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Monitoring Outcomes in Highly Specialised Cardiac Surgery

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1. Introduction

In the UK there are a small number of highly specialised areas of cardiac surgery that are centrally planned, funded and monitored these include Heart Transplantation in children and adults, Extra Corporeal Membrane Oxygenation (ECMO) in children and adults, Pulmonary Endarterectomy, and Ventricular Assist Devices (VAD) as a bridge to cardiac transplantation in children and adults.

In England, the National Specialised Commissioning Team (NSCT) is responsible for planning, funding and monitoring these highly specialised services within the English National Health Service (NHS) (Kenny et al., 2008). In total the NSCT commissions approximately 70 services, each of these service involves is commissioned centrally due to one or more of the following reasons:-

- Rare disease or condition, requiring significant expertise to manage
- Expensive drugs or technology
- Organisationally complex arrangements are needed for optimal management
- Technically demanding techniques or procedures

This chapter will discuss our approach, experience and the impact closely monitoring clinical outcomes has in this area of highly specialised surgery. While much that is written on monitoring outcomes focuses solely on formal data collection, analysis and interpretation we believe this is only a small, although important, part of the process of monitoring clinical outcomes when your aim is improvement of clinical services. Not only does formal data alone not give clear answers, but also they require detailed understanding of the service and interpretation. This is particularly true when the data refer to small volumes of clinical activity.

The small numbers of cases within these highly specialised areas are an issue for both the development of expert performance and for monitoring that performance. There is a significant sensitivity of any aggregate outcomes to the case-mix of the cases operated on and understanding how to interpret the results in a fair, measured, proportionate and transparent manner is essential.

If formal data alone are used for 'performance management' then even if the aim of the appraisal is performance improvement there are two more likely effects. The first is distortion of data and the second is distortion of the service, these occur because they appear to produce the same results, but it is much harder to produce real improvements in any system. Therefore, we strive to ensure that these data are never examined in isolation so that

inadvertent or deliberate distortion of either the service or the data are identified and prevented.

1.1 Our philosophy and approach

The basis of our approach is close personal working relationships, collaboration and mutual trust between those providing the service and those monitoring it. Each of these is equally important.

Close personal working relationships because although each of these service has detailed service specifications, exacting standards and a full and complex contract, we have found that when you have to resort to the use of these formal documents then you are unlikely to get the quality of service and the ongoing improvement that these highly complex service need.

Collaboration because there are synergies that arise from the joining of multiple perspectives. In the case of these highly specialised service when the perspectives of the provider, the purchaser and the patient are brought together to develop a service, solve a problem or resolve an issue the solutions are often far stronger and more long-sighted than the solution if only one perspective were considered.

Mutual trust because there are so many opportunities for the development of perverse incentives, short-term gain with long-term losses and gaming of any performance indicators that it is, in our opinion, very challenging to contract with people and organisations where such trust is undermined or becomes compromised.

Into each of these relationships, we believe we bring sensitivity and a thorough understanding of each service that allows us to use appropriately the 'dark art' of interpreting outcomes bases on small numbers.

We also insist on the development of clinical and managerial systems that wrap around these services and provide prompt, timely and appropriate feedback so that expert performance can develop (Klein, 1998). Encourage reflection so that each opportunity for learning from these scarce experiences is optimised for both individual learning and vicariously by the wider team and service. In addition, focus on performance improvement because however far a service has come however good it is, we find that either services improve or they deteriorate. Keeping a service's performance static requires as much if not more effort than improving it and our preference is, by far, for services that improve.

1.2 How the national specialised commissioning team uses the outcome data

Every service commissioned by the National Specialised Commissioning Team is allocated to a Triumvirate of a commissioning manager, a finance manager and a medical advisor. This Triumvirate oversees all elements of the commissioning process on an ongoing basis and through a number of simultaneously delivered processes.

The first process that underpins each service we commission is the development of clinical and service standards. These standards are developed collaboratively, with both our team and the service contributing fully to their development. In spite of this collaborative development, or maybe because of it, the standards are invariably high and most commonly represent, wherever possible, best practice, based on evidence rather than a lowest common denominator consensus.

The second process is formal twice-yearly face-to-face review meetings between each service provider and the Triumvirate. These twice-yearly review meetings cover all elements of the service and include a formal review of clinical audits, feedback on service in the form of complaints, compliments, patients surveys, satisfaction questionnaires and the key clinical

outcomes agreed for the service. The focus of the reviews is on how the service is developing and changing because of the information it is receiving from each of the preceding data sources.

The third process is an annual clinical audit day where all the providers of a service meet to go through the clinical outcomes of the service. These outcomes are based on 100% consecutive case-series of outcome reporting i.e. outcomes from every single patient cared for by a service in a given year.

The fourth process specific to the highly specialised cardiac services and the other transplant services takes the form of monthly monitoring of outcomes using the O-E (observed - expected) monitoring and tabular CUSUM (cumulative sum control chart). This monitoring allows each of the service providers and the National Specialised Commissioning Team to track any changes in outcomes in real-time, which allows early identification of any change from that which might be expected and allows the timely questioning of why such variation may have occurred. Details of such investigations are presented in the published UK Cardiothoracic Transplant Audit annual reports, leading to shared learning and shared service development and improvement based on centre level clinical outcome data and timely reporting and analysis.

Throughout each of these processes, our emphasis is on the use of data, from all sources, to provide feedback on the performance of the service and guide them to where the time would be most valuably spent improving.

We apply all of the above principles to all of the services we commission whether they are secure mental health services, diagnostic services, surgical services or those for cardiac transplantation (see www.specialisedservices.nhs.uk for the full list of services commissioned by the National Specialised Commissioning Team). To demonstrate this application we will use heart and lung transplantation as a case study, which includes a detailed reflection on an external review carried out at one of the heart and lung centres that involved a detailed statistical analysis of mortality data that informed the review findings.

We then conclude with summaries of the other nationally commissioned cardiac services and the use of outcome data within them.

2. Heart and lung transplantation

This section includes elements reproduced in full, or paraphrased, with permission from *The Royal College of Surgeons of England Clinical Effectiveness Unit and NHS Blood and Transplant UK Cardiothoracic Audit End of Year Report from the Audit Steering Group to the National Commissioning Group (Rogers et al., 2010)*. (These have been reproduced to ensure technical consistency and accuracy in relation to how transplant related data are collected, analysed and presented.

Heart and lung transplantation has been nationally commissioned in England since 2002. Currently cardiothoracic transplantation is provided by the following hospital Trusts:

- The Newcastle upon Tyne Hospitals NHS Foundation Trust (adults and children)
- University Hospitals Birmingham NHS Foundation Trust (adults only)
- University Hospital of South Manchester NHS Foundation Trust (adults only)
- Papworth Hospital NHS Foundation Trust (adults only)
- Royal Brompton and Harefield NHS Trust (adults only)
- Great Ormond Street Hospital for Children NHS Trust (children only)

Systems for monitoring early and late mortality for heart and lung transplants are linked to data routinely collected by NHS Blood and Transplant (NHSBT), a Special Health Authority

within the NHS with responsibility for “*optimising the supply of blood, organs, and tissues and raising the quality, effectiveness and efficiency of blood and transplant services*”. (NHS Blood and Transplant, 2011). Data have been recorded on all patients in the UK receiving a first heart, lung or heart and lung transplant since 01 July 1995. Reports using these data have been published annually for all patients receiving a cardiothoracic transplant from 01 July 1995 to present day.

Patient level information is submitted to NHSBT at key steps along the transplant pathway: (i) when the patient is registered on the national transplant waiting list; (ii) at the time of the transplantation; (iii) three months after having the transplant; (iv) and annually thereafter until death. These data are transferred on a monthly basis to the UK Cardiothoracic Transplant Audit team based at the Clinical Effectiveness Unit (CEU) of the Royal College of Surgeons of England (RCS). The data submitted are subjected to on-going process of validation including the use of computer-based validation and case notes reviews, and as a result are robust and reliable.

The database held by NHSBT / Royal College of Surgeons Clinical Effectiveness Unit forms the basis of the UK Cardiothoracic Transplant Audit. The UK Cardiothoracic Transplant Audit is a multi-centre prospective cohort study. The audit has donor, recipient and outcome data on all cardiothoracic transplants undertaken in the UK since July 1995 and allows for prospective and retrospective audit of the outcomes from cardiothoracic transplantation. Because the data are collected in a timely manner as outlined above the data collected also allows real-time monitoring of outcomes for each transplant centre that can be used for monitoring performance.

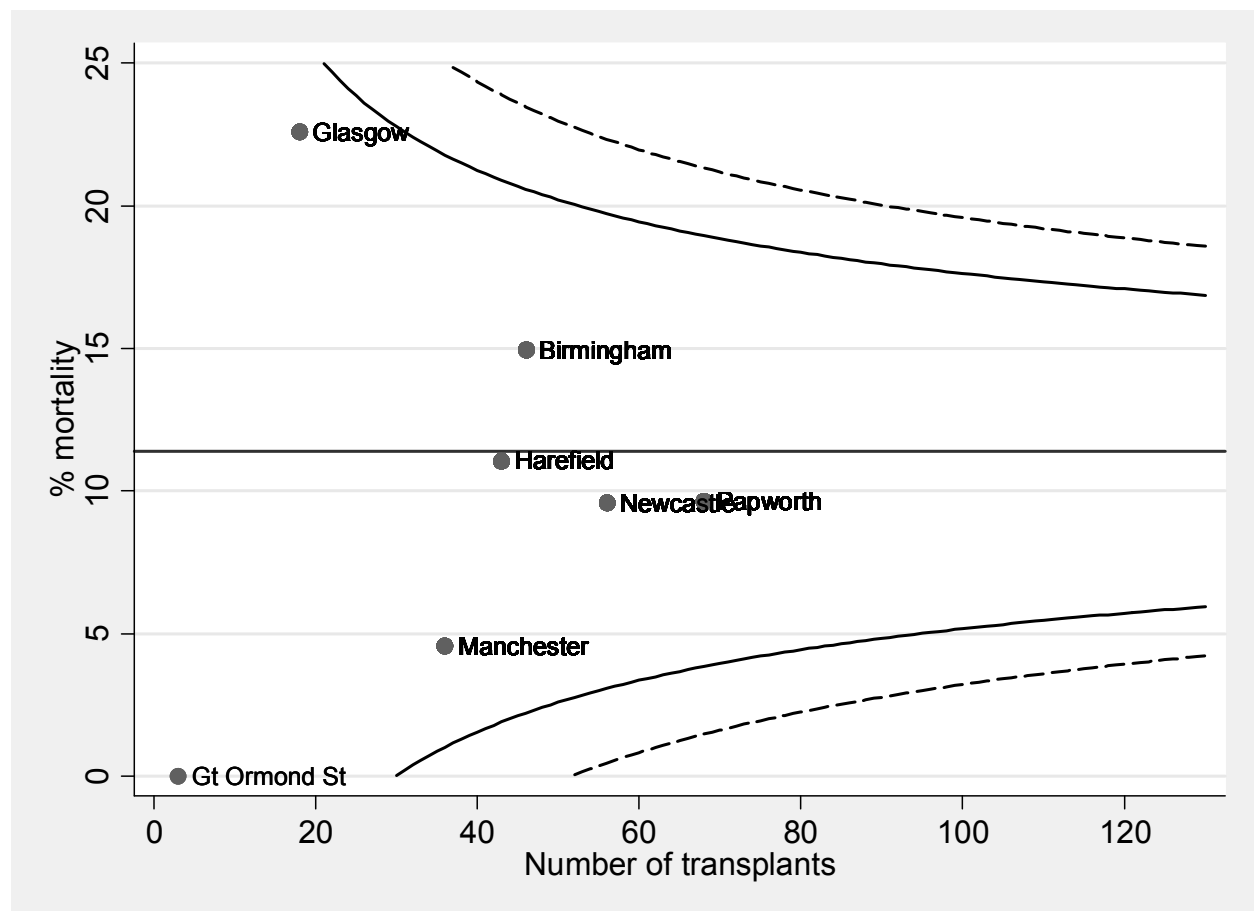
The audit is undertaken by a project team, overseen by a steering group, comprising the directors of all cardiopulmonary transplant centres in the UK, the director of the Royal College of Surgeons Clinical Effectiveness Unit, and representatives from NHSBT and the National Specialised Commissioning Team. The Steering Group approves all output from the audit prior to publication.

The UK Cardiothoracic Transplant Audit publishes on an annual basis the 30-day, 90-day, 1-year, 3-year, 5-year and 10-year mortality after first intrathoracic transplantation at all cardiopulmonary transplant centres in the United Kingdom. Centre-specific 30-day and 90-day mortality is reported for the more recent cohorts with 1-year and 3-year mortality being presented for the most appropriate recent cohort as well as for the period as a whole. Five and 10-year mortality rates are reported for the entire period as a whole. The Audits are available on the Royal College of Surgeons of England website (www.rcseng.ac.uk/surgical_research_units/ceu/docs.html) (see Rogers et al., 2010).

Results for adult (age ≥ 16 years at transplant) heart and lung transplants and paediatric heart and lung transplants are reported separately. The results for 30-day, 90-day and 1-year mortality after adult heart transplantation and 30-day and 90-day mortality after adult lung transplantation are presented both with and without adjustment for case-mix. The risk models used for case-mix adjustment have all been developed specifically for this audit.

The risk-adjusted estimates of early mortality after adult heart transplant for the most recent cohort of patients available (April 2007 – March 2010 [December 2009 for 90-day mortality]) are shown as funnel plots in Figures 1 and 2.

Figures 1 and 2 highlight that both the 30-day and 90-day mortality for each centre in the UK is within the range expected with no centre experiencing a mortality that was lower or higher than expected.



Note: Solid and dashed lines define the 95% and 99% confidence intervals

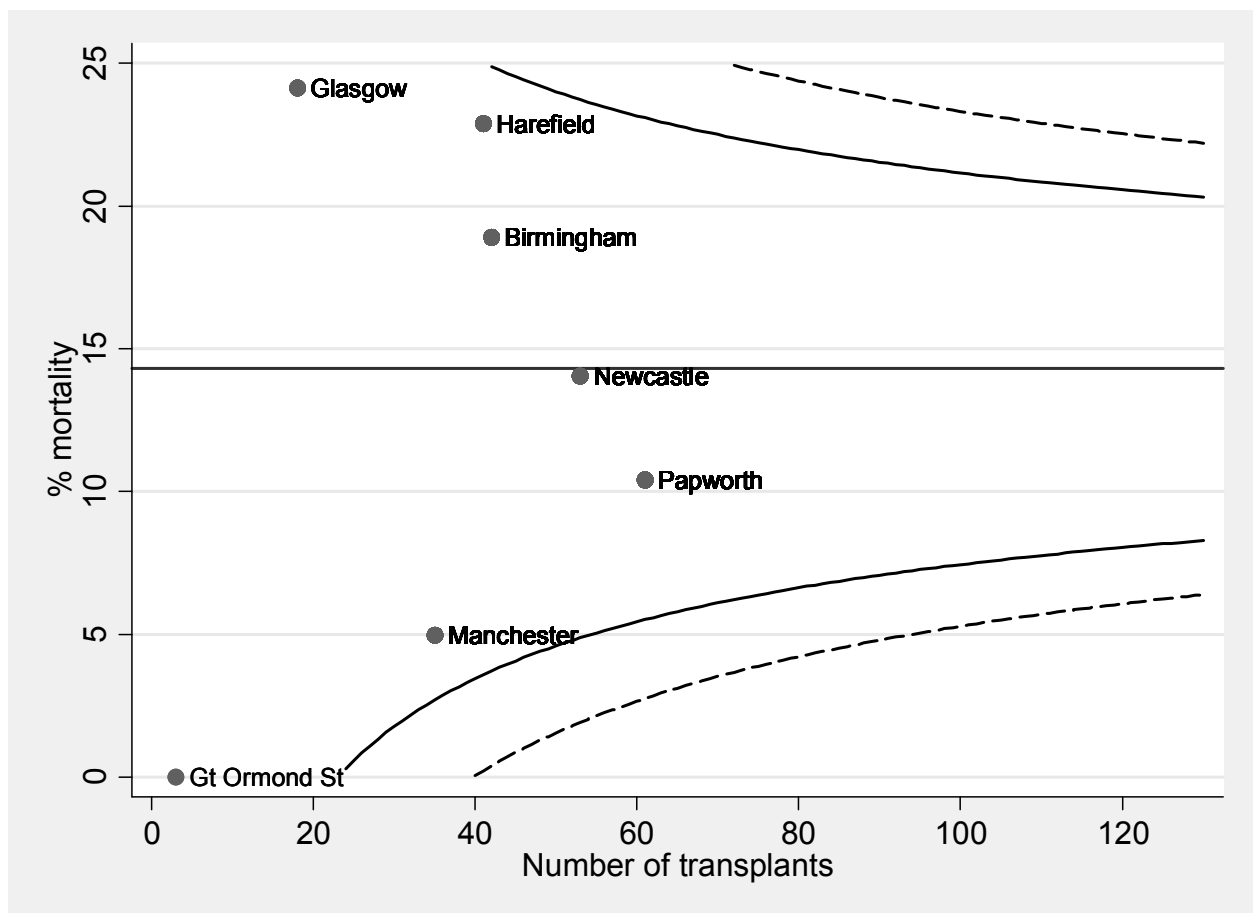
Fig. 1. Risk-adjusted estimates of early (30-day) mortality after adult heart transplantation, April 2007 – March 2010 (reproduced from the RCS / NHSBT UK Cardiothoracic Transplant Audit, August 2010, (Rogers et al., 2010)).

Data collected since January 2004 are used to continuously monitor 30-day and 90-day mortality, and presented both as a cumulative observed-expected (O-E) mortality and tabular CUSUM in the Annual Audit. For the adult transplant programmes the cumulative observed-expected mortality is presented both with and without risk adjustment. Paediatric recipient outcomes are only presented without risk adjustment.

In addition to the CUSUM monitoring presented in the annual report of the audit, real-time CUSUM monitoring has also been performed on a monthly basis since October 2006. This is especially important because it allows real-time monitoring of mortality outcomes and allows timely identification of any unexpected changes in mortality rates.

The O-E mortality chart plots the cumulative difference between the observed and expected patient mortality. For the continuous monitoring programme expected mortality rates are based on the national average mortality rate for transplants performed between 2000 and 2003, with more recent transplants given more weight. If the trend in the O-E chart goes downwards then this would indicate that the mortality rate observed is lower than might be expected, whilst an upward trend would suggest an observed mortality rate that is higher than expected.

An example of an O-E cumulative mortality chart for the five English centres is given in Figure 3.



Note: Solid and dashed lines define the 95% and 99% confidence intervals

Fig. 2. Risk-adjusted estimates of early 90-day mortality after adult heart transplantation, April 2007 – December 2009 (reproduced from the RCS / NHSBT UK Cardiothoracic Transplant Audit, August 2010, (Rogers et al., 2010)).

The tabular CUSUM chart is used to signal when a significant increase in mortality rate has been observed. The chart limit is set to signal when there is sufficient evidence to indicate that the mortality rate has doubled. A signal may indicate divergence from the national average. If an individual centre's CUSUM chart signals then following any appropriate investigation to understand what might have caused the signal, the CUSUM chart is reset to enable closer monitoring of the centre's performance in the following months.

Examples of tabular CUSUMs included in the most recent Royal College of Surgeons and NHSBT UK Cardiothoracic Transplant Audit, August 2010, (Rogers et al., 2010) for the 5 English adult cardiothoracic transplant centres are given in Figure 3 (30-day mortality) and Figure 4 (90-day mortality).

The CUSUM charts illustrate that recent 30 and 90-day mortality rates following adult heart transplantation have been as expected at Centre 1, Centre 4 and Centre 5.

However, they also show that Centre 2 experienced more deaths than might be expected in 2007 and Centre 3 experienced more deaths than might be expected in 2008. In all cases, the CUSUM charts signalled and the centres underwent an external review of their service. Since the signals, the 30-day mortality rates have returned to the expected level at each centre. After the signal in 2008, Centre 3 continued to experience more deaths within 90 days

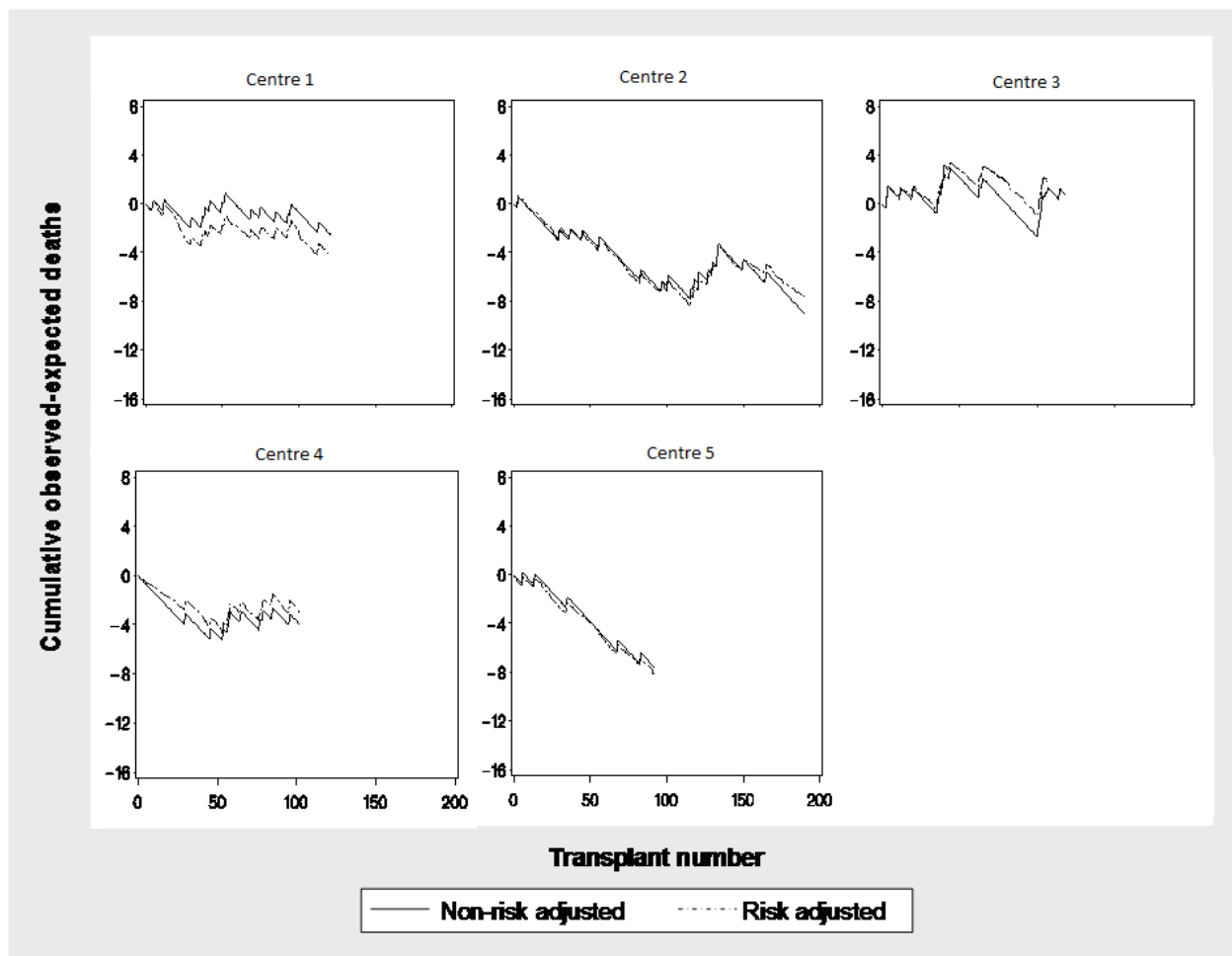


Fig. 3. Cumulative (observed - expected) 30-day mortality after adult heart transplantation, January 2004 to March 2010 (reproduced from the RCS and NHSBT UK Cardiothoracic Transplant Audit, August 2010, (Rogers et al., 2010)).

than expected and the 90-day CUSUM chart signalled again. This is because centres are monitored more closely after a signal and the charts are more sensitive.

2.1 Outcome monitoring to ensure maintenance of high quality clinical services

Real-time monitoring of mortality outcomes after heart and lung transplants have led to several reviews of services to understand why variation from expected might have occurred, and to put in place appropriate action plans when necessary. The conclusions of such reviews are published on the National Specialised Commissioning Team's website and are available at www.specialisedservices.nhs.uk.

Included below are some extracts taken from an external review undertaken at Harefield Hospital in 2008, the full report of which is in the public domain and available on the National Specialised Commissioning Team's website (NSCT, 2008). It outlines the background to the review and summarises the additional statistical analyses undertaken on the mortality data available for the service. The extracts below do not include the elements of the actual external review process, the details of which are available in the full report.

These highlight how rapid further analysis of available data can be undertaken to help understand why variability in outcomes might have occurred and demonstrate how this

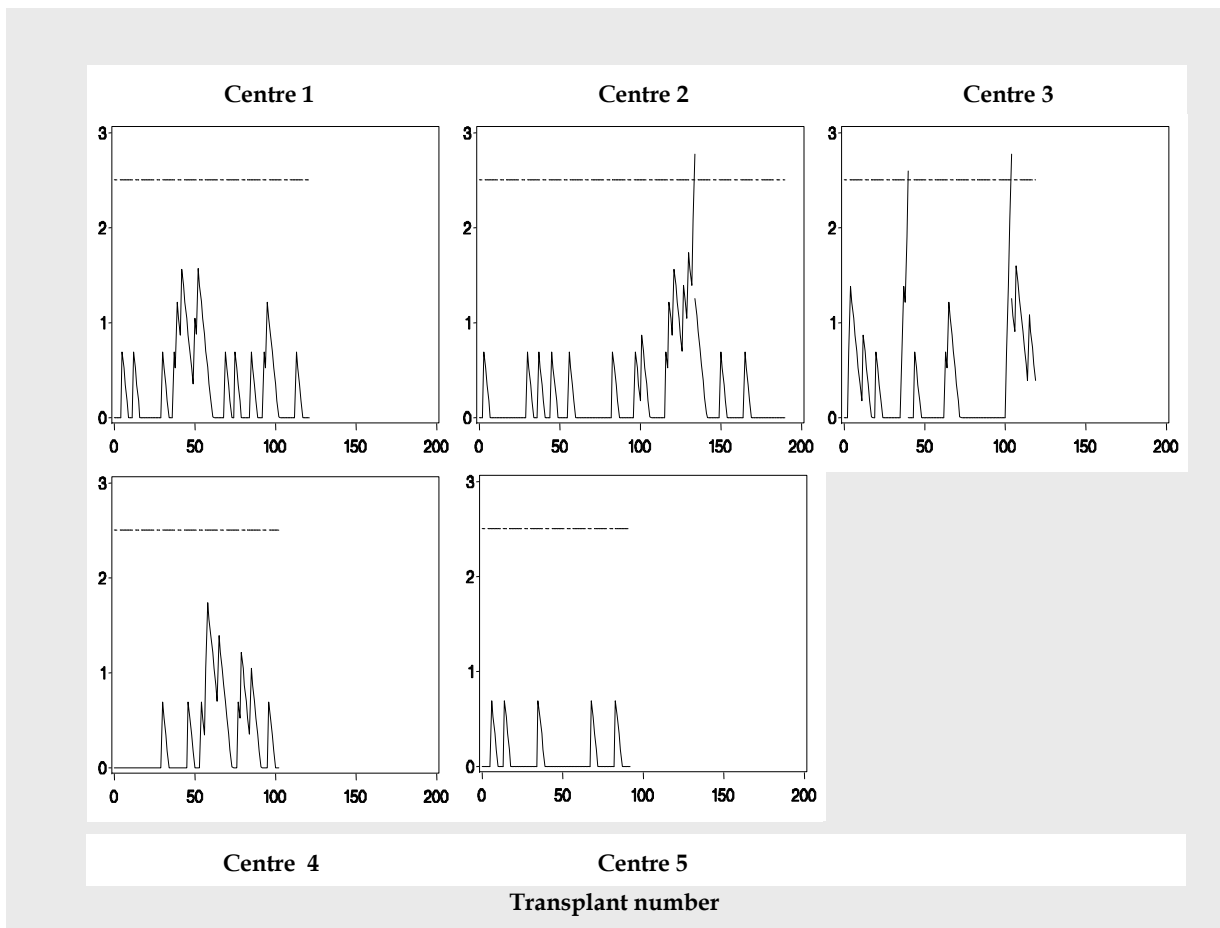


Fig. 4. Tabular CUSUM for 30-day mortality after adult heart transplant unadjusted for patient risk, January 2004 to March 2010 (reproduced from the RCS / NHSBT UK Cardiothoracic Transplant Audit, August 2010, (Rogers et al., 2010)).

understanding can then be used by clinicians and commissioners to support any necessary service changes.

One of the strengths of National Specialised Commissioning is the relationship and understanding that is built up between the commissioning team (medical advisor, commissioning manager and finance manager) with the clinical teams providing the service. This is exemplified in this example by the fact that the clinical team alerted the National Specialised Commissioning Team to a potential issue ahead of any alert signalling at NHSBT, demonstrating good clinical practice.

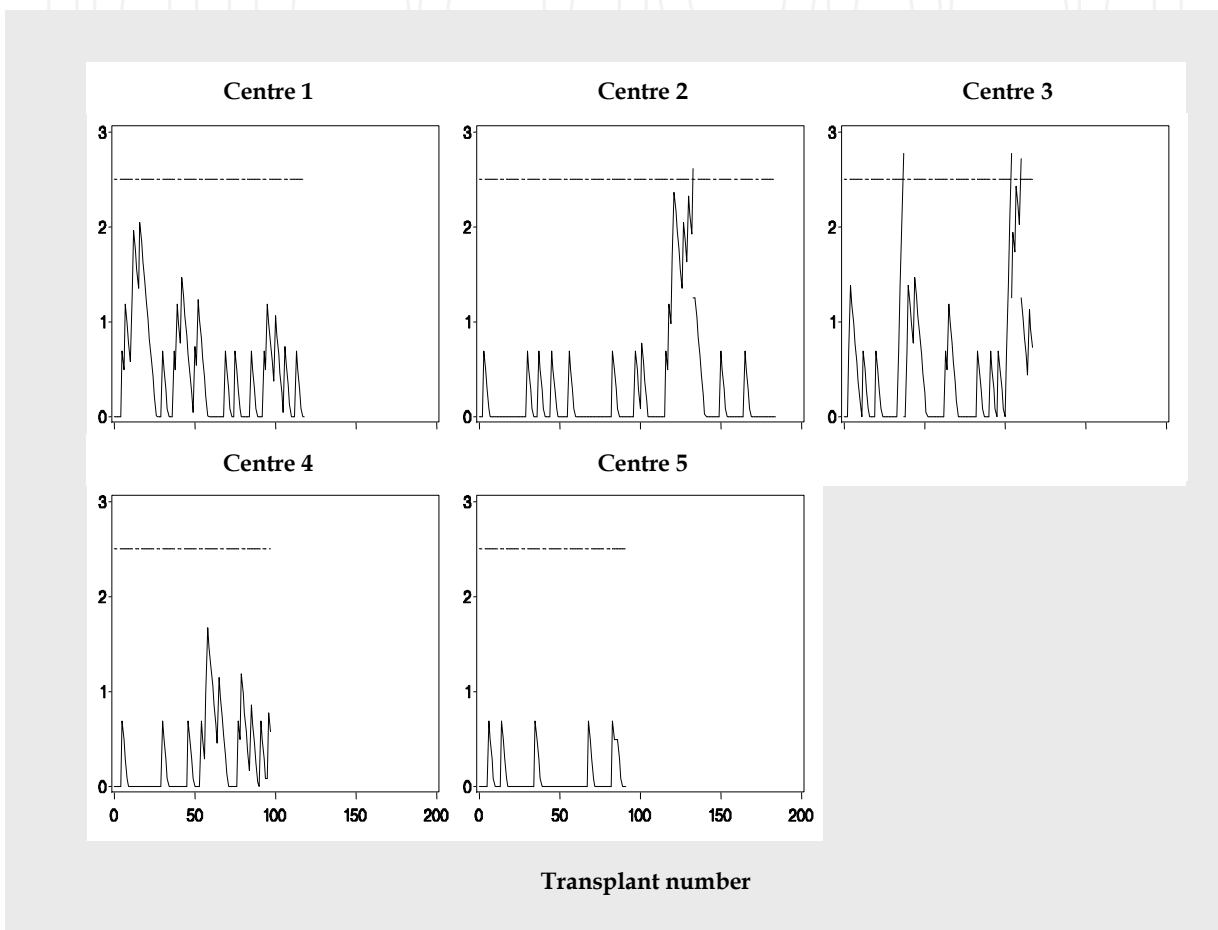


Fig. 5. Tabular CUSUM for 90-day mortality after adult heart transplant unadjusted for patient risk, January 2004 to March 2010 (reproduced from the RCS / NHSBT UK Cardiothoracic Transplant Audit, August 2010, (Rogers et al., 2010)).

Extracts as follows (Please note that all figures referred to have not been included in these extracts but are available in the full report available at <http://www.specialisedservices.nhs.uk/document/review-recent-outcomes-in-heart-transplant-service-at-harefield-hospital>). (NSCT, 2008)

**NATIONAL COMMISSIONING GROUP (NCG)
REPORT OF THE EXTERNAL REVIEW OF RECENT OUTCOMES IN THE HEART
TRANSPLANT SERVICE AT HAREFIELD HOSPITAL (2008)**

1. INTRODUCTION

1.1 This report summarises an external review of a higher than expected number of deaths following heart transplants performed at Harefield Hospital in July and August 2008.

1.2 The review was an agreed joint approach between the National Specialised Commissioning Team (NSC Team) and the Healthcare Commission (HCC). It was also agreed with the Royal Brompton and Harefield NHS Trust (RBHT). The HCC has reviewed the findings of this report.

2. BACKGROUND

2.1 On 4 September 2008, the Director of Cardiothoracic Transplantation at Harefield Hospital, Professor Gilles Dreyfus, told the NSC Team that: between 17 July and 3 September 2008 four consecutive heart transplant patients transplanted in July and August died within 30 days RBHT had begun an urgent internal review of these events.

2.2 These consecutive deaths were enough for the monthly sequential analysis carried out by NHS Blood and Transplant (NHSBT) statisticians to signal a subsequent alert (see paragraph 3.12 and Appendix A). Internal audit prompted Professor Dreyfus to inform the NSC Team without delay prior to this analysis being reported.

2.3 The RBHT internal review investigated these four deaths and three other deaths beyond 30 days in patients transplanted earlier in 2008. Seven (47%) of the 15 heart patients transplanted this year have died. The Internal Review is considered later in this report.

2.4 These events followed a period of low 30- and 90-day heart transplant mortality in 2006 and 2007. A statistical analysis of heart transplant outcomes carried out by the UK Cardiothoracic Transplant Audit (UKCTA) is summarised below in Section 3 of this report.

2.5 Early mortality following lung transplant has been low at Harefield this year: one death in 21 patients transplanted in 2008 (4.8%).

2.6 In 2005, the National Specialist Commissioning Advisory Group (NSCAG) undertook an

external review of the Harefield service because of an above expected early mortality following both heart and lung transplants. In contrast to the present situation, this review followed a gradual but non-statistically significant increase in early mortality compared to other transplant centres. The 2005 review found no single explanation but considered the outcomes in 2005 were linked to system and process problems in donor assessment, organ retrieval and intra-operative care. Harefield implemented a series of actions recommended by its own internal review and the external review.

2.7 Following completion of the RBHT internal review of deaths in 2008, the Trust, NSC Team and HCC agreed that an external review should be completed within one month by a heart transplant surgeon and a transplant cardiologist from other centres. If a suitable donor heart were to become available during the course of the review, the transplant team at Harefield would consult with the external reviewers before undertaking a transplant.

3. MORTALITY AFTER HEART TRANSPLANT: STATISTICAL ANALYSIS

3.1 The NSC Team commissioned a specific review of mortality after heart transplants carried out at Harefield between 1 January 2006 and 31 August 2008. This was compiled by members of the Audit Project Group of the Cardiothoracic Transplant Audit (UKCTA). The findings of the UKCTA report are summarised below. (see Appendix A for its executive summary and the limitations of statistical analysis – **this is available in the full report**)

Mortality within 30 days

3.2 30-day mortality at Harefield for the whole period (1 January 2006 to 31 August 2008) was similar to other UK centres: 10.3% (95% CI 3.9%-21.2%) compared to 12.3% (95% CI 8.3%-17.3%) elsewhere. Although the 30-day mortality of 26.7% (95% CI 7.8%-55.1%) at Harefield in 2008 was more than double the expected rate, the number of transplants was low and the difference from other centres was not statistically significant.

Mortality within 90 days

3.3 90-day mortality was not significantly different from other centres for the period 1 January 2006 to 30 June 2008: 9.6% (95% CI 3.2%-21%) at Harefield compared to 13.1% (8.9%-18.4%) elsewhere. Similarly, the difference in 90-day mortality for the nine transplants done between 1 January 2008 and 30 June 2008 was not statistically significant: 22.2% (95% CI 2.8%-60%) compared to 5.4% (95% CI 0.6%- 18.2%) elsewhere. But further analysis, when 90 days have elapsed after all the transplants undertaken up to 31 August 2008, will include the patients transplanted after 30 June and this will affect the estimate of statistical significance.

Mortality rates by donor organ retrieval centre

3.4 There was no evidence that donor hearts retrieved by Harefield were associated with higher mortality than those retrieved by other UK centres ($p=0.11$). However, nationally in the last three years, the 30-day mortality was significantly higher for donor hearts retrieved by any one centre and then transplanted in a different centre ($p=0.006$). The UKCTA report gives evidence that this was not the case before 2006.

Post-operative adverse events (PAE)

3.5 The rate of PAEs 7 within 30 days was significantly higher at Harefield than other UK centres: 67.2% (95% CI 53.7%-79%) for the whole period compared to 44.9% (38.3%-51.7%) elsewhere. In 2008, the difference was more marked: 93.3% (95 CI 68-99.8%) at Harefield and 42% (28.1%-56.8%) elsewhere. The UKCTA report commented that the high PAE rate "may be due, at least in part, to the risk profile of patients transplanted" (see paragraphs 3.7-3.11 below).

Ischaemic time

3.6 The median total ischaemia time for the whole period was similar but slightly lower at Harefield than elsewhere: 196 minutes (interquartile range 175-218) compared to 220 minutes (190-251) for the other centres combined. The corresponding figures for 2008 were 213 (160-229) and 227 (192-263). Transport and implant times were also slightly lower at Harefield. These times were stable at Harefield during 1 January 2006 - 31 August 2008.

Risk profile of heart transplant patients

3.7 The risk profile of heart transplant patients at Harefield was higher in 2008 than in 2007 and 2006 (Figure 1). The risk model has been developed by the UKCTA from a dataset that extends back 13 years and is used to adjust for factors found to be associated with an increased risk of early death after heart transplant. The risk factors are diabetes, reduced creatinine clearance (renal function), previous open heart operation, older donor age and longer ischaemic times.

3.8 Figure 2 shows that the proportion of transplant patients with individual risk factors (except for ischaemic time) was higher in 2008 than the previous two years.

3.9 The proportion of patients, who at the time of transplant had been receiving inotrope drugs to improve heart contraction or mechanical circulatory support by ventricular assist devices (VADs), extracorporeal membrane oxygenation (ECMO) and/or intra-aortic balloon pump (IABP), was significantly higher at Harefield than at other centres: 93% compared to 45% ($p=0.002$). These factors are not included in the UKCTA risk model.

3.10 The UKCTA report commented that "the data reported to the audit suggests that the majority of patients who underwent transplantation were high risk; only one of the patients transplanted this calendar year was not on inotropes, a VAD, ECMO or IABP at transplant".

Risk-adjusted mortality

3.11 Risk adjustment using the UKCTA risk model reduced the difference between the observed and expected number of deaths within 30 days at Harefield and at other UK centres in 2008. The centre effect estimate for Harefield reduced by more than 50% with risk adjustment and the UKCTA analysis found that "although mortality at Harefield remained 52% higher than expected using the risk model, the number of cases was low and Harefield was not identified as significantly divergent."

Sequential monitoring of mortality

3.12 The sequence of deaths in July and August 2008 was enough to cause the more sensitive technique of sequential monitoring using cumulative sum (CUSUM) method to signal an alert for

30-day mortality at Harefield. The signal occurred after Harefield had contacted the NSC Team as the charts are produced on a monthly basis when the 30-day follow-up point has passed.

Conclusion of the UKCTA report

3.13 "The number of operations reviewed is small as [heart] transplantation in the UK is a low volume procedure, with only around 288 transplants carried out nationally over the 32 months of the review. As a consequence differences and changes in mortality, which may appear large, are not necessarily identified as significant from a statistical perspective. Nonetheless, the rise in 30-day mortality at the end of the series was sufficient to trigger an alarm using the tabular CUSUM methodology. The rise in early mortality seen at Harefield can be explained, at least in part, by the risk profile of the patients, the majority of whom were high risk."

The additional statistical analyses were able to inform the review process and highlight the issues when basing analyses on very small numbers. They also highlight the importance of robust and appropriate case-mix adjustment which is yet another challenge we face in highly complex services that involve small numbers of cases.

3. Extracorporeal Membrane Oxygenation (ECMO)

Monitoring of the outcomes from extracorporeal membrane oxygenation (ECMO) is via the annual reporting of each centres activity and outcomes as submitted to the international voluntary Extracorporeal Life Support Organisation (ELSO). Membership of ELSO is a requirement of each centre as part of the national service and ensures that the data collected on outcomes are consistent internationally, thus allowing benchmarking of outcomes across organisations.

3.1 Extracorporeal membrane oxygenation (ECMO) for adults and children with potentially reversible severe respiratory failure

Extracorporeal Membrane Oxygenation (ECMO) for adults and children with potentially reversible severe respiratory failure has been nationally commissioned in England since 1997. Currently ECMO is provided by the current hospital Trusts:

- The Newcastle upon Tyne Hospitals NHS Foundation Trust (children only)
- Great Ormond Street Hospital for Children NHS Trust (children only)
- University Hospitals of Leicester NHS Trust (adults and children)

There is also a children's ECMO service in provided at Yorkhill Hospital, Glasgow, that is commissioned by National Services Division Scotland. The four providers of ECMO for children with potentially reversible severe respiratory failure work in collaboratively to ensure the needs of the UK are met.

All providers of the national ECMO programme (adult and / or paediatric) are registered with the Extracorporeal Life Support Organisation (ELSO) which is the international registry recording the outcomes for patients receiving ECMO. All centres provide their anonymised activity and outcome data on an annual basis to the National Specialised Commissioning Team as part of the end of year review visits to each centre.

This data collection and presentation is supplemented by an annual meeting of all the UK centres along with representatives from the ECMO service at the Karolinska Institute,

Stockholm, where each centre's anonymised activity and outcomes are presented along with agreed educational topics relating to recent experience or anticipated innovation. Again, this facilitates joint learning and service improvement in a very open and transparent setting.

National commissioning of the adult ECMO service enabled the definitive trial of ECMO in adults with potentially reversible severe respiratory failure to be commissioned jointly with the National Coordinating Centre for Health Technology Assessment (now part of the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre). The results of this trial were published in the *Lancet* in September 2009 (Peek et al., 2009) and as a NIHR Health Technology Assessment Monograph in 2010 (Peek et al., 2010).

4. Ventricular Assist Device (VAD) for bridging to heart transplantation

The provision of Ventricular Assist Devices (VADs) as a bridge to heart transplantation has been available at Papworth Hospital NHS Foundation Trust, the Royal Brompton and Harefield NHS Trust and The Newcastle upon Tyne Hospitals NHS Foundation Trust since 2002, and more recently at the other cardiothoracic transplant centres in the UK. Data on implantation, explantation, death and ongoing survival are recorded by NHSBT as part of the cardiothoracic transplant database.

NHSBT provide monthly reports to the National Specialised Commissioning Team on VAD activity and outcomes for each of the national centres. These data are shared with all centres at twice yearly meetings of the National VAD Forum convened and chaired by the National Specialised Commissioning Team and where representatives from each of the national cardiothoracic transplant centres are present. This allows an open and transparent forum for shared learning and has been the vehicle for developing the commissioning policy for expansion of the VAD service within the national cardiothoracic transplant programme.

Additionally, the UK Cardiothoracic Transplant Audit publishes the 30-day, 90-day, 1-year, 2-year and 3-year mortality for those individuals receiving short-term and long-term VADs as a bridge to transplantation, and highlights the survival experience with these devices. The audit also presents data on those VADs used to mechanically support a recently transplanted heart where primary graft failure is experienced, once again informing the development of the service and supporting quality improvement. These data are reviewed at the twice yearly National VAD Forum meetings.

A recent innovation is development of a much more comprehensive and bespoke VAD Database overseen by NHSBT that will allow much greater understanding of the experience with long-term VADs and provide a rich repository for research. The three early providers of long-term VADs (Papworth Hospital NHS Foundation Trust, the Royal Brompton and Harefield NHS Trust and The Newcastle upon Tyne Hospitals NHS Foundation Trust) are completing the population of the database with all historical cases receiving a long-term VAD, whilst all current providers are contributing to data entry on all prospective cases receiving a VAD.

This will provide anonymised data on the entire national cohort of patients receiving VADs and is expected to enable research to help further develop the evidence base in this rapidly changing technology.

5. Pulmonary endarterectomy – Introducing a new technology into the NHS

Chronic thromboembolic pulmonary hypertension (CTEPH) is a form of pulmonary hypertension that occurs as a result of chronic pulmonary embolic blood clots occluding the arteries to the lungs. Over time these emboli build up in the pulmonary arteries causing occlusion and scarring with narrowing of the vessels which eventually leads to reduced blood flow, pulmonary arterial hypertension and right sided heart failure.

Pulmonary endarterectomy (PEA, and previously known as PTE or pulmonary thromboendarterectomy) is a complex cardiac surgical procedure used to remove the blood clots and scarred elements of the vessel walls and restore blood flow through the lungs. It is used as a surgical treatment of CTEPH in those patients where this is appropriate (not all patients with CTEPH are surgical candidates).

This is technically difficult surgery which was introduced into the NHS in 2000 (through national commissioning) at a single centre in the UK at Papworth Hospital NHS Foundation Trust. This allowed the necessary expertise to be developed and outcomes were monitored using the established monitoring and reporting mechanisms established for adult heart and lung transplantation, and with which Papworth Hospital NHS Foundation Trust were already contributing to as an adult cardiothoracic transplant centre.

The concentration of expertise in this single centre aligned to real-time monitoring of mortality outcomes for all patients undergoing PEA has resulted in the outcome data (30-day mortality) at Papworth Hospital NHS Foundation Trust now being consistent with the best in the world.

The effectiveness of this approach will also be highlighted using the example of setting up routine systems for monitoring early mortality in pulmonary endarterectomy to monitor introduction of a new surgical technique into the UK in a single centre. The benefit of experience and systems that allow the development of expertise are shown in the learning curve attached to introducing this technique. Data are emerging that show that the international results are strongly linked to volume.

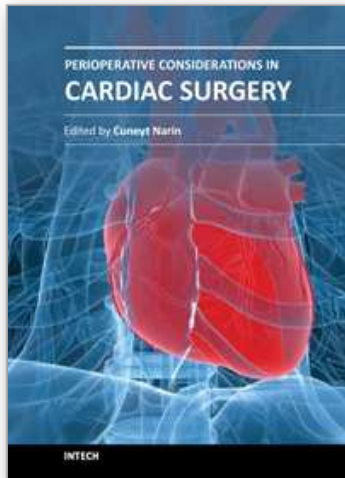
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This book considers mainly the current perioperative care, as well as progresses in new cardiac surgery technologies. Perioperative strategies and new technologies in the field of cardiac surgery will continue to contribute to improvements in postoperative outcomes and enable the cardiac surgical society to optimize surgical procedures. This book should prove to be a useful reference for trainees, senior surgeons and nurses in cardiac surgery, as well as anesthesiologists, perfusionists, and all the related health care workers who are involved in taking care of patients with heart disease which require surgical therapy. I hope these internationally cumulative and diligent efforts will provide patients undergoing cardiac surgery with meticulous perioperative care methods.

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