

To:	Trust Board			
From:	Jim Birrell – Interim Chief Executive			
Date:	30 August 2012			
CQC regulation:	As applicable			
Title:	Safe and Sustainable Update			
Author/Responsible Director: Dr Peter Barry, Consultant in Paediatric Intensive Care & Elizabeth Aryeetey, Lead Nurse, Service Manager / Jim Birrell, Interim Chief Executive				
Purpose of the Report: Next Steps on the Safe and Sustainable Children's Congenital Heart Services Review				
The Report is provided to the Board for:				
Decision	<input type="checkbox"/>	Discussion <input checked="" type="checkbox"/>		
Assurance	<input type="checkbox"/>	Endorsement <input checked="" type="checkbox"/>		
Summary / Key Points: This report gives an overview of UHL's response and actions following on from the decision made by the JCPCT on the future configuration of Paediatric Cardiac Surgery on July 4 th , 2012.				
In summary this report details:				
<ul style="list-style-type: none"> • The implications for UHL of the decision made by the JCPCT. • The local response from key stakeholders • The legal advice we have received • The clinical review of the decision • Proposed next steps 				
Recommendations:				
<ul style="list-style-type: none"> • The Trust Board are asked to note the Legal Advice and agree not to legally challenge the JCPCT's decision. • The Trust Board is asked to endorse the Clinical Case and approve its presentation to stakeholders and Commissioners for consideration. 				
Previously considered at another corporate UHL Committee? Executive Team				
Strategic Risk Register Risks 2, 4, and 8	Performance KPIs year to date N/A			
Resource Implications (eg Financial, HR) Losing Paediatric Cardiac Surgery will have financial and HR implications for the Trust.				

Paper D

Assurance Implications N/A
Patient and Public Involvement (PPI) Implications Public Consultation took place as part of the Safe and Sustainable Review.
Equality Impact An Equality Impact Assessment has been completed as part of the Safe and Sustainable Review.
Information exempt from Disclosure N/A
Requirement for further review? Update to be brought to next Trust Board

University Hospitals of Leicester NHS Trust

Report to: UHL Trust Board

Report From: Jim Birrell, Interim Chief Executive

Subject: Outcome of the Safe and Sustainable Children's Congenital Heart Services Review – Next Steps

1. Introduction

- 1.1 On July 4th, 2012 following a 4 year review of Children's Cardiac Services, the Joint Committee of Primary Care Trusts (JCPCT) announced its decision to designate 7 centres to provide paediatric cardiac surgery in the future. Leicester's East Midlands Congenital Heart Centre (EMCHC) was not one of the chosen centres.
- 1.2 On July 13th, 2012 Teresa Moss, Director of the National Specialised Commissioning Team, announced that "The Health Secretary has considered advice from the Chairman of the Advisory Group for National Specialised Services and has endorsed the recommendation that the children's respiratory ECMO service which is currently provided by University Hospitals of Leicester (UHL) NHS Trust should be relocated to Birmingham Children's Hospital."
- 1.3 On August 2nd, 2012 the Safe and Sustainable Review issued its Implementation Plan and Transfer to the NHS Commissioning Board. This outlines the governance arrangements for transition to the new model of children's cardiac services including a move of responsibility for commissioning to the NHS Commissioning Board (NHS CB) by April 2013.
- 1.4 This paper outlines the implications of this decision for UHL, the Trust's response to the decision and the next steps.

2. Implications

The implications of losing the Paediatric Cardiac Surgery Service have been considered by the UHL Trust Board on several occasions over the past 2 years. Below is a summary of some of the main considerations.

- 2.1 Maintaining a service during transition
- 2.1.1 There are significant risks to the maintenance of services during the transition period as outlined in the Safe and Sustainable implementation plan. Mitigation of these risks is a high priority and will form an important part of the dialogue between UHL and Birmingham Children's Hospital (BCH). An initial meeting between the Executive Teams of both Trusts was held in Birmingham on August 6th, 2012 with clinical representation from UHL by Dr Aidan Bolger, Lead Cardiologist for EMCHC and Elizabeth Aryeetey, Lead Nurse / Service Manager.

2.1.2 Timely and regular communication with staff is an important part of the Trust's strategy and response to issues raised will continue to be discussed and progressed by the weekly EMCHC Programme Board meeting chaired by Dr Aidan Bolger and attended by UHL Executive, Management and Clinical representatives.

2.2 Paediatric Cardiology Services post transition

2.2.1 One of the challenges with the Safe and Sustainable model is the assumption that you can maintain tertiary cardiology centres without surgery. It is the view of the EMCHC clinical team that ambitious, high calibre cardiologists will want to be part of the surgical centres not the cardiology centres as described. This has implications for the retention and further recruitment of specialist cardiology and paediatric intensive care staff.

2.2.2 To date one cardiologist has resigned from post due to the lack of interventional opportunities that Leicester will have in the future. Other interventional cardiologists will undoubtedly be approached by expanding centres and it is difficult to envisage how Leicester will continue to attract high calibre trainees without the benefits of surgical and interventional programmes. Specialist cardiology trainee programmes will inevitably be withdrawn from Leicester's congenital cardiac services with implications for providing sufficient staff to manage the complex out-patient service and the smaller in-patient workload.

2.2.3 Leicester has a highly experienced and dedicated paediatric cardiac investigations department which will be difficult to retain in the absence of a surgical and interventional cardiology programme with its associated intensive care and ward based activity. However, the out-patient service will continue to require this highly specialised skill set.

2.3 Clinical Perfusion post transition

2.3.1 Glenfield Hospital has a highly skilled clinical perfusion department which has been instrumental in the development of the Extracorporeal Membrane Oxygenation (ECMO) service. It is their expertise that has contributed to the development of the country's only paediatric mobile ECMO service. It is anticipated that Birmingham Children's Hospital will require additional perfusion staff to both accommodate the additional cardiac work and the ECMO programme.

2.4 Children's Services post transition

2.4.1 As outlined in the attached clinical case, removal of cardiac surgery from Leicester will destabilise Paediatric Intensive Care Unit (PICU) provision. Children's services would need to re-negotiate the PICO contract with Commissioners in order to maintain the Paediatric Intensive Care Society's standards of 500 ventilated cases per year. There is a possibility that some of the Intensive Care medical staff will not stay in a PICU that does not have cardiac and ECMO services.

2.4.2 There is likely to be a domino effect on the remaining tertiary children's services if PIC provision is lost from Leicester. These include:

- Paediatric surgery (circa 5,000 cases/year)
 - Oncology
 - Neurology (neuro-degenerative diseases)
 - Respiratory (long-term ventilation programme – currently 50 pts in the community with growth)
 - Neonatal unit (babies with surgical problems would be transferred)
- 2.4.3 To mitigate the risk to destabilizing PICU there is an opportunity to develop and expand the current provision at the LRI to create a hub and spoke model with BCH. This model exists between BCH and North Staffordshire PICU. General paediatric PICU admissions from Coventry and Warwick could be directed to Leicester alongside the repatriation of post-op cardiac patients from BCH requiring long-term ventilation.
- 2.5 ACHD Services**
- 2.5.1 Adult congenital surgery and interventional cardiology will not be supported in Leicester without paediatric cardiac surgery as the caseload for the operators will be insufficient to build or retain expertise. Currently 60-70 surgical cases are performed and 100 interventional catheters. The interventional cardiologists undertake both paediatric and adult cases, as do the surgeons. It is unclear what the transition arrangements will be for the adult congenital service, but it is likely that there will be an expectation of cross-site working between BCH and the Queen Elizabeth Hospital in Birmingham.
- 2.5.2 The transition of the adult service will create a small amount of additional capacity within the adult cardiology and cardiac surgical wards as well as in adult intensive care.
- 2.6 Research and Development**
- 2.6.1 The proposed expansion and growth of the paediatric cardiac service and existing ECMO services in Leicester presented exciting opportunities for the Cardio-Respiratory Research Centre in the future. However, it is recognised that the existing research portfolio of the services was not fully advanced and therefore the impact on the adult research programme of losing these services would not provide a significant risk to the Trust.
- 3. Local Response**
- 3.1 The Trust's immediate response to the decision on July 4th, 2012 was to continue to operate as "business as usual" to ensure our patients and families continued to receive a high quality and safe service. The clinical staff's response has been remarkable as one of their busiest periods followed the decision. The recently extended 10th PICU bed was in action within days. Support from senior Clinical Business Units and Divisional managers, accompanied by Executive Team walk rounds boosted morale. On-going communication via a written staff briefing is now a weekly feature across the service. Staff have been reassured about future job security as well as updated on the actions being taken by the Trust.
- 3.2 We would also like to acknowledge the overwhelming support from local stakeholders. In particular, the ongoing commitment to the unit from patients, families, the two Charities (Heartlink and Keep the Beat), the Local

Involvement Networks, the Joint Health Overview and Scrutiny Committee, local MPs has helped to maintain staff morale and focus during this extremely difficult time.

- 3.3 In parallel to maintaining the current service, we made a commitment as Board to carefully examine the JCPCT's findings and business case that informed their final decision. As part of this examination, we have sought advice from the clinicians running the service and our external legal advisors. The rest of this paper summarises the legal advice and clinical advice and recommends next steps.

4. Legal Advice

- 4.1 We have received detailed legal advice about whether there are grounds to commence a Judicial Review challenge to the decisions made by the JCPCT.
- 4.2 The advice we have received makes the point that as part of the Judicial Review launched by the Brompton, the Court of Appeal has already looked carefully at the lawfulness of the process undertaken by the JCPCT and confirmed that, in as much as the process was being challenged in the previous court case, it was a lawful process.
- 4.3 Our legal advisors also considered whether the JCPCT were entitled to rely on their past assessments of the strength of the existing centres, as assessed by a panel under Professor Sir Ian Kennedy in May and June 2010. The lawyers consider that it would have been open to the JCPCT to take the decision to undertake further assessments so that the final decision was taken with as much up to date information as possible. However that decision would have resulted in delay and would have introduced a measure of uncertainty into the process. There were accordingly arguments in favour of maintaining the original assessments. The advice we have received is that it was not "unfair" for the JCPCT to stick to its original plan by proceeding to take the decision based on the 2010 assessments.
- 4.4 The lawyers also examined the very difficult issue, which is recognised in the report, about the effect of the decision concerning the location of paediatric congenital heart surgery centres on the specialist ECMO services presently provided for paediatric patients by the Trust. Given all the factors, the lawyers do not consider that a court would conclude that delivering paediatric ECMO services was ignored or that this factor was treated in an irrational manner. It is therefore a decision which would not be struck down by the High Court.
- 4.5 In conclusion and based on a thorough examination of the process, the advice we have received is that a Judicial Review of the decisions of the JCPCT would not stand any realistic chance of success. Accordingly the legal advice is that the Trust Board accepts that the JCPCT has made a lawful decision.

5. Clinical Case Summary

- 5.1 Since the decision was made on 4th July the clinical team have spent a significant amount of time analysing the arguments underpinning the decision. The appendices of this report contain the detailed clinical cases for each of the three key areas of challenge summarised below: (We recommend that

colleagues read the summary below then the detailed clinical case for each of the areas of challenge)

- Predicted demand and capacity at Birmingham Children's Hospital (appendix 1 & 2 relate)
- ECMO and increased mortality (Appendix 3)
- Paediatric Intensive Care Capacity in the Midlands (Appendix 4)

5.2 Predicted demand and capacity at Birmingham Children's Hospital

- 5.2.1 The original national projections for demand for paediatric heart surgery used by the JCPCT suggested that demand was flat. The latest information from the CCAD, over the last 3 years shows that demand is increasing. This increase is before the 143 cases a year which are expected to shift from Northern Ireland to the mainland as a result of the Kennedy review into children's heart surgery in Belfast. (Published 1/8/12).
- 5.2.2 Birmingham are creating an extra 11 ICU beds, taking their capacity to 33. These extra beds were announced in March 2010 in response to the Healthcare Commission's concerns regarding the then high numbers of cancelled operations due to ICU capacity.
- 5.2.3 The July 4th decision will see Birmingham take Leicester's surgery work and the ECMO provision. Putting together the expected rise in demand, the transfer of Leicester cases and the already significant capacity issues in Birmingham, our modelling shows that the extra capacity announced in 2010 is already insufficient.

5.3 ECMO and increased mortality

- 5.3.1 ECMO practitioners in the UK and overseas have voiced their concerns over the transfer of the service to Birmingham. The ECMO expert who advised the panel has stated publicly that his views were overlooked. Our argument is not about whether ECMO can be transferred; of course it can, we simply wish to set out that we expect that the clinical outcomes will suffer for a number of years as a result of the transfer. The mortality rate for ECMO in Leicester is 20%. The national mortality rate (i.e. that of the other centres nationally commissioned centres) is 50% higher. That gap will close over time as each centre ascends the learning curve but the point is that Leicester's low mortality will not transfer with the service. To give an indication of real impact of this; if over the last 10 years Leicester's ECMO mortality had been at the national average, 62 more children would have died.

5.4 Paediatric intensive care capacity in the Midlands:

- 5.4.1 Capacity is already tight across the region. In 2010 (full year data) 86 children came to Leicester from the West Midlands. The transfer of services to Birmingham will mean the closure of the Glenfield PICU. The Glenfield and Leicester Royal PICU are run by one team in two locations. The review team concluded that the closure of the Glenfield PICU would have 'limited risk', that is not the case. We expect that when demand exceeds supply, general PICU patients from Leicester will have to travel elsewhere; the nearest is Nottingham, which is often full and that leaves BCH / Sheffield / Leeds. Also, given that Nottingham does not offer a retrieval service, the closure of

Glenfield PICU would mean the end of the paediatric retrieval service for the East Midlands.

- 5.5 In summary our concerns based on the clinical case are therefore that: Birmingham Childrens Hospital does not have the capacity to handle the expected demand; that ECMO mortality will increase during the transition and therefore lives will be lost not saved; and that general paediatric intensive care capacity in the Midlands and especially the East Midlands will be insufficient to deal with demand.

6 Next Steps

- 6.1 Based on a careful consideration of the points above, the conclusion of the Executive Team is that a legal challenge does not stand any realistic chance of success. However, we have concluded based on the evidence presented by the clinicians, there is a clinical case for the decision made by the JCPCT to be reconsidered. Not, we hasten to add from a starting point of whether the decision was ‘right’ or ‘wrong’ but from a dispassionate assessment of the ability of the NHS in the Midlands to cope with demand for these specialised services, safely and sustainably.
- 6.2 In this context, members of the Executive and Clinical Team are meeting with Sir Neil McKay (Chair of the JCPCT) on August 29th, 2012 to present the clinical arguments. We will provide a verbal update to the Trust Board on next steps at the meeting on August 30th, 2012.
- 6.3 We will also be presenting the findings of the clinical review to the Leicester, Leicestershire and Rutland Joint Overview and Scrutiny Committee on September, 4th, 2012 where they will be considering referring the JCPCT decision to the Independent Reconfiguration Panel.

7 Recommendations

- 1 The Trust Board are asked to note the Legal Advice and agree not to legally challenge the JCPCT’s decision.
- 2 The Trust Board is asked to endorse the Clinical Case and approve its presentation to stakeholders and Commissioners.

Predicted Demand:

Ignoring for the moment the discussion concerning the justification for a centre specific volume of 400 procedures, and the new minimum preferred volume of 500 procedures, we would also question the estimates of future activity (Chapter Y, Safe and Sustainable Cardiac Review, Decision Making Business Case (DMBC) pp189 - 193), as we believe that these potentially underestimate the future need.

- *Future activity projections are based on historical data that is now out of date*

Dr Martin Ashton-Key, Medical Advisor to Safe and Sustainable, prepared a paper entitled: "Congenital Cardiac Disease Review – An Overview of Surgical Activity (2006/07) and projections to 2025 based on National Statistics Population Projections". The analysis was conducted on the 2006/07 validated CCAD data which was the latest available validated data at the time of the analysis (August 2009). Aggregated activity for paediatric and adult surgical cases was extracted from CCAD for each year from 2002/03 to what was then the last available data (2006/07) and was thought to show a relatively stable paediatric workload but highlighted a 'slow and continuous rise' in adult surgical cases.

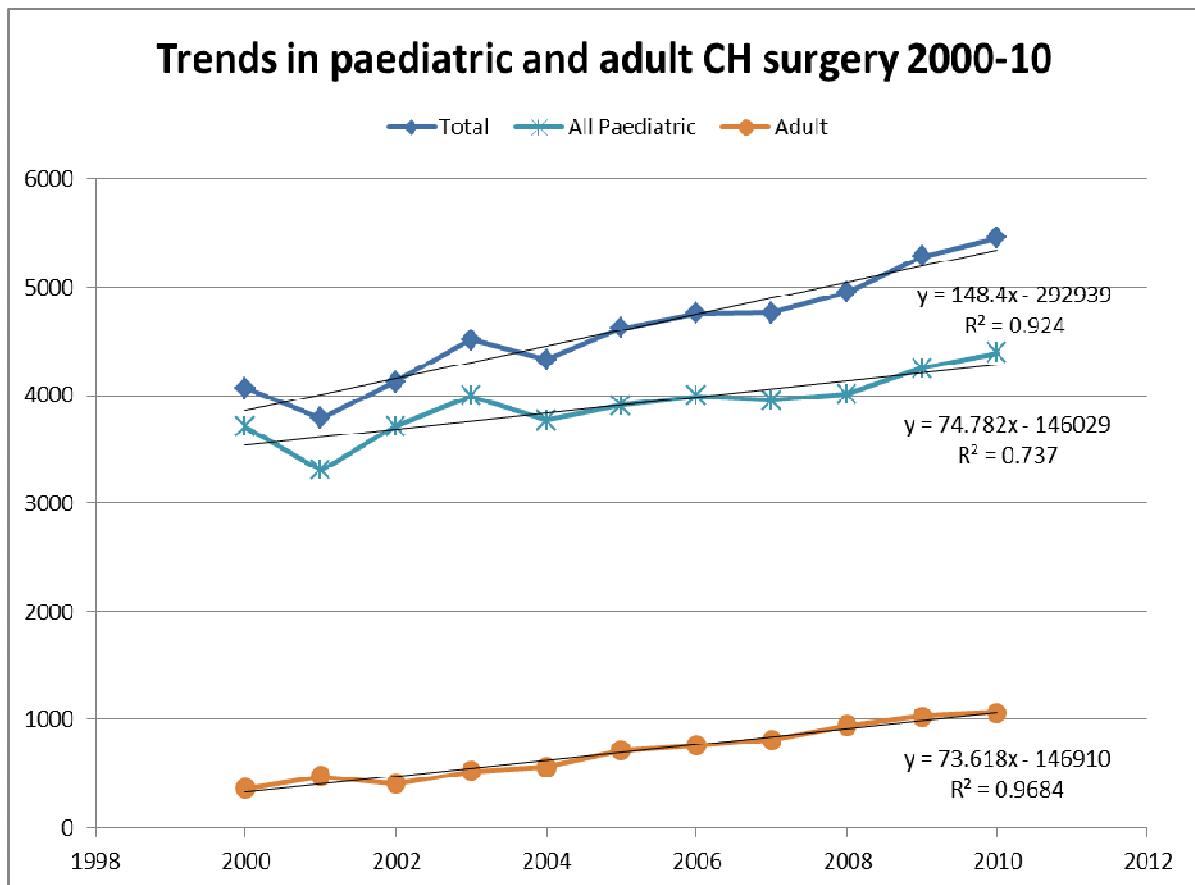
Validated CCAD data is now available for three more years (to 2009-10), with provisional (unvalidated) data for 2010-11 (See table below).

	Total	Neonate	Infant	Child	All Paediatric	Adult
2000	4067	804	1294	1608	3706	361
2001	3785	756	1165	1388	3309	476
2002	4122	787	1341	1586	3714	408
2003	4512	852	1399	1742	3993	519
2004	4326	771	1452	1544	3767	559
2005	4620	767	1562	1578	3907	713
2006	4754	836	1508	1647	3991	763
2007	4763	819	1463	1670	3952	811
2008	4953	865	1601	1545	4011	942
2009	5279	918	1675	1658	4251	1028
2010	5452	937	1170	1684	4391	1061

In contrast to Dr Ashton-Keys paper, this shows a steady, and statistically significant, rise in cases (see graph below). This rise is still present, even if the 2010-11 data is excluded.

The graph shows three data series, for adult, paediatric and total surgical activity. A linear trend line is imposed on each, and details of each are given on the graph. In view of concerns noted in the Draft Business Case (p189) about the reliability of more historical data on the CCAD database, the data has been analysed for alternate time periods (2002-10; 2004-10; and 2006-10). The trends remain essentially the same.

Using this data, one can project the future need for paediatric and congenital heart surgery. Many caveats are required, as changes in demographics, surgical techniques, social attitudes, and many other factors may affect the demand for surgery. Nevertheless, given that this analysis forms part of the safe and sustainable review, it seems appropriate to repeat their analysis using the latest, most up to date, information.

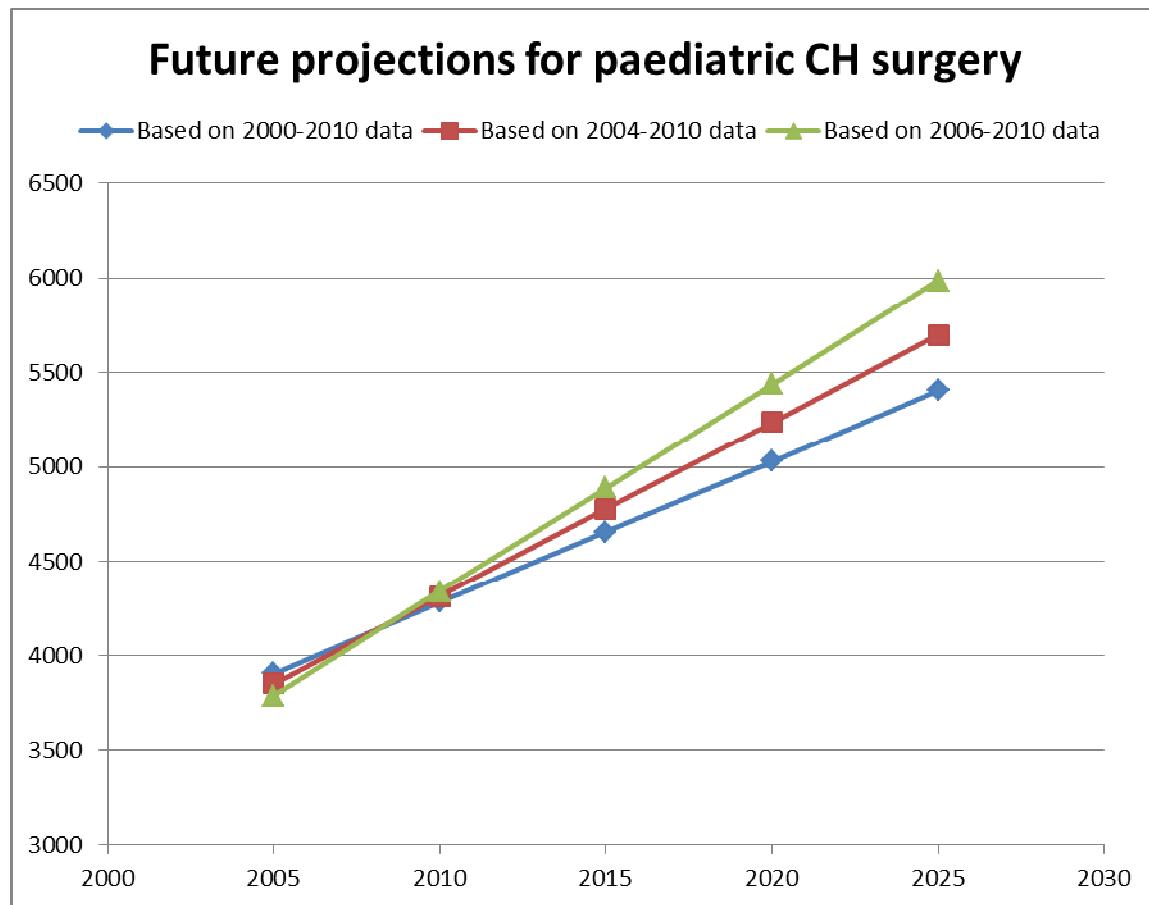


The table below gives the estimated number of cases at different years to 2025, based on the trends evident in the CCAD data, and using linear regression.

Because of the uncertainties around historical CCAD data (noted above), these predictions are made based on three sets of data – 2000-10; 2004-10; and 2006-10. To give an idea of the precision of these estimates, back forecasting to 2005 and 2010 has also been undertaken (for reference, the actual CCAD values for 2005/6 was 3907, and for 2010/11 was 4391).

Future projections using 2000-2010 data		Future projections using 2004-2010 data		Future projections using 2006-2010 data	
Year	Based on 2000-2010 data	Year	Based on 2004-2010 data	Year	Based on 2006-2010 data
2005	3908	2005	3854	2005	3790
2010	4282	2010	4315	2010	4339
2015	4656	2015	4776	2015	4889
2020	5030	2020	5236	2020	5438
2025	5404	2025	5697	2025	5988

This information is given graphically on the next page. The data clearly demonstrates that if the current trend in paediatric cardiac surgery activity continues, there will be around 5,500 cases in 2025.



But there are important caveats. Firstly, Safe and Sustainable's figures exclude foreign private patients on the grounds that 'future flows of foreign private patients are largely dependent on global economics and would never in any event be commissioned by the NHS' DMBC p189 . To account for this, S&S have multiplied CCAD totals by 0.85-0.88.

Secondly, the further one predicts into the future, the more uncertain those predictions become.

Thirdly, 'population projections by UK National Statistics suggest an increase in the paediatric population of England and Wales by 13.7% by 2025 which could reasonably translate into a corresponding increase in the need for paediatric cardiac surgery'. (DMBC p189). This was also examined by Dr Ashton-Key, and it is helpful to repeat his analysis, but this time using the most up to date data.

For this analysis I principally used data from the 2010-based National Population Projections, specifically Table A3-4, Principal projection - England population single year of age; Table A3-3, Principal projection - England & Wales population single year of age; and Table A3-7, Principal projection - Northern Ireland population single year of age, all released on 26 October 2011, and available from <http://www.ons.gov.uk/>.

Dr Ashton-key predicted an increase of 13.7% in children aged less than 14 years in England and Wales at 2025, and a smaller increase of 3.9% in Northern Ireland, based on 2006 projections (DMBC p192). Very similar results are obtained with the 2010 data, 15.9% increase for England and Wales, and a 3.5% increase for Northern Ireland. This increase would be expected to have an effect on the demand for congenital Cardiac Surgery Services

Dr Ashton-Key grouped his data into five year cohorts (0-4; 5-9; 10-14). By looking at the data by age last birthday, up to 15, interesting trends are seen (see table overleaf). It is projected that there will be an increase in the number of by over 6% in England and Wales in the period up to 2016, with the birth rate falling back after that, and the number of children under one year of age being only 2% higher in 2025 compared to now. As the majority of congenital cardiac surgery is in infants, this may mean that the population related increase in activity is not as great as might be expected from the overall 15.9% increase in the number of children in England and Wales. Conversely, the relatively greater rise in the number of infants and young children over the next few years would suggest that now is not a good time to be reducing capacity.

Population projections by the Office for National Statistics																
England & Wales																
PERSONS, thousands																
2010-based Principal projection																
% change from 2010 in Projected populations at mid-years by age last birthday																
Ages	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
0	0.0	1.9	4.4	5.9	6.6	6.5	6.2	5.8	5.2	4.8	4.5	4.2	3.7	3.2	2.6	2.0
1	0.0	1.7	3.6	6.1	7.7	8.4	8.3	8.0	7.6	6.9	6.5	6.3	6.0	5.5	5.0	4.4
2	0.0	(0.4)	1.3	3.2	5.7	7.2	7.9	7.8	7.5	7.1	6.4	6.0	5.8	5.5	5.0	4.5
3	0.0	4.4	3.9	5.7	7.7	10.3	11.8	12.5	12.4	12.2	11.7	11.1	10.6	10.4	10.0	9.6
4	0.0	3.2	7.7	7.3	9.1	11.1	13.8	15.4	16.1	16.0	15.8	15.3	14.6	14.2	13.9	13.6
5	0.0	2.2	5.5	10.1	9.6	11.5	13.6	16.3	18.0	18.7	18.6	18.3	17.8	17.1	16.7	16.5
6	0.0	1.4	3.6	7.0	11.6	11.1	13.0	15.1	17.9	19.6	20.3	20.2	19.9	19.4	18.7	18.3
7	0.0	3.6	5.0	7.4	10.8	15.6	15.1	17.1	19.3	22.1	23.8	24.6	24.5	24.2	23.7	23.0
8	0.0	3.1	6.8	8.3	10.7	14.2	19.2	18.6	20.6	22.9	25.8	27.6	28.4	28.3	28.0	27.5
9	0.0	0.1	3.2	6.9	8.4	10.8	14.3	19.3	18.7	20.7	23.0	25.9	27.7	28.5	28.4	28.1
10	0.0	(2.3)	(2.2)	0.8	4.5	5.9	8.2	11.7	16.5	16.0	18.0	20.2	23.0	24.8	25.6	25.5
11	0.0	(2.5)	(4.8)	(4.7)	(1.7)	1.8	3.2	5.5	8.8	13.5	13.0	14.9	17.1	19.9	21.6	22.4
12	0.0	(1.7)	(4.2)	(6.4)	(6.3)	(3.4)	0.1	1.4	3.7	7.0	11.6	11.1	13.0	15.1	17.8	19.5
13	0.0	(2.5)	(4.2)	(6.6)	(8.7)	(8.6)	(5.8)	(2.5)	(1.1)	1.0	4.3	8.8	8.3	10.1	12.2	14.8
14	0.0	0.8	(1.8)	(3.4)	(5.9)	(8.0)	(7.9)	(5.1)	(1.7)	(0.4)	1.8	5.0	9.6	9.1	10.9	13.0
15	0.0	(0.6)	0.1	(2.4)	(4.0)	(6.4)	(8.6)	(8.5)	(5.7)	(2.3)	(1.0)	1.1	4.4	8.8	8.4	10.2
Total	0.0	0.8	1.8	2.8	4.1	5.4	6.9	8.5	10.0	11.3	12.4	13.4	14.3	14.8	15.1	15.3
0-14	0.0	0.9	2.2	3.7	5.4	7.2	9.1	10.7	12.0	13.2	14.2	14.9	15.3	15.7	15.9	15.9

"Source: Office for National Statistics".

Population projections by the Office for National Statistics Northern Ireland PERSONS, thousands																
2010-based Principal projection																
% change from 2010 in Projected populations at mid-years by age last birthday																
Ages	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
0	0.0	0.5	1.0	1.2	1.1	0.7	0.2	(0.6)	(1.6)	(2.8)	(4.2)	(5.4)	(6.3)	(7.2)	(8.2)	(9.1)
1	0.0	(1.8)	(1.2)	(0.8)	(0.6)	(0.6)	(1.0)	(1.6)	(2.3)	(3.3)	(4.5)	(5.9)	(7.0)	(7.9)	(8.8)	(9.7)
2	0.0	0.1	(1.6)	(1.1)	(0.6)	(0.4)	(0.5)	(0.9)	(1.4)	(2.2)	(3.2)	(4.4)	(5.7)	(6.9)	(7.8)	(8.7)
3	0.0	6.0	6.1	4.3	4.9	5.3	5.5	5.4	5.0	4.5	3.6	2.6	1.3	(0.1)	(1.3)	(2.2)
4	0.0	4.0	10.2	10.3	8.4	9.0	9.5	9.7	9.6	9.2	8.6	7.8	6.7	5.4	3.8	2.6
5	0.0	1.3	5.4	11.7	11.8	9.9	10.5	11.0	11.2	11.1	10.6	10.0	9.2	8.1	6.8	5.2
6	0.0	1.2	2.6	6.7	13.1	13.2	11.3	11.9	12.4	12.6	12.4	12.0	11.4	10.6	9.4	8.1
7	0.0	2.9	4.2	5.6	9.9	16.4	16.6	14.6	15.2	15.7	15.9	15.8	15.3	14.7	13.8	12.7
8	0.0	(0.2)	2.8	4.0	5.5	9.7	16.2	16.3	14.3	15.0	15.4	15.6	15.5	15.1	14.5	13.6
9	0.0	(0.3)	(0.5)	2.4	3.7	5.1	9.3	15.8	16.0	13.9	14.6	15.1	15.3	15.1	14.7	14.1
10	0.0	(2.8)	(3.1)	(3.3)	(0.5)	0.8	2.2	6.2	12.5	12.7	10.7	11.3	11.8	12.0	11.9	11.5
11	0.0	(4.1)	(6.8)	(7.1)	(7.2)	(4.5)	(3.3)	(2.0)	1.9	7.9	8.1	6.2	6.8	7.2	7.4	7.3
12	0.0	(1.4)	(5.4)	(8.0)	(8.3)	(8.5)	(5.8)	(4.6)	(3.4)	0.5	6.4	6.6	4.7	5.3	5.8	5.9
13	0.0	(2.9)	(4.2)	(8.1)	(10.7)	(11.0)	(11.1)	(8.5)	(7.4)	(6.2)	(2.5)	3.4	3.5	1.7	2.3	2.7
14	0.0	1.4	(1.5)	(2.8)	(6.8)	(9.4)	(9.7)	(9.9)	(7.2)	(6.1)	(4.8)	(1.1)	4.8	4.9	3.1	3.7
15	0.0	2.0	3.5	0.5	(0.9)	(4.9)	(7.6)	(7.9)	(8.1)	(5.4)	(4.2)	(2.9)	0.9	6.9	7.0	5.2
Total	0.0	0.4	0.6	0.8	1.2	1.7	2.3	3.1	3.8	4.4	4.8	5.1	5.2	5.0	4.3	3.6
0-14	0.0	0.2	0.6	1.1	2.0	3.0	3.9	4.8	5.5	5.9	6.2	6.1	5.5	4.8	4.2	3.5

"Source: Office for National Statistics".

Conclusion

This summary paper, updating Dr Ashton-Key's important work, suggests that the future projections that form the basis of 'Safe and Sustainable' are not correct. This is explored further in the next section.

- Future activity projections based on current data suggest that capacity issues may be a problem for some centres

Dr Ashton Keys concluded his report by saying ‘The latest CCAD data confirms that current paediatric cardiac surgery activity has been constant for the past few years in the UK with approximately 3,600 paediatric cardiac surgery procedures performed each year’, but that population projections would suggest increases in the paediatric population in England and Wales which is likely to translate into a corresponding increase in the need for paediatric cardiac surgery activity by 2025 compared with 2006/07 activity levels’ and produced the table (below). Using the latest data, we believe this is an overly conservative estimate, and that demographic evidence points to an increase in the demand for congenital cardiac services that is much greater than can be accommodated under the ‘Safe and Sustainable Plan B’.

Original data from S&S:

Estimated paediatric cardiac surgery activity in 2025 based on National Statistics 2006-based National Population Projections applied to 2006/07 activity			
	Paediatric cardiac surgery activity (2006/07) – number of cases	Projected percentage change in paediatric population (using 0 – 14 years as the proxy for the whole paediatric population) from 2006 to 2025	Estimated paediatric cardiac surgery activity(2025) – number of cases
English paediatric cardiac surgery units (covering populations of England and Wales)	3,509	13.7%	3,990
Scottish paediatric cardiac surgery unit	273	(2.6)%	266
Northern Irish paediatric cardiac surgery unit	73	3.9%	76

Figure from Dr Ashton-Key, DMBC, p193.

The following tables give the updated estimated paediatric cardiac activity projections both in 2015 and 2025, allowing for projected increases derived from CCAD trends and ONS 2010 based national population projections.

2015	Paediatric cardiac activity 2010-11 (CCAD) corrected for overseas PP	Projected cardiac activity 2015 corrected for overseas PP	2015 pop ⁿ multiplier	2015 activity no of cases
England and Wales	3739	3958	7.2%	4243
N Ireland	77 ^b	82 [*]	3.0%	84
Total	3816	4040		4327

2025	Paediatric cardiac activity 2010-11 (CCAD) corrected for overseas PP	Projected cardiac activity 2025 corrected for overseas PP	2025 pop ⁿ multiplier	2025 activity no of cases
England and Wales	3739	4593	15.9%	5324
N Ireland	77 ^b	95 [*]	3.5%	98
Total	3816	4688		5422

* Assumes that activity increases in Northern Ireland at the same rate as England and Wales. ^b does not include patients operated on in Our Lady's Hospital, Dublin.

So taking the most conservative of the projections shown above, using the most conservative multiplier for foreign private patients, using the latest population projections, and only looking forward to 2015, we still project 4243 paediatric surgical cases from England and Wales, and possibly another 84 from Northern Ireland. If this is the case, it seems likely that some of the units in Plan B will have capacity issues, particularly if this activity is not equally spread over the year.

- *Population projections based on current data suggest important variability in regional population growth.*

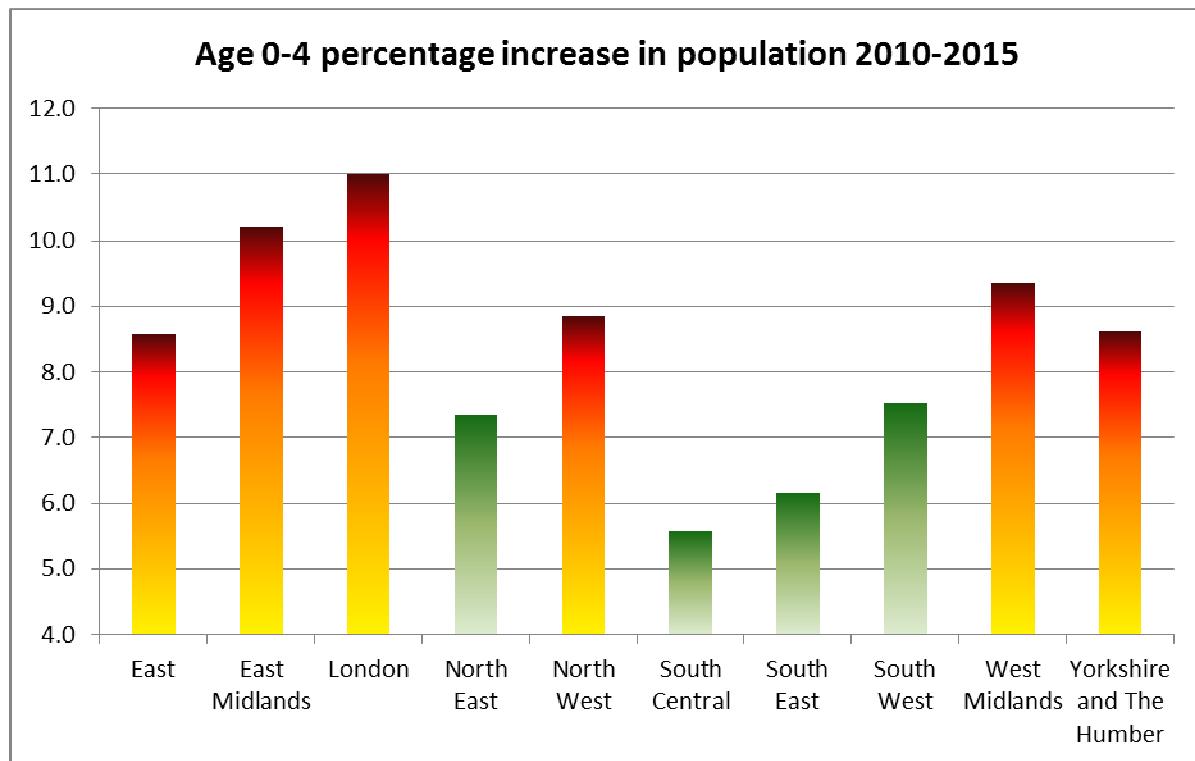
Population projections released by UK National Statistics are available in a number of forms, including by strategic health authority in England. This data was therefore analysed to see if there was any geographical variation in the projected population growth noted above.

For this analysis I principally used data from the 2010-based National Population Projections, specifically Table 3: 2010-based Subnational Population Projections by sex and quinary age; Strategic Health Authorities in England. The projections were published on 21 March 2012 and are based on the indicative 2010 mid-year population estimates. The data is available from <http://www.ons.gov.uk/>.

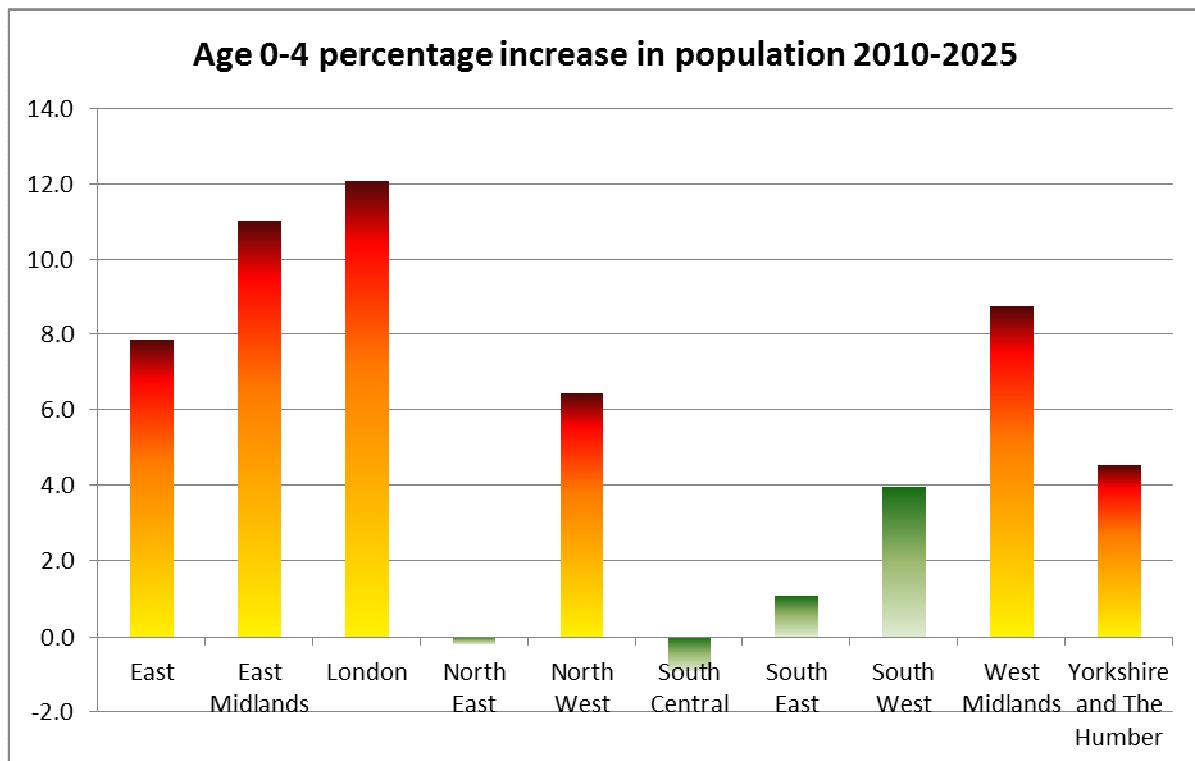
The analysis was confined to the 0-4-year quintile, as these patients are the heaviest users of congenital cardiac surgery services. The table below gives the base population age 0-4 in each SHA (thousands) in 2010, and the projected percentage change from that base in 2015 and 2025.

	2010	2015 (% change from 2010)	2025 (% change from 2010)
East	356	8.6	7.9
East Midlands	266	10.2	11.0
London	588	11.0	12.1
North East	148	7.3	-0.2
North West	429	8.8	6.4
South Central	258	5.6	-0.9
South East	520	6.2	1.1
South West	290	7.5	4.0
West Midlands	348	9.4	8.8
Yorkshire and The Humber	321	8.6	4.5

Expressed graphically, the increase in population in London and the Midlands becomes clear:



And is even more apparent when the projections are increased to 2025:



As has been mentioned, although these projections are only estimates, they may be useful in anticipating future capacity issues, and in informing decisions about where to locate services.

- *Provision of cardiac surgical services for Northern Ireland.*

On 1st August, 2012, ‘Safe and Sustainable’ announced that ‘The Health and Social Care Board in Northern Ireland has published the findings of an independent review into children’s congenital heart services at the Belfast Health and Social Care Trust. The review, led by Professor Sir Ian Kennedy, examined the safety and sustainability of the service and concluded that the Trust should cease carrying out children’s heart surgery because of the small number of children treated at the hospital. It is proposed that the service becomes a Children’s Cardiology Centre.’

In 2011-12, there were around 140 cardiac operations on Children from Northern Ireland, of which 90 were undertaken in Belfast, and the rest in Our Lady’s Children’s Hospital, Dublin, and centres in England, particularly Birmingham Children’s Hospital and Great Ormond St Hospital. Sir Ian’s report, available from <http://www.hscboard.hscni.net/publications/index.html>, concluded that the surgical caseload could be managed by expanding the surgical provision in Dublin, or by a surgical centre in England. It is clear from the report that the latter was the review team’s preferred outcome. These potential additional 90 cases have not been included in the figures for ‘Safe and Sustainable, England and Wales’.

Capacity at Birmingham Children's Hospital: unsustainable demand on a single surgical centre

This section analyses the capacity challenges facing Birmingham Children's Hospital that are likely to result from the creation of the Midlands network detailed in Option B of the Decision Making Business Case and the transfer to Birmingham of the nationally commissioned paediatric ECMO service from Glenfield Hospital.

The proposed Midlands network comprises 14 postcode regions spanning the breadth of the UK, from Skegness on the north Lincolnshire coast to Aberystwyth on the Welsh coast.

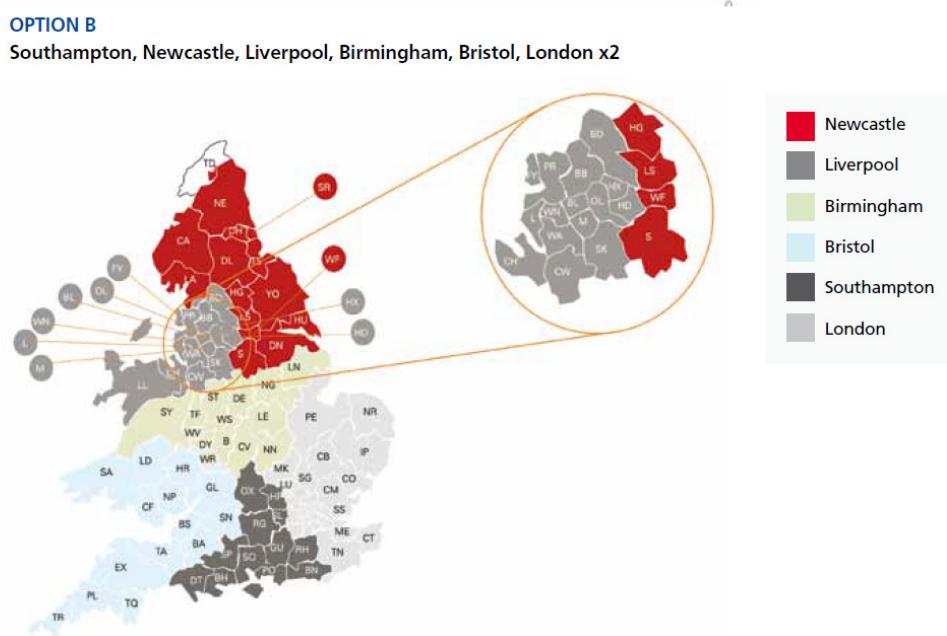


Figure from Safe and Sustainable Review of Children's Congenital Cardiac Services in England: July 2012,

Demands on the BCH surgical programme in this new Midlands network model will be dependent on the following:

- The current surgical demand within the postcodes comprising the network
- Population growth in the network
- The likely expansion of the Midlands network to include patients from adjacent networks more able to access BCH than the surgical centre of the network in which they find themselves.
- The provision of paediatric cardiac surgery at BCH for patients from Northern Ireland

The ability to manage the demand of the proposed Midlands network will be dependant on:

- PICU and ward capacity at BCH
- Theatre capacity at BCH
- Catheter laboratory capacity at BCH
- Recruitment of staff to BCH

A. Potential demand on the BCH surgical programme imposed by population rise and the network boundaries in Option B

Veracity and plausibility of population statistics

The baseline surgical demand attributed to each individual postcode in this document comes from the same data set used by the Safe and Sustainable team to produce the Decision Making Business Case. Future surgical demand attributed to each postcode (years 2015 and 2025) is based on the predicted population growth in each of those postcodes according to the detailed regional population growth forecasts outlined above.

Current and future surgical activity

It is our understanding BCH undertook 555 paediatric cardiac operations in 2010-11 and the surgical waiting list at BCH currently stands at 100 patients. Current activity includes a number of patients from Northern Ireland.

Option B attributes 611 cases per annum to Birmingham from postcodes in England and Wales (i.e. excluding cases from Northern Ireland), 56 cases more than current activity.

Due to the expected population growth outlined above, activity within the proposed network is unlikely to remain static. The table below gives the current and future predicted demand in the postcodes comprising the proposed Midlands network.

Postcode region	2010-11	2015	2025
B (Birmingham)	160	170	186
CV (Coventry)	73	76	84
DE (Derby)	32	34	38
DY (Dudley)	37	39	43
LE (Leicester)	43	45	50
LN (Lincoln)	12	14	15
NG (Nottingham)	51	54	61
NN (Northampton)	29	31	35
ST (Stoke)	58	61	67
SY (Shrewsbury)	24	30	33
TF (Telford)	19	20	22
WS (Walsall)	39	41	45
WV (Wolverhampton)	34	36	40

Total	611	651	719
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The model predicts that in 13 years time BCH will be required to handle an additional 108 operations per year, bringing the total annual demand to 719 cases from these 14 postcode alone.

Expansion of the Midlands network to adjacent areas

The Decision Making Business Case has ascribed particular postcodes to particular networks in a necessarily detailed way to ensure that the seven networks will each generate a work load of >400 operations per year for their respective surgical centres. The document acknowledges that this will result in particular postcode regions in one network lying geographically closer to a surgical centre in an adjacent network. It seems reasonable to suppose that where this is the case, there will be a demand from clinicians, patients and parents to expect a relatively nearby surgical centre, in what is technically an adjacent network, to undertake surgery, rather than this falling to a relatively distant surgical centre in what has been deemed their own network.

Data to support this notion comes from detailed work undertaken by the business analysts PwC¹, commissioned by Safe and Sustainable during the consultation period. Patients and public from 22 postcodes where this scenario could arise were interviewed and in the context of Option B, respondents from Leeds, Sheffield, Wakefield and Doncaster stated that they would prefer **not** to go to Newcastle but rather to Birmingham (and in some cases Liverpool) instead. This work also found that proximity of the surgical centre was the first priority for clinicians when referring patients for intervention.

Network expansion creep is thus most likely to occur from regions that have previously been managed by centres that have not been designated and find themselves distant from their newly designated centre, e.g. around Leeds, which becomes part of the Newcastle network in Option B. It may also occur where regions have been moved from the existing network of a designated centre to the new network of another designated centre. An example of this would be Hereford and Worcester postcodes. Patients here currently flow to Birmingham but these postcodes become incorporated into the Bristol network in Option B. Again, in such instances, the expectation seems to be that referrers will send their patients to a more distant surgical centre than they have access to now and could have access to in the future. There is not unreasonable doubt that this will happen in practice. PwC, for example, found that, in addition to proximity, existing joint working relationships are likely to be a strong influence on clinicians referring practice.

The following section models potential Midlands network expansion creep based on a number of postcode regions that are likely to be subject to the pressures described above.

¹ <http://www.specialisedservices.nhs.uk/document/testing-assumptions-future-patient-flows-manageable-clinical-networks-safe-sustainable/> (3 papers)

Sheffield

It seems very reasonable that, in the absence of a surgical programme in Leeds, (Option B), clinicians and patients in Sheffield would want to secure access to paediatric cardiac surgical services at their nearest surgical centre, i.e. BCH. We are aware that there has already been dialogue between BCH and clinicians in Sheffield with regard to establishing such a pathway. Patient flows from Sheffield postcodes to the Midlands network would add 86 cases per year to BCH activity by 2015 and add 93 cases per year by 2025.

Doncaster

If a similar pathway were to be established for patients from Doncaster postcodes, BCH activity would increase by 48 cases per year by 2015 and by 52 cases per year by 2025.

Hereford and Worcester

Hereford postcodes and Worcester postcodes currently constitute part of the Birmingham network and children from these areas are currently operated on at BCH.

The postcodes constituting the Bristol network in Option B in the Kennedy Consultation Document would have given Bristol only 360 cases and did not include Hereford and Worcester.

In Option B, as set out in the Decision Making Business Case, Hereford and Worcester postcodes move from the Birmingham network to the Bristol network. The Safe and Sustainable team asked executives at BCH to support this change in order to provide Bristol with a projected annual surgical activity of >400 cases per annum (49 operations were undertaken on children from Hereford and Worcester postcodes during the census year used in the Consultation Document).

Executives of BCH have declared their support for the movement of Hereford and Worcester postcodes from the Birmingham network to the Bristol network in principle but have publicly stated that it is their expectation that in practical terms patients and parents in these areas, particularly from Worcester postcodes, are likely to continue to want surgery at BCH. Again this seems entirely reasonable given the existing relationships between Worcester and BCH clinicians and given that Worcester is just 31 miles from BCH (44 minutes by car, 43 minutes by train) but 62 miles from Bristol (68 minutes by car, 94 minutes by train).

If patients in Worcester postcodes continue to attend BCH, activity would increase beyond the predicted 611 cases by 29 cases per year by 2015 and by 31 cases per year by 2025.

B. Potential demand on the BCH surgical programme due to changes to patient flows from Northern Ireland

Around 140 children from Northern Ireland undergo cardiac surgery each year of whom 90 are operated on in Belfast and the remainder on the UK mainland or in Dublin.

The Kennedy review of paediatric cardiac surgery in Belfast, published 01.08.12², recommended that paediatric cardiac surgery at the Belfast Health and Social Care Trust should cease and that alternative care pathways should be established. The favoured option is for children from Northern Ireland to have surgery on the UK mainland rather than in Dublin.

BCH currently provide a surgical service for a proportion of these patients and this activity accounts for a proportion of the 555 cases undertaken at BCH in 2010-11. The figure of 611 cases per annum forecast for BCH in the Decision Making Business Case however constitutes patients from England and Wales alone and does not include current or future activity from Northern Ireland.

If BCH continues to provide surgery for patients from Northern Ireland at current levels this will be in addition to the 611 cases forecast in the Decision Making Business Case. If BCH is considered the preferred option for all patients from Northern Ireland this would increase BCH activity beyond 611 cases to a predicted maximum of 143 cases per year by 2015 and 148 cases per year by 2025.

Cumulative effect

The tables below demonstrate the cumulative increase in BCH activity for all possible combinations of the above scenarios. If all pathways were established it is predicted that BCH would be required to undertake **957** cases per year by 2015 and **1043** cases per year by 2025.

² <http://www.hscboard.hscni.net/lnews/01%20August%202012%20-%20Review%20of%20the%20Paediatric%20Congenital%20Cardiac%20Service%20in%20Belfast%20-%20July%202012%20-%20PDF%20625KB.pdf>

Predicted surgical activity at BCH according to unattributed network expansion

2015

Option B	651	651	651	651	651	651	651	651	651	651	651	651	651	651	651	651	651
	1 addition to Network				2 additions to Network						3 additions to Network						All
Northern Ireland					143				143	143	143		143	143	143	143	143
Sheffield				86		86	86			86	86		86	86	86	86	86
Doncaster			48			48		48		48		48	48		48	48	48
Worcester		29				29	29		29			29	29	29			29
Total	651	680	699	737	794	728	766	785	823	842	880	814	871	909	928	957	

2025

Option B	719	719	719	719	719	719	719	719	719	719	719	719	719	719	719	719
	1 addition to Network				2 additions to Network					3 additions to Network				All		
Northern Ireland					148				148	148	148		148	148	148	148
Sheffield				93		93	93			93	93		93	93	93	93
Doncaster			52			52		52		52		52	52		52	52
Worcester		31				31	31		31			31	31	31		31
Total	719	750	771	812	867	802	843	864	898	919	960	895	950	991	1012	1043

Notes: Option B comprises the postcodes given in the DMBC. Both years exclude paediatric respiratory ECMO activity.

C. Resource Demands on a single centre Midlands network

In simple terms, when we talk about resource demands on a paediatric cardiac surgical centre we are referring to the availability of Paediatric Intensive Care Unit (PICU) beds, cardiology ward beds, operating theatres and catheter laboratories as well as the staff needed to provide the service in these areas.

Effect of the Review on ECMO provision

Summary

We believe that the effects of closing the ECMO centre in Leicester and re-establishing one in Birmingham Children's Hospital have not been adequately brought to the attention of the JCPCT. This document outlines our belief that:

- Outcomes for ECMO patients at Glenfield hospital are significantly better than elsewhere;
- International clinical advice supports this belief, and expresses concern that such good results will not be easily replicated elsewhere;
- A team of experts cannot just be picked up and moved to another city without a loss of expertise;
- Newly established centres will have a period of poor outcomes whilst they ascend a 'learning curve', and develop institutional expertise.

This process is likely to take some years, and during this time there will be an increase in mortality and morbidity for children and infants who need ECMO. These themes are summarised below, with more detail given in the accompanying appendices.

'The decision will improve clinical outcomes and save more children's lives'

(Sir Roger Boyle, former national clinical director for heart disease and stroke, 23 July 2012)

Data from the Paediatric Intensive Care Audit Network (PICANet³) shows that the ECMO service in Leicester has better clinical outcomes than any other UK ECMO centre.

Over the ten years 2002-2012, 1447 children and infants received ECMO support in the UK, 466 at Glenfield Hospital, 981 in other centres, including the three other nationally commissioned centres. The crude mortality rate in Leicester was 20%, but in other centres was over 50% higher, at 34%. If the national mortality rate had applied in Leicester, 62 more children would have died.

It is important to remember that the national mortality rate quoted includes the other nationally commissioned centres, Great Ormond St Hospital and Freeman Hospital, Newcastle. Even if a newly established centre immediately operated at the national average, the data presented here supports the view that there would be an increase in ECMO mortality.

Further data from the international registry, ELSO⁴, supports the good outcomes in Leicester. In the period from 2002-2012, 12,069 children and infants received respiratory ECMO support in ELSO

³ PICANet is an audit database recording details of the treatment of all critically ill children in paediatric intensive care units (PICUs). PICANet is endorsed by the Paediatric Intensive Care Society, and funding is provided by the Healthcare Quality Improvement Partnership (HQIP). PICANet is internationally recognised as a robust and impartial data source.

⁴ The Extracorporeal Life Support Organization (ELSO) is an international consortium of health care professionals and scientists who are dedicated to the development and evaluation of novel therapies for support of failing organ systems. Membership consists of over 160 ECMO centres from around the world.

registered centres, 435⁵ at Glenfield Hospital. The crude mortality rate in Leicester was 19%, but in other centres was over 75% higher, at 35%.

Both of these independent, validated data sources point to the high quality of ECMO care given at Leicester, and bring in to focus the dangers to our patients of closing the ECMO service at Leicester.

This is striking data that clearly demonstrates that clinical outcomes in Leicester are head and shoulders above the others. Closing the Leicester ECMO centre will not save children's lives.

Quality of care should be the most important factor

(Sir Neil McKay CB, Chairman of the Joint Committee of Primary Care Trusts, Wednesday, 4th July 2012)

'.....the quality of surgery and the outcomes for children come above all other considerations.'

(Pat Hamilton, Past President of the Royal College of Paediatrics and Child Health)

The quality of our care is not only measured by our outcomes for nationally commissioned respiratory ECMO, but also by the transfer of these skills to our cardiac ECMO programme. As part of their 2011 annual report, the UK Paediatric Intensive Care Audit Network (PICANet) commissioned a chapter on the use of ECMO for cardiac patients in UK PICUs. This was written by clinicians from Bristol and Birmingham. They found that the outcome (survival) for our cardiac patients receiving ECMO was the highest of the major centres, illustrating our high quality care. Survival in other centres was disturbingly low, with only two children surviving out of thirteen who received cardiac ECMO in one centre.

Other measures of quality should be considered. The ECMO team are recognised as clinical experts, and are frequently consulted by other clinicians. A senior nurse at Birmingham Children's Hospital recently commented that '*whenever I have a problem [with ECMO] the first thing I do is phone Gail [Faulkner, ECMO Co-ordinator, HeartLink ECMO Centre]*'. Speaking at the 2011 Paediatric Cardiac Intensive Care Society meeting in Cambridge, Dr JJ Cordingley, intensive care consultant at the Royal Brompton Hospital, paid tribute to the support given by the Heartlink ECMO team during the 2010-11 H1N1 pandemic. The quality of care, and the dedication of the team, was also recognised by the Chief Medical Officer in a letter to the Trust in 2010.

Patients and their families also attest to the quality of care, the IPSOS-MORI report on the 'safe and sustainable' consultation stating '*Comments made about Glenfield hospital were also overwhelmingly positive....Many of these respondents referred to the standard of care, the high quality services and staff and made positive assessments of Glenfield's facilities. There were also comments about the need to keep ECMO facilities in their current location'*'.

There has not been a Health Impact Assessment concerning the transfer of ECMO services from Leicester. Mott Macdonald, who undertook the Impact assessment for the cardiac review team, were asked to concentrate on cardiac surgery and were not asked to consider the transfer of ECMO (Kerry Schofield, Mott Macdonald, personal communication 24/7/12).

⁵ Differences in totals between PICANet and ELSO are due to slightly different reporting periods

'Expertise does not reside in bricks and mortar'

(Mr Leslie Hamilton, Vice Chair of the Safe and Sustainable Steering Group, Tuesday, 10th July 2012)

The quality and good outcomes noted above arise from the Heartlink ECMO Centre Clinical Team. This cannot just be picked up and transferred to the bricks and mortar of another institution. A local survey has demonstrated that very few of the Leicester team would be able to move to Birmingham; Anecdotal reports from similar moves elsewhere in the UK also suggest that health care professionals are unable to maintain their specialist skills by moving to a new location following service reorganisation. What little published literature there is confirms this.

So a new team for ECMO will need to be established in Birmingham. Whilst some clinicians from Leicester might move, and the training that some of the Birmingham team have received in Leicester will be beneficial, all the published evidence relating to establishing new teams or introducing new procedures suggests that there will be an increase in mortality relative to the status quo. This is confirmed by expert advice we have received from clinicians all over the world (see below).

'Mediocrity must not be our benchmark'

(Report of Sir Ian Kennedy, 2010)

The national team have noted that Birmingham Children's Hospital was designated as a surge centre for paediatric ECMO in planning for an H1N1 pandemic. This designation does not give any assurance of quality, as thankfully the pandemic did not lead to large numbers of paediatric patients requiring ECMO support, and BCH did not undertake any respiratory ECMO runs.

Of greater relevance is the adult ECMO experience. In 2009-10 the UK Mortality for adult H1N1 patients who received was 27%, with the majority of patients (64%) being cared for in Glenfield and the remainder in one of three other centres (Ref)); Glenfield provided training and, crucially, on-going advice to clinicians in these units (J Coldingley, PICS conference, Cambridge, 2010). Overall mortality in UK centres was 27%. In contrast, in Japan, where they did not have the benefit of a centralised expert resource, mortality was 64%⁶. International data supports the view that newly established units require a huge amount of input, and deliver worse outcomes.

Paediatric surge centres like Birmingham Children's Hospital were meant to be an additional resource if the nationally commissioned centres were overwhelmed. The fact remains that the paediatric surge centres did very little respiratory ECMO in 2011-2012, and to suggest that one of them can take over the work of the Heartlink ECMO centre is a bit like saying its ok if the Titanic is sinking, because we still have the lifeboats.

'I would not be involved in anything that would put children at risk'

(Mr Leslie Hamilton, Vice Chair of the Safe and Sustainable Steering Group, Tuesday, 24th July 2012)

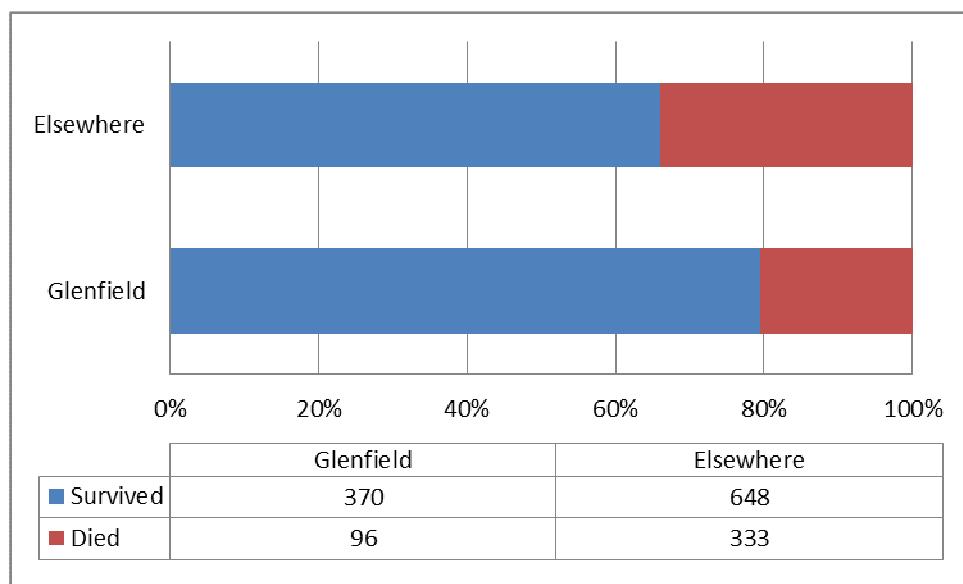
By its nature, respiratory ECMO has a high mortality, between 5% and 50% depending on the underlying diagnosis, compared to less than 5% for congenital cardiac surgery. Even a small percentage increase in ECMO mortality would result in a relatively large number of children dying.

⁶ J Anaesth 2012 DOI: 10.1007/s00540-012-1402-x e-pub ahead of print

To ignore the disadvantages of closing the UK's largest and most successful ECMO centre would indeed put children at risk.

PICANet outcome data for all UK ECMO, 2002-12

Data from the Paediatric Intensive Care Audit Network (PICANet)⁷ supports the quality of the ECMO service in Leicester. Over the ten years 2002-2012, 1447 children and infants received ECMO support in the UK, 466 at Glenfield Hospital, 981 in other centres, including the three other nationally commissioned centres. The crude mortality rate in Leicester was 20%, but in other centres was over 50% higher, at 34%.



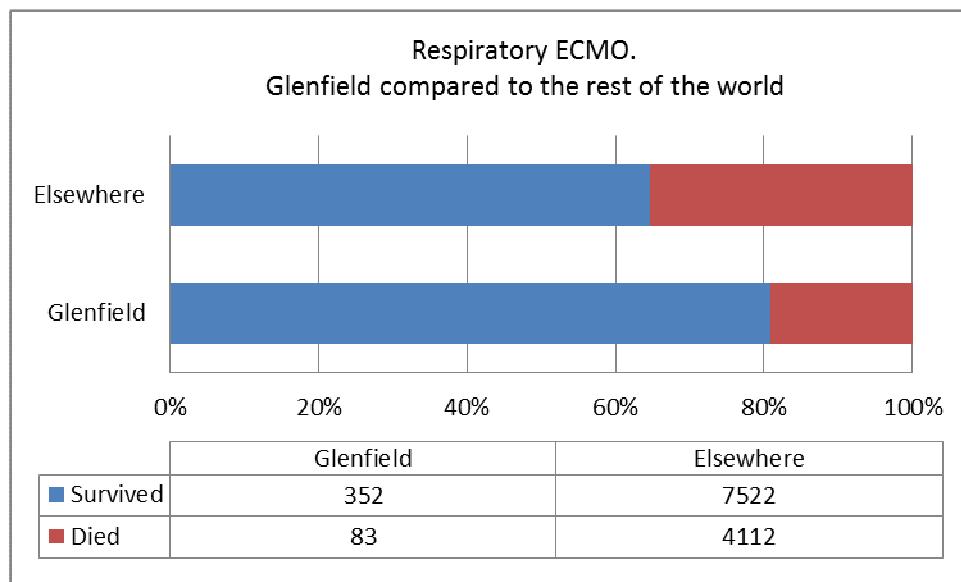
If the national mortality rate had applied in Leicester, 62 more children would have died. It is important to remember that the national mortality rate includes the other nationally commissioned centres. Even if a newly established centre operates at the national average, the data presented supports the view that there would be an increase in mortality.

There is no validated risk prediction model for ECMO, but applying the one used for UK PICU (the Paediatric Index of Mortality score); the difference in mortality is maintained even when severity of illness is taken into account. The data does not support the notion that Leicester's mortality is better because the children referred for ECMO in Leicester are not as sick as elsewhere, but does confirm a lower mortality for patients treated in Leicester.

⁷ PICANet is an audit database recording details of the treatment of all critically ill children in paediatric intensive care units (PICUs). PICANet is endorsed by the Paediatric Intensive Care Society, and funding is provided by the Healthcare Quality Improvement Partnership (HQIP). PICANet is internationally recognised as a robust and impartial data source.

[ELSO outcome data for Respiratory ECMO, 2002-12](#)

Further data from the international registry, ELSO⁸, supports the good outcomes in Leicester. In the period from 2002-2012, 12,069 children and infants received respiratory ECMO support in ELSO registered centres, 435 at Glenfield Hospital. The crude mortality rate in Leicester was 19%, but in other centres was over 75% higher, at 35%.



Both of these independent, validated data sources point to the high quality of ECMO care given at Leicester, and bring in to focus the dangers to our patients of closing the ECMO service.

This is striking data that clearly demonstrates that the results (survival) of ECMO at Glenfield are head and shoulders above the others.

Mortality rates for the ten major UK cardiac centres are currently very similar, with no significant difference between the major centres. This is not the case for ECMO.

Parents have said that they will go any distance to get the best possible care. After all, if you knew that one centre had a survival rate that was a third better than elsewhere, wouldn't you rather go there? If the Heartlink ECMO centre at Glenfield Hospital is closed, then patients will be denied that option.

⁸ The Extracorporeal Life Support Organization (ELSO) is an international consortium of health care professionals and scientists who are dedicated to the development and evaluation of novel therapies for support of failing organ systems. Membership consists of over 160 ECMO centres from around the world.

PICANet review of Paediatric Cardiac ECMO provision, 2005-10

Background

As part of their recently published annual report, the UK Paediatric Intensive Care Audit Network (PICANet) commissioned a chapter on the use of ECMO for cardiac patients in UK PICUs. This was written by Dr Peter Davis and Dr Gale Pearson from Bristol and Birmingham respectively.

Methods and findings

All episodes of ECMO support in England and Wales in the 6-year period 2005-2010 were identified and diagnostic information and outcome obtained. In this period there were 809 episodes of ECMO support reported to PICANet from 15 centres. The vast majority of the workload was performed in the three nationally commissioned centres (681 of 809 admissions; Leicester 284, Great Ormond Street 269, Newcastle 128).

The overall survival to PICU discharge for children supported on ECMO was 71.1% (234 deaths). 381 of the children supported on ECMO had a primary cardiac diagnosis. Survival for this 'cardiac ECMO' group was slightly lower at 60.5% (149 deaths). 'Cardiac ECMO' was only undertaken in 10 of 11 cardiac surgical centres.

The units undertaking the most 'cardiac ECMO' were the 3 designated 'specialist ECMO' centres. Leicester undertook a greater number of cardiac cases than Newcastle, despite having a similar size cardiac workload, possibly due to the number of children referred for respiratory ECMO who are subsequently found to have a cardiac diagnosis (36 patients), or the fact that Leicester offer ECMO for patients in need of a heart transplant whilst awaiting a bed in a transplant centre, or that the threshold for using ECMO is lower due to confidence and experience with the technique in the Heartlink ECMO centre.

Survival rates are greatest in the Heartlink ECMO centre in Leicester, and show wide variation between centres. On that basis, these figures should be interpreted with caution; it should be noted that further analysis is not possible as the figures are not risk adjusted for case selection for cardiac ECMO support in each centre. The authors of the PICANet report only gave the survival figures for the three nationally commissioned centres, preferring to amalgamate the smaller centres results (see table below).

Cardiac Surgical Centre	Number of children with primary cardiac diagnoses supported on ECMO	Percentage survival to PICU discharge
Great Ormond Street	117	64.1
Leicester	90	68.9
Newcastle	77	58.4
Royal Brompton	22	
Liverpool	19	
Birmingham	16	
Leeds	13	
Southampton	13	
Bristol	8	
Evelina	7	

Table 5 Number of children supported on ECMO and percentage survival to PICU discharge by cardiac surgical centre

From 'PICANet Annual Report 2008 – 2010' Page 29 ©2011 Universities of Leeds and Leicester

International Clinical Advice

International clinical advice supports our belief that outcomes for ECMO patients at Glenfield hospital are significantly better than elsewhere, and expresses concern that such good results will not be easily replicated if the service is moved to another centre:

'I opposing sharply if my name is used for transferring the ECMO unit from Leicester to Birmingham. **I have been very clear about that you cannot move a unit you can just destroy it and rebuilt with many years of decreasing survival rate and increasing morbidity.'**

Kenneth "Palle" Palmer
Director ECMO unit
Karolinska University Hospital
Stockholm Sweden

Dr Palmer was the only expert ECMO clinician invited to give advice to the 'Safe and Sustainable' team. He feels his advice was misunderstood, and he has now clarified in an email to Mr Andrew Lansley, Secretary of State for Health, quoted above.

The Extracorporeal Life Support Organization (ELSO) is an international consortium of health care professionals and scientists who are dedicated to the development and evaluation of novel therapies for support of failing organ systems. Membership consists of over 160 ECMO centres from around the world. ELSO was not consulted during the Safe and Sustainable Review Process, and prominent members of the ELSO steering committee have now written to Mr Lansley in order to express their concerns⁹:

⁹ Original letters and emails available from EMCHC

'.....We are united in our dismay at the proposed move of ECMO services from the Glenfield programme.... [which]...will have profound negative consequences on the outcomes of patients needing ECMO.....'

'...The institutional memory and expertise in the team cannot be quantified....'

'...If the aim of the review is to ensure excellence in the future provision of surgery, why has the panel recommended a mediocre solution for ECMO in babies and children?...'

James D Fortenberry MD FCCM FAAP
 Chair ECMO Leadership Council
 Paediatrician In Chief
 Children's Healthcare of Atlanta
 Professor of Paediatrics
 Division of Critical Care Medicine
 Emory University School of Medicine, Atlanta

Graeme McLaren MBBS FCICM FRACP FCCP FCCM
 Director of Cardiothoracic Intensive Care
 National University Hospital Singapore
 Chair of the Extracorporeal Life Support Special Interest Group

Matthew Paden MD FAAP
 Medical Director, Pediatric ECMO and Advanced Technologies
 Emory University School of Medicine, Atlanta

Gail Annich MD MS FRCP(C)
 Director of Pediatric ECMO
 Mott Children's Hospital
 University of Michigan, Ann Arbor

Ravi R Thiagarajan MD MPH
 Co-Chair, ELSO Registry
 Boston, MA

Mark T Ogino MD
 Children's Hospital of Philadelphia New-born Care
 Chair, ELSO Logistics and Education Committee
 University of Pennsylvania School of Medicine
 Philadelphia

Thomas V Brogan MD
 Associate Professor of Paediatrics
 University of Washington School of Medicine
 Associate Medical Director Extracorporeal Life Support Services
 Seattle Children's Hospital
 Seattle, Washington

Heidi J Dalton MD FCCM
 Chief, Critical Care Medicine
 Phoenix Children's Hospital
 Phoenix AZ

Matthew Bacchetta MD MBA MA
 Assistant Professor of Surgery
 Director of Adult ECMO
 Co-Director of the Center for acute Respiratory Failure
 Columbia University Medical Center

New York Presbyterian Hospital
Columbia New York

Other international experts have pointed out the difficulties of establishing a new service, and highlighted the dangers of a loss of expertise and 'institutional memory' in delivering safe care:

'.....After years of assisting centers establish their ECMO programs, I have found the best programs emerge when the ECMO team function and skill sets mature. It is very simple to institute a didactic educational program and to teach the practical procedures with high fidelity simulation. However this is not even half the battle, successful translation of this knowledge to the patient's bedside only occurs with time as teambuilding skills are mastered....
...When I was leading the Hawaii ECMO program, we found that we required years of patient care, endless case reviews, constant continuing education and simulation training, to achieve the quality benchmarks necessary to receive the designation as an ELSO ECMO Center for Excellence. As I develop my second ECMO program in the US, my timeline for education and team building is measured in years, not months.....'

.....If the Glenfield cardiac surgical and ECMO program is transferred to another institution, the new center will not replicate Glenfield's outcomes since the ECMO program will no longer have access to the established multidisciplinary team proficiency and institutional memories. I fear that your decision to consolidate the Cardiac Surgical programs without recognizing the importance of institutional experience will impact the United Kingdom's ability to remain a leader in Pediatric ECMO care. '

Mark T Ogino, MD, FAAP
Children's Hospital of Philadelphia New-born Care
Medical Director, Chester County Hospital Neonatology
Chair, ELSO Logistics and Education Committee
Associate Professor of Pediatrics
Perelman School of Medicine, University of Pennsylvania
Philadelphia, PA, USA

'.....ECMO is only used in the most severely sick patients with a high probability of death. Consequently, the use of ECMO demands a specialized training and a longstanding experience with patients and devices. Survival very much depends on competence. The necessary knowledge cannot be gained within some months, and centres with less expertise certainly will experience a higher mortality. Therefore, in the interest of best patient care the decision to close down the most experienced centre of the UK is difficult to comprehend for somebody from abroad.'

Dr. Thomas Müller
Consultant of Intensive Care Medicine and Pneumology
ECMO Co-director
University Medical Center Regensburg
Germany

In their consideration of nationally commissioned services, the JCPCT were advised that ‘While accepting the expert advice that transplant services could be moved if necessary, there is no international evidence that this has been successfully performed elsewhere.’ This is also the case for ECMO¹⁰, and it is unclear why the Review team have not sought, and taken account of, specific international ECMO experience and advice.

A team of experts cannot just be picked up and moved to another city without a loss of expertise;

ECMO requires a large multidisciplinary team with additional specific skills and training compared to either a “normal” PICU or to a children’s heart surgery unit. This team includes ECMO doctors, surgeons, intensivists, cardiologists, radiologists, perfusionists, laboratory staff and most importantly ECMO specialist nurses.

These specialist nurses are central to the safe and effective delivery of ECMO; they are experienced intensive care nurses who have completed additional training in ECMO. They are responsible for the ECMO circuit as well as the patient.

Leicester has built up a team of over 80 ECMO specialists. The majority of these are unable to move due to family commitments, and so their expertise is not transferable. Retention of staff at the Glenfield Heartlink ECMO centre is also important. Many of our senior nurses and ECMO specialists have worked at Glenfield for over 20 years, and they carry an institutional memory and expertise that will take a similar time to develop elsewhere. Staff turnover at Glenfield PICU is low, with only five nurses leaving in the past three years (and three of them to work on the Children’s cardiology ward at Glenfield). This is in marked contrast to the reported high levels of staff turnover in nearby large PICUs.

Members of the Glenfield PICU and Heartlink ECMO Centre clinical team responded to an anonymised survey, asking ‘If the surgical unit at UHL were too close - how likely are you to do any of the following:

- Move to Birmingham hospital if a relocation package was offered, or a travel allowance provided
- Seek alternative employment at UHL
- Consider leaving UHL/leaving the NHS’

Only three members of staff felt they were very likely to consider working in Birmingham, with nearly 80% not at all likely. Importantly, none of the ECMO specialists responding to the survey were willing to consider working in Birmingham, and a third of ECMO specialists responding felt they would have to consider leaving the NHS. This represents a terrible waste of a vital resource.

¹⁰ Limited data on the setting up of adult ECMO programmes in response to H1N1 pandemic is presented elsewhere in this document

The Heartlink ECMO centre has specific capacity and skills that will be lost in the proposed reconfiguration

Leicester ECMO Capacity

Leicester has one of the largest units in the world with one of the longest experiences, having started in 1989. It is the only unit in the UK which can treat all age groups, this was important during the H1N1 pandemic as Leicester was able to flex their service to treat up to 10 adults simultaneously whilst training the other adult centres and coordinating the national service by triaging all the patients and providing the majority of the patient transport.

The “normal” capacity in Leicester is 4-6 patients, these could be of any age or condition mix depending on clinical need (i.e. babies, children or adults, respiratory or cardiac). The demand for ECMO in babies and children seems to be increasing alarmingly at current referral rates Leicester will treat approximately 100 babies and children with respiratory ECMO support this year.

This accounts for approximately 80% of the current Neonatal and Paediatric activity in England and Wales, often taking patients from the catchment area of Great Ormond Street and Newcastle as they have very limited capacity due to the co-located heart failure, transplantation and VAD services. Leicester also admits patients from other countries such as Scotland, Sweden, Finland and Ireland.

Mobile ECMO

Leicester is the only unit in England and Wales to provide mobile ECMO for babies and children. This is where the ECMO team travels to the referring hospital and places the patient on ECMO prior to transferring back to base, as high frequency oscillation and nitric oxide use increase around the country mobile ECMO becomes increasingly necessary and expected by referring physicians. It is obviously more challenging providing this service than a “normal” ECMO service and requires many years of experience to do this safely in babies and children, mobile ECMO in adults is relatively straightforward in comparison.

Comparison with other nationally commissioned ECMO services in England and Wales

	Maximum number of simultaneous patients on ECMO	Mobile ECMO	CDH repair on ECMO	large child capability	Single Care-Giver
Leicester	10	yes	yes	yes	Yes
GOS	3	no	no	yes	No: 2 carers*
Freeman	2	no	no	no	No: 2 Carers*

* SINGLE CARE GIVER: This is where the ECMO specialist nurse cares for the patient and the ECMO circuit, a ratio of 1:1. Hitherto a 2:1 staffing ratio has been used with an ECMO specialist nurse and a non-specialist nurse for each patient. Obviously single care giver represents an enormous

improvement in cost efficiency. It is the standard of care being adopted in the best centres worldwide and requires a mature programme to be done safely.

National training and support

Leicester has been offering training and advice to other centres to support them in undertaking additional work as part of the UKs response to the H1N1 pandemic. Given that a future requirement to rapidly upgrade ECMO provision is not unlikely, it seems like poor planning to disperse the highest quality centre.

Newly established centres will have a period of poor outcomes whilst they ascend a ‘learning curve’, and develop institutional expertise.

The learning curve describes the process whereby improvement in an activity results from understanding gained from experience¹¹. This learning occurs at both an individual and an institutional level. A systematic review¹² of studies assessing the learning curve in medicine found that learning curves are rarely considered formally in health technology assessment. This was the case of the cardiac review, which did not consider the adverse effects of transferring ECMO services to another centre. They did acknowledge the importance of the learning curve in relation to other nationally commissioned services, stating that data they had received (in relation to cardiac transplant services) ‘.....would appear to confirm clinicians’ views that clinical outcomes improve with experience, which probably relates to cultural features such as team working, and is not merely a feature of individual clinician care. This statistically significant observation is in keeping with analysis which demonstrates, historically, an 8-10 year period of time before such a service matures to produce excellent clinical outcomes’ (DMBC p211). It is unclear why the review team apply this argument to some services, but not to ECMO.

Different procedures, and presumably different teams, will need a variable time to achieve competence. The table below (from ¹³) demonstrates this for different procedures. One report of outcomes following coronary artery surgery in North-West England¹⁴, found evidence of a learning curve over at least four years for newly appointed surgeons, despite the fact that they would have been trained to undertake the procedure. The time taken for a team to achieve competence in ECMO is not known, but is in part related to institutional and individual volume¹⁵. Thus the time taken for a new team to acquire competence might take longer for a relatively low volume intervention like ECMO, especially if that experience is spread thinly amongst a large number of clinicians in a large centre.

¹¹ Health Care Management Review 2003;28(1), pp 41-54

¹² Ramsay, Craig R.; Grant, Adrian M.; Wallace, Sheila A.; Garthwaite, Paul H.; Monk, Andrew F. and Russell, Ian T. (2000). Assessment of the learning curve in health technologies: a systematic review. International Journal of Technology Assessment in Health Care, 16(4), pp. 1095–1108.

¹³ Postgrad Med J 2007;83:777–779. doi: 10.1136/pgmj.2007.057190

¹⁴ BMJ 2004;329:421–4

¹⁵ Health Care Management Review 2003;28(1), pp 41-54

Table 1 Measures of outcome related to duration of time taken to achieve competence

Surgical procedure	Outcome	Time or number of cases to plateau	Reference
Laparoscopic fundoplication	Complication rate, conversion to open procedure, reoperation rate	20 cases	Meinke and Kossuth ¹²
Laparoscopic colorectal surgery	Conversion to open procedure, complication rate, operative time	55–80 cases	Tekkis <i>et al</i> ^{13,14}
Laparoscopic cholecystectomy	Bile duct injury rate	3 years	Richardson <i>et al</i> ¹⁵
D2 gastrectomy	Morbidity, mortality, LN harvest	18–24 months 15–25 cases	Parikh <i>et al</i> ¹⁶
Oesophagectomy	Operative time, blood loss, ITU stay, inpatient stay, LN harvest	Continuing improvement at 7 years or 150 cases	Sutton <i>et al</i> ¹⁷
Coronary artery surgery	Mortality	4 years	Bridgewater <i>et al</i> ¹⁸

ITU, intensive therapy unit; LN, lymph node.

Postgrad Med J 2007;83:777–779. doi: 10.1136/pgmj.2007.057190

Some comparisons may be made from the establishment of ECMO programmes for adult patients. Peris *et al*¹⁶ describe their experience of a new ECMO in an established tertiary centre in Florence, Italy. They had a dedicated team and had undergone ‘training in ECLS techniques’. 13 patients received VV ECMO for respiratory failure (primarily severe H1N1 infection), with a mortality of 38%. Mortality for the same group of patients in Leicester is 24%¹⁷. The Canadian Critical Care Trials Group reported their experience of low volume ECMO in adults with H1N1 infection¹⁸, and again had a crude mortality of 33%. In Japan, Takeda and colleagues¹⁹ describe the outcomes of patients treated with ECMO for H1N1 infection in their units, noting that ‘..none of the facilities had extensive experience with ECMO for respiratory failure’. Crude mortality was 64%. Adverse events on ECMO were noted in 93% of patients. Similar results were seen in a French hospital²⁰ who established a new ECMO programme in a hospital that already worked as a referral centre for severe respiratory infections. They describe their experience of treating 18 patients admitted with severe H1N1 infection from October 2009 to January 2010, 6 of whom were treated with veno-venous and 3 with veno-arterial ECMO. Crude mortality was 56%. In contrast, a study from Hong Kong²¹ reported only one death in a series of 7 patients (crude mortality 14%), and the Australasian response to the H1N1 pandemic, where ECMO was confined to larger centres that had some ECMO experience and crude mortality was comparable to the UK figures. Overall, the published data supports the view that newly established ECMO services have worse outcomes.

It is clear that a period of increased hazard for individual patients may occur when a specialist technique like ECMO is moved to a new unit or team²². This was addressed in the report of the

¹⁶ Peris *et al*. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine 2010, 18:28¹⁷ JAMA, October 19, 2011—Vol 306, No. 15 1659¹⁸ Can J Anesth/J Can Anesth (2010) 57:240–247¹⁹ J Anaesth 2012 DOI: 10.1007/s00540-012-1402-x e-pub ahead of print²⁰ Intensive Care Med (2010) 36:1899–1905²¹ Hong Kong Med J 2010;16:447-54²² BMJ 2000;320:1168–73

Bristol Inquiry, when the issue of learning curves for new surgical procedures was discussed. The size of the hazard, and its duration, are not clear, but obtaining informed consent from parents during this time of uncertainty is an ethical obligation for practitioners.

The transfer of a specialist service raises specific organisational and ethical problems. These have not been fully considered by the Cardiac review team. The Heartlink ECMO centre has over twenty years institutional experience, and the lead team of ECMO senior clinicians and co-ordinators have nearly two centuries equivalent of looking after patients on ECMO and their families. Such a resource should not be so lightly discarded.

August 2012

Impact of proposed changes on Paediatric Intensive Care Services

Background

The review consultation document states that the review team have assessed the risk to paediatric intensive care units following their proposed reorganisation. They conclude that losing paediatric cardiac surgery in Leicester represents limited risk to local and national paediatric intensive care provision, but that redesignation of units in Bristol, Leeds or Southampton represents a higher risk. We believe that this analysis is incorrect.

Current situation

Paediatric intensive care services are provided in one unit on a single site in Southampton; one unit on two sites in Leicester; two units on one site in Leeds; and Newcastle has three units on three sites. In the case of Southampton, Leeds and Leicester the consultant staff work on both cardiothoracic and general PICUs, and these are effectively considered as a single unit.

The activity of each centre is shown in the table (data from PICANET for year 2009):

Centre	Leicester	Southampton	Leeds	Newcastle
Total Cases	785	740	802	896
Cardiac cases	313	214	311	267
% cardiac ¹	40	29	39	30
% cardiac ²	n/a	29	39	n/a
ECMO	51	1	0	20
Non-Cardiac/ECMO ¹	421	525	491	609

¹ Arithmetic ² from Children's Congenital Heart Surgery consultation document for cross reference

Assessment

Taking the paediatric intensive care provision in each city as a whole, it is clear that the unit in Leicester is as much at risk as the other units, if not more so. This should be reflected in the Safe and Sustainable scoring for deliverability.

Consequences

Reduction and possible closure of intensive care facilities in the East Midlands would have a number of adverse consequences:

- General PICU patients from Leicestershire would need to travel elsewhere. The nearest unit in Nottingham is often full, and patients would need to be transferred to Birmingham, Sheffield, Leeds or Cambridge.
- Nottingham PICU does not currently offer a retrieval service. Options which redesignate Leicester PICU would likely mean that there would be no retrieval service for paediatric patients in the East Midlands.
- 86 non cardiac/ECMO patients were admitted to Leicester PICU from the West Midlands in 2010. These patients would need to be accommodated in Birmingham Children's Hospital or transferred out of region. We are not aware that the BCH business plan includes these patients.
- Sub specialty services currently provided in Leicester including paediatric surgery, paediatric respiratory medicine, and paediatric ENT would be under threat.

Conclusion

The adverse impact upon the paediatric intensive care provision in the East Midlands should be considered as a risk under current proposals, and to the care of children in UHL.