

November 2012

# UK Cardiothoracic Transplant Audit

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In patients who received a transplant  
between 1<sup>st</sup> July 1995 and 31<sup>st</sup> March 2012

**ANNUAL REPORT | UKCTA Steering Group**



**NHS**  
*Blood and Transplant*

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## 1. EXECUTIVE SUMMARY

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This annual report describes 30 and 90-day mortality after intrathoracic transplantation for patients who received a first heart, lung or heart-lung transplant between 1 July 1995 and 31 March 2012 in the UK.

Centre specific results are reported for the most recent periods, April 2009 to March 2012, and April 2011 to March 2012. Mortality rates at 1, 3, 5 and 10 years are also presented. One, three, five, and ten-year outcomes are reported for the period as a whole and (a) April 2008 to March 2011, (b) April 2006 to March 2009, (c) April 2004 to March 2007 and (d) April 1999 to March 2002 respectively. 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 and 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 2011 to March 2012. This is a change from the last report where the period from January 2004 onwards was monitored. 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. This year the report has been extended to include both patient survival and survival on VAD support.

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

**Adult heart transplantation:** During the study period 2476 transplants were reported, 107 more than included in our last annual report, which reported on transplants to March 2011. Overall, the unadjusted 30 and 90-day mortality remained stable at 12.3% (95%CI 11.0% to 13.7%) and 14.8% (95%CI 13.4% to 16.3%) respectively. 30-day mortality in the period since April 2009 was 14.1% (95%CI 10.3% to 18.7%) and 16.7% (95%CI 12.3% to 21.0%) 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. 57% in the year to March 2012). However, this has not translated into a notable increase in mortality.

For the period since April 2009, Harefield reported significantly more early deaths (within 90-days) than expected after adjustment for differences in case-mix, an increase that caused the continuous monitoring chart to signal in May 2011. Thirty-day mortality was also higher at Glasgow during this recent period. The increase, which was of borderline statistical significance, was sufficient to cause the continuous monitoring chart to signal in November 2011. Both centres self-reported a series of adverse outcomes before the real-time monitoring charts signalled and external reviews were conducted at both centres. During the last audit year Harefield had fewer deaths within 90-days than expected after adjustment for differences in case-mix but the number of transplants was few and this was not statistically significant.

The 1-year survival for the whole cohort was 81.0% (95%CI 79.3% to 82.5%); 75.7% (95%CI 74.0% to 77.4%) survived to 3-years and 71.1% (95%CI 69.2% to 72.9%) 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 88% (95%CI 84% to 91%) of 369 patients given a long-term VAD were alive at 30-days and 26% 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 7 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 been introduced which will allow such analyses in the future.

**Paediatric heart transplantation:** 453 paediatric patients received a first transplant during the study period, 32 more than included in our last annual report, which reported on transplants to March 2011. The 30-day mortality rate for the entire cohort was 4.4% (95%CI 2.7% to 6.7%) and 6.6% (95%CI 4.5% to 9.3%) died within 90-days. Since April 2009, five children (4.9%, 95%CI 1.6% to 11.0%) died within 30 days and nine (8.7%, 95%CI 4.1% to 15.9%) died within 90-days.

Overall, 91.3% (95%CI 88.2% to 93.5%) of children were alive at 1-year; 85.7% (95%CI 81.9% to 88.7%) were alive at 3-years and 81.6% (95%CI 77.2% to 85.2%) were alive at 5-years. Both short and long-term survival has improved over time.

**Adult lung transplantation:** 2278 adult lung transplants were identified, 175 transplants have been accrued since our last annual report. The 30-day mortality rate for the whole audit period was 9.8% (95%CI 8.6% to 11.1%). In all, 109 patients died between 30 and 90-days, giving a 90-day mortality of 14.6% (95%CI 13.2% to 16.1%). Early mortality has continued to fall with time; since April 2009, the 30-day mortality rate was 6.4% (95%CI 4.4% to 9.0%) and 10.3% (95%CI 7.7% to 13.4%) died within 90-days. In 2011/12 there were 10 deaths within 30-days (5.7%) and 20 (11.7%) 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 2009, no centre reported significantly more early deaths than expected after adjustment for differences in case-mix.

Overall, 76.6% (95%CI 74.8% to 78.3%) recipients were alive one year after their operation; 62.4% (95%CI 60.3% to 64.5%) were alive at 3 years and 52.3% (95%CI 50.0% to 54.6%) 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 (33% vs. 26%).

**Paediatric lung transplantation:** The paediatric lung transplant programme is very small with just 104 grafts reported since the audit began. The majority of children had cystic fibrosis and received a heart-lung transplant (38, 36%), although this is changing; in the last 3 years all transplants have been bilateral sequential lung grafts. The 30-day mortality for the group as a whole was 9.6% (95%CI 4.7% to 17.0%) and 83.4% (95%CI 74.7% to 89.4%) 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

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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 2009 to March 2012 and (b) April 2011 to March 2012. One, three, five and ten-year outcomes are reported for the period as a whole and for the periods April 2008 to March 2011 (1-year outcome), April 2006 to March 2009 (3-year outcomes), April 2004 to March 2007 (5-year outcomes) and April 1999 to March 2002 (10-year outcomes).

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 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 2011. 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 sixth 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 Surgeons of

England (RCS) on a monthly basis. At 31 March 2012, 5311 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. Results of the case note validation exercise for the VAD dataset can be found in our 2011 report to NSCT.

The content of this report has been extended to include

- more in-depth analysis of the use of and survival with ventricular assist devices
- 10-year mortality for the three-year period April 1999 to March 2002

In addition, in this report the continuous monitoring charts show performance since January 2011. Previously, the charts included activity from January 2004.

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 NSCT 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 NSCT 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 the autumn of 2009 enabling more detailed data collection and analysis of risk factors and outcomes. VAD centres have now almost completed entering retrospective data and further analysis will be included in a future report.

### **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 2011 (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. Since June 2012 the expected rate used to monitor for changes has been the national rate. For centres with previous mortality rates lower than the national rate, a chart monitoring against the centre-specific rate is also produced for internal centre auditing purposes only. Expected rates have been calculated based on transplants performed between 2008 and 2011, with more recent transplants given greater weight.

Since the last audit report, there have been signals on the CUSUM charts for adult heart transplantation at Harefield (May 2011) and Glasgow (November 2011). In both cases, the centre self-reported a series of adverse outcomes before the real-time monitoring charts signalled. External reviews were conducted at both centres and the CUSUM charts for these centres were made more sensitive in the period

immediately following the signal. No other centres have signalled in the period covered by this report. Since the signals occurred, the monitoring period for the CUSUM charts has been updated to run from January 2011, excluding some earlier deaths that contributed to these signals. The signals therefore do not appear in the charts shown in this report.



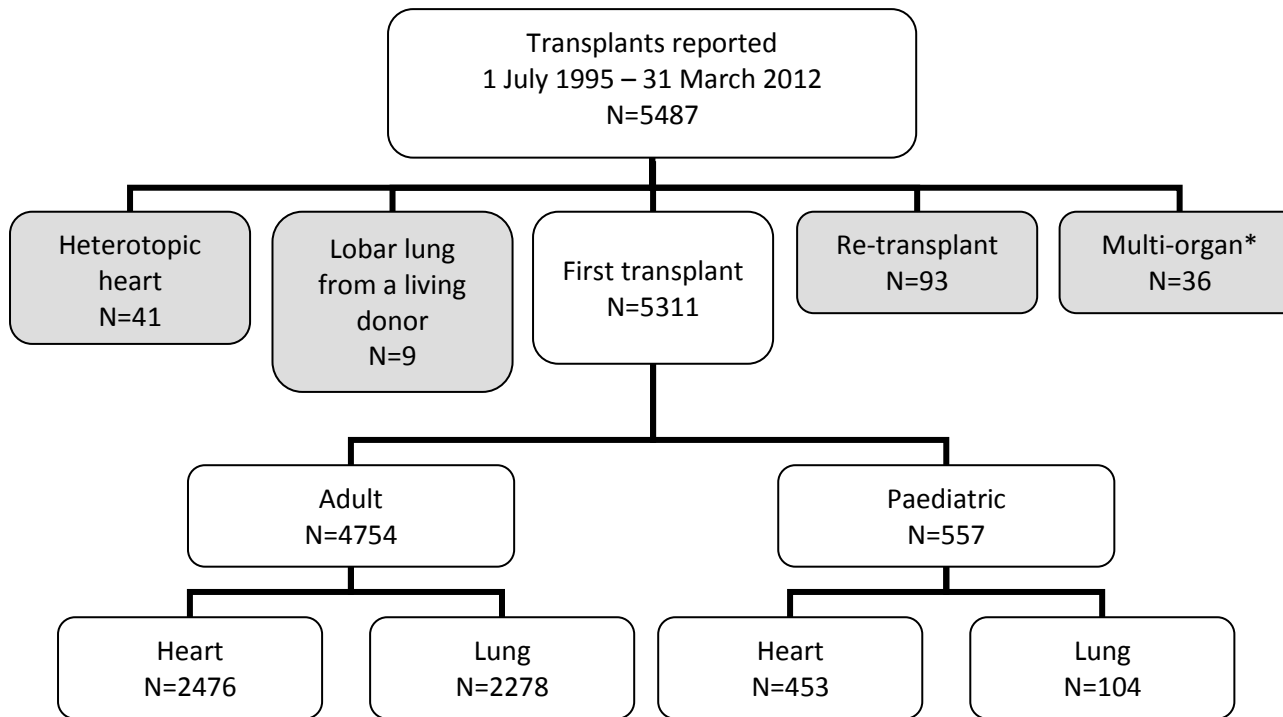
### 3. METHODS

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#### Patients

All patients who received their first heart and/or lung transplant between July 1995 and March 2012 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 176 transplants were excluded, 2.5% of the transplant cohort (see **Figure 1**). The last heterotopic transplant was carried out in September 2003. There have been two re-transplants in the last year (1 heart and 1 lung).

**Figure 1**      **Data cohort for the report**



\* 22 kidney and 14 liver, includes 3 re-transplants

### *30-day follow-up*

The 30-day outcome was known definitively for all but 2 patients. These 2 patients were discharged at 27 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 97.6% of transplants. For the remaining 126 transplants, the three month follow-up visit took place before the three-month anniversary (median 80 days). For this report the 117 patients followed for at least 60 days were assumed to be alive at 90 days. The other nine transplants were omitted due to insufficient follow-up.

### *1-year follow-up*

Twelve month data had been returned for all but 20 eligible transplants (i.e. transplants carried out before April 2011). The 1-year outcome was known definitively for 97.4% of these transplants. For the remaining 128 transplants, the 12-month follow-up visit took place before the first anniversary (median 343 days).

### *3-year follow-up*

Three-year data had been returned for all but 55 transplants carried out before April 2009. The 3-year outcome was known definitively for 97.6% of transplants. For the remaining 107 transplants, the 36 month follow-up visit took place before the third anniversary (median 1054 days).

### *5-year follow-up*

Five-year data had been returned for all but 82 transplants carried out before April 2007. The 5-year outcome was known definitively for 97.9% of transplants. For the remaining 80 transplants, the 5 year follow-up visit took place before the fifth anniversary (median 1790 days).

### *10-year follow-up*

Ten-year data had been returned for all but 64 transplants carried out before April 2001. The 10-year outcome was known definitively for 96.8% of transplants. For the remaining 77 transplants, the 10 year follow-up visit took place before the tenth anniversary (median 3614 days; 9.9 years).

### *Adult heart transplantation*

A total of 2476 adults received their first orthotopic heart transplant at one of the nine transplant centres. Fifteen adults were transplanted at the paediatric unit at Great Ormond Street.

Eight-one cases were excluded from the risk-adjusted analyses due to missing registration data (67 registered before the audit began). Of the excluded cases, only 10 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 453 paediatric (< 16 years) first heart transplants were undertaken between July 1995 and March 2012 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 2278 adults ( $\geq 16$  years) received their first lung transplant at one of the eight lung transplant centres. Twenty-five adults were transplanted at the paediatric unit at Great Ormond Street.

One hundred and twelve cases were excluded from the risk-adjusted analyses due to missing registration data (108 cases, 98 registered before the audit began) or missing transplant data (4). Of the excluded cases, only 11 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 and four children (<16 years) received their first lung transplant (all types) during the study period.

### **Patient waiting lists**

At 31 March 2012, a total of 401 patients were waiting for a cardiothoracic transplant, 46 more than at the same time in 2011. The greatest numbers 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 2012 (2011) in the UK, by centre**

Centre	Active transplant lists <sup>1</sup>									
	Heart				Heart/lung		Lung		All organs	
	Non-urgent		Urgent							
Newcastle	34	(23)	5	(7)	3	(1)	75	(64)	<b>117</b>	<b>(95)</b>
Papworth	42	(30)	2	(1)	6	(6)	23	(27)	<b>73</b>	<b>(64)</b>
Harefield	39	(30)	3	(0)	2	(2)	66	(57)	<b>110</b>	<b>(89)</b>
Birmingham	7	(8)	0	(2)	2	(2)	16	(20)	<b>25</b>	<b>(32)</b>
Manchester	16	(10)	1	(1)	0	(0)	24	(34)	<b>41</b>	<b>(45)</b>
Glasgow	8	(6)	1	(0)	0	(0)	0	(0)	<b>9</b>	<b>(6)</b>
Gt Ormond St	8	(9)	3	(3)	3	(2)	12	(10)	<b>26</b>	<b>(24)</b>
All centres	<b>154</b>	<b>(116)</b>	<b>15</b>	<b>(14)</b>	<b>16</b>	<b>(13)</b>	<b>216</b>	<b>(212)</b>	<b>401</b>	<b>(355)</b>

<sup>1</sup>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<sup>1</sup>. 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. 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<sup>2</sup>. 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

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<sup>1</sup> Christie, JD et al. J Heart Lung Transplant, 2011, doi:10.1016/j.healun.2011.08.004

<sup>2</sup> Christie, JD et al. J Heart Lung Transplant, 2011, doi:10.1016/j.healun.2011.08.004

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.

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 11.61% for heart transplantation and 5.84% for lung transplantation. The corresponding expected rates for 90-day mortality are 13.87% and 8.78% respectively. These figures correspond to the mortality rates in the UK for the 3-year period April 2006 to March 2009. These rates 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 2006 to March 2009 were chosen. For heart transplantation the expected 30 and 90 day mortality rates are set at 1.14% for both time points. 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 are reported. For 30 and 90-day mortality the risk-adjusted estimates are compared across centres using a funnel plot.<sup>3</sup> 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.

The monitoring charts consider first transplants since January 2011. NHS Group 2<sup>4</sup> patients are excluded from the charts, but lung transplants from donors after circulatory death (29 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 2008 and 2011, 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 has doubled. 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 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.

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<sup>3</sup> Spiegelhalter, DJ Statist. Med.2005 **24**:1185-1202.

<sup>4</sup> 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).

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 November 2011 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 2008 and 2011.

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 not funded via the NSCT bridge to transplant or recovery programme and so are excluded. Results are reported for implants between 9 May 2002 and 31 March 2012, with follow-up until 31 July 2012.

This year, for the first time, we present both patient survival and survival on VAD support. Patient survival describes survival from VAD implant to death, regardless of intervening events such as transplantation or device explantation. Survival on VAD support describes survival only while on a device and is therefore time from VAD implant to death on the device, censoring at transplantation or explantation.

## 4. RESULTS - ADULT HEART TRANSPLANTATION

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### Transplant activity

Heart transplantation in adults rose from 90 to 107 transplants in 2011/12. The current activity level remains just over 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 12.3% (95%CI 11.0% to 13.7%). In total, 305 patients died within the first 30 days after transplantation. 30-day mortality in the period April 2009 to March 2012 was 14.1% (95%CI 10.3% to 18.7%) and in the most recent period, April 2011 to March 2012, 14.0% (95%CI 8.1% to 22.1%) 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, 62 died between 30 and 90 days. 90-day mortality for transplants between April 2009 and March 2012 was 16.7% (95%CI 12.3% to 21.0%). For the cohort from April 2011 to March 2012, the 90-day mortality rate was 14.2% (95%CI 8.1% to 22.3%),

**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 81.0% (95%CI 79.3% to 82.5%, **1 a**) p=0.08; b) p=0.50

<sup>2</sup> expected mortality based on overall mortality for the period April 2006 to March 2009 (13.87%)

Table 4). Overall, 75.7% (95%CI 74.0% to 77.4%) of recipients survived to 3-years after their transplant; 71.1% (95%CI 69.2% to 72.9%) survived to 5 years and 57.0% (95%CI 54.8% to 59.2%) 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

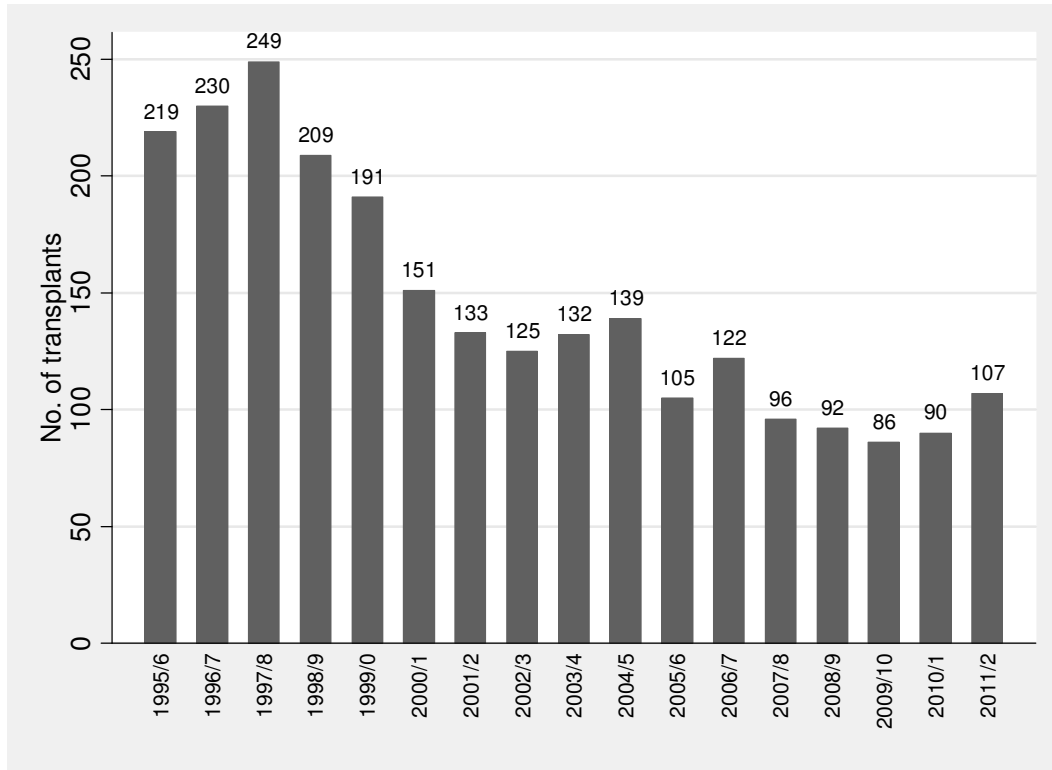
**Table 9.** For completeness, the transplants in patients aged 16 or over carried out at Great Ormond Street are included. Thirty-day mortality rates over the period April 2009 to March 2012 at centres ranged from 0% to 31.8%, but statistically there was no evidence of significant variation between centres (Fisher's exact test,  $p=0.10$ ). Over the last 12 months the 30-day mortality rate showed similar variability ranging from 0% to 33.3% across the 7 centres (Fisher's exact test,  $p=0.49$ ).

90-day mortality rates showed a similar pattern. Statistically there was no evidence of significant variation between centres for the period since April 2011 (Fisher's exact test,  $p=0.50$ ).

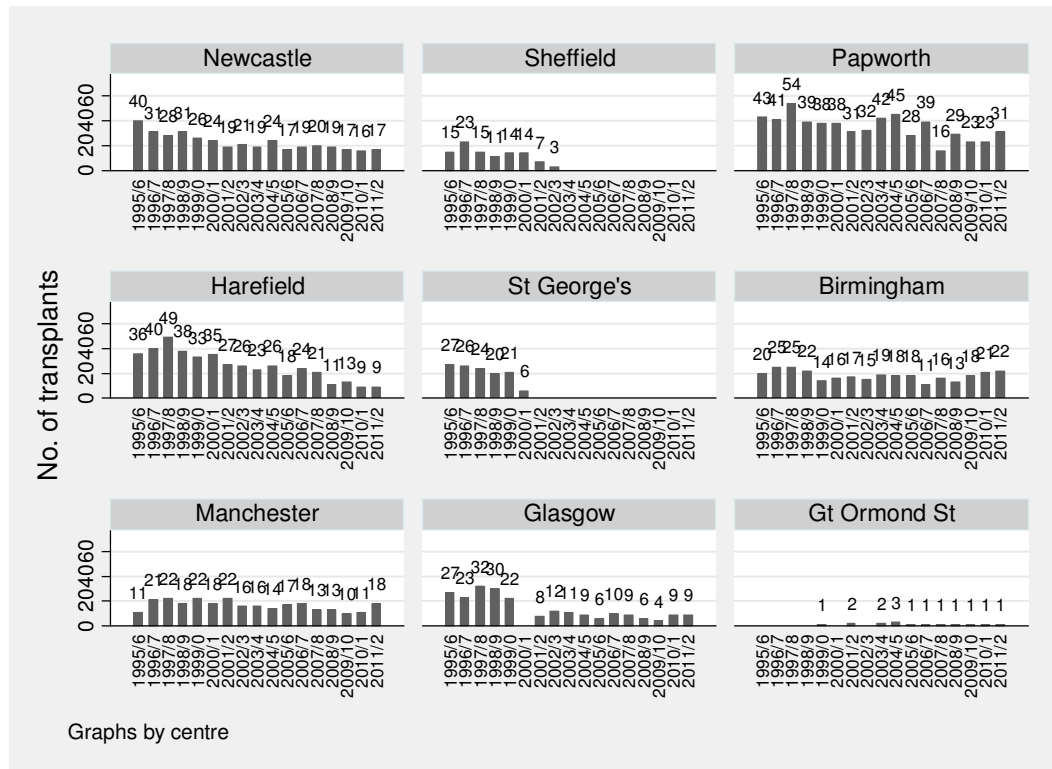


**Figure 2 Adult heart transplant activity by audit year**

**a) Overall**

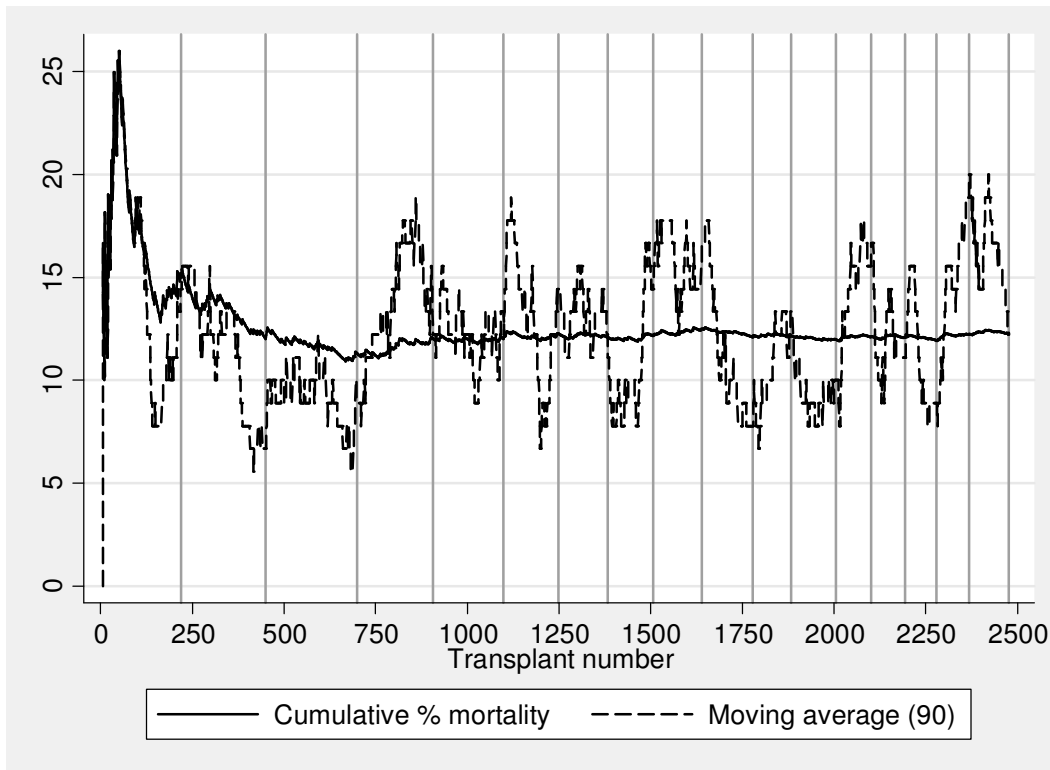


**b) By transplant centre**

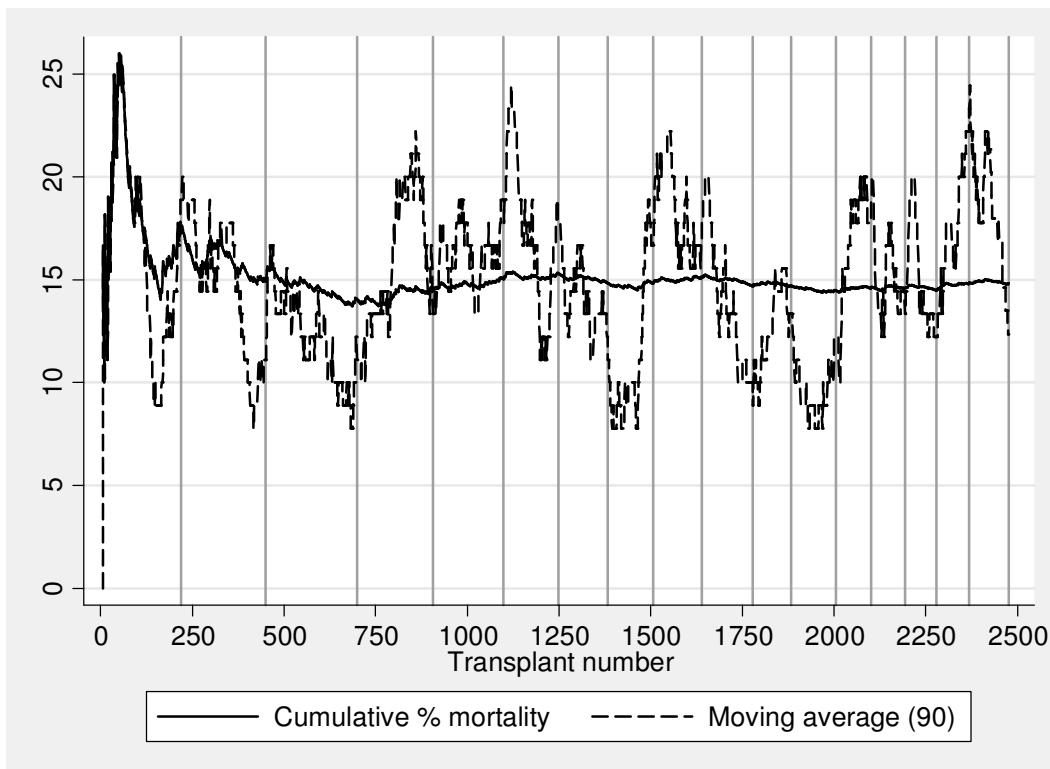


**Figure 3 Mortality after adult heart transplantation over time**

a) 30-day



b) 90-day



Note: Vertical lines represent the start of each audit year

Post-transplant survival to 10-years in all adult UK centres for the whole audit period is shown in **1**  $p=0.06$ ; <sup>2</sup>  $p=0.05$

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 46.8% to 63.7% (17.9% difference,  $p<0.01$ ,

**Table 7).**

For the recent cohort of 268 transplants between April 2008 and March 2011, there was evidence to suggest significant variation between centres at 1-year ( $p < 0.01$ ), due to the lower than expected survival at Harefield. In contrast, for the cohort from April 2006 and March 2009 (320 transplants), there was no evidence to suggest significant variation between centres in 3-year survival ( $p = 0.28$ ).

In **1**  $p = 0.06$ ; <sup>2</sup>  $p = 0.05$

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 1 year,  $p < 0.01$  at 3 years and  $p = 0.03$  at 5 years), but for the cohort surviving beyond 1-year, survival to 3-years was showed less variation across centres ( $p = 0.06$ ). Amongst 30-day survivors there was a 16.5% difference between the centres with the highest and lowest 3-year conditional unadjusted survival and 7.5% 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**. Newcastle, Manchester and Glasgow were the only centres in the last three years to use fewer than half the hearts they retrieved for a local recipient; Newcastle used 47.6%, Manchester used 41.3% and Glasgow used 31.8% of hearts retrieved for a local recipient. Overall, 54.4% of hearts retrieved were used locally and 51.9% 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 2009 to March 2012 was similar for hearts retrieved by the different centres (Fisher's exact test, 30-day:  $p = 0.44$ ). 90-day mortality rates showed a similar pattern (Fisher's exact test,  $p = 0.49$ ).

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,  $p = 0.37$ ; 90-day;  $p = 0.40$ ).

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

a) April 2009 – March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			Centre effect <sup>2</sup>	95%CI		
					to				to	
Newcastle	50	8	16.0	7.2	to	29.1	0.38	-0.41	to	1.72
Papworth	77	6	7.8	2.9	to	16.2	-0.33	-0.75	to	0.46
Harefield	31	7	22.6	9.6	to	41.1	0.94	-0.22	to	3.01
Birmingham	61	7	11.5	4.7	to	22.2	-0.01	-0.60	to	1.04
Manchester	39	5	12.8	4.3	to	27.4	0.10	-0.64	to	1.58
Glasgow	22	7	31.8	13.9	to	54.9	1.74	0.10	to	4.65
Gt Ormond St	3	0	0.0	0.0	to	70.8	-1.00	-1.00	to	9.59
<b>All centres</b>	<b>283</b>	<b>40</b>	<b>14.1</b>	<b>10.3</b>	<b>to</b>	<b>18.7</b>				

b) April 2011 – March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			Centre effect <sup>2</sup>	95%CI		
					to				to	
Newcastle	17	4	23.5	6.8	to	49.9	1.03	-0.45	to	4.19
Papworth	31	3	9.7	2.0	to	25.8	-0.17	-0.83	to	1.44
Harefield	9	1	11.1	0.3	to	48.2	-0.04	-0.98	to	4.33
Birmingham	22	2	9.1	1.1	to	29.2	-0.22	-0.91	to	1.83
Manchester	18	2	11.1	1.4	to	34.7	-0.04	-0.88	to	2.46
Glasgow	9	3	33.3	7.5	to	70.1	1.87	-0.41	to	7.39
Gt Ormond St	1	0	0.0	0.0	to	97.5	-1.00	-1.00	to	30.77
<b>All centres</b>	<b>107</b>	<b>15</b>	<b>14.0</b>	<b>8.1</b>	<b>to</b>	<b>22.1</b>				

<sup>1</sup> a) p=0.10; b) p=0.49

<sup>2</sup> expected mortality based on overall mortality for the period April 2006 to March 2009 (11.61%)

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

a) April 2009 – March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			Centre effect <sup>2</sup>	95%CI		
					to				to	
Newcastle	50	10	20.0	8.5	to	31.5	0.44	-0.31	to	1.65
Papworth	76	7	9.2	2.6	to	15.9	-0.34	-0.74	to	0.35
Harefield	31	9	29.0	12.1	to	46.0	1.09	-0.04	to	2.97
Birmingham	61	9	14.8	5.6	to	23.9	0.06	-0.51	to	1.02
Manchester	39	5	12.8	1.8	to	23.8	-0.08	-0.70	to	1.16
Glasgow	22	7	31.8	10.7	to	53.0	1.29	-0.08	to	3.73
Gt Ormond St	3	0	0.0	0.0	to	0.0	-1.00	-1.00	to	7.87
<b>All centres</b>	<b>282</b>	<b>47</b>	<b>16.7</b>	<b>12.3</b>	<b>to</b>	<b>21.0</b>				

b) April 2011 – March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			Centre effect <sup>2</sup>	95%CI		
					to				to	
Newcastle	17	4	23.5	6.8	to	49.9	0.70	-0.54	to	3.34
Papworth	30	3	10.0	2.1	to	26.5	-0.30	-0.86	to	1.04
Harefield	9	1	11.1	0.3	to	48.2	-0.20	-0.98	to	3.46
Birmingham	22	2	9.1	1.1	to	29.2	-0.34	-0.92	to	1.37
Manchester	18	2	11.1	1.4	to	34.7	-0.20	-0.90	to	1.89
Glasgow	9	3	33.3	7.5	to	70.1	1.40	-0.50	to	6.02
Gt Ormond St	1	0	0.0	0.0	to	97.5	-1.00	-1.00	to	25.60
<b>All centres</b>	<b>106</b>	<b>15</b>	<b>14.2</b>	<b>8.1</b>	<b>to</b>	<b>22.3</b>				

<sup>1</sup> a) p=0.08; b) p=0.50

<sup>2</sup> expected mortality based on overall mortality for the period April 2006 to March 2009 (13.87%)

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

a) *Whole audit period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	388	78.0	73.5	to	81.8	0.20	-0.04	to	0.48
Sheffield	102	92.2	84.9	to	96.0	-0.61	-0.83	to	-0.22
Papworth	592	84.5	81.3	to	87.2	-0.21	-0.37	to	-0.03
Harefield	438	78.5	74.3	to	82.1	0.15	-0.07	to	0.40
St George's	124	69.4	60.4	to	76.7	0.73	0.22	to	1.37
Birmingham	310	79.8	74.8	to	83.9	0.04	-0.20	to	0.34
Manchester	280	87.0	82.5	to	90.5	-0.34	-0.54	to	-0.08
Glasgow	227	77.0	70.9	to	82.0	0.27	-0.05	to	0.66
Gt Ormond St	15	80.0	50.0	to	93.1	0.03	-0.79	to	2.00
<b>All centres</b>	<b>2476</b>	<b>81.0</b>	<b>79.3</b>	<b>to</b>	<b>82.5</b>				

b) *April 2008 – March 2011*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	52	80.8	67.2	to	89.2	-0.02	-0.53	to	0.80
Papworth	75	90.7	81.4	to	95.4	-0.56	-0.82	to	-0.09
Harefield	33	54.5	36.3	to	69.6	1.60	0.46	to	3.29
Birmingham	52	74.2	59.6	to	84.2	0.29	-0.32	to	1.20
Manchester	34	88.2	71.6	to	95.4	-0.43	-0.84	to	0.46
Glasgow	19	78.9	53.2	to	91.5	0.15	-0.69	to	1.95
Gt Ormond St	3	100.0				-1.00	-1.00	to	4.58
<b>All centres</b>	<b>268</b>	<b>80.1</b>	<b>74.8</b>	<b>to</b>	<b>84.5</b>				

<sup>1</sup> a) p<0.01; b) p<0.01

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

a) *Whole audit period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
				to				to	
Newcastle	388	70.8	65.9	to	75.2	0.24	0.02	to	0.50
Sheffield	102	88.2	80.2	to	93.1	-0.54	-0.76	to	-0.20
Papworth	592	78.6	75	to	81.8	-0.16	-0.30	to	0.01
Harefield	438	76.8	72.6	to	80.5	-0.03	-0.21	to	0.18
St George's	124	64.5	55.4	to	72.2	0.60	0.16	to	1.14
Birmingham	310	73.7	68.2	to	78.4	0.07	-0.16	to	0.33
Manchester	280	80.2	74.9	to	84.5	-0.22	-0.42	to	0.02
Glasgow	227	71.7	65.3	to	77.1	0.22	-0.06	to	0.57
Gt Ormond St	15	72.0	41.1	to	88.6	0.12	-0.70	to	1.86
<b>All centres</b>	<b>2476</b>	<b>75.7</b>	<b>74.0</b>	<b>to</b>	<b>77.4</b>				

b) *April 2006 – March 2009*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
				to				to	
Newcastle	58	74.1	60.8	to	83.5	0.22	-0.32	to	1.01
Papworth	84	79.8	69.5	to	86.9	-0.07	-0.46	to	0.49
Harefield	56	75.0	61.5	to	84.4	0.18	-0.36	to	0.97
Birmingham	40	75.0	58.5	to	85.7	0.23	-0.41	to	1.26
Manchester	44	93.2	80.3	to	97.7	-0.71	-0.94	to	-0.16
Glasgow	25	71.8	49.7	to	85.4	0.32	-0.47	to	1.71
Gt Ormond St	3	66.7	5.4		94.5	0.43	-0.96	to	6.96
<b>All centres</b>	<b>310</b>	<b>78.4</b>	<b>73.4</b>	<b>to</b>	<b>82.6</b>				

<sup>1</sup> a) p<0.01; b) p=0.28



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

a) Whole Audit Period

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
				to				to	
Newcastle	388	67.3	62.2	to	71.8	0.18	-0.02	to	0.41
Sheffield	102	82.4	73.5	to	88.5	-0.44	-0.67	to	-0.11
Papworth	592	74.4	70.5	to	77.8	-0.15	-0.29	to	0.00
Harefield	438	73.3	68.8	to	77.2	-0.06	-0.22	to	0.13
St George's	124	61.2	52.1	to	69.2	0.48	0.09	to	0.96
Birmingham	310	68.0	62.1	to	73.2	0.09	-0.12	to	0.34
Manchester	280	72.7	66.7	to	77.8	-0.12	-0.31	to	0.12
Glasgow	227	66.6	59.9	to	72.5	0.22	-0.05	to	0.53
Gt Ormond St	15	61.7	29.7	to	82.5	0.25	-0.60	to	1.91
<b>All centres</b>	<b>2476</b>	<b>71.1</b>	<b>69.2</b>	<b>to</b>	<b>72.9</b>				

b) April 2004 – March 2007

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
				to				to	
Newcastle	60	65.0	51.5	to	75.6	0.38	-0.15	to	1.10
Papworth	112	77.4	68.4	to	84.1	-0.20	-0.48	to	0.18
Harefield	68	67.2	54.6	to	77.1	0.25	-0.22	to	0.89
Birmingham	47	72.3	57.1	to	82.9	0.02	-0.46	to	0.74
Manchester	49	79.6	65.4	to	88.5	-0.30	-0.66	to	0.29
Glasgow	25	75.8	53.8	to	88.3	-0.10	-0.67	to	0.97
Gt Ormond St	5	60.0	12.6	to	88.2	0.78	-0.78	to	5.44
<b>All centres</b>	<b>366</b>	<b>72.7</b>	<b>67.8</b>	<b>to</b>	<b>77.0</b>				

<sup>1</sup> a) p<0.01; b) p=0.31

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

a) *Whole Audit Period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	388	54.5	48.6	to	60.0	0.13	-0.04	to	0.32
Sheffield	102	63.6	53.4	to	72.1	-0.23	-0.46	to	0.06
Papworth	592	60.3	55.5	to	64.8	-0.13	-0.25	to	0.01
Harefield	438	63.7	58.7	to	68.4	-0.14	-0.28	to	0.01
St George's	124	52.8	43.6	to	61.2	0.23	-0.07	to	0.58
Birmingham	310	46.8	39.7	to	53.6	0.22	0.01	to	0.45
Manchester	280	59.3	52.2	to	65.8	-0.10	-0.28	to	0.10
Glasgow	227	48.0	40.6	to	55.0	0.28	0.04	to	0.55
Gt Ormond St	15	61.7	29.7	to	82.5	0.08	-0.65	to	1.53
<b>All Centres</b>	<b>2476</b>	<b>57.0</b>	<b>54.8</b>	<b>to</b>	<b>59.2</b>				

b) *April 1999 – March 2002*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	69	50.6	38.3	to	61.6	0.27	-0.12	to	0.78
Sheffield	35	54.3	36.6	to	69.0	-0.07	-0.47	to	0.52
Papworth	107	55.7	45.7	to	64.5	-0.01	-0.27	to	0.32
Harefield	95	67.3	56.8	to	75.7	-0.31	-0.53	to	-0.02
St George's	27	43.9	24.9	to	61.4	0.60	-0.11	to	1.63
Birmingham	47	52.8	37.6	to	65.9	0.09	-0.32	to	0.65
Manchester	62	58.1	44.8	to	69.2	-0.10	-0.41	to	0.32
Glasgow	30	50.0	31.3	to	66.1	0.22	-0.32	to	1.01
Gt Ormond St	3	33.3	0.9	to	77.4	0.95	-0.76	to	6.04
<b>All Centres</b>	<b>475</b>	<b>55.9</b>	<b>51.3</b>	<b>to</b>	<b>60.3</b>				

<sup>1</sup> a) p<0.01; b) p=0.06

**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

Centre	No cases	1-year				3-years				5-years			
		% Survival <sup>1</sup>	95%CI			% Survival <sup>1</sup>	95%CI			% Survival <sup>1</sup>	95%CI		
Newcastle	328	92.2	88.7	to	94.7	83.80	79.2	to	87.5	79.6	74.5	to	83.7
Sheffield	94	100.0				95.70	89.1	to	98.4	89.4	81.1	to	94.1
Papworth	540	92.6	90.0	to	94.5	86.20	82.8	to	88.9	81.5	77.8	to	84.7
Harefield	375	91.7	88.4	to	94.1	89.70	86.1	to	92.4	85.6	81.5	to	88.9
St George's	101	85.1	76.6	to	90.8	79.20	69.9	to	85.9	75.2	65.5	to	82.5
Birmingham	278	89.0	84.5	to	92.2	82.20	76.8	to	86.4	75.8	69.8	to	80.8
Manchester	254	95.9	92.6	to	97.8	88.40	83.6	to	91.9	80.1	74.2	to	84.8
Glasgow	188	93.0	88.2	to	95.9	86.60	80.6	to	90.8	80.5	73.7	to	85.6
Gt Ormond St	13	92.3	56.6	to	98.9	83.10	47.2	to	95.5	71.2	33.4	to	90
<b>All centres</b>	<b>2171</b>	<b>92.3</b>	<b>91.1</b>	<b>to</b>	<b>93.4</b>	<b>86.40</b>	<b>84.8</b>	<b>to</b>	<b>87.8</b>	<b>81.0</b>	<b>79.2</b>	<b>to</b>	<b>82.7</b>

<sup>1</sup> p<0.01; <sup>2</sup> p<0.01; <sup>3</sup> p=0.03

**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

Centre	No cases	3-years			5-years		
		% Survival <sup>1</sup>	95%CI		% Survival <sup>1</sup>	95%CI	
Newcastle	281	90.8	86.8	to 93.7	86.30	81.4	to 89.9
Sheffield	94	95.7	89.1	to 98.4	89.40	81.1	to 94.1
Papworth	467	93.1	90.3	to 95.1	88.10	84.6	to 90.8
Harefield	335	97.9	95.6	to 99.0	93.40	90.1	to 95.6
St George's	86	93.0	85.1	to 96.8	88.30	79.4	to 93.5
Birmingham	222	92.3	87.8	to 95.2	85.20	79.4	to 89.5
Manchester	225	92.2	87.7	to 95.1	83.50	77.7	to 88.0
Glasgow	165	93.1	87.9	to 96.1	86.50	80.1	to 91.0
Gt Ormond St	12	90.0	47.3	to 98.5	77.10	34.5	to 93.9
<b>All centres</b>	<b>1887</b>	<b>93.5</b>	<b>92.3</b>	<b>to 94.6</b>	<b>87.80</b>	<b>86.2</b>	<b>to 89.2</b>

<sup>1</sup>p=0.06; <sup>2</sup>p=0.05

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

a) Overall survival

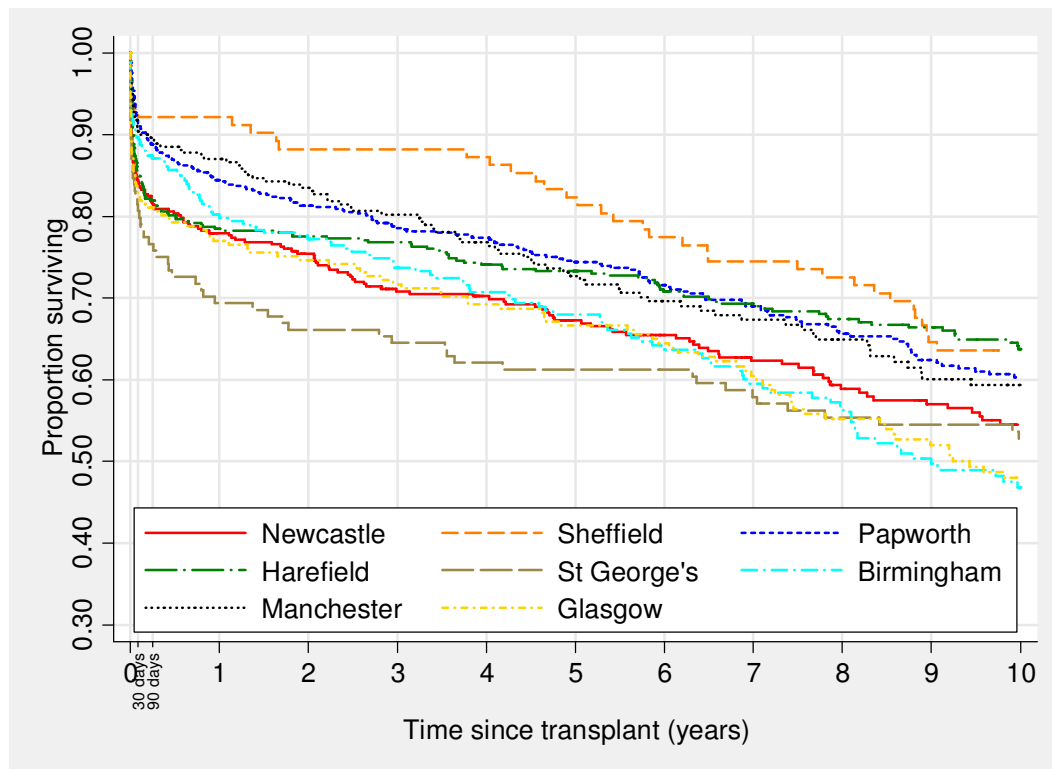
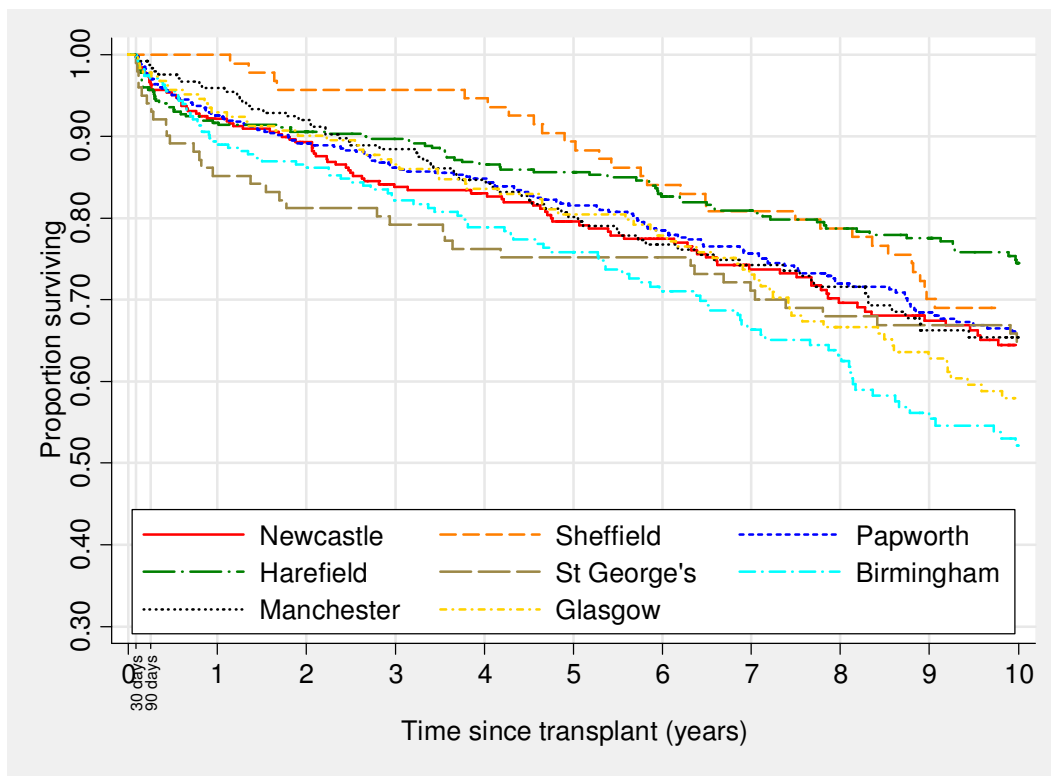
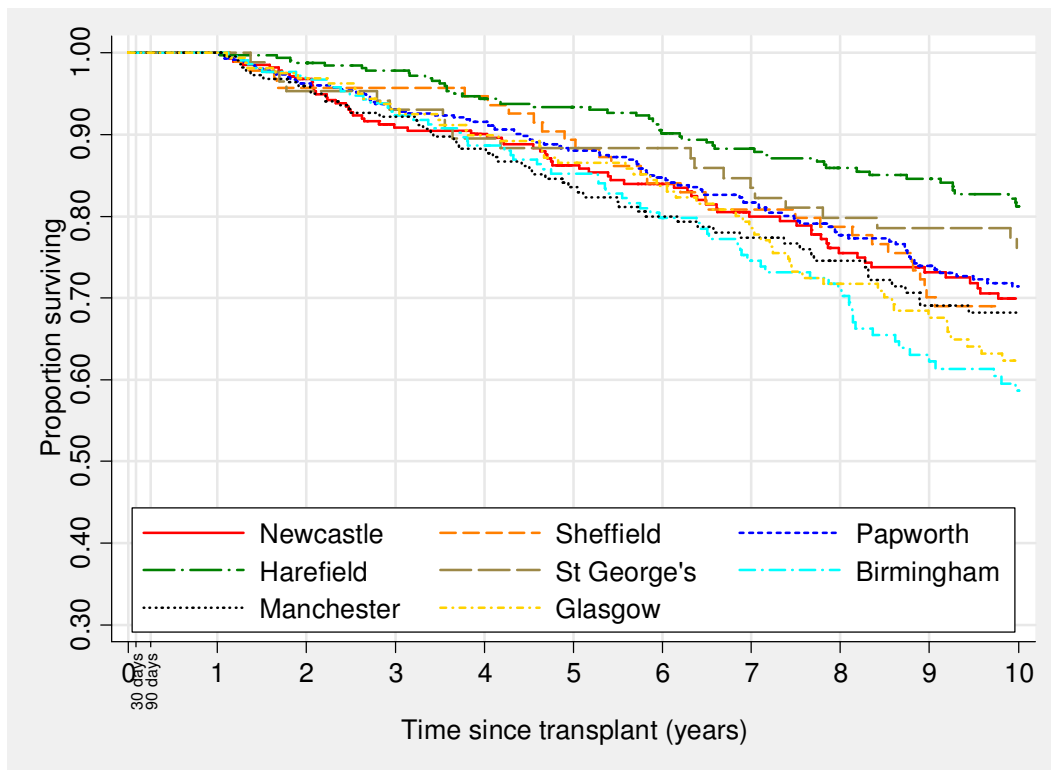


Figure 4 continued

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 2009 – March 2012

Retrieval Centre	30 days						90 days						% used locally	% used for UHAS patient
	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			No cases	No deaths	Mortality rate <sup>2</sup>	95%CI				
Newcastle	42	7	16.7	7.0	to	31.4	42	8	19.0	8.6	to	34.1	47.6	42.9
Papworth	73	5	6.8	2.3	to	15.3	72	7	9.7	4.0	to	19.0	71.2	58.9
Harefield	37	7	18.9	8.0	to	35.2	37	8	21.6	9.8	to	38.2	54.1	51.4
Birmingham	57	8	14.0	6.3	to	25.8	57	8	14.0	6.3	to	25.8	61.4	40.4
Manchester	46	8	17.4	7.8	to	31.4	46	10	21.7	10.9	to	36.4	41.3	58.7
Glasgow	22	4	18.2	5.2	to	40.3	22	5	22.7	7.8	to	45.4	31.8	59.1
Gt Ormond St	1	0	0.0	0.0	to	97.5	1	0	0.0	0.0	to	97.5	100.0	0.0
Other <sup>3</sup>	5	1	20.0	0.5	to	71.6	5	1	20.0	0.5	to	71.6	0.0	80.0
<b>All centres</b>	<b>283</b>	<b>40</b>	<b>14.1</b>	<b>10.3</b>	<b>to</b>	<b>18.7</b>	<b>282</b>	<b>47</b>	<b>16.7</b>	<b>12.5</b>	<b>to</b>	<b>21.5</b>	<b>54.4</b>	<b>51.9</b>

**Table 10** continued

b) April 2011 – March 2012

Retrieval Centre	30 days						90 days						% used locally	% used for UHAS patient
	No cases	No deaths	Mortality Rate <sup>1</sup>	95%CI			No cases	No deaths	Mortality Rate <sup>2</sup>	95%CI				
Newcastle	11	2	18.2	2.3	to	51.8	11	2	18.2	2.3	to	51.8	54.5	45.5
Papworth	35	2	5.7	0.7	to	19.2	34	2	5.9	0.7	to	19.7	77.1	60.0
Harefield	14	3	21.4	4.7	to	50.8	14	3	21.4	4.7	to	50.8	64.3	64.3
Birmingham	20	4	20.0	5.7	to	43.7	20	4	20.0	5.7	to	43.7	65.0	50.0
Manchester	22	3	13.6	2.9	to	34.9	22	3	13.6	2.9	to	34.9	54.5	63.6
Glasgow	2	0	0.0	0.0	to	84.2	2	0	0.0	0.0	to	84.2	50.0	50.0
Gt Ormond St	1	0	0.0	0.0	to	97.5	1	0	0.0	0.0	to	97.5	100.0	0.0
Other <sup>3</sup>	2	1	50.0	1.3	to	98.7	2	1	50.0	1.3	to	98.7	0.0	50.0
<b>All centres</b>	<b>107</b>	<b>15</b>	<b>14.0</b>	<b>8.1</b>	<b>to</b>	<b>22.1</b>	<b>106</b>	<b>15</b>	<b>14.2</b>	<b>8.1</b>	<b>to</b>	<b>22.3</b>	<b>64.5</b>	<b>57.0</b>

<sup>1</sup> a) p=0.44; b) p=0.37

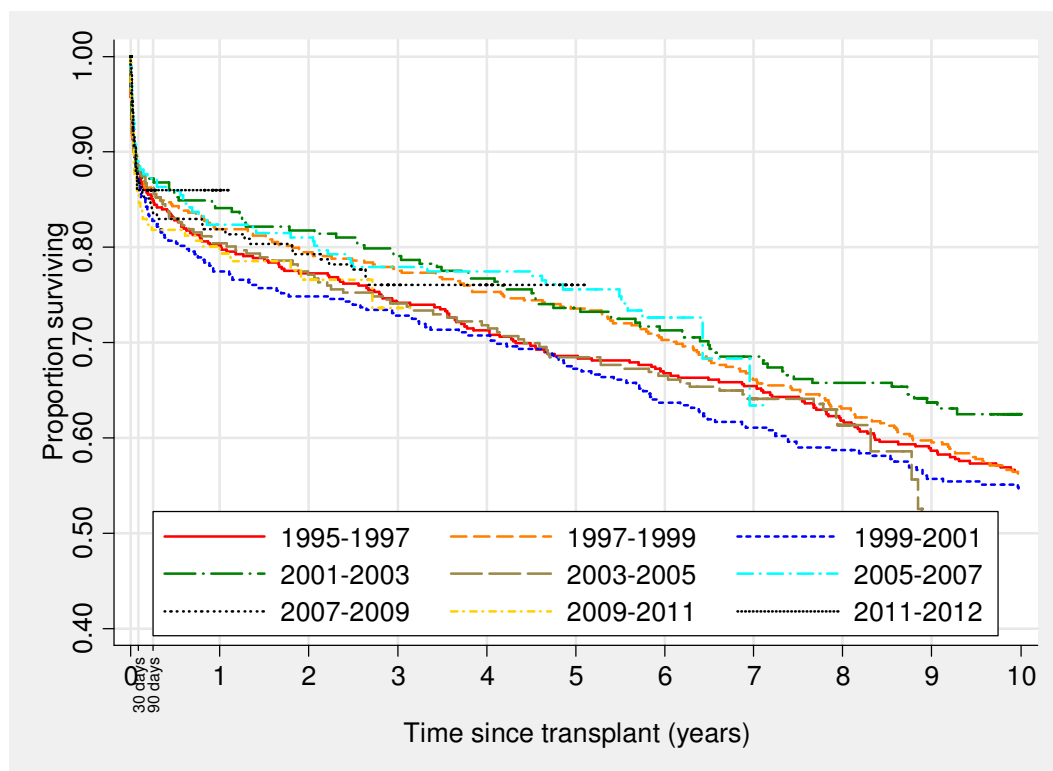
<sup>2</sup> a) p=0.49; b) p=0.40

<sup>3</sup> Republic of Ireland or other overseas centre

### 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 ( $p=0.19$ ). Similarly, no significant variation in 90-day mortality was found ( $p=0.17$ ). Longer-term survival to 1, 3, 5 and 10 years has also not changed significantly (log-rank test for trend, 1-year,  $p=0.56$ ; 3-year,  $p=0.63$ ; 5-year,  $p=0.34$ ; 10-year,  $p=0.29$ ). 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 since the early years of the audit 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 more recent eras is seen for most adult centres. Factors included in the risk adjustment are given in Appendix 1.

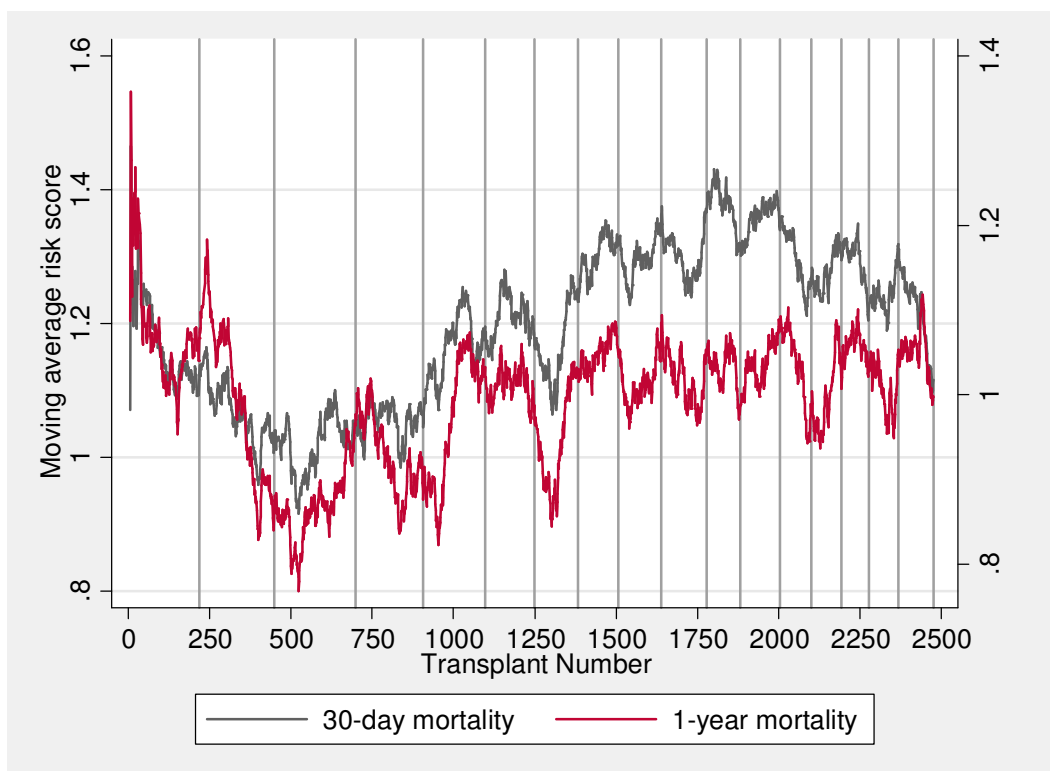


## Risk-adjusted mortality

### Centre specific mortality

**Table 11** shows the risk adjusted 30-day mortality rates and centre effect estimates following heart transplantation for the periods April 2009 to March 2012 and April 2011 to March 2012. The corresponding estimates for 90-day mortality are shown in **Error! Reference source not found..** 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.

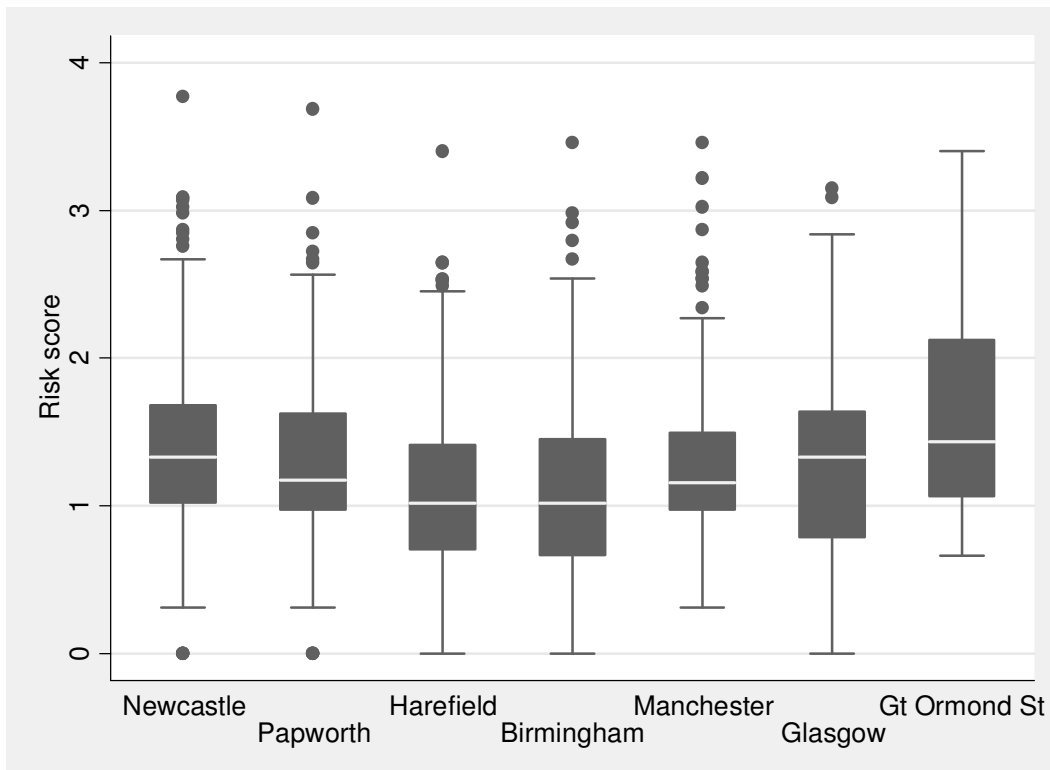
**Figure 6** Risk scores for 30-day and 1-year mortality after adult heart transplantation over time



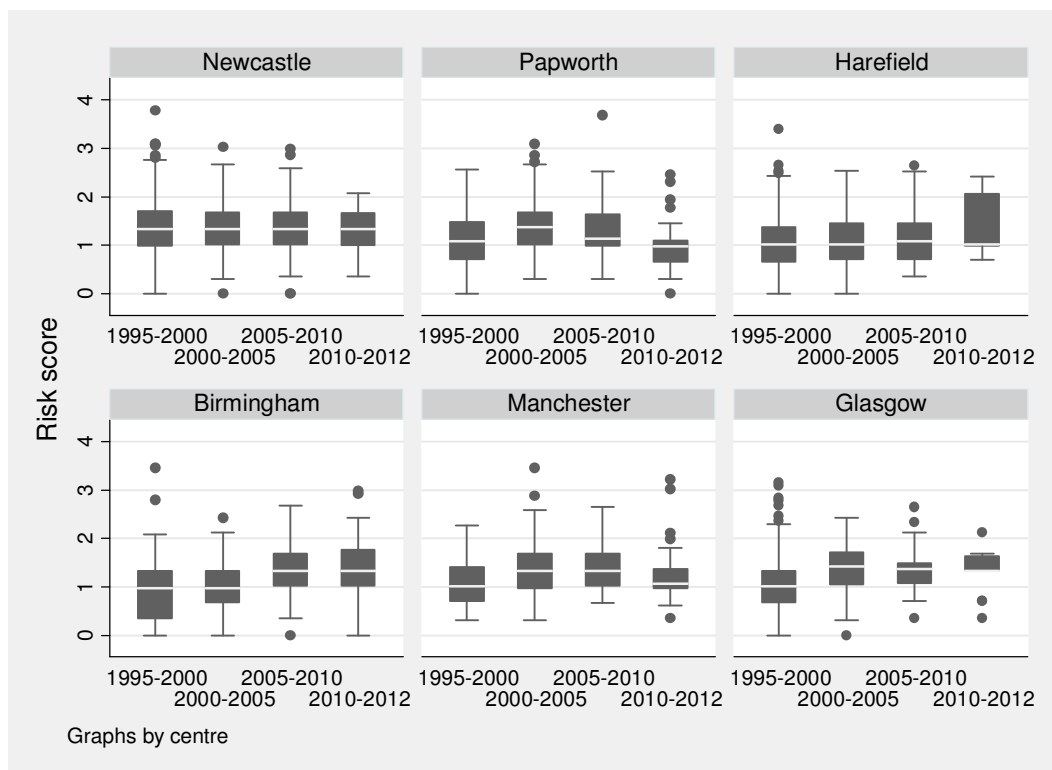
Note: Vertical lines represent the start of each audit year

**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*



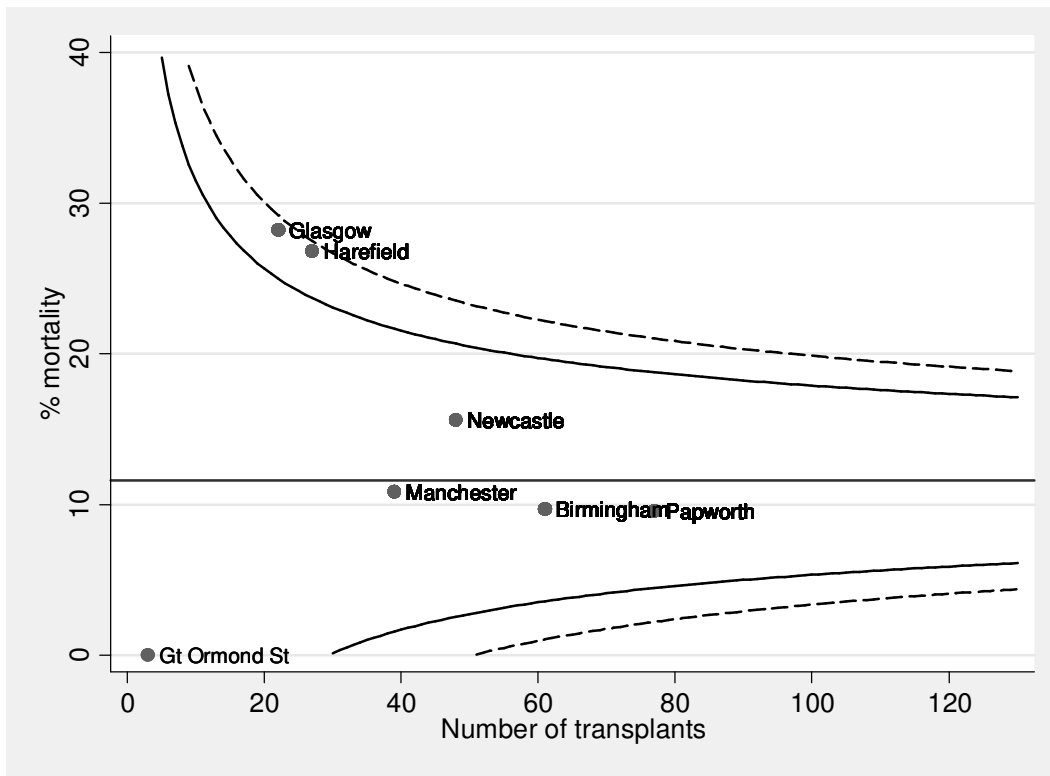
Graphs by centre

After risk adjustment, Harefield had significantly higher than expected mortality at 90 days during the period since April 2009, as indicated by the positive centre effect estimate. These data are further illustrated in **Error! Reference source not found.**, which shows the risk-adjusted mortality estimate for each centre with the 95% and 99% confidence intervals.

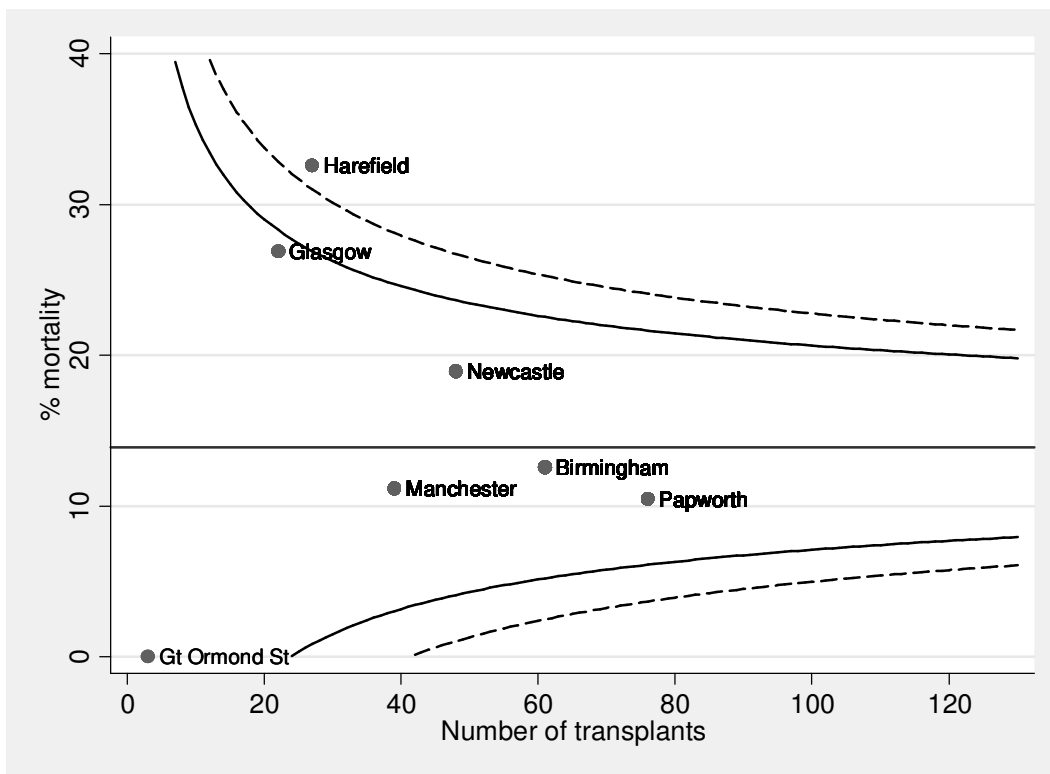
Risk adjusted centre effect estimates for 1-year mortality following heart transplantation for the whole audit, and for the period April 2008 to March 2011 are shown in

**Figure 8** Risk-adjusted estimates of early mortality after adult heart transplantation, April 2009 to March 2012

a) 30-days



b) 90-days



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

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 2008 to March 2011 two centres was identified as divergent; there were more deaths than expected at Harefield and fewer expected at Papworth.

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

a) *April 2009 – March 2012*

Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	48	15.0	7.1	to	25.8	0.34	-0.42	to	1.65
Papworth	77	9.8	3.8	to	19.1	-0.18	-0.70	to	0.79
Harefield	27	23.3	10.9	to	38.4	1.31	-0.07	to	3.76
Birmingham	61	9.9	4.2	to	18.4	-0.16	-0.66	to	0.72
Manchester	39	10.9	3.8	to	22.3	-0.07	-0.70	to	1.18
Glasgow	22	24.2	11.4	to	39.7	1.43	-0.02	to	4.00
Gt Ormond St	3	0.0	0.0	to	49.8	-1.00	-1.00	to	6.56

b) *April 2011– March 2012*

Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	15	25.5	8.6	to	46.8	1.61	-0.29	to	5.69
Papworth	31	14.4	3.3	to	32.9	0.28	-0.74	to	2.73
Harefield	7	11.9	0.3	to	43.0	0.03	-0.97	to	4.74
Birmingham	22	7.6	1.0	to	23.0	-0.37	-0.92	to	1.28
Manchester	18	9.9	1.3	to	28.3	-0.17	-0.90	to	2.01
Glasgow	9	25.6	6.6	to	50.1	1.62	-0.46	to	6.65
Gt Ormond St	1	0.0	0.0	to	83.7	-1.00	-1.00	to	38.11

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

a) *April 2009 – December 2012*

Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
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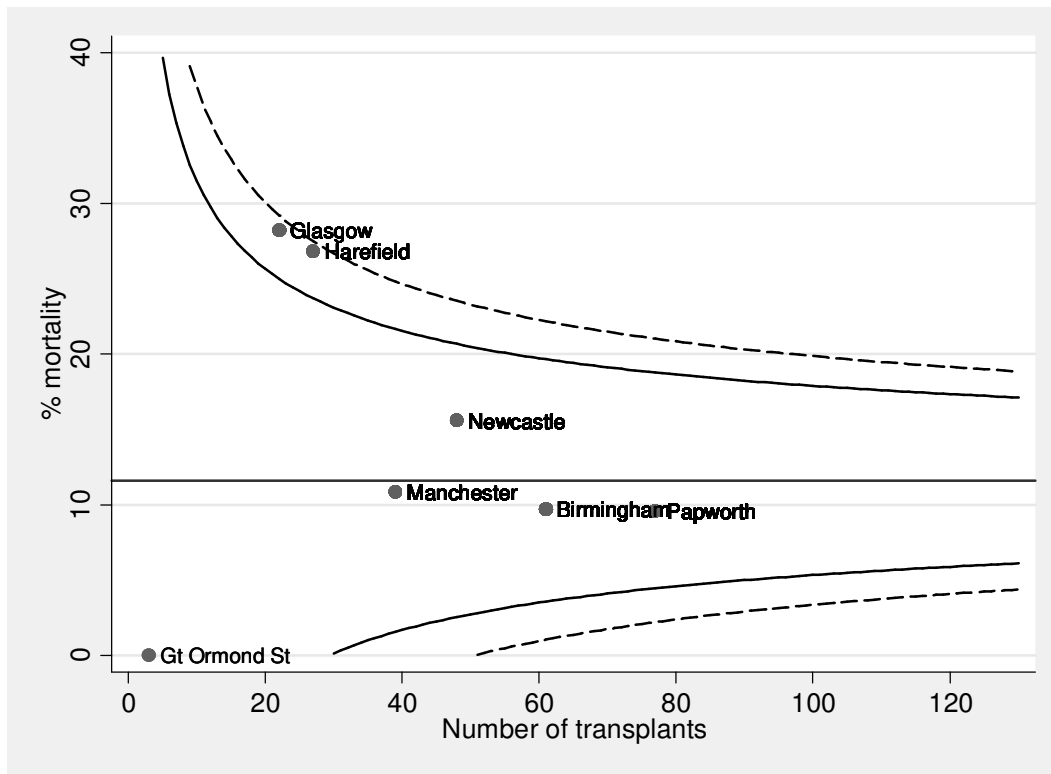
Newcastle	48	18.0	9.5	to	28.8	0.37	-0.35	to	1.51
Papworth	77	10.8	4.7	to	20.0	-0.25	-0.70	to	0.55
Harefield	27	27.5	14.8	to	41.8	1.35	0.07	to	3.46
Birmingham	61	12.7	6.3	to	21.7	-0.09	-0.59	to	0.72
Manchester	39	11.5	4.0	to	23.2	-0.20	-0.74	to	0.88
Glasgow	22	23.8	11.2	to	39.2	0.94	-0.22	to	3.00
Gt Ormond St	3	0.0	0.0	to	50.7	-1.00	-1.00	to	5.39

b) *April 2011 – March 2012*

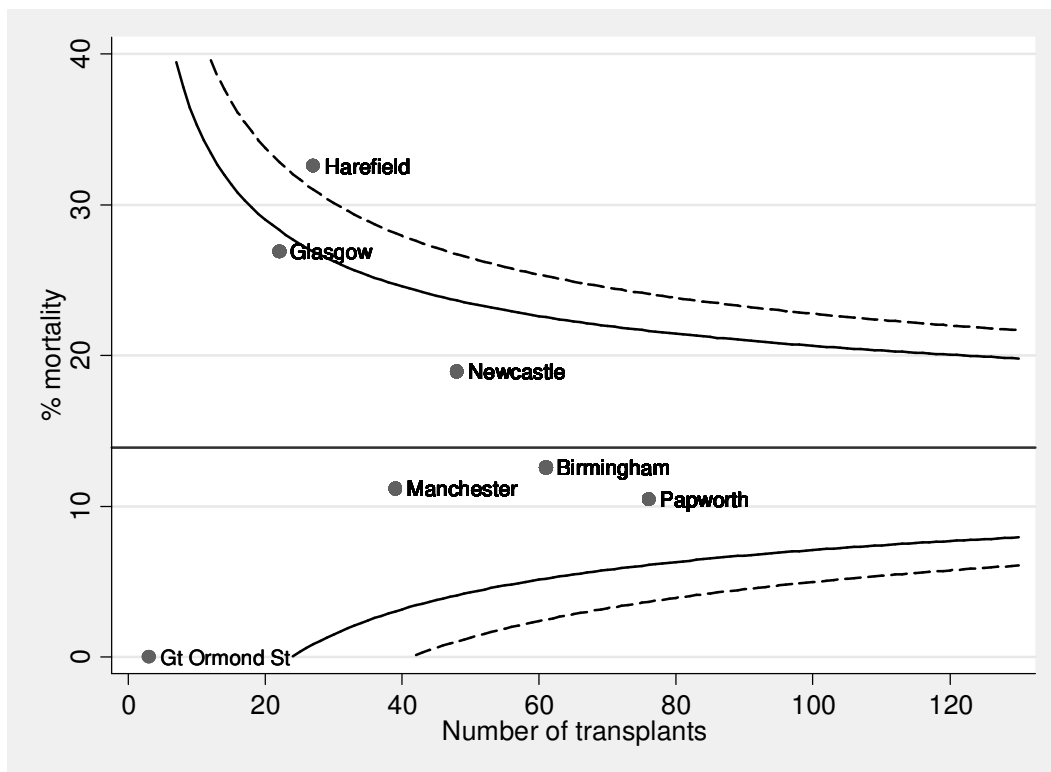
Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	15	25.1	8.4	to	46.1	1.08	-0.43	to	4.32
Papworth	31	13.3	3.1	to	31.0	-0.05	-0.80	to	1.79
Harefield	7	11.7	0.3	to	42.6	-0.17	-0.98	to	3.60
Birmingham	22	7.8	1.0	to	23.4	-0.47	-0.94	to	0.90
Manchester	18	10.2	1.4	to	29.1	-0.29	-0.91	to	1.55
Glasgow	9	24.6	6.3	to	48.8	1.03	-0.58	to	4.93
Gt Ormond St	1	0.0	0.0	to	82.6	-1.00	-1.00	to	28.44

**Figure 8 Risk-adjusted estimates of early mortality after adult heart transplantation, April 2009 to March 2012**

a) 30-days



b) 90-days



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	377	77.3	73.3	to	81.0	0.24	-0.01	to	0.53
Sheffield	87	91.8	82.8	to	97.2	-0.62	-0.88	to	-0.12
Papworth	584	85.2	82.4	to	87.7	-0.27	-0.41	to	-0.10
Harefield	410	77.8	73.9	to	81.4	0.20	-0.04	to	0.48
St George's	117	69.3	61.9	to	76.4	0.86	0.30	to	1.59
Birmingham	305	79.5	75.1	to	83.6	0.08	-0.18	to	0.40
Manchester	278	86.8	82.5	to	90.4	-0.36	-0.55	to	-0.11
Glasgow	222	77.3	72.1	to	82.0	0.24	-0.08	to	0.63
Gt Ormond St	15	83.0	62.5	to	95.9	-0.14	-0.82	to	1.53

b) *April 2008– March 2011*

Centre	No cases	% survival	95%CI			Centre effect	95%CI		
Newcastle	52	80.9	69.7	to	89.8	0.16	-0.44	to	1.13
Papworth	75	92.4	85.6	to	96.8	-0.60	-0.84	to	-0.17
Harefield	31	64.6	52.5	to	76.5	1.70	0.51	to	3.45
Birmingham	52	78.5	68.1	to	87.3	0.35	-0.28	to	1.30
Manchester	34	89.8	77.4	to	97.0	-0.44	-0.85	to	0.44
Glasgow	19	83.6	66.5	to	94.9	-0.03	-0.74	to	1.48
Gt Ormond St	3	100.0	41.0	to	100.0	-1.00	-1.00	to	6.06

### 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.

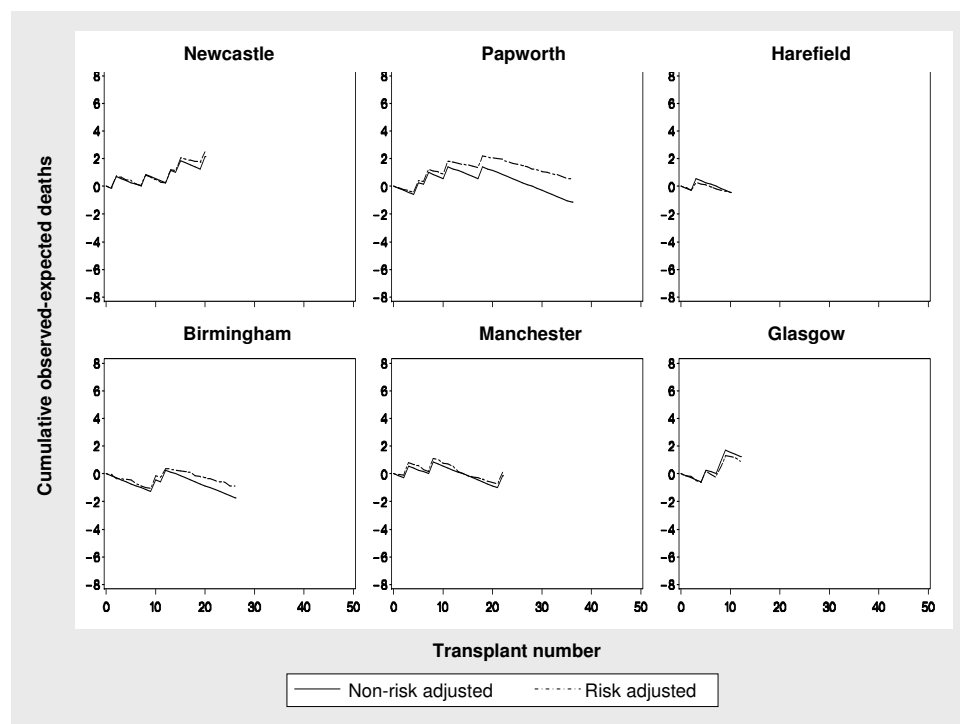
### Tabular CUSUM charts

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

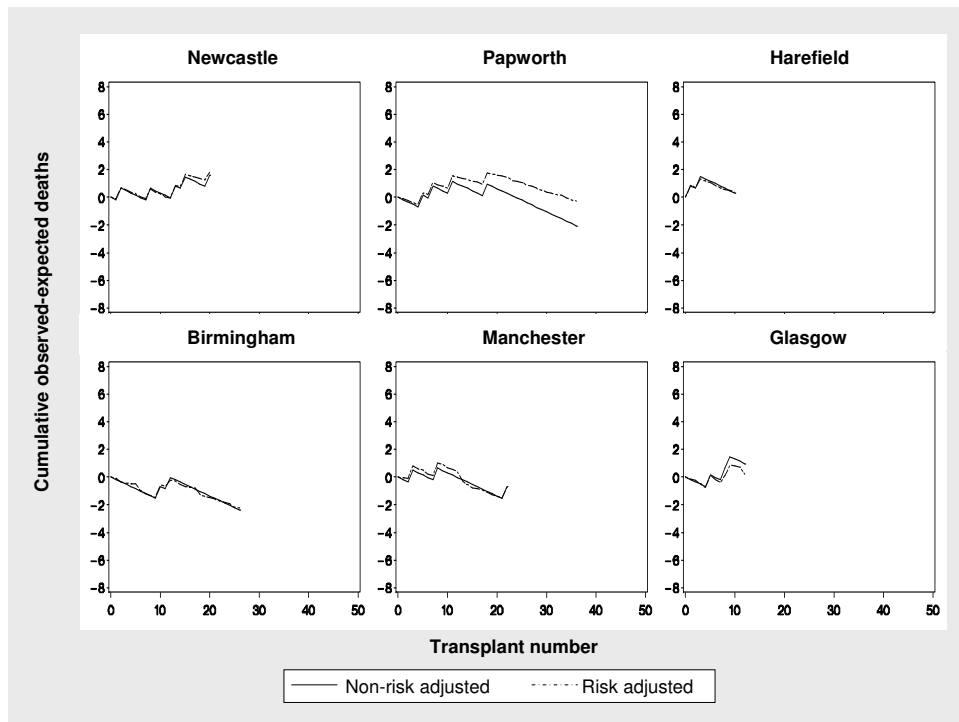
The CUSUM charts illustrate that since January 2011 the 30- and 90-day mortality rates following adult heart transplantation have been as expected at all centres.

As described in section 2, signals following adult heart transplantation at Harefield and Glasgow in 2011 have been investigated through external reviews of their service. These signals do not appear in the charts below due to a subsequent change in time period shown in the CUSUM charts (previously from January 2004 onwards, now from January 2011 onwards), excluding some earlier deaths that contributed to the signals.

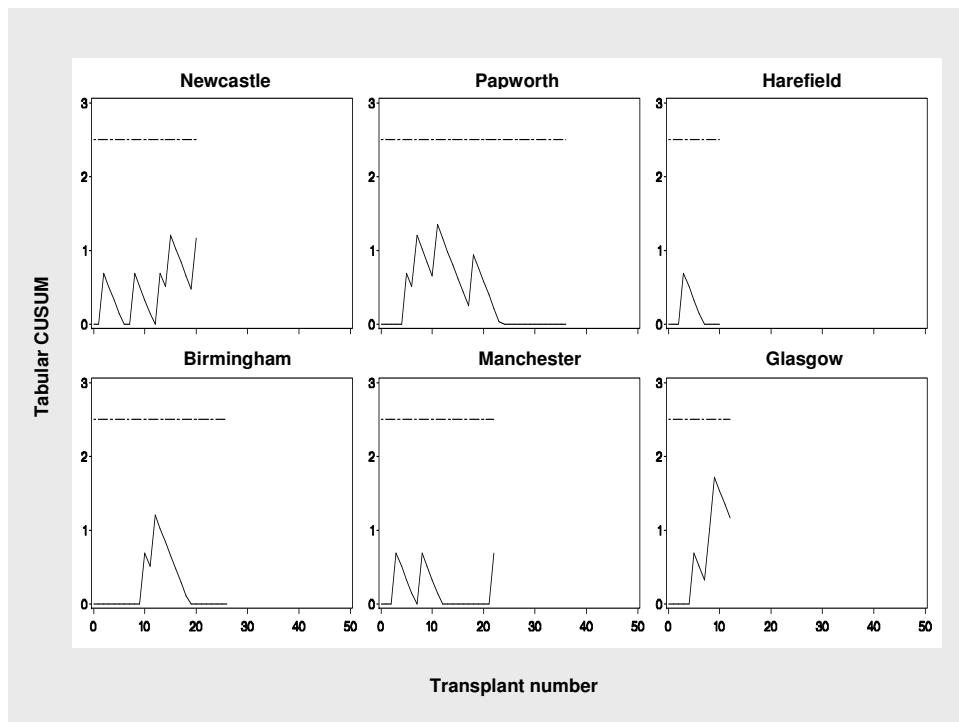
**Figure 9** Cumulative (observed – expected) 30-day mortality after adult heart transplantation, January 2011 to March 2012



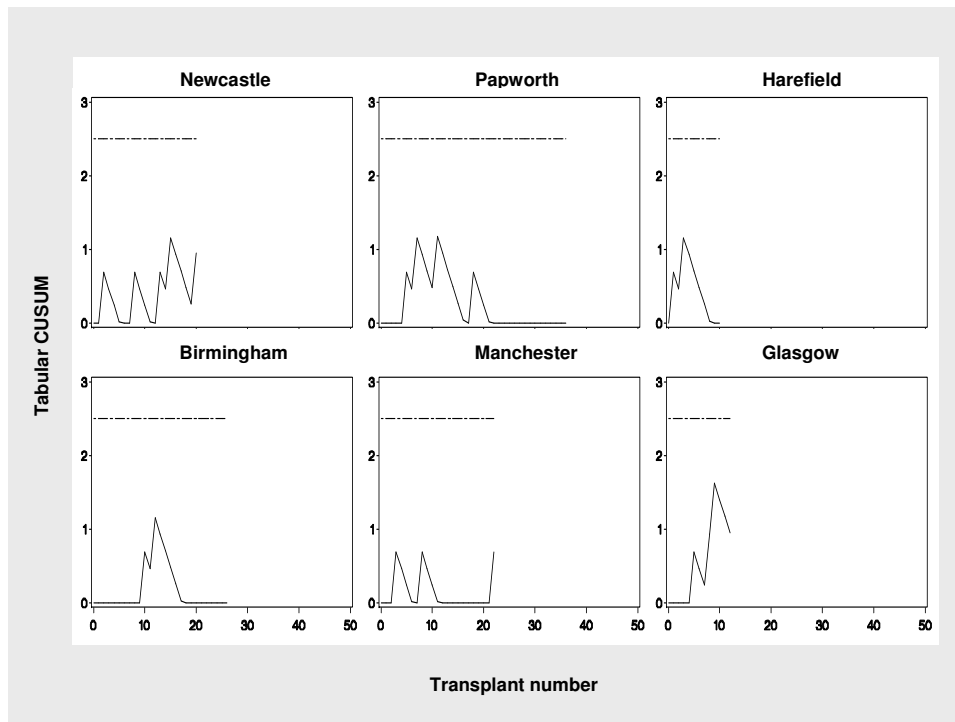
**Figure 10** Cumulative (observed – expected) 90-day mortality after adult heart transplantation, January 2011 to March 2012



**Figure 11** Tabular CUSUM for 30-day mortality after adult heart transplantation *unadjusted* for patient risk, January 2011 to March 2012



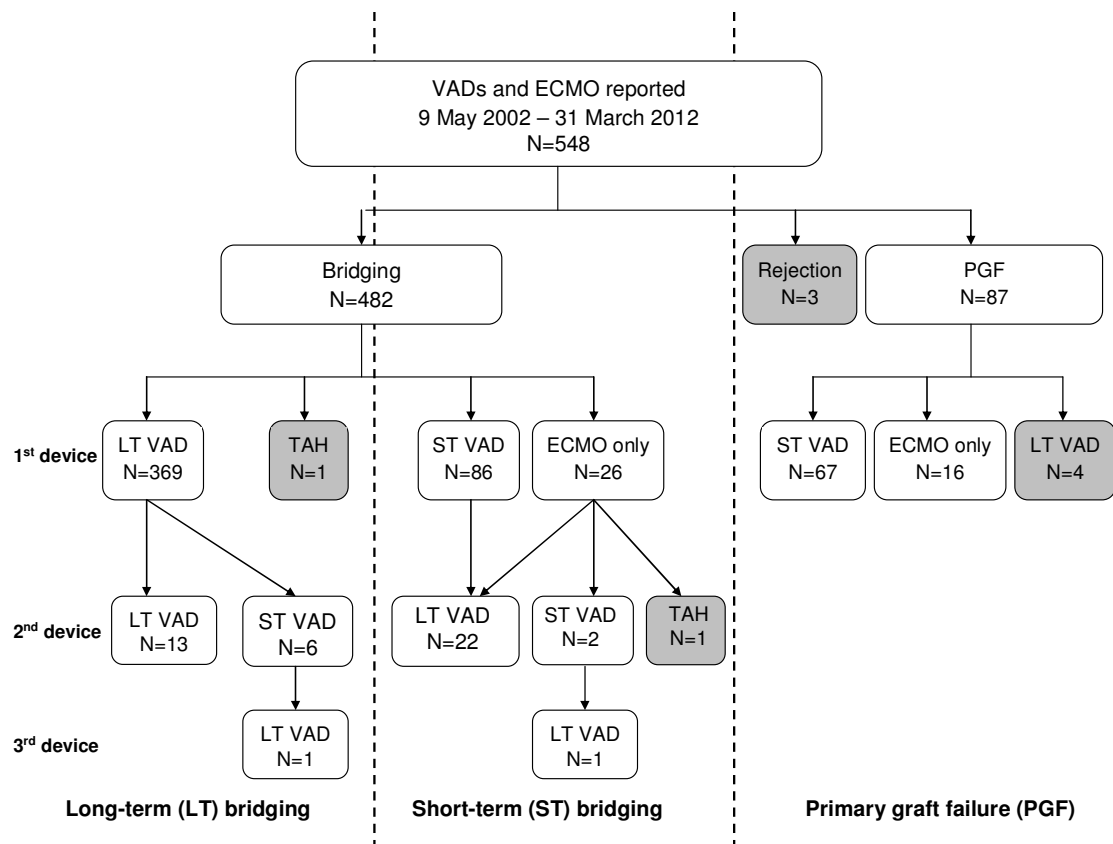
**Figure 12** Tabular CUSUM for 90-day mortality after adult heart transplantation *unadjusted* for patient risk, January 2011 to March 2012



### Ventricular assist devices

**Figure 13** shows the data cohort for the VAD section of the report. The results are presented in three main sections and the dotted lines and titles at the bottom of the figure indicate which patients are reported in each section. Note that some patients included in the bridging section also received a VAD for primary graft failure (PGF) and are included in both sections. Also, some patients may have received concurrent ECMO support with their VAD. Uncommon treatment options (shaded in grey) such as total artificial heart (TAH) bridging, treatment of rejection several years post-transplant and long-term VADs for PGF are presented in text only in the relevant section.

**Figure 13 Data cohort for the three VAD sections (N=number of patients)**



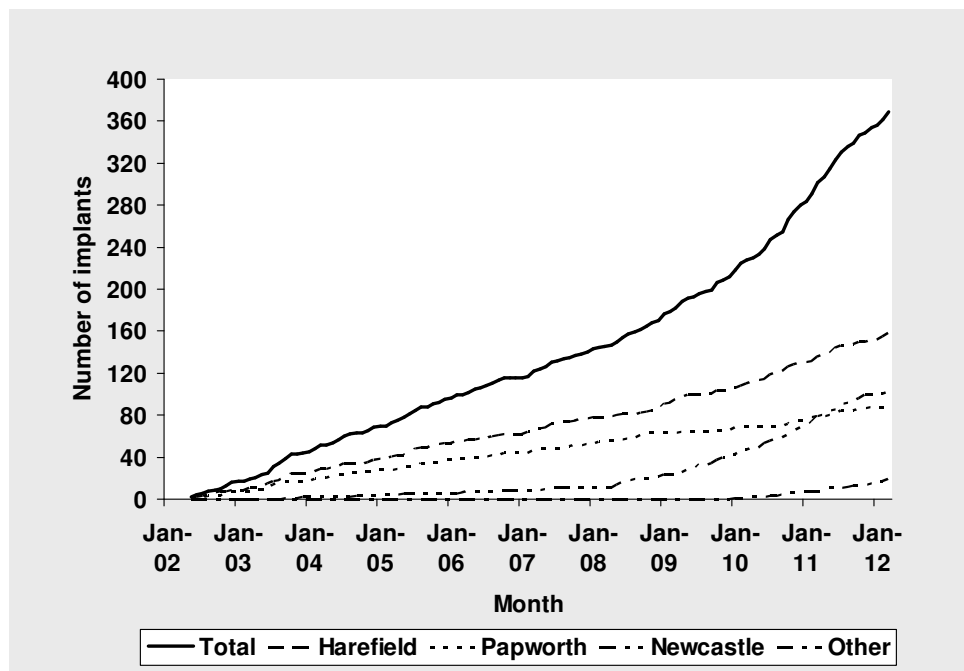
### Long term devices used for bridging

Long-term left ventricular assist devices (LVADs) were implanted for 392 patients at six implant centres in the UK. Eighteen patients received a short-term device and four 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 along with one patient who received a short-period of ECMO support and a short-term device prior to a long-term device. An additional patient received a total artificial heart (TAH) and is still on support as at 31 July 2012.

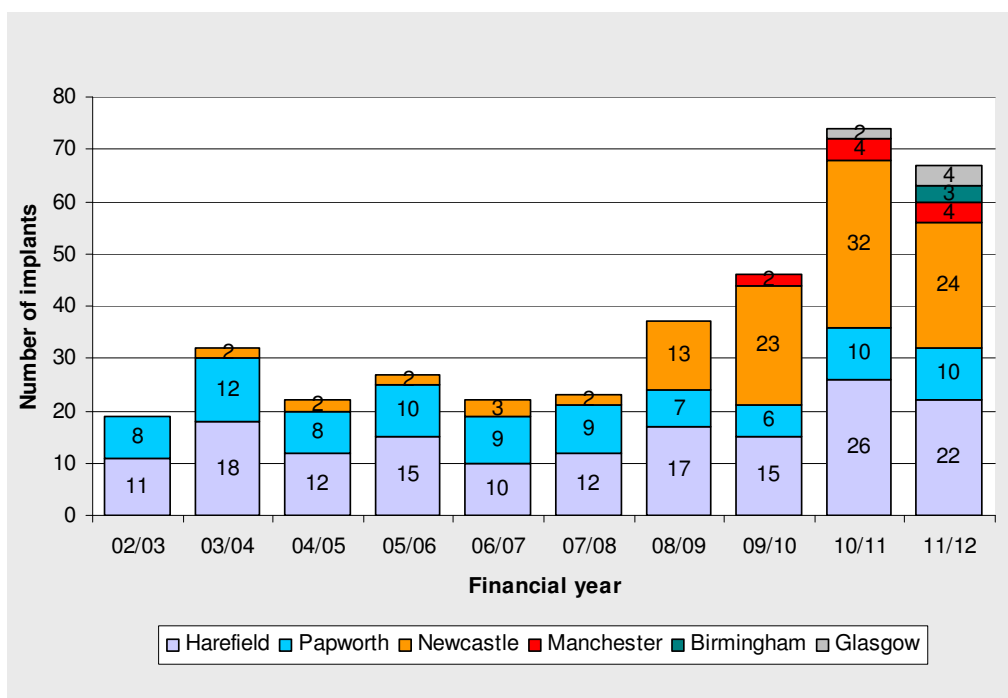
Of the remaining 369 patients, 158 devices have been implanted by Harefield, 103 by Newcastle, 89 by Papworth, 10 by Manchester, 6 by Glasgow and 3 by Birmingham. Forty-three of these patients also received long-term right ventricular assist devices (RVADs) and 43 received short-term RVADs. One patient 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. Thirteen patients had their long-term device replaced, and six patients had a short-term VAD implanted shortly after explant of the long-term device. One of these patients then received a long-term device as a third device (LT-ST-LT).

**Figure 14** shows the cumulative number of VADs implanted each month, overall and by centre, whilst **Figure 15** shows the number of VADs by financial year and centre. VAD activity has been broadly consistent across the time period, with increased VAD activity at Newcastle during the last three financial years.

**Figure 14** Cumulative long-term VAD activity, by month and implant centre, May 2002 to March 2012



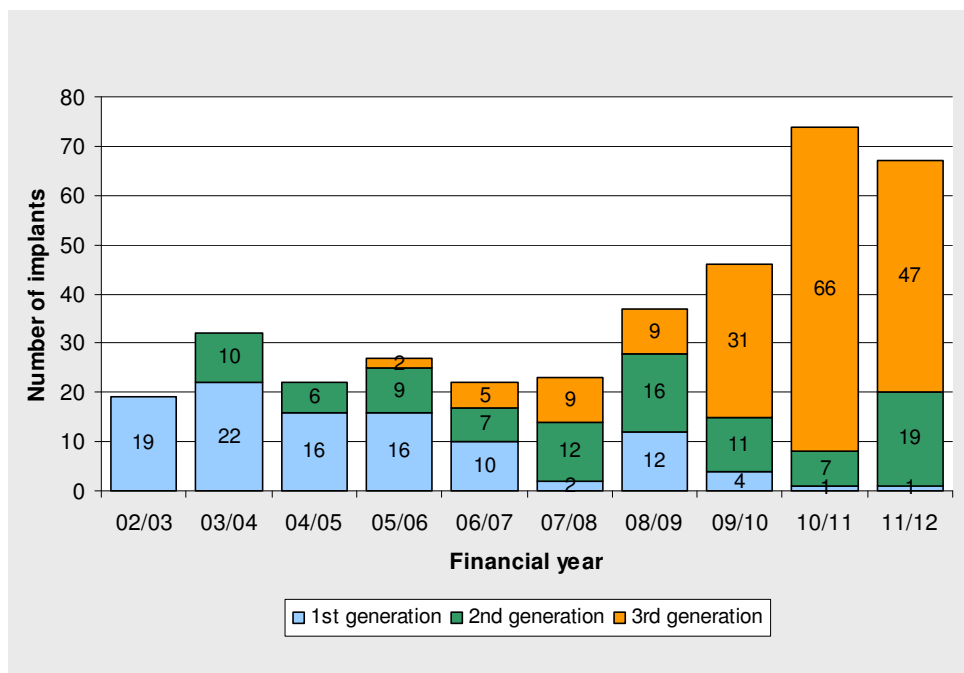
**Figure 15** Long-term VAD activity, by financial year and implant centre, May 2002 to March 2012



**Figure 16** shows the number of long-term devices categorised by generation of device and shows the majority of long-term devices implanted in the last three years were third generation.

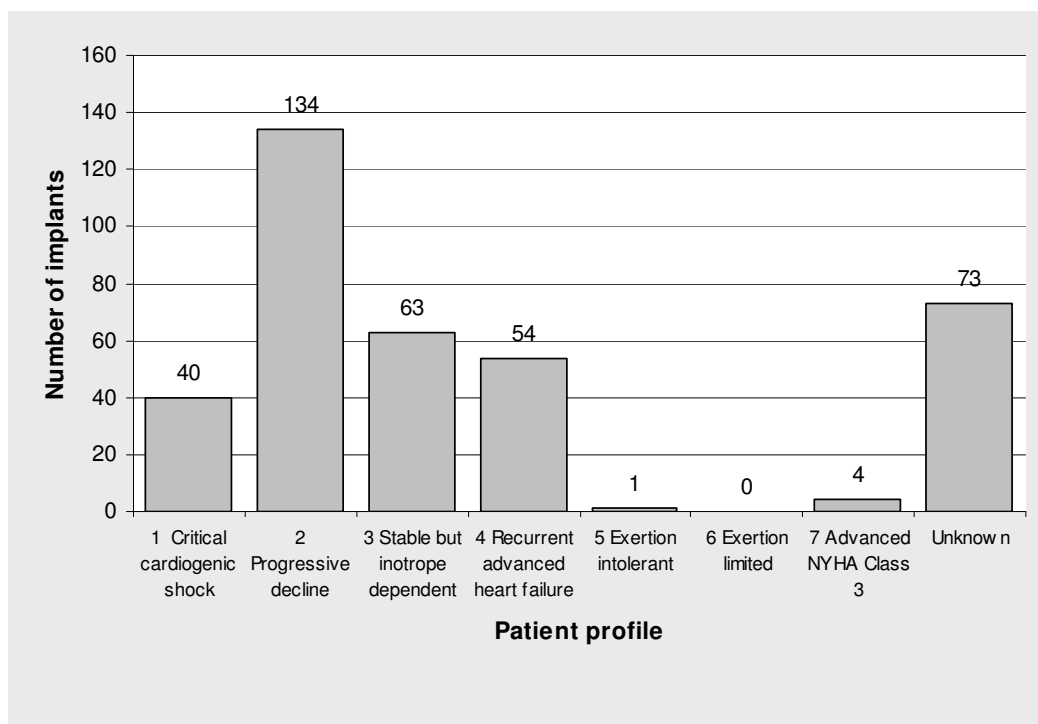
Of the patients who received a long-term device, dilated cardiomyopathy (62%) and ischaemic heart disease (30%) were the most frequently reported cardiothoracic diseases. The median age at implant was 47 years (inter-quartile range: 35-55 years) and the majority of recipients (82%) were male.

**Figure 16** Long-term VAD generation, by financial year, May 2002 to March 2012

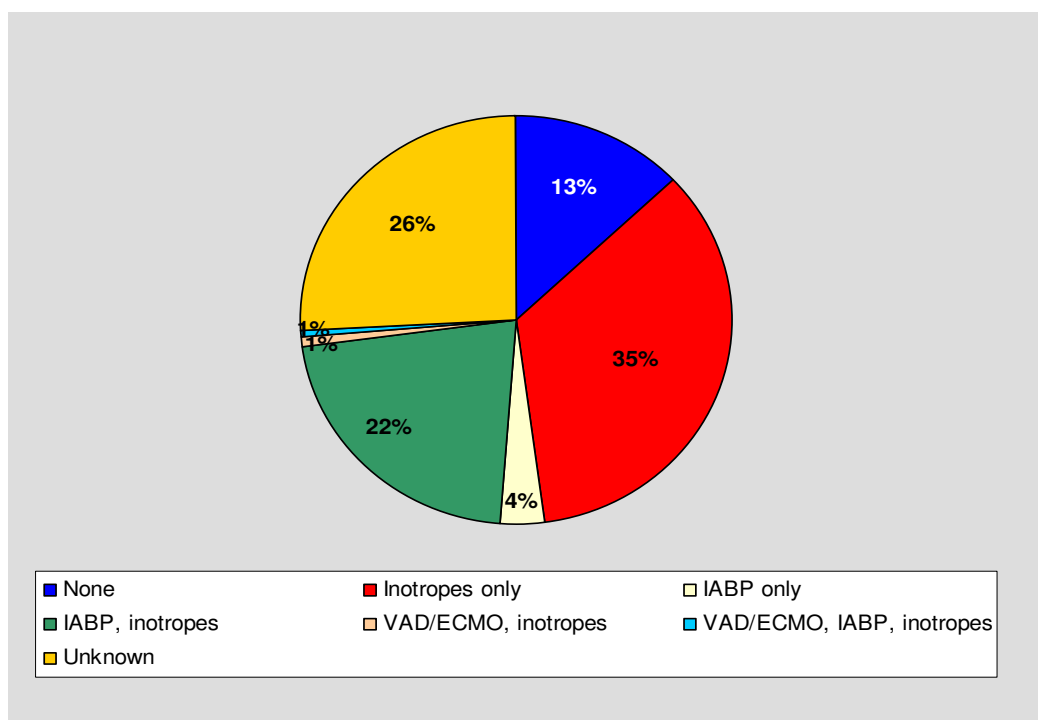


**Figure 17** shows the INTERMACS patient profile at time of VAD implantation and shows that the majority of patients had profiles 1, 2, 3 or 4. **Figure 18** shows the treatment prior to VAD implantation and shows that 59% were on inotropes at VAD implantation and 28% were on IABP. The unknown groups in **Figures 17** and **18** include patients whose data has not been entered onto the VAD database yet.

**Figure 17 Long-term VAD patient profile, May 2002 to March 2012**



**Figure 18 Treatment history prior to long-term VAD implantation, May 2002 to March 2012**





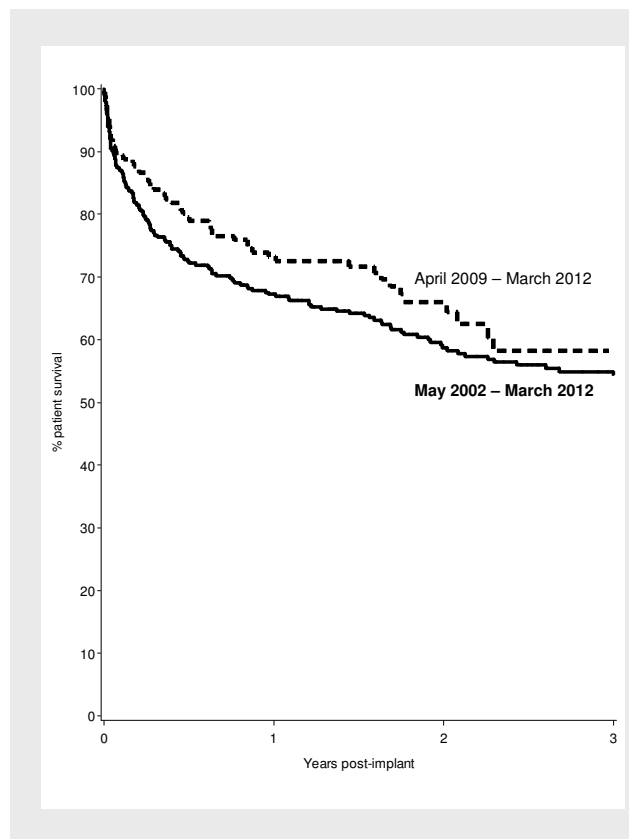
**Table 14** shows the long-term VAD outcome of recipients, by centre, for the whole time period and for the most recent three years. Nationally, 94 patients were transplanted, 28 survived explantation of the VAD, 126 died on support, two died within a month of explantation and 119 were still on support on 31 July 2012. Deaths which occur more than one year after transplant or device explant are not referenced in these tables.

Long-term VAD duration of support ranged between 0 and 2,658 days (seven years). Using the Kaplan-Meier estimation method, median long-term VAD duration for all patients was estimated to be 288 days (95% CI: 227 to 349 days).

**Table 15** shows Kaplan-Meier estimates of patient survival from time of first implant to death. Patients still alive were censored at 31 July 2012. Other events, such as device explantation or transplantation were not censored. Centre-specific survival rates for Manchester, Glasgow and Birmingham are not presented due to small numbers of implants performed. Overall survival rates are higher in the most recent three years (see **Figure 19**).

**Table 16** shows patient survival during VAD support. Unlike the survival estimates presented in **Table 15**, survival was censored at time of device explantation or transplantation. The survival during VAD support was similar to the overall patient survival for both the whole time period and the most recent three years. This is due to the majority of patients either being on support as at 31 July 2012 or dying whilst on VAD support, and survival during VAD support is identical to overall patient survival in these cases.

**Figure 19** Overall patient survival after implant of long-term VAD, by era, May 2002 to March 2012



**Table 14 Outcome of long-term VADs, by implant centre, May 2002 to March 2012**

a) *May 2002 to March 2012*

Outcome	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	11	11%	35	39%	23	15%	0	0%	1	10%	0	0%	70 <sup>2,0</sup>	19%
Alive (post explant)	4	4%	1	1%	21	13%	0	0%	1	10%	1	17%	28 <sup>3,3</sup>	8%
Alive with VAD	48	47%	18	20%	43	27%	2	67%	5	50%	3	50%	119 <sup>2,0</sup>	32%
<i>Total alive</i>	63	61%	54	61%	87	55%	2	67%	7	70%	4	67%	217 <sup>7,3</sup>	59%
Died (post transplant)	7	7%	5	6%	11	7%	0	0%	0	0%	1	17%	24 <sup>2,0</sup>	7%
Died (post explant)	0	0%	1	1%	1	1%	0	0%	0	0%	0	0%	2	1%
Died with VAD	33	32%	29	33%	59	37%	1	33%	3	30%	1	17%	126 <sup>4,3</sup>	34%
<i>Total died</i>	40	39%	35	39%	71	45%	1	33%	3	30%	2	33%	152 <sup>6,3</sup>	41%
<b>TOTAL</b>	<b>103</b>	<b>100%</b>	<b>89</b>	<b>100%</b>	<b>158</b>	<b>100%</b>	<b>3</b>	<b>100%</b>	<b>10</b>	<b>100%</b>	<b>6</b>	<b>100%</b>	<b>369<sup>13,6</sup></b>	<b>100%</b>

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

**Table 14**                      **Continued**

b)      *April 2009 to March 2012*

Outcome	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	4	5%	3	12%	3	5%	0	0%	1	10%	0	0%	11	6%
Alive (post explant)	4	5%	0	0%	2	3%	0	0%	1	10%	1	17%	8	4%
Alive with VAD	46	58%	16	62%	37	59%	2	67%	5	50%	3	50%	109 <sup>2,0</sup>	58%
<i>Total alive</i>	54	68%	19	73%	42	67%	2	67%	7	70%	4	67%	128 <sup>2,0</sup>	68%
Died (post transplant)	2	3%	1	4%	1	2%	0	0%	0	0%	1	17%	5 <sup>1,0</sup>	3%
Died (post explant)	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Died with VAD	23	29%	6	23%	20	32%	1	33%	3	30%	1	17%	54 <sup>3,2</sup>	29%
<i>Total died</i>	25	32%	7	27%	21	33%	1	33%	3	30%	2	33%	59 <sup>4,2</sup>	32%
<b>TOTAL</b>	<b>79</b>	<b>100%</b>	<b>26</b>	<b>100%</b>	<b>63</b>	<b>100%</b>	<b>3</b>	<b>100%</b>	<b>10</b>	<b>100%</b>	<b>6</b>	<b>100%</b>	<b>187<sup>6,2</sup></b>	<b>100%</b>

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

**Table 15 Overall patient survival after implant of long-term VAD by implant centre, May 2002 to March 2012**

a) *May 2002 - March 2012*

Centre	No. at risk on day 0	% patient survival (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
Newcastle	103	87	(79 - 92)	82	(73 - 88)	67	(57 - 76)	58	(47 - 68)	56	(44 - 66)
Papworth	89	90	(81 - 95)	75	(65 - 83)	66	(55 - 75)	60	(49 - 70)	59	(47 - 68)
Harefield	158	86	(80 - 91)	79	(72 - 85)	67	(59 - 74)	57	(49 - 65)	51	(43 - 60)
<b>All centres</b>	<b>369</b>	<b>88</b>	<b>(84 - 91)</b>	<b>79</b>	<b>(75 - 83)</b>	<b>67</b>	<b>(62 - 72)</b>	<b>59</b>	<b>(53 - 64)</b>	<b>54</b>	<b>(49 - 60)</b>
<b>No. at risk</b>		<b>323</b>		<b>293</b>		<b>219</b>		<b>137</b>		<b>99</b>	

b) *April 2009 - March 2012*

Centre	No. at risk on day 0	% patient survival (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
Newcastle	79	90	(81 - 95)	87	(78 - 93)	74	(62 - 82)	64	(50 - 75)	60	(44 - 72)
Papworth	26	96	(76 - 99)	88	(68 - 96)	77	(56 - 89)	68	(42 - 85)	68	(42 - 85)
Harefield	63	87	(76 - 93)	83	(71 - 90)	72	(58 - 81)	66	(52 - 77)	58	(40 - 72)
<b>All centres</b>	<b>187</b>	<b>90</b>	<b>(85 - 93)</b>	<b>86</b>	<b>(80 - 90)</b>	<b>73</b>	<b>(66 - 79)</b>	<b>66</b>	<b>(58 - 73)</b>	<b>58</b>	<b>(48 - 67)</b>
<b>No. at risk</b>		<b>168</b>		<b>161</b>		<b>108</b>		<b>42</b>		<b>9</b>	

**Table 16 Survival during long-term VAD support, by implant centre, May 2002 to March 2012**

a) *May 2002 - March 2012*

Device	No. at risk on day 0	% survival on a device (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
Newcastle	103	87	(79 - 92)	83	(74 - 89)	69	(58 - 77)	62	(49 - 72)	57	(41 - 69)
Papworth	89	90	(81 - 95)	78	(68 - 86)	65	(53 - 75)	52	(31 - 69)	52	(31 - 69)
Harefield	158	86	(80 - 91)	79	(72 - 85)	68	(59 - 75)	57	(47 - 66)	39	(24 - 54)
<b>All centres</b>	<b>369</b>	<b>87</b>	<b>(84 - 90)</b>	<b>80</b>	<b>(76 - 84)</b>	<b>68</b>	<b>(63 - 73)</b>	<b>59</b>	<b>(52 - 65)</b>	<b>46</b>	<b>(35 - 56)</b>
<b>No. at risk</b>	<b>-</b>	<b>315</b>		<b>276</b>		<b>139</b>		<b>50</b>		<b>17</b>	

**Table 16** continued

b) April 2009 - March 2012

Device	No. at risk on day 0	% survival on a device (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
Newcastle	79	90	(81 - 95)	87	(78 - 93)	75	(63 - 83)	66	(51 - 77)	60	(41 - 74)
Papworth	26	96	(76 - 99)	92	(73 - 98)	80	(59 - 91)	67	(33 - 86)	67	(33 - 86)
Harefield	63	87	(76 - 93)	82	(71 - 90)	71	(57 - 81)	68	(53 - 79)	54	(33 - 72)
All centres	187	90	(84 - 93)	86	(80 - 90)	74	(67 - 80)	68	(59 - 75)	55	(41 - 67)
No. at risk	-	167		159		93		29		4	

**Table 17** 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,  $p=0.002$ ), and for those implanted after April 2009 (log-rank test,  $p=0.003$ ). However, treatment has not been randomised and it is likely that the pre-implant illness was more severe in the BiVAD group. **Table 18** shows the survival whilst on support, which is similar to the patient survival estimates.

**Table 17** Overall patient survival after implant of long-term VAD, by LVAD/BiVAD, May 2002 to March 2012

a) May 2002 - March 2012

Device	No. at risk on day 0	% patient survival (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
LVAD only	283	90	(86 - 93)	83	(79 - 87)	71	(65 - 76)	63	(57 - 69)	59	(52 - 65)
BiVAD	86	80	(70 - 87)	65	(54 - 74)	55	(43 - 64)	45	(34 - 56)	41	(30 - 52)
Overall	369	88	(84 - 91)	79	(75 - 83)	67	(62 - 72)	59	(53 - 64)	54	(49 - 60)
No. at risk	-	323		293		219		137		99	

**Table 17 continued**

*b) April 2009 - March 2012*

Device	No. at risk on day 0	% patient survival (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
LVAD only	166	92	(86 - 95)	88	(82 - 92)	75	(68 - 81)	69	(61 - 77)	62	(51 - 72)
BiVAD	21	76	(52 - 89)	67	(43 - 83)	57	(34 - 75)	42	(18 - 64)	28	(6 - 55)
<b>Overall</b>	<b>187</b>	<b>90</b>	<b>(85 - 93)</b>	<b>86</b>	<b>(80 - 90)</b>	<b>73</b>	<b>(66 - 79)</b>	<b>66</b>	<b>(58 - 73)</b>	<b>58</b>	<b>(48 - 67)</b>
No. at risk	-	<b>168</b>		<b>161</b>		<b>108</b>		<b>42</b>		<b>9</b>	

**Table 18 Survival during long-term VAD support, by LVAD/BiVAD, May 2002 to March 2012**

*a) May 2002 - March 2012*

Device	No. at risk on day 0	% survival on device (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
LVAD only	283	90	(86 - 93)	84	(79 - 88)	72	(66 - 77)	62	(54 - 69)	49	(37 - 61)
BiVAD	86	80	(69 - 87)	68	(56 - 77)	55	(43 - 66)	48	(33 - 61)	35	(17 - 53)
<b>Overall</b>	<b>369</b>	<b>87</b>	<b>(84 - 90)</b>	<b>80</b>	<b>(76 - 84)</b>	<b>68</b>	<b>(63 - 73)</b>	<b>59</b>	<b>(52 - 65)</b>	<b>46</b>	<b>(35 - 56)</b>
No. at risk	-	<b>315</b>		<b>276</b>		<b>139</b>		<b>50</b>		<b>17</b>	

*a) April 2009 - March 2012*

Device	No. at risk on day 0	% survival on device (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
LVAD only	166	92	(86 - 95)	88	(83 - 92)	77	(69 - 83)	71	(62 - 78)	59	(44 - 72)
BiVAD	21	76	(52 - 89)	66	(42 - 82)	56	(32 - 74)	45	(19 - 68)	22	(2 - 58)
<b>Overall</b>	<b>187</b>	<b>90</b>	<b>(84 - 93)</b>	<b>86</b>	<b>(80 - 90)</b>	<b>74</b>	<b>(67 - 80)</b>	<b>68</b>	<b>(59 - 75)</b>	<b>55</b>	<b>(41 - 67)</b>
No. at risk	-	<b>167</b>		<b>159</b>		<b>93</b>		<b>29</b>		<b>4</b>	

*Short term devices used for bridging*

One hundred and twelve patients received a short-term device for bridging at six implant centres in the UK. Forty-one patients received devices at Harefield, 28 at Papworth, 16 at Birmingham, 13 at Glasgow, 10 at Manchester and four at Newcastle. Fifty-eight patients received a BiVAD (short-term device in both ventricles), 27 an LVAD only, one an RVAD only

and 26 received ECMO only support. Five patients on short-term VADs for bridging received ECMO support concurrently.

Eighteen of the 112 patients were bridged from a short-term device to a long-term device (bridge-to-bridge patients) and four further patients were bridged from ECMO only support to a long-term device. Two patients had their ECMO replaced with a short-term device, and one of these patients was subsequently bridged to a long-term device. One patient was bridged to a total artificial heart (TAH) and died shortly after implantation.

In addition, six patients had a short-term VAD implanted after the explant of a long-term VAD. These six VADs are excluded from this section and are reported in the long-term VAD activity section.

Of the patients who received a short-term device for bridging, dilated cardiomyopathy (63%) and ischaemic heart disease (27%) were the most frequently reported cardiac diseases. The median age at implant was 41 years (inter-quartile range: 27-50 years) and the majority of recipients (64%) were male.

**Figure 20** shows the INTERMACS patient profile at time of short-term VAD implantation, and shows that 88% of patients had either critical cardiogenic shock or progressive decline. **Figure 21** shows the treatment history and shows that 76% of patients were on inotropes prior to VAD implantation.

**Table 19** presents the short-term VAD outcome of recipients, by centre and devices received. Nationally, 28 were transplanted, 18 survived explantation of the VAD, 39 died on support, 24 were bridged to a long-term device and three died shortly after explantation. Deaths which occur more than one year after transplant or device explant are not referenced in these tables. When combining activity across the three device groups, the overall number of patients alive at the time of analysis was 56 out of 112 (50%).

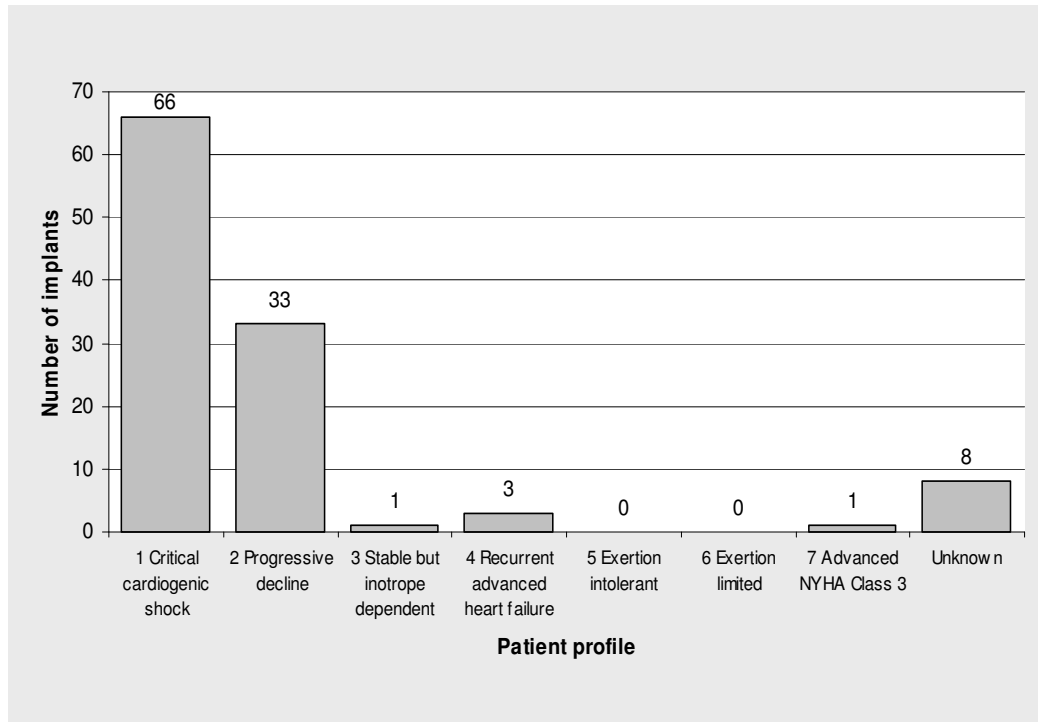
Short-term VAD duration of support for bridging ranged between 0 and 120 days. Using the Kaplan-Meier estimation method, median VAD duration was estimated to be 14 days (95% CI: 6 - 21 days). For those who were bridged onto a long-term VAD, long-term VAD duration of support ranged from 24 to 1,030 days.

**Table 20** shows overall patient survival from time of first implant to death for the patients receiving a short-term VAD. Patients still alive were censored at 31 July 2012. Other events, such as device explantation or transplantation were not censored. The five patients bridged from ECMO only support to a long-term device are included in the bridged to long-term device group, along with the patient bridged to a TAH. 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.

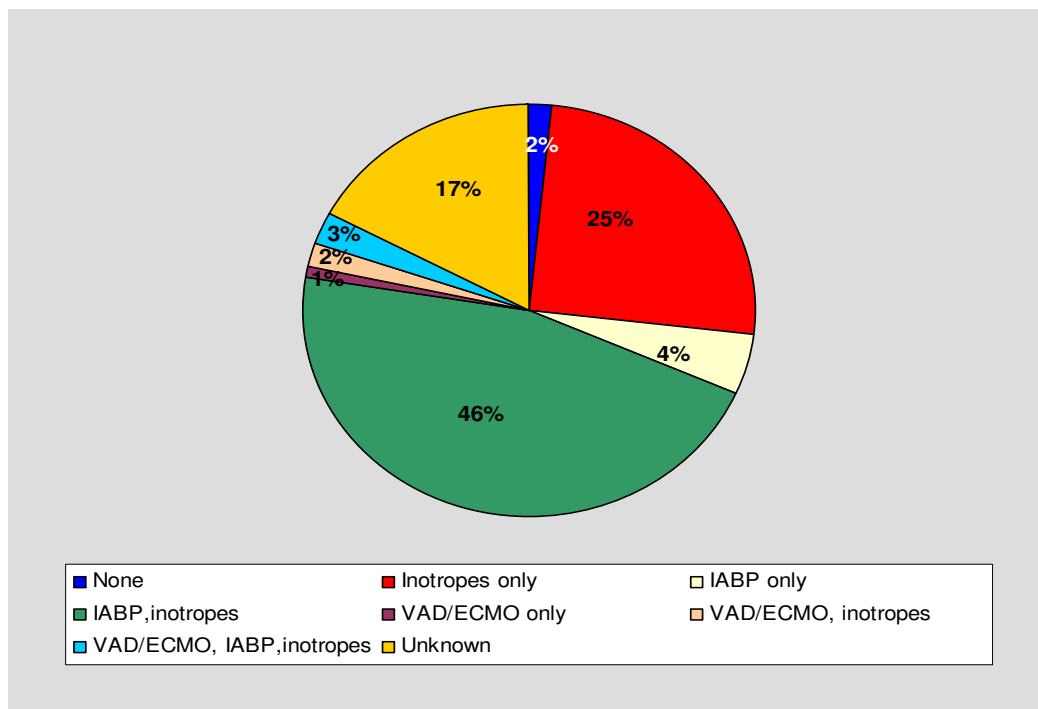
**Table 21** shows patient survival during VAD support by device group. Unlike the survival estimates presented in **Table 20**, survival was censored at time of device explantation or transplantation. The survival during VAD support was lower than the overall patient survival, as survival post-transplant and explant are not considered. However, care should be taken

in interpreting the survival estimates beyond 90 days due to the small number of patients at risk. In addition, ECMO only support was typically very short; all but two of the patients were on support for 12 days or less.

**Figure 20 Short-term VAD patient profile, May 2002 to March 2012**



**Figure 21 Treatment history prior to short-term VAD implantation, May 2002 to March 2012**





**Table 19 Outcome of short-term VADs used for bridging, by device group and implant centre, May 2002 to March 2012**

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%	6	43%	4	17%	4	44%	3	38%	0	0%	18	26%
Alive (post explant)	0	0%	1	7%	7	30%	2	22%	0	0%	3	30%	13	19%
Alive with VAD	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
<i>Total alive</i>	1	25%	7	50%	11	48%	6	67%	3	38%	3	30%	31	46%
Died (post transplant)	0	0%	1	7%	0	0%	1	11%	1	13%	0	0%	3	4%
Died (post explant)	0	0%	1	7%	0	0%	0	0%	0	0%	1	10%	2	3%
Died with VAD	3	75%	5	36%	12	52%	2	22%	4	50%	6	60%	32	47%
<i>Total died</i>	3	75%	7	50%	12	52%	3	33%	5	63%	7	70%	37	54%
<b>Total</b>	<b>4</b>	<b>100%</b>	<b>14</b>	<b>100%</b>	<b>23</b>	<b>100%</b>	<b>9</b>	<b>100%</b>	<b>8</b>	<b>100%</b>	<b>10</b>	<b>100%</b>	<b>68</b>	<b>100%</b>

**Table 19** continued

b) *ECMO only*

Outcome	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	0	0%	3	27%	0	0%	3	60%	1	100%	0	0%	7	35%
Alive (post explant)	0	0%	3	27%	0	0%	1	20%	0	0%	1	50%	5	25%
Alive with VAD	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
<i>Total alive</i>	0	0%	6	55%	0	0%	4	80%	1	100%	1	50%	12	60%
Died (post transplant)	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Died (post explant)	0	0%	0	0%	1	100%	0	0%	0	0%	0	0%	1	5%
Died with VAD	0	0%	5	45%	0	0%	1	20%	0	0%	1	50%	7	35%
<i>Total died</i>	0	0%	5	45%	1	100%	1	20%	0	0%	1	50%	8	40%
<b>Total</b>	<b>0</b>	<b>0%</b>	<b>11</b>	<b>100%</b>	<b>1</b>	<b>100%</b>	<b>5</b>	<b>100%</b>	<b>1</b>	<b>100%</b>	<b>2</b>	<b>100%</b>	<b>20</b>	<b>100%</b>

**Table 19** 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	18%	1	50%	0	0%	0	0%	4	17%
Alive (post explant)	0	0%	0	0%	2	12%	0	0%	0	0%	0	0%	2	8%
Alive with VAD	0	0%	1	33%	3	18%	1	50%	1	100%	1	100%	7	29%
<i>Total alive</i>	0	0%	1	33%	8	47%	2	100%	1	100%	1	100%	13	54%
Died (post transplant)	0	0%	1	33%	0	0%	0	0%	0	0%	0	0%	1	4%
Died (post explant)	0	0%	0	0%	1	6%	0	0%	0	0%	0	0%	1	4%
Died with VAD	0	0%	1	33%	8	47%	0	0%	0	0%	0	0%	9	38%
<i>Total died</i>	0	0%	2	67%	9	53%	0	0%	0	0%	0	0%	11	46%
<b>Total</b>	0	0%	3	100%	17	100%	2	100%	1	100%	1	100%	24	100%

**Table 20 Overall patient survival after implant of short-term VAD support, by device group, May 2002 to March 2012**

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	68	60	(48 - 71)	50	(38 - 61)	44	(32 - 55)	42	(30 - 54)	42	(30 - 54)
ECMO only	20	70	(45 - 85)	60	(36 - 78)	60	(36 - 78)	60	(36 - 78)	60	(36 - 78)
Bridged to LTD	24	100	( - )	83	(61 - 93)	65	(42 - 81)	65	(42 - 81)	45	(21 - 66)
<b>Overall</b>	<b>112</b>	<b>71</b>	<b>(61 - 78)</b>	<b>59</b>	<b>(49 - 67)</b>	<b>51</b>	<b>(42 - 60)</b>	<b>50</b>	<b>(40 - 59)</b>	<b>45</b>	<b>(35 - 55)</b>
No. at risk	-	79		66		49		34		24	

**Table 21 Survival during short-term VAD support, by device group, May 2002 to March 2012**

Device group	No. at risk on day 0	% survival on device (95% confidence interval)									
		30 days		90 days		1 year		2 years		3 years	
ST device only	68	51	(37 - 64)	34	(18 - 51)	-	-	-	-	-	-
ECMO only	20	44	(8 - 77)	-	-	-	-	-	-	-	-
Bridged to LTD	24	100	( - )	83	(60 - 93)	64	(37 - 81)	64	(37 - 81)	48	(16 - 74)
<b>Overall</b>	<b>112</b>	<b>65</b>	<b>(54 - 74)</b>	<b>48</b>	<b>(36 - 59)</b>	<b>35</b>	<b>(21 - 49)</b>	<b>35</b>	<b>(21 - 49)</b>	<b>26</b>	<b>(11 - 45)</b>
No. at risk		47		23		9		4		1	

### *Short-term devices used post-heart transplant*

Eighty-three patients received short-term devices for primary graft failure (PGF) post heart-transplant at six centres in the UK. Thirty-three patients received devices at Harefield, 20 at Manchester, 18 at Papworth, four at Newcastle, four at Birmingham and four at Glasgow. Forty-five devices were implanted as BiVAD (short-term device in both ventricles), 14 as RVAD only, 16 as ECMO only and eight as LVAD only. Fifteen 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 (58%) was the most frequently reported cardiac disease. The median age at implant was 48 years (inter-quartile range: 39-55 years) and the majority of recipients (70%) were male. 77 of the 83 short-term devices for PGF were implanted within four days of the transplant taking place.

Short-term VAD duration of support for PGF ranged between 0 and 45 days. Using the Kaplan-Meier estimation method, median VAD duration of support was estimated to be 7 days (95% CI: 5 – 9 days). **Table 22** presents the short-term VAD outcome of recipients treated for PGF, by centre. Nationally, eight were re-transplanted, 26 survived explantation of the VAD, 41 died on support and eight died shortly after explantation. Deaths which occur more than one year after transplant or device explant are not referenced in this table.

In addition to the 83 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. One patient at Newcastle was implanted with an RVAD Biomedicus device post-transplant and was explanted four days later. Finally, three patients at Newcastle received a Berlin Heart for primary graft failure shortly after transplant; all three died on support.

**Table 22 Outcome of short-term VADs used for primary graft failure by implant centre, May 2002 to March 2012**

Outcome	Newcastle		Papworth		Harefield		Birmingham		Manchester		Glasgow		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Alive (post transplant)	0	0%	2	11%	2	6%	0	0%	1	5%	0	0%	5	6%
Alive (post explant)	0	0%	3	17%	8	24%	1	25%	14	70%	0	0%	26	31%
Alive with VAD	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
<i>Total alive</i>	0	0%	5	28%	10	30%	1	25%	15	75%	0	0%	31	37%
Died (post transplant)	0	0%	0	0%	3	9%	0	0%	0	0%	0	0%	3	4%
Died (post explant)	0	0%	1	6%	5	15%	2	50%	0	0%	0	0%	8	10%
Died with VAD	4	100%	12	67%	15	45%	1	25%	5	25%	4	100%	41	49%
<i>Total died</i>	4	100%	13	72%	23	70%	3	75%	5	25%	4	100%	52	63%
<b>Total</b>	<b>4</b>	<b>100%</b>	<b>18</b>	<b>100%</b>	<b>33</b>	<b>100%</b>	<b>4</b>	<b>100%</b>	<b>20</b>	<b>100%</b>	<b>4</b>	<b>100%</b>	<b>83</b>	<b>100%</b>

## 5. RESULTS - PAEDIATRIC HEART TRANSPLANTATION

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### Transplant activity

Following a decline in activity in 2004/5 heart transplantation activity in children in the six years from April 2006 to March 2012 returned to the level seen over the seven years between April 1998 and March 2005 (**Figure 22**).

### Unadjusted mortality rates

#### *Overall mortality*

Twenty paediatric patients died within 30 days of their transplant, giving an overall 30-day mortality rate of 4.4% (95%CI 2.7% to 6.7%). A further ten patients died between 30 and 90-days, giving an overall 90-day mortality rate of 6.6% (95%CI 4.5% to 9.3%). Since April 2011 two patients have died within 30 days of their operation, giving an overall 30-day mortality rate of 6.3% (0.8% to 20.8%) for this period. One child died between 30 and 90-days between April 2011 and March 2012 (**Table 23** and **Table 24**).

Overall, 91.3% (95%CI 88.2% to 93.5%) of children who had a heart transplant were alive 1-year later, 85.7% (95%CI 81.9% to 88.7%) were alive at 3-years, 81.6% (95%CI 77.2% to 85.2%) at 5 years and 69.9% (95%CI 63.8% to 75.1%) at 10 years (**Table 25** to

**Table 28).**

*Mortality rates by transplant centre*

Mortality rates by centre, unadjusted for patient risk are given in **Table 25** to



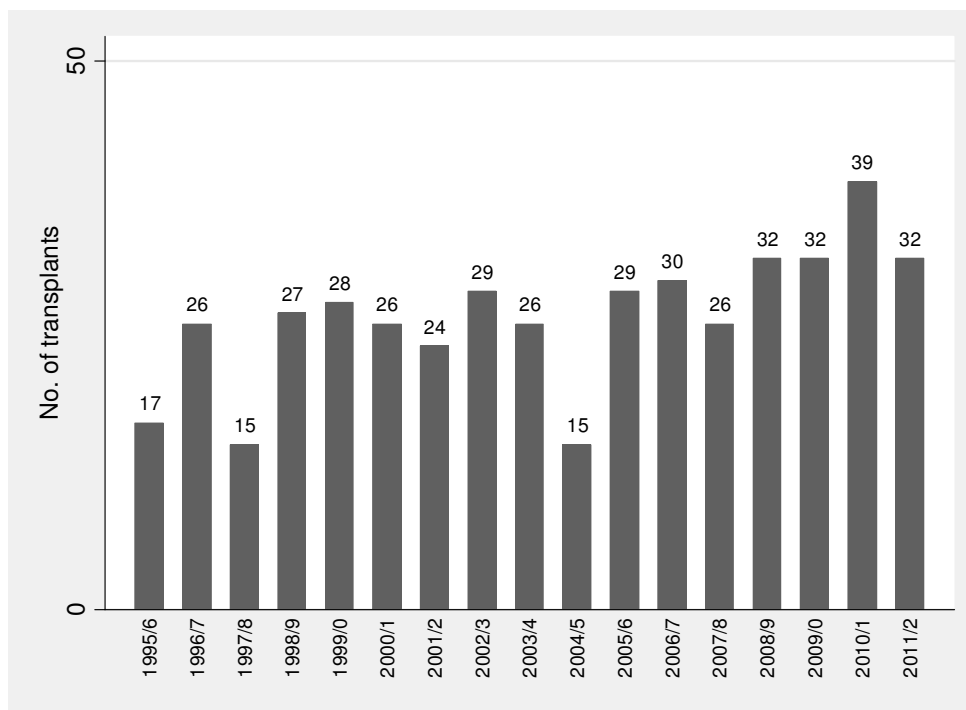
**Table 28.** There was no evidence to suggest that the 30 or 90-day mortality rate varied significantly between centres over the period since April 2009 (Fisher’s exact test,  $p=0.39$  and  $p>0.99$  respectively).

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 ( $p=0.11$ ,  $p=0.043$ ,  $p=0.12$  and  $p=0.038$  for 1, 3, 5 and 10-year survival respectively, log rank test, **Figure 23(a)**). In **Figure 23 (b)** and **Figure 23 (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 29** and **Table 30**, 30-day survivors,  $p=0.63$ ; 1-year survivors,  $p=0.26$ ).

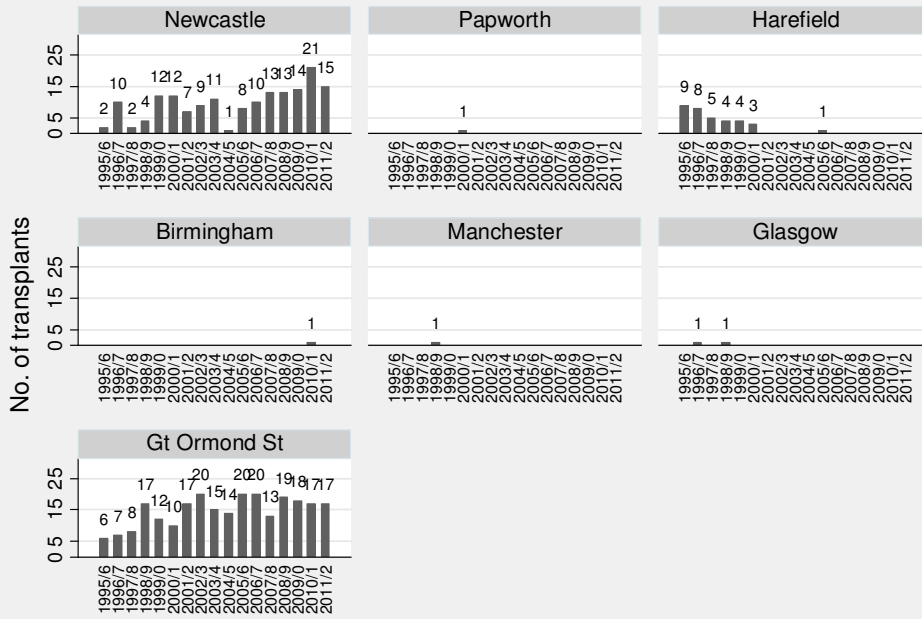
In 2001, Harefield stopped their paediatric heart transplant programme and Great Ormond Street instituted a number of changes to their transplant programme. For the cohort of transplants since 2001 the survival outcome to 5 years for patients transplanted at Newcastle and Great Ormond Street is similar ( $p=0.66$ , **Figure 23(d)**).

**Figure 22 Paediatric heart transplant activity by audit year**

a) Overall



b) By transplant centre



Graphs by centre

**Table 23** 30-day mortality after paediatric heart transplantation by centre *unadjusted* for patient risk

a) April 2009 – March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			Centre effect <sup>2</sup>	95%CI		
Newcastle	50	1	2.0	0.1	to	10.6	0.8	-1.0	to	8.8
Birmingham	1	0	0.0	0.0	to	97.5	-1.0	-1.0	to	322.6
Gt Ormond St	52	4	7.7	2.1	to	18.5	5.7	0.8	to	16.3
All centres	<b>103</b>	<b>5</b>	<b>4.9</b>	<b>1.6</b>	<b>to</b>	<b>11.0</b>				

b) April 2011 – March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			Centre effect <sup>2</sup>	95%CI		
Newcastle	15	1	6.7	0.2	to	31.9	4.8	-0.9	to	31.6
Gt Ormond St	17	1	5.9	0.1	to	28.7	4.2	-0.9	to	27.7
All centres	<b>32</b>	<b>2</b>	<b>6.3</b>	<b>0.8</b>	<b>to</b>	<b>20.8</b>				

<sup>1</sup> a) p=0.39; b) p>0.99

<sup>2</sup> expected mortality based on overall mortality for the period April 2006 to March 2009 (1.14%)

**Table 24** 90-day mortality after paediatric heart transplantation by centre *unadjusted* for patient risk

a) April 2009 – March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			Centre effect <sup>2</sup>	95%CI		
Newcastle	50	4	8.0	2.2	to	19.2	6.02	0.91	to	16.97
Birmingham	1	0	0.0	0.0	to	97.5	-1.00	-1.00	to	322.59
Gt Ormond St	52	5	9.6	3.2	to	21.0	7.43	1.74	to	18.68
All centres	<b>103</b>	<b>9</b>	<b>8.7</b>	<b>4.1</b>	<b>to</b>	<b>15.9</b>				

b) April 2011 – March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			Centre effect <sup>2</sup>	95%CI		
Newcastle	15	1	6.7	0.2	to	31.9	4.85	-0.85	to	31.58
Gt Ormond St	17	2	11.8	1.5	to	36.4	9.32	0.25	to	36.28
All centres	<b>32</b>	<b>3</b>	<b>9.4</b>	<b>2.0</b>	<b>to</b>	<b>25.0</b>				

<sup>1</sup> a)  $p > 0.99$  b)  $p > 0.99$

<sup>2</sup> expected mortality based on overall mortality for the period April 2005 to March 2008 (1.14%)

**Table 25 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	164	92.6	87.3	to	95.7	-0.30	-0.55	to	0.03
Papworth	1	100,0				3.49	-0.89	to	24.01
Harefield	34	82.2	64.7	to	91.6	0.32	-0.30	to	1.26
Birmingham	1	100,0				-1.00			38.29
Manchester	1	100,0				-1.00		to	8.35
Glasgow	2	50,0	0.6	to	91,0	5.87	-0.17	to	23.83
Gt Ormond St	250	91.9	87.7	to	94.7	0.11	-0.16	to	0.43
<b>All centres</b>	<b>453</b>	<b>91.3</b>	<b>88.2</b>	<b>to</b>	<b>93.5</b>				

b) *April 2001 – March 2011*

Centre	No cases	% survival	95%CI			Centre effect	95%CI		
Newcastle	122	92.5	86.1	to	96.0	0.09	-0.38	to	0.77
Harefield	1	100.0				-1.00		to	19.55
Birmingham	1	100.0				-1.00			57.27
Gt Ormond St	190	94.6	90.3	to	97.1	-0.04	-0.38	to	0.41
<b>All centres</b>	<b>314</b>	<b>93.9</b>	<b>90.5</b>	<b>to</b>	<b>96.0</b>				

c) *April 2008 – March 2011*

Centre	No cases	% survival	95%CI			Centre effect	95%CI		
Newcastle	48	91.7	79.3	to	96.8	0.06	-0.71	to	1.71
Birmingham	1	100.0				-1.00			44.61
Gt Ormond St	54	92.5	81.3	to	97.1	-0.03	-0.74	to	1.47
<b>All centres</b>	<b>103</b>	<b>92.2</b>	<b>85.0</b>	<b>to</b>	<b>96.0</b>				

<sup>1</sup> a) p=0.11; b) p=0.45; c) p=0.90 (excluding centres with <5 cases)

**Table 26** Three-year survival after paediatric heart transplantation by centre *unadjusted* for patient risk

a) *Whole audit period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	164	89.3	83.1	to	93.4	-0.30	-0.55	to	0.03
Papworth	1	100.0				3.49	-0.89	to	24.01
Harefield	34	73.0	54.4	to	84.9	0.32	-0.30	to	1.26
Birmingham	1					-1.00			38.29
Manchester	1	100.0				-1.00		to	8.35
Glasgow	2	50.0	0.6	to	91.0	5.87	-0.17	to	23.83
Gt Ormond St	250	85.3	80.1	to	89.3	0.11	-0.16	to	0.43
<b>All centres</b>	<b>453</b>	<b>85.7</b>	<b>81.9</b>	<b>to</b>	<b>88.7</b>				

b) *April 2001 – March 2009*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	122	87.6	79.4	to	92.7	0.09	-0.38	to	0.77
Harefield	1	100.0				-1.00		to	19.55
Birmingham	1					-1.00			57.27
Gt Ormond St	190	90.1	84.5	to	93.8	-0.04	-0.38	to	0.41
<b>All centres</b>	<b>314</b>	<b>89.2</b>	<b>84.9</b>	<b>to</b>	<b>92.4</b>				

c) *April 2006 – March 2009*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	36	88.9	73.1	to		0.25	-0.66	to	2.19
Gt Ormond St	52	92.3	80.8	to		-0.17	-0.77	to	1.14
<b>All centres</b>	<b>88</b>	<b>90.9</b>	<b>82.6</b>	<b>to</b>	<b>95.3</b>				

<sup>1</sup> a) p=0.04; b) p=0.50; c) p=0.57 (excluding centres with <5 cases)

**Table 27** Five-year survival after paediatric heart transplantation by centre *unadjusted* for patient risk

a) *Whole Audit period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
				to				to	
Newcastle	164	86.1	78.7	to	91.0	-0.30	-0.55	to	0.03
Papworth	1	100.0				3.49	-0.89	to	24.01
Harefield	34	73.0	54.4	to	84.9	0.32	-0.30	to	1.26
Birmingham	1					-1.00			38.29
Manchester	1	100.0				-1.00		to	8.35
Glasgow	2	50.0	0.6	to	91.0	5.87	-0.17	to	23.83
Gt Ormond St	250	79.9	73.7	to	84.8	0.11	-0.16	to	0.43
<b>All centres</b>	<b>453</b>	<b>81.6</b>	<b>77.2</b>	<b>to</b>	<b>85.2</b>				

b) *April 2001 – March 2007*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
				to				to	
Newcastle	122	85.2	75.2	to	91.4	0.09	-0.38	to	0.77
Harefield	1	100.0				-1.00		to	19.55
Birmingham	1					-1.00			57.27
Gt Ormond St	190	86.5	79.8	to	91.1	-0.04	-0.38	to	0.41
<b>All centres</b>	<b>314</b>	<b>86.1</b>	<b>80.9</b>	<b>to</b>	<b>89.9</b>				

c) *April 2004 – March 2007*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
				to				to	
Newcastle	19	94.7	68.1	to	99.2	-0.46	-0.99	to	1.99
Harefield	1	100.0				-1.00		to	36.30
Gt Ormond St	54	88.9	76.9	to	94.8	0.19	-0.56	to	1.59
<b>All centres</b>	<b>74</b>	<b>90.5</b>	<b>81.1</b>	<b>to</b>	<b>95.4</b>				

<sup>1</sup> a) p=0.12; b) p=0.66; c) p=0.45 (excluding centres with <5 cases)

**Table 28** Ten-year survival after paediatric heart transplantation by centre *unadjusted* for patient risk

a) *Whole Audit period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	164	80.4	71.2	to	87.0	-0.30	-0.55	to	0.03
Papworth	1					3.49	-0.89	to	24.01
Harefield	34	59.4	40.3	to	74.2	0.32	-0.30	to	1.26
Birmingham	1					-1.00			38.29
Manchester	1	100.0				-1.00		to	8.35
Glasgow	2					5.87	-0.17	to	23.83
Gt Ormond St	250	66.0	56.8	to	73.8	0.11	-0.16	to	0.43
<b>All centres</b>	<b>453</b>	<b>69.9</b>	<b>63.8</b>	<b>to</b>	<b>75.1</b>				

b) *April 2001 – March 2002*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	122	78.1	63.3	to	87.5	0.09	-0.38	to	0.77
Harefield	1			to		-1.00		to	19.55
Birmingham	1					-1.00			57.27
Gt Ormond St	190	80.3	70.7	to	87.0	-0.04	-0.38	to	0.41
<b>All centres</b>	<b>314</b>	<b>79.5</b>	<b>71.8</b>	<b>to</b>	<b>85.3</b>				

<sup>1</sup> a) p=0.038; b) p=0.68 (excluding centres with <5 cases)



**Table 29** 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 <sup>1</sup>	95%CI			% Survival <sup>2</sup>	95%CI			% Survival <sup>3</sup>	95%CI		
Newcastle	160	94.9	90.0	to	97.4	91.6	85.5	to	95.1	88.2	80.9	to	92.9
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	100.0											
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	239	96.1	92.6	to	98.0	89.3	84.3	to	92.8	83.6	77.5	to	88.2
All centres	<b>433</b>	<b>95.5</b>	<b>93.0</b>	<b>to</b>	<b>97.1</b>	<b>89.6</b>	<b>86.1</b>	<b>to</b>	<b>92.3</b>	<b>85.3</b>	<b>81.1</b>	<b>to</b>	<b>88.7</b>

<sup>1</sup> p=0.82 (excluding centres with <5 cases)

<sup>2</sup> p=0.68 (excluding centres with <5 cases)

<sup>3</sup> p=0.63 (excluding centres with <5 cases)

**Table 30** Three and five-year survival after paediatric heart transplantation by centre *unadjusted* for patient risk, for the subset of patients surviving beyond 1-year

Centre	No cases	3-years			5-years		
		% Survival <sup>1</sup>	95%CI		% Survival <sup>2</sup>	95%CI	
Newcastle	129	96.5	90.9	to 98.7	93.0	85.7	to 96.6
Papworth	1	100.0			100.0		
Harefield	27	88.7	69.0	to 96.2	88.7	69.0	to 96.2
Birmingham	1						
Manchester	1	100.0			100.0		
Glasgow	1	100.0		to	100.0	81.0	to 91.2
Gt Ormond St	212	92.9	88.3	to 95.7	87.0	85.3	to 92.4
<b>All centres</b>	<b>372</b>	<b>93.9</b>	<b>90.7</b>	<b>to 96.0</b>	<b>372</b>	<b>89.4</b>	<b>to 85.3</b>

<sup>1</sup> p=0.23 (excluding centres with <5 cases) <sup>2</sup> p=0.26 (excluding centres with <5 cases)

**Figure 23** Kaplan-Meier survival curves after paediatric heart transplantation by centre

a) Overall survival

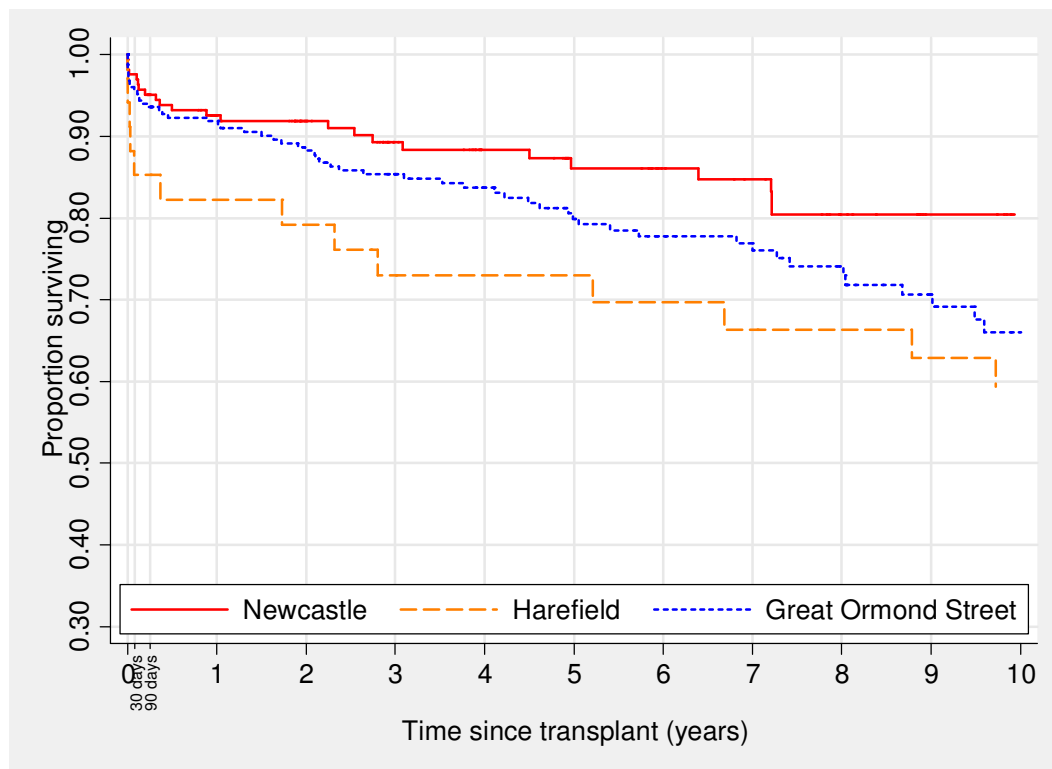
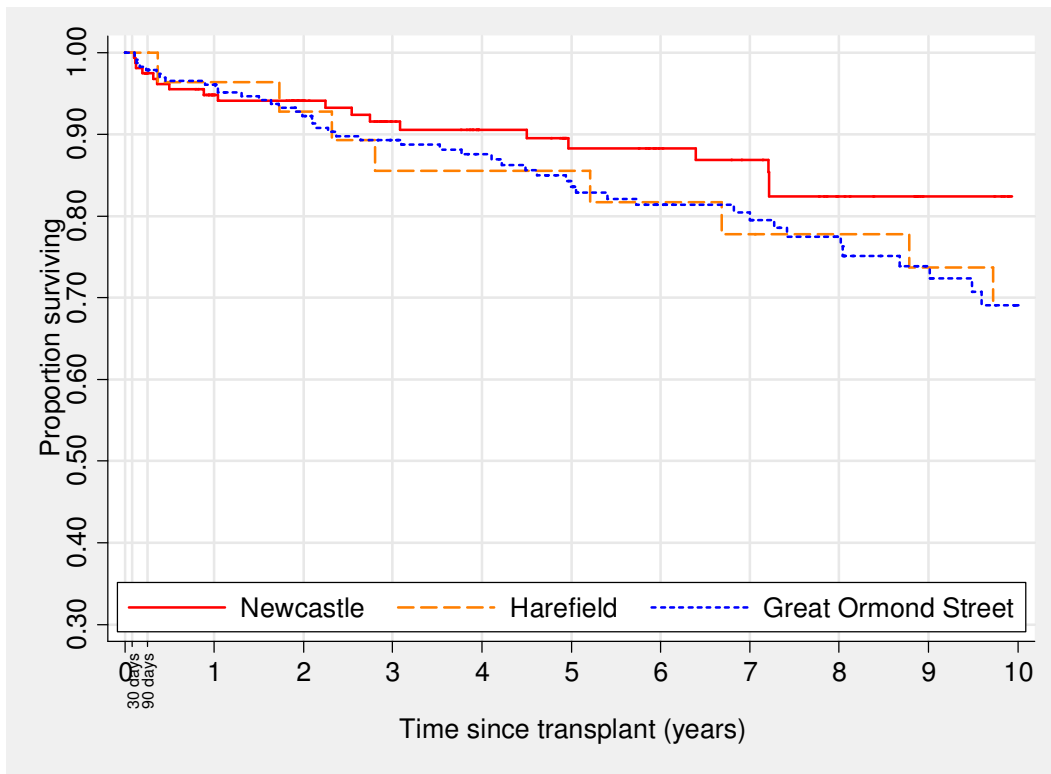
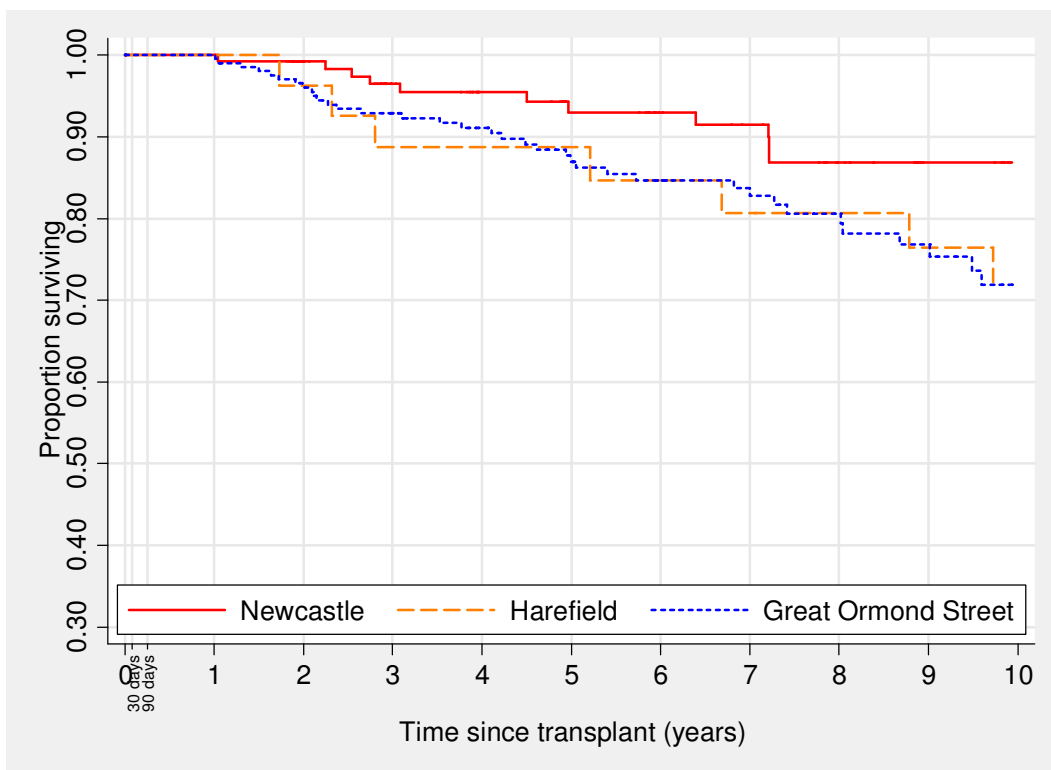


Figure 23 continued

b) *Conditional survival: patients alive at 30 days*

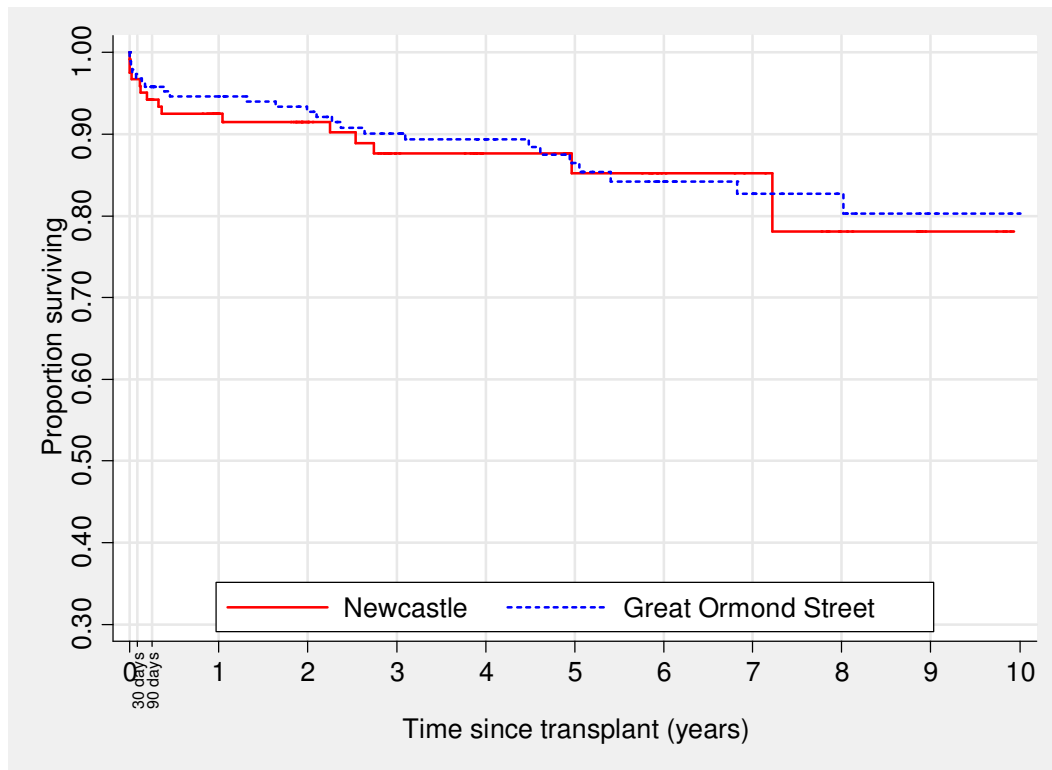


c) *Conditional survival: patients alive at 1-year*



**Figure 23 continued**

d) Overall survival (transplants since April 2001)



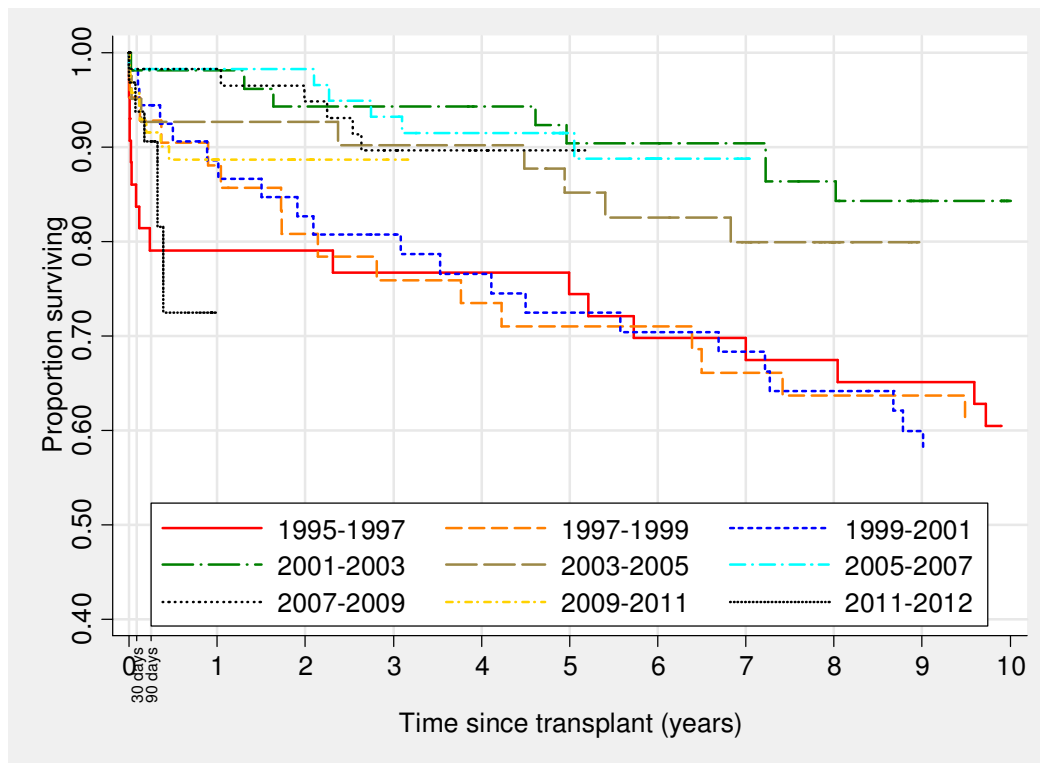
#### *Mortality rates by retrieval centre*

Mortality rates at 30 and 90-days by retrieval centre, unadjusted for patient risk are shown in **Table 31**. Over the period April 2009 to March 2012 Great Ormond Street and Newcastle used a similar proportion of the hearts they retrieved for a “local” recipient (87% & 91% respectively). Overall, 54% of hearts retrieved were used for a “local” recipient. Five recipients died within 30-days in the three-year period to March 2012. Data for the last audit year are not reported separately.

#### *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,  $p < 0.01$ ,  $p = 0.034$ ,  $p = 0.034$  and  $p = 0.048$  at 1, 3, 5 and 10-years respectively). Survival to 10 years by audit era shown in **Error! Reference source not found.** 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.

**Figure 24** 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 **Error! Reference source not found.** and **Figure 26** respectively.

#### *Tabular CUSUM charts*

Tabular CUSUM charts for 30-day and 90-day mortality are shown in **Figure 27** and **Figure 28** respectively.

The CUSUM charts show that recent 30- and 90-day mortality rates following paediatric heart transplantation have been as expected at both centres.

**Table 31 30 and 90-day mortality after paediatric heart transplantation by retrieval centre *unadjusted* for patient risk**

April 2009 – March 2012

Retrieval Centre	30 days						90 days						% used locally <sup>4</sup>
	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			No cases	No deaths	Mortality rate <sup>2</sup>	95%CI			
Newcastle	39	2	5.1	0.6	to	17.3	39	5	12.8	4.3	to	27.4	87.2
Papworth	9	0	0.0	0.0	to	33.6	9	0	0.0	0.0	to	33.6	0.0
Harefield	7	0	0.0	0.0	to	41.0	7	0	0.0	0.0	to	41.0	0.0
Birmingham	9	0	0.0	0.0	to	33.6	9	0	0.0	0.0	to	33.6	11.1
Manchester	5	0	0.0	0.0	to	52.2	5	1	20.0	0.5	to	71.6	0.0
Glasgow	7	1	14.3	0.4	to	57.9	7	1	14.3	0.4	to	57.9	0.0
Gt Ormond St	23	2	8.7	1.1	to	28.0	23	2	8.7	1.1	to	28.0	91.3
Other <sup>3</sup>	4	0	0.0	0.0	to	70.8	4	0	0.0	0.0	to	70.8	0.0
<b>All centres</b>	<b>103</b>	<b>5</b>	<b>4.9</b>	<b>1.6</b>	<b>to</b>	<b>11.0</b>	<b>103</b>	<b>9</b>	<b>8.7</b>	<b>4.1</b>	<b>to</b>	<b>15.9</b>	<b>54.4</b>

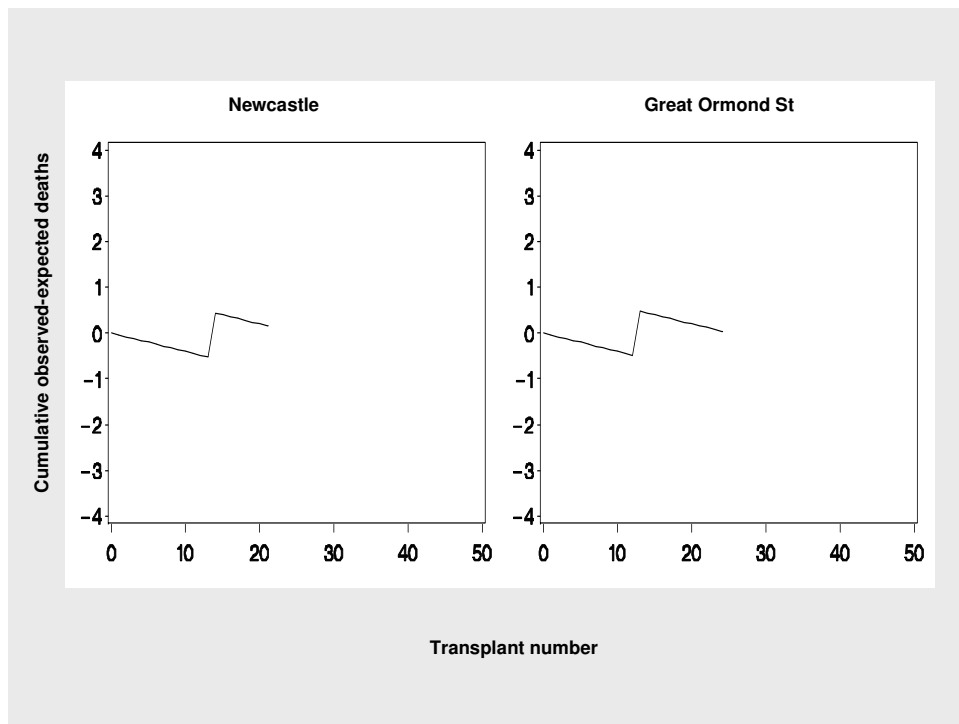
<sup>1</sup> p=0.81

<sup>2</sup> p=0.78

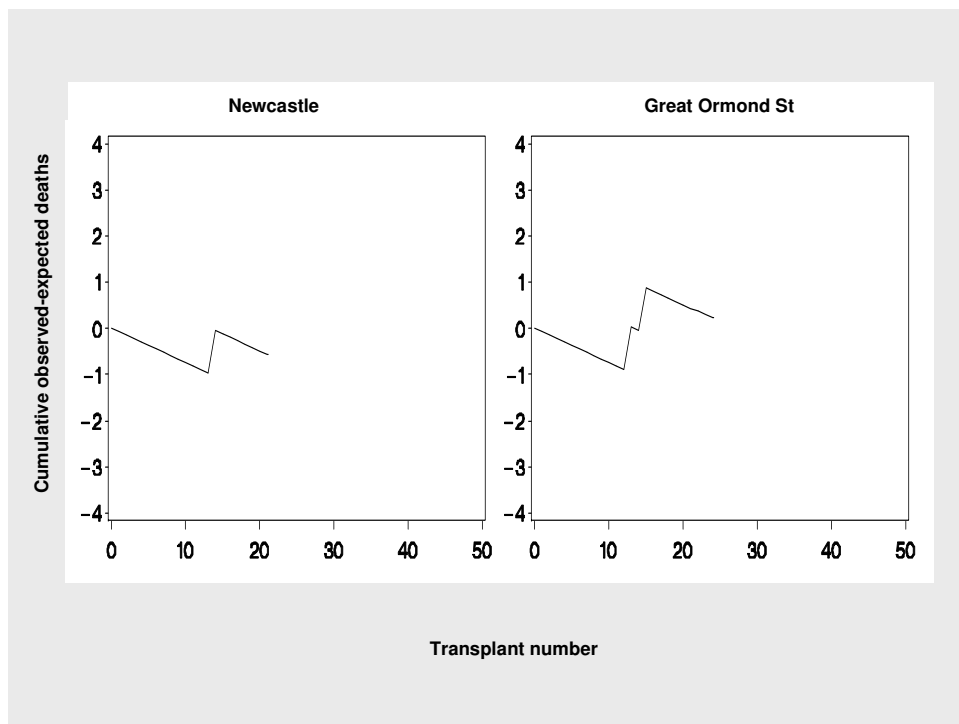
<sup>3</sup> Republic of Ireland or other overseas centre

<sup>4</sup> Retrieved by the centre who carried out the transplant

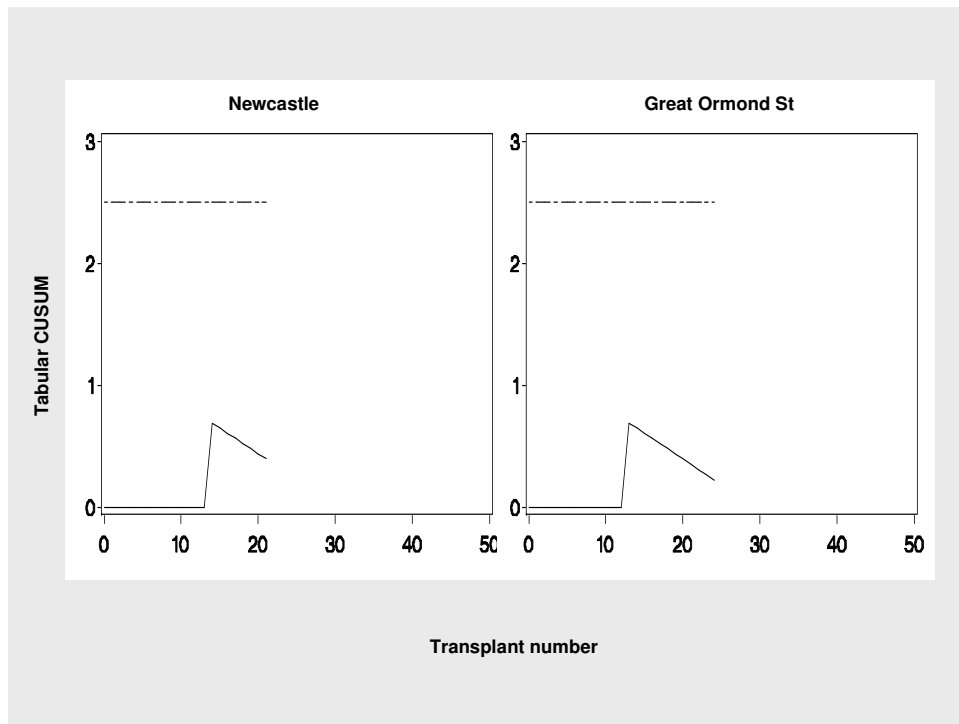
**Figure 25** Cumulative (observed – expected) 30-day mortality after paediatric heart transplantation unadjusted for patient risk, January 2011 to March 2012



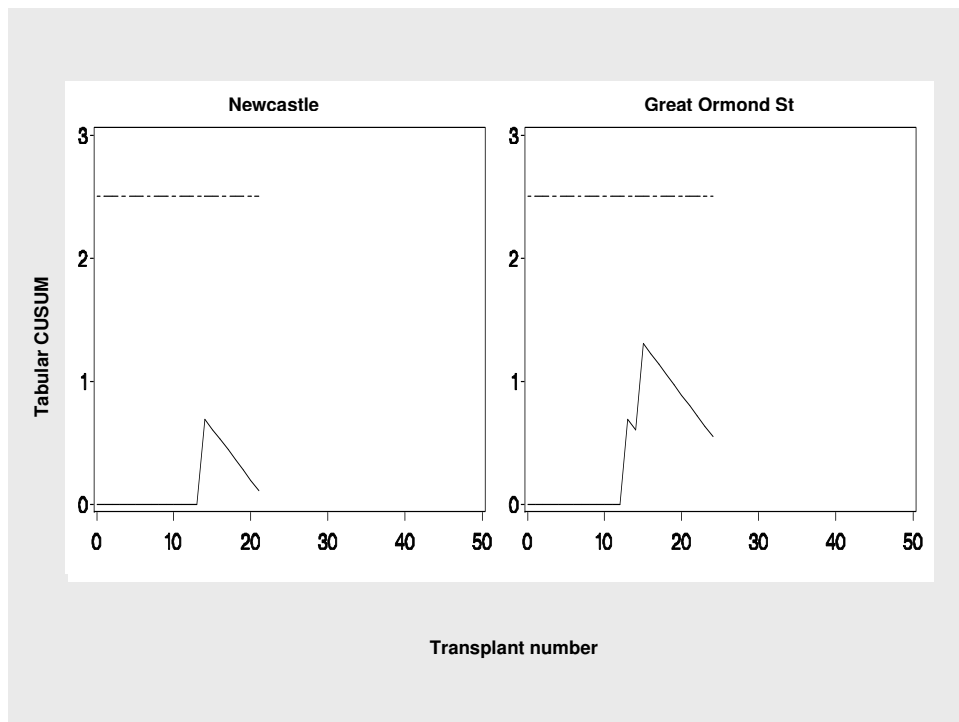
**Figure 26** Cumulative (observed – expected) 90-day mortality after paediatric heart transplantation unadjusted for patient risk, January 2011 to March 2012



**Figure 27** Tabular CUSUM for 30-day mortality after paediatric heart transplantation unadjusted for patient risk, January 2011 to March 2012



**Figure 28** Tabular CUSUM for 90-day mortality after paediatric heart transplantation unadjusted for patient risk, January 2011 to March 2012





## 6. RESULTS - ADULT LUNG TRANSPLANTATION

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### Transplant activity

Lung transplantation activity in the UK increased in 2011/12 with 175 transplants reported, 9 more than the previous year (**Figure** ). Overall, there have been 1,215 bilateral sequential lung grafts (53.4%), 683 (30.0%) single lung and 328 (14.4%) heart-lung transplants reported. The remaining 51 transplants were double lung grafts. Since April 2006 the number of bilateral sequential lung grafts has increased to 73.3% of the total activity (628 transplants) while the heart-lung transplant programme has decreased (29 transplants, 3.4%). In the last year just 5 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 9.8% (95%CI 8.6% to 11.1%) and 14.6% (95%CI 13.2% to 16.2%). Overall, 223 patients died within the first 30 days after transplantation and a further 109 died between 30 and 90 days. 30-day and 90-day mortality in the period since April 2009 was 6.4% (95%CI 4.4% to 9.0%) and 10.3% (95%CI 7.7% to 13.4%) respectively. There were 31 deaths within 30 days and 18 reported deaths between 30 and 90 days respectively (**Table 32** and **Table 33**).

Table 33 Over the last year, April 2011 to March 2012, mortality rates were 5.7% (95%CI 2.8% to 10.3%) at 30-days and 11.7% (95%CI 7.3% to 17.5%) at 90-days. The trend in early mortality over time is shown in **Figure 30** which shows the moving average estimates of overall mortality based on approximate 6 months activity.

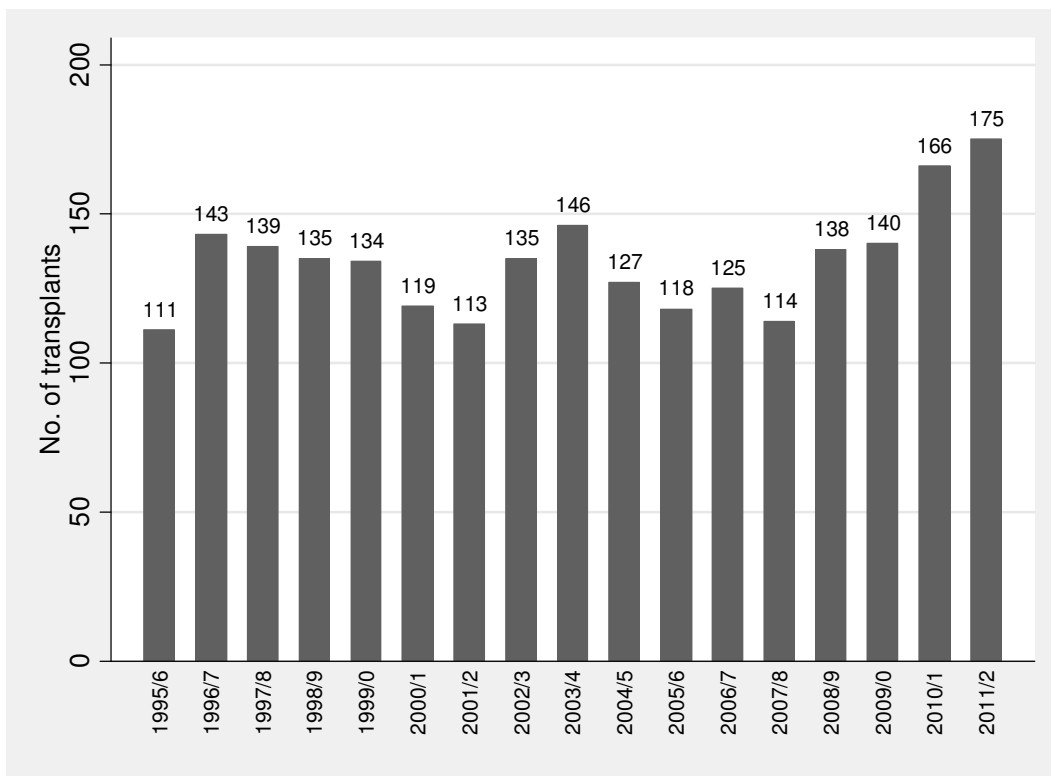
The 1-year survival for the whole cohort was 76.6% (95%CI 74.8% to 78.3%), with 83.1% (95%CI 79.2% to 86.3%) of the April 2008 to March 2011 cohort surviving to 1 year. Overall, 62.4% (95%CI 60.3% to 64.5%) of recipients survived to 3-years after their transplant and 52.3% (95%CI 50.0% to 54.6%) survived to 5 years. Overall, 33.3% (95%CI 30.7% to 36.0%) were alive at 10-years (**Table 34** to **Table 37**).

#### *Mortality rates by transplant centre*

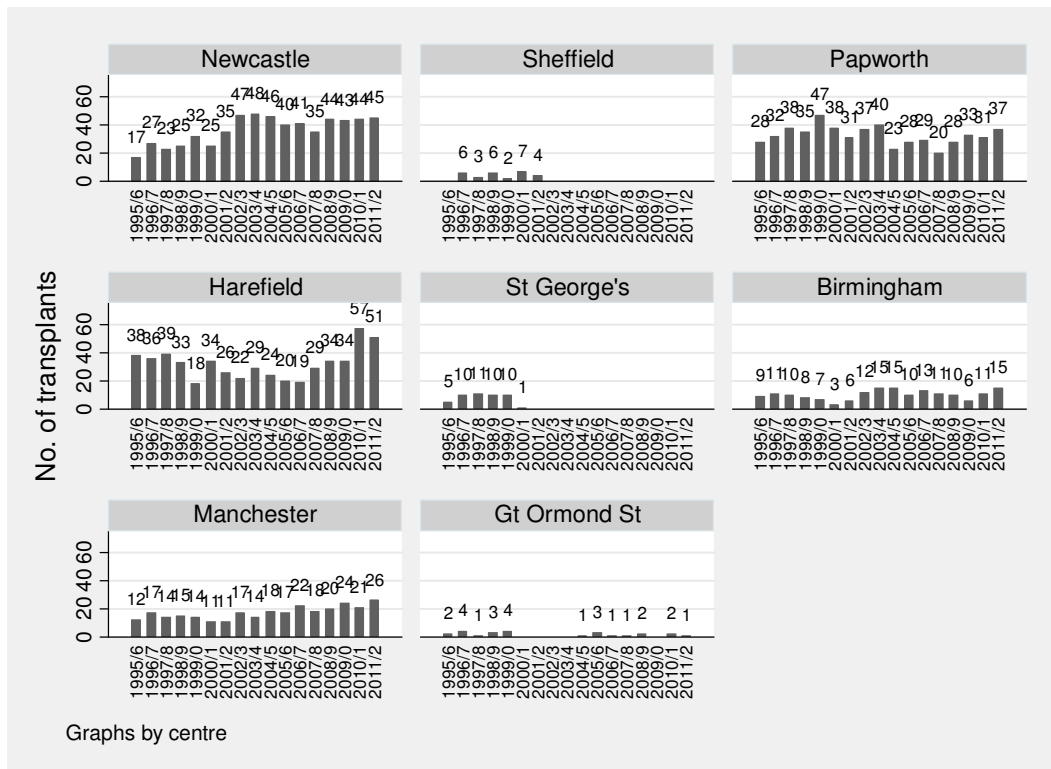
Centre specific mortality rates, unadjusted for patient risk are shown in **Table 32** to **Table 37**. For completeness, the transplants in patients aged 16 or over carried out at Great Ormond Street are included. Centre specific 30-day and 90-day mortality rates since April 2009 were similar across centres (Fisher's exact test,  $p=0.68$  and  $p=0.34$  respectively).

**Figure 29 Adult lung transplants by audit year**

**a) Overall**

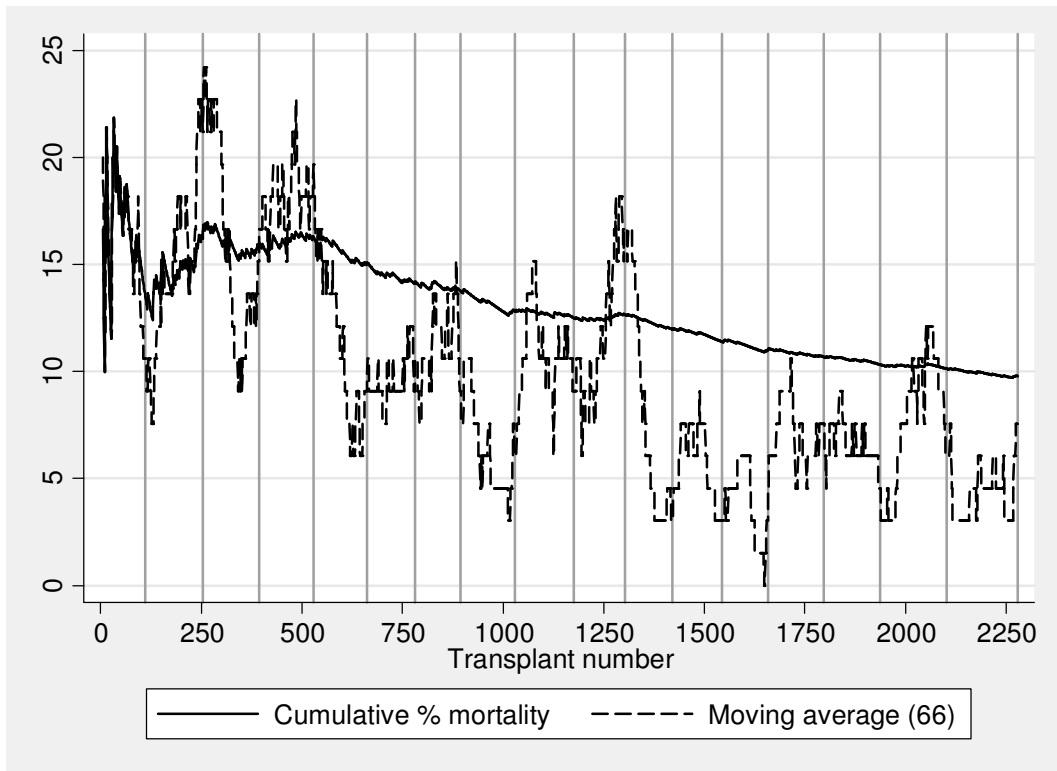


**b) By transplant centre**

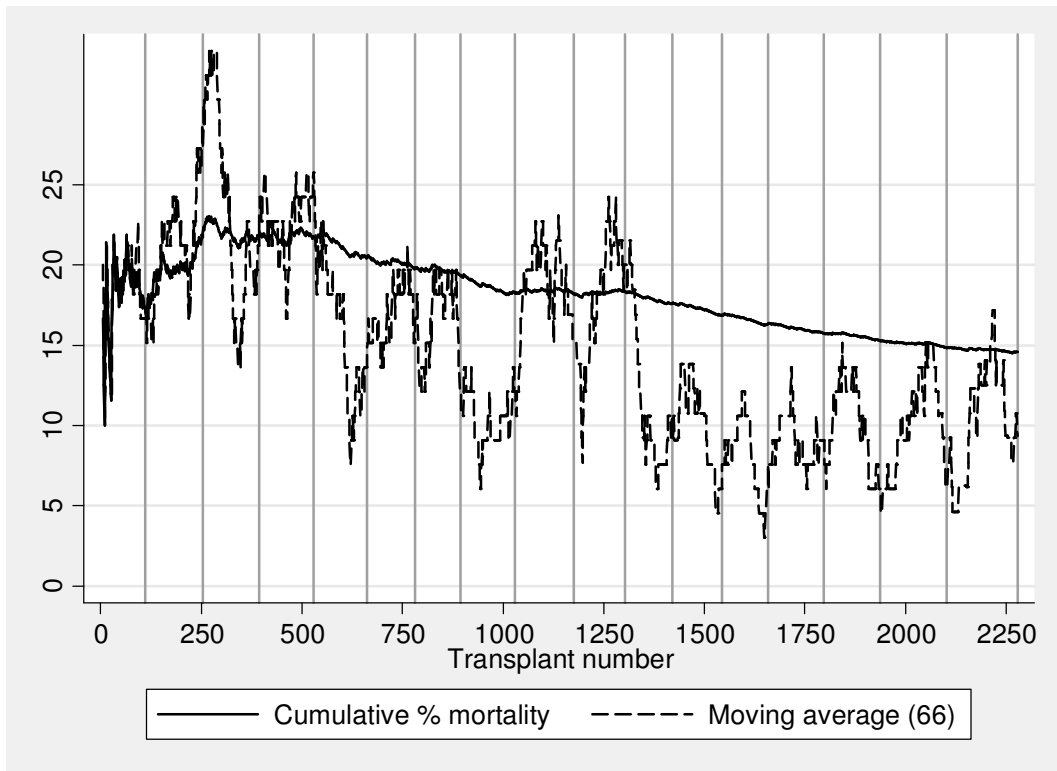


**Figure 30 Mortality after adult lung transplantation over time**

a) 30-day



b) 90-day



Note: Vertical lines represent the start of each audit year

**Table 32 30-day mortality after adult lung transplantation by centre *unadjusted* for patient risk**

a) April 2009– March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			Centre effect <sup>2</sup>	95%CI		
					to				to	
Newcastle	132	11	8.3	4.2	to	14.4	0.43	-0.29	to	1.55
Papworth	101	8	7.9	3.5	to	15.0	0.36	-0.41	to	1.67
Harefield	142	8	5.6	2.5	to	10.8	-0.04	-0.58	to	0.90
Birmingham	32	2	6.3	0.8	to	20.8	0.07	-0.87	to	2.87
Manchester	71	2	2.8	0.3	to	9.8	-0.52	-0.94	to	0.74
Gt Ormond St	3	0	0.0	0.0	to	70.8	-1.00	-1.00	to	20.06
<b>All centres</b>	<b>481</b>	<b>31</b>	<b>6.4</b>	<b>4.4</b>	<b>to</b>	<b>9.0</b>				

b) April 2011– March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			Centre effect <sup>2</sup>	95%CI		
					to				to	
Newcastle	45	3	6.7	1.4	to	18.3	0.14	-0.76	to	2.34
Papworth	37	2	5.4	0.7	to	18.2	-0.07	-0.89	to	2.34
Harefield	51	3	5.9	1.2	to	16.2	0.01	-0.79	to	1.94
Birmingham	15	1	6.7	0.2	to	31.9	0.14	-0.97	to	5.36
Manchester	26	1	3.8	0.1	to	19.6	-0.34	-0.98	to	2.67
Gt Ormond St	1	0	0.0	0.0	to	97.5	-1.00	-1.00	to	62.17
<b>All centres</b>	<b>175</b>	<b>10</b>	<b>5.7</b>	<b>2.8</b>	<b>to</b>	<b>10.3</b>				

<sup>1</sup> a) p=0.66; b) p>0.99

<sup>2</sup> expected mortality based on overall mortality for the period April 2005 to March 2008 (5.84%)

**Table 33 90-day mortality after adult lung transplantation by centre unadjusted for patient risk**

a) *April 2009 – March 2012*

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			Centre effect <sup>2</sup>	95%CI		
Newcastle	128	17	13.3	7.9	to	20.4	0.47	-0.15	to	1.35
Papworth	100	10	10.0	4.9	to	17.6	0.13	-0.46	to	1.07
Harefield	142	14	9.9	5.5	to	16.0	0.12	-0.39	to	0.88
Birmingham	32	5	15.6	5.3	to	32.8	0.78	-0.42	to	3.15
Manchester	71	3	4.2	0.9	to	11.9	-0.52	-0.90	to	0.41
Gt Ormond St	3	0	0.0	0.0	to	70.8	-1.00	-1.00	to	13.00
<b>All centres</b>	<b>476</b>	<b>49</b>	<b>10.3</b>	<b>7.7</b>	<b>to</b>	<b>13.4</b>				

b) *April 2011 – March 2012*

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			Centre effect <sup>2</sup>	95%CI		
Newcastle	42	6	14.3	5.4	to	28.5	0.52	-0.44	to	2.31
Papworth	36	3	8.3	1.8	to	22.5	-0.08	-0.81	to	1.70
Harefield	51	6	11.8	4.4	to	23.9	0.34	-0.51	to	1.92
Birmingham	15	4	26.7	7.8	to	55.1	2.04	-0.17	to	6.78
Manchester	26	1	3.8	0.1	to	19.6	-0.56	-0.99	to	1.44
Gt Ormond St	1	0	0.0	0.0	to	97.5	-1.00	-1.00	to	41.01
<b>All centres</b>	<b>171</b>	<b>20</b>	<b>11.7</b>	<b>7.3</b>	<b>to</b>	<b>17.5</b>				

<sup>1</sup> a) p=0.33; b) p=0.34

<sup>2</sup> expected mortality based on overall mortality for the period April 2005 to March 2008 (8.78%)

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

a) *Whole audit period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	617	80.6	77.2	to	83.5	-0.18	-0.32	to	-0.01
Sheffield	28	78.6	58.4	to	89.8	-0.06	-0.66	to	1.04
Papworth	555	72.9	68.9	to	76.5	0.17	-0.01	to	0.38
Harefield	543	78.4	74.6	to	81.7	-0.07	-0.23	to	0.12
St George's	47	55.3	40.1	to	68.1	1.29	0.42	to	2.50
Birmingham	172	68.9	61.3	to	75.4	0.36	0.02	to	0.78
Manchester	291	78.9	73.6	to	83.3	-0.14	-0.35	to	0.11
Gt Ormond St	25	87.8	66.8	to	95.9	-0.51	-0.90	to	0.44
<b>All centres</b>	<b>2278</b>	<b>76.6</b>	<b>74.8</b>	<b>to</b>	<b>78.3</b>				

b) *April 2008 – March 2011*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	131	82.1	74.3	to	87.8	0.08	-0.31	to	0.62
Papworth	92	81.1	71.3	to	87.8	0.11	-0.35	to	0.78
Harefield	125	86.4	79.0	to	91.3	-0.20	-0.53	to	0.28
Birmingham	27	70.4	49.4	to	83.9	0.93	-0.17	to	2.80
Manchester	65	85.3	73.5	to	92.1	-0.20	-0.64	to	0.52
Gt Ormond St	4	100.0				-1.00	-1.00	to	3.98
<b>All centres</b>	<b>444</b>	<b>83.1</b>	<b>79.2</b>	<b>to</b>	<b>86.3</b>				

<sup>1</sup> a) p<0.01; b) p=0.31

**Table 35** Three-year survival after adult lung transplantation by centre *unadjusted* for patient risk

a) *Whole audit period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
				to				to	
Newcastle	617	69.5	65.4	to	73.2	-0.22	-0.33	to	-0.09
Sheffield	28	67.9	47.3	to	81.8	-0.16	-0.62	to	0.59
Papworth	555	55.9	51.5	to	60.1	0.22	0.06	to	0.38
Harefield	543	65.1	60.5	to	69.2	-0.08	-0.21	to	0.07
St George's	47	46.8	32.2	to	60.2	0.80	0.16	to	1.65
Birmingham	172	52.5	44.3	to	60.0	0.36	0.08	to	0.71
Manchester	291	63.2	56.9	to	68.8	-0.06	-0.24	to	0.14
Gt Ormond St	25	67.3	42.8	to	83.1	-0.20	-0.68	to	0.60
<b>All centres</b>	<b>2278</b>	<b>62.4</b>	<b>60.3</b>	<b>to</b>	<b>64.5</b>				

b) *April 2006 – March 2009*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
				to				to	
Newcastle	120	74.4	65.2	to	81.5	-0.27	-0.51	to	0.05
Papworth	77	55.7	43.8	to	65.9	0.34	-0.07	to	0.87
Harefield	82	73.1	62.1	to	81.4	-0.24	-0.52	to	0.15
Birmingham	34	52.6	34.7	to	67.7	0.69	-0.03	to	1.75
Manchester	60	61.7	48.2	to	72.6	0.09	-0.31	to	0.63
Gt Ormond St	4	37.5	1.1	to	80.8	0.31	-0.84	to	3.72
<b>All centres</b>	<b>377</b>	<b>65.7</b>	<b>60.6</b>	<b>to</b>	<b>70.3</b>				

<sup>1</sup> a) p<0.01; b) p=0.043



**Table 36** Five-year survival after adult lung transplantation by centre *unadjusted* for patient risk

a) *Whole Audit Period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	617	58.4	53.8	to	62.8	-0.19	-0.29	to	-0.07
Sheffield	28	60.7	40.4	to	76.0	-0.21	-0.60	to	0.42
Papworth	555	45.6	41.0	to	50.1	0.21	0.07	to	0.36
Harefield	543	57.1	52.2	to	61.6	-0.11	-0.23	to	0.03
St George's	47	42.6	28.4	to	56.0	0.53	0.01	to	1.22
Birmingham	172	42.9	34.7	to	50.8	0.33	0.06	to	0.63
Manchester	291	50.4	43.6	to	56.8	-0.01	-0.18	to	0.18
Gt Ormond St	25	55.0	30.5	to	74.1	-0.17	-0.62	to	0.58
<b>All centres</b>	<b>2278</b>	<b>52.3</b>	<b>50.0</b>	<b>to</b>	<b>54.6</b>				

b) *April 2004 – March 2007*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	127	61.9	52.3	to	70.2	-0.24	-0.44	to	0.03
Papworth	80	41.7	30.7	to	52.4	0.39	0.02	to	0.85
Harefield	63	52.4	39.4	to	63.8	0.06	-0.29	to	0.51
Birmingham	38	44.6	28.5	to	59.4	0.35	-0.16	to	1.06
Manchester	57	59.4	45.4	to	70.9	-0.21	-0.50	to	0.19
Gt Ormond St	5	60.0	12.6	to	88.2	-0.14	-0.90	to	2.10
<b>All centres</b>	<b>370</b>	<b>53.5</b>	<b>48.1</b>	<b>to</b>	<b>58.5</b>				

<sup>1</sup>p<0.01; b) p=0.041

**Table 37** Ten-year survival after adult lung transplantation by centre *unadjusted* for patient risk

a) *Whole Audit Period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
			36.8	to	47.6		-0.29	to	-0.09
Newcastle	617	42.2	36.8	to	47.6	-0.19	-0.29	to	-0.09
Sheffield	28	39.3	21.7	to	56.5	-0.15	-0.50	to	0.36
Papworth	555	28.7	24.1	to	33.5	0.17	0.05	to	0.31
Harefield	543	38.8	33.3	to	44.3	-0.12	-0.22	to	0.00
St George's	47	22.5	11.7	to	35.3	0.48	0.03	to	1.04
Birmingham	172	24.0	14.6	to	34.7	0.29	0.05	to	0.57
Manchester	291	22.4	15.7	to	30.0	0.10	-0.07	to	0.28
Gt Ormond St	25	24.5	4.7	to	52.2	-0.07	-0.52	to	0.62
<b>All centres</b>	<b>2278</b>	<b>33.3</b>	<b>30.7</b>	<b>to</b>	<b>36.0</b>				

b) *April 1999 – March 2002*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
			38.2	to	59.8		-0.54	to	-0.13
Newcastle	92	49.5	38.2	to	59.8	-0.36	-0.54	to	-0.13
Sheffield	13	53.8	24.8	to	76.0	-0.45	-0.80	to	0.19
Papworth	116	28.4	20.5	to	36.7	0.24	-0.02	to	0.53
Harefield	78	34.4	23.9	to	45.1	0.01	-0.25	to	0.33
St George's	11	11.4	0.7	to	38.9	0.62	-0.26	to	2.08
Birmingham	16	6.3	0.4	to	24.7	0.93	0.08	to	2.19
Manchester	36	30.6	16.6	to	45.7	0.05	-0.32	to	0.55
Gt Ormond St	4	0.0		to		0.16	-0.86	to	3.20
<b>All centres</b>	<b>366</b>	<b>34.3</b>	<b>29.3</b>	<b>to</b>	<b>39.3</b>				

<sup>1</sup> a) p<0.01; b) 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 31 (a)**).

For the recent cohort transplanted between April 2008 and March 2011 (444 transplants) there was no evidence to suggest 1-year unadjusted survival rates differed between adult centres ( $p = 0.31$ ). In contrast, the analysis of the 3 and 5 year survival rates for the cohort transplanted between April 2006 and March 2009 and April 2004 and March 2007 respectively (377 and 370 transplants) showed some evidence of significant variation between centres, with a 20% difference between the highest and lowest unadjusted survival estimates amongst the adult centres.

Survival curves for the subset of patients who lived beyond 30-days and beyond 1-year are shown in **Figure 31 (b)** and **Figure 31 (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 23% and a 14% 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 38** and **Table 39**).

#### *Mortality rates by retrieval centre*

Mortality rates at 30 and 90-days by retrieval centre, unadjusted for patient risk are shown in **Table 40**. A similar proportion of lungs were used locally compared to the adult heart programme (64.9% vs. 64.5%). 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.

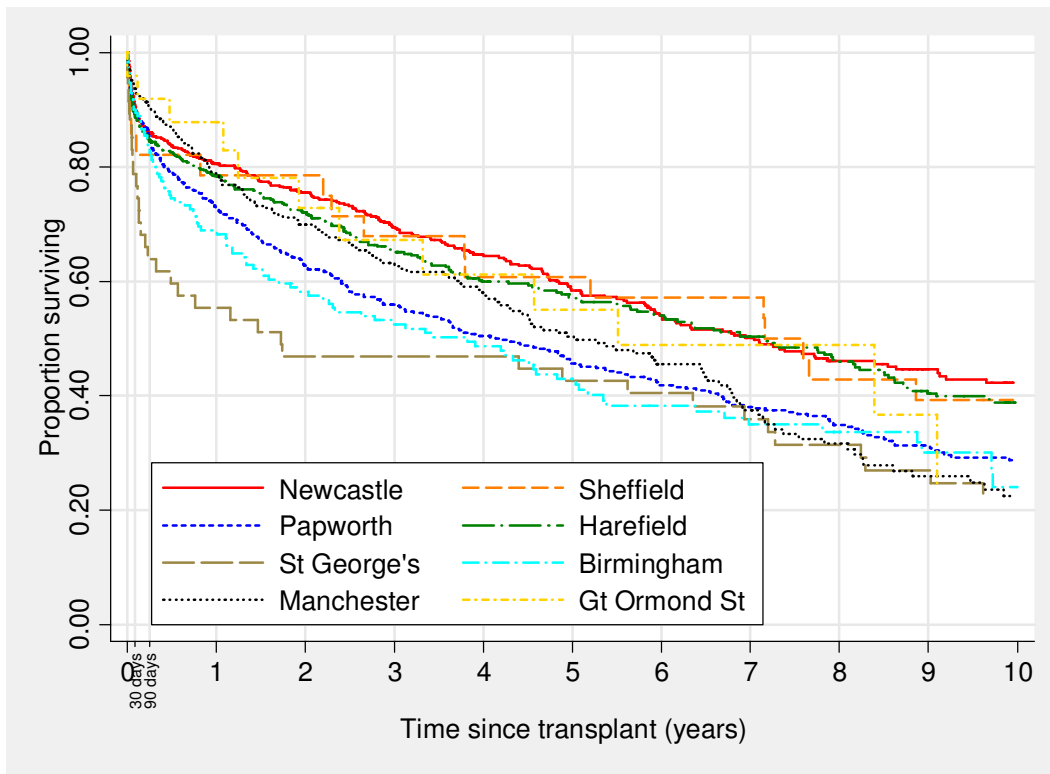
Of the six centres retrieving lungs from more than five adults, the unadjusted 30-day mortality rate since April 2009 was lowest for lungs retrieved by the Birmingham team (3.4%) and greatest from those retrieved by Glasgow (13.0%) but neither the 30 nor 90-day mortality rate varied significantly by retrieval centre (Fisher's exact test, 30-day:  $p = 0.67$ ; 90-day:  $p = 0.71$ ). Mortality rates in the last year also showed no statistically significant variation by retrieval centre (Fisher's exact test, 30-day:  $p = 0.89$ ; 90-day:  $p = 0.91$ ).

#### *Mortality rates by audit year*

As indicated in **Figure 30** 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 32**.

Figure 31 Kaplan-Meier survival curves after adult lung transplantation by centre

a) Overall survival



b) For patients alive at 30 days

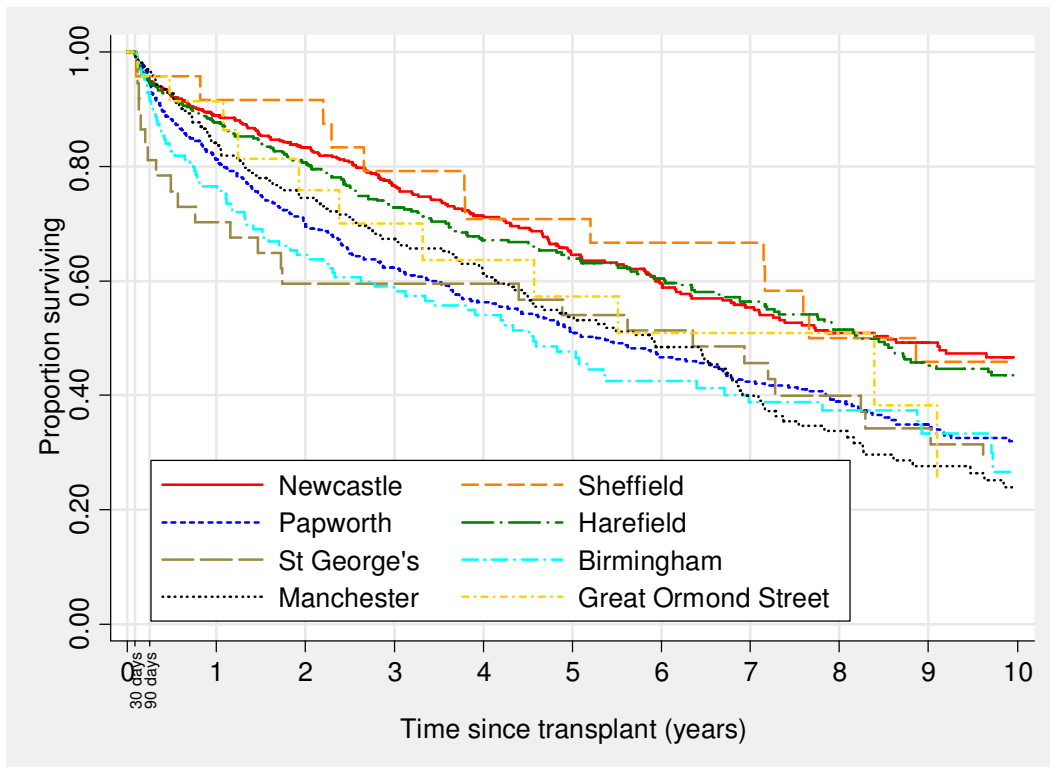
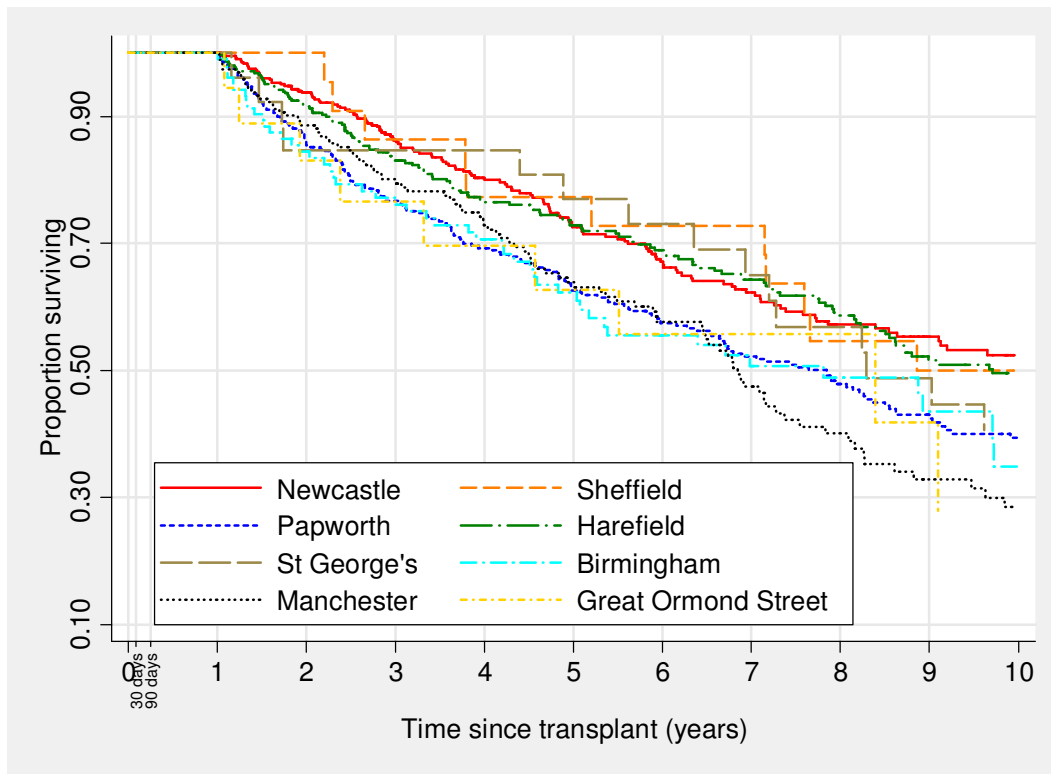


Figure 31 continued

c) For patients alive at 1-year



*Mortality rates by lung type*

Survival to 10-years by type of transplant is shown in

**Figure 33.** 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 38** 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

Centre	No cases	1-year				3-years				5-years			
		% Survival <sup>1</sup>	95%CI			% Survival <sup>2</sup>	95%CI			% Survival <sup>3</sup>	95%CI		
Newcastle	557	88.9	85.9	to	91.3	76.7	72.6	to	80.3	64.5	59.6	to	69.0
Sheffield	24	91.7	70.6	to	97.8	79.2	57.0	to	90.8	70.8	48.4	to	84.9
Papworth	498	81.2	77.4	to	84.5	62.3	57.6	to	66.7	50.9	45.9	to	55.6
Harefield	485	87.8	84.4	to	90.4	72.8	68.2	to	76.9	63.9	58.7	to	68.6
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	155	76.5	68.8	to	82.5	58.2	49.5	to	65.9	47.6	38.7	to	56.0
Manchester	273	84.1	79.0	to	88.1	67.3	60.9	to	73.0	53.7	46.6	to	60.3
Gt Ormond St	24	91.5	70.0	to	97.8	70.1	44.6	to	85.5	57.3	31.7	to	76.4
<b>All centres</b>	<b>2053</b>	<b>84.9</b>	<b>83.3</b>	<b>to</b>	<b>86.4</b>	<b>69.2</b>	<b>67.0</b>	<b>to</b>	<b>71.3</b>	<b>58.0</b>	<b>55.5</b>	<b>to</b>	<b>60.4</b>

<sup>1</sup> p<0.01 <sup>2</sup> p<0.01 <sup>3</sup> p<0.01

**Table 39** Three and five-year survival after adult lung transplantation by centre *unadjusted* for patient risk, for the subset of patients surviving beyond 1-year

Centre	No cases	3-years				5-years			
		% Survival <sup>1</sup>	95%CI			% Survival <sup>2</sup>	95%CI		
Newcastle	422	86.2	82.3	to	89.4	72.5	67.3	to	77.1
Sheffield	22	86.4	63.4	to	95.4	77.3	53.7	to	89.8
Papworth	366	76.7	71.9	to	80.8	62.6	57.0	to	67.6
Harefield	372	83.0	78.4	to	86.7	72.8	67.3	to	77.5
St George's	26	84.6	64.0	to	93.9	76.9	55.7	to	88.9
Birmingham	106	76.1	66.5	to	83.3	62.3	51.6	to	71.2
Manchester	193	80.1	73.5	to	85.1	63.8	55.9	to	70.7
Gt Ormond St	21	76.6	48.8	to	90.5	62.7	34.6	to	81.4
<b>All centres</b>	<b>1528</b>	<b>81.5</b>	<b>79.4</b>	<b>to</b>	<b>83.4</b>	<b>68.3</b>	<b>65.7</b>	<b>to</b>	<b>70.8</b>

<sup>1</sup> p=0.02; <sup>2</sup> p<0.01

**Table 40** 30 and 90-day mortality after adult lung transplantation by retrieval centre *unadjusted* for patient risk

a) April 2009 – March 2012

Retrieval Centre	No cases	30 days					No cases <sup>5</sup>	90 days					% used locally <sup>4</sup>	% DCD donors <sup>5</sup>
		No deaths	Mortality rate <sup>1</sup>	95%CI				No deaths	Mortality rate <sup>2</sup>	95%CI				
Newcastle	103	7	6.8	2.8	to	13.5	102	13	12.7	7.0	to	20.8	74.76	12.62
Papworth	107	8	7.5	3.3	to	14.2	106	12	11.3	6.0	to	18.9	71.96	7.48
Harefield	102	7	6.9	2.8	to	13.6	101	9	8.9	4.2	to	16.2	88.24	27.45
Birmingham	59	2	3.4	0.4	to	11.7	59	3	5.1	1.1	to	14.1	35.59	0.00
Manchester	86	4	4.7	1.3	to	11.5	84	9	10.7	5.0	to	19.4	54.65	10.47
Glasgow	23	3	13.0	2.8	to	33.6	23	3	13.0	2.8	to	33.6	0.00	0.00
Other <sup>3</sup>	1	0	0.0	0.0	to	97.5	1	0	0.0	0.0	to	97.5	0.00	0.00
<b>All centres</b>	<b>481</b>	<b>31</b>	<b>6.4</b>	<b>4.4</b>	<b>to</b>	<b>9.0</b>	<b>476</b>	<b>49</b>	<b>10.3</b>	<b>7.7</b>	<b>to</b>	<b>13.4</b>	<b>64.86</b>	<b>12.06</b>



**Table 40 continued**

b) April 2011 – March 2012

Retrieval Centre	No cases	30 days					No cases <sup>5</sup>	90 days					% used locally <sup>4</sup>	% DCD donors <sup>5</sup>
		No deaths	Mortality rate <sup>1</sup>	95%CI				No deaths	Mortality rate <sup>2</sup>	95%CI				
Newcastle	28	1	3.6	0.1	to	18.3	28	3	10.7	2.3	to	28.2	85.71	10.71
Papworth	39	2	5.1	0.6	to	17.3	38	4	10.5	2.9	to	24.8	66.67	10.26
Harefield	32	2	6.3	0.8	to	20.8	31	3	9.7	2.0	to	25.8	93.75	28.13
Birmingham	25	1	4.0	0.1	to	20.4	25	2	8.0	1.0	to	26.0	40.00	0.00
Manchester	43	3	7.0	1.5	to	19.1	41	7	17.1	7.2	to	32.1	46.51	11.63
Glasgow	8	1	12.5	0.3	to	52.7	8	1	12.5	0.3	to	52.7	0.00	0.00
<b>All centres</b>	<b>175</b>	<b>10</b>	<b>5.7</b>	<b>2.8</b>	<b>to</b>	<b>10.3</b>	<b>171</b>	<b>20</b>	<b>11.7</b>	<b>7.3</b>	<b>to</b>	<b>17.5</b>	<b>62.8</b>	<b>12.00</b>

<sup>1</sup> a) p=0.66; b) p=0.71

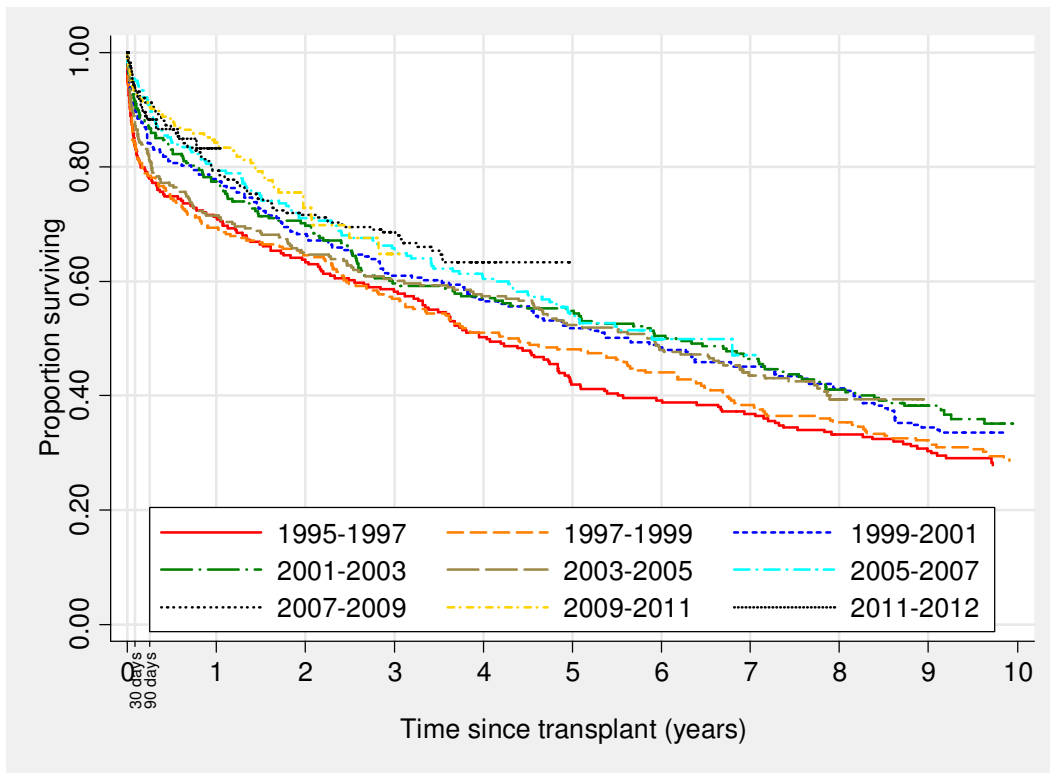
<sup>2</sup> a) p=0.89; b) p=0.91

<sup>3</sup> Republic of Ireland or other overseas centre

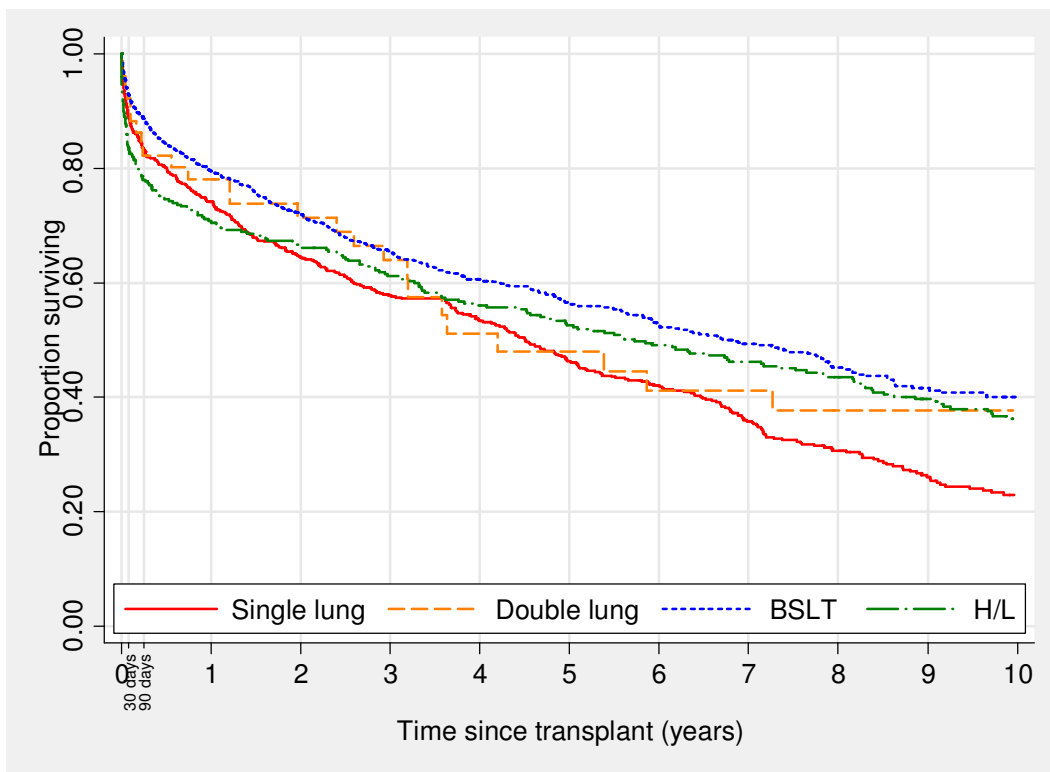
<sup>4</sup> Retrieved by the centre who carried out the transplant

<sup>5</sup> Donation after circulatory death

**Figure 32** Kaplan-Meier survival curves after adult lung transplantation by era



**Figure 33** Kaplan-Meier survival curves after adult lung transplantation by lung type



## Risk profile for 30-day and 1-year mortality

**Figure 34** 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 35**. The trend towards lower risk scores for transplants in the most recent era is seen across all centres.

## Risk-adjusted mortality

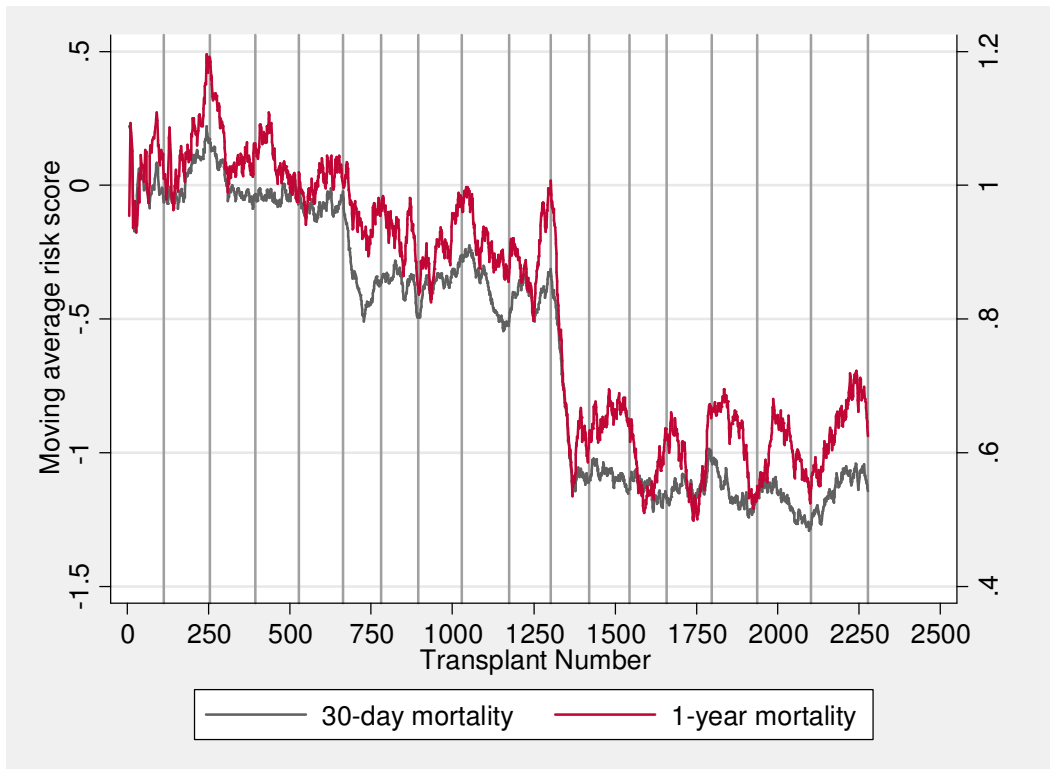
### *Centre specific mortality*

**Table 41** shows the risk adjusted 30-day mortality rates and centre effect estimates following lung transplantation for the periods April 2009 to March 2012 and April 2011 to March 2012. The corresponding estimates for 90-day mortality are shown in **Table 42**. 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, no centre had significantly higher than expected mortality at 30 days or at 90 days during the period since April 2009. These data are further illustrated in **Figure 36**, 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 2008 to March 2011 are shown in **Table 43**. 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 2008 to March 2011 no centre was identified as divergent after risk adjustment.

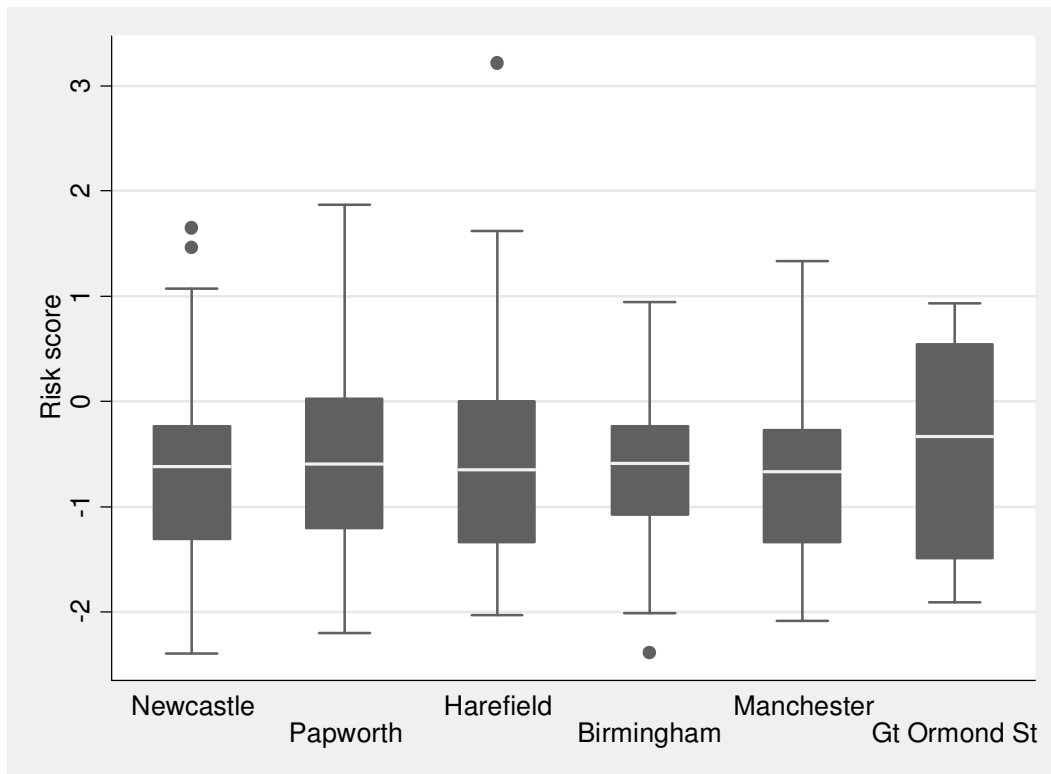
**Figure 34** Risk scores for 30-day and 1-year mortality after adult lung transplantation over time



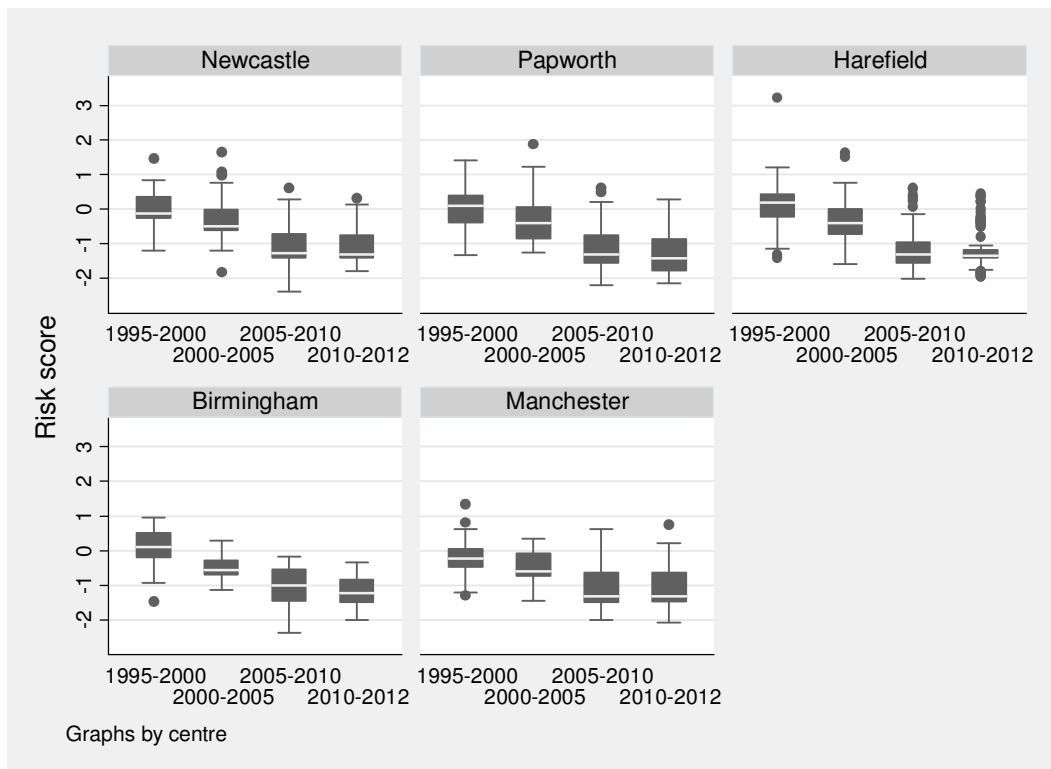
Note: Vertical lines represent the start of each audit year

**Figure 35** 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 41** 30-day mortality after adult lung transplantation by centre *adjusted* for patient risk

a) April 2009 – March 2012

Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	132	8.8	4.6	to	14.7	0.55	-0.23	to	1.78
Papworth	101	9.6	4.4	to	17.3	0.72	-0.26	to	2.38
Harefield	138	5.5	2.3	to	10.8	-0.06	-0.62	to	0.95
Birmingham	31	7.1	0.9	to	21.5	0.22	-0.85	to	3.42
Manchester	71	3.2	0.4	to	10.6	-0.47	-0.94	to	0.92
Gt Ormond St	3	0.0	0.0	to	61.6	-1.00	-1.00	to	24.84

b) April 2011 – March 2012

Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	45	6.9	1.5	to	17.8	0.19	-0.75	to	2.48
Papworth	37	6.6	0.8	to	20.2	0.13	-0.86	to	3.09
Harefield	47	4.3	0.5	to	13.9	-0.28	-0.91	to	1.59
Birmingham	15	7.6	0.2	to	31.5	0.33	-0.97	to	6.42
Manchester	26	3.9	0.1	to	18.6	-0.34	-0.98	to	2.68
Gt Ormond St	1	0.0	0.0	to	89.6	-1.00	-1.00	to	137.72

**Table 42** 90-day mortality after adult lung transplantation by centre *adjusted* for patient risk

a) April 2008 – March 2012

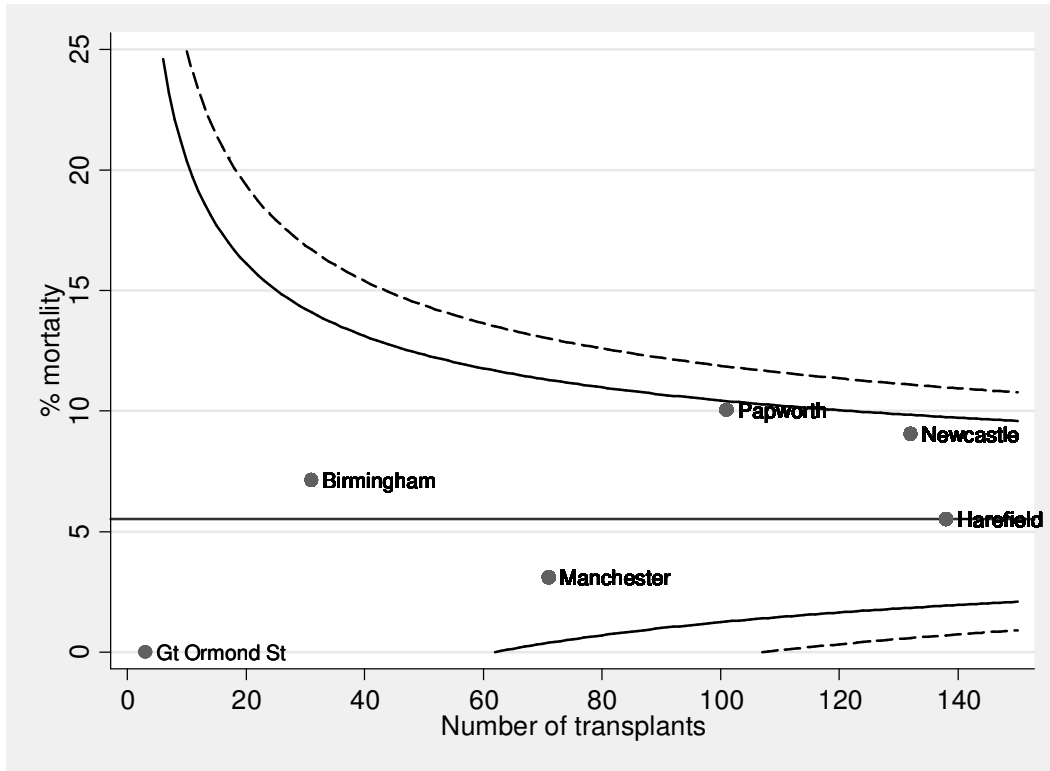
Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	132	12.0	7.4	to	17.9	0.42	-0.17	to	1.27
Papworth	101	11.2	5.7	to	18.8	0.30	-0.37	to	1.40
Harefield	138	9.5	5.3	to	15.3	0.09	-0.42	to	0.87
Birmingham	31	13.6	4.8	to	26.8	0.63	-0.47	to	2.80
Manchester	71	4.5	1.0	to	12.0	-0.52	-0.90	to	0.41
Gt Ormond St	3	0.0	0.0	to	63.7	-1.00	-1.00	to	17.25

b) April 2011 – March 2012

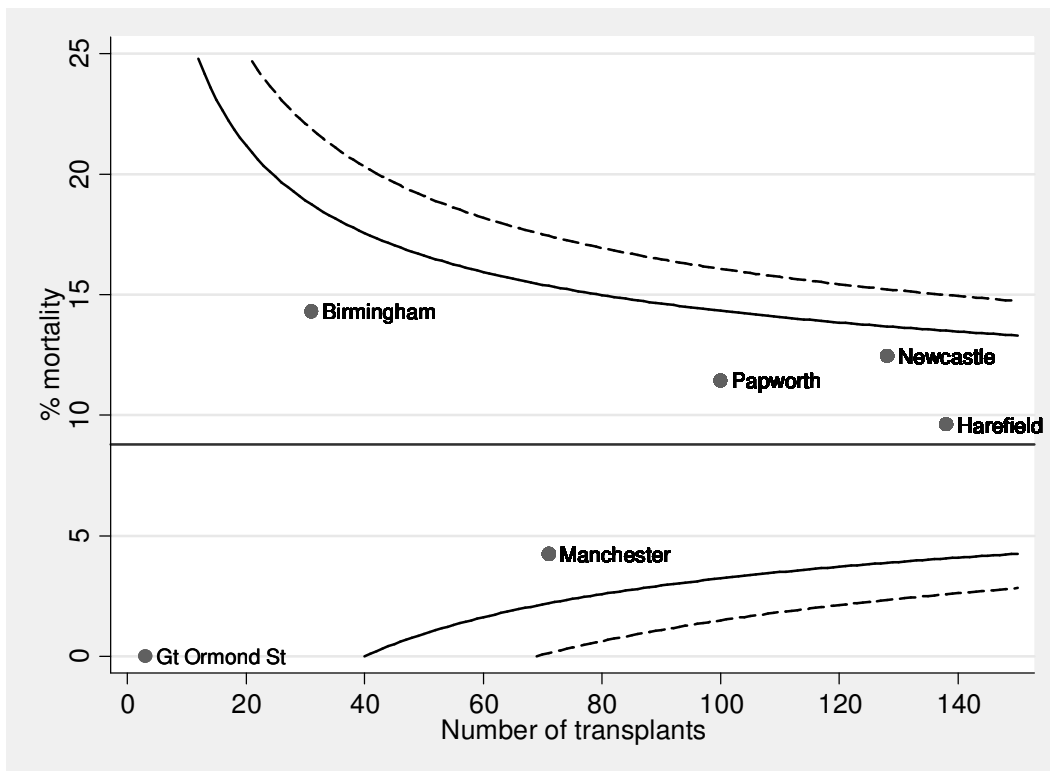
Centre	No cases	Mortality rate	95%CI			Centre effect	95%CI		
Newcastle	45	11.6	4.6	to	22.2	0.36	-0.50	to	1.96
Papworth	37	9.1	2.0	to	22.6	0.04	-0.79	to	2.03
Harefield	47	10.4	3.6	to	21.3	0.21	-0.61	to	1.82
Birmingham	15	21.2	6.8	to	40.8	1.80	-0.24	to	6.16
Manchester	26	3.9	0.1	to	18.6	-0.57	-0.99	to	1.37
Gt Ormond St	1	0.0	0.0	to	87.3	-1.00	-1.00	to	70.21

**Figure 36 Risk-adjusted estimates of early mortality after adult lung transplantation, April 2009 to March 2012**

a) 30-days



b) 90-days



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



**Table 43** 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	592	76.3	72.9	to	79.7	-0.11	-0.27	to	0.07
Sheffield	26	79.8	62.8	to	92.4	-0.27	-0.76	to	0.70
Papworth	534	72.2	68.8	to	75.6	0.11	-0.07	to	0.30
Harefield	496	75.4	71.6	to	79.0	-0.06	-0.24	to	0.14
St George's	47	56.2	45.6	to	67.4	1.24	0.39	to	2.43
Birmingham	166	68.3	62.1	to	74.4	0.33	-0.01	to	0.76
Manchester	282	78.1	73.2	to	82.6	-0.19	-0.39	to	0.05
Gt Ormond St	23	86.8	64.6	to	98.2	-0.56	-0.95	to	0.57

b) *April 2008 – March 2011*

Centre	No cases	% survival	95%CI			Centre effect	95%CI		
Newcastle	131	72.8	64.1	to	80.9	0.07	-0.32	to	0.61
Papworth	92	71.1	60.6	to	80.9	0.17	-0.32	to	0.87
Harefield	125	77.1	67.7	to	85.2	-0.14	-0.50	to	0.37
Birmingham	26	60.4	43.6	to	77.9	0.89	-0.19	to	2.72
Manchester	65	81.1	69.3	to	90.3	-0.33	-0.69	to	0.28
Gt Ormond St	4	0.0	28.3	to	100.0	-1.00	-1.00	to	6.29

## Continuous monitoring of mortality

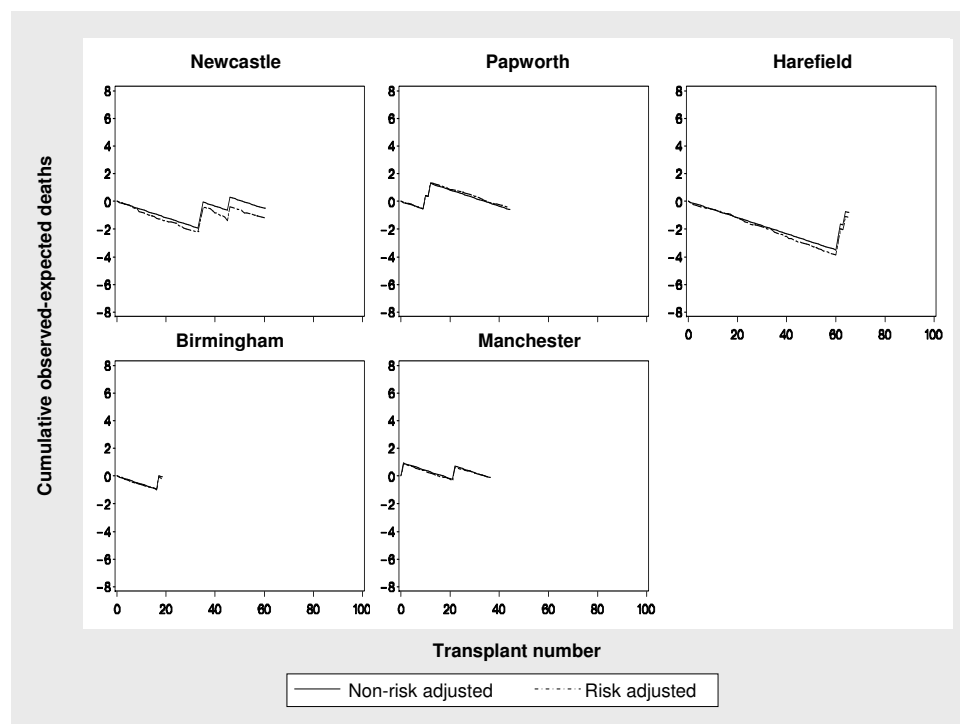
### *Observed – expected mortality*

The observed – expected charts, with and without risk adjustment, for 30-day and 90-day mortality after adult lung transplantation are shown in **Figure 37** and **Figure 38** respectively.

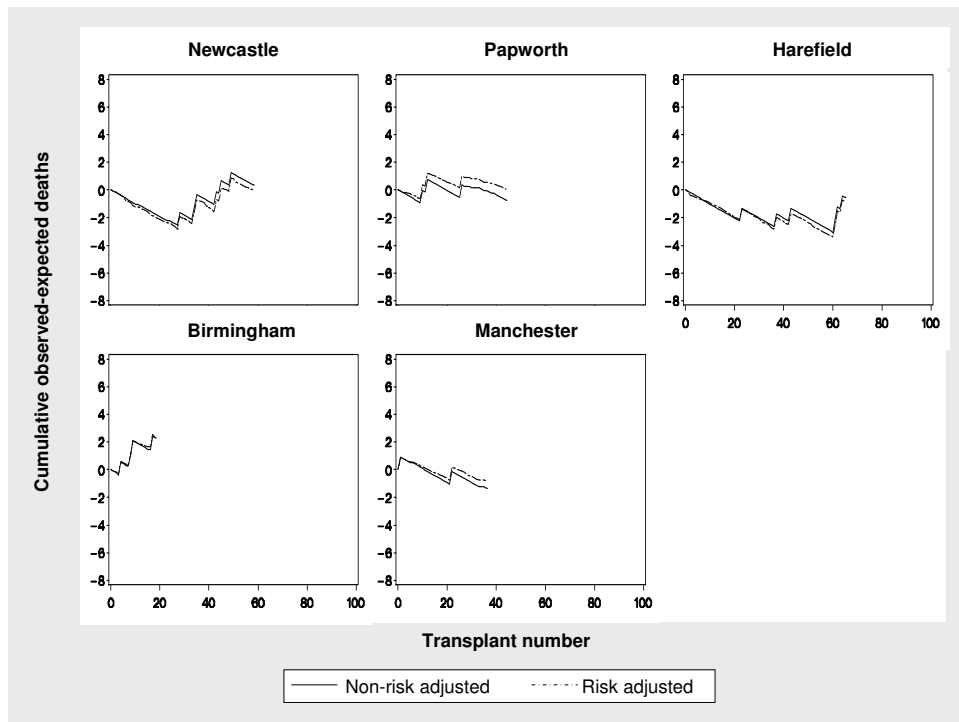
### *Tabular CUSUM charts*

Tabular CUSUM charts for 30-day and 90-day mortality are shown in **Figure 39** and **Figure 40** respectively. Mortality rates following adult lung transplantation have been consistent with the national average at all centres in recent years.

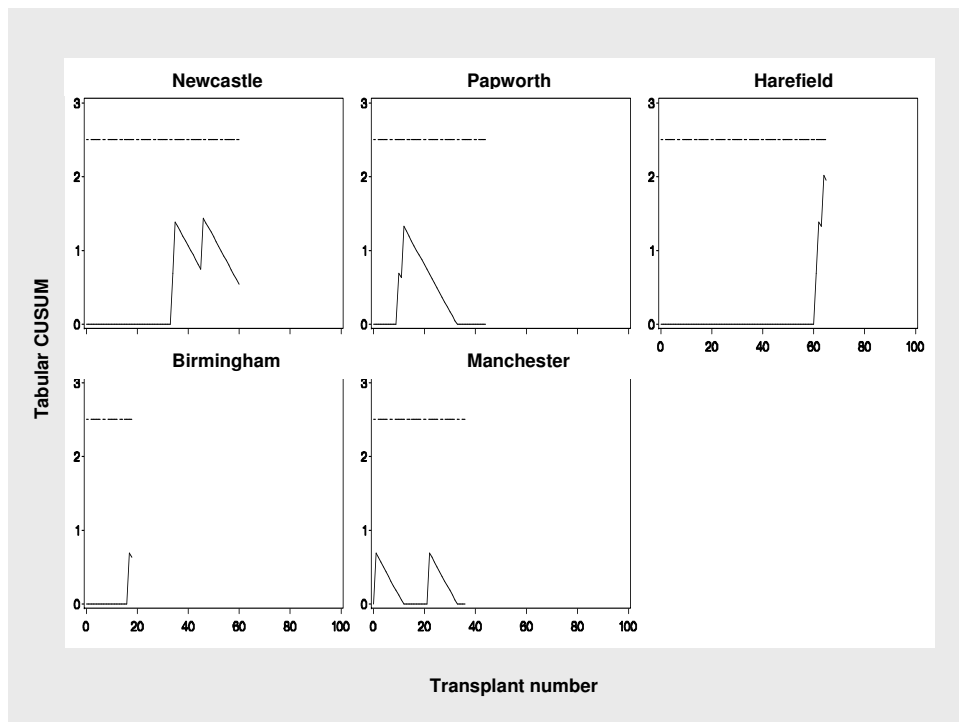
**Figure 37** Cumulative (observed – expected) 30-day mortality after adult lung transplantation, January 2011 to March 2012



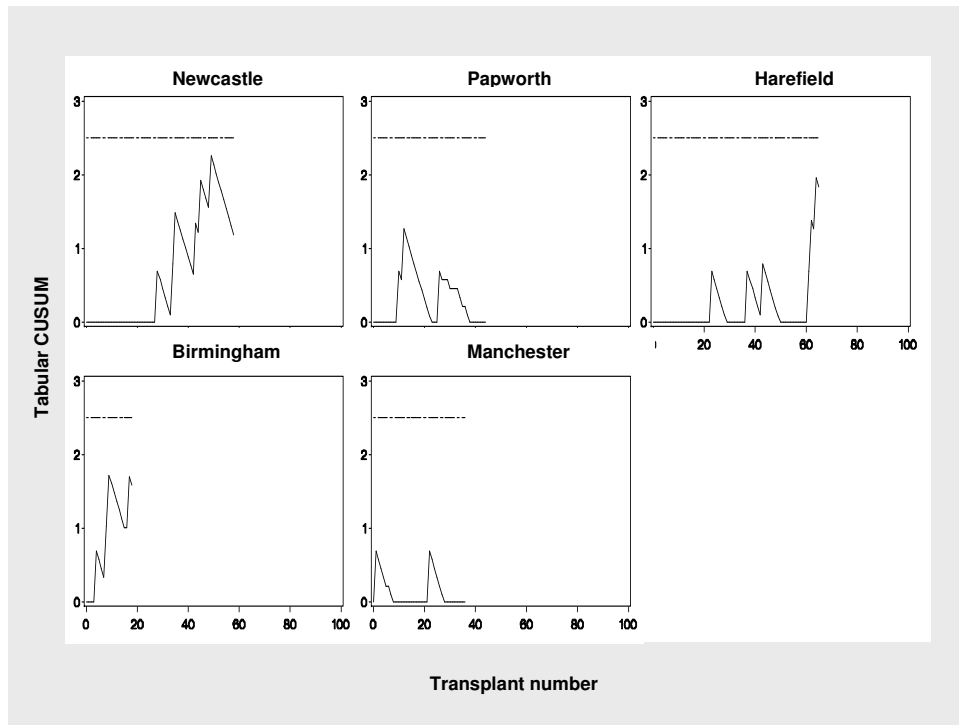
**Figure 38** Cumulative (observed – expected) 90-day mortality after adult lung transplantation, January 2011 to March 2012



**Figure 39** Tabular CUSUM for 30-day mortality after adult lung transplantation unadjusted for patient risk, January 2011 to March 2012



**Figure 40** Tabular CUSUM for 90-day mortality after adult lung transplantation unadjusted for patient risk, January 2011 to March 2012



## 7. RESULTS – PAEDIATRIC LUNG TRANSPLANTATION

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### Transplant activity

One-hundred and four 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 41**. Since April 2001, 63 paediatric lung grafts using lungs from cadavers have been carried out, 29 since April 2007. Unlike the adult programme, many of the children received a heart-lung graft (38, 36%), although the number of heart-lung grafts is falling and no heart-lung transplants have been reported in the last three years. All grafts were bilateral sequential lung procedures.

### Unadjusted mortality rates

#### *Overall mortality*

Ten recipients died within 30 days of their transplant, giving an overall 30-day mortality rate of 9.6% (95%CI 4.7% to 17.0%) for the whole audit period. There were a further 2 deaths between 30 and 90-days giving a 90-day mortality of 11.5% (95%CI 6.1% to 19.3%). Of 66 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 44** and **Table 45**).

Overall, 83.4% (95%CI 74.7% to 89.4%) of children were alive 1-year after their transplant; 74.7% (95%CI 64.8% to 82.2%) survived to 3-years; 62.7% (95%CI 51.6% to 72.0%) to 5-years and 40.0% (95%CI 26.4% to 53.8%) were alive after 10-years (**Table 46** to **Table 49**).

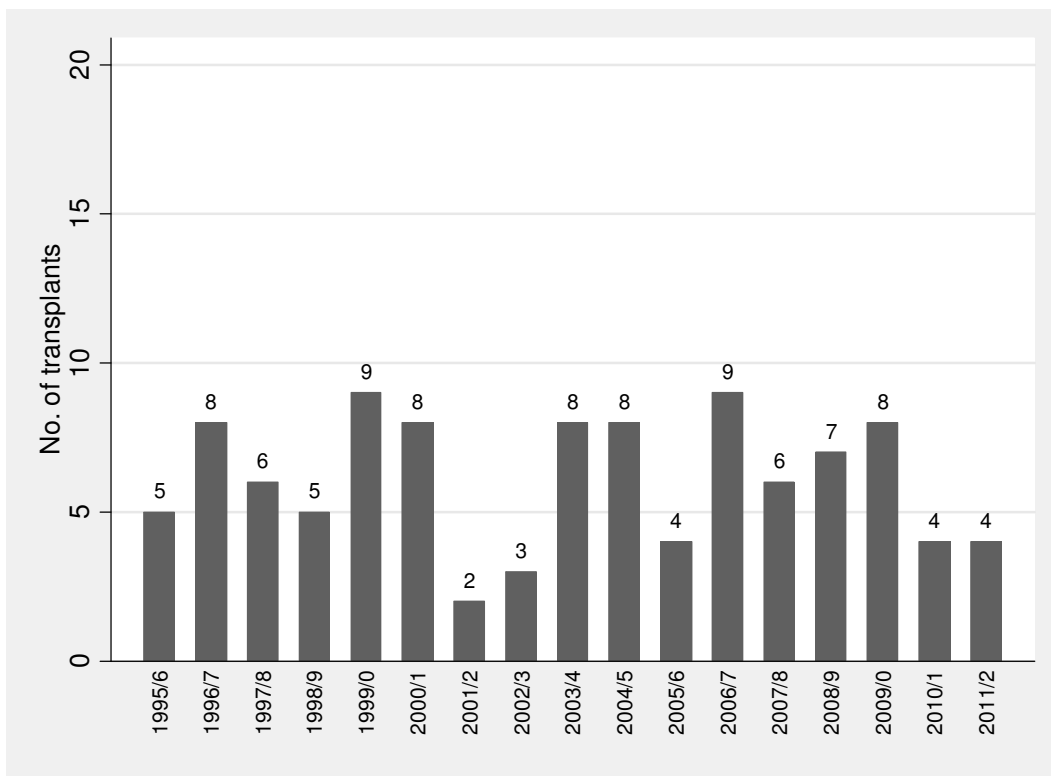
#### *Mortality rates by transplant centre*

Mortality rates at 30-days and 90-days by centre, unadjusted for patient risk, for the period April 2009 to March 2012 (30-days and 90-days), are given in **Table 44** and **Table 45**). As there were only two reported early deaths over this period centre effect estimates are omitted.

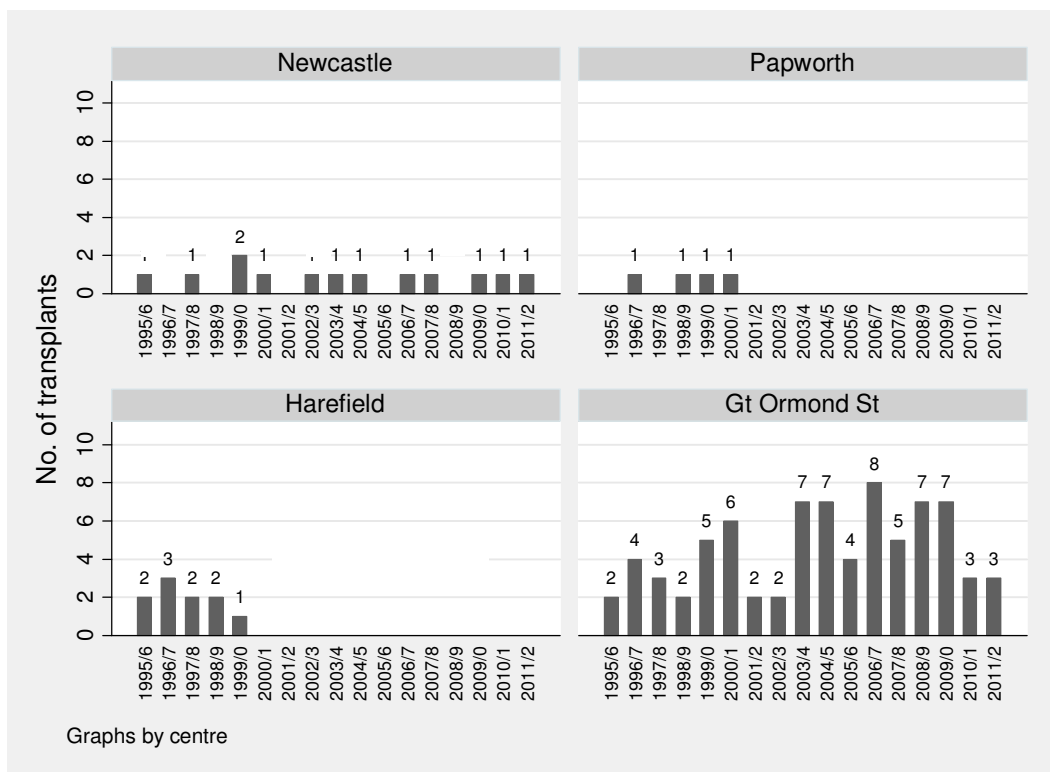
Focusing on the three centres with more than 5 transplants in there was no evidence to suggest that 1, 3, 5 and 10-year survival differed significantly between centres ( $p=0.09$ ,  $p=0.35$ ,  $p=0.45$  and  $p=0.85$  for 1,3, 5 and 10 year survival respectively) (**Figure 42**). The centre effect estimates also indicate that survival rates were similar across centres; all 95% confidence intervals encompass 0 (**Table 46** to **Table 49**).

**Figure 41 Paediatric lung transplant activity by audit year**

a) Overall



b) By transplant centre



**Table 44** 30-day mortality after paediatric lung transplantation by centre *unadjusted* for patient risk

a) April 2009 – March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI		
Newcastle	3	0	0.0	0.0	to	70.8
Gt Ormond St	13	2	15.4	1.9	to	45.4
All centres	16	2	12.5	1.6	to	38.3

b) April 2011– March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI		
Newcastle	1	0	0.0	0.0	to	97.5
Gt Ormond St	3	1	33.3	0.8	to	90.6
All centres	4	1	25.0	0.6	to	80.6

<sup>1</sup> a) p>0.99; b) p>0.99

**Table 45** 90-day mortality after paediatric lung transplantation by centre *unadjusted* for patient risk

a) April 2008 – March 2012

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI		
Newcastle	3	0	0.0	0.0	to	70.8
Gt Ormond St	13	2	15.4	1.9	to	45.4
All centres	16	2	12.5	1.6	to	38.3

b) April 2011– March 2011

Centre	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI		
Newcastle	1	0	0.0	0.0	to	97.5
Gt Ormond St	3	1	33.3	0.8	to	90.6
All centres	4	1	25.0	0.6	to	80.6

<sup>1</sup> a) p>0.99; b) p>0.99

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

a) *Whole audit period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	13	92.3	56.6	to	98.9	-0.53	-0.99	to	1.64
Papworth	4	75.0	12.8	to	96.1	0.39	-0.96	to	6.73
Harefield	10	60.0	25.3	to	82.7	1.63	-0.28	to	5.73
Gt Ormond St	77	85.6	75.5	to	91.8	-0.13	-0.57	to	0.56
<b>All centres</b>	<b>104</b>	<b>83.4</b>	<b>74.7</b>	<b>to</b>	<b>89.4</b>				

b) *April 2008 – March 2011*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	2	100.0				-1.00	-1.00	to	17.89
Gt Ormond St	17	94.1	65	to	99.1	0.11	-0.87	to	3.00
<b>All centres</b>	<b>19</b>	<b>94.7</b>	<b>68.1</b>	<b>to</b>	<b>99.2</b>				

<sup>1</sup> a) p=0.09 (excluding centres with < 5 cases); b) p=0.73



**Table 47** Three-year survival after paediatric lung transplantation by centre *unadjusted* for patient risk

a) *Whole audit period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	13	83.1	47.2	to	95.5	-0.36	-0.92	to	1.30
Papworth	4	50.0	5.8	to	84.5	0.90	-0.77	to	5.87
Harefield	10	60.0	25.3	to	82.7	0.83	-0.50	to	3.69
Gt Ormond St	77	76.7	65.1	to	84.9	-0.09	-0.47	to	0.46
All centres	<b>104</b>	<b>74.7</b>	<b>64.8</b>	<b>to</b>	<b>82.2</b>				

b) *April 2006– March 2009*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	2	50.0	0.6	to	91.0	3.23	-0.89	to	22.59
Gt Ormond St	20	90.0	65.6	to	97.4	-0.28	-0.91	to	1.61
All centres	<b>22</b>	<b>86.4</b>	<b>63.4</b>	<b>to</b>	<b>95.4</b>				

<sup>1</sup> a) p=0.35 (excluding centres with <5 cases); b) p=0.010

**Table 48** Five-year survival after paediatric lung transplantation by centre *unadjusted* for patient risk

a) *Whole Audit Period*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	13	72.7	36.3	to	90.4	-0.33	-0.86	to	0.96
Papworth	4	50.0	5.8	to	84.5	0.43	-0.83	to	4.18
Harefield	10	48.0	16.1	to	74.5	0.59	-0.48	to	2.70
Gt Ormond St	77	63.8	50.6	to	74.4	-0.04	-0.38	to	0.43
All centres	<b>104</b>	<b>62.7</b>	<b>51.6</b>	<b>to</b>	<b>72.0</b>				

b) *April 2004– March 2007*

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	2	100.0		to		-1.00	-1.00	to	11.04
Gt Ormond St	19	83.9	57.9	to	94.5	0.11	-0.77	to	2.25
All centres	<b>21</b>	<b>85.4</b>	<b>61.3</b>	<b>to</b>	<b>95.1</b>				

<sup>1</sup> a) p=0.45 (excluding centres with <5 cases) b) p=0.56

**Table 49** Ten-year survival after paediatric lung transplantation by centre *unadjusted* for patient risk

Centre	No cases	% survival <sup>1</sup>	95%CI			Centre effect	95%CI		
Newcastle	13	48.5	15.9	to	75.2	-0.19	-0.74	to	0.88
Papworth	4	50.0	5.8	to	84.5	-0.12	-0.89	to	2.18
Harefield	10	48.0	16.1	to	74.5	0.04	-0.66	to	1.42
Gt Ormond St	77	29.5	12.4	to	49.0	0.04	-0.29	to	0.47
All centres	<b>104</b>	<b>40.0</b>	<b>26.4</b>	<b>to</b>	<b>53.2</b>				

<sup>1</sup> p=0.85 (excluding centres with <5 cases)

#### *Mortality rates by retrieval centre*

Mortality rates by retrieval centre, for the period April 2009 to March 2012 are shown in **Table 50**. Of the 13 transplants carried out at Great Ormond Street, 3 used lungs retrieved by the local team and 10 were retrieved by another centre. One of the three 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=0.10). Survival to 1 and 3-years has also changed over time, (p=0.02 and p=0.053 respectively) but longer-term survival was similar (5-year, p=0.16; 10-year, p=0.30). Survival to 10 years by audit era is shown in **Figure 43**.

#### *Mortality rates by lung type*

Survival to 10-years by type of transplant is shown in **Figure 44**. 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=0.07).

**Table 50** 30 and 90-day mortality after paediatric lung transplantation by retrieval centre *unadjusted* for patient risk

April 2009 – March 2012

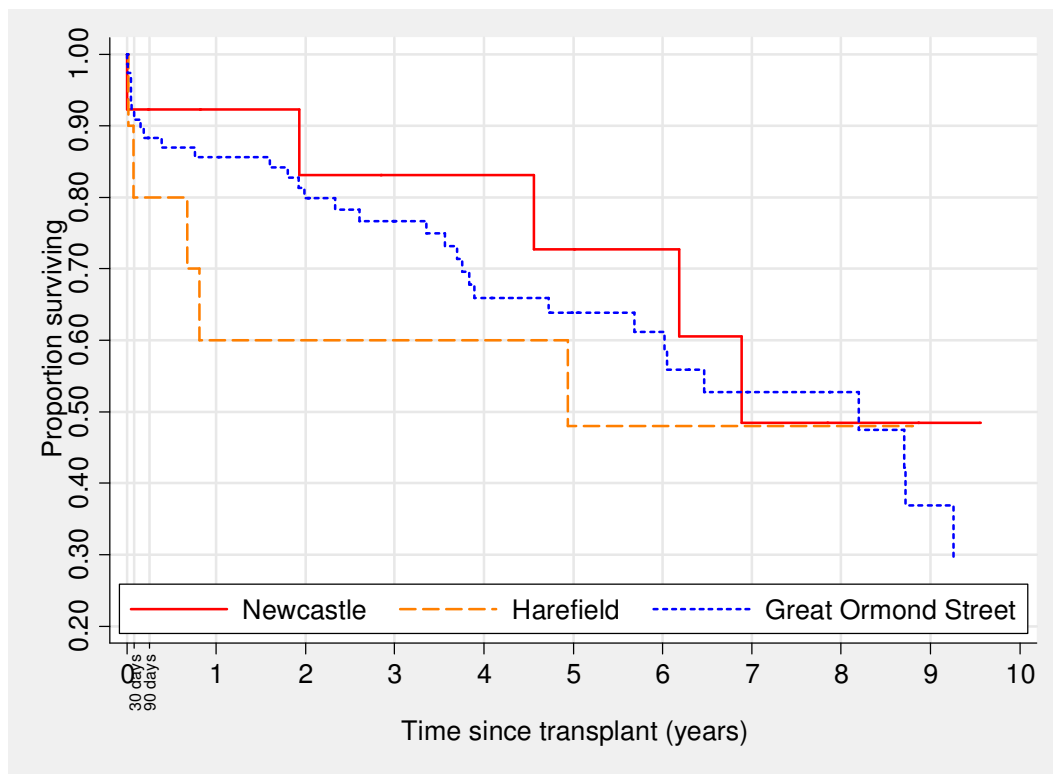
Retrieval Centre	30 days						90 days						% used locally <sup>3</sup>
	No cases	No deaths	Mortality rate <sup>1</sup>	95%CI			No cases	No deaths	Mortality rate <sup>2</sup>	95%CI			
Newcastle	4	0	0.0	0.0	to	60.2	4	0	0.0	0.0	to	60.2	25.0
Papworth	1	0	0.0	0.0	to	97.5	1	0	0.0	0.0	to	97.5	0.0
Harefield	2	0	0.0	0.0	to	84.2	2	0	0.0	0.0	to	84.2	0.0
Birmingham	5	2	40.0	5.3	to	85.3	5	2	40.0	5.3	to	85.3	0.0
Gt Ormond St	4	0	0.0	0	to	60.2	4	0	0.0	0	to	60.2	75.0
<b>All centres</b>	<b>16</b>	<b>2</b>	<b>12.5</b>	<b>1.6</b>	<b>to</b>	<b>38.3</b>	<b>16</b>	<b>2</b>	<b>12.5</b>	<b>1.6</b>	<b>to</b>	<b>38.3</b>	<b>25.0</b>

<sup>1</sup> p=0.53

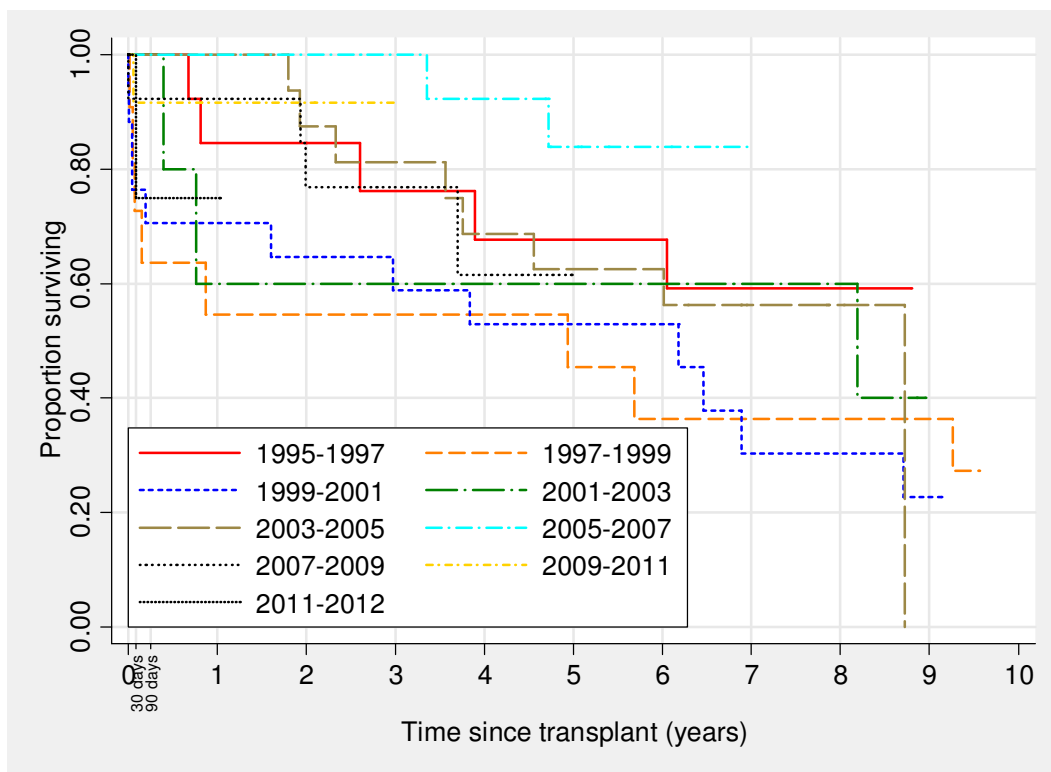
<sup>2</sup> p=0.53

<sup>3</sup> Retrieved by the centre who carried out the transplant

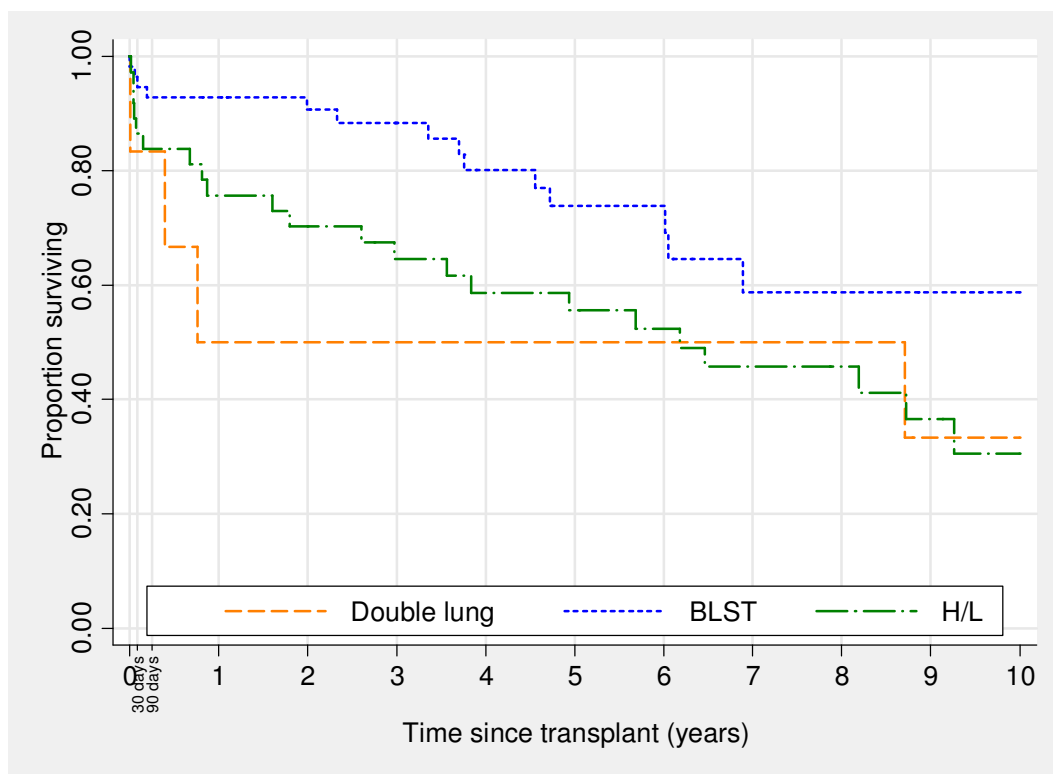
**Figure 42** Kaplan-Meier survival curves after paediatric lung transplantation by centre



**Figure 43** Kaplan-Meier survival curves after paediatric lung transplantation by era



**Figure 44** Kaplan-Meier survival curves after paediatric lung transplantation by lung type



### Continuous monitoring of mortality

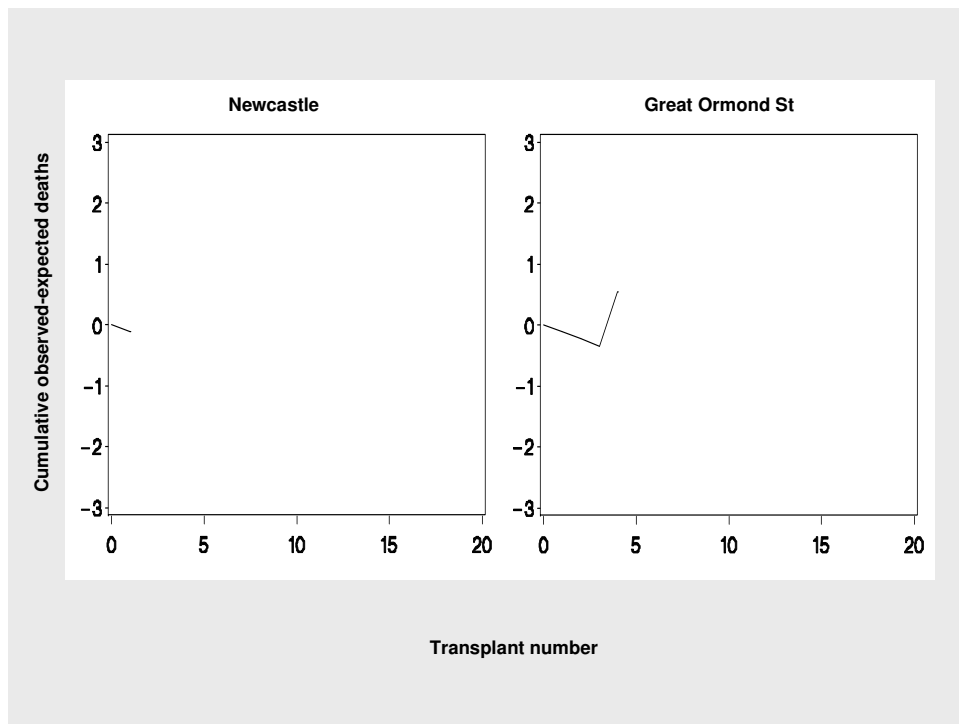
#### *Observed – expected mortality*

The observed – expected charts for 30-day and 90-day mortality after paediatric lung transplantation are shown in **Figure 45** and **Figure 46** respectively.

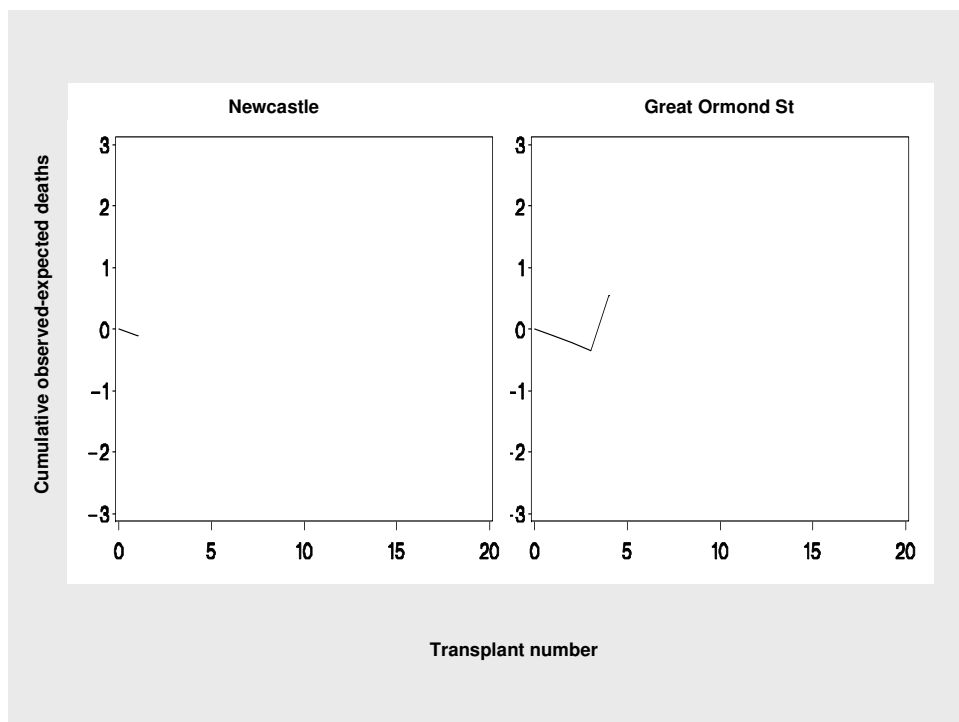
#### *Tabular CUSUM*

Tabular CUSUM charts for 30-day and 90-day mortality are shown in **Figure 47** and **Figure 48** respectively. Paediatric mortality rates after lung transplantation are consistent with the national average.

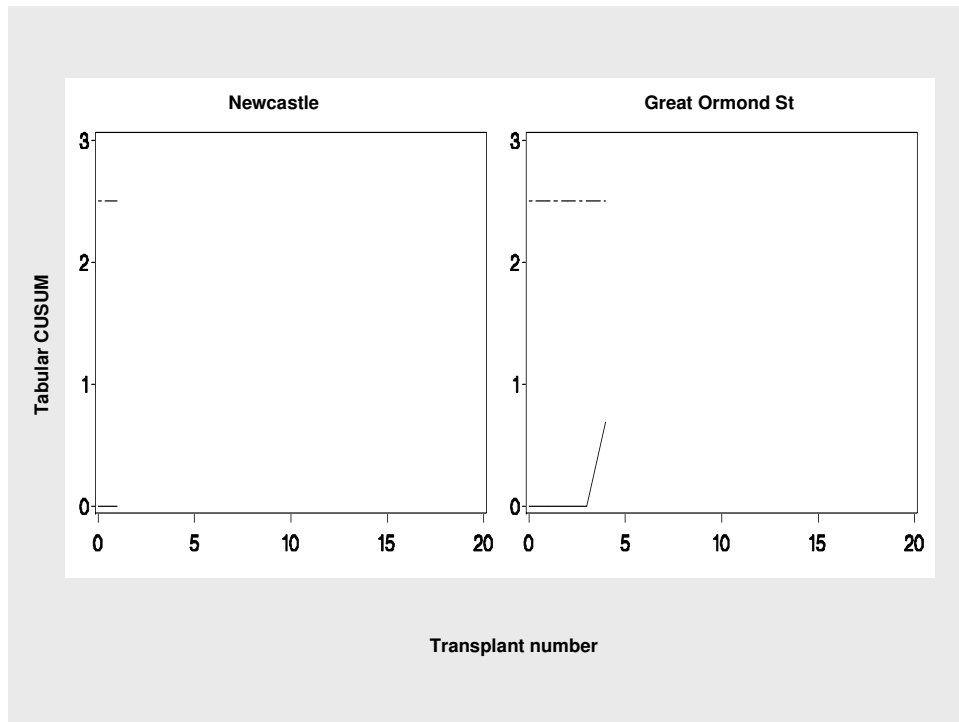
**Figure 45** Cumulative (observed – expected) 30-day mortality after paediatric lung transplantation *unadjusted* for patient risk, January 2011 to March 2012



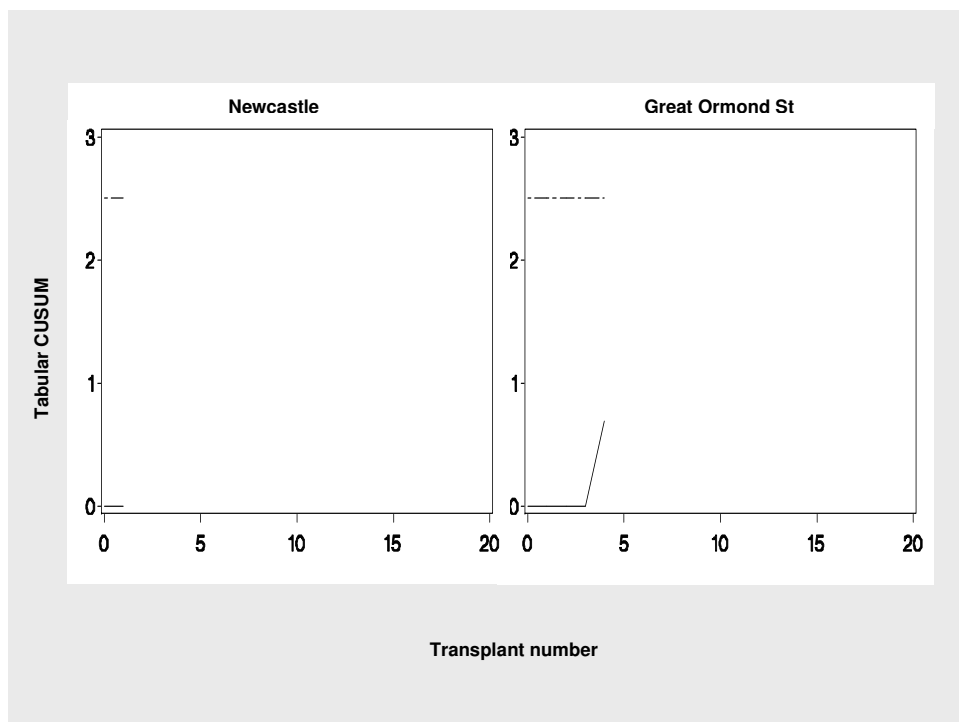
**Figure 46** Cumulative (observed – expected) 90-day mortality after paediatric lung transplantation *unadjusted* for patient risk, January 2011 to March 2012



**Figure 47** Tabular CUSUM for 30-day mortality after paediatric lung transplantation *unadjusted* for patient risk, January 2011 to March 2012



**Figure 48** Tabular CUSUM for 90-day mortality after paediatric lung transplantation *unadjusted* for patient risk, January 2011 to March 2012





## **8. DISCUSSION OF RESULTS**

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### **8.1 ADULT HEART TRANSPLANTATION**

The overall number of adult heart transplants rose from 90 transplants to 107 transplants in 2011/12. 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 12.2% to 12.3% and at 90-days the overall rate remained unchanged at 14.8%. Since April 2009, there has been an upward trend in both 30-day and 90-day mortality; 14.1% 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 heart transplants. However, excepting Glasgow, 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 2009, 30 and 90-day mortality, estimated with and without adjustment was higher in Harefield and Glasgow than at other centres and this higher mortality was sufficient to cause the continuous monitoring charts to signal in May 2011 and November 2011 respectively. However, both centres have seen an increase in the risk profile of their patients undergoing transplantation in recent years and in the last audit year since April 2011, the 90-day mortality rate at Harefield has been lower than expected after risk adjustment, although this was not statistically significant.

Patients given mechanical support post heart transplantation for primary graft failure had a VAD implanted for a median of 7 days. At the time of analysis, 31 of these patients (37%) 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 (81% vs. 87% at 1 year, 76% vs. 80% at 3 years, 71% vs. 74% at 5-years and 57% 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 2008 to March 2011 suggested that mortality was higher than expected at Harefield, this is in contrast with our last report when for transplants between April 2007 to March 2010 mortality was in line with that expected at all centres. This increase in mortality in Harefield is consistent with their 30- and 90-day outcomes in this period.

The report on VAD activity and outcome shows that 88% of patients given a long-term VAD were alive at 30-days and 67% 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.

## **8.2 PAEDIATRIC HEART TRANSPLANTATION**

Following a decline in activity in 2004/5, heart transplantation in children between 2005 and 2012 returned to the previous activity level. Thirty-day mortality was 4.9% for transplants since April 2009, which is higher than reported previously (2.9% for the three years from April 2008). 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, although there have been few combined heart and lung transplants in the recent era (5 in the last audit year). In contrast to the heart transplant programme, lung transplant activity has continued to increase with 175 transplants reported in the last year (9 more than the previous year and 35 more than 2 years ago), the highest annual total since the audit began. The overall 30-day mortality for the adult lung transplant programme as a whole is 9.8%, 0.3% lower than the overall rate reported in the last annual report. Overall 90-day mortality also declined from 15.1% to 14.6%.

For the period since April 2009 early mortality, with and without adjustment for case-mix, was as expected and did not vary significantly between centres.

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 (77% vs. 83% at 1 year, 64% vs. 68% at 3 years, and 52% vs. 55% at 5-years). At 10-years unadjusted survival is higher in the UK (33% vs. 26%).

Long term unadjusted 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 Birmingham (and Papworth at 3, 5 and 10 years ) had lower than expected survival rates. 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 unadjusted analyses. Amongst the active adult centres, differences in survival to 1-year for the cohort as a whole were no longer apparent after adjustment for case-mix.

## **8.4 PAEDIATRIC LUNG TRANSPLANTATION**

The paediatric programme in the UK continues to be very small with just 104 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 three reported

deaths within 90 days of transplantation since August 2000. Overall longer term survival to 5-years compares well with that of adult lung transplantation.

## **9. PRESENTATIONS AND PUBLICATIONS OF THE UKCTA**

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### **9.1 PRESENTATIONS**

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

*Annual Meeting for the British Transplantation Society, February 2012, Glasgow*

Chronic kidney disease after adult heart transplantation. HL Thomas, NR Banner, CL Murphy, R Steenkamp, R Taylor, D Fogarty and RS Bonser

### **9.2 PUBLICATIONS**

Manuscripts published since our last annual report:

Thomas HL, Banner NR, Murphy CL, Steenkamp R, Birch R, Fogarty DG, Bonser RS. Incidence, Determinants, and Outcome of Chronic Kidney Disease After Adult Heart Transplantation in the United Kingdom. *Transplantation*, 2012; 93: 1151-1157

## APPENDIX 1      FACTORS INCLUDED IN RISK ADJUSTMENT MODELS

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### 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 antiarrhythmics
	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
Donor: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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