Independent Mortality Review of Cardiac Surgery at St George's University Hospitals NHS Foundation Trust

March 2020

Contents

1. Introduction

1.1. Background

St George's Hospital (hereafter "St George's" or "the Trust") provides cardiac surgery services for patients from around South West London, Surrey and Sussex. The cardiac surgery unit provides support to the Major Trauma Centre and Heart Attack Centre based at the Trust.

Unit-based outcomes for cardiac surgery are reported nationally through the National Institute for Cardiovascular Outcomes Research (NICOR). Mortality rates are risk-adjusted to allow for differences in risk profile when comparing hospitals across the UK (for example a particular unit may operate on older patients or more patients with kidney disease). Risk-adjusted outcomes are reported on a three-year rolling basis.

The Trust received two alerts from NICOR concerning cardiac surgery, the first for the period April 2013 to March 2016 and the second for April 2014 to March 2017. An 'alert' is triggered when a unit's survival rate falls below a pre-determined 'safety limit', which is two standard deviations below the mean survival rate for all 31 cardiac surgery units in the UK.

After the first alert, the Trust undertook an internal review of deaths in that time period. The Trust developed an action plan based on the results of that review. After the second alert, the Trust commissioned an external review of the service (not a casenote review of individual patients) by Dr Mike Bewick, which was published in August 2018[1].

Following the second alert there was significant public and media attention focused on the cardiac surgery service at St George's.

NHS Improvement is responsible for overseeing all NHS Trusts and NHS Foundation Trusts. It supports providers to give patients consistently safe, high-quality, compassionate care within local health systems that are financially sustainable. NHS Improvement commissioned this independent mortality review to examine deaths following cardiac surgery during the period April 2013 to September 2018, later extended through a request from the Trust to 1 December 2018. The terms of reference for this panel review are published by NHS England and Improvement alongside this report.

The purposes of this panel review are to verify that the Trust has identified and addressed the concerns raised through both NICOR alerts and to inform the Trust's discussions with the coroner regarding the deaths.

1.2. Methodology

An independent panel (hereafter "the Panel") of 12 assessors was appointed by NHS Improvement. The Panel reviewed 202 deaths under its terms of reference.

The Panel was composed of consultant cardiac surgeons, consultant cardiologists and consultant cardiac anaesthetists with responsibility for intensive care. The review was completed over eight months in 29 sessions. Each session was attended by at least two surgeons, one cardiologist and one intensivist.

A Structured Judgement Review (SJR) was undertaken for each case, based on the methodology described by the Royal College of Physicians (RCP) of London[2] and the Michigan study (described below)[3] All available Trust case notes (in written and electronic format), reviews and investigations were evaluated by the Panel.

A review of mortality following adult cardiac surgery procedures in Michigan within a large study population (1780 patient deaths reviewed) defined a method to evaluate cardiac surgery mortality by analysis of the individual phases of care[3]. This approach was utilised for the case reviews, examining three phases: pre-operative; operative; and post-operative events, along with an overall care assessment. Care at each stage was graded separately on a scale of 1 to 5 (1 = very poor care, 2 = poor care, 3 = adequate care, 4 = good care, 5 = excellent care).

Following completion of the phase of care analysis, a "contribution to death score" was attributed to the overall case, considering all phases of care and using the grading below, as per the RCP methodology:

Score 1 Problems in care identified definitely contributed to the death

Score 2 Strong evidence that problems in care identified contributed to the death

Score 3 Problems in care identified probably (more than 50:50) contributed to the death

Score 4 Problems in care identified possibly contributed to the death but not very likely (less than 50:50)

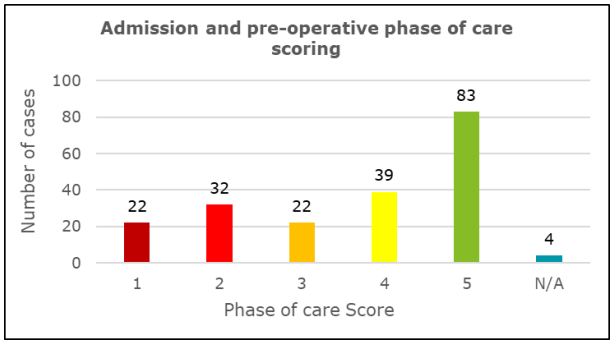
Score 5 Slight evidence only that problems in care identified contributed to the death

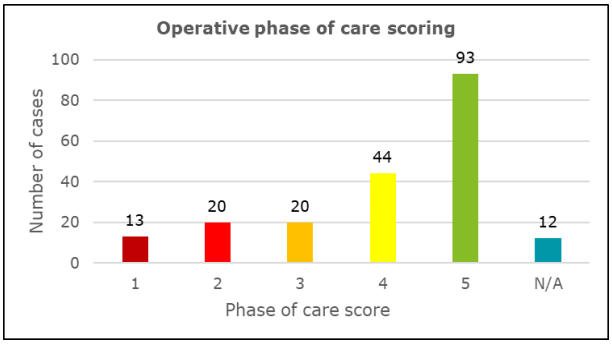
Score 6 No evidence that problems in care identified contributed to the death / no problems in care identified

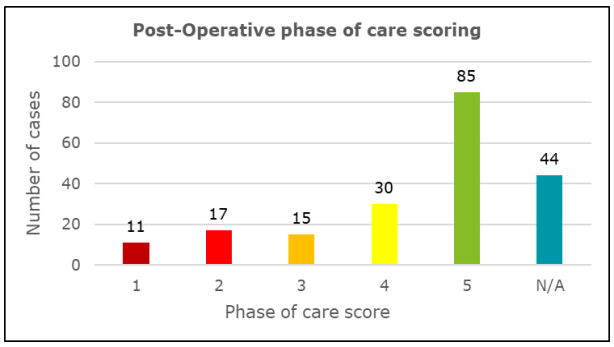
Consensus was achieved for each score, in both domains of analysis. The phase of care and the Contribution to Death were scored independently. If, for example, a key investigation was omitted pre-operatively but was not felt to have contributed to the death, then it would have been possible to have had a low phase of care score but a contribution to death score that indicated no evidence that problems in care had contributed to the death. A narrative was recorded for each phase of care, with an overall conclusion.

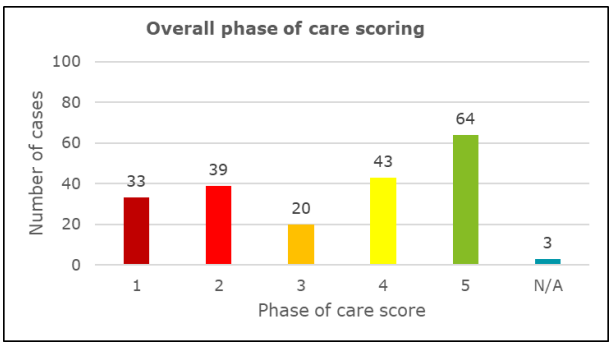
On completion of all the case reviews by the Panel, a factual accuracy check was made with the teams involved in looking after each individual patient. Following this review, the narrative statements and scoring were analysed. 67 cases (covering 125 procedures) were considered to have a contribution to death score of 1 to 3. Further analysis of the narratives associated with these cases allowed the distillation of several themes which were then scrutinised under the headings of "Professionalism", "Pre-operative care", "Operative care" and "Post-operative care". These headings form the basis for the chapters included in this report. Selected cases were used as a narrative to illustrate concerns and/or considerations regarding patient care.

The following graphs and table show the number of cases that were reviewed during the period April 2013 to December 2018, along with their 'contribution to death' score, with the graphs showing the separation into each phase of care:









Contribution to death Score							
1	2	3	4	5	6	N/A	**Total**
21	22	24	16	19	97	3	202

The following table shows the spread of the main procedures reviewed with contribution to death score:

CABG in isolation						
1	2	3	4	5	6	**Total**
4	10	9	4	7	18	**52**

CABG + AVR						
1	2	3	4	5	6	**Total**
0	0	1	0	0	0	**1**

Mitral valve repair/replacement in isolation						
1	2	3	4	5	6	**Total**
0	0	0	0	0	3	**3**

Mitral valve repair/replacement + any other procedure						
1	2	3	4	5	6	**Total**
6	2	5	3	3	5	**24**

AVR in isolation						
1	2	3	4	5	6	**Total**
0	0	1	0	0	5	**6**

Aortic Surgery						
1	2	3	4	5	6	**Total**
5	8	2	2	3	33	**53**

Redo Surgery						
1	2	3	4	5	6	**Total**
4	1	1	2	3	10	**21**

Note: These are the main procedures undertaken, other procedures were undertaken which are not represented in the figures above. Some patients had multiple procedures so the total numbers of procedures (341) is greater than the total number of patients reviewed (202).

Previous clinical reports have used clinical examples to illustrate the issues presented[4]. We have used a similar method, alongside more traditional graphical and tabular analysis.

1.3. "Cause for concern" process

When the panel identified any themes or concerns, such as that current and future patients might be at risk, the Panel Chair discussed the concern with the Chief Medical Officer of the Trust to ensure that local governance arrangements could be applied.

1.4. Caveats in the interpretation of historical data

a) This review looked only at the clinical histories of those patients who had died following cardiac surgery at St George's. The Panel had limited information on the many patients who survived. While every case record was reviewed as objectively as the Panel were able to, it is difficult to exclude having a lower threshold for criticism because the clinical outcome was already known.

b) This review looked at clinical material that was held at St George's Hospital. Patient records from referring hospitals were not available to the Panel. Further developments in information technology in the future, may allow full access to these records which may aid this type of analysis and allow the clinical teams, who were looking after these patients, full oversight of any previous medical history.

c) Clinical opinion changes over time. Wherever possible, the Panel have tried to compare the clinical management with the standard management and clinical guidelines in the year of the patient's operation.

d) Clinical practice for routine cases varies between individuals and centres. Much of this difference in practice reflects a weakness of the evidence base. Clinical opinion varies across the country and the point at which a suggested procedure moves from "very high risk" to "futile" may vary from centre to centre and within centres, from surgeon to surgeon.

e) In several instances where the Panel felt that errors in care had contributed to the patient's death, the Panel accepted that the patient's prognosis was already very poor. Although the Panel may not have recommended surgery in these particular clinical scenarios, they accepted that the patient's death may only have been brought forward by a matter of days or weeks.

2. Professionalism

2.1. Background

Cardiac surgery is a high-profile specialty, set against the ever-changing landscape of the NHS. Surgical teams are expected to operate with high levels of skill and judgement, whilst under increasing levels of scrutiny and accountability.

Since the 2001 report by Sir Ian Kennedy on high death rates in babies undergoing cardiac surgery at Bristol Royal Infirmary (BRI)[5], there has been a steadily increasing focus on cardiac surgical outcomes. Initially, the spotlight fell on the surgeons in the unit, but the full report attributed poor outcomes to a multiplicity of issues, many of which were the responsibility of the Trust rather than an individual surgeon. The report criticised; staff shortages, a lack of leadership, a lax approach to safety, a 'club culture' amongst doctors, secrecy about a doctor's performance and a lack of performance monitoring by management. It was recognised at the time of the failures of governance in Bristol that "*the heart scandal could happen again*"[6].

The metric that emerged from the BRI was that of surgeon specific mortality and this has provided a method to monitor outcomes in cardiac surgery. There is now a well-established system for regular reporting of cardiac surgical outcomes by unit and by surgeon[7,8].

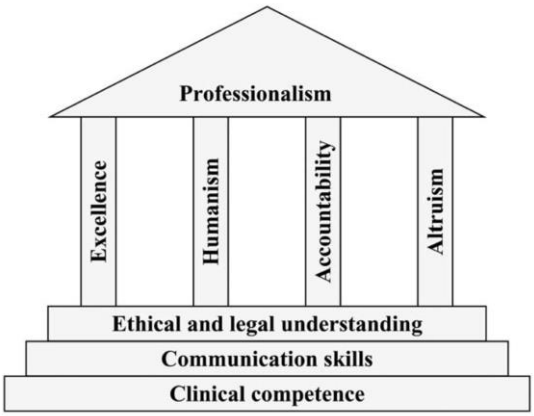
The Francis Report[9] following the Mid Staffordshire NHS Foundation Trust inquiry offered further evidence that the message around patient-centred care was not getting through. It recommended openness, transparency and a duty of candour around the care of vulnerable patients, described fundamental care standards for health care providers and recommended stronger health care leadership.

Despite the Kennedy and Francis Reports, there have been further recent examples of failures of professionalism and governance in health care in both maternity and neonatal services at the University Hospitals of Morecambe Bay NHS Foundation Trust[10], community health services in Liverpool[11], and surgical services in Birmingham[12]. If nothing else, this repeated pattern of behaviour suggests a failure of learning within the NHS.

It has become clear that the duty of professionalism incumbent upon doctors also applies to the health care institutions in which they work.

2.2. What is professionalism?

Traditional attributes of professionalism were defined by Arnold and Stern[13]. These are represented in the figure below:



The position of doctors in society has changed significantly since the Kennedy Report. A working party report from the Royal College of Physicians in 2005 stated:

"Medical professionalism signifies a set of values, behaviours and relationships that underpin the trust the public has in doctors."[14]

Sir Donald Irvine, a former President of the General Medical Council (GMC), who chaired the Conduct Committee at the time of the Bristol Inquiry, summarised the values expected by patients and their relatives, of medical professionals:

"For patients and their relatives, a good doctor is one whom they feel they can trust. They equate goodness with integrity, safety and up to date medical knowledge and skill, and an ability and willingness to form a good relationship with them. For patients, good doctors are clinically expert yet know their limitations."[15]

Guidance from the GMC came into effect on 22 April 2013 for all clinicians working and training in the United Kingdom, in the document "*Good Medical Practice".*[16] This described four domains:

- Knowledge, skills and performance;
- Safety and quality;
- Communication, partnership and team working; and
- Maintaining trust.

These four domains were refined within a surgical context by the Royal College of Surgeons when "*Good Surgical Practice*" was released by Dame Clare Marx in 2016.[17]

The Society for Cardiothoracic Surgery (SCTS) publishing in *"Patients Trust – Modern medical professionalism"* believes that: *"every single patient should always receive the best possible care from every surgeon undertaking cardiothoracic surgery"*[7].

Good practice in surgery requires effective teams which utilise the following methods:

New professionalism maintaining good practice

Doctors are most likely to maintain good practice when they work in teams which:

- Show leadership;
- Have clear values and standards;
- Are collectively committed to sustaining and improving quality;
- Foster learning through personal and team professional development;
- Care for each member;
- Have a *no blame* culture;
- Are committed to the principle of external review; and
- Are open about their professionalism.

Effective teams use:

- Clinical guidelines and operational protocols;
- Good systems;
- Good data;
- Good records;
- Focused education and skills training;
- Systematic audit of performance with feedback;
- Regular, formative peer appraisal;
- Critical incident review; and
- Risk management methods.

Figure: SCTS 2011 Maintaining patient's trust: modern medical professionalism[7]

The document recognises that professionalism is not solely dependent on the clinician but is also dependent on the organisation within which they work.

2.3. Observations on professionalism at St George's Hospital

During the review of cases, the Panel identified many examples of *Good Medical* and *Surgical Practice*, across all four domains. On occasion, the Panel noted areas in which they identified learning opportunities with regards to professionalism.

The standards quoted below in each domain are paragraphs taken from *'Good Medical Practice'*.[16]

Domain 1: Knowledge, skills and performance

No comment on Domain 1 will be made in this chapter as this domain will be covered in the remainder of this report.

Domain 2: Safety and quality

Paragraph 22: *"You must take part in systems of quality assurance and quality improvement to promote patient safety. This includes:*

a) *Taking part in regular reviews and audits of your work and that of your team, responding constructively to the outcomes, taking steps to address any problems and carrying out further training where necessary.*
b) *Regularly reflecting on your standards of practice and the care you provide."*

The team at St George's performed several SJRs, using similar methodology to this Panel. The Panel felt that their quality was variable and at times they lacked independence and rigour. Notably, the Panel reviews scored less favourably than the internal reviews. In 27 of 54 cases, the Panel found a greater than one point difference in the contribution to death scoring.

The Panel understand that following the initial review by teams that included some of the surgeons at the Trust, several further SJRs were performed by the Trust themselves. These were not seen by the Panel, but the Panel were able to see the subsequent report (published on 12 October 2017). This Trust report noted some of the conclusions that this independent report outlines, but missed some significant areas in all three phases of care.

For example, when considering Case 1 (below) the Panel was concerned that the operative assistant completed the surgical SJR and omitted to comment on significant post-operative blood loss and a possible myocardial infarction. The subsequent morbidity and mortality review appeared to concentrate on issues that were less relevant to the outcome for the patient and blamed the intensive care team. All phases of care rated by this assessor were scored as excellent, with no evidence of problems in care identified as contributing to the death. This was in marked contrast to the unfavourable assessment by the Panel, which concluded that the management of the patient definitely contributed to the patient's death.

Case 1

A patient in their mid-seventies was admitted for elective aortic root replacement and atrial septal defect (ASD) closure. The patient had significant bleeding post-operatively and suffered a VF arrest, with evidence of myocardial ischaemia on the ECG. This information was passed to the surgical team but the patient was not returned to theatre for seven hours. There appeared to be no consultant to consultant discussion at this stage.

The Panel felt that a root replacement was not required in this case; they would have replaced the aortic valve and ascending aorta. Despite a multi-disciplinary team discussion (see case 4 for explanation), there was evidence of poor surgical planning, as the root was not of a size on CT or echo that indicated replacement.

The Panel felt there was an opportunity to intervene during the early post-operative phase. Given the subsequent events, the Panel felt the decision to perform an aortic root replacement rather than a more straightforward procedure was key to the outcome for the patient. The patient died four days after surgery from multi-organ failure.

There was no documentation at the local mortality and morbidity review (M&M Review) meeting to show there had been significant blood loss or a post-operative anterior myocardial infarction. The subsequent SJR, involving the surgical assistant for the case, failed to recognise the likely contribution to death that these events may have had.

The mechanism for mortality case allocation was uncertain and of more concern; it was noted in Case 2 that the operating surgeon formed part of the team that reviewed the case and therefore reviewed their own work in the SJR. The assessor score differed considerably from the Panel's assessment.

Case 2

A patient in their late seventies was admitted for elective aortic valve replacement and coronary revascularisation.

The operative record from theatre was not clear despite a very long cross-clamp time and the myocardial protection strategy was uncertain. There was a discrepancy between the operation note and the intensive care unit (ICU) handover in relation to the presence or absence of a left superior vena cava. The patient sustained a cardiac arrest shortly after transfer to ICU and died three days later from right ventricular failure.

Domain 3 – Communication, partnership and teamwork

Paragraph 32: *"You must give patients the information they want or need to know in a way they understand."*

When a pre-operative patient consultation is completed, it is important to give clear information; including an operative plan and risk (for explanation of EuroSCORE risk calculation, see section 3.6.2), for both morbidity and mortality. This is particularly important in urgent, emergency and/or high-risk surgery where significant risk of death is anticipated. Unfortunately, this was not always evident in Case 3:

Case 3

A patient in their mid-seventies with previous aortic valve replacement (AVR), root enlargement, and mitral valve repair re-presented with recurrent early prosthetic aortic valve endocarditis, haemolysis because of a leak around the aortic valve and moderate recurrent mitral regurgitation.

The indication for an operation appeared to be haemolysis related to the aortic valve rather than mitral regurgitation, and the patient was consented for redo AVR +/- mitral valve surgery. The quoted Trust risk of death was 10–15%, but EuroSCORE II was calculated to be 33.7%.

The patient underwent urgent redo mitral valve replacement (only) and died three days later from liver failure.

The Panel judged that the operative decision-making was unclear, the patient received a different operation from that they had consented to and the actual risk of surgery was significantly higher than the risk they had been quoted.

Paragraph 35: *"You must work collaboratively with colleagues, respecting their skills and contributions."*

The cardio-thoracic Multi-Disciplinary Team (MDT)[18] discussion is an essential part of modern cardiac surgical practice. Representation by cardiac surgeons (with specialist interest) and cardiologists (interventional, imaging and other sub-specialties) allows a balanced discussion of all available treatment modalities. This was not evident in all cases.

Case 4

A patient in their mid-eighties underwent urgent CABG x3. The patient's management had been discussed at an MDT meeting. However, several comments documented in the case notes suggest that undue pressure was brought to bear on the surgical team to deliver a surgical solution for this patient.

These statements included: "Dr X (cardiologist) feels the patient is a clear-cut surgical candidate" and "Dr Y (cardiologist) wanted a decision for surgery, as opposed to PCI, approved by the MDT."

The review Panel felt that a patient in their eighties with a calculated EuroSCORE II of 25%, with further risk factors (not included in the EuroSCORE) of poor pre-operative right ventricular function and pre-existing cognitive impairment, was far from a "clear-cut surgical candidate". The Panel felt that the MDT did not appropriately weigh the relative risks of surgical and non-surgical treatment for this patient.

The surgical risk quoted to the patient on the consent form was 10%. Had an accurate assessment of risk been quoted to the patient, together with the risks of exacerbation of cognitive impairment and loss of independent living, the patient may have decided in favour of conservative treatment.

The patient died ten days after surgery from bi-ventricular failure.

Collaborative working is emphasised in '*Good Surgical Practice'* as follows: *"The provision of high quality surgical services requires effective team-working within and between teams. Good practice relies on collegiality, personal responsibility and a culture of openness, supportive discussion and accountability to offer safe and effective care to patients. Surgeons have a duty to promote a positive working environment and effective surgical team-working that enhances the performance of their team and results in good outcomes for patients"*[17]*.*

Case 5

A patient in their mid-sixties underwent urgent redo aortic repair.

It was unclear if circulatory arrest was instituted prior to opening the chest but there was a right ventricular injury during chest opening, which was subsequently repaired.

Post-operatively, there was evidence of dysfunctional team working between the cardiac surgeons and ICU consultants. There were angry notes with block capitals and many exclamation marks, which could reflect a challenging working environment. The difference of opinion between the surgical and ICU teams would have caused distress to the patient's relatives, if they had been aware. The Panel noted that this conflict would have also placed the junior medical teams in a very difficult position. The patient died six days after surgery from hypoxic brain injury.

Paragraph 42: *"You should be willing to take on a mentoring role for more junior doctors and other healthcare professionals."*

Every cardiac surgery operation in the UK should be performed under a named cardiac surgery consultant[8]. This consultant has overall responsibility for the care the patient receives. Any patient who has an operation performed by a trainee remains the responsibility of the named consultant. The training of surgeons is essential to ensure the future provision of cardiac surgical care. Appropriate supervision of trainee surgeons is an important part of the role of a consultant cardiac surgeon.

Case 6

A patient in their late sixties was transferred for CABG with an intra-aortic balloon pump in-situ from an outlying hospital. The patient was accepted for out-of-hours emergency surgery.

The operation started in the evening and was undertaken by a registrar with no consultant present; several consultants names were recorded in the casenotes but it was not clear which particular consultant had overall responsibility for the case. Arterial blood gas analysis during surgery showed possible inadequate perfusion on cardiopulmonary bypass (CPB), but this was not recognised or managed in theatre.

The patient died two days later from cardiogenic shock and multi-organ failure.

The Panel judged that emergency out-of-hours surgery was not indicated for a stable patient and that there was an opportunity to optimise medical therapy before surgery. There was no clear consultant ownership of this case; it was inappropriate for this high-risk case to have been undertaken by a registrar on their own, regardless of experience or seniority. A consultant should have been present for this operation. Potentially inadequate perfusion on CPB was not recognised or managed appropriately.

Paragraph 49: *"You must work in partnership with patients, sharing with them the information they will need to make decisions about their care, including:*

a) *Their condition, its progression and options for treatment, including associated risks and uncertainties.*
b) *The progress of their care.*
c) *Who is responsible for each aspect of patient care."*

The Panel were concerned regarding the investigation, management and "ownership" of patients with complex medical problems, particularly in the pre-operative phase. In Case 7, the care was often disjointed and there was little evidence that one individual was responsible for the overall management of the patient. Several individuals appeared to be working in an isolated fashion and appeared to be reluctant to co-operate or plan care with others.

Case 7

A patient in their mid-sixties with multiple co-morbidities was admitted for coronary revascularisation. The patient had several ongoing medical issues requiring investigation and management (anaemia, chest disease and mitral regurgitation in addition to ischaemic heart disease).

Despite a recent percutaneous coronary intervention with a stent, for an ST elevation myocardial infarction (STEMI) and ventricular fibrillation cardiac arrest, there were ongoing symptoms prompting readmission to the cardiology unit and an expedited referral for coronary artery surgery. Both anti-platelet drugs were discontinued in the week before the patient's admission. Investigations for the complex medical issues were undertaken over the following week.

The patient died before going to theatre from acute left ventricular failure, possibly related to stent thrombosis as a result of the cessation of the anti-platelet medications at an early stage after coronary stenting.

Domain 4 – Maintaining trust

Paragraph 71: "You must be honest and trustworthy when writing reports, and when completing or signing forms, reports or other documents. You must make sure that any documents you write or sign are not false or misleading."

The Panel reviewed discussions with the coroner from the available documentation and two important issues were noted:

1. Inaccurate certification of the cause of death:

Case 8

A patient in their mid-seventies was admitted for urgent coronary revascularisation.

The patient died 10 days after surgery. Their cause of death was reported to the coroner and documented as lower respiratory tract infection, coronary artery disease and Type II Diabetes Mellitus.

The Panel could find no evidence that there was a lower respiratory tract infection and were concerned that the coroner may not have had all the information required to make an appropriate decision.

2. Incomplete information:

Case 9

A patient in their mid-seventies with a short history of angina pectoris was transferred for urgent coronary revascularisation for severe left main-stem coronary disease.

Following transfer to ICU, there was significant haemodynamic instability and increasing vasopressor requirements. Two hours following return from theatre, the tip of the CVP line was noted not to be properly positioned in the central vein and was replaced. The patient died three days later.

The issue of the displaced central line noted at the time of haemodynamic instability does not appear to have been discussed with the coroner. The Panel felt that this issue contributed to the patient's death and that such a complication should have prompted a Serious Untoward Incident (SUI) investigation but could find no record of this. The Panel concluded that this demonstrated a potential failing of leadership.

2.4. Conclusion

Many of the cases that the Panel reviewed were complex cases in elderly patients with significant co-morbidity. Within each phase of care, good examples of patient management were seen.

The review of the cases has occasionally revealed a lack of leadership; poor relationships between teams and specialties; poor communication; MDT structures which lack rigour and consistency; poor multi-disciplinary working; and an apparent lack of governance. These issues have previously been noted in other reports, for example that undertaken by Wallwork[19] in 2010.

The Panel understand that the current Trust Board were not aware of the Wallwork Report until reference was made to it in the Bewick Report (2018). As previously noted, the Panel are aware that there have been multiple changes in Trust management in recent years.

The Wallwork Report made several recommendations, the implementation of which might have improved patient care at the Trust. During their SJRs, it was apparent to the Panel that not all of these recommendations had been fully implemented. In addition, the internal SJRs following the 2013 to 2016 NICOR report were often of poor quality and lacking in both independence and rigour. Whilst the Panel understand that a series of further SJRs (not seen by the Panel) were performed by the Trust subsequent to the reviews involving the surgeons, the resulting report published in October 2017 did not recognise a number of areas identified by this Panel, for this time cohort. For example: the quality of referrals to cardiac surgery from cardiology, the undue pressure placed on cardiac surgeons to accept patients for surgery even when they were high-risk, the concerns around the adequacy of myocardial protection and the failure to recognise post-operative myocardial infarction. The subsequent report was, therefore, limited in its analysis and prevented some of the appropriate lessons from being learnt.

Whilst we recognise the challenges that working in the modern NHS present to the professionalism of medical teams, the Panel believes that individuals and institutions must work within a system which is designed and supported to allow professionalism to flourish.

3. Pre-operative care

3.1. Background

Patients with heart disease may be referred to a cardiac surgeon for consideration of elective cardiac surgery following outpatient investigation, or for urgent surgery following emergency admission to hospital with new onset or worsening symptoms. The investigation and management of the patient is undertaken by a multi-disciplinary team but the initial referral for cardiac surgery is made by a cardiologist who has responsibility for the patient's care.

The decision to refer a patient for possible cardiac surgery is determined by the results of investigations, the influence of co-morbidity and the wishes of the patient. In the modern era, when many patients have multiple co-morbidities and are elderly, this decision-making can be complex. Although there are numerous guidelines to inform clinical practice in cardiology and cardiac surgery, many patients on account of extreme age, significant co-morbidity and frailty, would have been excluded from the clinical trials on which these guidelines are based.

The cardiology assessment of a patient should include a thorough investigation and interpretation of test results, a determination of the patient's quality of life and of the possible gains from an operative strategy. These possible benefits need to be balanced against the risks of the operation, not only of death, but of other adverse events that will further compromise the outcome (such as stroke). In patients where the indications for surgery are not clear-cut, symptoms and test results are discordant, or the patient has significant co-morbidity, the patient's management necessitates full discussion at an MDT meeting, where all possible treatment strategies can be reviewed, a provisional recommendation made and the various options subsequently discussed with the patient and their relatives or carers.

3.2. Referral from cardiology for consideration of cardiac surgery

The referral from the cardiology team to the cardiac surgical service should describe the following, as a minimum set of information:

- The patient's presentation and history;
- The patient's current symptoms on (and level of) medical therapy;
- The cardiologist's interpretation of the patient's investigations (e.g. functional study for ischaemia, echocardiogram, angiogram);
- The patient's co-morbidities; and
- The patient's preferences for treatment (if any).

If the patient meets accepted indications for surgery, he or she is listed for surgery following review by the cardiac surgeon. If the indication for surgical intervention is borderline (e.g. infrequent angina, atypical pain or breathlessness alone in a patient with coronary disease, or valve disease that is moderate rather than severe, or symptoms apparently out of proportion to the severity of disease), then a more detailed explanation is required from the cardiologist. This should explain why the patient is being referred for consideration of

surgery and MDT discussion should be the norm. By their nature, referrals for emergency and salvage surgery are usually made by telephone and are not usually discussed at an MDT.

3.2.1 Observations on patient referrals to St George's – General

Several referrals from the cardiology teams were not comprehensive and not tailored to the needs of the individual patient. There was a pattern of referral whereby the patient had undergone some investigations but these had not been fully interpreted by the cardiology team, with the responsibility to interpret the investigations and to decide whether surgery was likely to be in the patient's best interests transferred to the cardiac surgeon. This gives the impression of a lack of commitment and/or diagnostic rigour on the part of the referring cardiology teams and contributed to poor surgical case selection.

Some specific examples identified were as follows:

- Lack of clear description of patient's symptoms;
- Lack of additional investigation(s) when indicated;
- Lack of detail in description of co-morbidities; and
- Lack of discussion about benefits of intervention versus conservative management, particularly in frail, elderly patients or patients with major co-morbidities.

The Panel noted issues with referrals from cardiology from both "in-house" and external teams.

Case 10 describes a patient in whom the indication for elective Coronary Artery Bypass Grafts (CABG) surgery was not clear. Cases 11 and 12 describe patients in whom the cardiology investigations were incomplete and the possible benefit(s) from cardiac surgery were far from clear. All three patients required further investigation.

Case 10

A patient in their early eighties presenting with poor mobility and diabetes was admitted for elective CABG x5. The patient died six days after surgery from multi-organ failure.

The Panel felt that the indication for surgery was not clear. The patient had sustained a possible NSTEMI three months previously and at the time of their admission to hospital for cardiac surgery they were apparently asymptomatic. The clerking document reports "no chest pain and no breathlessness".

Furthermore, the risks and possible benefits of cardiac surgery do not appear to have been re-assessed (or re-discussed with the patient) following the finding of severe bilateral carotid artery disease. The operative risk quoted to the patient was 4%; the calculated EuroSCORE II risk was 12.9%.

Case 11

A patient in their mid-seventies was transferred from a district general hospital for urgent CABG x2. The patient died two days after surgery from myocardial infarction, ischaemic heart disease and lung cancer.

The patient had undergone radiotherapy for a lung cancer one year prior to their admission. The patient had a significant pericardial effusion which was not fully investigated. The pericardial effusion was clearly documented pre-operatively and would not be an expected feature of coronary artery disease. Biopsies taken at the time of surgery showed a metastatic adenocarcinoma.

On the evening before surgery the patient was reviewed by two registrars who both felt that the indication for surgery was not straightforward and that surgery should be deferred pending further investigation. It was unclear whether this patient's investigations were fully reviewed by the operating surgeon prior to taking this patient to theatre. The Panel acknowledged that the patient's prognosis was very poor but felt, nevertheless, that this was an inappropriate and unnecessary procedure. The timing of this lady's transfer was a further complicating factor and may have led to an incomplete assessment of the patient prior to them being taken to surgery.

Case 12

A patient in their early eighties was admitted acutely and subsequently underwent inpatient investigation followed by urgent aortic valve replacement and CABG x1. The patient died ten days after surgery from respiratory failure, chest infection, coronary artery disease and aortic stenosis.

The patient had three separate cardiac pathologies (possible right coronary artery stenosis, moderate aortic stenosis and paroxysmal atrial fibrillation). There seems to have been limited assessment of all three conditions and no MDT discussion about which of these conditions was likely to have been the cause of their symptoms and their acute presentation. Similarly, there was little or no pre-operative documentation as to whether non-surgical intervention or treatments of any one of these conditions (by PCI, TAVI, AF ablation) might have improved their quality of life without the need for cardiac surgery, which was always likely to be high risk. The patient was quoted an operative mortality of 4-5%; the calculated EuroSCORE II was 13.5%.

3.3. Referrals for coronary surgery

Coronary artery bypass surgery is a very effective treatment for the relief of angina and, in certain patient groups has been shown to improve prognosis. There are clear guidelines to underpin practice. The decision to refer for surgery is based on the patient's symptoms (on optimal medical therapy), evidence of ischaemia and the findings at diagnostic angiography. It is increasingly recognised that even experienced interventional cardiologists cannot, without functional information, accurately predict the significance of many intermediate stenoses on the basis of visual assessment alone. For this reason, surgery for intermediate coronary stenosis (50-90% narrowing) is indicated when there is corroborative evidence of ischaemia from functional testing (such as stress echo, stress perfusion imaging or stress MRI) or from intra-coronary measurements of stenosis severity (Fractional Flow Reserve (FFR))[20].

Furthermore, recent guidelines have highlighted the relatively good prognosis for patients with stable angina and recommend that cardiologists and cardiac surgeons should be more conservative with regard to decisions over revascularisation in patients with stable coronary artery disease, especially in; mildly symptomatic patients, patients without extensive demonstrable ischaemia, when a period of optimal medical treatment has not been adequately conducted[20,21], or if surgery is likely to be technically challenging.

3.3.1 Observations on the referral process at St George's - Patients referred for coronary surgery

Many of the referrals were appropriate but there were several cases in which the referral was less comprehensive than it might have been. Specific issues included the following:

- Lack of a clear description as to whether or not the patient had angina that was limiting their activities despite optimal medical therapy;
- In cases of both angina and presumed angina equivalent, a lack of documentation on ischaemia testing;
- Lack of clarity on indication for surgery (was the intended surgery for symptomatic benefit, prognostic benefit, or both?);
- There were instances of poor quality angiograms which were not of diagnostic quality;
- Some angiograms were not fully interpreted by the referring cardiologist, for example the cardiology report referred to "*moderate lesions*" with apparent underuse of ischaemia testing (stress studies prior to angiography or pressure wire assessment at the time of angiography); and
- There were several referrals where the cardiologist appeared to be leaving the cardiac surgeon to decide on the significance of the coronary disease.

Cases 13 and 14 describe patients in whom the history and/or investigations suggested that they were unlikely to benefit from CABG surgery, yet the procedures went ahead. Case 15 describes a patient referred to cardiac surgery with minimal cardiology input, leaving the surgeon to address the patient's co-morbidities.

Case 13

A patient in their mid-seventies underwent CABG x4 but died in theatre that day from heart failure.

A pre-operative cardiac MRI demonstrated very poor left ventricular function. The Panel felt that the MRI and coronary angiogram results indicated that surgery was very unlikely to improve heart function to a degree that would benefit the patient.

Case 14

A patient in their early sixties presented with an extensive anterior STEMI. At emergency angiography, the proximal left anterior descending artery (LAD) was re-opened but the distal vessel remained occluded. This was subsequently re-opened the following day. The patient then underwent CABG x3 surgery three days after admission; they died four days later of multi organ failure.

The Panel acknowledged the desire to help a relatively young patient with a very extensive myocardial infarction and that the preferred treatment option is total revascularisation during the index admission. However, there was a lack of consideration by both cardiology and cardiac surgery as to whether CABG surgery three days after the acute event would be of any benefit to the patient. The patient did have disease of the distal right coronary artery and the non-dominant circumflex, but these lesions did not appear to mandate emergency treatment. There was an underestimation of the Trust risk quoted to the patient; the risk quoted on the consent form was 5% against a calculated EuroSCORE II of 40.6%.

Case 15

A patient in their mid-seventies was referred for angiography following an assessment in a nurse-led, rapid access chest pain clinic.

On the basis of the angiogram findings, the patient was referred for CABG x4 surgery, but it appeared the only time they saw a cardiologist was during their angiogram. The only co-morbidity documented by the nurse was "white-coat hypertension". However, the patient had a long history of hypertension, significant neurological disease (including a subdural haematoma) and a chronic haematological condition. Although the cardiac surgeon who saw the patient made efforts to address these co-morbidities prior to surgery, the Panel felt that these conditions should have been recognised and considered by the cardiologist prior to referral to surgery being made.

3.4. Referrals for valve surgery

Surgical intervention for valvular heart disease is comparable to surgery for coronary artery disease in that it is driven by symptoms and, for some valve lesions, by prognostic considerations. In addition, valve surgery is undertaken to protect the heart from the damaging effects of progressive valve dysfunction. Inherent to the nature of the progression of valve disease are considerations related to optimal timing of intervention. Intervening too early exposes the patient to the risks of an unnecessary operation, intervening too late increases the risk of a poor outcome due to deterioration of cardiac function. For some valve lesions there are interventional (non-surgical) treatments, but non-surgical interventional treatment of valve lesions is less advanced than for coronary artery disease. Several valve interventions (e.g. balloon valvuloplasty) are temporising, while others (e.g. TAVI and MitraClip) are offered to patients deemed to be at prohibitively high-risk for surgery.

3.4.1 Observations on the referral process at St George's - patients referred for valve surgery

Many of the referrals for valve surgery were entirely appropriate, but the Panel felt there were referrals from cardiology to cardiac surgery that were sub-optimal. The specific deficiencies included the following:

1. Lack of a clear description of symptoms and functional status of the patient being referred;

2. Poor quality echocardiograms with incomplete valve assessment to guide management;

3. Lack of understanding by referring cardiologists about surgical risk in frail or elderly patients or in those patients requiring redo sternotomy;

4. Limited discussion on optimal timing of valve surgery;

5. Lack of consideration of non-surgical treatments, such as Trans Aortic Valve Implantation (TAVI)[22,23] or Balloon Aortic Valvuloplasty (BAV), either as a definitive treatment in a high-risk patient or, in the case of BAV, as a bridge to surgery; and

6. Lack of consideration of conservative, symptom-driven, medical treatment.

Cases 16 and 17 describe patients with valvular heart disease who underwent surgery. In both instances the Panel felt that the referrals were poor and that the likelihood of either patient experiencing significant symptomatic benefit, had they survived surgery, was small.

Case 16

A patient in their early seventies was admitted with coronary artery, aortic and mitral valve disease. Pre-operative assessment found very poor left ventricular function. The patient's condition was optimised and they had surgery two weeks later.

The pre-operative transoesophageal echocardiogram (TOE) by the anaesthetist found severe left ventricular dysfunction and only mild valve disease. The patient underwent aortic valve replacement, mitral valve replacement, tricuspid valve repair and CABG x5. They died on the intensive care unit four days later from cardiogenic shock and multi-organ failure.

The Panel were concerned that the patient had not been fully assessed before surgery and that not all options had been considered. The severity of their valvular disease was over-estimated and coronary angioplasty alone may have been adequate treatment for this patient. None of the surgeons on the Panel would have offered surgery. The Panel judged there was another opportunity to avoid unnecessary surgery after the pre-operative TOE found severe left ventricular dysfunction and only mild valve disease. Surgery could have been aborted before sternotomy to allow the opportunity to re-consider the best treatment option.

Case 17

A patient in their early eighties was recommended for elective tricuspid repair. The patient died four weeks later from bronchopneumonia, lung fibrosis and multi-organ failure.

In the setting of very poor left ventricular function and poor lung function (transfer factor <50%), the Panel felt this patient was unlikely to derive any benefit from surgery even had the patient survived to leave hospital. None of the cardiologists on the Panel would have referred the patient and none of the cardiac surgeons would have recommended surgery. The Panel felt that problems in care identified probably (more than 50:50) contributed to the death.

3.5. Multi-disciplinary team meetings

Guidance on the multi-disciplinary, co-ordinated management of patients with cardiac disease using a "Heart Team" model has been published elsewhere[4,18,20]. The overriding principle of an MDT meeting is to ensure best practice and to provide a consensus view as to which treatment strategy is superior or most appropriate to each individual patient. The decision is guided by the available evidence and the collective experience of the team present. It is important that an MDT meeting is quorate and re-evaluates the patient's treatment plan when new information becomes available, or if the patient's clinical condition changes. When decision-making is not straightforward, the MDT documentation should attempt to capture the essential elements of the discussion in order to justify any decision reached. In instances where there is deviation from the MDT decision (clinician or patient decision), this should be documented in the patient's medical records and the patient's management re-discussed at a subsequent MDT meeting.

3.5.1. Observations on St George's MDT meetings

There was evidence of MDT working and of good attendance at MDT meetings. However, a number of shortcomings were also noted, in several instances, including:

- Referrals where expected investigations were missing, for example, left ventricular (LV) viability assessment in a patient with poor LV function and ischaemic cardiomyopathy;

- Cardiology input lacked the expected rigour about the interpretation of diagnostic tests, understanding of the implications of co-morbidity and discussion of interventional options for treatment;

- Instances where decisions had been documented, but not the discussion which underpinned them. This is probably common to many units, but the MDT recommendations do stress that the discussion should be documented, particularly if the decision is to recommend high- risk surgery or high-risk percutaneous coronary intervention (PCI);

- The MDT process often felt like a one-way referral transaction from cardiology to cardiac surgery rather than tailored management of individual patients. Some of the MDT management decisions were surprising to the Panel, who felt that several high-risk patients might have been better served by interventional treatment (PCI, TAVI, valvuloplasty, etc.);

- There were instances where the cardiologists appeared to exert undue pressure on the cardiac surgeons to accept patients for surgery, even when this was high-risk. The decision-making process felt unbalanced, with the cardiology opinion being more forcefully expressed than that of the cardiac surgeon(s);

- There was a lack of acceptance that medical treatment may sometimes be the appropriate outcome of an MDT. This is clearly stated in the NCEPOD report[4]:

  "it should also be remembered that sometimes no intervention is appropriate and that palliative care, rather than a potentially futile intervention, is in the best interests of the patient."

- Failure to revisit decisions about complex patients when new information became available, for example re-assessment of LV function post myocardial infarction or following MRI assessment of viability; and

- Failure to revisit decisions when a patient's overall condition deteriorated. There was a desire to expedite surgery rather than consider whether surgery was still the appropriate treatment strategy.

Cases 4 (see page 14), 18 and 19 illustrate an MDT not functioning as well as it should. In Case 18, an appropriate MDT plan is made, but is then changed for no apparent reason. In Case 4 and Case 18, inappropriate pressure is put on the surgical team to offer a patient high-risk surgery. In Case 19, there is a lack of appreciation by the MDT that the operation being proposed is very unlikely to improve the patient's quality of life.

Case 18

A patient in their mid-seventies underwent urgent CABG x3 and died three days later. The decision to operate appears to have been made before an adequate pre-operative assessment was complete. The patient's left ventricular function was poor and the potential benefit(s) of surgery had not been established. An MDT discussion recommended a cardiac MRI to assess myocardial viability. The Panel felt that this was entirely appropriate clinical practice. However, a decision was then made to proceed to surgery without this information and the reason for the change from the original MDT plan was not explicit, but it did not appear to be based on clinical urgency.

Case 19

A patient in their early seventies was admitted for elective replacement of the ascending aorta and CABG x1. The patient had previously undergone aortic valve replacement many years earlier. The prosthetic aortic valve was competent and did not require re-replacement. The patient died 11 days after surgery.

The patient's main symptom was severe breathlessness and they were reviewed by the cardiology and respiratory teams prior to surgery. Nowhere was it made clear to the patient that the dilated ascending aorta was very unlikely to be the cause of their breathlessness and that aortic surgery was very unlikely to improve their breathlessness and quality of life. Although the diameter of their ascending aorta was above the threshold at which surgery should be considered, this measurement was unchanged between 2008 and the operation in 2016. The patient was quoted a mortality risk of 5%; the calculated EuroSCORE II was 38.6%. Had all of these factors been taken into account, the Panel felt that the patient may well have opted for conservative management.

3.6. Risk assessment and consent

3.6.1. Risk assessment

The decision to proceed to heart surgery requires a careful assessment of the balance of the possible benefits versus the risks of the operation. In older patients with co-morbidities (other medical problems in addition to their heart disease), this assessment becomes more important in choosing between medical therapy and surgery. In some patients, life expectancy may be affected more by their co-morbidity than by their heart disease and in patients without symptoms the benefits of surgery must be weighed carefully against the risks. The decision to offer heart surgery usually involves a multi-disciplinary 'Heart Team' of cardiologists, heart surgeons and other specialists, plus a detailed pre-operative assessment is required for an informed decision to be made and for appropriate consent to be taken.

3.6.2. EuroSCORE II

The current standard in the UK for predicting outcomes after heart surgery is based on the EuroSCORE (European System for Cardiac Operative Risk Evaluation). EuroSCORE is a widely used risk model to predict in-hospital mortality after heart surgery. The first version of EuroSCORE was based on a cohort of patients operated on in the mid-1990s and, although EuroSCORE remained powerful in discriminating between low-risk and high-risk patients, the original EuroSCORE risk model (and subsequent logistic EuroSCORE) over-predicted the risk of surgical practice as heart surgery became safer. Accordingly, an updated, more refined model, EuroSCORE II, was published in 2011. For the purposes of this report, EuroSCORE II will be the version used and referred to as "EuroSCORE".

The EuroSCORE risk for in-hospital mortality is calculated from several risk factors. The greater the number of risk factors or the more impact for an individual factor, the higher the risk of death after surgery. There are three categories of information to calculate the risk of death using EuroSCORE:

1. Patient-related factors: age, gender, degree of symptoms, previous heart surgery, and the presence of other medical conditions such as kidney disease, chest disease, or neurological disease;

2. Heart-related factors: heart function or recent myocardial infarction (heart attack); and

3. Operation-related factors: emergency surgery, type and number of procedures – coronary artery bypass surgery and/or valve surgery, and surgery on the thoracic aorta.

Risk models such as EuroSCORE (other models are used in other countries), are helpful in decision-making before surgery, guiding doctors and patients in the assessment of the benefits versus risks of surgery, and in informing patients and their relatives as part of the consent for surgery. Risk models also allow assessment of the performance of a service by comparing actual with predicted outcomes and facilitate comparison between the performance of different hospitals (and surgeons) by adjusting for differences in risk at different centres. However, no risk model is perfect - there are some common conditions that may increase surgical risk but are not included in EuroSCORE such as liver disease

or less than severe kidney or chest disease. Risk scores should be used to support clinical judgement in the decision to offer surgery.

It is acknowledged that during the timeframe of analysis for this report, that risk scoring systems were adapted from logistic EuroSCORE to EuroSCORE II. This report, for clarity, has used EuroSCORE II throughout. Had this report used logistic EuroSCORE as a risk calculator, we would have, most likely, predicted even higher risk for the cases that were reviewed. Since the criticisms of this aspect of care reflected an under-estimation of the risk given to some patients, the Panel feel that by using EuroSCORE II they have provided a liberal benchmark that allows comparison of the whole cohort.

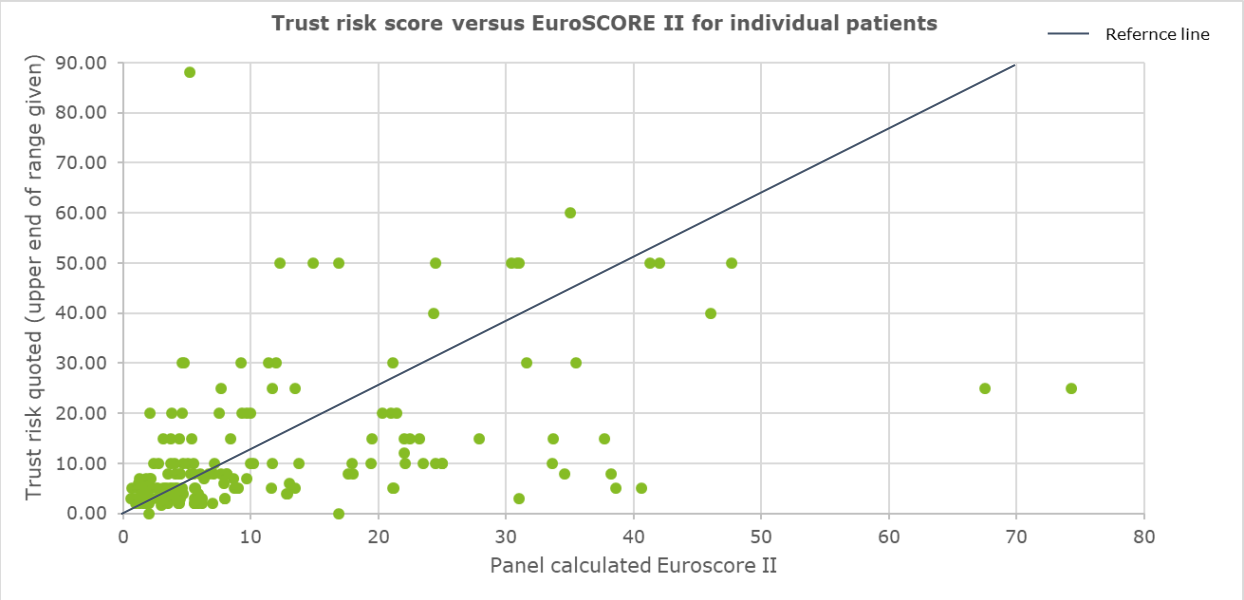
3.6.3. Consent

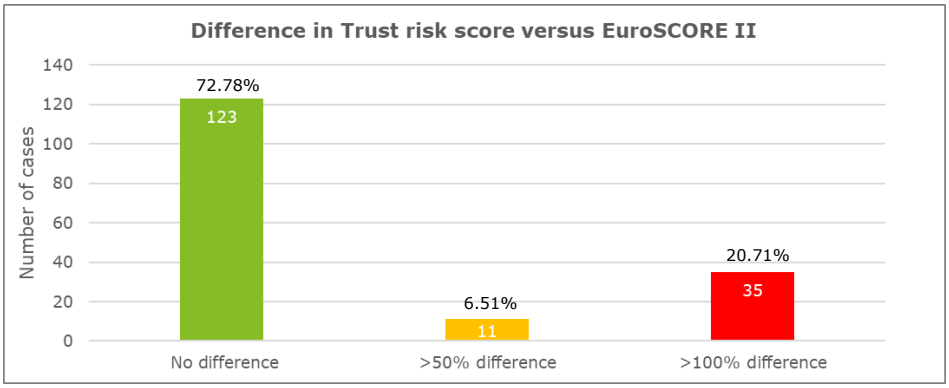
A patient's consent should be obtained before any operation. The validity of this consent depends on a patient being fully informed about the proposed operation, including the benefits and risks, whether there are alternative treatments, and what would happen if treatment does not go ahead. The surgeon's decision to operate and the patient's consent both depend upon an accurate assessment of the benefits and risks of surgery.[17]

The quoted mortality risk may influence the patient's decision if/when to go ahead with surgery. Inherent in this process is the need to reassess the risk as the patient's overall condition changes or new information becomes available.

3.6.4. Observations on the consent process at St George's

There were several instances in which the risk quoted by the surgical team was substantially lower than the risk calculated by the standardised risk scoring system (EuroSCORE). In 21% of the cases which the Panel reviewed, the calculated EuroSCORE II estimated risk was approximately double that of the risk quoted to the patient.





*There were 33 cases where a risk scoring was not appropriate (e.g. resuscitation surgery for stabbing or if the patient died before reaching surgery). These cases are excluded from this analysis.

It is impossible to know whether or not this would have influenced any patient to decide against surgery, but some patients may have opted for conservative treatment had they been quoted a more accurate (higher) risk for surgery. An example of significant under-estimation of risk is described in Case 20.

Case 20

A patient in their early eighties was admitted for urgent mitral valve repair, aortic valve replacement, and excision of the left atrial appendage (a procedure to reduce the risk of stroke in atrial fibrillation). The quoted risk was 5–8% against the calculated EuroSCORE II risk of almost 40%.

The Panel judged that there was evidence of poor MDT decision-making; they felt this patient should not have been offered surgery based on the balance of risks versus benefits. Surgery took longer than expected because of a decision to attempt a complex mitral valve repair. Furthermore there was an error on the perfusion chart with a mis-recording of the patient's height, leading to possible under-perfusion during cardiopulmonary bypass. Under-perfusion on bypass may have contributed to the patient's post-operative complications.

The patient died after 30 days on ITU from bronchopneumonia and multi-organ failure.

4. Operative care

4.1. Background

4.1.1. The cardiac surgical theatre team

The cardiac surgical theatre team comprises a minimum of seven members from different medical disciplines and professions, but in many cases there may be more. A successful heart operation relies upon careful interaction and communication between these team members.

Usually the team is led by a consultant cardiac surgeon and they will have at least one assistant, who may be a surgical registrar or a surgical care practitioner. There may also be a second assistant, who is often a more junior doctor or a surgical care practitioner. The surgical care practitioner is usually responsible for harvesting the saphenous vein from the lower limb or radial artery from the forearm for use as conduits in coronary artery bypass grafting.

The anaesthetic team is led by a consultant anaesthetist who may be assisted by an anaesthetic registrar. In most cases, the consultant anaesthetist is also the operator for TOE. The anaesthetic team is supported by an anaesthetic nurse or operating department practitioner. All operations requiring the use of the heart–lung machine (cardiopulmonary bypass) have at least one clinical perfusionist present to set up and run the cardiopulmonary bypass machine. There is always at least one scrub nurse who sets up and looks after all sterile instruments, and equipment, and stays within the sterile field for the duration of the case; this nurse is assisted by at least one theatre runner who may be a more junior nurse or a health care assistant, whose role is to pass equipment into the sterile field.

4.2. Principles of heart surgery

4.2.1. Heart-lung machine (cardiopulmonary bypass)

Most heart operations require the use of a heart–lung or cardiopulmonary bypass (CPB) machine. The bypass machine takes over the function of the heart and lungs for the duration of the procedure. Blood is drained into a reservoir from a cannula in the right side of the heart, usually the right atrium, and then oxygenated, filtered, and returned to the patient, usually through a cannula in the ascending aorta. The heart–lung machine can also cool a patient to below normal body temperature for a long or complex operation (e.g. aortic dissection surgery) and rewarm the patient afterwards.

The adequacy of perfusion (blood flow to the organs) during the operation is monitored closely using various inline parameters such as blood-flow (which is dependent on an individual patient’s height and weight), blood pressure and regular blood sampling.

Before a patient is established on cardiopulmonary bypass, their blood must first be anticoagulated using heparin to stop blood clots forming in the bypass circuit tubing. The successful management of the heart–lung machine requires close interaction between the perfusionist and anaesthetist as well as the practical aspects of cardiopulmonary bypass established by the surgeon.

Case 6 (page 15) and Case 20 (page 30) are examples where inadequate perfusion on cardiopulmonary bypass may have contributed to a poor outcome after surgery.

4.2.2. Myocardial protection

Most operations on the heart require the heart to be stopped. This is achieved by isolating the heart from the circulation with a clamp across the ascending aorta and then the administration of a solution with a high potassium concentration (cardioplegia) which stops and cools the heart. The cardioplegia can be administered through the antegrade route down a cannula in the ascending aorta (or directly into the ostia (mouths) of the coronary arteries if the aorta is opened), or it can be delivered in a retrograde manner through the coronary sinus and back along the veins that usually drain the heart. There are limitations to both techniques; but in particular, retrograde cardioplegia is less effective for protection of the right ventricle[24]. Cardioplegia administration needs to be repeated throughout the period that the cross clamp is applied (the ischaemic time) during which the heart is not perfused, usually after every twenty minutes. It is normal practice for the perfusionist to remind the surgeon of this throughout the case.

Inadequate myocardial protection (route, volume, and/or frequency) can contribute to poor ventricular function after surgery, leading to a need for inotropic support on ICU and a prolonged length of stay. Case 21 is an example in which the Panel judged that myocardial protection was inadequate.

Case 21

A patient in their late seventies was admitted for elective redo AVR and mitral valve repair. Unfortunately, surgery was postponed and they then developed endocarditis. The patient underwent surgery two weeks later.

The operation was performed by a non-consultant supervised by a consultant; there was a long ischaemic time (duration of aortic cross-clamping) and myocardial protection relied on antegrade cardioplegia induction, followed by repeated retrograde-only maintenance. The patient died from right ventricular failure two days after surgery.

The Panel judged that the strategy for myocardial protection was poorly planned and that inadequate myocardial protection contributed to post-operative right ventricular failure.

4.2.3. Coronary artery bypass surgery (CABG)

The overall mortality for elective CABG in the UK is approximately 1% and has continued to fall over the last decade, despite an increasingly adverse risk profile of patients undergoing surgery. CABG has excellent outcomes; approximately 80% of patients are alive a decade after surgery of whom a large majority (up to 90%) have not required intervention for recurrent angina[25].

Most CABG operations are performed through a median sternotomy (midline incision through the breastbone) which allows good access to the heart. The bypass grafts (conduits) are vessels harvested from elsewhere in the body.

Around 80% of all CABG operations are completed using CPB on a heart arrested with cardioplegia, but some surgeons prefer an off-pump approach (without the use of CPB)[26].

4.2.4. Valve surgery

Diseased heart valves can be repaired or replaced; the type of surgery is dependent on the valve involved, the nature of the disease, the presence of any adverse cardiac effects of valve disease and surgical expertise.

Mitral valve repair is a successful procedure in patients with degenerative mitral regurgitation (leaking) and has excellent long-term survival rates; some valves are too diseased for repair and replacement is required. In certain cases otherwise suitable for repair, mitral valve replacement is the best option if a less complex operation of shorter duration is desirable because of other patient factors, for example in the setting of impaired heart function or when additional heart procedures are needed.

Aortic valve disease (stenosis (narrowing) and/or regurgitation (leaking)), is usually treated with aortic valve replacement. A range of biological and mechanical valves (prostheses) is available for valve replacement. Patients with aortic stenosis may also be considered for TAVI when the risks of conventional surgery are high or prohibitive.

The majority of valve operations are performed through a median sternotomy on cardiopulmonary bypass, as described for CABG.

4.2.5. Aortic surgery

Thoracic aortic surgery is generally more complex and higher risk than the previously described cardiac procedures. Surgery for aortic aneurysm is usually performed for prevention of rupture or dissection (described below). According to international guidelines, patients with proximal (ascending and arch) aortic aneurysms are offered prophylactic surgery, based on aortic dimensions[27].

Aortic root replacement involves replacement of the aortic valve attached to a prosthetic conduit and re-implantation of the patients' own coronary ostia as 'buttons' onto the graft. A less complex operation for a dilated ascending aorta involves the replacement of the ascending aorta with an AVR. This is sometimes appropriate if the proximal aortic root is not dilated.

Aortic arch surgery requires specialist techniques to protect the brain during the procedure because the head and neck vessels need to be sutured in a bloodless operative field. The mainstay of these techniques is hypothermic circulatory arrest (the patient is cooled so that the brain 'hibernates' and the aorta can then be opened during a period of arrest). Circulatory arrest is often supplemented with selective antegrade cerebral perfusion, where the head vessels are perfused with cold oxygenated blood during the period of arrest.

Acute Type A dissection is the most common cardiac surgical emergency operation. It occurs when there is a tear in the innermost layer of the wall of the ascending aorta causing blood to track along between the layers of the aorta. It has >90% risk of death, but this can be reduced by emergency surgery. The overall mortality rate for this procedure remains around 15–25% depending on local expertise[28]. Such procedures often require the use of hypothermic circulatory arrest.

4.3. Complex procedures

Some heart operations are more complex than isolated CABG or valve surgery. For example, a patient may have severe valve disease and significant coronary artery disease requiring valve replacement and CABG during the same operation. Combined procedures such as these are higher risk than isolated procedures. Because the operations are longer, careful pre-operative planning is required to ensure smooth progress of surgery, with particular attention to the cardioplegia strategy to minimise damage to the heart and to reduce the risk of complications after surgery.

Some patients require a second heart operation after a first procedure because of the development of new cardiac disease, for example the development of severe aortic stenosis after a previous CABG. These “redo” procedures have a higher EuroSCORE II because of the risks of damage during re-opening the chest and freeing the heart from scar tissue (adhesions) after a previous operation. Redo surgery requires meticulous assessment and planning.

For some complex operations, it may be appropriate to have two consultant surgeons operating from the outset. This approach has recently been endorsed by the Society for Cardiothoracic Surgery (SCTS).

4.4. Common surgical complications

Heart surgery has become steadily safer, reflecting improvements in the medical management of patients as well as improvements in anaesthetic, surgical and perfusion techniques. The current overall mortality for all heart surgery is approximately 2% in the UK.

Non-fatal complications (morbidity) that may develop after surgery include: stroke, bleeding, sternal wound and other infections, myocardial infarction, kidney injury, abnormal heart rhythms or conduction problems, and bowel ischaemia.

Bleeding is a common problem after surgery because of the pre-operative use of drugs such as aspirin or clopidogrel. In addition, cardiopulmonary bypass itself can affect the body’s clotting mechanisms. Particular attention is necessary at the end of surgery to ensure there is no active bleeding; despite this, about 30-40% patients require blood or blood product transfusion. Excessive bleeding after surgery and the need for more blood transfusion are associated with poorer long-term survival after heart surgery. Approximately 4% of patients need to return to theatre to control bleeding after their initial cardiac surgery[29].

4.5. Operative planning and the conduct of surgery

A successful outcome after surgery depends on several factors:

- Patient related – heart disease and co-morbidities;
- The surgical theatre team – expertise and ability to deal with unexpected problems arising in theatre; and
- The operation – timing and complexity.

The Panel identified recurring themes in the operative phase of care which contributed to poor outcomes. These are highlighted in the case studies below; there is often more than a single theme in each example.

4.5.1. Lack of surgical expertise or experience

The risk of a particular surgical procedure can be highly variable. High-risk patients are usually best treated by experienced surgeons.

Unexpected difficulties can arise during any cardiac surgery and all surgeons should be prepared to ask for help from a colleague in these situations.

Case 21 (page 32) describes a complex case performed by a non-consultant under consultant supervision with inadequate myocardial protection leading to right ventricular failure. Case 22 describes a rare, highly complex procedure where the operative strategy was not entirely clear. Case 23 is an example of a case in which a surgeon with limited experience of the procedure had difficulty dealing with intraoperative complications and there was no call for more experienced help.

Case 22

A patient in their mid-eighties presented with an aneurysm of a coronary vein graft eroding through the chest wall. The patient was accepted for surgery after appropriate assessment and MDT discussion. During surgery, there was massive haemorrhage from the aneurysm sac before systemic cooling on CPB, leading to a prolonged period of poor perfusion and hypotension before deep hypothermic circulatory arrest. The heart failed to wean from CPB at the end of surgery and the patient died on the operating table.

The Panel were concerned by discrepancies between the anaesthetic and perfusion charts, and the operation note. There was haemorrhage from the aneurysm sac before systemic cooling and adequate control of the circulation, leading to a prolonged period of hypotension. However, the records disagree whether this was intentional or due to aneurysm rupture. The evidence presented was contradictory and not reflective of clear decision-making.

Case 23

A patient in their mid-seventies was admitted for elective mitral valve replacement and CABG x3. The case was allocated to a surgeon with limited recent mitral experience, despite the department having several experienced mitral surgeons. The operation was very long, with an almost six hour period of ischaemia. The patient died two days later from cardiogenic shock and multi-organ failure.

The Panel judged that surgery should have been undertaken by a more experienced surgeon and were concerned that despite (poorly documented) problems at surgery leading to a prolonged procedure, there had not appeared to have been any call for experienced help by any member(s) of the theatre team.

4.5.2. Consultant responsibility

No individual consultant is, or should be, available to manage their patients 'around the clock'. There should be well-defined arrangements to ensure that consultant cover is available when required and that the consultant responsible for a particular patient is clearly documented. The Panel found examples in which the consultant responsibility for the patient was not clearly defined at all times.

Case 6 (page 15) was performed out of hours by a registrar with no clear consultant supervision. Three consultants were mentioned in the notes but none appeared to have clear responsibility for the patient.

4.5.3. Surgical judgement

Patients may present with combinations of coronary artery, valve, and other heart disease. A detailed pre-operative assessment is necessary to determine which conditions are severe enough to merit treatment and which may be left alone, a combination of multiple severe conditions or pre-existing co-morbidities may render the risk of surgery prohibitive and non-operative treatment should be offered. A pragmatic approach in dealing with the most pressing of the surgical lesions may be appropriate rather than trying to treat all pathologies. Failure to follow this strategy may lead to unnecessary or overcomplicated surgery. Even if the full complexity of a case only becomes apparent on TOE at the start of surgery, there may still be an opportunity to stop and re-consider the most appropriate option for the patient.

Both Case 1 (page 12) and Case 16 (page 25) describe patients undergoing unnecessarily complex operations rather than receiving treatment for the most severe lesions. Case 24 describes a very complex patient unlikely to survive with or without surgery and the questionable use of post-operative mechanical support.

Case 24

A patient in their late seventies presented with an acute aortic syndrome. They had an extensive history of cardiac disease, including biventricular impairment and severe mitral regurgitation.

The risks of surgery were discussed with the patient and their family. The patient underwent aortic root and mitral valve replacement (although the need for mitral valve replacement was omitted from the consent form).

The patient suffered from right ventricular failure and failed to wean from CPB. A right ventricular assist device (RVAD) was implanted, but despite this, the patient died soon afterwards.

The Panel recognised that this was a challenging case, but none of the Panel judged that surgery was likely to succeed. The need for mitral valve replacement was not listed on the consent form, even though this was apparent in the patient's history. The Panel were surprised that such a complex and elderly patient was placed on mechanical circulatory support and felt that this would not have been offered in other centres.

4.5.4. Timing of surgery

Although there may be pressure on the surgical team to operate as soon as possible for patients admitted as an emergency, there may be benefits in delaying surgery for stable patients to allow for medical optimisation, or to allow urgent surgery to be scheduled within daylight hours or during the working week when more support is available. In addition, it is often appropriate for more complex cases (redo surgery or combined procedures) to be scheduled first on a theatre list.

Case 25 describes a case performed during the night as an emergency for reasons that were not clear.

Case 25

A patient in their early seventies was admitted following an out of hospital cardiac arrest. After a coronary angiogram, the patient was taken for emergency CABG on the night of admission but was pain free and haemodynamically stable. They died after eleven days on the ICU with a complicated post-operative course including early graft failure. The Panel felt there was no clear indication for emergency out-of-hours surgery.

4.5.5. Lack of adaptability or inability to manage unexpected findings

Surgeons need to be flexible and adaptable in response to unexpected findings or problems during surgery. The Panel found several examples in which a poor response to intra-operative challenges contributed to a poor outcome.

Case 16 (page 25) describes a patient where intraoperative transoesophageal echo demonstrated unexpected findings with regard to previously diagnosed valvular lesions. The operative plan was not changed in light of these findings.

4.5.6. Management of complications

Many cases reviewed by the Panel were complex and had difficult, high-risk surgery. Some complications are more common in particular cases and additional care is required to avoid predictable complications which may have a significant impact on a patient's progress.

Case 26 describes a patient who left theatre with active bleeding after a complex operation.

Case 26

A patient in their mid-sixties with previous AVR required urgent redo surgery for endocarditis.

The patient had a difficult operation and was transferred to the intensive care unit with active bleeding. Despite the surgical team being informed of a 1400ml blood loss on transfer to intensive care, re-exploration to control the bleeding was delayed. The patient died the day after surgery from bowel and lower limb ischaemia.

The Panel recognised that this was a complex, high-risk case but judged that the patient should not have left theatre with this degree of bleeding and coagulopathy. During the operation, there appeared to have been inadequate transfusion of clotting factors compared with red cell transfusion.

5. Post-operative care

5.1. Background

This section of the report considers care on the intensive care unit (ICU), high-dependency unit (HDU) and the ward.

Patients who have had cardiac surgery require careful post-operative management. This care is usually provided in two phases. Firstly, the patient is transferred to an intensive care environment (Level 3 care) and then once sufficiently recovered, the patient is returned to the ward (Level 1 care), where the hospital-based recovery is completed. Some patients require an intermediate level of care on a HDU (Level 2 care) prior to their transfer to the ward. Many patients are discharged home within a week following surgery.

The care of the post-operative cardiac surgical patient requires an MDT approach. It is essential that there should be input and support from cardiac surgical and cardiac intensivist teams throughout a patient's stay in hospital.

The routine pathway for a post-operative cardiac surgical patient is as follows:

- The patient is transferred to ICU ventilated, with invasive monitoring, appropriate inotrope and sedative drug infusions and surgical drains present;
- There is a detailed clinical handover and assessment by the ICU team with a plan for ongoing care. There is then regular review by the anaesthetic, critical care and surgical teams. In some cases there will be a need for additional invasive monitoring, cardiac imaging and organ support;
- The ventilated patient is nursed one-to-one until ready for extubation, according to the clinical situation. When extubated, the nursing staff ratio may change, taking into account a patient's dependency requirements;
- The patient is discharged from ICU to either a Level 1 or Level 2 care environment, dependent on local circumstances and the patient's clinical condition; and
- At each step, it is essential that adequate documentation is maintained to ensure good patient care.

The Intensive Care Society has recently produced *'Guidelines for the provision of Cardiothoracic Critical Care'*[29]. The document stresses that there should be:

- A designated lead consultant intensivist;
- A resident doctor with critical care training;
- An on-call cardiac surgeon;
- Care guided by a management plan set during a structured bedside ward round; and
- A consultant in charge who should coordinate input from members of the various teams involved in the daily care of the patient.

5.2. Areas of good practice

The Panel found many examples of an experienced ICU team delivering high quality care. These included:

- Good record keeping;
- Regular consultant review;
- Prompt escalation of inotropic and other organ support;
- Timely involvement of non-cardiac medical and surgical teams;
- Good communication with patients' families; and
- Appropriate contact with specialist nurses for organ donation.

5.3. Areas of concern

Despite the above examples of good practice, the Panel identified a number of areas where practice could have been improved.

5.3.1 Failure to recognise a deteriorating patient

5.3.1.1 Bleeding

Further to the discussion about bleeding in the operative phase of care section, there needs to be continuous assessment of post-operative blood loss and an ability to return the patient promptly to theatre, or to re-open the chest within the ICU. The late management of significant haemorrhage or delayed diagnosis of tamponade (accumulation of blood around the heart) may have significant implications for the recovery of the patient due to impaired cardiac function; leading to multi organ failure, a prolonged ICU stay and possibly death. A prompt return to theatre in these cases could control bleeding and/or relieve the tamponade, preventing these deleterious consequences.

The Panel noted several cases where there was a slow response to significant post-operative blood loss and a delay in returning to theatre, for example in Case 27. There were a number of examples of a delay in which an inadequate response to bleeding contributed to the death of the patient.

Case 27

A patient in their early eighties underwent urgent CABG surgery.

On admission to ICU, the patient was haemodynamically unstable (low blood pressure). In addition, there was excessive bleeding (1500ml in the first six hours, with a further 1600ml in the next twenty-four hours).

The Panel could find no documentation to explain why the patient was not returned to theatre for re-exploration. It appeared that the attending medical team were reassured by repeated echo examinations. However, the Panel judged that the patient should have been returned to theatre within a few hours of surgery.

The patient died two days later from multi-organ failure.

5.3.1.2 Post-operative myocardial infarction

Regular ECG analysis is a key component of post-operative care of the deteriorating patient. Significant changes should be recognised and acted upon when necessary.

The Panel noted several cases where serial ECGs demonstrated evolving myocardial ischaemia in the post-operative period and yet no action was taken, for example in Case 1 (page 12) and Case 28. On several occasions, the Panel felt that earlier recognition and appropriate action may have prevented subsequent mortality.

Case 28

A patient in their early eighties underwent elective AVR and CABG x4.

The operation took longer than expected (with a 4.5 hour duration of cardiopulmonary bypass); the reasons for this were not clearly documented. Post-operative ECGs showed clear evidence of an acute anterior myocardial infarction in ICU, a few hours after surgery.

The Panel found no documentation that the post-operative infarction was recognised or acted upon. It was felt that emergency angiography and attempted percutaneous intervention to re-open an occluded bypass graft or diseased coronary artery was indicated.

The patient died four days later from multi-organ failure.

5.3.1.3 Late deterioration

Complications may develop after patients have been transferred to the ward. Regular review by an experienced clinical team, with timely investigation and treatment, is essential.

In some hospitals, a critical care outreach team is available to support junior medical staff in the management of these patients.

The Panel noted several cases where earlier intervention may have avoided mortality, for example in Case 29 and Case 30.

Case 29

A patient in their mid-seventies underwent elective aortic valve replacement and aortic root surgery.

The patient's early recovery was uneventful and so they were discharged to the ward. However, the patient deteriorated over a period of several hours following transfer. Despite appropriate early intervention by the junior medical team, the patient continued to deteriorate with low blood pressure and reduced urine output.

Senior advice was sought but the remainder of the team were unable to attend. The patient remained in a critical condition and subsequently suffered a cardiac arrest. Their chest was re-opened and a significant tamponade was relieved.

The patient died 18 days after surgery from hypoxic brain injury.

Case 30

A patient in their early eighties underwent urgent AVR and CABG surgery.

The patient's initial ICU recovery was slow, but they made good progress and they were returned to the ward. Serial ECGs demonstrated a progressive prolongation of their PR interval which was not noted in the clinical record.

The patient suffered a cardiac arrest due to complete heart block and died 10 days after surgery.

5.3.2 Communication and team work

The Panel recognised that in many cases, there was good evidence of effective communication and team working. However, working within the complex environment of cardiac intensive care, it is inevitable that at times communication is challenging.

The Panel noted several examples where they felt team working and communication could have been improved. See Case 1 on page 12 and see Case 5 on page 15.

5.3.3 Leadership and responsibility on ICU

The Panel felt that there was generally good leadership within the ICU, however there were some cases where the final “ownership” of the patient seemed to be uncertain. See Case 9 on page 17.

Case 31

A patient in their late sixties, who had undergone previous aortic valve replacement, was admitted as an urgent case. The patient deteriorated to the extent that they required treatment on intensive care.

A series of echocardiograms revealed critical aortic stenosis with progressive dysfunction of the valve, possibly as a result of leaflet thrombosis. The Panel felt there was an earlier opportunity to intervene and were unsure why the patient waited nine days for their operation. The Panel felt that the individuals looking after the patient (cardiologists, cardiac surgeons, TAVI operators and intensivists) did not work effectively as a team and there was no clear leader.

The patient died prior to any intervention to the valve being undertaken.

6. Conclusion

The Panel have reviewed the case records of 202 patients who died after cardiac surgery at St George's Hospital, in the period 1 April 2013 to 1 December 2018, using a phase of care mortality analysis (POCMA) technique.

The Panel found many examples of good care. There were, however, several cases in which the evidence observed in the case note review suggested that the death of patients was avoidable, or that care was of a poorer standard than would have been expected. The reasons for these judgements have been examined in previous chapters.

Our discussion has outlined several clinical and institutional shortcomings that we feel have led to the NICOR alerts for the periods 2013 to 2016 and 2014 to 2017. The Panel have also described a number of deficiencies that have led to a failure to learn from these mortalities.

7. Recommendations

Below are the recommendations of the Panel. The Panel's aim in making these recommendations is to prevent these issues from happening again.

7.1.1 St George's cardiac services

- **Recommendation 1**

  The Trust should ensure the principles included in the GMC publication, "*Effective clinical governance for the medical profession: A handbook for organisations employing, contracting or overseeing the practice of doctors*."[30] are implemented.

  This publication lays out a framework that requires that clinical teams are supported by their employing organisations and boards, in their pursuit of good governance.

- **Recommendation 2**

  Each of the cardiac surgeons, the lead for cardiology, the lead for anaesthesia/ICU and the lead for perfusion should have an individualised feedback meeting with clinical representatives from the Independent Advisory and Mortality Review Panels. These should be confidential and formative. The purpose of these meetings is to allow for an explanation of the Panel findings, to allow for reflection and to form a platform for ongoing mentoring and support. The Trust's Chief Medical Officer should also be present at these feedback meetings.

- **Recommendation 3**

  A change of working relationships within and between cardiac surgery, cardiology and anaesthesia/intensive care teams should be fostered. This should include a mutually established "heads of agreement" document, outlining standards of inter-professional behaviour and mechanisms to ensure these values are maintained, with oversight from the Board. The document should enshrine the principles outlined in "*Duties of a Doctor".*[16]

  New and locum consultants should have formal mentorship arrangements put in place to support their professional development.

- **Recommendation 4**

  The cardiology department should attain full British Society of Echocardiography Departmental Accreditation.

7.1.2 Patient referral and assessment

- **Recommendation 5**

  The Trust should develop sub-specialist teams, if appropriate in collaboration with other hospitals in the network, in mitral, aortovascular and revascularisation surgery.

  The aortovascular and mitral teams should have at least two consultant surgeons in each group and no surgeon should be in both of these teams. The revascularisation team should comprise all cardiac surgeons at the Trust.

  Each team should have designated interventional and imaging cardiology consultants alongside radiology and anaesthesia/intensive care consultant representation, where appropriate.

- **Recommendation 6**

  All referrals for cardiac surgery should be discussed at the relevant sub-specialist MDT, which should ensure the availability of all necessary data before review of the clinical case. Subsequently the MDT should plan treatment (including an operative plan) and allocate a surgeon.

  The MDT should have a pre-defined minimal quorum, with full representation from sub-specialist cardiac surgery, interventional and non-interventional cardiology, and radiology. Anaesthetic advice should be available if required. Discussion, as well as decision, of the MDT should be recorded. If plans for treatment change after discussion at the MDT (either through patient choice or change in the clinical situation) then the patient should be re-discussed to ensure full MDT ratification and oversight of the adapted management plans. Any changes to the original plans should be documented clearly.

  The MDT should have the provision of the very best treatment for the patient as its aim; taking into consideration the full clinical picture. This will include a full review of the surgical, interventional and medical treatment options available.

- **Recommendation 7**

  Risk-scoring, using up to date risk scoring algorithms (for example EuroSCORE II) should be embedded in practice. The team must ensure all risk factors are considered and that data are sought to ensure an accurate risk prediction. This risk prediction must be recorded on the consent form as part of the discussion of the indications, risks and potential benefits of proposed treatments. On occasion, it is justified to include non-scored conditions (e.g. liver or haematological disease) to increase the quoted risk. Conversely, if the risk quoted is less than the calculated risk, then the reasons for this adjustment should be clearly documented in the case record.

  Consent procedure should follow the guidance laid out in the Royal College of Surgeons England publication, "*Consent: Supported Decision-Making. A guide to good practice*"[31].

- **Recommendation 8**

  Standard referral templates for cardiac surgery should be developed across the London network. Cardiologists referring patients for surgery should include details of the symptomatic status of the patient, investigations (and their interpretation), co-morbidity (and potential subsequent impact on proposed benefit(s) of surgery) and consideration of alternative interventional and medical therapies. For patients referred for revascularisation with intermediate angiographic stenoses, functional/ischaemia testing should be performed as part of the referral.

7.1.3 Patient management

- **Recommendation 9**

  The following guidelines/standard operating procedures (SOP) for patient care should be developed and implemented:

  1. An SOP for the management of urgent inter-hospital transfers. This should include a clear description of joint care (cardiology and cardiac surgery) arrangements and responsibilities. It should delineate necessary investigations and the management of medications, in line with best practice guidelines (for example the GIRFT report[28]).

  2. A guideline for management of myocardial protection. All theatre team members should consider themselves responsible for myocardial protection and there should be establishment of a ”flat” theatre hierarchy to ensure that the heart remains well protected during surgery.

  3. A guideline for the management of operative and post-operative haemorrhage. This should include clear indications for when return to theatre is indicated.

  4. A multi-disciplinary guideline for post-operative ECG interpretation, particularly focusing on ischaemia. Clear indications for when emergency repeat coronary angiography, or return to theatre, are warranted, should be included.

  5. A multi-disciplinary guideline for selection and management of patients requiring mechanical support, including Ventricular Assist Devices and Extra-Corporeal Membrane Oxygenation. This protocol should be developed with guidance from a transplant centre.

  6. The Trust should develop a guideline for outreach services for patients who are not in intensive care environments. Rapid, 24/7 expert review should be available to allow timely escalation for patients in need.

7.1.4 Clinical governance

- **Recommendation 10**

  The Trust should develop a robust, independent, multi-disciplinary review of mortality with appropriate governance oversight to ensure that lessons are learnt. The SJR structure of mortality review should be utilised. Panel phase of care and avoidability scores should be presented as part of the Mortality and Morbidity review of the case. Given the findings of the mortality review Panel, the SJR should also include assessments of whether the MDT operation plan was delivered and whether it was performed by the right person at the right time. Review of the case should include an appraisal of discussions made with the coroner.

  The Trust should ensure that it fulfils any responsibility it has under the duty of candour provision of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 subsequent to this review and ensure a robust system is in place for patients who receive care in the Trust going forward.

- **Recommendation 11**

  The Trust should adapt the coroner referral form. There should be only one signatory of the form, which should be that of the responsible consultant.

- **Recommendation 12**

  The Panel recognise the substantial contributions that national audits (such as NICOR) and programmes (such as GIRFT) have made to patient outcomes. It is clear that these oversight and review mechanisms are essential in ensuring patient safety in the UK. Indeed, this review would not have come about without the NICOR alert warnings. The Panel recommend continued funding of these national initiatives. Early warning systems should be developed to allow rapid identification of issues within cardiac surgery units, as they arise. Publication of benchmark outcomes (such as the SCTS "*Blue Book*") should be centrally supported.

8. Appendices

8.1. Appendix 1 – Glossary

ASD	Atrial Septal Defect
AVR	Aortic Valve Replacement
BAV	Balloon Aortic Valvuloplasty
BRI	Bristol Royal Infirmary
CABG	Coronary Artery Bypass Graft
CPB	Cardiopulmonary Bypass
ECG	Electrocardiogram
FFR	Fractional Flow Reserve
GIRFT	Getting It Right First Time
GMC	General Medical Council
HDU	High-Dependency Unit
ICU	Intensive Care Unit
IVUS	Intravascular Ultrasound
LAD	Left Anterior Descending Artery
LV	Left Ventricular
M&M Review	Mortality and Morbidity Review
MRI	Magnetic Resonance Imaging
MDT	Multi-Disciplinary Team
NHSI	National Health Service Improvement / NHS Improvement
NICOR	National Institute for Cardiovascular Outcomes Research
NSTEMI	Non-ST Elevation Myocardial Infarction
PCI	Percutaneous Coronary Intervention
POCMA	Phase of Care Mortality Analysis
RV	Right Ventricular
RVAD	Right Ventricular Assist Device
SJR	Structured Judgement Review
SOP	Standard Operating Procedure
STEMI	ST Elevation Myocardial Infarction
SCTS	Society for Cardiothoracic Surgery
SUI	Serious Untoward Incident
TAVI	Trans-catheter Aortic Valve Implantation
TOE	Transoesophageal Echocardiogram

8.2. Appendix 2 – Governance

Panel Review Team

Panel Chair:
Mr Michael Lewis MB ChB, BSc, MD, FRCS CtH, FFST
Consultant Cardiac Surgeon
Sussex Cardiac Centre, Brighton & Sussex University Hospitals NHS Trust, Brighton

Cardiologists:
Dr Will Davies PhD MRCP MRCS
Consultant Interventional Cardiologist
Royal Papworth Hospital NHS Foundation Trust

Dr P Rachael James MD, BSc, FRCP
Consultant Cardiologist & Deputy Medical Director (Standards & Revalidation)
Sussex Cardiac Centre, Brighton & Sussex University Hospitals NHS Trust, Brighton

Dr Jim McLenachan MD, FRCP (London)
Consultant Cardiologist
The Leeds Teaching Hospitals NHS Trust

Cardiac surgeons:
Mr Ian W. Colquhoun MB ChB FRCS Glas FRCS CTh Dip Clin Ed
Consultant Cardiothoracic Surgeon - Golden Jubilee National Hospital
Director of Clinical Skills - Clinical Anatomy Skills Centre and Macewen Facility, Royal College of Physicians and Surgeons of Glasgow.
Honorary Associate Clinical Professor and OSCE Lead - School of Medicine, Veterinary and Life Sciences, University of Glasgow

Miss Deborah Harrington MD FRCS CTh
Consultant Cardiac & Aortic Surgeon
Liverpool Heart & Chest Hospital

Mr Mark Jones MB ChB FRCS(Eng)
Retired Consultant Cardiothoracic Surgeon
Previously at University Hospital of South Manchester (now known as Central Manchester Foundation Trust)

Mr Rana Sayeed MA PhD MRCP FRCS(C-Th)
Consultant Cardiothoracic Surgeon, Clinical Lead for Cardiac Surgery and Head of Programme for Complex Mitral Valve Surgery
Oxford University Hospitals NHS Foundation Trust

Anaesthetists/Intensivists:
Dr Christopher M. Allsager MB ChB, FRCA, FICM
Clinical Director for Adult Intensive care, theatres, anaesthesia, pain and sleep services
Consultant cardiac anaesthetist and consultant in adult intensive care
University Hospital of Leicester NHS Trust

Dr Michael H Cross FRCA, FFICM
Consultant Cardiothoracic Anaesthetist
The Leeds Teaching Hospitals NHS Trust

Dr Ravi Gill BM FFICM
Consultant Anaesthetist
University Hospital Southampton NHS Foundation Trust

Dr Peter Robbins MBBS, FRCA, FFICM, PGCertMedEd, LL.M
Consultant in Cardiothoracic Anaesthesia and Intensive Care
University Hospitals Plymouth NHS Trust

The Panel reviewed cases, analysed the data and collectively compiled this report.

Acknowledgements

We would like to thank the following people at St George's University Hospitals NHS Foundation Trust who supported the Panel throughout the period of the case reviews:

Magdalene Dolphyne, Administrative Support
Kate Hutt, Clinical Audit and Effectiveness Manager
Dr Richard Jennings, Chief Medical Officer
Dr Nigel Kennea, Associate Director for Mortality
Adam Lewarne, Clinical Audit Manager
Mr Steve Livesey, Cardiac Surgery Lead and Associate Medical Director
Mark O'Donnell, Heart Failure Nurse Specialist, Cardiology
Elizabeth Palmer, Director of Quality Governance

Confidentiality and responsibility

The findings and recommendations contained in the Report represent the views of the Panel, reached in good faith following analysis of the clinical case information provided by the Trust and consideration of feedback provided by the individual clinicians involved in those cases. The Panel was and is not responsible for the adequacy, accuracy or completeness of the information provided to it. The Panel would also draw attention to the caveats in the interpretation of the historical data set out in section 1.4 of the Report.

The Panel has prepared the Report so as not to identify the individual patients, clinicians and other NHS staff involved in the cases reviewed by the Panel. Neither the Panel nor NHS Improvement, which is to publish the Report, authorises the public identification of any individuals in the Report. Any public identification by a third party of persons referred to in the report may constitute a breach of the Data Protection Act 2018.

Conflicts of interest

The Panel were appointed independently by NHS Improvement. Prior to each session of review, a conflict of interest declaration was made. The Panel were unaware of any conflicts at each review point.

8.3. Appendix 3 – Analysis

The Panel analysed the following cases:

Cohort 1: Cases from 01 April 2013 to 01 December 2018
193 cases reviewed
2 cases were not reviewed as there were insufficient patient records available.

Cohort 2: Patients who have died whilst waiting for cardiac surgery 01 March 2018 to 31 August 2018
5 cases reviewed

Cohort 3: Patients who died post-discharge from hospital before 30 days 01 March 2018 to 31 August 2018
0 cases identified by the Trust

Cohort 4: Patients families have requested specific review
4 cases reviewed

Total cases reviewed: 202

8.1. Appendix 4 – References

[1] Professor Mike Bewick & Dr Simon Haynes, *Independent Review of Cardiac Surgery Service at St Georges Hospital NHS Trust* [August 2018] Available from: https://www.stgeorges.nhs.uk/newsitem/cardiac-surgery-at-st-georges-updated-statement-thursday-9-august-2018/

[2] Royal College of Physicians. *National Mortality Case Record Review (NMCRR) programme resources* [5 October 2016] Available from: https://www.rcplondon.ac.uk/projects/outputs/national-mortality-case-record-review-nmcrr-programme-resources

[3] Fazzallari FL, Prager RL, Shannon FL, Sutcliffe KM, Theurer PF, A method to evaluate cardiac surgery mortality: Phase of care mortality analysis, Volume 93 (1), p. 36-43 Available from: https://www.annalsthoracicsurgery.org/article/S0003-4975(11)01819-4/fulltext

[4] Cooper, H, Findlay G, Martin IC, Mason DG, Mason M, Utley M. NCEPOD, *Death following a first time, isolated coronary artery bypass graft: The heart of the matter (2008)* Available from: https://www.ncepod.org.uk/2008cabgtoolkit.html

[5] *The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995 – Learning from Bristol* [July 2001] Available from: https://webarchive.nationalarchives.gov.uk/20090811143822/http:/www.bristol-inquiry.org.uk/final_report/the_report.pdf

[6] The Telegraph: "*Bristol heart scandal 'could happen again' warns lawyer. Martin Beckford"* [18 Jun 2011] Available from: https://www.telegraph.co.uk/news/health/news/8582836/Bristol-heart-scandal-could-happen-again-warns-lawyer.html

[7] Society for Cardiothoracic Surgery in Great Britain and Ireland, *Maintaining patient's trust: modern medical professionalism* [2011] Available from: https://scts.org/2011-maintaining-patients-trust-modern-medical-professionalism/

[8] NICOR, *Cardiac Audit Programme (NCAP).* Available from: https://www.nicor.org.uk/national-cardiac-audit-programme/

[9] Francis, R. The Mid Staffordshire NHS Foundation Trust Public Inquiry. *Independent Report of the Mid Staffordshire NHS Foundation Public Inquiry* [6 February 2013] Available from: https://www.gov.uk/government/publications/report-of-the-mid-staffordshire-nhs-foundation-trust-public-inquiry

[10] Kirkup, B. *The Report of the Morecambe Bay Investigation* [March 2015] Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf

[11] Kirkup, B. *Report of the Liverpool Community Health Independent Review* [January 2018] Available from: https://improvement.nhs.uk/documents/2403/LiverpoolCommunityHealth_IndependentReviewReport_V2.pdf

[12] Report of the independent inquiry into the issues raised by Paterson [February 2020] Available from: https://www.gov.uk/government/publications/paterson-inquiry-report

[13] Arnold I, Stern DT, ed. *Measuring Medical Professionalism*. New York, NY. Oxford University Press; 2006:19. Available from: https://global.oup.com/academic/product/measuring-medical-professionalism-9780195172263?cc=gb&lang=en&

[14] Royal College of Physicians. *Doctors in society: medical professionalism in a changing world. Report of a Working Party of the Royal College of Physicians of London* [2005] Available from: https://shop.rcplondon.ac.uk/products/doctors-in-society-medical-professionalism-in-a-changing-world?variant=6337443013

[15] Irvine DH. *The relationship between teaching professionalism and licensing and accrediting bodies. In: Teaching Medical Professionalism*. [Eds Cruess RL, Cruess SR, Steinert Y. New York: Cambridge University Press, 2009] Available from: https://www.cambridge.org/core/books/teaching-medical-professionalism/professionalism-professional-identity-and-licensing-and-accrediting-bodies/D905F752DA8556B28383159FCCF2792C

[16] General Medical Council. *Good Medical Practice* [29 April 2019] Available from: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice

[17] Royal College of Surgeons. *Good Surgical Practice: A guide to good practice*. Available from: https://www.rcseng.ac.uk/standards-and-research/gsp/

[18] Luckraz H, Norell M, Buch M, James R, Cooper G. *Structure and functioning of a multidisciplinary 'Heart Team' for patients with coronary artery disease: rationale and recommendations from a joint BCS/BCIS/SCTS working group.* [Eur J Cardiothorac Surg 2015;48:524–9] Available from: https://academic.oup.com/ejcts/article/48/4/524/2464969

[19] Professor J Wallwork. *Report on the Review of Surgical Services and other Associated Specialties* [14 April 2010] Available from: https://www.stgeorges.nhs.uk/newsitem/cardiac-surgery-at-st-georges-updated-statement-thursday-9-august-2018/

[20] *ESC on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology* [2013] Eur Heart J. 2013 Oct;34(38):2949-3003. doi: 10.1093/eurheartj/eht296. Epub 2013 Aug 30. Available from: https://www.ncbi.nlm.nih.gov/pubmed/23996286

[21] NICE Clinical Guideline CG126. *Stable angina: management* [23 July 2011] Available from: https://www.nice.org.uk/guidance/cg126

[22] Khosravi A, Wendler OE. Journal of Cardiology. *TAVI 2018: from guidelines to practice* [Vol 15, No 29 – 07 Feb 2018] Available from: https://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-15/TAVI-2018-from-guidelines-to-practice

[23] 2017 NICE Guidance. *Transcatheter aortic valve implantation for aortic stenosis* [26 July 2017] Available from: http://nice.org.uk/guidance/ipg586

[24] Allen BS, Winkelmann JW, Hanafy H, Hartz RS, Bolling KS, Ham J, Feinstein S. *Retrograde cardioplegia does not adequately perfuse the right ventricle. [June 1995]* Available from: https://www.ncbi.nlm.nih.gov/pubmed/7776676

[25] Taggart DP, Benedetto U, Gerry S, et al. New England Journal of Medicine, *Bilateral versus Single Internal-Thoracic-Artery Grafts at 10 Years* [2019; 380: 437–46] Available from: https://www.ncbi.nlm.nih.gov/pubmed/30699314

[26] NICOR: National Institute for Cardiovascular Outcomes Research, *National Adult Cardiac Surgery Audit Annual Report 2010–2011.* Available from: https://www.nicor.org.uk/wp-content/uploads/2019/02/annualreport2010-11.pdf

[27] Hiratzka H et al, Circulation. *Guidelines for the Diagnosis and Management of patients With Thoracic Aortic Disease*. [2010]; 121:e266-369. Available from: https://www.acc.org/~/media/clinical/pdf-files/approved-pdfs/2015/01/13/11/13/thoracic%20aortic%20disease%202010%20pocket%20guide.pdf

[28] Richens, D. *Cardiothoracic Surgery GIRFT Programme National Specialty Report* [March 2018] Available from: http://gettingitrightfirsttime.co.uk/wp-content/uploads/2018/04/GIRFT-Cardiothoracic-Report-1.pdf

[29] Intensive Care Society. *Guidelines for the Provision of Intensive Care Services* (Edition 2, 2019) Available from: https://www.ficm.ac.uk/standards-research-revalidation/guidelines-provision-intensive-care-services-v2

[30] Effective clinical governance for the medical profession: a handbook for organisations employing, contracting and overseeing the practice of Doctors. Available from: https://www.gmc-uk.org/-/media/documents/governance-handbook-2018_pdf-76395284.pdf

[31] Royal College of Surgeons of England, Consent: Supported Decision-Making. A guide to good practice. Available from: https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/consent/