

IRP

Independent Reconfiguration Panel

***ADVICE ON
SAFE AND SUSTAINABLE PROPOSALS
FOR CHILDREN'S CONGENITAL HEART SERVICES***

Submitted to the Secretary of State for Health

30 April 2013



Independent Reconfiguration Panel

6th Floor

157 – 197 Buckingham Palace Road

London SW1W 9SP

Tel: 020 7389 8045/8046

Email: info@irpanel.org.uk

Website: www.irpanel.org.uk

Press Office

Tel: 020 7025 7530

Email: press@irpanel.org.uk

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SUMMARY AND RECOMMENDATIONS

The Secretary of State for Health asked the IRP to advise whether it is of the opinion that the proposals for change under the “*Safe and Sustainable Review of Children’s Heart Services*” will enable the provision of safe, sustainable and accessible services and if not why not. Overall, the Panel is of the opinion that the proposals for change, as presented, fall short of achieving this aim.

The Panel’s view is that people - children and adults - with congenital heart disease in England and Wales will benefit from services commissioned to national standards for the whole pathway of their care.

The Panel agree that congenital cardiac surgery and interventional cardiology should only be provided by specialist teams large enough to sustain a comprehensive range of interventions, round the clock care, training and research.

However, the Panel has concluded the JCPCT’s decision to implement option B (DMBC – Recommendation 17) was based on flawed analysis of incomplete proposals and their health impact, leaving too many questions about sustainability unanswered and to be dealt with as implementation risks.

SUMMARY AND RECOMMENDATIONS

Throughout our review, people told us that being listened to was something they valued. The opportunity to change and improve services is widely recognised and, in taking forward our recommendations, those responsible must continue to listen to legitimate criticisms and respond openly.

We set out below recommendations to enable sustainable improvements for these services and learning for future national commissioning of health services.

- The proposals for children's services are undermined by the lack of co-ordination with the review of adult services. The opportunity must be taken to address the criticism of separate reviews by bringing them together to ensure the best possible services for patients.
- Patients should receive congenital heart surgery and interventional cardiology from teams with at least four full-time consultant congenital heart surgeons and appropriate numbers of other specialist staff to sustain a comprehensive range of interventions, round the clock care, training and research.

SUMMARY AND RECOMMENDATIONS

- **Before further considering options for change, the detailed work on the clinical model and associated service standards for the whole pathway of care must be completed to demonstrate the benefits for patients and how services will be delivered across each network**
- **For the current service and any proposed options for change, the function, form, activities and location of specialist surgical centres, children’s cardiology centres, district children’s cardiology services, outreach clinics and retrieval services must be modelled and affordability retested.**
- **NHS England should ensure that a clear programme of action is implemented to improve antenatal detection rates to the highest possible standard across England.**
- **Further capacity analysis, including for paediatric intensive care units, should consider recent and predicted increases in activity, and patient flows.**

SUMMARY AND RECOMMENDATIONS

- **NHS England must establish a systematic, transparent, authoritative and continuous stream of data and information about the performance of congenital heart services. These data and information should be available to the public and include performance on service standards, mortality and morbidity.**
- **NHS England and the relevant professional associations should put in place the means to continuously review the pattern of activity and optimize outcomes for the more rare, innovative and complex procedures.**
- **NHS England should reflect on the criticisms of the JCPCT's assessment of quality and learn the lessons to avoid similar situations in its future commissioning of specialist services.**
- **More detailed and accurate models of how patients will use services under options for change are required to inform a robust assessment of accessibility and the health impact of options so that potential mitigation can be properly considered.**
- **Decisions about the future of cardiothoracic transplant and respiratory ECMO should be contingent on the final proposals for congenital heart services.**

SUMMARY AND RECOMMENDATIONS

- **NHS England should assure itself that any wider implications for other services of final proposals are fully assessed and considered within a strategic framework for the provision of specialised services.**
- **NHS England should develop a strategic framework for commissioning that reflects both the complex interdependencies between specialised services provision and population needs.**
- **NHS England must ensure that any process leading to the final decision on these services properly involves all stakeholders throughout in the necessary work, reflecting their priorities and feedback in designing a comprehensive model of care to be implemented and the consequent service changes required.**
- **NHS England should use the lessons from this review and create with its partners a more resource and time effective process for achieving genuine involvement and engagement in its commissioning of specialist services.**

SUMMARY AND RECOMMENDATIONS

The Panel's advice has been produced in the context of changing and peculiar circumstances. Since 1 April 2013, responsibility for commissioning congenital heart services rests with NHS England, which has inherited the original proposals, a judicial review, responsibility for the quality of current services and the potential consequences of the IRP's advice, subject to the Secretary of State's decision.

The Panel's advice sets out what needs to be done to bring about the desired improvements in services in a way that addresses gaps and weaknesses in the original proposals. The Panel's recommendations stand on their own irrespective of any future decision by NHS England regarding the judicial review proceedings. We note that the court's judgment of 27 March 2013 appears congruent to our own advice and that a successful appeal on legal grounds will not, of itself, address the recommendations in this report.

The Panel's advice addresses the weaknesses in the original proposals but it is not a mandate for either the status quo or going back over all the ground in the last five years. There is a case for change that commands wide understanding and support, and there are opportunities to create better services for patients. The challenge for NHS England is to determine how to move forward as quickly and effectively as possible.

SUMMARY AND RECOMMENDATIONS

Work to address gaps in the clinical model and associated service standards (Recommendation Three above) is underway and should be brought to a rapid conclusion. In parallel, there are different potential approaches to effect positive change that might be considered. These include whether to bring forward proposals for reconfiguration again or adopt a more standards-driven process that engages providers more directly in the managed evolution of services to be delivered. The critical factor to consider, in the Panel’s view, is that engagement of all interested parties is the key to achieving improvements for patients and families without unnecessary delay.

List of abbreviations

ACHD	Adult congenital heart disease
AGNSS	Advisory Group for National Specialised Services
BAME	Black Asian and Minority Ethnic
BCCA	British Congenital Cardiac Association
CCAD	Central Cardiac Audit Database
CCC	Children's cardiology centre
CHD	Congenital heart disease
CHF	Children's Heart Federation
CIAG	Clinical Implementation Advisory Group
CQC	Care Quality Commission
DCCS	District children's cardiology services
DGH	District general hospital
DH	Department of Health
DMBC	Decision-making business case
EACTS	European Association for Cardio-Thoracic Surgery
ECMO	Extracorporeal membrane oxygenation
EP	Electrophysiology
GP	General practitioner
HDU	High dependency unit
HEHASC	Health Environmental Health and Adult Social Care
HES	Hospital Episode Statistics
HIA	Health impact assessment
HOSC	Health Overview and Scrutiny Committee
HSC	Health Scrutiny Committee
IRP	Independent Reconfiguration Panel
ITU	Intensive therapy unit
JCPCT	Joint Committee of Primary Care Trusts
Joint HOSC	Joint Health Overview and Scrutiny Committee
KPMG	Klynveld Peat Marwick Goerdeler – accountancy firm
LINKs	Local involvement networks
LLR	Leicester, Leicestershire and Rutland
MDT	Multi-disciplinary team

MP	Member of parliament
NHS	National Health Service
NICOR	National Institute for Cardiovascular Outcomes Research
NICU	Neonatal intensive care unit
NSCT	National Specialist Commissioning Team
NSF	National service framework
ONS	Office for National Statistics
PBR	Payment by results
PCBC	Pre-consultation business case
PCT	Primary care trust
PDA	Patent ductus arteriosus
PEC	Paediatrician with expertise in cardiology
PICU	Paediatric intensive care unit
PwC	Price Waterhouse Cooper – accountancy firm
SCG	Specialist Commissioning Group
SHA	Strategic health authority
SMR	Standard mortality ratio
SRO	Senior responsible officer
VLAD	Variable life adjusted displays
Y&H	Yorkshire and the Humber

OUR REMIT

What was asked of us

- 1.1 The Independent Reconfiguration Panel's (IRP) general terms of reference are included in Appendix One.
- 1.2 On 27 July 2012, Cllr Christine Talbot, Chair of the Health Scrutiny Committee for Lincolnshire Health (Lincolnshire HSC) wrote to the Secretary of State for Health to refer for his consideration proposals for children's congenital cardiac (heart) services developed by NHS Specialised Services. Decisions on the proposals- known as *Safe and Sustainable* - had been made by a Joint Committee of Primary Care Trusts (JCPCT) at a meeting on 4 July 2012. A further referral of the proposals was made on 7 September 2012 by Michael Cooke and Ruth Camamile, Chairman and Vice Chair of the Leicester, Leicestershire and Rutland Joint Health and Overview Scrutiny Committee (LLR Joint HOSC) (Appendix Two).
- 1.3 The Secretary of State wrote to Lord Ribeiro, IRP Chairman, on 8 August 2012 and 13 September 2012 requesting that the IRP undertake an initial assessment in accordance with the agreed protocol for handling contested proposals for reconfiguration of NHS services. The National Specialised Commissioning Team (NSCT) provided initial assessment information. The IRP set out its initial assessment of both referrals in a letter to the Secretary of State of 21 September 2012 (Appendix Three).
- 1.4 The Secretary of State wrote to Lord Ribeiro on 22 October 2012 asking the IRP to undertake a full review of the *Safe and Sustainable* proposals and attaching terms of reference (Appendix Four). The Panel was asked to submit its advice by 28 February 2013.
- 1.5 A further referral was made on 27 November 2012 by Cllr John Illingworth, Chair, Yorkshire and the Humber Joint Health Overview and Scrutiny Committee (Y&H Joint HOSC) (Appendix Two). The Secretary of State wrote

to Lord Ribeiro on 29 November 2012 requesting an initial assessment and asking the Panel to consider the suitability of incorporating the referral into the full review already underway.

1.6 The IRP responded to the Secretary of State on 7 December 2012 concluding that the Y&H Joint HOSC's referral was suitable for inclusion within its review of the *Safe and Sustainable* proposals.

1.7 Revised terms of reference were issued with the Secretary of State's letter of 10 December 2012 to Lord Ribeiro together with an amended date for submission of advice (Appendix Four). The Panel was asked to advise by 28 March 2013:

- a. *Whether it is of the opinion that the proposals for change under the "Safe and Sustainable Review of Children's Congenital Heart Services" will enable the provision of safe, sustainable and accessible services and if not, why not;*
- b. *On any other observations the panel may wish to make in relation to the changes*
- c. *On how to proceed in light of a. and b. above and taking account of the issues raised by the Health Scrutiny Committee for Lincolnshire, the Leicester, Leicestershire and Rutland Joint Health Overview and Scrutiny Committee and the Yorkshire and the Humber Joint Health Overview and Scrutiny Committee, subject to the proviso at d. below*
- d. *The decision of the secretary of State taken regarding the designation of Birmingham Children's Hospital as a nationally commissioned provider of the Extra Corporeal Membrane Oxygenation service for children with respiratory failure should not form part of this review as this decision was not taken by the Joint Committee of Primary Care Trusts.*

The deadline for this review is subject to any further instructions the Secretary of State may need to issue in relation to timing in light of the judicial review challenge brought against the Joint Committee of Primary Care Trusts¹.

- 1.8 The Secretary of State issued further instructions to the IRP on 15 March 2013 extending the deadline for submission of the Panel's advice to 30 April 2013 so that account could be taken of the decision on redress in the light of the judicial review finding against the JCPCT² (Appendix Four).
- 1.9 Changes to the structure of the NHS came into effect on 1 April 2013 - notably, in this instance, the abolition of primary care trusts and as a consequence the abolition of the JCPCT whose decisions are the subject of this referral. Commissioning of NHS specialised services is now the responsibility of NHS England.

¹ In October 2012, Save Our Surgery Ltd, an independent charity in Leeds, applied for a judicial review of the JCPCT's decision of 4 July 2012.

² On 7 March 2013, the Judge ruled against the JCPCT. The redress hearing took place on 27 March 2013 and the final written judgment was released on 24 April 2013.

OUR PROCESS

How we approached the task

- 2.1 The NSCT was asked to provide the Panel with relevant documentation and to help with arrangements for site visits, meetings and interviews with interested parties.
- 2.2 The Lincolnshire HSC, LLR Joint HOSC and Y&H Joint HOSC were also invited to submit documentation and suggest other parties to be included in meetings and interviews.
- 2.3 An IRP press release, advising that the Panel would be undertaking a review, was issued on 6 November 2012 and a media statement, confirming the inclusion of the Y&H Joint HOSC referral within the review, was issued on 11 December 2012 (Appendix Five).
- 2.4 All members of the IRP took part in the review. All ten sites currently providing children's congenital cardiac surgery and the cardiology centres in Manchester, Cardiff and Oxford were visited and evidence taken. The Panel undertook more than 25 days of oral evidence, meeting a wide cross section of individuals and organisations. Members were accompanied on visits and at evidence sessions by the IRP Secretariat. Details of the people seen during these sessions are included in Appendix Six.
- 2.5 All members of parliament in England and Wales were invited to submit views to the Panel. Panel members met Liz Kendall (Leicester West), Nicky Morgan (Loughborough), Jon Ashworth (Leicester South), Lilian Greenwood (Nottingham South), Keith Vaz (Leicester East), Heather Wheeler (South Derbyshire), the Bishop of Leicester and Lord Bach of Butterworth on 13 December 2012. Members met Greg Hands (Chelsea and Fulham) on 6 February 2013 and on 13 February 2013 met Stuart Andrew (Pudsey), Kevin Barron (Rother Valley), Hilary Benn (Leeds Central), Nic Dakin (Scunthorpe), Philip Davies (ShIPLEY), Fabian Hamilton (Leeds North East), Kris Hopkins

(Keighley), John Healey (Wentworth and Dearne), Jason McCartney (Colne Valley), Austin Mitchell (Grimsby), Greg Mulholland (Leeds North West), Meg Munn (Sheffield Heeley), Barry Sheerman (Huddersfield), Angela Smith (Penistone and Stocksbridge), Julian Smith (Ripon and Skipton), Julian Sturdy (York Outer), Martin Vickers (Cleethorpes), Rosie Winterton (Doncaster Central) and Lady Masham. Other MPs were represented by parliamentary researchers.

- 2.6 A list of all the written evidence received – from the NSCT, NHS trusts, scrutiny committees, MPs and all other interested parties – is contained in Appendix Seven. The Panel considers that the documentation received, together with the information obtained in meetings, provides a fair representation of the views from all perspectives.
- 2.7 Throughout our consideration of these proposals, and in addressing our terms of reference, the Panel’s focus has been the needs of patients, their families, the public and staff.
- 2.8 The Panel wishes to record its thanks to all those who contributed to this process. We also wish to thank all those who gave up their valuable time to present evidence to the Panel and to everyone who contacted us offering views.
- 2.9 The advice contained in this report represents the unanimous views of the Chairman and members of the IRP.

THE CONTEXT

A brief overview

- 3.1 Following a higher than expected number of deaths of children receiving heart surgery between 1984 and 1995, the Bristol Royal Infirmary Inquiry Report³ (the Kennedy report) was published in 2001 recommending that specialist expertise be concentrated in fewer surgical units in England. A report by the Paediatric and Congenital Cardiac Services Review Group (the Munro report) was published in 2003. Further consideration by the Department of Health (DH) and relevant medical bodies followed until, in May 2008, the National Specialised Commissioning Team (NSCT) was asked to undertake a review with a view to reconfiguring surgical services for children with congenital heart disease⁴. Taking into consideration concerns that surgeons and resources may be spread too thinly across the centres, the review considered whether expertise would be better concentrated on fewer sites than the current eleven in England.
- 3.2 The *Safe and Sustainable* team was established to manage the review process on behalf of the ten Specialised Commissioning Groups (SCG) and their local primary care trusts (PCT). In December 2008, an expert clinical Steering Group was formed to direct the process of developing a report to the NHS Management Board and DH Ministers.
- 3.3 Draft quality standards, against which surgical centres would be assessed, were published in September 2009 and sent directly to all health overview and scrutiny committees and other organisations for comment. A revised version of the standards was published in March 2010. Also in March 2010, following a number of post-surgical deaths, surgery at the paediatric cardiac unit at the John Radcliffe Hospital, Oxford, was suspended.

³ Bristol Royal Infirmary Inquiry, Learning from Bristol: The report of the public enquiry into children's heart surgery at the Bristol Royal infirmary 1984 to 1995 (the Kennedy report) July 2001

⁴ A working group to consider services for adults was also established in 2008. The working group published draft standards in 2009 (*Designation of Specialist Service providers for Adults with Congenital Heart Disease*). An Adults Congenital Heart disease group was re-convened in July 2011 to refine the standards and model of care in light of emerging *Safe and Sustainable* recommendations.

- 3.4 A process of self-assessment by surgical centres commenced in April 2010. In the same month, the *Safe and Sustainable* team published *Children's Heart Surgery – the Need for Change*. Later in April 2010, the NHS Operations Board recommended to DH Ministers that PCTs delegate their consultation responsibilities and decision-making powers to a joint committee of PCTs (JCPCT). The Secretary of State for Health approved the establishment of the JCPCT in June 2010. The revised NHS Operating Framework confirmed that the *Safe and Sustainable* review was expected to deliver recommendations for consultation in the autumn of 2010.
- 3.5 Between May and June 2010, an expert panel, chaired by Professor Sir Ian Kennedy, visited each surgical centre to meet staff and families and to assess each centre's ability to comply with the standards. Pre-consultation engagement events commenced in June 2010. In September 2010, the case for change was supported by the National Clinical Advisory Team and proposed processes for consultation were endorsed by OGC Gateway review. The JCPCT met for the first time as a formally constituted body in October 2010. Briefings for HOSCs by SCG representatives began the following month.
- 3.6 In August 2010, a review conducted by South Central Strategic Health Authority (SHA) recommended that the paediatric cardiac surgical service at the John Radcliffe Hospital, Oxford, should remain suspended pending the outcome of the *Safe and Sustainable* review.
- 3.7 In November 2010, on behalf of the JCPCT, a panel of experts chaired by Mr James Pollock, consultant congenital cardiac surgeon, investigated historical deaths at three surgical units in Leeds, Leicester and London (the Evelina Children's Hospital). The outcome of this investigation was presented to the Kennedy panel to consider whether it was necessary to revise its assessment of any of the three centres. The Kennedy panel found no cause to revise its assessment and the panel's report was published in December 2010.
- 3.8 Options for consultation were agreed by the JCPCT in February 2011 and a four-month public consultation began in March 2011. The consultation

proposed concentrating clinical expertise on fewer sites by reducing the number of surgical centres from eleven to either six or seven.

- 3.9 A briefing for scrutiny committees, informing them of the forthcoming launch of the consultation, was issued in February 2011. Earlier communications to HOSCs, notably a Centre for Public Scrutiny briefing in April 2010, had alerted them to the intention to conduct a formal consultation and encouraged them to consider the need for a joint committee. In recognition of changes to membership resulting from local elections in May 2011, the deadline for receipt of consultation responses from HOSCs was extended to 5 October 2011. In the event, no national joint committee was formed and arrangements for scrutiny varied around the country with a mixture of individual and area and regional joint committees ultimately responding to the consultation.
- 3.10 Representatives of East Midlands SCG provided a presentation on the *Safe and Sustainable* review to a meeting of the LLR Joint HOSC in March 2011 and Lincolnshire HSC in April 2011 and to two Deliberative Stakeholder Events in Lincoln and Sleaford in May 2011. Between March and September 2011, representatives of the Yorkshire and the Humber SCG attended several meetings of the Y&H Joint HOSC to answer questions on the review. Engagement activities were held with focus groups in Yorkshire locations during the same period.
- 3.11 On 22 June 2011, it was announced that an independent panel of national and international experts, chaired by Adrian Pollitt, a former director of national specialised commissioning, had been appointed to advise the JCPCT on the potential impact of the children's congenital heart proposals on other services at the Royal Brompton Hospital.
- 3.12 The formal public consultation closed on 1 July 2011 (except for HOSCs). An independent analysis of the consultation, commissioned from Ipsos MORI, was published in August 2011. That analysis acknowledged that the impact of the proposed changes on other services had been raised as an issue during consultation.

- 3.13 A judicial review of the proposal to reduce the number of surgical centres in London from three to two centres was initiated by the Royal Brompton & Harefield NHS Foundation Trust in July 2011.
- 3.14 During August 2011, representatives of East Midlands SCG provided briefings for East Midlands HOSCs about responses to the public consultation and on a draft final Health Impact Assessment. Representatives of the Yorkshire and the Humber SCG provided briefings for the Y&H Joint HOSC in October and December 2011.
- 3.15 In September 2011, the *Safe and Sustainable* Steering Group considered clinical issues raised during the consultation and advised the JCPCT to agree the quality standards and model of care as set out in the consultation document. A supplementary report in response to issues raised during the consultation was published by the Kennedy panel in October 2011.
- 3.16 The Report of the Independent Panel on the Relationship of Interdependencies at the Royal Brompton Hospital (the "*Pollitt Report*") was published on 15 September 2011. It stated that "... *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*".
- 3.17 The formal consultation with HOSCs concluded on 5 October 2011. Also in that month, at the JCPCT's request, the Kennedy panel published a supplementary report in response to issues raised during consultation. The panel clarified that University Hospital of Leicester NHS Trust did not meet the requirement for the co-location of core paediatric services.
- 3.18 The Y&H Joint HOSC referred the *Safe and Sustainable* review of children's congenital cardiac services to the Secretary of State on 14 October 2011. The referral was particularly concerned with services currently provided at Leeds

General Infirmary and the potential effects of the proposals on patients and residents in Yorkshire and the Humber.

- 3.19 On 7 November 2011, the judgment was delivered in the judicial review brought by the Royal Brompton & Harefield NHS Foundation Trust. The judge, whilst rejecting a number of the arguments put forward, found against the JCPCT on a matter of process. An appeal against the judgment was lodged.
- 3.20 Later in November 2011, the JCPCT invited the 11 centres providing children's congenital heart services to submit new evidence demonstrating their compliance with the national quality standards relating to innovation and research.
- 3.21 The IRP submitted its initial assessment advice on the referral by the Y&H Joint HOSC on 13 January 2012. As well as commenting on the consultation process, and on communication and relationships between the Y&H Joint HOSC and the JCPCT, the Panel offered advice in relation to a number of outstanding requests for information sought by the Committee. The Secretary of State announced on 23 February 2012 that he had accepted the Panel's advice in full.
- 3.22 The Royal Borough of Kensington and Chelsea Health Environmental Health and Adult Social Care (HEHASC) Scrutiny Committee referred the *Safe and Sustainable* review of children's congenital cardiac services to the Secretary of State on 27 March 2011. The referral was particularly concerned with services currently provided at the Royal Brompton Hospital and the potential effects of the proposals on patients and residents in west London and south east England.
- 3.23 On 19 April 2012, the Court of Appeal announced its decision, dismissing the grounds raised by the Royal Brompton & Harefield NHS Foundation Trust and finding the public consultation to be lawful and proper.
- 3.24 The IRP submitted its initial assessment advice on the referral by the Kensington and Chelsea HEHASC Scrutiny Committee 23 May 2012. The

Panel offered comments on the JCPCT's efforts to address concerns raised by respondents to the consultation process that would inform the JCPCT ahead of its forthcoming decision-making meeting. The Secretary of State announced on 15 June 2012 that he had accepted the Panel's advice in full.

- 3.25 In line with the IRP's initial assessment advice on the referrals by Y&H Joint HOSC and by Kensington and Chelsea HEHASC Scrutiny Committee, some further work was undertaken to inform the JCPCT before its decision-making meeting.
- 3.26 The JCPCT held its decision-making meeting on 4 July 2012 and agreed that seven managed clinical networks should be established across England (and serving Wales). Each network would be led by a surgical centre - based in the Freeman Hospital Newcastle (north), Alder Hey Children's Hospital Liverpool (north west and north Wales), Birmingham Children's Hospital (midlands), Bristol Royal Hospital for Children (south west and south Wales), Southampton General Hospital (south central) and Great Ormond Street Hospital for Children and Evelina Children's Hospital (London, East Anglia and the south east).
- 3.27 On 13 July 2012, the Secretary of State for Health, having accepted the advice of the Advisory Group for National Specialised Services, designated Birmingham Children's Hospital as a nationally commissioned provider of Extra Corporeal Membrane Oxygenation (ECMO) services for children with respiratory failure – in place of the existing unit at Glenfield Hospital, Leicester.
- 3.28 The Lincolnshire HSC referred the *Safe and Sustainable* proposals to the Secretary of State on 27 July 2012. The referral was particularly concerned with services currently provided at Glenfield Hospital, Leicester and the potential impact of the proposals on patients and residents in Lincolnshire.
- 3.29 The LLR Scrutiny Committee referred the *Safe and Sustainable* proposals to the Secretary of State on 7 September 2012. The referral was particularly

concerned with services currently provided at Glenfield Hospital, Leicester and the potential impact of the proposals on patients and residents in Leicester, Leicestershire and Rutland.

- 3.30 Following an initial assessment of both referrals by the IRP, the Secretary of State wrote to Lord Ribeiro on 22 October 2012 commissioning a full review of the *Safe and Sustainable* proposals from the Panel.
- 3.31 In October 2012, Save Our Surgery Ltd, an independent charity in Leeds, applied for a judicial review of the JCPCT's decision not to release scoring information related to the Kennedy panel assessment during the consultation period.
- 3.32 A further referral of the *Safe and Sustainable* proposals was made on 27 November 2012 by the Y&H Joint HOSC. The referral was particularly concerned about services currently provided at Leeds Children's Hospital (Leeds General Infirmary) and the potential impact of the proposals on patients and residents across Yorkshire and the Humber. In responding to the Secretary of State's request for initial assessment advice, the Panel confirmed the suitability of the Y&H Joint HOSC referral for inclusion within the full review already underway.
- 3.33 Revised terms of reference were issued with the Secretary of State's letter of 10 December 2012 to Lord Ribeiro together with an amended date for submission of the Panel's advice – 28 March 2013.
- 3.34 On 7 March 2013, the Judge ruled against the JCPCT in the judicial review brought by Save our Surgery Ltd and confirmed that a further hearing would be held on 27 March 2013 to consider redress.
- 3.35 On 15 March 2013, the Secretary of State issued further instructions to the IRP extending the deadline for submission of the Panel's advice to 30 April 2013 to enable the Panel to take account of the Judge's decision on redress.

- 3.36 On 18 April 2013, NHS England, the body that inherited responsibility for the *Safe and Sustainable* review from the JCPCT, started the process of appealing the judicial review.
- 3.37 The final written judgment was released on 24 April 2013. The order of the court was to quash the acceptance by the JCPCT, dated 4 July 2012, of Recommendation 17 contained in the Decision-Making Business Case of the *Safe and Sustainable* Review of Children's Congenital Cardiac Services in England, July 2012.

INFORMATION

What we found

4.1 A vast amount of written and oral evidence was submitted to the Panel. We are grateful to all those who took the time to offer their views and information. The evidence put to us is summarised below – firstly general background information followed by an outline of the proposals, the reasons for referral by the Lincolnshire HSC, LLR Joint HOSC, and Y&H Joint HOSC, issues raised by others and finally, the evidence gathered.

4.2 **What is congenital heart disease?**

4.2.1 Congenital heart disease (CHD) refers to defects in a child's heart that develop in the womb and are present at birth. CHD is a life-long condition that can be life threatening. It affects one in 133 children, such that around eight out of every 1,000 babies will have some form of congenital heart disease. To put this in context, there were 723,913 live births in England and Wales in 2011⁵. This means that approximately 5,800 babies with CHD were born that year. The number of children born with CHD is set to rise with projections of higher numbers of births in the period to 2025⁶.

4.2.2 There are two main types of CHD:

- Cyanotic heart disease – where the patient appears blue, is a heart defect which results in low blood oxygen levels
- Acyanotic heart disease – is a heart defect with normal levels of oxygen in the blood but abnormal blood flow may cause high blood pressures in vessels supplying the lung

4.3 **Who has CHD?**

4.3.1 In the majority of instances when a baby is born with CHD, there is no known reason for the heart to have formed improperly. Some types of congenital heart

⁵ Office for National Statistics October 2011

⁶ Office for National Statistics October 2011

defects can be related to an abnormality of an infant's chromosomes, for example, children with Down Syndrome have a high incidence of CHD.

4.3.2 The Health Impact Assessment Scoping Report⁷ identified that there are several 'at risk' groups which are, proportionally, more likely to be affected by CHD than the wider population. These are:

- Women who smoke and/or are obese during pregnancy
- Those in socio-economically deprived groups
- People living in areas with poor air quality
- Black, Asian and Minority Ethnic (BAME) Groups particularly those related to Indian, Pakistani, Bangladeshi and other Indian sub-continent populations

4.3.3 There are 35 medically recognised heart defects and prevalence by defect varies significantly as illustrated in Table 1.

Table 1: Congenital heart defect prevalence by defect

Defect	Median prevalence per 100,000 live births (lower quartile, upper quartile)	Prevalence per 100,000 live births
Aortic (valve) stenosis (AS)	26 (16, 39)	20
Atrial septal defect (ASD)	56 (37, 106)	28
Coarctation of the aorta (COA)	36 (29, 49)	35
Complete atrioventricular septal defect (CAVSD)	34 (24, 40)	277
Hypoplastic left heart (HLH) syndrome	23 (15, 28)	14
Interruption of the aorta arch (IAA)	[not cited]	8
Persistent (patent) ductus arteriosus (PDA)	57 (32, 78)	50
Pulmonary atresia (PA)	8 (8, 15)	21
Pulmonary stenosis (PS)	53 (35, 84)	65
Tetralogy of Fallot (TOF)	35 (29, 58)	31
Total anomalous pulmonary venous connection (TAPVC)	9 (6, 12)	9
Transposition of the great arteries (TGA)	30 (23, 29)	30
Ventricular septal defect (VSD)	Over 4000 (if series involving echocardiography at birth included)	197 (echocardiography not used to screen)

Source: Knowles R, Griebisch I, Dezateux C, *et al.* (2005)

⁷ Safe and Sustainable: Review of Children's Congenital Heart Surgery Services in England Health Impact Assessment: Final Scoping Report February 2011

4.4 **Caring for children with CHD**

- 4.4.1 CHD can, in some cases, be diagnosed in the womb. For other babies it is not identified until after birth or may even remain undetected until adulthood.
- 4.4.2 If, during a routine antenatal scan, the obstetrician or sonographer considers that a baby might have a heart problem, the mother would be referred to a fetal cardiologist for a specialist fetal cardiology assessment.
- 4.4.3 Prenatal diagnosis of major CHD improves results for children and can help to prevent serious complications such as brain damage. It also enables parents to consider whether to terminate the pregnancy. There has been a reduction in the percentage of pregnancies terminated in recent years due to improvements in diagnosis, the range of available interventions and outcomes.
- 4.4.4 If there is a diagnosis prior to birth, a plan of care would be set in place for mother and baby including, where clinically indicated, for the birth to take place in or near a cardiac surgical centre.
- 4.4.5 Those children diagnosed at a later stage of life might be seen initially by a GP or a paediatrician at a local hospital before being referred to a paediatric cardiologist.
- 4.4.6 Most children with CHD require monitoring and advice about their condition and its impact on daily life. Up to half of children with CHD will not need surgery. They will, however, require long-term expert cardiology support and a few children will require medication to treat their condition. Around 25-30 per cent of children with CHD have other significant healthcare needs.
- 4.4.7 Many children with CHD have problems eating and gaining weight and have to follow a special diet. Children with CHD are more susceptible to illnesses such as chest infections.
- 4.4.8 There is a wide range of different interventional cardiology procedures and over 150 different surgical procedures that are used to treat children with CHD. Sometimes surgeons and cardiologists will operate together or two

surgeons may operate on a child together. Procedures range in complexity from day cases to surgery for highly complex conditions that require multiple operations at stages throughout life. The majority of operations are planned, but some emergency procedures are undertaken. Some children stay in hospital for many weeks or even months and this can have a significant impact on children and their families.

4.4.9 Children with CHD are supported by a range of specialists such as paediatricians with expertise in cardiology, cardiac liaison nurses, psychologists, paediatric cardiologists and congenital cardiac surgeons. To support the surgical and interventional cardiology procedures, a team of specialists is required including cardiac anaesthetists, perfusionists, intensivists and specialist nurses.

4.5 **Caring for young people and adults with CHD**

4.5.1 Until relatively recently, fewer than 20 per cent of children born with CHD used to reach the age of 16. However, by the 1980s - due to advances in heart surgery and more recently interventional cardiology - 85 per cent of children reached adulthood. There are now more adults than children with CHD in the UK and the number of adults living with CHD is increasing rapidly. CHD has become a lifelong condition. However, major heart surgery for CHD is commonly carried out during childhood and currently children still account for the majority of all congenital heart operations.

4.5.2 An important stage in the care of CHD patients is 'transition'. This is when children move from being under the care of children's services to under the care of adult services. This can be a crucial time in ensuring that young people feel supported to address the implications of their condition as they move into adult life. Teenagers with CHD are often at more risk of emergency hospital admissions and deteriorations in their health, as well as psychological problems.

4.5.3 For some females born with CHD it is safe to have children but for others the risks of complications associated with getting pregnant and giving birth are

significant and unplanned pregnancy can be extremely serious. More women with CHD are giving birth as the number of adults with CHD increases.

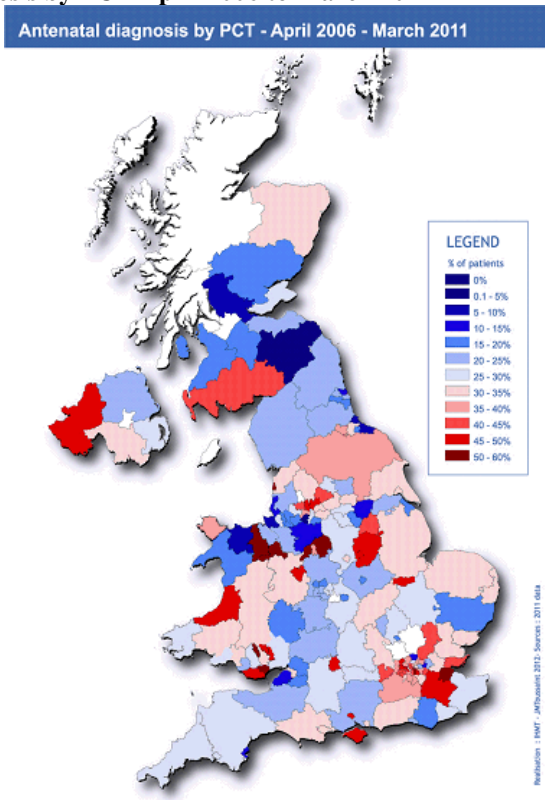
4.5.4 People with CHD face a range of issues in adulthood. For some, due to hereditary factors, the whole family is affected and need to be supported as a family unit. As more people with CHD get older, acquired heart problems become more common. Most adults with CHD will need lifelong monitoring and some will need surgery.

4.6 Current service provision

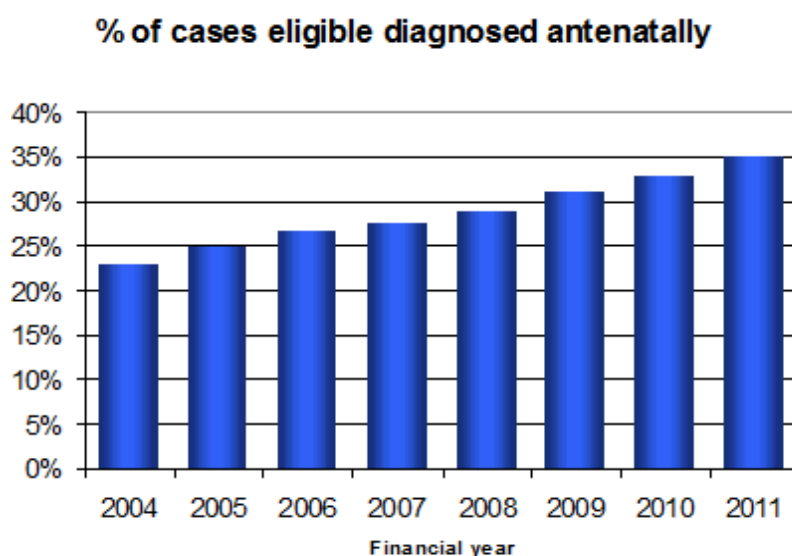
4.6.1 The start of the pathway of care for children with CHD may begin in the prenatal stage with a routine obstetric scan at their local maternity unit.

4.6.2 There is wide variation in the antenatal detection rates around the country as shown by the map below.

Map 1 Antenatal diagnosis by PCT April 2006 to March 2011



4.6.3 However, the percentage of cases of CHD that are being diagnosed antenatally is improving. The graph below shows the increase in detection rates between 2004 and 2011 for the UK.

Figure 1⁸

4.6.4 Following the antenatal scan, or initial assessment by a GP or paediatrician, children with suspected CHD are referred to the specialist children's congenital heart service.

4.6.5 NHS specialist services for children with congenital heart disease are currently provided principally at ten hospitals in England at the following NHS trusts:

- Freeman Hospital at Newcastle-Upon-Tyne Hospitals NHS Foundation Trust
- Leeds General Infirmary at Leeds Teaching Hospitals NHS Trust
- Alder Hey Children's NHS Foundation Trust
- Glenfield Hospital at University Hospitals of Leicester NHS Trust
- Birmingham Children's Hospital NHS Foundation Trust
- Great Ormond Street Hospital For Children NHS Foundation Trust
- Bristol Royal Hospital for Children at University Hospitals Bristol NHS Foundation Trust
- Royal Brompton Hospital at Royal Brompton & Harefield NHS Foundation Trust

⁸ Source NICOR:

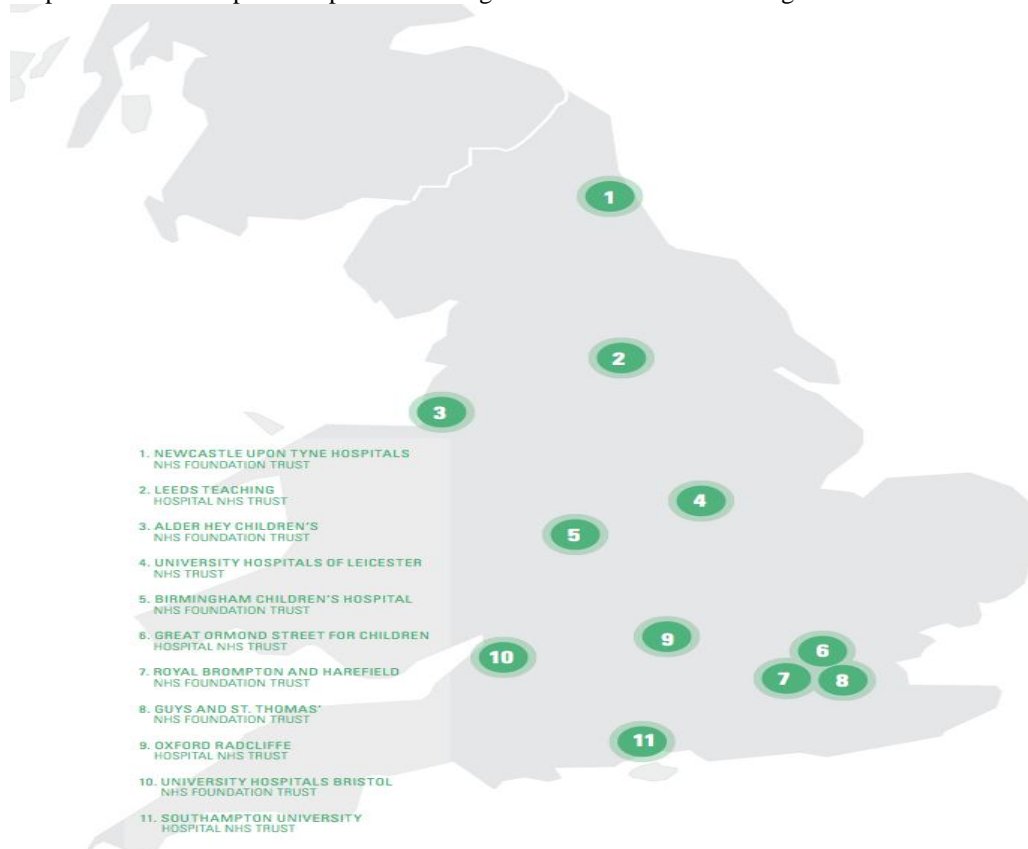
https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/vwContent/Antenatal%20Diagnosis?Opendocument

- Evelina Children’s Hospital at Guy’s and St Thomas’ NHS Foundation Trust
- Southampton General Hospital at Southampton University Hospitals NHS Foundation Trust

4.6.6 John Radcliffe Hospital in Oxford ceased to undertake paediatric congenital heart surgery in March 2010 and formed a joint network with Southampton University Hospitals NHS Foundation Trust. John Radcliffe Hospital continues to provide a paediatric congenital cardiology service.

4.6.7 The location of the hospitals is shown in Map 2 below.

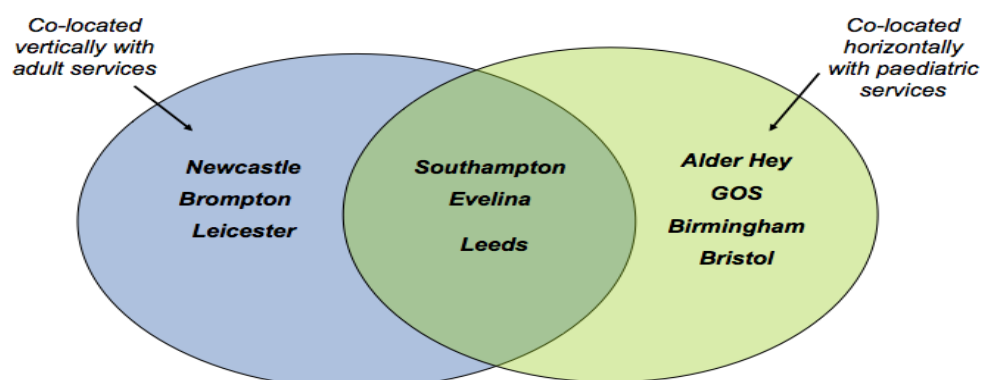
Map 2: Location of specialist paediatric congenital cardiac centres in England



4.6.8 Manchester Children’s Hospital at the University of Manchester Teaching Hospitals NHS Foundation Trust provides a paediatric congenital cardiology service in partnership with Alder Hey Children’s Hospital NHS Foundation Trust.

- 4.6.9 University Hospital of Wales in Cardiff ceased to undertake congenital heart surgery in 1998 and since 2001 has worked principally with the surgical unit in Bristol Royal Hospital for Children. University Hospital of Wales continues to provide a paediatric congenital cardiology service.
- 4.6.10 Paediatric cardiologists from each of the ten surgical centres provide outreach clinics in a number of district general hospitals in their network area. Outreach clinics are held in 157 locations. The location of these clinics is shown in the table in Appendix 10.
- 4.6.11 Children's congenital heart services are currently delivered in hospitals that fall into one of three categories:
- Specialist hospitals – Freeman Hospital, Royal Brompton Hospital and Glenfield Hospitals providing services for children and adults
 - Specialist children's hospitals– Great Ormond Street Hospital, Alder Hey, Birmingham Children's Hospital, Bristol Royal Hospital for Children
 - Specialist children's units within a large acute teaching hospitals – Leeds General Infirmary, Evelina Children's Hospital and Southampton General Hospital

Figure 2: pattern of co-location of children's congenital cardiac services



- 4.6.12 Table 2 sets out the number of surgical procedures in 2009/10, 20010/11 and 2011/12 by centre and the number of surgeons at each centre in June 2010 (as set out in the *Safe and Sustainable* consultation document) and in October 2012. Table 3 sets out the number of interventional cardiology procedures over the years 2009/10 to 2011/12.

Table 2: numbers of paediatric congenital heart surgery procedures and surgeons 2009/10 - 2011/12⁹

Children's Congenital Cardiac Centre	Paediatric surgical procedures			No. surgeons	
	2009/10	2010/11	2011/12 ¹⁰	Jun 2010	Oct 2012
Alder Hey Liverpool	398	434	393	3	3
Birmingham	553	478	499	3	4
Bristol	281	326	304	3	3
Evelina	350	387	401	3	3
Freeman Newcastle	241	265	252	2	3
Great Ormond Street	586	634	657	4	4
Glenfield Leicester	222	195	198	3	3
Leeds General Infirmary	300	335	316	3	4
Oxford Radcliffe	101	12	6	1	n/a
Royal Brompton	413	427	397	4	4
Southampton	231	333	341	2	3
Total	3,676	3,826	3,764		

Table 3: numbers of paediatric interventional cardiology procedures 2009/10 -2011/12¹¹

Children's Congenital Cardiac Centre	Paediatric interventional cardiology procedures		
	2009/10	2010/11	2011/12 ¹²
Alder Hey Liverpool	202	170	201
Birmingham	346	367	360
Bristol	173	211	221
Evelina	181	172	196
Freeman Newcastle	103	92	104
Great Ormond Street	261	287	307
Glenfield Leicester	136	123	122
Leeds General Infirmary	162	182	149
Oxford Radcliffe	86	40	3
Royal Brompton	207	218	297
Southampton	105	147	192
Total	1,962	2,009	2,152

4.6.13 Appendix 11 provides a profile of each of the ten centres covering:

- Surgical and interventional cardiology activity in 2011/12
- Numbers of key medical and nursing staff as at 31st Oct 2012
- Other associated clinical specialties located on the hospital site
- Accommodation for parents and families

⁹ Source CCAD - figures include foreign private patient activity (this activity was excluded from the figures used by the Safe and Sustainable Review)

¹⁰ Data for 2011/12 is provisional as it has not yet been validated

¹¹ Source CCAD - figures include foreign private patient activity (this activity was excluded from the figures used by the Safe and Sustainable Review)

¹² Data for 2011/12 is provisional as it has not yet been validated

4.6.14 The number of surgical and interventional procedures undertaken in England has increased by around nine per cent over the past six years as shown in Table 4 below.

Table 4: number of paediatric surgical and interventional cardiology procedures undertaken in England during 2006/07 to 2011/12¹³

Year	2006/ 07	2007/ 08	2008/ 09	2009/ 10	2010/ 11	2011/ 12 ¹⁴	% change
Surgical procedures	3,447	3,390	3,413	3,676	3,826	3,764	+9
Interventional cardiology	1,970	1,788	2,015	1,962	2,009	2,152	+9
Total	5,417	5,178	5,428	5,638	5,835	5,916	+9

4.7 Demography and at risk populations

4.7.1 The ten surgical centres in England serve the population of England and Wales for paediatric congenital heart surgery. In 2010, the population of 0-14 year olds in England and Wales was 9,661,000.

4.7.2 The latest population projections indicate that the population of 0-14 year olds will grow to 11,178,000 by 2025¹⁵, an increase of 16 per cent on the 2010 population. As shown in Table 5, population growth in the 0-14 age group is projected to be most pronounced in London (26 per cent), the East Midlands (19 per cent), East (17 per cent) and West Midlands (16 per cent). Within London, the growth is projected to be particularly focused on northeast London.

¹³ Figures include foreign private patient activity (this activity was excluded from the figures used by the Safe and Sustainable Review)

¹⁴ Data for 2011/12 is provisional as it has not yet been validated

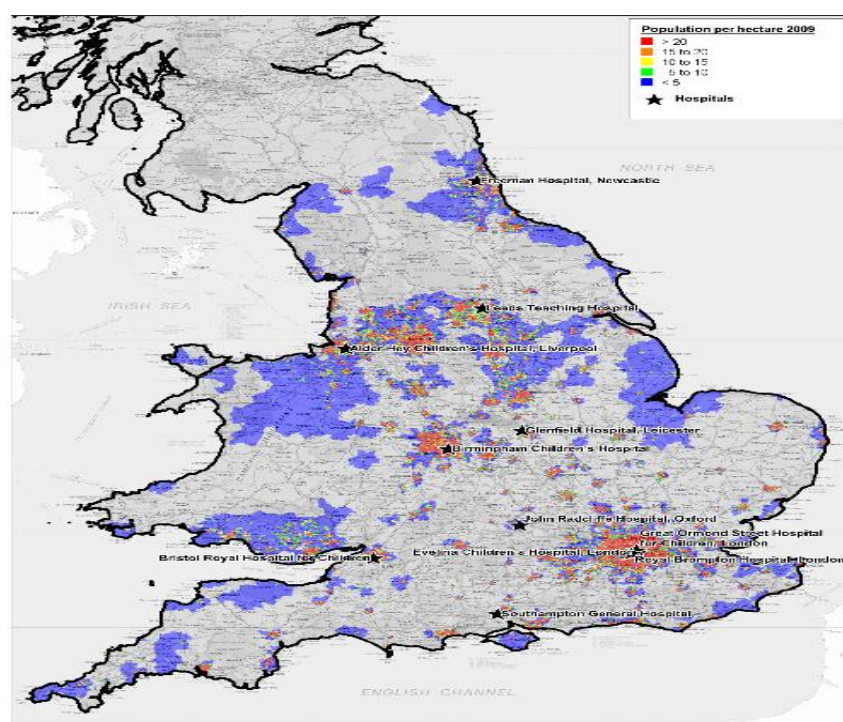
¹⁵ UK national statistics website. available at: www.statistics.gov.uk/hub/index.html

Table 5: projected population growth for 0-14 year olds in England and Wales 2010 to 2025¹⁶

Region	0-14 population 2010	0-14 population projection 2025	% change
England	9,150	10,610	16
Wales	511	568	
NE	427	465	9
NW	1,239	1,372	11
Y&H	908	1,031	13
WM	990	1,152	16
EM	765	912	19
East	1,026	1,199	17
London	1,455	1,829	26
SE	1,504	1,672	11
SW	861	959	11

4.7.3 Some populations have an increased risk of CHD. Map 3 below shows the postcode districts with high densities of two of more at risk groups.

Map 3: Postcode districts with high densities of two or more at risk groups¹⁷



¹⁶ UK national statistics website. available at: www.statistics.gov.uk/hub/index.html

¹⁷ Safe and Sustainable: Review of Children’s Congenital Heart Surgery Services in England Health Impact Assessment: Final Scoping Report February 2011. Contains Ordnance Survey data (c) Crown copyright and database right 2011

4.8 Service Quality

4.8.1 The Care Quality Commission (CQC) has inspected each of the hospitals providing services during the last year. The inspections do not, however, necessarily include the paediatric cardiac wards and services. The date of the latest inspection and the outcome is set out in Table 6 below.

Table 6: Date and outcome of most recent CQC inspections at the ten hospitals providing paediatric congenital heart services

Hospital	Date of CQC inspection	Outcome
Alder Hey	January 2013	Compliant
Birmingham Children's Hospital	December 2012	Improvements required for standards of staffing.
Bristol Royal Hospital for Children	September 2012	Formal warning issued to University Hospitals Bristol NHS Foundation Trust in relation to staffing levels on the cardiac ward. Trust judged by CQC to be compliant November 2012.
Evelina Children's Hospital	March 2013	Compliant
Freeman Hospital	July 2012	Compliant
Glenfield Hospital	December 2012	Compliant
Great Ormond Street Hospital	January 2013	Compliant
Leeds General Infirmary	October 2012	Compliant
Royal Brompton	February 2013	Compliant
Southampton General Hospital	December 2012	Findings of non-compliance in relation to 4 of 5 standards; care and welfare, staffing, management of medicines and records

4.8.2 The areas of non-compliance raised by CQC for Birmingham Children's Hospital related to support for staff and staffing levels in operating theatres. There had recently been a change in staff's job roles as theatre staff were moved to work as a single team. The Trust has advised CQC it has taken action to address the issues.

- 4.8.3 CQC issued a warning notice to Bristol Royal Hospital for Children due to concerns about staffing levels on the paediatric cardiac ward, particularly in relation to high dependency beds. CQC has since confirmed that the Trust has taken the necessary action and is now compliant.
- 4.8.4 CQC found evidence of non-compliance at Southampton General Hospital in December 2012. The concerns related to quality of care, staffing levels, management of medication and record keeping. As at 26 April 2013, CQC had not published any statement about the outcome of checks on action in response to non-compliance.
- 4.8.5 On 28 March 2013, a meeting took place between CQC, NHS England and Leeds Teaching Hospitals NHS Trust regarding preliminary data suggesting high mortality, concerns about staffing levels, whistle blowing information from clinicians, and complaints from patients. In response to the concerns raised, the Trust took the decision to suspend children's congenital cardiac surgery at Leeds General Infirmary while an independent review was undertaken. Operations resumed on 10 April 2013 with agreement from NHS England following completion of the first stage of a review by a multi-disciplinary independent clinical team. A second stage of the review is being undertaken by NHS England looking at other areas where improvement may be necessary. This will comprise:
- A review of the way complaints from patients are handled, including issues raised by the Children's Heart Federation and
 - Completion of a review of patients' case notes over the last three years.
- 4.8.6 In addition, NHS England will further explore issues that have been raised about referral practices to ensure they are clinically appropriate.
- 4.8.7 CQC has told the IRP that it supports this review and will consider the findings once available in the context of its own regulatory processes.

4.9 The proposals

4.9.1 For purposes of brevity, the *Safe and Sustainable* Review Team, the National Specialist Commissioning Team and secretariat are hereafter referred to as 'the NHS'. The *Safe and Sustainable* Review was initiated in 2008 to undertake a review of the provision of paediatric cardiac services in England. In summary, the reasons for the review were stated as:

- 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 treating the 'critical mass' of children necessary to maintain and develop their specialist skills
- Available research evidence identifies a relationship between higher volume surgical centres and better clinical outcomes
- 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

4.9.2 The aims of the review were to:

- Establish a network of specialist centres collaborating in research and clinical development, encouraging the sharing of knowledge across the network
- Achieve better results in the surgical centres with fewer deaths and complications following surgery
- Achieve better, more accessible diagnostic services and follow up treatment delivered within regional and local networks
- Reduce waiting times and ensure fewer cancelled operations

- Improve communication for parents between all of the services in the network that support their child
- Secure better training for surgeons and their teams to ensure the sustainability of the service
- Develop a trained workforce, expert in the care and treatment of children and young people with congenital heart disease
- Establish centres at the forefront of modern working practices and innovative technologies that are leaders in research and development

4.9.3 The review was based on the following principles:

- 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

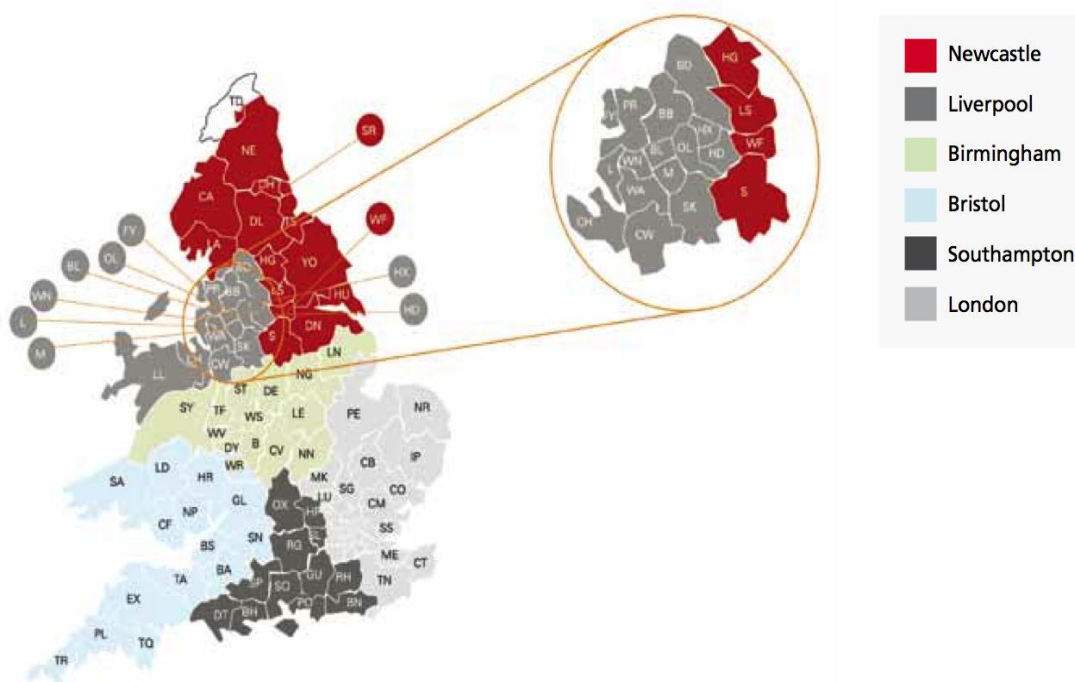
4.9.4 The proposals are to:

- Adopt new national quality standards covering seven key themes:
 - Congenital heart networks
 - Prenatal screening and services
 - Age appropriate care
 - Specialist surgical centres
 - Information and making choices
 - Family experiences
 - Ensuring excellent care
- Implement new systems for the analysis and reporting of mortality and morbidity data relating to treatments for children with CHD

- Develop congenital heart networks and reduce the number of children's heart surgery centres in England from ten to seven with 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
 - Evelina Children's Hospital at Guy's And St Thomas' NHS Foundation Trust
 - Great Ormond Street Hospital for Children NHS Foundation Trust
- De-commission the children's surgical services at Leeds General Infirmary, Glenfield Hospital Leicester and the Royal Brompton Hospital

4.9.5 The aim of the network model of care is to ensure that specialist tertiary centres, regional specialist centres, local hospitals, primary care and NHS commissioners plan, deliver and 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.

4.9.6 The proposed network areas to be served by the seven surgical centres can be seen in Map 4 below.

Map4: the seven proposed congenital heart networks¹⁸**OPTION B****Southampton, Newcastle, Liverpool, Birmingham, Bristol, London x2**

4.9.7 The proposed model of care is based on:

- **District Children's Cardiology Services (DCCS)** providing non-interventional assessment and ongoing care led by consultant paediatricians with expertise in cardiology in district general hospitals (DGH) with a maternity unit with over 3,000 deliveries per year and;
- **Specialist Surgical Centres:** which would be 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
- The consultation documents also proposed the possibility of establishing **Children's Cardiology Centres (CCC)** at the centres that cease to provide surgical services. If established, these would provide a tertiary specialist service led by consultant paediatric cardiologists providing

¹⁸ Source: Review of Children's Congenital Cardiac Services in England: July 2012 Decision Making Business Case

more complex non-interventional care, including diagnostic catheterization.

4.9.8 The JCPCT told the Panel that decisions on the number and locations of DCCS and CCCs would not be resolved until standards for these units have been developed and potential DCCS and CCCs have undergone an assessment process.

4.10 **Issues raised by scrutiny committees**

4.10.1 In its referral letter of 27 July 2012, the Lincolnshire HSC stated that it was not satisfied that the proposals were in the best interests of the health service in Lincolnshire and in particular they raised concerns regarding the following:

- The impact of the closure of the Glenfield Hospital children's heart surgery unit on Lincolnshire families, in terms of clinical safety and accessibility
- The impact of the removal of the extra corporeal membrane oxygenation equipment from Glenfield Hospital to Birmingham Children's Hospital
- The decision-making process of the JCPCT

4.10.2 In its referral letter of 7 September 2012, the LLR Joint HOSC stated that it supports the principles of the *Safe and Sustainable* Review but is concerned at the outcome, believing that the decision of the JCPCT is not in the best interest of the local health service and the population it serves. Particular concerns were raised regarding:

- The JCPCT prediction of demand and capacity at Birmingham Children's Hospital
- The impact of moving ECMO services and increased mortality
- Impact on paediatric intensive care capacity in the Midlands
- Impact on medical research at University Hospitals of Leicester NHS Trust (UHL) and Leicester University
- Accessibility of services
- The decision-making process of the JCPCT

4.10.3 In its referral letter of 27 November 2012, the Y&H Joint HOSC raised concerns that the overall patient experience for children and families across Yorkshire and the Humber will be significantly worse as a result of the proposals. Specific concerns were:

- The range of interdependent surgical, maternity and neonatal services are not co-located at proposed alternative surgical centres available to Yorkshire and the Humber children and their families
- The dismantling of the already well established and very strong cardiac network across Yorkshire and the Humber – and the implications for patients with the proposed Cardiology Centre at Leeds essentially working across multiple networks
- The current seamless transition between cardiac services for children and adults across Yorkshire and the Humber
- Considerable additional journey times and travel costs – alongside associated increased accommodation, childcare and living expense costs and increased stress and strain on family life at an already stressful and difficult time
- The implications of patient choice and the subsequent patient flows – resulting in too onerous caseloads (that is, overloading) in some surgical centres, with other centres unable to achieve the stated minimum number of 400 surgical procedures
- The validity of the Kennedy Panel ‘Quality Assessments’ in light of recent and/or forthcoming Care Quality Commission reports and/or compliance notices issued to current providers previously assessed by the Kennedy Panel
- The extent to which the JCPCT took account of the IRP’s previous advice (endorsed by the Secretary of State for Health) that the JCPCT should give due consideration to comments from the Y&H Joint HOSC in relation to the PwC report on assumed patient flows and manageable clinical networks
- The implications of an unpopular solution imposed by the JCPCT for patient choice within the NHS

- The JCPCT's use of population projections/estimates to determine potential future demand for services, both in terms of using the most up-to-date information and the lack of consideration of regional variations that may impact on the long-term sustainability of specific/individual surgical centres
- The appropriateness, or otherwise, of the JCPCT and its supporting secretariat refusing legitimate requests from the Y&H Joint HOSC for access to non-confidential information during its scrutiny inquiry
- The adequacy of the public consultation conducted by the JCPCT
- Decision-making by the JCPCT

4.10.4 In later correspondence, following the initial referral, the Y&H Joint HOSC raised concerns regarding membership of the various *Safe and Sustainable* subgroups and the pattern of investment in nationally commissioned services.

4.11 **Issues raised by others**

4.11.1 Evidence from other parties opposed to the change broadly mirrored these concerns. There were, however, some additional concerns raised with the IRP by patients, charities, MPs and NHS organisations. These were:

- The evidence that a minimum of 400 operations is associated with better outcomes
- The impact of the proposals on adults with CHD and the services they use
- The robustness/validity of the health impact assessment
- The viability and sustainability of children's cardiology centres and the lack of certainty about what they will do and where they will be
- The wider impact of the proposals on the workforce
- The implications of a lack of alignment with associated neonatal networks
- Impact on children with CHD who have a range of significant other healthcare needs
- The contention that the vast majority of children will only travel to the surgical centre once
- Whether in fact care would be delivered closer to home under the proposals

- The impact of the removal of children's congenital cardiac surgery from the Royal Brompton Hospital
- The impact of the proposals on electrophysiology services and the accessibility of these services to the local populations
- That there were alternative options that would result in better accessibility
- The range of issues which have been left to the implementation stage leaving uncertainties, risks and anxieties about key aspects of the service

4.11.2 The following sections of the report outline what we heard in relation to each of these issues.

4.12 **The clinical case and service quality**

4.12.1 *Background and policy context*

The *Safe and Sustainable* Review was initiated primarily due to concerns that some surgical and medical teams were not operating on sufficient numbers of children to maintain and develop their specialist skills and that, due to the small number of surgeons in some surgical centres, there were risks to the resilience of the service and the maintenance of 24/7 cover. There were also concerns that clinical networks were fragmented and that the various services that treat children with congenital heart disease could do better in working together.

4.12.2 In terms of the context for the review, the Pre-Consultation Business Case (PCBC) Consultation Document and the Decision Making Business Case (DMBC) refer to the following reports and statements that had called for a reduction in the number of surgical centres, minimum activity thresholds for cardiac surgeons and the development of clinical networks:

- Bristol Royal Infirmary Inquiry, Learning from Bristol: The report of the public enquiry into children's heart surgery at the Bristol Royal Infirmary 1984 to 1995 (the Kennedy report) July 2001
- The report of the Paediatric and Congenital Cardiac Services Review Group, (the Munro report) 2003

- Congenital cardiac services; report of workshop, Department of Health June 2006
- Surgery for children: delivering a 1st class service, The Royal College of Surgeons of England July 2007
- Commissioning safe and sustainable specialised paediatric services: a framework of critical inter-dependencies, Department of Health September 2008

4.12.3 The proposals for change also reflect policy set out in the NSF for Children¹⁹, the *Children's Plan*²⁰ and *Getting it right for children and young people*²¹. Reference is also made to the experience of centralisation in other clinical specialties such as stroke and vascular services as background to the review.

4.12.4 The *Safe and Sustainable Review* also draws on evidence of the benefits of developing managed network models of care in cancer services and highlights that the establishment of formal networks was one of the recommendations of the Framework of Critical Interdependencies report.

4.12.5 The evidence for the clinical case falls into three headings – the evidence of a relationship between volume and outcomes, the benefits of larger surgical teams and the benefits of clinical networks. The evidence relating to these issues formed the background to the proposed clinical model.

4.12.6 *The relationship between volume and outcomes*

The *Children's congenital cardiac services in England service standards* set a minimum number of surgeons and critical mass of surgical activity for children's congenital cardiac surgical centres. Standard C4 requires each surgical centre to be staffed by a minimum of four full-time consultant

¹⁹ National service framework for children, young people and maternity services 2004 Department of Health and Department for Education and Skills

²⁰ The Children's Plan: Building brighter futures 2007 Department of Education

²¹ *Getting it right for children and young people: Overcoming cultural barriers in the NHS so as to meet their needs* 2010 Sir Ian Kennedy Department of Health

congenital cardiac surgeons. Standard C6 requires surgical centres to perform a minimum of 400 paediatric cardiac surgical procedures each year. Standard C7 sets the optimum minimum activity level at 500 such paediatric procedures. The standards state that these 400-500 paediatric procedures must be “*sensibly distributed*” between all four of the surgeons.

4.12.7 The evidence supporting the adoption of these standards refers to:

- The Kennedy Report
- The Munro report
- Evidence from other surgical specialties
- The report on optimal structure of a congenital heart surgery department in Europe, European Association for Cardio-Thoracic Surgery 2002
- International experience of a move to create larger centres in several European countries and in Canada.

4.12.8 The NHS also relied on an independent review of the available literature around the relationship between volume and outcome in paediatric cardiac surgery undertaken by the Public Health Resource Unit. It is from this literature review that the NHS draws the conclusion in the Consultation Document that “*available research evidence identifies a relationship between higher-volume surgical centres and better clinical outcomes*”. Using the same source, the DMBC states that “*there is an inverse relationship between volume and inpatient hospital mortality which increased with the complexity of the operation*” and that there is evidence of a “*cumulative phenomena within institutions, in that higher-volume surgical units have increasingly better outcomes over time*”.

4.12.9 Reference is also made to precedents in the UK for the centralisation of congenital cardiac services for children - with the closure of paediatric cardiac surgical services in Cardiff and Edinburgh - because the centres recognised that the surgical volumes were too low to remain sustainable.

- 4.12.10 The Panel heard from a number of people who questioned the evidence base that a minimum volume of 400 to 500 operations in a surgical centre is associated with better outcomes. They also felt that the evidence that exists had been used in a misleading way in the PCBC, consultation document and DMBC.
- 4.12.11 The Panel reviewed the evidence sources referenced by the NHS and tested these assertions with a variety of clinicians.
- 4.12.12 From the documentary evidence submitted, the Panel found that the thresholds for minimum critical mass recommended by the Kennedy Report, Munro Report and the European Association for Cardio-Thoracic Surgery²² were substantially lower than 400-500 cases per surgical centre. The Kennedy Report suggested that paediatric congenital heart surgeons should perform a minimum of between 40 and 50 open–heart operations a year. The Munro report recommended that *“surgical centres should have a minimum of three paediatric cardiac surgeons performing a minimum of 300 paediatric surgical procedures per annum, on average, sensibly distributed between the surgeons to avoid occasional practice”*. The EACTS report concluded that *“there are no data in the scientific literature of an exact cut-off point between what is a too small, adequate or optimal case load and indeed it seems impossible to ensure such points as so much of medical service is dependent on the local culture and circumstances”*. The Report went on to recommend the optimal overall activity should be over 250 patients operated per year and each surgeon should perform 126 cardiac surgical procedures on adults or children.
- 4.12.13 Many people raised concerns regarding the way the conclusions that had been reached from the literature review undertaken by the Public Health Resource Unit²³ had been presented by the NHS.

²² Optimal structure of a congenital heart surgery department in Europe: European Association for Cardio-Thoracic Surgery 2002

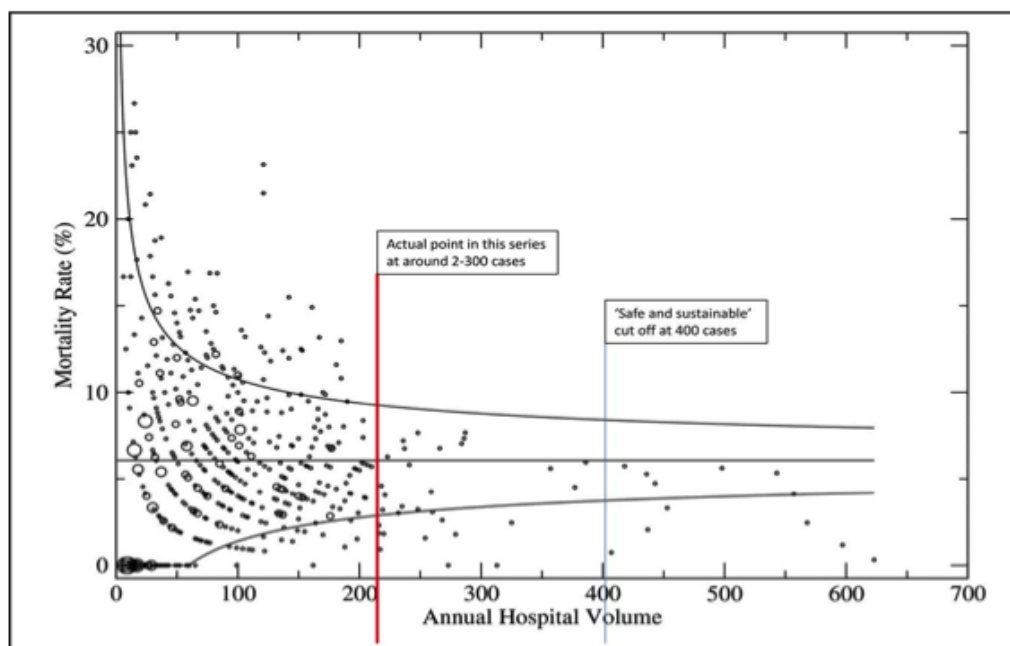
²³ Ewart, H. The Relation between Volume and Outcome in Paediatric Cardiac Surgery; Public Health Research Unit - A Literature Review for the National Specialised Commissioning Group, 2009.

4.12.14 The Panel noted that the final report from the Public Health Resource Unit, in response to the question set in the brief: *“Do the findings of the review allow the generation of evidence based recommendations for the minimum volume of paediatric surgical activity for individual procedures, individual surgeons and/or individual surgical units, stratified by the age of the patient?”* stated: *“Whilst confirming the association between volume and outcome in paediatric cardiac surgery, the 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 high complexity procedures at either institutional or surgeon level. Neither is it possible to stratify optimal volume by age of the patient. It is important to remember that volume is, in effect, a surrogate marker which subsumes a wide range of process and system characteristics which have yet to be identified or analysed for their association to outcome.”*

4.12.15 The Panel also noted that the report stated that *“in those studies expressing volume as a continuous variable no statistically significant inflection points were identified. This makes it difficult to make categorical recommendations on volume. The Bazzani study used a volume of 75 cases as the cut off between low and high volume and showed an association with outcome that may not have been statistically significant. Two Welke studies (2008, 2009) taken together suggest that a volume of over 250 cases per annum may be optimal”*.²⁴

Figure 3 : Data from the Welke study

²⁴ Page 14 of the above publication



4.12.16 The Panel noted that the PCBC, consultation document and decision-making business case were silent on the facts that the Kennedy, Munro and EACT reports had recommended substantially lower thresholds than were being suggested by the NHS.

4.12.17 The Panel noted that the consultation document and DMBC do not indicate the lower thresholds suggested by the literature review. They do however acknowledge that *“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”*.²⁵

4.12.18 Many parents told the Panel that they did not believe the clinical case to reduce the number of surgical centres could be made based on the evidence of

²⁵ Review of Children’s Congenital Cardiac Services in England: July 2012 Decision Making Business Case – page 55

the link between volume and outcomes given the level of activity undertaken in the current surgical centres.

- 4.12.19 Parents, clinicians and HOSC members also raised similar concerns that it was not made clear that the international experience of centralization of cardiac surgical services referenced in the PCBC, consultation document and DMBC was based on units with much lower activity levels than the current centres in the UK and in many cases related to units with identified concerns regarding mortality.
- 4.12.20 It was also highlighted to the Panel that comparisons with the re-organisation of stroke units in London were not felt to be justified given that in London there were a large number of units each undertaking relatively small caseloads.
- 4.12.21 The Panel heard a variety of concerns from parents and clinicians regarding centres undertaking small volumes of complex procedures such as the Norwood Procedure. The Panel was told by clinicians from a number of the centres around the country that, prior to the *Safe and Sustainable* Review, it had been usual clinical practice to refer certain complex cases to centres such as Birmingham Children's and Great Ormond Street hospitals as they had a recognised level of expertise in such procedures. Some clinicians told the Panel that one of the consequences of the review had been to reduce the level of clinical cooperation between surgical centres and to create pressures on centres to demonstrate that they undertook the full range of cardiac surgical procedures.
- 4.12.22 The Panel heard from other clinicians whose view was that the surgical centres should be sufficiently large to undertake the full range of procedures. The Panel received information from one of the largest congenital paediatric cardiac surgery centre in the USA, in Boston Massachusetts, that they had introduced sub-specialisation within the team as a means of further improving outcomes.

- 4.12.23 The Panel noted that the NHS had observed in the DMBC that the literature review indicated “*an inverse relationship between volume and inpatient hospital mortality which increased with the complexity of the operation*”.
- 4.12.24 The Panel sought the views of the Steering Group and the clinical adviser to the JCPCT who told the Panel that, in their view, complex and rare cases should not be restricted to a small number of surgical centres and that all centres should be large enough to have the competence to undertake the full range.
- 4.12.25 The Panel heard from a number of people who felt that it was misleading for the PCBC, Consultation Document and DMBC not to acknowledge the scale of change that had taken place since the Kennedy and Munro reports had been produced. At the time of the Kennedy Report, the surgical centre in Bristol had been undertaking around 47 paediatric operations per year. At the time of the Munro report, six centres in England and Wales were doing fewer than 200 cases a year and two were doing fewer than 100.
- 4.12.26 The Panel heard that the proposed standard for each cardiac surgeon of undertaking 100 -125 paediatric operations per year had not been endorsed by the professions as a whole. The Panel noted the PCBC acknowledged that the professional consensus was around 125 procedures taking into account operations on adults.
- 4.12.27 The Panel heard from the NHS that the final standards do not specify the number of paediatric procedures per surgeon but require the 400-500 paediatric procedures to be “*sensibly distributed between all four of the surgeons*”.
- 4.12.28 The Panel asked the National Institute for Cardiovascular Outcomes Research (NICOR) whether it was possible to identify the number of procedures undertaken by each surgeon to audit performance against the proposed standards. NICOR provided data that showed this is possible. Taking account of changes in personnel in year, the current data provided suggest each

surgeon in England undertakes between 75 and 190 paediatric operations per year.

4.12.29 *Benefits of larger teams*

A number of the standards proposed by the NHS relate to the numbers of staff required in a specialist surgical centre. Standard C4 requires that the surgical centres are staffed by a minimum of four full-time consultant congenital cardiac surgeons. Standard C8 requires a minimum of one consultant paediatric cardiologist per 0.5 million population. Standard C9 requires each surgical centre to provide sufficient appropriately trained and experienced medical and nursing staff for a full 24-hour emergency service, seven days a week within legally compliant rotas.

4.12.30 The Panel heard that these standards were based on the advice of the Steering Group. The Panel also heard that the Steering Group was mindful that their proposed clinical standards went beyond the recommendations of the Munro Report - a minimum of three surgeons in each surgical centre, based on professional consensus at the time - but were consistent with the Royal College of Surgeons of England report in 2007. The latter had recommended four or five surgeons in each centre based on the need to concentrate expertise in the interests of quality.

4.12.31 The Panel heard from the NHS and Steering Group that the minimum of four full-time surgeons per team is based on an assessment of the job plans and available sessions of the surgeons. A minimum of four full-time surgeons is needed to ensure that 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 a combination of ward rounds, management duties, audit and governance, study leave and research.

4.12.32 The JCPCT told the Panel that a critical mass of four full-time surgeons was also considered necessary to address the implications of surgical specialisation and succession planning in each centre and to support training. It was highlighted to the Panel that less experienced surgeons often operate with a

mentor, a more experienced surgeon, while they develop their competence. The JCPCT set out the benefits of larger surgical teams in providing a platform to train the next generation of surgeons.

- 4.12.33 The Panel heard from the clinical advisor to the JCPCT that congenital cardiac surgeons operate on all age groups, including adults with congenital problems. This emphasises the need for teamwork and the need to embed these children's services in established cardiac surgical centres, with the bigger team being able to cover all aspects of the service.
- 4.12.34 There was general support for the requirement of four surgeons, although some clinicians, including in centres that are to be retained under the proposals, felt that three surgeons was an acceptable number. The Panel noted that currently four of the ten surgical centres have four surgeons and six have three surgeons.
- 4.12.35 Clinicians in the existing centres told the Panel that having four surgeons and a large team of cardiologist, intensivists, cardiac anaesthetists, perfusionists, nurses and technicians was what made the difference to the environment for training, retention and recruitment and delivering a high quality service. The Panel heard support for the benefits of larger teams to support further sub-specialisation, training and a high level of consultant presence in the surgical centre.
- 4.12.36 The Panel heard from a number of clinical staff that the *Safe and Sustainable* Review had had been too narrowly focused on surgery and surgeons. They felt the review had not taken account of the contribution to achieving good outcomes of the wider teams who provide the seamless transitions from foetus to adulthood as well as the link to other specialist services. The Panel heard from many clinical teams that the improvements in outcomes over the years owe as much, if not more, to improvements in the quality of pre-surgical work up, new diagnostic imaging techniques, development of interventional cardiology and improvements in post surgical care, particularly in PICU, as they do to improvements in the quality of surgery.

4.12.37 *Benefits of networks*

The proposals are for the establishment of seven children's congenital heart networks in England. The DMBC sets out that these managed clinical networks are intended to deliver an integrated and co-ordinated approach to the care of 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. This would be achieved by the implementation of common protocols within defined patient pathways, with clear accountability and governance structures.

4.12.38 These networks would be led by the specialist surgical centre who would hold the responsibility to provide clear and effective leadership of the network. A board of clinicians from across the network and lay people would oversee the running of each congenital heart network and ensure that other relevant services such as antenatal screening, child health services, psychology services and GP services are encompassed.

4.12.39 The benefits of the network were stated to be:

- Addressing the current inconsistent stage of development of the existing networks around the country
- Addressing the fragmented and inconsistent pattern of current services through the establishment of standards and clinical protocols
- Better coordination of the pathway of care
- Better collaboration in the provision of care and undertaking research
- Better communication amongst clinicians and with parents
- More accessible services for children and their families
- The ability of effective regional networks to facilitate a national network of designated surgical units, working together to share learning, best practice and innovation.

4.12.40 In its referral, the Y&H Joint HOSC raised concerns regarding the dismantling of the already well-established and very strong cardiac network across

Yorkshire and the Humber. The Committee also had concerns about the implications for patients if the proposed cardiology centre at Leeds had to work across multiple networks.

- 4.12.41 The Panel heard from the JCPCT that the strength of the current network in Yorkshire and Humber was acknowledged. The JCPCT also acknowledged to the Panel that there had been numerous responses to the consultation that had made reference to the strength of the existing network in Yorkshire and Humber. The JCPCT stated that they concur with the Y&H Joint HOSC's recommendation that the strengths of the Yorkshire and Humber network should be retained and built upon as part of the future service model. The JCPCT told the Panel that the establishment of a formal network board would be the driver for developing the congenital heart network in the north of England and that clinical colleagues from the existing Yorkshire and Humber network would be key to its development.
- 4.12.42 The Panel sought clarification regarding the pattern of services that the JCPCT envisaged for children in the Bradford, Halifax and Huddersfield areas. The Panel were told that subject to the outcome of the future designation process for CCCs, children in these areas would be aligned with the CCC in Manchester and not Leeds as they reside in the proposed Liverpool network. The JCPCT acknowledged that this would involve a longer journey for these children but felt strengthening specialist inpatient and outpatient paediatric cardiac services at local hospitals in Bradford, Calderdale and Huddersfield would mitigate this impact. The JCPCT stated that if a CCC was created in Leeds it would only have a clinical relationship with the Newcastle surgical centre and would not work across multiple networks.
- 4.12.43 Parents and clinicians from a number of areas around the country, including from centres proposed to be designated as surgical centres, raised concerns about the lack of alignment and cogent geography between the proposed children's congenital cardiac networks and fetal, paediatric and adult cardiac networks. A particular concern was the implication for children who were not diagnosed antenatally and for the 25 to 30 per cent of children with CHD who

have multiple morbidities. The Panel was given examples of clinical scenarios where, given the proposed network boundaries, children could potentially be seen in up to four tertiary centres within the London networks resulting in a complicated set of relationships with different organisations and a high burden of travel to access services.

- 4.12.44 The Panel also heard concerns about the implications of a lack of alignment between paediatric and adult congenital cardiac networks and the particular challenges that would create for teenagers during transition to adult services. Clinicians advised the Panel that some patients do get lost to the service at the point of transition and that the scale of the loss increases with the geographic disconnection between paediatric and adult services. There are long-term implications for the health of patients who are lost to follow-up.
- 4.12.45 The Panel was told of the work underway by NHS London on the development of north/south hubs for specialist paediatric services and that this is not aligned with the network boundaries and patient flows assumed under the *Safe and Sustainable* proposals.
- 4.12.46 In a written response, the NHS told the Panel that NHS England “*will define the London networks with precision, taking account of the outcome of the separate on-going review of tertiary paediatric services in London. The development of formal paediatric networks in London provide an excellent framework for increased collaboration across Great Ormond Street and the Evelina Children's Hospital*”.
- 4.12.47 The Panel asked the JCPCT how Standard A6, which states congenital heart networks should be aligned to the networks for fetal and adult congenital services would be achieved. In a written response, the JCPCT stated that “*this is a network issue for implementation and alignment does not necessarily mean coterminous, reflecting the advice offered to the JCPCT by Prof Roger Boyle that coterminous was desirable but probably not achievable in all cases*”. In relation to fetal services, the Panel was told that this would be addressed by the Clinical Implementation Advisory Group (CIAG) and NHS

England during the implementation stage, as would the precise boundaries of the networks.

- 4.12.48 In relation to adult congenital services, the JCPCT told the Panel that the scope of the adult networks is not yet known, as the process for designating ACHD services will not conclude until 2014. The JCPCT stated that it would be for NHS England to determine how the ACHD networks align with paediatric networks. The Panel heard that there is broad consensus on the CIAG and the adult congenital heart disease advisory group that alignment should be achieved as far as possible, bearing in mind that not all surgical units provide both paediatric and adult congenital cardiac surgical services. The JCPCT stated that it has already reflected in the standards and model of care the importance of a seamless transfer of care from children to adult congenital services.
- 4.12.49 The Panel asked the JCPCT for further information about how they would make networks work effectively where they were not aligned. The Panel was told that where alignment cannot be achieved, the issues would be addressed by ensuring clarity about the relationships between different networks and establishing clear pathways for referral, clear structures, systems and processes. The JCPCT said that they believed that the issues around transition could be effectively managed even where transition was into a different network, through effective cardiac liaison nurse and transition nurse support.
- 4.12.50 The Panel heard proposals for alternative network options. The Y&H Joint HOSC had proposed an eight-centre model that retained Leeds as a surgical centre in addition to the seven proposed centres. Committee members told the Panel they felt this option would better support the population of Yorkshire and the Humber and that the Committee had put forward this proposal in its response to the consultation.
- 4.12.51 University Hospitals of Leicester NHS Trust told the Panel they had proposed a *Heart of England network* that would involve Birmingham Children's Hospital and Glenfield Hospitals in a joint venture providing surgery at both sites. The

Trust told the Panel that they considered this option would eliminate the concerns about lack of capacity, the risks to respiratory ECMO and the provision of paediatric intensive care in the Midlands area, as well as improving accessibility.

- 4.12.52 The Panel heard a similar proposal from Young Hearts, a charity in Oxfordshire, who proposed a model where surgery would take place in Oxford and Southampton with a joint group of 6-7 surgeons operating on both sites. Young Hearts told the Panel the proposals failed to give sufficient consideration to the risks associated with patients with CHD who require treatment in an emergency. They pointed out that John Radcliffe Hospital was a major trauma centre and a centre taking high-risk maternity patients. They highlighted to the Panel a range of implications of the proposals on other services at the John Radcliffe Hospital that they felt would be addressed under their alternative proposal.
- 4.12.53 The Royal Brompton & Harefield NHS Trust told the Panel they had proposed a three-centre network option for London.
- 4.12.54 The JCPCT told the Panel that they had considered all the responses put forward during the consultation. They had rejected these proposals on the basis that they did not comply with the standards in respect of the minimum number of surgical procedures per centre and minimum of four surgeons per centre who must be based permanently on a single site.
- 4.12.55 The Panel asked the NHS and the JCPCT what the arrangements for commissioning the services within the network would be and how CCCs and DCCS would receive their funding. The Panel was told that the commissioning arrangements have not yet being worked through. In response to further enquiries from the Panel, NHS England confirmed that, whilst it will commission all paediatric cardiac services from specialist surgical centres and CCCs, as well as paediatric and neonatal retrieval services, the responsibility for commissioning services provided directly by district cardiology services sits with clinical commissioning groups (CCG). NHS England also confirmed

that commissioning would not at this stage be through a lead provider arrangement although this model is in general development within NHS England and may be adopted in the future for specialised services.

4.12.56 *The model of care – children’s cardiology centres and district children’s cardiology services*

The DMBC sets out the model of care for the paediatric congenital cardiac network. In addition to the specialist surgical centres, it is proposed the networks would comprise DCCS and possibly, in some areas, CCCs as well.

4.12.57 CCCs are described as a tertiary specialist service, which would be led by consultant paediatric cardiologists and would provide more complex non-interventional care than the DCCS. It is envisaged they would act as tertiary referral units for a designated surgical centre working to the same standards and would provide a link to the DCCS in their network.

4.12.58 DCCS would provide non-interventional assessment and ongoing care and would be led by consultant paediatricians with expertise in cardiology (PEC). The intention set out in the PCBC is that PECs would have two sessions per week for this activity. The DCCS are proposed to be located at hospitals with maternity units delivering over 3,000 births per annum. At the time of preparing the consultation document, there were 94 trusts with such units in England.

4.12.59 The Panel noted that in the PCBC it was proposed that centres that are not designated as surgical units in the future *would* become children's cardiology centres, while in the consultation document it is stated that centres that are currently providing heart surgery that ceased to do so *may* become children's cardiology centres.

4.12.60 The DMBC records that a number of concerns regarding CCCs were raised during the consultation. These can be summarised as follows:

- The proposals are not well developed and it is not clear whether these centres would be sustainable

- More senior and experienced paediatric cardiologists would gravitate to specialist surgical units and CCCs would be unable to recruit and retain high quality staff
- Clinicians would not value the service provided by an intermediate tier
- In practice there would be no difference between a CCC and a DCCS
- Parents would not have confidence in the quality of services and safety at CCCs

4.12.61 The DMBC records that although CCCs are considered to be viable, the Steering Group considered there were potential risks to the sustainability of CCCs and highlighted to the JCPCT that mitigation of these risks would be a key issue for implementation. The JCPCT approved the recommendation in the DMBC that the proposed model of care, including CCCs is viable and should be implemented in England.

4.12.62 The Panel heard a range of concerns from clinicians (in surgical centres that are proposed to be retained and those proposed to be de-designated), representatives of professional associations and from parents regarding the viability of CCCs. The concerns mostly echoed the issues raised during consultation but there were some new issues.

4.12.63 Many people told the Panel that they could not see how a CCC at the Royal Brompton Hospital would be viable or add value given the proximity of the proposed surgical centres at Great Ormond Street and Evelina Children's hospitals.

4.12.64 The Panel heard from clinicians and professional associations that paediatric cardiologists are a scarce resource and there are concerns that the proposals for CCCs would be unattractive to existing consultants and to future trainees. A number of clinicians told the Panel of their concerns about the implications of failure of the CCC model for patients in large geographic areas of the country

which will be relying on the success of CCCs for access to specialist support for the day-to-day care of children with heart problems.

- 4.12.65 Issues were raised about the financial viability of CCCs as Trusts were not confident that the level of activity CCCs would undertake would attract sufficient payment under PBR to cover costs. The question of how attractive it would be to Trusts to provide these services was also raised.
- 4.12.66 The Panel was told by the NHS and the JCPCT that decisions on the number and locations of DCCS and CCCs would not be resolved until standards for these units have been developed and potential DCCS and CCCs have undergone an assessment process. The SRO for implementation told the Panel that work was underway to develop the standards for the CCCs and, on the basis of the standards, to work through the networks to identify where the cardiology centres should be. Potential CCCs would have to go through a self-assessment process and an external panel assessment in order to achieve designation. In terms of the funding for CCCs, the NHS told the Panel that the commissioning process is part of the implementation plan and would be picked up by NHS England but that the majority of funding would be via the payment by results tariff. The Panel was told that the financial viability of CCCs had not been assessed to date as the volume of activity these centres would undertake is not yet clear and would vary depending on network arrangements.
- 4.12.67 In relation to a CCC in London the JCPCT confirmed that there was a question over the value of a CCC given the proposed full range of services provided at the Evelina and Great Ormond Street hospitals.
- 4.12.68 The NHS and the JCPCT told the Panel that there was evidence that CCCs are a viable model as there are current centres in Edinburgh, Manchester and Cardiff. In addition, the former surgical centre at Oxford Radcliffe has begun to develop a relationship with Southampton, operating as a CCC.

4.12.69 The Panel visited Manchester, Cardiff and Oxford and spoke to commissioners from the National Services Division of the NHS in Scotland about the service in Edinburgh.

4.12.70 There were some common themes in the evidence the Panel received from the visits to Manchester, Cardiff and Oxford:

- All three centres cited the importance and benefits of retaining paediatric cardiology on site to support the needs of other specialist services, including non cardiac care of children with CHD, foetal and perinatal care
- Due to clinical governance considerations, Manchester and Cardiff no longer undertake diagnostic or interventional catheterisations nor electrophysiology (EP) except on older and larger children in Manchester who are treated by the adult EP service
- The number of post-procedural transfers from the surgical centres to the cardiology centres is small
- Mutual respect, communication and clear governance and accountability were essential to make the CHD pathway work effectively. However the Panel found different approaches to these issues had emerged in each centre
- Expectations about the demands of travelling for peripheral clinics, MDTs, emergencies and training need to be realistic – an hour's drive is considered at the outer limit of practice in Manchester and Cardiff
- Recruitment and retention of paediatric cardiologists has been an on-going issue

4.12.71 The Panel heard that there was a range of issues that would need attention if CCCs were to be established elsewhere:

- Enhancing the availability and capacity of retrieval and transfer teams
- Ensuring communication with the clinicians in the CCC is maintained when children are discharged from the surgical centre to home or to DCCS
- Testing capacity assumptions as distance has an impact on length of stay at the surgical centre and the level of day case activity tends to decline.

- Assessing and addressing the potential knock on effect of cessation of congenital cardiac surgery on referral patterns for other tertiary services provided by the de-designated surgical centres
- Developing contractual funding mechanisms that ensure the service is viable.

4.12.72 The Panel heard that the service in Cardiff is directly funded by commissioners and the clinicians in Cardiff control the onward referral of cases to surgical centres in England, most of which are to Bristol.

4.12.73 The Panel heard from the team at John Radcliffe Hospital Oxford regarding their experience of making the transition from a surgical centre to a cardiology centre. The team told the Panel that they have a very positive, constructive and mutually supportive relationship with their colleagues in Southampton.

4.12.74 They told the Panel about the challenges presented by relating to a surgical centre that is 60 miles away. In their view, the distance between the CCC and surgical centre would make a real difference to what it is possible to do at the CCC and to its viability and sustainability. Consequently, different solutions would be needed in different parts of the country. The team highlighted the importance of two issues - the clinical teams meeting face-to-face regularly and opportunities for staff in Oxford to work in Southampton to enable them to maintain confidence in caring for cardiac patients in the cardiology centre. Their experience is that this applies particularly to nursing (ward, high dependency and ITU) but also to anaesthetic and HDU/ITU physicians.

4.12.75 The Panel heard from Commissioners from the National Services Division of the NHS in Scotland that there are two cardiologists at Edinburgh, one of whom will shortly retire and it is unlikely that a replacement will be recruited as the volume of cases is not sufficient. They told the Panel that the service in Edinburgh is purely a medical cardiology service and diagnostic catheterisations and all interventions are undertaken in the surgical centre in Glasgow.

- 4.12.76 The Panel heard from a number of parents and clinicians who were concerned that the full impact on patients of the proposals had not been fully appreciated, particularly as 25-30 per cent of children with CHD have significant other healthcare conditions. They told the Panel that the range of services that could be retained in CCCs had been overstated and consequently the impact on patients had been understated. They highlighted the experience of Cardiff and Manchester in relation to EP and diagnostic catheterisations. In addition, they told the Panel CCCs would not have specialist paediatric cardiac anaesthetists and as a result, particularly over time, clinical skills and confidence in the remaining team would decline. As a result, children with congenital heart conditions who need an anaesthetic for any reason - from a diagnostic test to surgery un-related to their heart condition - would have to travel to the specialist surgical centre for treatment due to the clinical risks.
- 4.12.77 The Panel heard concerns from a number of parents and charities around the country about the implications for EP services. The Panel was told that children with rhythm abnormalities may require an implanted device as part of their management. Such devices are much more commonly used in adult patients and therefore a joint adult and paediatric service is better placed to provide optimum management of the children as they can use the extensive experience gained from adult patients.
- 4.12.78 The DMBC states that EP services would be provided in the CCCs working to protocols devised by the Network, which set size and weight parameters. The Panel heard from a number of clinicians around the country that they had significant doubts about the viability and clinical safety of providing EP services in centres that did not have on-site cardiac congenital surgical support. The evidence presented to the Panel included the results of a survey of paediatric electrophysiology clinicians.
- 4.12.79 The Panel heard that the experience of the Royal Brompton Hospital is that 30 per cent of children who have congenital cardiac surgery require EP or pacing (either as a child or as an adult) and for those that receive a cardiac catheter

procedure as a child, 16 per cent will require electrophysiology or pacing (either as a child or as an adult).

4.12.80 The Panel spoke to a wide range of clinicians and professional associations about their views on district children's cardiology services and the role of the PEC. There was strong support for the role of the PEC, and the Panel was told there are a substantial number of PECs already in post. The Panel heard that historically the reason for the emergence of the role of the PEC was the volume of less complex cardiology problems was swamping the small number of paediatric cardiologists nationally. The concept of the PEC was to underpin the work of the paediatric cardiologist. Some clinicians explained that one of the unintended consequences of having a good PEC is that there is some deskilling of other paediatric colleagues who may then rely on the PEC who cannot provide 24/7 cover and is not sufficiently trained to deal with the complex and acute cases. Some concerns were raised about the support or priority the proposal for PECs would receive from trusts whose pressing concerns are 24/7 consultant rotas, weekend working and acute paediatrics.

4.12.81 A number of clinicians raised a general concern with the Panel regarding the risk to patient care if there is insufficient development of CCCs and DCCS before changes are made to the existing surgical centres.

4.12.82 *The model of care – co-located maternity and children's services*

One of the major concerns raised with Panel by the Y&H Joint HOSC was the fact that currently Leeds General Infirmary provides a full range of interdependent surgical services, maternity and neonatal services on one site and in addition provides seamless transition between cardiac services for children and adults also on that site. This is in contrast to the proposed surgical centres that would be used by the Yorkshire and Humber population under the proposals, the Freeman Hospital in Newcastle, which is a specialist hospital, and the children's hospitals in Birmingham and Alder Hey which are stand alone children's hospitals and do not have fetal medicine and maternity services on the same site.

- 4.12.83 The Y&H Joint HOSC told the Panel that they believe that co-location of services in the way they are provided in Leeds can significantly reduce the potential negative impacts associated with the separation of the mother and baby immediately after birth. The Committee felt that these issues had not received sufficient consideration during the review and specifically when defining co-location.
- 4.12.84 The Y&H Joint HOSC referred to a statement issued in February 2011 by the BCCA referring to the numerous interdependencies between key clinical services from *'fetus to adult'* and setting out the BCCA's opinion that *'for these services at each centre to remain sustainable in the long term, co-location of key clinical services on one site is essential'*.
- 4.12.85 Committee members and local parents told the Panel that they could not understand a decision that would result in children from Yorkshire and the Humber being treated in hospitals that were not able to offer the level of co-location currently available. The Y&H Joint HOSC was critical of the definition of co-location used by the JCPCT which it felt did not reflect the definition that would be applied by the general public.
- 4.12.86 A number of parents from around the country told the Panel about stress on mothers and families of having their child being treated in a different place to where the mother had given birth. The Panel heard from families in other parts of the country how much they valued this integrated pattern of service delivery and the difference it had made them in terms of their experience. The Panel also heard from parents whose children had been treated in hospitals that did not have full co-location on one site who reported very positive experiences of the care that they had received.
- 4.12.87 A number of clinicians told the panel that given that 25-30 per cent of CHD children have co-morbidities they felt that co-location with specialist children's services was as significant to the quality of service as the size of the team and scale of the activity of the specialist surgical centre.

- 4.12.88 The Panel noted that the DMBC records that a variety of views were expressed during the consultation regarding the interpretation of co-location and that some respondents did argue that the range of services that should be incorporated in the definition of critical inter-dependencies should be broadened to include fetal, obstetrics, maternity, neonatal and general paediatric services.
- 4.12.89 The JCPCT told the Panel that they had accepted expert advice in respect of their definitions and interpretations in relation to critical interdependencies and co-location. In the view of the JCPCT while the Y&H Joint HOSC may be correct in stating that the public would generally consider co-location to mean services located on a single hospital site, in their view this is a complex issue that requires expert interpretation and on which they had taken expert advice. The JCPCT highlighted that in response to the respondents from Yorkshire and the Humber who suggested that the wrong definition of co-location had been used in the Kennedy Panel assessment, in August 2011 the JCPCT asked Prof Kennedy's Panel to reconsider its advice in the light of the evidence submitted during consultation. They told the Panel that the Kennedy Panel concluded, and they had accepted, that whilst the optimal arrangement was co-location of service on the same hospital site the assessments had been undertaken correctly.
- 4.12.90 The JCPCT highlighted that only two centres currently offer the full range of maternity and children's services on one site, Leeds Teaching Hospital and Southampton General Hospital and they therefore felt this demonstrated that the model is an exception rather than the rule. They told the Panel that they had undertaken sensitivity tests as part of the appraisal process in which the various criteria used in the Kennedy assessment process were re-weighted so co-location of services was the highest scoring criterion and when this was done Newcastle still scored higher than Leeds.
- 4.12.91 The Y&H Joint HOSC raised issues associated with potential obstetric referral patterns, the impact these may have on patient numbers at the proposed

designated surgical centres and to what extent such matters were taken into account within the JCPCT's decision-making processes.

4.12.92 The JCPCT told the Panel that there is no evidence to suggest that the obstetric services in Newcastle would have insufficient capacity to meet the needs of mothers who wished to be delivered, or whose clinical condition required delivery, close to the surgical centre in future. They also highlighted that standard F8 requires that there must be facilities in the surgical centres, including access to maternity staff, that allow the mothers of newborn babies who are admitted as emergency to stay with their baby for reasons of bonding, establishing breastfeeding and emotional health of mother and baby.

4.12.93 *The model of care - adult services*

All of the overview and scrutiny committees who have referred the proposals raised concerns about why the review had not taken account of the impact on adults with CHD or, been undertaken as a single review of the service required to treat people with this life-long condition. They told the Panel that doing so would have enabled better solutions to be found that had a higher level of support and reduced the impact on accessibility.

4.12.94 The Panel was told by some professional associations that the professions had suggested four surgeons each undertaking 125 cases per centre but that they had not said that these should all be paediatric and that they had made their views known that the review of paediatric services should not be undertaken in isolation. The Panel was shown a letter co-signed by 35 ACHD professionals to Dr Pat Hamilton (Chair of the paediatric *Safe and Sustainable* Steering Group) urging her to include adult services in the review in May 2010.

4.12.95 The Panel heard similar concerns from clinicians in a number of trusts, including those designated under the proposals, and from parents.

4.12.96 The Panel heard from some professional associations and clinicians that adult congenital heart disease patients are by far the larger proportion of the total congenital heart disease patient population and the numbers of adult patients is

set to increase substantially. They had concerns that the proposals would lead to a shortfall in capacity for ACHD patients. They also drew the Panel's attention to the fact that a substantial proportion of the workload of the 'paediatric' surgeons is ACHD patients. They told the Panel that the number of procedures on ACHD patients recorded on CCAD is only a partial dataset as many surgical procedures are carried out on ACHD patients by non-specialist surgeons. Their projections were that there are likely to be in excess of 3,000 adult congenital surgical procedures per year by 2025, plus a substantial volume of interventional procedures, the number of which is also increasing rapidly. They told the Panel that ACHD and paediatric surgical workload is likely to exceed 8,000 cases comfortably by 2025.

4.12.97 People told the Panel that the impact of the drive to move to larger centres was exaggerated by the decision to separate the review of paediatric and adult services. They did not feel it was right or appropriate that the future of adult congenital cardiac services should be determined by a review of children's services in which the needs of adult congenital heart disease patients had not been considered. People told the Panel they were concerned about the impact on patients if they had to move centres or networks when they transitioned to adult services. They told the Panel they were very concerned about the impact on vulnerable patients such as those with Down Syndrome who have a high incidence of congenital heart disease and patients who have a degree of neuro-disability.

4.12.98 Some clinicians told the Panel that in their view it will only be possible to be a designated ACHD surgical centre with an affiliated and closely geographically linked paediatric surgical centre.

4.12.99 The Panel heard from the JCPCT that Sir Bruce Keogh's letter of May 2008 asked the National Specialised Commissioning Group to establish a process of the reconfiguration of paediatric congenital cardiac services, and that the Secretary of State for Health's letter to Dame Ruth Carnall of August 2008 also refers to review of paediatric congenital cardiac services. They told the Panel that the process of two separate review processes across ACHD and

paediatric congenital heart services was endorsed by the professional associations on the *Safe and Sustainable* Steering Group in December 2008. They told the Panel that the minutes of that meeting record that the issue was discussed and members agreed that ACHD services would be taken into account only insofar as the transition from paediatric to ACHD services was concerned.

4.12.100 The Panel heard from the JCPCT that their view was that the total workload would be below 5,000 procedures per annum for adults and children. The JCPCT confirmed that the outcome of the paediatric review would have a major influence in terms of the configuration of adult services. They told the Panel that the draft standards that have been developed by the ACHD group stipulate that, in the future, adult congenital surgical services need to be co-located with paediatric congenital cardiac services. They highlighted to the Panel that this recommendation was made after the JCPCT had made its decision, so in their view there was no predetermination.

4.12.101 The Panel asked the JCPCT whether, in the light of two separate reviews that had inevitable inter-dependencies, it had assessed the impact of their proposals for children's congenital heart services on ACHD services, for similar reasons as it had assessed the impact on PICU, respiratory ECMO, transplant services and on specialist respiratory services at the Royal Brompton Hospital. The JCPCT told the Panel that they had not.

4.12.102 *The model of care – retrieval services*

The Panel heard from paediatric transport specialists and clinicians in surgical centres that retrieval services are an integral part of the paediatric congenital cardiac service and there is a pressing need to develop a comprehensive, consistent, high-quality retrieval service across the country. This requirement was all the more urgent due to the increased demands that would be placed on retrieval services as a result of the proposals. In their view, there was no reason for retrieval services to be a constraint on the location of delivery of children's congenital cardiac services provided the retrieval service is planned and resourced accordingly.

- 4.12.103 The Panel raised this issue with the JCPCT who told the Panel that retrieval is a *mission-critical* issue and they saw an important opportunity to address the issue of retrieval generally, which it was agreed was too patchy currently. They told the Panel that irrespective of the Safe and Sustainable Review, this work is being taken forward nationally as part of implementation.
- 4.12.104 *Service quality*
- The Y&H Joint HOSC raised questions with the Panel regarding the validity of the Kennedy Panel *Quality Assessments* in light of recent Care Quality Commission reports and enforcement action against University Hospitals Bristol NHS Foundation Trust.
- 4.12.105 The Panel asked Sir Ian Kennedy and the JCPCT about these issues. Sir Ian told the Panel that the assessments were a statement of what the assessment panel thought, in the light of the evidence they were presented with, about the level of safety and sustainability by reference to the Safe and Sustainable standards. Both he and the JCPCT highlighted that the standards applied by CQC are different and a significant period had elapsed between the *Safe and Sustainable* assessment process and the issues raised by CQC.
- 4.12.106 The NHS told the Panel that no concerns had been put to the Kennedy Panel by staff or parents at the time of the Kennedy Panel assessment that gave the Kennedy Panel any cause for concern in respect of matters highlighted by CQC.
- 4.12.107 The Panel noted that CQC has judged that Bristol Royal Hospital for Children has now complied with the CQC standards.
- 4.12.108 The Panel met with parents who had serious concerns regarding the quality of the services that they had received at some of the surgical centres. These concerns related to four of the surgical centres, three of which are proposed to be retained. Some of these families had experienced the death of their child and felt that there had been failings in the service that had contributed.

- 4.12.109 The Panel was troubled to hear some people assert that there were known and significant differences in the outcomes achieved by existing centres. The Panel sought the evidence behind these assertions. Data presented to the Panel, and in the public domain, about potential variation in outcomes in some cases suggested contradictory findings. The Panel asked the JCPCT, as commissioners, whether there existed any further information about the safety or performance of the current centres that would help inform the Panel's advice to the Secretary of State. The JCPCT confirmed that there did not.
- 4.12.110 The Panel heard a variety of views about the ability to use current data to identify variations in outcomes and in performance, as a means of driving up service quality. The key issues that constrain the ability to use data in this way are the small numbers of cases involved and the ability to stratify accurately the data to take account of the inherent risk of the procedure.
- 4.12.111 The Panel heard from the Medical Advisor to the JCPCT that NICOR had secured funding to roll out across all congenital cardiac providers in England a programme that allows individual providers to monitor their own performance using Variable Life Adjusted Displays (VLAD plots). In addition, further research is underway to obtain risk-adjusted standardized mortality ratios (SMRs) for each centre.
- 4.12.112 Having been informed on 18 March 2013 that the NICOR programme of research would likely lead to publication of SMRs for each centre in June 2013, the Panel notes that some results were used in the events surrounding the temporary closure of the Leeds surgical centre at the end of March. NHS England subsequently published, on 12 April 2013, comparative results for all ten current surgical centres using the new partial risk adjusted methodology.

4.13 Development of the proposals and assessment of the options

- 4.13.1 A substantial proportion of the concerns that were raised with the Panel related to the analysis that supported the development and assessment of the options

and the way in which information was used to reach the final decision. The concerns raised fall under a number of headings.

4.13.2 *Population projections*

The Panel heard from HOSCs, Trusts, clinicians and parents that the assumptions for the future surgical workload were flawed because they failed to take account of the latest ONS population projections. The Y&H Joint HOSC also raised concerns that the JCPCT had not taken into account any regional differences in population growth, which they felt, were material to judgements about the accessibility and sustainability of the proposals.

4.13.3 The Panel heard from some people that they could not see why two centres were justified in London to serve a population that was not much greater and more geographically compact than the Midlands.

4.13.4 People told the Panel that future population growth and within that, regional variation in population growth, might result in excessive demands being placed on some centres and others failing to meet the minimum activity thresholds.

4.13.5 There were also concerns expressed to the Panel about the impact of the significant population growth in northeast London and the impact this might have on Great Ormond Street Hospital.

4.13.6 The Panel heard from a number of parents that they could see no justification for the changes when projected population growth meant that the existing ten surgical centres could reach the threshold of 400-500 cases.

4.13.7 The NHS told the Panel that their capacity analysis was concluded by February 2012, before the latest ONS statistics were published in March 2012. In their view any differences as a result of the updated population projections will be marginal, given the low incidence of congenital heart disease overall. They stated that they had used projected growth in population as a proxy for projecting the future surgical caseload because the cumulative impact of various factors, such as improved antenatal diagnosis, more sophisticated

cardiology interventions or new drugs means that the number of operations required cannot be quantified with certainty. They told the Panel that if further capacity was required this could be accommodated in the proposed seven centres.

4.13.8 *Health impact assessment*

The Y&H Joint HOSC made a number of detailed criticisms of the health impact assessment (HIA) and identified some numerical inaccuracies in the document and errors in network maps. The Committee was also critical of the JCPCT's refusal to disclose information related to the HIA. Of particular concern was the fact that the health impact assessment did not consider impacts on a regional basis, that is, was the impact on the Yorkshire and the Humber population greater than the impact on other regions. Committee members told the Panel that they believe the 8-centre option recommended in their response to the consultation would have demonstrated this option had a lesser impact. The Panel was also told that the Committee believes that the proposals result in severe impacts on particular localised areas and vulnerable groups that are effectively masked by averaging them into a national picture. The Y&H Joint HOSC presented the Panel with data on the socio-demographic characteristics of the population in Kirklees and Leeds that demonstrated high levels of social deprivation. The Panel also received a regional impact assessment report that had been undertaken by Yorkshire and the Humber Specialised Commissioning Group that showed high levels of congenital cardiac health needs in the Bradford, Kirklees and Leeds areas.

4.13.9 Other HOSCs and local Trusts presented the Panel with detailed information on the demographic characteristics and health needs of vulnerable groups in other areas of the country whom they felt were adversely affected by the proposals. The Panel heard that the HIA demonstrated that option G had fewer negative impacts than option B.

4.13.10 The NHS told the Panel that their response to requests for information had been reasonable and that the HIA does not support the Y&H Joint HOSC view that there would be severe impacts on particular localised areas. Contrary to

the Committee's view, the NHS highlighted that the advice they received from the independent authors of the HIA was that the numbers of patients in vulnerable groups likely to experience impacts is very small under all the options and key vulnerable groups are expected to benefit disproportionately from the positive impact of improved health outcomes and care delivered closer to home.

4.13.11 Mott MacDonald, the authors of the HIA, acknowledged the errors identified by the Y&H Joint HOSC but stated that although regrettable, they made no material difference to the findings. They told the Panel that their analysis was based solely on the number of patients undergoing surgery and that they had not taken account of the impact on the patients and families who would have to travel to the specialist centre for interventional cardiology. The Panel asked if Mott MacDonald had been aware, at the time, that the standards that were consulted upon unequivocally stated that all interventional cardiology work would be undertaken in the surgical centres. Mott MacDonald confirmed that they were aware of this. They told the Panel that there were two reasons they did not take account of this. The first was for reasons of consistency, as the data used by KPMG in the access mapping, activity distribution mapping and development, assessment and scoring of the access criteria of the options was only for surgery. The second was that differing views were being expressed during the consultation about whether interventional cardiology would take place in the CCCs and, therefore, there were no reliable data on which to base an assessment. They also told the Panel that they had not attempted to assess the impact of the changes to district services for the same reason, that is, the absence of a reliable dataset.

4.13.12 The Panel asked Mott MacDonald what evidence they relied upon to conclude that the proposals would have significant benefits for particular vulnerable populations. The Panel heard that Mott MacDonald relied on the statements in the consultation document that the quality of care would be improved in the surgical centres and networks would be developed so as to bring more services closer to home. The Panel asked if any assessment had been undertaken to test this. The Panel was told that there had not.

- 4.13.13 The Panel noted that the HIA states that children who have CHD but also have significant other healthcare needs, referred to as children with “multiple morbidity” or “co-morbidity”, and children with Down Syndrome were acknowledged to be more likely to experience disproportionate effects and asked if the HIA had been able to identify impacts on these patients. The Panel was told this had not been included due to a lack of data.
- 4.13.14 The Panel asked Mott MacDonald how they had calculated the average length of stay used in their carbon assessment of 3.9 days for surgical patients. The Panel were told that this was based on 2008/09 HES data and the length of stay for a defined range of procedures. The Panel noted that the list of procedures was not consistent with the list of procedures in the rest of the HIA analysis and the average length of stay was significantly shorter than the length of stay reported to the Panel when it visited the ten surgical centres.
- 4.13.15 Almost without exception, the parents who met the Panel told them that they had multiple trips to the surgical centre for admissions and procedures. They did not understand how the figure used in the consultation document and the HIA that 88.4 per cent of patients would visit the surgical centre once could be true. Trusts presented data to the Panel that suggested that the number of patients who would visit the surgical centre once for surgery or interventional cardiology would be less than 70 per cent. Clinicians told the Panel of the importance of pre-surgical visits to familiarize children and families with the facilities and staff before the operation, to reduce anxiety and how this was particularly important for children with learning difficulties who make up a significant proportion of the patient group. The Panel heard that for these patients, arriving in a new unit for surgery without familiarization would be extremely difficult. The Panel also heard that around 25-30 per cent of patients have co-morbidities and, of these, a proportion will require any surgery for any condition, or any diagnostic test that requires anaesthetic, to be undertaken at the cardiac surgical centre due to clinical risk associated with their conditions and the need for specialist paediatric congenital anaesthetic support.

4.13.16 The Panel asked the NHS for the data that they had relied upon to produce the 88.4 per cent figure. The Panel was told that the data used was an analysis from HES data of the frequency of spells in hospital for children undergoing certain cardiac procedures over the period 2000 to 2010. The NHS explained that the Central Cardiac Audit Database (CCAD) has three broad groupings of procedures:

- **Excluded procedures** – which are not judged to be major procedures
- **Qualifying procedures** – everything except the above
- **Specific procedures** – a sub-set of the ‘qualifying procedures’

4.13.17 The Panel was told that the HES analysis covered the specific procedures but the NHS felt this was a reasonable sample as the specific procedures account for around 80 per cent of the qualifying procedures.

4.13.18 In response to further questions an analysis was provided which showed that the percentage of specific procedures that had actually been captured in the analysis was 62 per cent of qualifying surgical procedures and 36 per cent of qualifying interventional cardiology procedures, amounting to 52 per cent of all qualifying procedures.

4.13.19 *The report on testing patient flows*

The Y&H Joint HOSC told the Panel that they had welcomed the findings of the PwC report that had further tested assumptions about patient flows. They believed this report supported their view that children and families from across Yorkshire and Humber would not travel to the surgical centres assumed by the JCPCT. The Committee told the Panel that they did not believe that the JCPCT had taken account of their comments on this report and did not understand the rationale applied by the JCPCT of assuming that 25 per cent of patients from Doncaster Leeds, Sheffield and Wakefield would flow to Newcastle despite the findings from the PwC report. They stated that it would only take a further shift of less than two per cent from these postcode areas to render the Newcastle Centre unable to achieve the minimum number 400 procedures. They told the Panel that in their view it was likely a proportion of patients from Hull and

Halifax postcodes would also choose an alternative surgical centre to Newcastle. The Panel heard that, as a result of these issues, the Y&H Joint HOSC believed that option B, the proposed option, should have had a lower score for ‘sustainability’.

4.13.20 The Panel received a letter from 170 clinicians from all the hospitals in the Yorkshire and the Humber network stating that they did not support the proposals and wished to dispel any misconceptions about widespread clinician support for the proposals in the Yorkshire and the Humber area or the suggestion they would be happy to recommend that their patients travel to Newcastle.

4.13.21 The Panel heard from parents in Yorkshire and the Humber, and other areas affected by the proposals, who stated that they did not wish to travel to the centres in the network their postcode had been allocated to under the proposals and they would prefer to attend alternative centres. Parents told the Panel they felt the proposals ignored patient choice and the numbers of surgical cases that had been attributed to Newcastle, Bristol and Southampton relied on some people having to go to a centre that was not their nearest.

4.13.22 The Panel heard from PwC that their brief was to test the patient flows assumed under the four options in the consultation document in the options in 22 postcode areas with:

- The referring clinicians
- Parents or carers of children with CHD
- The general public

4.13.23 The methodology had involved surveys and focus groups. They told the Panel that the objective of the work was not a post-code analysis per se but to triangulate the views of these three groups.

4.13.24 The Panel asked PwC how they had engaged with parents and the public on the issues that would encourage them to travel to a centre that was not their

nearest under the proposals, given that one of the three key findings from their work as set out in the DMBC was that “*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’*”. The Panel wished to understand what factors would lead people to travel further than they needed to for the same quality of service (to the second nearest centre to their home for example). PwC told the Panel that, during the sessions, people were sensitised to the fact that quality would not necessarily be the same and therefore quality was the most important driving factor, and they would travel further to get the best for their child.

4.13.25 PwC told the Panel that in order to gain views from referring clinicians they sent surveys to the clinical directors and medical directors in a number of trusts and asked them to identify their referring clinicians. The Panel asked PwC if they had used the catchments of the obstetric and neonatal units and population flows associated with those as part of their methodology, given these would be the clinicians who would identify and refer the children with CHD. PwC commented that they had raised with the NHS that methodology as a possible approach, but it was not the approach they had adopted. They told the Panel they felt the methodology used was appropriate.

4.13.26 PwC told the Panel that, based on their findings, their view was that the proposals could work if clinicians advised patients to have treatment at the designated surgical centre and the networks were actively managed and developed.

4.13.27 The NHS told the Panel that their interpretation of the advice from PwC was that the Newcastle network could be made to work if it was properly managed and referrals were made in the right way. The JCPCT told the Panel that some patients from Yorkshire and the Humber already travel to Newcastle (61 in 2008/09). In making their decision, they told the Panel that option B was consistently the highest scoring option and the JCPCT acknowledged the risks to the viability of the proposed Newcastle network and that mitigation of these risks would take place during the implementation phase.

4.13.28 *Capacity*

All three HOSCs raised with the Panel their concerns that as a consequence of patient flows not following the assumptions made in the proposals, and as a result of population growth, in future some centres might have insufficient capacity to meet demand or would be so large that this had a negative impact on quality. Some parents and a number of clinical teams raised similar concerns. The Panel was told that using the latest national census data and CCAD data that the 13 postcodes allocated to Birmingham Children's Hospital would generate 719 cases per year by 2025. This compares with the activity projected in the DMBC of 611. The Panel was told that the impact of moving ECMO to Birmingham would be equivalent to a further 250 operations in terms of the demand on PICU.

4.13.29 The LLR Joint HOSC, some parents, professional associations and a number of clinical teams, including in units designated under the proposals told the Panel they were concerned about the impact on PICU capacity in the Midlands and nationally.

4.13.30 The Panel heard from the NHS that they had undertaken detailed capacity assessments as part of the planning process. The JCPCT told the Panel that they are satisfied that there is sufficient capacity to accommodate any increase in workload associated with population growth and the impact of any patient flows which are contrary to the network proposals, which they believe would be small in number.

4.13.31 The JCPCT told the Panel that the provision of adequate PICU capacity and effective arrangements for retrieval of patients is a requirement of the Safe and Sustainable Standards (C15, C60, C68). The Panel heard that the Capacity Working Group risk assessed the individual centres' plans for expansion of PICU to meet the needs of increased surgical cases. The JCPCT told the Panel that the CIAG terms of reference include the impact of reconfiguration on PICU and retrieval services and nationally a number of actions are underway to improve the effective operation of PICU and retrieval services. This includes the

establishment of a PICU clinical reference group, whose terms of reference are to assist NHS England in the strategic planning of PICU services and develop new service specifications for both PICU and retrieval services. These specifications will be used by NHS England as a tool for achieving consistent standards across the country from 2013/14.

4.13.32 *Financial planning*

The Y&H Joint HOSC told the Panel that they believe that under option B families across Yorkshire and Humber would not only endure a significantly worse patient experience but that this would also be at a considerable greater expense. The Panel heard concerns that the overall financial implications are likely to be very significant, in terms of establishing the new arrangements, developing the proposed network model of care and meeting very significant increases in transportation and retrieval costs. They told the Panel that they believed there had been insufficient consideration given to the financial implications of the proposals. The Committee was concerned that the DMBC suggested that there would be a reduced level of spending in future and that this did not reflect the increased investment that was suggested during public consultation.

4.13.33 The Y&H Joint HOSC was also concerned about the impact on Leeds Teaching Hospitals NHS Trust, which it understood, would have to find savings to cover circa £14 million of legacy costs. Committee members told the Panel that they felt costs should have been part of the options assessment process.

4.13.34 The Panel heard concerns from trusts, clinicians and professional associations about whether the necessary funding would be available to develop and sustain the wider network of services and staff, particularly in DCCS. Some trusts told the Panel that they felt that the threshold for economic viability of a surgical centre was nearer 500 procedures per annum than the proposed minimum of 400.

- 4.13.35 A number of clinicians, professional associations and parents were concerned that the costs of the necessary expansion of retrieval service had not been taken into account. Some Committee members and parents were also concerned about funding for additional ambulance services for post-operative, non-urgent transfers to CCCs and DCCS.
- 4.13.36 The JCPCT told the Panel they had not included in their financial plans the additional costs of retrieval and ambulance services. They had followed the advice of the professional associations on the Steering Group that the precise ramifications for retrieval services could not be known until the JCPCT made a decision on the future configuration of congenital heart services. They told the Panel it was not the aim of the review to make savings and therefore the point of the financial analysis was to answer the question, whether the reconfiguration options were affordable to commissioners and the financial impact manageable by providers. This was why the financial criterion was not weighted and compared with other non-financial criteria. The JCPCT told the Panel that under option B, the NHS has circa £31million of commissioning funds available from those providers no longer supplying paediatric cardiac surgery and the estimated cost of revenue investment under option B was approximately £12.6 million, and hence option B was considered affordable. The JCPCT told the Panel that they recognised that further work would be necessary during implementation to firm up the costs, including the impact on retrieval services, but the view of the JCPCT was that there was sufficient headroom between the resources available and the investment required to give a high degree of confidence that option B was affordable. The JCPCT told the Panel that in their view it is likely that even after investment in a safe and sustainable service, in the medium term the cost of the service would reduce, due to economies of scale. The JCPCT told the Panel that the Y&H Joint HOSC had misinterpreted the figures in relation to the impact on Leeds Teaching Hospital NHS Trust. They told the Panel that, after taking account of savings in variable costs, the Trust may have to find savings of approximately £4.3 million to cover the indirect and fixed costs and that this figure compared to an average of £4.9 million for other trusts. The JCPCT further informed the

Panel that this is a small proportion of the Trust's total income, representing around 0.4 per cent of its turnover.

4.13.37 *Scoring of the options*

The Y&H Joint HOSC told the Panel they considered there had been an over-reliance on the Kennedy Panel assessments to measure 'quality'. The Panel heard that in their view the assessment of quality should have utilised the NHS framework for quality based on the domains of clinical effectiveness, safety and patient experience first highlighted by Lord Darzi's NHS Review in 2008²⁶. In addition, in their view it was a particular flaw in the methodology not to include the impact of additional travel times and costs as part of the quality assessment, given its significance to patient experience. Committee members told the Panel they were also concerned that the Kennedy Panel assessment framework was based on only 35 per cent of the *Safe and Sustainable* Standards.

4.13.38 The Panel heard concerns from a significant number of parents that they did not understand how the Kennedy Panel scores could be described as a measure of 'quality' as the measures on which they were constructed were not those that they could relate to as a rounded assessment of quality. They told the Panel they did not think that these would be the measures of quality that parents had in mind when they were asked to score the relative importance of the appraisal criteria.

4.13.39 Some people told the Panel that outcome measures should have been used as part of the assessment and that a wider range of indicators of quality could have been used to triangulate the findings. They told the Panel they were concerned how few of the domains in the Kennedy Panel assessment were clinical measures.

4.13.40 The Panel heard from a number of people who were concerned that the Kennedy assessments were never intended to be used for comparative purpose

²⁶ High quality care for all, Department of Health 2008

and yet subsequently, had been used in that way. Some trusts told the Panel they were concerned that they did not have an opportunity to correct any factual inaccuracies in the Kennedy Panel assessments and did not have access to the sub-scores. The Panel heard a number of challenges to the Kennedy Panel assessment process, scope, scores and the weighting that was used in these scores. A number of people told the Panel that they believed the scores had been manipulated and the outcome had been pre-determined as there had been suggestions circulating for some years that the service at Leicester and Leeds should be closed.

4.13.41 The JCPCT told the Panel that the Kennedy assessments were based on the quality standards that were endorsed by the professional bodies and aligned to other professional standards and are consistent with the NHS definition of quality. The Panel heard that no challenges to this methodology had been received during consultation and the JCPCT considered that it had taken account of patient experience through membership of the Children's Heart Federation on the Steering Group and in the consultation process through interviews, workshops and focus groups with parents and children.

4.13.42 The Panel was presented with several detailed critiques of the scoring process used by the JCPCT to select the preferred option. The JCPCT presented counter arguments to the Panel.

4.13.43 Key concerns in relation to the scoring of options were:

- Failure to consider Oxford as a surgical centre
- How the weightings were decided
- The relative weightings given to criteria, particularly the weighting given to accessibility
- Small differences in the Kennedy Panel assessment scores translated into large differences in the quality scores for options
- Inconsistencies in scoring in relation to access, co-location, research, risks and nationally commissioned services
- The robustness of sensitivity testing

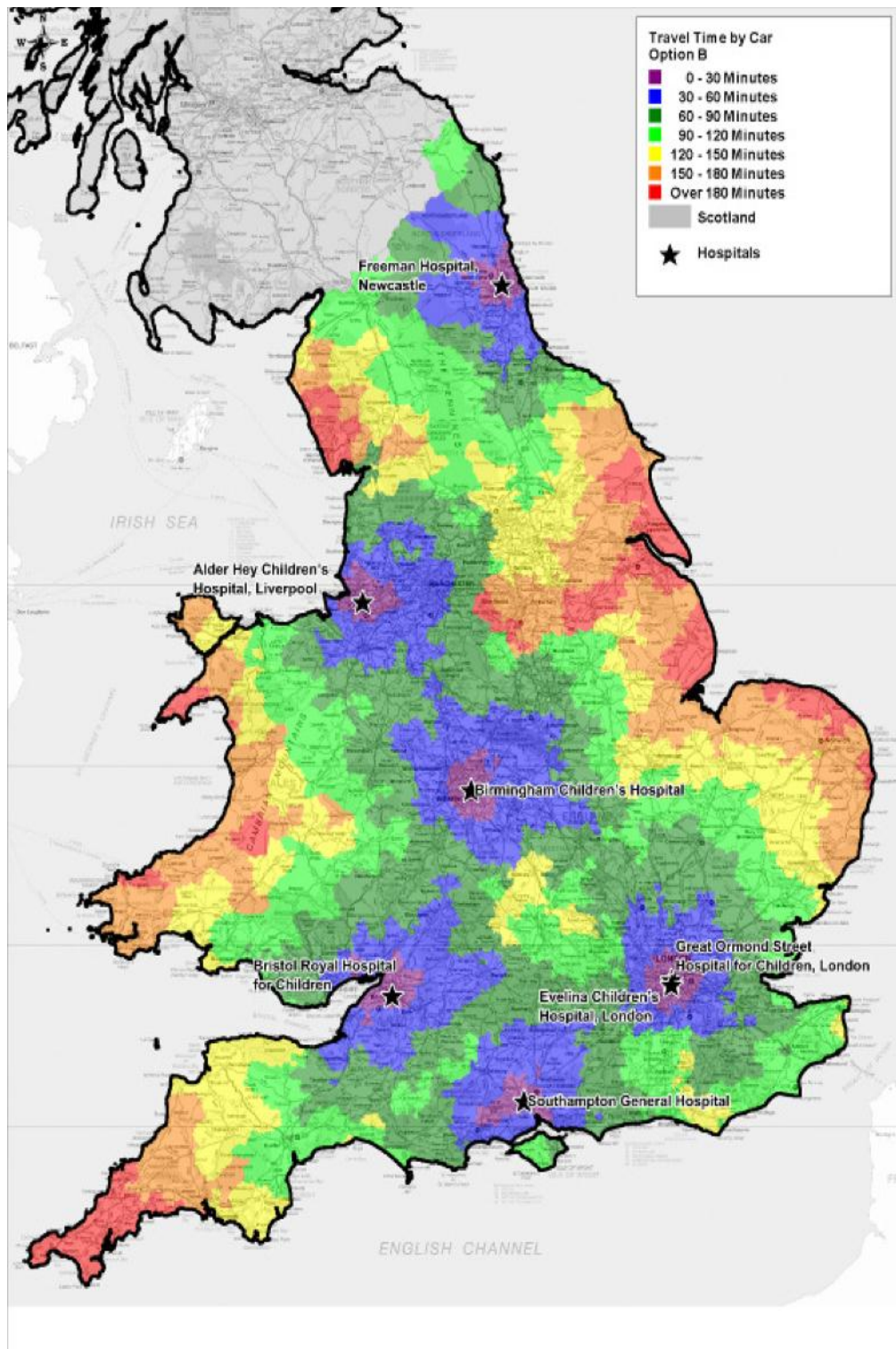
- Errors in attributing patient numbers to networks
- The inevitable outcome of weighting positively the options which included the “top three” scoring centres as two of these centres were in all options

4.14 **Accessibility**

4.14.1 All three referring scrutiny committees raised concerns regarding accessibility. The concerns focused on three issues - the planning methodology, the impact on local populations and the way in which the access component of the options assessment had been undertaken.

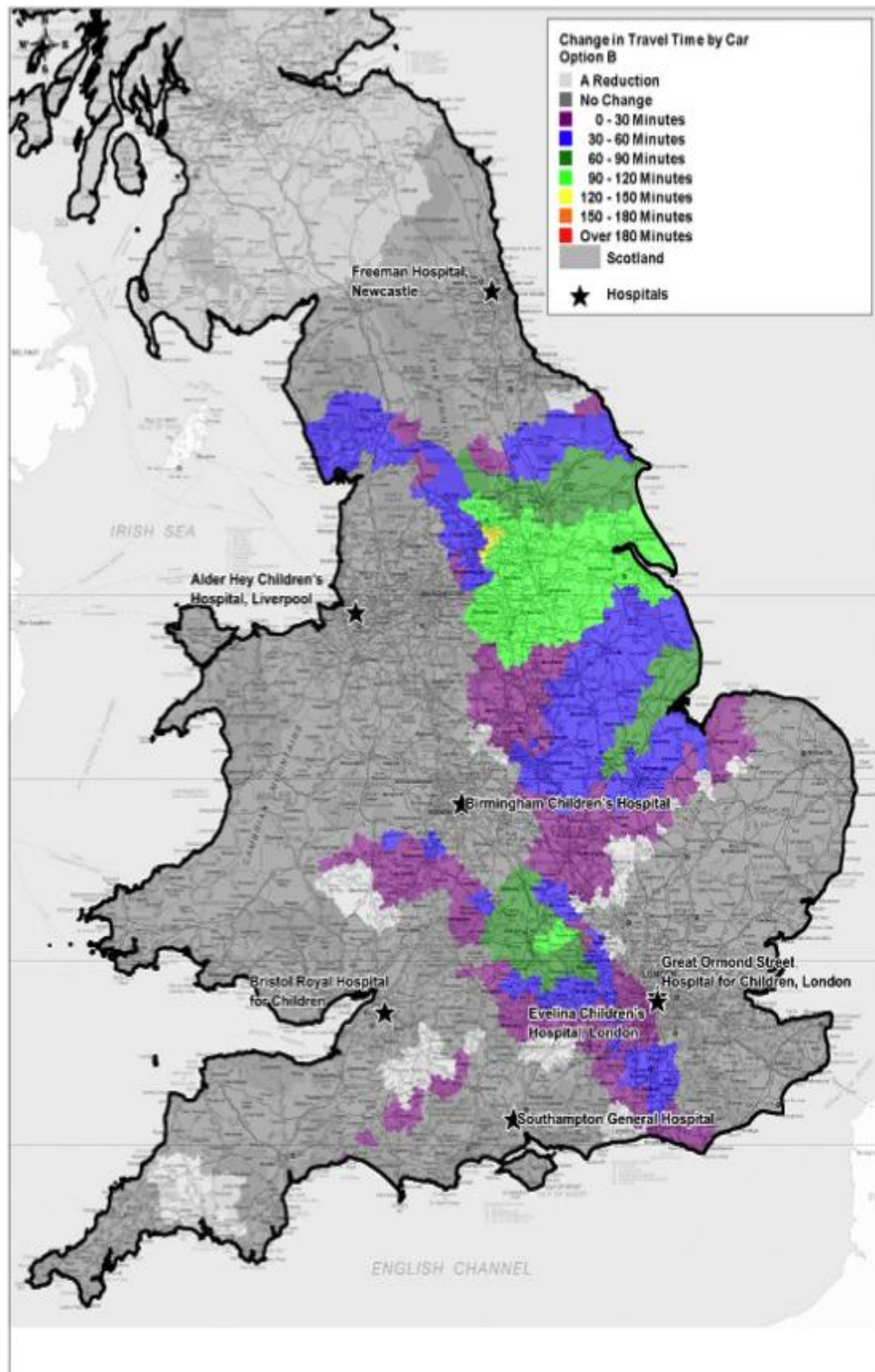
4.14.2 Access and transport links to the hospitals vary considerably around the country. Map 5 below shows the travel time to each of the proposed seven centres from within the proposed network areas. As can be seen, significant areas of the country (shown in yellow, orange and red) would have journey times in excess of over 120 minutes under the proposals. The direct impact of the changes on access for population is shown in Map 6, which shows the change in travel time under the proposals for different locations.

Map 5: travel time to surgical centres under the Safe and Sustainable proposals²⁷



²⁷ Safe and Sustainable: Review of Children's Congenital Heart Surgery Services in England Health Impact Assessment: Final Report June 2012. Contains Ordnance Survey data © Crown copyright and database right

Map 6 Change in travel time under the Safe and Sustainable proposals²⁸



²⁸ Safe and Sustainable: Review of Children’s Congenital Heart Surgery Services in England Health Impact Assessment: Final Report June 2012 Contains Ordnance Survey data © Crown copyright and database right

4.14.3 *Methodology*

The Lincolnshire HSC told the Panel they were not satisfied that the use of postcodes was an appropriate method to plan the network boundaries and assess the impact on accessibility. They considered that an alternative approach based on isochrones or the catchment areas of maternity and paediatric units would have been more appropriate.

4.14.4 The Y&H Joint HOSC highlighted to the Panel that the centre in Leeds currently undertakes a far higher volume of activity than the centre in Newcastle. They told the Panel that the population of Yorkshire and the Humber is in the region of 5.2 million people compared to 2.6 million in the NE and around 14 million people are within a two-hour drive of the current surgical centre at Leeds. They highlighted that the latest population projections show a higher rate of growth in the Yorkshire and the Humber area than in the north east of England. They questioned a planning methodology that did not take account of population and population density and stated they did not believe that the JCPCT had taken sufficient account of this when making its decision. They made reference to a statement from the BCCA in February 2011, which highlighted the need to reflect the distribution of the population in the planning of the location of the units in order to minimise disruption and strain on families.

4.14.5 The NHS told the Panel that they considered postcodes were a more accurate method than using isochrones and using the 2,292 postcode districts for the activity and journey time analysis had enabled them to gather a highly accurate picture of journey times and activity numbers.

4.14.6 The JCPCT told the Panel that the established aims of specialized commissioning are to commission from hospitals that can demonstrate that they have the necessary expertise. The Panel heard that other factors such as the availability of specific skills, management ability and interdependencies with other services are more important than population density. The JCPCT made reference to the 16 very rare and specialist treatments that are commissioned from the Newcastle upon Tyne Hospitals NHS Foundation

Trust. They told the Panel that to plan services on the basis of population density would go against the “*accepted logic*” for the commissioning of specialised services. However, they stated this did not mean that travel and population were irrelevant considerations as these issues were taken into account, but were not determinative.

4.14.7 *Impact on local populations*

The Panel heard concerns from all three referring HOSCs regarding the impact of the proposals on access for certain sections of their population. The issues of concern were:

- Travel times
- Poor transport links
- Low levels of car ownership
- Costs of travel, accommodation and childcare
- Adequacy of accommodation for parents and families at the proposed centres
- The impact on families including the social and personal burden of travel
- The impact on the availability of a wider support network for parents

4.14.8 The Panel heard from the Lincolnshire HSC and local parents that Lincolnshire is the largest rural county in England with very poor road and rail transport infrastructure and high levels of deprivation, particularly in the most remote parts of the county. Parents told the Panel that based on their own analysis they considered the assessments of the increases in travel time and the impact of travel had been substantially understated by the NHS. In particular, they consider the population of the north Lincolnshire coast is seriously disadvantaged by inclusion in the London network at a distance of 140 miles.

4.14.9 The Y&H Joint HOSC told the Panel that, under option B, 73 per cent of Yorkshire and the Humber patients would experience an increase in travel time of more than 1.5 hours compared to the national figure of 6.2 per cent and this demonstrates the disproportionate impact on those in Yorkshire and the

Humber. They told the Panel that they believe this analysis strengthens the case for a north of England solution that recognises and reflects the demographics and geography of that part of England. The eight centre solution put forward by the Y&H Joint HOSC would include Alder Hey, the Freeman and Leeds General Infirmary.

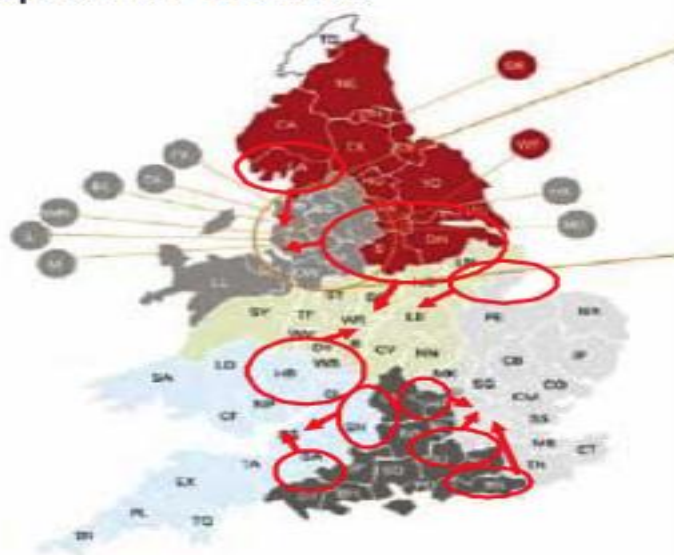
- 4.14.10 The Y&H Joint HOSC highlighted the impact on families in the Bradford, Halifax and Huddersfield area, who under the proposals would have to travel to the CCC in Manchester to receive services rather than the CCC in Leeds, which is much closer and a place with which they were familiar. This was felt to be particularly challenging for some of these populations due to low incomes, lack of access to cars and cultural issues for some sections of the population who rarely travel outside of their local community.
- 4.14.11 Leeds Teaching Hospitals NHS Trust presented an analysis of the impact on travel times for the population of Yorkshire and the Humber. This showed that under option B there was a more than five-fold increase in travel impact for the population of Bradford and a four-fold impact for other parts of Yorkshire and the Humber. The analysis also showed that with the exception of patients travelling from Grimsby and Scarborough all patients are currently within 70 minutes travel time of Leeds General Infirmary.
- 4.14.12 The Panel heard from parents in Yorkshire and the Humber, Lincolnshire and Leicestershire about their experiences of current travel times and how substantial the impact had been upon them and their wider family. The challenges of caring for siblings, the costs of travel, accommodation and difficulties of maintaining employment were highlighted by many, including LINKs and local charities. Many parents told the Panel that their child had stayed in hospital for many weeks and in some cases months. Parents told the Panel they found it hard to contemplate the journeys that they would experience in future should their child need further treatment at the surgical centres and they were concerned about the impact this would have on them. The Panel was told the thought of having to travel to an unfamiliar place that does not feature in a family's life in any other way for work or shopping or

days out is very unsettling to patients and families. The Panel heard concerns about the availability of accommodation in the proposed surgical centres. Parents were also concerned about whether there would be the retrieval and ambulance services in place to support transfers to the surgical centre and back to the CCC to limit the impact of distance on them. Parents told the Panel of their concerns about the impact on the families of those children diagnosed in future.

4.14.13 The Panel was told that people in nine areas of England would have to travel to a surgical centre that was not their nearest under the proposals. This includes patients from Surrey, Hertfordshire and Sussex - who would be required to travel to Southampton rather than London; patients from Oxford, Reading and Dorchester postcodes - who would be required to travel to Southampton rather than Bristol; patients from Hereford and Worcester - who would be required to travel to Bristol rather than Birmingham and a large section of the population in Yorkshire and Lincolnshire - who would be required to travel to Newcastle rather than Liverpool or Birmingham. These areas are highlighted in the map below with red arrows indicating the direction of the affected populations nearest surgical, as opposed to their designated, surgical centre.

Map 7

Option B: 7 networks



4.14.14 The Panel heard from a number of clinicians around the country about some of the challenges when children reach transition. They commented that young people and adults become very resistant to travelling because they can make up their own minds and have other pressures such as school, college, money, work or family commitments. Clinicians highlighted the importance of access as a key issue in minimising the number of patients who become lost to follow-up with potentially serious implications for patients long-term health. The Panel heard that people were concerned that they did not know what the implications for access to adult services would be.

4.14.15 *Assessment of accessibility in the options appraisal*

The Panel heard from many parents that they did not agree with the weighting that had been given to accessibility in the options scoring process. They told the Panel that they believed that the results of the survey undertaken by Ipsos MORI on behalf of the Children's Heart Federation had been misinterpreted to suggest that access was not important. While they agreed that quality was the primary concern of all parents, they stressed that accessibility was a key component of a quality service and did not understand why some of the networks that were being proposed resulted in people having to travel to the second or third nearest centre to their home to receive what should be an equal quality service.

4.14.16 Some trusts also raised concerns about the weighting for access and travel. They told the Panel that the weightings given by parents reported in the consultation document showed that they placed greater weight on access and travel and this should have informed the weighting used by the JCPCT, which instead was based on the Steering Group and SCG's views on weighting.

4.14.17 The Panel was told that options that did not include Southampton received a lower score than those that did, due to consideration of retrieval times from the Isle of Wight. The Panel heard that the scores erroneously presumed a relationship between retrieval standards and the travel times from congenital cardiac centres to the furthest parts of the proposed new networks. The Panel

was told that this was reflected in the scoring, such that if removal of a congenital cardiac surgical centre would result in a travel time from the nearest retained surgical centre that was in breach of the Paediatric Intensive Care Society's retrieval time standards of three hours - or four hours in remote areas - that option would receive a lower score. The Panel heard that people did not understand why this criterion had been used as the standard since the time taken for the retrieval team to reach the bedside, and the presence or absence of a congenital cardiac surgical centre, had no impact on the availability of, or the speed of response to, retrieval - be that on the Isle of Wight or anywhere else as they are two separate groups of staff and two separate services. The Panel heard that a retrieval services supporting the Isle of Wight or any other areas would be in place irrespective of the presence or absence of a congenital cardiac surgical centre.

4.14.18 The JCPCT told the Panel that the standards state that treatment would be provided closer to home 'wherever possible' although the primary objective was to reduce the number of surgical units in the interests of safety and resilience. While the JCPCT considered that increased journey times was relevant, they told the Panel that all stakeholders agreed that this was the least important factor in the decision making process.

4.14.19 The JCPCT told the Panel they considered their analysis of retrieval times was sound.

4.14.20 The JCPCT told the Panel that the assessment of journey times, activity and numbers of patients affected, which were used in the development of options and assessment of the access score in the option appraisal, was based on cardiac surgical procedures and it did not include patients undergoing cardiac catheterisation procedures or the impact on patients with co-morbidities.

4.14.21 *Safety and travel times*

The Panel heard from some clinicians and parents that there were concerns that distance would in some cases result in an adverse impact on outcomes for babies and children. The Panel was told that there were two clinical conditions

in particular where time to reach the surgical centre could have an impact on outcomes, these were:

- Patent ductus arteriosus (PDA)
- Septostomy

4.14.22 The Panel heard from a number of clinicians that PDA is a condition that affects very small, premature babies and the number of babies with this condition annually is small. Standard A29 states that neonates with PDA may receive surgical ligation in the referring neonatal intensive care unit (level 3) providing that the surgical team is dispatched from a designated specialist surgical centre and the unit is suitably equipped in terms of staff and equipment.

4.14.23 There were concerns that these patients would be harmed as a result of waiting to have their condition treated and that patients might wait longer than necessary to be treated if the surgical centre in their network was not the closest geographically.

4.14.24 Other clinicians told the Panel that PDA ligation is not a complex procedure nor is it time critical. The primary method of treatment is usually medication in the local hospital (NICU or Special Care Baby Unit); if medication fails to close the PDA, arrangements may be made for a surgical intervention on a planned basis. In many cases, correction of the PDA is not critical in the neonatal period. In such cases, children may be treated electively later in childhood. The Panel were told that issues of prematurity mean children with this condition have a high mortality rate.

4.14.25 The Panel asked the NHS if such patients would always have to be visited by the surgical team from the relevant network or if the team could be dispatched from another surgical centre if it was nearer, given the concerns that the child would have a longer wait than necessary.

- 4.14.26 The NHS told the Panel that the benefits of an integrated network approach (in particular, the benefits to clinical care and outcomes of the same medical and nursing teams in the NICUs and surgical unit developing a good working relationship) outweigh the perceived benefits of a model in which the NICU team would ‘shop around’ a number of potential ‘first available’ surgical units on a case by case basis. However, as an alternative to the above model, the baby could be transported as a day case to the surgical unit. As this would be on a planned basis, the NHS considered that the difference in transport time between the various surgical units would not be material. They highlighted that the standards stipulate that it would be for each Congenital Heart Network to determine local arrangements according to local circumstances for the management of PDA.
- 4.14.27 The Panel heard that some children require an urgent keyhole procedure called a septostomy. If the condition is not treated, the patient will die or be brain damaged due to acid in the blood. The Panel was told that the risk to these children is a function of how far/long they need to travel for a septostomy. The Panel heard that over the last four years, three babies in the Yorkshire and the Humber region have died because they did not get to Leeds quickly enough. A number of parents raised concern that deaths of these babies are not counted in the mortality statistics because they have not had an operation. People told the Panel they were concerned there would be more deaths due to greater distances for a significant proportion of the population in Yorkshire and the Humber, Leicestershire and Lincolnshire.
- 4.14.28 The Panel heard from Steering Group members that urgent septostomy is an important clinical issue. The Panel were told that most children requiring septostomy remain well in the early postnatal period but in a small percentage of cases there is an urgent need for this procedure and time is critical. Around 10 – 20 neonates per year require urgent septostomies in England. If the condition is identified antenatally, plans would be made for the delivery in or near the surgical centre. For those not diagnosed antenatally the critical issue is the time between birth and diagnosis and finally the transfer to a unit that can undertake the procedure (or in some cases the transfer of the team to the baby).

The availability of echocardiography (and a PEC/paediatric cardiologist) reduces the delay in diagnosis. The Panel were told that as most babies requiring septostomies are currently born outside a surgical centre there is an imperative to improve the ability to diagnose the condition antenatally, and improve the speed of post natal diagnosis and retrieval.

4.14.29 The NHS told the Panel that, as part of the implementation process, the professional associations had been asked to explore alternative models that would deliver the cardiology team to the neonate and Great Ormond Street Hospital is in the early stages of developing an outreach septostomy model in which the intervention would be performed in the outside neonatal unit. In addition, the resilience of surgical units to be able to respond to emergency situations would be strengthened in the future as an outcome of the concentration of medical expertise into larger teams.

4.14.30 *Care closer to home*

The Panel heard from parents who were unconvinced that, overall, care would be provided closer to home than it is now.

4.14.31 The Panel heard from trusts providing paediatric congenital cardiac services about the range of out-reach clinics that they currently undertake and the hospitals where there are PECs in place. The Panel heard from paediatric cardiologists at LGI that they had excellent PECs in 13 of the 17 locations where they undertake outreach clinics. They told the Panel that these PECs demonstrate how good their skills in echocardiography are by the fact that the paediatric cardiologists see no ‘innocent murmurs’ (that is, cases that do not need their expertise) in their clinics.

4.14.32 The NHS provided the Panel with a list of the locations where outreach clinics are held. The list can be found in Appendix 10. At the time of undertaking the review, there were 157 locations in England where outreach clinics were being held. The Panel heard from a number of Trusts that these services were well developed in a significant number of locations. The Panel noted that, under the

proposals, DCCS would be located in hospitals with over 3,000 births per annum (94 such units at the time of the consultation).

4.14.33 The NHS told the Panel that the 157 outreach clinics involve a cardiologist from the surgical unit visiting a local setting for routine management of patients. The NHS described a situation where:

- Often there are no formal protocols in place as the local hospital is not expected to be an integral part of the network;
- Often it merely provides a setting for the visiting cardiologist.
- The frequency of attendances by the cardiologist varies, but as often as once-weekly is rare.

4.14.34 They told the Panel that the development of DCCS does not preclude the continued presence of a paediatric cardiologist in outreach settings if this is considered appropriate by the network. By contrast, the DCCS would be integrated within the Congenital Heart Network; staffed by one or more dedicated Consultant Paediatricians with Expertise in Cardiology and a specialist support team including nursing, dietetics and clinical psychology, and linked to the surgical unit and CCC via telemedicine facilities.

4.14.35 The Panel heard that the range of services offered by the DCCS would be much broader than that available in outreach clinics as they would be equipped to provide a range of diagnostic tests including: electrocardiography, chest radiography, 24-hour ambulatory electrocardiography and blood pressure, monitoring, treadmill exercise testing and high quality echocardiography facilities. The Panel heard that children seen at the DCCS would generally be seen for the following reasons:

- Prenatal diagnosis
- Follow up of previously diagnosed congenital heart defects
- Follow up management of arrhythmias
- Follow up of post-operative cardiac surgical or intervention patients
- Referrals from GPs, paediatricians, community paediatricians, nurse specialists

- 4.14.36 As with the decisions on CCCs, the NHS told the Panel that decisions on which units are designated as DCCS would depend on the development of standards and an assessment of which hospitals meet the standards.
- 4.14.37 The JCPCT told the Panel that they had not undertaken any formal assessment of the impact of DCCS and CCCs on the delivery of care closer to home. However, they told the Panel that they were assured that the model would result in children and their families getting much better and more accessible local services than currently and, for the overwhelming majority of patients, the overwhelming majority of the care would be more local than currently. The JCPCT told the Panel that the decision to reduce the number of surgical centres would have been fully justified, and supported by the professional associations even if the JCPCT had not developed a mode of care that sought to bring non-interventional care into local settings.
- 4.14.38 The Panel asked the JCPCT if any assessment had been made of the impact on accessibility for children with co-morbidities. The JCPCT told the Panel this assessment had not been done and it was anticipated that these patients would be able to be treated in the CCCs because there would be cardiologists, anaesthetists and specialist nurses, working across the network, not just in the surgical centre.

4.15 **Sustainability**

4.15.1 *Networks*

The Panel heard consistent concerns from HOSCs, local charities, trusts and parents in areas affected by the proposals about the risks that a number of centres would not achieve the 400 surgical procedures threshold due to patient choice. For the proposed option B, the Panel heard that the viability and sustainability of Newcastle, Southampton and Bristol all depended on patients using a surgical centre that was not their closest. The Panel heard similar concerns from some trusts that are designated to remain surgical centres under the proposals.

4.15.2 The JCPCT acknowledged that some of the proposed surgical centres have been openly critical of the network boundaries proposed in the selected option, option B, in that it gives them a much lower surgical caseload than they would otherwise wish.

4.15.3 *Children's Cardiology Centres*

Other concerns that the Panel heard which relate to the sustainability of the proposals are all the issues raised about CCCs described above. They focused on:

- CCCs being unable to attract and retain staff
- CCCs being unable to sustain a viable range of activity due to deskilling of staff
- The sustainability of CCCs when there is a significant distance between the CCC and surgical centre
- The financial viability of CCCs
- Insufficient funding to develop the model of DCCC as planned
- As is noted elsewhere in this report, the JCPCT told the Panel:
- They consider the proposed networks are viable to deliver the 400 minimum surgical procedures
- That while the model of CCCs carries some risks these would be addressed during implementation.
- The commissioning frameworks for CCCs would be addressed by NHS England
- The financial analysis demonstrates there would be sufficient funding to implement the proposals

4.15.4 *Workforce*

The Panel heard from professional associations that they were concerned that paediatric cardiologists were in short supply and that there had not been adequate workforce planning to test the viability and sustainability of the proposals. The Panel heard some similar concerns about other professional groups.

4.15.5 The Panel heard from the JCPCT that KPMG undertook a workforce review on behalf of the JCPCT in early 2011. KPMG told the Panel that they looked at the implications of the options on different workforce groups, including surgeons perfusionists, cardiologists, nurses, anaesthetists and intensivists. They had looked at various issues such as the numbers of each workforce group in post at the time, the number of each of these professionals required under the proposals and the gaps in terms of workforce requirements under the proposals. Whilst they had undertaken this exercise, it had not fed through into the decision-making process due to the fact that it was not possible to second-guess how people would respond to the implementation of the proposals in terms of those staff who would be willing to transfer, those that would leave the service etc.

4.15.6 A number of people told the Panel that they were not convinced that the proposals would deliver the intended benefits, particularly taking account of the risks and disruption associated with the change process and potential loss of skilled and scarce staff.

4.15.7 *The Royal Brompton Hospital*

The Royal Brompton & Harefield NHS Foundation Trust presented the Panel with a detailed assessment of the implications of the proposals on the Trust. The Trust is a tertiary and quaternary centre specialising in the treatment of heart and lung disease.

4.15.8 Key issues were:

- The acknowledged impact that, as a result of the proposals (particularly the loss of PICU), other specialist respiratory services currently provided by the Trust would have to be delivered elsewhere
- Implications for PICU capacity in London due to the non-viability of the Brompton PICU if paediatric cardiac surgery is removed
- The clinical infrastructure supporting other services would be put at risk
- The impact on:
 - Fetal medicine services

- Adult congenital cardiac services
- Pulmonary hypertension services
- Electrophysiology services
- The inherited cardiac disease service that is only available in the UK at the Brompton
- The impact on research and clinical and research partnerships
- The impact on training
- Impact on the Trust's business model and financial sustainability
- The impact of population growth in London on demand for paediatric congenital heart services

4.15.9 The Panel heard that the proposals would result in the Trust losing £11m of income after the deduction of direct costs and facing redundancy costs of c£3 million if paediatric cardiology services were lost and c£8.7 million if all paediatric services were lost. The Panel heard the financial impact would put at risk the rest of the Trust's services and put back its capital investment programme for some years. The Trust was concerned the proposals bring into question the Trust's long-term financial viability and as a result they could be found in breach of their terms of authorization by Monitor.

4.15.10 The Trust told the Panel that, in their view, the best option for London would be delivered through a three-centre network model and they had put this option forward during consultation.

4.15.11 The Panel received many submissions from senior clinicians from abroad highlighting the international reputation of the services provide at the Royal Brompton Hospital and raising concerns regarding the impact of the proposals. A significant number of charities and parents also raised concerns about the impact of the proposals on children who are treated at the Royal Brompton Hospital for congenital heart disease or receive other specialist paediatric services. Particular concerns were the destabilizing effect of the closure of the PICU on the service to cystic fibrosis patients, which the Panel was told, is the largest paediatric cystic fibrosis service in Europe and about potential fragmentation of services for

children with respiratory conditions who currently receive a comprehensive service from the Royal Brompton Hospital. They were critical that the Pollitt report²⁹ had not considered issues of the longer-term sustainability of the services at the hospital.

4.15.12 The JCPCT told the Panel that the Pollitt report concluded that the services at the Royal Brompton Hospital would still be viable. They told the Panel that they had been criticized by the Trust for not incorporating respiratory services and adult services in the review but, the JCPCT believed it had to draw a line somewhere as there was a need to do something as quickly as possible about children's congenital heart services.

4.15.13 The NHS told the Panel that the Trust had argued strongly that adult services could continue in the absence of paediatric services but that the commissioners position is that they probably would not be able to because the standards developed by the ACHD review state services need to be co-located with paediatric services.

4.15.14 *Extracorporeal Membrane Oxygenation (ECMO)*

The referrals from LLR and Lincolnshire scrutiny committees raised concerns regarding the transfer of respiratory ECMO from Glenfield Hospital to Birmingham Children's Hospital. They highlighted that the ECMO service at Glenfield Hospital is the longest established ECMO service in the country and provides the majority (80 per cent) of the ECMO capacity nationally including mobile ECMO. They told the Panel that ECMO practitioners in the UK and overseas have voiced their concerns over the transfer of the service to Birmingham. The LLR Scrutiny Committee told the Panel that they accepted that ECMO can be moved in principle. However, they had been advised by recognised ECMO experts that the clinical outcomes would suffer for a number of years as a result of the transfer due to the disruption to established

²⁹ Report of the independent panel on the relationship of interdependencies at the Royal Brompton Hospital Sept 2011 The Pollitt report

teams and the learning curve any new team must undergo to maximise clinical performance.

- 4.15.15 The Panel was told that the mortality rate for respiratory ECMO in Leicester is 20 per cent, while the national mortality rate (that is, that of the other nationally commissioned centres) is 50 per cent higher. The concern is that Glenfield Hospital's low mortality rate would not transfer with the service. In terms of the impact on outcomes, if over the last 10 years Glenfield Hospital's ECMO mortality had been at the national average, 62 more children would have died.
- 4.15.16 There were also concerns about the ability to recruit staff to the new respiratory ECMO service. A survey of ECMO staff at Glenfield Hospital demonstrated that many of the skilled nursing staff involved in delivering the ECMO services had indicated that they would be unable to relocate their lives and families to Birmingham.
- 4.15.17 The LLR Scrutiny Committee told the Panel the JCPCT had not addressed this issue in sufficient detail and did not take into account the views of national and international experts. It also believes that the decision did not properly assess the evidence of the impact of such a move given that the Glenfield Unit is the largest such unit in the country.
- 4.15.18 The Panel heard from others who disputed the figures on the relative outcomes from the different respiratory ECMO centres.
- 4.15.19 The JCPCT and experts on the Advisory Group for National Specialised Services (AGNSS) told the Panel there were risks in moving respiratory ECMO services. However, the JCPCT told the panel that in their view those risks had been assessed in detail and could be mitigated to an acceptable level.
- 4.15.20 *Impact on medical research at University Hospitals of Leicester NHS Trust and Leicester University*
- The LLR Joint HOSC raised concerns regarding the impact of the proposals on research at University Hospitals Leicester NHS Trust. They told the Panel that

the University of Leicester has recently secured significant funding from the National Institute of Health Research. They told the Panel that the loss of children's congenital heart services and ECMO would impact adversely on the ability of the University and the Trust to continue to attract sponsorship and also to recruit the high-calibre staff needed to ensure that the existing high-quality research is maintained and further developed. The Panel heard that the University and the Trust employ some 30 academics, 150 researchers plus a considerable number of support staff in the Cardiovascular Biomedical Research and this could be put at risk in the future as a result of the decision to move services.

4.16 **Engagement, Consultation and Decision-making**

- 4.16.1 The Y&H Joint HOSC told the Panel they believed that a public consultation exercise should aim to encourage participation, make information accessible and allow people to contribute in a way, which is convenient and meaningful to them. The Panel heard concerns about the accessibility of the consultation document as it was 230 pages long and that local people had told the Committee that they found the consultation document and response form complex and not user-friendly. The Y&H Joint HOSC was concerned that the only means of responding for the first few weeks of the consultation was via an on-line questionnaire. They told the Panel this had disadvantaged some people and they did not feel that the communications plan had paid sufficient attention to the need to engage with BAME communities, particularly given these groups have an identified higher risk of congenital heart disease. The Panel heard that the consultation document was not translated into other languages until five weeks before the consultation closed.
- 4.16.2 The Panel heard similar concerns from other HOSCs, LINKs, parents, charities and local groups. These groups also raised concerns that the methods used to support engagement were not based on best practice nor sufficiently innovative to elicit a good response from all communities. In addition, people told the Panel there had been restrictions on the number of people able to attend consultation events and they had to press hard in order to get numbers increased.

- 4.16.3 Some parents who met the Panel were very upset that in their view, rather than in engaging in a proper debate about their genuine concerns, those connected to the NHS had portrayed them as selfish, emotional parents unable or unwilling to see the bigger picture. They told the Panel they had been portrayed as people acting out of ‘blind loyalty to a local unit’. Although they had a loyalty to the unit that had, in many cases, saved their children’s lives they highlighted that their loyalty to their children was greater than their loyalty to an institution and therefore their intentions were to support what they felt would deliver the best quality services. They told the Panel that the issue was that they did not feel the clinical case had been made and that the decision was based on flawed information in the HIA, in the planning assumptions and in the scoring. They did not feel the process had been transparent. The Panel heard from one parent who said that he felt that those leading the review had lost sight of the NHS constitution guiding principle that ‘the NHS belongs to the people’ and the requirement that NHS services must reflect the needs and preferences of patients, their families and their carers.
- 4.16.4 A number of parents and some charities raised concerns about the role played in the process by the Children's Heart Federation (CHF) in undertaking surveys that influenced the weighting given to the access criterion and the fact that this organisation was the sole voice for children and parents inside the process. For many parents who spoke to the Panel this arrangement become more problematic after the CHF itself issued public statements critical of those challenging the proposals.
- 4.16.5 The Panel found some of the media statements issued by the CHF and the NHS were seen to be combative in style, serving to polarise the debate and unnecessarily antagonize those raising their concerns.
- 4.16.6 The Y&H Joint HOSC told the Panel they were particularly concerned that insufficient weight had been given to the petition from Yorkshire and Humber residents, which over 600,000 people had signed. The LLR Joint HOSC and a number of charities and parents told the Panel they were concerned about how

the consultation responses had been interpreted and the weighting that was given to petitions, individual and organisational responses, particularly when a number of the organisations appeared to have no relationship to health services, such as banks and commercial retail organisations.

- 4.16.7 A number of people raised with the Panel a concern regarding bias. They highlighted that the membership of the Steering Group, although ostensibly based on representatives from professional associations, included people with a connection to all of the surgical centres included in the review with the exception of the three that were subsequently selected for de-designation at the end of the process. Their concern was heightened by individuals closely involved with the Steering Group and process both privately and publicly expressing views about which centres should close in advance of the options assessment. This included a statement issued by the CHF in 2010 about future services being provided at the seven centres that were finally selected.
- 4.16.8 The issue on which the Panel heard the greatest level of concern regarding the engagement and consultation process surrounded the decision-making at the JCPCT meeting on 4 July 2012. People told the Panel they felt it was completely unacceptable that there was no information circulated in advance of the meeting and this concern was much heightened by discovering the DMBC included eight new options that had not been subject to consultation nor had been communicated in advance. People told the Panel that they felt that ‘the goalposts had been changed’ due to the changes to the working assumptions and the rescoring methodologies that were applied. This issue was exemplified by the change in fortunes for option A, which appeared to emerge from the consultation as a strong option but in the DMBC was presented as relatively weak. They told the Panel there had been a lack of communication since the end of the consultation period.
- 4.16.9 The Panel heard concerns that the network boundaries of option B as set out for consultation were not the same as the network boundaries for option B as presented in the DMBC. The Panel was told that several postcode areas had been moved into different networks under the new option B and therefore it

was misleading to suggest that support for option B in the consultation was necessarily support for option B in the DMBC. The changes related to Hereford and Worcester who move from the Birmingham to the Bristol network and Dorchester, west Oxford and Reading who move from the Bristol to the Southampton network.

4.16.10 The Panel heard from many people who felt they had been denied the opportunity to consider the new proposals and give their views. Many people were concerned that the decision has been made in advance of the meeting and it was not a genuine decision-making meeting.

4.16.11 A number of parents and HOSCs told the Panel they had submitted Freedom of Information Act requests to obtain basic information such as agendas, minutes and terms of reference and they had found the NHS to be unresponsive and defensive, particularly in response to challenge to the proposals. The Y&H Joint HOSC told the Panel that they felt very strongly that that such information should have been made available for public scrutiny. The Y&H Joint HOSC told the Panel that they felt the JCPCT and NHS had displayed contempt towards legitimate public scrutiny of the review and its proposals and they had been denied the ability to discharge their scrutiny function as fully as they would have liked. However, they also told the Panel that they welcome the suggestion that the Centre for Public Scrutiny would be involved as part of the ‘lessons learned’ activity associated with the review and they wished to be actively involved in contributing to this process.

4.16.12 The Panel heard from Ipsos MORI, who reported the results of the consultation, that it was usual practice with consultations to treat petitions as one response. However, it is made clear in the report how many people signed the petition and petitions have their own chapter in the report on the consultation. They told the Panel that they reported clearly and accurately the findings from the consultation including the different volume of responses from different regions to enable the JCPCT to consider this information. In relation to responses from organisations, Ipsos MORI told the Panel that they list all responses from organisations so that people can see the range of bodies

who have responded. The Panel heard that the organizational response form encourages respondents to consider if they are genuinely responding on behalf of an organisation by asking questions about how they assembled members' views and how many people they were representing but the role of those reporting the results is not to make a judgment on how valid their view was.

4.16.13 The Panel heard from the NHS and the JCPCT that they considered that the engagement and consultation process had been thorough, robust and transparent and that the findings from engagement and consultation had been used to shape the standards, the options for consultation and the final proposals. The JCPCT told the Panel that the Y&H Joint HOSC was not a properly constituted joint HOSC because the Y&H Joint HOSC and all other joint HOSCs in England had failed to comply with the requirements of the legislation by not convening a single national joint scrutiny committee. Notwithstanding this issue, the JCPCT was of the view that the requests of the Y&H Joint HOSC had been dealt with reasonably up to the point of decision-making. In their view, their duty to provide information ended on 24 July 2012 when the Y&H Joint HOSC decided to refer the JCPCT's decision to the Secretary of State for Health.

4.16.14 The NHS told the Panel that before going to consultation they considered the number of different languages spoken across the country and followed what they considered to be standard best practice within the NHS which was to let people know that materials would be translated on request. They had responded promptly to requests for translation, but this took a month due to the scale of the task. They also redesigned the consultation workshops when the level of interest became apparent, which included changing the methodology to accommodate town-hall style debates.

4.16.15 The NHS told the Panel that the judicial review process had increased the time between consultation and decision and had limited their ability to engage and communicate with stakeholders. However, during this period Ipsos MORI published three reports on the outcome of consultation. The outcome of the Pollitt report on the impact on respiratory services at the Royal Brompton Hospital and

the outcome of the PwC work on assumptions around patient flows and manageable networks were also published along with a number of newsletters.

4.16.16 The JCPCT told the Panel that feedback from the consultation was reflected in the DMBC and had a significant influence, as evidenced in particular by the consideration of new options. The Panel heard that the DMBC made reference to the significant support for LGI and the JCPCT was mindful of the strength of feeling in Yorkshire and the Humber. However, this had to be balanced with the soundness of the arguments being put forward.

4.16.17 The NHS told the Panel that the secretariat and KPMG developed the additional options set out in the DMBC and the JCPCT asked them to undertake further analysis to test various assumptions as well as the viability of the original and new options. The JCPCT told the Panel they held several meetings over the period 30 June 2011 to 12 June 2012 to consider the options. The Panel heard that the draft DMBC was written by the secretariat, was finalised between 13 and 29 June 2012 and was signed off by the Chair of the JCPCT to be submitted to the JCPCT in advance of the public meeting on 4 July 2012. The JCPCT told the Panel that the DMBC included a list of recommendations that the JCPCT considered at the meeting on 4 July 2012, and on which it reached its conclusions at that meeting.

OUR ADVICE

Adding value

5.1 Introduction

- 5.1.1 The proposals for changing children’s congenital heart services, the subject of this review, are set out in the *Safe and Sustainable: Review of Children’s Congenital Cardiac Services in England; Decision Making Business Case* of July 2012. The DMBC set out 20 recommendations, all of which were approved by the JCPCT on 4 July 2012.
- 5.1.2 The review of children’s congenital heart services originates from a request in May 2008, from the NHS Medical Director, Sir Bruce Keogh on behalf of the NHS Management Board that “*the National Specialist Commissioning Group undertake a review of the provision of paediatric cardiac surgical services in England with a view to reconfiguration*”.
- 5.1.3 The intervening four years comprised three main phases:-
- The development of service standards
 - The assessment of current providers against service standards
 - The development of service change proposals to enable service standards to be achieved in the future
- 5.1.4 The proposals have faced a number of challenges since the consultation period in 2011:
- Previous referrals to the Secretary of State for Health by the Y&H Joint HOSC and Kensington and Chelsea HEHASC Scrutiny Committee in 2011 on which the IRP provided initial advice
 - A judicial review brought by the Royal Brompton & Harefield NHS Foundation Trust in 2011 which found in the Trust’s favour but was overturned by the Court of Appeal
 - A judicial review brought by Save our Surgery Ltd, a Leeds based charity, which found in favour of Save our Surgery Ltd in March 2013

- 5.1.5 This review is unique in the IRP's experience, being on a national footprint and about a set of specialised services that serve about eight in a thousand newborns - many of whom, with their families, live with the consequences of their condition for the rest of their lives. The JCPCT's proposals and, therefore, the review have been dominated by the arguments for and against concentrating the specialist surgery component of care in the fewer, larger centres identified in the DMBC. The rest of the care pathway, from antenatal screening through to provision of services for adults with congenital heart disease, has by comparison been largely ignored. This is illustrated by the paucity of evidence received during the review about the number of patients who are receiving NHS treatment for their CHD and prevalence of the condition in 0-16 year olds.
- 5.1.6 Much of the evidence that the Panel heard reflected the issues raised in the referrals from the three HOSCs, being focussed primarily on the NHS's analysis of, and the JCPCT's decision about, which of the ten surgical centres should continue. Significant other issues included the case for larger surgical centres, the sustainability of the proposed model of managed networks and the impact of the proposals on adults with congenital heart disease.
- 5.1.7 The Panel took evidence from the HOSCs, JCPCT, the Steering Group, Sir Ian Kennedy, expert advisors to the JCPCT, national specialised services' commissioners, professional associations and national charities. The Panel also took evidence in all ten surgical centres, the three cardiology centres and a number of retrieval services in England and Wales, giving the opportunity to meet and hear from many frontline staff, volunteers, local charities, parents and children involved with these services.
- 5.1.8 In common with the large quantity of correspondence received, those using the services described eloquently the skilled care they receive from highly motivated and committed staff, often over many months and years. The Panel also heard from some parents and others about poor quality of care and loss of confidence in services relating to a number of the surgical centres around the country - some that are proposed to be retained, and others that are not. Whilst

it is not the remit of the Panel to take up individual cases, all the evidence from parents and relatives is hugely valuable and we are grateful for their time and effort in sharing their experiences. Individuals using the services with concerns were advised to take them up with relevant organisations.

- 5.1.9 The phrase “*waiting for the next Bristol*” captures the almost morbid sense of spectatorship and foreboding that hangs over these services. The review and closure of the Oxford surgical centre in 2010 had served to bring history back into sharp relief. The nature of the service and the high level of public interest over a long period means that centres will, from time to time, find themselves under close scrutiny irrespective of the presence of any underlying causes for concern. It is also the case that services will give real cause for concern at times for patients, commissioners and regulators. The Panel understands the burden of both history and the responsibility for the current safety and quality of services. However, the focus of this review and the Panel’s advice is fundamentally about the longer-term future, mindful of the interests of both current patients and their families and those yet to be born.
- 5.1.10 Despite the uncertainty created by a succession of reviews since the Kennedy Report on the Bristol Inquiry in 2001, there have been many improvements in these services including most recently those stimulated by the process of assessment against national standards in 2010. Nevertheless, the current situation remains uncertain, holding back further decisions about investment in new facilities and permanent additional staff. The Panel also heard that the *Safe and Sustainable* process had been divisive, particularly for the professional staff involved. There is clearly a need to consider these issues when deciding how best to move forward in the interests of patients as quickly as possible.
- 5.1.11 Taking account of the current context, the Panel has considered in detail each of the issues raised before reaching its conclusions. In doing so, the Panel’s primary focus is the best interests of children with congenital heart disease, now and in the future.

- 5.1.12 **The Secretary of State for Health asked the IRP to advise as to whether it is of the opinion the proposals for change under the “*Safe and Sustainable Review of Children’s Heart Services*” will enable the provision of safe, sustainable and accessible services and if not why not. Overall, the Panel is of the opinion that the proposals for change, as presented, fall short of achieving this aim.**
- 5.1.13 **The Panel’s view is that people - children and adults - with congenital heart disease in England and Wales will benefit from services commissioned to national standards for the whole pathway of their care.**
- 5.1.14 **The Panel agree that congenital cardiac surgery and interventional cardiology should only be provided by specialist teams large enough to sustain a comprehensive range of interventions, round the clock care, training and research.**
- 5.1.15 **However, the Panel has concluded the JCPCT’s decision to implement option B (DMBC – Recommendation 17) was based on flawed analysis of incomplete proposals and their health impact, leaving too many questions about sustainability unanswered and to be dealt with as implementation risks.**
- 5.1.16 **Throughout our review, people told us that being listened to was something they valued. The opportunity to change and improve services is widely recognised and, in taking forward our recommendations, those responsible must continue to listen to legitimate criticisms and respond openly. We set out below recommendations to enable sustainable improvements for these services and learning for future national commissioning of health services.**
- 5.2 **The proposals for change**
- 5.2.1 The proposals for service change are driven by the adoption of national service standards covering seven key themes:
- Congenital heart networks

- Prenatal screening and services
- Specialist surgical centres
- Age appropriate care
- Information and making choices
- Family experience
- Ensuring excellent care

5.2.2 In particular, the JCPCT's decision to adopt the mandatory standards of a minimum of four full-time surgeons and 400 paediatric surgical procedures per surgical centre creates the need to reconfigure current centres, and an assessment of those centres against some of the service standards was a key component in the JCPCT's decision about which surgical centres should be closed.

5.2.3 The proposal for change that is the subject of this review is the implementation of seven congenital heart networks led by the following surgical centres:

- Freeman Hospital, Newcastle upon Tyne Hospitals NHS Foundation Trust
- Alder Hey Children's Hospital NHS Foundation Trust
- Birmingham Children's Hospital NHS Foundation Trust
- Bristol Children's Hospital, University Hospitals of Bristol NHS Foundation Trust
- Southampton University Hospitals NHS Foundation Trust
- Evelina Children's Hospital, Guy's and St Thomas' NHS Foundation Trust
- Great Ormond Street Hospital for Children NHS Foundation Trust

and de-commissioning of the children's congenital cardiac surgical services at Leeds General Infirmary, Glenfield Hospital Leicester and the Royal Brompton Hospital, London.

5.2.4 As the Panel quickly discovered, the proposals will have inevitable consequences for services for adults with congenital heart disease – who by definition are mainly the same group as the children, only older. Indeed, the Panel noted that in the course of the *Safe and Sustainable* review,

approximately one quarter of the children using services will have become adults. The separate consideration of services for children and adults was raised as an issue throughout the review, not least because a parallel review of ACHD services has been underway for some time. In the Panel's opinion, this issue needs to be considered upfront to address our terms of reference in the most comprehensive and useful way.

5.3 Services for adults with CHD

- 5.3.1 Due to improved rates of survival, there are now more adults living with CHD than there are children and the adult CHD population is projected to grow rapidly in the coming years. The Panel heard that adults with congenital heart disease will be directly affected by the proposals and this was not considered as part of the JCPCT's decision. The JCPCT said that adult services were not within their remit and the decision to undertake two separate reviews had been endorsed by the professional associations on the Steering Group. The JCPCT told the Panel that a line had to be drawn somewhere and that the alternative was to delay progress.
- 5.3.2 Given that it is the same surgeons and, in some cases, cardiologists providing the care, and the majority of current specialist centres provide both paediatric and adult congenital heart services, the impact of a decision about children's services cannot be separated from the future of adult services. The JCPCT told the Panel that the draft standards developed by the adult review stipulate that, in future, adult congenital cardiac services need to be co-located with paediatric congenital cardiac services. Consequently, the proposals for children's services threaten the future of the adult congenital heart services at Leeds and Manchester in the north, Leicester in the east Midlands and the largest service in London and the UK at the Royal Brompton Hospital - the Brompton also being the largest research centre in the UK for adult disease.
- 5.3.3 The practical implications of making the decision about children's services separately from consideration of adult services were brought to the Panel's attention. The Panel agrees that there are risks to continuity of service for adolescents as they transition to adult services and that the need to co-ordinate

implementation of changes to children’s services with changes to adult services is unavoidable.

5.3.4 Representations on the logic of looking at congenital heart services for children and adults together had been made by many parties, including professional associations, at various points during the four years of deliberation. The IRP heard likewise throughout its review. The Panel agrees with the view commonly expressed to it that a single review would have enabled better solutions to be found that commanded a higher level of support.

5.3.5 **Recommendation One**

The proposals for children’s services are undermined by the lack of co-ordination with the review of adult services. The opportunity must be taken to address the criticism of separate reviews by bringing them together to ensure the best possible services for patients.

5.4 **The JCPCT’s case for “larger surgical centres”**

5.4.1 The Panel reviewed the JCPCT’s case for change and sought views from all parties. The case for “larger surgical centres” for children’s heart surgery is presented by its proponents as incontrovertible – a principle that “*everyone has signed up to*”. What the Panel heard was less straightforward. The case for larger centres relies on two key arguments:

- The relationship between volume of cases per centre and per surgeon and better outcomes for patients
- Larger teams are more sustainable and hence provide higher quality services

5.4.2 *The relationship between volume and outcome*

In clinical medicine, it is observed that there is generally a positive association between doing more of something and getting better results for patients. For some specialty services, there is clear evidence for a strong positive relationship between volume of procedures and outcomes achieved. The Panel reviewed the relevant published literature for congenital heart disease and took

evidence from clinicians on this issue. Whilst there is some evidence of a positive relationship between volume of procedures and outcome at lower numbers per centre, for the current surgical centres in England and the proposed minimum of 400 procedures per centre, the evidence is that there is no significant positive relationship between increases in volume and expected outcomes.

- 5.4.3 The Panel found that the proposed standard of a minimum number of procedures per surgeon was initially set at 100 paediatric procedures, in addition to any adult caseload. However, the final standard moved away from setting the number of procedures per surgeon, to requiring each surgical centre to undertake a minimum of 400 and preferably 500 paediatric surgical procedures “*sensibly distributed between all four cardiac surgeons*”. This was in recognition that most surgeons undertake adult practice and the balance of adult and paediatric work tends to change over the surgeon’s career with the proportion of adult work increasing over time.
- 5.4.4 Some evidence suggests a more positive impact of volume on outcomes for relatively rare and complex procedures to treat, for example, hypoplastic left heart syndrome. This suggests either larger centres as proposed or concentrating such procedures in fewer centres. The Panel noted that much larger centres such as in Boston, USA were implementing surgical sub-specialisation to improve outcomes further.
- 5.4.5 The Panel was concerned that in presenting the case for change in the consultation document and the DMBC, the NHS failed to indicate that the evidence of a link between volume and outcome, and experience of rationalisation of services internationally, related to a much lower threshold of activity per centre than the standard of 400 cases per centre proposed. There was also a failure to explain that the Kennedy and Munro reports had suggested significantly lower thresholds per surgeon and per centre. The Panel met many well-informed parents as well as clinicians and HOSC members who had diligently read all the referenced material in the consultation document and DMBC. This failure to set information in context was at the

heart of feelings reported to the Panel by some parents, HOSCs and clinicians that the process lacked transparency and used information selectively.

5.4.6 *Larger teams*

The Panel found widespread support for the standard of at least four full-time surgeons per team. This has a range of benefits such as aiding recruitment and retention of staff, supporting sub-specialisation, mentoring, collaborative working on complex cases, cover for planned and unplanned absence, training, research and audit. A number of clinicians also highlighted the relationship between stable teams and high quality services. The importance of the wider team of specialists who are involved in the care of children with CHD, was also highlighted to the Panel by many who felt that the implications for these professions had not been sufficiently addressed by the proposals.

5.4.7 Patients relying on a specialist service expect experienced, skilled staff to be available round the clock to provide all the care that may be required. The Panel agrees that achieving this in a sustainable way requires a minimum of four full-time consultant surgeons in each team and a volume of procedures sufficient to develop and maintain the skills of surgeons, cardiologists and other personnel in providing a high quality, comprehensive service.

5.4.8 **Recommendation Two**

Patients should receive congenital heart surgery and interventional cardiology from teams with at least four full-time consultant congenital heart surgeons and appropriate numbers of other specialist staff to sustain a comprehensive range of interventions, round the clock care, training and research.

5.5 **The clinical model and managed clinical networks**

5.5.1 *The clinical model*

The successful implementation of the proposed clinical model and managed clinical networks is critical to the future quality, sustainability and accessibility of services. The model underpinning the proposals is described in terms of

service standards and three broad components - district children's cardiology services (DCCS), children's cardiology centres (CCC) and specialist surgical centres – working together as a managed network.

- 5.5.2 Whilst many people expressed support for the general concept of the proposed clinical model, those using the services were keen to know the detail – how it would work for patients and what services would be where. The necessary clarity and detail about the clinical model of services was not developed before consultation commenced and so the proposals appeared incomplete and uncertain. The JCPCT told the Panel that the number and location of CCCs and DCCS would not be known until standards had been developed for these services and potential centres had undergone an assessment process.
- 5.5.3 The Panel found some evidence of the proposed clinical model in working examples of paediatricians with an expertise in cardiology linked to a specialist centre. Despite the absence of clear standards and therefore consistency across the country, it was clear to the Panel that DCCS have real potential as part of a managed network providing suitably qualified paediatricians can be recruited and necessary facilities and activity funded.
- 5.5.4 The Pre-Consultation Business Case (PCBC), consultation document and DMBC all present the same confusion about why CCCs should be developed. It is unclear whether the intention was to provide a sop to de-designated surgical centres or that CCCs are an essential element of the model of care. The JCPCT told the Panel that, contrary to the proposal in the consultation document that the centres that cease to provide surgery may become CCCs, it was unlikely that a CCC at the Royal Brompton Hospital would be viable given the close proximity of the Evelina Children's Hospital and Great Ormond Street Hospital. Likewise, a CCC in Leicester could not be on the Glenfield Hospital site as on-site PICU is required and the PICU at Glenfield Hospital ceases to be viable with the loss of the surgical activity.
- 5.5.5 The lack of clarity is reinforced by references, as evidence of a viable model, to the existing CCCs in Manchester, Cardiff and Oxford. The Panel was not

persuaded that any of these provide ‘proof of concept’ for the CCC element of the proposed clinical model. The Panel found evidence that the scope of clinical services in these centres was reducing due to valid clinical governance issues. This was illustrated by the on-going debate about the ability to undertake all electrophysiology outside of the surgical centre. The Panel also found that cross-site working between the cardiology centre and the surgical centre was a critical factor for creating sustainable roles and sustaining specialist skills and confidence across the whole clinical team. The impact of distance and travel time for clinical staff is therefore a key consideration in developing a viable model of a CCC working in association with its surgical centre.

- 5.5.6 If non-interventional cardiology centres are an essential element of the clinical model, their unique functions should be described and the form matched to the population need. Until such time as a clear and credible description can be provided of the scope of the clinical services that will be provided, the staff and facilities that they will comprise and the clinical staff inter-relationship with the surgical centre, there will remain valid doubts about the ability of CCCs to attract and retain scarce specialist staff and provide a broad and sustainable range of services to their catchment population.
- 5.5.7 A particular concern raised by many people with the Panel were the needs of children with CHD who have significant other health conditions and rely on specialist cardiac anaesthetists for any intervention where anaesthetic is required. Around 25-30 per cent of children with CHD fall into this category. The Panel heard grave doubts from clinicians that these skills could be sustained in the proposed CCCs. The Panel did not find sufficient evidence that the impact on these patients had been properly assessed.

5.5.8

Recommendation Three

Before further considering options for change, the detailed work on the clinical model and associated service standards for the whole pathway of care must be completed to demonstrate the benefits for patients and how services will be delivered across each network

5.5.9 *Managed clinical networks*

The *Children's congenital cardiac services in England service standards* acknowledge that the “*precise shape of each Congenital Heart Network should be determined by local needs and local circumstances including geography and transport*” so that as much care as possible is delivered closer to home.

5.5.10 The lack of evidence of consideration of the issues of local needs, geography and transport, and the lack of detail about where and how the rest of the non-surgical care pathway would be delivered, was at the heart of much of the criticism of the proposals. Given that the vast majority of care for this lifelong condition is provided by cardiologists, liaison nurses and their teams locally, the absence of a clear and compelling description of the totality of the care pathway is a substantial deficiency in the proposals. Patients expect proposals for major service change to describe services for the whole pathway in equal detail. This has been a consistent point of learning from previous IRP reviews of contested proposals for service change.

5.5.11 The case for a standalone CCC will likely depend on the benefits for other on-site services from access to paediatric cardiology advice, the opportunity to reduce negative accessibility impacts for patients and ensuring workable distances from surgical centres to associated district cardiology services for outreach and in-reach activity. In this context, the Panel consider that it is unclear how the proposed Northeast and Midlands networks, for example, could function effectively because of the populations and distances involved within catchment areas.

- 5.5.12 For those areas potentially losing a specialist surgical centre, the proposed mitigation of bringing services closer to home is questionable given that people cannot as yet be told where these services would be delivered and what they would comprise. As a result, there is lack of confidence that the proposals will deliver the claimed benefits for patients and for many in the areas most affected there is genuine fear that the service will be substantially worse, particularly in terms of accessibility and its impact on families.
- 5.5.13 The Panel heard a range of concerns regarding the lack of alignment between the proposed Congenital Cardiac Networks and fetal, neonatal, paediatric and adult congenital cardiac networks. The Panel noted that the standards set out that these networks should be aligned and agrees this is in the best interests of patients. The Panel was not convinced that the implications for patients of the lack of alignment of networks had been assessed or that clear plans existed for how it would be addressed.
- 5.5.14 The Panel found that the proposals would impose substantial additional demands on retrieval services and that the current service was considered to be inconsistent across the country. The Panel was advised that retrieval is not a constraint on configuration of services provided the service is planned and resourced appropriately. The JCPCT confirmed that this had not been assessed as part of the DMBC.
- 5.5.15 Overall, the Panel found a paucity of basic information about the clinical needs of patients with this long-term morbidity and their profile of service utilisation to support effective commissioning, compared to other long-term conditions. Information on prevalence and the numbers of patients in England and Wales with CHD under active monitoring and treatment by the NHS does not routinely exist.
- 5.5.16 Given the absence of critical detail regarding the number of CCCs and DCCS and the scope of their clinical activity, the Panel was not assured that the affordability of the proposals had been sufficiently assessed, or that CCCs would be a financially viable proposition for providers. With regard to DCCS,

the nature, number, location and commissioner commitment from CCGs are all unknowns leaving huge doubts about the ability of the proposals to deliver care closer to home. There was insufficient clarity regarding the commissioning arrangements for the Panel to have confidence that the whole pathway would be effectively commissioned and underpinned by a sustainable contractual regime for providers.

5.5.17

Recommendation Four

For the current service and any proposed options for change, the function, form, activities and location of specialist surgical centres, children's cardiology centres, district children's cardiology services, outreach clinics and retrieval services must be described and financial viability and affordability retested.

5.5.18 *Antenatal detection*

The Panel was concerned about the lack of focus on addressing the stark variation in antenatal detection rates for CHD, across England. Given the evidence that antenatal detection has a beneficial impact on outcomes, and the variation in detection rates is not explained by the need to reduce the number of surgical centres, this is not acceptable and the NHS should be aiming to achieve consistently the highest possible rate.

5.5.19

Recommendation Five

NHS England should ensure that a clear programme of action is implemented to improve antenatal detection rates to the highest possible standard across England.

5.5.20 *Population, activity and capacity*

The Panel heard concerns from HOSCs, clinicians and parents that the planning assumptions for proposed change are flawed in the light of the latest activity data and population projections. There are risks that some centres, particularly Birmingham Children's and Great Ormond Street hospitals, may

see excessive demands placed upon them given the pattern of regional population growth.

- 5.5.21 The Panel noted the nine per cent increase in activity in the period 2006/07 to 2011/12 (excluding foreign private patients) and the latest population projections that suggest a 16 per cent increase in the 0-14 population in England and Wales between 2011 and 2025. This is compared to the planning assumption of a 13.7 per cent increase on 2006/07 activity by 2025 (excluding foreign private patients) used in the DMBC.
- 5.5.22 The Panel also noted that the viability of the proposed networks centred on Newcastle, Bristol, Southampton and Evelina are all vulnerable to modest changes in assumptions about patient flows.
- 5.5.23 The Panel heard general concerns about PICU capacity given that the proposals for change render the PICUs at the Royal Brompton and Glenfield hospitals unviable. Doubts were expressed about whether sufficient capacity would exist to avoid disruption to the delivery of planned cardiac interventions. This view was overlaid with concerns about the impact of rising birth rates, particularly in the Midlands and London.
- 5.5.24 The Panel was concerned about the substantial difference in the assessment of the future number of adult patients with CHD and their future healthcare needs predicted by commissioners on the one hand and clinicians and professional associations on the other.

5.5.25

Recommendation Six

Further capacity analysis, including for PICUs, should consider recent and predicted increases in activity, the latest population projections and patient flows.

5.6 The safety and quality of services

- 5.6.1 The proposals for change have not been argued on the grounds that current services are unsafe. For several years, standard data have been collected about each intervention and summary comparative analysis is publicly available on the NICOR website. The Panel were consistently told that the quality of the outcome data and the range of robust, publicly available data on paediatric cardiac surgery in the UK is the envy of the rest of the world. Published mortality rates are uniformly around two percent or less for primary surgical procedures in all the current surgical centres, and as such comparable with the best equivalent services internationally.
- 5.6.2 In this context, the Panel were troubled to hear some people assert that there were known and significant differences between the outcomes achieved by the existing centres. The Panel sought the evidence behind these assertions without receiving anything conclusive. At the end of the review, the Panel asked the JCPCT, as commissioners, whether there existed any further information about the safety or performance of the current centres that would help inform the Panel's advice to the Secretary of State. The JCPCT confirmed that there did not.
- 5.6.3 The use or not, of outcome data to assess and compare the safety and quality of the children's cardiac surgery centres has been the subject of some debate since the Bristol enquiry. The Panel shares the view expressed by others that the absence of evidence of underperformance should not be a source of comfort. Equally, the Panel found no suggestion that there exists or is likely to exist a convenient single bullet solution to answer questions about the relative quality of services and outcomes achieved by different centres.
- 5.6.4 In its visits to the ten surgical centres, the Panel observed the positive impact of adopting both the agreed service standards and the continuous review of clinical performance and outcomes in multidisciplinary teams. The Panel heard widespread support for the development of a wider range of indicators of outcomes such as, for example, neurological function, which can give a measure of long-term outcomes.

- 5.6.5 The use of relevant data as indicators of the need to investigate the quality of services and the availability of standardised analysis of comparative clinical performance are critical elements in securing and demonstrating the overall quality of services.
- 5.6.6 The Panel were pleased to hear that funding has been secured to roll out across all congenital cardiac providers in England a programme that allows individual providers to monitor their own performance using Variable Life Adjusted Displays (VLAD plots). In addition, further work is underway to obtain risk-adjusted standardized mortality ratios (SMRs) for each centre. While challenges will remain to comparing centres reliably, the Panel considers that this will be an additional drive to help improve quality.
- 5.6.7 Overall, the Panel shares the impatience expressed by many that more progress has not been made to develop and adopt a common approach to clinical governance, including a comprehensive range of quality and clinical outcome measures.
- 5.6.8 **Recommendation Seven**
NHS England must establish a systematic, transparent, authoritative and continuous stream of data and information about the performance of congenital heart services. These data and information should be available to the public and include performance on service standards, mortality and morbidity.
- 5.6.9 The Panel heard a variety of views about the potential benefits of reducing even further the number of surgical centres that undertake relatively rare and complex procedures. Some clinicians were in favour while some felt that all surgical centres in future should deal with all patients. The Panel saw evidence of a shift away from the historical pattern of certain rare and complex procedures being undertaken in only a few centres. The Panel is mindful of the fact that the

definition of what is a ‘complex’ procedure changes over time as clinical practice develops.

5.6.10 Rather than expecting every centre to be undertaking every type of procedure, the more likely pattern to be observed over time is a cycle of innovation, dissemination and some sub-specialisation. The Panel considers that this is desirable and should be encouraged. To ensure safe services of the highest possible quality for patients, this issue requires on-going and active monitoring, collaboration and management at a national level.

5.6.11 **Recommendation Eight**

NHS England and the relevant professional associations should put in place the means to continuously review the pattern of activity and optimize outcomes for the more rare, innovative and complex procedures.

5.6.12 The assessment of the current surgical centres against some of the service standards and subsequent use of that assessment to inform the scoring of options for quality has been the subject of enormous scrutiny and dispute. The Panel received a number of detailed critiques of both the assessment and scoring processes.

5.6.13 Whilst the proposed service standards were developed over a long period and were the subject of their own consultation, they remain the source of debate and some differences in interpretation. Co-location of services has been a particular source of dispute because of the differences between current surgical centres and the perceived benefits of more relevant services being on one site. The Panel recognises that there are real differences between the current surgical centres and considers that it was appropriate to adopt a method for scoring options on quality that reflected these differences.

5.6.14 Although incomplete and heavily dominated by input measures, the standards do describe professional consensus about the characteristics of a high quality

service and, through the assessment process, focussed centres on maintaining good standards and identifying areas for improvement. The Panel found evidence of the beneficial impact of the standards and the assessment process on quality improvement.

5.6.15 The JCPCT's decision to rely on the Kennedy scores as predictors of material differences in the capability of centres in the future, and the way in which the Kennedy scores were then translated into differences in the quality of service scores for options, opened the floodgate of criticism. This criticism was exacerbated by the lack of information about changes to the scoring regime and new options before the DMBC was made public at the meeting of the JCPCT on 4 July 2012.

5.6.16 The Panel along with many others, were clear that the Kennedy process and scores were not originally intended to be a basis for comparing existing surgical centres. This was the basis on which the Panel provided its initial advice on the referral from the Y&H Joint HOSC and its request for the detail of the Kennedy scores to be released to it. However, even if one accepted that it was sound for the JCPCT to use the Kennedy scores in the way they eventually did, the Panel found no logic or evidence to explain the relationship between the Kennedy scores and differences in scores for quality of services between options in the DMBC. The Panel agrees that these issues undermined the credibility of the JCPCT's decision, contributing to the view that there was a degree of pre-determination of the outcome.

5.6.17 **Recommendation Nine**

NHS England should reflect on the criticisms of the JCPCT's assessment of quality and learn the lessons to avoid similar situations in its future commissioning of specialist services.

5.7 **Impact on patients and their families**

5.7.1 The potential impact of reducing the number of centres was recognized from the outset. The consultation sought views on the issue, based on the

proposition that the vast majority of patients needing intervention only go to a surgical centre once and the networks of district services and children's cardiology centres will provide care closer to home. The subsequent analysis of accessibility and health impact assessment proceeded on the basis of these assumptions with no further scrutiny or analysis.

- 5.7.2 The Panel found that the assessment that 88 per cent of patients will travel to the surgical centre once was flawed. It was based on incomplete data regarding the number of stays in hospital per child over the period 2000-2010. Almost half of the procedures were missed from the analysis. In addition, the analysis did not assess the experience of the cohort of children who had their first intervention in 2000 by tracking the pattern of treatment over a ten-year period. As a result, the figure understated the number of interventions children have. Finally, no adjustment was made, or caveat stated to account for the fact that a ten-year data set cannot legitimately be used to represent the 16-year childhood experience of patients with CHD. The statement also gave no consideration to the need for patients and families to visit the surgical centre in advance to familiarise themselves with the centre and meet the team.
- 5.7.3 The Panel found that the Health Impact Assessment (HIA) used only data on the number of patients undergoing surgery and did not consider the impact on children undergoing interventional cardiology, who similarly would have to travel to the surgical centre under the proposals. This was despite equally robust, validated and detailed data being available for interventional cardiology as there is for cardiac surgery. Around 35 per cent of the patients receiving services at the surgical centre will be attending for interventional cardiology. The assessment, therefore, not only lacks important detail but is also based on flawed analysis of key data. Consequently, the downside impacts are systematically understated and the suggested mitigating impacts have no evidence to underpin them.
- 5.7.4 The Panel found that the assessment and scoring of the options on the access criterion was flawed for the same reason and systematically understated the impact and numbers of patients and families affected. The DMBC states

categorically that it identifies the numbers of patients and families affected and yet the findings are based on an analysis that does not account for a significant proportion of patients.

- 5.7.5 The Panel heard from parents and others the same concerns that had been expressed in response to the consultation – that whilst securing the best possible care is paramount, the impact of accessibility in terms of time, costs, and stress is their greatest concern about the proposals. The Panel found a significant mismatch between parents’ experiences and concerns and the JCPCT’s presentation of accessibility. The JCPCT told the Panel that the primary objective was to reduce the number of surgical centres and access was the least important factor. The statement that 88 per cent will travel only once was a frequently quoted justification for weighting access as the least important criterion in the options scoring process.
- 5.7.6 The absence of detail in the proposals about what services would be provided where outside the seven designated surgical centres exacerbated the concerns of parents. The fact is that the accessibility of the service, and consequently the impact, for large sections of the population of England under the proposals is unknown and the pledge that the proposals will result in care closer to home is unproven. This issue is of particular relevance to the populations most affected in Yorkshire and the Humber and in the east Midlands.
- 5.7.7 In the case of the former, this was one element of a previous referral by the Y&H Joint HOSC. The IRP’s advice of 13 January 2012 on this issue was that a suitably comprehensive health impact assessment was required to address the concerns raised. The JCPCT appears not to have noted this advice.
- 5.7.8 The Panel found that the proposals would have a disproportionate impact on people in Yorkshire and the Humber in terms of increase in travel times and potentially negative impacts on health inequalities due to the areas most affected having high concentrations of vulnerable groups. The Panel also had concerns about the impact on the population in some areas of the Lincolnshire coast for similar reasons.

- 5.7.9 The Panel was concerned that the network areas as proposed require some children and their families to travel to the CCC and/or surgical centre that is not the nearest, and in some cases not the second nearest to where they live. In effect the proposed network catchment areas place an excess social cost and burden on some children and families in order to achieve patient flows that generate 400 or more surgical procedures per centre per year. The statement that parents will ‘travel to the moon’ to access the best care for their children was stated frequently by those supporting the proposals, that is, people are willing to travel further to access a better quality service. However, the Panel found that for some patients and families the proposition is rather different, and they are being asked to travel further in future to a service that offers equal quality to one closer to them. The appropriateness and sustainability of designing a service on this assumption is clearly debatable and the legitimate concerns raised as a result were not addressed in a meaningful way.
- 5.7.10 A number of the surgical centres had themselves raised concerns about the sustainability of their proposed networks and the Panel agrees with them. Taking account of population density, geography and transport links there are clear challenges to sustainability for some of the proposed networks.
- 5.7.11 The Panel found that the standard of a minimum of 400 paediatric procedures per centre was based on professional opinion of the Steering Group, referencing the research evidence, and was devised before the implications for network boundaries and accessibility had been assessed. And yet the Panel found a complete unwillingness to debate the inevitable trade-offs that are inherent in the proposals between the potential benefits for outcomes of a threshold of 400 paediatric operations and the accessibility of the service to the population it serves.
- 5.7.12 The Panel concludes that the JCPCT’s decision used a flawed and incomplete analysis of accessibility based on an inadequate health impact assessment. Consequently, the real impacts of the proposals and their potential mitigations were missed.

5.7.13

Recommendation Ten

More detailed and accurate models of how patients will use services under options for change are required to inform a robust assessment of accessibility and the health impact of options so that potential mitigation can be properly considered.

5.8 Impact on other services

- 5.8.1 The impact of the proposals on PICU capacity, respiratory ECMO and paediatric heart transplantation were looked at in some detail for the options appraisal under the deliverability criterion. Specific advice was sought about the national specialised services and, in addition, a bespoke review was commissioned about the impact on specialist respiratory services at the Royal Brompton Hospital.
- 5.8.2 In considering the impact of the options for change, both respiratory ECMO and transplant services were presented as variables – that is capable of being relocated if required, though not without some downside risks and costs. Whilst this position held up in evidence for respiratory ECMO, doubt exists about the ability to relocate transplant services because only one possible alternative to Newcastle was identified (Birmingham) and a parallel national review of cardiothoracic transplantation centres put the future of existing centres in doubt. There was a mismatch between the DMBC and what the Panel heard about the impact of transplant services on the decision of the JCPCT.
- 5.8.3 The Panel heard different clinical opinions about the current performance of respiratory ECMO services, the impact of relocation on outcomes and their relationship with cardiac ECMO. Whilst cardiac ECMO is now regarded as an essential element of a high quality paediatric cardiac surgery service, its presence does not indicate capability to deliver high quality respiratory ECMO. Consequently, everyone agreed that relocation of respiratory ECMO is not entirely risk free and, therefore, weighing those risks against the benefits of

concentrating congenital heart services is a legitimate and necessary part of the decision.

5.8.4 In view of the relative impact on affected populations, the Panel agree that the transplantation and respiratory ECMO “tail” should not wag the CHD “dog”.

5.8.5 **Recommendation Eleven**

Decisions about the future of cardiothoracic transplant and respiratory ECMO should be contingent on the final proposals for congenital heart services.

5.8.6 The Panel heard concerns from a number of parents and the Royal Brompton & Harefield NHS Foundation Trust that the implications of the proposals on the wider range of services provided at the Royal Brompton Hospital and its future financial viability had not been assessed.

5.8.7 The Panel found that there are complex and sometimes subtle inter-relationships between tertiary services such that a change, like the loss of surgery for CHD, can trigger shifts in referral behaviour for other services. The Panel considers that these wider implications need to be understood fully to ensure the continued provision of safe, accessible and sustainable services across the whole tertiary services portfolio as well as the impact of change on research.

5.8.8 **Recommendation Twelve**

NHS England should assure itself that any wider implications for other services of final proposals are fully assessed and considered within a strategic framework for the provision of specialised services.

5.8.9 The focus on a single-issue mission of reducing the number of surgical centres undertaking children’s congenital heart surgery, which has dominated the *Safe and Sustainable* review, in the absence of a clear strategic view of specialised services as a whole has created some of the difficulties which these proposals

have encountered. This is exemplified by the review of the impact of the proposals on respiratory services at the Royal Brompton Hospital whilst ignoring the impact on adult services. The Panel is clear that this approach to commissioning specialised services is very unlikely to achieve the optimal pattern of services for the future.

5.8.10 The *Safe and Sustainable* Review has highlighted the tensions between the pattern of historic provision of specialised services and commissioning services based on population need, access and provider capability.

5.8.11 **Recommendation Thirteen**

NHS England should develop a strategic framework for commissioning that better reflects the complex interdependencies between existing specialised services provision and population needs.

5.9 **Engagement, consultation and decision-making**

5.9.1 The Panel accepts that undertaking the first national consultation of proposed changes to a complex, high profile service was not an easy task and it is clear that the NHS expended considerable effort to support engagement and consultation. The need to engage with HOSCs was identified early in the process and was a particular challenge given the absence of a national representative body. However, the approaches by a number of HOSCs around the country, such as those in Yorkshire and the Humber, to form a regional joint HOSC was a helpful and pragmatic response.

5.9.2 The Panel understands the concerns expressed by parents and others that the consultation document and response form was lengthy and complex. The Panel accepts that the ability to participate was hindered initially by limiting the response mechanism to an on-line system and not having translated materials available until five weeks before the end of the consultation.

- 5.9.3 It was also clear that the NHS was somewhat caught off guard by the substantial public response to consultation events in some parts of the country which left people feeling that there was an intention to limit debate.
- 5.9.4 The Panel found a climate of distrust had developed during the review. This emerged primarily due to two issues – concerns about a lack of transparency and the composition of the Steering Group.
- 5.9.5 As the IRP noted in its initial advice to the Secretary of State on the first referral from the Y&H Joint HOSC, the Committee has scrutinised the subject with considerable commitment and passion. There has been a clear mismatch in expectation between the three HOSCs who initiated this review and the NHS and JCPCT in relation to the interpretation of the NHS obligation to provide HOSCs with “*such information as the committee may reasonably require*” under the regulations. In addition, the NHS and JCPCT appeared to take an overly legalistic approach to the validity of the Y&H Joint HOSC rather than working with the spirit of scrutiny and their duty to involve. In the view of the Panel, the NHS was insufficiently responsive to legitimate requests for meetings and feedback from HOSCs. It is disappointing to observe, notwithstanding the difficult circumstances, that the relationship between the NHS and the Y&H Joint HOSC has broken down to the extent that it has.
- 5.9.6 A number of parents told the Panel they found it difficult to gain access to information they felt should be in the public domain and had to resort to Freedom of Information Act requests to obtain information such as minutes of meetings, membership of sub groups and data underpinning the NHS’s analysis.
- 5.9.7 The Panel heard concerns about the lack of weight given to public petitions in considering the findings from consultation. The Panel were satisfied that the results of the consultation were reported accurately and these issues had been dealt with appropriately in the independent report on the consultation.
- 5.9.8 The issue that generated the greatest level of concern was the lack of engagement and information sharing with interested parties between the end of

consultation and 4 July 2012 when the JCPCT met to make its decision. The concerns arose due to a lack of information about work undertaken in response to the consultation findings, such as the development and assessment of new options, and unexplained changes to the options scoring framework. This was compounded by the fact that the DMBC was not released until after the 4 July 2012 decision-making meeting. Confronted with eight new options and a changed scoring framework, people inevitably were left feeling denied access to information and the opportunity to comment and that the decision had been made in advance of the meeting with a significant degree of predetermination. More should have been done to provide information and engage with the interests of HOSCs and others in the period between the end of consultation and the JCPCT's decision on 4 July 2012. In this regard, both good practice and NHS guidance were not followed.

- 5.9.9 The Panel understands the reasons for selecting representatives from the professional associations to sit on the Steering Group and that they were there to represent their professional body and not their NHS organisation. However, the fact that this selection excluded anyone with a link to three of the ten centres was always going to be an issue that would attract attention. This sense of unease was subsequently given greater focus when the selected option excluded the centres that had no link to the Steering Group members. Given the inevitability of the concerns, this issue should have received greater consideration in constructing the governance arrangements for the review and in developing the stakeholder engagement plan for the review.
- 5.9.10 The Panel noted that there was a tendency for the NHS and JCPCT to present the views of the Steering Group, which were not always unanimous, as formal endorsement by the 'professional associations', which was not always the case.
- 5.9.11 The Panel heard from many parents in the areas most affected by the proposals that they felt that their legitimate concerns had not been listened to and they had found it very difficult to deal with being publicly accused in media statements issued by the NHS of 'putting lives at risk'.

- 5.9.12 The Panel found that there had been a strong emphasis on a communications strategy and the key messages to be transmitted but inadequate attention to developing a genuine engagement strategy from pre-consultation to decision, underpinned by a rigorous stakeholder analysis. The engagement process was over-reliant on the Children's Heart Federation (CHF) as the mechanism of engagement with children and parents and this placed CHF in the difficult position of being asked to deliver part of the process of pre-consultation activities as well as act as a representative body. The reality is that CHF and its role became a source of unhelpful divisiveness that undermined achieving the necessary engagement rather than delivering it. Other voices and organisations need to be more directly involved and engaged.
- 5.9.13 Much of the opposition to, and flaws in, the proposals originate in the lack of engagement of a wide range of stakeholders in the co-production of network models of care at the pre-consultation stage. This work should have been done at a level of detail to demonstrate how it subsequently informed options for change, revisions to those options and a final configuration of services at a level sensitive to local need, geography and transport as the service standards intended.
- 5.9.14 There is now a real opportunity to involve patients, public and other stakeholders in taking work forward as set out in the Panel's recommendations. This must be done in a way that shows there has been learning from the mistakes made, demonstrating a clear link between stakeholders' priorities and feedback in the development of the network model of care and the final configuration of services.
- 5.9.15 **Recommendation Fourteen**
NHS England must ensure that any process leading to a final decision on these services properly involves all stakeholders throughout in the necessary work, reflecting their priorities and feedback in a comprehensive model of care to be implemented and the consequent service changes required.

5.9.16 The Panel has reflected on the implications of the resources and time taken to review this one nationally commissioned service in the context of likely drivers for change in other nationally commissioned services. The Panel considers that it would be unsustainable to adopt a similar approach for each potential service. The IRP suggests that NHS England needs to consider the lessons that can be learned from this process and develop a different approach for other services.

5.9.17 However, the Panel is of the view that, irrespective of the footprint on which a service is provided, the basic principles of good practice in engagement and consultation should be adhered to and the work led by specialists with a depth of experience in community and patient engagement and consultation. The lessons learned from other IRP reviews of contested service changes provide a good framework to support the design of an effective process.

5.9.18

Recommendation Fifteen

NHS England should use the lessons from this review and create with its partners a more resource and time effective process for achieving genuine involvement and engagement in its commissioning of specialist services.

5.10 Next steps

5.10.1 The Panel has produced its advice in the context of changing and peculiar circumstances. Since 1 April 2013, responsibility for commissioning congenital heart services rests with NHS England, which has inherited the original proposals, a judicial review, responsibility for the quality of current services and the potential consequences of the IRP's advice, subject to the Secretary of State's decision.

5.10.2 The Panel's advice sets out what needs to be done to bring about the desired improvements in services in a way that addresses gaps and weaknesses in the original proposals. The Panel's recommendations stand on their own irrespective of any future decision by NHS England regarding the judicial

review proceedings. We note that the court's judgment of 27 March 2013 appears congruent to our own advice and that a successful appeal on legal grounds will not, of itself, address the recommendations in this report.

5.10.3 The Panel's advice addresses the weaknesses in the original proposals but it is not a mandate for either the status quo or going back over all the ground of the last five years. There is a case for change that commands wide understanding and support, and there are opportunities to create better services for patients. The challenge for NHS England is to determine how to move forward as quickly and effectively as possible.

5.10.4 Work to address gaps in the clinical model and associated service standards (Recommendation Three above) is underway and should be brought to a rapid conclusion. In parallel, there are different potential approaches to effect positive change that might be considered. These include whether to bring forward proposals for reconfiguration again or adopt a more standards-driven process that engages providers more directly in the managed evolution of services to be delivered. The critical factor to consider, in the Panel's view, is that engagement of all interested parties is the key to achieving improvements for patients and families without unnecessary delay.