NHS

Specialised Services

SAFE AND SUSTAINABLE

Review of Children's Congenital Cardiac Services in England: July 2012

Decision Making Business Case

Contents

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Introduction

01

This document represents the culmination of a three-year review of children's congenital cardiac services in England. In truth, the process started long before, with the tragic events in Bristol in the 1990s. That we find ourselves finally making a decision in response to those events twelve years later warrants a moment of sober reflection.

Professor Sir Bruce Keogh's challenge to the NHS in 2009 was to deliver recommendations that would lead to the reconfiguration of children's congenital cardiac services. His choice of words was stark: he said that a failure this time round to deliver change would be '*a stain on the soul of the specialty*'.

His challenge was put to all of us. It extended to the professional associations to show real leadership during this uncertain time, to clinicians and managers in the NHS to put aside personal and institutional ambitions, and to parents to take part in objective debate.

This has been the most extensive review of a single clinical specialty in the history of the NHS. The contributions to the debate by NHS staff, charities, parents and patients have helped to shape ideas and to challenge and develop the evidence on which the review has relied.

This document has been prepared by the National Specialised Commissioning Team in its role as secretariat to the Joint Committee of Primary Care Trusts. It constitutes the final element of the process of advising the JCPCT on the relative strengths and weaknesses of potential options for change and on the available evidence on which to base a decision.

This document refers to the evidence that is available to JCPCT members, and which was produced before, during and after the public consultation that was held in 2011. All of the evidence has been made available to JCPCT members in its entirety and has been discussed at previous meetings of the JCPCT. In making limited references to the evidence submitted during consultation this document does not replace the evidence, but merely sign-posts the JCPCT members to the full, detailed submissions.

The evidence has been publicly available via the *Safe and Sustainable* website at www.specialisedservices.nhs.uk/safe_sustainable/childrens-congenital-cardiac-services

Some of the evidence is attached to this document in the form of appendices. In the interests of keeping the document manageable some appendices are referred to but not attached to the document; they may be found on the website or are available by writing to the Safe and Sustainable Team, 2nd Floor Southside, 105 Victoria Street, London, SW1E 6QT (020 7932 9128).

01 Introduction

SUMMARY OF RECOMMENDATIONS MADE TO THE JCPCT

Need for Change

Recommendation 1: The need for change to the way in which children's congenital heart services in England are planned and delivered remains compelling, and the case for change supports the proposals set out in this document.

Key principles underpinning the review

Recommendation 2: There is overall support for the key principles that underpin the development of proposals for change.

Model of care

Recommendation 3: The proposed model of care is viable and should be implemented in England; this will involve establishing a number of congenital heart networks in England; a reduction in the number of hospitals that provide heart surgical services for children; and the development of District Children's Cardiology Services and Children's Cardiology Centres for which standards will need to be developed.

Recommendation 4: Children's Cardiology Centres must not provide interventional cardiology services but may provide diagnostic catheterisation.

Recommendation 5: Electrophysiology services may be provided in dedicated children's services outside of a specialist surgical centre provided the congenital heart network has developed clear protocols.

Recommendation 6: Accept the advice of Professor Sir Ian Kennedy's panel about the panel's application of the term 'co-location' as defined by the *Framework of Critical Interdependencies*.

Recommendation 7: Accept the requirements for the co-location of services as stipulated in the *Safe and Sustainable* standards.

Recommendation 8: The proposed model of care is consistent with the principle of 'patient choice'.

Recommendation 9: There is an urgent need to conclude the review of children's congenital cardiac services in England, and this necessitates the JCPCT making a decision before the separate review of services for adults with congenital heart disease has concluded.

Standards

Recommendation 10: Agree (subject to recommendation 11) each of the 156 standards together with the 4 additional standards set out in Appendices A and B.

Recommendation 11: Agree the revisions to the proposed standards relating to antenatal screening as set out in Appendix C.

Data reporting and monitoring

Recommendation 12: Agree the proposals for improving the collection, reporting and analysis of outcome data as set out in the consultation document.

Scoring of viable options

Recommendation 13: Agree the assumptions that have been applied to identify viable options.

Recommendation 14: Agree the proposed criteria for the evaluation of options, and the weightings applied to each criteria.

Recommendation 15: Agree the proposed scoring of options against the weighted criteria.

Recommendation 16: Option B is consistently the highest scored option when sensitivity tests are applied

Testing the evidence for and against other options

Recommendation 17: Agree option B for implementation and the designation of congenital heart networks led by the following surgical centres:

- Newcastle upon Tyne Hospitals NHS Foundation Trust
- Alder Hey Children's Hospital NHS Foundation Trust
- Birmingham Children's Hospital NHS Foundation Trust
- University Hospitals of Bristol NHS Foundation Trust
- Southampton University Hospitals NHS Foundation Trust
- Two surgical units in London

London

Recommendation 18: Agree the designation of the Evelina Children's Hospital and Great Ormond Street Hospital for Children as providers of paediatric congenital cardiac surgery in the event of the JCPCT deciding an option with two surgical units in London.

Recommendation 19: Accept the findings of the Pollitt report: that paediatric respiratory services will remain viable at the Royal Brompton Hospital in the absence of a viable paediatric intensive care unit, though alternative arrangements would have to be made for a small number of children.

Affordability and capacity

Recommendation 20: The JCPCT's proposals are affordable and providers have demonstrated realistic plans to increase capacity.

02 Background

Congenital Heart Disease is relatively rare. Around 8 of every 1000 babies born will have some form of congenital heart disease[1]. Services for children with congenital heart disease are becoming increasingly complex. Surgical and cardiology interventions demand great technical skill and expertise from all of the professionals in the cardiac teams.

At the request of national parent groups, NHS clinicians and their professional associations the National Specialised Commissioning Team has reviewed how the NHS in England delivers congenital heart services to children in England and Wales through the *Safe and Sustainable* review.

Safe and Sustainable was instigated in response to long standing concerns that some congenital heart units for children are too small to be able to deliver a safe and sustainable 24/7 service. There were also concerns that clinical networks are fragmented and that the various services that see children with congenital heart disease could do better in working together.

The aim of the review is to design and deliver a national service that has better clinical outcomes with fewer deaths and complications following surgery, and a trained clinical workforce expert in the care and treatment of children and young people with congenital heart disease.

At the time the review began there were 31 consultant congenital cardiac surgeons in England spread across 11 NHS hospitals.

Surgical Centre	Number of surgeons (heads)[2]	Number of paediatric surgical procedures[3]
Birmingham Children's Hospital NHS Foundation Trust	3	555
Great Ormond Street Hospital for Children NHS Foundation Trust	4	541
Alder Hey Children's NHS Foundation Trust	3	400
Royal Brompton & Harefield NHS Foundation Trust	4	353
Guy's and St Thomas' Hospitals NHS Foundation Trust	3	337
Leeds Teaching Hospitals NHS Trust	3	316
University Hospitals Bristol NHS Foundation Trust	3	277
Newcastle upon Tyne Hospitals NHS Foundation Trust	2	255
Southampton University Hospitals NHS Foundation Trust	2	231
University Hospitals of Leicester NHS Foundation Trust	3	225
Oxford Radcliffe Hospitals NHS Trust	1	108

[1] Central Cardiac Audit Database. Available at: https://nicor5.nicor.org.uk/__80257061003D4478.nsf/vwContent/home?OpenDocumentt

[2] Headcount based on submissions by the NHS Trusts to the secretariat as at 30 June 2010 and panel visits

[3] 2009/10 data validated by the Central Cardiac Audit Database

There have been long-standing concerns that medical expertise is spread too thinly across England to be able to deliver the highest quality service around the clock in every centre. This view has developed over many years amongst experts in the field, and there is an almost over-whelming feeling that in 2012 the time for change is overdue. The review is supported by:

- The Children's Heart Federation
- The British Heart Foundation
- Little Hearts Matter
- The Royal College of Surgeons of England
- The Royal College of Paediatrics and Child Health
- The Royal College of Nursing
- The Society for Cardiothoracic Surgery in Great Britain and Ireland
- The British Congenital Cardiac Association
- The Paediatric Intensive Care Society, and
- The Specialised Healthcare Alliance

The *Safe and Sustainable* review began in December 2008 and has involved:

- extensive stakeholder engagement and a comprehensive national public consultation (one of the largest ever undertaken by the NHS)
- the collection of evidence from a prodigious number of clinical and lay experts
- proposed new standards that children's congenital cardiac centres must meet in the future, including minimum surgical volumes and minimum surgeon numbers
- the assessment of each of the current centres against the standards by an independent expert panel, chaired by Professor Sir Ian Kennedy
- a consideration of a number of potential configuration options against other important criteria including access, travel times, deliverability and sustainability

Strategic context: the Kennedy recommendations (2001)

The eventual decisions to be implemented as an outcome of *Safe and Sustainable* are the end-stage of a process that began as far back as 2001 when, following a public inquiry into children's heart surgery in the NHS, the Kennedy Report[4] made a number of recommendations for delivering a safe, high quality service:

- **National standards** – '*these should be developed, as a matter of priority, for all aspects of the care and treatment of children with congenital heart disease. The standards should address diagnosis, surgical and other treatments, and continuing care. They should include standards for primary and social care, as well as for hospital care. The standards should also address the needs of those with CHD who grow into adulthood*' (recommendation no. 192).
- **Larger specialist centres** – *'the standards should stipulate the minimum number of procedures which must be performed in a hospital over a given period of time in order to have the best opportunity of achieving good outcomes for children. Heart surgery on children must not be undertaken in hospitals which do not meet the minimum number of procedures'* (recommendation no. 193).

[4] Bristol Royal Infirmary Inquiry, *Learning from Bristol: The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 -1995*, (The Kennedy Report), HM Government, July 2001

02 Background

- **Low volume equates to high risk** – *'an investigation should be conducted as a matter of urgency to ensure that heart surgery is not currently being carried out on children where the low volume of patients or other factors make it unsafe to perform such surgery'* (recommendation no. 198).

In 2003 a previous review group[5] published its findings and in line with the recommendations of the Kennedy Report called for the establishment of fewer, larger surgical centres in England in order to eradicate the risk of occasional practice of heart surgery on children.

In the absence of a robust commissioning framework for specialised services at the time these recommendations were not implemented.

Concerns persisted. In 2006 an extraordinary national meeting of surgeons and cardiologists from each of the 11 paediatric cardiac surgery centres, other NHS staff and national parent groups was jointly convened by the National Director for Heart Disease and Stroke and the National Clinical Director for Children, Young People and Maternity. There was unanimous consensus that the current configuration of children's heart surgery services in England was unsustainable, and the meeting called for the establishment of fewer, larger centres of expertise[6]. This recommendation was echoed by the Royal College of Surgeons of England in an independent report[7] in 2007 when it called for fewer, larger paediatric cardiac surgical centres, and repeatedly by the Children's Heart Federation, the country's leading support organisation for parents of children with congenital heart disease.

In 2008, a working group of experts in specialised paediatric services produced a document called "*Commissioning Safe and Sustainable Specialised Paediatric Services: A Framework of Critical Inter-Dependencies*". This document was endorsed by relevant professional associations and two of the services covered by it are paediatric cardiothoracic surgery and paediatric cardiology. It concluded that "*Specialised paediatric services are facing a number of pressures to change, and standing still is not a safe or sustainable option*"[8] and it recommended that "*Centres providing specialised paediatric services must have a sufficient volume of specialised paediatric care to ensure that they can provide sustainable and comprehensive support services*"[9].

STRATEGIC CONTEXT: SPECIALISED CHILDREN'S SERVICES

Restricting clinical expertise to a small number of specialist centres where this is desirable and appropriate in the interests of delivering the best clinical outcomes is well established in the NHS, either through national or regional specialised commissioning.

The aims and objectives of the review (and the clinical standards that have been developed) are concordant with relevant policy initiatives and best practice guidance for the planning and delivery of NHS and social care for children and families. This includes the Department of Health's 2010 report on 'Getting it Right for Children and Young People'[10], the 'National Service Framework for Children'[11] and the 'Children's Plan'[12].

Safe and Sustainable also builds upon evidence of the benefits of developing managed network models of care[13]. A network model of care requires specialist tertiary centres, regional specialist centres, local hospitals, primary care and NHS commissioners to plan, deliver and

[5] Department of Health, Paediatric and Congenital Cardiac Services Review Group, January 2001 – December 2003

[6] Department of Health, *Congenital Cardiac Services*; Report of Workshop, June 2006

[7] The Royal College of Surgeons of England, *Surgery for children: Delivering a first class service*, London, July 2007

[8] Department of Health, *Commissioning safe and sustainable specialised paediatric services: a framework of critical inter-dependencies*, September 2008, p15

[9] Department of Health, *Commissioning safe and sustainable specialised paediatric services: a framework of critical inter-dependencies*, September 2008, recommendation F, p16

[10] Department of Health, *Getting it Right for Children and Young People*, September 2010

[11] Department of Health, *National service framework for children, young people and maternity services*, September 2004

[12] Department for Education, *The Children's Plan: Building Brighter Futures*, December 2007

[13] For example, following the Calman/ Hine Report cancer networks were established to implement the Cancer Plan. These networks of cancer care were established, reaching from primary care to cancer units, treating the more common cancers and assessing and diagnosing rarer cancers, to cancer centres, treating the rarest cancers and providing highly specialised treatment such as radiotherapy and bone marrow transplantation. Department of Health, *The Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales*, April 1995

manage an entire pathway of care that delivers the best possible care for patients at every stage of treatment, including assessment, treatment and follow-up. One of the recommendations of the *Critical Interdependencies Framework* was:

"To support the safe and effective delivery of accessible services for children with specialist needs, informal clinical networks will need to be replaced with formal managed networks. These will need to agree:

i evidence-based care pathways supporting local protocols;

ii integrated clinical information systems and clinical audit;

iii service delivery by appropriately accredited practitioners and skilled multi-disciplinary teams;

iv where and when care is to be delivered (in the right place, at the right time); and

v a common clinical governance structure with an improvement process to identify and rectify weak points on the pathway or within the network, so that the best clinical outcomes are achieved[14]*".*

In some specialties, such as paediatric cardiac surgery, clinical practice has become so sophisticated and the technology has become so advanced that those patients who would otherwise have died only 10 years ago can now be safely treated with confidence. However, an increasing trend for sub-specialisation in these specialties presents challenges around the safety and sustainability of services in the future.

"The number of children with specialised conditions is relatively small, and services are increasingly sub-specialising. These factors will inevitably mean fewer, bigger centres. At the same time, we want to minimise the disruption to the lives of these children and young people, and their families, and to provide them with services as close to home as possible where appropriate. In addition, we are clear that planning the provision of specialised services must address other competing pressures – maximising efficiency in one service can compromise provision of key services for other children, and specialised commissioners must optimise outcomes and balance access."

Dr Sheila Shribman CBE
National Clinical Director for Children, Young People and Maternity[15]

STRATEGIC CONTEXT: INTERNATIONAL EXPERIENCE

In recent years many countries have identified the same concerns around the safety and sustainability of their congenital cardiac services for children. Different health systems have sought to address these problems according to local requirements but common themes are clear: the unsustainable nature of fragmented models of care for children with congenital heart disease (Australia, 2006[16]), the need for congenital heart services to comply with quality standards that set minimum staffing and activity requirements (Germany, 2010[17] and the Netherlands, 2009[18]) and the relationship between cardiac surgical volumes and outcomes (Canada, 2002[19] and Sweden, 2000[20]).

In the United Kingdom there are precedents for the centralisation of congenital cardiac services for children based on the need for centres of expertise to meet minimum activity thresholds. In the past 16 years the congenital cardiac services in Cardiff and Edinburgh have ceased performing heart surgery on children because the centres recognised that their surgical volumes were too low to remain sustainable.

[14] Department of Health, *Commissioning safe and sustainable specialised paediatric services: a framework of critical inter-dependencies*, September 2008, recommendation D, p15

[15] Foreword to, Department of Health, '*Commissioning safe and sustainable specialised paediatric services: a framework of critical inter-dependencies*', September 2008

[16] Queensland Government - Queensland Health, *Report of the Taskforce on Paediatric Cardiac Services*, August 2006

[17] Federal Ministry of Justice, *Proclamation of a resolution of the Federal Joint Committee regarding a guideline over quality assurance measures over cardiac surgery care for children and teenagers in accordance with §137 Paragraph 1 Number 2 of the fifth book of Social Security Statute Book (SGB V), Guidelines for paediatric cardiac surgery: First Edition*', February 2010. Document translated from German by London Translation

[18] Commission for Paediatric Heart Interventions, *Concentration of congenital heart surgery and catheter interventions*, June 2009. Document translated from Dutch by Ubiqus, London

[19] Ontario Ministry of Health and *Long-Term Care, Specialized Paediatric Services Review - Report of the Minister's Advisory Committee*, April 2002

[20] Lundström, NR, Berggren, H, Björkhem, G, Jögi, P, Sunnegardh, J, *Centralization of Pediatric Heart Surgery in Sweden, Pediatric Cardiology*, 2000, 21:353-357

03 Governance and Quality Assurance

Safe and Sustainable was initiated in 2008 to 'undertake a review of the provision of paediatric cardiac surgical services in England with a view to reconfiguration[21]'. This request was made of the National Specialised Commissioning Group representing the 10 Specialised Commissioning Groups and their constituent Primary Care Trusts (the National Specialised Commissioning Team acts as the secretariat to the National Specialised Commissioning Group).[22]

Specialised paediatric cardiology and cardiac surgical services are complex treatments that are defined as 'specialised services' by the National Specialised Services Definition Set[23]. These services are currently commissioned by Primary Care Trusts via the 10 Specialised Commissioning Groups in England. There are also three very specialised services that are subject to the *Safe and Sustainable* review (as they are dependant upon support from consultant congenital cardiac surgeons) and which are commissioned on a national basis by the National Specialised Commissioning Team on behalf of PCTs: paediatric cardiothoracic transplantation (and mechanical 'bridge to transplant' services); Extra-Corporeal Membrane Oxygenation for children with respiratory failure; and complex tracheal surgery. Responsibility for commissioning all of these services will transfer to the new NHS Commissioning Board in 2013/14.

Given the inter-relationship between the current 11 surgical centres it was clear that a review of children's congenital cardiac services warranted a national approach. With the endorsement of the NHS Operations Board and Secretary of State for Health when appropriate, the National Specialised Commissioning Team has established the following structures:

Joint Committee of Primary Care Trusts

The inter-relationship between the current 11 surgical centres and the relatively low national caseload meant that the NHS had to undertake the review of options for reconfiguration of services at a national level. An attempt by Specialised Commissioning Groups to use their existing delegated powers to make a decision on a national reconfiguration would not withstand legal scrutiny.

Given the need for a single consultation on the options, based on a single model of care, with a decision made by a single commissioning body, a Joint Committee of Primary Care Trusts was established with delegated powers for consultation and decision making[24].

The JCPCT comprises the Chair of each of the 10 Specialised Commissioning Groups in England (or the nominated PCT representative) and the Director of National Specialised Commissioning; it is chaired by the Chief Executive of NHS Midlands and East. The establishment of a JCPCT ensures that each region and each Primary Care Trust in England is represented on the decision-making body by the relevant Specialised Commissioning Group Chair, or other senior Specialised Commissioning Group representative.

[21] National Specialised Commissioning Team, *Letter from Professor Sir Bruce Keogh, NHS Medical Director, May 2008*. Available at: www.specialisedservices.nhs.uk/document/background-children-s-congenital-cardiac-services-1

[22] Department of Health, *Review of Commissioning Arrangement for Specialised Services* (Carter Report), May 2006

[23] Definition number 23; National Specialised Commissioning Team, *Specialized Services National Definitions Set*. Available at: www.specialisedservices.nhs.uk/documents/index/document_category_id:26

[24] The NHS (Functions of Strategic Health Authorities and Primary Care Trusts and Administrative Arrangements) (England Regulations 2002 SI 2002/2375) allocates certain of those functions to Primary Care Trusts and amongst other provisions authorises those Trusts to make arrangements for their functions to be exercisable jointly with other NHS bodies and permits the delegation of the exercise of those functions to committees or sub-committees including joint committees. If a body delegates its relevant functions to a joint committee and that committee reaches a decision the body will be bound by that decision.

The Secretary of State for Health considered a number of options for consultation and decision-making. His view was that the establishment of a JCPCT is consistent with the principle of local-decision making, whilst being legally robust.

The JCPCT's terms of reference are (Appendix D):

- Approve the method and scope of the consultation on paediatric cardiac services in England
- Approve the text of and issue the consultation document
- Act as the formal body in relation to the Joint Overview and Scrutiny Committees established for this Consultation by the relevant Local Authorities
- Take decisions on issues which are the subject of the consultation

Safe and Sustainable review team

Day–to-day management of the review has been led by the National Specialised Commissioning Team on behalf of the 10 Specialised Commissioning Groups. The National Specialised Commissioning Team established a review team managed by a dedicated *Safe and Sustainable* Programme Director, reporting to the Director of National Specialised Commissioning. The review team also comprised a medical adviser experienced in the commissioning of cardiothoracic services, and dedicated commissioning, finance and administrative support. External communications and analysis support was procured.

Advisory Expert Steering Group

The JCPCT has received advice on relevant clinical matters by a Steering Group chaired by Dr Patricia Hamilton CBE in her role as Immediate Past President of the Royal College of Paediatrics and Child Health. The Steering Group comprised a majority of clinical experts nominated or endorsed by, and representing their professional bodies. The group also included the Chief Executive of the Children's Heart Federation and other lay representation. The role of the Steering Group was advisory in nature; it had no part in decision-making. The most notable achievements of the Steering Group were the creation of new quality standards and a network based model of care (Appendix A).

Financial working group

A Capacity and Finance Working Group was established to:

- validate the 'finance data capture' returns supplied by the NHS Trusts subject to the review
- identify what further financial data is required to consider the affordability of potential configuration options
- identify relevant work streams which may need to be addressed in the implementation phase of *Safe and Sustainable*

In terms of capacity, the group sought to risk assess against the following questions:

- Can designated surgical centres achieve the required service change with low levels of risk?
- Can centres develop the facilities on site in a timely fashion?

- Can centres recruit staff and develop the skills required in the timescales required?
- Can centres do this without adversely impacting on other services provided to the local health economy?

This work was undertaken in three phases due to the iterative nature of the process to identify options. The group was chaired by Stephanie Newman, Director of Specialised Commissioning of South East Coast Specialised Commissioning Group and included Specialised Commissioning Group commissioners, a clinical lead, senior finance staff from Specialised Commissioning Groups and the secretariat. The full group completed the risk assessment of the 4 consultation options. A sub-group completed the risk assessment on additional new options. The same information and approach was adopted for all the risk assessments.

Independent Expert panels

Four independent expert panels were formed to advise the JCPCT chaired by the following people:

1 **Professor Sir Ian Kennedy** (former Chair of the Healthcare Commission and Chair of the public inquiry of children's heart surgical services in 2001)

The panel was convened to assess the 11 centres against the designation criteria (Appendix E for terms of reference and panel biographies).

Centres were assessed against written submissions in April 2010, followed by on-site visits in May and June 2010. The panel submitted two further reports at the request of the JCPCT: a report which responded to suggestions of factual inaccuracy made by some respondents to consultation and which reiterated the panel's approach to the application of the term 'co-location' (October 2011) and a report which provided advice on new evidence submitted in their consultation responses by some centres as evidence of compliance with standards relating to 'innovation and research' (February 2012).

2 **Mr James Pollock** (Consultant Congenital Cardiac Surgeon)

The panel was convened in November 2010 to undertake a limited review of case notes relating to specific surgical procedures during specific time periods at three of the eleven centres. These limited reviews were in response to an analysis of mortality data that was received by the review team in September 2010 that suggested that these three centres had higher than expected mortality rates. The findings and recommendations of this panel were considered by Professor Kennedy and his panel in January 2011. Professor Kennedy's panel did not find that there was cause to reconsider its previous findings for any of the three centres. The reports of Mr Pollock and Professor Kennedy and the terms of reference for Mr Pollock's panel are set out at Appendices F, G and H.

3 **Dr Patricia Hamilton CBE** (Immediate Past President of the Royal College of Paediatrics and Child Health)

This panel was convened in July 2010 to provide the JCPCT with advice on the extent to which centres could, if required, develop and provide one or more of the three very specialised services that are commissioned on a national basis and which require on-site paediatric cardiac surgical back-up:

- paediatric cardiothoracic transplantation (and mechanical device as a 'bridge' to transplant)
- complex tracheal surgery, and
- Extra Corporeal Membrane Oxygenation for children with severe respiratory failure

The advice offered by the panel was used by the JCPCT to develop options for consultation and will be offered to the JCPCT in the process for agreeing a preferred option. A full description of this panel's work is provided at Appendix I.

4 **Adrian Pollitt OBE** (former Director of National Specialised Commissioning)

The panel was established in September 2011 to explore concerns raised by the Royal Brompton & Harefield NHS Foundation Trust about the potential impact of removing paediatric critical care services at the Royal Brompton to the Trust's paediatric respiratory services. The panel advised the JCPCT that paediatric respiratory services would remain viable at the Royal Brompton Hospital in the absence of a paediatric intensive care unit, although alternative arrangements would have to be made for a small number of children. This evidence will be offered to the JCPCT in the process for agreeing a preferred option.

Terms of reference are set out at Appendix J and the panel's report is set out at Appendix K.

Health Impact Assessment Steering Group

An independent steering group, accountable to the JCPCT, was convened to steer the development of the Health Impact Assessment. It was chaired by Professor Michael Simmonds. The purpose of the Health Impact Assessment is to produce independent advice to members of the JCPCT on how best they can promote and protect the health and well-being of local populations. The Health Impact Assessment will answer two key questions:

- What are the positive and negative impacts of the proposed changes on communities within England and Wales, particularly in respect of (a) health; (b) health inequalities; (c) access; (d) carbon footprint and (e) equalities taking due regard, but not exclusively, to the impact on people with protected characteristics as defined in the Equalities Act 2010.
- How can any adverse impacts be mitigated and positive impacts enhanced?

Terms of reference and membership are provided at Appendix L.

Other sources of expertise that have been available to the JCPCT and *Safe and Sustainable* team:

- **Central Cardiac Audit Database** – The activity data relied upon by *Safe and Sustainable* has been validated by the Central Cardiac Audit Database, which oversees a continuous process for the collection, validation and analysis of activity data submitted by each paediatric cardiac surgical unit in the United Kingdom. The Central Cardiac Audit Database information portal was developed in collaboration between the Society for Cardiothoracic Surgery in Great Britain and The British Congenital Cardiac Association and is hosted by the National Institute for Cardiovascular Outcomes Research.

03 Governance and Quality Assurance

The process of review established by the National Specialised Commissioning Team on behalf of the JCPCT has itself been quality assured in a number of ways.

STRATEGIC HEALTH AUTHORITIES

The process for delivering a robust public consultation and in reaching a final decision has been quality assured by NHS London on behalf of all Strategic Health Authorities in England.

The Revision to the Operating Framework for the NHS in England 2010/11, published June 2010, set out four new tests that proposals for reconfiguration must meet and requires SHAs to ensure they have:

- support from GP commissioners
- strengthened public and patient engagement
- clarity on the clinical evidence base, and
- consistency with current and prospective patient choice

On behalf of all SHAs in England NHS London concluded that *Safe and Sustainable* had met the four tests.

STEERING GROUP

In January 2011 the following members of the Steering Group, representing their professional associations, endorsed the JCPCT's process for delivering options for consultation[25]:

- Dr Patricia Hamilton CBE, Immediate Past President of the Royal College of Paediatrics and Child Health and Chair of the Steering Group
- Mr William Brawn CBE, Immediate Past President of the British Congenital Cardiac Association
- Professor Martin Elliott, British Congenital Cardiac Association
- Mr Leslie Hamilton, President of the Society for Cardiothoracic Surgery of Great Britain and Ireland
- Maria von Hildebrand, lay representative
- Dr Ian Jenkins, Immediate Past President of the Paediatric Intensive Care Society
- Anne Keatley Clarke, Chief Executive of the Children's Heart Federation
- Dr Sally Nelson, public health representative
- Professor Shakeel Qureshi, President of the British Congenital Cardiac Association
- Dr Tony Salmon, President-Elect of the British Congenital Cardiac Association

[25] Only one member of the steering group dissented. Dr Kate Grebenik, representing the Association of Cardiothoracic Anaesthetists, declined to endorse the process on the grounds that "too many decisions were made outside" of the steering group including "potential options for reconfiguration" (Association of Cardiothoracic Anaesthetists, response to consultation). The Chair of the Steering Group, Dr Hamilton, responded to the ACA by clarifying that it was not the role of the Steering Group to make decisions, including on options for reconfiguration.

- Fiona Smith, Adviser on Children's and Young People's Services, Royal College of Nursing
- Dr Graham Stuart, British Congenital Cardiac Association
- Dr Dirk Wilson, British Congenital Cardiac Association (NHS Wales)

OFFICE OF GOVERNMENT COMMERCE 'GATEWAY REVIEW'

The 'Health Gateway Review' of *Safe and Sustainable* was carried out in September 2010. The primary purposes of a Health Gateway Review strategic assessment are to review the outcomes and objectives for the programme (and the way they fit together) and confirm that they make the necessary contribution to government, departmental, NHS or organisational overall strategy.

The Gateway Review positively assessed *Safe and Sustainable*.

Positive indicators were:

- Excellent clinician, patient and key stakeholder engagement
- Production of a new set of standards
- Robust assessment process
- Breaking new governance ground which could help future projects
- An appropriately resourced programme
- Accolades for the National Specialised Commissioning Team in driving the review forward
- A supportive National Clinical Advisory Team review

NATIONAL CLINICAL ADVISORY TEAM REVIEW

The National Clinical Advisory Team (NCAT) is invited to conduct a clinical review whenever a major reconfiguration of service is required. The NCAT review of *Safe and Sustainable* was held in September 2010. It was agreed with the chair of NCAT that a desk top review was the appropriate means by which NCAT could carry out its review in view of the substantial work undertaken by the *Safe and Sustainable* team in collecting and reviewing evidence and visiting hospital sites.

The NCAT review concluded that there is a compelling case for providing children's heart surgical procedures in fewer, larger units. NCAT supported the clinical 'Case for Change' and endorsed the minimum surgeon and activity levels for each surgical centre proposed by the *Safe and Sustainable* clinical standards. NCAT also supported the proposed network model of care and other proposed clinical standards.

COMPETITION AND COOPERATION PANEL

NHS guidance[26] sets out a requirement for reconfiguration proposals to seek informal advice from the Competition and Cooperation Panel on the patient choice and competition implications of the plans. The panel has considered the *Safe and Sustainable* review and confirmed in May 2012 that there is no need for the JCPCT to seek formal advice.

[26] *Service reconfiguration*: Letter from Sir David Nicholson KCB CBE, NHS Chief Executive, 29 July 2010

04 Matters consulted upon by the Joint Committee of Primary Care Trusts

In March 2011 the JCPCT consulted the public on the following:

The key principles driving the *Safe and Sustainable* review

- The need of the child comes first in all considerations
- All children who need heart surgery must receive the very highest standards of NHS care
- The same high quality of service must be available to each child regardless of where they live or which hospital provides their care
- The care that every congenital heart service plans and delivers must be based around the needs of each child and family
- Other than surgery and interventional procedures all relevant cardiac treatment should be provided by competent experts as close as possible to the child's home

The need for change

Respondents were asked about the extent to which they supported or opposed the statement that '*without change the service will not be safe or sustainable in the future*'.

The evidence supporting the case for change

Respondents were asked about the extent to which they supported or opposed the statement that '*research evidence identifies a relationship between higher volume centres and better clinical outcomes*'.

Improved systems for measuring quality

New systems for the collection, analysis and reporting of outcome data, including the development of morbidity data.

New standards of care

156 standards of care that would be met by designated surgical units in the future, and which aim to enhance the quality of care for children and their families.

Key standards included a minimum of four consultant congenital cardiac surgeons in each surgical unit and a preferred minimum caseload of 500 paediatric surgical procedures a year at each surgical unit.

Congenital Heart Networks

The development of managed clinical networks that would coordinate the delivery of the range of services that see children with congenital heart disease, including antenatal diagnosis, maternity and obstetric services through to the transition to adult services.

Fewer surgical units in England

A proposal to reduce the number of hospitals that provide children's heart surgical services in England from the current 11 units to 6 or 7 units, including a proposal to reduce the number of units in London from 3 to 2 units.

Four options were set out, but respondents were told that views were sought on any other reconfiguration options favoured by respondents.

Option A	Option B
Liverpool	Southampton
Newcastle	Newcastle
Birmingham	Liverpool
Leicester	Birmingham
Bristol	Bristol
London (two centres)	London (two centres)
Option C	**Option D**
Liverpool	Leeds
Newcastle	Liverpool
Birmingham	Birmingham
Bristol	Bristol
London (two centres)	London (two centres)

Patient flows

Respondents were asked for their views on the assumptions that the JCPCT had made about potential patient flows under the four options.

05 How the JCPCT consulted

The public consultation on children's congenital cardiac services was the most exhaustive ever undertaken by the NHS in England. Over 75,000 responses to consultation were received.

PRE-CONSULTATION

The JCPCT's options for consultation were underpinned by a pre-consultation engagement.

The draft standards against which surgical units would be assessed were shared with charities, professional organisations and Health Overview Scrutiny Committees in England and Wales for comment between September and November 2009. The draft standards and the emerging model of care were discussed in October 2009 at a national stakeholder event for all professionals and parents with an interest in the *Safe and Sustainable* review, attended by 200 participants. Responses were summarised in draft standards published in December 2009 and in the case for change ('*Children's Heart Surgery – the Need for Change*') published in April 2010.

The case for change, draft standards and the model of care were further discussed with the public at 10 engagement events that were held for NHS staff, parents, patients and public in England and Wales. The report from these events was considered by the JCPCT during the development of options.

PUBLIC CONSULTATION

Public consultation ran for four months from 1 March to 1 July 2011, for longer than the statutory minimum period in view of the scope and complexity of the exercise. Health Overview Scrutiny Committees had seven months – until 5 October 2011 – to respond.

INDEPENDENT ANALYSIS

So as to ensure expert objectivity in the consultation process the JCPCT commissioned Ipsos Mori, an independent third party, to assist in developing the consultation questions and response form, and to report on an analysis of responses. The reports of Ipsos Mori are presented to the JCPCT as Appendices M and N.

HOW THE JCPCT PUBLICISED CONSULTATION

The consultation was publicised through a number of channels with the aim of reaching the widest possible audience. The main message encouraged people to take part as "your views count".

It was important that respondents were reassured that the JCPCT had an open mind, that consultation was genuine and that there were no pre-determined outcomes.

> *"I want you to consider whether you think the proposed changes outlined in this document will deliver better care. Are there better solutions? We need an objective debate".*
>
> Introduction to the consultation document by **Professor Sir Bruce Keogh**, NHS Medical Director

Media interest was significant, and as such the review team sought to publicise the existence of the consultation through national and regional media outlets, including in Wales, Scotland and Northern Ireland. The consultation was also publicised by advertisements in a number of Black and Minority Ethnic newspapers.

The consultation was also publicised on the *Safe and Sustainable* website and of those of third parties within the NHS and the voluntary sector. A seven-minute video that explained the background to the review, including real-life stories, and which encouraged people to take part was professionally produced and was placed on the *Safe and Sustainable* website.

Communications briefings were issued to local authorities, MPs, Health Overview and Scrutiny Committees, LINks and London Assembly members.

Copies of the consultation document, together with response forms that were developed with input from Ipsos Mori were available from the *Safe and Sustainable* website, and were posted in large bundles to NHS Trusts, national and local parent groups, professional associations and SCGs. Respondents were also told that other forms of submission such as letters and emails were acceptable.

DIFFERENT LANGUAGE VERSIONS OF THE CONSULTATION DOCUMENT

Respondents were told in the consultation document that it could be translated into other languages upon request. Requests for different languages were acted upon as soon as they were received. In the event documents and response forms were translated into the following languages with 6 weeks of the consultation remaining: Arabic, Urdu, Farsi, Gujarati, Punjabi, Cantonese, Polish, Somali, Hindi and Bengali.

Ipsos Mori reported that 20 % of respondents to consultation were from Black and Minority Ethnic backgrounds, which is higher than the total percentage of BAME people in England[27].

EASY-READ VERSION OF THE CONSULTATION DOCUMENT

An "easy-read" version of the consultation document, aimed primarily at children and young people, was published.

LONDON CONSULTATION DOCUMENT

In view of the unique aspects of consultation around the three London centres, including the implications of the judicial review lodged by the Royal Brompton & Harefield NHS Foundation Trust in March 2011, a supplemental consultation leaflet on the London centres was published in May 2011 shortly before the London consultation events.

TEXT RESPONSES

A facility for consultees to "text" responses by mobile phone was introduced by Ipsos Mori. This was aimed primarily at children and young people.

[27] According to the 2001 census, 7% of England's population is represented by Black or Black British and Asian or Asian British communities

05 How the JCPCT consulted

CONSULTATION EVENTS

Over 2000 people attended 16 consultation events in England and Wales:

- Birmingham – 4 April 2011
- Cardiff – 5 April 2011
- Newcastle – 7 April 2011
- Oxford – 4 May 2011
- London – 7 May 2011, 11am–1pm
- London – 7 May 2011, 2pm–4pm
- Warrington – 9 May 2011
- Leeds – 10 May 2011, 3pm–5pm
- Leeds – 10 May 2011, 6pm–8pm
- Gatwick – 19 May 2011
- Cambridge – 23 May 2011
- Southampton – 24 May 2011, 3pm–5pm
- Southampton – 24 May 2011, 6pm–8pm
- Taunton – 7 June 2011
- Leicester – 16 June 2011, 3pm–5pm
- Leicester – 16 June 2011, 6pm–8pm

Clinicians from the *Safe and Sustainable* Steering Group were present at the events to answer questions put by the audience. Professor Sir Roger Boyle CBE, former National Director of Heart Disease and Stroke, was present at most events to give the background to the review and to explain the 'need for change'. The events were facilitated by an experienced, independent facilitator.

In some locations an additional event was held on the same day in response to demand. A free crèche facility was available to facilitate access for parents. Interpreters were made available.

A report on the themes raised at the events is produced for the JCPCT at Appendix O.

In addition, three young people's discussion groups were held in:

- Birmingham – 9 March 2011
- London – 19 March 2011
- York – 14 May 2011

TARGETED FOCUS GROUPS

In an attempt to obtain even more qualitative information Ipsos Mori was asked to run focus groups targeted at specific groups: The aim was to conduct qualitative research to explore the issues raised throughout the consultation in depth. Parents of children with congenital heart disease and young people who currently use children's congenital heart services were asked about their views on the proposals. They were identified by the centres hospitals and parent groups.

Ipsos MORI also conducted qualitative research with the general public from Black and Minority Ethnic (BAME) groups, focusing on parents from a South Asian origin given the available research evidence that suggests that there is a higher relative incidence of congenital heart disease for some conditions amongst South Asian populations[28]. Participants in the BAME groups were of Bangladeshi or Pakistani origin and from a range of socio-economic backgrounds.

Focus groups with parents of children with congenital heart disease

- London – 17 May 2011
- Leeds – 31 May 2011
- Leicester – 1 June 2011
- Newcastle – 7 June 2011
- Oxford – 8 June 2011

[28] Sadiq M, Stumper O, Wright JG, De Giovanni JV et al (1995) *Influence of ethnic origin on the pattern of congenital heart defects in the first year of life.* British Heart Journal; 73(2): 173-176

- Southampton – 14 June
- Taunton – 15 June 2011
- Manchester – 21 June 2011
- London – 21 June 2011
- Birmingham – 22 June 2011
- Cardiff family interviews – 29th June 2011

Focus groups with children with congenital heart disease

- Leicester – 1 June 2011
- Southampton – 14 June 2011

Focus groups with people from BAME groups:

- Oxford – 8 June 2011
- Southampton – 14 June 2011
- Manchester – 21 June 2011
- London–- 22 June 2011
- London – 22 June 2011
- Birmingham – 22 June 2011
- Leicester – 28 June 2011
- Leeds – 28 June 2011
- Cardiff – 29 June 2011
- Newcastle – 29 June 2011
- Cambridge – 30 June 2011

In addition interviews were offered either on the phone or in the home with people who could not attend the groups.

HEALTH IMPACT ASSESSMENT ENGAGEMENT

As part of the process for developing the Health Impact Assessment around 2000 people and organisations were invited to take part in events run by Mott McDonald, the independent third party commissioned to deliver the Health Impact Assessment. Over 800 invitees were from vulnerable socio-demographic groups. The actual number of people who received the invitation was higher as it was forwarded on to other community organisations by the stakeholders who had received it originally.

Events to explore the potential impacts of service change to vulnerable populations and health inequalities:

- Bristol – 23 March 201
- Southampton – 28 March 2011
- Leeds – 1 April 2011
- Oxford – 4 April 2011
- London – 5 April 2011
- Newcastle – 14 April 2011
- Leicester – 21 June 2011
- Leeds – 29 June 2011
- Bradford – 12 July 2011
- Leicester – 19 July 2011
- Kirklees – 21 July 2011

All those who could not attend these workshops were interviewed on the phone, including participants in Birmingham and Liverpool (the phone interviews took place because of the low number of attendees).

In addition, 42 families were interviewed in-depth to ascertain the impacts on those considered to be most vulnerable to the proposed changes; these were families who live within the postcode districts with highest densities of children, people from Asian backgrounds, socio-economically deprived backgrounds, and with poor health levels, and who have a child undergoing heart surgery.

05 How the JCPCT consulted

Summary of evidence received by the JCPCT		
	Title	**Author**
1	Analysis of responses to consultation (August 2011)	Ipsos Mori
2	Qualitative research: parents and young people using congenital heart services and Black and Minority Ethnic groups (August 2011)	Ipsos Mori
3	Responses to consultation from organisations and individuals (March 2011 to June 2012)	Various respondents
4	Responses to consultation from Members of Parliament and London Assembly members (March to July 2011)	Various respondents
5	Summary report on consultation events	Secretariat
6	Health Impact Assessment: Interim Report (August 2011) and Final Report (June 2012)	Mott McDonald
7	Reports on testing assumptions for future patient flows and manageable clinical networks (October 2011)	PwC
8	Responses to the reports on testing assumptions for future patient flows and manageable clinical networks (March 2012)	Various respondents
9	Report on the relationship of interdependencies at the Royal Brompton Hospital (September 2011)	Independent panel chaired by Adrian Pollitt
10	Report to the JCPCT by the *Safe and Sustainable* Steering Group (October 2011)	Dr Patricia Hamilton, Chair of the Steering Group
11	Report from Professsor Sir Ian Kennedy's independent expert panel to the JCPCT on issues of factual accuracy and compliance with the requirements for co-location (October 2011)	Professor Sir Ian Kennedy
12	Letter from Professor Sir Ian Kennedy on behalf of the expert panel addressing comments made by respondents on quality (October 2011)	Professor Sir Ian Kennedy

Summary of evidence received by the JCPCT		
	Title	**Author**
13	Report of Professor Sir Ian Kennedy's Panel in response to additional evidence submitted in relation to 'Innovation and Research' (February 2012)	Professor Sir Ian Kennedy
14	Report from Southampton University Hospital NHS Foundation Trust on the safe retrieval of critically ill children from St Mary's hospital on the Isle of Wight (August 2011)	SUHT NHSFT
15	Letter from Jeremy Glyde to Sir Neil McKay on the safe retrieval of critically ill children from St Mary's hospital on the Isle of Wight (August 2011)	Secretariat
16	Report of an analysis of retrieval times to the Isle of Wight commissioned by Guy's and St Thomas's NHS Foundation Trust (October 2011)	JSC Transport Planning
17	Letter from Jeremy Glyde to Sir Neil McKay on the report of an analysis of retrieval times to the Isle of Wight commissioned by Guy's and St Thomas's NHS Foundation Trust (November 2011)	Secretariat
18	Correspondence from Glenfield Hospital (October and December 2011) on ENT services and PICU	University Hospitals of Leicester NHS Trust
19	Capacity Review (February 2012)	Secretariat
20	Advice from Advisory Group for National Specialised Services on paediatric cardiothoracic transplant services (April 2012)	Advisory Group for National Specialised Services
21	Report on "Option AB" submitted by University Hospitals of Leicester NHS Trust (June 2012)	University Hospitals of Leicester NHS Trust
22	Report on outcome of engagement with users of paediatric respiratory services at the Royal Brompton Hospital (June 2012)	London Specialised Commissioning Group

06 The need for change

- Congenital heart services for children have developed on an ad hoc basis
- Smaller centres are not sustainable
- Smaller centres struggle to provide safe 24/7 cover
- Smaller centres have more problems with recruitment and retention of surgeons and other key staff
- Many patients and carers have to travel long distances for routine follow-up care, as this is not always available closer to their homes

Services for children with congenital heart disease are becoming increasingly complex and it is vital that those clinical teams responsible for ensuring the safety of these vulnerable and very sick children have the highest possible levels of competencies and expertise.

At the outset of the review there were eleven centres providing paediatric cardiac surgery in England. Of these eleven centres, four had two or fewer paediatric surgeons as at June 2010[29]. This creates challenges for on call rotas and means that in some centres there will be times when there is no surgeon available to deal with routine cases or with emergencies. Smaller centres struggle to provide safe 24/7 cover.

The minimum requirement of four surgeons per centre proposed by *Safe and Sustainable* is predicated on the minimum requirements to ensure safe 24/7 care. This ensures there are enough surgeons in each centre to meet the day-to-day demands of performing operations in theatre, being on call to respond to emergencies, undertaking ward rounds and holding outpatient clinics as well as other core activities.

> "I would say that all surgeons, all paediatric cardiac surgeons – we were the ones who instigated this [review] because we were worrying about the small numbers … so yes, we have voted by our feet, saying that we will be prepared to move if the decision comes to a situation where we are asked to move".
>
> **Mr Asif Hasan**, Consultant Congenital Cardiac Surgeon, Newcastle consultation event

Smaller centres with low volumes of activity tend to struggle to recruit and retain new surgeons, making it challenging for smaller centres to plan future staffing and activity levels. This is because smaller centres undertake a narrower range of procedures so junior surgeons are less likely to be exposed to the full range of surgical techniques necessary to deal with the complex and varied caseload of congenital heart disease. Furthermore these centres are unable to provide the same opportunities

[29] WTE based on centre's submissions to the National Specialised Commissioning Team, as at 30th June 2010

for senior surgeons to mentor junior surgeons because smaller centres with fewer surgeons mean limited time and opportunities for team working and cross-cover.

There is also concern that the various NHS services that see children with congenital heart disease could work better together. If the services across the child's pathway of care were better coordinated, worked more collaboratively in the provision of care and research and communicated with each other more effectively, this would lead to a better quality, more accessible service for children and their families.

In summary:

- The different NHS services that care for children with congenital heart disease could work together better
- Clinical expertise is spread too thinly over 11 surgical centres
- Small teams cannot deliver a safe 24 hour emergency service
- Smaller centres are vulnerable to sudden and unplanned closure
- There is too much variation in the expertise available from centres
- Fewer surgical centres are needed to ensure that surgical and medical teams are meeting the 'critical mass' of children to maintain and develop their specialist skills
- Available research evidence identifies a relationship between higher-volume surgical centres and better clinical outcomes[30]
- Having a larger and varied caseload means larger centres are best placed to recruit and retain new surgeons and plan for the future
- The delivery of non-surgical cardiology care for children in local hospitals is inconsistent; strong leadership is required from surgical centres to develop expertise through regional and local networks
- Increasing the national pool of surgeons is not the answer, as this would result in surgeons performing fewer surgical procedures and increase the risk of occasional surgical practice

WHAT DOES THE REVIEW AIM TO ACHIEVE?

- A network of specialist centres collaborating in research and clinical development, encouraging the sharing of knowledge across the network
- Better results in the surgical centres with fewer deaths and complications following surgery
- Better, more accessible diagnostic services and follow up treatment delivered within regional and local networks
- Reduced waiting times and fewer cancelled operations
- Improved communication for parents between all of the services in the network that support their child
- Better training for surgeons and their teams to ensure the sustainability of the service
- A trained workforce, expert in the care and treatment of children and young people with congenital heart disease
- Centres at the forefront of modern working practices and innovative technologies that are leaders in research and development

[30] Ewart, H. The Relation Between Volume and Outcome in Paediatric Cardiac Surgery; Public Health Research Unit – A Literature Review for the National Specialised Commissioning Group (2009). Available at: www.specialisedservices.nhs.uk/document/developing-model-care

06 The need for change

Respondents were asked to indicate the extent to which they supported or opposed the statement that without change the service will not be safe or sustainable in the future.

Personal respondents:
46% support / 33% oppose

Organisations:
64% support / 19% oppose

Source: Ipsos Mori[31]

Ipsos Mori reported that amongst personal respondents opposition was highest amongst those who have congenital heart disease themselves.

There is an apparent inconsistency in the evidence submitted to the JCPCT, in that while Ipsos Mori reports limited support for change amongst personal respondents, there was considerable support for the proposed standards (around 91% of personal respondents were in support of the standards). Implementation of the proposed standards would itself bring significant change to the national model of care: fewer surgical units via the standards that would stipulate a minimum of 4 consultant congenital cardiac surgeons in each unit and a minimum of 400 paediatric surgical procedures per unit (ideally a minimum of 500 paediatric procedures).

Nearly all of the national organisations who wrote to the JCPCT directly supported the need for change:

"Without changes, the cracks already seen in the children's heart care service will widen – some children will die unnecessarily and some will suffer the avoidable side-effects of treatment. Without reorganisation failures of the current service – long waiting lists for surgery and cancellations – will persist".

Children's Heart Federation, response to consultation

"We believe the rationale and evidence for the proposals to concentrate expertise on a smaller number of sites to be in the best interests of children and their families".

Royal College of Paediatrics and Child Health, response to consultation

[31] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p34

"We support both the case for change and the new standards proposed as we believe that this will deliver the safest and highest quality care and best outcomes for children … We support the proposal to concentrate expertise in fewer centres to help ensure that every young person receives the highest quality of care, regardless of where they live".

British Heart Foundation, response to consultation

"The British Congenital Cardiac Association remains supportive of the underlying principles of the review and in particular the need for fewer centres performing larger volumes of congenital cardiac procedures to improve the quality of care provided by the whole cardiac service".

Council of the British Congenital Cardiac Association, response to consultation

RECOMMENDATION 1:

The JCPCT is advised to agree that the need for change to the way in which children's congenital heart services in England are planned and delivered remains compelling, and that the case for change supports the proposals set out in this document.

07 Five key principles

For the purpose of consultation the JCPCT offered five key principles under-pinning the proposals:

- **Children**: the need of the child comes first in all considerations
- **Quality**: all children in England and Wales who need heart surgery must receive the very highest standards of NHS care
- **Equity**: the same high quality of service must be available to each child regardless of where they live or which hospital provides their care
- **Personal service**: the care that every congenital heart service plans and delivers must be based around the needs of each child and family
- **Close to families' homes where possible**: other than surgery and interventional procedures, all relevant cardiac treatment should be provided by competent experts as close as possible to the child's home

The JCPCT is referred to pages 18–29 of the Ipsos Mori 'quantitative' report for a detailed understanding of respondents' views. In summary, Ipsos Mori reports that there was agreement with the principles overall.

> *"Among those who answered these questions, there was strong agreement, particularly with the principles on Children, Quality, Equity and Personal Service. Of those answering the question, around nine in ten agreed.*
>
> *Views toward the fifth principle, that treatment should be close to families' homes where possible, were less positive than for the other four principles, though a majority still agreed.*
>
> *The majority of organisations did not give an opinion… However, levels of agreement were relatively consistent across all five principles, and very few organisations disagreed with each principle"*[32].

In respect of the principle that received the least support (close to families' homes where possible) Ipsos Mori reported:

> *"More respondents commenting on the principles referred specifically to this principle than to any other and their responses suggested that many of those disagreeing with it were particularly concerned that surgery and interventional procedures had been excluded from the commitment to treatment close to home. They agreed that all relevant cardiac treatment should be provided as close to home as possible but also thought that this should apply to surgery and other interventions"*[33].

The concerns that are reported by Ipsos Mori touch upon the JCPCT's proposed model of care and quality standards. A more detailed consideration of the evidence submitted about these elements of the consultation are set out in chapters 8 and 9 of this document but in summary, there was significant support for the model of care and the standards.

Ipsos Mori also reported in respect of this principle that:

> *"The majority of comments made related to travel issues. Of these, most said that ease of access or the location of services or short travel was necessary, important or paramount, while some said that travelling should be minimised to reduce distress or risk to the child's life, or that it is negligent to force a patient to travel long distances for treatment".*

The concerns reported here by Ipsos Mori relate to issues of convenience and travel. A more detailed consideration of the evidence submitted about these elements of consultation are set out in chapter 12 and Appendix R of this document.

RECOMMENDATION 2:

The JCPCT is advised to agree that there is overall support for the key principles that underpin the development of proposals for change.

[32] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p18

[33] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p28

Congenital heart networks

08

Background

Professor Sir Ian Kennedy's panel concluded that the current model of care is fragmented. While there are some examples of good practice, networks are not generally formalised, are not well coordinated and quite often have developed around personal relationships.

> "Too often centres seemed at a loss about the complex relationships that must be made and developed to make a network successful. There was perhaps a general feeling that networks are 'something that happen to you' rather than as an outcome of a well thought out and well managed strategy'.
>
> "Formal arrangements must address care pathways, sharing of data, training, governance and audit trails and working relationships between the various services in the network".
>
> Report of **Professor Sir Ian Kennedy**, December 2010

This is unsatisfactory in that it can lead to a disjointed service for children with congenital heart disease. While some children can receive their cardiac assessment and follow-up care from children's heart experts at their local hospital, some have to travel longer distances to receive this care from a surgical unit. This results in longer travel times for some families, and means that some surgical units are providing care that could be provided locally.

Parents have consistently said at engagement events that the various NHS services that see children with congenital heart disease should work together better. The JCPCT has proposed that if the services across the child's pathway of care were better coordinated, worked more collaboratively in the provision of care and research and communicated with each other more effectively, this would lead to a better quality, more accessible service for children and their families.

Better regional networks would also facilitate a national network of designated surgical units, working together to share learning, best practice and innovation.

The proposed model of care

The professional associations represented on the *Safe and Sustainable* steering group recommended the development of managed clinical networks across the country that would deliver an integrated and coordinated approach to the care of children with congenital heart disease. This would be achieved by the implementation of common protocols within defined patient pathways, with clear accountability and governance structures.

08 Congenital heart networks

The JCPCT consulted on proposals to establish regional networks of linked hospitals working together to pool expertise and experience.

The JCPCT suggested that these managed clinical networks – "Congenital Heart Networks" – would comprise all of the NHS services that provide care to children with congenital heart disease and their families, from antenatal screening and maternity services through to the transition to services for adults with congenital heart disease.

It was proposed in consultation that Congenital Heart Networks would comprise three main elements of service provision, though network groups (chaired by a senior clinician and comprising clinicians from across the network) would also ensure that other relevant services such as antenatal screening, child health services, psychology services and GP services are encompassed.

District Children's Cardiology Services: non-interventional assessment and ongoing care led by Consultant Paediatricians with Expertise in Cardiology

Children's Cardiology Centres: a tertiary specialist service led by Consultant Paediatric Cardiologists providing more complex non-interventional care; it was proposed for consultation that CCCs would not deliver diagnostic catheterisation

Specialist Surgical Centres: a quaternary service comprising Consultant Congenital Cardiac Surgeons, Consultant Paediatric Cardiologists and a specialist medical team providing surgery, interventional cardiology and diagnostic catheterisation as well as assessment and routine care

Respondents were asked to indicate the extent to which they supported or opposed the proposal to develop Congenital Heart Networks.

Personal respondents:
77% support / 4% oppose

Organisations:
85% support / 4% oppose

Source: Ipsos Mori[34]

Ipsos Mori reported that[35]:

"Support for Congenital Heart Networks was relatively high across the majority of the different sub-groups responding to the public consultation, with very few differences"

"We strongly support the principle of commissioning whole patient pathways, and for teams to work in a clinical networked arrangement".

Royal College of Paediatrics and Child Health, response to consultation

Of the specific comments received Ipsos Mori reported[36] a concern that 'some areas may be left without adequately trained cardiologists' based on a concern that expertise may naturally flow to bigger units that undertake interventional work. Such concerns relate to the viability of the proposed Children's Cardiology Centres, on which the Steering Group's advice is set out later in this document.

[34] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, pp 30 and 32

[35] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p 35

[36] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p 35

Respondents' views on the proposals for District Children's Cardiology Services

The JCPCT proposed for consultation that a District Children's Cardiology Service would be based in a local hospital that has a larger maternity unit with over 3,000 births a year (larger units were proposed because of the need to ensure that specialised children's services are seeing enough children each year to maintain and develop specialist skills).

It was proposed that the services would be led by Consultant Paediatricians with Expertise in Cardiology who would work directly with a named Consultant Paediatric Cardiologist from the Surgical Centre or Children's Cardiology Centre. This would include shared clinics held in the local hospital.

Paediatricians with Expertise in Cardiology would provide all-round non-interventional care for children with congenital heart disease in local hospitals, including the diagnosis of the presence of congenital heart defects and the ongoing treatment and management of children with heart problems in liaison with the tertiary services in their networks.

Paediatricians with Expertise in Cardiology are competent in electrocardiography and echocardiography and have an understanding and awareness of non-invasive imaging, cardiac catheterisation, interventional cardiology, electrophysiology and different surgical operations in congenital heart disease. Paediatricians with Expertise in Cardiology also play an important role in the education of other professionals who work in paediatric cardiology networks and in supporting paediatric colleagues in decision making around cardiac issues within a number of specialties as well as general paediatric and neonatal settings.

Although there are a number of Paediatricians with Expertise in Cardiology working in cardiology networks at the moment, the NHS has not previously sought to develop their work in a coordinated way. The Royal College of Paediatrics and Child Health and the British Congenital Cardiac Association have introduced a joint curriculum[37] that sets out training standards for paediatricians wishing to become PECs, and the *Safe and Sustainable* review has worked closely with both organisations to explore how best to strengthen the role of Paediatricians with Expertise in Cardiology in Congenital Heart Networks in the future.

> "We are highly supportive of the concept of a Paediatrician with Expertise at District General Hospitals with support from a Cardiac Liaison Nurse. This is central to the delivery of a District Children's Cardiology Service (DCCS). A DCCS should be available at every DGH with a children's ward and paediatric A&E and should be within one hour travel by road… Whenever possible, routine appointments, tests and treatment should be undertaken at the DCCS local to the family".
>
> **Parent representatives** of the former South East Zonal Group, response to consultation

[37] Curriculum for Paediatrician with Special expertise in Cardiology

08 Congenital heart networks

Respondents were asked to indicate the extent to which they supported or opposed the proposal to increase the role of Paediatricians with Expertise in Cardiology in District Children's Cardiology Services.

Personal respondents:
51% support / 24% oppose

Organisations:
72% support / 12% oppose

Source: Ipsos Mori[38]

Ipsos Mori reported[39] a '*clear difference in opinion between patients and clinicians*'. While 22% of respondents with congenital heart disease opposed the proposal, this reduced to 11% of respondents who were carers of people with CHD.

Strong regional differences were also reported, with 75% of respondents from Yorkshire and Humber opposing the proposal but 74% of respondents from the North-East supporting the proposal.

Ipsos Mori reported that some respondents expressed concern that Paediatricians with Expertise in Cardiology '*would not be an adequate replacement*' for a cardiologist, whereas the JCPCT and steering group members envisage that they would complement the role of the cardiologists, not replace them. Other respondents expressed concern that the consultation document proposes that services would comprise a single Paediatrician with Expertise in Cardiology rather than a team which would be regarded as a more resilient approach to the delivery of care.

Interestingly, Ipsos Mori also reported that some parents who were existing users of congenital heart services had limited confidence in the ability of local services (which could be interpreted as a basis for supporting the proposal to improve and develop local services) but that in fact this experience had made them sceptical about the proposals to develop non-surgical services locally:

> "*The lack of confidence felt by many parents in the discussion groups and interviews was underpinned by low levels of confidence in local services … Their lack of trust in local hospitals and GPs influenced their attitudes towards the proposed networks, and some feared that they would have to rely on professionals who would not understand their child or the condition and who were risk-averse and thus unable to provide adequate treatment*[40]".

Respondents' views on the proposed Children's Cardiology Centres

The JCPCT proposed for consultation that centres that are currently providing children's heart surgery and that are not designated as surgical units in the future may become Children's Cardiology Centres. The centres would act as tertiary referral units for a designated Surgical Centre and would work to equally high standards (to be developed) to ensure a consistent service for children. These centres would also be linked to the District Children's Cardiology Services in their networks.

It was proposed that Children's Cardiology Centres would be led by trained and experienced Consultant Paediatric Cardiologists and would provide a specialist tertiary service, including outreach clinics and a

[40] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Qualitative research with parents and young people using congenital heart services and Black and Minority Ethnic groups*, 2011, p 63

24/7 emergency service. Their teams would perform the full range of non-interventional inpatient and outpatient care for children with congenital heart disease.

Children's Cardiology Centres would provide a 24/7 service so that urgent care can be provided out of hours where necessary.

Respondents were asked to indicate the extent to which they supported or opposed the proposal that units not designated for surgery in the future may become Children's Cardiology Centres.

Personal respondents:
49% support / 12% oppose

Organisations:
62% support / 11% oppose

Source: Ipsos Mori[41]

Ipsos Mori reported that opposition to the proposal was higher among respondents with prior experience of two surgical units that had not appeared as 'preferred centres' in any of the JCPCT's four options for consultations: the Royal Brompton Hospital and the John Radcliffe Hospital.

A number of respondents expressed concern that the more senior and experienced cardiologists would gravitate to specialist surgical units.

"The need to ensure that the general public / patients and their families recognise the Children's Cardiology Centres as centres of expertise. Many patients will receive the majority of their care within a Cardiology Centre and be transferred to a specialist surgical centre for their surgical episode only. It is therefore important that these patients feel confident that they are receiving the best possible treatment and care and are not under the impression that all of the expertise is concentrated within the surgical centre".

Central Manchester University Hospital NHS Foundation Trust, response to consultation

Ipsos Mori also reported that some respondents believed that in practice there would be no difference between a Children's Cardiology Centre and a local hospital. This proved to be a lively debate during consultation, including amongst health professionals, particularly within the context of the extent to which Children's Cardiology Centres would be able to provide diagnostic catheterisation.

[41] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p 40

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Respondents were asked to indicate the extent to which they supported or opposed the proposal that in the future interventional cardiology should be provided only by designated Specialist Surgical Centres.

Personal respondents:
57% support / 10% oppose

Organisations:
75% support / 7% oppose

Source: Ipsos Mori[42]

While there was majority support for the proposal that in the future interventional cardiology should continue to be provided only by designated surgical units, a more contentious proposal made by the JCPCT for consultation was that the delivery of diagnostic catheterisation be restricted to surgical units given the small risk of an emergency requiring surgical support.

The concerns expressed by a number of respondents can be summarised by the response to consultation by the Oxford Radcliffe Hospitals NHS Trust:

> '*The proposals for Children's Cardiology Centres are not well-developed and it is not clear whether these centres would be sustainable in the way that the proposals envisage. Firstly, there is ambiguity about what procedures would be undertaken at the CCCs … If all catheterisation procedures are deemed to require on-site surgical cover, the CCCs would be able to offer very little in the way of diagnosis and treatment beyond echocardiography and simple medical management … Such centres are unlikely to attract referrals in the long-term and would be unlikely to attract or retain key staff*'.

> "Ultimately what keeps their children safe is the network; and I think there's been a very good demonstration this evening of how a network can work together. What I think has been missing from the *Safe and Sustainable* process is any clear vision of what they mean by a world class tertiary centre that doesn't do surgery".
>
> **Mr Marcus Haw**, Consultant Congenital Cardiac Surgeon, Southampton consultation event

The potential role of Children's Cardiology Centres was discussed at a meeting in July 2011 between the *Safe and Sustainable* steering group and around 50 members of the British Congenital Cardiac Association. At this meeting the Scottish experience was discussed: on the one hand it was suggested by some participants that few clinical staff had chosen to re-locate after the centralisation of child heart surgical services to Glasgow in 2000. Initially diagnostic catheterisation had continued in Edinburgh, but this had then ceased a few years later and no invasive investigation or treatment now occurs outside the surgical centre in Glasgow.

On the other hand, participants referred to the cardiology centres in Cardiff and Manchester as being examples of how the model works in practice. The Cardiff cardiology service has existed without cardiac surgery for 12 years, and has grown from two to four cardiology consultants. It was suggested that the

[42] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p 39

Cardiff centre offers a comprehensive cardiology service in close partnership with the cardiac surgical unit in Bristol. Although Cardiff had ceased diagnostic catheterisation, the lead cardiologist from that centre explained that this was attributable to the surgical unit in Bristol developing an ability to provide outreach septostomy in emergencies, and in his view it was possible for Children's Cardiology Centres to carry out low-risk catheters without on-site surgical back-up.

In September 2011 Steering Group members received advice from Professor Shakeel Qureshi, President of the British Congenital Cardiac Association (at the time) that revised guidance from the BCCA would recommend that interventional cardiology services for children should only be performed in designated surgical centres, but that diagnostic catheterisation may be performed in the proposed Children's Cardiology Centres in view of the lower risk of a cardiologist requiring immediate assistance from a surgeon.

Respondents' views on the proposed Specialist Surgical Centres

The JCPCT proposed for consultation that a Specialist Surgical Centre would be responsible for leading each congenital heart network, working to ensure that services are better coordinated and working to common protocols.

The standards on which the JCPCT consulted would require Specialist Surgical Centres to be sufficiently staffed and equipped to provide emergency care around the clock.

For children who live close by, a Specialist Surgical Centre would also provide assessment and routine care.

Ipsos Mori reported[43] that '*the need for 24/7 care in each of the Specialist Surgical Centres generated the highest level of support among both personal and organisation responses*'.

During public consultation respondents were asked 'Please indicate the extent to which you support or oppose the statement that there is a need for 24/7 care in each of the Specialist Surgical Centres'.

Personal respondents:
94% support /
< 1% oppose

Organisations:
94% support /
< 1% oppose

Source: Ipsos Mori[44]

As reported in more detail in chapter 9, Ipsos Mori also reported strong support for the proposed standards for Specialist Surgical Centres. Over 90% of personal respondents and organisations supported the standards generally, and 89% of personal respondents and 93% of organisations supported the specific standards under the heading of 'Specialist Surgical Centres'[45].

[43] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p 36

[44] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p 36

[45] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, pp 44 to 54

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Summary of advice to the JCPCT from the *Safe and Sustainable* Steering Group

1 Having taken into account the evidence submitted during consultation, Steering Group members have advised the JCPCT that the proposed model of care is a viable proposition. This includes the development of District Children's Cardiology Services and Children's Cardiology Centres. The Steering Group members are mindful of existing precedents such as the successful transition of the Cardiff centre from a surgical centre to a non-interventional centre in the last decade.

2 The Steering Group advises the JCPCT that while interventional cardiology must only be provided in designated surgical units as proposed by the standards, the JCPCT should amend the proposed model of care to allow for diagnostic catheterisation to be carried out in the proposed CCCs in line with BCCA guidance.

3 The Steering Group also advises the JCPCT that further work will be required during implementation to establish appropriate governance arrangements across the network and to develop standards against which the District Children's Cardiology Services and Children's Cardiology Centres will be monitored.

> "The consultation document is silent about how the recommended options would provide at least equivalent levels of paediatric electrophysiology services".
>
> **The Ben Williams Trust**, response to consultation

4 The Steering Group has also advised the JCPCT that the provision of electrophysiology can be delivered outside of a designated surgical centre provided that the local congenital heart network has developed clear protocols, including a consideration of local governance arrangements, and that local network governance arrangements determine the size and weight parameters for undertaking interventional electrophysiology on children without paediatric surgical backup. Steering Group members emphasise that children requiring electrophysiology should be seen in dedicated children's services, not adult services as is current practice in some parts of the country. It is recommended that this advice is reflected in future standards for Children's Cardiology Centres.

5 Although Children's Cardiology Centres are considered to be viable, the Steering Group was mindful of the potential risks to ensuring the sustainability of the Children's Cardiology Centres as described by a number of respondents during consultation. Steering Group members endorsed the JCPCT's analysis of the potential risks as set out in the pre-consultation business case and they highlighted that mitigation will be a key issue for implementation:

The pre-consultation business case reads:

Although there are precedents for this model of care (existing Children's Cardiology Centres at Manchester, Edinburgh and Cardiff support nearby surgical centres) one of the key challenges for the NHS in the implementation phase of Safe and Sustainable is how to manage the transition from surgical unit to non-surgical unit and the potential movement of key staff away from these centres. A further challenge for the leadership of the Congenital Heart Networks is to ensure that staff and patients of the Children's Cardiology Centres do not consider these units to have been 'down graded' in any way. This will be an immediate challenge, but also over time as new cohorts of children receive their operations at the newly designated surgical centres, the cohort of children previously operated on at the Children's Cardiology Centres mature and transition to adult services and local hospitals gradually shift their referral patterns for acutely ill children. The risk is that this perception could cause reluctance amongst clinical staff to care for complex cardiac patients, with a resulting reduction in the skill level and experience of clinical staff. However, the establishment of robust Congenital Heart Networks with good collaborative working across the services would mitigate against these risks[46].

Co-location of paediatric cardiac surgical services with other essential paediatric services

While there was strong support for the designation of surgical units against the proposed standards, there was some debate about the interpretation and application of the standards which require the 'co-location' of children's heart surgical units with other key paediatric services.

1 Requirements of the Framework of Critical Interdependencies

The standards propose, in the interests of safety and good clinical outcomes, that Specialist Surgical Centres must be co-located with four specialised paediatric services identified by the *Framework of Critical Interdependencies* (*the Framework*): ENT (Airways), paediatric surgery, paediatric critical care and paediatric anaesthesia.

The *Framework* was published in 2008 by an expert working group established by the Department of Health. It was the outcome of a comprehensive review and analysis of the critical inter-dependencies across specialised paediatric services. This work produced, for the first time, a framework of interdependencies which identifies the various levels of co-dependency between 23 specialised paediatric services and sets out how these relationships need to be taken into account when commissioning services or when proposing changes to service delivery. The *Framework* was endorsed by the relevant Royal Colleges and professional associations.

The *Safe and Sustainable* standards refer to co-location 'as defined by' the *Framework*.

> *"Co-location in this context was defined as meaning either:*
>
> *location on the same hospital site; or*
>
> *location in other neighbouring hospitals if specialist opinion and intervention were available within the same parameters as if services were on the same site"*

[46] *Safe and Sustainable, Review of children's congenital cardiac services in England – pre-consultation business case*, 2011. p 37

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A number of respondents to consultation proposed an interpretation of the term 'co-location' that would require co-location of the relevant services on a single site.

The British Congenital Cardiac Association wrote:

> '*For* [paediatric cardiac surgical] *services at each centre to remain sustainable in the long term, co-location of key clinical services on one site is essential*'.

The Paediatric Intensive Care Society wrote:

> '*It is clear to us that the individual centres do differ significantly in their ability to meet the co-location standards. We would dismiss any suggestion that a service located on another hospital within the same city can be regarded as being equivalent to a service located on the same hospital site … The designation of a provider that does not meet the co-location requirements should only be considered if there is a clear plan to establish co-location of specialist paediatric services within a short and defined time scale*'.

> "I would like to have some discussion around the issues of co-location on the same site as other essential paediatric sub-specialties and specifically that some of the centres that are included within some of the options do not actually meet the core co-dependencies that are required".
>
> **Dr Kevin Morris**, President of the Paediatric Intensive Care Society, Birmingham consultation event

The Royal College of Paediatrics and Child Health did not suggest that co-location of all services on one-site was necessary, but it wrote:

> '*We emphasise the importance of considering very carefully in decision making the requirements for co-location of critically interdependent services … We strongly recommend that the JCPCT review the options with respect to compliance with the service standards and seek assurances that these can be met*'.

If an absolute definition were applied, three of the surgical centres would be unable to meet the co-location requirements and the corresponding *Safe and Sustainable* standards given the location of some of these services on a different site to the surgical unit.

Provider	Location of paediatric cardiac surgical services	Location of specialised paediatric surgical services	Location of Ear Nose Throat (Airway) services
Newcastle upon Tyne NHS Foundation Trust	Freeman Hospital	Great North Children's Hospital	Freeman Hospital
University Hospitals of Leicester NHS Trust	Glenfield Hospital	Leicester Royal Infirmary	Leicester Royal Infirmary
Royal Brompton & Harefield NHS Foundation Trust	Royal Brompton Hospital	Chelsea & Westminster Hospital	Chelsea & Westminster Hospital

Alternative advice was offered to the JCPCT by these centres[47]:

"The PICS Council appear to us to be confusing quality of outcomes with absolute co-location. The implication of their response is that absolute physical co-location of all interdependent services is essential for high quality care and good clinical outcomes to be delivered, beyond that specified in the [Framework]. Our experience is that the quality (including timescale) of other specialities' input to paediatric cardiac patients is much more important and influential on the ultimate outcome than is absolute physical co-location".

Newcastle-upon-Tyne Hospitals NHS Foundation Trust[48]

"Royal Brompton enjoys an advantageous relationship with the Chelsea & Westminster Hospital in the form of fixed service level agreements. C&W is 10 minutes walk from Royal Brompton, less time than it takes to cross the campus at many a larger hospital and certainly less time than it takes to reach, for example, the Evelina from Guy's or Lewisham Hospital, the Freeman Hospital from the Royal Victoria Infirmary or Leeds General Infirmary from St James' Hospital in Leeds".

Royal Brompton & Harefield NHS Foundation Trust, response to consultation

The response to consultation by the chair of the working group that developed the *Framework*, Professor Edward Baker, deserves some attention. While on the one hand Professor Baker suggests that "*co-location was defined very precisely*" in the *Framework* he goes on to acknowledge that the definition applied by the *Framework* is not an absolute one that necessarily envisages co-location on the same site. He writes "*the [*Framework*] makes it clear that a co-located service is either in the same building or it is available within the same parameters as if services were on the same site*". Professor Baker offers a personal view that this could mean "*a paediatric surgical team based in a neighbouring building*" but not "*a visiting surgical team being available within a nominal 15 minutes across town*". Professor Baker thus acknowledges that the working group's definition of co-location requires a degree of subjectivity in interpretation.

[47] See pages 3-4 of the response from University Hospital Leicester NHS Trust for a detailed account of the co-location of interdependent paediatric services as perceived by the Trust

[48] Letter to secretariat dated 11 August 2011

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In August 2011 the JCPCT asked Professor Kennedy's panel[49] to respond to suggestions that the panel had incorrectly applied the definition of 'co-location' as set out in the *Framework* and asked the panel to clarify the extent to which the three surgical centres meet the requirements for co-location.

Having considered relevant evidence submitted during consultation the panel advised the JCPCT in October 2011 that it was content that it had correctly applied the term 'co-location' as it appears in the *Framework*. The panel reminded the JCPCT that it had previously advised that the co-location of services on a single site was optimal (and that the extent to which this 'gold standard' was met was reflected in each centre's score as awarded by the panel), and further advised:

> '*In response to the representations made to the JCPCT during consultation to the effect that the intention of the Framework was to define 'co-location' as meaning 'immediately adjacent' (or such equivalent) the panel members note that the Framework does not state this either explicitly nor sufficiently through the context and by implication. In the panel's opinion the use of the words 'neighbouring' and 'within the same parameters' and references to 'job plans and on-call rotas' invites a subjective consideration of the meaning of 'co-location' that encourages an interpretation not limited to that which is 'immediately adjacent*'.

The panel advised that the services at the Freeman Hospital and the Royal Brompton Hospital met the requirements of co-location as they are '*sufficiently close to the paediatric cardiac surgical services to fall 'within the same parameters' required by the critical interdependencies framework*'.

The panel advised that the service at Glenfield Hospital did not meet the standards in this respect.

> *'The panel was not persuaded that the ENT service at the Leicester Royal Infirmary is sufficiently close to the paediatric cardiac surgical service at Glenfield Hospital to ensure that service delivery would not be impaired by being on a different site. The panel therefore reiterates that University Hospitals of Leicester NHS Trust does not meet the co-location requirements and notes with some concern that the Trust saw no reason to remedy this situation.*
>
> *The panel wishes to emphasise that their conclusions in this respect are not based solely on a consideration of distance and travel times. Where services were not on the same site the panel also took account of staff rotas and job plans and the extent to which there is a need for an immediate response from the relevant clinical service. In the panel's opinion a differentiating factor between the centres is that ENT services are considered by the panel to be more 'time critical' than other relevant interdependent services.*
>
> *Taking all of this evidence into account, the panel concluded that the ENT service in Leicester cannot be regarded as being 'co-located' despite the fact that the services which are not on the same site are roughly the same distance away in both Leicester and Newcastle. The Royal Brompton Hospital's ENT service is much closer to the paediatric cardiac surgical service than it is in Leicester, and as such it does, in the panel's opinion, meet the co-location requirements of the critical interdependencies framework'.*

[49] Professor Kennedy's panel includes Julia Stallibrass MBE, former Deputy Director of National Specialised Commissioning, who was also a member of the working group that wrote the Critical Interdependencies Framework

2 Co-location with other services not identified by the *Framework*

A number of respondents to consultation suggested that the standards and model of care should provide for the co-location of the surgical unit on a single site with fetal, obstetrics, maternity, neonatal and general paediatric services. This is particularly relevant to the location of the delivery of babies who have been antenatally diagnosed with congenital heart disease and the immediate care needs of the baby and mother after delivery. Ipsos Mori reported[50] that "*Parents of children with multiple chronic conditions [who took part in the focus groups] stressed the value to them of having all of the relevant specialists in a single hospital. These parents felt that this was of critical clinical importance to them*".

Of the current 11 surgical centres, 3 centres have all of these services co-located with paediatric cardiac surgical services: Leeds Teaching Hospital, the John Radcliffe Hospital and Southampton General Hospital.

> "If fetal cardiac centres are not co-located with maternity services this will have a detrimental effect on holistic prenatal diagnosis … the gold standard for women carrying a baby with a congenital heart anomaly should be to deliver in a hospital with a cardiac surgical unit on site or very close to the site".
>
> **British Maternal & Fetal Medicine Society**, response to consultation

> "It is highly desirable to have prenatal diagnostic services on the same site as feto-maternal medicine, neonatal and paediatric services. If these departments are also in a hospital where cardiac surgery and the full range of cardiovascular services for adults (including pregnant or recently delivered women with congenital heart disease) exist, there is the scope for extremely closely coordinated specialist care. This important aspect of clinical interdependence does not appear to have been considered in the review".
>
> **Oxford Radcliffe Hospitals NHS Trust**, response to consultation

> "There is reason to believe that the presence of a co-located neonatal intensive care unit can improve the welfare of a critically ill newborn and possibly reduce mortality of this very vulnerable group".
>
> **Southampton University Hospital NHS Foundation Trust**, response to consultation

A number of consultation responses from Yorkshire and The Humber gave emphasis to '*the genuine synergy of the co-located services at Leeds General Infirmary*'[51] compared to the situation in Newcastle where neonatal, paediatric and maternity services are located on a different hospital site to paediatric cardiac surgical services.

[50] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Qualitative research with parents and young people using congenital heart services and Black and Minority Ethnic groups*, 2011, p 39

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"The great strengths of the co-location of services within Leeds have not been considered adequately. Leeds is able to provide all of the elements of the patient pathway on a single site, from in-utero transfer of the fetus with an antenatal diagnosis to delivery of the baby, cardiology assessment, cardiac surgery and ongoing care for intercurrent problems, to care of the adult with congenital heart disease and the specialised care of pregnant mothers who have CHD themselves. In addition, care for children with multiple congenital abnormalities is provided on the same site".

Paediatric Critical Care Network, North, East and West Yorkshire, response to consultation

"Maintaining the 'gold standard' of children's services all under one roof [at Leeds General Infirmary] is very important to our families. Many have expressed dismay that a move to Newcastle or Leicester would signal a step back in care to a 'stand alone heart hospital' … This issue is of particular importance to our significant number of BME families because of the increased likelihood of children from this ethnic background to call upon the other paediatric services".

Children's Heart Surgery Fund, response to consultation

"Leeds General Infirmary have already invested £90m to achieve multi-disciplinary practice for cardiac services under the one roof and it is the only cardiac centre in the UK with all relevant specialities on one site[52] – paediatrics, neonatology, adolescents and adult cardiac services. Leeds also has an established cardiology network with extensive outreach".

Dr Aiwyne Foo, Consultant Paediatrician, on behalf of paediatricians at Chesterfield Royal Hospital, response to consultation

The JCPCT did not, for the purpose of consultation, propose co-location of these services with paediatric cardiac surgical units. For example, with regard to maternity and obstetric services the standards propose that services within the Congenital Heart Network would plan and deliver services in close collaboration with each-other and with the parents[53]

[51] Response from Dr Carrie MacKenzie on behalf of the Yorkshire, Humber and North Trent Paediatric Cardiology Clinical Network

[52] The statement that Leeds is the 'only' such unit is incorrect

Standard B3 – Each specialist surgical Centre will agree and establish protocols with feto-maternal medicine units and tertiary neonatal units in their Congenital Heart Networks for the care and treatment of pregnant women whose foetus has been diagnosed with a major heart condition.

Standard B8 – At diagnosis [of CHD antenatally] a plan should be agreed between the Specialist Surgical Centre, the specialist feto-maternal unit, the local obstetric unit, the neonatal team, paediatricians and the parents about arrangements for the delivery of the baby. The plan should be updated throughout pregnancy.

Standard B9 – In all cases where a baby is likely to require immediate post-natal intervention or surgery the parents must be given the choice of delivering the baby either at or close to the Specialist Surgical Centre if necessary

Standard B10 – If the plan is for the delivery of the baby at the local maternity unit this should include arrangements for the transfer of the mother and baby to the Specialist Surgical centre if early intervention or assessment is required.

While co-location of these services on a single site was not proposed in consultation, the assessment process allowed surgical units to demonstrate the extent to which they met the 'gold standard' of co-location of these services on a single site and for such compliance, to the extent that it was found, to be reflected in each centre's score as awarded by Professor Kennedy's panel.

With regard to neonatal intensive care and general paediatrics, the proposed standards require these services to be 'co-located' with paediatric congenital cardiac surgical services as defined by the *Framework*.

3 Co-location of paediatric congenital heart services with adult congenital heart services

The standards on which the JCPCT consulted did not propose the co-location of paediatric cardiac surgical services with services for adults with congenital heart disease (neither did the draft standards for adult congenital heart services developed by a separate working group in 2009 propose co-location with paediatric services).[54]

Rather, the standards address the need for a good transition to adult services via a 'seamless pathway of care led jointly by paediatric and adult cardiologists'.[55]

> "A seamless transition from paediatric to adult services is optimal for the patient but this does not necessitate the co-location of paediatric and adult services. More important is the quality of the different services and how they relate to each other".
>
> Report of **Sir Ian Kennedy**, December 2010

Some respondents emphasised the perceived benefits of co-location of adult and paediatric congenital heart services on one site. These responses tended to be made by respondents who were associated with, or who had experience of, a hospital that delivers both adult and paediatric services from the same site.

[53] See also standards C36, C37 and C38, National Specialised Commissioning Team, Safe and Sustainable: Children's Congenital Cardiac Services in England Service Standards, March 2010. Available at: www.specialisedservices.nhs.uk/library/30/Paediatric_Cardiac_Surgery_Standards_1.pdf

[54] National Specialised Commissioning Group, Designation of Specialist Service Providers for Grown-Ups with Congenital Heart Disease (GUCH) / Adults with Congenital Heart Disease (ACHD) (Including National GUCH service specification Standards), 2009. Available at: www.specialisedservices.nhs.uk/document/designation-specialist-service-providers-grown-ups-with-congenital-heart-disease-guch-adults-with-co-1/search:true

[55] Standard D7, National Specialised Commissioning Team, Safe and Sustainable: Children's Congenital Cardiac Services in England Service Standards, March 2010. Available at: www.specialisedservices.nhs.uk/library/30/Paediatric_Cardiac_Surgery_Standards_1.pdf

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"It is easier to achieve better continuity of care if young adults are dealt with at a clinic attended by what is widely seen as the strongest team of ACHD specialists in London, as well as by the paediatricians who have looked after them throughout their lives and who are well known to them and their families".

Royal Brompton & Harefield NHS Foundation Trust, response to consultation

"Due to the co-location of services on the Leeds General Infirmary site there is a seamless transition of care for those with congenital heart conditions … It is not clear how the Safe and Sustainable review will account for the impact on adult congenital cardiac services, but the co-location of these services is recognised by the experts and the patients as an advantage".

Leeds Teaching Hospital NHS Trust, response to consultation

"ACHD services are co-located [at Southampton General Hospital] with paediatric cardiology providing a seamless integration of congenital cardiac services. Congenital surgeons do not have to be away working at two sites".

Southampton University Hospital NHS Foundation Trust, response to consultation

Some respondents have also suggested that the minimum threshold of 400 surgical procedures per year at each centre should be measured with reference to paediatric and adult congenital surgical procedures, rather than to just paediatric procedures as proposed in consultation:

"In Leeds the same surgeons treat both children and adults with congenital heart disease on the same site and there is continuity of care for patients from childhood through into adulthood. With three surgeons in post, in 2010 there were 392 surgical procedures (adults and children combined) undertaken at the current surgical centre in Leeds. By considering the number of paediatric and adult cardiac surgical procedures in totality, a completely different landscape is provided that significantly affects the number of surgical centres required across the country. Enough to justify retaining another two centres if the suggested minimum number of 400 surgical procedures is applied".

Cllr Lisa Mulherin, Chair of Yorkshire and Humber Joint Health Overview and Scrutiny Committee

It is worth noting in this regard that the *Safe and Sustainable* steering group specifically proposed a minimum of 400 *paediatric* congenital cardiac surgical procedures which it envisaged could be *in addition* to adult congenital cardiac surgical procedures. This proposal was based on the need to avoid the risk of an individual consultant congenital cardiac surgeon – or an individual congenital cardiac centre – undertaking occasional surgical practice with regard to children in circumstances where this could be effectively 'masked' by the adult congenital caseload.

Notwithstanding these comments there was clear majority support for the proposed standards (around 91% of respondents supported the standards) and for the proposed model of care. Having taken account of the evidence submitted during consultation the *Safe and Sustainable* steering group has advised the JCPCT to agree the standards as proposed in consultation.

Patient choice

> "What implications, if any, will the changes have for parents being able to opt for a particular surgical centre".
>
> **Parent**, Cardiff consultation event

> "The options currently available go against natural patient flow and appear to negate the issue of patient choice, as enshrined in the NHS consultation".
>
> **Children's Heart Surgery Fund**, response to consultation

A number of respondents questioned the impact of patient choice to the JCPCT's analysis of potential flows and its assumptions around the configuration of networks in each of the potential options. Ipsos Mori also reported that "*negative reactions to the proposal for a reduction in surgical centres*" from participants in the focus groups with Black and Minority Ethnic Groups "*was underpinned by the perception that the reduction in the number of surgical centres meant a reduction in choice*[56]".

The JCPCT is advised that while there is strong evidence that managed clinical networks – in which all relevant services work to common protocols and care pathways – can bring significant improvements to the way in which care is planned and delivered[57], the JCPCT's proposal for the establishment of congenital heart networks in England is consistent with the principle of patient choice. Congenital Heart Networks will, via a commissioner led process, deliver a planned approach to treatment but not at the expense of patient choice. Some aspects of patient choice would actually be increased as an outcome of the JCPCT's proposals, for example in the development of non-interventional paediatric cardiac services locally.

Although the impact of the exercise of patient choice in the future is difficult to quantify (and so no firm assumptions have been incorporated into the analysis of patient numbers in each of the networks) the JCPCT is advised to take the view that the impact is unlikely to be material to the viability of individual surgical centres and individual networks[58] save for specific potential scenarios that are set out in detail elsewhere in this document (for example, in response to

[56] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Qualitative research with parents and young people using congenital heart services and Black and Minority Ethnic groups*, 2011, p76

[57] For example, the experience the NHS in establishing of stroke and trauma networks and cancer networks

[58] For example, PwC reported that parents / public are likely to accept the recommendation of their referring clinician in the choice of surgical unit for the child

08 Congenital heart networks

the views of respondents in Yorkshire and Humber about assumptions around travel to Newcastle, which were made known during consultation and during the PwC analysis of potential patient flows).

Separate review of services for adults with congenital heart disease

The *Safe and Sustainable* review does not include services for adults with congenital heart disease. Rather, a separate review process is being led by the National Specialised Commissioning Team on behalf of PCTs in England which has included the establishment of an expert advisory group chaired by Professor Sir Roger Boyle CBE, the former National Director for Heart Disease and Stroke.

Although many respondents are of the view that the JCPCT is responsible for the decision to hold two separate reviews, the separate review of adult services precedes the establishment of the JCPCT. It was initiated by the National Specialised Commissioning Group in 2008 with the establishment of an expert working group (the majority of whom were surgeons and cardiologists nominated by the British Congenital Cardiac Association and Society for Cardiothoracic Surgery of Great Britain) tasked with the development of new quality standards for services for adults with congenital heart disease. The group's terms of reference did not include paediatric services.

The group published draft standards in 2009[59]. The standards did not propose the co-location of congenital cardiac surgical services for paediatric and adult patients but it did recommend that the development of the adult standards should not be finalised until a decision had been made on the appropriate standards for paediatric cardiac surgical units[60]. There was thus an early acknowledgement by this group that a decision on the paediatric review would (or should) precede a decision in respect of the review of adult services.

Some respondents have suggested that the two reviews should be combined in view of the perceived commonality in terms of scope and inter-relationships. Yorkshire and Humber Joint Health Overview Scrutiny Committee wrote:

> "*Adult cardiac services and the overall number of congenital cardiac surgical procedures carried out should be considered within the scope of this review and used to help determine the future configuration of surgical centres. As a minimum there should be a moratorium on any decision to designate children's cardiac surgical centres until the review of the adult congenital cardiac services is completed and the two can be considered together*".

The legal powers of consultation and decision making delegated to the JCPCT do not extend beyond services for children with congenital heart disease. Therefore the JCPCT cannot lawfully choose to include services for adults with congenital heart disease within the scope of *Safe and Sustainable*.

The JCPCT could, if it so wished, decide to delay a decision on the future configuration of services for children with congenital heart disease in the expectation of the NHS taking decisions on the separate adult and paediatric reviews at the same time in the future. The current timeline for the adult review assumes that a decision could be made in late 2013 / early 2014 following a period of pre-consultation public engagement, an assessment of centres against

[59] National Specialised Commissioning Group, *Designation of Specialist Service Providers for Grown-Ups with Congenital Heart Disease (GUCH) / Adults with Congenital Heart Disease (ACHD) (Including National GUCH service specification Standards)*, September 2009. Available at: www.specialisedservices.nhs.uk/document/designation-specialist-service-providers-grown-ups-with-congenital-heart-disease-guch-adults-with-co-1/search:true

[60] National Specialised Commissioning Group, *Designation of Specialist Service Providers for Grown-Ups with Congenital Heart Disease (GUCH) / Adults with Congenital Heart Disease (ACHD) (Including National GUCH service specification Standards)*, September 2009. Available at: www.specialisedservices.nhs.uk/document/designation-specialist-service-providers-grown-ups-with-congenital-heart-disease-guch-adults-with-co-1/search:true

compliance with proposed standards and a period of formal public consultation.

In considering whether further delay to concluding the *Safe and Sustainable* review would be considered reasonable by the majority of respondents, and what the implications of a further delay could be to children with congenital heart disease, the JCPCT should be mindful of the public statements that have recently been made by relevant professional associations and national charities which refer to the 'urgent need' to conclude the paediatric review:

> "Changing services is not easy, but the NHS must continue its vital work and make decisions as a matter of urgency to ensure better outcomes for children with congenital heart disease in the future".
>
> **Professor Norman Williams**, President of the Royal College of Surgeons
>
> **Dr David Shortland**, Vice President of the Royal College of Paediatrics and Child Health
>
> **Dr Peter Carter**, Chief Executive & General Secretary of the Royal College of Nursing
>
> November 2011

> "The reconfiguration of congenital cardiac services is long overdue having been recommended over ten years ago following the Bristol enquiry. Any further delay to the conclusion of this process could lead to the lives of children being put at risk as the current service is unable to offer the highest standard of care to all".
>
> **Chief Executive**, Little Hearts Matter, November 2011

Such statements focus on the 'urgent' need to change congenital heart services for children, as distinct to services for adults. Heart surgery and interventional procedures for children are regarded by the experts as being more technically complex than surgery and interventions performed on adults; very sick babies and children intrinsically present more 'high risk' than adults. Notwithstanding a strong view from many professionals that a single review would have been optimal, the pressing need to reconfigure children's congenital cardiac services was no doubt apparent to the clinical members of the *Safe and Sustainable* steering group when, representing their professional associations, they endorsed the decision for separate reviews in 2008[61]. So too did the authors of the *Critical Interdependencies Framework* (a document endorsed by the professional associations) acknowledge in 2008 the relative importance of children's services in this regard in one of their recommendations:

> "*While links to adult specialised services are important, the inter-dependencies between specialised children's services should take precedence*[62]".

[61] See minutes of Safe and Sustainable Steering Group, December 2008

[62] Department of Health, *Commissioning safe and sustainable specialised paediatric services: a framework of critical inter-dependencies*, September 2008, recommendation F, p16

08 Congenital heart networks

The JCPCT should also consider whether support for an emphasis on children's services is evident from the finding by Ipsos Mori that "around nine in ten" respondents (who answered the question) supported the principle that "*the need of the child comes first in all considerations*[63]".

> "I would urge that the Joint Committee proceeds to make its final decision on 4 July, as the Committee believes that the uncertainty of the last eighteen months has been disruptive to the children and their parents, as well as the staff involved in children's heart services. I would hope that the matter can be resolved as soon as possible".
>
> Letter from **Chairman of the Health Scrutiny Committee for Lincolnshire,** 24 May 2012

Although there has been increased criticism of the decision to hold separate reviews as *Safe and Sustainable* has progressed, the JCPCT is advised that there is an acceptance from the professional associations that further delay would present serious risks. The uncertainty around the future configuration of services has caused obvious anxiety and has bred planning blight. It is not true that the JCPCT's decision will pre-determine the outcome of the adult review as this will partly depend on the consideration of issues that are being addressed solely by the adult review. If in the future any changes are proposed to services for adults with congenital heart disease, the NHS will fully consult with the public on any proposed changes.

> "The BCCA position remains that stated after the original poll a number of years ago – we are supportive of the principles of this review because we feel that rationalisation of services represents an opportunity to ensure the best possible future for both patients and professionals serving them. This does not mean that there have not been issues upon which BCCA and the review have disagreed. These have been pointed out consistently and in an appropriate manner to those running the review.
>
> Clearly we are concerned that the process itself was found unlawful in the recent judicial review – this matter will now only be resolved through the appeal process and therefore we see little point in making public statements of any kind other than to point out that the uncertainty has caused severe strain on professionals, patients and families. To avoid further uncertainty this

[63] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p 22

process now needs to be brought to a conclusion as soon as possible.

One of the issues that BCCA consistently campaigned for prior to and then within the paediatric review was a process that took into account the hugely important clinical issue of interlinked services for adult patients with congenital heart disease. This was initially ignored by the review process for reasons that as a clinical association we failed to understand. However towards the end of the paediatric review there was an announcement from the S&S team that there was to be a separate review for ACHD services. We remain nervous that there are potentially serious implications with regard to the separation of the two reviews of congenital heart disease services. However despite this we feel that BCCA must be central in this review".

Newsletter of the **British Congenital Cardiac Association,** December 2011

THE JCPCT IS ADVISED TO AGREE THE FOLLOWING RECOMMENDATIONS:

3 The proposed model of care is viable and will be implemented in England; this will involve establishing a number of congenital heart networks in England; a reduction in the number of hospitals that provide heart surgical services for children; and the development of District Children's Cardiology Services and Children's Cardiology Centres for which standards will need to be developed.

4 Children's Cardiology Centres must not provide interventional cardiology services but may provide diagnostic catheterisation.

5 Electrophysiology services may be provided in dedicated children's services outside of a specialist surgical centre provided the congenital heart network has developed clear protocols.

6 To accept the advice of Professor Sir Ian Kennedy's panel about the panel's application of the term 'co-location' as defined by the *Framework of Critical Interdependencies* in respect of the four services identified by the Framework as needing to be 'co-located'.

7 The requirements for co-location of services as stipulated in the *Safe and Sustainable* standards.

8 That the proposed model of care is consistent with the principle of 'patient choice'.

9 That there is an urgent need to conclude the review of children's congenital cardiac services in England, and that this necessitates making a decision before the separate review of services for adults with congenital heart disease has concluded.

09 The standards

The JCPCT sought views on 156 separate quality standards which had been developed by an expert working group and endorsed by relevant professional associations. The standards were wide ranging, covering the delivery of treatment in the network as well as the surgical unit and addressing the transition to adult congenital services.

Surgical units would be continuously monitored against compliance with the standards. If they are implemented as proposed, the standards would be the mechanism by which major service change to children's congenital heart services – long recommended by experts in the field – will finally be achieved.

- A reduction in the number of surgical units in England via standards that stipulate larger surgical teams (a minimum of 4 consultant congenital cardiac surgeons in each unit) and a minimum caseload of 400 paediatric surgical procedures a year (ideally a minimum of 500 paediatric surgical procedures a year)
- An ability to deliver expert cardiac care in each surgical unit day or night around the clock, including at weekends via standards that provide for larger medical and nursing teams

The standards were set out with reference to seven key themes:

A Congenital Heart Networks
B Prenatal screening and services
C Specialist Surgical Centres
D Age appropriate care
E Information and making choices
F Family experience
G Ensuring excellent care

Ipsos Mori reported that '*amongst those that have responded, there was extremely strong support across each of the seven themes*[64]'. JCPCT members are referred to pages 44 to 54 of the Ipsos Mori report for a detailed analysis of consultation responses.

Respondents in support of the standards as a percentage of those who responded to the question

Surgical Centre	Personal respondents	Organisations
Congenital Heart Networks	91%	93%
Prenatal screening	91%	92%
Specialist Surgical Centres	89%	93%
Age appropriate care	91%	94%
Information and choices	91%	91%
Family experience	92%	93%
Excellent care	93%	94%

[64] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p 44

Although Ipsos Mori reported few negative comments about the proposed standards[65] as a response to the consultation questionnaire, some negative views were reported in the focus groups held by Ipsos Mori with parents and young people who are existing users of congenital heart services, and members of the public from Black and Minority Ethnic groups[66]. For example, "*most participants in this research were opposed to the creation of larger and fewer specialised surgical centres*" *primarily "because they did not believe that the proposals would provide a better quality of service to them than the service already received*[67]".

Some respondents to consultation addressed the evidence for the proposal of a minimum of 4 surgeons and a minimum surgical caseload of 400 paediatric surgical procedures in each surgical unit. These criticisms were reported by Ipsos Mori[68] and were raised at a number of consultation events including by health professionals.

"There is no evidence that supports the proposition that centres larger than 300 cases per annum have any advantages".

Royal Brompton & Harefield NHS Foundation Trust, response to consultation

"We do not support the argument that each centre should undertake a minimum of 400, preferably 500 procedures per annum. We remain convinced that it is possible to provide safe and effective services at lower levels than those suggested by the consultation document and yet meet the higher quality standards proposed for the new service. Oxford [John Radcliffe Hospital] has always met CCAD targets and like every other centre reviewed is regarded as having provided safe services".

and

"Recent research evidence published in the New England Journal of Medicine (Finks J F et al New England Journal of Medicine 2011: 364:2128-37 Trends in Hospital Volume and Operative Mortality for High Risk Surgery) demonstrates that there is no evidence that larger units achieve better outcomes for straightforward procedures but that better outcomes are achieved for rare complex procedures by concentrating expertise in one or two larger centres".

Young Hearts, response to consultation

[65] Evidence received about the interpretation and application of standards relating to the 'co-location' of services is set out in chapter 8 of this report.

[66] Ipsos Mori reported (page 81) that members of the public from Black and Minority Ethnic groups were "more ready to support and accept the evidence around the national quality standards" than parents who are existing users of the service as their responses were "not based on long engagement" with current services but that "their concerns about the consultation reflected the particular needs of their communities for more suitable information, cultural sensitivity when being managed in a health context, and support for the family unit"

[67] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Qualitative research with parents and young people using congenital heart services and Black and Minority Ethnic groups*, 2011, p 8

[68] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p 50

09 The standards

The Pre-Consultation Business Case provides a reminder of the available evidence in this respect:

"A recommendation for the concentration of medical and nursing expertise in smaller centres of excellence providing children's congenital cardiac services was made as far back as 2001 in the report of the public inquiry into paediatric cardiac surgical services at the Bristol Royal Infirmary[69]. Subsequent working groups and reports have endorsed the recommendation, most recently by the Royal College of Surgeons in 2007[70].

The evidence base for ensuring a critical mass of surgical procedures per surgical unit is drawn from other examples in surgery which show that the more frequently a surgeon is performing a particular procedure, the better the outcomes in both morbidity and mortality[71]. Studies also suggest cumulative phenomena within institutions, in that higher-volume surgical units have increasingly better outcomes over time[72].

In recent years many countries have identified concerns around safety and sustainability in their congenital cardiac services for children. A report from Canada states 'a recurring theme across jurisdictions is the positive relationship between volumes of procedures and favourable outcomes[73]'.

The Safe and Sustainable review team asked the Public Health Resource Unit to carry out an independent review of the available literature around the relationship between volume and outcome in paediatric cardiac surgery[74]. The conclusion of this report was that there is an inverse relationship between volume and inpatient hospital mortality which increased with the complexity of the operation.

Two particular studies from that review are worth highlighting. The first was published in 2008 and was significant in that it was based on a study of a large number of operations of more than 55,000 over a period of 17 years[75]. This study concluded that large volume hospitals performed more complex operations and achieved superior results. A further study[76] based on over 32,000 patients found that for more difficult surgical procedures smaller surgical units performed significantly worse.

In 2010 the independent National Clinical Advisory Team (NCAT) undertook a review of the strength of the clinical case for change underpinning the Safe and Sustainable review, including the evidence on which the review has relied. The NCAT report (Appendix P) concluded:

'…there is a good case for reducing the number of units, supported by the available clinical evidence and the need to create sustainable units … NCAT can support the case for reconfiguring paediatric cardiac surgery, reducing the number of cardiac surgery centres'.

AVAILABLE EVIDENCE FOR MINIMUM NUMBER OF SURGEONS

The standards recommend that children's congenital cardiac units are staffed by a minimum of 4 consultant congenital cardiac surgeons.

In 2003 the report of the Paediatric and Congenital Cardiac Services Review Group[77] recommended a minimum of three surgeons in each surgical centre, based on professional consensus.

[69] *Bristol Royal Infirmary Inquiry, Learning from Bristol: The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995*,(The Kennedy Report), HM Government, July 2001

[70] The Royal College of Surgeons of England, *Surgery for children: Delivering a first class service*, London, July 2007

[71] Halm EA, Lee C, Chassin MR. *Is volume related to outcome in health care? A systemic review and methodologic critique of the literature.* Ann Intern Med. 2002; 137:511–520.

[72] Chowdhury MM, Dagash H, Pierro A. *A systematic review of the impact of volume of surgery and specialization on patient outcome.* British Journal of Surgery 2007; 94:145-161.

[73] Ontario Ministry of Health and Long-Term Care (2002), *Specialized Pediatric Services Review, Report of the Minister's Advisory Committee*, 1-36.

[74] Ewart, H. *The Relation Between Volume and Outcome in Paediatric Cardiac Surgery; Public Health Research Unit - A Literature Review for the National Specialised Commissioning Group*, 2009. Available at: www.specialisedservices.nhs.uk/document/developing-model-care

[75] Welke, K. and Diggs, B. et al (2008), *The Relationship between Hospital Surgical Case Volumes and Mortality Rates in Paediatric Cardiac Surgery: a National Sample 1988-2005*. The Annals of Thoracic Surgery, 86, 889-896

[76] Welke, K. et al (2009), *The complex relationship between paediatric cardiac surgical case volumes and mortality rates in a national clinical database.* The Journal of Thoracic and Cardiovascular Surgery, 137, 1133-1140

[77] Department of Health, Paediatric and Congenital Cardiac Services Review Group, January 2001 – December 2003

However, in 2007 the Royal College of Surgeons of England recommended 'four or five surgeons' in each centre[78] *based on the need to concentrate expertise in the interests of quality.*

When considering the available evidence the Safe and Sustainable steering group was mindful that their proposed clinical standards would go beyond the recommendations of the 2003 report by stipulating that:

> *'each surgical centre must provide appropriately trained and experienced medical and nursing staff sufficient to provide a full 24 hour emergency service, 7 days a week within legally compliant rotas*[79]*'*

The minimum of 4 surgeons per team can also be supported by looking at the job plans and available sessions of the surgeons. At all times there should be a surgeon available to be in theatre; a surgeon on-call for emergencies; a surgeon available for outpatient clinics; and a surgeon available to undertake ward rounds. In addition, given the average of 40 weeks at work per year (the remaining time being spent on annual leave, study leave or conducting research), there may only ever be 3 of the surgeons at work, available to cover all of the above positions at any one time. This is thought to be a minimum staffing level to achieve the coverage listed above. In addition, this does not take account of the management duties some surgeons will have, training and mentoring, research interests and audit and governance responsibilities or unavoidable unplanned absence.

Consequently, the JCPCT proposed that four consultant congenital cardiac surgeons – rather than three – is the minimum number required in each centre to ensure safe 24/7 cover within a legally compliant rota. The JCPT also proposed that this number of surgeons would address concerns about appropriate surgical specialisation and succession planning in each centre.

AVAILABLE EVIDENCE FOR MINIMUM ACTIVITY LEVELS

The standards recommend that children's congenital cardiac units must perform a minimum of 400 paediatric cardiac surgical procedures each year, with an optimum minimum activity level of ideally 500 such procedures.

Whilst confirming an association between volume and outcome in paediatric cardiac surgery the JCPCT has acknowledged that the scientific papers reviewed do not provide sufficient evidence to make firm recommendations regarding the cut-off point for minimum volume of activity for paediatric cardiac procedures overall, or for specific procedures at an institutional level. The standards are therefore based on the consensus of the professional societies, which in turn are based on the available evidence.

In developing a recommendation for the minimum or maximum number of surgical procedures that a surgical centre staffed with four surgeons must meet, the JCPCT accepted the findings of the European Association for Cardio-Thoracic Surgery[80]*. Whilst acknowledging that the available research evidence does not identify an 'exact cut-off point between what is a too small, adequate or optimal a case load' the society suggested a minimum caseload of 126 surgical procedures each year for a full time surgeon.*

[78] The Royal College of Surgeons of England, *Surgery for children: Delivering a first class service*, London, July 2007

[79] Standard C9, National Specialised Commissioning Team, *Safe and Sustainable: Children's Congenital Cardiac Services in England Service Standards*, March 2010. Available at: www.specialisedservices.nhs.uk/library/30/Paediatric_Cardiac_Surgery_Standards_1.pdf

[80] 'Optimal Structure of a Congenital Heart Surgery Unit in Europe' Congenital Heart Surgery Committee on behalf of the European Association for Cardio-Thoracic Surgery, April 2003

09 The standards

It is not stated that these 126 procedures per surgeon must all be in paediatric cardiac surgery; they could include procedures for adults with congenital heart disease. The JCPCT used 500 paediatric procedures per unit as the optimal figure and set the minimum number at 400 paediatric procedures per unit which would provide each of the four surgeons with 100 paediatric cardiac surgery procedures per year as a minimum (in addition to any adult congenital surgical caseload).

The JCPCT's recommendation of a minimum of 400 / 500 surgical procedures is therefore derived from a combination of the need to ensure a sufficient volume of paediatric surgery for four full-time consultant congenital cardiac surgeons in a unit, the need for 24/7 cover with a legally compliant surgical rota[81], the available evidence and professional consensus."

During public consultation respondents were asked '*Please indicate the extent to which you support or oppose the statement that there is a relationship between higher-volume and better clinical outcomes*'.

Personal respondents:
52% support / 32% oppose

Organisations:
70% support / 16% oppose

Source: Ipsos Mori

[81] Directive 2003/88/EC of the European Parliament and of the Council of 4 November 2003 concerning certain aspects of the organisation of working time

SUMMARY OF ADVICE TO THE JCPCT FROM THE *SAFE AND SUSTAINABLE* STEERING GROUP

In October 2011, having considered the evidence submitted during public consultation the Steering Group members advised the JCPCT to agree the standards as set out in the consultation document including the standards for minimum staffing levels and minimum surgical caseloads.

The Steering Group further advised the JCPCT to accept the additional standards as set out in Appendix B around Patent *Ductus Arteriosus* and around publication of the standards and audits of compliance.

SAFE AND SUSTAINABLE STANDARDS RELATING TO ANTENATAL SCREENING

During the period of consultation the British Congenital Cardiac Association (BCCA) and the NHS Fetal Anomaly Screening Programme (FASP) began joint work to develop an antenatal care pathway for congenital heart disease. As an outcome of this work a pathway has been proposed which does not include any new standards but which represents an amalgamation of the existing FASP and BCCA standards.

The proposed *Safe and Sustainable* standards have been amended to reflect this pathway where necessary (Appendix B).

RECOMMENDATIONS:

10 The JCPCT is advised to agree each of the 156 standards together with the 4 additional standards set out in Appendix A and B.

11 The JCPCT is advised to agree the revisions to the proposed standards relating to antenatal screening. See Appendix C.

Improving the collection, reporting and analysis of outcome data

10

> "One of the things that concerns me greatly is that the quality of life measurements are not really out there. We know some international studies have been done, but we still don't have decent measuring tools to look and see what the long term will be. So that is a big issue".
>
> Representative of **Little Hearts Matter,** Cambridge consultation event

The JCPCT proposed for consultation six recommendations for improving current arrangements for the submission, monitoring, analysis and reporting of mortality and morbidity outcome data. The recommendations were:

1. Congenital cardiac units must have robust audit processes and cycles that provide early warning of system deficiencies. These units should implement a real time alert system for monitoring clinical outcomes in this specialty. This should be achieved by 2013 and monitored by the relevant NHS commissioner.
2. The Central Cardiac Audit Database should make available information on expected mortality by procedure groups in such a way that facilitates units to construct the appropriate statistical process control charts.
3. The Central Cardiac Audit Database should consider how the outcome of real time alert systems used in the surgical units relates to its own reporting of data and analyses in the future.
4. The Central Cardiac Audit Database should review its systems for the collection, validation and coding of data so that there is assurance that the reporting of data is timely, accurate and meaningful.
5. Designated specialist surgical centres should undertake greater scrutiny of their results, to ensure that the Central Cardiac Audit Database presents on its public portal a fair, accurate and transparent portrayal of their results such that parents and the public can readily understand them.
6. The professional associations, Central Cardiac Audit Database and NHS commissioners should develop a system for the routine collection, analysis and reporting of morbidity data. The aim should be for routine reporting by 2013.

Ipsos Mori reported that:

"When asked to what extent they agreed or disagreed with the proposals that *systems should be implemented to improve the collection, reporting and analysis of mortality and morbidity data*, seven in ten personal respondents said they agreed (71%), with over half *strongly* agreeing (53%). Very few personal respondents disagreed (one per cent). Similarly, among organisations, only one per cent disagreed that the systems should be implemented. Fewer organisations than personal respondents agreed that systems should be implemented to improve the collection, reporting and analysis of mortality and morbidity data (35%), but many more organisations did not give a response (60%). **Of those responding, there were high levels of agreement – 85% of personal responses and organisations".**

10 Improving the collection, reporting and analysis of outcome data

Respondents were asked: to what extent do you agree or disagree that systems should be implemented to improve the collection, analysis and reporting of mortality and morbidity data.

Personal respondents:
85% agree / 1% disagree

Organisations:
85% agree / 1% disagree

Source: Ipsos Mori

After considering the evidence submitted during consultation, the *Safe and Sustainable* steering group members have advised the JCPCT to agree the proposals for improving the monitoring and reporting of outcome data[82].

RECOMMENDATION 12:

The JCPCT is advised to agree the proposals for improving the collection, reporting and analysis of outcome data.

[82] Report to the Joint Committee of PCTs by Dr Patricia Hamilton CBE, Chair of the Safe and Sustainable Steering Group, on behalf of Steering Group members, October 2011

Scoring of viable options

11

The scoring of viable options against the JCPCT's proposed criteria for the evaluation of options is one part of the process for identifying a preferred option but it is not determinative. The JCPCT is advised to consider the outcome of the scoring process alongside all of the other evidence that is available as an outcome of consultation.

The JCPCT identified six viable options for consultation, and of these expressed a preference for four options. The four options for consultation were:

Option A	Option B
Liverpool Newcastle Birmingham Leicester Bristol London (two centres)	Southampton Newcastle Liverpool Birmingham Bristol London (two centres)
Option C	**Option D**
Liverpool Newcastle Birmingham Bristol London (two centres)	Leeds Liverpool Birmingham Bristol London (two centres)

11 Scoring of viable options

NEW OPTIONS

The JCPCT did not seek to limit consultation to the four preferred options, nor indeed to the six options identified as viable. Respondents to consultation were expressly told that new options would be considered by the JCPCT if they were found to be viable, and the consultation response form provided respondents with the opportunity to suggest new configuration options.

The secretariat has sought to assess the viability of other potential options by 'testing' previous working assumptions and considering potential new assumptions that were suggested by respondents during consultation.

Previous assumptions tested against evidence received during consultation	Advice to JCPCT
Each centre must perform a minimum of 400 paediatric procedures as required by the *Safe and Sustainable* standards	Apply the assumption: Based on advice of Steering Group, and the strong support for the Standards amongst respondents
Only 6 or 7 surgical units are viable in an option	Disregard the assumption: Options with 8 centres may be viable based on new analysis of patient flows and projected caseloads
London requires at least 2 surgical units	Apply the assumption: Based on JCPCT's analysis of patient flows and projected caseloads and capacity analysis
John Radcliffe Hospital is not a viable surgical unit	Apply the assumption: Based on views submitted during consultation (see below)
The Birmingham centre must be included in all options	Apply the assumption: Based on analysis of patient flows and projected caseloads which suggest that other centres would be unable to safely assume this high caseload
The Southampton and Bristol centres cannot both appear in the same option	Disregard the assumption: Based on new analysis of patient flows and projected caseloads (see below)
The Bristol centre must appear in all options due to emergency retrieval	Disregard the assumption: Based on the advice set out on Appendix R of this report
The North of England needs 2 centres, and of these the Newcastle and Leeds centres cannot co-exist in the same option	Apply the assumption: Based on analysis of patient flows and projected caseloads which suggest that three centres could not reasonably meet the minimum critical mass thresholds, and that Alder Hey Children's Hospital should appear in all options as other centres could not assume the caseload while maintaining reasonable networks

TESTING THE ASSUMPTION: JOHN RADCLIFFE HOSPITAL IS NOT A VIABLE SURGICAL UNIT

For the purpose of consultation the JCPCT proposed that the John Radcliffe Hospital was not a viable provider of paediatric congenital cardiac surgical services. This was based on the findings of the Kennedy panel's assessment, which placed the hospital as a statistical outlier in receiving the lowest ranking assessment by a significant margin, and also on an analysis of potential patient flows undertaken by the secretariat which concluded that the hospital would fail to reasonably generate a sufficient annual caseload (to meet 400 paediatric surgical procedures) even if surgery were to cease in Bristol and Southampton.

The paediatric congenital cardiac surgical service at the John Radcliffe Hospital remains suspended pending the JCPCT's decision, in line with the recommendations of a separate investigation initiated by South Central Strategic Health Authority in 2010. Since 2010 the John Radcliffe Hospital has provided non-interventional paediatric cardiology services within a South Central network with the surgical unit at Southampton General Hospital.

The JCPCT is advised that the evidence submitted during consultation does not support the resumption of paediatric cardiac surgery at the John Radcliffe Hospital. Rather, NHS organisations in South Central England speak positively of the hospital's existing and future role as a provider of non-surgical and non-interventional cardiac services in a South of England congenital heart network led by the surgical unit at Southampton General Hospital. For further detail the JCPCT is referred to submissions from:

- South Central Strategic Health Authority
- Oxford Radcliffe Hospitals NHS Trust
- Southampton University Hospitals NHS Foundation Trust
- Oxford Healthcare NHS Foundation Trust
- Solent NHS Trust
- Southern Health NHS Foundation Trust

Some respondents have suggested that the establishment of a South Central England congenital heart network supports the case for the resumption of surgery at the John Radcliffe Hospital. The local support group 'Young Hearts' writes:

> "*We believe the proposed South of England congenital heart network, which is a joint partnership between the Oxford and Southampton Paediatric Cardiac Congenital Heart Network Service will offer an even better option of 6/7 surgeons working across both the Oxford and Southampton sites*".

However, the JCPCT is advised that a model of care that envisages a spilt-site surgical arrangement across Oxford and Southampton would be contrary to the *Safe and Sustainable* standards which require a surgical team of at least four congenital cardiac surgeons based permanently on a single surgical site, and could not be implemented under the proposed model of care.

11 Scoring of viable options

TESTING THE ASSUMPTION: THE SOUTHAMPTON AND BRISTOL CENTRES CANNOT BOTH APPEAR IN THE SAME OPTION

The detailed analysis establishing the viability of options that include both Southampton and Bristol is set out in Appendix Q. This report, which proposes changes to how some postcodes are assigned to the Southampton, Bristol and London networks, is the outcome of an analysis by the secretariat that takes into account evidence submitted for this purpose by relevant surgical units and Specialised Commissioning Groups, a consideration of evidence submitted during consultation from other respondents (including as reported by Ipsos Mori) and the report of PwC on patient flows and networks.

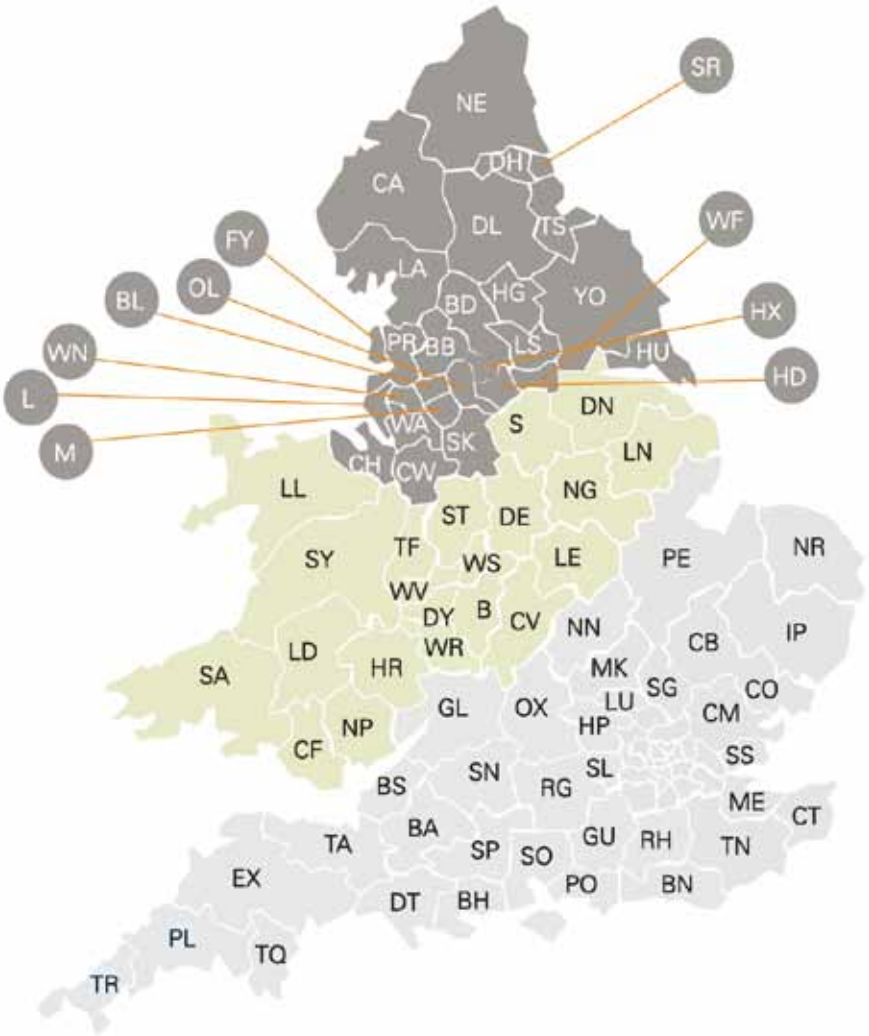
New potential assumptions suggested by respondents	Advice to JCPCT
5 surgical units constitutes a viable option	Disregard the assumption: Based on analysis of patient flows and projected caseloads
8 surgical units constitutes a viable option	Apply the assumption: Options with 8 centres may be viable based on new analysis of patient flows and projected caseloads
The Bristol and Southampton centres can both appear in the same option	Apply the assumption: Based on new analysis of patient flows and projected caseloads
There is no requirement for the Bristol centre to be in every option	Apply the assumption: Based on the advice set out on Appendix R of this report
The Leicester, Newcastle and Great Ormond Street Hospital services must be present in every option as ECMO services must remain in their current locations	Disregard the assumption: Based on advice of Steering Group, Advisory Group for National Specialised Services and other respondents
The future location of the three Nationally Commissioned Services should not be a consideration in the JCPCT's process for identifying a preferred option	Disregard the assumption: Based on advice of Steering Group, Cardiothoracic Transplant Advisory Group, Advisory Group for National Specialised Services and other respondents
The Leeds centre should be present in every option for the same reasons as the Birmingham and Liverpool centres	Disregard the assumption: Based on the JCPCT's analysis of patient flows and projected caseloads
The Leicester centre should be present in every option as the Birmingham centre would not have sufficient capacity	Disregard the assumption: Based on JCPCT's capacity analysis
The Southampton centre should be present in every option because of the retrieval of children from the Isle of Wight	Disregard the assumption: Based on the advice given to the JCPCT on Appendix R of this report
The surgical centre in Glasgow should be included in the JCPCT's process	Disregard the assumption: The Glasgow centre is not within the JCPCT's remit being subject to a separate devolved administration

TESTING THE ASSUMPTION: 5 SURGICAL UNITS CONSTITUTES A VIABLE OPTION

The most commonly suggested alternative option put forward by respondents (as reported by Ipsos Mori) comprised five centres in England: three centres in London plus Alder Hey Children's Hospital and Birmingham Children's Hospital. The JCPCT is advised that this option is not viable as the centres outside of London could not reasonably meet the forecast caseloads, being significantly above their stated maximum capacity.

Network	Projected annual caseload
London (3 centres)	1,958
Birmingham	908
Alder Hey	875

Figures based on assumption that patients would flow to their nearest centre



11 Scoring of viable options

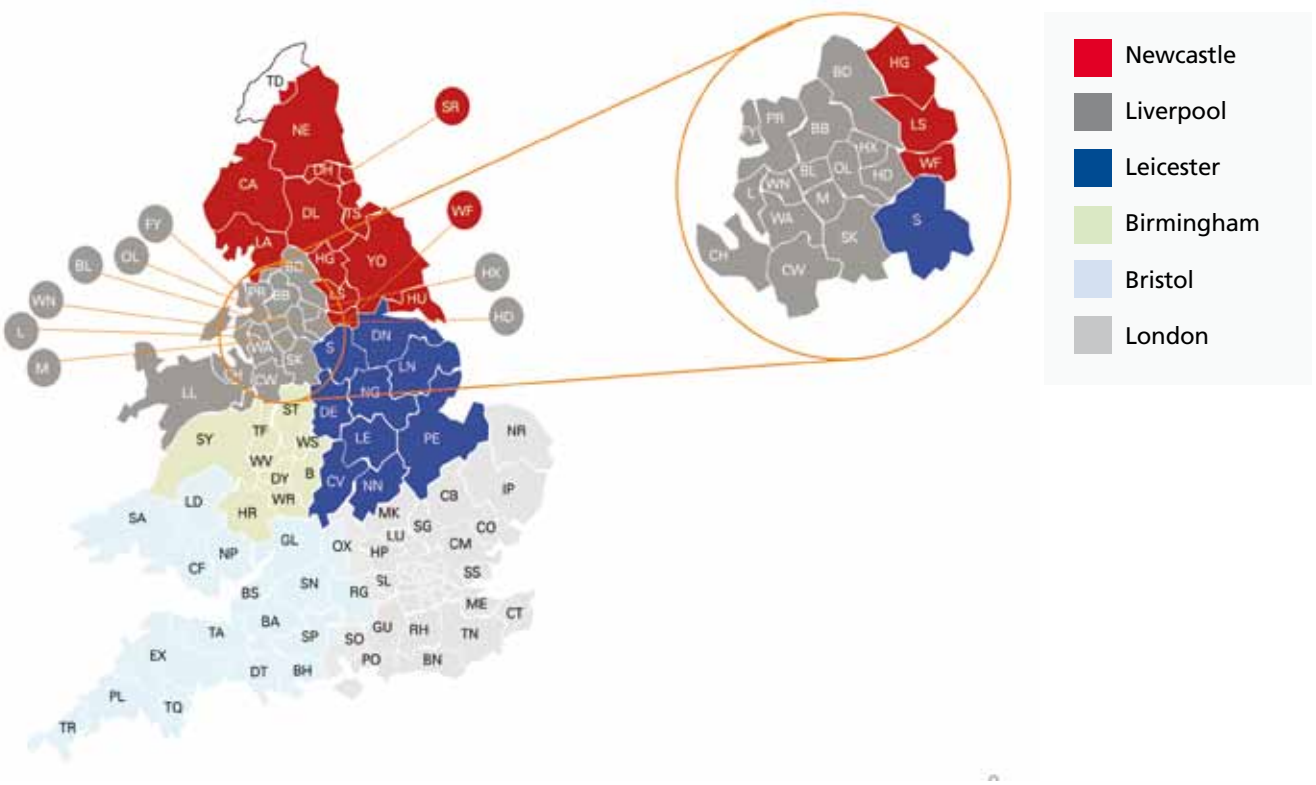
Based on an application of the former and new working assumptions the JCPCT is advised to accept six additional viable options for consideration.

The 12 Congenital Heart Networks presented in these options are:

	Options originally scored by the JCPCT						New options scored by the JCPCT					
Option	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**
London (1)	■	■	■	■	■	■	■	■	■	■	■	■
London (2)	■	■	■	■	■	■	■	■	■	■	■	■
London (3)					■	■		■				■
Southampton		■					■		■	■		
Birmingham	■	■	■	■	■	■	■	■	■	■	■	■
Bristol	■	■	■	■	■	■	■	■	■		■	■
Newcastle	■	■	■		■			■	■	■		
Liverpool	■	■	■	■	■	■	■	■	■	■	■	■
Leicester	■							■	■	■	■	■
Leeds				■		■	■				■	■
Oxford												
Total Centres	**7**	**7**	**6**	**6**	**7**	**7**	**7**	**8**	**8**	**7**	**7**	**8**

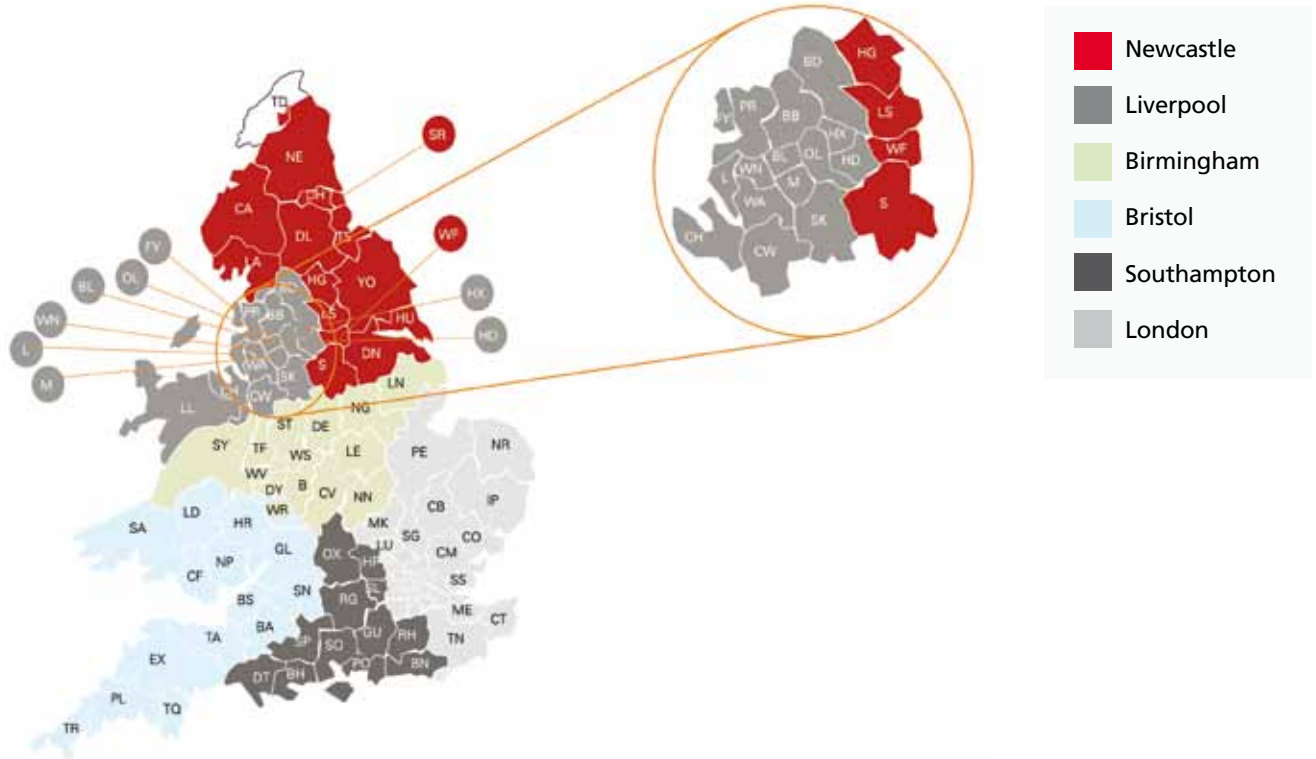
OPTION A

Liverpool, Newcastle, Birmingham, Leicester, Bristol, London x2



OPTION B

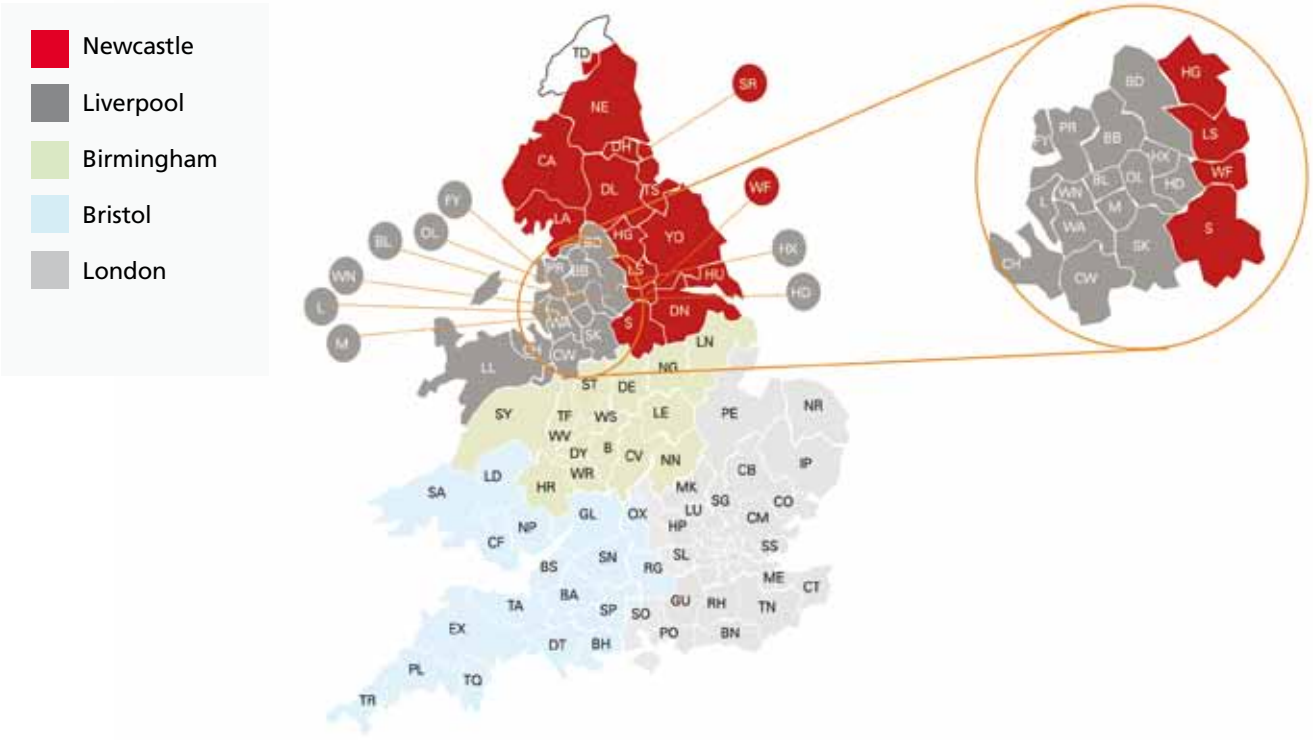
Southampton, Newcastle, Liverpool, Birmingham, Bristol, London x2



11 Scoring of viable options

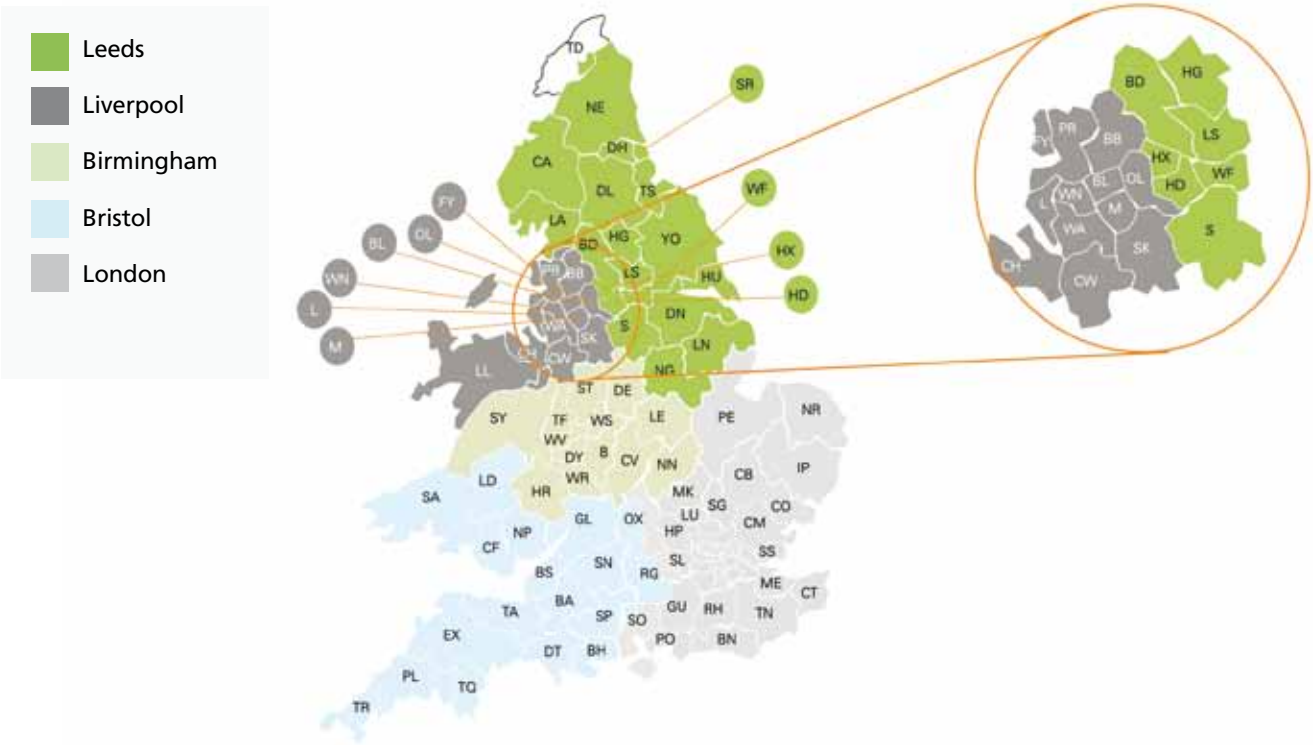
OPTION C

Newcastle, Liverpool, Birmingham, Bristol, London x2



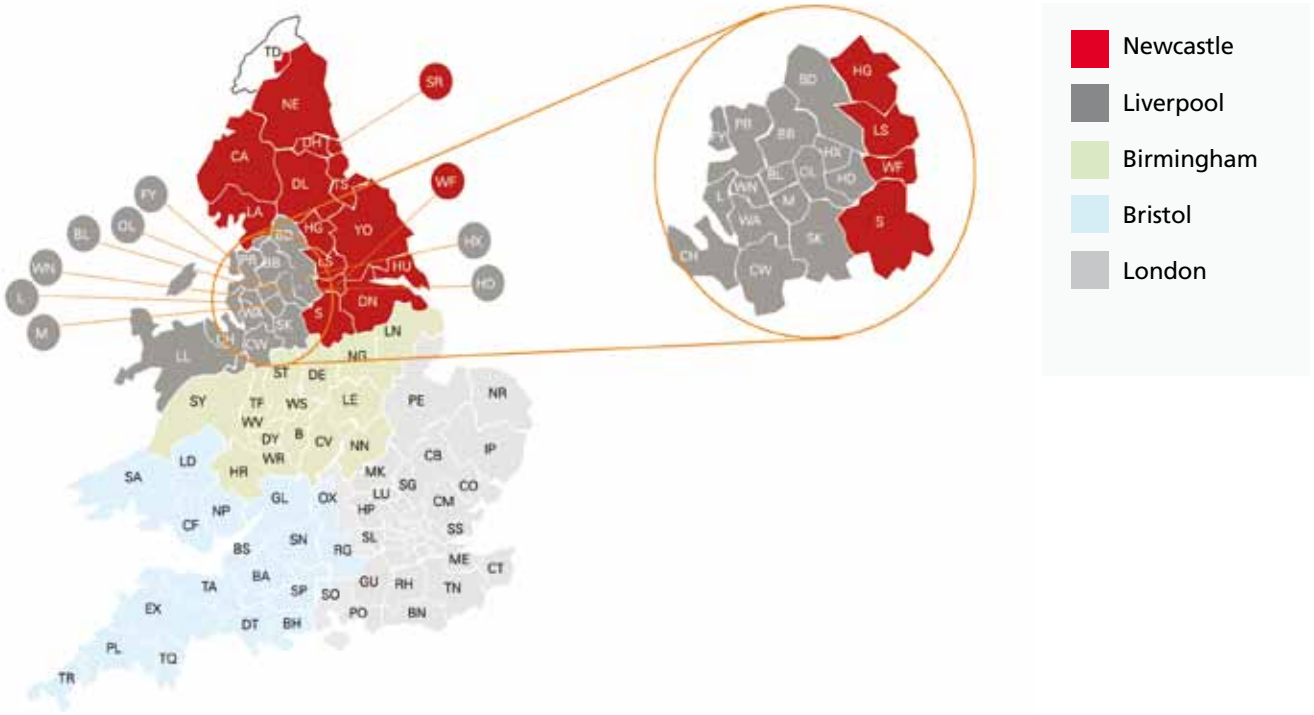
OPTION D

Liverpool, Leeds, Birmingham, Bristol, London x2



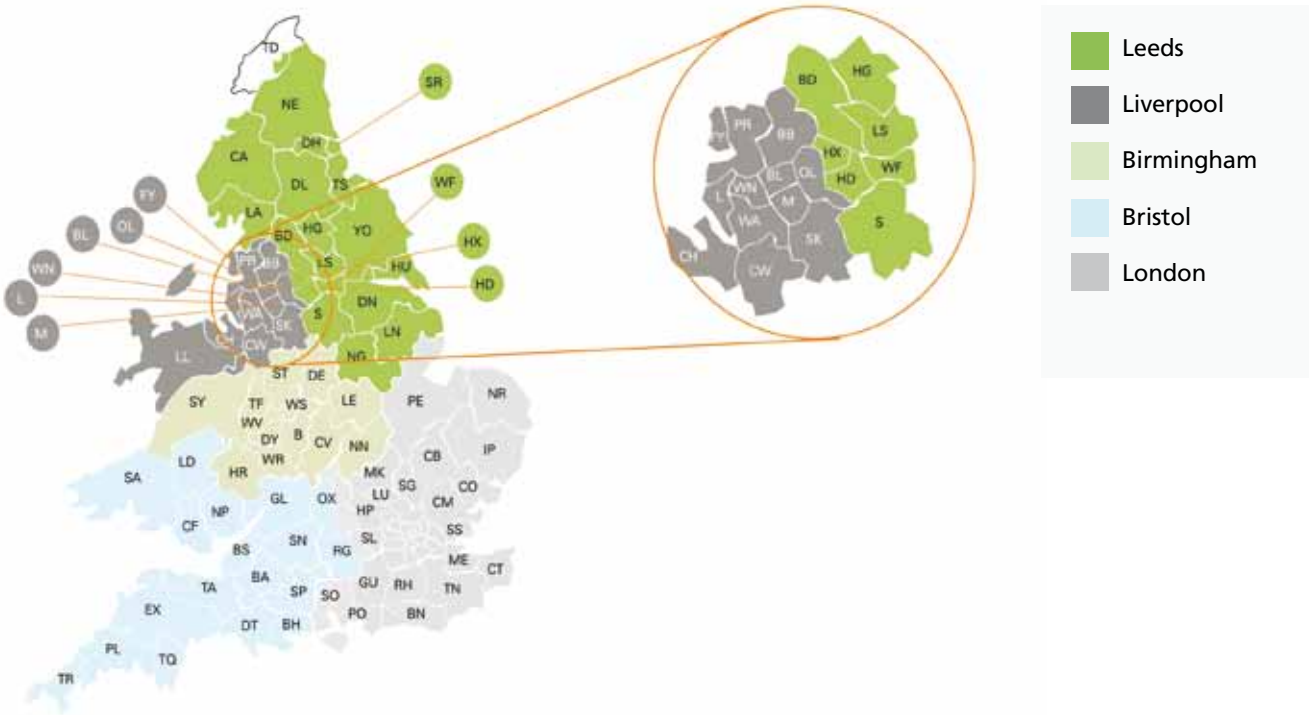
OPTION E

Newcastle, Liverpool, Birmingham, Bristol, London x3



OPTION F

Liverpool, Leeds, Birmingham, Bristol, London x3

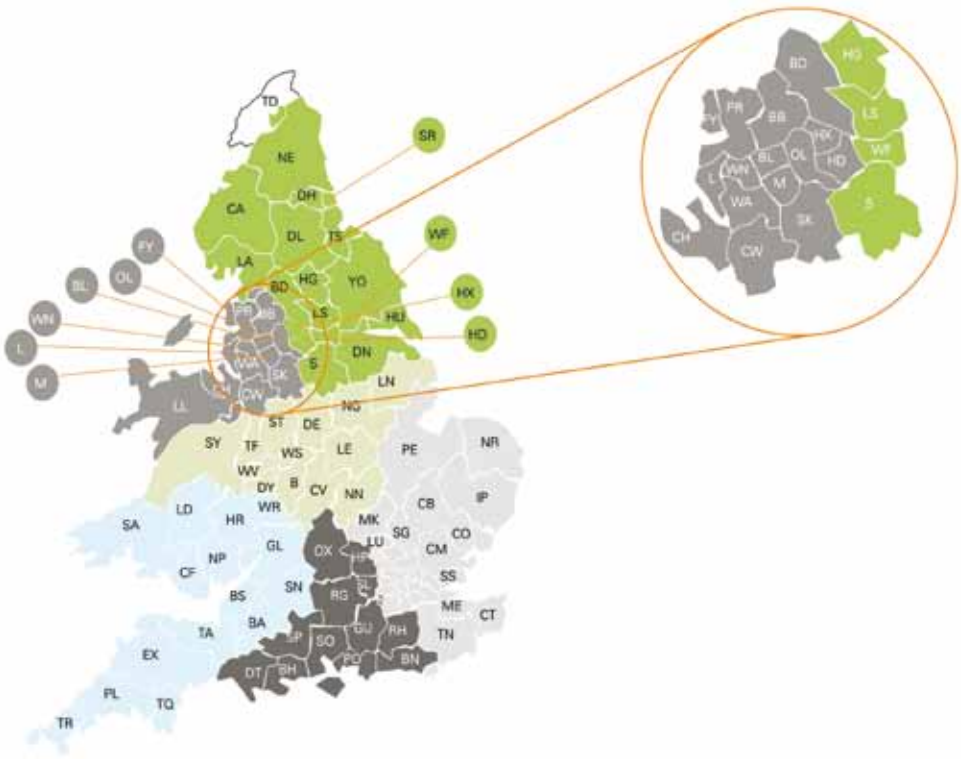


11 Scoring of viable options

OPTION G

Southampton, Leeds, Liverpool, Birmingham, Bristol, London x2

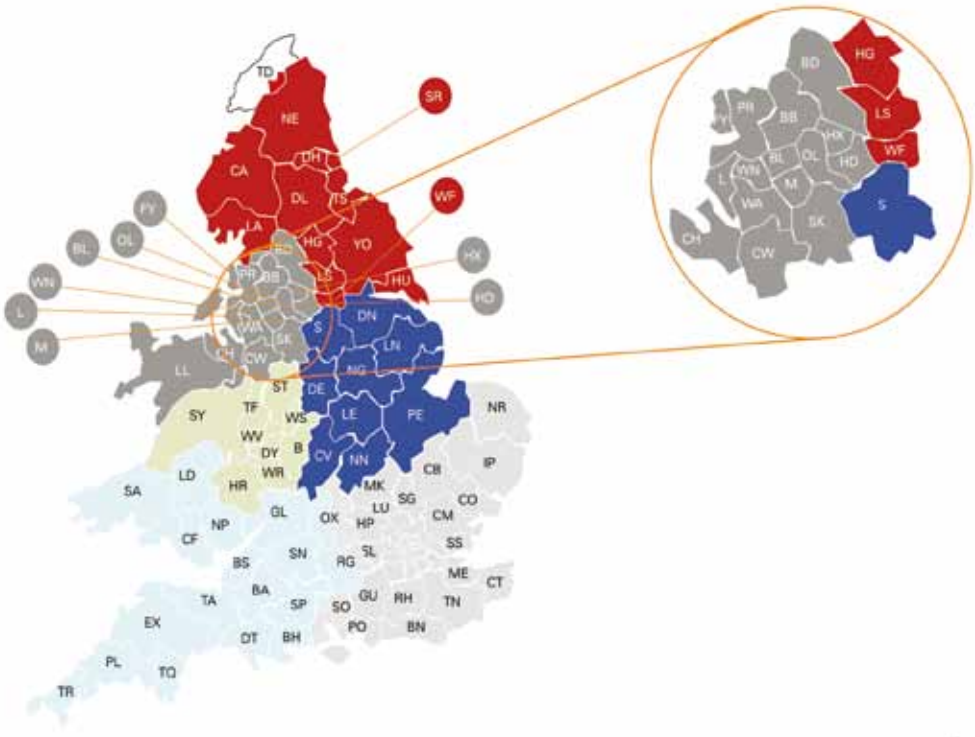
- Leeds
- Liverpool
- Birmingham
- Bristol
- Southampton
- London



OPTION H

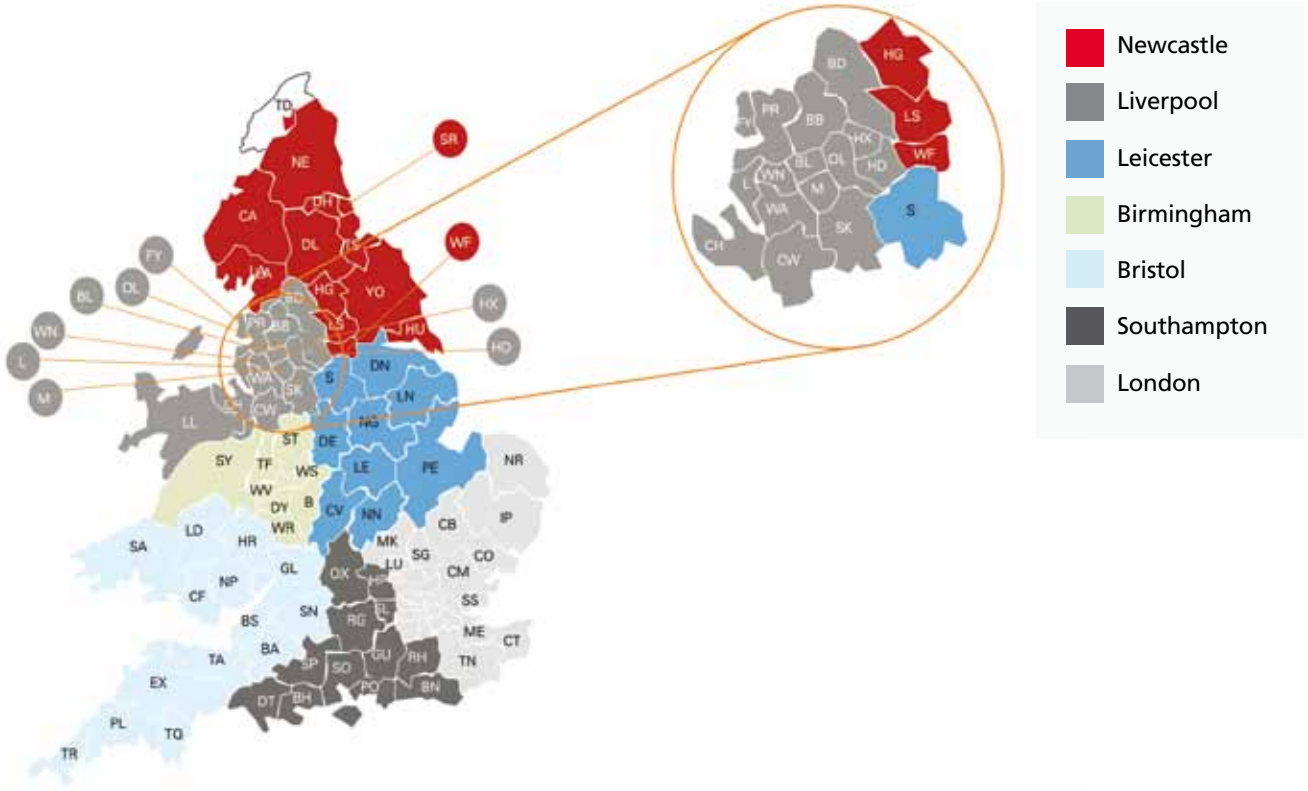
Liverpool, Newcastle, Birmingham, Leicester, Bristol, London x3

- Newcastle
- Liverpool
- Leicester
- Birmingham
- Bristol
- London



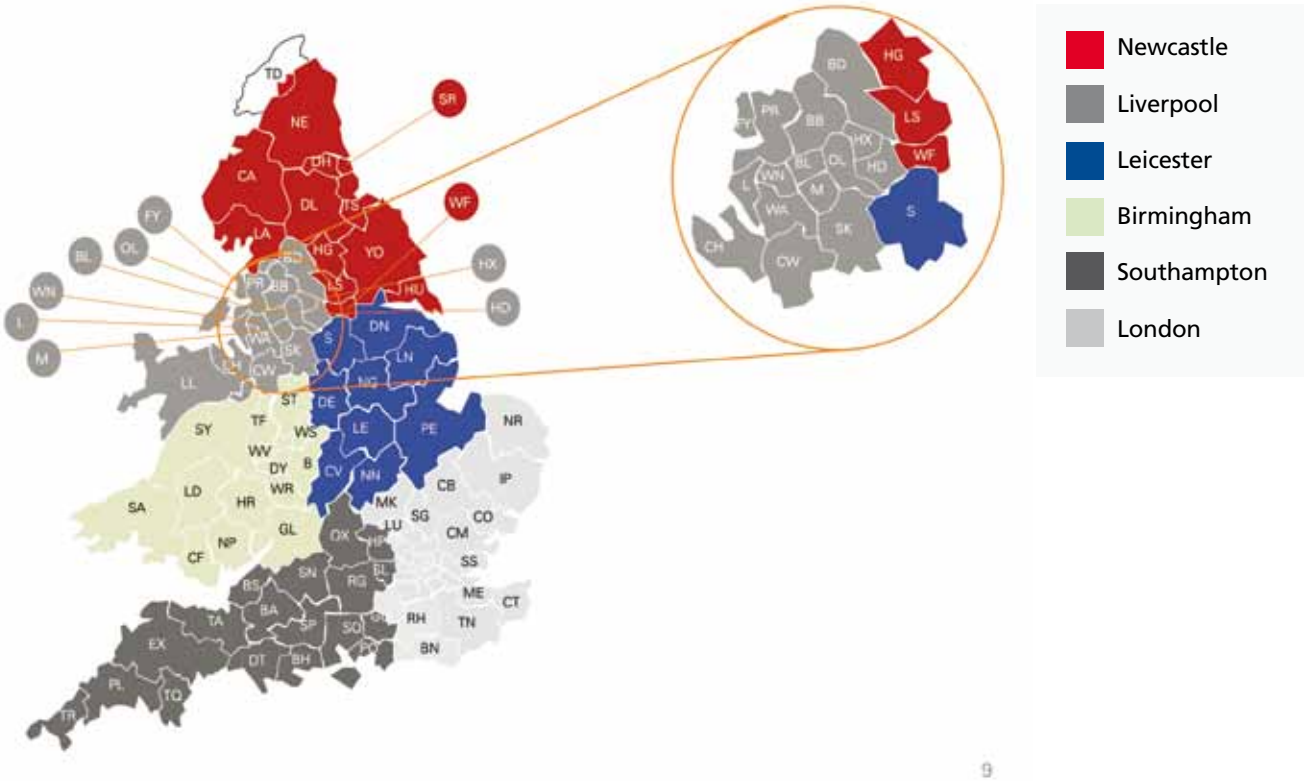
OPTION I

Southampton, Newcastle, Liverpool, Birmingham, Bristol, Leicester, London x2



OPTION J

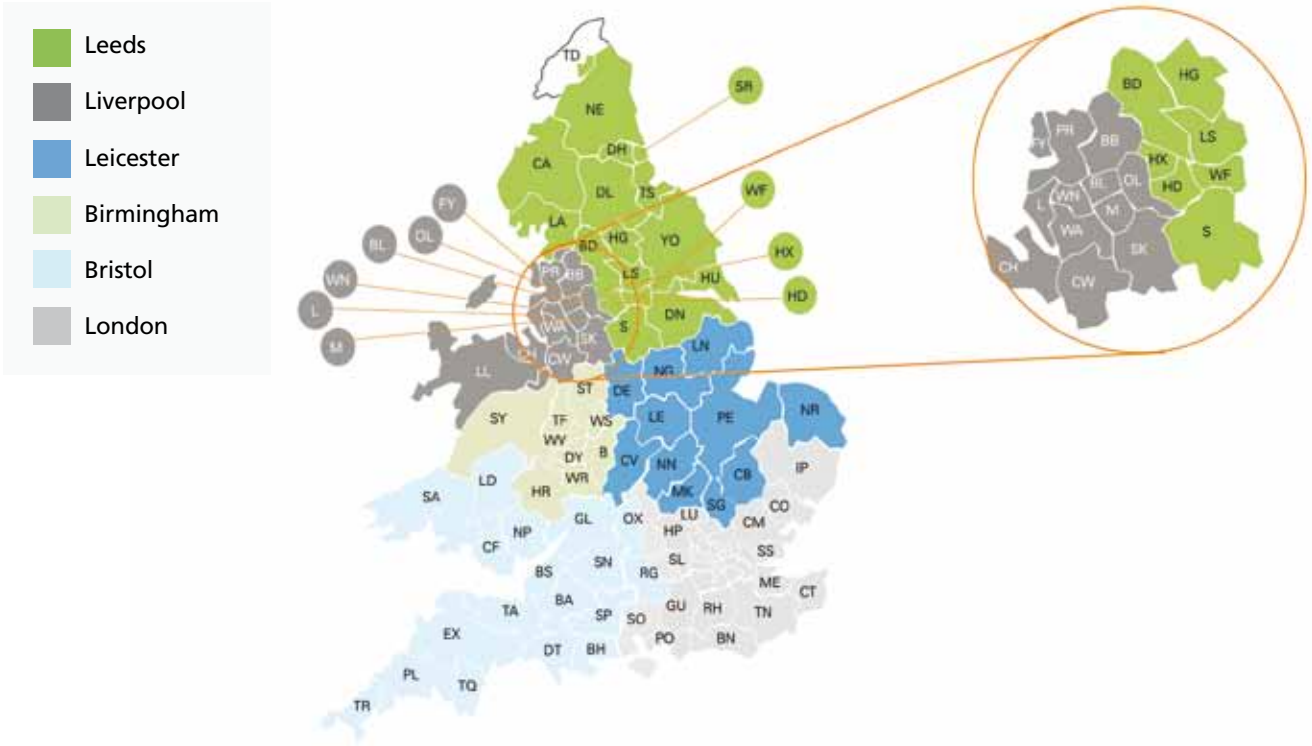
Liverpool, Newcastle, Birmingham, Leicester, Southampton, London x2



11 Scoring of viable options

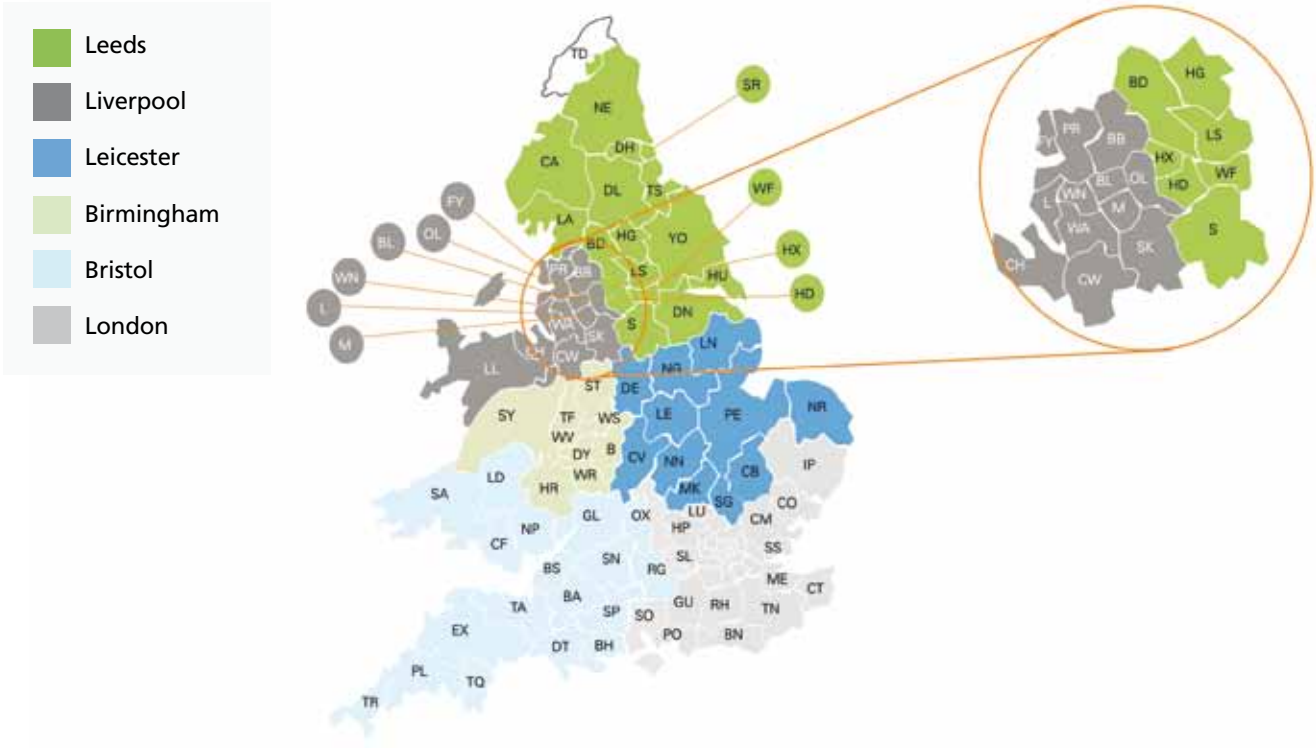
OPTION K

Liverpool, Leeds, Leicester, Birmingham, Bristol, London x2



OPTION L

Liverpool, Leeds, Leicester, Birmingham, Bristol, London x3



The forecast activity levels in these options are:

	Forecast Activity using 2010/11 Activity Levels											
Options >	A	B	C	D	E	F	G	H	I	J	K	L
London	1538	1252	1578	1578	1578	1578	1252	1536	1212	1354	1394	1394
Southampton		428					428		428	502		
Birmingham	414	611	653	589	653	589	547	414	398	567	414	414
Bristol	470	412	470	470	470	470	412	470	385		470	470
Newcastle	432	559	559		559			432	432	432		
Liverpool	479	479	479	420	479	420	420	479	479	479	420	420
Leicester	406							406	406	407	425	425
Leeds				683		683	683				618	618

SCORING THE 12 VIABLE RECONFIGURATION OPTIONS AGAINST THE EVALUATION CRITERIA

The JCPCT is advised to score the 12 options against the weighted criteria that were previously applied to evaluate viable options for consultation.

Although no respondents to consultation have specifically challenged the numerical weighting applied to the criteria, some respondents have encouraged the JCPCT to give greater / lesser emphasis to a number of the criteria. In many cases the advice is conflicting across different respondents (for example, that the JCPCT has given too much / not enough emphasis to issues of travel and convenience). Where appropriate this evidence has informed the advice given to the JCPCT as set out elsewhere in this document. The JCPCT is advised to retain the previous criteria and weightings for the purpose of identifying a preferred option in the absence of any compelling evidence that would support a change to the previous method (which was itself informed by the outcome of an engagement exercise held with key stakeholder groups in 2010).

The JCPCT is advised to include option I in the scoring process even though in this option the Bristol Royal Hospital for Children is forecast to fall short of the required minimum of 400 paediatric congenital surgical procedures by 15 procedures and Birmingham Children's Hospital is forecast to fall short by 2 procedures (in this option Birmingham Children's Hospital is forecast to experience a 28% reduction in its caseload[83]). This advice is based on a view that some respondents to consultation, not necessarily those who have a relationship with the Bristol and Birmingham centres, may consider it unreasonable to exclude this option from consideration altogether taking into account accepted margins of error when forecasting future caseloads.

[83] Against 2009/10 CCAD validated data

11 Scoring of viable options

Evaluation criteria and weighting	
i) Access and travel times • The negative impact on travel times for elective admissions is kept to a minimum • The retrieval team should arrive at the referring unit within three hours of the decision to retrieve the child in accordance with the PIC Society 'Standards for the Care of Critically Ill Children, 2010'	14
ii) Quality • Designated surgical centres will deliver a high quality service • Innovation and research is present across the networks and the national service • Clinical networks are manageable, taking account of population and geography and the need for clear leadership and communication	39
iii) Deliverability • The NHS in England will continue to provide high quality: – paediatric cardiothoracic transplantation services in two centres – ECMO services for children with severe respiratory failure in at least three centres – complex tracheal surgery in one centre • The negative impact for the provision of paediatric intensive care and other interdependent services is kept to a minimum • The negative impact on the NHS workforce is kept to a minimum • Transitional plans for implementation are in place by April 2013	22
iv) Sustainability • All designated centres are likely to perform at least 400 paediatric procedures per year, ideally 500 • No one designated surgical centre will receive too onerous a caseload that would exceed that centre's capacity to manage it • All designated centres will be able to recruit and retain newly qualified surgeons and other specialist staff, will provide mentoring and training of junior surgeons and will be able to develop robust succession plans	25

The JCPCT is advised to score options against a five point scale, as shown below:

Scoring scale	
0	Does not meet any elements of the criteria
1	Meets SOME elements of the criteria (areas where there are gaps in compliance exceed areas where there is compliance)
2	Meets MOST elements of the criteria (areas where there are gaps in compliance are fewer than areas where there is compliance)
3	Meets all elements of the criteria
4	Exceeds the criteria

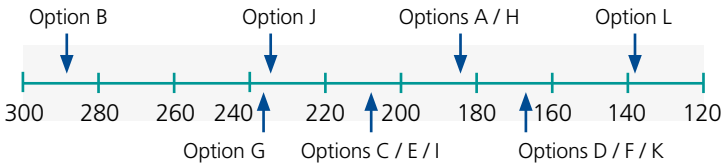
The JCPCT is advised to apply scores against the options as set out in the table below:

	Options											
Absolute scores	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**
Total score for travel and access	2	2	1	2	1	2	3	2	3	1	2	2
Total score for quality	1	3	2	1	2	1	2	1	2	2	1	1
Total score for deliverability	3	3	2	1	2	1	2	3	3	3	1	1
Total score for sustainability	2	3	3	3	3	3	3	2	1	3	3	2

The JCPCT is advised to apply the multipliers in the table on page 72 to the absolute scores as set out in the table above to reach the following weighted scores:

	Options											
Weighted scores	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**
Total score for travel and access	28	28	14	28	14	28	42	28	42	14	28	28
Total score for quality	39	117	78	39	78	39	78	39	78	78	39	39
Total score for deliverability	66	66	44	22	44	22	44	66	66	66	22	22
Total score for sustainability	50	75	75	75	75	75	75	50	25	75	75	50
Total scores	**183**	**286**	**211**	**164**	**211**	**164**	**239**	**183**	**211**	**233**	**164**	**139**

This would result in the following ranking of options:



The proposed scores are explained elsewhere in this document:

Access and Travel – Appendix R
Quality – Appendix S
Sustainability – Appendix T
Deliverability – Appendix U

Additionally, the JCPCT requested that a number of sensitivity tests be run for comparison with the initial ranking of options. Nine sensitivity tests have been applied, all of which confirm options B and G as the highest scored options, with option B the highest scored. The sensitivity tests are described in Appendix V. Appendix W explains the variance in the previous and current proposed scoring for option A.

RECOMMENDATIONS:

13 The JCPCT is advised to agree assumptions that have been applied to identify viable options

14 The JCPCT is advised to agree the proposed criteria for the evaluation of options, and the weightings applied to each criteria

15 The JCPCT is advised to agree the proposed scoring of options against the weighted criteria

16 The JCPCT is advised to agree that option B is consistently the highest scored option when sensitivity tests are applied

12 Testing the evidence for Option B

Although the scoring process has consistently highlighted option B as the highest scored option the JCPCT should not regard the scoring process as determinative. Rather, the JCPCT's decision should be based on a consideration of all of the available evidence in the round, including the evidence for and against alternative options.

This section of the Decision Making Business Case seeks to test option B against the other evidence available to the JCPCT.

A Quantitative analysis of consultation responses

Ipsos Mori reported that:

> *"Options A and B were the most commonly supported options both for personal respondents and organisations. However, among personal responses, Option A was the most widely supported, with just under three in five showing their support, while organisations were more likely to support Option B (just over three in five) … Option C received the lowest level of support – around one in twenty responses from personal respondents and organisations supported this option. Support of Option D was slightly higher, and was highly concentrated among individuals based in Yorkshire and Humber*[84]*".*

JCPCT members are referred to pages 61 to 77 of the report for a detailed analysis of respondents' comments in this regard.

B Quality

Ipsos Mori reported that the JCPCT received many submissions that 'quality' should be the JCPCT's main consideration. Many respondents expressed support for Professor Kennedy's recommendation that "*mediocrity must not be our benchmark for the future*[85]".

Option B offers for designation the five centres outside of London that were scored the highest by the Kennedy panel and proposes two centres in London[86]. The Kennedy assessments were comprehensive covering current and future aspects of care, facilities, leadership, staffing, clinical governance and network arrangements.

The strength of an option that would comprise the actual top seven centres as assessed by the Kennedy panel has been considered. This option would offer three centres in London and would exclude Alder Hey Children's Hospital (which was ranked eighth by the panel). The JCPCT is advised that this option is not viable as it would leave only one centre (the Freeman Hospital in Newcastle) covering the populations of North West England, North East England and Yorkshire and Humber, which would exceed that centre's stated capacity. This would also increase the caseload at Birmingham Children's Hospital to an extent that would not be sustainable.

Some respondents have suggested that an aspect of 'quality' is the extent to which paediatric cardiac surgical services are co-located with other core paediatric services as defined by the *Critical Interdependencies Framework*. Reflecting the advice offered by numerous professional organisations during

[84] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, pp 62-63

[85] Safe and Sustainable, *Review of children's congenital cardiac services in England – Report of the independent expert panel chaired by Professor Sir Ian Kennedy*, 2010

[86] *Safe and Sustainable, Review of children's congenital cardiac services in England – Report of the independent expert panel chaired by Professor Sir Ian Kennedy*, 2010.

[87] See page 169

consultation[87] the JCPCT is invited to accept the view that the ideal is the co-location of relevant clinical services on the same site. In this regard option G, which includes Leeds Teaching Hospital, offers advantages over option B given that specialised paediatric surgical services in Newcastle are located at the Great North Children's Hospital rather than at the Freeman Hospital, which is where paediatric cardiac surgery is performed. Leeds Teaching Hospital also offers the co-location of paediatric cardiac surgery with maternity, obstetrics and foetal services.

However, the Kennedy panel concluded that paediatric services in Newcastle meet the requirements of 'co-location' as defined by the *Safe and Sustainable* standards and the *Critical Interdependencies Framework* – albeit over a split-site arrangement.

The significance of 'co-location' has been tested in the JCPCT's process for scoring by giving more prominence in the weighting of the Kennedy scores to centres that have all relevant clinical services on the same site (see page 169). Even then the Newcastle centre scores higher than the Leeds centre overall, reflecting overall better current and future compliance with the standards as reported by the Kennedy panel.

Although option B comprises the higher scoring centres, there are important differences across these seven centres in their ability to meet the quality standards in the future.

> "There are some units that have come out of Kennedy's analysis which scored far lower who are in all the configurations and they're going to need a lot of support to get themselves up to the standard of the top units. How's that going to happen".
>
> Representative of **Little Hearts Matter,** Birmingham consultation event

Implementation of consistent quality standards across all centres, a rigorous 'streamlined' commissioning process for monitoring and improvement, and the high profile of these services within the commissioning framework will provide commissioners with effective levers to improve aspects of care and outcomes across all centres and networks in the future.

C Travel, access and convenience

The clinical case for fewer surgical units is compelling and has garnered strong support from professional associations and national charities even though it is recognised that reconfiguration would result in longer travelling times for some children requiring surgery or interventional cardiology services.

12 Testing the evidence for Option B

In some regions, respondents gave significant emphasis to issues around travel and population density:

> "Patient and family access to the proposed surgical centres should be a key consideration in determining the future configuration model. In this regard, we believe the current surgical centre in Leeds has excellent transport links to and from the city. This includes the motorway and road network (including access to the M1, M62 and A1 (M)), the rail network (including direct access to the high speed East Coast mainline and the Transpennine rail route) and access by air via Leeds-Bradford. It is unclear how such factors have been factored into the review process to date".
>
> **Yorkshire and Humber Joint Health Overview Scrutiny Committee**, response to consultation

The Yorkshire and Humber Joint Health Overview Scrutiny Committee also wrote that the JCPCT should give more prominence to population density in options that propose the cessation of surgery at Leeds Teaching Hospital:

> *"The population of Yorkshire and the Humber is in the region of 5.5 million people. However, it should be recognised that a total population of around 14 million people are within a 2-hour drive of the current surgical centre at Leeds. In planning the delivery of NHS services and to help ensure that we make best use of public resources, it would seem logical to ensure that specialist surgical centres are located within areas of high population and demand".*

> "In preferring Newcastle over Leeds as the surgical centre for these regions, the JCPCT disregarded the inconvenience this would cause to twice as many people than if Leeds were the preferred centre. Additionally, Leeds is a central rail and road hub offering access to the Unit within two hours of travel for an estimated 14 million people".
>
> **Children's Heart Surgery Fund**, response to consultation

By contrast, other respondents encouraged the JCPCT to disregard issues of convenience:

> "We would urge the review to take note of the experience in Sweden where the two highest quality [children's cardiac] centres were designated (closing five centres) despite those centres being located near to each other at one end of the country. Those involved describe the decision as popular with patients and well-supported by clinicians".
>
> **Southampton University Hospital NHS Foundation Trust**, response to consultation

The analysis set out in this document has considered the impact of longer elective journey times for surgery. Under the current configuration of services 35% of families are over an hour away from their closest surgical centre; this would rise to 47% in option B. The evidence available to the JCPCT suggests that this equates to 92 more families in or around Yorkshire and Humber who would experience an increased journey time of over 1 hour in option B compared to option G, the next highest scored option[88].

The submissions quoted above call upon the JCPCT to give greater weighting to the criterion of 'access and travel' in its evaluation of configuration options. The JCPCT has been advised elsewhere in this document that:

> "*the quality of care provided was the most frequently mentioned issue for respondents discussing either specific hospitals or the options more generally. In fact, quality of care featured heavily throughout the consultation responses, at each of the questions posed in the response form and in the letters and emails that were submitted. There was a strong belief amongst many that quality should be the deciding factor in service planning*[89]".

The JCPCT is therefore invited to conclude that the significant quality potential offered by option B outweighs the relatively limited impact to elective travel times.

However, the impact to family life of increased travel times is clearly important to those individuals affected, particularly to those families whose children have multiple surgical procedures. The consultation process has highlighted particular concerns from parents in Yorkshire and Humber and East Midlands[90]. The implementation plan should consider the extent to which potential mitigations suggested by respondents are achievable. For example, participants interviewed by PwC suggested that the following remedies be considered as ways of making the options more amenable and accessible:

- financial assistance with additional travel costs and car parking
- personal transport for very remote areas
- affordable overnight accommodation
- more information on travel times, distances and routes
- more information on each hospital in terms of specialists, waiting times and facilities
- flexible visiting times, ideally to fit with off-peak public transport

The potential impacts to vulnerable groups are set out on page 79.

The JCPCT has sought to minimise inconvenience to families by proposals to develop non-interventional care locally so that children only have to travel to a surgical unit for a very small number of times over the course of their childhood. The JCPCT has proposed that this will be achieved through the development of Children's Cardiology Centres and District Children's Cardiology Services. The JCPCT's model of care therefore envisages that under option B children, including those in Yorkshire and Humber, East Midlands, Oxford and South East England, will have greater access to Children's Specialist Cardiac Nurses and Paediatricians with Expertise in Cardiology working across the local networks. These proposals were supported during consultation.[91]

[88] See Appendix R

[89] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p7

[90] See for example, direct responses from respondents, the Health Impact Assessment and the PwC report on travel flows

[91] See pages 33-35

12 Testing the evidence for Option B

D Population density

Related to issues of 'access and travel' the Yorkshire and Humber Joint Health Overview Scrutiny Committee and the Children's Heart Surgery Fund have suggested that the JCPCT has been inconsistent in its approach to considerations of population density:

> "*We also believe that population density has been a significant consideration in identifying other centres as part of each of the consultation options put forward, including the surgical centres in Liverpool, Bristol, Birmingham and the need for two centres in London*[92]".

The JCPCT is advised that it has been consistent in its approach to considerations of population density:

Liverpool and Birmingham

The JCPCT concluded for the purpose of consultation that two surgical units are needed in the North of England, and that one of these units must be based at Alder Hey Children's Hospital based on an analysis of projected caseloads and patient flows that suggest that Birmingham Children's Hospital would be overwhelmed in terms of caseload in scenarios that remove surgery from Alder Hey Children's Hospital. However, the analysis does not suggest that Birmingham Children's Hospital would be at risk of being overwhelmed in scenarios that remove surgery from Leeds Teaching Hospital, in view of the smaller caseload at Leeds and the impact of potential patient flows in these options. The findings of the capacity analysis undertaken by the secretariat and local commissioners and the evidence submitted during consultation do not change the advice offered to the JCPCT in this respect.

London

The JCPCT concluded for the purpose of consultation that at least two surgical units are needed to reasonably serve the populations of London, South East England and Eastern England (which account for around 35% of the population of England). The findings of the capacity analysis undertaken by the secretariat and local commissioners and the evidence submitted during consultation do not change the advice offered to the JCPCT in this respect.

Bristol

It is assumed that the reference to Bristol refers to the conclusions that the JCPCT made for the purpose of consultation from its analysis of emergency retrieval times (the JCPCT concluded at the time that the Bristol centre should be present in all options for consultation). The JCPCT is advised that it adopted a consistent approach to the analysis of retrieval times at the time save for the exclusion in error of St Mary's Hospital on the Isle of Wight. The secretariat's most recent advice to the JCPCT on the application of the standards relating to emergency retrieval times, which is addressed elsewhere in this document (Appendix R), also proposes a consistent approach to all regions and all populations.

[92] Page 10, response to consultation, Yorkshire and Humber Joint Health Overview Scrutiny Committee

E Impact to health outcomes, health inequalities and to vulnerable groups

The JCPCT has been mindful of the potential impact of change to vulnerable groups throughout its process of review and has responded appropriately to the need to consider the potential impact of its final decision to health outcomes, health inequalities and to vulnerable groups and to those with protected characteristics under the Equalities Act 2010[93]. This has included asking Ipsos Mori to hold focus groups specifically for people from Black and Ethnic Minority Groups, and the JCPCT commissioned an independent expert third party to analyse and report on health impacts by way of a Health Impact Assessment which is presented as Appendix X and to which the JCPCT is referred for a detailed assessment.

> *"Health Impact Assessments do not determine the decision about which option should be selected; rather they assist decision makers by giving them better information on how best they can promote and protect the health and well-being of the local communities they serve … The Health Impact Assessment specifically focuses on the patient caseload and highlights whether any geographical communities or, in particular, certain socio-economic or equality groups are affected to a disproportionate extent[94]".*

The HIA reports that the differences between the options are "*fairly marginal*[95]" and one may reasonably conclude that no single option presents significant risk to health outcomes or to vulnerable groups.

In terms of health outcomes, the HIA reports positively that "*the concentration of surgical expertise onto fewer sites and the provision of more secondary services closer to home would be likely to create benefits in terms of better clinical outcomes for **all** children requiring paediatric cardiac services*[96]".

In terms of vulnerable groups, these are defined in the HIA as those who have a "higher propensity to experience congenital heart disease, and therefore a higher need for children's heart surgery services":

- Children under 16 years with congenital heart disease
- Children of mothers who smoke during pregnancy
- Children of mothers who are obese during pregnancy
- People who experience socio-economic deprivation
- People from Asian ethnic groups, particularly those with an Indian, Pakistani, Bangladeshi and other Indian sub-continent heritage[97]

The impact of service change to Black and Minority Ethnic Groups has been highlighted in particular by respondents in Yorkshire and Humber and East Midlands:

[93] That 20% of responses to consultation were from people who recorded themselves as belonging to BAME groups (as reported by Ipsos Mori) is encouraging evidence of the extent to which BAME groups engaged in consultation (the percentage of people in England from BAME groups is 7%)

[94] Mott MacDonald, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Health Impact Assessment*, 2012, p2

[95] Mott MacDonald, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Health Impact Assessment*, 2012, p11

[96] Mott MacDonald, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Health Impact Assessment*, 2012, p14

[97] Ipsos Mori makes the point that "research suggests that certain socio-demographic groups are at higher relative risk of having children with congenital heart disease, although the *absolute* impact on the number of children born with congenital heart disease is quite small'. Page 6, "Qualitative Research" report

12 Testing the evidence for Option B

"We believe that Yorkshire and the Humber has a significant concentration of vulnerable groups, including a large South Asian population in Kirklees, Bradford and Leeds who we know are more susceptible to congenital cardiac conditions … We are also concerned that the needs of people in areas with high levels of deprivation eg: Hull (ranked 10th out of 326 local authorities in the Indices of Deprivation in England 2010), Bradford (ranked 26th) and Doncaster (ranked 39th) have not been sufficiently taken into consideration … We have also seen evidence from the 2001 Census that a high proportion of households in our region do not have access to a car or van, including 44% of households in Hull, 36% in Sheffield and 34% in Leeds".

Yorkshire and Humber Joint Health Overview Scrutiny Committee

The Health Impact Assessment concludes that while some options may impact more on vulnerable groups than other options "*the numbers of patients from vulnerable groups likely to experience impacts are very small under all of the options*[98]".

The Health Impact Assessment also makes the point that the impacts will also be positive and that "*vulnerable groups are expected to benefit disproportionately from the positive impacts of improved health outcomes and care delivered closer to home*[99]" that present under all options.

In terms of travel and access impacts, the Health Impact Assessment reports that (as would be expected) all of the potential options will lead to increased travel times for some children who require surgery but the report adds "*it should be noted that the majority of these patients would already have long journey times under the present service configuration*".

[98] Mott MacDonald, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Health Impact Assessment*, 2012, p 204

[99] Mott MacDonald, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Health Impact Assessment*, 2012, p16

Overall the Health Impact Assessment concludes:

- The differences between the twelve different options are fairly marginal. However, overall, Option C, E and J could potentially give rise to slightly more negative effects than the other nine options, whilst Options G and I would induce fewest negative impacts.
- Option I will result in fewest patients being referred to a new surgical network (under 700). Options B, C and E would result in most patients being referred to a different network (over 900).
- All options, apart from Options A, H and I would require at least one surgical centre to undertake over 250 more surgical procedures than is currently the case. The centres affected by these particularly large increases are Leeds (Options D, F, G, K and L), Newcastle (Options B, C and E) and Southampton (Option J).
- In terms of access, Options C, E and J will see more patients experiencing significant journey time impacts by car and Option J by public transport as compared to the other options. Access by private transport is likely to be better under Options G and I, whilst public transport impacts will be fewest under Option G.
- Negative access impacts for patients from vulnerable groups are likely to be most significant in Options C and E by both private car and public transport and also for Option J by public transport.
- Option G and I are likely to involve fewest patients from vulnerable postcode districts experiencing significant travel impacts by private car and Option G by public transport.
- The impacts on carbon emissions are highest for Option J and lowest for Option G.

12 Testing the evidence for Option B

Impact		Option A	Option B	Option C	Option D	Option E	Option F
Overall impacts[1]							
Number of (and proportion of total) patients referred to a new network		778 (21%)	909 (24%)	911 (24%)	846 (23%)	911 (24%)	846 (23%)
Hospital networks likely to receive most new surgical cases		London (212) Leicester (186)	Newcastle (288) Southampton (175)	Newcastle (288) London (251)	Leeds (347) London (251)	Newcastle (288) London (251)	Leeds (347) London (251)
Access impacts[2]							
Number and proportion of patients who would experience significant travel impacts[3]	By private car	351 (9%)	358 (10%)	489 (13%)	400 (11%)	480 (13%)	390 (10%)
	By public transport	515 (14%)	525 (14%)	542 (14%)	462 (12%)	542 (14%)	462 (12%)
Impacts on vulnerable groups[4]							
Number and proportion of patients living within vulnerable postcode districts who would experience and increase in journey time	By private car	786 (28%)	800 (29%)	900 (32%)	847 (30%)	560 (20%)	506 (18%)
	By public transport	576 (21%)	628 (23%)	614 (22%)	570 (21%)	485 (17%)	440 (16%)
Number and proportion of patients living within vulnerable postcode districts who would experience significant travel impacts	By private car	233 (8%)	264 (10%)	350 (13%)	285 (10%)	346 (12%)	281 (10%)
	By public transport	346 (12%)	360 (13%)	381 (14%)	319 (11%)	381 (14%)	319 (11%)
Number and proportion of patients from vulnerable postcode who would be within an hour's journey from a surgical centre	By private car	1694 (61%)	1672 (60%)	1621 (58%)	1663 (60%)	1653 (60%)	1695 (61%)
	By public transport	669 (24%)	676 (24%)	676 (24%)	716 (26%)	694 (25%)	734 (26%)
Carbon emission impacts[5]							
Net increase in transport emissions from the baseline (371 tonnes CO^2e	Tonnes CO^2e	9 tonnes CO^2e	10 tonnes CO^2e	11 tonnes CO^2e	6 tonnes CO^2e	10 tonnes CO^2e	6 tonnes CO^2e
	% increase	17%	18%	20%	11%	19%	10%

1 The data presented below distinguishes between the number of patients affected due to being assigned to a different hospital to the one which they are currently using and the number of children who would be assigned to a new network. These figures are different because London is treated as a single network; as such, any London patients needing to use a different care centre in future will remain in the same network. **2** Note these figures relate only to trips to surgical centres because data is not available for the journeys for secondary care. **3** 'Significant' is described as having an increase in journey time over one hour AND/OR and overall journey time of over three hours by private car AND/OR four hours by public transport. **4** Proportion figures are expressed as a proportion of all patients in vulnerable postcode districts. The total number of patients in vulnerable postcode districts is 2,783. **5** Note this modelling is based on trips to surgical centres only and does not account for the shorter journeys to local centres for follow-on care.

Impact		Option G	Option H	Option I	Option J	Option K	Option L
Overall impacts[1]							
Number of (and proportion of total) patients referred to a new network		844 (23%)	778 (21%)	670 (18%)	790 (21%)	812 (22%)	812 (22%)
Hospital networks likely to receive most new surgical cases		Leeds (347) Southampton (175)	London (212) Leicester (186)	Leicester (186) Southampton (175)	Southampton (274) Leicester (186)	Leeds (282) Leicester (204)	Leeds (282) Leicester (204)
Access impacts[2]							
Number and proportion of patients who would experience significant travel impacts[3]	By private car	268 (7%)	342 (9%)	220 (6%)	478 (13%)	423 (11%)	414 (11%)
	By public transport	445 (12%)	515 (14%)	488 (13%)	601 (16%)	564 (15%)	564 (15%)
Impacts on vulnerable groups[4]							
Number and proportion of patients living within vulnerable postcode districts who would experience and increase in journey time	By private car	747 (27%)	445 (16%)	676 (24%)	880 (32%)	783 (28%)	442 (16%)
	By public transport	538 (21%)	447 (16%)	580 (21%)	686 (25%)	575 (21%)	445 (16%)
Number and proportion of patients living within vulnerable postcode districts who would experience significant travel impacts	By private car	199 (7%)	229 (8%)	147 (5%)	314 (11%)	292 (10%)	288 (10%)
	By public transport	299 (11%)	346 (12%)	325 (12%)	380 (14%)	352 (13%)	352 (13%)
Number and proportion of patients from vulnerable postcode who would be within an hour's journey from a surgical centre	By private car	1714 (62%)	1727 (62%)	1751 (63%)	1691 (61%)	1731 (62%)	1763 (63%)
	By public transport	716 (26%)	686 (25%)	669 (24%)	652 (23%)	703 (25%)	721 (26%)
Carbon emission impacts[5]							
Net increase in transport emissions from the baseline (371 tonnes CO^2e	Tonnes CO^2e	5 tonnes CO^2e	9 tonnes CO^2e	8 tonnes CO^2e	14 tonnes CO^2e	6 tonnes CO^2e	6 tonnes CO^2e
	% increase	9%	16%	15%	26%	11%	11%

12 Testing the evidence for Option B

In comparing Option B with Option G (the next highest-scored option) the HIA reports that:

- 909 patients (24% of total) would be referred to a new network in Option B compared to 844 patients (23% of total) in Option G. This is a difference of 65 patients.
- 358 patients (10% of total) would experience a 'significant travel impact' in Option B by car compared to 268 patients (7% of total) in Option G. This is a difference of 90 patients.
- 525 patients (14% of total) would experience a 'significant travel impact' in Option B by public transport compared to 445 patients (12% of total) in Option G. This is a difference of 80 patients.
- 264 patients from vulnerable postcodes (10% of patients in vulnerable postcodes) would experience a 'significant travel impact' in Option B by car compared to 199 patients (7% of patients in vulnerable postcodes) in Option G. This is a difference of 65 patients.
- 360 patients from vulnerable postcodes (13% of patients in vulnerable postcodes) would experience a 'significant travel impact' in Option B by public transport compared to 299 patients (11% of patients in vulnerable postcodes) in Option G. This is a difference of 61 patients.

The JCPCT is also referred to the report of Ipsos Mori on the outcome of "*Qualitative research with parents and young people using congenital heart services and Black and Minority Ethnic groups*". This report provides a detailed description of views submitted by members of the public from BAME groups during focus groups that were held during the consultation process. The views submitted do not address specific surgical centres or specific options but highlight issues of importance as reported by participants.

F Carbon emissions

The Health Impact Assessment reports that impacts on carbon emissions are highest for Option J and lowest for Option G but does not propose that any option is regarded as non-viable in this regard. JCPCT members are referred to the Health Impact Assessment for a more detailed assessment.

G Population projections

Data validated by the Central Cardiac Audit Database demonstrates that the volume of paediatric congenital cardiac surgery activity has been relatively constant with approximately 3,600 paediatric cardiac surgery procedures performed each year. Population projections produced by UK National Statistics would suggest increases in the paediatric population in England and Wales in the order of 13.7 % by 2025 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. This equates to an estimated increase of approximately 480 cases per annum by 2025. A more detailed analysis of projected growth is set out in Appendix Y.

The review has considered the future need of areas with Black and Minority Ethnic groups in response to evidence that the projected birth rate may be higher for some ethnic community groups, and evidence that there is a higher prevalence of some types of

congenital heart disease amongst some Asian communities, although absolute numbers are small.

The population data that has been applied by the review has been sourced from a specialist geographic information solutions third-party. It is taken from census data which is updated typically twice per year. The original Census counts are from the 2001 Census but counts are projected based on movements in delivery counts form the most up-to-date postcode release at the time.

Therefore, account has been taken of the growth up to 2010 at locality level. Future growth has been projected at national level. The JCPCT is advised that this level of detail is appropriate in view of the relatively low incidence of activity nationally, and the small absolute numbers. Given the relatively low absolute number representing growth and the time scale over which it will be achieved , the JCPCT is advised that there is confidence that the national network proposed by option B will build sufficient capacity.

H Validity of the Newcastle network

A key issue for JCPCT members will be to consider the extent to which the Newcastle network envisaged by option B can be considered viable in view of some respondents in Yorkshire and Humber expressing alternative preferences for centres in Liverpool, Birmingham and London.

Current network configurations across England are generally informal and sometimes illogical, having been developed through personal contacts and with no strategic direction. However, the existing network led by Leeds Teaching Hospital was assessed positively by the Kennedy panel:

"The network is well established and the Trust was proactive in setting up the network; the network approach is collaborative and not top-down; the network is already strong, and the Trust has demonstrated some leadership within the network[100]*"*

> "It makes little sense to supplant an existing well-developed network in Leeds with the weaker one at Newcastle. Indeed, clinicians interviewed [by PwC] warn that under [options that exclude Leeds] Leeds would be part of multiple networks, and that the confusion which would arise when deciding to send a sick baby, especially during the middle of the night, would be a clinical risk".
>
> **Children's Heart Surgery Fund**, response to consultation

The viability of the Newcastle centre in option B partly depends upon patient flows from Yorkshire and the Humber, including from the Doncaster, Sheffield, Hull, Wakefield and Leeds postcodes (though not all of these postcodes need to be allocated to the Newcastle network for this option to be viable). These postcodes currently have strong links to the surgical unit in Leeds.

Appendix Z provides an analysis of how postcodes have been assigned to the Newcastle network.

[100] Safe and Sustainable, *Review of children's congenital cardiac services in England – Report of the independent expert panel chaired by Professor Sir Ian Kennedy*, 2010. p 67

12 Testing the evidence for Option B

Evidence submitted from parents, clinicians and members of the public in Yorkshire and Humber suggest that there are reasonable grounds for considering the extent to which these patient flows would be achievable based on alternative stated preferences for the Liverpool, Birmingham and London centres.

"It would appear that 'heroic' assumptions have been made about the flow of patients to Newcastle … Local feedback and intelligence from the Specialised Commissioning Group suggest that patient choice and more realistic assumptions mean that it is unlikely that Newcastle can achieve the minimum requirement of 400 cases and will therefore not be sustainable under any of those scenarios".

Leeds Teaching Hospitals NHS Trust, response to consultation

"The patient flows predicted under options A-C suggest patient travel patterns from the Yorkshire and Humber region that do not appear to match local knowledge".

Yorkshire and Humber Joint Health Overview Scrutiny Committee, response to consultation

"We believe the [PwC] analysis backs up what we have long argued: that it is impossible for Newcastle ever to meet the 400 minimum yearly surgical procedures' let alone the optimum number of 500. Instead, the Leeds Unit, with an extra surgeon, greater population coverage taking in parts of the North East and with a high birth rate, is likely to easily meet the 400 threshold and would soon attain 500".

Children's Heart Surgery Fund, response to consultation

"You have to engineer the flows so you get enough patients going to Newcastle and unfortunately that means in some cases 222 out of 320 patients being sent to Newcastle, when it would be much closer to go to Liverpool".

Dr Mike Blackburn, Consultant Paediatric Cardiologist, Leeds Teaching Hospitals NHS Trust, Leeds consultation event

The significant support for the retention of surgery at Leeds centre from respondents in Yorkshire and Humber is quite evident from the various submissions to consultation. A petition[101] supporting the Leeds centre received around half a million signatures and various written submissions from associations and organisations in Yorkshire have been consistent in their stated intention to choose to travel to centres other than Newcastle in the event of Option B being chosen[102].

In order to test further the viability of the networks proposed for consultation and the travel assumptions that were applied in developing the networks the JCPCT commissioned an independent third party (PwC) to interview key consultees (clinicians, parents and members of the public) and to report on the viability of the proposed networks with reference to 22 postcodes[103]. Of these, 10 postcodes have a proposed relationship with the Newcastle or Leeds surgical centres.

JCPCT members are referred to the PwC report (Appendix AA) for a full description of terms of reference, methodologies for interview and analysis, findings and conclusions.

When the authors of the report presented to the JCPCT in October 2011 the headline message was that the report did not identify any 'show stoppers' in that all of the options consulted upon were reported to be viable and deliverable, albeit with different degrees of risk.

The Executive Summary[104] reads:

> *"There were some postcode areas identified by clinicians and also the majority of parents and the public, where the indication would be that the Safe and Sustainable assumed surgical centre would not be the preferred choice. If patient flows for these postcode areas were factored into assumptions and projected levels of activity, they may have implications in particular for the Newcastle centre under Options A, B and C".*

PwC reported that parents and the public from four postcodes highlighted that they would not prefer the Newcastle centre, reflecting submissions made during consultation by some respondents in Yorkshire and Humber. The postcodes were: **Leeds, Wakefield, Doncaster and Sheffield**. *Prima facie* these findings may present a risk to the viability of Option B in that the absolute exclusion of these postcodes from the proposed Newcastle network would not enable the Newcastle centre to attain the minimum critical mass of 400 surgical procedures (under this scenario Newcastle would be forecast to attain 351 procedures per year excluding population growth projections).

But these findings should be considered in the full context. The report went on to advise that 96% of referring clinicians who were interviewed would refer in line with the networks envisaged by Option B even though 50% of these referrers would have to change current referral practice.

PwC also reported that:

> *"The majority of parents and the public also indicated if told / advised to go to an alternative centre compared to their preferred centre, they would consider the alternative. However, there was more reluctance amongst members of the public to consider travelling to Newcastle as a centre."*

[101] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p8

[102] This show of local support is not unique as there have also been well-coordinated campaigns by local groups in support of the heart centres that are popularly perceived as being more at risk of non-designation: Southampton, Oxford, Leicester and the Royal Brompton.

[103] The criteria for inclusion in this exercise was postcodes which are at least roughly equidistant to two surgical centres or where the postcode is closer to an alternative surgical centre that appears in the relevant option

[104] PWC, *National Specialised Commissioning Team (NSCT) – Testing assumptions for future patient flows and manageable clinical networks, Executive Summary*, October 2011, p4

12 Testing the evidence for Option B

> "We strongly support the principle of commissioning whole patient pathways, and for teams to work in a clinical networked arrangement".
>
> **Royal College of Paediatrics and Child Health**, response to consultation

The support by referrers of the proposed networks in option B and the willingness of parents to accept the advice of their referring clinician in this regard supports the JCPCT's proposal to establish a number of Congenital Heart Networks across England. It is proposed that NHS commissioners will oversee the development of the congenital heart networks via the establishment of Congenital Heart Network Boards. Each Board will be managed by a lead clinician from the designated surgical unit in the network and will comprise representatives of the various NHS services in the network that see children with congenital heart disease. Each Network Board will be required to deliver a consistent, joined-up approach across the entirety of the patient pathway which reasonably responds to any particular local issues identified by respondents to public consultation, and which works to common clinical protocols and guidelines across the network.

Thus, while PwC reports a relative immediate-term risk to Option B in that there is limited support for the Newcastle centre amongst parents and the public who were interviewed from the four postcodes in Yorkshire, there is evidence of the willingness of clinicians interviewed to refer in line with the proposed network. In view of the willingness of parents who were interviewed to accept referrer advice, there is evidence that the long-term viability of Option B can be secured via the development of Congenital Heart Networks within which referring clinicians would adhere to agreed clinical pathways of care and common clinical protocols.

As set out elsewhere in this document, the proposal for the establishment of networks is consistent with the principle of patient choice, which will not be impinged upon by the proposal. But a sensitivity analysis suggests that even a significant exercise of patient choice away from the Freeman Hospital from parents in the four postcodes (Leeds, Wakefield, Doncaster and Sheffield) would not jeopardise the viability of Option B.

For example, if in practice the impact of patient choice were that:

- Half of the forecast caseload from the four postcodes were to choose to not travel to Newcastle: Option B would remain viable with the Newcastle centre attaining a projected caseload of 455 procedures per year (excluding projected population growth)
- Three-quarters of the forecast caseload from the four postcodes were to choose to not travel to Newcastle: Option B would remain viable with the Newcastle centre attaining a projected caseload of 403 procedures per year (excluding projected population growth)

There are strong personal allegiances amongst parents and patients who are existing users of their local surgical unit, including those in Yorkshire and Humber. But JCPCT members are establishing networks for the future and while they

must take account of local opinion, they must not lose focus of the national perspective. The JCPCT is invited to consider that whilst the implementation phase and the immediate period thereafter present risks of disruption that will require mitigation, those risks (such as allegiances to local centres) will dissipate naturally over time and allegiances will change.

A number of respondents have noted the "well established" and "developed" congenital cardiac network that already exists in Yorkshire and Humber[105]. Although these views were made in support of the retention of Leeds Teaching Hospital as a provider of surgical services they should strengthen – not weaken – confidence in the ability of the Leeds and Newcastle units to develop a well-managed single network. Clinicians and managers from both centres spoke positively to the Kennedy panel of their belief in the benefits of managed clinical networks and in the significant contribution that their teams could make in this regard.

I Validity of the Southampton network

Some respondents to consultation have questioned the viability of the Southampton network that is proposed under option B. For example, Guy's and St Thomas' NHS Foundation NHS Trust[106] has queried the basis on which the Guildford and Redhill postcodes have been allocated to the Southampton network (though Southampton University Hospital NHS Foundation Trust provided evidence on the viability of the proposed arrangements during the same exercise).

The detailed analysis that proposes the viability of options that include both Southampton and Bristol is set out in Appendix Q. This report, which proposes some changes to how some postcodes are assigned to the Southampton, Bristol and London networks, is the outcome of an analysis that takes into account evidence submitted for this purpose by relevant surgical units and Specialised Commissioning Groups, a consideration of evidence submitted during consultation from other respondents (including as reported by Ipsos Mori) and the report of PwC on patient flows and networks. Based on this analysis the JCPCT is advised that it is reasonable to propose the viability of the Southampton network as envisaged in option B.

Were the JCPCT minded to regard the Southampton network as not viable in option B, the JCPCT would be advised that the next two highest-scoring options would also have to be disregarded as 'not viable' for the same reason: options G and I. In this event, the JCPCT would be advised to consider option J, which is a seven-site option that excludes Bristol but retains Southampton. Option J is the next highest scoring option and which scores the highest of the alternative viable options in most of the sensitivity tests.

J Emergency retrieval times in Yorkshire and Humber

A number of respondents in Yorkshire and Humber set out concerns about the impact of ceasing surgery at Leeds Teaching Hospital to emergency retrieval times and the impact to local retrieval services.

[105] See for example responses to consultation from Mid-Yorkshire Hospitals NHS Trust and the Children's Heart Surgery Fund

[106] Letter dated 16 April 2012 in response to the PwC report

12 Testing the evidence for Option B

"Based on figures for 2008-10 closure of the Leeds surgical unit would result in an additional 80 transfers of critically ill infants out of Leeds and more than double the transfer time for a further 200 transfers from DGHs. These transfers will include highly time critical cases such as transposition of the great arteries who need an immediate surgical procedure to survive".

Dr Carrie MacKenzie, Consultant Paediatrician, on behalf of Yorkshire, Humber and North Trent Paediatric Cardiology Clinical Network Paediatricians (as listed)

"The costs and risks of transporting our larger (as compared to Newcastle) population have been under-played. The overall cost and risk rise as the size of the population to be moved increases. We know from personal experience that lives are put at risk by increasing the length of transfer. The greater the population to be moved the greater the risk of unnecessary death. Furthermore the burden of transporting the children will stretch the capacity of our combined paediatric / neonatal retrieval service unless there is significant investment".

Dr Mark Darowski and **Linda Daniel** on behalf of the Paediatric Critical Care Network, North, East and West Yorkshire

"Should Sheffield Teaching Hospital NHS Foundation Trust need to transfer neonatal patients to a specialist centre outside the Yorkshire and Humber region there is a real concern that the distance these babies and their families would need to travel could be excessive".

Chief Executive of **Sheffield Teaching Hospitals NHS Foundation Trust**, response to consultation

For the purpose of consultation the JCPCT sought to measure the 'worst case' impact of the proposals to emergency retrieval times. The approach taken, on professional advice from the Paediatric Intensive Care Society and the *Safe and Sustainable* Steering Group, was to assume for the purpose of this exercise that emergency retrievals would not be undertaken by retrieval teams based at centres that were not designated for paediatric congenital cardiac surgery[107].

Potential 'worst case' journey times were accordingly measured from District General Hospitals to the proposed surgical units in each of the options to assess compliance with the Paediatric Intensive Care Society standards which require retrieval teams to arrive at the referring hospital within 3 hours.

Some respondents queried whether the analysis was sufficiently sensitive to gauge the impact of longer journey times. The Chair of the Paediatric Intensive Care Society's *Acute Transport Group*, Dr Marriage, wrote to the JCPCT:

[107] The Steering Group agreed to advise the JCPCT to retain this method for the purpose of analysing 'worst case' journey times in February 2012

"There is some concern that [the PICS standard] may be being used as a dichotomous variable (that is to say all retrievals under 3 hours are acceptable, all others are too long) when its intention is to set down a maximum acceptable response time … There is a measurable reduction in child deaths by delivering specialist paediatricians to the child's bedside quickly; until that team arrives, care is in the hands of non-specialists".

The Association of Cardiothoracic Anaesthetists' wrote in its response to consultation:

"Transferring sick neonates to distant centres by ambulance is not without risk".

This begs the question: what is the available evidence that would allow the JCPCT to objectively quantify the impact and potential risk of each longer journey? The published research evidence concludes that *"the distance travelled by patients to access emergency paediatric critical care did not seem to affect their outcome*[108]*"*. Dr Marriage advises that:

"This may seem surprising on first inspection, until the data are more closely examined: the upper quartile (that is the longest 25% of journeys) included all transports over 60km – just 38 miles. It is therefore difficult to comment specifically on the safety of longer journeys from the data in this paper".

Dr Marriage adds:

"Clinical experience suggests that if a child can be stabilised – by the provision of care by appropriately trained personnel – then the duration of the transport becomes of secondary importance. However, some children will have time-critical conditions, in which case minimising transfer times may become crucial".

So Dr Marriage makes the point that although **overall** journey times would be longer for some children (when also taking into account the time taken for the 'second stage' of the journey from the referring hospital to the surgical unit) the usual 'time critical' aspect of the entire journey – and the aspect that is under scrutiny within this exercise – is the time that it takes for the specialist retrieval team to travel from base to the local hospital so that the child may be stabilised. Once stabilised, the child may be transported to the surgical unit by the retrieval team under non-emergency conditions.

The Association of Paediatric Anaesthetists of Great Britain and Ireland, who wrote that it is 'very supportive' of the review, addressed the issue of longer retrieval times for an acutely ill child with congenital heart disease presenting at a local hospital:

"There will be a concurrent increase in the necessity for local hospitals to resuscitate and stabilise prior to the arrival of a transport team. Local anaesthetists will inevitably be involved in this process and will require support and a clear pathway for 24/7 advice from the children's heart or surgical centre[109]*"*.

The association concluded that:

" None of these problems are insuperable but the solution will depend on the configuration of the model that is finally selected".

[108] Ramnarayan, P., Thiru, K., Parslow, R. C., Harrison, D. A., Draper, E. S., & Rowan, K. M. (2010). Effect of specialist retrieval teams on outcomes in children admitted to paediatric intensive care units in England and Wales: a retrospective cohort study. Lancet, **376**, 698–704

[109] Similar advice was offered to the JCPCT by the Resuscitation Council (UK), a charity with the principal objective of producing guidelines and training in cardiopulmonary resuscitation

12 Testing the evidence for Option B

The JCPCT's analysis suggests that even within 'worst case scenarios' all referring hospitals in the Newcastle and Leeds networks could be reached within 3 hours in compliance with the standards.

However, whilst the JCPCT has been assessing 'worst case scenarios' evidence suggests that retrievals would continue to be undertaken by the existing dedicated paediatric retrieval team in Yorkshire (Embrace) even in options that do no designate the Leeds centre as a surgical unit.

> *"Embrace is the United Kingdom's first combined infant and children's transport service. It undertakes neonatal transfers alongside paediatric retrievals for the 23 hospitals in the Yorkshire and Humber region, serving four tertiary neonatal units and two paediatric intensive care units … This paper models the service implications for Embrace of the proposals put forward as part of the Safe and Sustainable review*[110]*".*

Although the analysis by Embrace concludes that "*it is unclear within this region as to the impact upon the Embrace transport service*" (in terms of resource and planning requirements) it is clear that Embrace expects to continue to undertake neonatal and paediatric retrievals, including for cardiac children, in the event that the Leeds centre is not designated as a paediatric cardiac surgical unit.

> *"We do not anticipate any problems with continuing to take responsibility for transferring cardiac patients who present in Yorkshire and Humber if Leeds is de-designated. In fact because the numbers of cardiac cases requiring transfer is likely to rise, because of a reduction of in-utero transfers, our skills and performance are likely to improve*[111]*".*

This means that in practice journey times would be considerably shorter in Option B for the children of Yorkshire and Humber than the 'worst case' journey times assumed by the JCPCT for the purpose of consultation. Actual journey times would be measured by the time taken for Embrace to travel from base in Barnsley to the referring hospital (rather than measuring the time taken for a retrieval team based at the Great North Children's Hospital in Newcastle to reach the referring hospital).

Having considered all of the responses to consultation, the *Safe and Sustainable* Steering Group advised the JCPCT that:

> *"In all of the options submitted for consultation larger numbers of critically ill children will move over greater distances. However, the Steering Group advises that this does not present increased risk to the child provided the options comply with the maximum journey time thresholds as set out in the Paediatric Intensive Care Society standards for the care of critically ill children. The evidence is that these distances have not been shown to be associated with increased risk*[112]*".*

K Emergency retrieval times in the South

Option B (with options G and I) achieves the best compliance with the retrieval standards in the south of the country including for areas that present challenges for a timely retrieval due to geography: Great Yarmouth, Isle of Wight, South West of England and South Wales. However, the JCPCT is advised that the relative overall strength of option B when assessed against the other criteria is apparent even after disregarding the Paediatric Intensive Care Society standards for the purpose of sensitivity testing.

[110] Embrace's response to public consultation (as an Appendix to the response from Leeds Teaching Hospitals NHS Trust)

[111] Clinical lead of Embrace to Immediate Past President of PICS, Letter from Ian Jenkins, February 2012. Appendix BB

[112] Appendix CC

L Impact to other retrieval services

Option B presents limited impact to paediatric retrieval services in terms of an ability to maintain and develop existing arrangements, though the NHS in England has already acknowledged a need to review during implementation how paediatric retrieval services are planned, delivered and resourced. The submissions from the President of the Paediatric Intensive Care Society, the Chair of the PICS Acute Transport Group and from *Embrace* list a number of implications to paediatric retrieval services that will need to be addressed by commissioners in the implementation phase[113].

Under option B the emergency retrieval of children with congenital heart disease would continue to be delivered by:

North East England	PICU-based retrieval team at the Great North Children's Hospital
Yorkshire and Humber	Embrace, a dedicated paediatric retrieval team based in Barnsley
North West England and North Wales	The 'North West and North Wales Paediatric Transport Service' is hosted by Central Manchester University Hospitals NHS Foundation Trust in collaboration with Alder Hey Children's NHS Foundation Trust.
Midlands	KIDS (Kids Intensive Care and Decision Support) operates from the PICUs of Birmingham Children's Hospital and the University Hospital of North Staffordshire. The future role of the paediatric retrieval service provided by University Hospitals of Leicester NHS Trust would be planned under the auspices of the proposed Midlands Congenital Heart Network.
South West England and South Wales	The South West Paediatric Retrieval Service, a partnership between University Hospitals Bristol NHS Foundation Trust and Great Western Ambulance Service, is based at the Bristol Royal Hospital for Children.
South Central England and Isle of Wight	Retrievals would be undertaken by a single stand alone paediatric retrieval service provided jointly by Southampton University Hospitals NHS Foundation Trust and the Oxford Radcliffe Hospitals NHS Trust.
London, Eastern and South East England	Retrievals would continue to be undertaken by the South Thames Retrieval service which operates from the PICU at the Evelina Children's Hospital and the Children's Acute Transport Service, a collaboration currently across Great Ormond Street Hospital, the Royal London Hospital, St Mary's Hospital and the Royal Brompton Hospital.

[113] An expert working group has been convened by the Director of National Specialised Commissioning whose remit is to advise NHS commissioners on the process for strengthening paediatric retrieval services in England. The proposed group includes the President of PICS, the Chair of the Acute Transport Group and the clinical lead from Embrace

12 Testing the evidence for Option B

M Paediatric cardiothoracic transplant services and mechanical device as a 'bridge to transplant' services

> "It would appear that the smaller, stand alone heart hospitals have featured in significantly more options that Leeds due to the nationally commissioned services they provide. I and many of the families we represent feel that these services, which serve a very small number of children, should not have been allowed to dominate the issues".
>
> Director of the **Children's Heart Surgery Fund**, response to consultation

A successful paediatric cardiothoracic transplant programme and mechanical device as a 'bridge to transplant' service requires particular skill and expertise from the various members of the medical and nursing team, and not just in the surgical technique or medical management of the patient.

A paediatric cardiothoracic transplant procedure involves the removal of the heart and / or lungs from a deceased infant or child at a local hospital by a surgical team from the transplant unit. For a number of reasons the availability of donor organs has reduced significantly in the United Kingdom over the past ten years and great skill is required to successfully match scarce donor organs with potential transplant recipients. The matching process is complex, involving a number of clinical considerations relating to both the donor and recipient. Particular expertise is also required for management of the child post-transplant, not least given the risk of rejection of the organ.

A 'bridge to transplant' involves the insertion of a mechanical 'ventricular assist device' (or 'artificial heart') in very sick children whose hearts are too weak to pump blood around the body and who would otherwise die. This requires an operation that takes around seven hours, during which the child is supported by pulmonary bypass.

It is not unusual for a child to remain on a mechanical device for many months while awaiting a transplant. Transplant patients (and 'bridge to transplant' patients) are heavy users of paediatric intensive care units and require careful management.

Option B would retain paediatric cardiothoracic transplant services (including the provision of mechanical devices as a 'bridge' to transplant) in their current locations: Great Ormond Street Hospital for Children in London (19 cardiothoracic transplants and 17 'BTT' procedures in 2011/12) and the Freeman Hospital in Newcastle (10 cardiothoracic transplants and 16 'BTT' procedures in 2011/12).

Although it did not address the issue of transplantation directly, in its response to consultation Great Ormond Street Hospital advised the JCPCT that it "*would support any of the configurations presented*", which would include options that proposed the re-location of the transplant service from the Freeman Hospital to Birmingham Children's Hospital. The Cardiothoracic Transplant Advisory Group (NHS Blood and Transplant) concluded that options that remove transplant services from the Freeman Hospital to Birmingham

Children's Hospital would be "*viable*" though it cautioned that "*there would need to be a migration of expertise that should not be lost to the national service*". The *Safe and Sustainable* Steering Group noted that the JCPCT had received conflicting advice on the nationally commissioned services and concluded in its advice to the JCPCT that "*while the re-location of a nationally commissioned service presents some potential risks, these risks can, in the view of the Steering Group, be managed*". However, the advice from these organisations and committees was based on options for consultation that assumed at the time that there is an alternative NHS provider in England that could safely develop a paediatric cardiothoracic transplant and 'bridge to transplant' service, which the JCPCT solely identified in the consultation document as being Birmingham Children's Hospital. This is because were re-location of a transplant service necessary, the JCPCT was advised by an independent expert panel that Birmingham Children's Hospital is the only alternative viable provider in England.

The panel had previously advised the JCPCT that two transplant services are optimal for England, and that the only alternative viable provider of paediatric cardiothoracic transplant services would be BCH based on an assessment of submissions from a number of paediatric cardiac surgical providers that covered the potential for necessary expertise, infrastructure, facilities, recruitment, networks, training and governance . This was also reflected in the advice by NHS Blood and Transplant's *Cardiothoracic Transplant Advisory Group* (CTAG)[114] that an alternative paediatric transplant services must be co-located or 'closely networked' with a provider of adult cardiothoracic transplant services. BCH is the only alternative provider of paediatric cardiac surgical services in England that could be regarded as being co-located with a provider of adult transplant services (Queen Elizabeth II Hospital, Birmingham)[115].

However, the JCPCT is advised that as an outcome of recent work by the National Specialised Commissioning Team to test capacity assumptions and assess infrastructure risks (undertaken jointly with local commissioners) the NSC Team is currently unable to provide assurance at this time that planning and implementation plans for receiving paediatric cardiothoracic transplant are sufficiently well developed at Birmingham Children's Hospital and that as such, assurance cannot be given at this time around the safe re-location of the transplant service to Birmingham Children's Hospital.

The Chief Executive of Birmingham Children's Hospital has also acknowledged that assurance cannot be given by the Trust that arrangements to safely deliver transplant services could be implemented within appropriate timescales[116].

> *"We are in the process of shaping a new high dependency strategy for the hospital which will transform the way we provide high dependency care, out of which we will identify additional high dependency capacity. However, until this work is complete, we will not know if this will be sufficient to deliver a high quality and safe cardiac transplant and bridge to transplant service under a two centre approach…. We recognise that the challenges of increased capacity, recruitment and training of new staff,*

[114] Response to consultation

[115] Save possibly for the Royal Brompton & Harefield NHS Foundation Trust, though adult transplants are performed at Harefield Hospital in Uxbridge and the Trust did not indicate an interest in developing paediatric cardiothoracic transplant services during the *Safe and Sustainable* process

[116] Appendix DD

12 Testing the evidence for Option B

and of operationalizing a significant service not previously delivered, poses much greater challenges in terms of timescales … The risk in moving swiftly to a two-centre option including BCH is that this safety and quality could not be guaranteed to our usual high standard."

The preference of the Board of Birmingham Children's Hospital during consultation was for option B which would retain transplant services in their current locations.

Newcastle-upon-Tyne Hospitals NHS Foundation Trust questioned whether a re-location of transplant services was in fact safe:

"It would be impossible to move all the essential components of this team to Birmingham. Redeployment of this service would therefore entail establishing a new service with an unavoidable learning curve and it would take several years before it could achieve a similar high standard producing the same quality of outcome as is happening presently at the Freeman hospital[117]".

These concerns are reflected in the advice given to the JCPCT by the Advisory Group for National Specialised Services (AGNSS).[118]

AGNSS, while noting that the JCPCT has recommended for consultation the retention of paediatric cardiac surgery at Great Ormond Street Hospital for Children,has queried whether the more specialist aspects of the service provided by the other provider – the Freeman Hospital - could be replicated in other centres. The Freeman Hospital performed the first infant cardiothoracic transplant in the United Kingdom in 1985[119] and is widely regarded as having pioneered the use of the 'Berlin Heart' ventricular assist device:

> "[The Freeman Hospital] currently has developed expertise in aspects of paediatric cardiothoracic transplantation which are not currently delivered elsewhere in the UK. These include the management of children with single ventricle on mechanical support prior to transplantation, desensitisation for ABO incompatibility and the management of children with mitochondrial disease. This specialist expertise would need to be replicated if the service were to be transferred: this may be difficult where other clinical specialties (immunology, cardiac intensivists) are involved. This may not realistically be possible, as such highly specialised services require multidisciplinary clinical teams. Indeed, [Freeman Hospital] currently provides the only UK expertise for the management of children with single ventricle progressing to heart transplantation".
>
> Report of the **Advisory Group for National Specialised Services**, March 2012

[117] Letter to secretariat, 11 August 2011, from Clinical Director of Great North Children's Hospital, Medical Director of the Trust and Consultant in Paediatric Intensive Care Medicine at the Freeman Hospital

[118] The Advisory Group for National Specialised Services is a committee that advises health Ministers on which services should be nationally commissioned and the centres that should provide them. Given the small number of patients or procedures involved and the very high level of clinical expertise required to provide such treatments, most nationally commissioned services are provided in a very small number of centres, usually no more than three or four.

[119] NUTH NHSFT response to consultation

In summary, AGNSS advises the JCPCT that:

"The [paediatric cardiothoracic transplant] programme provided at Newcastle upon Tyne Hospitals provides excellent clinical outcomes and has developed expertise in aspects of paediatric cardiothoracic transplantation which are unique to the UK, and has an international reputation in this respect.

There is evidence to support the clinical viewpoint that it takes around 8 to 10 years for a new programme to develop full expertise.

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 paper has set out for members of the JCPCT the significant risks which, in the opinion of AGNSS members, present with a proposal to re-locate the paediatric cardiothoracic transplant service from Newcastle upon Tyne Hospitals NHS Foundation Trust. Birmingham Children's Hospital found it could not guarantee that it would be able to address the complex risks in accordance with the advice of the expert panel and Safe and Sustainable steering group, and to its usual high standard of quality and safety within the timeframes set out by the JCPCT. From an AGNSS perspective the delay of three years by BCH to establish the service would present significant challenges and risks to being able to maintain the existing service at Newcastle in the interim".

Some respondents to consultation proposed that the Leeds centre should be designated as a provider of paediatric cardiothoracic transplantation in place of the Freeman Hospital. The suggestion was that if Leeds was designated to provide transplantation services, it would therefore follow that the arguments for retaining paediatric cardiac surgery in Leeds (and thus implementation of option G) would be much stronger.

The submission made by Leeds Teaching Hospitals NHS Trust in support of its claim to provide cardiothoracic transplant services was considered by the independent expert panel. The panel concluded that the application made by the Leeds centre was not convincing on the grounds that it was "*unfocussed, unrealistic and had lacked the necessary level of detail*". As such, the panel advised that Leeds Teaching Hospital could not be regarded as a viable provider of paediatric cardiothoracic transplant services.

Additionally, CTAG advised the JCPCT[120] that a paediatric cardiothoracic transplant programme should be co-located or "closely networked" with an adult cardiothoracic transplant programme, a requirement that could not be met by Leeds Teaching Hospital as there is no adult cardiothoracic transplant service in Leeds (the closest adult transplant service to Leeds is in Manchester).

[120] Response to consultation by CTAG

12 Testing the evidence for Option B

N Extra Corporeal Membrane Oxygenation services for children with severe respiratory failure

Extra Corporeal Membrane Oxygenation (ECMO) supports babies and children who have severe potentially reversible respiratory failure by oxygenating the blood through an artificial lung machine. Children on ECMO require intensive care and are usually referred to their local hospital once they are well enough to discontinue ECMO.

There are three providers of ECMO for children with respiratory services in England[121]: Freeman Hospital in Newcastle, Great Ormond Street Hospital for Children in London and Glenfield Hospital in Leicester. Four other hospitals have been assessed by NHS commissioners as being competent to deliver respiratory ECMO on a 'surge' basis during periods of heavy usage of paediatric intensive care capacity nationally, for example during pandemics: Alder Hey Children's Hospital, the Royal Brompton Hospital, Birmingham Children's Hospital and the Evelina Children's Hospital.

Option B would necessitate the re-location of ECMO services from Glenfield Hospital as ECMO cannot be safely provided in the absence of support from on-site consultant congenital cardiac surgeons (and would remove a 'surge' centre from the national network by way of the Royal Brompton Hospital if the JCPCT decided that this would not be one of the designated centres in London).

The JCPCT has been advised by an independent expert panel that while the optimum arrangement in this regard would be the retention of the three designated ECMO services in their current locations, the services may be moved safely with adequate planning.

In this regard, options A, H, I and J offer advantages over option B in that they would retain ECMO services in all of the current locations. However, as noted elsewhere, Option I could be regarded as not viable as the Bristol and Birmingham centres are forecast to fail to reach the minimum critical mass threshold of 400 paediatric surgical procedures. This option also scores low against the criteria for the evaluation of options when compared to options B and G[122]. Option A consistently scores low against the sensitivity tests.

Glenfield Hospital has one of the largest ECMO centres in the world[123] and delivers the majority of respiratory ECMO in England[124]. It possesses an excellent reputation for the delivery of respiratory ECMO services and for the training of professionals in this field. In 2010/11 the hospital's ECMO service was widely commended for its response to the H1N1 pandemic. The expertise, dedication and professionalism of its ECMO team is not in doubt.

However, the paediatric cardiac surgical service at Glenfield Hospital received a low score from the Kennedy panel in regard to current and future compliance with the *Safe and Sustainable* standards.

[121] There is also a paediatric ECMO service at Yorkhill Hospital in Glasgow and there is close cooperation across all four ECMO centres in the UK

[122] For a detailed case in support of Option I by University Hospitals Leicester NHS Trust, JCPCT members are referred to the Trust's paper headed "A proposal for an alternative configuration: Option AB" dated June 2012

[123] Two of the five randomised controlled trials of ECMO vs conventional treatment in the world scientific literature were undertaken by Glenfield Hospital (UHL NHS Trust response to consultation) and the Head of service, Mr Giles Peek, was the lead clinical investigator on the CESAR trial

[124] For example, see responses from UHL NHS Trust

"There were extremely strong feelings in response to the national team's apparent lack of recognition of the national and international role Glenfield's ECMO had played in the earlier months of the year, which had a significant impact on the number of planned heart operations carried out on children due to the medical and nursing highly skilled staff being used on the pandemic … ECMO is used for a variety of health issues and age ranges at Glenfield, providing critical services for other parts of the country and continent. Glenfield is the national training centre and participants could not understand why that facility and resource should move from Glenfield".

Leicestershire LINk, response to consultation, 2011

"We're the only team in the UK that provides a real-time mobile ECMO team. Leslie Hamilton mentioned TAPVD as the only diagnosis where you have to rush into theatre. At least half the emergency TAPVD patients we see as referred with respiratory failure and come for ECMO. ECMO is absolutely crucial to cardiac surgery".

Mr Giles Peek, Consultant Congenital Cardiac Surgeon (Glenfield Hospital), Leicester consultation event

The response to consultation made by University of Leicester NHS Trust gives great emphasis to the potential risks of re-locating the ECMO service from Glenfield Hospital, and JCPCT members are referred to Appendix 5 of the Trust's submission for a detailed description of these risks.

"If the children's cardiac surgical service at Glenfield were to close the ECMO service would be unsustainable. In order to provide the current level of service in other hospitals approximately 100 ECMO specialist nurses will need to be trained – this will take approximately 5 years in the current environment where they could be trained in Leicester, but could take much longer and be more costly if this facility were not available. The additional beds required to support this level of ECMO provision has not been allowed for in the expansion plans under options B,C or D. In addition to the capacity issues the clinical teams in these hypothetical new ECMO centres will be led by consultants who would not have undergone formal training in ECMO, who will have little experience and will take several years to obtain similar results to those obtained currently in Leicester".

University Hospitals of Leicester NHS Trust, response to consultation

12 Testing the evidence for Option B

The Trust's submission goes on to advise the JCPCT that a failure to designate Glenfield Hospital would result in the death of at least 76 infants, children and adults per year for 5 years due to the loss of the ECMO service in Leicester. This is a strong statement that demands that the JCPCT considers the extent to which this statement is supported by other respondents to consultation.

Neither of the two other ECMO providers in England chose to highlight potential risks of moving an ECMO service. Great Ormond Street Hospital advises that it "*would support any of the configurations presented*" by the JCPCT.

Great Ormond Street Hospital goes on to recommend an *increase* in the number of hospitals that provide respiratory ECMO by designating all future providers of paediatric cardiac surgery as providers of respiratory ECMO. This proposal was also made by Alder Hey Children's NHS Foundation Trust in its response to consultation. Great Ormond Street suggests that this would "*negate the need to consider the provision of 3 centres nationally in the* [JCPCT's] *decision making process as there will be 6 or 7 centres capable of undertaking this service*" and proposes that 20 ECMO runs a year would be necessary to maintain critical skills, in line with international ELSO guidelines (the world ECMO organisation).

The professional associations have considered the evidence submitted during consultation by way of the *Safe and Sustainable* Steering Group[125] and the Advisory Group for National Specialised Commissioning[126]. Both committees have advised the JCPCT that while the re-location of an ECMO service presents some potential risks, these risks can be safely managed with adequate planning.

Were the JCPCT to decide to implement option B, NHS commissioners have plans to ensure that the national provision of respiratory ECMO for children is safely maintained via the development of a respiratory ECMO service at Birmingham Children's Hospital. The Birmingham centre was assessed by an independent expert panel to be capable of delivering a respiratory ECMO service, and Birmingham was also assessed by commissioners last year as being able to provide children's respiratory ECMO if further capacity had been needed in the winter of 2010/11. An analysis of capacity at Birmingham undertaken by an independent capacity working group, comprising commissioners and finance staff, has advised the JCPCT that there is sufficient capacity for respiratory ECMO at Birmingham Children's Hospital.

However, the retention to the national service of the considerable expertise that resides in the Glenfield ECMO team, including ECMO Coordinators, must be considered a priority by NHS commissioners. The Director of the ECMO programme at Glenfield Hospital has advised that a transfer within 1 or 2 years would be reasonably achievable provided there is a coherent and adequately resourced implementation plan for the re-location of the ECMO team to Birmingham Children's Hospital, and with adequate support for the 'surge' centres (Appendix EE). The process for developing the plan must benefit from the experience of the clinical and management team at Glenfield Hospital, and would require a real and equitable partnership across the Birmingham and Glenfield teams.

Commissioners, clinicians and managers should be ambitious in their intentions: this is an opportunity to make an

[125] Appendix CC

[126] Appendix DD

excellent ECMO service even better by a union of the skills, expertise and dedication that reside in the two teams, based in a hospital that was assessed positively by the Kennedy panel for its compliance with the standards.

In view of the volume and complexity of the ECMO caseload undertaken by Glenfield Hospital the implementation plan must address how to ensure the continued functioning of the ECMO service at Glenfield Hospital in the short-term after the JCPCT's decision. There must also be plans for maintaining a high standard of training for professionals in this field given Glenfield's acknowledged national training role in this regard.

There is an established process for the designation by Ministers of NHS Trusts as providers of nationally commissioned services, on receipt of advice from the Advisory Group for National Specialised Services[127] (AGNSS). In the event that the JCPCT agrees on option B, AGNSS would be asked to advise the Secretary of State for Health on the designation of Birmingham Children's Hospital NHS Foundation Trust as a nationally commissioned provider of ECMO for children with respiratory failure.

Regarding the relationship between children's and adult respiratory ECMO services (which has been pioneered by Glenfield Hospital) the Medical Director of University Hospitals of Leicester NHS Trust has confirmed with the National Specialised Commissioning Team that while there would be short-term challenges associated with service change, the Trust is working to ensure the long-term provision of an adult ECMO service that is not critically dependent on the paediatric service[128].

O Impact on paediatric intensive care units

Implementation of option B would render the PICUs at Glenfield Hospital, Leicester and the Royal Brompton Hospital unviable as they predominantly exist to support cardiac children.

The JCPCT has been advised by Professor Sir Ian Kennedy's panel of concerns around the viability of the PICU at Glenfield Hospital. During consultation Glenfield Hospital suggested that the entire provision of PICU services in the city of Leicester could be rendered unviable in the absence of cardiac work at Glenfield Hospital[129]. This submission was shared with the Paediatric Intensive Care Society, who advised the secretariat that the paper submitted by the Trust does not offer any compelling evidence that the PICU at the Leicester Royal Infirmary would be rendered unviable. It said that the city of Leicester does not face unique challenges in responding to reduced PICU activity. The figures put forward by Glenfield Hospital itself for the expected number of non-cardiac and non-ECMO admissions to the PICU at the Leicester Royal Infirmary (421 admissions a year) would meet the requirements for a viable Level-3 PICU.

Regarding the Royal Brompton Hospital, the JCPCT has commissioned an independent report from the Pollitt panel on the implications of the loss of PICU services from the Royal Brompton Hospital, the conclusion of which was that paediatric respiratory services would remain viable at the Royal Brompton in the absence of a PICU (see Appendix K for details of the Pollitt panel's report), though there would be an impact for a small number of children for whom alternative arrangements would have to be made.

[127] Response AGNSS membership includes representatives of Royal Colleges of Medicine, specialised commissioners, public health experts and lay representation. See www.specialisedservices.nhs.uk/info/agnss

[128] Email to National Specialised Commissioning Team

[129] Appendix FF

12 Testing the evidence for Option B

The JCPCT is advised that under option B the PICUs at the John Radcliffe Hospital and Leeds Teaching Hospital would remain viable as cardiac patients account for around 35% of PICU admissions. The PICU at the John Radcliffe Hospital has indeed remained viable since cessation of paediatric cardiac surgery in February 2010.

The Leeds PICU would continue to achieve a level of activity sufficient for a Level 3 PICU in option B, though commissioners would need to work with the hospital to mitigate the risk of depleted resilience and less flexibility particularly in response to winter pressures. The Director of National Specialised Commissioning, on behalf of the Directors of the Specialised Commissioning Groups in England, is actively implementing a number of relevant work streams including the development of capacity plans for PICUs, and strengthening paediatric and neonatal retrieval services.

P Capacity at Birmingham Children's Hospital

University Hospitals of Leicester NHS Trust has questioned whether Birmingham Children's Hospital would be able to meet the required surgical caseload in options that exclude Glenfield Hospital. The submissions make reference to the population size of the Midlands and potential capacity constraints in BCH:

> *"The Midlands with a population of >11 million needs two surgical centres. London, after all, with a population of 9 million retains two centres*[130]*".*

The JCPCT is advised that this observation is incorrect and does not support the case for two centres in the Midlands. Whereas the Midlands represents around 19% of the population of England, the network envisaged for the London surgical units (covering London, South East and Eastern England) represents around 35% of the population of England[131]. Option A, which proposes the retention of surgery at Glenfield Hospital and Birmingham Children's Hospital, is forecast to result in a combined annual surgical caseload of 820 surgical procedures for the Midlands, compared to a combined annual surgical caseload of 1,538 surgical procedures for the London centres.

> *"We request to see the evidence that Birmingham has the capacity and capability to undertake both an increased cardiac surgical workload and build a new ECMO service, as well as increase its capacity for neurosurgical and renal work as outlined in a recent Healthcare Commission report. We also request to know how involved the Midlands' specialist commissioners have been in testing these assumptions. Within the last 12 months Leicester was asked by the West Midlands Commissioners to undertake a number of surgical cases from Birmingham Children's Hospital due to long waiting lists*[132]*".*

The JCPCT is advised that the capacity analysis undertaken by the secretariat in partnership with local commissioners provide reassurance about the ability of Birmingham Children's Hospital to build sufficient capacity to meet the requirements of option B, including the forecast ECMO caseload (the capacity analysis is set out in more detail in chapter 14).

[130] Page 11 of the Trust's response

[131] Estimated populations based on figures set out on page 110 of the Ipsos Mori report

[132] Page 13 of the Trust's response

Q 6 site options v 7 site options

Option B is a 7 site option, which prompted the secretariat to consider whether there are any particular benefits of a 6-site option. A potential benefit of 6-site options may be increased sustainability for the national service in that surgical centres serve a larger population and generally have a higher surgical caseload. There may also be financial benefits in greater concentration of surgical activity.

> "Within [a] six centre model, we believe the key to truly high quality, sustainable surgical services is the spread of workload between centres as evenly as geography allows, avoiding both the creation of extremely high volume centres which have associated risks and of centres operating at the margins of 400 cases where achieving even the lowest designation standards proposed by *Safe and Sustainable* will be a challenge ... The additional investment received by a unit attracting 500 cases a year will be significant and offers the potential to transform the ability of that unit to deliver outcomes that are comparable to the best in the world".
>
> **University Hospital of Bristol NHS Foundation Trust**, response to consultation

No firm conclusions can be drawn around the respective 'quality' of 6 centre options to those of 7 centre options as this depends on the individual surgical units that comprise the options though as a general principle, 6-site options may present a greater risk of losing higher quality centres and destabilising PICUs. Option B consistently scored highest partly because it comprises the top-scoring centres as assessed by the Kennedy panel and generally scores high against the agreed criteria for evaluation.

In any event Ipsos Mori reported limited support for the 6-centre options, and the Safe and Sustainable steering group has previously advised the JCPCT against 6-centre options on the grounds of resilience (particularly around paediatric intensive care provision in the winter) and deliverability.

R London and the South East / Eastern England network

Option B would result in two surgical centres in London. The JCPCT's preference during consultation was two, rather than three, surgical units in London as two centres would be better placed to reach the ideal minimum critical mass of 500 procedures per year and in view of geography and projected patient flows would be better placed to lead congenital heart networks across London and Southern / Eastern England.

> "We are firmly of the view that it would be helpful to explore what the London model would look like as a three-site network, taking into consideration the need to link with networks of care and support from all the areas that the hospitals would need to serve".
>
> Health, Environmental Health and Adult Social Care Scrutiny Committee, **Royal Borough of Kensington and Chelsea,** response to consultation

12 Testing the evidence for Option B

Some respondents have expressed a preference for the retention of three surgical units in London. The secretariat has tested the extent to which this may be achievable in view of i) the proposal for all designated surgical units to perform at least 400 paediatric cardiac surgical procedures a year and ii) the JCPCT's preference for the purpose of consultation for two surgical units in London that could each reach the higher threshold of at least 500 paediatric cardiac surgical procedures a year[133]. Options E, F, H and L propose three surgical units in London.

Potential scenarios for distributing the total London caseloads in options with three London centres

Options >		E	F	H	L
Total London		1578	1578	1536	1394
Equal distribution of caseload					
Evelina		526	526	512	465
GOSH		526	526	512	465
RBH		526	526	512	465
Existing split					
Evelina	27	432	432	420	382
GOSH	44	693	693	675	613
RBH	29	453	453	440	400
Divide increase equally					
Evelina		453	453	439	391
GOSH		657	657	643	595
RBH		469	469	455	407

i. Threshold of at least 400 paediatric cardiac surgical procedures a year

The JCPCT is advised that it is reasonably possible for three surgical units in London to perform at least 400 paediatric cardiac surgical procedures a year. Options E, F and H are considered to be viable in that the different permutations for allocating the projected caseload amongst three units reasonably suggests that all three could perform in excess of 400 surgical procedures. In option L the Evelina Children's Hospital falls short of the threshold by around 8 or 9 procedures but this option has been included as viable as the application of a 'margin of error' to activity projections may suggest that in the event this option is viable.

Options E, F, H and L have been included in the proposed scoring process. All of the options scored relatively low overall when assessed against the four criteria for the evaluation of options.

[133] A number of respondents suggested that this would be optimal solution for London, including the Royal Brompton & Harefield NHS Foundation Trust and Parent Representatives of the former South East Zonal Group

ii. Threshold of at least 500 paediatric cardiac surgical procedures a year

The JCPCT is advised that there are no viable options where it is likely that all three centres would achieve at least 500 paediatric cardiac surgical procedures a year. Analysis by the secretariat suggests that in order to achieve such a caseload at each of the three centres patients would have to be diverted from South Central and South West England such that surgery would have to cease at Southampton General Hospital and Bristol Children's Hospital. This would create very large and possibly counter-intuitive congenital heart networks in the South of England. Also, the 'knock on' impact to patient flows between the South West and the Midlands would overload Birmingham Children's Hospital to an extent that it would not be reasonable to assume that it could cope with the resulting increase in surgical activity.

The secretariat has also explored the extent to which it may be possible for three centres in London to each perform at least 500 surgical procedures in options E, F, H and L. The JCPCT is advised that while this is theoretically possible in some cases, the practical difficulties of achieving this make this outcome unlikely.

There are three methods that could reasonably be employed to allocate surgical activity across three centres in London:

a) Divide the total surgical caseload equally across the three centres

The table demonstrates that, theoretically, a division of the total surgical caseload from London, South East and Eastern England could enable each centre to perform at least 500 surgical procedures a year in options E, F and H. Each centre would exceed the threshold by 26 procedures in options E and F and 12 procedures in option H. However, the JCPCT is advised that it is unrealistic to assume that this is reasonably possible. In order to achieve this referral protocols would have to be established within three congenital heart networks across London, South East and Eastern England with fine precision.

As it is doubtful that this method could reasonably ensure that all three London centres achieve at least 500 surgical procedures, the process for scoring options against the criterion of 'sustainability' (which takes account of the number of centres in each option that can reasonably meet the threshold of 500 procedures) assumes that two, rather than three, London centres can achieve 500 procedures in options E, F, and H. However, sensitivity test I explores the impact to the scoring of the 'sustainability' criterion by assuming that all three London centres can achieve 500 surgical procedures.

b) Divide the total surgical caseload to reflect the existing split of activity

Using this method, only Great Ormond Street Hospital is reasonably forecast to achieve at least 500 surgical procedures. The Evelina Children's Hospital is not forecast to even meet the lower threshold of 400 surgical procedures in option L.

c) Divide the projected increase in the surgical caseload equally across the three centres

Using this method, only Great Ormond Street Hospital is reasonably forecast to achieve at least 500 surgical procedures. The Evelina Children's Hospital is not forecast to even meet the lower threshold of 400 surgical procedures in option L.

The numbers of foreign private patients seen by the three London centres (109 patients based on 2010/11 CCAD figures) are excluded from these figures on the grounds that future flows of such patients are largely dependent on international economics and would never be commissioned by the NHS. But these

[134] Healthcare for London, *Children and Young People's Project: London's Specialised Children's Services, Guide for Commissioners*, March 2011

numbers are not material in any event, and their inclusion in the analysis does not support the case for three centres in London in this regard.

The forecast caseload representing the populations of London, South East and Eastern England in option B is 1252 surgical procedures a year. Thus, this option would not allow three surgical units in London even when the lower threshold of 400 surgical procedures is applied given the precision that would be required to achieve this. Option B *prima facie* enables two London centres to reasonably attain the ideal minimum critical mass of 500 surgical procedures per year. The JCPCT has never attempted to define the London networks, viewing this as an implementation issue for London SCG given London's unique position in requiring at least two surgical units, and in view of the separate review of tertiary paediatric services that are expected to define paediatric networks for London.

A potential outcome of the separate review of specialised tertiary paediatric services in London has raised the possibility of two paediatric networks in London, north and south of the river Thames. *NHS London* previously advised that the JCPCT should proceed on the understanding that the eventual configuration for paediatric congenital cardiac services does not have to conform to a potential North – South proposal for London, partly given the direction by the separate London review document[134] that "*any service reconfiguration decisions* [in London] *will be informed* ***by the outcome of national reviews****, for example, the National Paediatric Congenital Cardiac Review*" [emphasis added].

So whereas the JCPCT is not required to define the congenital heart networks for London, but is reasonably assured that two centres in London are better placed than three centres to each attain at least 500 procedures per year, consideration may need to be given by London commissioners as to the extent to which the critical mass of 500 procedures could be achieved at both centres via a North – South London network envisaged by the separate review of tertiary paediatric services in London[135].

The secretariat has tested this scenario to provide the JCPCT with an understanding of the extent to which this may be possible:

The tables below, produced by the Secretariat, suggests that in Option B:

- GOSH would deliver 779 procedures and the Evelina would deliver 473 procedures at the point of implementation within North – South London networks
- Both centres would attain over 500 procedures at the point of implementation when a higher margin of sensitivity is applied to the forecast
- Both centres would attain 500 procedures in any event due to projected growth in the population

Forecast activity at London centres at point of implementation assuming implementation of a North-South London network

	2009/10 actual	Option B applying a North-South London network	Applying population growth to 2025/26 based on average national forecast
GOSH	541	779	858
Evelina	337	473	521
RBH	353	0	0
London total	1231	1252	1379

[135] Healthcare for London, *Children and Young People's Project: London's Specialised Children's Services, Guide for Commissioners*, March 2011, page 49

Forecast activity at London centres at point of implementation assuming implementation of a North-South London network and application of a higher margin of sensitivity at 7.5%			
	2009/10 actual	Option B applying a North-South London network with margin of sensitivity	
GOSH	541	837	
Evelina	337	508	
RBH	353	0	
London total	1231	1345	

Central Cardiac Audit Database data demonstrates that congenital cardiac surgical activity naturally fluctuates each year, nationally and within individual centres and as such, application of an appropriate 'margin of error' (an accepted method for analysing activity data) would illustrate the likely negative or positive variance against the baseline figure. For the current purpose it may be reasonable to focus on the higher sensitivity of 7.5% to reflect a number of factors that suggest a higher than average growth in the number of surgical procedures performed by the London centres compared to the rest of the country based on factors reported by the Office for National Statistics:

- Higher than average percentage of women of child bearing age
- Higher than average fertility, conception and birth rates
- Higher than average black and ethnic minority population as reported by the Office for National Statistics, including South Asian communities who have a higher incidence of congenital heart disease for some conditions
- Higher than average immigrant population

Anecdotally, the faster population growth in London may be compounded by the large 'hidden' population that is not properly recorded as they are not on council registers or GP lists.

Guy's and St Thomas' NHS Foundation Trust has disagreed with the secretariat's assumptions around how quickly the Evelina would attain 500 procedures after implementation of Option B within the confines of 'North-South' London networks, but accepts that this would enable the Evelina Children's Hospital to attain 500 paediatric surgical procedures at a future point:

"Whilst we recognise that the Evelina can expect to benefit from activity growth driven by growth in the child population of south London over the next few years, we do not feel reassured that this will result in activity levels in excess of 500 cases for a number of years were the networks currently proposed under option B to be implemented[136]".

The Evelina's position is based on:

- An assumption that the number of referrals to the Evelina from outside London will reduce once designated surgical units are obliged to meet minimum activity levels as an outcome of *Safe and Sustainable*

[136] Email from Joint Director of Strategy of the Trust, 21 March 2012

[137] The secretariat has sought clarification from London SCG on potential networks in London, but the SCG is not in a position to provide clarity at this time

12 Testing the evidence for Option B

- Disagreement with the secretariat's assumptions around population growth in London and South East England
- Disagreement with the secretariat's assumptions around the allocation of postcodes to possible 'North – South' London networks

At present the future configuration of paediatric networks in London is unknown[137], which means that London commissioners may decide to consider the extent to which they would plan for a larger increase in the caseload at the Evelina Children's Hospital by disregarding a North-South London network. In this case, the current discussion across the secretariat and the Evelina is irrelevant to the future planning of caseloads in London and the South East as it is a discussion limited to one potential scenario.

In any event, even if the Evelina is correct in suggesting that it will take longer than assumed for two centres in London to each attain 500 procedures within a North-South network, and if the North-South network is in fact implemented by London commissioners, this would not support the case for a third centre in London. Option B would remain viable with GOSH attaining in excess of 500 procedures and the Evelina attaining in excess of 400 procedures at the point of implementation, and two units in London – rather than three – would each be better placed to achieve the 500 threshold over time. Moreover, viable options that propose the retention of three centres in London (options E, F, H and L) have been objectively tested in the scoring process, and the result was that they score relatively low when assessed against the four evaluation criteria (quality; access and travel; deliverability; sustainability).

In correspondence the Evelina Children's Hospital and Great Ormond Street Hospitals have expressed a preference for an option that secures at least 600 procedures at the Evelina and around 800 procedures at GOSH. These caseloads could not be achieved in Option B as the presence of Southampton in this option limits the flow of potential activity into London. Such caseloads in London could only be achieved via an alternative 6-centre option that excludes the Southampton centre (options C and D) or via a variation of option J which is a 7-centre option that excludes the Bristol centre but which retains the Southampton centre[138].

The *Safe and Sustainable* expert steering group advised the JCPCT against a 6-centre option based on concerns around resilience and deliverability and Ipsos Mori reported that there was very limited support for the 6-centre options (C and D) during public consultation. Of the three options J was the highest scored but they all scored relatively low against the criteria for the evaluation of options.

Forecast annual surgical caseloads in 6-site options

Options >	C	D
London total	1578	1578
Birmingham	653	589
Bristol	470	470
Newcastle	559	0
Liverpool	479	420
Leeds	0	683

[138] The necessary variation would be around how postcodes would be assigned to the Southampton and London networks

RECOMMENDATION 17:

The JCPCT is advised to agree option B for implementation and the designation of congenital heart networks led by the following surgical centres:

- Newcastle upon Tyne Hospitals NHS Foundation Trust
- Alder Hey Children's Hospital NHS Foundation Trust
- Birmingham Children's Hospital NHS Foundation Trust
- University Hospitals of Bristol NHS Foundation Trust
- Southampton University Hospitals NHS Foundation Trust
- Two surgical units in London (see chapter 13)

Option B offers:

- Best compliance with the quality standards, now and in the future
- Viable, manageable congenital heart networks across England and Wales
- Good compliance with the Paediatric Intensive Care Society's standards for the retrieval of critically ill children
- Compliance with the requirements of co-location of services as defined by the *Critical Interdependencies Framework*
- Viable Paediatric Intensive Care Units at the two hospitals with integrated PICUS and which are not recommended for designation as surgical units: Leeds Teaching Hospitals NHS Trust and the John Radcliffe Hospitals NHS Trust
- Retention of paediatric cardiothoracic transplant services, paediatric 'bridge to transplant' services and paediatric respiratory ECMO services at the Freeman Hospital in Newcastle
- A safe and manageable transfer of the respiratory ECMO service from Glenfield Hospital to Birmingham Children's Hospital
- Marginal impacts to vulnerable groups and those with protected characteristics
- Reasonably limited negative impact to travel times for elective admissions overall
- No significant negative impact to other paediatric services

13 London

How many centres?

Currently three surgical units serve the populations of London, East of England and South East England. The hospitals are the Royal Brompton Hospital, Great Ormond Street Hospital for Children and the Evelina Children's Hospital.

For the purpose of consultation the JCPCT proposed two surgical units in London, rather than the current three. This was partly based on a view that two centres would each be better placed to meet the JCPCT's preferred minimum critical mass of 500 paediatric procedures per year. Although the *Safe and Sustainable* standards stipulate that a minimum of 400 procedures is acceptable in the London hospitals and elsewhere, the JCPCT suggested that London's unique position of having three centres in close proximity means that attaining the preferred minimum caseload of 500 procedures at two centres in London was an achievable ideal.

However, the JCPCT also proposed that options with three London centres were viable and respondents to consultation were asked for their views on the optimal number of units for London.

Of those responding, the majority supported the JCPCT's preference for two centres in London.

Respondents were asked 'Do you support the proposal for two Specialist Surgical centres in London?'

Personal respondents:
75% support / 12% oppose

Organisations:
74% support / 17% oppose

Source: Ipsos Mori

Ipsos Mori reports[139] that in London support fell to 47% of respondents, with the majority of the remainder expressing a preference for the retention of three centres in London based on the perceived quality of all three London hospitals and the potential for collaboration amongst them[140].

In other parts of the country support for the proposal was also lower but for a different reason. Only 10% of respondents from Yorkshire and the Humber and 34% of respondents from the North East supported the proposal, with the majority of the remainder expressing a preference for only one surgical unit in London. This was based on a view that a single centre in London would be sufficient to serve the local population and a wish for fewer centres in London to result in a higher number of centres across the rest of the country.

Ipsos Mori reported that of those respondents who chose to comment on specific hospitals, the Royal Brompton Hospital received the most mentions, with the majority of those comments being positive (quality of care and perceived strength of relationship with Great Ormond Street Hospital).

[139] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, pp56-57

[140] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, pp56

If two centres, which two?

In the event that the JCPCT decides upon an option with two centres in London, it will have to decide which two centres should be designated for surgery.

The JCPCT proposed for the purpose of consultation that a two-centre option should comprise the Evelina Children's Hospital and Great Ormond Street Hospital for Children.

Respondents were asked 'If there were to be only two Specialist Surgical Centres in London, please indicate whether you support this choice (GOSH and Evelina) or whether you think that the Royal Brompton should replace one of these other two hospitals'

Personal respondents:
65% = GOSH and Evelina
16% = RBH and Evelina
8% = GOSH and RBH

Organisations:
56% = GOSH and Evelina
5% = RBH and Evelina
11% = GOSH and RBH

Source: Ipsos Mori

When the analysis is separated to look at possible preferences for individual centres[141]:

Personal respondents:
81% = Evelina
73% = GOSH
24% = RBH

Organisations:
67% = GOSH
61% = Evelina
16% = RBH

Ipsos Mori reported that in London 34% of personal respondents supported the proposal, with 12% supporting GOSH – RBH and 5% supporting RBH – Evelina.

Nine written submissions were received by the JCPCT directly from NHS Trusts who reside in the traditional London catchment area. Of these, nine Trusts[142] supported the retention of the Evelina Children's Hospital as a surgical unit and one Trust also supported the Royal Brompton Hospital (Maidstone and Tunbridge Wells NHS Trust). Only two of these Trusts addressed the issue of how many surgical units there should be in London (Kings College Healthcare NHS Foundation Trust and Lewisham Healthcare NHS Trust) and both of them expressed a preference for two units.

Two written submissions were received by clinical teams in NHS Trusts who reside in the traditional London catchment: of these, one expressed concern that two units in London would not have sufficient capacity (paediatricians from East Kent Hospitals University NHS Foundation Trust); the other expressed a preference for the retention of surgery at the Royal Brompton Hospital and for an alternative preference for the service at Southampton General Hospital were surgery to cease at RBH (Ashford and St Peters' Hospitals NHS Foundation Trust.

[141] Care must be taken as to how these figures are interpreted as respondents were asked to comment on configurations that each comprised two centres rather than individual centres

[142] Brighton and Sussex University Hospitals NHS Foundation Trust, East Sussex Healthcare NHS Trust, Epsom and St Helier University NHS Trust, Kings College Healthcare NHS Foundation Trust, Lewisham Healthcare NHS Trust, Maidstone and Tunbridge Wells NHS Trust, Royal Marsden NHS Foundation Trust, Surrey and Sussex Healthcare NHS Trust

13 London

Direct submissions from health scrutiny committees were received representing six London boroughs. Of these, four boroughs supported a preference for two surgical centres in London – Great Ormond Street and the Evelina Children's Hospital (Barnet, Enfield, Haringey and Islington). Two boroughs supported the retention of surgery at the Royal Brompton (Hillingdon and Royal Borough of Kensington and Chelsea). One borough asked for further consideration to be given to three surgical units in London (Royal Borough of Kensington and Chelsea).

One professional group addressed specifically the issue of the London providers: the Cardiothoracic Transplant Advisory Group (NHS Blood and Transplant) supported the retention of surgical services at Great Ormond Street Hospital for Children given its status as a provider of paediatric cardiothoracic transplant services.

In terms of hospital-specific comments, of those who chose to provide comments to Ipsos Mori the majority related to the Royal Brompton Hospital and were positive (quality of care and research, co-location of child and adult services, current compliance with core standards and capacity to provide "a full range" of services). A number of respondents also expressed concern about the potential impact to paediatric respiratory services at the Royal Brompton.

Most comments relating to Great Ormond Street Hospital and the Evelina were also positive (quality of care and range of services).

On behalf of their Boards, the Chief Executives of Guy's and St Thomas' Hospital NHS Foundation Trust and Great Ormond Street Hospital for Children NHS Foundation Trust supported the proposal for two centres in London and the proposed choice of centres. The Chief Executive of the Royal Brompton & Harefield NHS Foundation Trust opposed the proposal for two centres in London, instead preferring the retention of three centres. No indication was given by the RBH as to which two units it would prefer in the event of the JCPCT deciding upon two centres in London.

Paediatric respiratory services

The JCPCT explained in the consultation document that were paediatric cardiac surgery services to cease at the Royal Brompton, the Paediatric Intensive Care Unit at the Royal Brompton would become unviable due to the PICU's reliance on cardiac cases (nearly 90% of the PICU workload is cardiac related). Based on a consideration of the requirements of the Department of Health's *Critical Interdependencies Framework*, which does not suggest that there is a requirement for paediatric respiratory services to be co-located

with a PICU, the JCPCT concluded that the viability of paediatric respiratory services at the Royal Brompton would not be at risk. However, the JCPCT gave an undertaking in the consultation document to explore further the potential impact to children with non-cardiac conditions who use the relevant PICUs.

Although RBH has acknowledged that the incidence of admission to PICU for respiratory conditions is very low many respondents took the opportunity afforded by the consultation to set out concerns about the loss of the Brompton's PICU to paediatric respiratory services at RBH[143].

"The importance of respiratory medicine to these children cannot be over stated. A significant proportion of children being treated for cardiac disease also need the attention of respiratory physicians and vice versa. Royal Brompton has the strongest respiratory team in London led by Professor Andrew Bush and indeed that team is relied upon by the Evelina Children's Hospital to assist with some of their cardiac surgical cases".

Royal Brompton & Harefield NHS Foundation Trust, response to consultation

"It is in our view clear that the services currently provided to paediatric Cystic Fibrosis patients at the Royal Brompton Hospital could not continue to be provided safely in the event that the PICU were to close".

Group of parents who have children with Cystic Fibrosis under the care of the Royal Brompton Hospital, response to consultation

"There are 932,000 children with asthma in England and 47,000 have severe asthma. Severe asthma can be a very debilitating condition and those with severe asthma need access to quality care from specialists … The Royal Brompton has explained that the respiratory unit is dependent on the existence of the PICU which, as the consultation acknowledges, will become unviable if the cardiac unit is closed".

Asthma UK, response to consultation

"We are very concerned that the children's congenital heart services could be made safe and sustainable at the expense of making paediatric Cystic Fibrosis care unsafe and unsustainable given the apparent lack of attention to the impact on co-dependent services … this challenge is acute at the Royal Brompton Hospital as the consultation document clearly indicates the non viability of the PICU service if as proposed the children's cardiac surgery service at that hospital closes".

Cystic Fibrosis Trust, response to consultation

[143] The Royal Brompton Hospital has conceded that it has not carried out any formal assessment of the risk posed to paediatric respiratory services by the potential loss of paediatric cardiac surgery

13 London

"There is a risk that the removal of children's cardiac surgery from the Royal Brompton Hospital would render the PICU potentially unviable. Concerns have been expressed that the potential impact on services provided by the RBH anaesthetic department would be significant if children's cardiac surgery was no longer provided; complex bronchoscopies needing intensive treatment would have to be referred elsewhere and complex cystic fibrosis cases might have to go elsewhere for specific aspects of their management".

Hillingdon External Services Scrutiny Committee, response to consultation

"The evaluation of interdependencies has been extraordinarily superficial. In specific regard to the Royal Brompton it is simply stated that because the unit exists primarily to serve cardiac patients "this presents limited risk to local and national paediatric intensive care provision". This simplistic approach fails to ascertain what other services are dependent on intensive care provision. In the case of the Royal Brompton this is primarily their Cystic Fibrosis unit".

The Brompton Fountain, response to consultation

"If children's cardiac surgery is taken away from the [Royal Brompton] hospital it would eventually undermine the services provided for their patients with thoracic illness. It could lead eventually to the closure of a centre of excellence which provides high quality care for cardiac and respiratory patients".

Harefield Tenants and Residents Association, response to consultation

The JCPCT convened a panel of international experts to provide independent advice on this issue as it related to the Royal Brompton Hospital. The terms of reference required the panel to advise on the extent to which paediatric respiratory services and diagnostic bronchoscopy could be safely delivered at the Royal Brompton Hospital in the absence of a paediatric cardiac surgical service and a viable PICU.

In September 2011 the panel convened for five days in London. The panel considered written evidence which had been supplied by the Royal Brompton Hospital, the London Specialised Commissioning Group and the National Specialised Commissioning Team (as commissioners of paediatric respiratory services at RBH), and it met with RBH clinicians and management staff[144] for a full day at the RBH, including a tour of facilities. The panel also interviewed senior managers[145] and respiratory experts on-site at Great Ormond Street Hospital for Children, Barts and the London Hospital and the Evelina Children's Hospital and it met with respiratory specialists from Southampton General Hospital.

[144] Including Mr Bob Bell, Chief Executive of the Royal Brompton & Harefield NHS Foundation Trust and Professor Timothy Evans, Medical Director

[145] Including Sir Ron Kerr, Chief Executive and Dr Ian Abbs, Medical Director of Guy's and St Thomas' NHS Foundation Trust; and Dr Jane Collins, Chief Executive and Professor Martin Elliott, Medical Director of Great Ormond Street Hospital for Children NHS Foundation Trust

The panel's summary advice to the JCPCT reads:

'The panel has no doubt that the RBH provides a world class respiratory service with an impressive respiratory research programme. Elements of the service that it provides for children can be regarded as specialist tertiary or quaternary respiratory services, though not encompassing the full range of such services.

The panel agrees that the removal of paediatric cardiac surgical services from the RBH site would render the PICU unviable. The panel further agrees that anaesthesia provision is essential to maintain paediatric respiratory services, and that a reduction in paediatric surgical activity would affect the ability of the RBH to provide anaesthesia services for children in their current form.

However, although there would be an impact on the range of activity at the RBH the panel has concluded that paediatric respiratory services would remain viable at the RBH site in the absence of an on-site PICU *[bold emphasis as per the report]*

Some individual complex cases may need to be seen elsewhere in the future, and collaborative arrangements put in place with other hospitals.

The panel has considered the Department of Health's report on 'The Framework of Critical Interdependencies[146]*'. This concludes that, for paediatric respiratory services, there is no absolute requirement for co-location with a PICU. We have tested this conclusion with the experts whom we met and find it to be valid.*

The panel has heard that there is already significant partnership working between the RBH clinicians and other hospitals in London, for example around the admission of a child to a PICU at a different hospital to that which is the main provider of treatment. This has given the panel confidence in the willingness and ability of clinicians across London to continue to work together in the interests of children and young people.

The panel was encouraged to hear senior managers and clinicians at the RBH agree on the desirability and necessity of collaboration with other hospitals. Among other evidence, the panel received a description of how the RBH enjoys an advantageous relationship with the Chelsea and Westminster Hospital, and the RBH staff talked positively about the benefits of collaboration with Great Ormond Street Hospital for Children (GOSH) as described in a 2009 joint collaborative document[147]*.*

"We spoke with the Brompton for a year about trying to create something bigger, special, which was going to be a combination in a single centre of cardiac and respiratory and I just think we shouldn't lose sight that there is still that potential between the centres to create the kind of centre that mirrors some of the centres that we look up to in the States".

Representative from **Great Ormond Street Hospital for Children,** Cambridge consultation event

[146] Department of Health, *Commissioning Safe and Sustainable Specialised Paediatric Services: A Framework of Critical Interdependencies*, 2008. The Pollitt panel included three members of the working group that published the document: Adrian Pollitt OBE, former Director of National Specialised Commissioning, Julia Stallibrass MBE, former Deputy Director of National Specialised Commissioning, and Dr Ted Wozniak, former Medical Adviser in Paediatrics and Child Health, Department of Health.

[147] A Collaboration Between Royal Brompton & Harefield NHS Trust and Great Ormond Street Children's Hospital: A Proposal to Establish a National and International Service for Children with Heart and Lung Disease', 2009

13 London

London Specialised Commissioning Group is leading an engagement process in its role as commissioner of paediatric respiratory services in London. The engagement is initially aimed at respiratory service users, their carers, families and organisations representing patients with an interest in the potential cessation of children's congenital heart surgery at the Royal Brompton Hospital and consequent changes to PIC services in the hospital.

One purpose of the engagement is to ensure that the impact of these potential service changes, and the opportunities for mitigating actions, are understood so that implementation of a potential decision of the JCPCT is informed by the service user's perspective.

London SCG reports that subsequent phases of this process will contribute to the development of care pathways for all respiratory patients at RBH and elsewhere in London, as part of the wider review of specialised respiratory and other paediatric services in London. Thus, the views gathered during the engagement will also inform the planning and future commissioning of paediatric respiratory services in London as part of the London tertiary paediatric review.

The SCG's report on the outcome of the initial phase of the engagement is presented to the JCPCT in Appendix GG.

Scoring of London centres

The scoring exercise is intended to inform the JCPCT's deliberations around which two centres should be designated in the event of the JCPCT deciding upon an option with two centres in London. It is not determinative, and the JCPCT is required to have regard to all of the other evidence submitted during consultation.

The JCPCT is advised to score the London centres against the evaluation criteria used to score configuration options – as it did for the purpose of identifying preferred centres for the purpose of consultation. The Royal Brompton Hospital suggested during judicial review proceedings that this method was unfair as it resulted in individual centres being scored against a criteria that was meant to apply only to the scoring of options. However, the Court held that this was an entirely appropriate method, merely being a 'shorthand' way of scoring the different permutations of options that propose two centres in London.

Access and travel

Although potential networks in London have not yet been defined by commissioners, it is proposed that all centres are given an equal score. It is proposed that there are no material differences across the centres in this regard given their proximity to each other.

	GOSH	Royal Brompton	Evelina
Total Score for Travel and Access	3	3	3
Travel times for elective admissions			
Retrieval times			

Quality: Designated surgical centres will deliver high quality services

It is proposed that the Evelina Children's Hospital receives the highest score for this sub-criterion, reflecting its status as the centre that was given the highest score by the Kennedy panel for current and future compliance with the *Safe and Sustainable* standards. It is proposed that Great Ormond Street and Royal Brompton are equally scored, reflecting the equal score that was awarded by the Kennedy panel for compliance with the standards.

	GOSH	Royal Brompton	Evelina
Total Score for Quality			
High quality service	3	3	4
Innovation and Research			
Clinical Networks			

Quality: innovation and research is present across networks and the national service

In February 2012 the Kennedy panel considered new evidence submitted by the Royal Brompton Hospital of its compliance with the standards relating to 'innovation and research'. The panel concluded that the Royal Brompton had submitted 'acceptable evidence of compliance' with the standards:

> *"While recognising the Trust's reputation in the field of clinical research, in the panel's opinion the evidence submitted by the Trust is limited in its references to paediatric cardiac surgical services and paediatric interventional cardiology services. An embedded culture of research and innovation within the paediatric congenital cardiac service itself is not evident from the evidence submitted to the panel. For example, the cardiovascular strategy has limited reference to paediatric cardiac surgical services and although the evidence submitted by the Trust uses headings that would appear to relate directly to paediatric cardiac surgical and paediatric interventional cardiology services, the detail in these sub-sections is of limited relevance to the Trust's performance against the relevant standards".* [148]

[148] Report of the panel, February 2012

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The panel's assessment of Great Ormond Street Hospital and the Evelina Children's Hospital were that these hospitals had submitted 'exemplary evidence' of compliance with the standards. It is therefore proposed that the following scores are applied:

	GOSH	Royal Brompton	Evelina
Total Score for Quality			
High quality service			
Innovation and Research	4	2	4
Clinical Networks			

Quality: Clinical networks are manageable

The report of the Kennedy panel suggests that there may be some differences across the centres in their ability to manage clinical networks, but that the differences are not material. No other evidence has been submitted during consultation which would suggest that this was an incorrect assessment. It is proposed that all centres receive an equal score against this sub-criterion.

	GOSH	Royal Brompton	Evelina
Total Score for Quality			
High quality service			
Innovation and Research			
Clinical Networks	4	4	4

In line with the proposed approach to the scoring of configuration options (page 154) it is proposed that the dominant component of the quality scoring are the scores applied against the sub-criterion 'designated surgical centres will deliver high quality services'. However, sensitivity testing is presented to the JCPCT at page 172 which takes account of the sub-criterions of 'innovation and research' and 'clinical networks'.

	GOSH	Royal Brompton	Evelina
Total Score for Quality	3	3	4
High quality service	3	3	4
Innovation and Research	4	2	4
Clinical Networks	4	4	4

Deliverability: The NHS in England will continue to provide the relevant high quality nationally commissioned services

About 60 highly specialised services are commissioned nationally by NHS Specialised Services. Generally speaking, these are services that affect fewer than 500 people across England or involve services where fewer than 500 highly specialised procedures are undertaken each year[149].

Great Ormond Street Hospital is the only hospital in the United Kingdom that provides all three of the relevant nationally commissioned services: paediatric cardiothoracic transplant services, ECMO for children with severe respiratory conditions and complex tracheal surgery. It is the largest provider of paediatric cardiothoracic transplant services in the UK and it is the *only* hospital in the UK designated to provide the complex tracheal service.

A description of transplant and ECMO services is set out elsewhere in this document.

The Complex Tracheal Disease Service "assesses and treats children with severe and rare conditions affecting the windpipe and air passages in the lungs, including a complex condition known as long segment tracheal stenosis. This is a rare life-threatening condition affecting one in five million children and which causes the main air passage of the lung (the trachea) to become very narrow. A surgical operation called a slide tracheoplasty is performed, which involves reconstructing the trachea to create a new section of trachea"[150].

Neither the Royal Brompton Hospital nor the Evelina Children's Hospital are designated to provide any of the services, save for the exceptional delivery of respiratory ECMO should the designated national service experience critical capacity pressures (such as at a time of a pandemic).

The risks associated with moving the paediatric cardiothoracic transplant service are set out in more detail at pages 94 to 97. Such a proposal would be contrary to the advice of the Advisory Group for National Specialised Services.

In its response to consultation the Cardiothoracic Transplant Advisory Group (NHS Blood and Transplant) supported the retention of Great Ormond Street as one of the two providers of cardiac transplant services in England.

In view of the evidence submitted during consultation it is proposed that Great Ormond Street Hospital receives the highest score of '4' and that the Evelina and Royal Brompton receive a score of '1'.

	GOSH	Royal Brompton	Evelina
Total Score for Deliverability			
NCS	4	1	1
PICU and Interdependent Services			

[149] NHS Specialised Serviced website, available at: www.specialisedservices.nhs.uk/info/nhs-specialised-services

[150] NHS Specialised Services website, available at: www.specialisedservices.nhs.uk/service/complex-tracheal-disease/search:true

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Deliverability: The negative impact for the provision of paediatric intensive care and other interdependent services is kept to a minimum

Some respondents, most notably those with a relationship to the Royal Brompton Hospital (and including the Trust itself), suggested that the JCPCT's method of scoring against this sub-criterion was flawed in that options should be regarded as 'higher risk' if they exclude one of the three centres whose PICUs would be rendered unviable by the removal of paediatric cardiac surgical services (Royal Brompton Hospital, Glenfield Hospital and the Freeman Hospital). These comments were usually accompanied by views on the potential impact of an unviable PICU to other paediatric services at the Royal Brompton Hospital.

The JCPCT is advised that as the method against this particular sub-criterion aims to establish the potential risk of removing paediatric cardiac surgery from a hospital to local and national PICU provision, the method is correct and reasonable for this purpose[151]. The criticisms of the process in this regard relate to another aspect of the analysis, which is the potential impact to other paediatric services.

Non-cardiac cases account for around 60% of the caseloads at the PICUs at the Evelina Children's Hospital and Great Ormond Street Hospital. Both PICUs would remain viable if paediatric cardiac surgery were removed from their hospitals and would therefore retain a role in the provision of PICU services in London and nationally. Both hospitals would experience a reduction in the number of PICU beds reflecting the loss of the cardiac caseload. Thus, options which remove paediatric cardiac surgery from Great Ormond Street Hospital and the Evelina would reduce the overall resilience and sustainability of the London PICU network (and national PICU network). By contrast, the closure of the PICU at the Royal Brompton would have limited impact to the London PICU network as non-cardiac cases account for only 12% of its caseload.

There would also be implications for the training of PICU specialists. The PICUs at Great Ormond Street and the Evelina Children's Hospital are two of the five PICUs in England that are recognised as specialist training centres for PICU specialists. The PICU at the Royal Brompton Hospital has no such distinction[152].

This criterion also requires the JCPCT to consider the impact of removing paediatric cardiac surgery on other interdependent services. As set out in detail previously, a number of respondents suggested that the loss of PICU would render paediatric respiratory services at the Royal Brompton Hospital unviable. However, the Pollitt panel has advised the JCPCT that while a small number of respiratory children would need to be seen elsewhere, and arrangements would need to be put in place with other hospitals (for example, in the provision of safe anaesthetic servces) paediatric respiratory services would remain viable in the absence of a PICU at the Royal Brompton and it concurred with the findings of the Department of Health's *Critical Interdependencies Framework* in this regard (the *Framework* is itself endorsed by the relevant royal colleges of medicine and other professional associations).

It is proposed to apply a score of '3' to Great Ormond Street Hospital and the Evelina Children's Hospital, meaning that they 'meet all elements of the criteria'. This is a change from the score of '4' (criteria is 'exceeded') which was applied before consultation to reflect the findings of the Pollitt panel about the small number of children for whom alternative arrangements would have to be made.

[151] During consultation the Paediatric Intensive Care Society wrote that it agreed with the JCPCT's assessment of potential risk to PICUs

[152] See the response to consultation by the Paediatric Intensive Care Society

	GOSH	Royal Brompton	Evelina
Total Score for Deliverability			
NCS			
PICU and Interdependent Services	3	2	3

The proposed total scores for the 'deliverability' criteria are:

	GOSH	Royal Brompton	Evelina
Total Score for Deliverability	4	2	3
PICU and Interdependent Services	4	1	1
Workforce	3	2	3
Transition Plans	Not scored as addressed during implementation		

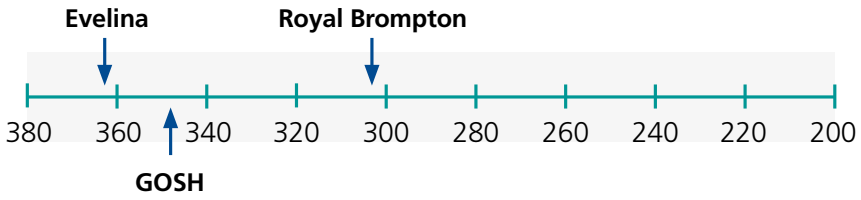
Sustainability: All designated centres are likely to perform at least 400 procedures each year, ideally 500 paediatric procedures each year AND no one designated surgical centre will receive too onerous a caseload that would exceed the centre's capacity to manage it

The JCPCT is advised that all three centres have sufficient capability and capacity to perform at least 500 paediatric procedures, and that no centre is forecast to receive too onerous a caseload under any of the options. London SCG has provided the secretariat with confirmation that it is assured about the capacity at GOSH to meet its forecast high caseload.

	GOSH	Royal Brompton	Evelina
Total Score for Sustainability	4	4	4
Perform a minimum of 400 procedures per year	4	4	4
Too onerous a caseload	4	4	4
Recruit and retain newly qualified surgeons	Not scored as addressed during implementation		

ABSOLUTE SCORES	GOSH	Royal Brompton	Evelina
Total Score for Travel and Access	3	3	3
Total Score for Quality	3	3	4
Total Score for Deliverability	4	2	3
Total Score for Sustainability	4	4	4

WEIGHTED SCORES	GOSH	Royal Brompton	Evelina
Total Score for Travel and Access	42	42	42
Total Score for Quality	117	117	156
Total Score for Deliverability	88	44	66
Total Score for Sustainability	100	100	100
Total Scores	347	303	364

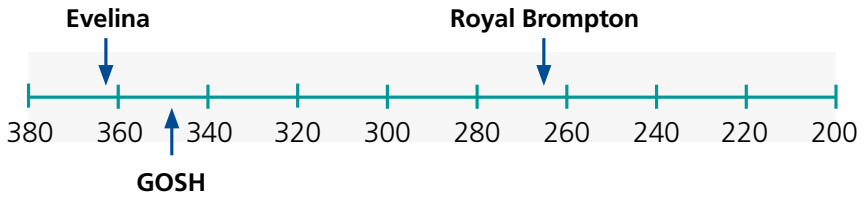


Sensitivity test A

This sensitivity test assumes that the sub criteria for quality are weighted equally which permits the sub-scores for 'innovation and research' and 'networks' to influence the overall scores for quality. The impact that this has on the scores is shown below:

	GOSH	Royal Brompton	Evelina
Total Score for Quality	3	2	4
High quality service	3	3	4
Innovation and Research	4	2	4
Clinical Networks	4	4	4

WEIGHTED SCORES	GOSH	Royal Brompton	Evelina
Total Score for Travel and Access	42	42	42
Total Score for Quality	117	78	156
Total Score for Deliverability	88	44	66
Total Score for Sustainability	100	100	100
Total Scores	347	264	364



Sensitivity test B

This sensitivity test assumes that Royal Brompton Hospital was awarded the maximum possible score for evidence of compliance with the standards relating to 'innovation and research'. This test has been applied in response to concerns submitted by Royal Brompton Hospital about other sources of information that the JCPCT has not relied upon for this purpose, such as the RAND analysis and Research Assessment Exercise. The Kennedy panel addressed this issue in its report of February 2012:

"Overall there is limited evidence of activity relating to paediatric congenital cardiac services and, of that set out, much of it is historical. It therefore follows that the Trust's assessment of the implications of the RAND analysis is largely irrelevant in that it relates to 'cardiovascular and respiratory' research with no indication of the extent to which it relates to research in the field of paediatric cardiac surgical services or paediatric interventional cardiology services at the Royal Brompton Hospital.

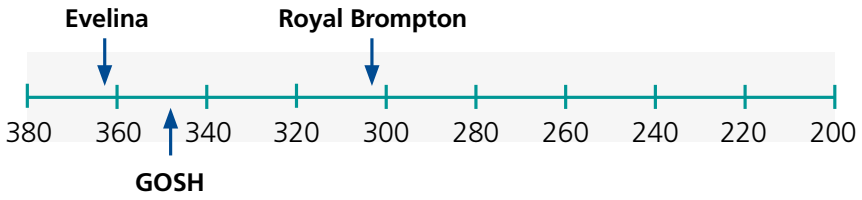
The Trust has offered to the panel the outcome of the 2008 'Research Assessment Exercise' (RAE) as evidence of compliance with the standards. The Trust acknowledges in its submission that the RAE does not reveal the extent to which research at the Trust is relevant to paediatric cardiac surgical services and paediatric interventional cardiology services but the Trust has suggested that the outcome of research in other medical fields may go on to benefit the care of children with congenital heart disease. While the panel acknowledges that research in related fields of medicine may demonstrate a contribution to the improvement of care of children with congenital heart disease (and the panel has taken into account the Trust's contribution to research in fetal cardiology and morphology in this respect), the panel considers that there is limited evidence of research activity specifically relating to paediatric cardiac surgical services and paediatric interventional cardiology services at the Royal Brompton".

13 London

The sensitivity has been applied to test the significance of the impact of the application of the scores relating to evidence of compliance with the standards around 'innovation and research'. The sensitivity demonstrates that even were the maximum score to be applied to Royal Brompton Hospital against this criterion, this would still leave Royal Brompton Hospital placed below the other two centres.

	GOSH	Royal Brompton	Evelina
Total Score for Quality	3	3	4
High quality service	3	3	4
Innovation and Research	4	4	4
Clinical Networks	4	4	4

WEIGHTED SCORES	GOSH	Royal Brompton	Evelina
Total Score for Travel and Access	42	42	42
Total Score for Quality	117	117	156
Total Score for Deliverability	88	44	66
Total Score for Sustainability	100	100	100
Total Scores	347	303	364



RECOMMENDATIONS:

18 The JCPCT is advised to agree the designation of the Evelina Children's Hospital and Great Ormond Street Hospital for Children as providers of paediatric congenital cardiac surgery in the event of the JCPCT deciding an option with two surgical units in London

19 The JCPCT is advised to agree the findings of the Pollitt report that that paediatric respiratory services will remain viable at the Royal Brompton Hospital in the absence of a viable paediatric intensive care unit, though alternative arrangements would have to be made for a small number of children

Financial Analysis and Review of Capacity

14

PURPOSE

The core objective of *Safe and Sustainable* is to improve services for children with congenital heart conditions and not for the purposes of achieving financial savings. Nevertheless it is important to consider affordability and value for money.

SUMMARY OF CONCLUSIONS

The key focus of the financial analysis has been to provide relevant information to enable the JCPCT to assess the financial implications of the viable options.

The key conclusions are:

- The options are affordable to NHS commissioners as the spending released from providers who will cease to deliver paediatric cardiac surgery will offset the increased costs in the designated centres.
- Providers have Board level approved capital plans in place, some of which are in the process of being refreshed.
- Providers are expected to manage the impact of loss of income from not being designated.
- Some providers will incur a net increase in costs, whilst others will gain net income. There is a *prima facie* financial argument in favour of options that propose 6 surgical units rather than 7 surgical units in terms of sustainability as it is more likely that increased costs in a centre will be more than offset by additional income.
- A fully costed transition and implementation plan cannot be developed before the JCPCT's decision, but should be delivered as soon as possible once a decision has been made.
- **When capital costs (the investment) are compared against the points scored in the non-financial analysis Options G and B demonstrate best value for money.**

ANALYSIS

Whilst the spend on paediatric congenital cardiac services (including surgery, interventional cardiology and critical care) in England in 2010/11 was £110m, a large sum in absolute terms, it was relatively small compared to the overall spend on the NHS representing less than 0.2% of the total commissioning spend.

A further financial data capture template was issued to the centres in June 2011 to respond to the specific activity levels required under the consultation options to the non recurrent set up costs and potential impact of losing cardiac surgery status. These returns form the basis of the further analysis used below.

FINDINGS

1 Affordability to Commissioners

As these procedures are covered by the national PbR tariff[153], commissioners will continue to purchase the activity at tariff. There is no increase in overall activity, other than that arising from the forecast growth in population over time, and other things being equal, the total cost to commissioners should be the same. In principle however any expenditure increases in providers feed into reference costs and ultimately tariff. These increases in cost should be offset by economies of scale. The following factors have the potential to change costs:

[153] Department of Health, *Confirmation of Payment by Results (PbR) arrangements for 2010-11*, February 2010

14 Financial Analysis and Review of Capacity

A Meeting the Standards

The new quality standards developed by the professional associations will increase the costs to providers. Bristol Children's Hospital has demonstrated an increased need to spend £1m p.a. to meet the standards, particularly around staffing. Other providers are already nearer to meeting the staffing demands and therefore should cost less than £1m p.a., but assuming all providers need to spend around £1m p.a. to meet the standards this would imply a total increased spend of £6m to £7m p.a.

B Meeting Capacity

There are also revenue consequences of the providers' capital spend to increase capacity (see paragraph 2a) which will filter into reference costs and tariff over time. These capital charges (revenue consequences of the capital spend) could range from £1.5m to £2.2m p.a.

C Clinically Managed Networks

Other additional costs relate to the development of formal clinically managed networks. The model of care proposes formal networks of Specialist Surgical Centres, Children's Cardiology Centres and District Children's Cardiology Services. In order to ensure the network operates effectively it is recommended that paediatricians with expertise in cardiology are deployed at some District General Hospitals. The number and disposition of these paediatricians has to be considered during the implementation phase by local commissioners in conjunction with the network. Medical teams may have to travel further to hold out-patient clinics and will have to maintain more formal multi disciplinary team (MDT) working. This is likely to mean additional cost but such costs can be controlled and timed to suit local circumstances, and paid for from tariff income. The network approach may also reduce costs as tele-medicine is extended through the networks and the paediatricians with an expertise will be able to assess and care for children who do not need the care of a cardiologist, thereby reducing unnecessary appointments and repeat assessments.

At present there are some, largely informal networks across various geographical patches with paediatricians in place who have gained expertise through experience or more recently studied the joint curriculum[154]. The Royal College of Paediatrics and Child Health has found it difficult to substantiate the number and level of skill of these paediatricians, and hence to estimate whether there is sufficient number to meet future needs.

It can take 12-18 months for a Consultant Paediatrician to train to acquire the necessary skills and recognition as a paediatrician with expertise in cardiology. There are clearly opportunity costs and potential actual costs as paediatricians undertake the training and their normal workload needs to be covered. The exact impact depends on the eventual number and whether there is a need to backfill the employing Trust's salary costs.

Currently individual District General Hospitals employ these paediatricians and charge local commissioners for the activity for outreach outpatient clinics. The specialist centre recharges the District General Hospital for the time of the cardiologist attending the clinics. Given that the model of care needs more formalised networks working effectively across the country it is proposed that the JCPCT recommends to NHS commissioners that this approach will be facilitated by identifying the paediatric cardiac service,

[154] Curriculum for Paediatrician with Special expertise in Cardiology

including the network, as specialist, and for the commissioners to contract with the specialist surgical centres for the network. The specialist centres would then contract with the district cardiac services for the time of the paediatrician/equipment/facilities engaged on paediatric cardiac services. This should enable all networks to be consistently resourced, and for the specialist centre to lead on the development of the network. The contracting arrangements will need to form part of the implementation phase. The estimated recurrent costs of establishing these networks is shown in table 1 below.

The main increased cost of maintaining the managed networks and implementing the model of care is the need to invest in paediatricians with expertise in cardiology. The advice of the *Safe and Sustainable* Steering Group is to base the paediatricians in maternity units with births in excess of 3000 births per annum. This would require approximately 130 paediatricians to be trained and spending 0.2 wte of their time on paediatric congenital cardiac services. The gross cost of this time commitment of these paediatricians would be circa £2.88m per year. This cost would be offset by those paediatricians who are already in post, and so represents the worst case scenario.

D Spending Saved from Ceasing Surgery

In each option there are 3–5 centres which would no longer be required to provide paediatric cardiac surgery. That would mean commissioners would retain an estimated spending of between £19m to £41m p.a to re-invest in the centres carrying out the surgery. This indicates that the increased costs for the providers continuing to supply paediatric cardiac surgery can be met by the existing resource, after taking account of the marginal costs of delivering the increased activity (many of which are covered by the investment in meeting the standards) and other costs.

Table 1 below summarises the additional costs and spending released.

Table 1: Summary of Estimated Recurring Costs £'000

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Network Directors	700	700	600	600	700	700	700	800	800	700	700	800
Clinical Leads	140	140	120	120	140	140	140	160	160	140	140	160
Paediatricians with Expertise	2,880	2,880	2,880	2,880	2,880	2,880	2,880	2,880	2,880	2,880	2,880	2,880
Meeting the standards	7,000	7,000	6,000	6,000	7,000	7,000	7,000	8,000	8,000	7,000	7,000	8,000
Capital Charges	1,700	1,922	1,836	1,473	2,226	1,859	1,555	2,089	1,767	1,766	1,438	1,828
Gross Costs	12,420	12,642	11,436	11,073	12,946	12,579	12,275	13,929	13,607	12,486	12,158	13,668
Spending Available	33,000	31,000	41,000	41,000	27,000	27,000	31,000	19,000	23,000	28,000	33,000	19,000

Initially as there is no forecast change in activity and no change in tariff, the spend by commissioners should be the same. The reduced spending referred to above should be reflected in reference costs, however, and after three years (on the grounds of current practice) should filter into a reduced tariff provided the issues raised in the following paragraphs can be managed and contained through a commissioning and implementation strategy.

E Network Leading to More Spells

The main thrust of the network model is to ensure that as much of the care as possible can be delivered locally to the child, with only the specialist surgery and interventional cardiology interventions potentially requiring a longer journey. An implication of this is that once the child has recovered post surgery, s/he would be transferred to the most appropriate local setting for his continued recovery. This would mean the one spell is split into two, or even three, and if nothing changed the commissioner could be charged for those spells. It is proposed that the JCPCT should recommend to NHS commissioners that the tariff is split to recognise this changing world. The view of the national PbR team is that local PbR flexibilities should allow this change to be recognised and adjusted for by commissioners. This will need to form part of the implementation plan.

F Local Prices

There are local prices for Paediatric Intensive Care Units (PICU) and on a few occasions additional charges for high cost drugs and devices. It is recommended that the local prices for PICU would need to be renegotiated (in line with the national operating framework for 2012/13) as the PICUs expanded or reduced capacity as required. It is the view of the group that consideration should be given to a national tariff for PICU. The PbR National Team at the Department of Health has agreed a national currency for adult and neo natal intensive care and this is being collected from 1 April 2011 in advance of work on national tariffs for these services. No such work is planned for paediatric intensive care at this stage. Re-negotiation of local prices should assist in controlling these costs but there could still be a differential impact on commissioners as discussed above.

The National PbR Team state that some of the costs of critical care are already included in admitted patient care Health Resource Groups (HRGs) and hence tariff, and implementing a national tariff before the activity and total cost baseline is understood (and therefore taking them out of the admitted patient care tariffs) would lead to commissioners paying for this activity twice.

Furthermore, a time of strategic change in a service with both potentially fluctuating costs and activity is not the time to introduce a national tariff. For these reasons there will need to be re-negotiation of local prices around the country.

G Market Forces Factor

There could be increased costs as activity is transferred from low cost areas to high cost areas. This should not be significant, although the more activity that flows to London (which has a high 'market forces factor' reflecting the higher cost of living) the greater the cost increase will be.

H Economies of Scale and Efficiency Savings

NHS commissioners have made clear that they expect the providers to deliver the required efficiencies implied in the national tariff. Over and above this the providers should be able to realise further economies of scale as activity is concentrated in fewer providers and this should lead to a reduction in reference costs.

I Managing the Market

The commissioning strategy for this service will determine to a large extent whether this ultimately costs more to commissioners.

The findings above suggest that there should be sufficient resources already invested in this service, with further economies of scale to be derived to meet the increased costs and therefore this is affordable to commissioners.

2 Viability of Providers

The following factors are the responsibility of the providers and have a bearing on their viability, albeit as discussed above some of these costs will potentially impact on reference costs and the tariff.

A Set-up Costs

It is recognised that there will be set-up costs and stepped costs involved in increasing capacity to deliver additional procedures in the designated paediatric surgery centres. The commissioner expects designated surgery centres to meet such costs from their capital programmes, tariff income and savings, and centres are planning and have indicated their intentions to do this in their returns.

Table 2 below represents the non -recurrent set up costs, the majority of which is capital.

Table 2: Set-up Costs £'000

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Liverpool	970	970	970		970			970	970	970		
Birmingham	0	3,184	3,184	3,184	3,184	3,184	3,184	0	0	3,184		
Bristol	3,499	3,499	3,499	3,499	3,499	3,499	3,499	3,499	3,499		3,499	3,499
Newcastle	4,000	5,700	5,700	50	5,700	50	50	4,000	4,000	4,000	50	50
Leicester	2,612							2,612	2,612	2,612	2,612	2,612
Leeds				560		560	560				560	560
Oxford												
Southampton		1,425					1,425		1,425	1,425		
Evelina	11,900	11,900	11,900	11,900	11,900	11,900	11,900	11,900	11,900	11,900	11,900	11,900
GOSH	5,350	5,350	5,350	5,350	0	0	5,350	0	5,350	5,350	5,350	0
Brompton					11,842	11,842		11,842				11,842
	28,331	32,028	30,603	24,543	37,095	31,035	25,968	34,823	29,756	29,441	23,971	30,463
No of centres	7	7	6	6	7	7	7	8	8	7	7	8
Average	4,047	4,575	5,101	4,091	5,299	4,434	3,710	4,353	3,720	4,206	3,424	3,808

The set up costs in table 2 are estimates based on the information supplied by the centres.

The capital investment required ranges from £25m to £37m across the options, and centres have Board level approved plans to deliver the level of investment required. This will allow centres to increase capacity to deliver the required activity for surgical and interventional cardiology procedures. The typical spend per centre is £3m-£6m, but centres with modest additional activity need minimal investment. Other centres have made space for the expansion within a hospital reconfiguration and this is why options containing Leeds Teaching Hospitals NHS Trust are relatively low cost. As part of creating a children's hospital this Trust has already moved adult services and left space for children's services. Alder Hey Hospital is being re-developed under a PFI scheme.

B Impact of De-Designation on Providers – Legacy Costs

This is the most significant known financial factor to be considered. Those centres losing paediatric cardiac surgery status will lose income and have surplus capacity and there are potential knock on implications for other services. In relative terms the income generated by cardiac surgery and inter dependent services is small for the large acute hospitals involved at less than 2% of total income. On average the costs of providing the service are 70% direct costs, 10% indirect and 20% fixed costs. On this basis the hospital could be left with legacy costs of between 20% to 30% of the cost which represents less than 0.4% to 0.6% of the total annual income. Some of this lost income may be regained from children transferring for post operative recovery to the cardiology centre. Nevertheless there would be a marginal increase to each hospital's savings programme in order to recover the legacy costs. There may be some one-off costs associated with reducing surgical capacity, the key one being staffing, and that is discussed below. Commissioners expect providers to manage the impact of loss of income and staffing costs.

Table 3: Legacy Costs £'000

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Liverpool												
Birmingham												
Bristol										3,646		
Newcastle				11,310		11,310	11,310				11,310	11,310
Leicester		9,813	9,813	9,813	9,813	9,813	9,813					
Leeds	14,345	14,345	14,345		14,345			14,345	14,345	14,345		
Oxford	1,757	1,757	1,757	1,757	1,757	1,757	1,757	1,757	1,757	1,757	1,757	1,757
Southampton	15,600		15,600	15,600	15,600	15,600		15,600			15,600	15,600
Evelina												
GOSH												
Brompton	11,685	11,685	11,685	11,685			11,685		11,685	11,685	11,685	
	43,387	37,600	53,200	50,165	41,515	38,480	34,565	31,702	27,787	31,433	40,352	28,667
Est Legacy Costs	21,196	19,460	24,140	23,229	12,455	11,544	18,549	9,511	16,516	17,609	20,285	8,600
No of centres affected	4	4	5	5	4	4	4	3	3	4	4	3
Average	5299	4865	4828	4646	3114	2886	4637	3170	5505	4402	5071	2867

Table 3 above compares the impact across the configuration options of losing paediatric cardiac surgery and the potential impact on inter dependent services including nationally commissioned services.

The legacy costs range from £9m to £24m across the options, but with the differing numbers of centres affected this averages out at between £3m to £5m per centre. The Royal Brompton Hospital has identified legacy costs of nearly £12m and estimate that it will take them approximately 3 years to cover these fixed costs though new income. Commissioners expect providers to manage the impact of loss of income and staffing costs.

C Workforce implications and risks

The potential financial implications are recruitment, relocation costs, retraining and redundancy costs. The latter will be avoided as far as possible. It is difficult to determine accurately these costs as they depend on decisions made by individual members of staff once the JCPCT has made a decision[155]. Some options are potentially more disruptive for staff than others, requiring more re-location or re-training of staff. A more detailed piece of work is required during the implementation phase to determine the optimal staffing structures for the agreed configuration option, but for the purposes of considering options a draft 'to be' structure was identified and used to assess the risk of the staffing changes required.

Further risks are associated with the potential re-location of staff from non designated centres.

In cost terms two of the larger centres estimated potential redundancy costs to be c£2m per centre and based on the estimates of these two NHS Trusts the potential total redundancy cost could be between £8- £10m. However, the aim of the NHS is to minimise loss of medical and nursing expertise and a more detailed analysis of the workforce implications will be undertaken once a decision has been made.

D Income v Expenditure

As discussed in above, concerns have been expressed by some providers regarding the risk to them of having to spend up to £1m p.a. to achieve the standards without sufficient additional activity to cover these costs which depend on patient flows.

This has led Bristol Children's Hospital for example to promote 6 site options as the favoured approach, as this implies less risk around patient flows. This makes financial sense but clearly there are other non financial factors to consider (such as the need for designated centres to be meeting the minimum quality standards set by the professional associations).

3 Costs of Implementation and Transition

Table 4 below summarises the derived level of costs associated with the implementation and transition arrangements. The costs incurred by the providers are as discussed above. The set up costs are planned to be met by capital programmes, contract income and savings. Redundancy, legacy costs and other staffing costs would also need to be met from provider savings.

From the commissioner's point of view in order to implement the decision it is recommended to establish a resourced project approach. Much of this will be provided by existing post-holders and hence represents opportunity costs. There will, however, need to be some additional dedicated investment at national and network levels to assure successful implementation and achievement of the benefits and savings as early as possible. The table below and its costs are for the two year implementation period.

A fully costed transition and implementation plan should be compiled as soon as possible including how risks will be managed though the process.

[155] The professional associations, via the *Safe and Sustainable* steering group, has advised the JCPCT that workforce implications can only be reasonably determined once a decision has been made

Table 4: Outline Costs of Implementation and Transition												
Option >	A	B	C	D	E	F	G	H	I	J	K	L
Providers												
Set up Costs	28,331	32,028	30,603	24,543	37,095	31,035	25,968	34,823	29,756	29,441	23,971	30,463
HR Implications	9,000	9,000	11,000	11,000	9,000	9,000	9,000	7,000	7,000	9,000	9,000	7,000
	37,331	41,028	41,603	35,543	46,095	40,035	34,968	41,823	36,756	38,441	32,971	37,463
Provider Savings to be Found												
Legacy Costs	21,196	19,460	24,140	23,229	12,455	11,544	18,549	9,511	16,516	17,609	20,285	8,600
Number of centres	4	4	5	5	4	4	4	3	3	4	4	3
Commissioners (2 yrs)												
Project Management	600	600	600	600	600	600	600	600	600	600	600	600
Network Directors	1,400	1,400	1,400	1,400	1,400	1,400	1,400	1,400	1,400	1,400	1,400	1,400

4 Synthesis of Financial and Non Financial

Table 5: Points per £m Invested												
Option >	A	B	C	D	E	F	G	H	I	J	K	L
Points	158	261	186	139	186	139	214	158	211	208	139	114
Cost (£m)	28	32	31	25	37	31	26	35	30	29	24	30
Point/£m	5.58	8.15	6.08	5.66	5.01	4.48	8.24	4.54	7.09	7.06	5.80	3.74
Rank	8	2	5	7	9	11	1	10	3	4	6	12

Table 5 attempts to link the non financial and financial analysis, by taking the number of preliminary points presented to the JCPCT in the non financial assessment and dividing that by the capital investment made in growing the capacity. This gives a points per £m outcome. In this B and G are the highest ranked options. The main difference is the relatively low investment required at Leeds Teaching Hospitals NHS Trust to meet a significant increase in activity. The costs in option G would have to rise by only £340,000 to equal the points/£m for option B.

5 Quality, Innovation, Productivity and Prevention

There is international evidence to suggest that in centres with more surgeons carrying out more procedures the outcomes are better than smaller centres with fewer surgeons carrying out fewer procedures[156].

The proposed standards require each designated surgical centre to have a minimum of 4 consultant congenital cardiac surgeons carrying out at least 400 paediatric surgical procedures and ideally 500 paediatric surgical procedures This should lead to improved outcomes and a more resilient service.

The intention is that the surgeons will each undertake a minimum of 100 to 125 paediatric congenital cardiac surgical procedures each year. This will avoid occasional surgical practice, develop surgical skills and hence improve productivity and outcomes.

Nationally improved productivity will lead to reductions in unit price which will feed into future reference costs and tariff.

[156] Ewart, H. The Relation Between Volume and Outcome in Paediatric Cardiac Surgery; Public Health Research Unit – A Literature Review for the National Specialised Commissioning Group (2009). Available at: www.specialisedservices.nhs.uk/document/developing-model-care

14 Financial Analysis and Review of Capacity

CAPACITY REVIEW

JCPCT members are referred to the report on the review of capacity in the NHS Trusts seeking designation for children's heart surgical services (February 2012) for a detailed account of the process that was followed to test capacity assumptions (Appendix LL).

The purpose of the capacity exercise was to allow the JCPCT to understand the Trusts' state of readiness and the risks associated with the delivery of the activity proposed under each of the options.

- Can the centres required to deliver extra procedures achieve the service change with low levels of risk?
- Can centres develop the facilities on site in a timely fashion?
- Can centres recruit staff and develop the skills required in the timescales required?
- Can centres do this without adversely impacting on other services provided to the local health economy?

Centres were asked to submit information on following areas:

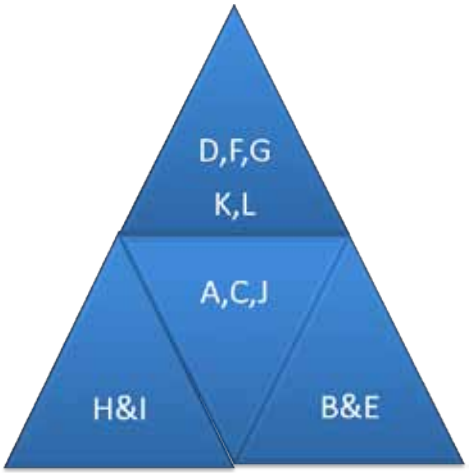
- Theatre capacity, workforce and availability issues and percentage of postponed planned surgery with explanation
- Number of PICU beds staffed and unstaffed, number of HDU beds, workforce, % of PICU and HDU used for cardiac surgery and the number of refused admissions due to PICU in 2010/11 with explanation
- Arrangements for retrieval and number of children retrieved by air and road in 2010/11 and what percentage were cardiac patients
- Availability and configuration of ward beds, percentage occupancy and number of outliers in 2010/11
- Number of Outpatient clinics run at the centre and as outreach, number supported by a paediatrician with expertise and Outpatient attendance numbers for 2010/11
- Number of individual family accommodation rooms and number of refusals for accommodation in 2010/11
- Legacy / Financial position

All centres were cooperative. The information received raised further questions and the process became interactive.

The baseline and option templates for each centre were risk assessed using the information provided by the centre and an overarching template was produced which will allow the JCPCT to see the comparative risks identified by centre for any one of the four options.

A framework was developed to 'risk assess' the readiness of the centres and therefore the options to deliver the activity expected. The main report provides individual risk assessments by each centre within each option. Overleaf is a diagram that categorises the risk by option:

High risk



Low risk

In terms of potential risk the options can be categorised as :

- Options H and I present the least potential risk given that they are both 8 centre options. They do however tend to under-utilise the London and Birmingham centres (Birmingham Children's Hospital would see a significant decrease in activity under this option). Also, as highlighted elsewhere in this document, there are doubts about the viability of Option I as two centres are forecast to struggle to meet the required minimum critical mass of procedures.
- Options B and E are both 7 centre options, with option E having 3 centres in London. The capacity review has identified some risks in both these options regarding the ability of the centres in Newcastle and Bristol to fully recruit to a level needed to deliver the activity. Both options would require the transfer of ECMO from Glenfield Hospital to Birmingham Children's Hospital. The capacity review provides assurance that Birmingham Children's Hospital has credible plans to build the necessary capacity.
- Options A,C and J are 7, 6 and 7 centre options respectively. In addition to the recruitment risks at Newcastle and Bristol, potential recruitment pressures are increased at the Evelina Children's Hospital and the Royal Brompton Hospital would struggle to meet the capacity requirements for the activity required. Option C requires ECMO to transfer from Glenfield Hospital to Birmingham Children's Hospital but Birmingham Children's Hospital has credible plans to build the necessary capacity. The relatively high activity demanded at Southampton General Hospital in Option J is likely to increase the pressure on recruitment and managing the retrieval network at that centre and means the risk is similar to that of Option A.
- Options K and L require paediatric cardiothoracic transplantation, paediatric 'bridge to transplant' services and ECMO to transfer from the Freeman Hospital in Newcastle to Birmingham Children's Hospital. This in itself is recognised as a significant risk by the Advisory Group on National Specialised Services, but as the baseline paediatric congenital cardiac surgery is reduced for Birmingham Children's Hospital and as ECMO remains at Leicester and there is no requirement to re-provide services at Bristol, options K and L present less potential risk than options D,F and G.

- Options D, F and G are respectively 6, 7 and 7 centre options. Option F has 3 centres in London. In addition to the recruitment risks above, the key potential risks are the need to transfer ECMO from Glenfield Hospital and the Freeman Hospital to both Birmingham Children's Hospital and Bristol Children's Hospital, and to re-locate paediatric cardiothoracic transplant services and paediatric 'bridge to transplant' services from the Freeman Hospital to Birmingham Children's Hospital. The simultaneous transfer of three nationally commissioned services is a significant risk and this has been recognised by the Advisory Group for National Specialised Services.

AREAS OF RISK IDENTIFIED FOR TRANSITION AND IMPLEMENTATION

Workforce

All centres have a workforce strategy and have credible plans to develop their own staff into specialist roles as well as actively recruiting externally. In reality the ability of centres to train and recruit existing and new staff could vary once a decision has been made by the JCPCT and decisions are made by individual staff about their future careers. The Safe and Sustainable steering group has advised the JCPCT that the workforce implications of service reconfiguration cannot be reasonably assessed until the phase of implementation.

Paediatric Retrieval Services

Initial risk analysis has identified that additional resources may be needed to respond to changes in geographical area and number of cases. Some of the Trusts also raised this as an issue during this process as in some areas retrieval services are already reported to be at capacity. The Director of National Specialised Commissioning has initiated work to strengthen the planning and delivery of paediatric retrieval services in England during the phase of implementation.

Paediatric Intensive Care

Planned surgery is sometimes postponed due to pressures in paediatric intensive care. Centres have plans to expand PICU capacity and this has been taken into account in the risk evaluation. The Director of National Specialised Commissioning has initiated work with the Paediatric Intensive Care Society to strengthen the planning and delivery of paediatric intensive care services in England during the phase of implementation.

RECOMMENDATION 20:

The JCPCT is advised to agree that option B is affordable to NHS commissioners and manageable by providers, and that providers have demonstrated credible plans to increase capacity.

Appendices

Appendices

The following appendices are reproduced in this document

B Proposed Additional Standards by the *Safe and Sustainable* Steering Group to the JCPCT, October 2011

C Proposed Revisions to the *Safe and Sustainable* Standards relating to antenatal care

Q Establishing the viability of options that include Southampton and Bristol

R Proposed Scores for Travel and Access

S Proposed Scores for Quality

T Proposed Scores for Sustainability

U Proposed Scores for Deliverability

V Sensitivity Testing

W Analysis of movement in scoring of option A

Y Future Activity Projections

Z Analysis of the proposed Newcastle Networks

CC Final Advice from the Steering Group to JCPCT, October 2011

DD Report of the Advisory Group for National Specialised Services, March 2012

The following appendices are online at www.specialisedservices.nhs.uk/safe_sustainable/childrens-congenital-cardiac-services

A Proposed *Safe and Sustainable* Service Standards, March 2010

D JCPCT Terms of Reference

E Terms of Reference for Professor Sir Ian Kennedy's Panel and Panel Member Biographies

F Report of Mr James Pollock, December 2010

G Report of Professor Sir Ian Kennedy's Panel, December 2010

H Terms of Reference for Mr Pollock's Panel

I Terms of Reference for Panel Convened to assess applications to deliver a Nationally Commissioned Service and outcome of that panel's work

J Terms of Reference for Panel chaired by Adrian Pollitt OBE to explore the impact to interdependent services at the Royal Brompton Hospital

K Pollitt Report

L Health Impact Assessment Steering Group Terms of Reference and Membership

M Ipsos Mori – Report of the Public Consultation, August 2011

N Ipsos Mori – Qualitative Research, August 2011

O Consultation Events Report

P National Clinical Advisory Team Report

X Final Report of the Health Impact Assessment, June 2012

AA PwC Report – Testing assumptions for future patient flows and manageable clinical networks for *Safe and Sustainable*

BB Correspondence from the Immediate Past President of the Paediatric Intensive Care Society to secretariat about retrieval services, February 2012

EE Letter from the Director of ECMO at Glenfield to the Director of National Specialised Commissioning

FF Glenfield Hospital Submission to Consultation on impact to PICU and option "'AB"

GG London SCG initial phase engagement report on paediatric respiratory services at the Royal Brompton Hospital

HH Independent analysis of road journey times between Evelina Children's Hospital and the Isle of Wight

II Analysis of Retrieval Times

JJ Report of Professor Sir Ian Kennedy's Panel in Response to Additional Evidence Submitted in Relation to 'Innovation and Research', February 2012

KK Correspondence from the Immediate Past President of the Paediatric Intensive Care Society to secretariat about Impact to PICUs, February 2012

LL Capacity Analysis, February 2012

MM Report of Professor Sir Ian Kennedy's Panel, October 2011

NN Letter from Professor Sir Ian Kennedy, October 2011

Proposed Additional Standards by the *Safe and Sustainable* Steering Group to the JCPCT, October 2011

B

1 Patent *Ductus Arteriosus*

Background

In response to issues raised in the consultation response by the Oxford Radcliffe Hospitals NHS Trust:

In full term babies the *ductus arteriosus (arterial duct)* usually closes naturally within the first few days of life. In babies born prematurely it may remain open ('patent') resulting in extra blood flow through the lungs – this may delay / prevent weaning from the ventilator. It is the practice to refer these babies for surgical ligation of their patent *ductus arteriosus* (PDA). These babies are cared for in the Neonatal Intensive Care Unit / Special Care Baby Unit and the practice in some centres has been for the neonatal team to transfer the baby to the surgical centre for operation. With larger surgical teams in the Specialist Cardiac Surgical centres, alternative pathways may be developed.

The following standards were endorsed by the British Association of Perinatal Medicine in January 2012.

	Designation standard	Measures	Compatible Evidence Base
A29	As the sole exception to the *Safe and Sustainable* standards which stipulate that heart surgery on children must be performed in a designated Specialist Surgical Centre it is permissible for neonates with *patent ductus arteriosus* (PDA) to receive surgical ligation in the referring neonatal intensive care unit (level 3) provided that the visiting surgical team is despatched from a designated Specialist Surgical Centre and is suitably equipped in terms of staff and equipment.	Written protocols	Gould D et al (2003) 'A comparison of on-site and off-site Patent Ductus Arteriosus ligation in premature infants', *Pediatrics* Vol 112, 6
A30	It will be for each Congenital Heart Network to determine whether this arrangement is optimal (rather than transferring the neonate to the Specialist Surgical Centre) according to local circumstances, including a consideration of clinical governance and local transport issues.	Written protocols and audit of compliance	
A31	All Congenital Heart Networks must have clear protocols that address the provision of surgical ligation for neonates with PDA.	Written protocols	

B

2 Publication of the standards and audits of compliance

Background

In response to a number of participants at consultation events:

A number of participants at consultation events sought reassurance that surgical centres will continue to be audited against the standards once the designation process has concluded. This proposed standard does not stipulate a timetable for future audits (that is for the commissioning body to stipulate outside of the standards document) but it does ensure that the standards themselves and the outcome of future audits are widely publicised.

	Designation standard	Measures	Compatible Evidence Base
E14	Specialist Surgical Centres must make parents and carers aware of the *Safe and Sustainable* standards and the outcome of audits of compliance. As a minimum this will include publishing the *Safe and Sustainable* standards on the centre's website and informing parents of their existence in first appointment letters and other relevant literature.	Patient / parent literature Compliance audits	*National Service Framework for Children, Young People and Maternity Services* (2003 and as modified)

Proposed Revisions to the *Safe and Sustainable* Standards relating to antenatal care

C

	Designation standard	Measures	Compatible evidence base	Status
B	**PRENATAL SCREENING AND DIAGNOSIS**			
B1	Specialist Surgical Centres and Children's Cardiology Centres must adhere to the screening and diagnostic standards formulated by the NHS Fetal Anomaly Screening Programme and the British Congenital Cardiac Association.	Written protocols and audit of compliance	British Congenital Cardiac Association (BCCA) Fetal Cardiology Standards (2012 revised edn) Draft ' NHS FASP Clinical Care Pathway for Congenital Heart Disease' (2012) NHS Fetal Anomaly Screening Programme 18+0 – 20+6 weeks Fetal Anomaly Scan National Standards and Guidance for England (2010)	Mandatory
B2	Children's Cardiology Centres and District Children's Cardiology Services that do not provide a fetal diagnostic cardiology service must work within the protocols defined by the Specialist Surgical Centre in their network and in accordance with NHS Fetal Anomaly Screening Programme 18+0 – 20+6 weeks Fetal Anomaly Scan National Standards and Guidance for England.	Written protocols and audit of compliance	Draft ' NHS FASP Clinical Care Pathway for Congenital Heart Disease' (2012) NHS Fetal Anomaly Screening Programme 18+0 – 20+6 weeks Fetal Anomaly Scan National Standards and Guidance for England (2010)	Mandatory
B3	Each Specialist Surgical Centre will agree and establish protocols with feto-maternal medicine units and tertiary neonatal units in their networks for the care and treatment of pregnant women whose fetus has been diagnosed with a major heart condition. The protocols must meet the BCCA Fetal Cardiology Standards, the NHS Fetal Anomaly Screening Programme 18+0 – 20+6 weeks Fetal Anomaly Scan National Standards and Guidance for England (2010) and newly devised NHS FASP clinical care pathway for congenital heart disease.	Written protocols and audit of compliance	British Congenital Cardiac Association (BCCA) Fetal Cardiology Standards (2012 revised edn) Draft ' NHS FASP Clinical Care Pathway for Congenital Heart Disease'(2012) NHS Fetal Anomaly Screening Programme 18+0 – 20+6 weeks Fetal Anomaly Scan National Standards and Guidance for England (2010) National Service Framework for Children, Young People and Maternity Services (2003 and as modified)	Mandatory
B4	The timing of fetal cardiac scans for high risk mothers should be in line with the BCCA Fetal Cardiology Standards and adhere to the NHS Fetal Anomaly Screening Programme clinical care pathway for congenital heart disease.	Written protocols and audit of compliance	British Congenital Cardiac Association (BCCA) Fetal Cardiology Standards (2012 revised edn) Draft ' NHS FASP Clinical Care Pathway for Congenital Heart Disease' 2012) NHS Fetal Anomaly Screening Programme 18+0 – 20+6 weeks Fetal Anomaly Scan National Standards and Guidance for England (2010)	Mandatory

C

	Designation standard	Measures	Compatible evidence base	Status
B	**PRENATAL SCREENING AND DIAGNOSIS**			
B5	If the 18+0 -20+6 week fetal anomaly scan indicates that the fetus may have a cardiac malformation, the woman should be offered a specialist fetal cardiology assessment within the time limits stipulated by the NHS Fetal Anomaly Screening Programme and the British Congenital Cardiac Association.	Written protocols and audit of compliance	British Congenital Cardiac Association (BCCA) Fetal Cardiology Standards (2012 revised edn) NHS Fetal Anomaly Screening Programme 18+0 – 20+6 weeks Fetal Anomaly Scan National Standards and Guidance for England (2010)	Mandatory
B6	Counselling for major congenital cardiac anomalies should be performed by fetal cardiology specialists with support from other members of the multi-disciplinary team. Support from a Clinical Psychologist or Nurse Counsellor or specialist nurse practitioner should be available at an early stage to work with families.	Written protocols and audit of compliance Job descriptions	British Congenital Cardiac Association (2010) 'Fetal Cardiology Standards' National Reference Group for Psychologists working in Paediatric Cardiology (2010)	Mandatory
B7	A specialist nurse counsellor / specialist nurse practitioner / specialist practitioner will be present during the consultation or will contact all prospective parents whose baby has been given an antenatal diagnosis of cardiac disease to provide information and support within 48 hours of diagnosis. Parents should also be given contact details for relevant local and national support groups at this point.	Job descriptions	British Congenital Cardiac Association (2010) 'Fetal Cardiology Standards'	Mandatory
B8	At diagnosis a plan should be agreed between the Specialist Surgical Centre, the specialist feto-maternal unit, the local obstetric unit, the neonatal team, paediatricians and the parents about arrangements for the delivery of the baby. The plan should be updated throughout pregnancy.	Written protocols and audit of compliance	Draft ' NHS FASP Clinical Care Pathway for Congenital Heart Disease' (2012) British Congenital Cardiac Association (2010) 'Fetal Cardiology Standards' British Congenital Cardiac Association (2009) 'Requirements for Provision of Outreach Cardiology Service'	Mandatory
B9	In all cases where a baby is likely to require immediate post-natal intervention or surgery the parents must be given the choice of delivering the baby either at or close to the Specialist Surgical Centre if necessary (for example, at a linked obstetric unit).	Written protocols and audit of compliance	Draft ' NHS FASP Clinical Care Pathway for Congenital Heart Disease' (2012) British Congenital Cardiac Association (2010) 'Fetal Cardiology Standards' British Congenital Cardiac Association (2009) 'Requirements for Provision of Outreach Cardiology Service'	Mandatory
B10	If the plan is for the delivery of the baby at the local maternity unit this should include arrangements for the transfer of the mother and baby to the Specialist Surgical Centre if early intervention or assessment is required. A competent neonatologist should be present at the delivery and a neonatal team must be available to care for the baby whilst awaiting transfer. In cases not requiring urgent assessment arrangements for early postnatal cardiac evaluation should be made after delivery.	Written protocols and audit of compliance	British Congenital Cardiac Association (2010) 'Fetal Cardiology Standards' British Congenital Cardiac Association (2009) 'Requirements for Provision of Outreach Cardiology Service' Report of the Paediatric Congenital Cardiac Services Review Group (2003)	Mandatory

Establishing the viability of options that include Southampton and Bristol

Q

What evidence is there that these options are viable?

Ipsos Mori

Firstly, the analysis of consultation responses by Ipsos Mori who have reported high support for Option B amongst respondents to consultation. In expressing support for Option B it may reasonably be assumed that respondents are expressing an opinion on the viability of the networks.

One of the questions specifically asked of respondents was around the assumptions that the JCPCT has made around networks and patient flows. Respondents were invited to comment on any of the postcodes in the proposed networks. Ipsos Mori has reported that there was no significant disagreement in respect of the postcodes relating to the Bristol and Southampton networks.

PwC analysis of patient flows and networks

PwC was commissioned to provide an independent review of assumptions around patient flows and viable networks. The report was published on 27 October 2011 and delivers three key messages:

1. There are no 'show stoppers' – all networks can be delivered, albeit with differing degrees of risk
2. The vast majority of referrers (96%) have said that they would change their referral practices in line with the networks envisaged by Option B even though 50% of them would have to change current referral patterns
3. And parents have said – notwithstanding a preference for travelling closer to home where possible - that a significant factor for where they send their child is 'where their cardiologist tells them to go'

These three key messages together – with the outcome of the Ipsos Mori analysis – provides strong *prima facie* evidence that networks can be made to work that would retain both Bristol and Southampton in the same option.

Additional evidence

The secretariat invited additional evidence from the relevant centres (Bristol, Southampton, Birmingham and the three London centres) and the relevant Specialised Commissioning Groups. The following proposals are based on a triangulation of the various sources of evidence including submissions made by organisations during public consultation ('white mail' responses).

Taking all of this evidence into account, the secretariat has concluded that it is reasonable to advise the JCPCT that options that retain both Southampton and Bristol are viable, and for the JCPCT to revise some of its previous assumptions about these networks:

London network

BN (Brighton) – It is proposed that all populations of this postcode are allocated to the London network save for the West of this postcode representing Chichester which has an existing strong relationship with Southampton. Chichester currently refers to Southampton for paediatric cardiology services, and the Paediatrician with Expertise in Cardiology at St Richard's Hospital in Chichester is a member of Southampton's Regional Paediatric Cardiac Network Group. Chichester and Worthing are more accessible to Southampton than other parts of this postcode which flow more naturally to London. The proposal for Brighton to be part of the London network reflects the view of London SCG, South East Coast

SCG, the Evelina Children's Hospital and is supported by clinicians, members of the public and parents who were interviewed by PwC.

HH (Hemel Hempsted) – While it may seem counter intuitive to expect patients to travel from Hemel Hempsted to Southampton, the West of this postcode has historically referred to Oxford, which now forms a single congenital heart network with Southampton. Validated activity data recently provided by South Central SCG identifies a caseload of around 10 surgical cases per year to Southampton from the HH postcode, and Southampton and Oxford report a good relationship with referrers. However, in acknowledging that patients in the East of the HH postcode may flow more naturally to Great Ormond Street Hospital (as suggested by London SCG, South East Coast SCG and parents of children currently being seen at GOSH) it is proposed to allocate most of the HH postcode to London, and the remainder (in the west) to the Southampton / Oxford network. This is proposed even though members of the general public who were interviewed by PwC accepted the proposal for a network with Southampton and even though Great Ormond Street Hospital did not raise any objection to the allocation of HH to the Southampton network in the Trust's submission.

KT / TW (Chertsey) – Currently the paediatric cardiology service at Ashford and St Peter's Hospital in Chertsey refers to the Royal Brompton Hospital, and the Royal Brompton holds outreach clinics there. The service at Ashford and St Peter's Hospitals has written to the JCPCT to express a preference for the continuation of the Royal Brompton as a surgical centre, but has also written directly to the Chief Executive of Southampton University Hospitals NHS Foundation Trust to state that in the event of surgery ceasing at the Brompton its preference would be to refer to Southampton. It is therefore proposed that whilst the areas of Twickenham and Kingston fall clearly within the London network, the limited catchments for these two hospitals (bordering the M25 and M3 route to Southampton) would fall within the Southampton network.

Southampton and Oxford network

OX and RG (Oxford and Reading) – The secretariat advises the JCPCT that the Southampton / Oxford congenital heart network is sufficiently strong to be viable. It is therefore proposed that the Oxford and Reading postcodes flow to the Southampton centre. It has been suggested that some patients may choose to travel to London based on journey times but there are direct train lines from Oxford and Reading to Southampton and good road links. The proposal has not been disputed by Great Ormond Street Hospital which has a presence in some parts of the regions. The proposal reflects the strength of the Southampton / Oxford network as reported by both centres during consultation, and reflecting the view of South Central SCG and South Central SHA. Although South East Coast SCG and members of the general public interviewed by PwC have suggested that some parts of the region may flow to Bristol, PwC has reported that clinicians in Oxford are more likely to not refer to Bristol. In its response to consultation the parent group in Oxford 'Young Hearts' has expressed a preference for Southampton over Bristol, and during consultation letters of support for Southampton have been received from a number of NHS

Q

Trusts in Oxfordshire. Southampton reports that referrers in Reading are already starting to refer directly to them. In a letter to the secretariat dated 20 October 2011 the Chief Executive of the Bristol centre acknowledged that these are not regions that look to Bristol for paediatric care and he said that in his view these regions would choose Southampton rather than Bristol particularly given strength of the network with Oxford.

DT (Dorchester) – The JCPCT is advised that patients from the DT postcode would more naturally flow to Southampton rather than Bristol. Currently Southampton provides outreach clinics to Dorchester, Poole and Yeovil and local NHS services have submitted letters of support for Southampton during consultation. The proposal is supported by numerous organisations and respondents including Dorset and Poole health overview and scrutiny committees. Both South Central and South East Coast SCGs consider this proposal to be reasonable and reflects the views of parents and clinicians interviewed by PwC.

SP (Salisbury) – The secretariat has tested the allocation of the SP postcode to the Southampton network. Currently Southampton provides outreach clinics at Salisbury District Hospital and the Consultant Paediatrician with Expertise in Cardiology at Salisbury Hospital is a member of Southampton's Regional Paediatric Cardiac Network Group. The Chief Executive of the Bristol centre has acknowledged to the secretariat in writing that links to the Bristol centre are rare.

The remainder of the proposed Southampton network is as set out by the JCPCT in the consultation document:

GU (Guildford) – South East Coast SCG has questioned whether patients in the north of the postcode may flow more naturally to London. In the north of the postcode activity has historically flowed to GOSH. In the PwC report parents of children already receiving treatment at GOSH have said that they would tend to travel to London but in the same report members of the general public accepted the proposal for a network with Southampton. Great Ormond Street Hospital did not dispute the proposal for Guildford to flow to Southampton; neither was the proposal disputed by London SCG.

The JCPCT is advised that Southampton already has a strong presence in this postcode. Frimley Park Hospital refers to Southampton for paediatric cardiology, including emergency referrals which now go to Southampton through their PICU and surgical programme. Dr Tony Salmon, Consultant Cardiologist at Southampton and President of the British Congenital Cardiac Association, holds an outreach clinic there every month with the local Paediatrician with Expertise in Cardiology. The frequency of the Southampton outreach clinic will increase to every two weeks in 2012. Currently around 170 outreach patients are seen by Southampton each year, in addition to the GU patients that are seen at Southampton General itself for cardiac surgery and for ongoing cardiology management. The Paediatrician with Expertise in Cardiology at Frimley Park Hospital is a member of Southampton's Regional Paediatric Cardiac Network Group.

Q

SL (Slough) – Slough historically has had links with the Oxford network. The Paediatrician with Expertise in Cardiology based at the Slough service travels to the paediatric cardiology service at the John Radcliffe Hospital for joint fetal cardiology clinics. Great Ormond Street Hospital has an outreach service there but Great Ormond Street has not disputed the proposal to allocate Slough to the Southampton / Oxford network. Additionally, the proposal has not been disputed by London SCG or South East Coast SCG nor by the Evelina Hospital, and this postcode was not disputed during consultation as reported by Ipsos Mori. Members of the general public who were interviewed by PwC accepted the proposal for a network with Southampton, as did the clinicians who were interviewed by PwC.

RH (Redhill) – Historically the Redhill population has had links with the Royal Brompton Hospital and Evelina Children's Hospital. The Evelina holds 4 outreach clinics a year and a letter of support for the designation of the Evelina as a surgical unit was submitted during consultation by the local service. The only direct representation to the secretariat querying the proposal for the RH postcode to form part of the Southampton was by the Evelina Children's Hospital who wrote that '*they are not convinced*' of the proposal based on a consideration of journey times. London SCG has not disputed the proposal but South East Coast SCG has asked whether patients in the north may flow more naturally to London. Parents of children currently being seen by the London providers have suggested that they would tend to travel to London. However, the clinicians and members of the general public who were interviewed by PwC supported the proposal for a network with Southampton, and the proposal was not disputed during public consultation as reported by Ipsos Mori. Anecdotally, members of the JCPCT and Steering Group witnessed support for the Southampton centre from residents of Redhill and parts of Surrey that are 'closer to London' at the Gatwick public consultation event.

The Bristol network

HR / WR (Hereford / Worcester)
In September 2011 a meeting was held involving referring clinicians from Hereford and Worcester, the Associate Medical Director of Birmingham Children's Hospital, the Chief Medical Officer from University Hospital Bristol, the Director of Women's and Children's Services at University Hospital Bristol and senior commissioners from West Midlands SCG and South West SCG. On 21 September 2011 the Chief Executive of Birmingham Children's Hospital wrote to the secretariat:

> *'It is clear from the discussion that there is full support, indeed enthusiasm, for implementing [this option] and there is general consensus that challenges are far from insurmountable. There is a clear will amongst everyone concerned to make this option viable such is the level of clinical support for what is now widely considered to be the 'quality' option".*

Additionally, on 4 August 2011 Sir Ian Carruthers, the Chief Executive of South West SHA, wrote to the secretariat:

> *'Our preferred way forward is Option B and this is strongly supported because it would preserve good access to services for residents throughout the region'.*

In its formal response to consultation the Bristol centre did not express a preference for Option B; Bristol instead wished for the cessation of surgery at Southampton, and for Bristol to be the sole surgical centre in the South West, sharing the South Central network with London in a 6-site option.

In a letter dated 20 October 2011 the Chief Executive of University Hospital Bristol, Mr Robert Woolley, raised three possible objections to the proposal around Hereford and Worcester:

The first relates to a proposal by local clinicians that the non-surgical elements of care be delivered locally rather than at Bristol. He suggested that this was contrary to the aims of *Safe and Sustainable*. However, the secretariat advises the JCPCT that a proposal to move non-surgical care away from the surgical unit is consistent with the *Safe and Sustainable* model of care. As the exercise to establish the viability of Option B involves a consideration of surgical numbers only, the secretariat advises that this is not a persuasive in this regard.

Secondly, Mr Woolley raised the point that patients from these postcodes may flow more naturally to Birmingham, and thirdly he suggested that whilst there was support amongst Hereford and Worcester clinicians for a network with Bristol their '***preference***' would be to retain Birmingham.

Given the clear indications of support from local clinicians acknowledged in both the Bristol and Birmingham letters, the secretariat advises the JCPCT that the objections raised by Bristol reveal legitimate challenges that need to be addressed, but which do not lead one to the conclusion that the proposal itself is not viable.

Taking all of this into account, the forecast annual activity levels for the centres in Option B would be as follows, demonstrating reasonable compliance with the *Safe and Sustainable* standards.

London total	**1252**
Southampton	**428**
Birmingham	**611**
Bristol	**412**
Newcastle	**559**
Liverpool	**479**

Incidentally, Bristol would be viable in this option even if the JCPCT were to allocate the Worcester (WR) postcode to the Birmingham network.

R Proposed Scores for Travel and Access

The JCPCT is advised to score options against this criterion as follows:

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Total score for Travel and Access	**2**	**2**	**1**	**2**	**1**	**2**	**3**	**2**	**3**	**1**	**2**	**2**
Travel times for elective admissions	2	2	1	2	1	2	3	2	3	1	2	2
Retrieval times	2	3	2	2	2	2	3	2	3	2	2	2

The combined score for the travel and access criteria is an amalgamation of the scores for the two sub criteria, and both sub criteria are given equal weighting.

"The negative impact on travel times for elective admissions is kept to a minimum"

The previous method applied by the JCPCT for scoring options against this sub-criterion attempted to evaluate both absolute journey times and the changes to journey times by road.

These two factors were combined in a subjective manner.

There are two reasons for advising the JCPCT to adapt its scoring method and the data relied upon:

i The original method for scoring elective travel and access was deemed by some respondents as being inappropriate as it considered both absolute journey times and increases in journey times. Moreover the scoring method did not explicitly define what was 'good' or 'acceptable' in terms of increase in travel times and absolute journey times. Thus the JCPCT was asked to combine a number of different data points for each configuration option to arrive at a single score for elective travel and access. This involved an element of subjectivity in weighting the relative importance of different factors that was not acceptable to some respondents.

ii The analysis did not accurately measure travel times from the Isle of Wight, because the travel analysis software modelled road travel times only. The software therefore assumed that the travel time from the Isle of Wight exceeded 4 hours to every potential centre, including Southampton General Hospital. A more sophisticated analysis suggests that total road and ferry times to Southampton from the Isle of Wight are, generally, significantly shorter than 4 hours.

The JCPCT is therefore advised to adapt its analysis for elective journey times so as to consider solely the change to journey times, measuring the number of families who would / not have an increase of 1 hour to their journey. This enables the JCPCT to more clearly distinguish between the options in a more and objective transparent way that is understandable to respondents.

The JCPCT is also advised to take account of a more sophisticated analysis of data that more accurately measures journey times from the Isle of Wight. Applying the above method, the JCPCT is advised that families from the Isle of Wight would have an increase in journey time of over 1 hour in all options that do not include Southampton.

The table below shows the number of patients who have an increase in journey time of up to one an hour and an increase in journey time of over 1 hour.

Option >	A / H	B	C / E	D / F	G	I	J	K / L
Up to 1 hour	3,446	3,430	3,308	4,400	3,522	3,567	3,310	3,406
Over 1 hour	295	311	433	341	219	174	431	335

Source: Population figures per postcode district in England and Wales and travel times data is for road journeys using 24 hour average speeds per road type. Underlying data base from Geoplan, Access Mapping Consultancy

The findings of the Health Impact Assessment around travel and access are worth highlighting in this regard:

- Option I will result in fewest patients being referred to a new surgical network (under 700)
- Options B, C and E would result in most patients being referred to a different network (over 900)
- In terms of access, Options C, E and J will see more patients experiencing significant journey time impacts by car and Option J by public transport as compared to the other options
- Access by private transport is likely to be better under Options G and I, whilst public transport impacts will be fewest under Option G
- Negative access impacts for patients from vulnerable groups are likely to be most significant in Options C and E by both private car and public transport and also for Option J for public transport
- Option G and I are likely to involve fewest patients from vulnerable postcode districts experiencing significant travel impacts by private car and Option G by public transport

The JCPCT is advised that options G and I perform better than the other options in this regard as they have the most number of families with a **shorter** increase in journey time of up to one hour. Therefore it is suggested that these options receive a high score of 3. It is suggested that a score of 4 should not be used as under these options some families have an increase in journey time of over 1 hour and therefore the criteria cannot be said to have been 'exceeded'.

Options C, E, and J have the largest number of families who experience an increase in journey times. It is therefore proposed that these options receive a lower score of 1. It is suggested that a score of 0 should not be applied because these options meet some elements of the criteria as even in these options most patients experience only a short increase in journey times.

The proposed scores are consistent with the findings of the Health Impact Assessment around travel and access, including potential impacts to vulnerable groups.

> ***"The retrieval team should arrive at the referring unit within three hours (extended to four hours in remote areas) of the decision to retrieve the child in accordance with the PIC Society 'Standards for the Care of Critically Ill Children, 2010'"***

Summary of previous approach

The JCPCT's previous method for evaluating options against this sub-criterion involved an analysis of road journey times between the surgical centres proposed in each option and District General Hospitals located at the extremities of mainland England and Wales. Options were assessed against their compliance with the Paediatric Intensive Care Society's standard for the retrieval of critically ill children which requires a specialist retrieval team to reach the child within three hours of the decision to retrieve. It was agreed with the Paediatric Intensive Care Society that the road journey time between the hospitals would be an appropriate measurement for this purpose without building into the method an estimated time for the retrieval team to 'gear up' once the decision to retrieve has been made.

Retrieval by air was disregarded for the purpose of this exercise as the JCPCT was looking to reasonably identify 'worst case scenarios' in all cases rather than likely scenarios. Also, air retrievals are not usually made at night or in difficult weather.

The JCPCT decided to regard this sub-criterion as an absolute requirement in that options that were deemed to not meet the three-hour threshold in respect of all potential journeys within each option were disregarded as not viable.

For this reason, options that did not include Bristol Children's Hospital were disregarded by the JCPCT as not viable as a retrieval team from Southampton or Birmingham (the closest alternative surgical units) were deemed unable to reach significant populations in the South West of England and Wales[2] within three hours.

[2] Truro, Barnstaple, Plymouth, Haverfordwest and Carmethen

Isle of Wight

During consultation numerous respondents in South Central England remonstrated that the JCPCT's analysis was flawed in that it excluded a consideration of journey times between the surgical units in each option and St Mary's Hospital on the Isle of Wight. The point made by respondents was that if the Isle of Wight had been included in this analysis then it would have been unreasonable for the JCPCT to consult on any option that excluded the Southampton surgical unit, as it was suggested that retrieval teams from Bristol and London (the nearest alternative surgical units) would be unable to reach the Isle of Wight within three hours.

The Chair of the JCPCT asked the secretariat to explore this issue further. In October 2011 the secretariat advised JCPCT members that:

> *'There is no available evidence that could reasonably suggest that a retrieval team from London or Bristol could reach the Isle of Wight in compliance with the time limits stipulated by the PICS standards, even if the Isle of Wight is considered to be a 'remote area' and measured by the higher time threshold of 4 hours. This advice is concordant with that provided to the JCPCT by the Paediatric Intensive Care Society in its formal response to consultation dated 23 June 2011 …. The secretariat will further advise the JCPCT to take these conclusions about retrievals from the Isle of Wight into account when considering the outcome of public consultation as part of the committee's deliberations to agree an eventual configuration option, and in any necessary re-scoring of options.'*

In developing this advice to the JCPCT the secretariat considered an independent analysis of road journey times between the Evelina Children's Hospital and the Isle of Wight commissioned by Guy's and St Thomas' Hospital NHS Foundation Trust[3]. Although this paper suggested that a journey time under three hours was possible, the secretariat concluded that this was dependent in all cases on a favourable ferry timetable, which is seasonal and over which the NHS has no influence. Thus the secretariat advised the JCPCT that the Evelina's paper did not demonstrate that the time threshold could be ***reasonably*** met in all cases.

The proposed approach for scoring

Were the JCPCT to continue to regard this sub-criterion as an absolute requirement (requiring the presence of Bristol and Southampton in all options for the reasons set out above) 3 options would remain viable (options B, G and I). The remaining 9 options would be disregarded without any consideration of their suitability beyond retrieval times.

There are two reasons for advising the JCPCT against this approach.

The first is that other options that the JCPCT may consider worthy of consideration would be deemed un-viable solely because of retrieval issues in the South of England. The JCPCT is invited to consider whether this would be considered reasonable by the numerous respondents who expressed an alternative preference during consultation.

[3] Appendix HH

Secondly, the JCPCT's own analysis identifies that even options that include both Southampton and Bristol do not themselves ensure reasonable compliance with the standard in all cases: a retrieval team from Bristol remains unable to reach Truro within three hours, a retrieval team from London remains unable to reach Great Yarmouth within three hours, and a retrieval team from Southampton remains unable to reach St Mary's Hospital on the Isle of Wight within three hours (or four hours) when the Solent ferry is closed for prolonged periods (which is not uncommon within the winter timetable).

In other words, the PICS standards are not met now in the way that the JCPCT has applied them for the purpose of consultation. Given that the JCPCT has proposed a reduction in the number of centres, rather than an increase, it would be impossible for the eventual configuration option to meet the PICS standards in all cases. The JCPCT is advised that there has to be some relaxation in the way that it approaches this issue.

The JCPCT is therefore advised ***not*** to regard this sub-criterion as an absolute requirement, but to assess *the extent to which* – in the JCPCT's opinion – each option satisfies the criterion via a scoring scale between 0 (does not meet any elements of the criterion) and 4 (exceeds the criterion). For this purpose, it is proposed that the reference to 'most of the criteria' in the scoring definition is deemed to refer to 'most of the population'.

Proposed scoring for retrieval

The JCPCT is advised to score options as set out in the table on page 148. The scores are based on a consideration of journey times as set out in Appendix II[4].

- Options A, C, D, E, F H K and L do not include Southampton which means that a retrieval team may not reach the Isle of Wight in compliance with the standards
- Option J does not include Bristol which means that a retrieval team may not reach the South West Peninsular and South Wales in compliance with the standards
- All other options reasonably allow for retrieval times within 3 hours save for the examples provided above.

It is therefore proposed that options A, C, D, E, F, H J K and L receive a score of 2 to indicate that they meet most elements of criteria, as a significant number of road journeys will be less than 3 hours. It is proposed that options B, G and I receive a score of 3 to reflect that these options ensure best reasonable compliance with the standards in that most road journeys in these options will be less than 3 hours.

[4] In response to evidence submitted during consultation, journey times starting in Yorkshire and Humber and the North West of England have been measured from a different postcode in options which retain the Leeds and Liverpool centres, reflecting the location of the retrieval team's base rather than the location of the surgical unit. This has had no material impact on the analysis.

Ipsos Mori reported that:

> *"the quality of care provided was the most frequently mentioned issue for respondents discussing either specific hospitals or the options more generally. In fact, quality of care featured heavily throughout the consultation responses, at each of the questions posed in the response form and in the letters and emails that were submitted. There was a strong belief amongst many that quality should be the deciding factor in service planning[1]".*

The importance of high-quality care is also evident in respondents' views on one of the key principles underpinning the proposals that "all children in England and Wales who need heart surgery must receive the very highest standards of NHS care". Ipsos Mori reported that "Almost all respondents answering the question agreed with the principle – 98% of personal respondents and 99% of organisations[2]".

A number of respondents queried the JCPCT's previous approach to scoring options against the 'quality' criterion.

"The focus on quality gets lost in the document and other factors such as patient access times, retrieval times and volume of activity appear to be more heavily weighted. This loss of focus on, and weighting given to, quality is of grave concern".

Dorset Health Scrutiny Committee, response to consultation, 2011

"We note the weightings ascribed for scoring the options against the evaluation criteria and would support the emphasis put on quality as the most important consideration. However, we note that the quality scores ascribed to the different options in practice result in very little differentiation between options, in that five of the six final options score'3' points and one scored '4' points. This is in marked contrast to the findings of the initial evaluating visits when, using a different quality scoring system, the panel recorded a wide range of quality".

President of the **Paediatric Intensive Care Society,** response to consultation

"The centres that were assessed by Sir Ian Kennedy in 2010 demonstrated a wide variation in progress towards the delivery of the agreed standards although this does not appear to have been considered by the JCPCT. We wholeheartedly support the statement 'mediocrity must not be our benchmark for the future' and remain of the view that the option appraisal process gave inappropriate weighting to travel and access".

Hampshire Health Overview Scrutiny Committee, response to consultation

[1] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p7

[2] Ipsos Mori, *Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation*, 2011, p23

S

> "The Leicester Health Scrutiny Committee is firmly of the view that quality of care should be the paramount consideration when determining the future configuration of children's congenital heart services".
>
> Health Community and Involvement Scrutiny Committee, **Leicester City Council,** response to consultation

Some respondents suggested that the outcome of the Kennedy's panel report was that there was no material difference across the centres, such as the suggestion that "*all centres are within 95% of the top scoring centre*[3]" (though this statement is incorrect and may be based on – but misquotes and misunderstands – a sentence in the pre-consultation business case that "all options got between 95% and 100% of the maximum score").

Such was the concern of how the JCPCT should reflect the findings of the panel around the scoring of 'quality' that the chair of the panel, Professor Sir Ian Kennedy, wrote to the JCPCT in October 2011:

"The panel is of the view that its report has identified important differences in the extent to which the centres can meet the quality standards in the future; panel members have reflected these differences in their scores and in the report. It is our view that the outcome of the panel's work would be rendered redundant were the JCPCT to interpret the report's conclusions as finding that there are no material differences across the centres in their ability to meet the quality standards in the future. This interpretation would not be justified. To repeat, there are important differences".

It is therefore proposed that the sub-criterion 'high quality service' has the greatest influence on the total score for quality based on a strong theme from respondents during consultation – that 'quality' of service should be the most important of the JCPCT's considerations[4]. The table below shows the proposed scores against this criterion.

However, sensitivity testing is presented to the JCPCT at page 172 which takes account of the sub-criterions of 'innovation and research' and 'clinical networks'.

[3] University Hospitals of Leicester NHS Trust, response to consultation

[4] Ipsos Mori, Safe and Sustainable Review of Children's Congenital Heart Services in England – Report of the public consultation, 2011

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Total score for Quality	**1**	**3**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**2**	**1**	**1**
High quality service	1	3	2	1	2	1	2	1	2	2	1	1
Innovation and Research	2	3	2	2	2	2	3	2	3	2	2	2
Clinical Networks	2	2	2	3	2	3	3	2	2	2	3	3

"Designated surgical centres will deliver a high quality service".

The proposed scores against this sub-criterion are based on the scores applied by Professor Kennedy's panel against compliance with the *Safe and Sustainable* service standards[5].

Kennedy Panel Scores		
1	Evelina	**535**
2	Southampton	**513**
3	Birmingham Children's	**495**
4	Great Ormond Street	**464**
4=	Royal Brompton	**464**
6	UH Bristol	**449**
7	Freeman, Newcastle	**425**
8	Alder Hey, Liverpool	**420**
9	Glenfield, Leicester	**402**
10	Leeds	**401**
11	John Radcliffe	**237**

The JCPCT is advised to consider the extent to which each option includes the three highest scoring centres (which would increase an option's score) and the three lowest scoring centres in any option (which would lower an option's score).

- Options B, G, I and J include the three highest scoring centres. All other options include only two of the top three scoring centres
- Options B, C and E include only one of the lower-scoring centres. All other options include two lower-scoring centres
- Option B contains the most high scoring centres and the fewest low scoring centres so it is proposed that it receives a score of 3
- Options C and E have only one low scoring centre so it is proposed that it receives a score of 2
- Options G, I and J have all three high scoring centres, but two low scoring centres so it is proposed that they receive a score of 2
- Options A, D, F H K and L all have two high scoring centres and two low scoring centres so it is proposed that they receive a score of 1

[5] Leeds Teaching Hospital NHS Trust and University of Leicester NHS Trust suggested during consultation that the panel's report contained factual inaccuracies in respect of their services and that as such a re-scoring was required. These submissions were considered by the panel, which advised the JCPCT in October 2011 that it was content that there were no factual inaccuracies and that no re-scoring was necessary.

S

"Innovation and research is present across the networks and the national service"

The proposed scores against this sub-criterion are based on the Kennedy panel's assessment of the evidence submitted by each centre against its compliance with the standards that relate to 'innovation and research'.

The panel's report of February 2012 is at Appendix JJ.

The proposed scoring is based on a consideration of the extent to which the respective options retain the higher-scored centres, and also a consideration of the total scores of the centres in each option as applied by the Kennedy panel so that the impact of including lower-scoring centres may be analysed. The proposed score for options against this sub-criterion is a composite measure of the number of high scoring centres retained in an option (giving an indication of the total quality of research and innovation) and the total score for research and innovation (giving and indication of the research and innovation capacity).

Score	Centre
5	Evelina
	GOSH
4	Birmingham
	Bristol
	Southampton
3	Newcastle
	Royal Brompton
2	Leeds
	Leicester
	Liverpool
	Oxford

Key

2 Poor (limited evidence supplied)

3 Acceptable (evidence supplied is adequate)

4 Good (evidence supplied is good)

5 Excellent (evidence supplied is exemplary)

- Options B, G and I include all 5 of the highest scoring centres that receive a score of 4 or 5 for research and the total combined score for research and innovation for all centres included in the option is high. It is therefore proposed that these options receive a score of 3 for research and innovation
- Option E also includes the 5 centres with the highest score for research and innovation; however the total combined score for research and innovation for all centres included in this option is lower. It is therefore proposed that this option receives a score of 2 for research and innovation.
- Options A, C, D, F, H J K and L include 4 of the 5 highest scoring centres for research and innovation and it is proposed that receive a score of 2, indicating that they meet most elements of the criteria but not all, as they may lose some current and future research capability from high scoring centres.

"Clinical networks are manageable, taking account of population and geography and the need for clear leadership and communication"

The proposed scores against this sub-criterion are based on a consideration of the evidence submitted during consultation on the viability and manageability of the proposed networks.

Most significantly, a notable number of respondents from Yorkshire and the Humber indicated during consultation that they would choose units other than Newcastle[6]. PwC reported that – although all networks were considered viable as an outcome of their analysis – options that include Newcastle present a greater degree of risk because of the evidence submitted by respondents who have a current relationship with the surgical unit in Leeds.

It is therefore proposed that options A, B, C, E, H, I and J, which include Newcastle, receive a score of 2 indicating that the criterion is reasonably met for most of the networks around the country but not all. It is proposed that options D, F G K and L which do not include Newcastle receive a higher score of 3, indicating that the criteria is reasonably met for all networks.

The JCPCT is advised not to apply a score of '4' to options D, F G K and L as it cannot be reasonably claimed that these options would 'exceed' this sub-criterion due to the potential challenges that the Leeds centre and other respondents have identified around managing this network (in other words, many of the potential challenges apply to the Yorkshire and Humber / North East network regardless of which surgical unit is designated to lead it).

[6] For example, see responses from the Children's Heart Surgery Fund and the Yorkshire and Humber Joint Health Overview and Scrutiny Committee

T

Proposed Scores for Sustainability

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Total score for Sustainability	**2**	**3**	**3**	**3**	**3**	**3**	**3**	**2**	**1**	**3**	**3**	**2**
Perform a minimum of 400 procedures per year	2	3	3	3	3	3	3	2	1	3	3	2
Too onerous a caseload	3	3	3	3	3	3	3	3	3	3	3	3

"All designated centres are likely to perform at least 400 paediatric surgical procedures per year, ideally at least 500 paediatric surgical procedures"

The table below shows the estimated annual surgical procedures referred to each centre under the 12 options. The analysis is based on the following assumptions:

- 2010/11 CCAD validated data is used as the base data.
- Activity is re-distributed from non-designated centres to designated centres based on the populations of the postcode districts within each networks.
- Networks are future estimated networks under each option as agreed with the SCG Directors.

	Forecast Activity using 2010/11 Activity Levels											
Options >	A	B	C	D	E	F	G	H	I	J	K	L
London	1538	1252	1578	1578	1578	1578	1252	1536	1212	1354	1394	1394
Southampton		428					428		428	502		
Birmingham	414	611	653	589	653	589	547	414	398	567	414	414
Bristol	470	412	470	470	470	470	412	470	385		470	470
Newcastle	432	559	559		559			432	432	432		
Liverpool	479	479	479	420	479	420	420	479	479	479	420	420
Leicester	406							406	406	407	425	425
Leeds				683		683	683				618	618

As set out elsewhere, it is doubtful whether three London centres could each reach 500 surgical procedures in options E, F,H and L. The scoring therefore assumes that two London centres could meet the 500 threshold in options E, F and H and that one London centre can meet the 500 threshold in option L. Sensitivity test I explores the impact to the scoring of assuming that three London centres could meet the 500 threshold in options E, F and H

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Number of centres undertaking fewer than 400 procedures per year	0	0	0	0	0	0	0	0	2	0	0	0
Number of centres undertaking 400-499 procedures	5	3	2	2	3	3	3	6	5	3	4	6
Number of centres undertaking 500+ procedures	2	4	4	4	4	4	4	2	1	4	3	2

During public consultation some respondents suggested that the JCPCT's scoring method did not sufficiently differentiate between options where centres were more likely to exceed 500 procedures a year and options where centres were more likely to undertake 400-500 procedures a year. The analysis presented to the JCPCT therefore identifies the number of centres that would be undertaking 400-499 procedures and the number of centres that would be undertaking 500+ procedures in each option; the more centres undertaking 500+, the higher the proposed score for the option under the 'sustainability' criterion.

All centres are able to meet the minimum 400 threshold in all options except for Option I. It is therefore proposed that option I scores a '1' indicating that it meets some elements of the criteria. The secretariat did consider applying a score of '0' to option I but this score could be considered un-reasonable given that the application of a margin of error to forecast activity levels may suggest that the criteria is met. In options A, H and L two centres are forecast to meet the optimal threshold of 500 procedures per year. It is therefore proposed that these options score a '2' indicating that they perform better than option I in this regard. All other options have three or four centres that are able to meet the optimal minimum threshold of 500 surgical procedure per year so it is proposed that they receive a score of '3' indicating that they perform better than options A, H and L in this regard.

"No one designated surgical centre will receive too onerous a caseload that would exceed that centre's capacity to manage it"

Some centres clarified their maximum caseloads during consultation. The Leeds centre confirmed that its maximum caseload was not restricted to 600 paediatric procedures[1] and the Evelina Children's Hospital clarified that its maximum was 750 paediatric procedures[2].

All centres were asked to state their maximum capacity level in a capacity assessment (see Appendix LL). As an outcome of that analysis, no centre is forecast to exceed its maximum capacity level in any option. As such it is proposed that all options receive a score of 3 for not having "too onerous" a caseload.

Recruit and retain newly qualified surgeons

The JCPCT is advised not to score this sub-criterion having received advice from the steering group[3] that the potential implications to workforce and training cannot be identified before the phase of implementation.

[1] A maximum of 600 had not been relied upon by the JCPCT as the Consultation Document set out an option that assumed a caseload of 636 procedures for Leeds

[2] Capacity report

[3] Report to the Joint Committee of PCTs by Dr Patricia Hamilton CBE, Chair of the Safe and Sustainable Steering Group, on behalf of Steering Group members, October 2011

U Proposed Scores for Deliverability

The table below shows the breakdown of suggested scores presented to the JCPCT for discussion against this criterion. The proposed combined total score for deliverability is an amalgamation of the scores for the two sub criteria that the JCPCT scored, i.e. that of nationally commissioned services and PICU and interdependent services.

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Total score for Deliverability	**3**	**3**	**2**	**1**	**2**	**1**	**2**	**3**	**3**	**3**	**1**	**1**
NCS	4	3	3	1	3	1	1	4	4	4	1	1
PICU and Interdependent Services	1	2	1	2	1	2	3	1	2	1	2	2
Workforce	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Transition plans	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

"The NHS in England must continue to provide high quality:

- ***paediatric cardiothoracic transplantation services in two centres***
- ***ECMO services for children with severe respiratory failure in at least three centres***
- ***complex tracheal surgery in one centre"***

Transplantation

As part of the expert panel analysis of the proposed options for reconfiguration in the *Safe and Sustainable* Review, existing centres were asked to submit proposals for the three relevant nationally commissioned paediatric services.

For the cardiothoracic transplantation programme, the national caseload and geography supports a proposal for two centres in England as optimum. This proposal was supported by the Cardiothoracic Transplant Advisory Group (NHS Blood and Transplant) in its response to consultation[1]. The expert panel also advised that while transplant services could be re-located if necessary, the optimum arrangement would be to leave them in their current locations if possible, because the panel suggested that it would be considerably more complex to move transplant services than ECMO. This also reflects the advice of the *Safe and Sustainable* steering group[2].

Of the four centres who submitted proposals, the expert panel advised that only Birmingham Children's Hospital demonstrated a sufficient ability to assume paediatric cardiothoracic transplant services and 'bridge to transplant' services if required.

However, as an outcome of further analysis undertaken during consultation with management and clinical staff at Birmingham Children's Hospital NHS Foundation Trust the Chief Executive of BCH has concluded that, while such a proposal would be feasible, there would be significant potential risks in re-locating a transplant service to BCH based on capacity, recruitment, training and timescales. In its formal response to consultation, Birmingham Children's Hospital stated a preference for Option B, which would retain transplant services in Newcastle.

[1] CTAG also recommended that Great Ormond Street Hospital be retained as a transplant centre, and that the second centre in England should be co-located with an adult cardiothoracic transplant programme.

[2] Appendix DD

In April 2012 the Advisory Group for National Specialised Services advised the JCPCT as follows:

> *"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 paper has set out for members of the JCPCT the significant risks which, in the opinion of AGNSS members, present with a proposal to re-locate the paediatric cardiothoracic transplant service from Newcastle upon Tyne Hospitals NHS Foundation Trust. BCH found it could not guarantee that it would be able to address the complex risks in accordance with the advice of the expert panel and Safe and Sustainable steering group, and to its usual high standard of quality and safety within the timeframes set out by the JCPCT. From an AGNSS perspective the delay of three years by BCH to establish the service would present significant challenges and risks to being able to maintain the existing service at Newcastle in the interim".*[3]

Extra-Corporeal Membrane Oxygenation

The Expert Panel concluded that, whilst three centres were reasonable, four centres might be optimum to ensure appropriate distribution of caseload. Long PICU stays for this service are a risk to potential providers and pose difficulties for parents.

While the retention of ECMO services in their current locations is optimal[4], the secretariat can offer reasonable assurance of a safe transfer of the national paediatric respiratory ECMO service to Birmingham Children's Hospital, if necessary, for the following reasons:

- BCH was considered by the Expert Panel to be able to provide paediatric respiratory ECMO services if it became necessary to re-locate this service
- In the winter of 2010/11, NSCT put in place plans to have additional paediatric respiratory ECMO capacity available in case of increased demand. The service at BCH was identified as a potential provider and underwent assessment against the national hospital surge standards. This included a visit by a review team that included clinicians from the current service provider at Leicester. BCH was judged as competent to deliver surge paediatric respiratory ECMO if required and staff at BCH have received training by the lead clinician at Leicester
- As part of winter planning for 2011/12, the NSCT has sought assurance from BCH that it could provide paediatric respiratory ECMO if required

The capacity review presented to the JCPCT gives reasonable confidence that the planned physical capacity at Birmingham Children's Hospital is sufficient for the safe transfer of the paediatric respiratory ECMO service and that there would be no adverse impact on access to services for the local population.

Some of the options presented to the JCPCT exclude two current providers of ECMO: Newcastle and Leicester. This would require Bristol to assume ECMO services in addition to BCH. Although assessed as potentially competent to deliver ECMO by the expert panel, the panel's confidence in Bristol was limited. Also, Bristol has not been scrutinised as much as Birmingham Children's Hospital by commissioners in this regard as it has not been assessed by NSC Team as a potential provider against national hospital surge standards.

[3] Full report available as Appendix LL

[4] The JCPCT is referred to the response to consultation by University of Leicester NHS Trust and other respondents for evidence submitted on the potential risks of moving an ECMO service

This position is supported by AGNSS members, who concluded in December 2011 that they can support *"the assurances of the NSCT that BCH, currently providing a 'surge' ECMO service, could safely develop as a full paediatric respiratory ECMO nationally designated service by 2013, following the planned expansion of its PICU capacity"*[5].

In summary, following assessments undertaken during the winter of 2010/11 (including 'surge' capacity planning during the H1N1 flu epidemic) and training developed and provided by the expert team at Leicester, the secretariat can provide reasonable assurance that paediatric respiratory ECMO could be transferred safely to Birmingham Children's Hospital if required. Further work would be needed to be undertaken to assess the readiness of Bristol.

Complex Tracheal Surgery

This is currently only provided at one surgical unit in England, at Great Ormond Street Hospital for Children. The expert panel did not have confidence in the ability of any other provider to provide this service.

For the purpose of consultation the JCPCT identified GOSH and Evelina Children's Hospital as the two preferred providers in London. At page 124 of this report, the JCPCT is invited to agree on Great Ormond Street Hospital and Evelina Children's Hospital as the two preferred providers in London for options which propose two centres in London, based on a consideration of the evidence submitted during consultation.

For this reason, the JCPCT is advised that the future location of complex tracheal surgery is not a material factor for the purpose of scoring the options against the 'deliverability' criterion at this stage of the process, as opposed to taking it into account when choosing which London centres to designate should only two be chosen.

When this analysis is applied to the shortlisted options it results in the following ranking of the options:

Opt A	Opt B	Opt C	Opt D	Opt E	Opt F	Opt G	Opt H	Opt I	Opt J	Opt K	Opt L
✓	✓	✓	✗	✓	✗	✗	✓	✓	✓	✗	✗

Key

✓ Options containing both Newcastle and Leicester
✓ Options containing Newcastle but not Leicester
✗ Options that contain Newcastle but not Leicester
✗ Options containing neither Newcastle nor Leicester

Therefore it is proposed that Options A, H, I and J receive a score of 4 in 'exceeding' the criterion, that options D, F and G K and L receive a score of 1 and that the remaining options a score of 3.

[5] Appendix DD

"The negative impact for the provision of paediatric intensive care and other interdependent services is kept to a minimum"

1 Impact on Paediatric Intensive Care Services

The JCPCT previously considered the impact on local and national provision of paediatric intensive care of removing cardiac work from each of the 11 paediatric intensive care units, taking account of both cardiac and other caseloads.

Percentage of cardiac activity (2009) into PICUs in current centres[6]	
Royal Brompton	**88%**
Freeman Hospital, Newcastle	**78%**
Glenfield Hospital, Leicester	**71%**
Birmingham Children's Hospital	**45%**
Evelina Children's Hospital	**43%**
Alder Hey Children's Hospital	**41%**
Great Ormond Street Hospital for Children	**40%**
Bristol Royal Hospital for Children	**40%**
Leeds Teaching Hospitals	**39%**
John Radcliffe Hospital, Oxford	**33%**
Southampton General Hospital	**29%**

[6] Based on analysis of PICANET reports (2007, 2008 and 2009) and analysis of PICU minimum data set

The table below shows the number of PICU admissions to each hospital[7] in 2009 *less* the number attributable to paediatric cardiac cases.

	Total 2009 admissions	2009 cardiac admissions	2009 non-cardiac admissions
Royal Brompton Hospital	451	398	53
Freeman Hospital	317	248	69
Glenfield Hospital	390	277	113
John Radcliffe	335	112	223
Bristol Royal Hospital for Children	738	293	445
Leeds TH	802	311	491
Southampton	740	214	526
Alder Hey	1103	453	650
Evelina Children's	1151	498	653
Birmingham Children's	1314	593	721
GOSH	1620	653	967

The method for scoring options was informed by discussions with the President of the Paediatric Intensive Care Society at the time.

The JCPCT was previously advised:

- Some PICUs would become unviable as a consequence of losing paediatric cardiac surgery (Leicester, Freeman and Brompton). However, as these PICUs exist predominately to support cardiac surgery (and because all three cities have existing alternative PICU provision for non-cardiac admissions) the JCPCT was advised that this presents limited risk to local and national PICU provision. The above table suggests that the number of non-cardiac admissions per year to these PICUs which would require admission elsewhere in regional or national PICU networks is relatively low, at 236 cases in total.
- All other PICUs in the other hospitals would remain '*viable*'. The John Radcliffe Hospital would continue to meet the critical mass necessary for a Level 2 PICU (200 to 350 admissions); Bristol and Leeds would sustain the critical mass necessary for a Level 3 PICU (350 to 500 admissions); the remaining centres would meet the critical mass for Lead PICU Centre (500+ admissions).

[7] Based on analysis of PICANET reports (2007, 2008 and 2009) and analysis of PICU minimum data set

In assessing the '*resilience*' of depleted PICUs the JCPCT was advised to take account of the degree of risk to local and national PICU provision were the resilience of the integrated PICUs to be diminished through loss of paediatric cardiac surgery. A reduction in overall PICU capacity may result in less flexibility in responding to historical winter pressures, for example. The JCPCT was advised to consider:

- The ability of smaller PICUs to maintain retrieval services, staffed by Consultant Intensivists, would also need to be considered, as would the implications of units designated to provide paediatric cardiac surgery having to retrieve children from larger geographical areas (manpower and retrieval time issues).
- The impact of a PICU's ability to continue to recruit and retain high-calibre staff over time; there may be a move of skilled staff to the larger PICU units over time and there may be a de-skilling of staff in smaller units that provide a reduced range of specialised children's services.
- Smaller PICUs may be less equipped to act as training units, with a particular impact on anaesthetic training. PICUs whose ventilated admissions fall below 350 admissions a year can only be recognised for a 1-year training programme as opposed to the 2-year programme.
- The need for assurance that hospitals that are designated to provide paediatric cardiac surgery are able to sufficiently increase PICU provision.

In re-assessing viable options the JCPCT is advised to consider the following evidence submitted during consultation:

Paediatric Intensive Care Society and Steering Group

The Paediatric Intensive Care Society advised the JCPCT that "*We would in general agree with the statements in the Consultation Document regarding the potential effects of closure of a cardiac surgical programme on remaining PICU activity and ability to deliver a PIC service*". Similar advice is provided by the steering group in its report to the JCPCT on the outcome of consultation[8] and the Pollitt report agreed that the PICU at the Royal Brompton Hospital would be rendered unviable in the absence of cardiac work[9].

The Paediatric Intensive Care Society also advised that the implications for training had not been adequately considered by the review particularly in respect to PIC training. The JCPCT was advised that the Consultation Document had mistakenly suggested that Southampton was not designated to deliver a two-year programme and that as such the potential implications for Southampton needed to be re-evaluated by the JCPCT, and that the training programme at Leeds (in partnership with Liverpool) would need to be re-evaluated to assess suitability to continue as a training centre in the absence of cardiac work.

Royal Brompton Hospital

Some respondents, most notably those with a relationship to the Royal Brompton Hospital (and including the Trust itself), suggested that the JCPCT's method of scoring against this sub-criterion was flawed in that options should be regarded as 'higher risk' if they exclude one of the three centres whose PICUs would be rendered unviable by the removal of paediatric cardiac surgical services. These comments were usually accompanied

[8] Report to the Joint Committee of PCTs by Dr Patricia Hamilton CBE, Chair of the Safe and Sustainable Steering Group, on behalf of Steering Group members, October 2011

[9] Report of the independent panel on the relationship of interdependencies at the Royal Brompton Hospital, September 2011

by views on the potential impact of an unviable PICU to other paediatric services at the Royal Brompton Hospital. The JCPCT is advised that as the method against this particular sub-criterion aims to establish the impact of removing paediatric cardiac surgery from a hospital to local and national PICU provision, the method is correct and reasonable for this purpose. The criticisms of the process referred to in this regard in truth relate to another aspect of the analysis, which is the potential impact of reconfiguration to other paediatric services (this analysis is addressed on page 167).

Glenfield Hospital

Glenfield Hospital submitted that the entire provision of PICU services in the city of Leicester could be rendered unviable in the absence of cardiac work at Glenfield Hospital[10]. This submission has been considered by the JCPCT.

The JCPCT is advised that the paper submitted by the Trust does not offer any compelling evidence that the PICU at the Leicester Royal Infirmary would be rendered unviable. The Paediatric Intensive Care Society has considered the Trust's paper and has advised the secretariat that the Leicester Royal Infirmary does not face unique challenges in responding to reduced PICU activity (Appendix KK). The figures put forward by Glenfield Hospital itself for the expected number of non-cardiac and non-ECMO admissions to the PICU at the Leicester Royal Infirmary (421 admissions a year) would meet the requirements for a Level-3 PICU.

In summary, having considered the relevant evidence submitted during consultation the JCPCT is advised to adopt a scoring method on the following principles:

- All PICUs would remain 'viable' in the absence of paediatric cardiac surgical services except for the three PICUs that primarily support cardiac surgery: Glenfield Hospital in Leicester, Freeman Hospital in Newcastle and the Royal Brompton Hospital in London.
- The loss of these three PICUs to the national network would be 'low risk' in the event of these centres not being designated for cardiac surgery as they support low numbers of non-cardiac patients
- Although the remaining PICUs would remain 'viable' in the absence of paediatric cardiac surgical services professional associations have agreed with the JCPCT's analysis of potential risks, and as such there will be a need for NHS commissioners to address issues of resilience during the implementation phase
- Based on an analysis of patient-volumes and current arrangements for training of PICU staff there would be a potential relative greater impact to the PICUs at Bristol, Southampton and Leeds than the other centres in the event that paediatric cardiac surgical services were removed from these hospitals.

[10] Appendix FF

Impact on services that have a relationship with paediatric cardiac surgery

This sub-criterion requires the JCPCT to assess the impact to relevant interdependent services within local health economies in the event of de-designation of a current provider of paediatric cardiac surgery.

The *Critical Interdependencies Framework*[11] identifies four clinical services (other than paediatric cardiology) that have a relationship with paediatric cardiac surgery:

Oncology (Amber 1 relationship)

Major trauma (Amber 2 relationship)

ENT Airway (Amber 2 relationship)

Specialised Paediatric Surgery (Amber 1 relationship)

An Amber relationship is defined as a '*relationship under some circumstances, requiring varying levels of access and contact between specialists, but not necessarily co-location*'

Amber 1 is defined as '*a planned intervention in a timescale as required*'

Amber 2 is defined as '*visit by consultant or transfer of care by the next working day*'

As the *Critical Interdependencies Framework* does not consider paediatric cardiac surgery to be a core service upon which any of the four services is reliant, the JCPCT was previously advised that the removal of paediatric cardiac surgery does not threaten the viability of any of the four services that may also be provided by the hospital in question. This advice was based on consideration of detailed descriptions from each of the current 11 centres on existing protocols with other NHS Trusts in their catchment areas that provide one or more of the four services.

There is no evidence submitted during consultation that causes the secretariat to change its advice in this regard and as such the JCPCT is advised that this sub-criterion has no material bearing on the scoring[12].

Evidence submitted by respondents on the impact to paediatric respiratory services (which is not identified as an 'interdependent service' by the Interdependencies Framework) at the Royal Brompton Hospital is set out in detail at chapter 13.

[11] Department of Health, '*Commissioning safe and sustainable specialised paediatric services: a framework of critical inter-dependencies*', September 2008

[12] Southampton University Hospitals NHS Foundation Trust suggested that a 'downgrading of paediatric intensive care services' would 'impact' upon the hospital's designated status as a trauma centre (page 32 of the hospital's response to consultation) but no evidence was submitted that the viability of the trauma centre would be at risk.

Conclusions on PICU and interdependent services

When this analysis is applied to the shortlisted options it results in the following ranking of options:

Opt A	Opt B	Opt C	Opt D	Opt E	Opt F	Opt G	Opt H	Opt I	Opt J	Opt K	Opt L
✗	✓	✗	✓	✗	✓	✓	✗	✓	✗	✓	✓

Key

✓ Options containing Bristol, Leeds and Southampton

✓ Options containing both Bristol and Southampton but not Leeds. Or Bristol and Leeds but not Southampton

✗ Options containing Bristol but not Southampton or Leeds or Southampton but not Bristol or Leeds

Therefore the JCPCT is advised that Option G receives a score of 3, Options A, C, E, H and J receive a score of 1 and all other Options a score of 2.

"The negative impact to the NHS workforce is kept to a minimum"

Some respondents have suggested during consultation that potential impacts on the NHS workforce must be identified and assessed by the JCPCT as part of the process for agreeing a final configuration option. However, the Steering Group has advised the JCPCT that the potential impact of reconfiguration on the workforce cannot be determined with confidence before the JCPCT has made a final decision and, as such, should not be a consideration in the JCPCT's process for agreeing a final decision .

Thus, the JCPCT is advised that this is an issue for implementation and should not form part of the current scoring process.

Sensitivity A:

Increasing the weighting for 'co-location' of core paediatric services

Sensitivity A responds to evidence submitted during consultation that the JCPCT had taken insufficient account of the co-location of paediatric services that are considered to be interdependent with paediatric cardiac surgical services (ENT Airways, paediatric surgery, paediatric critical care and paediatric anaesthesia). In particular, these comments were made by numerous respondents who supported the retention of surgery at Leeds Teaching Hospital NHS Trust.

> "Given the significant benefits to the patient and their families of genuinely co-locating relevant services, we believe genuine co-location should receive greater recognition and weighting when determining future service provision".
>
> **Yorkshire and Humber Joint Health Overview Scrutiny Committee,** response to consultation

In August 2011 the JCPCT asked Professor Sir Ian Kennedy's panel to respond to suggestions that the panel had incorrectly applied the definition of 'co-location' as set out in the *Framework* and asked the panel to clarify the extent to which the three surgical centres met the definition of co-location.

Having considered relevant evidence the panel advised the JCPCT in October 2011 that it was content that it had correctly applied the term 'co-location' as it appears in the Framework. The panel reminded the JCPCT that it had previously advised that the co-location of services on a single site was optimal (and that the extent to which the gold standard was met was reflected in each centre's score as awarded by the panel), and further advised:

> *'In response to the representations made to the JCPCT during consultation to the effect that the intention of the Framework was to define 'co-location' as meaning 'immediately adjacent' (or such equivalent) the panel members note that the Framework does not state this either explicitly nor sufficiently through the context and by implication. In the panel's opinion the use of the words 'neighbouring' and 'within the same parameters' and references to 'job plans and on-call rotas' invites a subjective consideration of the meaning of 'co-location' that encourages an interpretation not limited to that which is 'immediately adjacent'.*

The panel advised that the services at the Freeman Hospital and the Royal Brompton Hospital met the requirements of co-location as they are '*sufficiently close to the paediatric cardiac surgical services to fall 'within the same parameters' required by the critical interdependencies framework*'.

The panel advised that the service at Glenfield Hospital did not meet the standards in this respect.

In recognition that the 'gold standard' is the co-location of services on a single site the secretariat has tested the implications of increasing the weighting attached to the criterion of 'co-location' of services within the process of assessment by Sir Ian Kennedy's panel so that it becomes the joint highest weighted criterion.

Criterion	Original	Revised	Variance
Staffing and activity	130	130	0
Leadership and Strategic Vision	120	102	-18
Strength of Network	70	60	-10
Interdependent Services	**70**	**130**	60
Facilities and Capacity	70	60	-10
Excellent Care	60	51	-9
Age Appropriate Care	45	38	-7
Information and Choice	45	38	-7

The JCPCT is advised that the outcome of an application of the re-weighted scores is that there would be only limited movement within the panel's ranking of centres. This is because the less optimal elements of the Leeds service – as perceived by the Kennedy panel – remain significant such that even a much higher weighting to the element of 'co-location' (Interdependent Services) does not move it above the Newcastle service, even though Newcastle does not meet the 'gold standard' of co-location of relevant services on the same site.

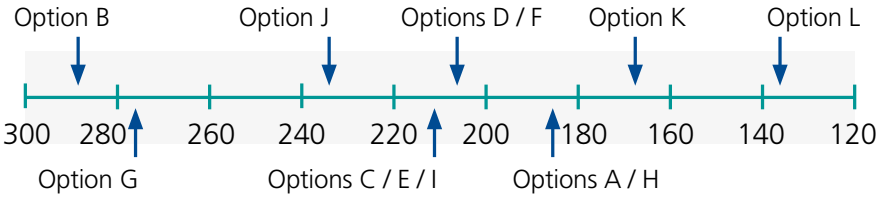
This movement would not alter the centres that appear in a viable option with the highest scoring centres. Therefore Option B would retain the seven centres that were scored highest by the panel and would retain its high score overall.

Movement of centres in Kennedy ranking						
Original Scores			Re-weighted Scores			Var
1	Evelina	535	1	Evelina	541	+6
2	Southampton	513	2	Southampton	513	0
3	Birmingham Children's	495	3	Birmingham Children's	507	+12
4=	Great Ormond Street	464	4	Great Ormond Street	478	+14
4=	Royal Brompton	464	5	Royal Brompton	468	+4
6	UH Bristol	449	6	UH Bristol	453	+4
7	Freeman, Newcastle	425	7	Alder Hey, Liverpool	430	+10
8	Alder Hey, Liverpool	420	8	Freeman, Newcastle	421	-4
9	Glenfield, Leicester	402	9	Leeds	414	+13
10	Leeds	401	10	Glenfield, Leicester	382	-20
11	John Radcliffe	237	11	John Radcliffe	237	0

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Total score for Quality	**1**	**3**	**2**	**2**	**2**	**2**	**3**	**1**	**2**	**2**	**1**	**1**
High quality service	1	3	2	2	2	2	3	1	2	2	1	1
Innovation and Research	2	3	2	2	2	2	3	2	3	2	2	2
Clinical Networks	2	2	2	3	2	3	3	2	1	2	3	3

Absolute Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	2	2	1	2	1	2	3	2	3	1	2	2
Total Score for Quality	1	3	2	2	2	2	3	1	2	2	1	1
Total Score for Deliverability	3	3	2	1	2	1	2	3	3	3	1	1
Total Score for Sustainability	2	3	3	3	3	3	3	2	1	3	3	2

Weighted Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	28	28	14	28	14	28	42	28	42	14	28	28
Total Score for Quality	39	117	78	78	78	78	117	39	78	78	39	39
Total Score for Deliverability	66	66	44	22	44	22	44	66	66	66	22	22
Total Score for Sustainability	50	75	75	75	75	75	75	50	25	75	75	50
Total Score	**183**	**286**	**211**	**203**	**211**	**203**	**278**	**183**	**211**	**233**	**164**	**139**



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Sensitivity B:

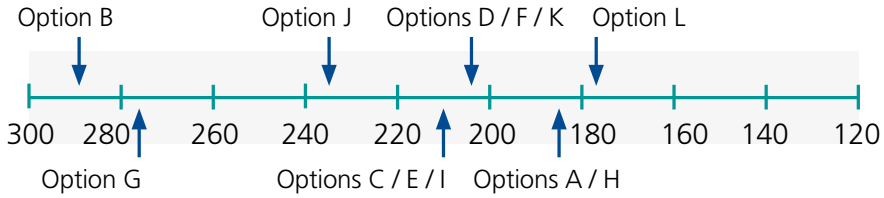
Equal weighting of 'Quality' sub-criteria

Sensitivity B assumes that the sub criteria for quality are weighted equally. The impact that this has on the scores is shown below:

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Total score for Quality	**1**	**3**	**2**	**2**	**2**	**2**	**3**	**1**	**2**	**2**	**2**	**2**
High quality service	1	3	2	1	2	1	2	1	2	2	1	1
Innovation and Research	2	3	2	2	2	2	3	2	3	2	2	2
Clinical Networks	2	2	2	3	2	3	3	2	2	2	3	3

Absolute Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	2	2	1	2	1	2	3	2	3	1	2	2
Total Score for Quality	1	3	2	2	2	2	3	1	2	2	2	2
Total Score for Deliverability	3	3	2	1	2	1	2	3	3	3	1	1
Total Score for Sustainability	2	3	3	3	3	3	3	2	1	3	3	2

Weighted Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	28	28	14	28	14	28	42	28	42	14	28	28
Total Score for Quality	39	117	78	78	78	78	117	39	78	78	78	78
Total Score for Deliverability	66	66	44	22	44	22	44	66	66	66	22	22
Total Score for Sustainability	50	75	75	75	75	75	75	50	25	75	75	50
Total Score	**183**	**286**	**211**	**203**	**211**	**203**	**278**	**183**	**211**	**233**	**203**	**178**



Under this scenario Option B remains the highest scoring option but option G receives a higher score. Options L remains the lowest scoring option.

Sensitivity C:

Assume that there are significant risks to the manageability of the Newcastle network *and* that the Quality sub-criteria are equally weighted.

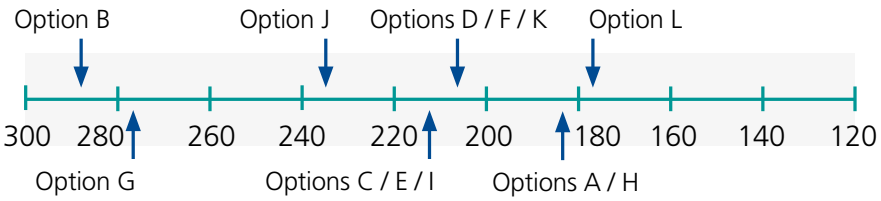
If we assume that there are significant risks to the manageability of Newcastle's network, the JCPCT may decide to reduce the score for 'manageability of clinical networks' further. The JCPCT is advised that this will only make a difference to the overall scoring of the options if the sub-criteria of quality are equally weighted.

The impact of this is shown below:

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Total score for Quality	**1**	**3**	**2**	**2**	**2**	**2**	**3**	**1**	**2**	**2**	**2**	**2**
High quality service	1	3	2	1	2	1	2	1	2	2	1	1
Innovation and Research	2	3	2	2	2	2	3	2	3	2	2	2
Clinical Networks	1	1	1	3	1	3	3	1	1	1	3	3

Absolute Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	2	2	1	2	1	2	3	2	3	1	2	2
Total Score for Quality	1	3	2	2	2	2	3	1	2	2	2	2
Total Score for Deliverability	3	3	2	1	2	1	2	3	3	3	1	1
Total Score for Sustainability	2	3	3	3	3	3	3	2	1	3	3	2

Weighted Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	28	28	14	28	14	28	42	28	42	14	28	28
Total Score for Quality	39	117	78	78	78	78	117	39	78	78	78	78
Total Score for Deliverability	66	66	44	22	44	22	44	66	66	66	22	22
Total Score for Sustainability	50	75	75	75	75	75	75	50	25	75	75	50
Total Score	**183**	**286**	**211**	**203**	**211**	**203**	**278**	**183**	**211**	**233**	**203**	**178**



Option B remains the highest scoring option

V

Sensitivity D:

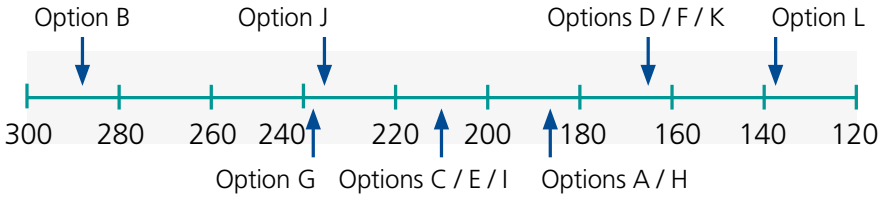
Weighting nationally commissioned services more highly within 'Deliverability'

In reaching a total score for deliverability the JCPCT weighted the sub-criteria for deliverability equally. If the JCPCT were to weight NCS more heavily regarding it as a more material issue, this would have altered the score for deliverability for options G and H. The impact of these changes are shown below:

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Total score for Deliverability	**3**	**2**	**2**	**1**	**2**	**1**	**1**	**3**	**3**	**3**	**1**	**1**
NCS	4	3	3	1	3	1	1	4	4	4	1	1
PICU and Interdependent Services	1	2	1	2	1	2	3	1	2	1	2	2
Workforce	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Transition plans	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Absolute Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	2	2	1	2	1	2	3	2	3	1	2	2
Total Score for Quality	1	3	2	1	2	1	2	1	2	2	1	1
Total Score for Deliverability	3	2	2	1	2	1	1	3	3	3	1	1
Total Score for Sustainability	2	3	3	3	3	3	3	2	1	3	3	2

Weighted Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	28	28	14	28	14	28	42	28	42	14	28	28
Total Score for Quality	39	117	78	39	78	39	78	39	78	78	39	39
Total Score for Deliverability	66	66	44	22	44	22	44	66	66	66	22	22
Total Score for Sustainability	50	75	75	75	75	75	75	50	25	75	75	50
Total Score	**183**	**286**	**211**	**164**	**211**	**164**	**239**	**183**	**211**	**233**	**164**	**139**



This indicates that there is no change to the highest or lowest scored option.

Sensitivity E:

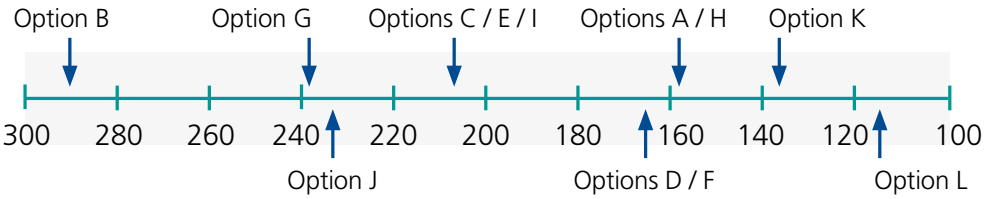
Assuming that only the number of centres undertaking 500+ procedures per year is used to score sustainability

In reaching a total score for sustainability the number of centres undertaking 400-499 procedures per year and the number of centres undertaking 500+ procedures are equally as important. This sensitivity assumes that the greater the number of centres undertaking 500+ procedures the better the option. The impact of this is shown below:

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Number of centres undertaking fewer than 400 procedures	0	0	0	0	0	0	0	0	1	0	0	0
Number of centres undertaking 400-499 procedures	5	3	2	2	3	3	3	6	5	3	4	7
Number of centres undertaking 500+ procedures	2	4	4	4	4	4	4	2	2	4	3	1

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Total score for Sustainability	**1**	**3**	**3**	**3**	**3**	**3**	**3**	**1**	**1**	**3**	**2**	**1**
Perform a minimum of 400 procedures per year	1	3	3	3	3	3	3	1	1	3	2	1
Too onerous a caseload	3	3	3	3	3	3	3	3	3	3	3	3
Recruit and retain newly qualified surgeons	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Weighted Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	28	28	14	28	14	28	42	28	42	14	28	28
Total Score for Quality	39	117	78	39	78	39	78	39	78	78	39	39
Total Score for Deliverability	66	66	44	22	44	22	44	66	66	66	22	22
Total Score for Sustainability	25	75	75	75	75	75	75	25	25	75	50	25
Total Scores	**158**	**286**	**211**	**164**	**211**	**164**	**239**	**158**	**211**	**233**	**139**	**114**



This indicates that there is no change to the highest or lowest scoring option.

V

Sensitivity F:

Assuming that 75% of the patients from the Sheffield, Doncaster, Leeds and Wakefield postcodes travel to Newcastle

In response to respondents who have questioned the viability of the proposed Newcastle networks (particularly respondents who support the retention of surgery at Leeds Teaching Hospital NHS Trust), this sensitivity assumes that 75% of the patients in the Sheffield, Doncaster, Leeds and Wakefield postcode areas are included in the Birmingham Network and not Newcastle. The impact that this has on the scores for sustainability is shown below:

	Forecast Activity using 2010/11 Activity Levels											
Options >	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**
London	1538	1252	1578	1578	1578	1578	1252	1536	1212	1354	1394	1394
Southampton		410					410		410	502		
Birmingham	414	611	653	589	653	589	547	414	398	567	414	414
Bristol	470	439	470	470	470	470	439	470	412		470	470
Newcastle	372	403	403		403			372	372	372		
Liverpool	479	635	635	420	635	420	420	479	479	479	420	420
Leicester	406							406	406	407	425	425
Leeds				683		683	683				618	618

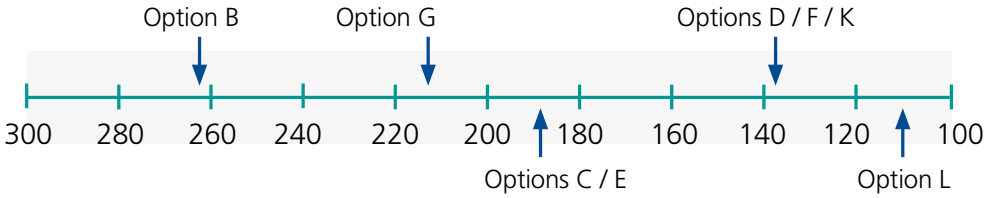
Option >	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**
Number of centres undertaking fewer than 400 procedures	1	0	0	0	0	0	0	1	1	1	0	
Number of centres undertaking 400-499 procedures	4	3	2	2	3	3	3	5	5	2	4	7
Number of centres undertaking 500+ procedures	2	4	4	4	4	4	4	2	2	4	3	1

Option >	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**
Total score for Sustainability	–	2	2	2	2	2	2	–	–	–	2	1
Perform a minimum of 400 procedures per year	–	2	2	2	2	2	2	–	–	–	2	1
Too onerous a caseload	3	3	3	3	3	3	3	3	3	3	3	3

Sensitivity F (continued):

Absolute Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	2	2	1	2	1	2	3	2	3	1	2	2
Total Score for Quality	1	3	2	1	2	1	2	1	2	2	1	1
Total Score for Deliverability	3	3	2	1	2	1	2	3	3	3	1	1
Total Score for Sustainability	–	2	2	2	2	2	2	–	–	–	2	1

Weighted Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	28	28	14	28	14	28	42	28	42	14	28	28
Total Score for Quality	39	117	78	39	78	39	78	39	78	78	39	39
Total Score for Deliverability	66	66	44	22	44	22	44	66	66	66	22	22
Total Score for Sustainability	–	50	50	50	50	50	50	–	–	–	50	25
Total Score	–	**261**	**186**	**139**	**186**	**139**	**214**	–	–	–	**139**	**114**



This indicates that there is no change to the highest or lowest scoring option.

V

Sensitivity G:

Using different time brackets for assessing elective travel and access

This sensitivity tests the impact of assessing the number of patients with increases in travel times of up to 30 minutes and over 30 minutes. This makes no material difference to the scoring as the ratio of patients travelling up to 30 minutes and over 30 minutes is close to that of patients travelling up to 60 minutes and over 60 minutes.

Option >	A / H	B	C / E	D / F	G	I	J	K / L
Up to 1 hour	3,401	3,462	3,264	3,356	3,523	3,569	3,312	3,364
Over 1 hour	340	279	477	385	218	172	429	377

Option >	A / H	B	C / E	D / F	G	I	J	K / L
Up to 30 minutes	3,246	3,190	3,106	3,207	3,290	3,335	3,055	3,232
Over 30 minutes	495	551	635	533	451	406	686	509

Sensitivity H:

Using different time brackets for assessing elective travel and access

This sensitivity tests the impact of assessing the number of patients with increases in travel times of up to 90 minutes and over 90 minutes. The impact that this has on the scores for travel and access is shown below:

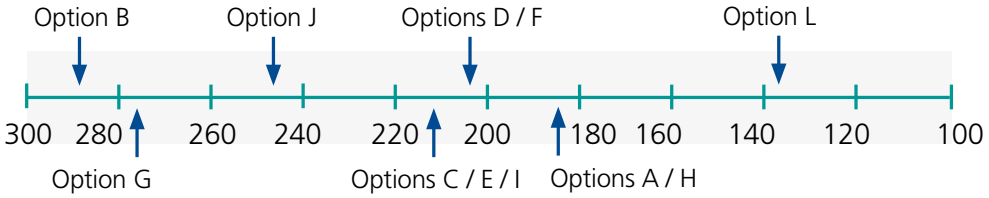
Option >	A / H	B	C / E	D / F	G	I	J	K / L
Up to 90 minutes	3,595	3,503	3,468	3,591	3,626	3,631	3,578	3,591
Over 90 minutes	146	238	273	150	115	110	163	150

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Total score for Travel and Access	**2**	**2**	**1**	**2**	**1**	**2**	**3**	**2**	**3**	**2**	**2**	**2**
Travel times for elective admissions	2	1	1	2	1	2	3	2	3	2	2	2
Retrieval times	2	3	2	2	2	2	3	2	3	2	2	2

Sensitivity H (continued):

Absolute Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	2	2	1	2	1	2	3	2	3	2	2	2
Total Score for Quality	1	3	2	1	2	1	3	1	2	2	1	1
Total Score for Deliverability	3	3	2	1	2	1	2	3	3	3	1	1
Total Score for Sustainability	2	3	3	3	3	3	3	2	1	3	3	2

Weighted Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	28	28	14	28	14	28	42	28	42	28	28	28
Total Score for Quality	39	117	78	78	78	78	117	39	78	78	39	39
Total Score for Deliverability	66	66	44	22	44	22	44	66	66	66	22	22
Total Score for Sustainability	50	75	75	75	75	75	75	50	25	75	75	50
Total Score	**183**	**286**	**211**	**203**	**211**	**203**	**278**	**183**	**211**	**247**	**164**	**139**



Option B remains the highest scoring option

V

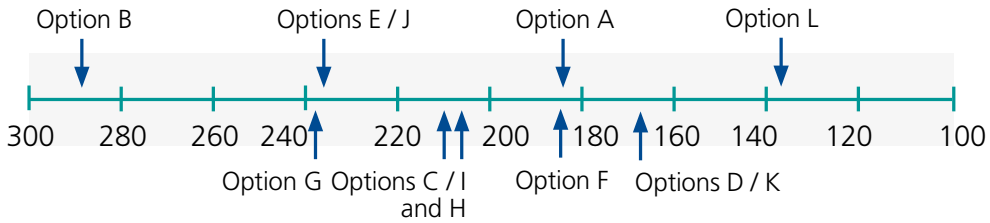
Sensitivity I:

This sensitivity test assumes that all three surgical units in London in options E, F and H achieve at least 500 surgical procedures per year. Increasing the score for these options against the sustainability criterion does not materially impact on the overall scoring. Option E becomes the third highest scored option overall, but options B and G remain the highest scored.

Option >	A	B	C	D	E	F	G	H	I	J	K	L
Number of centres undertaking fewer than 400 procedures	0	0	0	0	0	0	0	0	2	0	0	0
Number of centres undertaking 400-499 procedures	5	3	2	2	2	2	3	5	5	3	4	6
Number of centres undertaking 500+ procedures	2	4	4	4	5	5	4	3	1	4	3	2

Absolute Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total score for Travel and Access	2	2	1	2	1	2	3	2	3	1	2	2
Total score for Quality	1	3	2	1	2	1	2	1	2	2	1	1
Total score for Deliverability	3	3	2	1	2	1	2	3	3	3	1	1
Total score for Sustainability	2	3	3	3	4	4	3	3	1	3	3	2

Weighted Scores	A	B	C	D	E	F	G	H	I	J	K	L
Total Score for Travel and Access	28	28	14	28	14	28	42	28	42	14	28	28
Total Score for Quality	39	117	78	39	78	39	78	39	78	78	39	39
Total Score for Deliverability	66	66	44	22	44	22	44	66	66	66	22	22
Total Score for Sustainability	50	75	75	75	100	100	75	75	25	75	75	50
Total Score	**183**	**286**	**211**	**164**	**236**	**189**	**239**	**208**	**211**	**233**	**164**	**139**



Analysis of movement in scoring of option A

In the options presented for consultation option A was the highest scored option against the criteria for the evaluation of options, whereas in the current scoring process it is proposed that it scores relatively low. This section of the business case explains the movement in the proposed scoring.

To understand the movement in proposed scoring it must be appreciated that this is a relative scoring system, which means that the proposed score for each option partly depends on the relative strength and weaknesses of other options. This means that the proposed score for Option A against one of the criteria could change by virtue of the introduction of other new options, even if the conclusions about Option A's compliance with the criteria remain the same as before.

Table: Previous and current proposed scores for option A

Criteria	Absolute score in February 2011	Absolute score in July 2012	Weighted score in February 2011	Weighted score in July 2012	Difference in weighted score
Travel / Access	4	2	56	28	-28
Quality	3	1	117	39	-78
Deliverability	3	3	66	66	0
Sustainability	3	1	75	25	-50

Elective travel and access

Scoring Process Used in February 2011

- Option A received a 'green' for absolute travel times because it had the most patients with a journey time of up to one hour (1,958) and 1-2 hours (1,194)
- Option A also received a 'green' for measuring the increase in journey times because it had the most patients with an increase in journey time of less than 30 minutes (3,135) and the fewest patients with an increase in journey time of more than 90 minutes (126)
- Option A was therefore the deemed as the 'best' centre for elective travel admissions compared to the other viable options at the time.

Change to the scoring process

- The original method for scoring elective travel and access was deemed by some respondents as being inappropriate as it considered both absolute journey times and increases in journey times. Moreover the scoring method did not explicitly define what was 'good' or 'acceptable' in terms of increase in travel times and absolute journey times. Thus the JCPCT was asked to combine a number of different data points for each configuration option to arrive at a single score for elective travel and access. This involved an element of subjectivity in weighting the relative importance of different factors that was not acceptable to some respondents.
- Respondents to consultation also observed that the previous methodology did not effectively take into account travel times from Isle of Wight.

- By considering just the change in journey time this removes the subjectivity. It will also account for changes in journey time for patients from the Isle of Wight.

Revised Scoring

- Option A had 3,446 patients with an increase in journey time of up to 1 hour.
- This was not as good as option G (which is a new viable option) which had 3,522 patients and option C which had 3,308 patients with an increase in journey time of up to 1 hour.

Emergency retrieval

Scoring Process Used in February 2011

- Previously the Paediatric Intensive Care Society standards were applied as an absolute requirement. All options presented in February 2011 were deemed to comply with the PIC standards for retrieval so all options received a score of 4.

Change to the scoring process

- The JCPCT has been advised not to apply the PICS standards as an absolute requirement, and instead to score the 'extent to which' the options comply with the PICS standards. The reasons for this advice are set out on page x.

Revised Scoring

- The score for all options under this sub-criterion has been reduced from the maximum '4' to reflect the finding that in all options there is a reasonable lack of confidence that all parts of England can be reached within the 3 hours stipulated by the PICS standards.
- Option A does not include Southampton General Hospital, which means that in this option there is a reasonable lack of confidence that an emergency retrieval team from London or Bristol would be able to reach the Isle of Wight within the 3 hours stipulated by the PICS standards.
- It is therefore proposed that option A scores a '2' against this sub-criterion.

Overall score for travel and access

In view of the relative better compliance by other options against the two criteria, for which a maximum of '3' is proposed, the JCPCT is advised to apply a score of '2' to option A ("meets most elements of the criteria").

Quality

HIGH QUALITY SERVICES

Scoring Process Used in February 2011

- Option B included all of the highest scoring centres (with the exception of the Royal Brompton Hospital) and therefore received the highest score for high quality services (4)
- All other options received a score of 3 because they were within 95% of the total score of option B.

Change to the scoring process

- During public consultation there was a view that the scoring of 'high quality services' did not sufficiently differentiate between options that retained more centres that were scored high by the Kennedy panel and options that did not.
- It is proposed that greater differentiation can be introduced across the options by considering the number of centres that were in the top three high scoring centres and the number of centres that were in the bottom three low scoring centres from Sir Ian Kennedy's assessment visits,

Revised Scoring

- Option A includes only 2 of the highest scoring centres (Birmingham and Evelina) and two of the low scoring centres (Liverpool and Leicester)
- It is therefore proposed that option A receives a score of '1' for 'high quality services' because other options include either all of the top 3 high scoring centres or only 1 of the low scoring centres
- Option B includes all three high scoring centres and only 1 of the low scoring centres

RESEARCH AND INNOVATION

Scoring Process Used in February 2011

- The score was based on the total innovation scores for 'research and innovation' and the number of high scoring centres for 'research and innovation' included in each option
- Option A did not include all the high scoring centres for research and innovation and received a total score for research and innovation, which was 'in the middle of the pack'
- Only option B included all of the highest scoring centres and a high total score for research and innovation. Therefore option B received a score of '4' for research and innovation and all other options received a score of '3'.

Change to the scoring process

- The methodology for scoring research and innovation did not change; however the assessment panel were reconvened to re-score centres who chose to submit new evidence of compliance with the standards relating to 'research and innovation'. The scores for the John Radcliffe Hospital and the Royal Brompton Hospital were increased.

Revised Scoring

- The JCPCT is advised to apply a scoring scale of '2' or a '3' for research and innovation instead of '3' and '4' on the basis that no option could be said to 'exceed' the requirement in terms of compliance with the standards relating to innovation and research.
- It is proposed that option A receives a score of 2 on the basis that it met most elements of the criterion but did not retain all of the highest scoring centres for research and innovation, as other options did (and so which score a '3').

MANAGEABLE CLINICAL NETWORKS

Scoring Process Used in February 2011

- All options, with the exception of option B, were deemed to have manageable clinical networks. Therefore all options except option B received the highest score of 4 for manageable clinical networks.

Change to the scoring process

- On the basis of consultation responses and the travel analysis undertaken by PwC, the JCPCT is advised that options that include the Freeman Hospital presents a greater risk to the manageability of the network than options that do not because of forecast patient flows in the north of the country.

Revised Scoring

- Option A includes the Freeman Hospital and it is therefore proposed that it receives a score of '2' compared with options that do not include the Freeman Hospital, which it is proposed receive a score of '3'.

OVERALL SCORE FOR QUALITY

Scoring Process Used in February 2011

- Option B received a score of '4' for the sub-criteria of 'high quality services' and 'research and innovation' whilst other options received a score of 4 for 'clinical networks' only. Therefore option B received an overall score for quality of '4' whilst the other options received an overall score of '3'.

Change to the scoring process

- **Evidence submitted during consultation indicated that the ability to deliver a high quality service should be paramount. The JCPCT is advised to base the overall score for 'quality' on the outcomes of Professor Kennedy's assessment panel.**

Revised Scoring

- Option A received a score of 1 for 'high quality services and it is therefore proposed that it receives a total score of '1' for 'quality'.

Deliverability

NATIONALLY COMMISSIONED SERVICES

Scoring Process Used in February 2011

- Option A includes Great Ormond Street Hospital, Freeman Hospital and Leicester and therefore no nationally commissioned services would require relocation.
- Therefore option A received the highest score of '4' against this sub-criterion.

Change to the scoring process

- There is no proposed change to the scoring process.

Revised Scoring

- There is no proposed change to the score against this sub-criterion. It is proposed that option A retains a score of '4'.

PICU AND INTERDEPENDENT SERVICES

Scoring Process Used in February 2011

- The JCPCT proposed for consultation that all PICUs would remain 'viable' save for the three PICUs that primarily support cardiac surgery: Leicester, Newcastle and Royal Brompton.
- The JCPCT also proposed for consultation that the loss of these three PICUs to the national network is 'low risk' in the event of these centres not being designated for paediatric cardiac surgery given the low incidence of non-cardiac cases.
- Although the remaining PICUs remain 'viable' there are potential risks around 'destabilisation' on which the JCPCT must take a view. The JCPCT proposed that Bristol, followed by Leeds and then Southampton are most at risk of destabilisation.
- Option A contains only Bristol from the PICUs that are at risk of destabilisation so receives a score of '1' for PICU and interdependent services.

Change to the scoring process

- There is no proposed change to the scoring process.

Revised Scoring

- There is no proposed change to the score. It is proposed that option A retains a score of '1' for PICU and interdependent services.

OVERALL SCORE FOR DELIVERABILITY

Scoring Process Used in February 2011

- Compliance with the criterion relating to nationally commissioned services was deemed by the JCPCT as being marginally more significant than compliance with the criterion relating to PICU and Interdependent services.
- Option A received a score of 4 for nationally commissioned services; however it received a lower score of 1 for PICU and interdependent services.
- The JCPCT therefore concluded that option A could not receive the maximum score of '4' and applied an overall score of '3' against this criterion.

Change to the scoring process

- It is proposed that the criteria relating to nationally commissioned services and PICU and interdependent services are given equal weighting. Therefore it is proposed that the total score against this criterion is based on the combined score for nationally commissioned services and PICU and interdependent services.

Revised Scoring

- It is proposed that option A receives a score of '3' for deliverability because the total combined score for nationally Commissioned Services and PICU and interdependent services is relatively high at '5'.
- It is proposed that no option scores the maximum '4' as no option can reasonably be regarded as 'exceeding' the criterion relating to deliverability.
- It is therefore proposed that option A scores a '3' against this criterion.

Sustainability

All centres are likely to perform at least 400 paediatric procedures, ideally at least 500 paediatric procedures

Scoring Process Used in February 2011

- All centres were deemed to be capable of attaining the minimum 400 procedure threshold save for Bristol and Southampton in option B.
- All options were therefore scored a '3' except option B which scored a '1'.

Change to the scoring process

- During public consultation some respondents suggested that the JCPCT's scoring method did not sufficiently differentiate between options where centres were more likely to exceed 500 procedures a year and options where centres were more likely to undertake 400-500 procedures a year . The analysis presented to the JCPCT therefore identifies the number of centres that would be undertaking 400-499 procedures and the number of centres that would be undertaking 500+ procedures in each option; the more centres undertaking 500+, the higher the proposed score for the option under the 'sustainability' criterion.

Revised scoring

- It is proposed that all centres in all options (including option B) are able to meet the 400 minimum threshold. However in options A, H and I only two centres are forecast to meet the optimal minimal threshold of 500 procedures per year.
- It is therefore proposed that options A, H and I receive a score of '1' indicating that they meet some but not all elements of the criteria. All other options have 5 centres that are able to meet the optimal minimal threshold of 500 procedures per year so it is proposed that they receive a score of '2', indicating that they meet most of the criterion.

NO CENTRES UNDERTAKE TOO ONEROUS A CASELOAD

Scoring Process Used in February 2011

- Based on information gathered during the assessment visits and the centres' written submissions the JCPCT took a view on the maximum potential capacity at each centre
- Scores were predicated on the number of centres that were reasonably likely to exceed their maximum caseload
- Option A received a score of '3'. The maximum score of '4' was not applied due to the high forecast caseloads in London.

Change to the scoring process

- During consultation the JCPCT has received further intelligence about the maximum capacity at each centre.
- The JCPCT is advised that under no option is any centre forecast to breach its maximum capacity level.

Revised Scoring

- It is proposed that all options receive a score of '3' against this sub-criterion.

OVERALL SCORE FOR SUSTAINABILITY

Scoring Process Used in February 2011

- The two sub-criteria were equally weighted as being of equal importance.
- The total score for the two sub-criteria was used to identify an overall score for sustainability relative to other options at the time.
- Option A therefore scored relatively high compared to other options.

Change to the scoring process

- Under the new scoring methodology the only sub-criterion that shows any variation for sustainability is the centres ability to perform a minimum caseload of 400 procedures per year, ideally a minimum of 500 procedures.
- It is therefore proposed that each option's relative score for performing a minimum of 400 procedures per year ideally 500 is applied to the total score for 'sustainability'.

Revised Scoring

- It is proposed that option A is scored relatively low against this sub-criterion as only two centres are forecast to exceed the 500 threshold. It is therefore proposed that the total score against 'sustainability' for option A is '1'.

Future Activity Projections

The *Safe and Sustainable* review needs to ensure that the future configuration of congenital cardiac services has sufficient capacity for current and projected activity levels.

The *Safe and Sustainable* review has assumed a current national caseload for the English surgical centres as 3,600 operations on children per year. This figure is the result of a validation exercise undertaken by CCAD[1] with the surgical centres in July 2010. This includes children seen in English surgical units who live in Wales, Scotland, Northern Ireland, Channel Islands and Isle of Man.

The 2009/10 data has been independently validated and is shown below. The 2009/10 data (representing 1 April 2009 to 31 March 2010) has been used to underpin most of the analysis given it is the most up to date validated data available and in view of concerns (recognised by CCAD) about the reliability of more historical data on the CCAD database. The projected activity levels for each centre in the various potential options are shown in Appendix AG.

The figure excludes 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. The figure includes UK private patients as it is feasible that these patients may in the future choose to have their treatment funded by the NHS.

Centres	2009/10
Liverpool	**400**
Birmingham	**555**
Bristol	**277**
Newcastle	**255**
GOSH	**541**
Leicester	**225**
Evelina	**337**
Leeds	**316**
Royal Brompton	**353**
Oxford	**108**
Southampton	**231**
Total	**3,598**

CCAD and the professional associations advise that the incidence of CHD in children over recent years has been steady, though there has been a gradual increase in the number of adults with CHD due to better diagnosis and treatment of children. Other countries also report these findings)[2].

In proposing, for planning purposes, an assumption of limited growth consistent with the projected birth rate for England and Wales, the review has considered a number of factors that may individually contribute towards an increase or decrease in future need.

Factors that may suggest an increase in future need:

Projected growth in the birth rate – population projections by UK National Statistics[3] 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.

[1] 2009/10 CCAD validated data, surgical procedures only

[2] Commission for Paediatric Heart Interventions, *Concentration of congenital heart surgery and catheter interventions*, June 2009. Document translated from Dutch by Ubiqus, London

[3] UK National Statistics website. Available at: www.statistics.gov.uk/hub/index.html

More timely and accurate antenatal diagnosis – improved screening practices that increase the incidence of diagnosis of CHD before birth may result in a higher need for paediatric cardiac surgery (and because there is an association between antenatal diagnosis and better outcomes). However, we cannot make any firm projection based on this factor as many babies who are currently not diagnosed in the womb are subsequently diagnosed with CHD after birth and receive surgery.

Improved neonatal care – improved neonatal rescue including advanced techniques in neonatal intensive care may suggest an increased need for paediatric cardiac surgery, but difficult to quantify at this time.

Population growth for specific populations – the review has considered the future need of areas with high Black and Ethnic Minority groups in response to evidence that the projected birth rate may be higher for some ethnic community groups[4]. It has also been suggested that there may be a higher incidence of congenital heart defects in the offspring of consanguineous couples. The population data that has been applied by the review has been sourced from a specialist geographic information solutions third-party. It is taken from Census data which is updated typically twice per year in line with 'Postcode Release' updates. The original Census counts are from the 2001 Census but counts are projected based on shifts in delivery counts from the most up to date postcode release at the time. Therefore, account has been taken of the growth up to 2010 at locality level. Future growth has not been projected at postcode level, but nationally. It has been proposed that for planning purposes, at this stage in the process this level of detail is not required given that the relatively low incidence of total activity nationally suggests that it is reasonable to assume that any higher rates of incidence in specific areas can be managed within planned capacity assumptions.

Factors that may suggest a decrease in future need:

More timely and accurate antenatal diagnosis – this may increase the number of terminated births in the future, but is difficult to quantify.

More sophisticated cardiology interventions – as interventional cardiology procedures become more sophisticated they are replacing surgery as the preferred intervention for some congenital heart conditions.

Better quality surgical services – the professional associations advise that one of the potential benefits of a higher quality service in the future (achieved through the establishment of fewer, larger surgical centres and the development of managed paediatric cardiology networks) is a reduced incidence of 're-operations' following the primary surgical procedure.

New technology and drugs – medical advances in such areas as gene therapy and the introduction of new drugs may also reduce the need and frequency of some operations.

The review has taken into account population distribution and means that no area or population should be unduly disadvantaged by reducing the number of surgical centres. However, the Health Impact Assessment will provide a thorough means of assessing the impact of options for consultation on specific minority groups.

[4] Sadiq M, Stümper O, Wright JG, De Giovanni JV, *et al*. (1995). Influence of ethnic origin on the pattern of congenital heart defects in the first year of life. British Heart Journal; 73(2): 173–176

Below is a summary of the paper prepared by Dr Martin Ashton-Key, Medical Advisor to *Safe and Sustainable* on: "Congenital Cardiac Disease Review – An Overview of Surgical Activity (2006/07) and projections to 2025 based on National Statistics Population Projections".

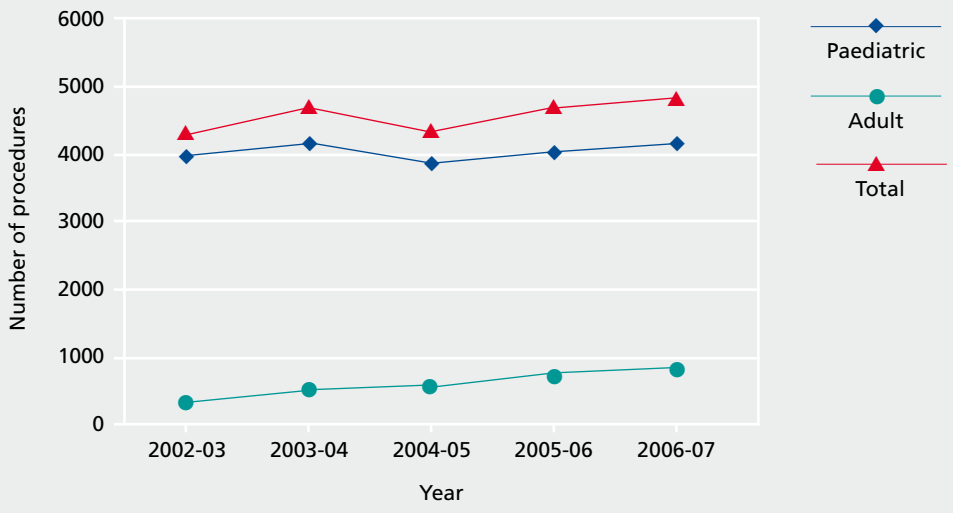
Source of data

The analysis was conducted on the 2006/07 validated CCAD[5] data which was the latest available validated data at the time of the analysis (August 2009).

Aggregated Surgical Activity Trends 2002 – 2007

Aggregated activity for paediatric and adult surgical cases was extracted from CCAD for each year from 2002/03 to the last available data (2006/07) and shows the relatively stable paediatric workload but highlights the slow and continuous rise in adult surgical cases.

Figure 1: Aggregated annual number of procedures performed for congenital cardiac disease in the UK (CCAD data)



[5] Congenital Heart Disease website (or CCAD website). Available at: www.ccad.org.uk/congenital

Estimated future trends (2006 – 2025) in paediatric cardiac surgery based on National Statistics Population Projections

Population projections are produced by UK National Statistics[6]. The 2006-based National Population Projections present modelled annual populations in 5-year age bands from 2006 to 2031 for England, England and Wales, Scotland, Northern Ireland, Great Britain and the United Kingdom, with longer range predictions to 2081.

For the purpose of estimating possible future trends in paediatric cardiac surgical activity the following age ranges were used (0 – 4 years, 5 – 9 years and 10 – 14 years) to establish the projected changes in the paediatric population. The next age range (15 – 19 years) was not included because three of the five years included cover an adult population. Population projections beyond 2025 were not assessed.

These data revealed very small percentage changes in the paediatric population over the coming two to three years for each of the UK nations. However, the longer term projections from 2006 to 2025 suggest significant and variable percentage changes in the paediatric populations of the UK nations and are summarised in Table 1.

Percentage change in the paediatric population (by 5-year age band) between 2006 and 2025 for UK countr(y/ies) based on the National Statistics 2006-based National Population Projections

Age (Years)	England	England and Wales	Scotland	Northern Ireland	Great Britain	United Kingdom
0 – 4	16.0 %	15.6 %	-0.2 %	6.2 %	14.4 %	14.1 %
5 – 9	18.0 %	17.3 %	0.0 %	6.0 %	15.9 %	15.5 %
10 – 14	9.0 %	8.4 %	-7.0 %	-0.3 %	7.1 %	6.9 %
0 – 14	14.2 %	13.7 %	-2.6 %	3.9 %	12.3 %	12.0 %

Assuming the epidemiology of congenital cardiac disease at an individual level does not change over the coming years and assuming the current activity reflects the true need, then a pragmatic approach to modelling the future need for paediatric cardiac surgery would be to apply the percentage change in population size to the 2006 paediatric cardiac surgery activity related to the countr(y/ies) of interest. Table 2 gives the estimated annual paediatric cardiac surgery activity for English paediatric cardiac surgical units (covering English and Welsh patients) and the paediatric cardiac surgical units in Scotland and Northern Ireland (thus reflecting the UK workload).

[6] UK National Statistics website Available at: www.statistics.gov.uk/hub/index.html

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

As can be seen the national caseload in Scotland and Northern Ireland is not projected to change significantly by 2025. However, the national caseload for England and Wales combined (reflecting the patterns of activity in the current English paediatric cardiac surgery units) is estimated to increase by approximately 480 cases per annum by 2025.

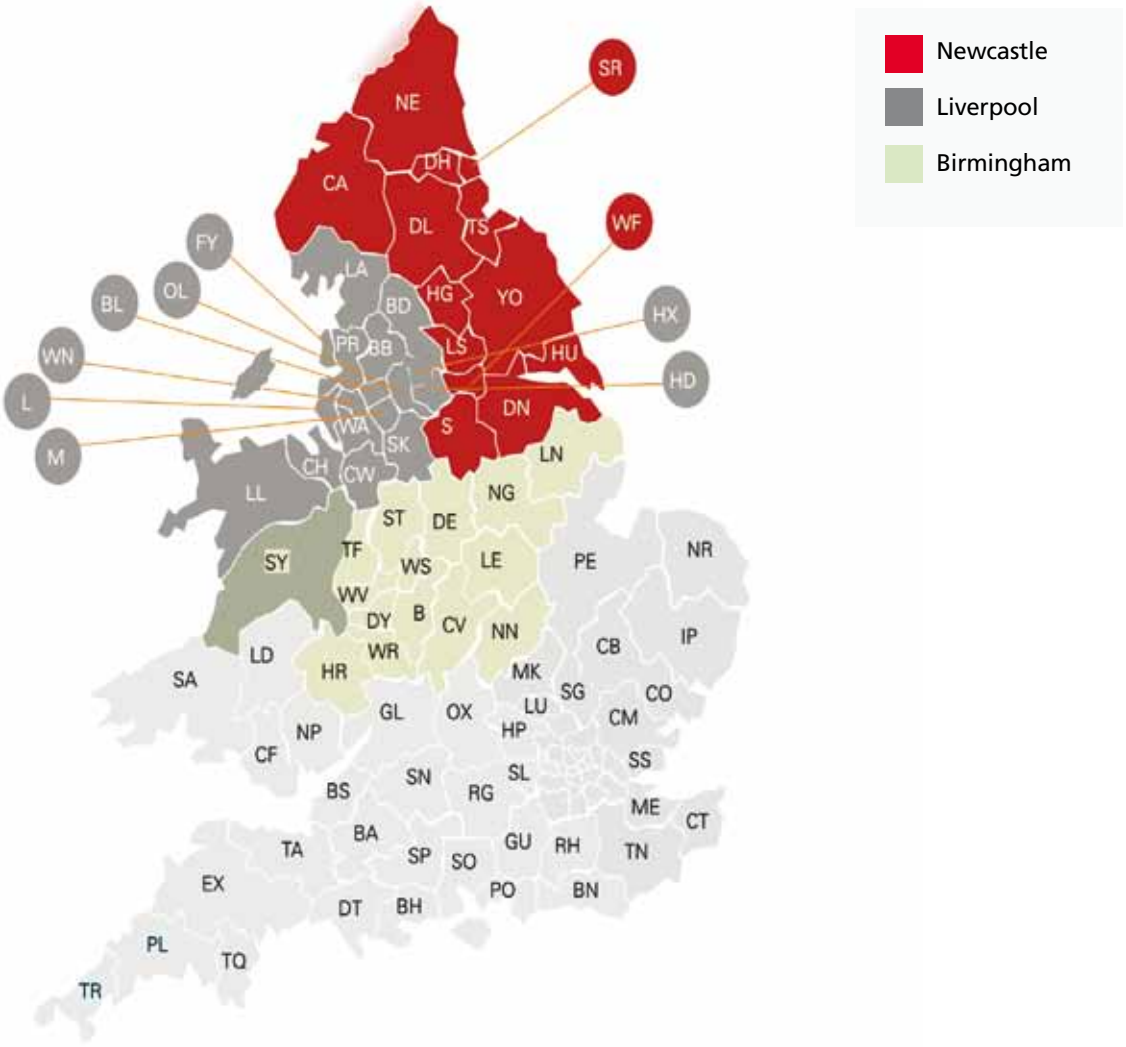
Conclusions

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 there is a slow but continuing increase in the number of surgical procedures performed on adults with congenital cardiac disease.

However, population projections produced by UK National Statistics would suggest increases in the paediatric population in England and Wales in the order of 13.7 % by 2025 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. Smaller and less significant changes are projected for activity in Scotland and Northern Ireland.

Z Analysis of the proposed Newcastle Networks

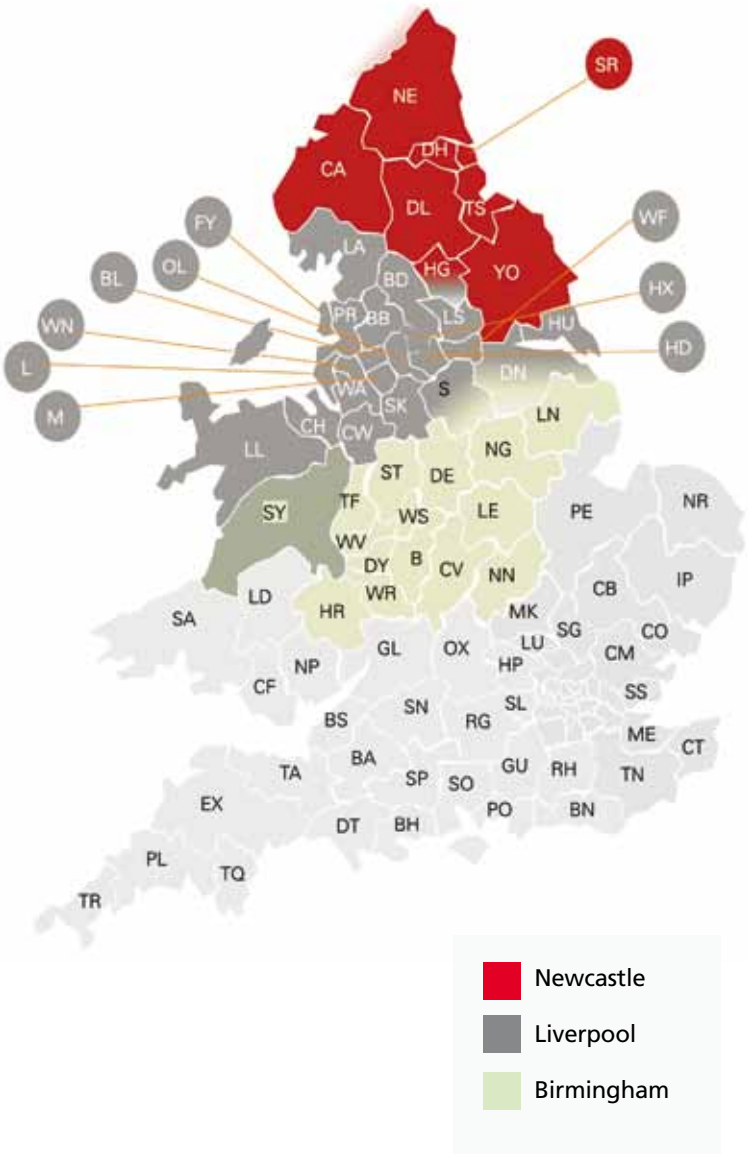
The network for Newcastle under Option B includes the CA, DH, DN, DL, HG, HU, LA, LS, NE, S, SR,TS, WF and YO postcode areas. Newcastle's network was defined on the basis of conversations with SCGs and JCPCT representatives and it receives 559 patients per year. This network, is shown on the map below:



On the basis of consultation responses and the travel analysis undertaken by PwC, the JCPCT is advised that options that include the Freeman Hospital presents a greater potential risk to the manageability of the network than options that do not because of forecast patient flows in the north of the country. Therefore further analysis was undertaken, relating to option B, the highest scoring option.

Analysis of the networks in the north of the country indicate that if patients travelled to their nearest centre only, then Newcastle would receive patients from the entire postcode districts NE, SR, CA, DH, DL, TS, YO, TD and also patients from HG3, HG4, HG5 and TD12 and TD 15. This assumes that the total population of the Newcastle catchment area would be 3,732,475 and that Newcastle would receive 248 patients.

The networks showing patients travelling to their nearest centre for option B is shown on the map below:



Z

In order for Newcastle to receive more than 400 patients, the network would have to expand to include the following postcodes:

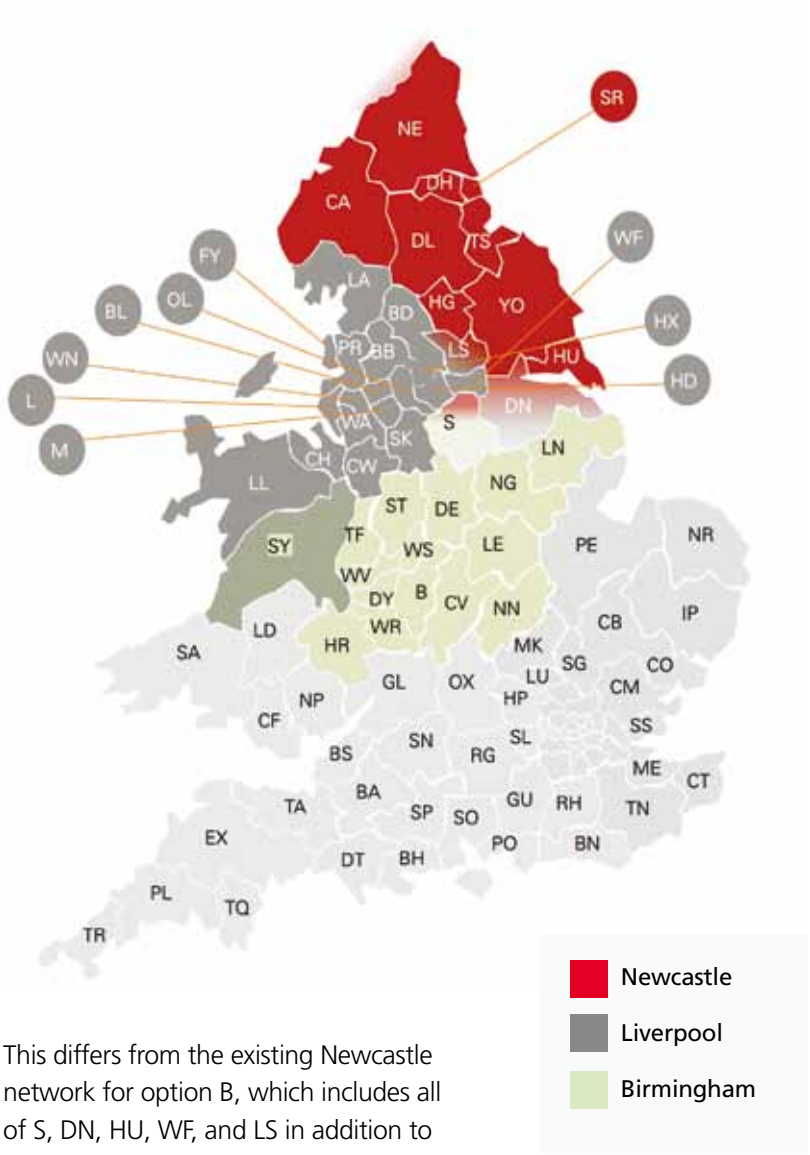
- All of LA
- All of HG
- All of HU
- DN14, DN 15, DN16, DN17, DN18, DN19, DN20, DN31, DN32, DN33, DN34, DN35, DN36, DN37, DN38, DN39, DN40, DN41, DN6, DN7, DN8, DN9,
- LS14, LS17, LS21, LS22, LS23, LS24, LS25, S71, S72, S75.

These postcode districts were selected because they have the shortest increase in journey time from their existing nearest centre under 'Option B', which would be either Birmingham or Liverpool, as indicated on the map above. The increase in journey times for these families if they were to travel to Newcastle would be no more than an additional 30 minutes to the increase in journey times than they would experience if travelling to Liverpool or Birmingham.

All of these postcode areas have an increase in journey time of less than 31 minutes when compared with the travel times to either Birmingham or Liverpool.

Under these assumptions Newcastle would receive 407 patients per year.

The expanded network that would ensure that Newcastle would receive a minimum of 400 patients per year is shown below:



This differs from the existing Newcastle network for option B, which includes all of S, DN, HU, WF, and LS in addition to the postcodes shown in the map above.

The postcode areas that were regarded as most at risk to the mangeability of the Newcastle network based on PwC's analysis were those LS, WF, S and DN. The implications of some patients from these postcode areas choosing to be treated at another hospital than Newcastle is explored under the sensitivity testing in Appendix V.

Final Advice from the Steering Group to JCPCT, October 2011

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Report to the Joint Committee of PCTs by Dr Patricia Hamilton CBE, Chair of the *Safe and Sustainable* Steering Group, on behalf of Steering Group members

This paper sets out the Steering Group's further advice to the JCPCT having taken into account the evidence submitted by respondents during public consultation.

17 October 2011

1. Introduction

1.1 As an outcome of public consultation Steering Group members have received and considered the following evidence:

i. Report on the outcome of consultation published by Ipsos Mori on 23 August 2011

ii. Report on the outcome of focus groups held by Ipsos Mori, published on 25 August 2011

iii. Responses to consultation made by organisations by letter or email (and a summary of such responses prepared by the secretariat)

iv. Report on the consultation events dated August 2011

v. Notes of the meeting between the Steering Group and members of the British Congenital Cardiac Association held on 12 July 2011

vi. Health Impact Assessment interim report dated August 2011

1.2 Additionally, a number of Steering Group members were present at public consultation events as members of the panel (attendance details are provided in the summary report on the consultation events).

1.3 This paper sets out the Steering Group's further advice to the JCPCT having taken this evidence into account. The Steering Group's advice to JCPCT Members was agreed at a meeting of the Steering Group on 13 September 2011 and covers the:

i. Proposed *Safe and Sustainable* standards for Specialised Surgical Centres

ii. Proposed model of care that envisages the development of congenital heart networks across England comprising Children's Cardiology Centres and District Children's Cardiology Centres

iii. Recommendations made by the Steering Group for improving the monitoring and reporting of outcome data

iv. Implementation of the JCPCT's eventual decision

v. Responses to consultation on which the Steering Group's advice has been sought on relevant clinical issues

2. Proposed *Safe and Sustainable* standards for Specialised Surgical Centres

2.1 Having considered the evidence submitted during public consultation Steering Group members advise the JCPCT to agree the standards as set out in the consultation document.

2.2 Steering Group members further advise the JCPCT to accept the additional standards as set out in Appendix A subject to further advice that is being sought from the British Association of Perinatal Medicine around proposed standards A29 to A31 (the Steering Group's final advice will be reported at the meeting of the JCPCT in November 2011).

3. Proposed model of care

3.1 Having considered the evidence submitted during public consultation Steering Group members advise the JCPCT that the proposed model of care is viable. Specific elements of the model of care considered by the Steering Group are as follows:

Viability of the proposed Children's Cardiology Centres (CCCs)

3.2 Steering Group members were conscious that this issue has generated significant debate during consultation and that the medium to long-term viability of the CCCs has been questioned by some respondents; these concerns are based around the potential loss of specialist expertise at these centres given the JCPCT's proposal that they do not provide interventional cardiology services in the future.

3.3 Steering Group members advise the JCPCT that the CCCs are a viable proposition, and they are mindful of existing precedents such as the successful transition of the Cardiff centre from a surgical centre to a non-interventional cardiology centre in the past decade.

3.4 However, there are potential risks that need to be managed. When surgery is lost to a cardiology unit, a potential risk is that there may be insufficient motivated staff to make the CCC model work. Based on the Cardiff experience, staff turnover may be high. After an unsteady three years following the decision to cease surgery the service was made stable, due in part to the appointment of a cardiologist dedicated to making the model work. The inducements for retaining key staff could include favourable job plans, clear PAs for joint working and sufficient allowance in job plans for travel.

3.5 Steering Group members recommend that designation standards are developed for the CCCs and that potential risks are addressed during the phase of implementation.

Role of the proposed Children's Cardiology Centres / Interventional Cardiology / Diagnostic Catheterisation

3.6 Based on existing professional guidance the JCPCT's consultation document proposed that CCCs do not provide interventional cardiology services nor diagnostic catheterisation services given the (small) risk of an emergency requiring surgical support.

3.7 On 13 September Steering Group members received a briefing from the President of the British Congenital Cardiac Association (BCCA) which suggests that the revised professional guidance (due in October 2011) is likely to continue to recommend that interventional cardiology services should only be performed in designated surgical centres; but that diagnostic catheterisation may be performed in the proposed CCCs. On the understanding that this description is reflected in the impending BCCA guidance the Steering Group members advise the JCPCT to reflect this guidance in the model of care and the standards for the Specialised Surgical Centres and the CCCs.

3.8 Steering Group members further considered the delivery of Electrophysiology (EP) for children with congenital heart disease. As with interventional cardiology and diagnostic catheterisation there is a small risk of an emergency requiring surgical support. Steering Group members advise that that the provision of EP can be delivered outside of a designated surgical centre provided that the local congenital heart network has developed clear protocols, including a consideration of local governance arrangements, and that local network governance arrangements determine the size and weight parameters for undertaking interventional EP on children without paediatric surgical backup. Steering Group members emphasise that children requiring EP should be seen in dedicated children's services, not adult services as is current practice in some parts of the country. It is recommended that this advice is reflected in future standards for CCCs.

Role of the proposed District Children's Cardiology Services

3.9 Steering Group members advise that the proposed District Children's Cardiology Services – which envisage a local service delivered by Consultant Paediatricians with Expertise in Cardiology - is a viable proposition. Further work will be required during the implementation phase to establish appropriate governance arrangements across the network and to develop standards against which the DCCS will be measured.

4. Recommendations made by the Steering Group for improving the monitoring and reporting of outcome data

4.1 Steering Group members advise the JCPCT to agree the proposals for improving the monitoring and reporting of outcome data as set out in the JCPCT's consultation document.

5. Implementation issues

5.1 Potential impact to Paediatric Intensive Care Units (PICU)

5.1.1 In de-designated centres, a decrease in caseload resulting from the loss of cardiac work will have effects on staff retention in the first place then, potentially, recruitment.

5.1.2 In de-designated centres, there will be an expectation that the PICU can still meet demands of its catchment, particularly seasonal winter surges. Discussions held within the Steering Group have highlighted that PICUs that lose cardiac surgery may then lose the ability to flex their bed numbers by decreasing cardiac surgical throughput on a seasonal basis. This extent to which this flexibility can be extended to the PICUs that retain cardiac surgery is uncertain as these units will then be under pressure to perform more cases overall and with lower rates of cancellations than tolerated previously (as per the proposed standards).

5.1.3 Consequently, there may need to be a continuing investment in non-cardiac PICUs to avoid winter crises.

5.1.4 Cardiology is an essential service to PICU patients to detect hitherto undetected underlying cardiac disease, be that congenital or acquired. It was accorded 'Amber 3' status in the Critical Interdependencies Framework (meaning that it does not 'necessarily' require co-location with PICU) but care must be taken to preserve cardiology services in de-designated centres.

5.1.5 Already there are difficulties associated with admitting children from areas that border the catchments of other tertiary centres, particularly when they suffer from multiple conditions. These families can then be subject to disparate referral patterns where they may be seen in two or even three different tertiary centres. In creating new referral flows to support the new cardiac surgical options, the congenital heart networks will need to develop mitigation strategies to ensure that such fragmentation of care is not exacerbated.

5.2 Potential impact to retrieval services

5.2.1 Steering Group members advise the JCPCT that the precise ramifications for retrieval services cannot be known until the JCPCT has made a decision on the future configuration of congenital heart networks. However, some potential difficulties are self-evident.

5.2.2 In all of the options submitted for consultation larger numbers of critically ill children will move over greater distances. However, the Steering Group advises that this does not present increased risk to the child provided the options comply with the maximum journey time thresholds as set out in the Paediatric Intensive Care Society standards for the care of critically ill children. The evidence is that these distances have not been shown to be associated with increased risk.

5.2.3 As an outcome of reconfiguration there may be more District General Hospitals that are relatively remote to the surgical centre. Some experience of this already exists in England such as the South West Peninsula and its relationship with the Bristol centre, and Great Yarmouth and its relationship with London. The evidence is that these distances have not been shown to be associated with increased risk. However, there is consensus within the Paediatric Intensive Care Society that, in the context of sparse and hitherto unreliable air transport infrastructure in the UK, the current limits of transfer times as set out by PICS

standards are realistically safe limits. In the Northeast and Yorkshire Regions, for example, if one of the two cardiac surgical units ceases cardiac surgery the remaining unit will need to reach all the populations at the other 'extremity' through a working partnership with the other retrieval team (and perhaps other surrounding teams) with clearly defined operating procedures and, almost certainly, significant investment. The same principles would potentially apply to the South Central England, Southwest England, East Midlands and Wales depending on the JCPCT's eventual decision.

5.2.4 Consequently, consideration needs to be given to consolidating the remaining retrieval services that have not amalgamated. In the last eighteen months, three new amalgamated services have been commissioned with sustainability and economies of scale in mind: 'NEWTS' (Liverpool & Manchester), serving NW England & NW Wales; 'WMPRS' (Stoke & Birmingham) serving the W Midlands; and 'EMBRACE' (Leeds & Sheffield) serving Yorkshire & Humberside. London already has two large, amalgamated transport services, CATS & STRS. This leaves Newcastle, Leicester, Nottingham, Southampton, Oxford, Bristol & Cardiff as un-amalgamated unit-based services. The JCPCT's proposal for Congenital Heart Networks across England supports the case to form further acute transport groupings in the future. Experience of setting up the other amalgamated services shows that this needs to be financially supported.

5.2.5 The matter of transfer of children back from the surgical centre was discussed at the Steering Group. It was suggested that retrieval services should be commissioned in such a way that 'repatriating' children back to local services should be part of the contract with both the retrieval service and ambulance providers.

5.3 Potential impact on workforce

5.3.1 The Steering Group is aware that some respondents have suggested during consultation that potential impacts on the NHS workforce must be identified and assessed by the JCPCT as part of the process for agreeing a final configuration option. However, the Steering Group agrees with the JCPCT's position as set out in the consultation document, which is that the potential impact of reconfiguration on the workforce cannot be determined with confidence before the JCPCT has made a final decision and, as such, should not be a consideration in the JCPCT's process for agreeing a final decision. Rather, this is an issue for implementation, and it will be important for the Congenital Heart Networks and commissioners to identify and resource education and training requirements, particularly for nurses.

6 The following sections of this report provide the Steering Group's response to submissions made to the JCPCT during consultation and on which the JCPCT has sought clinical advice from the Steering Group.

6.1 Rare and complex procedures

6.1.1 A number of respondents have suggested that the delivery of 'rare and complex' surgical procedures should be restricted to a very small number of designated surgical units, reflecting a recommendation in the report of the Bristol Inquiry in 2001.

6.1.2 Steering Group members advise the JCPCT that 'rare and complex' procedures are not currently defined; in any event they would not advise that rare and complex procedures are restricted to a smaller number of centres. Steering Group members do not consider that reconfiguration poses particular risks for rare diagnoses and they advise that the impact of reconfiguration to the delivery of rare and complex procedures can be managed within appropriate clinical governance frameworks. This is because Steering Group members are reassured that the relevant concerns set out in the Bristol report in 2001 can be safely addressed by the larger, expert surgical centres proposed by the JCPCT; a rigorous clinical governance framework across the national congenital heart network (with the active participation of commissioners, providers, professional associations and lay organisations) will enable a safe service planning for rare and complex procedures across the network.

6.2 Nationally commissioned services

6.2.1 The JCPCT has received opposing evidence about the significance that the JCPCT should attach to the current location of the nationally commissioned services.

6.2.2 Steering Group members advise the JCPCT that the recommendations of the separate expert panel that reported on nationally commissioned services in 2010 remain valid. While the re-location of a nationally commissioned service presents some potential risks, these risks can, in the view of the Steering Group, be managed.

6.3 Analysis of mortality data

6.3.1 It has been put to the JCPCT during consultation that Professor Spiegelhalter's analysis of mortality data (which was published following the separate review of the paediatric cardiac surgical service at the John Radcliffe Hospital in 2010) should be applied by the JCPCT to differentiate between high quality and low quality surgical units.

6.3.2 The Steering Group's previous advice was that owing to a low national caseload and difficulties in adjusting for complexity, mortality outcomes should not be used to identify potential configuration options. As such, mortality outcomes have not been analysed by the JCPCT[1] or played any part in the development of configuration options.

6.3.3 The Steering Group does not advise the JCPCT to apply an analysis of mortality data in the future process for agreeing a configuration option for the reasons previously explained.

[1] Except for the limited purpose of receiving Mr Pollock's report in response to the publication of Professor Spiegelhalter's analysis in December 2010

APPENDIX A

Proposed additional standards

Background

In full term babies the ductus arteriosus (arterial duct) usually closes naturally within the first few days of life. In babies born prematurely it may remain open ('patent') resulting in extra blood flow through the lungs – this may delay / prevent weaning from the ventilator. It is the practice to refer these babies for surgical ligation of their patent ductus arteriosus (PDA). These babies are cared for in the Neonatal Intensive Care Unit / Special Care Baby Unit and the practice in some centres has been for the neonatal team to transfer the baby to the surgical centre for operation. With larger surgical teams in the Specialist Cardiac Surgical centres, alternative pathways may be developed.

	Designation standard	Measures	Compatible Evidence Base	Status
A29	As the sole exception to the *Safe and Sustainable* standards which stipulate that heart surgery on children must be performed in a designated Specialist Surgical Centre it is permissible for neonates with *patent ductus arteriosus* (PDA) to receive surgical ligation in the referring neonatal intensive care unit (level 3) provided that the visiting surgical team is despatched from a designated Specialist Surgical Centre and is suitably equipped in terms of staff and equipment.	Written protocols	Gould D et al (2003) 'A comparison of on-site and off-site Patent Ductus Arteriosus ligation in premature infants', Pediatrics Vol 112, 6	Mandatory
A30	It will be for each Congenital Heart Network to determine whether this arrangement is optimal (rather than transferring the neonate to the Specialist Surgical Centre) according to local circumstances, including a consideration of clinical governance and local transport issues.	Written protocols		Mandatory
A31	All Congenital Heart Networks must have clear protocols that address the provision of surgical ligation for neonates with PDA.	Written protocols		Mandatory

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Background

A number of participants at consultation events sought reassurance that surgical centres will continue to be audited against the standards once the designation process has concluded. This proposed standard does not stipulate a timetable for future audits (that is for the commissioning body to stipulate outside of the standards document) but it does ensure that the standards themselves and the outcome of future audits are widely publicised.

	Designation standard	Measures	Compatible Evidence Base	Status
E14	Specialist Surgical Centres must make parents and carers aware of the *Safe and Sustainable* standards and the outcome of audits of compliance. As a minimum this will include publishing the *Safe and Sustainable* standards on the centre's website and informing parents of their existence in first appointment letters and other relevant literature.	Patient / parent literature Compliance audits	National Service Framework for Children, Young People and Maternity Services (2003 and as modified).	Mandatory

PAEDIATRIC CARDIOTHORACIC TRANSPLANTATION AND BRIDGE TO RECOVERY: IMPLICATIONS OF *SAFE AND SUSTAINABLE* REVIEW OF PAEDIATRIC CONGENITAL CARDIAC SURGERY SERVICES

1. Introduction

1.1. The Safe and Sustainable Review of children's congenital cardiac services proposes to reduce the number of centres performing paediatric congenital cardiac surgery in England to ensure clinical caseloads remain sufficient to assure excellent clinical outcomes.

1.2. Certain of the reconfiguration options entail the proposed closure of the PCCS centres that also provide three relevant nationally commissioned services: complex tracheal surgery, paediatric respiratory ECMO and paediatric cardiothoracic transplantation / bridge to transplantation or recovery (PCTTx/B2Tx: Table 1).

Table 1: Current distribution of nationally commissioned services relevant to PCCS reconfiguration

	Complex tracheal surgery	Respiratory ECMO	PCTTx/B2Tx
GOSH	✓	✓	✓
NUTH	✗	✓	✓
UHL	✗	✓	✗

1.3. As part of the expert panel analysis of the proposed options for reconfiguration in the Safe and Sustainable Review, existing PCCS centres were asked to submit proposals for the three relevant nationally commissioned paediatric services.

1.4. The expert panel suggested that the national caseload for complex tracheal surgery, currently provided at Great Ormond Street Hospital for Children NHS Trust (GOSH) supports a single centre in England as optimum for this service. For the cardiothoracic transplantation programme, the national caseload, and geography, supports two centres as optimum. The expert panel also advised that while ECMO and transplant services could be re-located if necessary, the optimum arrangement would be to leave them in their current locations if possible (although the panel suggested that it would be considerably more complex to move transplant services than ECMO). This also reflected the advice of the Safe and Sustainable steering group.

1.5. Of the four centres who submitted proposals, the expert panel advised that only Birmingham Children's Hospital demonstrated a sufficient ability to assume paediatric cardiothoracic transplant services and 'bridge to transplant' services if required.

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1.6. If University Hospitals of Leicester NHS Trust were no longer to provide paediatric congenital cardiac surgery, its paediatric respiratory ECMO activity would need to be redistributed: patient flow modelling suggests that this activity would be most likely to flow to Birmingham Children's Hospital NHS Foundation Trust (BCH). This was discussed and noted at AGNSS on December 8th 2011.

1.7. It has since become evident, following the public consultation on the Safe and Sustainable review proposals that, owing to geographical patient flows and critical mass, any option that proposes the cessation of paediatric congenital cardiac surgery at NUTH is likely to require Leeds Teaching Hospitals NHS Trust to provide paediatric congenital cardiac surgery. This would mean that there may be insufficient patient flow to retain paediatric congenital cardiac surgery at UHL. BCH, identified by the expert panel as potentially capable of providing both respiratory ECMO and PCTTx/B2Tx services, would need to absorb the clinical caseload of both these cardiac surgery programmes. This may have implications for the residual capacity of BCH to deliver other nationally commissioned services, including respiratory ECMO activity from both UHL and Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH). Bristol Royal Hospital for Children (BRHC) would therefore also be required to provide ECMO in order to maintain three centres providing this service. BRHC is not currently designated either as a full nor as a surge respiratory ECMO centre, but could be supported by existing services to achieve this. Under this model there would be no paediatric respiratory ECMO provider (in England) north of Birmingham.

1.8. BCH was the only centre whose bid for PCCTx/B2Tx was accepted as potentially feasible by the expert panel. At the time of original submission, however, this proposal was to become a third (rather than a replacement) service, and did not initially aim to treat children below 10 years old. It is also germane that the expert panel did not consider the impact to a single institution of assimilating both ECMO and transplant services at the same time (this was outside the panel's terms of reference) and recent analyses undertaken by local commissioners and BCH itself have identified concerns about the ability of BCH to safely develop these services within the time constraints envisaged by Safe and Sustainable. The expressed preference of the Board of BCH, in June 2011, was to support the proposed option B in the Safe and Sustainable Review, which would retain NUTH as a paediatric congenital cardiac surgery centre, and therefore as a centre for PCTTx/B2Tx.

1.9. Overall activity, for both cardiothoracic transplantation and long-term mechanical circulatory support, is increasing in both existing centres currently. The Organ Donation Taskforce (ODTF) target to increase all donations by 50% by 2013 continues to apply to paediatric hearts and lungs, although availability of very small donor organs remains challenging.

1.10. An earlier paper for the AGNSS meeting of 8th December 2011 looked at the implications of some proposed reconfiguration options for paediatric respiratory ECMO and for PCTTx/B2Tx programmes. AGNSS members supported the assurances of the NSCT that BCH, currently providing a 'surge' ECMO service, could safely develop as a full paediatric respiratory ECMO nationally designated service by 2013, following the planned expansion of its PICU capacity.

1.11. AGNSS members, at this meeting, however, were concerned about the inherent clinical complexity of a paediatric cardiothoracic transplant and long-term mechanical circulatory support programme, and wished to convey to JCPCT their strong concerns about any proposed transfer of PCTTx/B2Tx from NUTH to BCH. It was recognised that the existing PCTTx/B2Tx service at NUTH delivers excellent clinical outcomes and has a reputation as an innovative service.

1.12. This paper looks in closer detail at the risks entailed in such a proposal: to patients, to the national programme overall and to both NUTH and BCH.

2. Background

Collection of evidence

2.1. To explore this further, and to obtain immediate activity and outcomes data, NSCT commissioners visited the existing cardiothoracic transplantation teams at both GOSH and NUTH in December 2011, along with Mrs Gail Fortes Mayer, Assistant Director of the West Midlands Specialised Commissioning Group (SCG) and lead commissioner for PICU. Senior NSCT staff also met with the Chief Executive Officer of BCH, Ms Sarah-Jane Marsh, and key members of her clinical and management team.

2.2. In compiling this report, the NSCT has worked closely with the West Midlands SCG and with the Safe and Sustainable Review team.

2.3. Data from the Statistics and Clinical Audit division of NHSBT, both routinely provided and following individual requests for analysis, have been used where necessary.

2.4. An updated proposal, giving further detail about the proposals to increase conventional paediatric cardiac surgery, deliver respiratory ECMO as a full nationally designated centre and to develop / deliver PCTTx/B2Tx, was received from BCH on 12th January 2012.

International evidence

2.5. A review of the international published literature could find no description of the clinical consequences of transferring or moving an established paediatric cardiothoracic transplantation programme, although such international comparisons should always be treated with caution. The only example of a newly established PCTTx service in Europe had been developed from an existing service for adults.

2.6. Some international evidence is available, from the International Society for Heart and Lung Transplantation (ISHLT) on the relationship between clinical caseload and long term survival in paediatric cardiothoracic transplantation, suggesting the minimum caseload to be > 8 cases per unit per year if the relative risk of mortality at 15 years is to be <1. Whilst the national caseload for paediatric cardiothoracic transplantation is increasing, this would not support the development of a third service for paediatric cardiothoracic transplantation in the UK on current caseload volume.

2.7. Detailed guidance describing the necessary 'pathways to competence' for the management of patients with advanced heart failure and those undergoing transplantation was published in 2010 by the American Heart Association in conjunction with ISHLT , but does not provide comprehensive recommendations for competence in the management of these conditions in children, nor cover the competence standards necessary for surgical management.

2.8. The training programme for cardiothoracic surgeons wishing to specialise in transplantation and the surgical management of advanced heart failure is lengthy and complex, requiring further sub-specialisation following acquisition of Certificate of Completion of Training (CCT). Declining activity levels for transplantation and the unpredictable and arduous nature of the work have contributed to a shortage of suitably qualified candidates.

The existing nationally commissioned PCTTx/B2Tx service

2.9. The most recent data obtained from NHSBT shows that, in 2011/12 (YTD to December), a total of 16 paediatric heart transplants and 3 lung transplants have been performed by GOSH. NUTH have performed 10 paediatric heart transplants and 0 lung transplants in the same time period.

2.10. In recent years, NUTH activity has increased, in comparison with GOSH (Figure 1): both units now perform similar annual numbers of heart transplants. Very few paediatric lung transplants are currently performed nationally: with the majority of these having been performed by GOSH.

Figure 1: Paediatric heart transplant activity, 2005-2011 by centre
Source: UKCTA, 2011

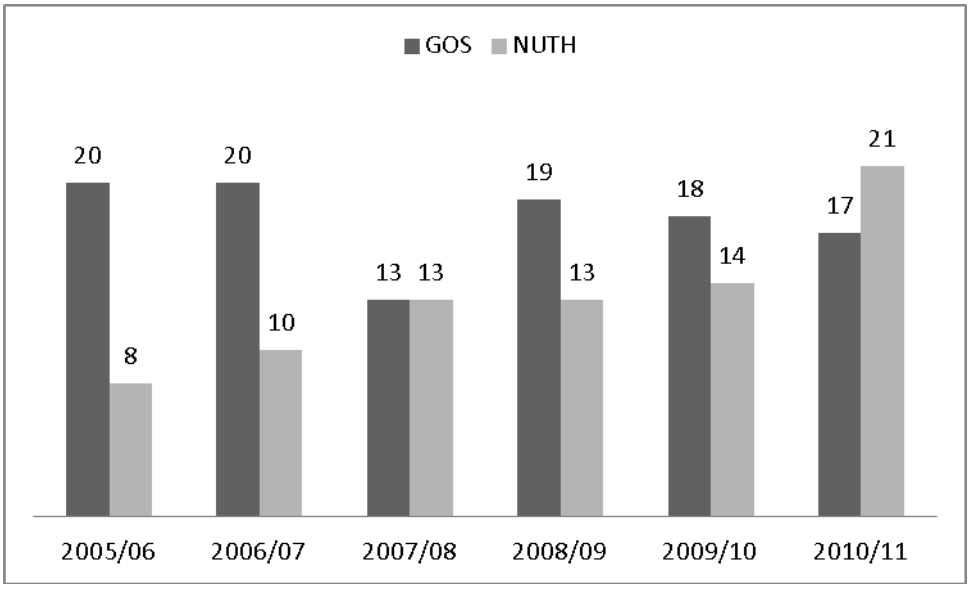

Table 2: 5 year survival after paediatric heart transplantation by centre, March 2005-April 2010. Source: UKCTA, 2011					
Centre	**No cases**	**% survival**	**95%CI**	**Centre effect**	**95%CI**
NUTH	20	90.0	65.6 – 97.4	-0.24	-0.91 – 1.76
Harefield	1	100	n/a	-1.00	-1.00-25.4
GOSH	49	85.1	71.2 – 92.6	0.12	-0.55 – 1.31

2.11. NUTH have performed around 10-17 bridge to transplant procedures each year since 2006/07, with increasing (and now almost exclusive) use of the Berlin Heart technology since 2004. Whilst some mobilisation is possible once stabilised on the Berlin Heart, in practice these children must remain in hospital under clinical supervision (although not necessarily in the highest category of intensive care support) until a suitably sized organ becomes available. For children below 20kg, the shortage of organs can entail long stays on mechanical circulatory support. At NUTH the length of stay for such patients has steadily increased, owing to the shortage of donor organs, to around 40 days on average. Since 2006, at NUTH, 76 heart transplants have been performed in total, 41 of whom were on a Berlin Heart at the time of transplantation.

2.12. Between December 2010 and December 2011, of 349 admissions to PICU at NUTH, whilst 22% were due to advanced heart failure or transplantation, these accounted for 40% of total bed days. Data on Ventricular Assist Devices (VADs) in children are not yet routinely collected by NHSBT, but NSCT financial activity data show that, in 2010/11, GOSH used 9 long term devices, whilst NUTH used 13.

Proposal from BCH for cardiothoracic transplantation and bridge to transplantation

Implications for the respiratory ECMO nationally commissioned service

2.13. The closure of either UHL or NUTH as a paediatric cardiac surgery centre would require BCH to become a fully designated nationally commissioned centre for paediatric respiratory ECMO. This would place further pressure on PICU beds at BCH, which already operate at an acuity level that is significantly higher than average. Activity by provider, for respiratory ECMO, is shown in Table 3. An important feature of the paediatric respiratory ECMO caseload is that it is less subject to seasonal variation, since indications for its use are not entirely due to winter respiratory infection.

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Table 3: Clinical caseload for paediatric respiratory ECMO, 2010/11, by centre. Source: NSCT provider monitoring data				
	Children		Neonates and infants	
	Cases	OBDs	Cases	OBDs
GOSH	7	47	25	210
NUTH	1	46	10	53
UHL	10	163	28	269

2.14. BCH are currently in the process of expanding both theatre and PICU capacity, as part of its internal strategy and in readiness for any potential expansion of conventional paediatric cardiac surgery following implementation of the Safe and Sustainable Review. Current estimates suggest a likely caseload of 600-650 paediatric cardiac surgery cases per year, from a current caseload of 487 (CCAD database 2010/11) in addition to the additional respiratory ECMO from UHL and/or NUTH. This expansion of surgical facilities and resources entails increased operating theatre capacity (an additional theatre has already opened, and a third is planned) and a phased expansion of PICU beds from the current complement of 22 beds, to 26 by July 2012 and 31 by 2014. This should allow the absorption of both the increased conventional cardiac operative caseload, and the necessary flexibility for respiratory ECMO admissions and support by 2013 if necessary.

2.15. In their recent updated submission to NSCT, however, BCH have recognised the additional challenges entailed in developing as a second national centre for PCTTx/B2Tx, and that these could only be delivered over a longer timescale (Appendix 1). The Trust has stated this significant service expansion "would need a series of changes and investments made' before being able to commit to this safely and to a consistently high standard." These investments entail:

- An additional consultant (surgeon)
- A cardiologist with a special interest in transplantation
- Increased activity in organ retrieval (either 2 Staff Grade surgeons or 2 SpR level posts)
- A further 2 senior nurses, with lead time to train to the required standard
- An additional perfusionist
- Consideration of a further additional operating theatre

2.16. The updated submission recognised the significant pressures on intensive care and other infrastructure brought about by the unpredictable and unusual nature of paediatric transplantation and mechanical circulatory support. This would require a remodelled approach to ICU and HDU delivery, including the need to respond to surge in activity during winter pressures or at other times of unexpected increased demand on services. The Trust proposes a 'seasonalised' approach to patient flow, with routine surgery planned over eight months of the year and the remaining four winter months being used for seasonal respiratory admissions and neonatal emergency cardiac surgery.

2.17. The increased cardiothoracic activity proposed would have an impact on theatre utilisation and scheduling, in particular affecting existing liver, small bowel and renal transplant activity and other acute cardiac theatre usage. The proposal explores the option of building a third theatre, requiring both significant capital (£1.3M) and additional staff costs.

2.18. In responding to requests from NSCT for detailed plans for the delivery of both respiratory ECMO and PCTTx/B2Tx as nationally commissioned services, should it be necessary to transfer either or both of these services from either UHL or NUTH, the Chief Executive of BCH has written:

"We are in the process of shaping a new high dependency strategy for the hospital which will transform the way we provide high dependency care, out of which we will identify additional high dependency capacity. However, until this work is complete, we will not know if this will be sufficient to deliver a high quality and safe cardiac transplant and bridge to transplant service under a two centre approach…. We recognise that the challenges of increased capacity, recruitment and training of new staff, and of operationalizing a significant service not previously delivered, poses much greater challenges in terms of timescales."

2.19. BCH expects that it would take at least three years before this can be fully operational, and has no desire to do this in a way that compromises safety or quality:

"The risk in moving swiftly to a two-centre option including BCH is that this safety and quality could not be guaranteed to our usual high standard."

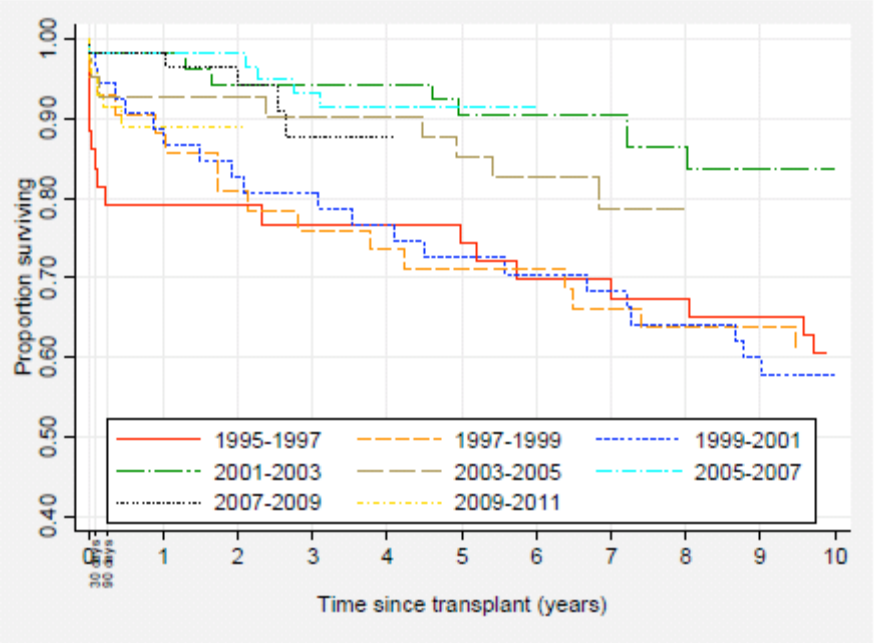
Risks in transferring the PCTTx/B2Tx from NUTH to BCH

2.20. The expert panel and the Safe and Sustainable steering group advised that the re-location of a complex and highly emotive nationally commissioned service such as this entails a number of risks, which are described in more detail. Although the risks could be managed, they are complex and it is important to bear in mind the high quality clinical outcomes, interdisciplinary research activity and esteem in which the service at NUTH is currently held. Any proposed move would also impact significantly on GOSH, in terms of the mentoring and support that would be necessary as the new service develops.

Clinical outcomes

2.21. Data shared initially by GOSH appears to demonstrate a relationship between survival following paediatric cardiothoracic transplantation and clinical era of the transplant service. Further analysis carried out by NHSBT (Appendix 2) confirms a highly significant relationship between survival (at 30 days, 90 days and 5 years) and era at GOSH. This relationship is less clear at NUTH, (perhaps related to smaller numbers at the outset) although it is still significant at 30 days and 1 year. This 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 (Figure 2).

Figure 1: Paediatric heart transplant activity, 2005-2011 by centre
Source: UKCTA, 2011



Adults with congenital heart disease

2.22. Cardiothoracic transplantation for adults with congenital heart disease (ACHD) is a key component of any paediatric cardiothoracic transplantation. The CTAG submission to the Safe and Sustainable review recommended, in fact, that a paediatric cardiothoracic transplant service should always be located alongside an adult cardiothoracic transplant service to facilitate a smooth transition and shared management between the two services, and to optimise survival likelihood should cardiothoracic transplantation become necessary. This reinforces the view of the original panel that no other site than BCH could be considered for PCTTx/B2Tx. Whilst GOSH provides a service for some patients with ACHD, the hospital is not located with an adult transplant service. In contrast, the NUTH PCTTx/B2Tx service is actually located on an adult hospital site and provides excellent opportunities to deliver a combined service. Indeed, many ACHD patients require mechanical circulatory support in addition to transplantation: it is therefore essential that this expertise be maintained for the growing numbers of ACHD patients. If the NUTH programme were to be transferred to BCH, although not unworkable, it would present important additional challenges for delivering the majority of the national ACHD caseload. This is because BCH is not on the same hospital site as the adult cardiothoracic transplant centre, although it has developed limited (to date) experience in shared management and transplant of ACHD in collaboration with the surgical team at QEHB. Experience in adult mechanical circulatory support at QEHB, whilst now established, is not at the same level as that at NUTH, one of the early nationally commissioned programmes for mechanical circulatory support.

2.23. Data from the National Institute for Cardiovascular Outcomes Research (NICOR) indicate that, between 2007 and 2010, GOSH had performed a total of 52 heart transplants on adults with congenital heart disease, with a 30 day survival rate of 94.2%. Over the same time period at NUTH, the only other UK centre performing this surgery, were 44 cases and 97.7% 30 day survival respectively.

Specialist expertise

2.24. NUTH currently has developed expertise in aspects of paediatric cardiothoracic transplantation which are not currently delivered elsewhere in the UK. These include the management of children with single ventricle on mechanical support prior to transplantation, desensitisation for ABO incompatibility and the management of children with mitochondrial disease. This specialist expertise would need to be replicated if the service were to be transferred: this may be difficult where other clinical specialties (immunology, cardiac intensivists) are involved. This may not realistically be possible, as such highly specialised services require multidisciplinary clinical teams. Indeed, NUTH currently provides the only UK expertise for the management of children with single ventricle progressing to heart transplantation.

2.25. Successful cardiothoracic transplantation programmes require an intricate donor management and retrieval service. NUTH currently undertakes paediatric cardiothoracic organ retrieval for the entire Northern half of England, and for Scotland and Northern Ireland. NUTH have also offered to undertake retrieval for European paediatric cardiothoracic retrieval. BCH would need to develop detailed plans for the management of organ retrieval for this whole area, if the cardiothoracic transplantation activity is not to decline.

Specialist staff

2.26. An established PCTTx/B2Tx service requires highly specialised multidisciplinary staff, working effectively together in a team with strong clinical and managerial leadership. Key components of this team include:

- consultant surgeons
- transplant cardiologists
- cardiac intensivists with expertise in extracorporeal life support
- perfusionists
- senior nursing staff
- transplant coordinators
- retrieval teams
- paediatric immunologists

2.27. Any transfer of the PCTTx/B2Tx service from Newcastle to Birmingham may mean the loss of valuable clinical expertise to the nationally commissioned service, in view of the geographical distance between the two centres. This would not take place without a full consultation process with affected staff.

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Capacity

2.28. Increased capacity requirements for any proposed transfer of activity need to consider the entire clinical pathway, and are not merely related to the management of the acute surgical admission. Although numbers may appear relatively small, the clinical caseload for outpatient management and follow-up is much larger, and cumulative. Children need highly specialist multidisciplinary follow-up: it is unlikely that there would be sufficient residual expertise in Newcastle for this to continue to be delivered there, should the programme transfer to BCH. The updated submission from BCH includes consideration of OPD increased capacity, but would require further scrutiny.

2.29. BCH estimates that, to deliver all of the required expansion (modelled on a total of 725 cardiac surgery cases, respiratory ECMO and PCTTx/B2Tx) would require an additional 1500 PICU bed days per year, equivalent to an additional 5 beds. This would perhaps seem a rather conservative estimate for total additional workload given that NUTH, at any one time, have between 3.7 and 7.2 children in PICU beds per 24 hr period with advanced heart failure or following transplantation (source: NUTH internal audit data). In addition, the proposal to 'seasonalise' elective cardiac surgery would require 50% extra PICU bed capacity during this period of enhanced activity for elective surgery alone. Given that the requirement for respiratory ECMO does not necessarily follow a seasonal pattern, but the clinical need is always urgent, there may not be sufficient PICU flexibility despite expansion of the service. Both GOSH and NUTH recognise the difficulties in retaining this flexibility to admit at short notice, when carrying the highly complex caseload involved in surgical management of children with advanced heart failure.

2.30. The PCTTx/B2Tx service adds additional complexity. Availability of donor organs is the main driver of transplantation activity and requires an active organ retrieval service at all times. Transplantation is, by definition, an unpredictable and resource-intensive activity. The shortage of donor organs, especially in smaller (<20 kg) children, is responsible for increased numbers of children on long term mechanical circulatory support (Berlin Hearts) and attendant long PICU and HDU stays. Transplantation or mechanical circulatory support admissions therefore have high potential for interfering with the delivery of the increased 'seasonalised' elective activity proposed by BCH, and with the capacity to deliver the necessary year-round respiratory ECMO service.

2.31. BCH has recognised that it would take at least three to four years to deliver a fully functional and safe PCTTx/B2Tx programme. Significant capital (in particular an additional operating theatre) and additional multidisciplinary staffing would be necessary. This is a highly specialist field and experienced staff would need to be trained and developed over a period of at least 2 years. Transfer of existing Newcastle staff could not necessarily be relied upon, and there may be unavoidable employment consequences for scarce specialist staff.

Reputation

2.32. BCH has already stated that there are risks in moving swiftly to any proposed service transfer, and it is unlikely to risk compromising its reputation for clinical excellence and safety. Any proposed transfer would therefore need to be undertaken over at least a three to four year timescale, which may not align with those necessary to achieve the objectives of the Safe and Sustainable Review.

2.33. NUTH are in the process of developing further expertise in transplantation, regenerative medicine and interdisciplinary research. The Trust has recently opened a large, integrated 'state of the art' Institute of Transplantation and clearly sees the ongoing provision of paediatric PCTTx/B2Tx as part of its long term strategic plan.

Summary

2.34. There is wide clinical support for the proposition that Safe and Sustainable needs to deliver its objectives of a reconfigured paediatric congenital cardiac surgery service as soon as possible.

2.35. The PCTTx/B2Tx programme provided at NUTH provides excellent clinical outcomes and (as noted in 2.24) has developed expertise in aspects of paediatric cardiothoracic transplantation which are unique to the UK, and has an international reputation in this respect.

2.36. There is evidence to support the clinical viewpoint that it takes around 8 to 10 years for a new PCTTx/B2Tx programme to develop full expertise.

2.37. 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 paper has set out for members of the JCPCT the significant risks which, in the opinion of AGNSS members, present with a proposal to re-locate the paediatric cardiothoracic transplant service from Newcastle upon Tyne Hospitals NHS Foundation Trust. BCH found it could not guarantee that it would be able to address the complex risks in accordance with the advice of the expert panel and Safe and Sustainable steering group, and to its usual high standard of quality and safety within the timeframes set out by the JCPCT. From an AGNSS perspective the delay of three years by BCH to establish the service would present significant challenges and risks to being able to maintain the existing service at Newcastle in the interim.

2.38. Most notably, there are significant caveats of assurance in the letter dated 12 January 2012 by the Chief Executive of Birmingham Children's Hospital NHS Foundation Trust (Appendix 1) around the necessary level of intensive care / high dependency provision, staffing establishment, theatre capacity and ability to implement the necessary changes in line with the period of implementation envisaged by the Joint Committee of PCTs.

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Funding and resources

2.39. Any proposed transfer of the paediatric cardiothoracic transplantation and bridge to recovery / transplantation programme would require a detailed appraisal of the financial and resource implications at a later stage. However, the need for additional theatre space at BCH if PCTTx/B2Tx services were to be transferred should be noted.

Risk assessment

2.40. A detailed risk assessment would be integral to any proposed service transfer proposal.

Summary of issues that will be addressed through implementation

A detailed implementation plan will be presented to the JCPCT on 4 July 2012. This is a summary of implementation issues that have been identified by the Decision Making Business Case:

1. Establishment of congenital heart networks by NHS commissioners and relevant NHS Trusts (page 31)
2. Development of standards for Children's Cardiology Centres and Children's District Cardiology Services by NHS commissioners working with the professional associations (page 38)
3. Implementation of a mitigation strategy in response to the potential risks around the viability of Children's Cardiology Centres by NHS commissioners working with the professional associations (page 39)
4. Implementation of the *Safe and Sustainable* standards in centres that are designated to provide children's heart surgical services by NHS commissioners and designated surgical centres (page 56)
5. Establishment of processes to take forward the JCPCT's recommendations for improving the collection, analysis and reporting of outcome data by NHS commissioners working with the professional associations and the National Institute for Cardiovascular Outcomes Research (page 58)
6. Explore how the impact of longer journeys can be mitigated for children and families by NHS commissioners, NHS Trusts and national charities (page 77)
7. Establishment of a process to strengthen the planning and delivery of paediatric retrieval services in England by NHS commissioners working with the professional associations (page 93)
8. Establishment of a process for the safe re-location of the ECMO service from Glenfield Hospital to Birmingham Children's Hospital by NHS commissioners working with both NHS Trusts (page 100)
9. Establishment of processes to strengthen the provision of Paediatric Intensive Care services in England by NHS commissioners working with the professional associations (page 102)
10. Define the congenital heart networks in London, South East and Eastern England by London Specialised Commissioning Group (page 107)
11. Develop a detailed costing of the implementation plan by NHS commissioners and NHS Trusts (page 125)
12. Assess the need for the future number and location of Paediatricians with Expertise in Cardiology by NHS commissioners and the professional associations (page 126)
13. Develop appropriate contracting arrangements across NHS services in each congenital heart network by NHS commissioners and NHS Trusts (page 127)
14. Assess the workforce implications of the JCPCT's eventual decision by NHS commissioners and NHS Trusts (page 131)

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Specialised Services