older adults was not submitted. We also learnt that whilst individual cases requiring aortic valve reconstruction were deliberated at MDT, the type of reconstruction, including possible Ozaki cases, was not explicitly discussed.

The panel considers that within the directorate there was no clear governance process for maintaining oversight of newly approved procedures. This includes seeking approval for extension of the Ozaki programme and the monitoring and reporting to NIPG of adverse events

**Safety recommendations**

**The directorate to develop robust governance processes in place for all applications to NIPG, ensuring there are no departmental extensions to the approved application without further NIPG oversight.**

**The directorate to maintain oversight of any adverse events occurring in patients undergoing recently approved, new procedures, ensuring such events are reported via Datix and directly to NIPG.**

## Incident reporting

Review of the Datix system showed that incident reporting is largely reserved for low level incidents. There is no trigger list for staff to use for incident reporting. Staff had poor awareness of how incident reporting works and a number of staff described Datix being used as a mechanism to criticise clinical practice rather than a tool for learning . There was a reluctance from some senior staff to accept that processes and policies within the department need to change [redacted] Deaths after elective surgery are traditionally considered recognised complications in the department and not reported via Datix. This means that learning is not captured and Duty of Candour is not fully embedded or consistently completed. One patient had had a recent pregnancy, this was not flagged for statutory reporting.

**Safety recommendations**

**The directorate to develop and publicise a trigger list for incident reporting.**

**The directorate to ensure that all deaths after elective surgery are reported through Datix for consideration at Trust Serious Incident Triage Panel.**

**The directorate to ensure that Duty of Candour is completed for all cases where moderate harm or above is sustained (including recognised complications).**

**The Trust to ensure that deaths within a year of pregnancy, regardless of place and circumstance, are conveyed by the relevant specialty team to CGARD for statutory reporting.**

## Documentation

The investigation considers that the records reviewed were, on occasion, lacking in detail. During the consent process, several of the cases reviewed demonstrated time was spent meeting with patients in clinic and we were told about the explanations provided to patients, which included diagrams to explain the proposed surgery. We found that there was inconsistent documentation of the magnitude of risk for patients. We found several cases where post -operative risk may have been underestimated.

Many of the operating notes reviewed were incomplete and did not always reflect the degree of complications. It was not clear when help was summoned or necessarily why, or who completed which part of the procedure. There were several cases where the narrative during the interviews was significantly different from other accounts, we were unable to clarify from the records and we could not reconcile the different accounts. In some of the cases, reports to the Coroner were brief and lacked detail..

The panel considers application of Duty of Candour was inconsistent and remains incomplete for some of the cases reviewed. Although there is evidence of letters and/or discussions with patient's families on e-Record, the investigation considers that a number of these letters lack the level of detail required to satisfy the requirements for Duty of Candour.

**Safety recommendations**

**The directorate to ensure a consistent approach when obtaining informed consent, accurate record keeping and compliance with Duty of Candour in accordance with recognised national standards; to develop an assurance process to demonstrate these are consistently achieved.**

## M&M

It was clear that key individuals were not always invited to M&M and that the meetings focused entirely mortality with no opportunity to learn from serious morbidity. We also heard that the presentations were biased in the opinion of some and weighted towards a particular narrative.

Of the cases investigated, seven were discussed at M&M. Of these cases, five were recorded as Hogan 2 or above but no learning was documented.

**Safety recommendations**

**The directorate to ensure that learning is captured and shared from all cases rated Hogan 2 or above at M&M.**

**The Trust, via CGARD, to ensure that Trust wide learning is captured and shared from all cases rated Hogan 2 or above at M&M.**

**The Trust, via CGARD, to develop a robust audit process to gain assurance that the mortality review process is embedded in all directorates.**

## Support after adverse events

We found that a number of staff were deeply distressed by some of the peri-operative deaths and had not had the opportunity to discuss these together. We learnt that debriefs were not usual practice in the department and that the forum for discussion, the M&M was avoided by some staff because of its combative nature.

We learnt that there was no established forum for shared learning involving the whole team post-transplant cases. Where these did occur, they took place in individual teams.

**Safety recommendations**

**The directorate to embed constructive and supportive debriefs, involving all relevant disciplines, following an adverse event or where there is an opportunity for learning.**

**To consider additional psychological support available for staff following particularly traumatic or distressing events.**

## Data including surgeons' performance outcomes

The National Institute for Cardiovascular Outcomes Research (NICOR) collects data and produces analysis to enable hospitals and healthcare improvement bodies to monitor and improve the quality of care and outcomes of cardiovascular patients. NICOR data is several years old by the time of publication and has been checked for missing data, adjusted by morbidity (Euroscore) and cleaned before publication.

We heard differing views as to who was responsible for outcome monitoring and the associated governance within the directorate (and in fact wider Trust), with discordant views and/or ambiguity

regarding the role of the Clinical Director, Head of Department, Clinical Director Quality and Safety and directorate Governance Leads.

We learnt that although there is a database with outcome data, the department has no formal system for producing real time data on morbidity (stroke rate, MI rate, VTE rate, re-opening rate) and mortality. We were told that presenting this data within the department might cause discomfort and that data would be sent annually to individual surgeons.

The investigating considers that quarterly data is required for all surgeons, with mortality funnel plots or similar based on cases to date (rather than specific time frames), morbidity data and details of case mix and that sharing this data openly and honestly is indicated both within the surgical team and beyond to anaesthetists, cardiology and trust governance. The organisation should be aware of the unit's outcome data well in advance of national publication through NICOR.

**Safety recommendation**

**The directorate to ensure that quarterly M&M data is available for all surgeons together with quarterly Euroscore data.**

**5. Leadership**

This is a large directorate with lots of varied groups and interests (cardiology, adult cardiac surgery, congenital cardiac surgery, anaesthesia, perfusion, intensive care, transplant).

The Clinical Director has overall responsibility for the running of the directorate. The management structure in the directorate is not clear and we heard varying accounts of leadership within the department. The most consistent view was that the Head of Department was now a nominal role with no real accountability. We heard there is a formal Heads of Department meeting for these individuals to interface with the Clinical Director and directorate management team. We also heard that leadership styles have differed [redacted] This has led to tension. The investigation acknowledges the challenges that the Clinical Director has faced over the last few years.

[redacted]. The absence of an open reporting culture, engagement with established governance processes and robust data to support the concerns raised, may have contributed to this.

There seemed to be a reluctance from some senior members of staff to take responsibility for behaviours and concerns around safety in the department. We learnt that a previous Clinical Director signed the application for the Ozaki programme in congenital cardiac surgery and that the application did not extend to adults. This was also known by other senior staff in the department, but the programme continued. Some senior staff were reluctant to accept that changes need to be made in the department moving forward and were keen to defer the responsibility for this onto other colleagues.

There was more consistency regarding the perceptions of how the senior trust management subsequently handled the situation when concerns were first raised. This appears to have resulted in simmering tensions between colleagues going forward such that rather than have concerns being addressed openly they have been discussed internally.

The raised tensions and subsequent reluctance to openly discuss issues in an appropriate environment have been compounded by several the issues discussed earlier, specifically the lack of clear governance processes and outcome reporting, dysfunctional MDTs and M&M meetings. This has resulted in surgeons occasionally operating in relative isolation, without collegiate support from peers to support decision making and operative interventions, or a tendency to ask for such support late in the situation.

**Safety recommendations**

**The directorate to define clear roles and responsibilities to ensure robust governance and effective leadership within the directorate.**

**The directorate, with support from senior management, to create a psychologically safe climate for individuals to share experiences or concerns and for others to listen without reacting.**