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UK Cardiothoracic Transplant Audit

In patients who received a transplant

between 1st July 1995 and 31st March 2011

ANNUAL REPORT | UKCTA Steering Group

NHS
Blood and Transplant

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1. EXECUTIVE SUMMARY

This annual report describes 30-day mortality after intrathoracic transplantation for patients who received a first heart, lung or heart-lung transplant between 1 July 1995 and 31 March 2011 in the UK. Ninety-day mortality is reported for transplants between 1 July 1995 and 31 December 2010, as 90-day outcomes were awaited for a significant proportion of transplants in the last 3 months of the reporting period.

Centre specific results are reported for the most recent periods, April 2008 to March 2011, and April 2010 to March 2011. Mortality rates at 1, 3, 5 and 10 years are also presented. One, three and five-year outcomes are reported for (a) the period as a whole, (b) April 2007 to March 2010, (c) April 2005 to March 2008 and (d) April 2003 to March 2006. Ten year results are reported for the whole period only. Centre specific survival curves to 10 years are presented. Curves are constructed for the cohort as a whole and for the subsets of patients who survived beyond 30-days and beyond 1-year.

The results are presented separately for adult heart transplantation, paediatric (<16 years) heart transplantation, and lung transplantation in adults. A brief report on lung transplantation in children is also included.

As previously, 30 and 90-day mortality is compared with and without case-mix adjustment for major risk factors for adult heart and adult lung transplantation. One-year outcomes after adult heart transplantation are also presented with adjustment for case-mix. For the first time, one-year outcomes after adult lung transplantation are also presented with adjustment for case-mix. Paediatric heart and lung transplant outcomes continue to be presented without case-mix adjustment, as there are insufficient data to develop risk models for these groups. In addition to reporting results by transplant centre, we also report early mortality by retrieval centre.

The “centre-effect” measure used to compare outcomes across centres remains unchanged from our previous annual reports: we have continued to use the ratio of (observed-expected deaths)/expected deaths. We also compare centres by showing risk-adjusted mortality rates at 30 and 90-days on a funnel plot with 95% and 99% confidence limits.

The report shows cumulative observed-expected 30 and 90-day mortality after heart and lung transplantation, without risk adjustment (all transplants) and with risk-adjustment (adult transplants only) for transplants in the period January 2004 to March 2011 (30-day mortality) or December 2010 (90-day mortality). Tabular CUSUM charts for this period are also reported. As previously, overall cumulative mortality rates, and moving average rates based on six months data are presented.

The case-mix adjustments for the adult heart and lung transplant programmes have been used in an attempt to take account of differences in risk between patients treated at different centres. The datasets have relatively small numbers of cases on which to base the adjustment; so there may be important factors that have not been included because there is insufficient power to be able to detect them. Risk adjustment is an approximation; it is always incomplete and inadequate.

As last year the use and outcome of ventricular assist devices (VAD) as a bridge to transplantation and as short-term support after heart transplantation is described.

For paediatric heart transplantation, the additional subgroup analyses included in the last three reports have been updated.

***Adult heart transplantation*:** During the study period 2369 transplants were reported, 90 more than included in our last annual report, which reported on transplants to March 2010. Overall, the unadjusted 30 and 90-day mortality remained stable at 12.2% (95%CI 10.9% to 13.6%) and 14.8% (95%CI 13.4% to 16.3%) respectively. 30-day mortality in the period since April 2008 was 13.1% (95%CI 9.3% to 17.7%) and 16.7% (95%CI 12.2% to 21.9%) died within 90-days.

In recent years, centres have carried out more "high risk" transplants than previously, due to increasing use of organs from older donors and longer ischemia times. The recipients themselves are also sicker, as evidenced by an increase in the numbers transplanted under the urgent heart allocation scheme (29% in the year to March 2008 vs. 54% in the year to March 2011). However, this has not translated into a notable increase in mortality.

For the period since April 2008, Harefield reported significantly more early deaths (within 30-days and within 90-days) than expected after adjustment for differences in case-mix. This increase in mortality caused the continuous monitoring chart to signal in August 2008 for both 30-day and 90-day mortality and in June 2009 (90-day mortality). During the last audit year Harefield continued to have more deaths than expected after adjustment for differences in case-mix but the number of transplants is few and was not sufficient to cause further signalling of the continuous monitoring chart.

The 1-year survival for the whole cohort was 80.8% (95%CI 79.1% to 82.3%); 75.6% (95%CI 73.8% to 77.3%) survived to 3-years and 70.8% (95%CI 68.8% to 72.6%) survived to 5-years. These survival rates are slightly lower than those reported by the United Network for Organ Sharing (UNOS) in the United States (87%, 79% and 72% at 1, 3 and 5 years respectively)

The report on VAD activity and outcome shows that 86% (95%CI 82% to 90%) of 303 patients given a long-term VAD were alive at 30-days and 30% went on to receive a transplant. In patients given mechanical support post transplantation for primary graft failure the VAD was implanted for a median of 8 days. These observations are based on small numbers and we are currently unable to adjust for case-mix both because of the small number of events and the limitations of the data available. A more comprehensive dataset has recently been introduced which will allow such analyses in the future.

***Paediatric heart transplantation*:** 421 paediatric patients received a first transplant during the study period, 39 more than included in our last annual report, which reported on transplants to March 2010. The 30-day mortality rate for the entire cohort was 4.3% (95%CI 2.6% to 6.7%) and 6.6% (95%CI 4.4% to 9.5%) died within 90-days. Since April 2008, three children (2.9%, 95%CI 0.6% to 8.3%) died within 30 days and six (6.7%, 95%CI 2.5% to 13.9%) died within 90-days.

Overall, 92.0% (95%CI 89.0% to 94.3%) of children were alive at 1-year; 86.1% (95%CI 82.1% to 89.2%) were alive at 3-years and 81.4% (95%CI 76.8% to 85.2%) were alive at 5-years. Both short and long-term survival has improved over time.

***Adult lung transplantation**:* 2103 adult lung transplants were identified, 166 transplants have been accrued in the year to March 2011, since our last annual report. The 30-day mortality rate for the whole audit period was 10.1% (95%CI 8.9% to 11.5%). In all, 98 patients died between 30 and 90-days, giving a 90-day mortality of 15.1% (95%CI 13.6% to 16.8%). Early mortality has continued to fall with time; since April 2008, the 30-day mortality rate was 6.8% (95%CI 4.6% to 9.5%) and 9.9% (95%CI 7.2% to 13.3%) died within 90-days. In 2010/11 there were 13 deaths within 30-days (7.8%) and 15 (13.2%) deaths within 90-days.

In contrast to the adult heart transplant programme, the transplant "risk" for lung transplantation has declined over time. Previous analyses of the audit cohort have shown that this is due, at least in part, to the increased use of bilateral sequential lung transplantation in preference to single lung and heart lung transplantation, a change which has contributed to the reduction in mortality.

For the period since April 2008, Birmingham reported significantly more deaths within 30-days than expected after adjustment for differences in case-mix. This was sufficient to trigger a signal on the continuous monitoring chart in 2009, but only retrospectively after the target mortality rates were changed. The prior period had included a short run of deaths in 2008 that had already been investigated internally. In the last audit year, there have been no deaths within 30-days in the eleven patients transplanted at Birmingham.

Overall, 76.0% (95%CI 74.1% to 77.8%) recipients were alive one year after their operation; 61.8% (95%CI 59.5% to 64.0%) were alive at 3 years and 51.7% (95%CI 49.2% to 54.0%) were alive at 5 years. Again these survival rates are slightly lower than those reported by UNOS (83%, 68% and 55% at 1, 3 and 5 years respectively. However, at 10-years unadjusted survival is higher in the UK (32% vs. 26%).

***Paediatric lung transplantation**:* The paediatric lung transplant programme is very small with just 100 grafts reported since the audit began. The majority of children had cystic fibrosis and received a heart-lung transplant (38, 38%), although this is changing; only two heart-lung transplants have been carried out since April 2007. The 30-day mortality for the group as a whole was 9.0% (95%CI 4.2% to 16.4%) and 83.7% (95%CI 74.8% to 89.7%) were alive at 1-year. Of the transplants carried out since August 2000 there have been three deaths within 90-days of surgery.

Finally, the interpretation of results presented in this report is not straightforward. There are several caveats: (1) some of the analyses are unadjusted for risk factors and case-mix, (2) risk adjustment (when present) is always incomplete and inadequate, (3) there were multiple comparisons, which incorporates dangers related to performing multiple statistical tests, and risks obtaining 'chance' findings (4) we cannot take account of differences in the

management of patients on the waiting list for intrathoracic transplantation or differences in post-transplant management with the data currently available.

Where results are unadjusted for risk factors interpretation should proceed with extreme caution, as should comparisons with data from other registries, which may not have rigorous data validation procedures. Furthermore, in many analyses the number of transplants considered is relatively small and estimates will necessarily be imprecise. An analysis of the *potential causes of the differences between the centres* can only be done within a collaboration of the audit and cardiopulmonary transplant centres. This has not been undertaken, so it would be inappropriate to go beyond the conclusions that are presented in this report.

2. INTRODUCTION

In this report 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 is presented. Centre-specific 30-day and 90-day mortality is reported for the more recent cohorts (a) April 2008 to March 2011 (December 2010 for 90-day mortality) and (b) April 2010 to March 2011 (December 2010 for 90-day mortality). One-year outcomes are reported for the period as a whole and for the period April 2007 to March 2010, 3-year outcomes are reported for the period as a whole and for the period April 2005 to March 2008 and 5-year outcomes are reported for the period as a whole and for the period April 2003 to March 2006. Ten-year mortality rates are reported for the whole period only.

Results for adult (age $\geq$ 16 years at transplant) heart and lung transplants and paediatric heart and lung transplants are reported separately. All lung transplants are considered together. Centre-specific outcome results are not presented separately for heart-lung, single and bilateral sequential lung grafts as the number of grafts accrued to each sub-programme each year is few. A report on the paediatric lung programme is also included.

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.

Continuous monitoring charts for 30 and 90-day mortality (cumulative observed-expected mortality and tabular CUSUM) are presented for data accrued since January 2004. For the adult transplant programmes the cumulative observed-expected mortality is shown with and without adjustment for risk. Paediatric recipient outcomes are unadjusted for risk.

The additional subgroup analyses of the cohort undergoing paediatric heart transplantation added to the 2008 report at the request of the transplant team from Great Ormond Street have been updated.

For the fifth year the report also includes data on the use and outcomes of ventricular assist devices (VAD).

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 April 1995. Information is submitted to NHSBT when the patient is registered on the national transplant waiting list, at transplantation, and three months post transplant and annually thereafter until death. These data are transferred to UK Cardiothoracic Transplant Audit team based at the Clinical Effectiveness Unit (CEU) of the Royal College of Surgeon's of England (RCS) on a monthly basis. At 31 March 2011, 5166 transplants had been registered with the Audit (see **Figure 1**). This dataset is subjected to on-going computer-based validation for missing and inconsistent data and a number of validation

checks against case notes have been undertaken. Results of the last case note validation exercise can be found in our 2008 report to NSCT.

The content of this report has been extended to include

- risk adjustment for 1-year mortality after adult lung transplantation
- 5-year mortality for the three-year period April 2003 to March 2006

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 CEU, and representatives from NHSBT and the National Commissioning Group. The Steering Group approves all output from the audit prior to publication. All units received a draft of this report and feedback received has been incorporated in this final report.

Key issues in the analysis and interpretation of data

The key issue in the interpretation of possible differences in mortality amongst centres is that of trying to explain *variability.* There are 3 possible sources of variability:

(1) Differences between patient and donor risk factors ("case-mix")

(2) Differences between centres in the process of care

(3) Random variation

Adjustments for case-mix where possible and the quantification of the uncertainty in the mortality estimates are therefore essential elements in the comparison of transplant centres. Adjustment for case-mix is an approximation; it is always incomplete and inadequate. Case-mix can never be excluded as a source of differences between centres, even when risk adjusted estimates are available. This is due to what is sometimes referred to as "residual confounding". Residual confounding can affect the size of the adjustment but not its direction (i.e. whether the risk adjusted estimates are higher or lower than the unadjusted estimates).

Ventricular assist device audit

The UK ventricular assist device (VAD) service was provisionally designated and commissioned by NCG from April 2001 as a method to bridge patients with severe heart failure to heart transplantation. Detailed data were collected on all patients implanted with VADs between April 2002 and December 2004 as part of the Evaluation of Ventricular Assist Device Program UK (EVAD) study, funded by the NHS R&D Health Technology Assessment (HTA) programme. Following the EVAD study, Papworth Hospital continued to record VAD activity at Papworth, Harefield and Newcastle for VADs that were funded by NCG for the purposes of bridge to transplant. From January 2007, it was agreed that the responsibility for data collection and reporting would transfer to NHS Blood and Transplant.

Data collection had been limited and focused on basic outcome and demographic information. A more extensive audit was launched in Autumn 2009, which will enable more detailed data collection and analysis of risk factors and outcomes.

Real time monitoring of early mortality following transplantation

In addition to the CUSUM monitoring presented in this report, real-time CUSUM monitoring has been performed on a monthly basis since October 2006 and is ongoing. Unadjusted observed – expected (O-E) mortality charts, with any signals resulting from a tabular CUSUM superimposed, and tabular CUSUM charts are sent to centres and show performance since January 2004 (see section 3 for further details). Real-time monitoring provides a tool for internal auditing and enables the prompt detection of any significant changes in mortality rates. The expected rate used to monitor for changes differs between the centres. For centres with previous mortality rates higher than the national rate, the national rate is used as the expected rate while for centres with mortality rates below the national rate a centre-specific rate is used. Expected rates have been calculated based on transplants performed between 2000 and 2003, with more recent transplants given greater weight.

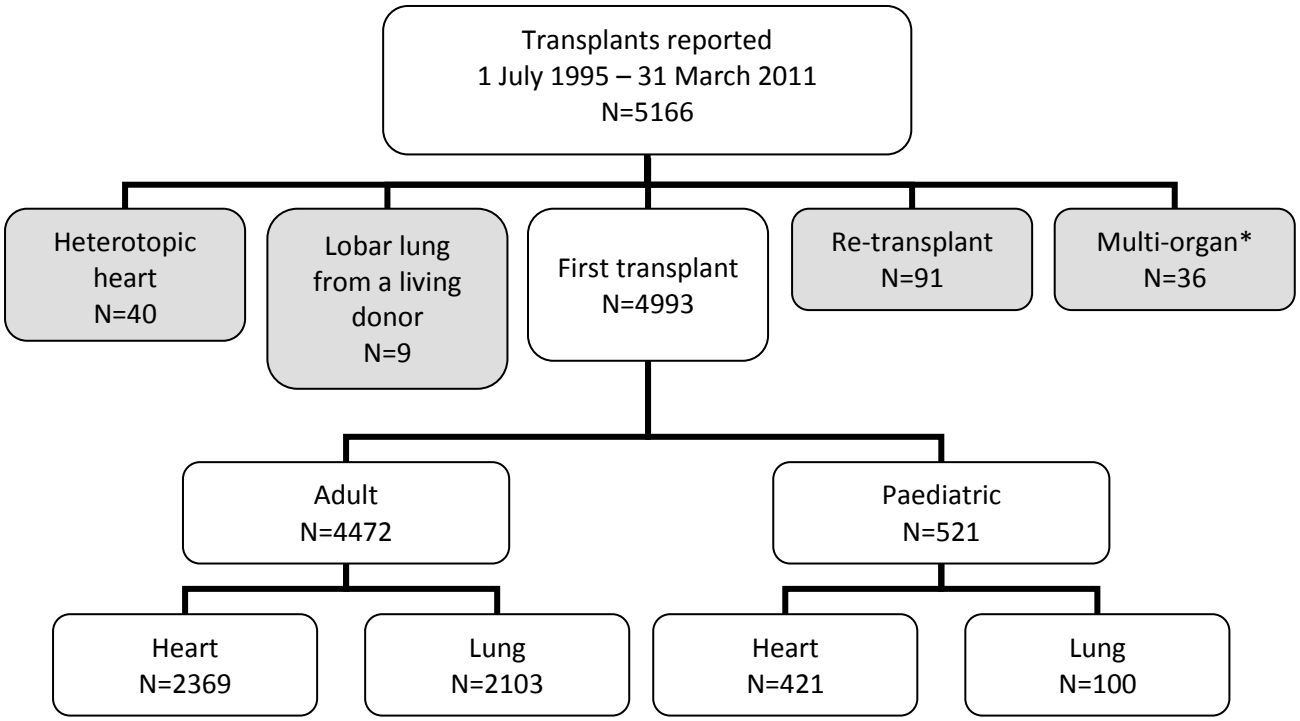
Details of adult heart transplant signals at Papworth and Glasgow in 2007, and Harefield in 2008 were presented in the 2008 audit report. Details of an adult lung transplant signal at Birmingham and a paediatric heart transplant signal at Great Ormond Street Hospital were subsequently presented in the 2010 audit report.

3. METHODS

Patients

All patients who received their first heart and/or lung transplant between July 1995 and March 2011 inclusive were considered. Multi-organ transplants (e.g. combined heart and kidney grafts), re-grafts, heterotopic heart transplants and living donor lobar-lung transplants were excluded. In total 173 transplants were excluded, 3.3% of the transplant cohort (see **Figure 1**). The last reported heterotopic transplant was carried out in September 2003. There have been 4 re-transplants in the last year (2 heart and 2 lung).

Figure 1 Data cohort for the report



* includes 3 re-transplants

30-day follow-up

The 30-day outcome was known definitively for all but 3 eligible adults. These 5 patients were discharged at 19, 27 and 29 days after the transplant and no follow-up data has been reported since then. For this report these patients were assumed to be alive at 30 days.

90-day follow-up

The 90-day outcome was known definitively for 98.0% of transplants. For the remaining 55 transplants, the three month follow-up visit took place before the three-month anniversary (median 81 days). For this report the 48 patients followed for at least 60 days were assumed to be alive at 90 days. The other seven transplants were omitted due to insufficient follow-up.

1-year follow-up

Twelve month data had been returned for all but 18 eligible transplants (i.e. transplants carried out before April 2010). The 1-year outcome was known definitively for 96.7% of these transplants. For the remaining 162 transplants, the 12-month follow-up visit took place before the first anniversary (median 338 days).

3-year follow-up

Three-year data had been returned for all but 56 transplants carried out before April 2008. The 3-year outcome was known definitively for 96.3% of transplants. For the remaining 182 transplants, the 36 month follow-up visit took place before the third anniversary (median 1034 days).

5-year follow-up

Five-year data had been returned for all but 72 transplants carried out before April 2006. The 5-year outcome was known definitively for 96.7% of transplants. For the remaining 165 transplants, the 5 year follow-up visit took place before the fifth anniversary (median 1738 days).

10-year follow-up

Ten-year data had been returned for all but 55 transplants carried out before April 2001. The 10-year outcome was known definitively for 97.5% of transplants. For the remaining 123 transplants, the 10 year follow-up visit took place before the tenth anniversary (median 3523 days; 9.6 years).

Adult heart transplantation

A total of 2369 adults received their first orthotopic heart transplant at one of the nine transplant centres. Fourteen adults were transplanted at the paediatric unit at Great Ormond Street.

Eight-two cases were excluded from the risk-adjusted analyses due to missing registration data (79 cases, 67 registered before the audit began) or missing transplant data (3). Of the excluded cases, only 11 were transplants since April 2001, the remaining 71 transplants were carried out earlier, 46 in the first audit year.

Paediatric heart transplantation

A total of 421 paediatric (< 16 years) first heart transplants were undertaken between July 1995 and March 2011 inclusive. All but five were undertaken at one of three transplant centres: Newcastle, Harefield and Great Ormond Street. The other five transplants, in children aged 12-15 years, were carried out at three different centres: Glasgow (2), Papworth (1), Manchester (1) and Birmingham (1). Harefield ceased transplanting paediatric patients in March 2001. In May 2005 one further paediatric transplant in a 15-year old was reported.

Adult lung transplantation

A total of 2103 adults (≥ 16 years) received their first lung transplant at one of the eight lung transplant centres. Twenty-four adults were transplanted at the paediatric unit at Great Ormond Street.

One hundred and eleven cases were excluded from the risk-adjusted analyses due to missing registration data (107 cases, 98 registered before the audit began) or missing transplant data (4). Of the excluded cases, only 10 were in transplants since April 2001, the remaining 101 transplants were carried out earlier, 50 in the first audit year.

Paediatric lung transplantation

One-hundred children (<16 years) received their first lung transplant (all types) during the study period.

Patient waiting lists

At 31 March 2011, a total of 355 patients were waiting for a cardiothoracic transplant, 37 fewer than at the same time in 2010. The greatest number of patients were waiting for a lung transplant **(Table 1**).

Patient mortality

Unadjusted mortality at 1-year and beyond is estimated using the Kaplan-Meier method, thereby allowing all recipients to be included, irrespective of the duration of follow-up. Patients who remain alive at the end of follow-up are treated as censored observations.

All estimates of mortality are reported with 95% confidence intervals.

Table 1 **Patients on the cardiothoracic transplant lists at 31 March 2011 (2010) in the UK, by centre**

	Active transplant lists									
Centre	Heart				Heart/lung		Lung		All organs	
	Non-urgent		Urgent							
Newcastle[1]	23	(18)	7	(3)	1	(1)	64	(78)	95	(100)
Papworth	30	(24)	1	(1)	6	(6)	27	(26)	64	(57)
Harefield	30	(31)	0	(0)	2	(2)	57	(77)	89	(110)
Birmingham	8	(14)	2	(0)	2	(3)	20	(21)	32	(38)
Manchester	10	(17)	1	(1)	0	(0)	34	(45)	45	(63)
Glasgow	6	(7)	0	(0)	0	(0)	0	(1)	6	(8)
Gt Ormond St	9	(7)	3	(3)	2	(0)	10	(6)	24	(16)
All centres	116	(118)	14	(8)	13	(12)	212	(254)	355	(392)

[1] Adult and paediatric patients on the transplant list

Risk adjustment

Sufficient data have been accrued to the audit database to allow for the assessment of risk factors for early mortality after heart and lung transplantation in adults, and the calculation of risk adjusted estimates of mortality. The numbers of paediatric transplants undertaken remains insufficient to enable risk adjustment, so results from these programmes are *unadjusted* for potential risk factors.

The 30-day risk model for adult heart transplantation was described in our 2003 annual report. Validation of the heart model in a cohort of 386 transplants was reported in the 2004 annual report. For this report the 30-day model for adult heart transplantation was extended to include adjustment for transplants in patients with congenital heart disease, as this risk-factor reached statistical significance at the 10% level (p=0.09) after adjustment for the factors previously identified. The 30-day risk model for adult lung transplantation was reviewed and updated for this report. Factors considered for inclusion in the risk adjustment model were (a) those identified previously from this audit and (b) those identified from the International Society for Heart and Lung Transplantation Registry[1]. Factors which reached statistical significance at the 10% level were retained in the final model, which included diagnosis group, transplant type, ischemia time, recipient pre-transplant bilirubin, difference between donor and recipient height and era of transplant.

As many of the factors pertinent to 30-day survival will also be relevant for 90-day survival for this report we have again used a model with the same risk factors as the 30-day models.

[1] Christie, JD et al. J Heart Lunt Transplant, 2011, doi:10.1016/j.healun.2011.08.004

For this report the coefficients (relative importance of each factor) for both 30 and 90-day mortality were estimated using data to March 2008.

The risk models for 1-year mortality after adult heart and lung transplantation use the Cox proportional hazards regression model, rather than the logistic regression model, which was used for our early outcome models. The Cox model was chosen for two reasons: firstly it considers actual survival times and so distinguishes between patients who die soon after their transplant and those who survive several months, the logistic model would not distinguish between a death at 10 days and a death at 10 months; and secondly it allows all recipients to be included, irrespective of the duration of follow-up. As the time since transplant increases the patient's follow-up appointments often fail to coincide with the audit follow-up points. By analysing the actual time from transplant, patients whose follow-up appointment falls short of the anniversary of their transplant are not excluded. All patients who remained alive at 1-year or at the end of follow-up (if less than 1 year) are treated as censored observations. Details of the risk factors considered and included in the model for adult heart transplantation were given in the 2005 annual report.

For this report a risk model for 1-year mortality after lung transplantation was developed. Factors considered for inclusion in the risk adjustment model were (a) those included in the 30-day mortality model and (b) those identified from the International Society for Heart and Lung Transplantation Registry[2]. Factors which reached statistical significance at the 10% level were retained in the final model, which included recipient age at transplant. forced vital capacity (FVC) at listing, pre-transplant bilirubin, diabetes, ventilated pre-transplant, diagnosis group, transplant type, ischemia time, donor CMV positive and recipient CMV negative and era of transplant.

Missing data

Missing data for specific risk factors were treated as follows: for risk factors with fewer than 2% missing data, cases with missing data were assigned to the most prevalent risk category. For recipient risk factors with 2% or more missing data, missing values were imputed, where it was felt that there was sufficient clinical data available on which to base the imputation. For other recipient variables and all donor variables with 2+% missing data, a specific "data missing" category was created. The imputation methods used were described in our 2003 annual report.

Centre comparisons: the centre effect

The standardised difference between the observed and expected number of deaths at each centre, as estimated from the risk models, was used as a basis for the comparison between centres. A negative value for the standardised difference (centre effect) indicates fewer deaths than expected and a positive value more deaths than predicted. If no deaths are observed during the study period the standardised difference reduces to –1.

[2] Christie, JD et al. J Heart Lunt Transplant, 2011, doi:10.1016/j.healun.2011.08.004

For completeness, centre effects, *unadjusted* for patient risk, are also reported for all transplant programmes. Expected mortality rates are derived from the audit. Expected 30-day mortality rates for transplants in adults have been set at 12.38% for heart transplantation and 5.04% for lung transplantation. The corresponding expected rates for 90-day mortality are 14.24% and 9.01% respectively. These figures correspond to the mortality rates in the UK for the 3-year period April 2005 to March 2008. These are the same rates as used in previous reports (December 2005 onwards) and were chosen to reflect recent practice. For heart transplantation the national mortality rate has fairly remained stable over the 15-years of the audit but for lung transplantation there has been a notable reduction in early mortality in recent years.

For paediatric heart transplantation activity is much lower and the estimates much less precise. In previous reports in order to use as precise an estimate as possible the expected mortality rate was derived from the full audit period. However, using an estimate based on 15-years of activity did not acknowledge that mortality rates have reduced in recent years. To better reflect current practice for this report mortality rates in the UK for the 3-year period April 2002 to March 2005 were chosen. For heart transplantation the expected 30 and 90 day mortality rates are set at 2.86% and 4.29% respectively. Centre effect estimates are not given for the paediatric lung programme as only 2 early deaths have occurred since April 2005.

For outcomes at 1-year and beyond the expected number of deaths was calculated from the cumulative hazard.

Risk-adjusted estimates of mortality

In this report, risk-adjusted estimates of early mortality reported. For 30 and 90-day mortality the risk-adjusted estimates are compared across centres using a funnel plot.[3] The risk-adjusted mortality estimate for a centre is defined as the overall (unadjusted) expected mortality rate for the period $\times$ (observed number of deaths $\div$ expected number of deaths after risk adjustment). Centre estimates which fall outside the confidence intervals are considered outliers.

Continuous monitoring of mortality

In this report we present two types of cumulative sum (CUSUM) chart: the 'Observed minus Expected' (O-E) mortality chart and the tabular CUSUM to monitor 30-day and 90-day patient mortality.

[3] Spiegelhalter, DJ Statist. Med.2005 **24**:1185-1202.

The monitoring charts consider first transplants since January 2004. NHS Group 2[4] patients are excluded from the charts (none in this period), but lung transplants from donors after circulatory death (60 cases) are included.

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. A downward trend in the O-E chart indicates a lower than expected mortality rate whereas an upward trend points to an observed mortality rate that is higher than expected.

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 is double the pre-specified rate. Signals from the tabular CUSUM are superimposed on the O-E charts presented and are identified by the associated transplant date. A signal may indicate divergence from the national average.

After a signal and a review of local practice the tabular CUSUM is reset at a point half-way between zero and the chart limit. This enables closer monitoring of centre performance following a signal.

The O-E mortality charts for early mortality for transplants in adults are presented with and without risk adjustment. The risk factors are those reported previously (30-day mortality model following adult lung transplantation is described in the September 2002 audit report and the 30-day mortality model following adult heart transplantation is described in the September 2003 audit report). Coefficients for both models have been re-estimated using transplants performed between 2000 and 2003.

As risk factors relating to 30-day mortality are also considered relevant for 90-day mortality the same risk models have been used with re-estimated coefficients.

No risk-adjustment is performed for paediatric transplantation.

Ventricular assist devices

VAD data are collected for all long-term devices used for the purposes of bridging and for all short-term devices used for bridging or in the treatment of primary graft failure. Devices used post-cardiotomy are excluded. Results are reported between 9 May 2002 and 31 March 2011, with follow-up until 30 June 2011.

[4] Patients are not entitled to NHS funded treatment. A person in Group 2 cannot receive an organ if there is a clinically suitable person who is entitled to NHS funded treatment (NHS Group 1).

4. RESULTS - ADULT HEART TRANSPLANTATION

Transplant activity

Heart transplantation in adults rose from 86 to 90 transplants in 2010/11. The current activity level remains less than half that reported in the early audit years (average 197 transplants per year between 1996 and 2002) (**Figure 2**).

Unadjusted mortality rates

Overall mortality

The 30-day mortality rate for the whole cohort is 12.2% (95%CI 10.9% to 13.6%). In total, 290 patients died within the first 30 days after transplantation. 30-day mortality in the period April 2008 to March 2011 was 13.1% (95%CI 9.3% to 17.7%) and in the most recent period, April 2010 to March 2011, 20.0% (95%CI 12.3% to 29.8%) of transplant recipients died within 30-days (**Table 2**).

The 90-day mortality rate for the whole cohort is 14.8% (95%CI 13.4% to 16.3%). Overall, 61 died between 30 and 90 days. 90-day mortality for transplants between April 2008 and December 2010 was 16.7% (95%CI 12.2% to 21.9%). For the cohort from April 2010 to December 2010, the 90-day mortality rate was 26.5% (95%CI 16.5% to 38.6%, **Table 3**).

The trend in early mortality is seen in **Figure 3**, which shows the moving average estimates of overall mortality based on 90 transplants.

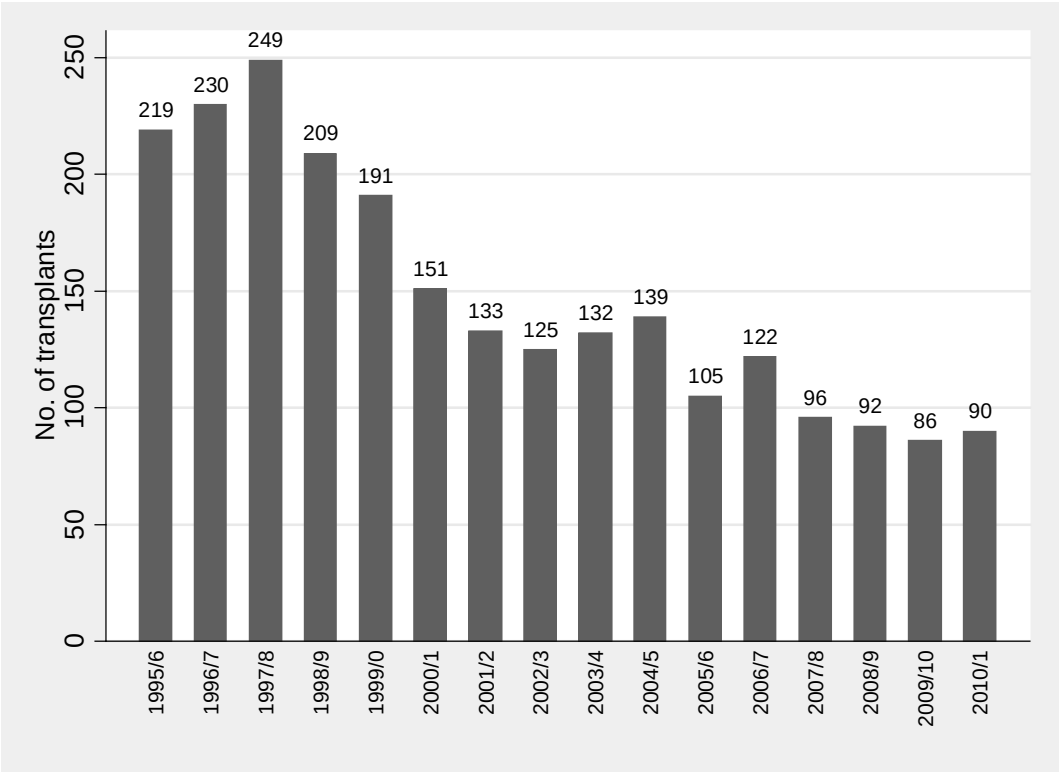
The 1-year survival for the whole cohort was 80.8% (95%CI 79.1% to 82.3%,, **Table 4**). Overall, 75.6% (95%CI 73.8% to 77.3%) of recipients survived to 3-years after their transplant; 70.8% (95%CI 68.8% to 72.6%) survived to 5 years and 56.5% (95%CI 54.2% to 58.8%) survived to 10 years (**Table 5** to **Table 7**).

Mortality rates by transplant centre

Centre specific mortality rates, unadjusted for patient risk are shown in **Table 2** to **Table 9**. For completeness, the transplants in patients aged 16 or over carried out at Great Ormond Street are included. Thirty-day mortality rates over the period April 2008 to March 2011 at centres ranged from 0% to 30.3%, but statistically there was no evidence of significant variation between centres (Fisher's exact test, p=0.052). Over the last 12 months the 30-day mortality rate showed greater variability ranging from 0% to 44.4% across the 7 adult centres, but activity rates were low and these differences were not statistically significant (Fisher's exact test, p=0.45).

Figure 2 Adult heart transplant activity by audit year

a) Overall



b) By transplant centre

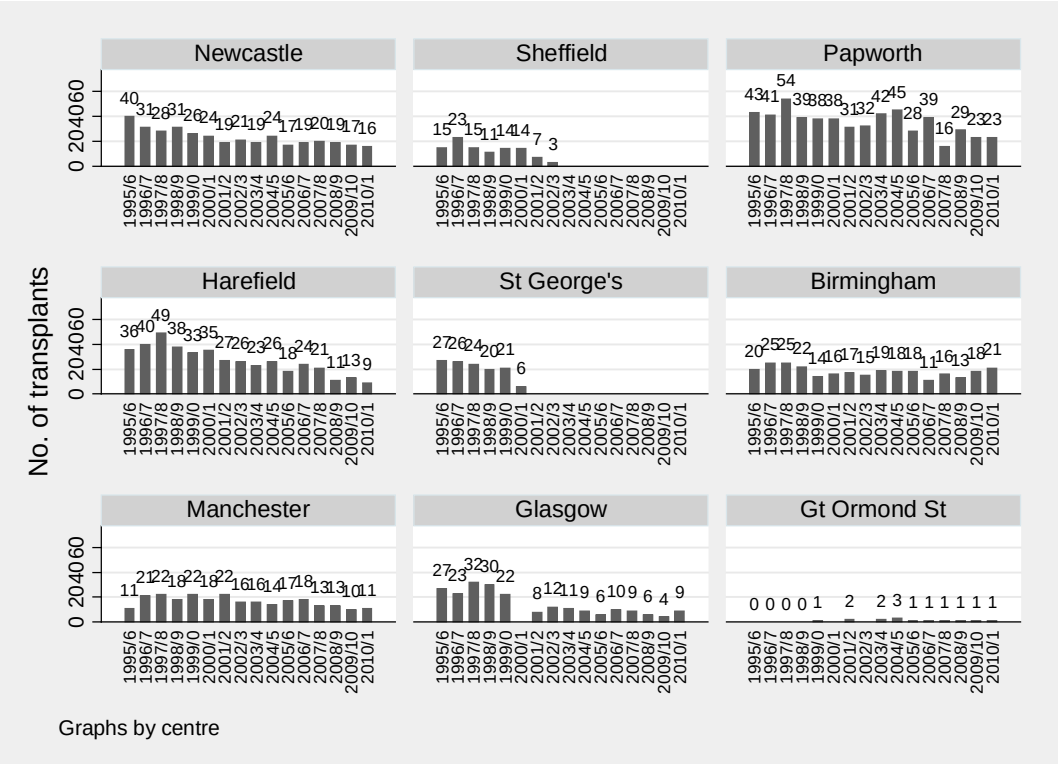
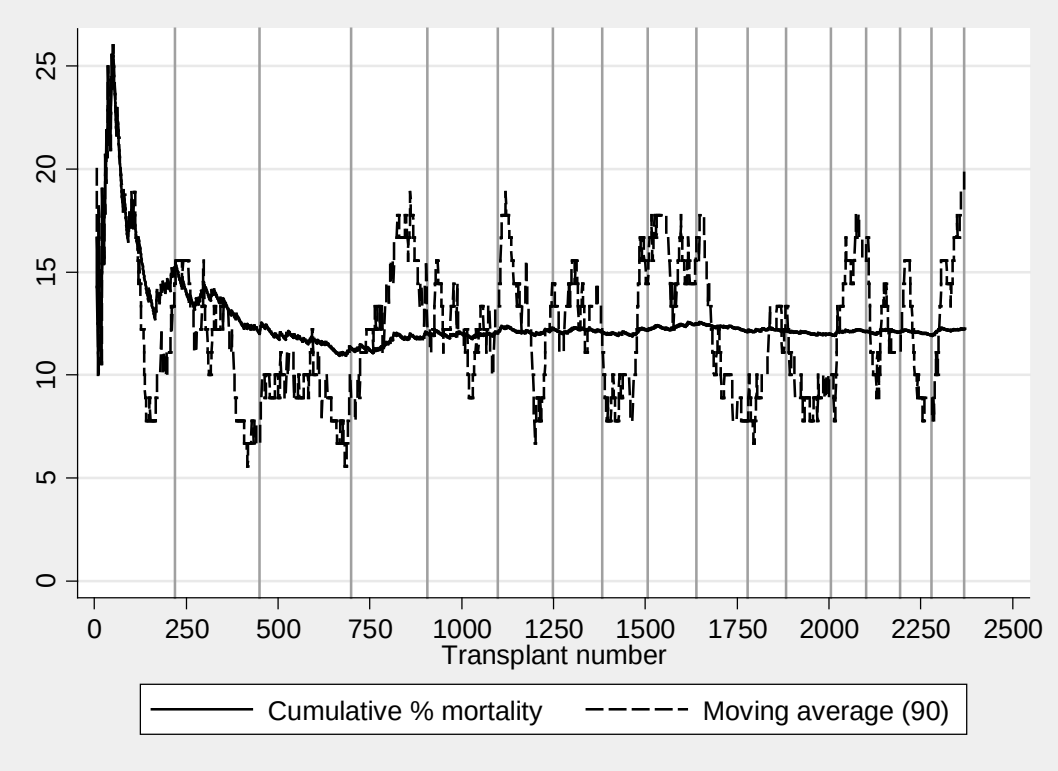
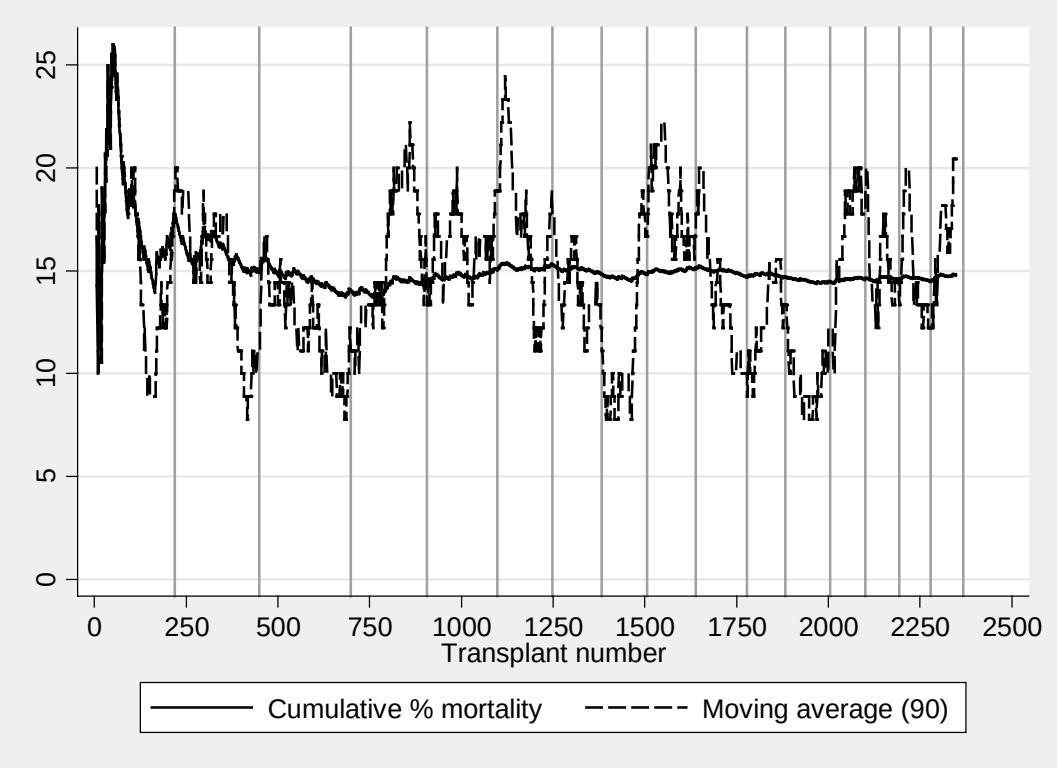


Figure 3 Mortality after adult heart transplantation over time

a) 30-day



b) 90-day



Note: Vertical lines represent the start of each audit year

90-day mortality rates showed a similar pattern. Statistically there was no evidence of significant variation between centres for the period since April 2007 (Fisher's exact test, p=0.12).

Post-transplant survival to 10-years in all adult UK centres for the whole audit period is shown in **Figure 4**(a). As previously, analyses of the complete cohort found evidence of significant variation in the unadjusted survival rates across centres, with St George's reporting lower survival and Sheffield higher survival than other centres. These centres closed in September 2000 and September 2002 respectively. Amongst the active adult centres survival at 10-years ranged from 45.3% to 62.9% (17.6% difference, p<0.01, **Table 7**).

For the recent cohort of 274 transplants between April 2007 and March 2010, there was no evidence to suggest significant variation between centres at 1-year (p=0.11). Similarly, for the cohort, April 2005 and March 2008 (323 transplants), there was no evidence to suggest significant variation between centres in 3-year survival (p=0.48).

In **Figure 4**(b) and **Figure 4**(c) survival curves for the subset of patients who lived beyond 30-days and beyond 1-year are shown. As for the overall unadjusted survival, there was evidence of significant variation between centres for the cohort surviving beyond 30-days (p<0.01 at 1year, p=0.015 at 3 years and p=0.06 at 5 years), but for the cohort surviving beyond 1-year, survival to 3-years was showed less variation across centres (p=0.07). Amongst 30-day survivors there was a 16.5% difference between the centres with the highest and lowest 3-year conditional unadjusted survival and 8% difference between the active adult centres (**Table 8**).

Mortality rates by retrieval centre

Mortality rates at 30 and 90-days by retrieval centre, unadjusted for patient risk, are shown in **Table 10.** Manchester, Glasgow and Harefield were the only centres in the last three years to use fewer than half the hearts they retrieved for a local recipient; Manchester used 38.2% of hearts retrieved for a local recipient, Glasgow used 28.6% and Harefield used 44.1%. Overall, 51.1% of hearts retrieved were used locally and 47.8% of all hearts transplanted were given to an urgent patient listed under the Urgent Heart Allocation Scheme (UHAS).

The unadjusted 30-day mortality rate over the period April 2008 to March 2011 was similar for hearts retrieved by the different centres (Fisher's exact test, 30-day: p=0.86). 90-day mortality rates showed a similar pattern (Fisher's exact test, p=0.50).

Over the last audit year 30 and 90-day mortality rates by retrieval centre ranged from 0% to 50%, but activity rates were low and these differences were not sufficient to suggest statistically significant between-centre variation (Fisher's exact test, 30-day, p=0.50; 90-day; p=0.38).

Table 2 **30-day mortality after adult heart transplantation by centre *unadjusted* for patient risk**

a) *April 2008 – March 2011*

Centre	No cases	No deaths	Mortality rate[1]	95%CI			Centre effect[2]	95%CI		
Newcastle	52	6	11.5	4.4	to	23.4	-0.07	-0.66	to	1.03
Papworth	75	5	6.7	2.2	to	14.9	-0.46	-0.83	to	0.26
Harefield	33	10	30.3	15.6	to	48.7	1.45	0.17	to	3.50
Birmingham	52	7	13.5	5.6	to	25.8	0.09	-0.56	to	1.24
Manchester	34	3	8.8	1.9	to	23.7	-0.29	-0.85	to	1.08
Glasgow	19	4	21.1	6.1	to	45.6	0.70	-0.54	to	3.35
Gt Ormond St	3	0	0.0	0.0	to	70.8	-1.00	-1.00	to	8.93
All centres	**268**	**18**	**13.1**	**9.3**	**to**	**17.7**				

b) *April 2010 – March 2011*

Centre	No cases	No deaths	Mortality rate[1]	95%CI			Centre effect[2]	95%CI		
Newcastle	16	3	18.8	4.0	to	45.6	0.51	-0.69	to	3.43
Papworth	23	3	13.0	2.8	to	33.6	0.05	-0.78	to	2.08
Harefield	9	4	44.4	13.7	to	78.8	2.59	-0.02	to	8.19
Birmingham	21	3	14.3	3.0	to	36.3	0.15	-0.76	to	2.37
Manchester	11	2	18.2	2.3	to	51.8	0.47	-0.82	to	4.31
Glasgow	9	3	33.3	7.5	to	70.1	1.69	-0.44	to	6.87
Gt Ormond St	1	0	0.0	0.0	to	97.5	-1.00	-1.00	to	28.8
All centres	**90**	**18**	**20.0**	**12.3**	**to**	**29.8**				

[1] a) p=0.052; b) [2] p=0.45

[2] expected mortality based on overall mortality for the period April 2005 to March 2008 (12.38%)

Table 3 **90-day mortality after adult heart transplantation by centre *unadjusted* for patient risk**

a) *April 2008 – December 2010*

Centre	No cases	No deaths	Mortality rate[1]	95%CI			Centre effect[2]	95%CI		
Newcastle	48	8	16.7	7.5	to	30.2	0.17	-0.49	to	1.31
Papworth	69	5	7.2	2.4	to	16.1	-0.50	-0.84	to	0.17
Harefield	32	13	40.6	23.7	to	59.4	1.85	0.52	to	3.88
Birmingham	48	9	18.8	8.9	to	32.6	0.32	-0.40	to	1.50
Manchester	30	2	6.7	0.8	to	22.1	-0.53	-0.94	to	0.69
Glasgow	16	4	25.0	7.3	to	52.4	0.76	-0.52	to	3.50
Gt Ormond St	3	0	0.0	0.0	to	70.8	-1.00	-1.00	to	7.64
All centres	**246**	**41**	**16.7**	**12.2**	**to**	**21.9**				

b) *April 2010 – December 2010*

Centre	No cases	No deaths	Mortality rate[1]	95%CI			Centre effect[2]	95%CI		
Newcastle	12	3	25.0	5.5	to	57.2	0.76	-0.64	to	4.13
Papworth	17	3	17.6	3.8	to	43.4	0.17	-0.76	to	2.42
Harefield	8	4	50.0	15.7	to	84.3	2.51	-0.04	to	7.99
Birmingham	17	4	23.5	6.8	to	49.9	0.65	-0.55	to	3.23
Manchester	7	1	14.3	0.4	to	57.9	0.00	-0.97	to	4.59
Glasgow	6	3	50.0	11.8	to	88.2	2.51	-0.28	to	9.26
Gt Ormond St	1	0	0.0	0.0	to	97.5	-1.00	-1.00	to	24.9
All centres	**68**	**18**	**26.5**	**16.5**	**to**	**38.6**				

[1] a) p=0.002; b) 2 p=0.51
[2] expected mortality based on overall mortality for the period April 2005 to March 2008 (14.24%)

Table 4 **One-year survival after adult heart transplantation by centre *unadjusted* for patient risk**

a) *Whole audit period*

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	371	78.0	73.4	to	81.9	0.18	-0.06	to	0.47
Sheffield	102	92.2	84.9	to	96.0	-0.61	-0.83	to	-0.23
Papworth	561	84.1	80.8	to	86.9	-0.21	-0.36	to	-0.02
Harefield	429	78.3	74.1	to	81.9	0.14	-0.08	to	0.40
St George's	124	69.4	60.4	to	76.7	0.71	0.21	to	1.34
Birmingham	288	79.1	73.9	to	83.4	0.07	-0.18	to	0.38
Manchester	262	87.0	82.2	to	90.5	-0.34	-0.54	to	-0.08
Glasgow	218	77.4	71.2	to	82.4	0.23	-0.09	to	0.62
Gt Ormond St	14	78.6	47.2	to	92.5	0.09	-0.77	to	2.20
All centres	**2369**	**80.8**	**79.1**	**to**	**82.3**				

b) *April 2007 – March 2010*

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	56	83.9	71.4	to	91.3	-0.03	-0.56	to	0.83
Papworth	68	89.7	79.6	to	95.0	-0.40	-0.76	to	0.23
Harefield	45	73.3	57.8	to	83.9	0.61	-0.17	to	1.81
Birmingham	47	76.3	61.3	to	86.2	0.44	-0.28	to	1.57
Manchester	36	94.4	79.6	to	98.6	-0.68	-0.96	to	0.15
Glasgow	19	73.7	47.9	to	88.1	0.67	-0.46	to	2.89
Gt Ormond St	3	100.0				-1.00	-1.00	to	5.68
All centres	**274**	**83.1**	**78.1**	**to**	**87.1**				

[1] a) $p<0.01$; b) $p=0.11$

Table 5 **Three-year survival after adult heart transplantation by centre *unadjusted* for patient risk**

a) *Whole audit period*

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	371	70.7	65.7	to	75.2	0.24	0.01	to	0.50
Sheffield	102	88.2	80.2	to	93.1	-0.55	-0.77	to	-0.21
Papworth	561	78.5	74.8	to	81.8	-0.16	-0.30	to	0.01
Harefield	429	76.6	72.3	to	80.3	-0.02	-0.20	to	0.19
St George's	124	64.5	55.4	to	72.2	0.59	0.15	to	1.13
Birmingham	288	73.0	67.3	to	77.9	0.09	-0.14	to	0.37
Manchester	262	80.3	74.8	to	84.7	-0.23	-0.43	to	0.02
Glasgow	218	72.3	65.8	to	77.8	0.19	-0.10	to	0.53
Gt Ormond St	14	69.8	37.8	to	87.6	0.20	-0.67	to	2.08
All centres	**2369**	**75.6**	**73.8**	**to**	**77.3**				

b) *April 2005 – March 2008*

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	56	71.4	57.7	to	81.4	0.34	-0.23	to	1.17
Papworth	83	80.7	70.4	to	87.7	-0.13	-0.50	to	0.41
Harefield	63	77.7	65.3	to	86.2	0.02	-0.44	to	0.71
Birmingham	45	77.8	62.6	to	87.4	0.03	-0.50	to	0.90
Manchester	48	85.4	71.8	to	92.8	-0.38	-0.75	to	0.28
Glasgow	25	67.8	45.7	to	82.4	0.53	-0.34	to	2.02
Gt Ormond St	3	100.0				-1.00	-1.00	to	3.95
All centres	**323**	**77.9**	**73.0**	**to**	**82.1**				

[1] a) $p<0.01$; b) $p=0.48$

Table 6 **Five-year survival after adult heart transplantation by centre *unadjusted* for patient risk**

a) *Whole Audit Period*

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	371	66.8	61.5	to	71.5	0.18	-0.02	to	0.42
Sheffield	102	82.4	73.5	to	88.5	-0.44	-0.67	to	-0.12
Papworth	561	74.0	69.9	to	77.6	-0.15	-0.29	to	0.01
Harefield	429	72.9	68.3	to	76.9	-0.05	-0.22	to	0.14
St George's	124	61.2	52.1	to	69.2	0.46	0.08	to	0.94
Birmingham	288	67.5	61.3	to	72.8	0.11	-0.11	to	0.37
Manchester	262	72.0	65.8	to	77.3	-0.11	-0.31	to	0.13
Glasgow	218	67.4	60.5	to	73.4	0.17	-0.09	to	0.48
Gt Ormond St	14	58.2	25.2	to	80.9	0.34	-0.57	to	2.13
All centres	**2369**	**70.8**	**68.8**	**to**	**72.6**				

b) *April 2003 – March 2006*

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	60	66.6	53.2	to	77.0	0.14	-0.31	to	0.75
Papworth	115	72.6	63.4	to	79.9	-0.15	-0.42	to	0.21
Harefield	67	65.0	52.1	to	75.2	0.17	-0.26	to	0.76
Birmingham	55	69.0	55.0	to	79.5	-0.01	-0.42	to	0.59
Manchester	47	72.3	57.2	to	82.9	-0.15	-0.55	to	0.46
Glasgow	26	65.4	44.0	to	80.3	0.26	-0.42	to	1.40
Gt Ormond St	6	66.7	19.5	to	90.4	0.13	-0.86	to	3.08
All centres	**376**	**69.1**	**64.2**	**to**	**73.6**				

[1] a) $p<0.01$; b) $p=0.74$

Table 7 **Ten-year survival after adult heart transplantation by centre *unadjusted* for patient risk**

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	371	53.4	47.3	to	59.2	0.14	-0.04	to	0.34
Sheffield	102	63.1	52.8	to	71.7	-0.23	-0.46	to	0.06
Papworth	561	59.6	54.5	to	64.3	-0.12	-0.24	to	0.02
Harefield	429	62.9	57.6	to	67.7	-0.13	-0.27	to	0.03
St George's	124	52.8	43.6	to	61.2	0.21	-0.08	to	0.56
Birmingham	288	45.3	37.8	to	52.5	0.23	0.02	to	0.47
Manchester	262	60.2	52.7	to	66.9	-0.12	-0.30	to	0.08
Glasgow	218	48.6	40.9	to	55.9	0.23	-0.01	to	0.50
Gt Ormond St	14	58.2	25.2	to	80.9	0.21	-0.61	to	1.82
All Centres	**2369**	**56.5**	**54.2**	**to**	**58.8**				

[1] $p<0.01$

Table 8 **One, three and five-year survival after adult heart transplantation by centre *unadjusted* for patient risk, for the subset of patients surviving beyond 30-days**

		1-year				*3-years*				*5-years*			
Centre	No cases	% Survival[1]	95%CI			% Survival[1]	95%CI			% Survival[1]	95%CI		
Newcastle	315	91.9	88.2	to	94.5	83.3	78.5	to	87.1	78.7	73.4	to	83.1
Sheffield	94	100.0				95.7	89.1	to	98.4	89.4	81.1	to	94.1
Papworth	512	92.2	89.5	to	94.2	86.1	82.6	to	88.9	81.1	77.1	to	84.4
Harefield	367	91.5	88.2	to	94.0	89.5	85.9	to	92.3	85.2	81.0	to	88.5
St George's	101	85.1	76.6	to	90.8	79.2	69.9	to	85.9	75.2	65.5	to	82.5
Birmingham	258	88.3	83.6	to	91.7	81.5	76.0	to	85.9	75.3	69.1	to	80.5
Manchester	238	95.7	92.2	to	97.7	88.3	83.3	to	91.9	79.3	73.0	to	84.2
Glasgow	182	92.7	87.7	to	95.7	86.6	80.6	to	90.9	80.8	73.9	to	86.0
Gt Ormond St	12	91.7	53.9	to	98.8	81.5	43.5	to	95.1	67.9	28.2	to	88.8
All centres	**2079**	**92.0**	**90.8**	**to**	**93.1**	**86.2**	**84.6**	**to**	**87.6**	**80.6**	**78.8**	**to**	**82.3**

[1] $p<0.01$; [2] $p=0.015$; [3] $p=0.06$

Table 9 **Three and five-year survival after adult heart transplantation by centre *unadjusted* for patient risk, for the subset of patients surviving beyond 1-year**

		3-years				*5-years*			
Centre	No cases	% Survival[1]	95%CI			% Survival[1]	95%CI		
Newcastle	266	90.6	86.4	to	93.6	85.6	80.5	to	89.5
Sheffield	94	95.7	89.1	to	98.4	89.4	81.1	to	94.1
Papworth	441	93.4	90.5	to	95.4	87.9	84.3	to	90.8
Harefield	326	97.8	95.5	to	99.0	93.0	89.5	to	95.4
St George's	86	93.0	85.1	to	96.8	88.3	79.4	to	93.5
Birmingham	208	92.3	87.6	to	95.3	85.3	79.3	to	89.7
Manchester	214	92.3	87.7	to	95.2	82.8	76.6	to	87.5
Glasgow	162	93.5	88.2	to	96.4	87.1	80.6	to	91.6
Gt Ormond St	10	88.9	43.3	to	98.4	74.1	28.9	to	93.0
All centres	**1807**	**93.6**	**92.4**	**to**	**94.7**	**87.6**	**85.9**	**to**	**89.1**

[1] p=0.07; [2] p=0.14

Figure 4 **Kaplan-Meier survival curves after adult heart transplantation by centre**

a) *Overall survival*

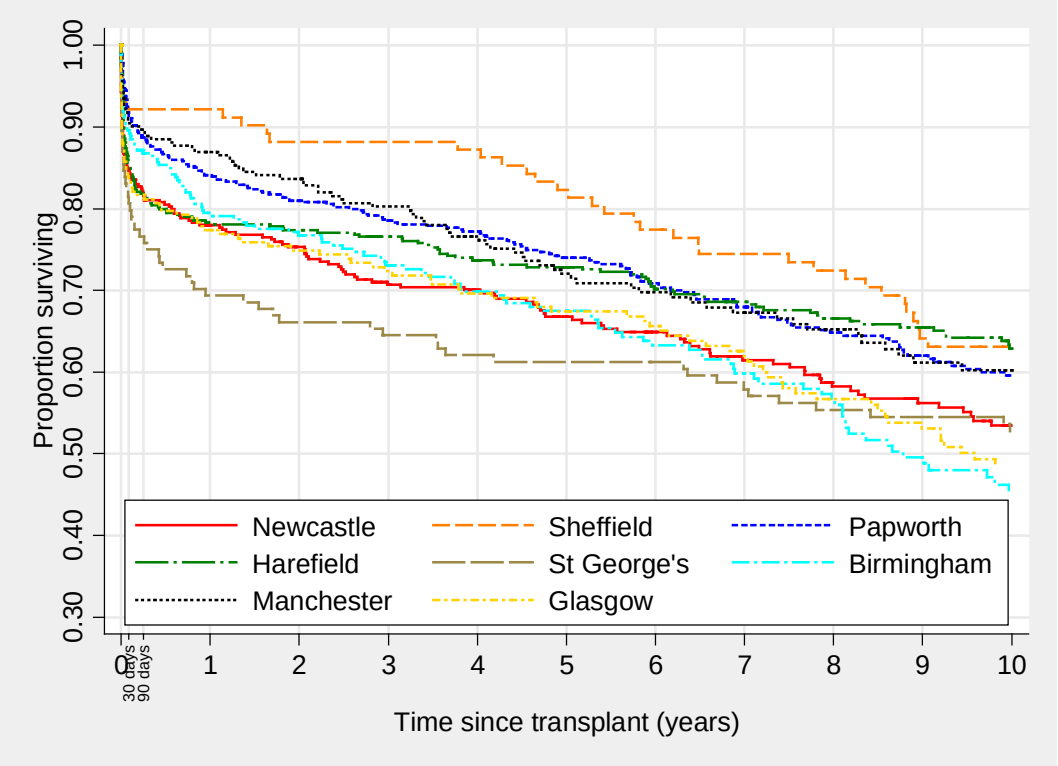
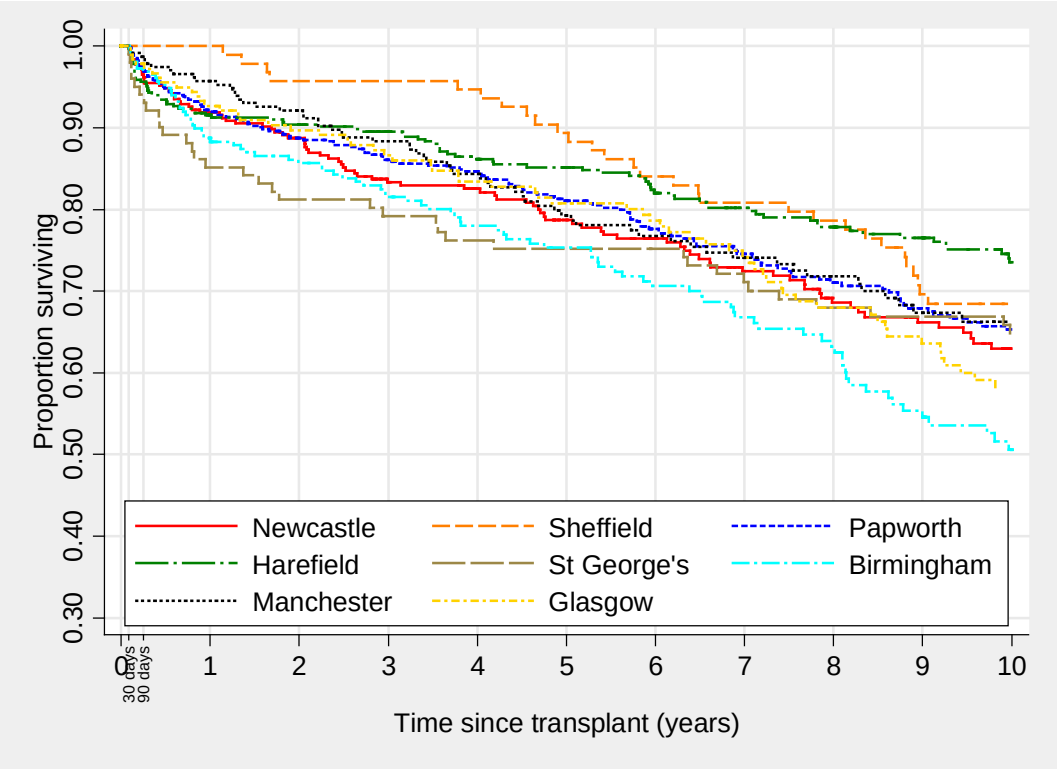


Figure 4 continued

b) Conditional survival: patients alive at 30 days



c) Conditional survival: patients alive at 1-year

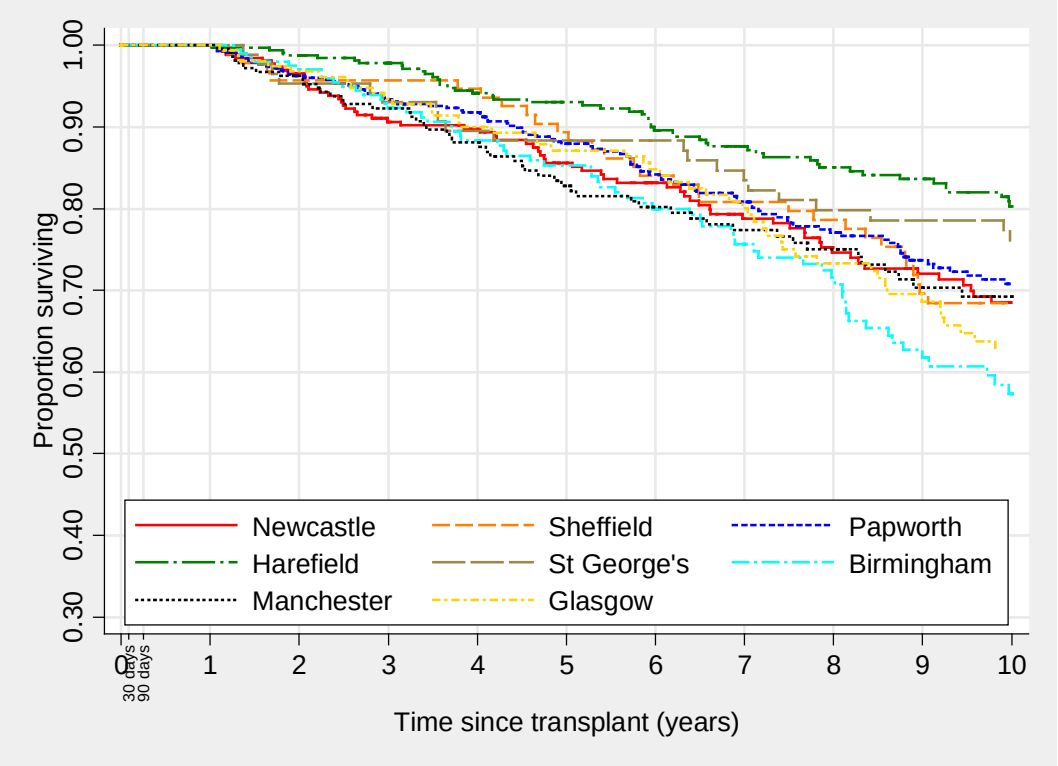


Table 10 30 and 90-day mortality after adult heart transplantation by retrieval centre *unadjusted* for patient risk

a) April 2008 – March 2011

Retrieval Centre	*30 days*						*90 days*						% used locally	% used for UHAS patient
	No cases	No deaths	Mortality rate[1]	95%CI			No cases[4]	No deaths	Mortality rate[2]	95%CI				
Newcastle	44	6	13.6	5.2	to	27.4	39	7	17.9	7.5	to	33.5	50.0	45.5
Papworth	71	7	9.9	4.1	to	19.3	67	9	13.4	6.3	to	24.0	66.2	50.7
Harefield	34	6	17.6	6.8	to	34.5	32	7	21.9	9.3	to	40.0	44.1	41.2
Birmingham	54	6	11.1	4.2	to	22.6	50	5	10.0	3.3	to	21.8	59.3	38.9
Manchester	34	6	17.6	6.8	to	34.5	29	7	24.1	10.3	to	43.5	38.2	47.1
Glasgow	28	4	14.3	4.0	to	32.7	26	6	23.1	9.0	to	43.6	28.6	64.3
Other[3]	3	0	0.0	0.0	to	70.8	3	0	0.0	0.0	to	70.8	0.0	100
All centres	**268**	**35**	**13.1**	**9.3**	**to**	**17.7**	**246**	**41**	**16.7**	**12.2**	**to**	**21.9**	**51.1**	**47.8**

Table 10 continued

b) April 2010 – March 2011

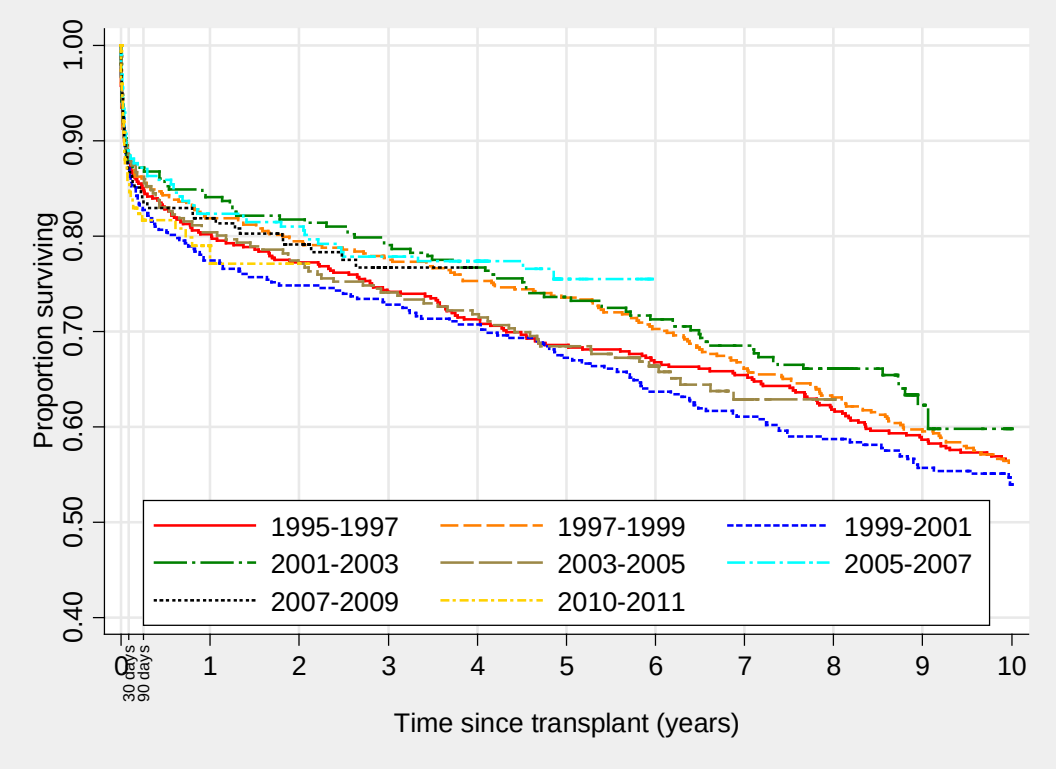
Retrieval Centre	*30 days*						*90 days*						% used locally	% used for UHAS patient
	No cases	No deaths	Mortality Rate[1]	95%CI			No cases[4]	No deaths	Mortality Rate[2]	95%CI				
Newcastle	13	3	23.1	5.0	to	53.8	8	3	37.5	8.5	to	75.5	38.5	53.8
Papworth	17	2	11.8	1.5	to	36.4	13	2	15.4	1.9	to	45.4	70.6	58.8
Harefield	13	3	23.1	5.0	to	53.8	11	3	27.3	6.0	to	61.0	30.8	53.8
Birmingham	20	3	15.0	3.2	to	37.9	16	2	12.5	1.6	to	38.3	55.0	40
Manchester	15	5	33.3	11.8	to	61.6	10	5	50.0	18.7	to	81.3	20.0	53.3
Glasgow	11	2	18.2	2.3	to	51.8	9	3	33.3	7.5	to	70.1	36.4	72.7
Other[3]	1	0	0.0	0.0	to	97.5	1	0	0.0	0.0	to	97.5	0.0	100
All centres	**90**	**18**	**20.0**	**12.3**	**to**	**29.8**	**68**	**18**	**26.5**	**16.5**	**to**	**38.6**	**43.3**	**54.4**

[1] a) p=0.86; b) p=0.79
[2] a) p=0.50; b) p=0.38
[3] Republic of Ireland or other overseas centre
[4] Transplants to December 2010

Mortality rates by audit year

There was no evidence to suggest any significant variation in the overall 30-day mortality rate across the fifteen-year study period (p=0.15). Similarly, no significant variation in 90-day mortality was found (p=0.11). Longer-term survival to 1, 3, 5 and 10 years has also not changed significantly (log-rank test for trend, 1-year, p=0.89; 3-year, p=0.83; 5-year, p=0.64; 10-year, p=0.58). Survival to 10 years by audit era is shown in **Figure 5**.

Figure 5 Kaplan-Meier survival curves after adult heart transplantation by era



Risk profile for 30 day and 1-year mortality

Figure 6 plots the average risk score for 30-day and 1-year mortality over time as a moving average based on 90 transplants. As a result of the trend towards increased ischemia times and the change in the donor age profile the risk score for early mortality has increased steadily in recent years but this increased risk has not translated into a notable increase in early mortality. In contrast to the 30-day model, risk scores for 1-year mortality have shown less variability.

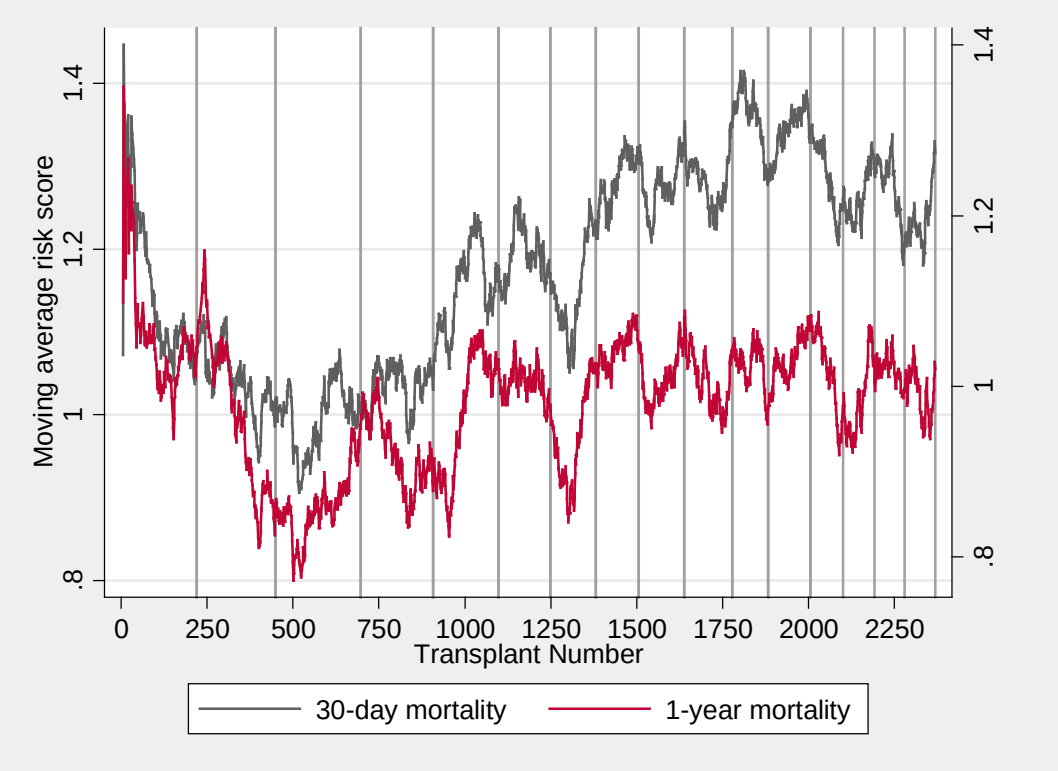
The distribution of risk profiles (including adjustment for adult congenital heart disease, ACHD) is broadly similar for patients transplanted at the different centres, as shown in **Figure 7.** The trend towards higher risk scores for transplants in the most recent era is seen for most adult centres. Factors included in the risk adjustment are given in Appendix 1.

Risk-adjusted mortality

Centre specific mortality

Table 11 shows the risk adjusted 30-day mortality rates and centre effect estimates following heart transplantation for the periods April 2008 to March 2011 and April 2010 to March 2011. The corresponding estimates for 90-day mortality for transplants to December 2010 are shown in **Table 12.** These fixed centre effects are estimated independently for each centre and express the difference between the observed and expected number of deaths as a proportion of the total number of expected deaths.

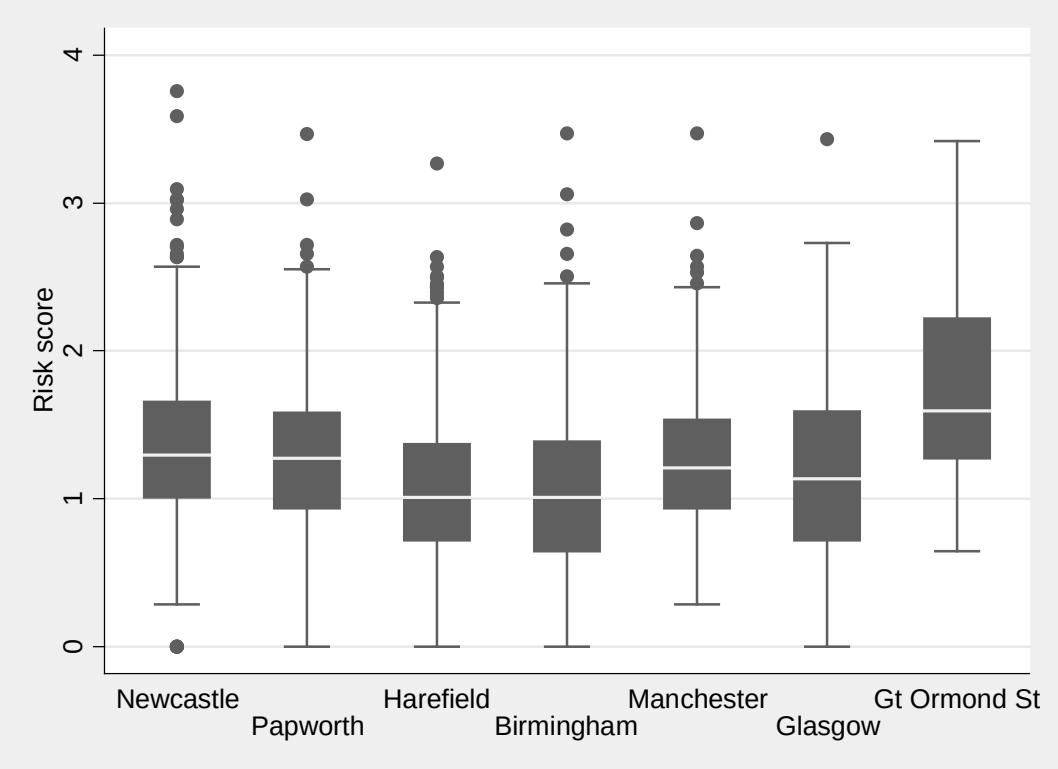
Figure 6 **Risk scores for 30-day and 1-year mortality after adult heart transplantation over time**



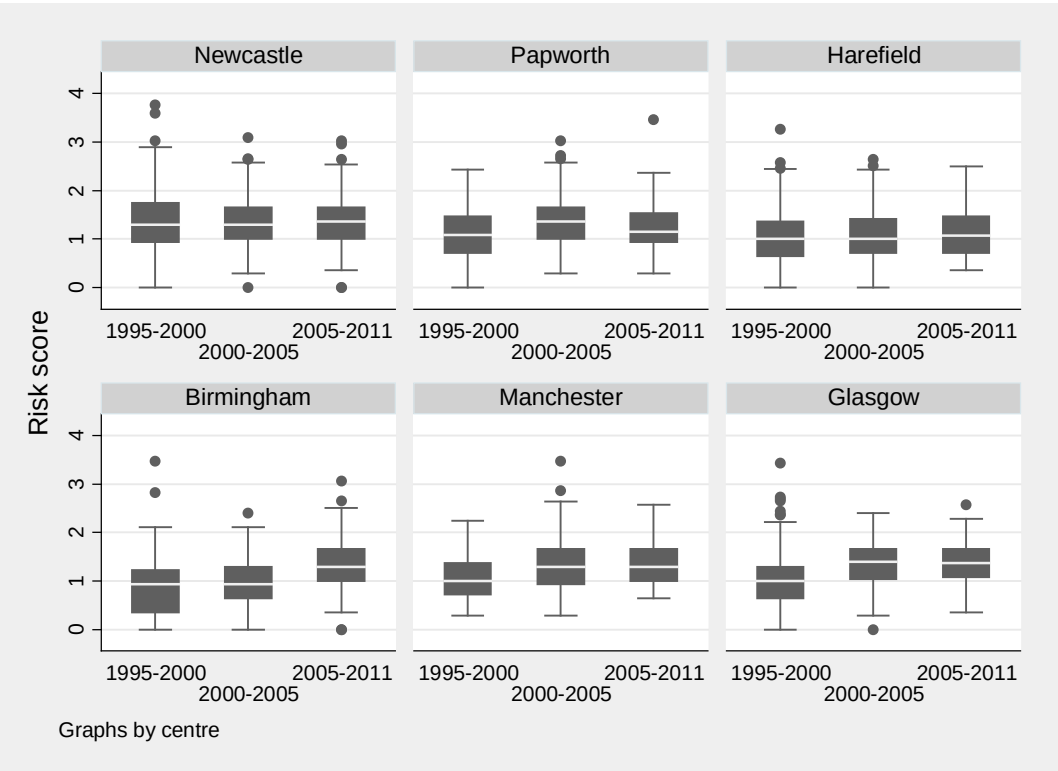
Note: Vertical lines represent the start of each audit year

Figure 7 **Distribution of risk scores derived from risk model for 30-day mortality after adult heart transplantation**

a) By centre



b) By centre and era



After risk adjustment, Harefield had significantly higher than expected mortality at 30 and 90 days during the period since April 2008 and during the last year to March 2011, as indicated by the positive centre effect estimates. These data are further illustrated in **Figure 8**, which shows the risk-adjusted mortality estimate for each centre with the 95% and 99% confidence intervals.

Risk adjusted centre effect estimates for 1-year mortality following heart transplantation for the whole audit, and for the period April 2007 to March 2010 are shown in **Table 13**. Over the whole audit period four centres are identified as divergent, Sheffield, Papworth, St George's and Manchester. The centre effects for Sheffield, Papworth and Manchester are negative indicating significantly fewer deaths than expected, while the estimate for St George's is positive, suggesting the converse. Over the period April 2007 to March 2010 no centre was identified as divergent.

Table 11 **30-day mortality after adult heart transplantation by centre *adjusted* for patient risk**

a) *April 2008 – March 2011*

Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	49	8.9	3.1	to	18.6	-0.31	-0.78	to	0.62
Papworth	75	8.6	2.9	to	17.9	-0.34	-0.79	to	0.54
Harefield	30	26.8	14.3	to	41.0	1.59	0.18	to	3.91
Birmingham	52	12.8	5.6	to	23.2	0.04	-0.58	to	1.14
Manchester	34	8.6	1.9	to	21.5	-0.34	-0.86	to	0.94
Glasgow	18	17.6	5.5	to	35.3	0.51	-0.59	to	2.86
Gt Ormond St	**3**	**0.0**	**0.0**	**to**	**48.1**	**-1.00**	**-1.00**	**to**	**5.55**

b) *April 2010 – March 2011*

Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	13	13.1	1.8	to	35.2	0.07	-0.87	to	2.85
Papworth	23	14.6	3.4	to	33.3	0.21	-0.75	to	2.54
Harefield	8	37.8	14.2	to	60.8	3.29	0.17	to	10.00
Birmingham	21	11.8	2.7	to	28.1	-0.05	-0.80	to	1.77
Manchester	11	16.4	2.3	to	41.5	0.39	-0.83	to	4.02
Glasgow	8	28.9	7.7	to	54.2	1.87	-0.41	to	7.39
Gt Ormond St	**1**	**0.0**	**0.0**	**to**	**76.2**	**-1.00**	**-1.00**	**to**	**21.7**

Table 12 **90-day mortality after adult heart transplantation by centre adjusted for patient risk**

a) *April 2008 – December 2010*

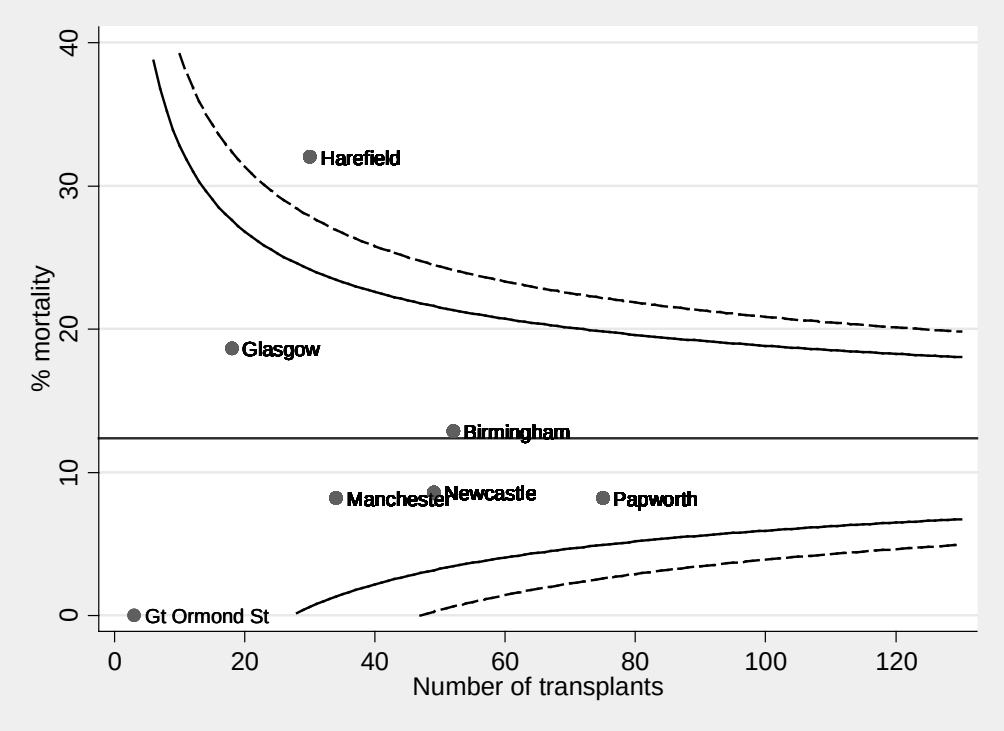
Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	46	12.9	5.6	to	23.4	-0.11	-0.64	to	0.84
Papworth	70	8.6	3.0	to	18.0	-0.43	-0.82	to	0.33
Harefield	29	32.3	19.8	to	45.5	1.87	0.48	to	4.02
Birmingham	48	17.6	8.9	to	28.8	0.28	-0.41	to	1.43
Manchester	30	6.7	0.9	to	20.6	-0.57	-0.95	to	0.56
Glasgow	16	19.4	6.2	to	38.1	0.45	-0.61	to	2.71
Gt Ormond St	3	0.0	0.0	to	49.2	-1.00	-1.00	to	4.84

b) *April 2009 – December 2010*

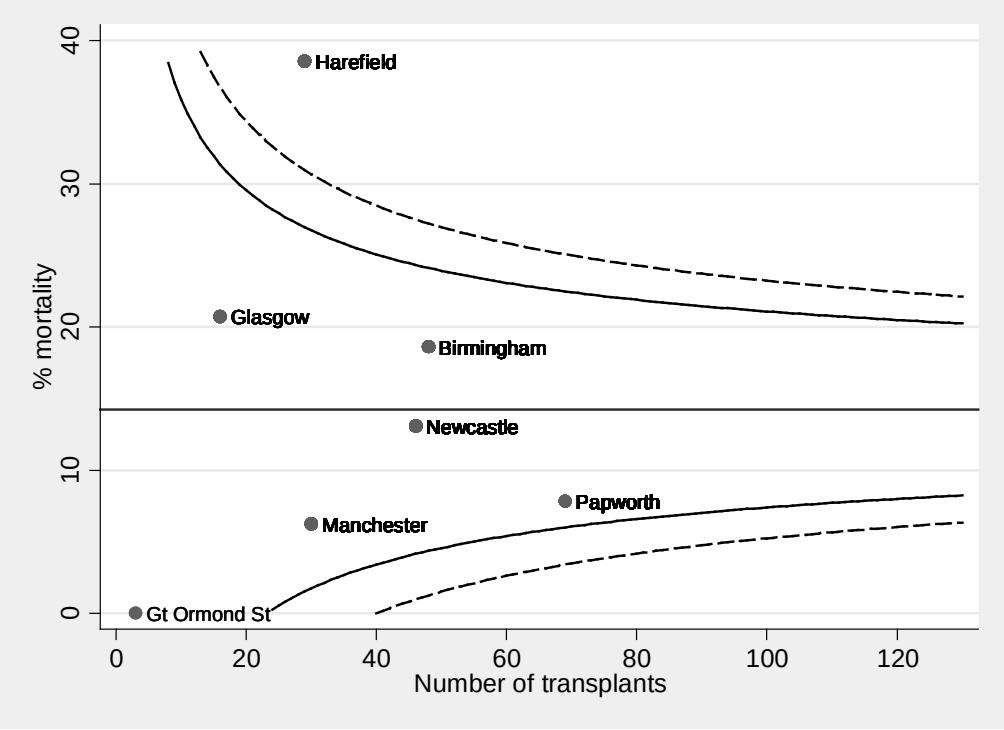
Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	10	16.5	2.3	to	41.6	0.19	-0.86	to	3.29
Papworth	18	17.5	4.2	to	38.3	0.28	-0.74	to	2.74
Harefield	7	38.6	14.6	to	61.7	2.79	0.03	to	8.71
Birmingham	17	19.7	6.3	to	38.6	0.48	-0.60	to	2.79
Manchester	7	14.6	0.4	to	48.7	0.03	-0.97	to	4.71
Glasgow	6	35.3	10.1	to	61.4	2.28	-0.32	to	8.60
Gt Ormond St	1	0.0	0.0	to	75.6	-1.00	-1.00	to	17.62

Figure 8 **Risk-adjusted estimates of early mortality after adult heart transplantation, April 2008 to March 2011**

a) 30-days



b) 90-days (transplants to December 2010)



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

Table 13 **1-year survival after adult heart transplantation by centre *adjusted* for patient risk**

a) Whole audit period

Centre	No cases	% survival	95%CI			Centre effect	95%CI		
Newcastle	358	78.2	74.3	to	82.0	0.19	-0.06	to	0.49
Sheffield	87	92.1	83.4	to	97.3	-0.63	-0.88	to	-0.14
Papworth	539	85.4	82.6	to	88.0	-0.27	-0.42	to	-0.09
Harefield	399	78.0	74.1	to	81.7	0.21	-0.04	to	0.50
St George's	117	70.1	62.8	to	77.1	0.83	0.27	to	1.54
Birmingham	283	79.1	74.5	to	83.3	0.13	-0.14	to	0.47
Manchester	260	87.0	82.7	to	90.7	-0.36	-0.56	to	-0.10
Glasgow	212	78.0	72.7	to	82.8	0.21	-0.11	to	0.61
Gt Ormond St	14	82.2	61.3	to	95.7	-0.07	-0.81	to	1.71

b) April 2007 – March 2010

Centre	No cases	% survival	95%CI			Centre effect	95%CI		
Newcastle	56	79.8	67.6	to	89.6	0.28	-0.41	to	1.43
Papworth	66	90.0	81.4	to	95.7	-0.44	-0.77	to	0.16
Harefield	41	75.3	63.0	to	85.9	0.66	-0.17	to	1.97
Birmingham	47	78.5	67.1	to	88.0	0.39	-0.31	to	1.48
Manchester	36	94.6	82.9	to	99.3	-0.71	-0.97	to	0.04
Glasgow	19	77.1	59.1	to	91.2	0.50	-0.51	to	2.50
Gt Ormond St	3	100.0	47.3	to	100.0	-1.00	-1.00	to	4.65

Continuous monitoring of mortality

Observed – expected mortality

Observed – expected mortality charts, with and without risk adjustment, for 30-day and 90-day mortality after adult heart transplantation are shown in **Figure 9** and **Figure 10** respectively.

Tabular CUSUM charts

Tabular CUSUM charts, unadjusted for risk, for 30-day and 90-day mortality are shown in **Figure 11** and **Figure 12** respectively.

The CUSUM charts illustrate that recent 30- and 90-day mortality rates following adult heart transplantation have been as expected at Newcastle, Birmingham and Manchester.

Papworth and Glasgow experienced more deaths than expected in 2007 and Harefield experienced more deaths than 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, Harefield continued to experience more deaths within 90 days than expected and the 90-day CUSUM chart signalled again twice. Centres are monitored more closely after a signal and so the charts are more sensitive.

Figure 9 **Cumulative (observed – expected) 30-day mortality after adult heart transplantation, January 2004 to March 2011**

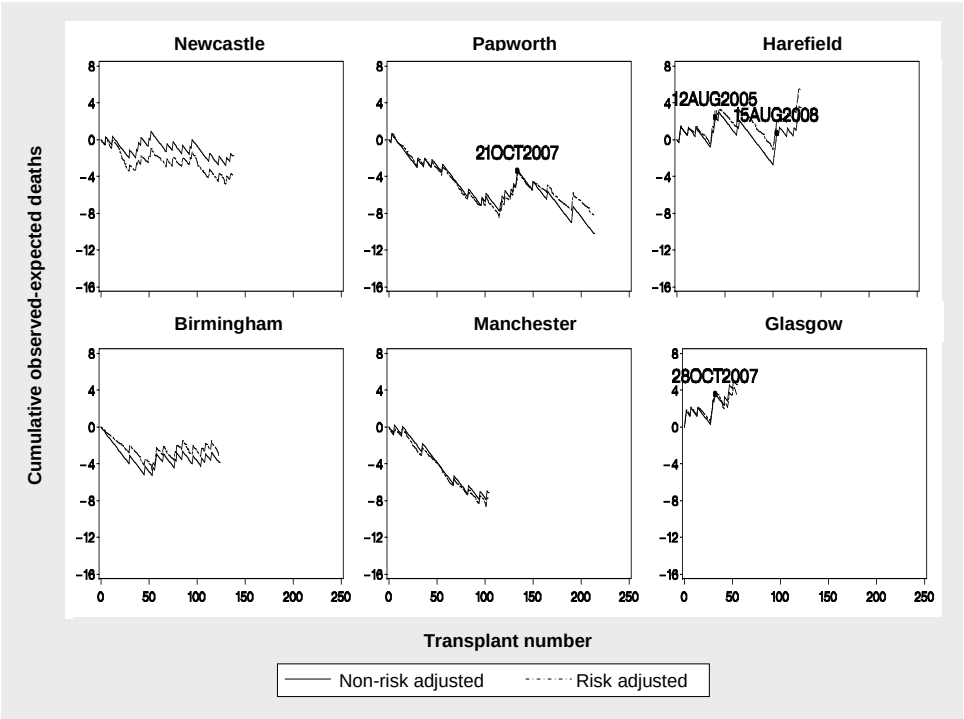


Figure 10 **Cumulative (observed – expected) 90-day mortality after adult heart transplantation, January 2004 to December 2010**

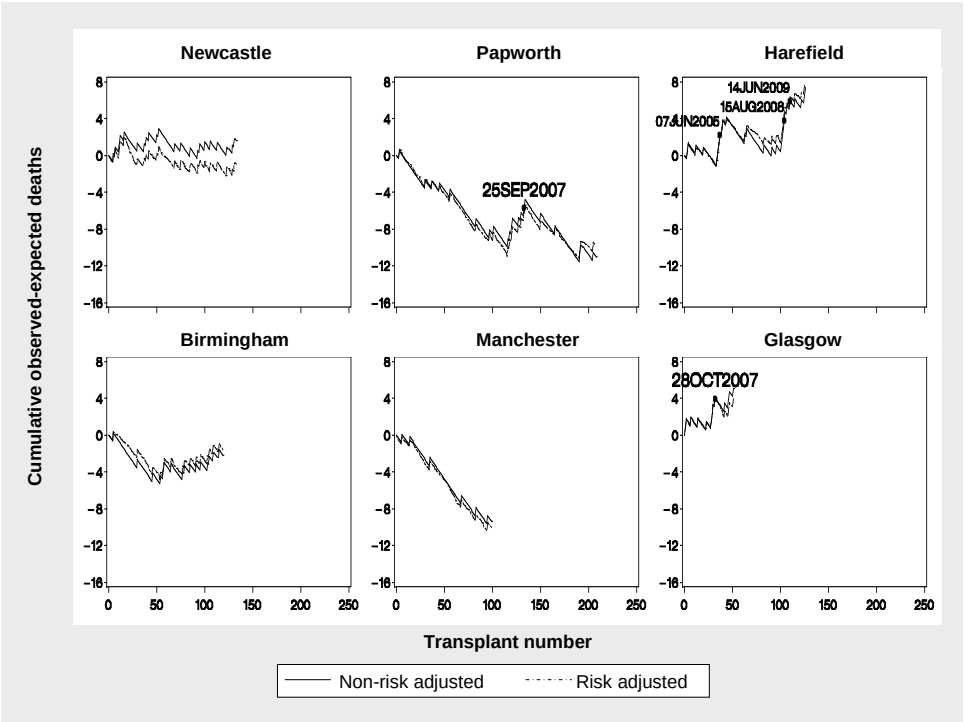


Figure 11 **Tabular CUSUM for 30-day mortality after adult heart transplantation *unadjusted* for patient risk, January 2004 to March 2011**

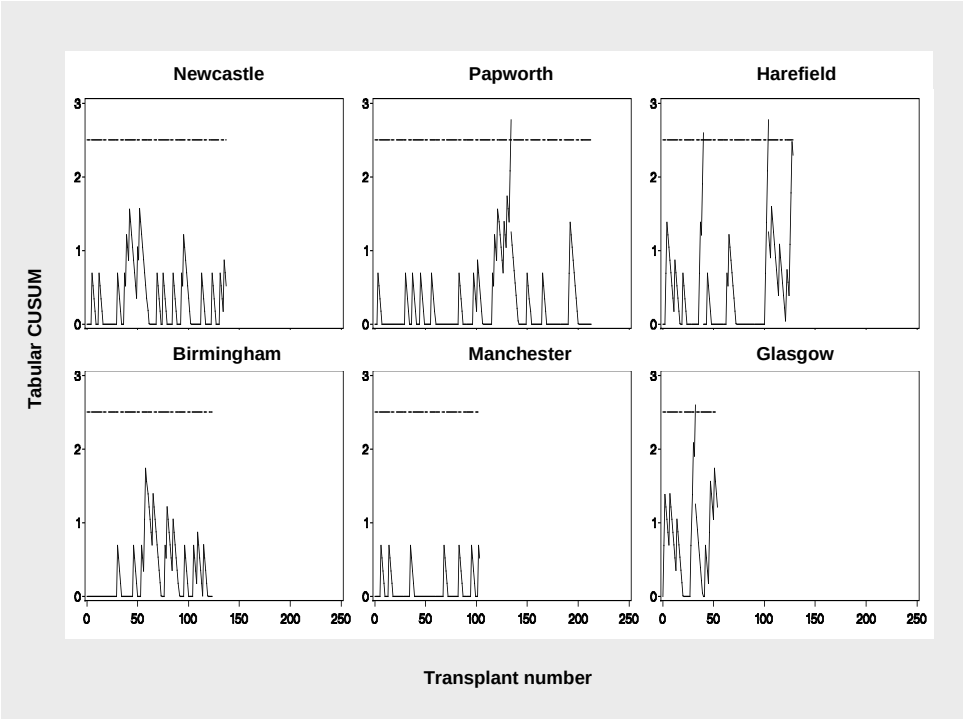
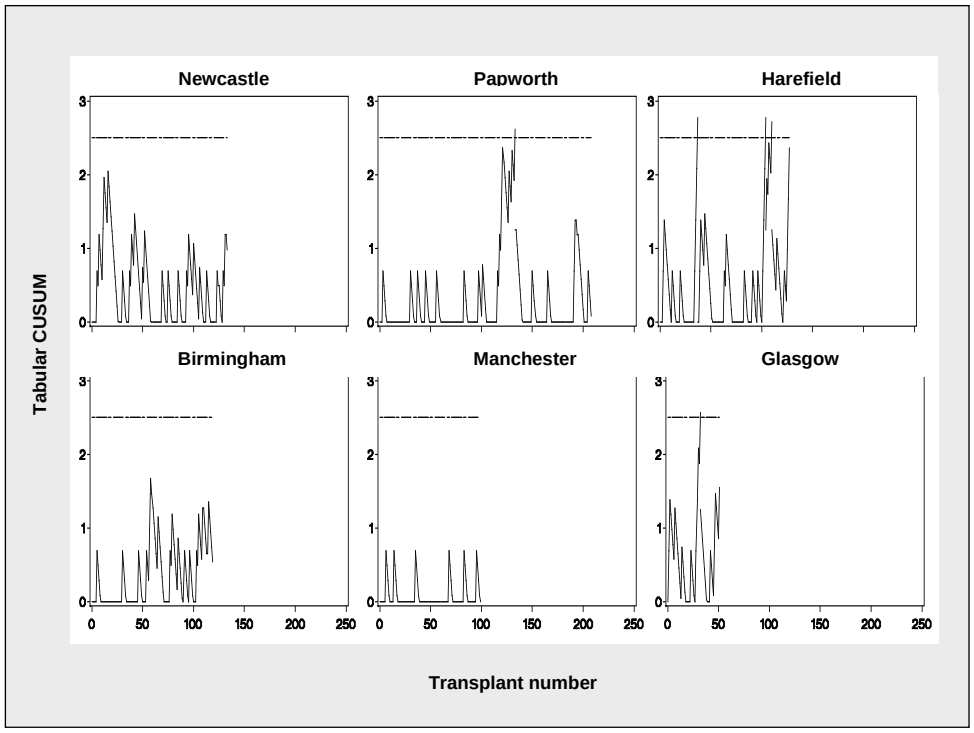


Figure 12 Tabular CUSUM for 90-day mortality after adult heart transplantation *unadjusted* for patient risk, January 2004 to December 2010



Ventricular assist devices

Long term devices used for bridging

Long-term left ventricular assist devices (LVADs) were implanted for 319 patients at six implant centres in the UK. Since the last report, Birmingham have implanted their first long-term device. Fourteen patients received a short-term device and two patients received a short period of ECMO support prior to a long-term device. They are excluded from this section and reported in the short-term bridging section. Of the remaining 303 patients, 136 devices have been implanted by Harefield, 79 by Papworth, 79 by Newcastle, 6 by Manchester and 3 by Glasgow.

Forty-three of these patients also received long-term right ventricular assist devices (RVADs) and 34 received short-term RVADs. Two patients on a long-term VAD for bridging received a short period of ECMO support concurrently. Two BiVAD patients received a third device that was in place at the same time as the BiVAD. Eight patients had their long-term device replaced, and five patients had a short-term VAD implanted shortly after explant of the long-term device.

Of the patients who received a long-term device, dilated cardiomyopathy (67%) and ischemic heart disease (21%) were the most frequently reported cardiac diseases. The median age at implant was 46 years (inter-quartile range: 35-55 years) and the majority of recipients (81%) were male.

Figure 13 shows the cumulative number of VADs implanted each month, overall and by centre. VAD activity has been broadly consistent across the time period. Newcastle activity has increased considerably since 2008.

Figure 13 Cumulative long-term VAD activity by month and implant centre, May 2002 to March 2011

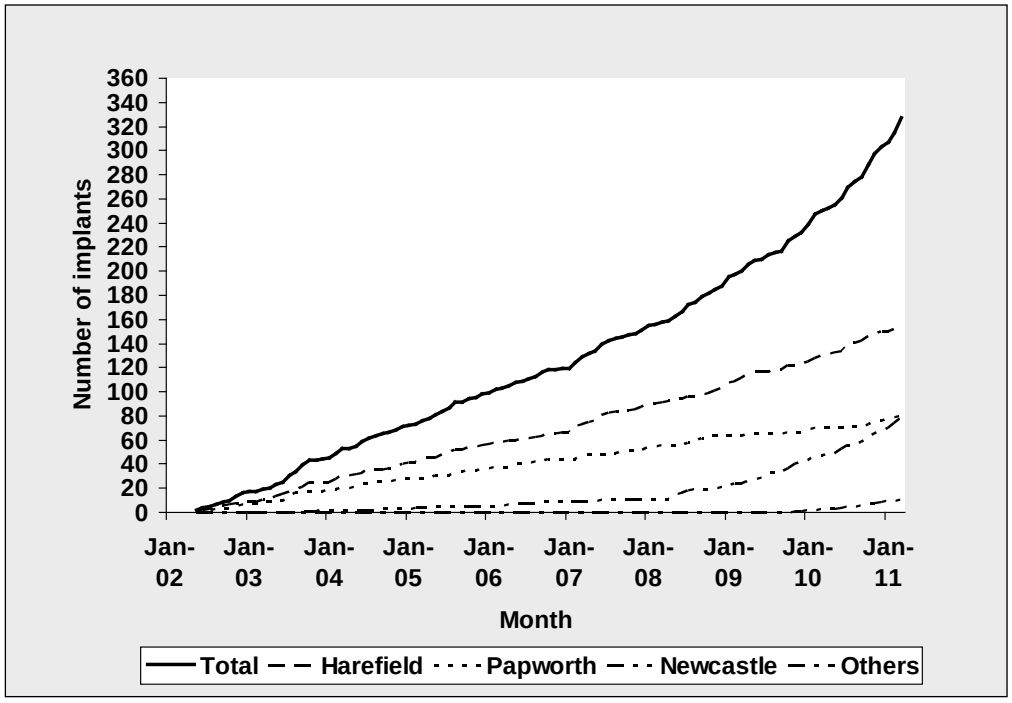


Table 14 shows the long-term VAD outcome of recipients, by centre. Nationally, 89 patients were transplanted, 20 survived explantation of the VAD, 96 died on support, two died within a month of explantation and 96 were still on support on 30 June 2011. Thirteen people had their VAD replaced; eight received a second long-term device and five received a short-term device shortly after explant of the first device.

Long-term VAD duration ranged between 0 and 2,261 days (six years). Using the Kaplan-Meier estimation method, median long-term VAD duration for all patients was estimated to be 253 days (95% CI: 197 to 309 days).

Table 15 shows Kaplan-Meier estimates of patient survival from time of first implant to death. Patients still alive were censored at 30 June 2011. Other events, such as device explantation or transplantation were not censored. Centre-specific survival rates for Manchester and Glasgow are not presented due to small numbers of implants performed. Overall survival rates are higher in the most recent three years.

Table 16 compares patient survival for patients receiving an LVAD only with those receiving both an LVAD and an RVAD (BiVAD). There is evidence of a difference in survival between the two groups for the whole cohort (log-rank test, p=0.01), and for those implanted after April 2008 (log-rank test, p=0.01). However, treatment has not been randomised and it is likely that the pre-implant illness was more severe in the BiVAD group.

Table 14 Outcome of long-term VADs by implant centre, May 2002 to March 2011

Outcome	Newcastle		Papworth		Harefield		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	7	9%	34	43%	25	18%	0	0%	0	0%	$66^{2,2}$	22%
Alive (post explant)	1	1%	1	1%	18	13%	0	0%	0	0%	$20^{2,1}$	7%
Alive with VAD	41	52%	14	18%	34	25%	6	100%	1	33%	$96^{1,0}$	32%
Total alive	*49*	*62%*	*49*	*62%*	*77*	*57%*	*6*	*100%*	*1*	*33%*	$182^{5,3}$	*60%*
Died (post transplant)	7	9%	4	4%	11	8%	0	0%	1	33%	$23^{1,0}$	8%
Died (post explant)	0	0%	1	1%	1	1%	0	0%	0	0%	2	1%
Died with VAD	23	29%	25	32%	47	35%	0	0%	1	33%	$96^{2,2}$	32%
Total died	*30*	*38%*	*30*	*38%*	*59*	*43%*	*0*	0%	*2*	*67%*	$121^{3,2}$	*40%*
TOTAL	**79**	**100%**	**79**	**100%**	**136**	**100%**	**6**	**100%**	**3**	**100%**	$\mathbf{303^{8,5}}$	**100%**

Superscripts indicate the number of patients receiving a second device, e.g. ^{2,1} indicates two patients received a second long term device and one patient received a short term device after explantation of a long-term device

Long-term VAD duration ranged between 0 and 2,261 days (six years). Using the Kaplan-Meier estimation method, median long-term VAD duration for all patients was estimated to be 253 days (95% CI: 197 to 309 days).

Table 15 shows Kaplan-Meier estimates of patient survival from time of first implant to death. Patients still alive were censored at 30 June 2011. Other events, such as device explantation or transplantation were not censored. Centre-specific survival rates for Manchester and Glasgow are not presented due to small numbers of implants performed. Overall survival rates are higher in the most recent three years.

Table 16 compares patient survival for patients receiving an LVAD only with those receiving both an LVAD and an RVAD (BiVAD). There is evidence of a difference in survival between the two groups for the whole cohort (log-rank test, p=0.01), and for those implanted after April 2008 (log-rank test, p=0.01). However, treatment has not been randomised and it is likely that the pre-implant illness was more severe in the BiVAD group.

Table 15 **Patient survival after implant of long-term VAD by implant centre, May 2002 to March 2011**

a) *May 2002 - March 2011*

Centre	No. at risk on day 0	% patient survival (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
Newcastle	79	86	(76 - 92)	80	(69 - 87)	60	(47 - 70)	55	(42 - 66)	55	(42 - 66)
Papworth	79	89	(79 - 94)	73	(62 - 82)	65	(54 - 75)	60	(48 - 71)	59	(47 - 69)
Harefield	136	85	(78 - 90)	78	(70 - 84)	68	(59 - 75)	55	(45 - 63)	53	(43 - 61)
All centres	**303**	**86**	**(82 - 90)**	**78**	**(72 - 82)**	**65**	**(60 - 71)**	**56**	**(50 - 62)**	**54**	**(48 - 60)**

b) *April 2008 - March 2011*

Centre	No. at risk on day 0	% patient survival (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
Newcastle	68	88	(78 - 94)	87	(76 - 93)	67	(52 - 77)	61	(46 - 73)	61	(46 - 73)
Papworth	23	91	(69 - 98)	78	(55 - 90)	74	(50 - 87)	59	(25 - 82)	59	(25 - 82)
Harefield	58	90	(78 - 95)	84	(72 - 92)	78	(65 - 87)	56	(38 - 71)	56	(38 - 71)
All centres	**158**	**89**	**(83 - 93)**	**85**	**(78 - 90)**	**72**	**(64 - 79)**	**58**	**(47 - 68)**	**58**	**(47 - 68)**

Table 16 **Patient survival after implant of long-term VAD by LVAD/BiVAD, May 2002 to March 2011**

a) May 2002 - March 2011

Device	No. at risk on day 0	% patient survival (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
LVAD only	226	88	(84 - 92)	82	(77 - 87)	69	(63 - 75)	61	(53 - 67)	59	(51 - 66)
BiVAD	77	81	(70 - 88)	64	(52 - 73)	53	(42 - 64)	44	(33 - 55)	43	(31 - 54)
Overall	**303**	**86**	**(82 - 90)**	**78**	**(72 - 82)**	**65**	**(60 - 71)**	**56**	**(50 - 62)**	**54**	**(48 - 60)**

b) April 2008 - March 2011

Device	No. at risk on day 0	% patient survival (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
LVAD only	129	91	(84 - 95)	88	(81 - 93)	76	(66 - 83)	64	(51 - 74)	64	(51 - 74)
BiVAD	29	83	(63 - 92)	69	(49 - 82)	55	(36 - 71)	39	(19 - 58)	39	(19 - 58)
Overall	**158**	**89**	**(83 - 93)**	**85**	**(78 - 90)**	**72**	**(64 - 79)**	**58**	**(47 - 68)**	**58**	**(47 - 68)**

Short term devices used for bridging

Eighty-four patients received a short-term device for bridging at six implant centres in the UK. Thirty-five patients received devices at Harefield, 19 at Papworth, nine at Birmingham, nine at Manchester, eight at Glasgow and four at Newcastle. Fifty patients received a BiVAD (short-term device in both ventricles), 20 an LVAD only, one an RVAD only and 13 received ECMO only support. Fourteen of the 84 patients were bridged from a short-term device to a long-term device (bridge-to-bridge patients) and two further patients were bridged from ECMO only support to a long-term device. Three patients on short-term VADs for bridging received ECMO support concurrently.

In addition, five patients had a short-term VAD implanted after the explant of a long-term VAD. These five VADs are excluded from this section and are included in the long-term VAD activity section. An additional patient received a short-term VAD at a non-transplant unit and was subsequently transplanted at Newcastle. This patient is excluded from this section.

Of the patients who received a short-term device for bridging, dilated cardiomyopathy (64%) and ischemic heart disease (20%) were the most frequently reported cardiothoracic diseases. The median age at implant was 38.5 years (inter-quartile range: 26-50 years) and the majority of recipients (62%) were male.

Table 17 presents the short-term VAD outcome of recipients, by centre and devices received. Nationally, 21 were transplanted, 13 survived explantation of the VAD, 33 died on

support, 16 were bridged to a long-term device and one died shortly after explantation. When combining activity across the short-term device only and bridged to long-term device groups, the overall number of patients alive at the time of analysis was 39 out of 84 (46%).

Short-term VAD duration for bridging ranged between 0 and 104 days. Using the Kaplan-Meier estimation method, median VAD duration was estimated to be 18 days (95% CI: 11 - 24 days). For those who were bridged onto a long-term VAD, long-term VAD duration ranged from 33 to 1,030 days.

Table 18 shows patient survival from time of first implant to death for the patients receiving a short-term VAD. Patients still alive were censored at 30 June 2011. Other events, such as device explantation or transplantation were not censored. The two patients bridged from ECMO only support to a long-term device are included in the bridged to long-term device group. There is no statistical comparison of the outcomes due to a selection bias in the bridged to long-term device group, as the patients must have survived until the device was replaced.

Table 17 Outcome of short-term VADs used for bridging by implant centre, May 2002 to March 2011

a) Short-term device only

Outcome	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	1	25%	3	33%	4	18%	3	43%	3	37%	0	0%	14	25%
Alive (post explant)	0	0%	1	11%	7	32%	1	14%	1	13%	1	14%	11	19%
Alive with VAD	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Total alive	*1*	*25%*	*4*	*44%*	*11*	*50%*	*4*	*57%*	*4*	*50%*	*1*	*14%*	*25*	*44%*
Died (post transplant)	0	0%	1	11%	0	0%	1	14%	1	13%	0	0%	3	5%
Died (post explant)	0	0%	1	11%	0	0%	0	0%	0	0%	0	0%	1	2%
Died with VAD	3	75%	3	33%	11	50%	2	29%	3	37%	6	86%	28	49%
Total died	*3*	*75%*	*5*	*56%*	*11*	*50%*	*3*	*43%*	*4*	*50*	*6*	*86%*	*32*	*56%*
Total	**4**	**100%**	**9**	**100%**	**22**	**100%**	**7**	**100%**	**8**	**100%**	**7**	**100%**	**57**	**100%**

Table 17 continued

b) ECMO

Outcome	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	0	0%	2	22%	0	0%	1	100%	1	100%	0	0%	4	36%
Alive (post explant)	0	0%	2	22%	0	0%	0	0%	0	0%	0	0%	2	18%
Alive with VAD	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Total alive	*0*	0%	*4*	*44%*	*0*	0%	*1*	100%	*1*	100%	*0*	0%	*6*	*55%*
Died (post transplant)	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Died (post explant)	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Died with VAD	0	0%	5	56%	0	0%	0	0%	0	0%	0	0%	5	45%
Total died	*0*	0%	*5*	*56%*	*0*	0%	*0*	0%	*0*	0%	*0*	0%	*5*	*45%*
Total	**0**	**0%**	**9**	**100%**	**0**	**0%**	**1**	**100%**	**1**	**100%**	**0**	**0%**	**11**	**100%**

Table 17 continued

c) Bridged to long-term device

Outcome	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	0	0%	0	0%	3	23%	0	0%	0	0%	0	0%	3	19%
Alive (post explant)	0	0%	0	0%	2	15%	0	0%	0	0%	0	0%	2	13%
Alive with VAD	0	0%	0	0%	1	8%	1	100%	0	0%	1	100%	3	19%
Total alive	*0*	*0%*	*0*	*0%*	*6*	*46%*	*1*	*100%*	*0*	*0%*	*1*	*100%*	*8*	*50%*
Died (post transplant)	0	0%	1	100%	0	0%	0	0%	0	0%	0	0%	1	6%
Died (post explant)	0	0%	0	0%	1	8%	0	0%	0	0%	0	0%	1	6%
Died with VAD	0	0%	0	0%	6	46%	0	0%	0	0%	0	0%	6	38%
Total died	*0*	*0%*	*1*	*100%*	*7*	*54%*	*0*	*0%*	*0*	*0%*	*0*	*0%*	*8*	*50%*
Total	**0**	**0%**	**1**	**100%**	**13**	**100%**	**1**	**100%**	**0**	**0%**	**1**	**100%**	**16**	**100%**

Table 18 Patient survival after implant of short-term VAD, May 2002 to March 2010

Device group	No. at risk on day 0	% patient survival (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
ST device only	57	58	(44 - 69)	46	(32 - 58)	44	(31 - 56)	42	(29 - 54)	42	(29 - 54)
ECMO only	11	73	(37 – 90)	55	(23 – 78)	55	(23 – 78)	55	(23 - 78)		-
Bridged to LTD	16	100	(-)	81	(52 - 94)	68	(39 - 85)	68	(39 - 85)	39	(13 - 64)
Overall	**84**	**68**	**(57 - 77)**	**54**	**(42 - 64)**	**50**	**(39 - 60)**	**48**	**(37 - 58)**	**42**	**(31 - 53)**

Short-term devices used post-heart transplant

Sixty-nine patients received short-term devices for primary graft failure (PGF) post heart-transplant at six centres in the UK. Thirty-two patients received devices at Harefield, 16 at Papworth, 13 at Manchester, five at Newcastle, two at Birmingham and one at Glasgow. Thirty-nine devices were implanted as BiVAD (short-term device in both ventricles), 14 as RVAD only, 10 as ECMO only and six as LVAD only. Twelve patients implanted with short-term VADs post-transplant received a short-period of concurrent ECMO support.

Of the patients who received a short-term device for PGF, dilated cardiomyopathy (65%) was the most frequently reported cardiac disease. The median age at implant was 48 years (inter-quartile range: 35-55 years) and the majority of recipients (74%) were male. One of the short-term devices for PGF was implanted 15 days post-transplant, one 12 days post-transplant and one seven days post-transplant, but all the rest were implanted within four days of the transplant taking place.

Table 19 presents the short-term VAD outcome of recipients treated for PGF, by centre. Nationally, eight were re-transplanted, 22 survived explantation of the VAD, 34 died on support and five died shortly after explantation.

Short-term VAD duration for PGF ranged between 0 and 84 days. Using the Kaplan-Meier estimation method, median VAD duration was estimated to be 8 days (95% CI: 6 – 10 days).

In addition to the 69 patients above, one patient at Papworth and two patients at Newcastle were implanted with short term devices following acute rejection several years post-transplant; two patients died on support and one patient was successfully re-transplanted. Finally, one patient at Newcastle was implanted with an RVAD Biomedicus device post-transplant and was explanted four days later.

Table 19 Outcome of short-term VADs used for primary graft failure by implant centre, May 2002 to March 2011

Outcome	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	0	0%	2	13%	2	6%	0	0%	1	8%	0	0%	5	7%
Alive (post explant)	0	0%	3	19%	9	28%	1	50%	9	69%	0	0%	22	32%
Alive with VAD	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Total alive	*0*	0%	*5*	*31%*	*11*	*34%*	*1*	*50%*	*10*	*77%*	*0*	0%	*27*	*39%*
Died (post transplant)	0	0%	0	0%	3	9%	0	0%	0	0%	0	0%	3	4%
Died (post explant)	0	0%	1	6%	4	13%	0	0%	0	0%	0	0%	5	7%
Died with VAD	5	100%	10	63%	14	44%	1	50%	3	23%	1	100%	34	49%
Total died	*5*	*100%*	*11*	*69%*	*21*	*66%*	*1*	*50%*	*3*	*23%*	*1*	*100%*	*42*	*61%*
Total	**5**	**100%**	**16**	**100%**	**32**	**100%**	**2**	**100%**	**13**	**100%**	**1**	**100%**	**69**	**100%**

5. RESULTS - PAEDIATRIC HEART TRANSPLANTATION

Transplant activity

Following a decline in activity in 2004/5 heart transplantation activity in children in the five years from April 2006 to March 2011 returned to the level seen over the seven years between April 1998 and March 2005 (**Figure 14**).

Unadjusted mortality rates

Overall mortality

Eighteen paediatric patients died within 30 days of their transplant, giving an overall 30-day mortality rate of 4.3% (95%CI 2.6% to 6.7%). A further nine patients died between 30 and 90-days, giving an overall 90-day mortality rate of 6.6% (95%CI 4.4% to 9.5%). Since April 2008 three patients have died within 30 days of their operation, giving an overall 30-day mortality rate of 2.9% (0.6% to 8.3%) for this period. Three children died between 30 and 90-days between April 2008 and December 2010 (**Table 20** and **Table 21**).

Overall, 92% (95%CI 89.0% to 94.3%) of children who had a heart transplant were alive 1-year later, 86.1% (95%CI 82.1% to 89.2%) were alive at 3-years, 81.4% (95%CI 76.8% to 85.2%) at 5 years and 68.4% (95%CI 61.6% to 74.2%) at 10 years **(Table 22** to **Table 25**).

Mortality rates by transplant centre

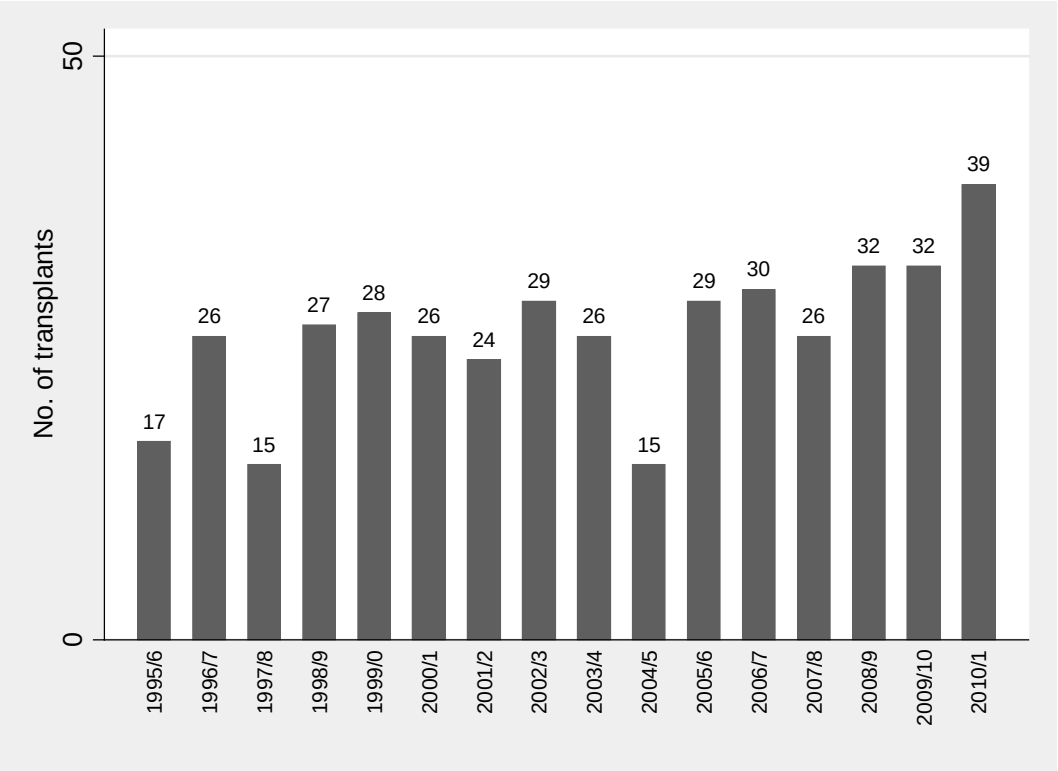
Mortality rates by centre, unadjusted for patient risk are given in **Table 20** to **Table 25.** There was no evidence to suggest that the 30 or 90-day mortality rate varied significantly between centres over the period since April 2008 (Fisher's exact test, p>0.99).

Focusing on outcomes for the three centres each reporting over 30 transplants during the full audit period, there was evidence of significant variation in the 1+ year unadjusted mortality rates across centres (p=0.06, p=0.022, p=0.056 and p=0.027 for 1, 3, 5 and 10-year survival respectively, log rank test, **Figure 15**(a)). In **Figure 15**(b) and **Figure 15**(c) survival curves for the subset of patients who lived beyond 30-days and 1-year respectively are shown. For the subsets of recipients surviving beyond 30-days and beyond 1-year, there is a 6%+ difference between the highest and lowest 5-year conditional unadjusted survival respectively (**Table 26** and **Table 27**, 30-day survivors, p=0.46; 1-year survivors, p=0.18).

In 2001, Harefield stopped their paediatric heart transplant programme and Great Ormond Street instituted a number of changes to their transplant programme. For the cohort of transplants since 2001 the survival outcome to 5 years for patients transplanted at Newcastle and Great Ormond Street is similar (p=0.93, **Figure 15** (d)).

Figure 14 Paediatric heart transplant activity by audit year

a) Overall



b) By transplant centre

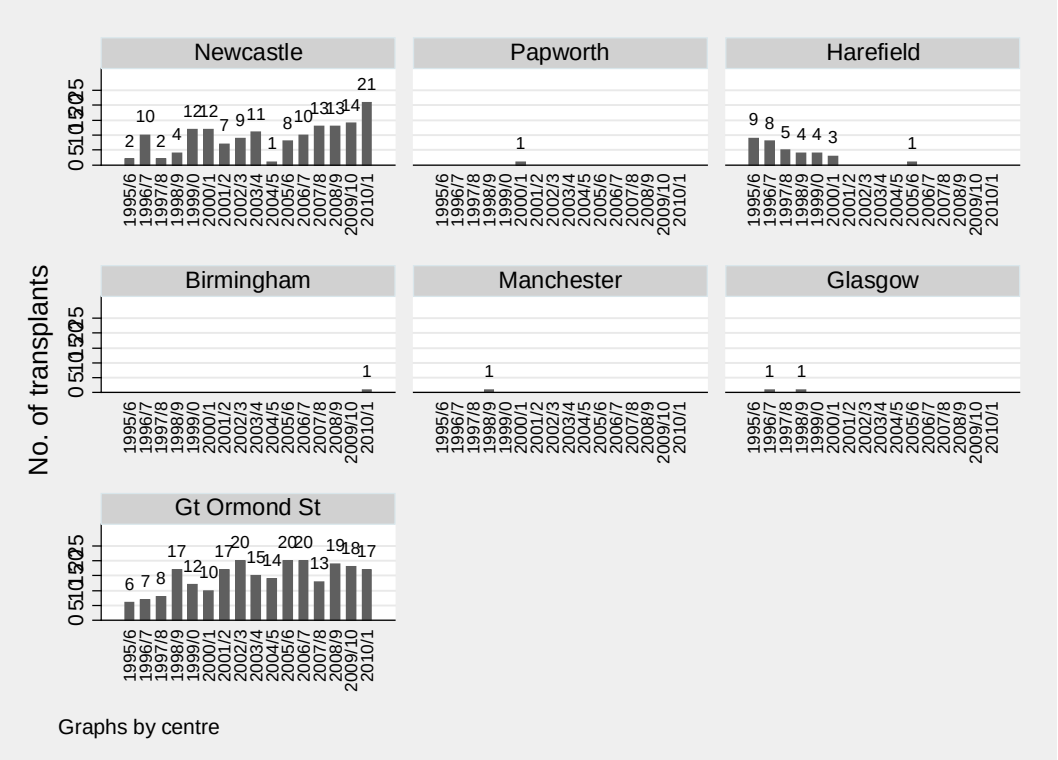


Table 20 **30-day mortality after paediatric heart transplantation by centre *unadjusted* for patient risk**

a) *April 2008 – March 2011*

Centre	No cases	No deaths	Mortality rate[1]	95%CI			Centre effect[2]	95%CI		
Newcastle	48	0	0.0	0.0	to	7.4	-1.00	-1.00	to	2.30
Birmingham	1	0	0.0	0.0	to	97.5	-1.00	-1.00	to	156.0
Gt Ormond St	54	3	5.6	1.2	to	15.4	1.40	-0.50	to	5.90
All centres	**103**	**3**	**2.9**	**0.6**	**to**	**8.3**				

b) *April 2010 – March 2011*

Centre	No cases	No deaths	Mortality rate[1]	95%CI			Centre effect[2]	95%CI		
Newcastle	21	0	0.0	0.0	to	16.1	-1.00	-1.00	to	6.50
Birmingham	1	0	0.0	0.0	to	97.5	-1.00	-1.00	to	156.0
Gt Ormond St	17	0	0.0	0.0	to	19.5	-1.00	-1.00	to	8.20
All centres	**39**	**0**	**0.0**	**0.0**	**to**	**9.0**				

[1] a) p=0.27
[2] expected mortality based on overall mortality for the period April 2005 to March 2008 (2.35%)

Table 21 **90-day mortality after paediatric heart transplantation by centre *unadjusted* for patient risk**

a) *April 2008 – December 2010*

Centre	No cases	No deaths	Mortality rate[1]	95%CI			Centre effect[2]	95%CI		
Newcastle	42	3	7.1	1.5	to	19.5	2.04	-0.37	to	7.88
Gt Ormond St	48	3	6.3	1.3	to	17.2	1.66	-0.45	to	6.77
All centres	**90**	**6**	**6.7**	**2.5**	**to**	**13.9**				

Table 21 **continued**

b) *April 2010 – December 2010*

Centre	No cases	No deaths	Mortality rate[1]	95%CI			Centre effect[2]	95%CI		
Newcastle	15	1	6.7	0.2	to	31.9	1.84	-0.93	to	14.8
Gt Ormond St	11	0	0	0.0	to	28.5	-1.00	-1.00	to	13.3
All centres	**26**	**1**	**3.8**	**0.1**	**to**	**19.6**				

[1] a) p>0.99 b) p>0.99
[2] expected mortality based on overall mortality for the period April 2005 to March 2008 (2.35%)

Table 22 **One-year survival after paediatric heart transplantation by centre *unadjusted* for patient risk**

a) *Whole audit period*

Centre	No cases	% survival	95%CI			Centre effect	95%CI		
Newcastle	149	93.8	88.4	to	96.7	-0.23	-0.65	to	0.45
Papworth	1	100.0				-1.00	-1.00	to	43.49
Harefield	34	82.2	64.7	to	91.6	1.38	-0.13	to	4.18
Birmingham	1								
Manchester	1	100.0				-1.00	-1.00	to	43.49
Glasgow	2	50.0	0.6	to	91.0	6.47	-0.81	to	40.60
Gt Ormond St	233	92.6	88.4	to	95.3	-0.07	-0.46	to	0.48
All centres	**421**	**92.0**	**89.0**	**to**	**94.3**				

b) *April 2001 – March 2010*

Centre	No cases	% survival	95%CI			Centre effect	95%CI		
Newcastle	86	94.2	86.6	to	97.5	0.19	-0.62	to	1.77
Harefield	1	100.0				-1.00	-1.00	to	72.02
Gt Ormond St	156	95.5	90.8	to	97.8	-0.09	-0.64	to	0.87
All centres	**243**	**95.1**	**91.5**	**to**	**97.2**				

Table 22 **continued**

c) *April 2007 – March 2010*

Centre	No cases	% survival	95%CI			Centre effect	95%CI		
Newcastle	40	92.5	78.5	to	97.5	-0.04	-0.80	to	1.81
Gt Ormond St	50	92.0	80.1	to	96.9	0.03	-0.72	to	1.64
All centres	**90**	**92.2**	**84.4**	**to**	**96.2**				

[1] a) p=0.06; b) p=0.64; c) p=0.93 (excluding centres with <5 cases)

Table 23 **Three-year survival after paediatric heart transplantation by centre *unadjusted* for patient risk**

a) *Whole audit period*

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	149	90.9	84.5	to	94.8	-0.35	-0.66	to	0.14
Papworth	1	100.0				-1.00	-1.00	to	23.6
Harefield	34	73.0	54.4	to	84.9	1.11	-0.03	to	3.01
Birmingham	1								
Manchester	1	100.0				-1.00	-1.00	to	23.6
Glasgow	2	50.0	0.6	to	91.0	3.98	-0.87	to	26.7
Gt Ormond St	233	85.4	79.8	to	89.5	0.04	-0.29	to	0.48
All centres	**421**	**86.1**	**82.1**	**to**	**89.2**				

b) *April 2001 – March 2010*

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	59	89.8	78.8	to	95.3	0.32	-0.52	to	1.86
Harefield	1	100.0				-1.00	-1.00	to	44.3
Gt Ormond St	119	93.2	86.9	to	96.6	-0.15	-0.63	to	0.68
All centres	**179**	**92.2**	**87.1**	**to**	**95.3**				

Table 23 continued

c) April 2005 – March 2008

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	31.0	87.1	69.2	to	95	0.57	-0.57	to	3.03
Harefield	1	100.0				-1.00	-1.00	to	41.9
Gt Ormond St	53.0	94.3	83.3	to	98.1	-0.31	-0.86	to	1.01
All centres	**85**	**91.7**	**83.4**	**to**	**96.0**				

[1] a) p=0.022; b) p=0.42; c) p=0.37 (excluding centres with <5 cases)

Table 24 Five-year survival after paediatric heart transplantation by centre *unadjusted* for patient risk

a) Whole Audit period

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	149	87.3	79.5	to	92.3	-0.33	-0.63	to	0.10
Papworth	1	100.0				-1.00	-1.00	to	17.0
Harefield	34	73.0	54.4	to	84.9	0.65	-0.25	to	2.12
Birmingham	1								
Manchester	1	100.0				-1.00	-1.00	to	17.0
Glasgow	2	50.0	0.6	to	91	2.91	-0.90	to	20.8
Gt Ormond St	233	79.1	72.4	to	84.4	0.10	-0.21	to	0.50
All centres	**421**	**81.4**	**76.8**	**to**	**85.2**				

b) April 2001 – March 2010

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	36	88.8	72.9	to	95.6	-0.04	-0.74	to	1.46
Harefield	1	100.0				-1.00	-1.00	to	29.0
Gt Ormond St	86	88.0	78.9	to	93.4	0.03	-0.51	to	0.89
All centres	**123**	**88.4**	**81.1**	**to**	**93.0**				

Table 24 **continued**

c) April 2005 – March 2010

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	20	90.0	65.6	to	97.4	-0.24	-0.91	to	1.76
Harefield	1	100.0				-1.00	-1.00	to	25.4
Gt Ormond St	49	85.1	71.2	to	92.6	0.12	-0.55	to	1.31
All centres	**70**	**86.9**	**76.2**	**to**	**92.9**				

[1] a) p=0.08; b) p=0.91; c) p=0.63 (excluding centres with <5 cases)

Table 25 **Ten-year survival after paediatric heart transplantation by centre *unadjusted* for patient risk**

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	149	80.9	70.8	to	87.8	-0.38	-0.63	to	-0.03
Papworth	1	0.0				3.52	-0.89	to	24.2
Harefield	34	59.1	39.9	to	74.0	0.48	-0.21	to	1.53
Birmingham	1								
Manchester	1	100.0				-1.00	-1.00	to	8.73
Glasgow	2	0.0				5.89	-0.17	to	23.9
Gt Ormond St	233	62.8	52.0	to	71.9	0.12	-0.17	to	0.46
All centres	**421**	**68.4**	**61.6**	**to**	**74.2**				

[1] p=0.027 (excluding centres with <5 cases)

Mortality rates by retrieval centre

Mortality rates at 30 and 90-days by retrieval centre, unadjusted for patient risk are shown in **Table 28**. Over the period April 2008 to March 2011 Great Ormond Street and Newcastle used a similar proportion of the hearts they retrieved for a "local" recipient (90% & 89% respectively). Overall, 50% of hearts retrieved were used for a "local" recipient. Three recipients died within 30-days in the three-year period to March 2011. Data for the last audit year are not reported separately.

Table 26 **One, three and five-year survival after paediatric heart transplantation by centre *unadjusted* for patient risk, for the subset of patients surviving beyond 30-days**

	No	*1-year*				*3-years*				*5-years*			
Centre	cases	% Survival[1]	95%CI			% Survival[2]	95%CI			% Survival[3]	95%CI		
Newcastle	146	95.7	90.7	to	98.0	92.8	86.5	to	96.2	89.1	81.3	to	93.8
Papworth	1	100.0				100.0				100.0			
Harefield	29	96.4	77.2	to	99.5	85.6	66.0	to	94.3	85.6	66.0	to	94.3
Birmingham	1												
Manchester	1	100.0				100.0				100.0			
Glasgow	2	50.0	0.6	to	91.0	50.0	0.6	to	91.0	50.0	0.6	to	91.0
Gt Ormond St	223	96.8	93.3	to	98.4	89.2	83.9	to	92.8	82.7	76.0	to	87.7
All centres	**403**	**96.1**	**93.7**	**to**	**97.7**	**89.9**	**86.2**	**to**	**92.7**	**85.1**	**80.5**	**to**	**88.7**

[1] p=0.86 (excluding centres with <5 cases)
[2] p=0.53 (excluding centres with <5 cases)
[3] p=0.46 (excluding centres with <5 cases)

Table 27 **Three and five-year survival after paediatric heart transplantation by centre *unadjusted* for patient risk, for the subset of patients surviving beyond 1-year**

	No	*3-years*				*5-years*			
Centre	cases	% Survival[1]	95%CI			% Survival[2]	95%CI		
Newcastle	111	97	90.9	to	99	93.1	85.2	to	96.9
Papworth	1	100.0				100.0			
Harefield	27	88.7	69	to	96.2	88.7	69	to	96.2
Manchester	1	100.0				100.0			
Glasgow	1	100.0				100.0			
Gt Ormond St	194	92.2	87.1	to	95.3	85.5	78.8	to	90.2
All centres	**335**	**93.5**	**90.1**	**to**	**95.8**	**88.5**	**84.1**	**to**	**91.8**

[1] [1] p=0.18 (excluding centres with <5 cases) [2] p=0.18 (excluding centres with <5 cases)

Figure 15 **Kaplan-Meier survival curves after paediatric heart transplantation by centre**

a) *Overall survival*

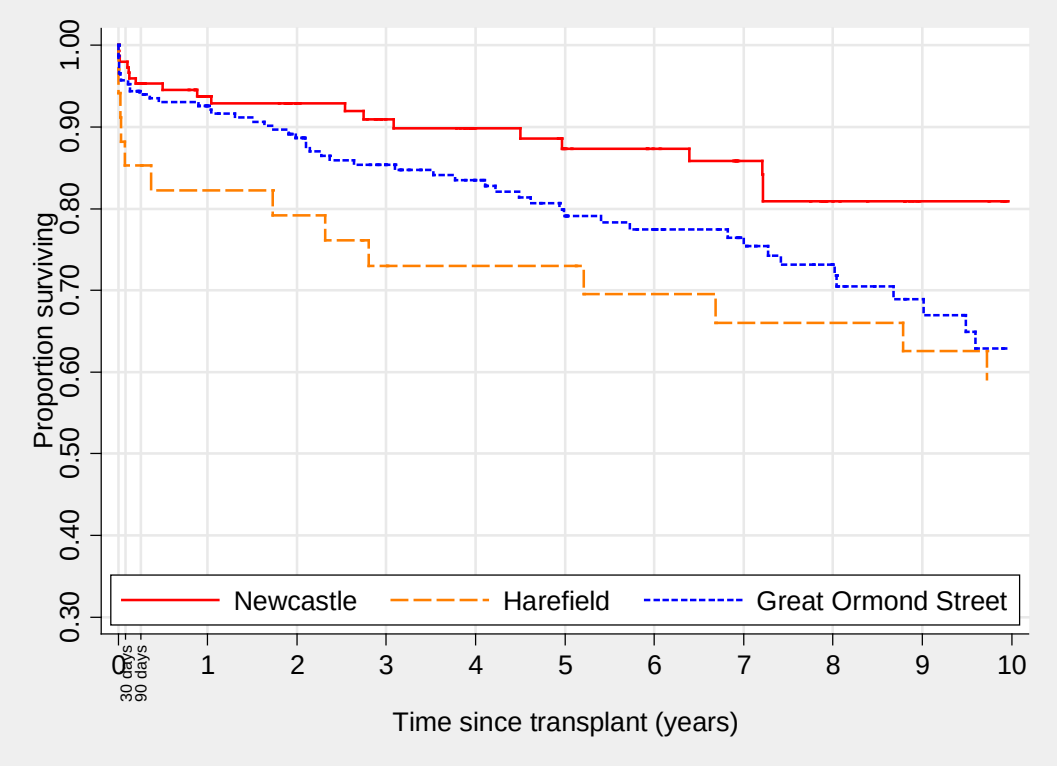
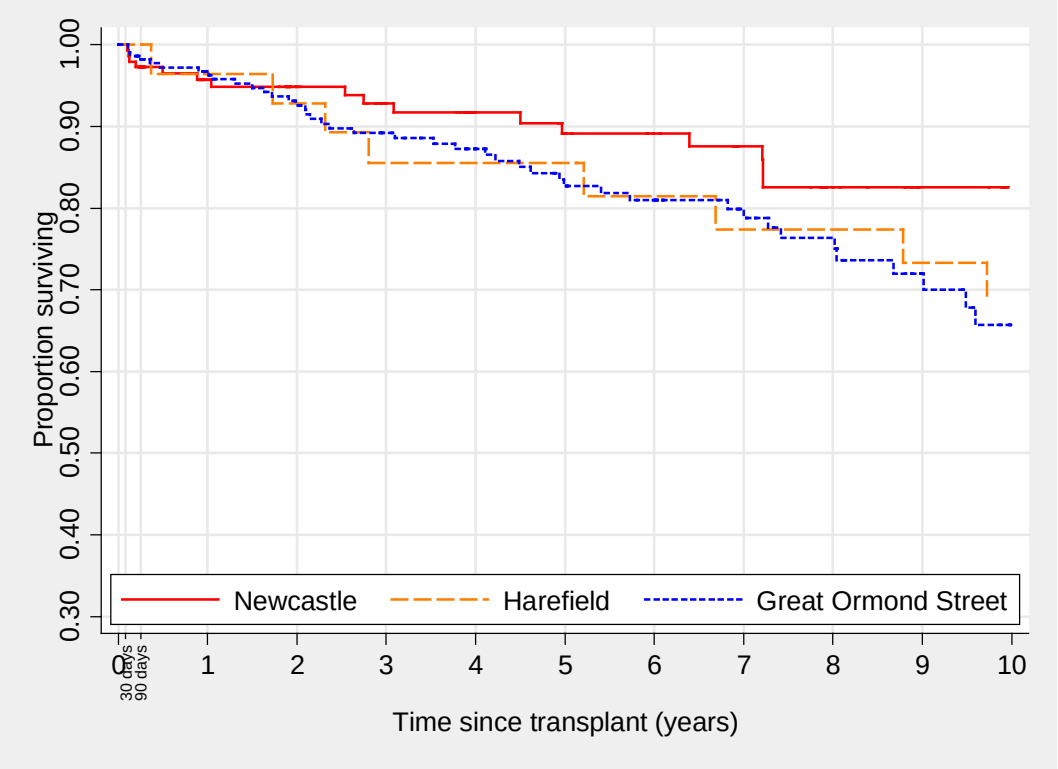


Figure 15 continued

b) Conditional survival: patients alive at 30 days



c) Conditional survival: patients alive at 1-year

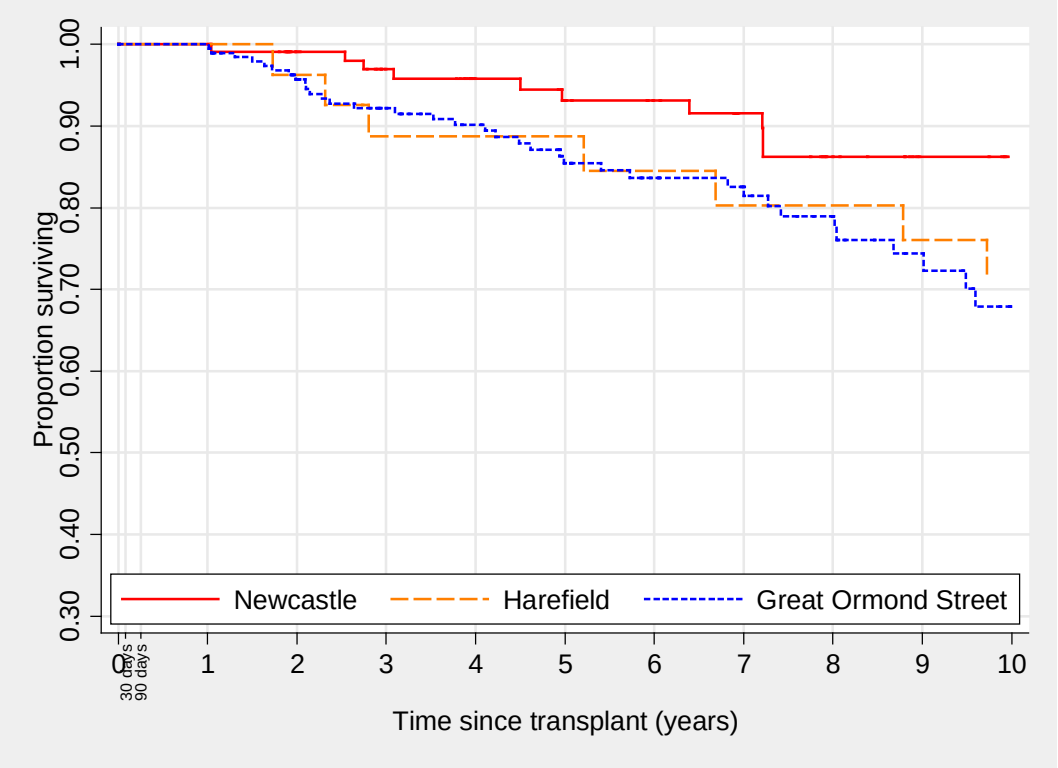
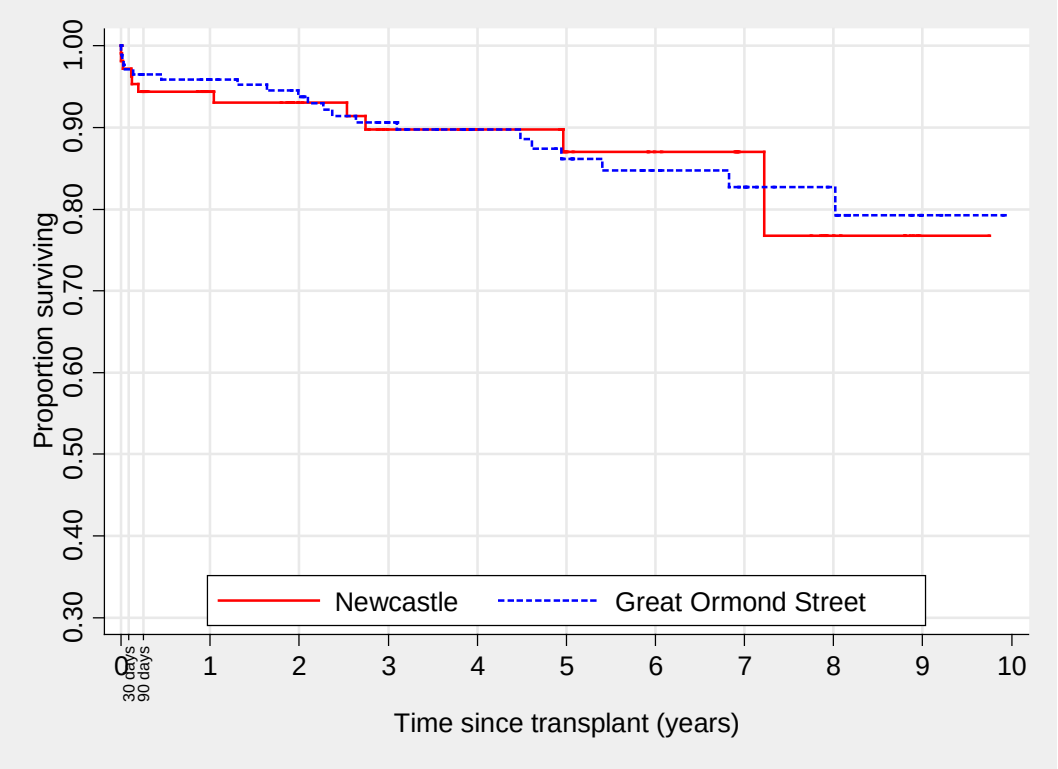


Figure 15 continued

d) Overall survival (transplants since April 2001)



Mortality rates by audit year

There was evidence of significant variation in the overall 30-day and 90-day mortality rate across the 16-year study period (Fisher's exact test, 30-day, $p<0.01$; 90-day, $p<0.01$). Longer-term survival to 1, 3, 5 and 10 years has also changed over time (log-rank test, $p<0.01$, $p=0.01$, $p=0.01$ and $p=0.01$ at 1, 3, 5 and 10-years respectively). Survival to 10 years by audit era shown in **Figure 16** shows clearly the high early mortality for transplants in the first two audit years (shown by the solid line) and the much reduced mortality for the more recent patient cohorts transplanted since April 2001.

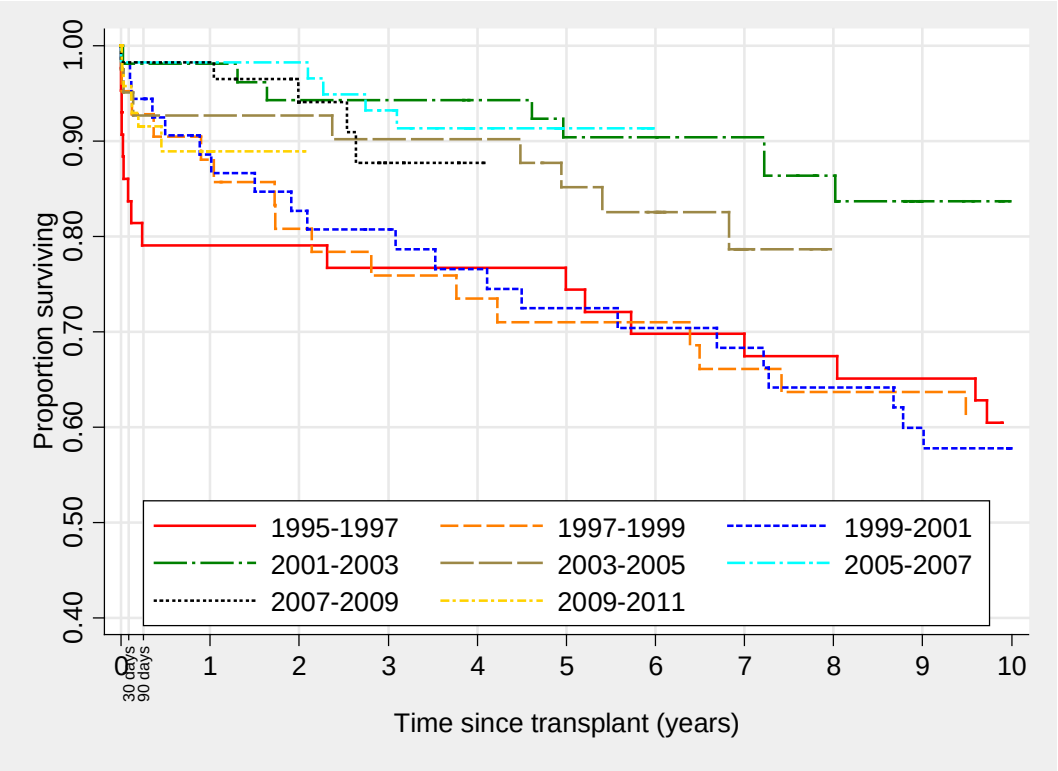
Table 28 30 and 90-day mortality after paediatric heart transplantation by retrieval centre *unadjusted* for patient risk

April 2008 – March 2011

Retrieval Centre	*30 days*						*90 days*						% used locally[4]
	No cases	No deaths	Mortality rate[1]	95%CI			No cases[5]	No deaths	Mortality rate[2]	95%CI			
Newcastle	37	1	2.7	0.1	to	14.2	34	4	11.8	3.3	to	27.5	89.2
Papworth	10	0	0.0	0.0	to	30.8	10	0	0.0	0.0	to	30.8	0.0
Harefield	9	0	0.0	0.0	to	33.6	9	0	0.0	0.0	to	33.6	0.0
Birmingham	8	0	0.0	0.0	to	36.9	5	0	0.0	0.0	to	52.2	12.5
Manchester	6	0	0.0	0.0	to	45.9	6	0	0.0	0.0	to	45.9	0.0
Glasgow	7	1	14.3	0.4	to	57.9	5	1	20.0	0.5	to	71.6	0.0
Gt Ormond St	20	1	5.0	0.1	to	24.9	16	1	6.3	0.2	to	30.2	90.0
Other[3]	6	0	0.0	0.0	to	52.2	5	0	0.0	0.0	to	60.2	0.0
All centres	**103**	**3**	**2.9**	**0.6**	**to**	**8.3**	**90**	**6**	**6.7**	**2.5**	**to**	**13.9**	**50.5**

[1] p=0.62
[2] p=0.79
[3] Republic of Ireland or other overseas centre
[4] Retrieved by the centre who carried out the transplant
[5] Transplants to December 2010

Figure 16 Kaplan-Meier survival curves after paediatric heart transplantation by era



Continuous monitoring of mortality

Observed – expected mortality

Observed – expected mortality charts, for 30-day and 90-day mortality after paediatric heart transplantation are shown in **Figure 17** and **Figure 18** respectively.

Tabular CUSUM charts

Tabular CUSUM charts for 30-day and 90-day mortality are shown in **Figure 19** and **Figure 20** respectively. Thirty day mortality rates after paediatric heart transplantation at Newcastle are consistent with the national average. However, in 2010, Newcastle experienced more deaths within 90 days than expected and the CUSUM chart signalled. The centre then conducted an internal review of their service.

Great Ormond Street Hospital also experienced more deaths than expected in 2009 and the CUSUM chart signalled. The centre then conducted a review of their service with an external expert. Note that the expected mortality rate for Great Ormond Street Hospital is very low due to no deaths after transplants between 2000 and 2003.

Figure 17 **Cumulative (observed – expected) 30-day mortality after paediatric heart transplantation unadjusted for patient risk, January 2004 to March 2011**

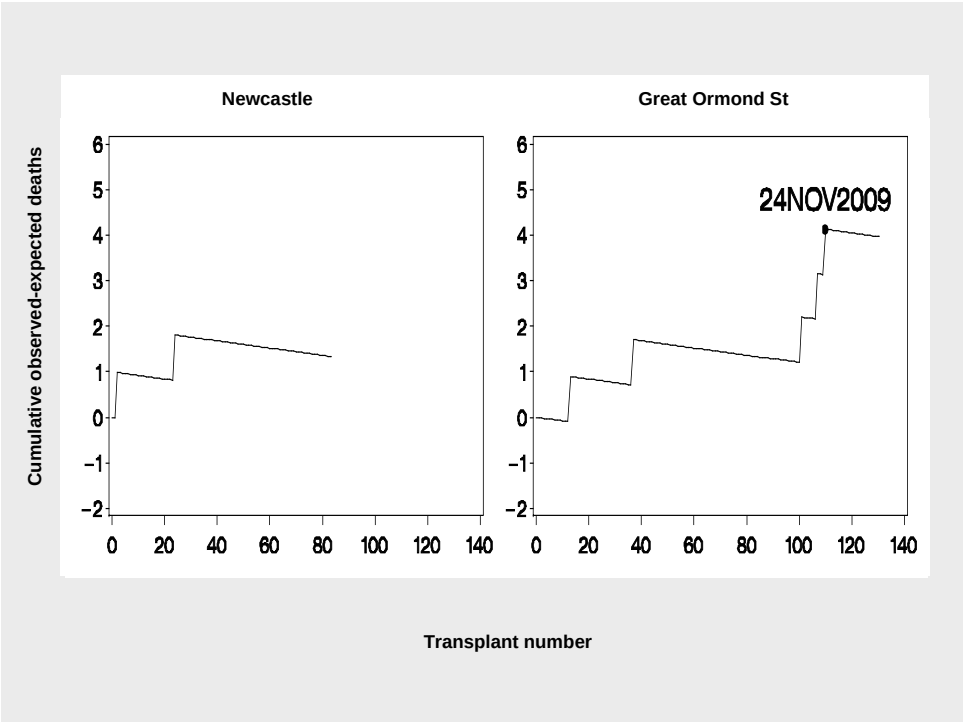


Figure 18 **Cumulative (observed – expected) 90-day mortality after paediatric heart transplantation unadjusted for patient risk, January 2004 to December 2010**

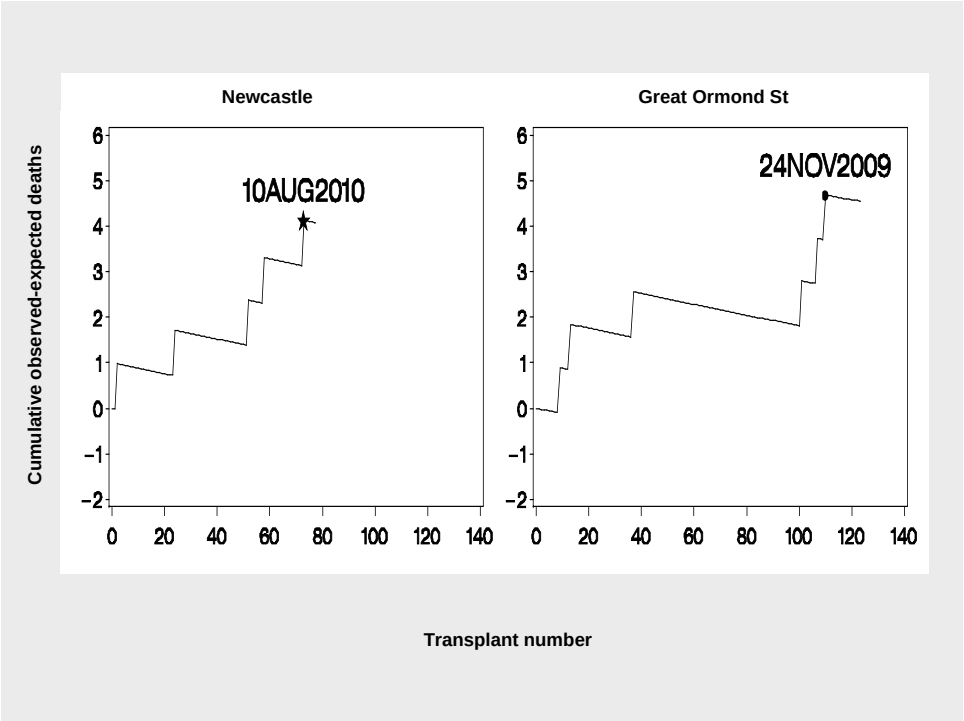


Figure 19 **Tabular CUSUM for 30-day mortality after paediatric heart transplantation unadjusted for patient risk, January 2004 to March 2011**

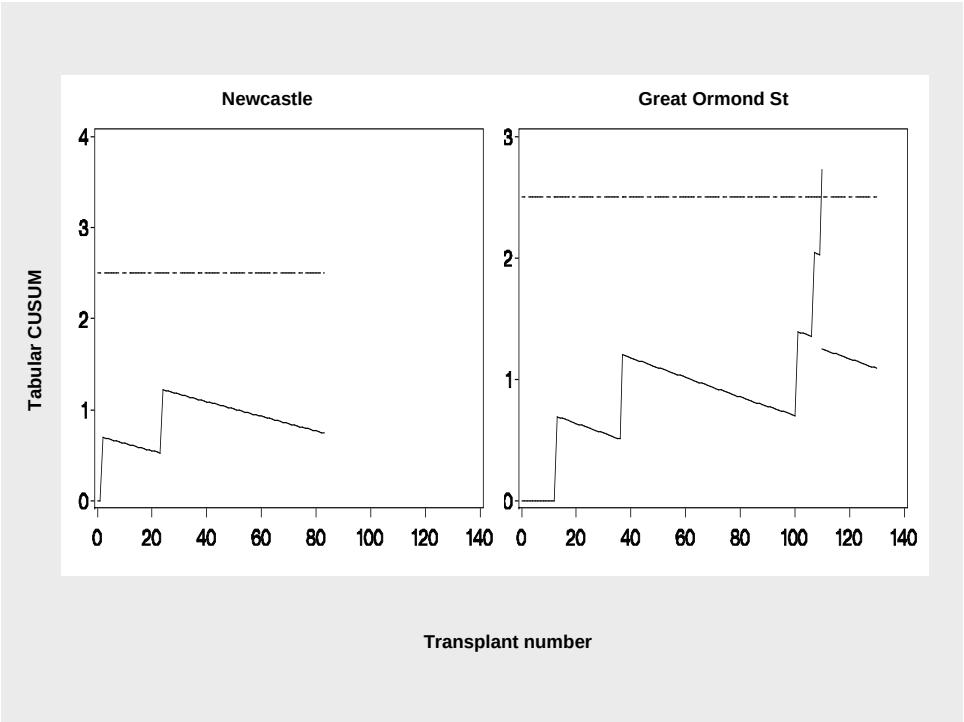
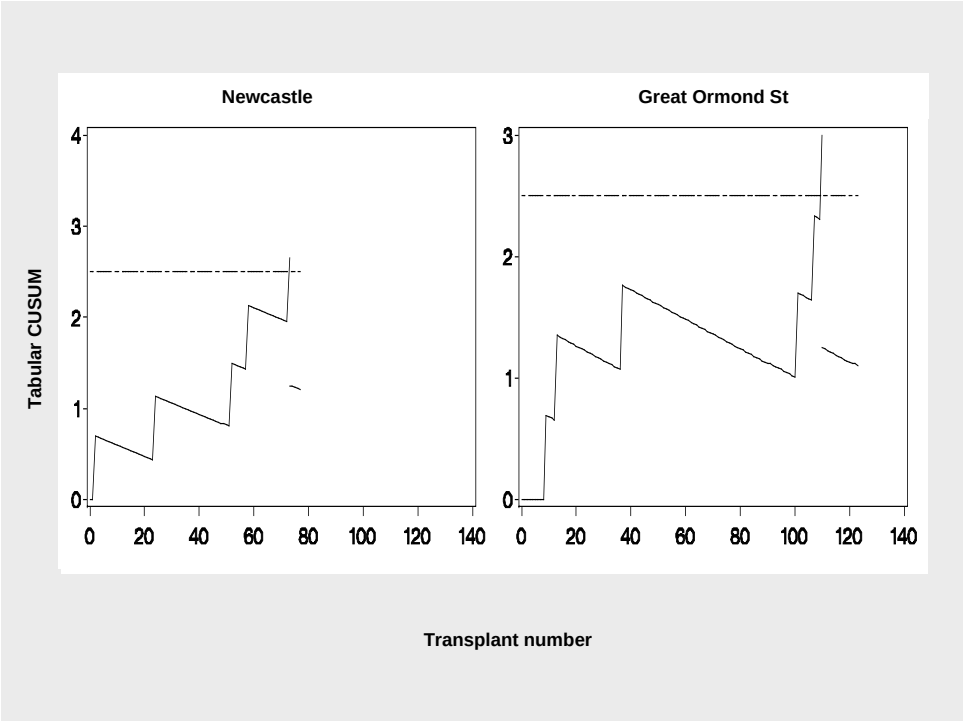


Figure 20 **Tabular CUSUM for 90-day mortality after paediatric heart transplantation unadjusted for patient risk, January 2004 to December 2010**



6. RESULTS - ADULT LUNG TRANSPLANTATION

Transplant activity

Lung transplantation activity in the UK increased in 2010/11 with 166 transplants reported, 26 more than the previous year **(Figure 21**). Overall, there have been 1,081 bilateral sequential lung grafts (51.4%), 649 (30.9%) single lung and 323 (15.4%) heart-lung transplants reported. The remaining 48 transplants were double lung grafts. Since April 2006 the number of bilateral sequential lung grafts has increased to 72.3% of the total activity (494 transplants) while the heart-lung transplant programme has decreased (24 transplants, 3.5%). In the last year just 6 heart lung procedures were carried out.

Unadjusted mortality rates

Overall mortality

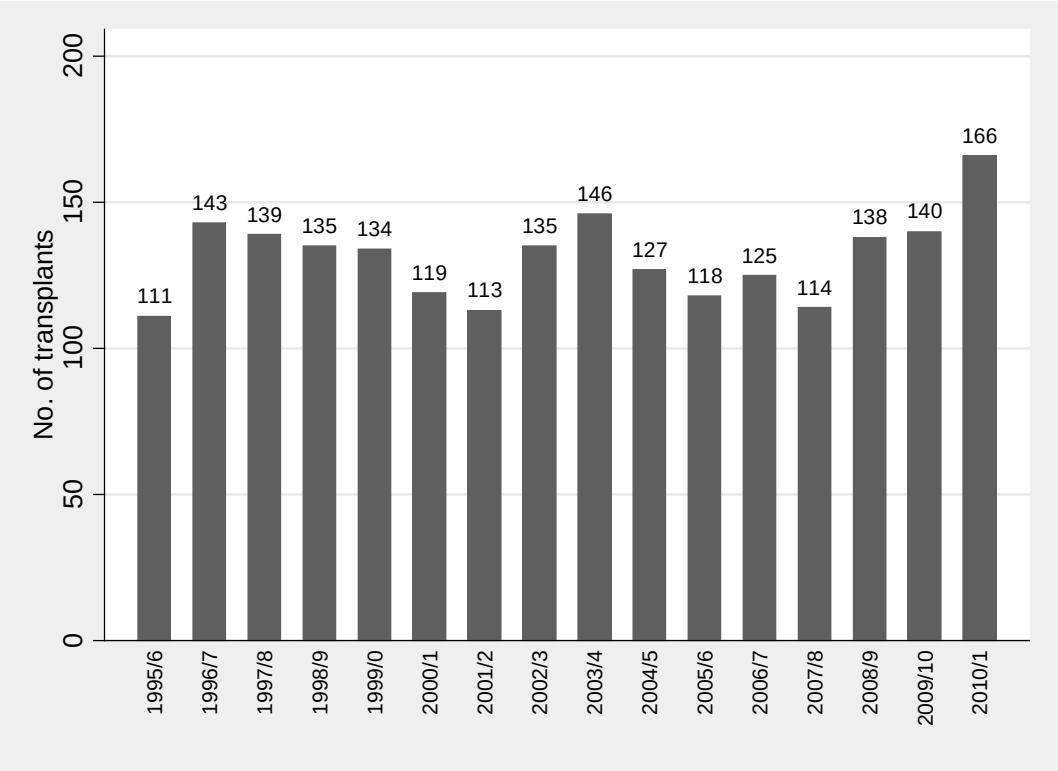
The overall 30-day and 90-day mortality rates for the whole cohort are 10.1% (95%CI 8.9% to 11.5%) and 15.1% (95%CI 13.6% to 16.8%). Overall, 213 patients died within the first 30 days after transplantation and a further 98 died between 30 and 90 days. 30-day and 90-day mortality in the period since April 2008 was 6.8% (95%CI 4.6% to 9.5%) and 9.9% (95%CI 7.2% to 13.3%) respectively. There were 30 deaths within 30 days and 10 reported deaths between 30 and 90 days respectively (**Table 29** and **Table 30**).

Over the last year, April 2010 to March 2011, mortality rates were 7.8% (95%CI 4.2% to 13.0%) at 30-days and 13.2% (95%CI 7.6% to 20.8%) at 90-days (transplants to December 2010 only). The trend in early mortality over time is shown in **Figure 22,** which shows the moving average estimates of overall mortality based on approximate 6 months activity.

The 1-year survival for the whole cohort was 76.0% (95%CI 74.1% to 77.8%), with 81.5% (95%CI 77.2% to 85.0%) of the April 2007 to March 2010 cohort surviving to 1 year. Overall, 61.8% (95%CI 59.5% to 64.0%) of recipients survived to 3-years after their transplant and 51.7% (95%CI 49.2% to 54.0%) survived to 5 years. 31.8% (95%CI 29.1% to 34.6%) were alive at 10-years **(Table 31** to **Table 34**).

Figure 21 Adult lung transplants by audit year

a) Overall



b) By transplant centre

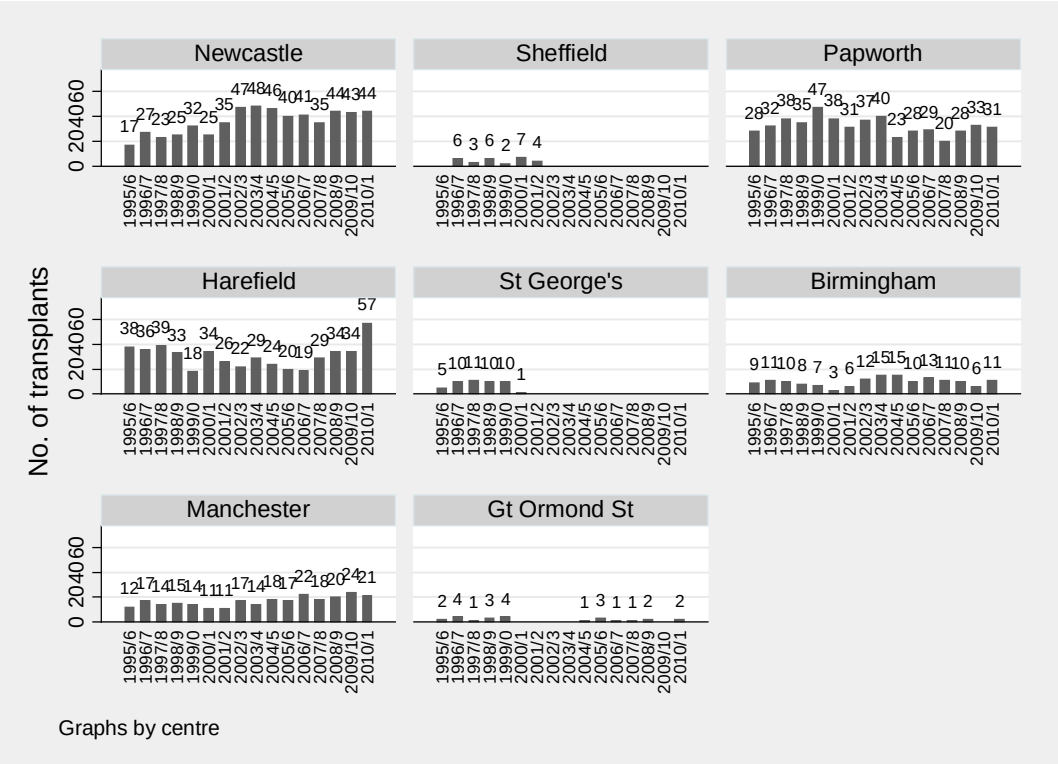
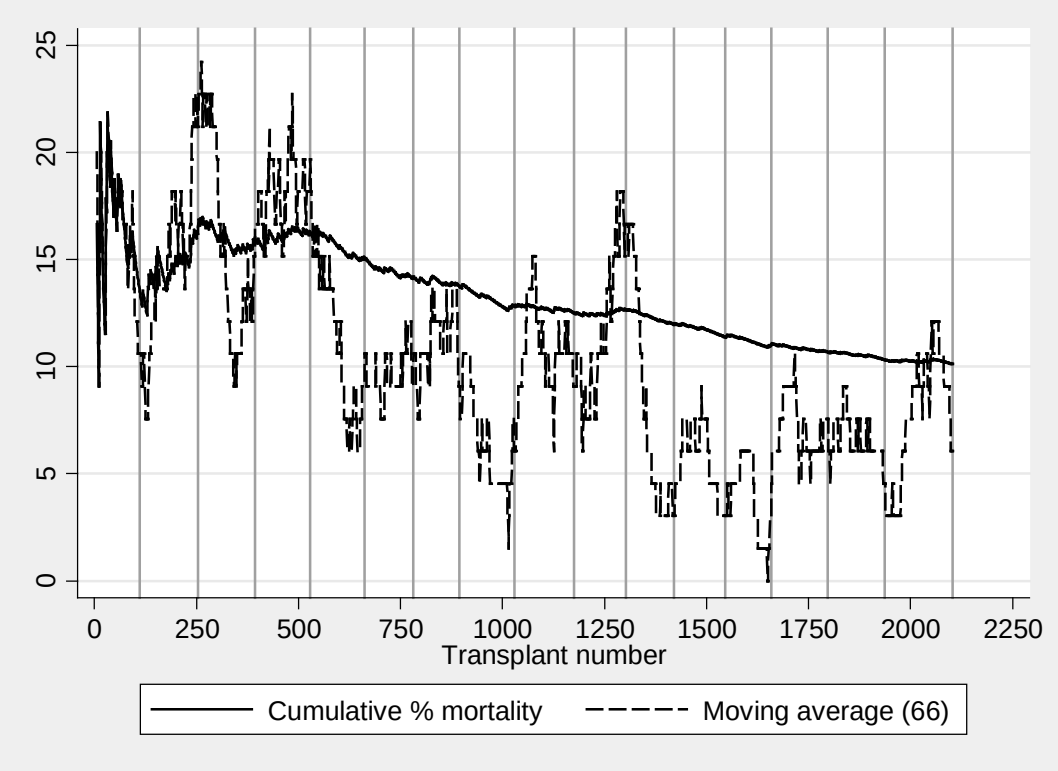
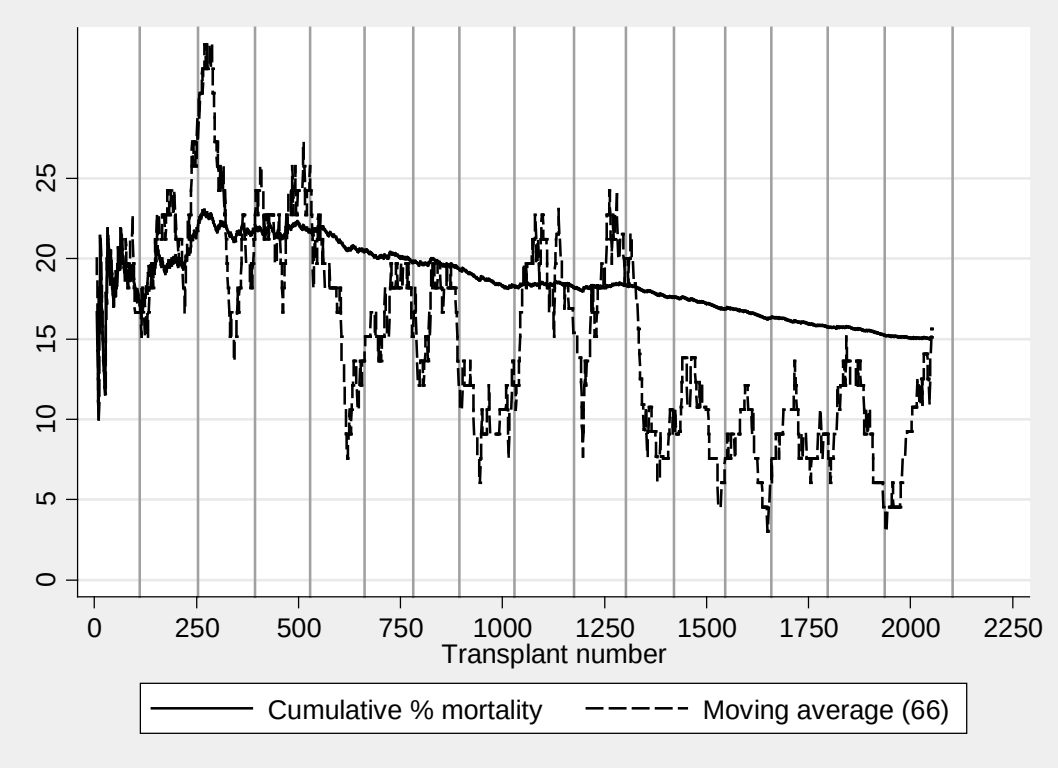


Figure 22 Mortality after adult lung transplantation over time

a) 30-day



b) 90-day



Note: Vertical lines represent the start of each audit year

Mortality rates by transplant centre

Centre specific mortality rates, unadjusted for patient risk are shown in **Table 29** to **Table 36**. For completeness, the transplants in patients aged 16 or over carried out at Great Ormond Street are included. Centre specific 30-day mortality rates since April 2008 varied across centres (Fisher's exact test, p=0.0.075), with mortality rates ranging from 0.0% to 18.5%. Centre effect estimates highlight Birmingham as the divergent centre, with a significantly higher mortality rate than expected, based on the overall mortality for the three years 2005 to 2008. Over the 12-months to March 2011 the mortality rate was 7.8% across all centres (Fisher's exact test, p=0.622).

90-day mortality rates since April 2008 varied across centres (Fisher's test, p=0.086). In contrast, the variability in the 90-day mortality rate for transplants in the 9-months to December 2010 was similar across the centres (p=0.58).

Table 29 **30-day mortality after adult lung transplantation by centre *unadjusted* for patient risk**

a) April 2008 – March 2011

Centre	No cases	No deaths	Mortality rate[1]	95%CI			Centre effect[2]	95%CI		
Newcastle	131	11	8.4	4.3	to	14.5	0.67	-0.17	to	1.98
Papworth	92	7	7.6	3.1	to	15.1	0.51	-0.39	to	2.11
Harefield	125	6	4.8	1.8	to	10.2	-0.05	-0.65	to	1.07
Birmingham	27	5	18.5	6.3	to	38.1	2.67	0.19	to	7.57
Manchester	65	1	1.5	0.0	to	8.3	-0.69	-0.99	to	0.70
Gt Ormond St	4	0	0.0	0.0	to	60.2	-1.00	-1.00	to	17.3
All centres	**444**	**30**	**6.8**	**4.6**	**to**	**9.5**				

Table 29 continued

b) April 2010 – March 2011

Centre	No cases	No deaths	Mortality rate[1]	95%CI			Centre effect[2]	95%CI		
Newcastle	44	5	11.4	3.8	to	24.6	1.25	-0.27	to	4.26
Papworth	31	4	12.9	3.6	to	29.8	1.56	-0.30	to	5.56
Harefield	57	3	5.3	1.1	to	14.6	0.04	-0.78	to	2.05
Birmingham	11	0	0.0	0.0	to	28.5	-1.00	-1.00	to	5.65
Manchester	21	1	4.8	0.1	to	23.8	-0.06	-0.98	to	4.26
Gt Ormond St	2	0	0.0	0.0	to	84.2	-1.00	-1.00		35.6
All centres	**166**	**13**	**7.8**	**4.2**	**to**	**13.0**				

[1] a) p=0.075; b) p=0.622
[2] expected mortality based on overall mortality for the period April 2005 to March 2008 (5.04%)

Table 30 90-day mortality after adult lung transplantation by centre unadjusted for patient risk

a) April 2008 – December 2010

Centre	No cases	No deaths	Mortality rate[1]	95%CI			Centre effect[2]	95%CI		
Newcastle	115	15	13.0	7.5	to	20.6	0.44	-0.20	to	1.37
Papworth	83	8	9.6	4.3	to	18.1	0.06	-0.54	to	1.08
Harefield	111	10	9.0	4.4	to	15.9	0.00	-0.52	to	0.84
Birmingham	24	5	20.8	7.1	to	42.2	1.31	-0.25	to	4.40
Manchester	55	1	1.8	0.0	to	9.7	-0.80	-0.99	to	0.12
Gt Ormond St	4	0	0.0	0.0	to	60.2	-1.00	-1.00	to	9.24
All centres	**392**	**39**	**9.9**	**7.2**	**to**	**13.3**				

Table 30 continued

b) April 2010 – December 2010

Centre	No cases	No deaths	Mortality rate[1]	95%CI			Centre effect[2]	95%CI		
Newcastle	28	6	21.4	8.3	to	41.0	1.30	-0.16	to	4.00
Papworth	22	4	18.2	5.2	to	40.3	0.93	-0.47	to	3.94
Harefield	43	4	9.3	2.6	to	22.1	0.03	-0.72	to	1.64
Birmingham	8	0	0.0	0.0	to	36.9	-1.00	-1.00	to	4.12
Manchester	11	1	9.1	0.2	to	41.3	0.01	-0.97	to	4.62
Gt Ormond St	2	0	0.0	0.0	to	84.2	-1.00	-1.00		19.5
All centres	**114**	**15**	**13.2**	**7.6**	**to**	**20.8**				

[1] a) p=0.086; b) p=0.58
[2] expected mortality based on overall mortality for the period April 2005 to March 2008 (9.01%)

Table 31 One-year survival after adult lung transplantation by centre *unadjusted* for patient risk

a) Whole audit period

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	572	80.9	77.4	to	84.0	-0.21	-0.36	to	-0.05
Sheffield	28	78.6	58.4	to	89.8	-0.09	-0.67	to	0.98
Papworth	518	72.3	68.2	to	76.0	0.17	-0.01	to	0.38
Harefield	492	77.3	73.3	to	80.8	-0.04	-0.22	to	0.16
St George's	47	55.3	40.1	to	68.1	1.23	0.38	to	2.40
Birmingham	157	68.6	60.6	to	75.3	0.33	-0.02	to	0.77
Manchester	265	77.6	72.0	to	82.3	-0.11	-0.33	to	0.15
Gt Ormond St	24	87.1	65.0	to	95.7	-0.49	-0.90	to	0.49
All centres	**2103**	**76.0**	**74.1**	**to**	**77.8**				

Table 31 continued

b) April 2007 – March 2010

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	122	83.5	75.6	to	89.0	-0.07	-0.43	to	0.43
Papworth	81	81.9	71.3	to	88.9	-0.05	-0.48	to	0.60
Harefield	97	86.5	77.9	to	92.0	-0.27	-0.61	to	0.25
Birmingham	27	55.6	35.2	to	71.8	1.91	0.50	to	4.08
Manchester	62	80.0	67.4	to	88.1	-0.01	-0.49	to	0.73
Gt Ormond St	3	100.0				-1.00	-1.00	to	5.02
All centres	**392**	**81.5**	**77.2**	**to**	**85.0**				

[1] a) p<0.01; b) p=0.004

Table 32 Three-year survival after adult lung transplantation by centre *unadjusted* for patient risk

a) Whole audit period

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	572	69.5	65.2	to	73.4	-0.23	-0.35	to	-0.10
Sheffield	28	67.9	47.3	to	81.8	-0.18	-0.62	to	0.56
Papworth	518	55.5	50.9	to	59.9	0.21	0.05	to	0.38
Harefield	492	63.7	58.8	to	68.1	-0.05	-0.19	to	0.11
St George's	47	46.8	32.2	to	60.2	0.76	0.14	to	1.60
Birmingham	157	52.4	43.9	to	60.2	0.34	0.04	to	0.69
Manchester	265	62.3	55.7	to	68.3	-0.06	-0.24	to	0.16
Gt Ormond St	24	66.2	41.5	to	82.4	-0.20	-0.68	to	0.64
All centres	**2103**	**61.8**	**59.5**	**to**	**64**				

Table 32 continued

b) April 2005 – March 2008

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	116	76.7	67.4	to	83.7	-0.35	-0.58	to	-0.03
Papworth	77	51.2	39.4	to	61.8	0.51	0.06	to	1.08
Harefield	68	73.5	61.3	to	82.4	-0.25	-0.56	to	0.18
Birmingham	34	52.9	35.1	to	67.9	0.59	-0.09	to	1.57
Manchester	57	64.9	51.1	to	75.7	-0.02	-0.40	to	0.51
Gt Ormond St	5	40.0	5.2	to	75.3	0.84	-0.62	to	4.38
All centres	**357**	**65.6**	**60.3**	**to**	**70.4**				

[1] a) p<0.01; b) p<0.011

Table 33 Five-year survival after adult lung transplantation by centre *unadjusted* for patient risk

a) Whole Audit Period

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	572	59.1	54.1	to	63.7	-0.21	-0.32	to	-0.09
Sheffield	28	60.7	40.4	to	76.0	-0.22	-0.61	to	0.39
Papworth	518	44.9	40.1	to	49.5	0.21	0.06	to	0.36
Harefield	492	55.7	50.5	to	60.5	-0.08	-0.21	to	0.06
St George's	47	42.6	28.4	to	56.0	0.49	-0.02	to	1.17
Birmingham	157	41.4	32.9	to	49.8	0.33	0.05	to	0.65
Manchester	265	49.1	42.0	to	55.8	0.00	-0.18	to	0.21
Gt Ormond St	24	54.2	29.7	to	73.4	-0.15	-0.61	to	0.62
All centres	**2103**	**51.7**	**49.2**	**to**	**54.0**				

Table 33 continued

b) April 2003 – March 2006

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	134	57.0	47.7	to	65.3	-0.09	-0.32	to	0.20
Papworth	91	47.9	37.2	to	57.8	0.20	-0.12	to	0.59
Harefield	73	53.4	41.4	to	64.1	0.03	-0.29	to	0.44
Birmingham	40	50.0	33.8	to	64.2	0.13	-0.31	to	0.74
Manchester	49	60.9	45.8	to	73.0	-0.21	-0.53	to	0.23
Gt Ormond St	4	75.0	12.8	to	96.1	-0.49	-0.99	to	1.84
All centres	**391**	**54.1**	**48.9**	**to**	**59.0**				

[1]p<0.01; b) p=0.61

Table 34 Ten-year survival after adult lung transplantation by centre *unadjusted* for patient risk

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	572	41.4	35.4	to	47.2	-0.21	-0.31	to	-0.11
Sheffield	28	39.3	21.7	to	56.5	-0.17	-0.52	to	0.32
Papworth	518	27.3	22.5	to	32.3	0.17	0.04	to	0.31
Harefield	492	37.4	31.7	to	43.1	-0.11	-0.22	to	0.02
St George's	47	22.5	11.7	to	35.3	0.43	0.00	to	0.97
Birmingham	157	20.6	11.2	to	31.9	0.31	0.06	to	0.60
Manchester	265	20.1	13.5	to	27.8	0.12	-0.06	to	0.31
Gt Ormond St	24	24.1	4.7	to	51.6	-0.05	-0.51	to	0.65
All centres	**2103**	**31.8**	**29.1**	**to**	**34.6**				

[1] p<0.01

For the cohort as a whole, there was evidence of significant variation in the 1, 3, 5 and 10-year unadjusted mortality rates across centres (p<0.01 for 1, 3, 5 and 10-year survival, log rank test). The centre effect estimates highlight Newcastle, St George's, Papworth and Birmingham as the divergent centres; Newcastle with a higher than expected survival and St George's, Papworth and Birmingham with a low survival rate; however, these estimates are not adjusted for risk. St George's last transplant was in September 2000 (**Figure 23**(a)).

For the recent cohort transplanted between April 2007 and March 2010 (392 transplants) there was evidence to suggest 1-year unadjusted survival rates differed between adult centres (p=0.004), with Birmingham identified as the divergent centre with a higher than expected unadjusted mortality rate. In contrast, the analysis the 3-year survival rate for the cohort transplanted between April 2005 and March 2008 (357 transplants), identified Papworth and Newcastle as the divergent centres, with a higher and lower than expected unadjusted mortality rates respectively.

Survival curves for the subset of patients who lived beyond 30-days and beyond 1-year are shown in **Figure 23**(b) and **Figure 23**(c) respectively. There was evidence of significant variation between centres for all subsets (post 30-day survivors, p=<0.01 for 1, 3 and 5 years). There was a 18.4% and a 16.9% difference between the centres with the highest and lowest 5-year conditional unadjusted survival estimates for the post-30-day and post-1-year survivors respectively (**Table 35** and **Table 36**).

Figure 23 Kaplan-Meier survival curves after adult lung transplantation by centre

a) Overall survival

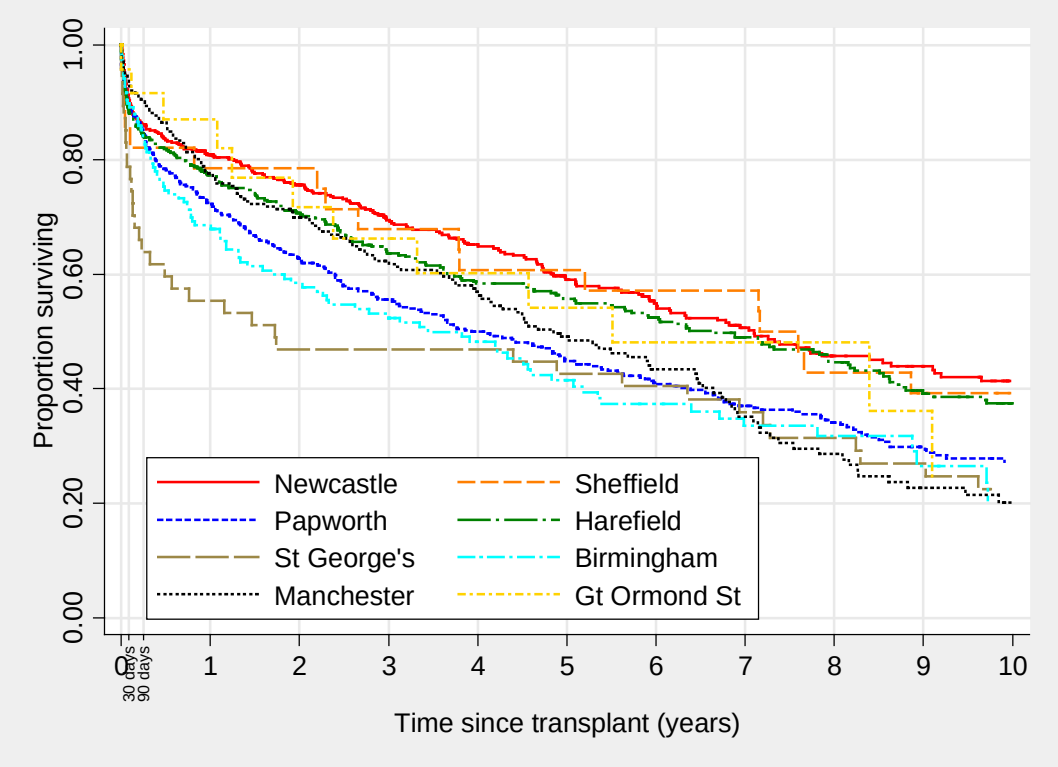
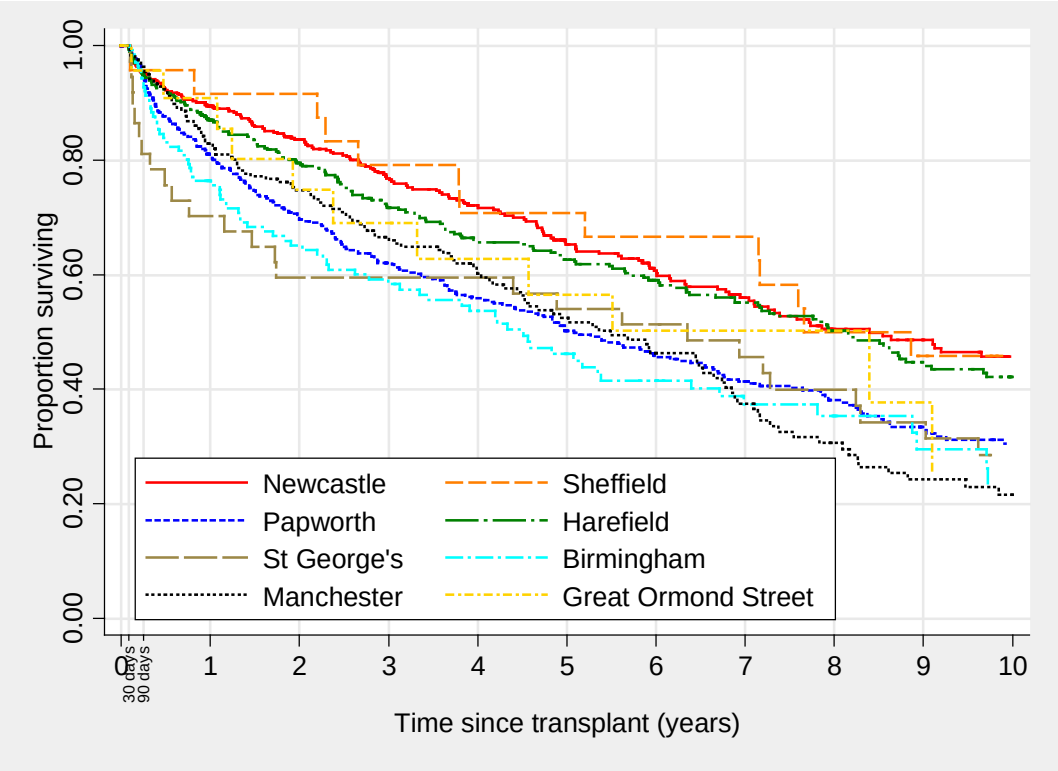


Figure 23 continued

b) For patients alive at 30 days



c) For patients alive at 1-year

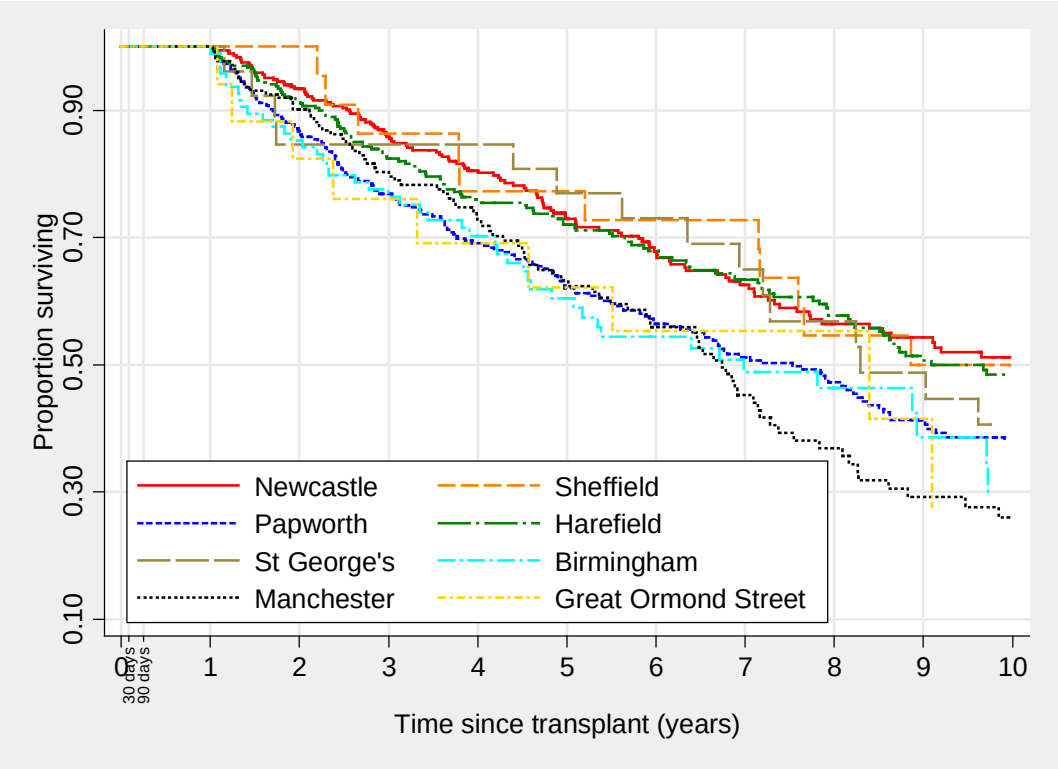


Table 35 **One, three and five-year survival after adult lung transplantation by centre *unadjusted* for patient risk, for the subset of patients surviving beyond 30-days**

	No	*1-year*				*3-years*				*5-years*			
Centre	cases	% Survival[1]	95%CI			% Survival[2]	95%CI			% Survival[3]	95%CI		
Newcastle	514	89.6	86.5	to	92.0	76.9	72.5	to	80.7	65.3	60.1	to	70.1
Sheffield	24	91.7	70.6	to	97.8	79.2	57.0	to	90.8	70.8	48.4	to	84.9
Papworth	463	80.9	76.9	to	84.2	62.1	57.2	to	66.6	50.2	45.1	to	55.1
Harefield	437	87.0	83.4	to	90.0	71.7	66.7	to	76.1	62.7	57.2	to	67.7
St George's	37	70.3	52.8	to	82.3	59.5	42.0	to	73.2	54.1	36.9	to	68.4
Birmingham	141	76.4	68.3	to	82.7	58.3	49.3	to	66.4	46.1	36.8	to	55.0
Manchester	248	82.9	77.5	to	87.2	66.6	59.8	to	72.6	52.4	45.0	to	59.3
Gt Ormond St	23	90.9	68.1	to	97.6	69.1	43.4	to	84.9	56.5	31.0	to	75.7
All centres	**1887**	**84.6**	**82.8**	**to**	**86.2**	**68.8**	**66.4**	**to**	**71.0**	**57.5**	**54.9**	**to**	**60.0**

[1] p<0.01 [2] p<0.01 [3] p<0.01

Table 36 **Three and five-year survival after adult lung transplantation by centre *unadjusted* for patient risk, for the subset of patients surviving beyond 1-year**

	No	*3-years*				*5-years*			
Centre	cases	% Survival[1]	95%CI			% Survival[2]	95%CI		
Newcastle	384	85.9	81.7	to	89.2	73.0	67.5	to	77.7
Sheffield	22	86.4	63.4	to	95.4	77.3	53.7	to	89.8
Papworth	337	76.8	71.7	to	81.1	62.1	56.2	to	67.3
Harefield	309	82.4	77.4	to	86.3	72.0	66.2	to	77.0
St George's	26	84.6	64.0	to	93.9	76.9	55.7	to	88.9
Birmingham	98	76.4	66.4	to	83.8	60.4	49.0	to	70.0
Manchester	177	80.3	73.3	to	85.7	63.2	54.8	to	70.5
Gt Ormond St	19	76.0	48.0	to	90.3	62.2	34.1	to	81.1
All centres	**1372**	**81.3**	**79.0**	**to**	**83.4**	**67.9**	**65.1**	**to**	**70.6**

[1] p=0.04 [2] p<0.01

Mortality rates by retrieval centre

Mortality rates at 30 and 90-days by retrieval centre, unadjusted for patient risk are shown in **Table 37.** A greater proportion of lungs were used locally compared to the adult heart programme (64.9% vs. 51.1%). Birmingham was the only lung transplant centre in the last three years to use less than half the lungs they retrieved for a local recipient.

Of the six centres retrieving lungs from more than five adults, the unadjusted 30-day mortality rate since April 2008 was lowest for lungs retrieved by the Manchester team (3.8%) and greatest from those retrieved by Glasgow (12.9%). 90-day mortality rates showed a similar pattern. Neither the 30 nor 90-day mortality rate varied significantly by retrieval centre (Fisher's exact test, 30-day: p=0.75; 90-day: p=0.43). Mortality rates in the last year also showed no statistically significant variation by retrieval centre (Fisher's exact test, 30-day: p=0.66; 90-day: p=0.20).

Mortality rates by audit year

As indicated in **Figure 22** 30-day mortality has changed significantly over time (p<0.001). Similarly significant variation in 90-day mortality was found (p<0.001). Longer-term survival to 1, 3, 5 and 10 years has also changed significantly over time (trend test, p<0.01). Survival to 10 years by audit era is shown in **Figure 24.**

Mortality rates by lung type

Survival to 10-years by type of transplant is shown in **Figure 25.** Survival was highest for patients given a bilateral sequential lung transplant and lowest for those who had a single lung. Survival varied significantly across the four patient groups (p<0.001), but the differences may decrease when patient risk is accounted for.

Table 37 30 and 90-day mortality after adult lung transplantation by retrieval centre *unadjusted* for patient risk

a) April 2008 – March 2011

Retrieval Centre	No cases	*30 days*					No cases[5]	*90 days*					% used locally[4]	% DCD donors[6]
		No deaths	Mortality rate[1]	95%CI				No deaths	Mortality rate[2]	95%CI				
Newcastle	107	7	6.5	2.7	to	13.0	94	11	11.7	6.0	to	20.0	73.8	15.9
Papworth	106	8	7.5	3.3	to	14.3	98	10	10.2	5.0	to	18.0	71.7	4.7
Harefield	93	5	5.4	1.8	to	12.1	84	7	8.3	3.4	to	16.4	87.1	24.7
Birmingham	53	4	7.5	2.1	to	18.2	44	4	9.1	2.5	to	21.7	34.0	0.0
Manchester	52	2	3.8	0.5	to	13.2	42	2	4.8	0.6	to	16.2	65.4	7.7
Glasgow	31	4	12.9	3.6	to	29.8	29	5	17.2	5.8	to	35.8	0.0	0.0
Other[3]	2	0	0.0	0.0	to	84.2	1	0	0.0	0.0	to	97.5	0.0	0.0
All centres	**444**	**30**	**6.8**	**4.6**	**to**	**9.5**	**392**	**39**	**9.9**	**7.2**	**to**	**13.3**	**64.9**	**11.0**

Table 37 continued

b) April 2010 – March 2011

Retrieval Centre	No cases	*30 days*					No cases[5]	*90 days*					% used locally[4]	% DCD donors[6]
		No deaths	Mortality rate[1]	95%CI				No deaths	Mortality rate[2]	95%CI				
Newcastle	37	3	8.1	1.7	to	21.9	24	4	16.7	4.7	to	37.4	75.7	18.9
Papworth	32	3	9.4	2.0	to	25.0	24	5	20.8	7.1	to	42.2	75.0	9.4
Harefield	39	4	10.3	2.9	to	24.2	30	4	13.3	3.8	to	30.7	89.7	28.2
Birmingham	24	0	0.0	0.0	to	14.2	15	0	0.0	0.0	to	21.8	33.3	0.0
Manchester	23	1	4.3	0.1	to	21.9	13	0	0.0	0.0	to	24.7	52.2	4.3
Glasgow	10	2	20.0	2.5	to	55.6	8	2	25.0	3.2	to	65.1	0.0	0.0
Other[3]	1	0	0.0	0.0	to	97.5	0	0			to		0.0	0.0
All centres	**166**	**13**	**7.8**	**4.2**	**to**	**13.0**	**114**	**15**	**13.2**	**7.6**	**to**	**20.8**	**64.5**	**13.3**

[1] a) p=0.75; b) p=0.43
[2] a) p=0.66; b) p=0.20
[3] Republic of Ireland or other overseas centre
[4] Retrieved by the centre who carried out the transplant
[5] Transplants to December 2010
[6] Donation after circulatory death

Figure 24 **Kaplan-Meier survival curves after adult lung transplantation by era**

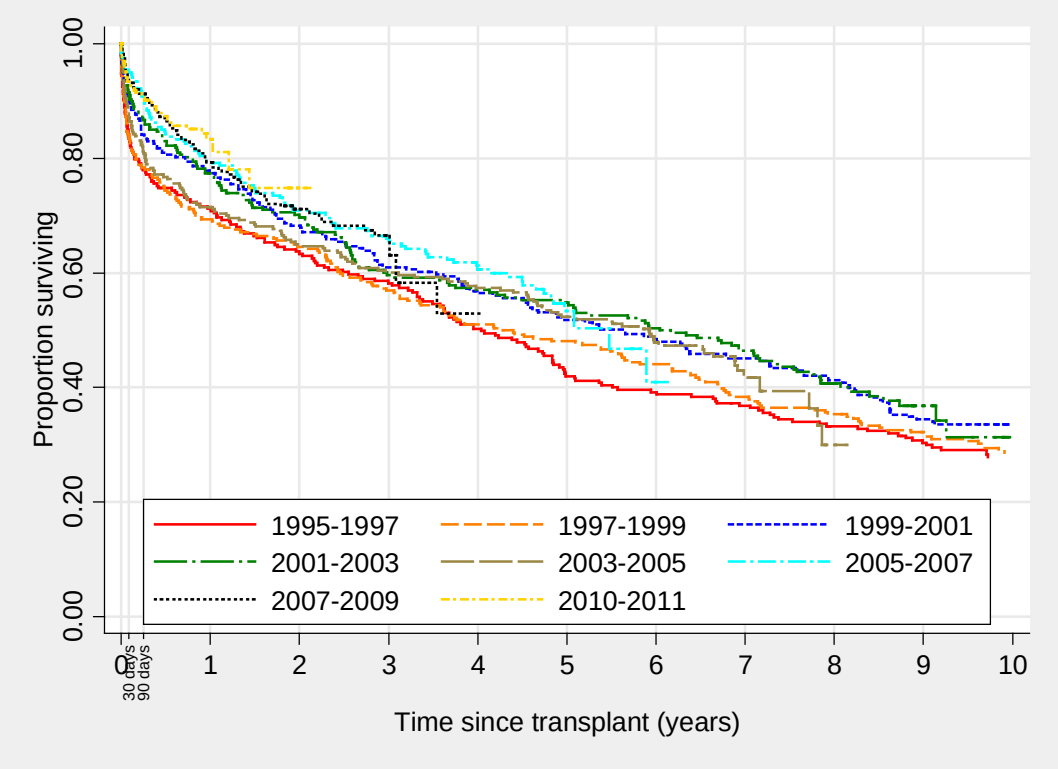
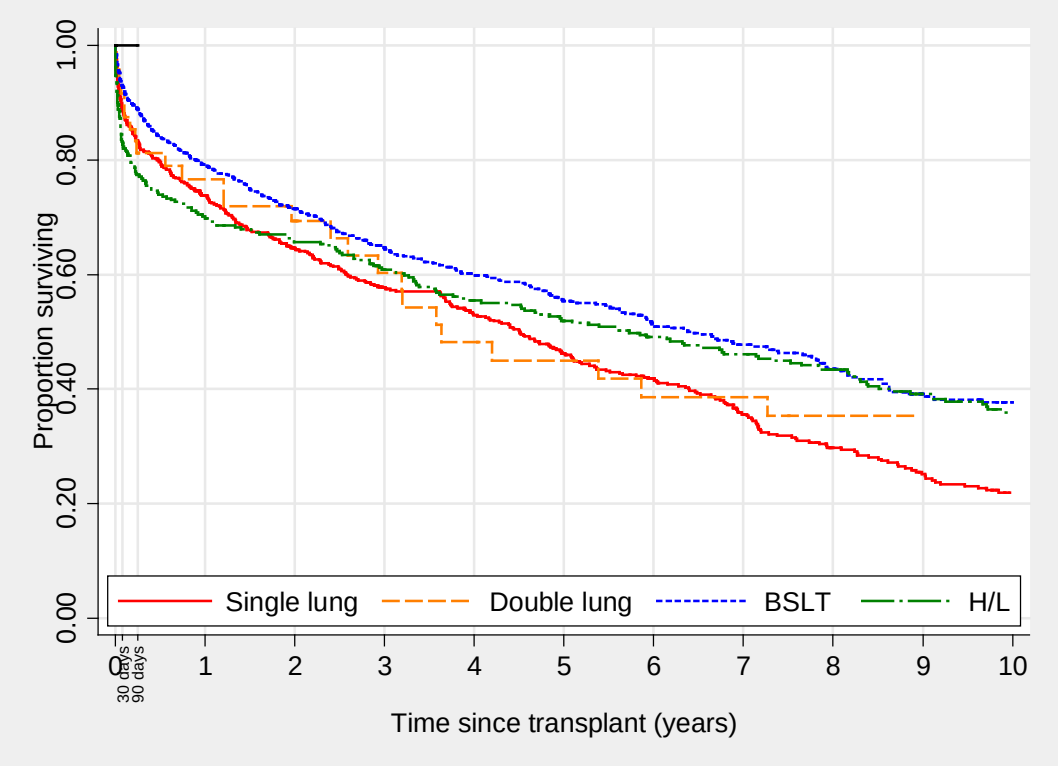


Figure 25 **Kaplan-Meier survival curves after adult lung transplantation by lung type**



Risk profile for 30-day and 1-year mortality

Figure 26 plots the average risk score for 30-day and 1-year mortality over time as a moving average based on 66 transplants. Despite the trend towards increased ischemia times in the recent period (data not shown) the risk score for early mortality has declined over time. After allowing for established risk factors, including ischemia time, one of the strongest predictors of early mortality was transplant era, with a much reduced risk in the period since 2005 compared with transplants prior to this, as shown by the significant decline in risk during 2005/6. Factors included in the risk adjustment are given in Appendix 1.

The distribution of risk profiles is broadly similar for patients transplanted at the different active adult centres, as shown in **Figure 27.** The trend towards lower risk scores for transplants in the most recent era is seen across all centres.

Risk-adjusted mortality

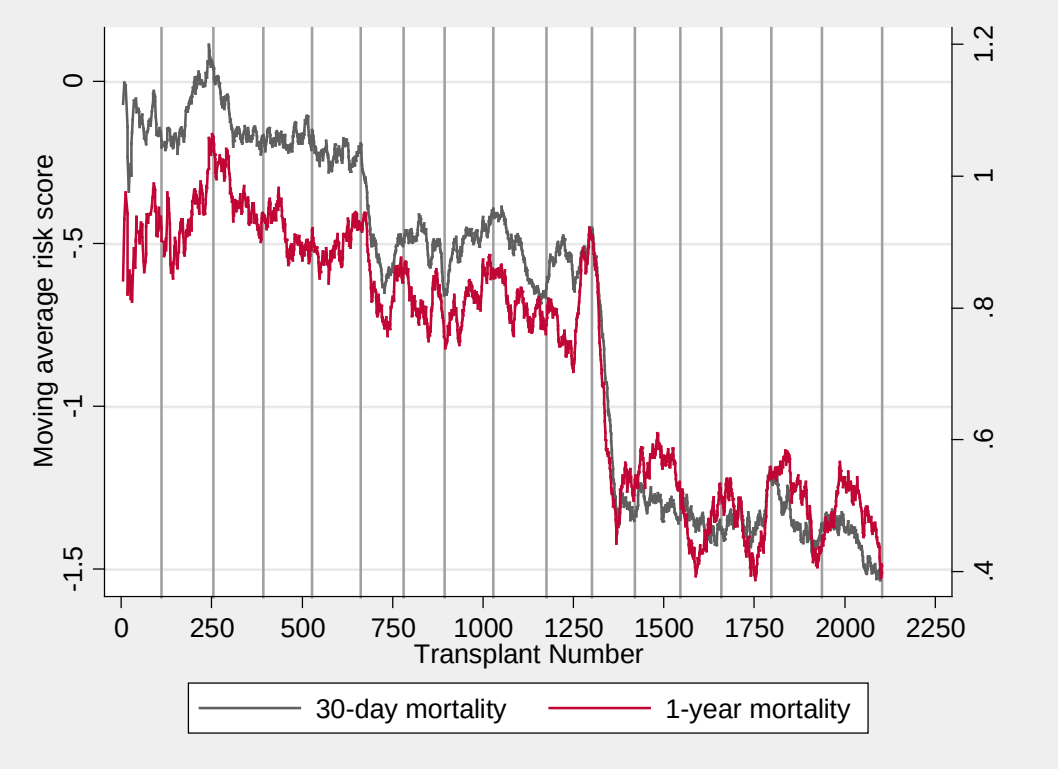
Centre specific mortality

Table 38 shows the risk adjusted 30-day mortality rates and centre effect estimates following lung transplantation for the periods April 2008 to March 2011 and April 2010 to March 2011. The corresponding estimates for 90-day mortality are shown in. **Table 39** (for transplants to December 2010). These fixed centre effects are estimated independently for each centre and express the difference between the observed and expected number of deaths as a proportion of the total number of expected deaths.

After risk adjustment, Birmingham had significantly higher than expected mortality at 30 days during the period since April 2008, as indicated by the positive centre effect estimates, In contrast, 90-day mortality at Manchester was significantly lower than expected during the same period. These data are further illustrated in **Figure 28**, which shows the risk-adjusted mortality estimate for each centre with the 95% and 99% confidence intervals.

Risk adjusted centre effect estimates for 1-year mortality following lung transplantation for the whole audit, and for the period April 2007 to March 2010 are shown in **Table 40**. Over the whole audit period one centre, St George's is identified as divergent; the centre effect estimate is positive indicating significantly more deaths than expected. Over the period April 2007 to March 2010 Birmingham was identified as divergent, with more deaths than expected after risk adjustment.

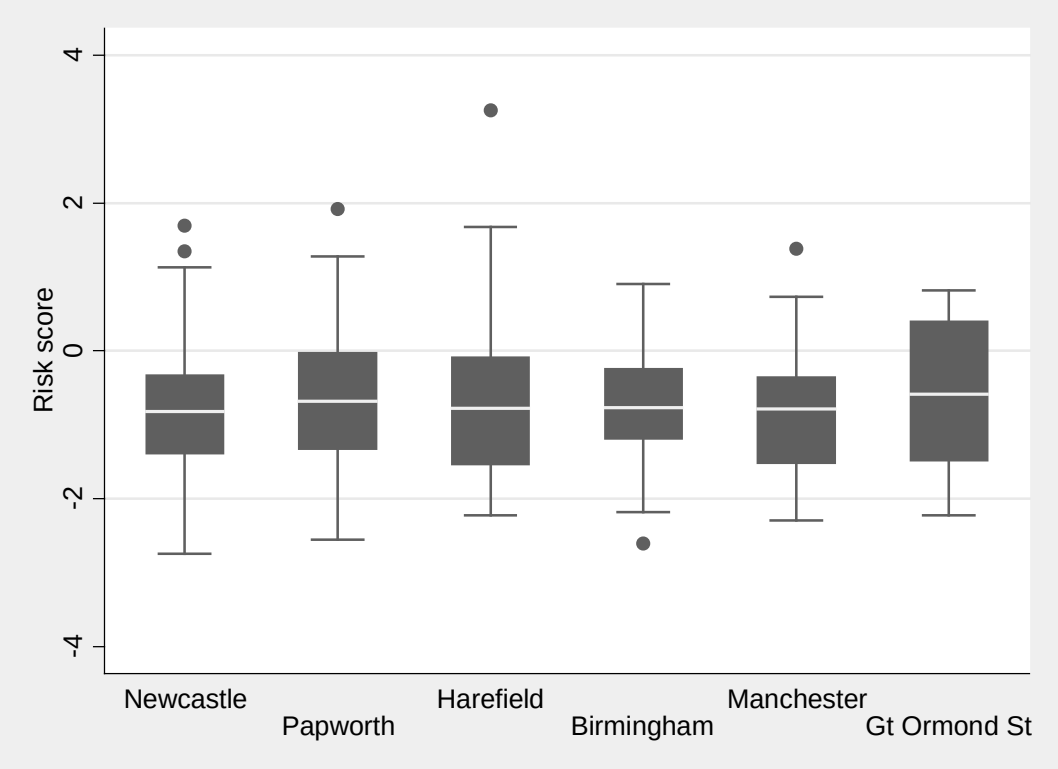
Figure 26 **Risk scores for 30-day and 1 –year mortality after adult lung transplantation over time**



Note: Vertical lines represent the start of each audit year

Figure 27 **Distribution of risk scores derived from risk model for 30-day mortality after adult lung transplantation by centre**

a) By centre



b) By centre and era

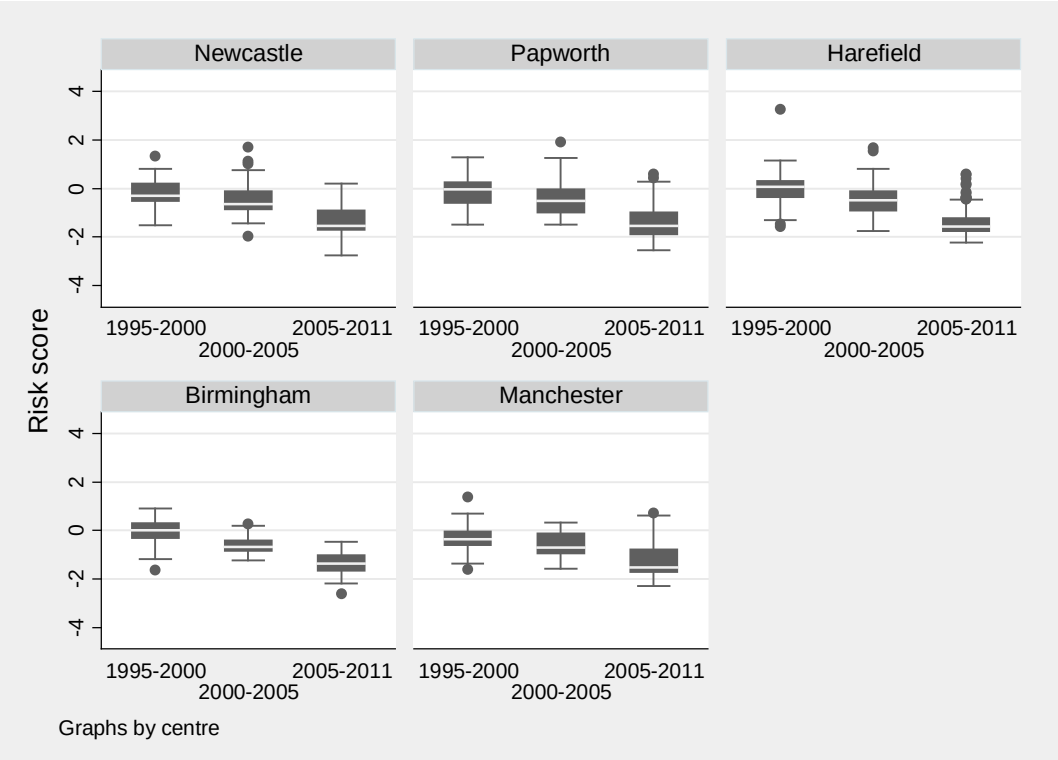


Table 38 **30-day mortality after adult lung transplantation by centre *adjusted* for patient risk**

a) *April 2008 – March 2011*

Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	128	7.0	3.3	to	12.5	0.42	-0.35	to	1.70
Papworth	92	8.1	3.4	to	15.4	0.66	-0.33	to	2.42
Harefield	125	5.3	2.0	to	10.8	0.05	-0.62	to	1.28
Birmingham	25	18.2	6.8	to	34.2	3.20	0.37	to	8.81
Manchester	65	1.4	0.0	to	7.2	-0.74	-0.99	to	0.47
Gt Ormond St	4	0.0	0.0	to	53.7	-1.00	-1.00	to	20.9

b) *April 2010 – March 2011*

Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	41	7.3	1.6	to	18.8	0.49	-0.69	to	3.35
Papworth	31	14.3	4.4	to	29.9	2.14	-0.14	to	7.05
Harefield	57	6.2	1.3	to	16.2	0.25	-0.74	to	2.64
Birmingham	10	0.0	0.0	to	30.2	-1.00	-1.00	to	7.13
Manchester	21	4.6	0.1	to	21.2	-0.09	-0.98	to	4.06
Gt Ormond St	2	0.0	0.0	to	62.9	-1.00	-1.00	to	31.0

Table 39 **90-day mortality after adult lung transplantation by centre *adjusted* for patient risk**

a) *April 2008 – December 2010*

Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	114	11.5	6.5	to	18.2	0.32	-0.30	to	1.25
Papworth	84	10.3	4.7	to	18.5	0.16	-0.50	to	1.29
Harefield	111	9.5	4.8	to	16.2	0.06	-0.49	to	0.96
Birmingham	22	17.5	6.4	to	33.1	1.14	-0.31	to	3.99
Manchester	55	1.7	0.0	to	8.8	-0.83	-1.00	to	-0.03
Gt Ormond St	4	0.0	0.0	to	57.7	-1.00	-1.00	to	12.8

Table 39 **continued**

b) *April 2010 – December 2010*

Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	27	15.6	4.8	to	32.2	0.87	-0.49	to	3.79
Papworth	23	17.9	5.6	to	35.8	1.20	-0.40	to	4.63
Harefield	43	9.6	2.8	to	21.3	0.07	-0.71	to	1.73
Birmingham	7	0.0	0.0	to	33.5	-1.00	-1.00	to	4.08
Manchester	11	8.0	0.2	to	32.6	-0.12	-0.98	to	3.89
Gt Ormond St	2	0.0	0.0	to	69.7	-1.00	-1.00	to	22.3

Figure 28 **Risk-adjusted estimates of early mortality after adult lung transplantation, April 2007 to March 2010**

a) *30-days*

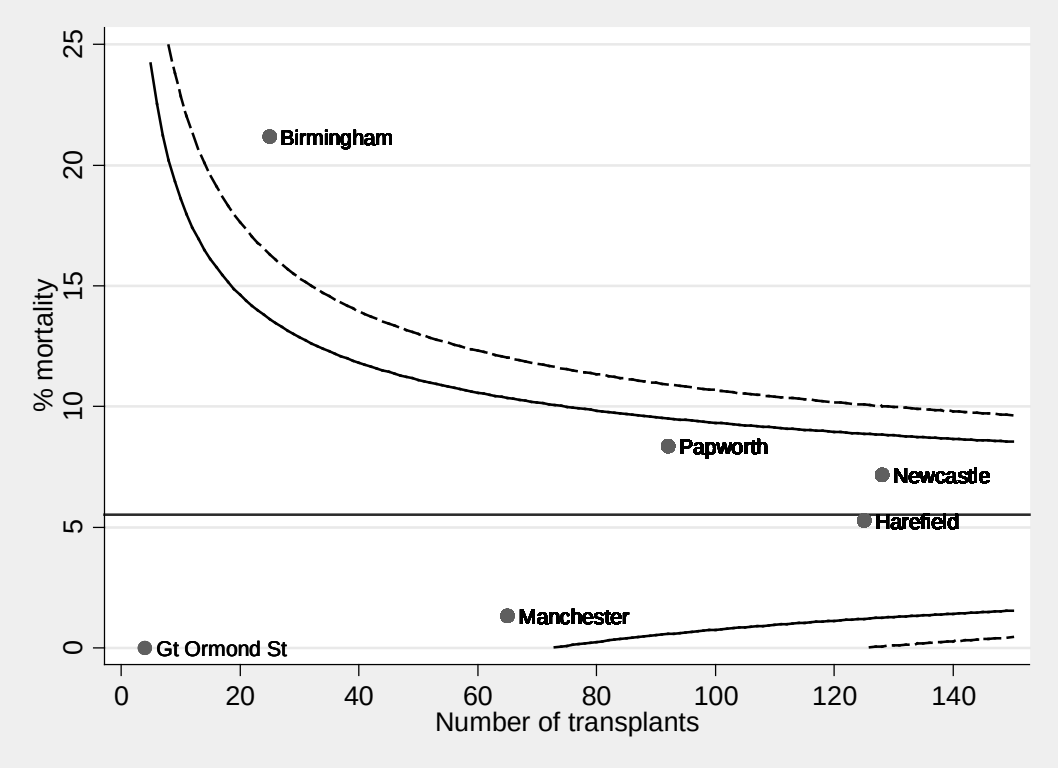
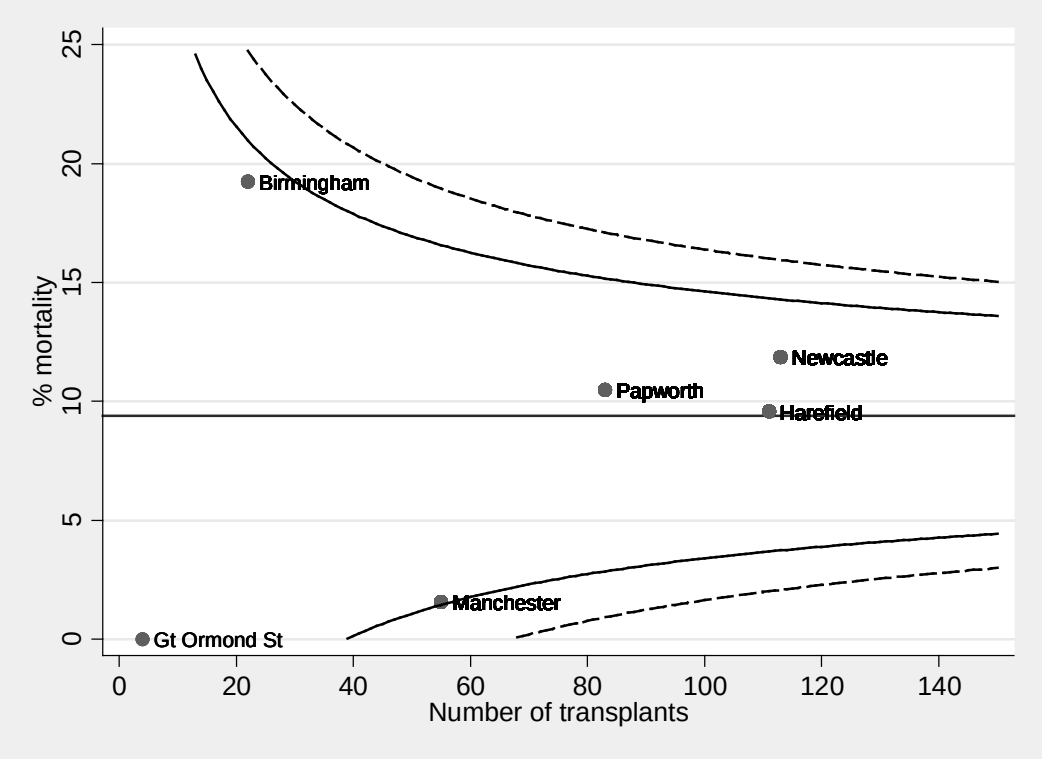


Figure 28 continued

b) 90-days (transplants to December 2010)



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

Table 40 1-year survival after adult lung transplantation by centre *adjusted* for patient risk

a) Whole audit period

Centre	No cases	% survival	95%CI			Centre effect	95%CI		
Newcastle	544	78.9	75.4	to	82.1	-0.15	-0.31	to	0.03
Sheffield	26	81.4	65.2	to	93.1	-0.27	-0.76	to	0.69
Papworth	497	73.6	70.2	to	76.9	0.13	-0.05	to	0.34
Harefield	450	76.7	72.9	to	80.3	-0.04	-0.22	to	0.18
Birmingham	47	58.3	47.8	to	69.3	1.26	0.40	to	2.46
Manchester	150	70.9	64.7	to	76.9	0.30	-0.05	to	0.73
Glasgow	256	79.5	74.7	to	83.8	-0.18	-0.39	to	0.07
Gt Ormond St	22	88.4	67.9	to	98.4	-0.59	-0.95	to	0.49

Table 40 continued

b) April 2007 – March 2010

Centre	No cases	% survival	95%CI			Centre effect	95%CI		
Newcastle	122	83.3	76.4	to	89.1	-0.12	-0.46	to	0.36
Papworth	81	81.3	72.2	to	88.8	0.01	-0.45	to	0.70
Harefield	97	84.1	75.6	to	90.9	-0.17	-0.56	to	0.42
Birmingham	26	62.3	48.6	to	76.2	1.66	0.38	to	3.65
Manchester	62	83.7	74.6	to	90.9	-0.14	-0.56	to	0.50
Gt Ormond St	3	100.0	33.7	to	100.0	-1.00	-1.00	to	7.66

Continuous monitoring of mortality

Observed – expected mortality

The observed – expected charts, with and without risk adjustment, for 30-day and 90-day mortality after adult lung transplantation are shown in **Figure 29** and **Figure 30** respectively.

Tabular CUSUM charts

Tabular CUSUM charts for 30-day and 90-day mortality are shown in **Figure 31** and **Figure 32** respectively. Mortality rates following adult lung transplantation have been consistent with the national average at all centres apart from Birmingham in recent years. Birmingham signalled in 2009, following 5 deaths in an 18-month period, including the short run of deaths in 2008 identified in the real-time monitoring when the expected rates were updated, and investigated internally at the time.

Figure 29 **Cumulative (observed – expected) 30-day mortality after adult lung transplantation, January 2004 to March 2011**

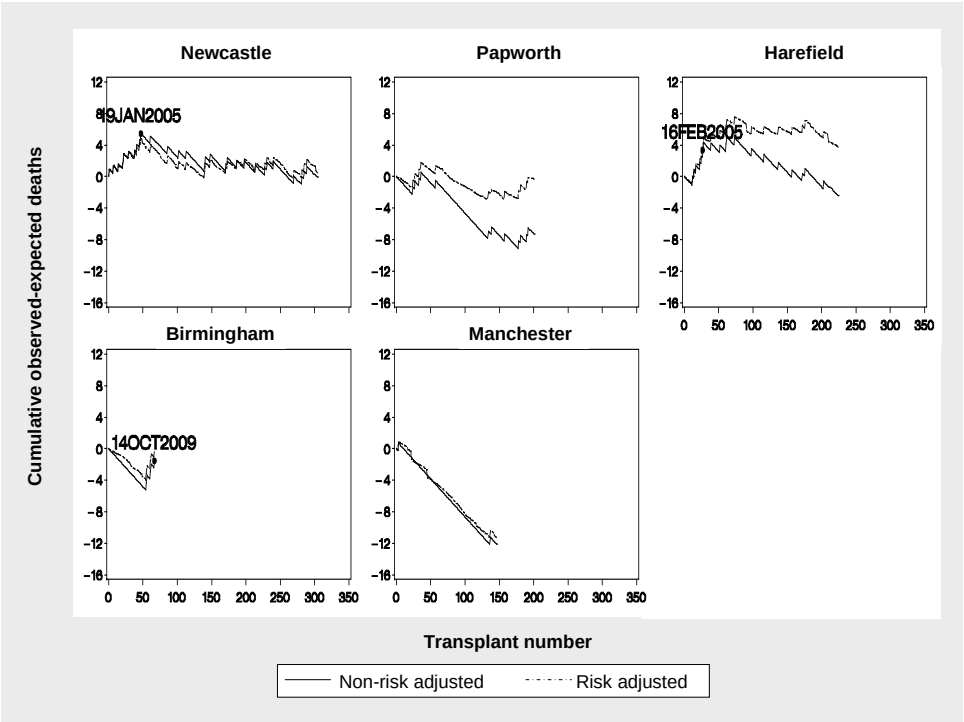


Figure 30 **Cumulative (observed – expected) 90-day mortality after adult lung transplantation, January 2004 to December 2010**

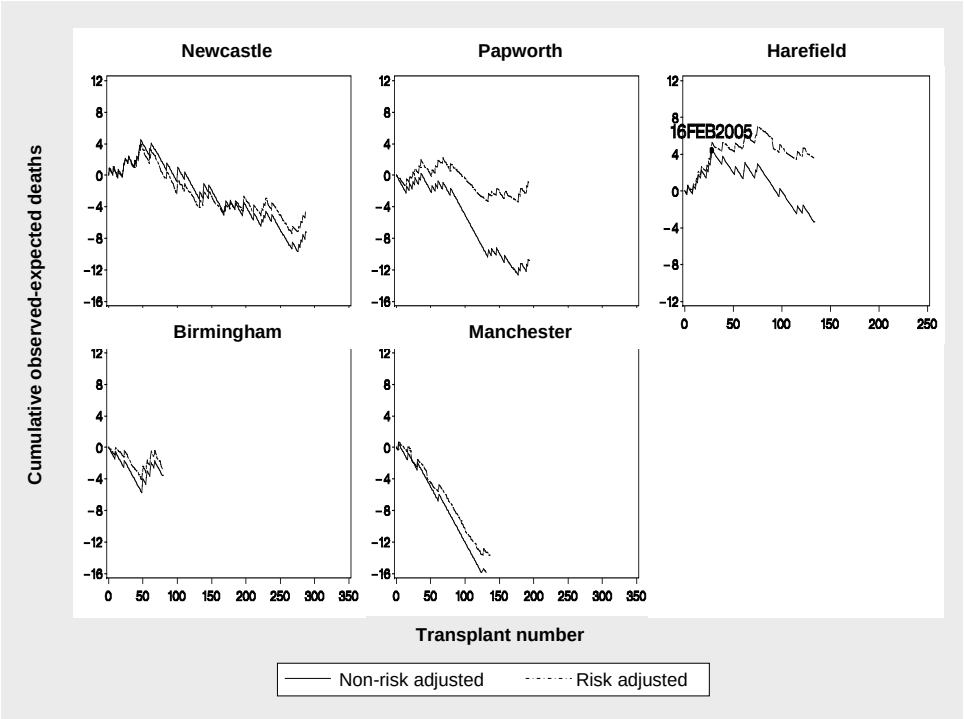


Figure 31 **Tabular CUSUM for 30-day mortality after adult lung transplantation unadjusted for patient risk, January 2004 to March 2011**

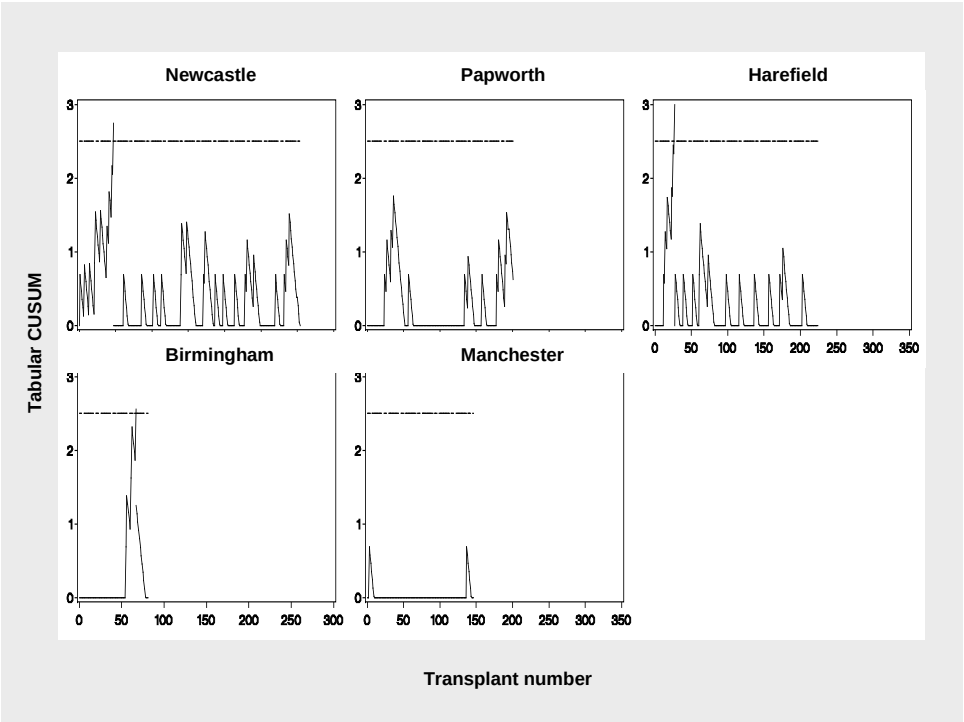
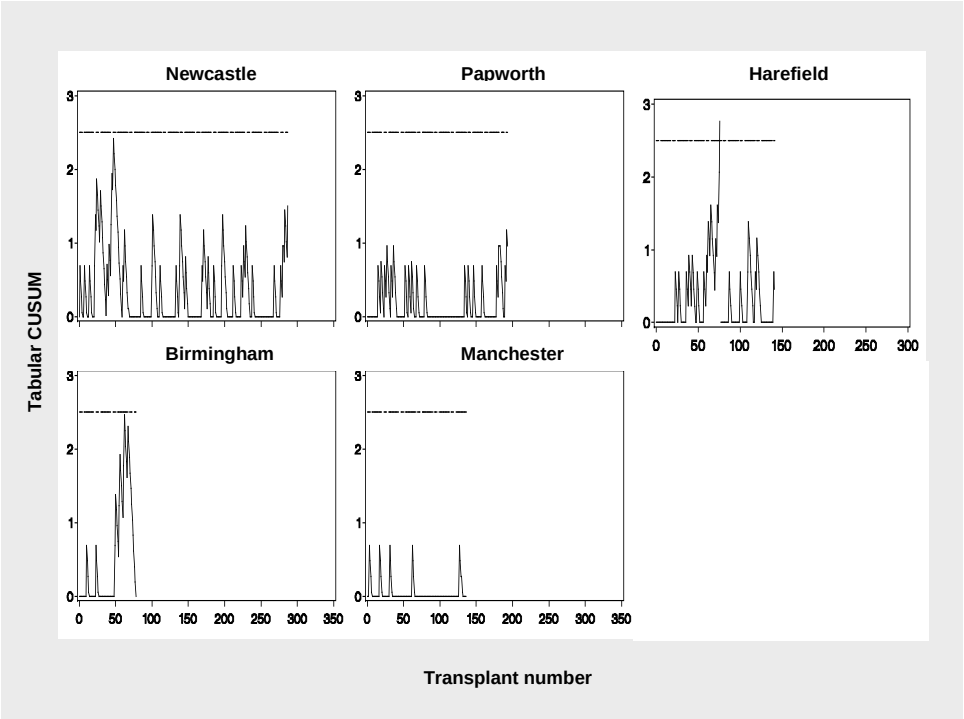


Figure 32 **Tabular CUSUM for 90-day mortality after adult lung transplantation unadjusted for patient risk, January 2004 to December 2010**



7. RESULTS – PAEDIATRIC LUNG TRANSPLANTATION

Transplant activity

One-hundred children (<16 years) have received a lung transplant in the period since the audit started; the majority had cystic fibrosis. The youngest child transplanted was two years old and the median was 13 years. The total number of transplants reported by audit year is shown in **Figure 33**. Since April 2001, 59 paediatric lung grafts using lungs from cadavers have been carried out, 25 since April 2007. Unlike the adult programme, many of children received a heart-lung graft (38, 38%), although the number of heart-lung grafts is falling, only one heart-lung transplant has been reported in the last three years. All the remaining grafts were bilateral sequential lung procedures.

Unadjusted mortality rates

Overall mortality

Nine recipients died within 30 days of their transplant, giving an overall 30-day mortality rate of 9.0% (95%CI 4.2% to 16.4%) for the whole audit period. There were a further 2 deaths between 30 and 90-days giving a 90-day mortality for transplants to December 2010 of 11.1% (95%CI 5.7% to 19.0%). Of transplants carried out since August 2000, there have been three reported deaths within 30 days of the operation and no deaths between 30 and 90-days **(Table 41** and **Table 42**).

Overall, 83.7% (95%CI 74.8% to 89.7%) of children were alive 1-year after their transplant; 73.8% (95%CI 63.4% to 81.7%) survived to 3-years; 62.9% (95%CI 51.1% to 72.6%) to 5-years and 43.3% (95%CI 29.0% to 56.8%) were alive after 10-years **(Table 43** to **Table 46**).

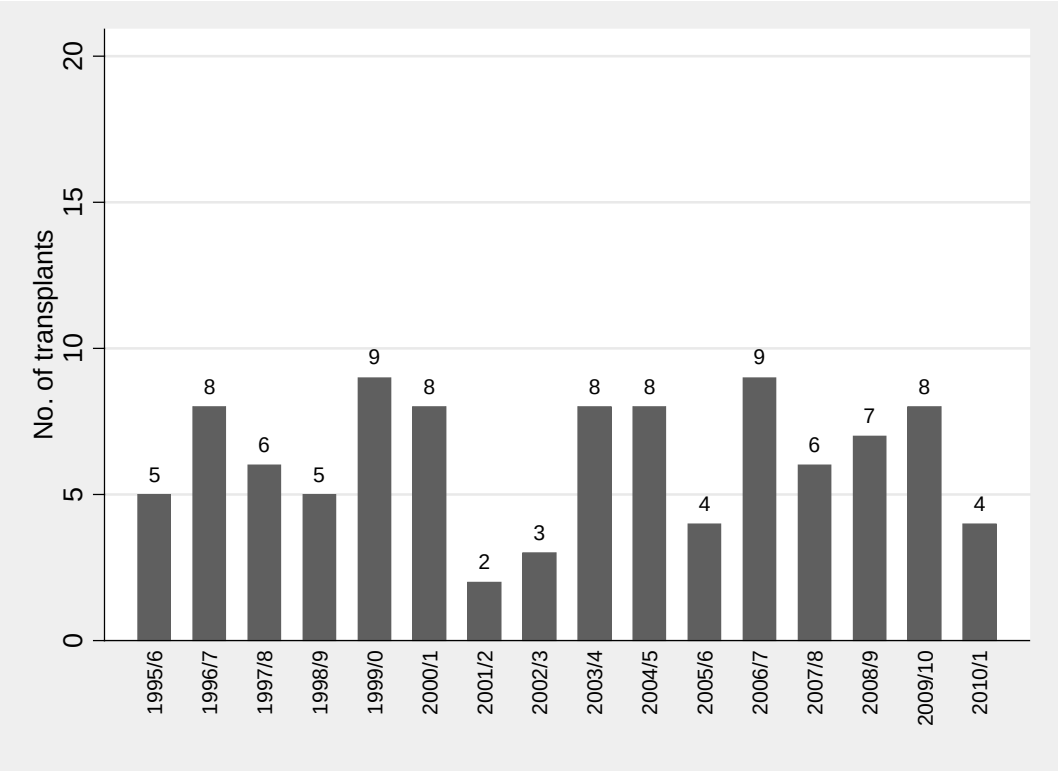
Mortality rates by transplant centre

Mortality rates at 30-days and 90-days by centre, unadjusted for patient risk, for the period April 2008 to March 2011 (30-days) or to December 2010 (90-days), are given in **Table 41** and **Table 42**. As there was only one reported early death over this period centre effect estimates are omitted.

Focusing on the three centres with more than 5 transplants in there was no evidence to suggest that 1, 3, 5 and 10-year survival differed significantly between centres (p=0.09, p=0.39, p=0.48 and p=0.95 for 1,3, 5 and 10 year survival respectively) (**Figure 34**). The centre effect estimates also indicate that survival rates were similar across centres; all 95% confidence intervals encompass 0 (**Table 43** to **Table 46**).

Figure 33 Paediatric lung transplant activity by audit year

a) Overall



b) By transplant centre

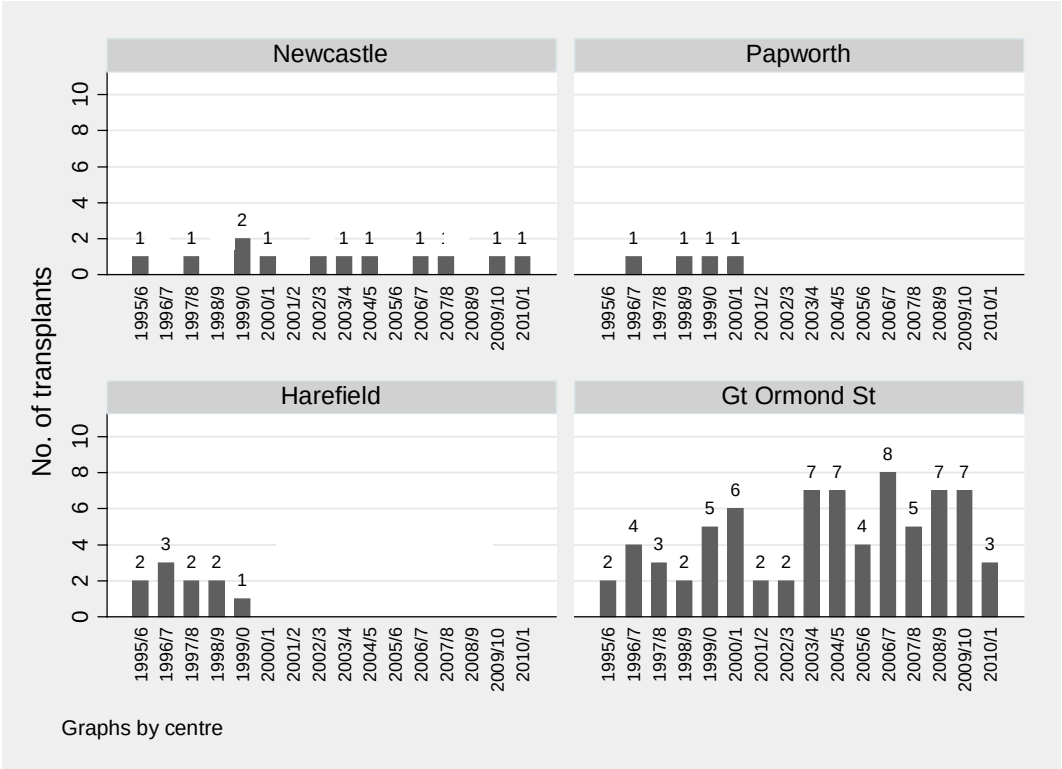


Table 41 **30-day mortality after paediatric lung transplantation by centre *unadjusted* for patient risk**

a) *April 2008 – March 2011*

Centre	No cases	No deaths	Mortality rate[1]	95%CI
Newcastle	2	0	0.0	0.0 to 84.2
Gt Ormond St	17	1	5.9	0.1 to 28.7
All centres	**19**	**1**	**5.3**	**0.1 to 26.0**

b) *April 2010 – March 2011*

Centre	No cases	No deaths	Mortality rate[1]	95%CI
Newcastle	1	0	0.0	0.0 to 97.5
Gt Ormond St	3	0	0.0	0.0 to 70.8
All centres	**4**	**0**	**0.0**	**0.0 to 60.2**

[1] a) p>0.99;

Table 42 **90-day mortality after paediatric lung transplantation by centre *unadjusted* for patient risk**

a) *April 2008 – December 2010*

Centre	No cases	No deaths	Mortality rate[1]	95%CI
Newcastle	2	0	0.0	0.0 to 84.2
Gt Ormond St	16	1	6.3	0.2 to 30.2
All centres	**18**	**1**	**5.6**	**0.1 to 27.3**

b) *April 2010 – December 2010*

Centre	No cases	No deaths	Mortality rate[1]	95%CI
Newcastle	1	0	0.0	0.0 to 97.5
Gt Ormond St	2	0	0.0	0.8 to 84.2
All centres	**3**	**0**	**0.0**	**0.6 to 70.8**

[1] a) p>0.99;

Table 43 **One-year survival after paediatric lung transplantation by centre unadjusted for patient risk**

a) *Whole audit period*

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	12	91.7	53.9	to	98.8	-0.47	-0.99	to	1.93
Papworth	4	75.0	12.8	to	96.1	0.41	-0.96	to	6.88
Harefield	10	60.0	25.3	to	82.7	1.67	-0.27	to	5.84
Gt Ormond St	74	86.3	76.0	to	92.4	-0.16	-0.60	to	0.55
All centres	**100**	**83.7**	**74.8**	**to**	**89.7**				

b) *April 2007 – March 2010*

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	2.0	100.0				-1.00	-1.00	to	17.89
Gt Ormond St	19.0	89.5	64.1	to	97.3	0.11	-0.87	to	3.00
All centres	**21**	**90.5**	**67.0**	**to**	**97.5**				

[1] a) p=0.09 (excluding centres with < 5 cases); b) p=0.64

Table 44 **Three-year survival after paediatric lung transplantation by centre *unadjusted* for patient risk**

a) *Whole audit period*

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	12	81.5	43.5	to	95.1	-0.32	-0.92	to	1.44
Papworth	4	50.0	5.8	to	84.5	0.85	-0.78	to	5.68
Harefield	10	60.0	25.3	to	82.7	0.78	-0.51	to	3.56
Gt Ormond St	74	76.0	63.6	to	84.7	-0.10	-0.48	to	0.47
All centres	**100**	**73.8**	**63.4**	**to**	**81.7**				

Table 44 continued

b) April 2005 – March 2008

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	2.0	50.0	0.6	to	91	3.49	-0.89	to	24.00
Gt Ormond St	17.0	94.1	65.0	to	99.1	-0.44	-0.99	to	2.14
All centres	**19**	**89.2**	**63.1**	**to**	**97.2**				

[1] a) p=0.39 (excluding centres with <5 cases); b) p=0.08

Table 45 Five-year survival after paediatric lung transplantation by centre *unadjusted* for patient risk

a) Whole Audit Period

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	12	69.8	31.8	to	89.4	-0.28	-0.85	to	1.12
Papworth	4	50.0	5.8	to	84.5	0.43	-0.83	to	4.17
Harefield	10	48.0	16.1	to	74.5	0.59	-0.48	to	2.71
Gt Ormond St	74	64.8	50.6	to	75.9	-0.06	-0.42	to	0.44
All centres	**100**	**62.9**	**51.1**	**to**	**72.6**				

b) April 2003 – March 2006

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	2.0	50.0	0.6	to	91	0.39	-0.96	to	6.76
Gt Ormond St	18.0	71.4	44.3	to	87	-0.05	-0.69	to	1.21
All centres	**20**	**69.1**	**43.6**	**to**	**84.8**				

[1] a) p=0.48 (excluding centres with <5 cases) b) p=0.72

Table 46 **Ten-year survival after paediatric lung transplantation by centre *unadjusted* for patient risk**

Centre	No cases	% survival[1]	95%CI			Centre effect	95%CI		
Newcastle	12	43.7	11.7	to	72.6	-0.11	-0.71	to	1.08
Papworth	4	50.0	5.8	to	84.5	-0.06	-0.89	to	2.40
Harefield	10	48.0	16.1	to	74.5	0.11	-0.64	to	1.59
Gt Ormond St	74	35.4	15.4	to	56.1	0.01	-0.34	to	0.47
All centres	**100**	**43.3**	**29.0**	**to**	**56.8**				

[1] p=0.95 (excluding centres with <5 cases)

Mortality rates by retrieval centre

Mortality rates by retrieval centre, for the period April 2008 to March 2011 are shown in **Table 47**. Of the remaining 16 transplants carried out at Great Ormond Street, 4 used lungs retrieved by the local team and 12 were retrieved by another centre. One of the two recipients at Newcastle had lungs which were retrieved by the local team.

Mortality rates by audit year

30-day mortality after paediatric lung transplantation has not changed significantly over time (Fisher's exact test, p=0.40). 90-day mortality has declined (Fisher's exact test, p=0.09). Survival to 1 and 3-years has also changed over time, (p<0.01 and p=0.054 respectively) but longer-term survival was similar (5-year, p=0.11; 10-year, p=0.18). Survival to 10 years by audit era is shown in **Figure 35.**

Mortality rates by lung type

Survival to 10-years by type of transplant is shown in **Figure 36.** Four single lung transplants have been omitted. Survival was highest for patients given a bilateral sequential lung transplant. Unadjusted survival to 10-years varied across the three patient groups (p=0.08).

Table 47 30 and 90-day mortality after paediatric lung transplantation by retrieval centre *unadjusted* for patient risk

April 2008 – March 2011

Retrieval Centre	*30 days*						*90 days*						% used locally[3]
	No cases	No deaths	Mortality rate[1]	95%CI			No cases[4]	No deaths	Mortality rate[2]	95%CI			
Newcastle	3	0	0.0	0.0	to	70.8	3	0	0.0	0.0	to	70.8	33.3
Papworth	3	0	0.0	0.0	to	70.8	3	0	0.0	0.0	to	70.8	0.0
Harefield	3	0	0.0	0.0	to	70.8	3	0	0.0	0.0	to	70.8	0.0
Birmingham	4	1	25.0	0.6	to	80.6	4	1	25.0	0.6	to	80.6	0.0
Glasgow	1	0	0.0	0.0	to	97.5	1	0	0.0	0.0	to	97.5	0.0
Gt Ormond St	5	0	0.0	0.0	to	52.2	4	0	0.0	0.0	to	60.2	80.0
All centres	**19**	**1**	**5.3**	**0.1**	**to**	**26.0**	**18**	**1**	**5.6**	**0.1**	**to**	**27.3**	**26.3**

[1] p=0.74
[2] p>0.99
[3] Retrieved by the centre who carried out the transplant
[4] Transplants to December 2010

Figure 34 **Kaplan-Meier survival curves after paediatric lung transplantation by centre**

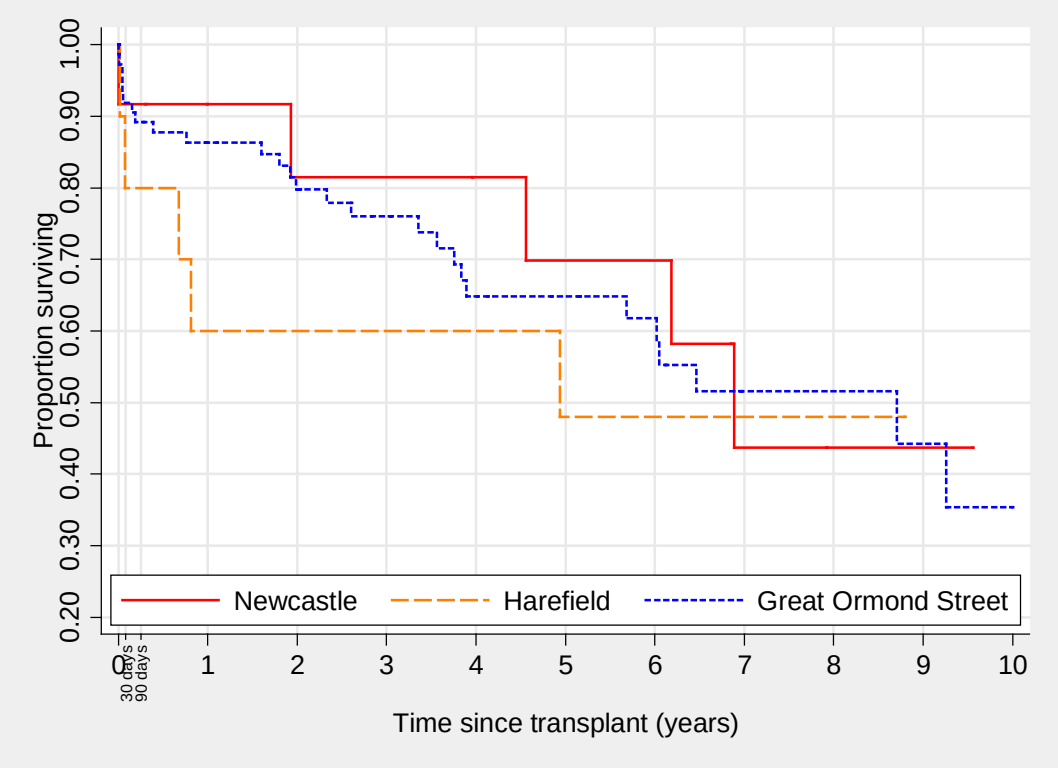


Figure 35 **Kaplan-Meier survival curves after paediatric lung transplantation by era**

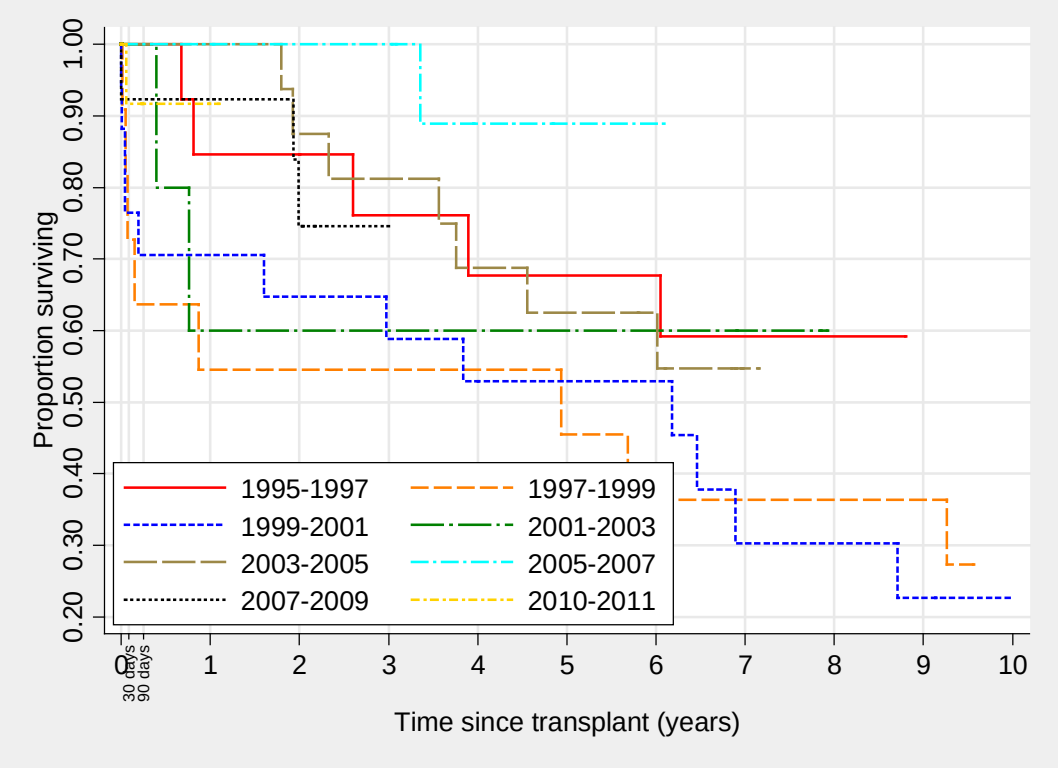
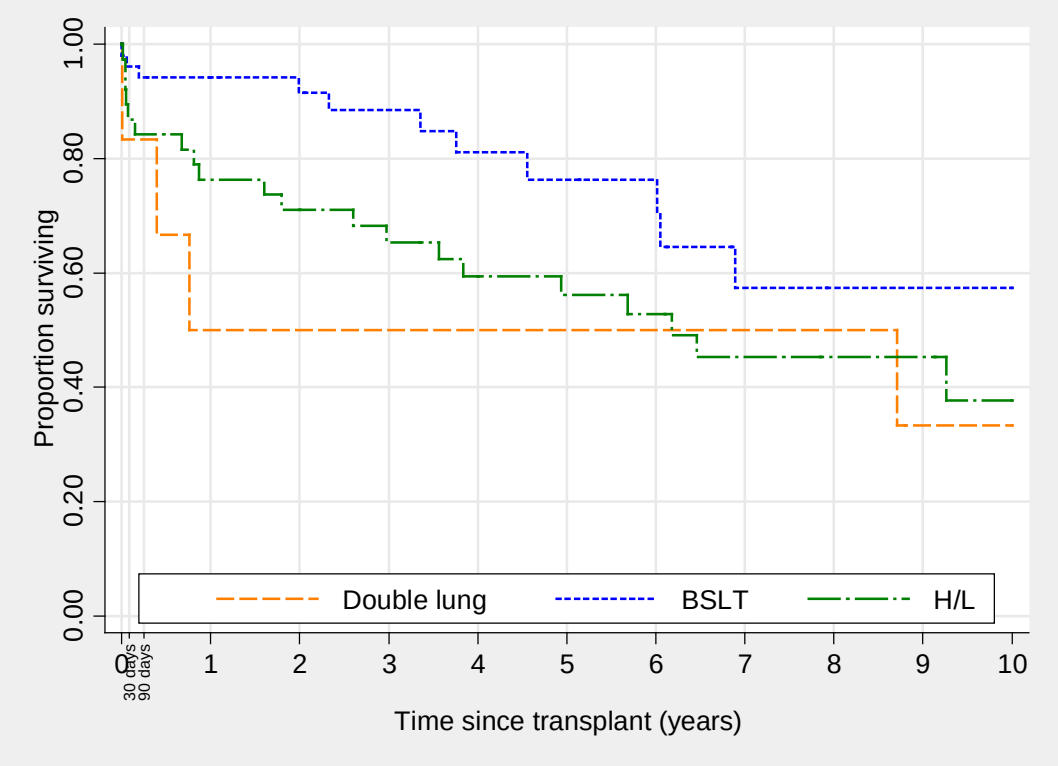


Figure 36 Kaplan-Meier survival curves after paediatric lung transplantation by lung type



Continuous monitoring of mortality

Observed – expected mortality

The observed – expected charts for 30-day and 90-day mortality after paediatric lung transplantation are shown in **Figure 37** and **Figure 38** respectively.

Tabular CUSUM

Tabular CUSUM charts for 30-day and 90-day mortality are shown in **Figure 39** and **Figure 40** respectively. Paediatric mortality rates after lung transplantation are consistent with the national average.

Figure 37 **Cumulative (observed – expected) 30-day mortality after paediatric lung transplantation *unadjusted* for patient risk, January 2004 to March 2011**

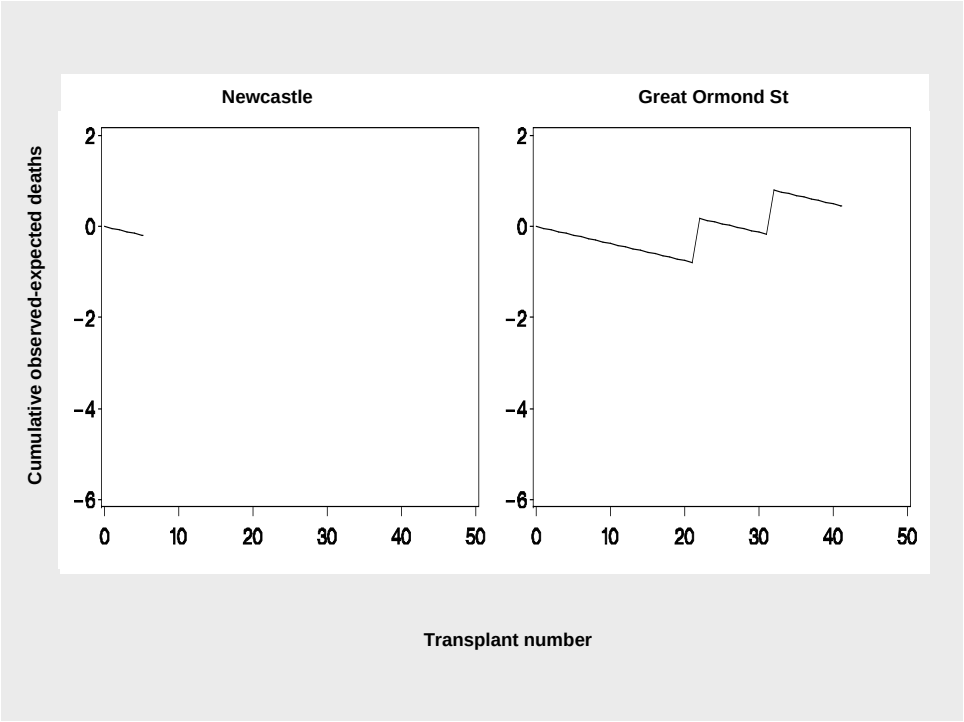


Figure 38 **Cumulative (observed – expected) 90-day mortality after paediatric lung transplantation *unadjusted* for patient risk, January 2004 to December 2010**

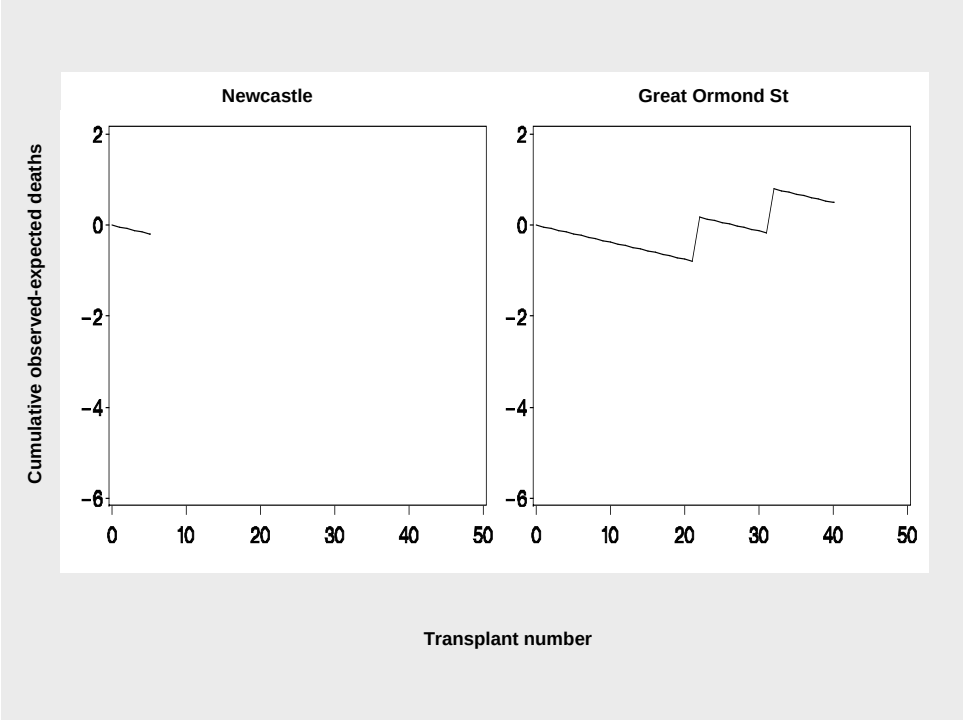


Figure 39 **Tabular CUSUM for 30-day mortality after paediatric lung transplantation *unadjusted* for patient risk, January 2004 to March 2011**

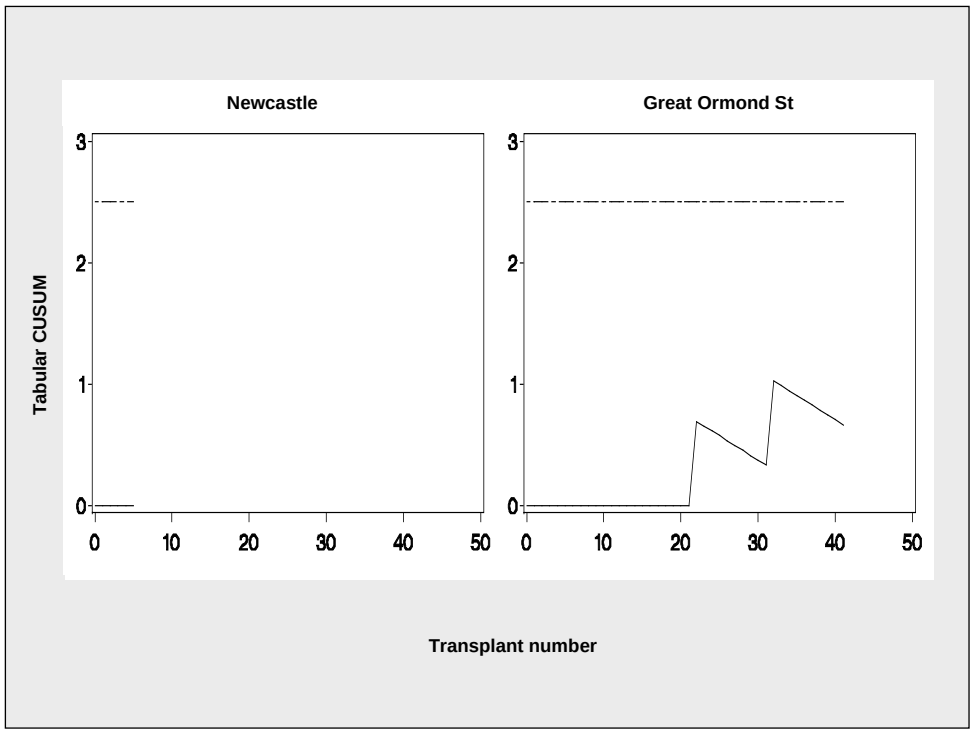
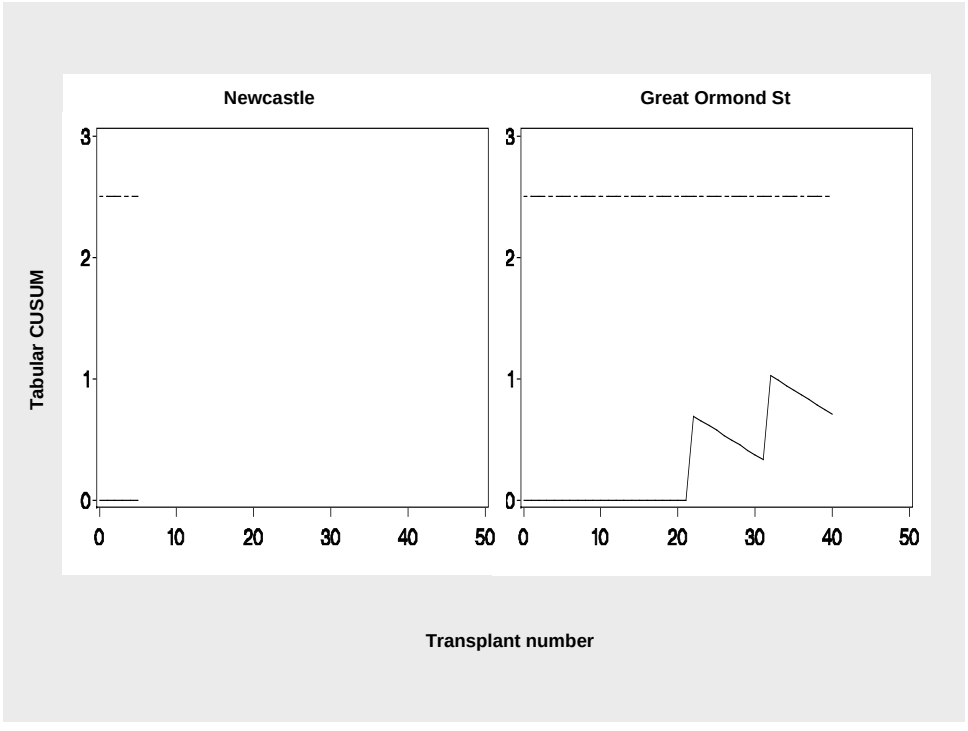


Figure 40 **Tabular CUSUM for 90-day mortality after paediatric lung transplantation *unadjusted* for patient risk, January 2004 to December 2010**



8. DISCUSSION OF RESULTS

8.1 ADULT HEART TRANSPLANTATION

The overall number of adult heart transplants rose from 86 transplants to 90 transplants in 2010/11. On the whole, the results remain consistent with previous reports; the point estimate for the overall unadjusted 30-day mortality rate for the complete cohort increased from 11.9% to 12.2% and at 90-days the overall rate increased by 0.2% from 14.6% to 14.8%. Since April 2008, there has been an upward trend in both 30-day and 90-day mortality; 13.1% of patients died within 30-days and 16.7% died within 90-days of their transplant. Early mortality remains higher than that reported by the US United Network for Organ Sharing (UNOS) who report a 90-day mortality of between 6.0% (18-34 years) and 9.2% (65+ years) for adults receiving transplants in the period 2006-2007. However, excepting Harefield, all centres encompassed the 10% 30-day mortality rate, advised by the British Transplantation Society, within their 95% confidence intervals.

Over the 3-year period since April 2008, 30 and 90-day mortality, estimated with and without adjustment for differences in case mix, varied significantly between transplant centres, with Harefield reporting higher than expected mortality.

Following signals on the continuous monitoring charts for three centres between October 2007 and August 2008 (reported previously) the target mortality rates on which the charts are based were revised to better reflect the most recent transplant practice.

Patients given mechanical support post heart transplantation for primary graft failure had a VAD implanted for a median of 8 days. At the time of analysis, 27 of these patients (39%) were alive.

No differences in early mortality by retrieval centre were found.

The results for 1, 3, 5 and 10-year unadjusted survival rates have not changed significantly with time. Rates for the UK are lower than those reported by UNOS, although the difference lessens as the follow-up increases (83% vs. 87% at 1 year, 78% vs. 80% at 3 years, 69% vs. 74% at 5-years and 56% vs. 54% at 10-years).

Risk-adjusted centre-specific results at 1-year for the whole audit period continued to highlight Papworth, Sheffield and Manchester as reporting significantly fewer deaths than expected, with more deaths than anticipated at St George's. Analyses of survival to 1-year for the period April 2007 to March 2010 suggested that mortality was in line with that expected at all centres, this is in contrast with our last report when for transplants between April 2006 to March 2009 Manchester had fewer deaths in the first transplant year than expected.

The report on VAD activity and outcome shows that 86% of patients given a long-term VAD were alive at 30-days and 65% were alive at 1-year. Data shows a 3-year survival of 54% for the whole study period and 58% in the most recent era. We are currently unable to adjust

for case-mix both because of the small number of events and the limitations of the data available. A more comprehensive dataset is now being introduced.

8.2 PAEDIATRIC HEART TRANSPLANTATION

Following a decline in activity in 2004/5, heart transplantation in children between 2005 and 2011 returned to the previous activity level. Thirty-day mortality was 2.9% for transplants since April 2008, which is lower than reported previously (4.4% for the three years from April 2007). Unadjusted survival to 1, 3 and 5-years is also consistently better than reported worldwide.

8.3 ADULT LUNG TRANSPLANTATION

Lung and heart-lung transplantation is reported as a single entity as in previous reports. In contrast to the heart transplant programme, lung transplant activity increased with 166 transplants reported in the last year (140 in 2009/10), the highest annual total for 7 years. The overall 30-day mortality for the adult lung transplant programme as a whole is 10.1%, 0.1% lower than the overall rate reported in the last annual report. Overall 90-day mortality also declined from 15.6% to 15.1%.

For the period since April 2008 Birmingham has had more deaths within 30-days than expected after adjustment for differences in case-mix. This was sufficient to trigger a retrospective signal on the continuous monitoring chart in 2009 after the target mortality rates were changed. Prior to the signal, there had been an internal investigation and the situation was discussed with NHSBT. In the last audit year, there were no deaths within 30-days in the eleven patients transplanted at Birmingham.

In line with the decline in early mortality, the 1, 3, 5 and 10-year unadjusted survival rates have also changed over time. However, overall rates for the UK remain lower than those reported by UNOS, although the difference lessens as the follow-up increases (81% vs. 83% at 1 year, 66% vs. 68% at 3 years, and 54% vs. 55% at 5-years). At 10-years unadjusted survival is higher in the UK (32% vs. 26%).

Long term un-adjusted survival following lung transplantation varied significantly across centres. Amongst the active adult centres Newcastle was identified as having significantly higher survival (i.e. fewer deaths than expected) at 1, 3, 5 and 10-years, while Papworth and Birmingham had lower than expected survival rates at 3, 5 and 10 years. Reasons for this apparent variability across centres are unclear but is likely due to a combination of case-mix and organs transplanted, neither of which have been accounted for in these analyses. Differences in survival to 1-year, for the cohort as a whole, were no longer apparent after adjustment for case-mix. However, for transplants in the period April 2007 to March 2010 1-year survival at Birmingham was lower than expected, after adjustment for case-mix.

8.4 PAEDIATRIC LUNG TRANSPLANTATION

The paediatric programme in the UK continues to be very small with just 100 transplants (4 more than the last report) in the under 16s, too few to draw any robust conclusions regarding performance at the different centres. There have been only two reported deaths within 90 days of transplantation since July 2000. Overall longer term survival to 5-years compares well with that of adult lung transplantation.

9. PRESENTATIONS AND PUBLICATIONS OF THE UKCTA

9.1 PRESENTATIONS

Presentations given on behalf of the Steering Group of the UK Cardiothoracic Transplant Audit in the last audit year:

31th Annual meeting of the International Society for Heart and Lung Transplantation, April 2011, San Deigo

- **US-derived quantitative donor risk score predicts mortality after orthotopic heart transplantation in the UK** CA Rogers, A Emin, RS Bonser, NR Banner

- **Use of Long-term Ventricular Assist Devices in Bridging to Heart Transplantation – A UK National Survey** A Emin, CA Rogers, HL Thomas, S Tsui, G MacGowan, J Parameshwar, NR Banner

Annual Meeting for the Society of Cardiothoracic Surgery of Great Britain and Ireland, Annual Meeting, March 2011, London

- **US-derived quantitative donor risk score predicts mortality after orthotopic heart transplantation in the UK** A Emin, CA Rogers, RS Bonser, NR Banner

- **Donor Biomarkers Associated with Primary Graft Dysfunction (PGD) in the Heart Transplant (HTx) Recipient** V Dronavalli, D Ward, W Wei, P Johnson, RB Bonser

Annual Meeting for the British Cardiovascular Society, Annual Meeting, June 2011, Manchester

- **Management of Advanced Heart Failure in the UK: Trends in Heart Transplantation and Mechanical Circulatory Support** A Emin, CA Rogers, HL Thomas, S Tsui, S Schueler, G MacGowan, A Simon, RS Bonser, J Parameshwar, NR Banner

9.2 PUBLICATIONS

Manuscripts published since our last annual report:

1. A Emin, CA Rogers, RS Bonser, NR Banner on behalf of the Steering Group of the UK Cardiothoracic Transplant Audit. Antithymocyte globulin induction therapy for adult heart transplantation. Heart Lung Transplant. 2011 Jul;30(7):770-7. Epub 2011 Mar 27

2. HL Thomas, VB Dronavalli, J Parameshwar RS Bonser, NR Banner on behalf of the Steering Group of the UK Cardiothoracic Transplant Audit. Incidence and outcome of Levitronix CentriMag support as rescue therapy for early cardiac allograft failure: A UK national study. Eur J Cardiothorac Surg. 2011 Dec;40(6):1348-1354. Epub 2011 Apr 14

3. Q Wang, CA Rogers, RS Bonser, NR Banner, N Demiris, LD Sharples on behalf of the Steering Group of the UK Cardiothoracic Transplant Audit. Assessing the relative benefit of accepting a single lung now or waiting for a double lung in patients with Idiopathic Pulmonary Fibrosis and Chronic Obstructive Pulmonary Disease. Transplantation. 2011 Apr 27;91(8):921-6

10. INDEPENDENT VALIDATION OF VAD DATA

Data validation procedures were undertaken at 3 centres; Newcastle, Papworth and Harefield. Five VAD patients were selected from the cohort who had a record on the VAD database. These patients were selected to maximise representation across the VAD cohort and to include a case mix of both retrospective and prospective patients. Key fields were examined within the database for errors in data input.

Starred (*) fields were selected from each page of the dataset and cross checked with patient records. Incorrect fields were highlighted and centres notified of areas where improvement in data input were required. Starred fields represent the most important variables within each section of the dataset and were selectively examined. Subsequent reports may examine all fields within the dataset.

All centres were accurate and precise in data collection and entry showing approximately 95% correctness of data fields entered within the database; Harefield - 23 incorrect fields identified out of 456, Newcastle – 18 incorrect fields identified out of 420, Papworth – 16 incorrect fields identified out of 319.

Only 3 centres have been assessed thus far, but these represent the majority of VAD implanters in the UK. Other centres data input will be validated for future reports.

APPENDIX 1 FACTORS INCLUDED IN RISK ADJUSTMENT MODELS

Adult heart transplantation

30 and 90-day model	1-year model
Recipient vascular disease	Recipient age
Recipient ventilated pre transplant	Recipient gender
Recipient diabetes	Recipient diagnosis
Recipient creatinine clearance	Recipient vascular disease
Previous open heart surgery	Recipient ventilated pre transplant
Adult congenital heart disease	Recipient in hospital pre transplant
Donor age	Recipient diabetes
Ischemia time	Recipient creatinine clearance
	Previous open heart surgery
	Recipient body mass index
	Recipient antiarrythmics
	Recipient acid
	Large male recipient
	Donor age
	Donor gender
	Donor cause of death
	Donor diabetic
	Donor history of drug abuse
	Donor on inotropes
	Donor: recipient size mis-match
	Donor CMV+:recipient CMV-
	Ischemia time

Adult lung transplantation

30 and 90-day model	1-year model
Transplant type	Recipient age
Recipient diagnosis	Transplant type
Recipient bilirubin	Recipient diagnosis
Donr:recipient height mis match	Recipient bilirubin
Ischemia time	Recipient diabetes
Era of transplant	Recipient forced vital capacity (FVC) at listing
	Recipient ventilated pre transplant
	Donor CMV+:recipient CMV-
	Ischemia time
	Era of transplant

APPENDIX 2 STEERING GROUP MEMBERS

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