

Congenital Heart Disease Services:

Decision Making Business Case

November 2017

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Table of Contents

EXECUTIVE SUMMARY	6
PART ONE: NHS ENGLAND'S WORK ON CONGENITAL HEART DISEASE	7
Introduction	7
Congenital Heart Disease	8
Congenital Heart Disease Services	11
Current demand	11
Future demand	12
Outcomes	13
NHS England's work	17
The case for change	21
Vision for the future	24
Model of care	24
More about level 2 care	25
More about level 3 care	25
The standards	27
Surgeon working requirements	28
Interdependency requirements	29
Services that meet the standards	30
Early diagnosis	31
Better information	32
How things will be better	34
How were the original proposals on which we consulted developed?	35
The assessment	36
Agreeing the proposals	37
Level 1 (surgical) CHD Services	38
Level 2 (medical) CHD Services	39
Why was change proposed at centres assessed as amber/red or red?	40
PART TWO: CONSULTATION	50
Approach to consultation	50
Provision of information	51

Feedback and analysis	58
The response to consultation	58
PART THREE: BEST PRACTICE ASSURANCE.....	61
Assurance of readiness for decision making.....	61
PART FOUR: INFORMATION TO SUPPORT DECISION MAKING	64
Review of the proposals for change on which we consulted	65
The proposal that surgery and interventional cardiology for adults should cease at Central Manchester University Hospitals NHS Foundation Trust (Central Manchester does not undertake surgery in children).	65
The Original Proposal.....	65
Assessment Against the Standards	65
Consultation Response	65
Impact of implementing the original proposals.....	67
Alternative Proposals.....	67
Developed Recommendations.....	67
Implementing the Developed Recommendations.....	68
Impact of Implementing the Developed Recommendations.....	69
The proposal that surgery and interventional cardiology for children and adults should cease at University Hospitals of Leicester NHS Trust.....	71
The Original Proposal.....	71
Assessment Against the Standards	71
Consultation Response	73
Alternative Proposals.....	75
Developed Recommendations.....	76
Implementing the Developed Recommendations.....	77
Impact of implementing the developed recommendations.....	79
Impact on CHD services	79
Impact on other interdependent services if L1 CHD services cease.....	80
Financial impact	80
Impact on staff	80
Impact on patients	80
The proposal that surgery and interventional cardiology for children and adults should cease at Royal Brompton & Harefield NHS Foundation Trust.	82
The original proposal	82
Assessment against the standards.....	82

Consultation response	83
Alternative proposals.....	84
Developed Recommendations.....	87
Implementing the Developed Recommendations.....	88
Impact of Implementing the Developed Recommendations.....	90
Impact on CHD services	90
Impact on other interdependent services if L1 CHD services cease.....	90
Financial Impact	91
Impact on Staff.....	91
Impact on Patients	91
The proposal that surgery and interventional cardiology for children and adults should continue at Newcastle Hospitals NHS Foundation Trust (children’s and adult services)	92
The Original Proposal.....	92
Assessment Against the Standards	92
Consultation Response	93
Alternative Proposals.....	94
Developed Recommendations.....	95
Implementing the Developed Recommendations.....	96
Impact of implementing the developed recommendations.....	97
PART FIVE: IMPLEMENTATION TO ENSURE THE STANDARDS ARE MET.....	98
Implementation	98
Planning and delivery.....	98
Managing the risks of change	99
Using the standards to ensure services improve for patients	100
Better information	100
Networks.....	101
Peer review	101
PART SIX: CONCLUSIONS.....	102
APPENDIX 1: BEST PRACTICE ASSURANCE	104
THE FIVE TESTS.....	104
Test 1: A clear clinical evidence base.....	104
Review of published evidence	105
Evidence from the national CHD audit	107
Clinical expert advice	108

Evidence from experience of earlier changes to CHD services.....	111
Test 2: Strong patient and public engagement.....	114
Patient and public engagement in the development and agreement of the standards	115
Patient and public engagement in work to implement the agreed standards.....	117
Engagement with elected representatives	119
Test 3: Support for original proposals from clinical commissioners.....	121
Test 4: Consistency with current and prospective need for patient choice	123
Test 5: The requirement to demonstrate that sufficient alternative provision, including workforce, will be put in place alongside or ahead of bed closures.	124
LEGAL CONSIDERATIONS	125
Compliance with sections 13C-13Q of the National Health Service Act 2006.....	125

EXECUTIVE SUMMARY

This document summarises the information necessary for the Board of NHS England to reach decisions on its proposals for congenital heart disease services. It builds upon the pre-consultation business case. It describes NHS England's work, how the original proposals were developed, how we consulted on those proposals and the response to that consultation, including the alternative proposals that were put forward. It describes the recommendations we expect to be considered by the Board and, where these are different from the original proposals, explains why.

Patients and their families told us that while it was a good thing to have standards, they only really mattered if we ensured that they were met. Otherwise, they were a waste of time. That message has deeply influenced our thinking. At the heart of our proposals, therefore, is our aim that every patient should be confident that their care is being delivered by a hospital that meets the required standards. To achieve this, we proposed that in future, NHS England would only commission CHD services from hospitals that are able to meet the standards. The recommendations that the Board is now expected to consider, will, over time, ensure that our aim is met.

This will mean that all children with heart disease will receive their inpatient care in a holistic children's environment, so that they can receive optimum care for any non-cardiac clinical problems without either the child or the specialist having to travel to another hospital with the potential compromises involved. Daily interaction between teams will be facilitated which is particularly important for children with complex conditions and multiple medical needs.

It will mean that every operation or cardiology intervention for CHD patients will be carried out by specialist doctors with a volume of practice sufficient to develop and maintain their skills. Centres will be larger and more resilient, with bigger teams, providing an assurance of full 24 hour seven day specialist care and the ability to cope with challenging events, for example the loss of a surgeon. Larger centres result in better outcomes, particularly for patients with high risk, complex needs.

The recommendations modify NHS England's original proposals, taking into account the views expressed in consultation, and the new proposals that have emerged. The centres in Leicester, Royal Brompton and Newcastle will continue to provide level 1 CHD care, but in the longer term this will be dependent on them successfully meeting the standards through the plans set out or to be developed. In the North West, the recommendation affirms the importance of delivering level 2 care in Manchester as part of the network, and the transfer of level 1 services to Liverpool is contingent upon this.

If implemented, these recommendations will mean that we have met our aim of ensuring that patients can be assured about the quality of their care wherever it is provided, and will result in a service for congenital heart disease patients that will be resilient and ready for the future.

PART ONE: NHS ENGLAND'S WORK ON CONGENITAL HEART DISEASE

Introduction

1. This paper, the Decision Making Business Case (DMBC¹) is a technical and analytical document that summarises the information necessary for the Board of NHS England to reach decisions on its proposals for congenital heart disease services. It builds upon the pre-consultation business case. Taken together with its appendices the DMBC provides all the information necessary for the Board to reach its decisions.
2. It describes NHS England's work, the original proposals and how they were developed, the consultation process, what we heard in response to the consultation, and the alternative proposals that arose during the consultation. It then describes the developed recommendations that we expect to be considered by the Board and, where these are different from the original proposals, explains why.
3. The DMBC makes the case for the developed proposals. Of necessity this includes making the case for the original proposals, because, in some cases, the developed recommendations are to continue commissioning only if certain conditions are met, and to revert to the original proposal to decommission if they are not met.
4. The DMBC has been through NHS England's internal assurance process, and has been reviewed and endorsed by the Oversight Group for Service Change and Reconfiguration (OGSCR) and the Investment Committee (IC). The IC, at its meeting on 3 November 2017, approved the work moving forward to decision making by the NHS England Board at its meeting on 30 November 2017. The Committee was assured that the requirements had been satisfied, for the Board to take decisions on the proposals for CHD service change in England.
5. The DMBC is published alongside the Board papers when NHS England's Board is meeting to make its decisions. However, the DMBC is not intended to be the main mechanism through which we will explain our decisions to the public. This will be set out, in a public facing way, in the Board paper and in the record of the Board's discussions in reaching its decisions.
6. This paper should be read in conjunction with the supporting materials set out below:

¹ The DMBC should be read in association with the Board paper, the consultation report and those other documents cross referenced in the DMBC.

	Title	Description
Annex 1	Congenital Heart Disease Consultation Document	Setting out the original consultation proposals in context.
Annex 2	Integrated Equalities Impact Assessment	Refreshed assessment in light of consultation.
Annex 3	Assessment of the impact of implementing the proposals on which NHS England consulted	Refreshed assessment in light of consultation.
Annex 4	Paediatric Co-location	A paper prepared for the Royal Borough of Kensington and Chelsea, October 2017.
Annex 5	Clinical Advisory Panel Report, September 2017	Advice from the panel on various clinical issues.
Annex 6	National Panel Report, September 2017	Report of the panel's refreshed assessment against the standards and of the impacts of NHS England's consultation proposals.

Congenital Heart Disease

7. Congenital heart disease means a heart condition or defect that develops in the womb, before a baby is born. There are many different types of congenital heart disease. For example, a baby's heart valves may not be properly formed or there may be holes between the chambers of their heart.
8. Many cases of congenital heart disease are diagnosed before a baby is born during an ultrasound scan in pregnancy. However, it's not always possible to detect congenital heart defects in this way.
9. For many babies diagnosed with congenital heart disease, their condition is minor. Other conditions are more serious and may need immediate surgery, at or even before birth. Sadly, some children do not survive. However, thanks to advances in early diagnosis and treatment, most children will grow up to become adults and lead full and active lives.
10. Some of the more common defects include:

septal defects – where there's a hole between two of the heart's chambers (commonly referred to as a "hole in the heart");

coarctation of the aorta – where the main large artery of the body, called the aorta, is narrower than normal;

pulmonary valve stenosis – where the pulmonary valve, which controls the flow of blood out of the lower right chamber of the heart to the lungs, is narrower than normal;

transposition of the great arteries – where the pulmonary and aortic valves and the arteries they're connected to have swapped positions.

11. Congenital heart disease is one of the most common types of birth defect. Estimates of its incidence vary from 5 to 9 in every 1,000 babies born in the UK²³⁴. This would be equivalent to approximately 3,500 to 6,300 babies born with CHD in England and Wales each year.
12. The number of babies born with CHD will increase if the total numbers of babies being born continues to rise⁵. Future birth rates are very difficult to predict. In their 'principal' projections, the Office of National Statistics (ONS) predicts that birth rates will fall over the next 10 years. But under their 'high' projections, ONS recognises that birth rates could rise.⁶
13. The number of operations and other interventional procedures has been increasing at three to four times the rate of population growth, and this is expected to continue.
14. Because of improvements in treatment, people with CHD can now expect to live longer than ever before. Between the periods 1979-1983 and 2004-2008, the number of deaths from CHD in children under 15 years fell by 83% in the UK⁷. As a result, the number of people living with CHD is rising. This means that in the future we are likely to see the service moving from one that has been centred on children, to one that is treating a growing number of young people and adults.
15. In most cases, no obvious cause of congenital heart disease is identified. However, some things are known to increase the risk of the condition, including:
 - a family history of congenital heart disease;

² Children and young people statistics, BHF, 2013 found at:

<https://www.bhf.org.uk/publications/statistics/children-and-young-people-statistics-2013>

³ NHS Choices: <http://www.nhs.uk/conditions/Congenital-heart-disease/Pages/Introduction.aspx>

⁴ Table 1.1 and 5.1, "Congenital Anomaly Statistics 2011, England and Wales", BINOCAR, September 2013, found at: http://www.binocar.org/content/Annual%20report%202011_FINAL_040913.pdf

⁵ ONS Population Estimates 2002-2010 available at: <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-269171>

⁶ ONS Population projection 2012-2037 available at: <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-318453>

⁷ Mortality with congenital heart defects in England and Wales, 1959-2009: exploring technological change through period and birth cohort analysis Knowles RL, Bull C, Wren C, Dezateux C (2012) Arch Dis Child, 2012 Oct; 97(10): 861-5

- Down's syndrome – a genetic disorder that affects a baby's normal physical development and causes learning difficulties;
 - the mother having certain infections, such as rubella, during pregnancy;
 - the mother taking certain medications while pregnant (anticoagulants or antiepileptics);
 - the mother having poorly controlled type 1 or type 2 diabetes; and
 - other chromosome defects, where genes may be altered and can be inherited.
16. The National Institute for Cardiovascular Outcomes Research (NICOR) analysed⁸ risk factors that could be associated with outcomes, on behalf of NHS England. The analysis showed:
- that Asian⁹ ethnicity had a statistically significant association with outcome;
 - a trend towards lower mortality at centres with larger case volumes;
 - no statistically significant links between distance from home and outcome; and
 - no statistically significant links between the other factors explored (ethnicity other than Asian, deprivation, sex, year, volume, weekday or weekend) and 30-day mortality outcome.
17. A higher rate of congenital heart disease is reported in children born of multiple births than those born of single births. A light birthweight is associated with a greater risk of congenital heart disease.
18. As so little is known about the causes of congenital heart disease, there's no guaranteed way of avoiding having a baby with the condition, nor any effective prevention programme.
19. Early diagnosis, through fetal screening as part of the 18+0 to 20+6 week mid-pregnancy scan, allows parental choice as to whether to continue with the pregnancy, and if so for appropriate planning for delivery, and ultimately better experience and outcomes.

⁸ Nicholas O et al, Analysis of candidate risk factors in Paediatric Cardiac Surgery 30-day risk modelling: Ethnicity, Deprivation, Sex, Year, Volume, Distance from home, Weekday or weekend, NICOR, 2015

⁹ NICOR's analysis used data with a limited number of ethnicity fields and so could not examine whether particular Asian populations were more affected.

Congenital Heart Disease Services

Current demand

20. The number of people with congenital heart disease is not known. Hospitals do not keep comprehensive and specific records of all patients 'on their books'. Some patients will have been lost to follow up with transition to adult services and moving home being key risks. A new initiative by Public Health England, the National Congenital Anomaly and Rare Disease Registration Service (NCARDS), should over time build up a more comprehensive picture, both of the number of people with CHD and of their life course.
21. Our understanding of demand for services is therefore based on historic patterns of service usage.
22. 12,998 patients (3,084 adults and 9,914 children) had one or more admissions to a level 1 or level 2 CHD provider in 2015/16 because of their CHD¹⁰. Not all of these admissions were for a procedure.
23. 8,572 CHD procedures were undertaken in 2014/15 in England. The breakdown of these procedures is shown in Table 1 below:

Table 1: CHD Surgical and Interventional Activity

CHD Procedures in England submitted to NICOR in 2014-15 ¹¹			
Type	Paediatric	Adult	Total
Interventional	2,265	1,577	3,842
Surgical	3,787	943	4,730

24. In 2015, ten hospitals performed operations and interventional catheter procedures in children with CHD, while 24 hospitals performed operations and/or interventional catheter procedures in adults with CHD.
25. Analysis of activity outside the recognised specialist centres showed that the larger number of hospitals involved in offering procedures to adults with CHD is part of a pattern of continuing occasional practice, that is, small volumes of surgery and interventional cardiology being undertaken in hospitals that do not offer specialist expertise in this field. This kind of

¹⁰ Source: NHS England analysis, SUS data where the primary diagnosis is CHD.

¹¹ Source: National Congenital Heart Disease Audit Report 2012-15, 2016, NICOR available here: [https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/9791867eff401e0d8025716f004bb8f2/5983f27e0b3ff3b080257d5d005cec4a/\\$FILE/NCHDA%20Aggregate%20report%202012_15%20v1%20%20published%2027042016.pdf](https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/9791867eff401e0d8025716f004bb8f2/5983f27e0b3ff3b080257d5d005cec4a/$FILE/NCHDA%20Aggregate%20report%202012_15%20v1%20%20published%2027042016.pdf)
NICOR data is accepted to be the authoritative source for data relating to procedures. 2014/15 is the most recent year for which NICOR provides validated data.

practice is explicitly ruled out by the standards as it is not in the best interests of patients.

Future demand

26. NHS England analysts undertook detailed analysis of historic trends in the delivery of CHD services and modelled likely future demand¹². The number of operations and other interventional procedures has been increasing at greater than the rate of population growth and this is expected to continue. Our analysis suggests that the main factors behind further growth in CHD activity are:
- Population growth (which is a function of birth rate, migration and life expectancy)
 - Increased proportion of patients who are of Asian ethnicity
 - Technical and medical advances
 - Increased patient longevity and survival
 - Increased expectations of treatment (patients) and willingness to provide treatment (clinicians)
 - Increased complexity and severity of the condition of patients undergoing treatment.
27. In 2015 NHS England undertook detailed analysis of changing activity levels, taking account of both population growth and the rising number of procedures per head of population. We cannot forecast either of these with 100% accuracy. However, based on the Office of National Statistics (ONS) 2012 principal population projection¹³ and existing trends in the number of procedures per head of population, we expect that there will be growth in the number of procedures that need to be commissioned in the next ten years.
28. Taking into account the most recent surgical data¹⁴, we now expect the trend to be **0.61% growth** per annum for paediatrics and **2.2% growth** per annum for adults.
29. We estimate the number of operations that will be undertaken in 2021/22, in the level 1 centres, will be in the range 5260 to 5532. These projections must be considered a guide for planning rather than an exact prediction. The projections are highly sensitive to the chosen starting year as there is considerable year to year variation. These projections do not account for:

¹² The summary of analytical work, Appendix 8 of the New Congenital Heart Disease Review: Final Report is available here: <https://www.england.nhs.uk/wp-content/uploads/2015/07/Item-4-CHD-Report.pdf>

¹³ Office of National Statistics (ONS) 2012 available here: http://www.ons.gov.uk/ons/publications/re-reference-tables.html?newquery=*%&newoffset=0&pageSize=25&edition=tcm%3A77-318453

¹⁴ 2016/17 surgical activity data is unvalidated data based on analysis undertaken by NICOR and checked with Trusts but not subject to full validation.

- Changes in patient flows between centres, except where this is already in the baseline.
 - The potential effects of Brexit, with immigration previously having had a significant effect on birth rates.
30. Although it is clear, taking all this together, that future capacity will need to be able to cope with increased demand, the Clinical Advisory Panel was concerned that this did not mean there would be enough surgical activity nationally to support ten centres meeting the surgical activity standards set by the NHS England Board in July 2015.
31. The National Panel shared the Clinical Advisory Panel's concern. They noted that the number of procedures/operations required by the standards are a minimum and each service and operator should aspire to undertake more than the minimum figures to ensure compliance. They noted that while there has been a year on year increase in the number of procedures (surgical and interventional, adult and paediatric) undertaken and activity levels have increased by almost 40% since 2003, they now appear to have largely stabilised over the last few years.

Outcomes

32. The UK is one of only three countries with universal participation in national audit of paediatric cardiac surgery, the other two being Sweden and Poland, giving us a good picture of the quality of services right across the country.
33. The most recent survival rates for the ten centres in England undertaking paediatric surgery are shown in Table 3 below, indicating that survival rates are high at all centres in England.

Table 3: Survival Rates (paediatric surgery 2012-2015) before risk adjustment¹⁵

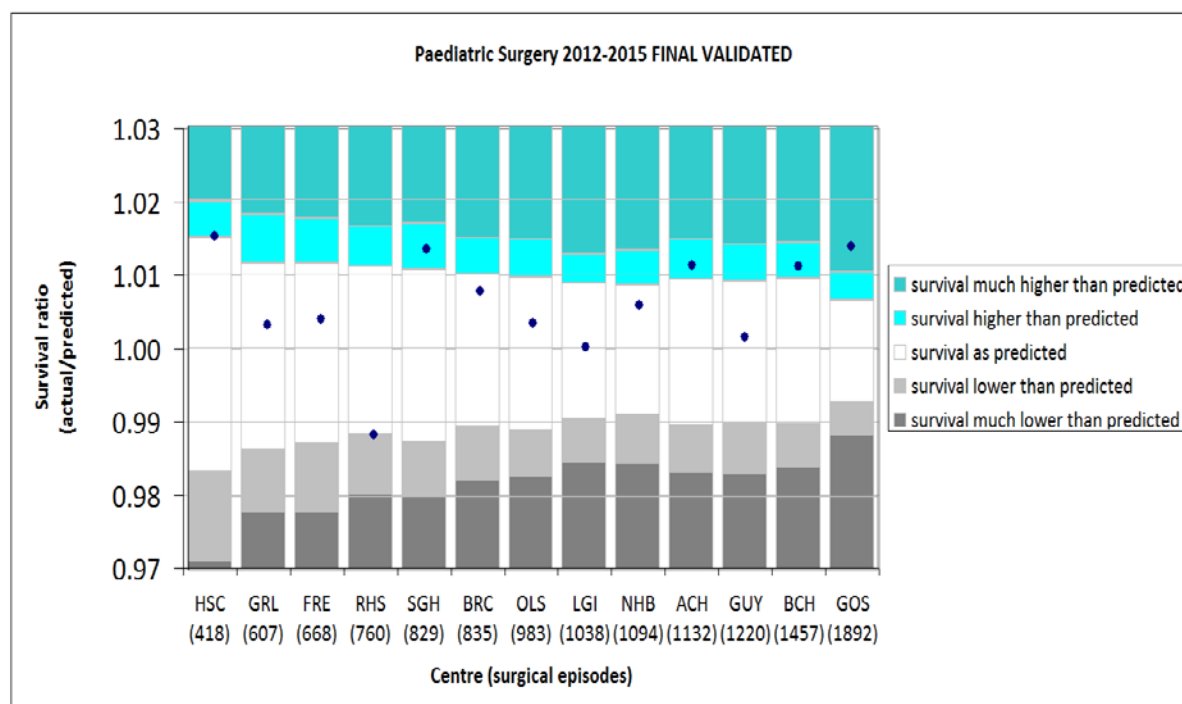
	Number of operations	Actual Survival (%)
Guy's and St Thomas'	1220	97.1
Birmingham Children's	1457	97.5
Leicester, Glenfield	607	97.7
Newcastle, Freeman	668	97.8

¹⁵ National Congenital Heart Disease Audit Report 2012-2015, NICOR, 2016 available here: [https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/9791867eff401e0d8025716f004bb8f2/5983f27e0b3ff3b080257d5d005cec4a/\\$FILE/NCHDA%20Aggregate%20report%202012_15%20v1%20%20published%2027042016.pdf](https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/9791867eff401e0d8025716f004bb8f2/5983f27e0b3ff3b080257d5d005cec4a/$FILE/NCHDA%20Aggregate%20report%202012_15%20v1%20%20published%2027042016.pdf)
More recent data has not yet been published.

Leeds General	1038	97.9
Liverpool, Alder Hey	1132	98.2
Southampton	829	98.3
Bristol Royal	835	98.3
Royal Brompton	1094	98.3
Great Ormond Street	1892	99.0

34. Actual survival rates are important, but because the mix of patients at each centre differs (as does the mix at an individual centre over time) NICOR uses a risk adjustment algorithm, PRAiS2, to allow comparison of actual survival rates with expected survival taking into account patient and disease factors. Knowing these factors for each child allows us to predict the percentage of children within a group that will survive, even though we cannot predict exactly whether individual children will survive.
35. NICOR's most recent report, showed (see figure 1 below) that overall centre survival rates are statistically either as predicted or better than predicted at all centres in England. In the case of Great Ormond Street, survival rates were much higher than expected.

Figure 1: Risk adjusted outcome analysis: paediatric cardiac surgery 2012-2015¹⁶



Key to figure 1	
Code	Hospital
RVB	Belfast, Royal Victoria Hospital
HSC	London, Harley Street Clinic
GRL	Leicester, Glenfield Hospital
FRE	Newcastle, Freeman Hospital
RHS	Glasgow, Royal Hospital for Sick Children
BRC	Bristol Royal Hospital for Children
SGH	Southampton Hospital
LGI	Leeds General Infirmary
OLS	Dublin, Our Lady's Children's Hospital
NHB	London, Royal Brompton Hospital
ACH	Liverpool, Alder Hey Hospital
GUY	London, Evelina London Children's Hospital
BCH	Birmingham Children's Hospital
GOS	London, Great Ormond Street Hospital for Children

36. NICOR does not publish a comparable risk adjusted, centre level, analysis for adult survival rates, though the data is collected. We therefore developed a research proposal with the aim of developing an adult risk adjustment model that will allow this to be done in future. This has been approved by the Research Needs Panel and will now go forward for further development and commissioning.

¹⁶ National Congenital Heart Disease Audit Report 2012-2015, NICOR, 2016 available here: [https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/9791867eff401e0d8025716f004bb8f2/5983f27e0b3ff3b080257d5d005cec4a/\\$FILE/NCHDA%20Aggregate%20report%202012_15%20v1%20%20published%2027042016.pdf](https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/9791867eff401e0d8025716f004bb8f2/5983f27e0b3ff3b080257d5d005cec4a/$FILE/NCHDA%20Aggregate%20report%202012_15%20v1%20%20published%2027042016.pdf)

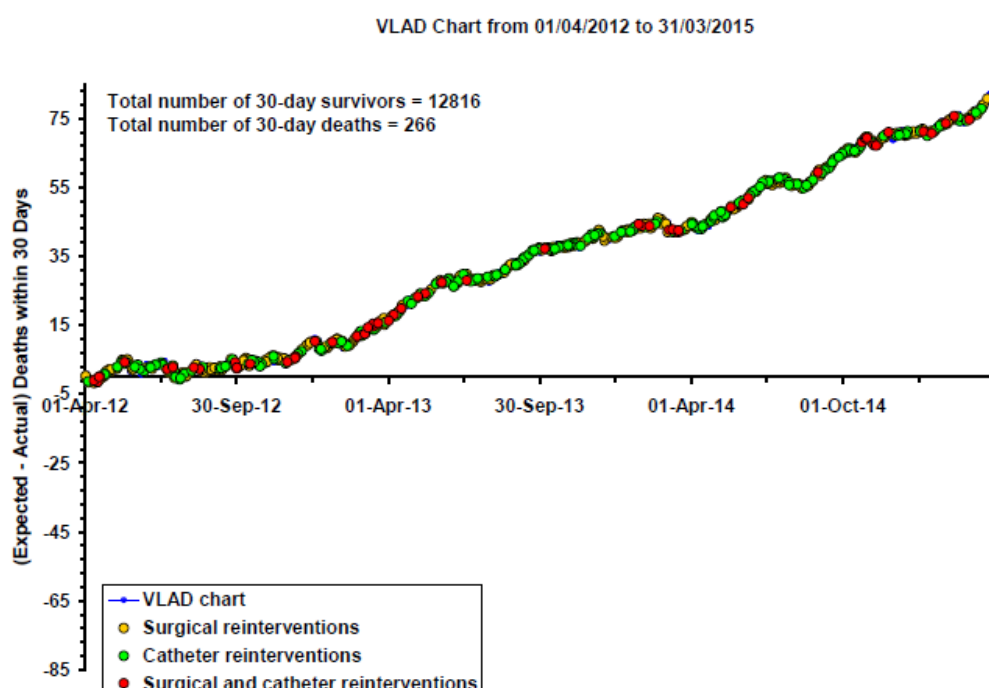
37. NHS England statistical analysis¹⁷ of crude survival rates did not suggest any providers are clear low outliers compared to the national average, providing some reassurance that there are no obvious safety problems. However as this data is not risk adjusted the analysis is significantly limited and the results should be treated with caution.
38. In addition to overall centre outcomes, NICOR also examines performance for 73 specific individual procedures in children and adults (surgical and interventional). In the period 2012 to 2015 NICOR reported two outliers:
- Liverpool Heart and Chest Hospital was below the warning limit (98% confidence) for the atrial septal defect (ASD) repair procedure (adult procedure).
 - Evelina London Children's Hospital was below the warning limit (98% confidence) for the Norwood Procedure (Stage1) (paediatric procedure).
39. These were followed up and responses from both hospitals have been reviewed by members of the National Congenital Heart Disease Audit (NCHDA) Steering Committee and the President/President-Elect of the British Congenital Cardiac Association (BCCA) and the Society of Cardio-Thoracic Surgeons (SCTS). In both cases the quality of local services was assured.
40. A 2014 analysis of the ten year trend in 30 day mortality¹⁸ showed that while the number of procedures performed in the UK increased over the last decade, raw 30-day mortality rate for paediatric cardiac surgical episodes in the UK fell from 4.3% in 2000 to 2.6% in 2009/2010. These rates compare favourably internationally
41. The fall in mortality was seen across the lower three bands of risk (92.9% of surgical episodes) but not in the highest risk band. Case mix has become more complex suggesting a greater proportion of more patients with complex conditions in the later years. There is a trend towards earlier definitive repair in infancy. The authors consider that 'we must now shift our focus [from 30 day mortality] to measures of morbidity, longer term survival and functional outcomes'.
42. Examination of the national Variable Life Adjusted Display (VLAD) plot (including all centres in the UK and Ireland) shows a trend to improved survival over the period 2012-15, with survival increasing markedly over

¹⁷ Source: Unpublished NHS England analysis of data from UK providers as reported to NICOR for the years 2010/11 - 12/13 across 46 different procedures. Note that not all ACHD providers report outcomes to NICOR.

¹⁸ Brown et al, Trends in 30-day mortality rate and case mix for paediatric cardiac surgery in the UK between 2000 and 2010, Open Heart 2015;2: doi:10.1136/openhrt-2014-000157

the most recent 24 month period. During this 3 year period more than 75 fewer deaths were observed than were predicted, demonstrating the continued rise in quality of congenital cardiac surgery in the UK and Ireland.

Figure 2. Variable Life Adjusted Display (VLAD) Chart for all 14 centres undertaking procedures in patients under 16 years of age, 2012-15¹⁹.



43. Taken together these data provide a good level of assurance that survival after surgery and interventional procedures is good at all the specialist centres in England. However, while survival after a procedure is clearly very important these data do not tell the whole story about quality. We have therefore made considerable efforts to expand the range of information about the quality of services, including, for example, patient reported experience.

NHS England's work

44. In summer 2016 NHS England published proposals for changes to CHD services that represented the latest milestone in a very long journey, stretching back almost 20 years, in which the NHS has tried to take action

¹⁹ National Congenital Heart Disease Audit Report 2012-2015, NICOR, 2016 available here: [https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/9791867eff401e0d8025716f004bb8f2/5983f27e0b3ff3b080257d5d005cec4a/\\$FILE/NCHDA%20Aggregate%20report%202012_15%20v1%20%20published%207042016.pdf](https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/9791867eff401e0d8025716f004bb8f2/5983f27e0b3ff3b080257d5d005cec4a/$FILE/NCHDA%20Aggregate%20report%202012_15%20v1%20%20published%207042016.pdf)

to improve the delivery and quality of congenital heart disease (CHD) care.

45. The NHS has been trying to improve care for patients with CHD since 2001, following publication of the report of a public inquiry into concerns about the care of children receiving complex cardiac surgery at Bristol Royal Infirmary between 1984 and 1995. This was followed by the Safe and Sustainable review, launched by the Department of Health, in 2008, which ended in two separate legal challenges, and the findings of the review being overturned.
46. We know, from talking to stakeholders that previous reviews of CHD services left them feeling exhausted and frustrated and created uncertainty within the service, particularly because previous reviews did not result in a coordinated programme of change.
47. Patients' confidence in the service has been undermined by many years of repeated review and investigation, and regular adverse stories in the media. Recruitment and retention of skilled staff has been affected and Trusts have sometimes been cautious about investing in their service while the future is unclear. Relationships between centres providing CHD services have been strained.
48. The 2014 report on CHD services at Leeds Teaching Hospitals NHS Trust recommended that NHS England should act to dispel the "almost morbid sense of spectatorship and foreboding that hangs over these services". Clear resolution is now needed to bring the stability the service needs to move forward.
49. However, despite the fact that previous reviews have not resulted in a coordinated programme of change, progress has been made. Outcomes for CHD surgery and interventional procedures across England are good, and compare well with other countries. We also know, from talking to patients, their families and carers in particular, that the quality of CHD care delivered in hospitals is very good. We have heard many, many positive stories about individual patient experiences, and recognise that each of those personal testimonies carries real weight, and shapes how people feel about the NHS service which has cared for, or saved the life of, their loved ones.
50. During the period of NHS England's work on CHD services, outcomes have improved further, rates of early diagnosis have risen and a much wider range of measures of service quality are now collected and monitored. Implementation of the standards will result in further substantial improvements in services for patients. Many hospitals have already taken steps to address issues highlighted in their assessment. Ongoing peer review will ensure this improvement continues in the future.

51. In taking forward this work, NHS England sought to learn from what had gone before, using what was good, for example building on the standards developed by the Safe and Sustainable review²⁰. We also learnt from the problems and criticisms of earlier work, giving particular attention to the Independent Reconfiguration Panel's (IRP) report on the Safe and Sustainable review²¹.
52. When NHS England took on responsibility for the commissioning of CHD services in 2013, we were told by patients, families, doctors and nurses alike, that the best way to deal with the ongoing uncertainty and its results was through the development of service standards, setting out how a good CHD service should be set up, organised and run.
53. We worked with these groups of stakeholders for more than two years to create a set of standards that covered the entire patient pathway, from diagnosis, through treatment, and on into care at home, and including end of life care, to make sure that every child, young person and adult with CHD, in every part of the country, would receive the same high standard of treatment.
54. Surgeons told us how many operations should be done by each surgeon every year, as a minimum, in order to maintain the surgeons' skills. Similarly, specialist doctors and nurses told us what medical care should be available by the bedside of a child in a critical condition.
55. Patient representatives led the work in developing the standards covering communication, facilities and bereavement. Additionally, for the first time ever, the transition from children's services to adult services was included in the standards, to ensure that care is truly joined up.
56. The standards have never been considered as an end in themselves. They were developed in the full expectation that their implementation at

²⁰ The Safe and Sustainable review was established in 2008, with a view to reconfiguring surgical services for children with CHD. 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 in fewer sites. In July 2012, a joint committee of Primary Care Trusts (JCPCT) made a series of decisions on the future of children's congenital heart services in England including changes to the configuration of surgical services, which would have reduced the number of centres providing children's heart surgery from ten to seven, with surgery ceasing at Leeds, Leicester and the Royal Brompton. The decision regarding configuration resulted in two separate challenges: a judicial review (JR) and referrals to the Secretary of State, who in turn asked the Independent Reconfiguration Panel (IRP) to consider the JCPCT findings. The JR quashed the decision to reconfigure surgical services, and on 12 June 2013 the Secretary of State announced in Parliament that he accepted the IRP's advice, and that "the [Safe and Sustainable] proposals cannot go ahead in their current form". He went on to say that "it is right we continue with this process, albeit in a different way" and that "NHS England now must move forward on the basis of these clear recommendations".

²¹ The IRP report is available here: <https://www.gov.uk/government/publications/irp-advice-national-childrens-congenital-heart-services> A report of how the new CHD review took account of and responded to the IRP's recommendations is available here: <https://www.england.nhs.uk/wp-content/uploads/2014/11/5-chd-34-nchdr-lessons-learnt.pdf>

every hospital in the country providing CHD services would be the means by which the aims of our work would be delivered:

- securing best outcomes for all patients – not just reducing the number of deaths, but reducing disability caused by disease, and improving people's quality of life;
- tackling variation, so that services are consistent in meeting standards, each of them offering 24/7 care, seven days a week, as part of a nationally resilient service;
- improving patient experience, including provision of better information for patients, plus more consideration of access and support for families when they are away from home.

57. The standards were agreed by NHS England's Board, in July 2015 following a 12-week period of public consultation, after which we started to look at how we might implement them.
58. Patients and their families told us early on that, while it was a good thing to have standards, they only really mattered if we ensured that they were met. Otherwise, they were a waste of time. That message has deeply influenced our thinking throughout this process.
59. Phase 1 of our work to ensure that all CHD providers would meet the standards was specifically designed to look at whether the hospitals themselves, by working more closely together, could find new ways of working that would mean that the standards could be met across the country. Unfortunately, that did not prove to be possible. The submissions received from providers did not provide a national solution to meeting the standards.
60. It was decided, therefore, that each hospital should be assessed against a specific number of the standards, i.e. those considered to be most closely, and directly, linked to the measureable outcomes, and to effective systems for monitoring and improving quality and safety.
61. Having assessed hospitals against these standards and discovered that some were not able to meet all of the standards and were unlikely to be able to do so in future, without changes to the way they worked, we believed that we had to act to secure the best care possible for patients and their families.
62. At the heart of our proposals is our aim that every patient should be confident that their care is being delivered by a hospital that meets the required standards. In order to achieve this, we propose that in future,

NHS England will only commission CHD services from hospitals that are able to meet the standards within the required timeframes²².

63. The proposals for change set out in July 2016 would achieve this improvement. The proposals are set out in detail below in paragraphs 161-168 below. Since that time we have conducted a full formal public consultation on the proposals. We have continued to be in dialogue with hospitals that would be affected by the proposed changes. The recommendations which we expect the Board to consider take account of what we heard, and have changed in some respects from the original proposals. In this DMBC we have set out how we developed the original proposals, and the work we have done to assess the impact of implementing them, if that was what the Board decided to do. We also set out what we heard in consultation and the resulting recommendations for the Board to consider (again assessing the impact of implementing them if that is what the Board decides to do). We think it is very important to present all the information here so that it is possible to see how our thinking has developed, and also so that the Board can weigh the choices it now needs to make.

The case for change

64. The proposals on which we consulted, and which are described in detail below, would, if implemented, mean that, in future, CHD services would only be provided by hospitals which already meet the standards required, or will meet the standards within the required timeframe as a result of the improvement plans they are putting in place²³. The proposals recognised that not every hospital was in this position.
65. The standards describe how to deliver CHD services of the very highest quality. They are – rightly – challenging, and it was acknowledged by the Board, at the time of their agreement, that it would be difficult for all hospitals to meet them, unless changes were made to the way in which they work. This is why the timeline for meeting some of the standards differs, as it was recognised that the meeting of some standards would take longer than others, for instance, the co-location of children's CHD services with other children's services might require physical changes to a hospital's structure or layout.
66. Our assessment focussed on 24 paediatric standards (and the corresponding adult standards) considered to be most closely and directly linked to measurable outcomes (including the surgical and

²² There is one exception to this; Newcastle Hospitals NHS Foundation Trust. The reasons for this are set out in paragraphs 200-213.

²³ As previously noted, our proposals included one exception to this principle; Newcastle Hospitals NHS Foundation Trust. The reasons for this are set out in paragraphs 200-213.

interdependency standards previously highlighted) and to effective systems for monitoring and improving quality and safety.

67. We have recently reviewed and refreshed our assessment of each hospital, considering not only these standards but also the related activity and co-location standards that came into effect on 1 April 2017, and those that will take effect in 2019 and 2021.
68. This is only the first stage of the work to ensure that all the standards are met at every centre. Once the Board has made its decisions we will issue revised improvement plans for each hospital that does not yet meet all the standards assessed. We will also introduce a peer review process, facilitated by NHS England's Quality Surveillance Team, which will address the remainder of the standards to ensure that patients get the full benefits of standards.
69. This means that people with CHD who are being treated at those hospitals will be receiving care that meets the highest possible standards.
70. Patients, their families and carers, told us that this means:
 - timely and accurate diagnosis;
 - access to skilled and timely treatment and interventions;
 - clear pathways for follow up, as close to their home as possible;
 - higher levels of support from specialist nurses and psychologists;
 - improved communication and information, so that newly diagnosed patients have a better understanding of their condition; the care provided; treatment options; and how to take part in decisions about their own care;
 - better managed transition from children's to adult services; and
 - improved palliative and end of life care, with specific standards focussed on support for bereaved families and carers.
71. For clinicians, and their teams, the implementation of the standards in full means:
 - hospitals caring for people with CHD have the right staffing and skill mix, with minimum staffing and activity levels, which support the maintenance of skills and expertise;
 - improved resilience and mutual support provided by a networked model of care;
 - enhanced opportunities for developing sub-specialisation;
 - enhanced training and mentorship; sharing learning and skills; quality assurance and audit;

- elimination of isolated and occasional practice – this is when small volumes of surgery and interventional cardiology are undertaken in hospitals that do not offer specialist expertise in this field.
72. These are tangible benefits, things that will really make a difference to the care of patients with CHD, and to the teams caring for them. We believe that every patient receiving care for CHD should be guaranteed these highest possible standards of care, regardless of where they receive their treatment.
 73. We have already seen the benefit of a commissioning approach committed to ensuring the standards are met. Amongst level 1 centres Birmingham Children's is now assessed as meeting all requirements, and Great Ormond Street and Guys and St Thomas' are very close to this. Amongst level 2 centres Norfolk and Norwich and Oxford both meet all the requirements and Papworth has moved from a position of neither meeting the standards nor having convincing plans to do so, to meeting the requirements, or where it does not meet them, having good plans to do so.
 74. Fully implementing the standards will bring an end to the uncertainty that has affected CHD services and described in the introduction above.
 75. The result will be larger centres with bigger teams, more effectively networked with other centres, that will be more resilient, providing an assurance of full 24 hour, seven day care and the ability to cope with challenging events, for example the loss of a surgeon.
 76. A number of centres were assessed as presenting a risk. While we have no evidence that outcomes have so far been compromised, the combination of low activity, inadequate out of hours care and cover, combined in some cases with a failure to submit outcome data to the national audit mean that we cannot be complacent.
 77. In the recent past there have been reviews of services in Oxford (in 2009/10), Leeds (in 2014) and Bristol (in 2016). While the issues raised by these reviews have been addressed this history shows that quality and safety concerns continue to emerge across the service and if we do not take co-ordinated action now there is a risk that patients will receive sub-optimal care or even be harmed.
 78. Since our original assessment, the service at Central Manchester has been suspended by the Trust. Our original assessment recognised the vulnerability of a service based on a single surgeon. Since that time, that surgeon has moved to a new post at a different hospital. As a result of the suspension of service, patients who previously received their care from the Central Manchester team now receive much of that care from the clinical teams at Leeds, Newcastle and Birmingham.

79. In addition, we continue to have concerns about the fragility of the service offered by University Hospitals of Leicester, the Trust itself saying that it runs a significant risk of unplanned service demise.
80. It is therefore essential that clear decisions are taken in the near future in order to bring clarity and certainty to the provision of CHD services.

Vision for the future

Model of care

81. Congenital heart disease services will work together in networks so that neighbouring hospitals have good systems for referring patients and passing information back and forth. Networks help local services to work closely with specialist centres, to ensure that patients receive the care they need in a setting with the right skills and facilities, as close to home as possible.
82. The standards are based on a three tier model of care with clear roles and responsibilities (and standards) for each tier, where level 1 centres provide the most specialist care including surgery. Level 2 and level 3 centres will allow patients to receive as much of their care as is appropriate in a centre closer to home and allow level 1 centres to focus on the most complex patients. The three tiers are:

Level 1 Specialist Surgical and Interventional CHD Centres: These centres manage all patients with highly complex CHD and provide the most highly specialised diagnostics and care, including all surgery and interventional cardiology. Every network must contain at least one level 1 centre.

Level 2 Specialist Medical Cardiology Centres: These centres are able to provide the same level of specialist medical care as a level 1 centre, but not surgery or interventional cardiology (except for one specific minor procedure at selected adult centres). Level 2 centres have specialist paediatric cardiologists and adult CHD cardiologists as well as specialist CHD nurses like level 1 centres. They focus on diagnosis and ongoing care and management. Every network will not necessarily include a level 2 centre. This will depend on local requirements for access and capacity.

Level 3 Local Cardiology Services: Accredited services in local hospitals run by general paediatricians / cardiologists with a special interest in congenital heart disease. They provide initial diagnosis and ongoing monitoring and care, including joint outpatient clinics with specialists from a level 1 or level 2 centre, allowing more routine and follow-up care to be given nearer to home.

More about level 2 care

83. Our recent assessment is the first time there has been an official process to recognise level 2 CHD centres. In addition, we are also exploring the potential for the provision of level 2 medical services at hospitals where implementation of our proposals would mean level 1 services would cease.
84. The standards for level 2 centres are the same as for level 1 centres and our requirement is that the quality of the care should be just as good. The difference is only that level 2 centres do not offer surgery, interventional cardiology (with the exception of atrial septic defects (ASD) closures) and very complex imaging and invasive diagnostics which patients would still receive at a level 1 centre. Although most care at a level 2 centre will be outpatient care, level 2 centres also offer inpatient care where appropriate. Some level 2 adult CHD centres also offer interventional ASD closure. Level 2 centres can provide care for both children and adults though some only offer adult services.
85. Most patients with access to a level 2 centre will be able to receive all of their care at the level 2 centre except for surgery and catheter interventions, one pre-operative visit and one post-operative check-up (even these may sometimes be performed at their level 2 centre).
86. Only a small number of patients with complex needs (such as feeding problems or infections) require a longer stay in hospital following any intervention. Even these patients can be considered for transfer back to their level 2 centre for post-operative care.
87. For patients and their families with good access to a level 2 centre, receiving their care there will often be more convenient than always attending their level 1 centre. Travel will be easier and less costly. The number of journeys to the level 1 centre can be minimised and should they require a surgical or catheter intervention this should only require two or three visits to the level 1 centre with the rest of their care being provided more locally.
88. As patients get older, and particularly for adults with CHD, the majority of their care will be outpatient care. And as life expectancy continues to improve the number of CHD patients in long term follow-up continues to rise so that the care offered by level 2 centres is an important complement to level 1 centres, and allows the level 1 centres to focus on the most acute care and the sickest, most complex patients.

More about level 3 care

89. Level 3 services form part of the wider CHD service model across the country. These services will offer high quality standardised care closer to

home, wherever possible. They do not stand alone but are part of, and provide the gateway into networks of CHD care.

90. A number of hospitals operate CHD services that are broadly in line with the level 3 requirements. Others offer CHD care but would be unlikely to meet the requirements of the standards. There has never been an official process to recognise level 3 CHD services.
91. Wider development of level 3 services will require the development of a shared vision for these services. The need for level 3 services may vary from one part of the country to another, and may be different for paediatric and adult services. There is a challenge for the service to introduce a clear definition and associated criteria for level 3 services onto a pre-existing structure where hospital Trusts vary in facilities, resource and service provision, along with local commissioning agreements.
92. Level 3 services are not part of the nationally defined range of specialised services, and are therefore commissioned by Clinical Commissioning Groups (CCGs) as part of local paediatric and cardiac contracts.
93. NHS England works closely with CCGs which commission the non-specialised services in the same pathway. Collaborative commissioning provides a framework within which NHS England can work more closely with CCGs to agree an appropriate approach across different elements of the pathway and with different commissioners. Sustainability and Transformation Plan (STP) footprints also provide an opportunity to address this issue.
94. While commissioning of level 3 services rests with local clinical commissioners, the development of these services depends on CHD networks working with local champions. Where there is a paediatrician with expertise in cardiology (PEC) or a cardiologist with a specialist interest in congenital heart disease they will provide the focus and energy necessary for services to develop, with the support of network leaders.
95. NHS England is continuing to work with professional societies, the Clinical Reference Group (CRG) and CCGs to develop implementable proposals for the further development of level 3 services.
96. Implementing the standards will also bring to an end occasional and isolated practice (small volumes of surgery and interventional cardiology undertaken in hospitals without sufficient specialist expertise). This has been a big concern, particularly for charities representing adults with CHD.

The standards

97. On 23 July 2015, the NHS England Board agreed new standards and service specifications for CHD services²⁴, with the expectation that in future all providers would meet the standards, leading to improvements in service quality, patient experience and outcomes. These standards were themselves the subject of extensive consultation and they are not the subject of this DMBC as they have already been agreed.
98. The standards and associated service specifications describe the way in which CHD services are to be organised and run to give nationally consistent services. They will ensure that all patients have access to high quality care and minimise unexplained differences between centres. They cover a wider range of subjects than previous standards, reflecting the views of patients and their families about what matters to them. In particular, the standards will improve patient experience through: higher levels of support from specialist nurses and psychologists; improved communication and improved management of newly diagnosed patients; transition from children's to adult services; palliative and end-of-life care. Importantly, they cover care for adults as well as children. These were all issues which our public and patient groups told us were important, but had often been neglected in parts of the service.
99. Standards have been set for the following:
- Section A: The Network Approach
 - Section B: Staffing and skills
 - Section C: Facilities
 - Section D: Interdependencies
 - Section E: Training and Education
 - Section F: Organisation, governance and audit
 - Section G: Research
 - Section H: Communication with patients
 - Section I: Transition
 - Section J: Pregnancy and Contraception
 - Section K: Fetal diagnosis
 - Section L: Palliative Care and Bereavement
 - Section M: Dentistry

²⁴ The standards and service specifications can be viewed here:
<https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/03/chd-spec-standards-2016.pdf>

100. Each standard has an associated implementation timeline. Some were for immediate implementation. For others, the timeline shows the maximum amount of time, from the go-live date, allowed for hospitals to meet the standard. It does not mean hospitals must wait this long before they meet the standard, indeed it will always be preferable to meet the standard sooner. But it does recognise that some standards will be harder for some hospitals to achieve.
101. Throughout our work there has been more debate about two aspects of the standards than any other: those covering surgeon working (the number of surgeons at each hospital and the minimum number of operations they perform) and service interdependencies (the other services CHD patients depend upon and which need to be co-located on the same hospital site).
102. It was acknowledged during the discussions about the setting of the standards that these two standards in particular were both very important to service quality and also difficult for all hospitals to meet under current working practices.

Surgeon working requirements

103. Surgeons told us that the number of operations they each carried out was the most important factor in achieving good surgical outcomes. They advised that we should require CHD surgeons to perform at least 125 congenital heart operations a year (the equivalent of about three a week).
104. We were also advised that there should be at least four surgeons in each team (at least three from April 2016 and at least four by April 2021).
105. All surgeons agree that the number of operations done by each surgeon is more important than the number of surgeons in a team. We are clear that we would not want to see teams of four or more in a unit too small to provide each surgeon with sufficient activity levels.
106. There is good evidence, from a large number of studies, for a link between centre size and outcomes from studies²⁵. Both surgeon numbers and activity levels are a proxy for centre size. There is also good evidence that individual surgeon operating outcomes for complex procedures are linked to the number of times the surgeon carries out that operation. However, the evidence does not give precise answers to questions about the optimum size of centres or surgeon caseloads.
107. Larger teams help to ensure that surgeons can cover all aspects of the service during the day while a team of at least four surgeons (who are

²⁵ The Evidence base for the new standards & specifications, Appendix 7 of the New Congenital Heart Disease Review: Final Report is available here: <https://www.england.nhs.uk/wp-content/uploads/2015/07/Item-4-CHD-Report.pdf>

required to provide 24/7 emergency cover and to be able to reach the patient bedside within 30 minutes) will reduce the risks associated with fatigue. Teams of at least four surgeons were recommended by the Independent Reconfiguration Panel in their report on the Safe and Sustainable review. Bigger teams are better able to cope when one of their number is unavailable or leaves. They are also better able to support the full range of surgical procedures and the development of very specialised practice.

- 108. This tells us that if we want to make sure that services reliably achieve the best results we need to commission high volume services.
- 109. While most attention has focussed on surgeon working, similar standards have been set for interventional cardiology with minimum numbers of procedures and team size, and these bring similar challenges for hospitals.

Interdependency requirements

- 110. The standards require that specialist children's cardiac services are only delivered in settings where a wider range of other specialist children's services are also present on the same hospital site. This determines what medical care is available by the bedside for a child in a critical condition, which is important because many children with CHD have multiple medical needs.
- 111. However, while this responsiveness is one important element behind the co-location requirement, it is not the only one. Our clinical advisers told us that co-location with specialised paediatric services is also important because it allows much closer working relationships to develop between paediatric cardiology specialists and the wider specialised paediatrics team. Delivering these services effectively requires the input of the wider paediatric multidisciplinary team, and the interaction between these teams on a daily basis, when co-located, was considered by the Clinical Advisory Panel to be of significant benefit to patients. This way of working brings paediatric cardiac care into line with expectations in other specialist children's services, because most other specialist paediatric services have moved to a paediatric environment, including liver transplantation; bone marrow transplant; stem cell/cancer therapy; and gastroenterology. This follows the accepted international norm and is why the standard requires co-location on the same hospital site, not just the ability to get to bedside within 30 minutes of call. A fuller exposition of the evidence and arguments for paediatric colocation was prepared for the overview and scrutiny committee of the Royal Borough of Kensington and Chelsea and may be found in **Annex 4**.
- 112. Earlier in the process, our clinical advisers said that in their view it was not appropriate to care for children with complex conditions and co-

morbidities (a high proportion of whom will need input from other specialties) in settings where other paediatric services were not on site. Having all tertiary specialties on one site means neither the child nor the specialist has to travel with the potential compromises involved in the care environment, access to the full team and equipment and timeliness of advice and intervention.

113. Meeting again in August 2017, the Clinical Advisory Panel affirmed its support for the co-location requirements. It advised that care for children should be provided in a holistic children's environment with on-site access to the full range of paediatric specialties and services²⁶.
114. The Royal College of Paediatrics and Child Health told us: "Isolated children's services are unacceptable; children's cardiac services must be co-located within a hospital providing a broad range of paediatric specialties and services".
115. At its earlier meetings, the National Panel told us that it considered it particularly important that level 1 paediatric CHD services were delivered from sites achieving the required service interdependencies.
116. Meeting again in August 2017 it affirmed this position, and further stated that a holistic paediatric environment involved not just meeting the co-location standards but was also about culture, environment and patient experience²⁷.

Services that meet the standards

117. We did not spend so much time and energy on agreeing standards as an end in itself. From the beginning, NHS England supported the development of service standards in the expectation that their implementation at every provider in the country would be the means by which the aims of our work would be delivered. Those aims were:
 - Securing the best outcomes for all patients, not just lowest mortality but reduced disability and an improved opportunity for people with congenital heart disease to lead better lives;
 - Tackling variation so that services across the country consistently meet national standards and are able to offer resilient 24/7 care; and
 - Improving patient experience, including how information is provided to patients and their families, and consideration of access and support for families when they have to be away from home.

²⁶ See Annex 5: Clinical Advisory Panel Report, September 2017

²⁷ See Annex 6: National Panel Report, September 2017

118. As a result we have devoted the same levels of energy and determination to the process of ensuring that patients in every part of the country could be confident that the care they receive will meet those standards, as we did to the earlier work setting the standards.

Early diagnosis

119. Stakeholders consistently told us that early diagnosis was an important topic even though it is often overshadowed by the debate about surgical centres.

120. Early detection of CHD improves outcomes because it:

- avoids the complications, morbidity and mortality associated with cardiovascular collapse following delayed diagnosis;
- results in fewer emergency transfers at birth;
- improves family experience throughout the pathway; and permits choice of birth place optimising postnatal management.

121. NICOR reports that antenatal diagnosis of congenital heart disease has improved over the past 7 years though there is variation between regions, and the detection rate in England is below the average for the UK as a whole.

122. Between 2010 and 2015, almost 50% of infants who required a procedure to treat a congenital heart malformation in the first year of life were diagnosed through antenatal screening. This is as good as, or better than, annual reported diagnostic rates in North America from 2006-12, although the gap has narrowed in recent years.

123. The current Fetal Anomaly Screening Programme (FASP) standard for detection of major cardiac anomalies is 50%. Table 2 below shows that across England this target is close to being met, however there is marked geographical variability across the country. Early indications are that this gradual upwards trend has been continuing. There is an expectation that as the target is achieved it will be reviewed by FASP.

124. The standards aim to increase early diagnosis of CHD by ensuring that national standards are consistently applied and results reported.

Table 4: Rates of antenatal detection (2010-2015)²⁸

	2010-11	2011-12	2012-13	2013-14	2014-15
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²⁸ National Congenital Heart Disease Audit Report 2012-2015, NICOR, 2016 available here: [https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/9791867eff401e0d8025716f004bb8f2/5983f27e0b3ff3b080257d5d005cec4a/\\$FILE/NCHDA%20Aggregate%20report%202012_15%20v1%20%20published%207042016.pdf](https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/9791867eff401e0d8025716f004bb8f2/5983f27e0b3ff3b080257d5d005cec4a/$FILE/NCHDA%20Aggregate%20report%202012_15%20v1%20%20published%207042016.pdf)

England	38.1%	40.0%	42.5%	46.9%	47.1%
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125. While our proposed service standards will be helpful, they cannot address all the factors affecting early diagnosis. We have worked with partners to ensure that programmes to address these important issues are taken forward:
126. Training in the newer three vessel and trachea (3VT) scanning has now been completed in virtually all maternity units in England.
127. The new National Congenital Anomaly and Rare Disease Registration Service (NCARDS) which will collect information on everyone in England with rare disease, including cases identified through antenatal screening, will publish its first report in 2019.
128. Health Education England has been reviewing education and training approaches for sonographers and has commissioned career and competence frameworks for diagnostic radiography and sonography from Skills for Health.
129. The National Screening Committee (NSC) has assessed the effectiveness of pulse oximetry used within the Newborn and Infant Physical Examination screening programme (NIPE) for detecting otherwise undiagnosed CHD. During the pilot almost 33,000 babies were screened and only eight critical CHD cases were detected. NSC is now evaluating the risk:benefit for all babies screened as well as the economics of the programme before a final decision on whether to recommend this test next year.

Better information

130. Good outcomes of surgery (or cardiology intervention) are clearly vital for patients, but they are not the whole story when considering how good services are or the quality of life for patients and their families. We have given a high priority to improving patient experience and to the quality of care and support patients can expect; to the development of better information to give us a more rounded picture of care and help us monitor implementation of the new standards; and to support patients to make informed choices about the provision of their care.
131. While the work of NICOR means that the outcomes data we have is very reliable, it only gives a narrow picture of the quality of care received by patients, and gives no insight into longer term outcomes including quality of life which we know is very important for patients and their families. We

have therefore been working with NICOR, the CHD clinical reference group²⁹ and others to improve the information available.

132. In order to enable us to measure patient experience, we have funded the development of a patient experience survey. Final field testing is now underway. All centres have agreed to participate and we expect full national roll out by April 2018. This survey will play an important role in enabling centres to learn from patients' experiences of their CHD service and represents a unique opportunity to hear condition specific feedback from both adults and children.
133. The quality dashboard we have developed with the CRG has brought together a much bigger set of measures than have previously been available, including:
- Complications
 - Re-interventions
 - Last minute cancellations
 - Patient experience
 - Risk adjusted mortality
134. One year's data has been collected so far. We are now in a transitional period during which data definitions have been refined and steps are being taken to assure data quality. As more data becomes available we will develop appropriate control limits for the new metrics. In the meantime the dashboard is reviewed regularly by the CRG and regional commissioners. The centre's 'VLAD plot' (Variable Life Adjusted Display) - a way of showing the trend in 30 day outcome of all cardiac surgery taking account the mix of patients and their expected outcome – is also reviewed when available.
135. NICOR data has been linked to PICANET³⁰ data by researchers, for example in the Infant Mortality Study, the findings of which informed the CHD standards. A bid for funding has been submitted that would allow routine linkage of NICOR, PICANET and adult intensive care databases which it is hoped will yield new measures of outcomes in CHD patients and tools for improvement. Analysis of these data is not currently possible outside a research setting.
136. We therefore developed a research proposal to investigate longer term outcomes, by diagnosis, using linked data from NICOR, PICANET and other sources. This has been approved by the Research Needs Panel and

²⁹ Clinical reference groups are groups of clinicians and patient representatives that give advice to NHS England on specialised commissioning.

³⁰ PICANET is the Paediatric Intensive Care Audit Network.

will now go forward for further development and commissioning. It is hoped that, together with new work to be undertaken by the Clinical Operational Research Unit (CORU) at University College London to link NICOR, PICANET and adult intensive care databases new measures of outcomes in CHD patients and tools for improvement will emerge.

How things will be better

137. NHS England's aim remains that every patient can be confident that the care they receive is provided by a hospital that meets the standards. The standards set out what doctors, nurses, patients and others told us makes for the best CHD service possible. We know that developing the standards will only be worthwhile if we make sure that they are met.
138. The main impact of both our original proposals, and the developed recommendations that we expect the Board to consider, would therefore be the assurance that every service meets the standards and that patients could therefore be confident about the quality of care they will receive. This is the first time that such an assurance could be based on an external assessment that has tested every hospital providing CHD services against agreed standards.
139. We know from talking to patients and their families and others that there are concerns about the way the proposed changes would affect them, and about the effects they may have on other services and on the hospitals themselves. We acknowledge that these are real concerns and have addressed them in the modifications to the proposals that we have made since the Pre-Consultation Business Case (PCBC) was considered by the Investment Committee (IC). Later in this document we describe our understanding of the likely impact of the proposed changes, if they are implemented, and the steps we are proposing to take to maximise the benefits while addressing any concerns that could arise.
140. The standards were set to reflect the best evidence, expert advice and the experience of patients and families about what makes for the best services. We believe that making the changes we have proposed will ensure that no matter where they live, patients and their families will receive excellent care.
141. The standards cover every aspect of care including important issues like: transition from children's to adult services; providing information; better communication; and compassionate care at end of life and during bereavement.
142. Ensuring that every centre providing care for people with CHD meets the standards is the best way of assuring consistent high quality.
143. As part of our process of applying the standards we have also addressed occasional and isolated practice (small volumes of surgery and

interventional cardiology being undertaken in institutions that do not offer sufficient specialist expertise in this field) which is not permitted by the standards. This is an issue that has been raised with us as a real concern by patient groups, and we are pleased to say that we are well on the way to completely eliminating occasional practice.

How were the original proposals on which we consulted developed?

144. The proposals on which we consulted were developed in response to an assessment of all providers of level 1 and level 2 CHD services against a specific number of the new standards.
145. From the beginning, our intention has been to agree service standards for CHD services that set out the best way in which such services should be organised and delivered.
146. Again, from the beginning it has always been our intention to commission services against those standards in such a way as to be able to assure patients that wherever they received their care it would meet those standards and so ensure that every child, young person and adult with CHD, in every part of the country, would receive the same high standard of treatment.
147. Patients and their families made clear that simply setting standards without taking action to ensure they were met would not be useful.
148. The NHS England Board recognised that the standards were challenging, and that it would be hard for hospitals to meet all of them. Initially, therefore, we asked hospitals to see whether, by working more closely together, they could find new ways of working that would mean that the standards could be met across the country. Unfortunately, that did not prove to be possible. The submissions received from providers did not provide a national solution to meeting the standards³¹.
149. The outcome of this process was considered by the Specialised Commissioning Oversight Group at its meeting on 12 November 2015 and the Executive Group Meeting on 3 December 2015. It was agreed that action should be taken to provide assurance of safety and quality from 1 April 2016 and to require action plans and appropriate mitigation from providers unable to meet the standards. This approach was endorsed by the Specialised Services Commissioning Committee (SSCC) a sub-committee of the NHS England Board at its 22 February 2016 meeting.

³¹ A full report of this work is available here: <https://www.england.nhs.uk/wp-content/uploads/2016/01/nhse-chd-report-national-panel.pdf>

150. This process – starting with a self-assessment against selected standards – was in line with the normal specialised service processes within NHS England when a new specification has been introduced³².
151. In addition to assessing specialist providers of CHD care, SSCC also agreed that the process should address the issue of occasional practice.
152. The National Panel then assessed each hospital's ability to meet selected standards, based on the evidence submitted by the Trust.

The assessment

153. The selection of the standards for assessment and the original assessment process were previously described in detail in the report of the National Panel³³ and the Pre-Consultation Business Case.
154. The panel found that, at the time of the assessment, none of the centres met in full all of the standards tested. This was not unexpected as the standards were designed to ensure that all services were brought up to the level of the best of existing practice - to be stretching and drive improvement without being unrealistic. The panel considered not only whether a centre met the standards at the time of assessment but, if not, whether the centre was likely to meet them within one year. Finally the panel considered the risk to patients presented by services that did not meet the standards.
155. The assessment of each centre at that time³⁴, based on the evidence submitted is summarised in Table 5 below.

³² See Appendix 2: Specialised Services Specification Compliance, Standard Operating Procedure, NHS England, London Region, 2014

³³ A full report of the assessment is available here: <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/07/chd-national-panel-report.pdf>

³⁴ Individual centre assessment reports can be found here: https://www.engage.england.nhs.uk/consultation/chd/supporting_documents/NHS%20England%20Provider%20Impact%20Assessment%20Report.pdf

Table 5: Assessment of level 1 CHD centres, 2016

	Green	Green / Amber	Amber	Amber / Red	Red
	Meets all the requirements.	Meets most of the requirements and has good plans to meet the rest within max. 12 months.	Should be able to meet the requirements with further development of their plans.	Does not meet all the requirements and is unlikely to be able to do so.	Current arrangements are a risk.
North			Alder Hey Leeds	Newcastle	Central Manchester
Midlands and East		Birmingham Children's	UH Birmingham	Leicester	
London		Great Ormond Street	Barts Guy's and St Thomas'	Royal Brompton	
South			Bristol Southampton		

Agreeing the proposals

156. The panel was not responsible for deciding what action to take as a result of that assessment. Rather, the panel's assessment was considered by the Specialised Services Commissioning Committee (SSCC), at the end of June 2016. SSCC recognised that the status quo could not continue and that NHS England needed to ensure that patients, wherever they lived in the country, had access to safe, stable, high quality services. SSCC also recognised that achieving this within the current arrangement of services would be problematic.
157. SSCC determined that, subject to appropriate public involvement and/or consultation, a change in service provision was appropriate³⁵.
158. Representatives of clinicians who provide the service and of patients and their families were full members of the National Panel which completed the assessments of centres against the standards. While not involved in determining the proposals, members were aware of the likely consequences of the assessments.

³⁵ Specialised Services Commissioning Committee (SSCC) Update to the NHS England Board, July 2016, available here: <https://www.england.nhs.uk/wp-content/uploads/2017/05/item13-iii-28-07-16.pdf>

159. Panelists were not directly involved in the discussions within the SSCC that resulted in the proposals. The commissioning proposals were formulated by NHS England. Stakeholders were not involved in formulating those proposals because this was considered a commissioning activity appropriately undertaken by NHS England in its role as the single national commissioner.
160. Following that consideration, NHS England proposed that in future it would only commission CHD services from hospitals that are able to meet the standards within the required timeframes³⁶. These proposals were announced³⁷ on 8 July 2016.

Level 1 (surgical) CHD Services

161. If implemented, these proposals would have meant that in future level 1 CHD services in England would be provided by the following hospitals:

Alder Hey Children's Hospital NHS Foundation Trust (children's services) and **Liverpool Heart and Chest Hospital NHS Foundation Trust** (adult service)

Birmingham Children's Hospital NHS Foundation Trust (children's services) and **University Hospitals Birmingham NHS Foundation Trust** (adult service)

Great Ormond Street Hospital for Children NHS Foundation Trust (children's services) and **Barts Health NHS Trust** (adult service)

Guy's and St Thomas' NHS Foundation Trust (children's and adult services)

Leeds Teaching Hospitals NHS Trust (children's and adult services)

Newcastle Hospitals NHS Foundation Trust (children's and adult services)

University Hospitals Bristol NHS Foundation Trust (children's and adult services)

University Hospital Southampton NHS Foundation Trust (children's and adult services)

162. If implemented, the proposals on which we consulted would have resulted in the following changes at hospitals that have provided level 1 CHD services:

Surgery and interventional cardiology for adults would cease at **Central Manchester University Hospitals NHS Foundation Trust**. Central Manchester does not undertake surgery in children.

³⁶ With the exception of Newcastle Hospitals NHS Foundation Trust. The reasons for this are set out in paragraphs 200-213.

³⁷ The announcement is available here: <https://www.england.nhs.uk/2016/07/chd-future/>

Surgery and interventional cardiology for children and adults would cease at **Royal Brompton & Harefield NHS Foundation Trust**.

Surgery and interventional cardiology for children and adults would cease at **University Hospitals of Leicester NHS Trust**.

163. NHS England also suggested that level 1 adult CHD services, including surgery, could potentially continue at the Royal Brompton Hospital by partnering with another level 1 CHD centre in London that is able to provide care for children and young people with CHD that meets the required standards.

Level 2 (medical) CHD Services

164. Changes were also proposed to the provision of level 2 specialist medical CHD care. While not the subject of the consultation they are described here for completeness.

165. If implemented, these proposals would have meant that in future level 2 CHD services in England would be provided by the following hospitals:

Brighton and Sussex University Hospitals NHS Trust (adult service)

Central Manchester University Hospitals NHS Foundation Trust³⁸
(children's services)

Norfolk & Norwich University Hospitals NHS Foundation Trust (adult service)

Oxford University Hospitals NHS Foundation Trust (children's and adult services)

166. Following the announcement of the proposals, NHS England continued its discussions about the potential for the provision of level 2 medical services at hospitals where level 1 care would cease (Central Manchester, University Hospitals of Leicester).

167. If implemented, these proposals would have resulted in the following changes at hospitals that currently provide adult CHD services:

Specialist medical care and interventional cardiology would cease at **Blackpool Teaching Hospitals NHS Foundation Trust**

Specialist medical care and interventional cardiology would cease at **Imperial College Healthcare NHS Trust**

³⁸ Since the original assessment and proposals Central Manchester University Hospitals NHS Foundation Trust has merged with University Hospital of South Manchester NHS Foundation Trust to form Manchester University Hospitals. The original Trust names are retained in this report to avoid confusion. Our proposal would be expected to result in level 2 adult CHD services being provided at the Central Manchester campus but not Wythenshawe.

Specialist medical care and interventional cardiology would cease at
Nottingham University Hospitals NHS Trust

Specialist medical care and interventional cardiology would cease at
Papworth Hospital NHS Foundation Trust³⁹.

Specialist medical care and interventional cardiology would cease at
University Hospital of South Manchester NHS Foundation Trust⁴⁰

168. In addition, a small number of hospital Trusts not recognised as specialist centres, which were found to be involved in occasional practice/interventions, have been instructed to make arrangements for such patients to be cared for at a specialist centre in future. This process has now all-but eliminated occasional practice, with follow-up action to be taken against providers if they continue.

Why was change proposed at centres assessed as amber/red or red?

169. As set out in this document, the standards were set in 2015, and our aim, agreed then, as now is for all providers to meet them. In July 2016 we assessed Royal Brompton & Harefield NHS Foundation Trust, University Hospitals of Leicester NHS Trust and Central Manchester University Hospitals NHS Foundation Trust, as amber/red or red, and subject to further engagement with them and full public consultation, proposed to cease commissioning Level 1 CHD services from each of them, because none of them were meeting or were likely to meet all of the relevant standards within the required timescale.
170. Our assessment showed that, with the exception of Newcastle Hospitals NHS Foundation Trust, each of the hospitals where we proposed that services should be provided in future either already met the standards required, or was likely to meet those standards within the required timeframe, as a result of the improvement plans they were putting in place.
171. **Central Manchester:** We assessed Central Manchester as not meeting the requirements for the number of surgeons working at the hospital and

³⁹ Papworth developed revised proposals and following a further assessment process NHS England considered that it either met the requirements or had good plans to do so within the required timescale and could in future therefore continue to provide specialist medical care. Papworth suspended its interventional cardiology service but intends to look at restarting this programme once its position as a provider of level 2 services has been confirmed.

⁴⁰ South Manchester voluntarily ceased providing CHD services. Since the original assessment and proposals University Hospital of South Manchester NHS Foundation Trust has merged with Central Manchester University Hospitals NHS Foundation Trust to form Manchester University Hospitals. The original Trust names are retained in this report to avoid confusion. Our developed recommendations would be expected to result in level 2 adult CHD services being provided at the Central Manchester campus but not Wythenshawe.

the number of operations performed. Each surgeon must conduct at least 125 CHD operations per year. From April 2016 there must be at least three surgeons in the team. By April 2021, there must be at least four surgeons in the team. At the time of the assessment Central Manchester had only one surgeon performing CHD operations. That surgeon undertook fewer than 125 procedures per year. Central Manchester therefore did not meet the April 2016 standard. We assessed those arrangements as a risk because of the lack of resilience of a service dependent on a single surgeon.

172. Surgeons told us that the number of operations they each carried out was the most important factor in achieving good surgical outcomes. Our research has shown that there is good evidence of a link between the number of operations done at a hospital and outcomes. There is also good evidence that individual surgeon operating outcomes for complex procedures are linked to the number of times the surgeon carries out that operation.
173. Larger teams help to ensure that surgeons can cover all aspects of the service during the day while a team of at least four surgeons (who are required to provide 24/7 emergency cover and to be able to reach the patient bedside within 30 minutes) will reduce the risks associated with fatigue. Teams of at least four surgeons were recommended by the Independent Reconfiguration Panel in their report on the Safe and Sustainable review⁴¹. Bigger teams are better able to cope when one of the team is unavailable or leaves. They are also better able to support the full range of surgical procedures and the development of very specialised practice.
174. Therefore, if we want to make sure that services reliably achieve the best results we need to commission high volume services.
175. Central Manchester was also assessed as not meeting the requirements for the number of specialist ACHD interventional cardiologists at the hospital and the number of procedures they perform. The requirement for a level 1 CHD provider is to have both a lead interventionist who performs a minimum of 100 procedures and a minimum of three additional interventionists who each perform a minimum of 50 procedures. Central Manchester performed 54 relevant procedures in total, and so did not meet this requirement.
176. We also assessed Central Manchester as not meeting the out of hours surgical requirements. Central Manchester had only one surgeon who

⁴¹ Available here: <https://www.gov.uk/government/publications/irp-advice-national-childrens-congenital-heart-services>

provided all out of hours cover except when on leave, whereas the standard requires that rotas must be no more frequent than 1 in 3 immediately and 1 in 4 by 2021.

177. We considered whether, having assessed the hospital's current arrangements as posing a risk, it would be appropriate to take enforcement action and impose an immediate cessation of level 1 care. In deciding not to pursue this course of action we noted that:

- Any risk arising from the way services were arranged was not new, but rather a longstanding risk now being formally recognised.
- There was no evidence of concerns being raised or of incidents.
- Outcome data had been consistently good.
- Urgent enforcement action would require that patients were diverted to other centres for their care. This would be an unplanned change and this would carry its own risks which needed to be balanced against the risks of not changing⁴².

178. As set out throughout this DMBC, NHS England places great weight on providers' ability to meet the standards. However, the standards cannot be applied automatically or in isolation; other relevant factors must also be considered. This was recognised in paragraph 98 of the Report to the meeting of NHS England Board in July 2015 in which it approved the standards themselves:

'Our commissioning decisions will need to take into account and balance all the main factors, including affordability, impact on other services, access, and patient choice, and not treat the standards as though they exist in isolation'⁴³

179. In Central Manchester's case, NHS England did not consider that any other relevant factors outweighed the aim of ensuring that services are commissioned from providers that meet the standards. A detailed summary of NHS England's analysis of other relevant factors is set out in **Annex 3** 'Impact Assessment: Implementing NHS England's CHD Consultation Proposals' accompanying this paper⁴⁴ including a full assessment of the likely impact of the proposal on other services. A summary of this analysis was reflected in the public consultation

⁴² This assessment was overtaken by events when the Trust suspended the service and new arrangements had to be put in place for patients.

⁴³ Final report of the New Congenital Heart Disease Review to the NHS England Board, July 2015 available here: <https://www.england.nhs.uk/wp-content/uploads/2015/07/Item-4-CHD-Report.pdf>

⁴⁴ In the section entitled 'The impact of the proposal that surgery and interventional cardiology for adults should cease at Central Manchester University Hospitals NHS Foundation Trust'.

documents to ensure that those consulted were able to understand the issues and give informed responses.

180. **Leicester:** We assessed University Hospitals of Leicester (UHL) as not meeting the April 2016 requirement for three CHD surgeons each undertaking 125 operations per year and as being unlikely to meet by April 2021 requirement for a team of four surgeons each undertaking at least 125 operations per year.
181. At the time of the assessment, UHL's reported surgical activity for 2015/16 was 326 procedures⁴⁵. This level of activity is insufficient to meet the current requirement for three surgeons to perform a minimum of 125 procedures per year. Validated 2016/17 activity data was not available to the panel but the Trust indicated that it was 'likely to fall slightly short'⁴⁶.
182. As part of its evidence for our assessment, UHL submitted a surgical growth plan which it considered would result in them achieving the minimum level of activity required to ensure four surgeons are able to perform a minimum of 125 procedures per year by 2021. In this plan, the increase in activity depends on population growth, technical advances, and changes to referral patterns (which UHL stated would be helped if NHS England supported the flow to the Trust of all patients for whom it is the closest centre).
183. The National Panel considered it likely that UHL would, in time, reach activity levels sufficient to support a team of three surgeons each undertaking 125 operations per year but that it was not clear when this would happen. At the time, the Trust expected that this would be achieved in 2017/18.
184. The panel considered that UHL had not provided sufficient evidence to provide confidence that it would achieve the minimum surgical activity requirements to ensure four surgeons are able to perform a minimum of 125 procedures per year by 2021 because:
- It had not reached the current requirement that came into effect on 1 April 2016.
 - The changes to referral pathways described by UHL were not considered sufficient to bring about the level of growth required for them to meet the 2021 requirements. In order for these requirements to be met their activity would need to increase by 53% from 2015/16

⁴⁵ NICOR data. At the time of the initial National Panel report Leicester reported its activity for 15/16 as 321 and subsequently amended this to 331 operations. NICOR validated activity is considered the gold standard measure and has therefore been used as the basis for NHS England's assessments.

⁴⁶ Data made available to NHS England by NICOR in September 2017, still unvalidated, but accepted by the Trust as accurate, shows that UHL's surgical activity in 2016/17 was 349 operations.

levels in five years, when the previous five years have only resulted in a total growth of 24%.

- UHL did not provide any evidence of formal agreements with other providers to change referral patterns or any basis for its assertions about the amount of additional activity they would receive from changed referral pathways.
- NHS England has previously stated that it does not intend to mandate patient flows because it does not consider it appropriate to override clinical judgement and patient choice.

185. In light of this, the panel remained unconvinced that the changes to patient flow required to achieve the necessary growth are likely to occur.
186. Surgeons told us that the number of operations they each carried out was the most important factor in achieving good surgical outcomes. Our research has shown that there is good evidence of a link between the number of operations done at a hospital and outcomes. There is also good evidence that individual surgeon operating outcomes for complex procedures are linked to the number of times the surgeon carries out that operation.
187. Larger teams help to ensure that surgeons can cover all aspects of the service during the day while a team of at least four surgeons (who are required to provide 24/7 emergency cover and to be able to reach the patient bedside within 30 minutes) will reduce the risks associated with fatigue. Teams of at least four surgeons were recommended by the Independent Reconfiguration Panel in their report on the Safe and Sustainable review⁴⁷. Bigger teams are better able to cope when one of their number is unavailable or leaves. They are also better able to support the full range of surgical procedures and the development of very specialised practice.
188. Therefore if we want to make sure that services reliably achieve the best results we need to commission high volume services.
189. At the time the National Panel carried out its assessment it considered that UHL did not meet the requirement that Specialist Surgical Centres must have key specialties or facilities located on the same hospital site and that it was unlikely to do so when this requirement came into effect in April 2019. This was because University Hospitals of Leicester did not have paediatric surgery or gastroenterology located on-site and University Hospitals of Leicester's plan for meeting this requirement depended on

⁴⁷ Available here: <https://www.gov.uk/government/publications/irp-advice-national-childrens-congenital-heart-services>

the building of a new children's hospital, the timetable and funding for which was uncertain⁴⁸.

190. NHS England places great weight on providers' ability to meet the standards. However, the standards cannot be applied automatically or in isolation; other relevant factors must also be considered. This was recognised in paragraph 98 of the Report to the meeting of NHS England Board in July 2015⁴⁹ in which it approved the standards themselves:

'Our commissioning decisions will need to take into account and balance all the main factors, including affordability, impact on other services, access, and patient choice, and not treat the standards as though they exist in isolation'.

191. In Leicester's case, NHS England did not consider that any other relevant factors outweighed the aim of ensuring that services are commissioned from providers that meet the standards. A detailed summary of NHS England's analysis of other relevant factors is set out in **Annex 3** 'Impact Assessment: Implementing NHS England's CHD Consultation Proposals' accompanying this paper⁵⁰ including a full assessment of the likely impact of the proposal on other services. A summary of this analysis was reflected in the public consultation documents to ensure that those consulted were able to understand the issues and give informed responses.
192. UHL considers that the scale and quality of its ECMO service should be taken into account in reaching a decision. While NHS England accepts that the proposals on which it consulted would have an impact on UHL's ECMO service (in that it would no longer be able to provide cardiac, respiratory or mobile ECMO for children or cardiac ECMO for adults with CHD) we do not consider that this means that we need to change our proposals for CHD services. A number of other providers already offer ECMO and could be commissioned to expand their capacity if our original proposals were to be implemented. We would undertake the necessary planning and preparation to commission the necessary capacity elsewhere and re-commission mobile ECMO from an appropriate provider(s) if our consultation proposals were to be implemented.

⁴⁸ UHL has since developed an alternative plan that will involve moving paediatric cardiac services to the Leicester Royal Infirmary by 2019, independently of the children's hospital development which would allow it to be fully compliant with the co-location requirements. The panel considered that UHL's proposal to move paediatric cardiac Level 1 services to the Infirmary site would allow it to achieve full compliance with the requirements. However, the panel considered that UHL needed to set out their plans in more detail to be fully reassuring that this move could and would be achieved by the required deadline.

⁴⁹ Available here: <https://www.england.nhs.uk/wp-content/uploads/2015/07/Item-4-CHD-Report.pdf>

⁵⁰ In the section entitled 'The impact of the proposal that surgery and interventional cardiology for adults should cease at University Hospitals of Leicester NHS Trust'.

193. **Royal Brompton:** We assessed Royal Brompton as unable to meet the requirement to co-locate key paediatric services (paediatric surgery and gastroenterology) by April 2019.
194. This standard was highlighted by our clinical advisers as particularly important for allowing much closer working relationships to develop between paediatric cardiology specialists and the wider paediatric multidisciplinary team. Delivering these services effectively requires the input of the wider paediatric multidisciplinary team, and the interaction between these teams on a daily basis, when co-located, is considered by the Clinical Advisory Panel to be of significant benefit to patients. This way of working brings paediatric cardiac care into line with expectations in other specialist children's services, because most other specialist paediatric services have moved to a paediatric environment, including liver transplantation; bone marrow transplant; stem cell/cancer therapy; and gastroenterology. This follows the accepted international norm.
195. Having all tertiary specialties on one site means neither the child nor the specialist has to travel with the potential compromises involved in the care environment, access to the full team and equipment and timeliness of advice and intervention.
196. We conducted extensive pre-consultation engagement with Royal Brompton. By the time of the consultation Royal Brompton had not provided any concrete plans to co-locate relevant services by April 2019. Royal Brompton argued that co-location was unnecessary in light of a service level agreement between Royal Brompton and Chelsea and Westminster NHS Foundation Trust. It noted that the proximity of the two hospitals meant that clinicians travelling from Chelsea and Westminster to the Royal Brompton could have less far to travel than some clinicians undertaking a journey within one large site or across a multi-site Trust. However, the co-location standard requires services to be provided from the same site – a multi-site trust providing relevant services from different hospitals would not meet that standard. In addition, the distance travelled is only part of the equation; the part that is also addressed by the 30 minutes to bedside standard. The need for cohesive working relationships between teams cannot be addressed through a service level agreement, nor can the need to avoid institutional conflicts if more than one patient requires a particular service at once. These are the key reasons why the standard was adopted in this form.
197. In the Royal Brompton's case, NHS England did not consider that any other relevant factors outweighed the aim of ensuring that services are commissioned from providers that meet the standards. A detailed summary of NHS England's analysis of other relevant factors is set out in **Annex 3** 'Impact Assessment: Implementing NHS England's CHD

Consultation Proposals' accompanying this paper⁵¹ including a full assessment of the likely impact of the proposal on other services. A summary of this analysis was reflected in the public consultation documents to ensure that those consulted were able to understand the issues and give informed responses.

198. NHS England places great weight on providers' ability to meet the standards. However, the standards cannot be applied automatically or in isolation; other relevant factors must also be considered.
199. RBH considered that the impact of our proposals on its specialist paediatric respiratory services should be taken into account in reaching a decision. At the time the proposals were developed NHS England had not fully assessed this impact, but accepted that its proposals would have an impact on RBH's specialist paediatric respiratory services, if a decision is taken that results in closure of the Paediatric Care Unit (PICU) at the Royal Brompton. During consultation NHS England worked with the Trust to understand further the impact on paediatric respiratory services.
200. **Newcastle:** Our assessment showed that Newcastle did not meet the 2016 activity requirement and was unlikely to be able to meet the 2021 activity requirement. It also did not meet the 2019 paediatric co-location requirements or have a realistic plan to do so by April 2019. However Newcastle has a unique role in delivering care for CHD patients with advanced heart failure, including heart transplant and bridge to transplant, and that this could not be replaced in the short term without increasing risks for patients. On balance therefore our view was that it would be better to continue to commission level 1 CHD services from Newcastle.
201. At the time of the original assessment Newcastle's reported surgical activity (2015/16) was 337 procedures including ventricular assist devices (VADs). This level of activity is insufficient to meet the current requirement for three surgeons to perform a minimum of 125 procedures per year.
202. While our aim is to commission level 1 services only from providers that meet the standards, NHS England has recognised that the standards cannot be taken in isolation and that the objective of achieving compliance with the standards must be considered in the round together with other relevant factors.
203. In the case of Newcastle, when developing the original proposals, we needed to take into account their advanced heart failure and heart transplant programmes and the impact that any change might have on these important national services.

⁵¹ In the section entitled 'The impact of the proposal that surgery and interventional cardiology for adults should cease at Royal Brompton & Harefield NHS Foundation Trust'.

204. Advanced heart failure amongst people with CHD is increasing as a result of increased life expectancy. Comprehensive treatment programmes offer heart transplantation and 'bridge to transplantation' using mechanical circulatory support. This is important because demand for heart transplant outstrips the supply of donor hearts. These programmes are run as an extended part of a CHD service and depend on CHD surgeons.
205. Newcastle is one of only two centres providing paediatric heart transplant for the UK (the other is Great Ormond Street). Adult CHD patients with end stage heart failure have limited access to heart transplant and the unit in Newcastle is recognised as delivering more care to this group than other transplant centres nationally. This service is intimately connected to the CHD service and can only be delivered at a level 1 CHD provider. No other provider currently has this capability so while in principle it would be possible to commission these services from an alternative provider, the learning curve would be long and initially outcomes would not be as good.
206. On balance therefore, our view was that our proposal should be to continue to commission level 1 CHD services from Newcastle, and to test this in consultation.
207. In reaching this view we departed from one of the recommendations of the Independent Review Panel set up to consider the *Safe and Sustainable* programme. The IRP recommended that:
- 'Decisions about the future of cardiothoracic transplant...should be contingent on the final proposals for congenital heart services'.⁵²
208. We considered that this departure was justified by the risk of poorer outcomes for advanced heart failure and transplant patients that could arise from a decision to decommission CHD services from Newcastle in the short term.
209. This was not considered to mean that change at Newcastle Hospitals NHS Foundation Trust would not happen in the longer-term. Under the proposals on which we consulted, the hospital Trust would have been required to meet the standards in the same way as all of the other Level 1 surgical centres, though timeframes for doing might differ.
210. Under the proposal on which we consulted, we would have worked closely with the hospital to ensure that patients receiving CHD care at Newcastle Hospitals NHS Foundation Trust were not compromised in any way. These arrangements would be time limited and subject to further review by 2021.

⁵² Available here: <https://www.gov.uk/government/publications/irp-advice-national-childrens-congenital-heart-services>

211. NHS England's CHD Programme did not specifically consider the provision of services relating to advanced heart failure. Heart transplant services were outside the scope of our work. If our proposals are implemented we may need to review the future of advanced heart failure services in England, including the potential of moving the advanced heart failure programme for people with CHD including heart transplantation and 'bridge to transplantation' using mechanical circulatory support from Newcastle to another provider.
212. Once this is complete NHS England will consider what action is needed, if any, to ensure that all patients can benefit from high quality CHD services that meet the standards.
213. We do not consider that these unique circumstances exist elsewhere, because while other linked services may be affected at other hospitals (for example paediatric respiratory services at Royal Brompton or ECMO at Leicester) a number of other providers already offer these services and could be commissioned to expand their capacity if our proposals are implemented. Our full consideration of the impact of our proposals on other services was published in and alongside the consultation document.

PART TWO: CONSULTATION

Approach to consultation

214. Having considered NHS England's obligations under section 13Q and having considered the Statement of Arrangements, we decided to conduct a full public consultation in relation to our proposals for level 1 centres. For the following reasons, however, we did not consider that full public consultation would be proportionate in relation to our proposals for level 2 centres:

- The low volume of interventional cardiology being undertaken by the potentially affected providers means that few patients will be affected.
- Patients undergoing ASD closure as adults will often require only short term follow up rather than ongoing care. Few patients will therefore need to transfer their care to another centre and directing new referrals elsewhere will have minimal impact on patients.
- The absence of sufficient dedicated adult congenital cardiologist time at the centres concerned not only fails to meet the requirements set out in the agreed standards but also suggests that a comprehensive CHD service is not being offered, with most patients having at best limited ongoing care.
- Stopping the provision of ASD closure in adults at the centres concerned is expected to have little or no impact on any other services offered by those Trusts.

215. For the same reasons, NHS England's view was that the proposals in relation to level 2 centres did not amount to substantial developments requiring formal consultation with local authorities.

216. We have worked with affected hospitals and patient groups to plan and manage the changes proposed for level 2 centres by:

- notifying people of the proposals for level 2 centres by inclusion in our consultation materials and the blog;
- holding events in locations relevant to the level 2 centres – Nottingham; Blackpool; London; Cardiff; Norwich; and Papworth.

217. Formal public consultation on level 1 proposals ran from Thursday 9 February 2017 to 17 July 2017. This was significantly in excess of the required statutory minimum of 12 weeks in recognition of the restricted periods in relation to both local and national elections held during the consultation period. Consultation continued during these periods, the consultation hub remained open and responses continued to be received. There were, however, restrictions on local authorities and

parliamentarians, and NHS England did not conduct any consultation events during this period.

218. The focus of the consultation was on services for patients resident in England, but in consultation we recognised that there are children and adults living in Wales who depend on hospitals in England for level 1 services and that residents of Scotland and Northern Ireland also use CHD services in England.
219. Responses were received from across the UK. The consultation analysis includes the views of residents of Wales, Scotland and Northern Ireland. Selected consultation materials were translated into Welsh, in line with advice received from the NHS in Wales.
220. In broad terms, consultation activity focussed on three main objectives:
- The provision of information;
 - Providing opportunities for stakeholders to test/challenge our proposals; and
 - Providing opportunities for stakeholders to respond to our proposals.
221. Consultees were able to respond to the consultation in a variety of ways:
- Submission of responses via the online consultation survey
 - Submission of responses by post or email

Provision of information

222. NHS England set out a clear core narrative in a consultation document, written in plain English and made available in the following ways:

Consultation document – setting out the proposals in context; available via the NHS England consultation hub website and as hard copy on request (available as Annex 1 accompanying this document);

Summary – summarising the key points from the consultation document, and also available via the NHS consultation hub website;

PowerPoint presentations – used at consultation meetings to summarise key elements of the consultation document and a method of contributing to the consultation;

Easy Read – a short and concise document for those with learning difficulties, young children and those whose first language may not be English, or those who did not wish to read the full document;

Alternative language formats – summary versions of the consultation documents in the following languages: Polish, Punjabi, Hindi, Gujarati, Urdu, Tamil and Welsh were made available across England and Wales and available via the NHS consultation hub website;

Young People CHD website - with an animation and a secure portal so that children and young people were able to understand the proposals and share their thoughts on the proposals;

Additional detailed information – was available for those who wanted to delve into the background to the proposals and their potential impact in more detail, and made available via the NHS consultation hub website, including:

- NHS England Provider Impact Assessment Report
- Equalities and Health Inequalities Impact Assessment
- National Panel Assessment Report
- Question and answer documents – one produced for the launch of consultation and a second made available following the restricted period associated with local and national elections

Opportunities to test/challenge the proposals

223. Consultation included the following opportunities to understand, test and challenge the proposals:

Engagement with local government

224. Following the announcement of the proposals and following advice from the Centre for Public Scrutiny, we wrote to all top tier local authorities to:

- notify them of all the proposed changes;
- explain that while the proposed changes in relation to level 1 centres do represent a substantial development on which NHS England will consult with affected local authorities, in our view the proposals in relation to level 2 centres are not substantial developments, for the same reasons that we do not consider full public consultation would be proportionate; and
- indicate that, for level 1 changes, we intended to work most closely with those authorities closest to the hospitals potentially affected by change and that other authorities that consider the proposals to represent a substantial development for their residents may have wished to be involved in these arrangements either before or during formal consultation. For level 2 changes, we did not propose to conduct formal consultation with any local authorities, as we did not consider these to be 'substantial developments' requiring formal consultation; however, we would provide full details of our proposals and would offer to provide further information to local authorities on request.
- offer to provide further briefing or attend Health and Wellbeing Boards or Overview and Scrutiny Committees (OSCs) on request

225. **Overview and Scrutiny Committees, and Health and Wellbeing Boards** – we briefed local government colleagues during the pre-consultation phase, via the Local Government Association. During consultation we attended all meetings of Overview and Scrutiny Committees, and Health and Wellbeing Boards to which we were invited. Although not public meetings, these meetings were held in public and in some cases public participation was permitted.
- 2 March 2017** North East Health Scrutiny Committee, Hartlepool Borough Council
- 6 March** Derbyshire Health Scrutiny Committee, Matlock County Council
- 14 March** Nottingham/Nottinghamshire OSC, Nottinghamshire County Council
- 14 March** Joint Leicester, Leicestershire and Rutland OSC, Leicester City Council
- 15 March** Lincolnshire OSC, Lincolnshire County Council
- 20 March** Northampton HOSC, Northampton
- 28 March** Rutland Health and Wellbeing Board, Rutland County Council
- 27 June** Leicester, Leicestershire, Rutland Joint OSC, Leicester City Council
- 5 July** Joint Yorkshire and the Humber OSC, Leeds City Council
- 11 July** Kensington & Chelsea OSC, Chelsea Old Town Hall
- After consultation
- 6 September** Hillingdon External Scrutiny Committee
- 10 October** Manchester City OSC, Manchester Town Hall
226. **Face-to-face events** – we held a range of face to face meetings across the country with geography largely determined by the location of level 1 and level 2 CHD hospitals. More meetings were held in areas where change was proposed. We did not hold a meeting for patients and staff in Brighton at the request of the hospital. Some events were open meetings, some were more focussed on patients, their families and staff. Although there was considerable criticism of the choice of venues, timing of meetings and the capacity of these venues, these were all chosen taking local advice from our regional teams, the hospitals concerned and patient support groups and charities. The physical capacity of venues in areas where we expected a high level of interest meant that we made these ticketed events, but we were always able to accommodate everyone who was able to come including those who arrived on the day without booking.

28 February 2017, 1.30pm– 4pm: Norfolk & Norwich Patient, Public and Staff Event, Norfolk and Norwich University Hospital

3 March, 10.30am – 12.30pm: Oxford Patient, Public and Staff Event, John Radcliffe Hospital

7 March, 6pm - 8pm: London Question Time

9 March, 2pm – 4pm: Leicester Staff Briefing

9 March, 6pm - 8pm: Leicester Question Time

11 March, 10am – 12pm: Manchester Patient, Public and Staff event, Manchester Art Gallery

15 March, 1.30pm – 4pm: Cardiff Patient, Public and Staff event, University Hospital Wales

16 March, 1.30pm – 4pm: Birmingham Patient, Public and Staff Event, Birmingham Children's Hospital

18 March: Little Hearts Matter Patient and Families Event, Birmingham

21 March, 5pm – 7pm: Leeds Patient, Public and Staff event, Leeds General Infirmary

22 March, 1.30pm – 4pm: Barts Patient, Public and Staff event, Barts Hospital

23 March, 4pm – 7pm: Alder Hey Patient, Public and Staff event, Institute in the Park – Alder Hey Children's Hospital

25 March, 10am – 12pm: Papworth Patient Event, Papworth Hospital

27 March, 2.30pm – 4.30pm: Great Ormond Street Patient, Public and Staff Event, Great Ormond Street Hospital

28 March, 5pm – 7pm: Evelina/Guys Patient, Public and Staff event, Evelina Hospital

31 March, 3pm – 6pm: Southampton Patient, Public and Staff event, Southampton General Hospital

14 June, 5pm – 7pm: Wrexham Patient, Public and Staff event, Holt Lodge Hotel

15 June, 3pm – 6pm: Blackpool Patient, Public and Staff event, Lancashire Cardiac Centre, Blackpool Hospital

19 June, 2pm – 5pm: Bristol Patient, Public and Staff event, Education Centre, Bristol Royal Infirmary

22 June, 1.00pm – 3.00pm: Lincolnshire Patient, Public and Staff event, New Life Centre Sleaford

24 June, 11am - 2pm: Royal Brompton Patient and family event, Royal Brompton Hospital

27 June, 6pm – 8pm: Newcastle Patient, Public and Staff event, Newcastle Civic Centre

28 June, 6pm – 8.30pm: Middlesbrough Patient, Public and Staff event, St Mary's Centre, Corporation Road, Middlesbrough

30 June, 1pm - 3pm: Nottingham Patient, Public and Staff event, The Education & Conference Centre, Nottingham University Hospitals, City Hospital Campus

1 July, 1pm - 4pm: Leicester Patient and Family event, Glenfield Hospital

227. **Digital events** – given the national nature of this consultation, we were hoping to make best use of NHS England's digital facilities in order to support people making a contribution to the consultation, without having to travel. We ran three Webinars:

1 March 2017, 5–7pm (open to all)

2 March, 2–4pm (for CCGs)

2 March, 5–7pm (for families and carers of those with CHD and Learning Disabilities)

228. We also recorded and webcast the two Question Time events in order to expand access to those who were not able to attend on the day. A number of the OSC meetings described above were also webcast.

229. **Engagement with MPs** – Many MPs who had expressed an interest received regular email updates including the blog. Briefings were offered to MPs interested in CHD services in the Summer and Autumn of 2016 following the announcement of the proposals. Meetings took place on the following dates:

11 July 2016 – all MPs

20 July 2016 – all MPs

29 November 2016 – Midlands & East MPs

6 December 2016 – North MPs – briefing offered no MP accepted

7 December 2016 – London MPs

25 January 2017 – Leicester MPs

230. We provided support for a Westminster Hall debate secured by Liz Kendall MP for Leicester West on 19 October 2016 and a House of Lords debate on 20 July 2017, as well as a number of written and oral questions from MPs and Peers submitted to Ministers, Department of Health or direct to NHS England.
231. We responded to all correspondence from MPs and Peers, before, during and after the consultation.
232. **Engagement with CCGs** – We notified all CCGs of consultation in the NHS England CCG bulletin and via NHS Clinical Commissioners. We arranged a webinar for CCGs, though this did not prove to be a popular means of engagement.
233. **Targeted engagement** – we made specific efforts to ensure that we heard the views of those groups identified in our pre-consultation equalities analysis as potentially more affected by the proposals.

Children and Young People

234. We have previously undertaken specific engagement activities with children and young people⁵³, and sought to ensure that the things that matter to them were reflected in the standards. We also took steps to ensure we heard from children and young people during the consultation on proposals for change to CHD services. We provided an EasyRead version of the consultation document and also provided a website designed for children and young people's feedback.
235. We engaged with two separate expert companies to help us do this.
236. We worked with Therapy Box to create an EasyRead⁵⁴ version of the proposed possible changes, this used recognised illustrations and simple direct language that could be used by a parent or carer of a child, young person or someone who has learning difficulties to help them understand what we were consulting on and therefore be able to elicit their thoughts and opinions. Parents and carers then fed this in through the usual consultation route or via organisations that represented their opinion.
237. We worked with Considered Creative to create a web portal⁵⁵ where questions were posed in a simple direct format, a more youth friendly mechanism for young people to directly send us their thoughts and opinions. The site had simple mechanics such as animation to explain the

⁵³ See Appendix 6: 'Engagement with public, patients and their representatives' - of the CHD paper considered by the NHS England Board at its meeting on 23 July 2015 and available here: <https://www.england.nhs.uk/wp-content/uploads/2015/07/Item-4-CHD-Report.pdf>

⁵⁴ Available here:

https://www.engage.england.nhs.uk/consultation/chd/supporting_documents/chdproposaleasyread.pdf

⁵⁵ Available here: <http://youngpeoplechd.co.uk/>

details of the proposals and 'sliders' to share how they thought about the proposals.

- 238. Once the methods of engagement were created we promoted this through our charity stakeholders who work with young people; and used them at events to gather thoughts and opinions.
- 239. Where young people were present we used the animation to explain the proposals and then used either drawing techniques or group working to think about what they thought about the proposals and about what it might be like to go to another hospital, as well as what they would like to be there to make any change as good as it could be.
- 240. Specific sessions for children and young people were held at the annual conference of a national charity⁵⁶. 21 young people aged 11-18 years old and 10 children aged 8-11 years old were present in two separate sessions. They were shown the video from the children and young people's website and then worked in groups to think through the implications of the proposals.

People of Asian ethnicity with CHD

- 241. We made considerable efforts to engage with black and minority ethnic groups before and during consultation. Consultation materials were provided in 5 languages (Urdu, Tamil, Gujarati, Hindi and Punjabi) for CHD patients and families from South Asian backgrounds, additionally all CHD clinicians were written to, to encourage patients of South Asian descent to contribute to the consultation and NHS England made the offer of translators.

People with learning disabilities and CHD, and their families

- 242. We worked closely with two charities with a particular interest in learning disabilities (LD) and CHD throughout: Down's Heart Group and Max Appeal. We have also been in regular contact with 22 Crew. We were able to meet with and hear from young people with LD during our engagement events for children and young people during the consultation on standards. Their views informed the standards. We also sought their advice on the impact of the proposals on this group, and on our approach to consultation. Advice from CHD specific learning disability charities was taken to ensure the EasyRead version enabled as many people to interact with the consultation as possible; an online webinar meeting was held rather than a physical meeting for families of those with CHD and LD. One respondent to consultation considered that more information should have been made available in an easy-read format.

⁵⁶ Little Hearts Matter, 18 March 2017

Feedback and analysis

243. An independent organisation experienced in the analysis of consultations, Participate Ltd, was engaged (following a competitive process) by NHS England to prepare a report on the consultation responses.
244. Their analysis included feedback gathered through the on-line survey and other written answers as well as the key points and considerations raised through the question-time events, meetings with patient organisations, webinars and focus groups.
245. The consultation questionnaire recorded demographic information which formed part of the analysis of responses. Consultation questions mixed 'Y/N', rating scale and narrative answers to give the most insight into respondents' reasoning. Analysis considered these factors to identify different patterns of response.
246. The analysis will be published alongside the NHS England Board papers and will include information about the number, type and other characteristics of the responses, giving us a good picture of the views expressed.

The response to consultation

247. The analysis of consultation response is based on:
 - 7673 online survey responses
 - 79 letters/emails
 - Themes to have emerged from the consultation meetings
 - Overall feedback from the 'Young People with CHD' survey report.
248. More responses were from members of the public (44% or 3381 responses) than any other group. Only 4% (297 responses) were from current patients, with 11% (872 responses) from parents, family members or carers of current CHD patients. A further 4% (324 responses) were from clinicians.
249. Responses were received from respondents across the age spectrum, including the traditionally harder to reach 19-29 year olds. Only 1% of responses were from under 18s but there were a significant number of responses from parents, family members or carers that are likely to relate to younger patients. The views of children and young people were also contributed through the separate children and young people website. A greater proportion of responses (61%) were from female respondents, which, we are advised, is common in terms of survey completion.
250. Approximately 9.4% of responses to the survey were from people of Asian ethnicity. 7.5% of the population of England and Wales has Asian ethnicity according to the National Census 2011, while 11.2% of patients admitted to level 1 CHD centres in England are of Asian ethnicity.

251. More responses (71%) were from the Midlands and East region than any other region. This is likely to reflect the significant public visibility of campaigning in this region as well as the degree of concern about the proposals felt in this part of the country. Responses to the survey therefore have a strong regional bias towards the perceived impact on services in the Midlands and East region. Responses from other areas of the country where change has been proposed were at a much lower level (London – 8%; South East – 5%; East of England – 3%; North West – 3%; North East – 2%).
252. The consultation was not a vote on whether or not the proposals should be implemented. Rather it was an opportunity to hear views about our proposals, which we will take into account when we make our decisions. Because of this we wanted to understand the reasons behind consultees' views, and the consultation questions were therefore structured accordingly.
253. Overall NHS England's guiding principle that in future Congenital Heart Disease services will only be commissioned from hospitals that are able to meet the full set of standards within set timeframes was strongly opposed by a significant majority of respondents (86%).
254. Clinicians and national organisations showed higher levels of agreement with the proposal.
255. The two principal membership organisations for specialist congenital heart disease doctors provided support: the Society for Cardio-Thoracic Surgery stated in its consultation response that it strongly supported the principle; the British Congenital Cardiac Association has told us that it has always supported the standards and looks forward to their implementation.
256. In its consultation response, Tiny Tickers, a charity working to improve the early detection and care of babies with serious heart conditions told us that it: 'fully supports the approach the review has taken of establishing new standards of care and then assessing units' capabilities to meet those standards. We believe this is the correct approach and that the introduction of agreed new standards represents the best method of ensuring continued and constantly improving quality of care for patients with CHD and their families. We recognise that questions regarding the future of CHD services have caused uncertainty for NHS staff and patient families for many years, and believe this review is an opportunity to build a stable national service for future generations – ending the constant conversation about reconfiguration of services.'
257. In its consultation response, the Somerville Foundation, a national charity representing adult congenital heart disease patients, told us that they 'strongly support the principle that in future CHD services will only be

commissioned from hospitals that are able to meet the full set of standards within the set timeframes. However, a degree of pragmatism needs to be used in order to ensure the best long-term outcome can be achieved. Rigidity in itself to timeframes might result in a worse position rather than better, more especially in the short-term’.

258. Respondents from Midlands and East felt that University Hospitals Leicester was not being treated fairly or consistently in the application of the standards, comparisons being drawn with Newcastle which was seen as being given additional time to meet the standards. The view that the standards do not make sense clinically or for patients was also expressed. Respondents believed that Leicester would meet the standards in 2018.
259. Respondents in the London area wanted patient outcomes to be the focus rather than standards. Respondents felt that insisting on physical co-location of services would not improve outcomes for patients and should not be the decisive factor that led to a CHD unit closing. Respondents also disagreed with NHS England’s assessment and considered that the Royal Brompton met the required co-location standards in partnership with Chelsea and Westminster Hospital.
260. Respondents in the North West considered that the standards must make clinical and patient sense. There was a concern amongst respondents that services needed to be local and that if this were not to be the case the risk of dying in an emergency was raised. Respondents also thought more consideration should be given to the effect on quality of life for families that had to travel for care.
261. A summary of consultation responses was made available to the Clinical Advisory Panel and the National Panel as part of their briefing packs.
262. More information on the consultation response in relation to each hospital where change was proposed is given in part 4 of this document below.

PART THREE: BEST PRACTICE ASSURANCE

Assurance of readiness for decision making

263. The assurance of best practice is summarised in this section of the DMBC. A full description of how the requirements derived from the legislation, regulations and best practice guidance, including NHS England's own guidance, may be found in **Appendix 1** of this paper.
264. When the Board comes to take decisions as to whether to implement its proposals or whether to take an alternative course of action it must:
- give conscientious consideration to the results of the consultation;
 - ensure that NHS England has met the requirements of the Secretary of State's Four Tests (and the fifth test set by the Chief Executive of NHS England) and has respected NHS England's Service Change Guidance;
 - ensure that NHS England has met its legal duties including those set out in sections 13C - Q of the NHS Act 2006 and in the Equality Act 2010, the Human Rights Act 1998 and the Children Act 2004;
 - take into account all the relevant factors and no irrelevant factors; and
 - satisfy itself that due process has been followed.
265. **The results of the consultation:** We received 7673 consultation online form responses (survey) and 79 'other responses' in the form of letters/emailed documents. The analysis of the consultation responses can be found in the report from Participate Ltd, available as **Annex 1** accompanying this paper. Further detail from the responses has been woven into this paper.
266. **The Five Tests:** The Secretary of State's Four Tests are:
- A clear, clinical evidence base
 - Strong patient and public engagement
 - Consistency with patient choice
 - Support for proposals from clinical commissioners
267. A fifth test was introduced by NHS England Chief Executive Simon Stevens in April 2017, the most relevant aspect of which is the requirement to demonstrate that sufficient alternative provision is being put in place alongside or ahead of bed closures, and that the new workforce will be there to deliver it.
268. NHS England has ensured that it has met the requirements of the five tests. This is described in detail in Part 2 of the DMBC. In reviewing and accepting the DMBC, the Oversight Group for Service Change and

Reconfiguration (OGSCR) and Investment Committee (IC) have considered that this requirement was met.

269. **NHS England's Service Change Guidance:** confirmation that our process has followed NHS England's Service Change Guidance comes from the endorsement of this DMBC by OGSCR, the group that provides NHS England's internal assurance that the guidance has been followed, from the IC, and from our legal advisers.
270. **Compliance with the relevant legal requirements:** Our legal advisers, DAC Beachcroft LLP have reviewed our compliance with sections 13C to 13Q of the NHS Act 2006 and the public sector equality duty. This is described in more detail in **Appendix 1** of this paper. In reviewing and accepting the DMBC, OGSCR also considered that this requirement was met.
271. **Taking account of all the relevant factors:** NHS England has undertaken a full impact assessment to identify the potential impact of implementing its proposals and any appropriate mitigations of its proposals. This includes both a refreshed equalities impact assessment available as **Annex 2** accompanying this paper, and advice from the National Panel.
272. NHS England has received advice on the current (as at August 2017) assessment of each hospital providing level 1 and 2 CHD services against purposefully selected standards; and the impacts of implementing NHS England's proposals and any appropriate mitigations of these impacts. These assessments were undertaken by a specially convened National Panel including national and regional commissioners, clinical and patient representatives and chaired by Dr Vaughan Lewis. The Panel also considered alternative proposals that emerged during consultation. The panel met in August 2017. A report of its work is available as **Annex 6** accompanying this paper. Its advice is reflected throughout the DMBC.
273. NHS England has received advice on a range of clinical issues in the light of consultation including issues raised by respondents to the consultation from a specially convened Clinical Advisory Panel chaired by Professor Sir Michael Rawlins. The panel met in August 2017. A report of its work is available as **Annex 5** accompanying this paper. Its advice is reflected throughout the DMBC.
274. A full assessment of the financial impact of NHS England's proposals was included in the paper presented to the Investment Committee (IC) in January 2017. This confirmed that implementing the standards is affordable for NHS England under tariff. In developing and agreeing the CHD standards, NHS England has been clear throughout that no additional funding will be provided to meet compliance costs for those

providers wishing to offer these services. Implementing the Board's proposals would result in capital costs for some Trusts. NHS England has been clear throughout that no specific central funds are available for capital investment. The risk around capital funding requirement is considered minimal. There will be a cost to establishing formal networks. We have given a commitment to pump priming the development of CHD networks for a limited period, in a similar way to other Operational Delivery Networks and using similar funding mechanisms from within the Specialised Commissioning budget.

275. **Confirmation that due process has been followed:** Confirmation that our process has followed due process comes from the endorsement of this DMBC by OGSCR and Investment Committee and from the review and advice of our legal advisers.
276. Similarly, the proposals (set out in a pre-consultation business case) were also assured by the OGSCR, the IC and our legal advisers before proceeding to public consultation on our proposals.

PART FOUR: INFORMATION TO SUPPORT DECISION MAKING

277. The National Panel has confirmed that their refreshed assessment of hospitals against the standards did not change the basis of the original proposals.
278. NHS England has undertaken an updated equalities impact assessment (see **Annex 2**).
279. NHS England has carried out a full assessment of the potential impacts of the proposals on which it consulted (see **Annex 3**). In doing so it has taken account of the advice of the Clinical Advisory Panel (see **Annex 5**), the work of the National Panel (see **Annex 6**) and the views expressed in consultation. The assessment both identifies the potential impacts of the proposals and, where these impacts are potentially negative, considers how they could be mitigated or managed. The assessment considers both the specific impacts associated with the hospitals where change has been proposed, and the cross-cutting impacts that could be felt more widely.
280. This confirms that the original proposals could be implemented by the NHS England Board and the impacts of doing so could be appropriately managed.
281. The recommendations that the Board is now expected to consider modify NHS England's original proposals, taking into account the views expressed in consultation, and the new information that has been provided by the hospitals affected. These recommendations were informed by detailed discussions at a Board Development Session on 27 October 2017.
282. The impact of implementing these new recommendations has also been considered, to identify their potential impacts and, where these impacts are potentially negative. We have also considered how they could be mitigated or managed. This is reflected in the following discussion relating to each of the proposals for change.

Review of the proposals for change on which we consulted

The proposal that surgery and interventional cardiology for adults should cease at Central Manchester University Hospitals NHS Foundation Trust⁵⁷ (Central Manchester does not undertake surgery in children).

The Original Proposal

283. Central Manchester did not meet and was not expected to be able to meet a range of standards including surgical activity and staffing and interventional activity and staffing. For this reason, Level 1 CHD services for adults⁵⁸, including surgery and interventional cardiology, would cease at Central Manchester. NHS England would work with Alder Hey and Liverpool Heart and Chest to safely transfer CHD level 1 adult CHD services from Central Manchester. Level 2, mainly specialist medical services for adults may be retained at Central Manchester.

Assessment Against the Standards

284. At the time of the original assessment, published in July 2016, Central Manchester was assessed as Red – ‘Does not meet all the April 2016 requirements and is unlikely to be able to do so. Current arrangements are a risk.’
285. At the time of the current assessment (August 2017) the level 1 adult CHD service previously provided by Central Manchester had been suspended by the Trust for an indefinite period. The National Panel did not consider that refreshing the earlier assessment was possible or appropriate.

Consultation Response

286. The main themes from respondents in the North West (NW) were:
- Facilities need to be local to avoid risk to patients including death
 - Think about the effect on families having to travel and quality of life
 - Retain the excellent services at Manchester
287. Unlike other affected regions a significant proportion of respondents in the North West also said that the principle, that in future Congenital Heart Disease services will only be commissioned from hospitals that are able to meet the full set of standards within set timeframes, was a good idea and that the standards set out sensible guidelines.

⁵⁷ On 1 October 2017 Central Manchester University Hospitals NHS Foundation Trust merged with University Hospital of South Manchester NHS Foundation Trust (UHSM) to form Manchester University NHS Foundation Trust. To avoid confusion and for purposes of continuity, this paper continues to refer to the Trust as Central Manchester.

⁵⁸ Central Manchester does not provide level 1 services for children.

288. Respondents had a range of concerns about the proposed model of maternity care for women with CHD in the North West of England.

- Whether maternity care for congenital heart patients will continue at Manchester
- How services in Liverpool would work and concern that as the model would involve several different hospitals (Liverpool Heart and Chest; Liverpool Women's; Alder Hey) this would be inherently less good, and potentially more risky than the current arrangements in Manchester. It would also mean more transfers for women and their babies and for the staff caring for them. There is also uncertainty as to how on-call obstetric arrangements would work if there was a need to cover multiple sites.
- A concern that there has been too much focus on the availability of cardiac surgery for women with CHD at the time of delivery when this is very rarely needed.

289. The Trust in its response:

- Supported commissioning against agreed evidence based clinical standards but believed that NHS England had placed too much emphasis on compliance with a comparatively small number of the standards, and questioned the evidence behind particular standards.
- Suggested an alternative arrangement in which the paediatric and adult CHD surgical team could work across both Liverpool and Manchester with support in Manchester from adult (non-congenital) cardiac surgeons.
- Expressed concern that the proposal would result in less safe care for pregnant women with Congenital Heart Disease in the North West of England and suggested that instead a maternity hub should remain in Manchester, networked with the level 1 centre, with the care of complex women discussed at a multidisciplinary meeting to determine the best place for delivery. Women with lower risk lesions could deliver closer to home as is current practice.
- Stated that although not in favour of the proposed approach, it would, if the proposal was implemented, and as far as possible, ensure that unintended consequences were mitigated.
- Confirmed that it would like to agree the clinical model for the North West in order to provide certainty for patients and staff.

290. Greater Manchester commissioners (Greater Manchester Clinical Commissioning Groups and the Chief Officer of the Greater Manchester Health and Social Care Partnership) in their response:

- Stated that there was real urgency for NHS England to use their commissioning powers to drive joint, locally driven work on the future service model for the North West. Given the current unavailability of a NW based adult surgical service a final decision should be reached as soon as feasible and the timescales for transition agreed.
- Suggested that maternity services should be given special consideration – and echoing the concerns of Central Manchester, sought assurance that managing pregnant women with moderate or high risk congenital heart disease in Liverpool rather than in Manchester, would not result in a reduction in both safety and quality of care.
- Considered that Manchester should be regarded as a Level 2 centre with the ability to undertake ASD closures and more complex interventional procedures, with the exception of those very complex procedures that require a congenital surgeon to be present.

291. NHS England asked whether consultees supported the commissioning of level 2 services in Manchester, if Central Manchester no longer provided level 1 services. Most respondents neither supported nor opposed this proposal.

Impact of implementing the original proposals

292. NHS England has assessed the impact of implementing the proposals on which we consulted, and confirmed that these could be appropriately managed. Full details of this assessment are reported in **Annex 3**.

Alternative Proposals

293. No alternative proposals were received.

Developed Recommendations

294. There has been no change to NHS England's assessment of Central Manchester's ability to meet the standards for level 1 adult CHD services.

295. We have assessed the impact of implementing the proposals and confirmed that they could be implemented and the impacts of doing so could be appropriately managed.

296. If the proposals are implemented, NHS England has said that it would commission level 2 adult CHD services in Manchester. This would support Central Manchester's aspirations to continue to provide maternity care for women with CHD and interventional cardiology for adults with CHD. It would also support our aim to ensure that patients can receive as much care as possible, as close to home as possible. NHS England would expect the Liverpool Trusts to support this approach within a network arrangement.

297. The recommendations expected to be put before the Board for consideration are:

- To confirm that the Board is content to proceed with implementing its 'minded to' decision to commission adult level 1 CHD services from Liverpool Heart and Chest Hospital NHS Foundation Trust, with the full range of level 2 services to be commissioned from Manchester University Hospitals NHS Foundation Trust, as part of a North-West England CHD Network.
- Under these network arrangements, we would expect Manchester University Hospitals to continue to play an important role in providing maternity care for women. We would expect that care for women with complex needs would be discussed at the NW CHD Network multidisciplinary team meeting, to determine the best place for delivery.
- The Board's decision to support these network arrangements should be conditional on the Liverpool Trusts providing robust and adequate support for level 2 services in Manchester.

Implementing the Developed Recommendations

298. NHS England will monitor progress in the North-West towards meeting the standards and take commissioning action, if it becomes clear that the standards will not be met according to the timescale set out in the implementation schedule. These timescales are informed by the Trusts' own plans and the original timetable set out in the standards.

299. Alder Hey Children's Hospital Trust, Liverpool Heart and Chest Hospital, The Royal Liverpool and Broadgreen Hospitals, Liverpool Women's Hospital and Manchester University Hospitals will be required to re-provide all level 1 and level 2 services for adults with CHD within the NW CHD Network by January 2019. A detailed implementation schedule can be found below:

Milestone- no later than	Deliverable	Commissioner action if not delivered
		Trust required to produce, and agree with NHS England, a recovery plan.
January 2018	NWCHDN Network MDT meets at least weekly.	If milestone missed.
April 2018	NWCHDN Network Board established.	If milestone missed.
September 2018	All outpatient appointments for adults with CHD delivered within the NWCHDN at both LHCH and MFT (and outreach), excluding patients whose care is delivered elsewhere because of patient choice or for clinical reasons.	Less than 85% outpatient appointments for adults with CHD delivered within the NWCHDN at both LHCH and MFT, excluding patients whose care is delivered elsewhere because of patient choice or for clinical reasons.
November 2018	All cardiology interventional procedures for adults with CHD delivered within the NWCHDN at both LHCH and MFT, excluding patients whose care is delivered elsewhere because of patient choice or for clinical reasons.	Less than 85% interventional procedures for adults with CHD delivered within the NWCHDN at both LHCH and MFT, excluding patients whose care is delivered elsewhere because of patient choice or for clinical reasons.
January 2019	All cardiac surgery for adults with CHD delivered within the NWCHDN at LHCH, excluding patients whose care is delivered elsewhere because of patient choice or for clinical reasons.	Less than 85% cardiac surgery for adults with CHD delivered within the NWCHDN at LHCH, excluding patients whose care is delivered elsewhere because of patient choice or for clinical reasons.
January 2019	All non-cardiac surgery for adults with CHD delivered within the NWCHDN at the appropriate centre, excluding patients whose care is delivered elsewhere because of patient choice or for clinical reasons.	Less than 85% non-cardiac surgery for adults with CHD delivered within the NWCHDN at the appropriate centre, excluding patients whose care is delivered elsewhere because of patient choice or for clinical reasons.
January 2019	All inpatient admissions for adults with CHD delivered within the NWCHDN at the appropriate centre, excluding patients whose care is delivered elsewhere because of patient choice or for clinical reasons.	Less than 85% inpatient admissions for adults with CHD delivered within the NWCHDN at the appropriate centre, excluding patients whose care is delivered elsewhere because of patient choice or for clinical reasons.

Impact of Implementing the Developed Recommendations

300. The recommendation is, essentially, to implement the proposal on which we consulted, and confirming that NHS England would commission level

2, mainly specialist medical services for adults with CHD from Central Manchester.

301. Therefore the impact assessment for the proposals on which we consulted remains valid and confirms that these impacts could be appropriately managed. Full details of this assessment are reported in **Annex 3**.

The proposal that surgery and interventional cardiology for children and adults should cease at University Hospitals of Leicester NHS Trust.

The Original Proposal

302. For reasons mainly linked to surgical volumes, Level 1 CHD services including surgery and interventional cardiology for children and adults would cease at University Hospitals of Leicester NHS Trust (UHL). NHS England would work with UHL to safely transfer these services to appropriate alternative hospitals. Level 2, specialist medical services, may be retained in Leicester.

Assessment Against the Standards

303. At the time of the original assessment, published in July 2016, University Hospitals of Leicester was assessed as **Amber/Red** – ‘Does not meet all the April 2016 requirements and is unlikely to be able to do so’.
304. The National Panel’s current assessment undertaken in August 2017 (including progress and future plans for any standards not yet met – including 2019 and 2021 standards) was as follows.
305. April 2016 and April 2017 requirements – **Amber** - ‘Should be able to meet the requirements with further development of its plans’.
306. At the time of the current assessment although the Trust had agreed plans to ensure that all adult CHD interventional patients from Nottingham University Hospitals would be transferred to UHL, this had not been implemented. In order to meet the standards, assurances are still required from UHL that no CHD interventional activity is undertaken at Nottingham University Hospitals.
307. University Hospitals of Leicester must ensure that all of its surgeons perform a minimum of 125 operations per year. The Trust does not currently have sufficient activity to meet the April 2016 standard requiring a team of three surgeons each performing a minimum of 125 procedures each year. Their growth plan suggested they would achieve this level of activity by 2019.
308. University Hospitals of Leicester must now establish a 1:3 consultant surgeon rota. At the time of completing this report, although Leicester employed three surgeons, only two were taking part in the on-call rota. Leicester provided assurances that this arrangement was temporary.
309. University Hospitals of Leicester must now establish a 1:4 interventional cardiology rota. The Trust currently has three interventional cardiologists. The service is augmented by three other interventional congenital cardiologists, who are employed elsewhere, but have contracts with University Hospitals of Leicester for their work at the Trust. They plan to recruit additional interventional cardiologists this year to establish a

substantive 1:3 rota and will increase this to 1:4 in the future. The panel noted the fragility of the current arrangements. It noted that under the revised definitions of interventional activity Leicester has sufficient activity to maintain a team of four interventional congenital cardiologists and therefore would be able to comply with this standard without requiring significant growth.

310. April 2019 co-location requirements – **Green/Amber** - ‘Meets most of the requirements and has good plans to meet the rest within max. 12 months’.
311. Paediatric cardiac services are not currently co-located with a full range of other paediatric specialist services. Leicester has now developed a detailed plan to achieve paediatric co-location with the key paediatric specialties at the Leicester Royal Infirmary site, and funding for this has been secured. The National Panel noted that the timetable within the plan expected completion of the work necessary in July 2019. A timetable for the transfer of services and patients is not given. Nonetheless the panel considered that, assuming there was no significant slippage in delivery, this was an acceptable plan.
312. April 2021 surgical activity requirements - **Amber/Red** – ‘Does not meet all the April 2021 surgical activity requirements and is unlikely to be able to do so’.
313. The panel noted that NICOR reported that surgical activity at University Hospitals of Leicester was:
- 299 for 2013/14
- 282 for 2014/15
- 323 for 2015/16
- 349⁵⁹ for 2016/17.
314. Currently the Trust does not have enough surgical activity to support a team of three surgeons each undertaking at least 125 operations per year. Leicester has submitted a plan to achieve the 2016 and 2021 surgical activity requirements. The Trust’s growth plan suggests that it will be able to reach the required volume of activity for three surgeons by 2019 and that it will have enough activity to be able to support a team of four surgeons each undertaking at least 125 operations a year from 2021.
315. The National Panel considered the growth plan to be optimistic. It was concerned that the plan did not give sufficient recognition to patient choice or the attraction of the Birmingham and London hospitals. The panel

⁵⁹ 2016/17 surgical activity data is unvalidated data based on analysis undertaken by NICOR and checked with Trust but not subject to full validation.

recognised that the continued uncertainty potentially made it difficult for Leicester to attract the best candidates and that, in turn, this could have a negative effect on its attractiveness to patients and referring clinicians. It was concerned that there was not enough in the plan to change referring clinician preferences. This was of particular concern to the panel because the scale of the shortfall is considerable.

316. Leicester is one of only two centres yet to reach 375 operations per year⁶⁰. The panel was concerned that in order to succeed, Leicester would need to move from a position where a high proportion of patients in its natural catchment at present receive their care elsewhere to a position where almost all these patients receive their care at Leicester.
317. It noted that NHS England had requested further assurances on the additional referrals identified within this plan, and considered this an appropriate way forward.

Consultation Response

318. The majority of survey respondents in the Midlands and East region strongly opposed the proposal that CHD services will only be commissioned from hospitals that are able to meet the full set of standards within set timeframes.
319. The main themes from Midlands and East respondents were:
- A desire to see the standards applied fairly and consistently.
 - A concern that the standards did not make sense clinically or for patients.
 - A view that, in the long term, UHL is set to 'meet the standards' in the future.
320. They supported Leicester in its relationships with the network of referring hospitals and wanted to see NHS England support growth plans and network referrals. They felt that all patients in that area should be given the choice of Leicester.
321. Respondents from the Midlands and East region raised concerns about the potential loss of ECMO services from UHL, which was seen by them as an international centre of excellence. The view was put forward that UHL's ECMO service should be regarded in the same light as Newcastle's transplant service and seen as a reason to continue commissioning CHD services from UHL, even if some standards are not met.

⁶⁰ The other being Newcastle.

322. There were concerns about where patients would receive this care in the future if it was not provided by UHL, and the new reconfiguration test introduced by Simon Stevens in April 2017 was cited⁶¹.

323. A standard response drawn up by supporters of the service at UHL (though submitted in this form by very few respondents) stated:

‘Crucial information needed to inform the consultation - The review into ECMO services is a crucial aspect of this consultation and it is inappropriate that the results of that review are not part of this consultation process...

...NHS England assumptions are that the current ECMO caseload for ECMO delivered by EMCHC can easily and safely be delivered dispersed across the remaining cardiac surgical centres, all of whom in theory can undertake ECMO as it may be required after cardiac surgery.

It is a huge assumption that the ECMO currently provided by EMCHC (over 50% of the UK requirements) will be able to be delivered by the units spread across the country. They are proposing to dilute ECMO practice whilst using concentration of cardiac surgical practice as a rationale for service reconfiguration...

...The assumption that there will be appropriately trained clinical and nursing staff available to deliver this specialist care across all of the units is severely challenged by the fact the majority of ECMO provided by EMCHC is provided for children with catastrophic respiratory and cardiac failure not related to cardiac surgery and in which other Level 1 centres have little or indeed no expertise. (This is currently evidenced by the fact the EMCHC ECMO team travel the country including to the current surgical centres to place patients in this situation on ECMO and bring them back to Glenfield for optimal expert care). Replicating this expertise will be as difficult as expecting all centres to deliver transplant surgery – the key rationale for the derogation being applied to Newcastle.’

324. Concerns were expressed about the potential impact of the proposals for change at Leicester on UHL’s fetal cardiology service. Respondents considered that the strength of the East Midlands network, built on long established relationships, could not be replicated working with paediatric cardiac services in the West Midlands.

325. NHS England asked whether consultees supported the commissioning of level 2 services in Leicester if University Hospitals of Leicester no longer

⁶¹ This requires local NHS organisations to show that significant hospital bed closures which are subject to the current four consultation tests can meet one of three new conditions before NHS England will approve them to go ahead. The most relevant of these is the requirement to demonstrate that sufficient alternative provision is being put in place alongside or ahead of bed closures, and that the new workforce will be there to deliver it.

provided level 1 services. Most respondents neither supported or opposed this proposal. The Trust itself does not support the proposal.

326. The Trust in its response to consultation told us that it agrees that the standards are appropriate; but disagrees with the proposed approach to applying the standards particularly in respect to timeframes. They express a view that ‘there should be equity across all providers in the way that they are supported to meet the standards and over what time period’.
327. In its response, the Trust refers to its updated growth plan and asks NHS England to accept the plan and support the Trust in developing its network.

Alternative Proposals

328. No alternative proposals were received. However, during consultation University Hospitals Leicester provided a more detailed exposition of its growth plan.
329. NHS England gave this growth plan detailed consideration. In correspondence with the Trust we stated that:
- While we had a different view about some of the underlying assumptions, we, broadly, agreed that the Trust’s natural catchment (that area for whose residents it is the closest level 1 CHD centre) should contain enough CHD patients to produce sufficient surgical activity to be able to appoint a fourth surgeon by no later than April 2021 to be part of a team of surgeons each undertaking at least 125 countable surgical procedures from that point onwards, as required by the standards.
 - We agreed that demographic growth would make only a very modest contribution to meeting the growth requirement.
 - We expressed our view that the future growth the Trust requires would therefore almost all need to be as a result of changing referral practices as it aimed to ensure that a much greater proportion of patients resident in your natural catchment area are referred to, and come under the care of, the CHD team at the Trust.
330. As a result NHS England asked the Trust to provide a higher level of assurance that this could be achieved. To achieve this we asked them to enter into dialogue with all of the acute Trusts within their natural catchment with the potential to refer significant numbers of CHD patients – both those that already refer some patients, and those that do not, at present, refer any patients to UHL. We asked that this dialogue involve referring clinicians and not just managers, and that they should be given an opportunity to explain why they have, to date, not referred the majority

of their patients to UHL, despite it being their local centre, and what would be needed to change their practice.

331. Arising from this dialogue we asked that UHL should seek statements of support which should:

- Be signed by the Medical Director and relevant Clinical Director as representing the views of referring clinicians;
- Confirm the proportion of CHD patients that the Trust would in future expect to refer (noting that there may be clinical reasons, or patient preferences that make an alternative centre the right choice for any particular patient);
- Clarify whether they intend to refer patients of all diagnoses to UHL or whether they would refer complex cases elsewhere.
- We asked that UHL should compile these intentions to show how they close the gap between the Trust's current level of activity and that required to meet the surgical activity standards.
- We indicated that if, as a result of this, we have a high level of confidence that UHL can meet the required surgical activity standards, within the required timescale, this would then present an opportunity for NHS England to move away from its 'minded to' decision, and the Board would give this due consideration.
- We stated that if the Board was sufficiently assured about these plans to take a decision to continue to commission level 1 CHD services from UHL, we would closely monitor delivery against this plan, and in the event that it became clear that the surgical activity standards were not going to be met, we would take commissioning action to terminate our contract with UHL for level 1 CHD services.

Developed Recommendations

332. We have assessed the impact of implementing the proposals on which we consulted and confirmed that they could be implemented and the impacts of doing so could be appropriately managed.

333. UHL has gained support from many of the surrounding hospitals for its work as a level 1 CHD centre, and confirming an expectation of some growth in referrals in future. We also know from the consultation that, assuming UHL is meeting the standards, people want to see them continue to provide a level 1 CHD service.

334. Taking these developments into account we think it is now reasonable to give the Trust the opportunity to prove that it can implement its plans to meet the standards. To succeed, it will need to change the choices made by referring doctors and their patients, so neither we nor the UHL leadership can be absolutely certain what will happen. We plan, therefore, to monitor UHL's progress against their plan closely, and should it

become clear that it is not going to be able to deliver its commitments and so meet the requirements, we will take the necessary action.

335. If UHL succeeds in attracting additional patients as planned, it will, of necessity, mean that activity levels at other hospitals will fall. Our analysis shows that the greatest impact is likely to be on Great Ormond Street and the Birmingham hospitals. The scale of the likely impact should not materially affect any other hospital's ability to meet the standards.
336. The recommendations expected to be put before the Board for consideration are:
- To confirm that the Board is content to continue to commission level 1 services from Leicester, conditional on the Trust achieving full compliance with the standards within the required timeframes, as described in its new plan to do so, and the Trust demonstrating convincing progress in line with the implementation milestones and key performance indicators (KPIs) set out in NHS England's implementation schedule.
 - Should this not be achieved, referral to the Specialised Services Commissioning Committee will be made to confirm that the process of decommissioning level 1 services should begin, with alternative arrangements put in place to ensure patients are able to benefit from receiving care from centres compliant with the required standards.

Implementing the Developed Recommendations

337. University Hospitals of Leicester NHS Trust will be required to achieve full compliance with the standards within the required timeframes, and specified milestones.
338. NHS England will monitor UHL's progress towards meeting the standards and take commissioning action if it becomes clear that the standards will not be met according to the agreed timescale and KPIs. These timescales and KPIs are informed by the Trust's own plans and the original timetable set out in the standards.
339. University Hospitals of Leicester NHS Trust will be required to achieve full compliance with the standards within the timeframes set out in the detailed implementation schedule (below). This includes achieving full co-location for all inpatient paediatric CHD care by April 2020 and increasing surgical activity so that it has a team of at least four surgeons, each undertaking at least 125 operations per year, from April 2021.

Milestone- no later than	Deliverable	Commissioner action if not delivered	
		Trust required to produce, and agree with NHS England, a recovery plan.	Referral to Specialised Services Commissioning Committee for decision whether to terminate the contract to provide level 1 CHD services.
April 2018	Surgical activity for the year 2017/18 at least 375 operations.	Surgical activity less than 356.	Surgical activity is less than 337.
	Surgeons undertaking at least 125 operations per year.	One or more surgeons undertook fewer than 125 operations in 2018/19.	Fewer than three surgeons in post; no appointment made for replacement(s).
April 2019	Surgical activity for the year 2018/19 at least 403 operations.	Surgical activity less than 382.	Surgical activity is less than 362.
	Three surgeons undertaking at least 125 operations per year.	One or more surgeons undertook fewer than 125 operations in 2018/19.	Fewer than three surgeons in post; no appointment made for replacement(s).
April 2020	Surgical activity for the year 2019/20 at least 435 operations.	Surgical activity less than 418.	Surgical activity is less than 402.
	Three surgeons undertaking at least 125 operations per year.	One or more surgeons undertook fewer than 125 operations in 2019/20.	Fewer than three surgeons in post; no appointment made for replacement(s). One or more surgeons undertook fewer than 125 operations a year averaged across 2018/19 or 2019/20.
	Full co-location achieved for all inpatient paediatric CHD care.		Full co-location not achieved for all inpatient paediatric CHD care.
April 2021	Surgical activity for the year 2020/21 at least 471 operations.	Surgical activity less than 453.	Surgical activity is less than 435.
	Three surgeons	One or more	Fewer than three surgeons in

	undertaking at least 125 operations per year.	surgeons undertook fewer than 125 operations in 2020/21.	post. One or more surgeons undertook fewer than 125 operations a year, on average across the years 2018/19, 2019/20 and 2020/21.
	Fourth surgeon appointed and in post.		No appointment made for fourth surgeon.
April 2022	Surgical activity for the year 2021/22 at least 500 operations.	Surgical activity less than 487.	Surgical activity is less than 475.
	Four surgeons undertaking at least 125 operations per year.	Fewer than four surgeons in post. One or more surgeons undertook fewer than 125 operations in 2021/22.	Fewer than three surgeons in post.

Impact of implementing the developed recommendations

340. If implemented, the recommendations would be different in impact to the proposals on which we consulted.
341. NHS England has therefore considered these impacts and, where they are potentially negative, how they could be managed.
342. Overall, in the short term, if Leicester continues to be commissioned to provide level 1 services whilst working towards its growth plan there would be no major change to its provision of CHD services. Uncertainty would be reduced because the decision provides a path to the long term survival of the service. However, the remaining uncertainty over the service may continue to impact on staff recruitment and retention.
343. However, the acceptance of Leicester's growth plan and the confirmation of a path to a long term future can be expected to enhance Leicester's reputation. This would be reinforced in the long term if Leicester achieves the activity indicated by its growth plan: the increased size of its service, its compliance with the standards and the long term security of the service would have a positive reputational impact on the Trust.

Impact on CHD services

344. CHD services would continue to function as they currently do at Leicester up until 2019, though there may be improvements in service levels if recruitment and retention are improved by the decision.
345. At this point the paediatric CHD service would relocate to Leicester Royal Infirmary (LRI) to comply with the co-location standards.

346. Prior to 2019 the necessary mitigations and emergency arrangements are in place to provide the necessary assurances for these services in the short term.

Impact on other interdependent services if L1 CHD services cease.

PICU

347. PICU and paediatric HDU facilities would continue to function as they currently do up until 2019. At this point it is expected that all PICU and paediatric HDU services will be centred at LRI and those at Glenfield will close.

ECMO

348. ECMO services would continue to function as they currently do up until 2019. At this point it is expected that paediatric ECMO services will be centred at LRI.
349. The provision of paediatric ECMO services may change nationally following the outcome of NHS England's review of paediatric critical care services and this could affect services at Leicester.

Financial impact

350. The relocation of Leicester's paediatric CHD service to the LRI will involve capital expenditure. However, this has been sourced from the Trust's ongoing budget for capital resources and charitable donations.
351. The growth in activity indicated by Leicester's growth plan would result in a significant increase in the income being received by Leicester for its CHD services and would be expected to lead to economies of scale and make full implementation of the standards more affordable.

Impact on staff

352. Uncertainty for staff will decrease, potentially positively affecting both existing staff and attractiveness to future staff (retention and recruitment) and staff morale.
353. However uncertainty would remain over the long term future of Leicester's level 1 CHD services which may continue to negatively impact staff.
354. It is difficult to predict the impact on recruitment and retention. The risk that Leicester will find it difficult to retain or recruit the necessary staff could potentially continue.

Impact on patients

355. In the short term, while CHD services at Leicester would be provided in the same way as now, uncertainty about future care arrangements could affect clinician-patient relationships and the choices patients make. Until 2019, paediatric patients will continue to receive their CHD care from a

hospital without the benefit of a holistic children's environment as required by the standards.

356. In the longer term, if the uncertainty impacts on the ability of Leicester to recruit and retain the appropriate staff, there is a risk that patients do not receive appropriate levels of care due to staff shortages. By 2021 the uncertainty should be fully resolved.

The proposal that surgery and interventional cardiology for children and adults should cease at Royal Brompton & Harefield NHS Foundation Trust.

The original proposal

357. For reasons mainly linked to co-location with other paediatric services, Level 1 CHD services including surgery and interventional cardiology for children and adults would cease at the Royal Brompton site. NHS England would work with Royal Brompton to safely transfer these services to appropriate alternative hospitals. Level 1 adult CHD services, including surgery could be retained at Royal Brompton. This would involve the hospital partnering with another Level 1 CHD hospital in London, that meets the required standards and that cares for children and young people.

Assessment against the standards

358. At the time of the original assessment, published in July 2016, the Royal Brompton was assessed as **Amber/Red** – ‘does not meet all the April 2016 requirements and is unlikely to be able to do so’.
359. The National Panel’s current assessment undertaken in August 2017 (including progress and future plans for any standards not yet met – including 2017, 2019 and 2021 standards) was as follows:
360. April 2016 / April 2017 requirements – **Green/Amber** – ‘Meets most of the requirements and has good plans to meet the rest within max. 12 months’.
361. Royal Brompton must ensure that all surgeons meet the minimum requirements of 125 operations per year. The panel was informed that this will be achieved when one of the surgeons retires at the end of 2017.
362. At the time of the current assessment, although the Trust has offered to take over all interventional CHD activity from Imperial College Healthcare (which was assessed as not meeting the level 2 standards), this change had not been formally accepted by Imperial. Assurances are therefore still required from the Royal Brompton that no CHD interventional activity is being undertaken at Imperial as one of the hospitals within their network.
363. April 2019 co-location requirements – **Amber/Red** - ‘Does not meet all the April 2019 co-location requirements and is unlikely to be able to do so.
364. Paediatric surgery and paediatric gastroenterology are not co-located on the same site as the Royal Brompton’s paediatric cardiac service.
365. The Trust has not presented firm plans for co-locating these services at its present site or by 2019. The panel noted that Royal Brompton’s clinicians were working with clinicians from Guys and St Thomas’s to develop joint protocols. The panel also noted that stronger multidisciplinary working had been demonstrated. However the National Panel also noted the Clinical

Advisory Panel's view that the current arrangements at the Royal Brompton were not viable and that a solution must be found that would ensure that children in future received their care from a holistic paediatric environment.

366. The Trust has presented an alternative proposal which would allow these standards to be met following relocation of the service. The panel considered that these plans are not yet sufficiently developed to provide an assurance that they could and would be delivered. Even if the plan was implemented as described, co-location would not be achieved until 2021/22.
367. April 2021 surgical activity requirements - **Green** - 'Meets all of the 2021 surgical activity requirements'.

Consultation response

368. The main themes from respondents in the London area were that:
- Patient outcomes should be the main focus
 - The Royal Brompton is well respected and meets all standards in partnership with Chelsea and Westminster
369. This linked to their perception that insisting on physical co-location of services would not improve outcomes for patients and should not be the decisive factor in closing a CHD unit.
370. Respondents considered that the Royal Brompton delivered an excellent service.
371. A number of respondents from the London region submitted a standardised response that stated that, if implemented, our proposals could potentially have an impact on children's respiratory care and research.
372. Concerns were expressed about the potential impact of the proposals for change at the Royal Brompton on the specialist cardiac obstetric service at Chelsea and Westminster Hospital. This was not reflected in the consultation response from Chelsea and Westminster Hospital though the Trust does say there will be an impact on its cardiac obstetric service, though it does note a risk that clinical support to CWFT services will be affected including MDT support to obstetrics and to the high risk pregnancy clinic.
373. Concerns were expressed about the potential impact of the proposals for change at the Royal Brompton on the Royal Brompton's fetal cardiology service which supports clinics at Queen Charlotte's Hospital, St Mary's, St George's and Chelsea and Westminster. This is said to be one of the largest such services in the country and the fear expressed is that it would be fragmented if RBH was no longer a level 1 CHD centre.

374. The Trust provided a detailed response outlining the impact they believed that NHS England's proposals would have on a range of other services at the Trust. The impact on research is also highlighted. Concern is expressed about whether sufficiently detailed planning has been undertaken on re-providing the care currently provided by the Royal Brompton. The Trust also states that it considers that it meets the paediatric co-location standards 'in partnership with Chelsea and Westminster Hospital which is closer than many same site co-located hospitals'.
375. NHS North West London Collaboration of Clinical Commissioning Groups said in their consultation response stated that they support the centralising of specialist services when it improves clinical outcomes and quality of care for our patients. However they express concerns about the evidence base for the proposals, management of the transition if the change is agreed, assurance about the decision making process and the assessment of the impact on the Royal Brompton, its finances and its other services. Given this they say they would need to be confident that in making its decision the NHS England Board has the full depth of evidence and assurance to support the proposed changes. They also state that while a 'quality outcome [is] more important than whether the service is located within NWL...we are supportive of NWL acute providers coming together to propose a design solution'.

Alternative proposals

376. A number of alternative proposals emerged during consultation.
377. The National Panel endorsed the Clinical Advisory Panel's view that any solution needed to be one for all paediatric services currently delivered by the Royal Brompton and not just paediatric cardiac. The solution must ensure that these children in future received their care from a holistic paediatric environment. The National Panel considered that this included meeting the co-location standards but was also about culture, environment and patient experience. While the National Panel considered the current arrangements to be safe in the short term, in the long term it could not support continued commissioning of paediatric cardiac services from the Royal Brompton site.
378. The panel also affirmed the view that while a vertically integrated model (integration of paediatric and adult care) is ideal, it is not as important as a horizontally integrated model (integration of specialist paediatric cardiac and respiratory services with the full range of paediatric specialties and services) and a holistic children's environment. It is easier to manage the absence of vertical integration.

Royal Brompton providing an adult only (level 1) service

379. In consultation NHS England noted that the Royal Brompton could meet the standards for providing surgical (level 1) services for adults by working in partnership with another hospital that provides surgical (level 1) services for children. This option has not been supported by The Royal Brompton.
380. We asked consultees to what extent they supported or opposed the proposal that the Royal Brompton provide an adult only (level 1) service as an alternative to decommissioning the adult services. Respondents from the London region disagreed with this proposal. Concerns were raised that this approach would lose best practice learning from co-location of paediatric and adult services and that it could potentially impact upon pregnant women.

Bringing together existing services from the Royal Brompton and Guys and St Thomas'

381. A joint consultation response was received from the Royal Brompton (RBH) and Kings Health Partners (KHP) that proposes a model for CHD services bringing together the existing services of RBH and Guy's and St Thomas' (part of KHP) to deliver a joint, world class, service for all CHD patients from ante-natal to adulthood including:
- delivery of CHD services for children (both those currently provided by GSTT and those from RBH) from new buildings of Evelina London. Services would move as soon as capacity is available, which should be by 2021/22 when further capital development at the Evelina London is completed.
 - the joint development of a newly created specialist heart and lung centre on the Westminster Bridge campus. Adult services would be expected to move to the new specialist heart and lung centre at the Westminster Bridge Campus by the mid to late 2020s as this is completed.
382. The timing of moves would be subject to planning considerations.
383. The Trusts expect that this model would allow all standards to be met once co-location is achieved, as well as delivering benefits to patients through improved equity of access to specialist care, world class outcomes in a sustainable model and a leading research and education offering for the next generation of staff and therapies.
384. Noting that the Royal Brompton had been involved in discussions about this issue stretching back over years with many proposals emerging but none coming to fruition, the National Panel nonetheless considered that this proposal was very attractive, and although at a very early stage of development they considered that it should be supported and rapidly

developed because the advantages of the proposed model, if it could be delivered, would be very significant. Amongst these advantages is that this solution also addresses the parallel challenge for paediatric respiratory services, and that it facilitates keeping together the Royal Brompton's clinical and research teams.

Transferring the Royal Brompton's Paediatric Services to Chelsea and Westminster

385. A consultation response was received from Chelsea and Westminster Hospital NHS Foundation Trust setting out proposals that would further develop the established integration between the two Trusts' services. It argues that this would be the most practical and deliverable option and would not incur the same level of risk as implementing NHS England's proposals. The response said this proposal would build on existing joint working and shared governance and would minimise disruption of existing clinical, service and education relationships. The proposal describes two options:
386. Option 1 would create a single children's service for NW London at Chelsea and Westminster. This is the Trust's preferred option. This would see the transfer of inpatient paediatric cardio-respiratory and PICU services from RBH to the CWFT site. The Trust would expect this model to meet the national standards.
387. Option 2 would see the creation of additional Paediatric HDU (level 2) capacity at Chelsea and Westminster with the transfer from the Royal Brompton of patients for whom this is a suitable level of care (including respiratory; surgical: ENT, cranio-facial, orthopaedics and others; 'Complex' surgical where underlying cardiac condition stable; and post-operative cardiac but ventilation required). This partial and more incremental approach does not appear to meet the national standards.
388. Few stakeholders were aware of any of these proposals as they emerged very late in the consultation period.
389. The Somerville Foundation, a charity that works with and on behalf of adults with congenital heart disease released a statement outlining its position on NHS England's proposals relating to the Royal Brompton, which states:
- '...The Brompton have also advised that it has plans to relocate the hospital onto the St Thomas' Hospital site that would enable it to comply with all the standards. We believe that 'derogation' (agreed delay to enable matters to be resolved) must be considered, as it has been for another unit...'
390. Imperial College Healthcare in its consultation response did not directly comment on the new proposals outlined above, but stated their view that

continuing to provide these services in north west London with closer collaboration between providers would benefit the people of north west London and the north west London health economy.

Developed Recommendations

391. Since the original assessment a number of elements of concern have been resolved. However, NHS England's assessment of the Royal Brompton's ability to meet the standards for level 1 CHD services in August 2017 remained at Amber/Red because it does not meet all the April 2019 co-location requirements and is unlikely to be able to do so: Paediatric surgery and paediatric gastroenterology are not co-located on the same site as the Royal Brompton's paediatric cardiac service and the Trust has not presented firm plans for co-locating these services at its present site or by 2019.
392. The Trust presented an alternative proposal which would allow these standards to be met following relocation of the service. The National Panel considered that these plans were not yet sufficiently developed to provide an assurance that they could and would be delivered and even if the plan was implemented as described, co-location would not be achieved until 2021/22. As a result, it did not consider it appropriate to change its assessment.
393. We have assessed the impact of implementing the proposals on which we consulted and confirmed that they could be implemented and the impacts of doing so could be appropriately managed.
394. The alternative proposal, provided as a joint consultation response from the Royal Brompton and Kings Health Partners, proposes a model for CHD services that brings together the existing services from RBH and Guy's and St. Thomas' to deliver a joint, world class, service for all CHD patients from ante-natal to adulthood that would allow all standards to be met once co-location is achieved:
- delivery of CHD services for children (both those currently provided by GSTT and those from RBH) from new buildings of Evelina London. Services would move as soon as capacity is available, which should be by 2021/22 when further capital development at the Evelina London is completed.
 - the joint development of a newly created specialist heart and lung centre on the Westminster Bridge campus. Adult services would be expected to move to the new specialist heart and lung centre at the Westminster Bridge Campus by the mid to late 2020s as this is completed.
395. The Clinical Advisory Panel considered that sustaining the current arrangements at the Royal Brompton was not appropriate, and that any

solution needed to be a solution for all paediatric services currently delivered by the Royal Brompton and not just paediatric cardiac. The solution must also ensure that these children in future received their care from a holistic paediatric environment.

396. Considering the proposal from the Royal Brompton and King's Health Partners, they considered that it would be appropriate to support such a development despite the long timescale if it ensured that children received their care in a holistic paediatric environment in future.
397. The National Panel did not support continued commissioning of paediatric cardiac services from the Royal Brompton site in the long term. Continued commissioning of the service in the short term was considered appropriate as it would give the opportunity to develop the proposal to a stage where it could be properly assessed. It considered that the advantages of the proposed model, if it could be delivered, would be very significant as it would provide a solution for all paediatric services currently delivered by the Royal Brompton and not just paediatric cardiac, ensuring that all of these children would in future receive their care in a holistic paediatric environment.
398. The recommendations expected to be put before the Board for consideration are:
- To confirm that NHS England should work with RBH and other potential partners on the full range of options for delivering a solution that could deliver full compliance with the standards and ensure the sustainability of other connected services. Progress should be reviewed by the NHS England Board over the next two years.
 - Should a credible solution not have been presented by the end of November 2019, in the form of a submitted Outline Business Case, supported by NHS England, referral to the Specialised Services Commissioning Committee will be made to confirm that the process of decommissioning level 1 services for children should begin, with alternative arrangements put in place to ensure patients are able to benefit from receiving care from centres compliant with the required standards.

Implementing the Developed Recommendations

399. NHS England will monitor RBH's progress towards meeting the standards, and take commissioning action, if it becomes clear that the standards will not be met according to the timescale set out in the implementation schedule below. These timescales are informed by the Trust's own plans and a realistic planning schedule. NHS England will expect the following:
- Strategic Outline Case prepared by the Trust, supported by NHS England and submitted for approval by 30 June 2018

- Outline Business Case prepared by the Trust, supported by NHS England and submitted for approval by 30 November 2019
- Full Business Case approved by 30 August 2021

400. RBH will be required to develop and deliver a credible solution for meeting the co-location requirements for its paediatric services. RBH should develop its plans (working with potential partners as appropriate) following Treasury guidance for preparing a Public Sector Business Case and using the five case model.

401. RBH will be required, as part of its planning process, to develop and deliver a detailed plan with clear milestones, that will achieve full co-location for all RBH paediatric specialist services by April 2022 at the latest.

Milestone- no later than	Deliverable	Commissioner action if not delivered	
		Trust required to produce, and agree with NHS England, a recovery plan.	Referral to Specialised Services Commissioning Committee for decision whether to terminate the contract to provide level 1 CHD services.
June 2018	Strategic Outline Case (SOC) prepared by the Trust, supported by NHS England, and submitted for approval.		SOC not submitted.
April 2019	Early priorities for joint working implemented.		
	Detailed plan to achieve full co-location for all inpatient paediatric specialist services.	Co-location plan not delivered.	Further slippage to delivery of co-location plan vs recovery plan.
November 2019	Outline Business Case (OBC) prepared by the Trust, supported by NHS England, and submitted for approval.		OBC not submitted.

August 2021	Full Business Case.		Approved FBC not delivered.
April 2022	Full co-location achieved for all inpatient paediatric specialist services.	Full co-location not achieved for all RBH paediatric specialist services.	Full co-location not achieved for all inpatient paediatric CHD care.

Impact of Implementing the Developed Recommendations

402. If implemented, the recommendations would be different in impact to the proposals on which we consulted.
403. NHS England has therefore considered these impacts and, where they are potentially negative, how they could be managed.
404. While the Royal Brompton develops plans for co-locating its paediatric CHD service, there would be no major change in the short term to its provision of CHD services. There would however be continued uncertainty for staff and patients. This could affect staff recruitment and retention.
405. In the longer term the co-location of CHD services with other paediatric services provides an opportunity for the Royal Brompton to continue to grow and develop its reputation through being a part of a service offering a much wider range of paediatric services.
406. The proposal holds out the prospect of improved clinical care and research opportunities across the whole range of the Royal Brompton's services.

Impact on CHD services

407. CHD services would continue to function as they currently do in the short term, but with the potential for greater collaboration between the Royal Brompton and St Thomas'.
408. Appropriate mitigations and emergency arrangements are in place to provide the necessary assurances for these services in the short term.

Impact on other interdependent services if L1 CHD services cease.

PICU and HDU

409. PICU and paediatric HDU facilities would continue to function as they currently do in the short term.

Specialist respiratory services

410. Specialist respiratory services would continue to function as they currently do in the short term.
411. Any plans developed to co-locate CHD services would need to consider the impact on PICU, paediatric HDU and paediatric respiratory services currently offered by the Royal Brompton.

Financial Impact

412. The co-location of paediatric services would involve significant capital expense. The current proposals suggest an initial estimate of capital cost in the region of £800m. There is an expectation that this could be partly offset from receipts from the sale of the Royal Brompton site. This would be subject to the necessary planning agreements and agreement that these funds would flow to the Trust. There would also be issues of phasing to be managed as capital outlays could be required before the receipts of sales were available. These issues would need detailed development as part of a business case if the Board approves further development of the proposal by the Trust.
413. Prior to any relocation there is a risk of either a lack of investment in the current estate or the requirement for ongoing investment in an estate which will not be used in the long term, with the potential for financial waste or inefficiencies in the short term.

Impact on Staff

414. Uncertainty for staff will increase across the whole organisation, potentially negatively affecting both existing staff and attractiveness to future staff (retention and recruitment) and staff morale.
415. It is difficult to predict the impact on recruitment and retention. There is a risk that Royal Brompton will find it more difficult to retain or recruit the necessary staff in the short term until a definitive decision can be taken.

Impact on Patients

416. In the short term, while clinical services at the Royal Brompton would be provided in the same way as now, uncertainty about future care arrangements could affect clinician-patient relationships and the choices patients make. Paediatric patients (CHD and respiratory) will continue to receive their CHD care from a hospital without the benefit of a holistic children's environment as required by the standards.
417. In the longer term, if services move to a different location this will affect patients. The uncertainty over the long term future of the Royal Brompton's paediatric services will continue to affect patients until a definitive decision can be made.

The proposal that surgery and interventional cardiology for children and adults should continue at Newcastle Hospitals NHS Foundation Trust (children's and adult services)

The Original Proposal

418. Although Newcastle does not meet the required standards now and is unlikely to be able to do so within the required timeframe, we proposed that surgery and interventional cardiology for adults and children would continue under time-limited derogation. This recognises Newcastle's unique role in delivering care for CHD patients with advanced heart failure including heart transplant and bridge to transplant, and that this could not be replaced in the short term without a negative effect on patients. These arrangements will be time limited and subject to further review by 2021. We will also assess the potential for moving the advanced heart failure programme to another provider.

Assessment Against the Standards

419. At the time of the original assessment, published in July 2016, Newcastle Hospitals was assessed as Amber/Red – 'Does not meet all the April 2016 requirements and is unlikely to be able to do so.'
420. The National Panel's current assessment undertaken in August 2017 (including progress and future plans for any standards not yet met – including 2019 and 2021 standards) was as follows:
421. April 2016 / April 2017 requirements: the panel assessed Newcastle as **Amber** - 'Should be able to meet the requirements with further development of their plan'.
422. Newcastle upon Tyne Hospitals must ensure that their consultant interventional cardiology cover is provided solely by consultant interventional paediatric cardiologists.
423. April 2019 co-location requirements: the panel assessed Newcastle as **Amber** – 'Should be able to meet the April 2019 co-location requirements with further development of their plans'.
424. Paediatric cardiac services are not currently co-located with a full range of other paediatric specialist services. The Trust had carried out a scoping exercise to generate options for achieving co-location. As a result the Trust Board recommended that the best service would be achieved by moving both paediatric and adult services to one site at the Royal Victoria Infirmary. The Trust was, however, concerned about the associated capital costs. While it was committed to achieving the requirement in principle, it considered it inappropriate to proceed without an assurance over the long term status of their CHD service, in light of its inability to meet the surgical activity requirement. If these plans to achieve co-

location were to be implemented, the Trust expects that they would take time to complete, potentially beyond 2021.

425. April 2021 surgical activity requirements: the panel assessed Newcastle as **Amber/Red** – ‘Does not meet all the April 2021 surgical activity requirements and is unlikely to be able to do so’.
426. The panel noted that NICOR reported that surgical activity at Newcastle was:
- 391 for 2013/14
- 367 for 2014/15
- 324 for 2015/16
- 345 for 2016/17⁶²
427. The National Panel noted that the Trust does not have enough surgical activity to support a team of three surgeons each undertaking at least 125 operations per year, and therefore does not meet the current requirement, which is in effect until March 2021.
428. While the Trust has said that it is confident it will reach the minimum 375 operations required to meet the current requirement, it does not consider it likely that it will have enough activity to be able to support a team of four surgeons each undertaking at least 125 operations a year from April 2021. The panel therefore considered it unlikely that this standard would be met.

Consultation Response

429. The main themes from respondents in the North East region were that:
- Newcastle has cutting edge facilities and should be kept
 - Standards should set out sensible guidelines and make patient sense
 - Standards are a good idea
430. While the majority of respondents, nationally, opposed the proposal to continue level 1 services at Newcastle, whilst working with them to deliver standards within a different timeframe, the great majority of respondents from the North East support the proposal.
431. Most of the responses which opposed this proposal were from the East or Midlands regions (87% of the responses which strongly oppose the proposal). This is in line with the concern expressed that Newcastle is perceived to be receiving ‘special treatment’ and that all standards/timeframes should be applied consistently.

⁶² 2016/17 surgical activity data is unvalidated data based on analysis undertaken by NICOR and checked with the Trust but not subject to full validation.

- 432. There was stronger clinical support that Newcastle should continue to be commissioned as it provides the full range of paediatric cardiology services and is a transplant centre, and work to a different timeframe for meeting the standards.
- 433. A number of respondents wrote in recognition of the specialist transplant services provided by Newcastle.
- 434. One respondent stated that decisions about the future of cardiothoracic transplant and respiratory ECMO should be contingent on the final proposals for congenital heart services.
- 435. A quarter of responses to the question asking for any other comments expressed the view that NHS England's minded decision is biased towards some hospitals / vested interest / Newcastle.
- 436. At consultation meetings some attendees expressed the view that Newcastle does not / will not meet the standards even given more time. This theme was also seen in written responses which were concerned that this was evidence of special treatment.
- 437. Some written responses recognised that Newcastle provides specialist transplant services.
- 438. One respondent stated that decisions about the future of cardiothoracic transplant and respiratory ECMO should be contingent on the final proposals for congenital heart services.
- 439. In its consultation response the Trust welcomes the standards but said that it strongly opposed the principle that services would in future only be commissioned from hospitals able to meet the standards because it would not be able to achieve co-location of paediatric services, or the required surgical activity level within the set timeframe.
- 440. The Trust emphasises the importance of drawing to a conclusion the work of re-organising cardiac surgical services 'so that units can be supported in planning and recruiting to the key specialist posts required to build teams with the necessary skills, age and experience profile which can deliver the breadth and complexity of care needed for the congenital heart population'.
- 441. The Trust expresses a concern that mortality rates are still used as a surrogate for this. It states that, in practice, certain units, including Newcastle, take on higher risk cases.

Alternative Proposals

- 442. No alternative proposals emerged during consultation.
- 443. However, Newcastle has provided a more detailed appraisal of options for achieving the paediatric co-location requirements. Five potential relocation

options were considered by the Trust. Their view is that re-locating all paediatric and adult services, while more costly, preserves the advantages of clinical symbiosis between these services and reduces inefficiencies in deploying specialist clinical staff who support both children and adults. This achieves the wider goal of co-location with fetal, neonatal and adult cardiac services so that seamless care from fetal to old age can become a reality for current and future patients.

444. Newcastle's preferred option, a new build adjacent to the Great North Children's Hospital, would therefore be the initial phase of a two-stage plan to move all cardiothoracic services. The capital cost of the new build and fit-out for paediatric cardiac services has been estimated at £40M. The Trust therefore consider that further development of this proposal should be dependent on confirmation of the longevity of service provision in Newcastle by NHS England.

Developed Recommendations

445. Since the original assessment Newcastle has completed a more detailed option appraisal on how to achieve paediatric co-location with the key paediatric specialties at the Great North Children's Hospital site. Funding has not been identified. NHS England agrees with the Trust that it would be inappropriate, given the cost of the scheme, to proceed before the long term future of the service is clear.
446. NHS England's assessment of Newcastle's ability to meet the standards for level 1 CHD services in August 2017 remained at Amber/Red because it does not meet all the April 2021 surgical activity requirements and was considered unlikely to be able to do so. The Trust has indicated that it does not consider it likely that it will be able to meet this requirement.
447. We have assessed the impact of implementing the proposals on which we consulted and confirmed that they could be implemented and the impacts of doing so could be appropriately managed.
448. The developed recommendations expected to be put before the Board for consideration are:
- To confirm that the commissioning of level 1 CHD services at Newcastle Hospitals NHS Foundation Trust should continue until at least March 2021.
 - Recognising the importance of the quality and sustainability of both the CHD service and the interdependent advanced heart failure and transplant service, to agree that further consideration should be given to the future commissioning of both. This will inform our commissioning approach from 2021 to ensure services meet the required standards. Until the outcome of this work is known, derogation against the 2019 co-location standard should be assumed.

Implementing the Developed Recommendations

449. NHS England will further consider its commissioning approach for both the CHD and the transplant service at Newcastle Hospitals from April 2021 onwards. It will confirm its plans by no later than April 2019.
450. NHS England will monitor Newcastle Hospitals' progress towards meeting the standards, and take commissioning action, if it becomes clear that the standards will not be met according to the timescale set out in the implementation schedule, and subject to the relevant derogations. These timescales are informed by the Trust's own plans and the original timetable set out in the standards.
451. Newcastle Hospitals will be required to develop and deliver a plan to increase surgical activity so that it has a team of at least three surgeons, each undertaking at least 125 operations per year from 2019/20, in line with the detailed implementation schedule which can be found below.
452. Newcastle Hospitals will not be required to meet the 2019 deadline for full co-location for paediatric cardiac services, but will be required to meet these standards if NHS England confirms a plan to commission level 1 CHD services beyond March 2021.

Milestone- no later than	Deliverable	Commissioner action if not delivered	
		Trust required to produce, and agree with NHS England, a recovery plan.	Referral to Specialised Services Commissioning Committee for decision whether to terminate the contract to provide level 1 CHD services.
February 2018	Growth plan to increase surgical activity to at least 375 operations a year by 2019/20.	Plan not delivered.	Further slippage to delivery of plan vs recovery plan.
April 2019	NHS England to produce a commissioning plan for CHD services including advanced heart failure and heart transplant for children and adults with CHD.	n/a	n/a
April 2020	Surgical activity for	Surgical activity less	Surgical activity is

	the year 2019/20 at least 375 operations.	than 365.	less than 356.
	Three surgeons undertaking at least 125 operations per year.	One or more surgeons undertook fewer than 125 operations in 2019/20.	Fewer than three surgeons in post.
To be confirmed if long term commissioning of level 1 CHD confirmed.	Full co-location achieved for paediatric cardiac services.		Full co-location not achieved for all inpatient paediatric CHD care.

Impact of implementing the developed recommendations

453. The recommendation is, essentially, to implement the proposal on which we consulted.
454. Therefore the impact assessment for the proposals on which we consulted remains valid and confirms that these impacts could be appropriately managed. Full details of this assessment are reported in **Annex 3**.

PART FIVE: IMPLEMENTATION TO ENSURE THE STANDARDS ARE MET

Implementation

Planning and delivery

455. We have continued our dialogue with all Trusts including those hospitals which we expect would need to provide care for more patients if the original proposals were implemented. They have looked at what they would need to do to increase the number of patients they care for and have assured us that they understand what is required and would be able to do what is needed to manage extra patients.
456. If a decision to move services is made, work would begin to turn those 'agreements in principle' into firm plans. Clinicians at all the affected centres will be involved in developing plans for how the service would work in the future. We can already see this happening in the north west where staff from the hospitals in Manchester and Liverpool are working together to plan how services would work if the proposals are implemented.
457. Whatever the Board's decisions, they will involve a series of linked changes in several parts of the country. This will require a nationally co-ordinated, consistent approach recognising that the changes are in response to a national service specification. Successful delivery is expected to be supported by NHS England both nationally and regionally.
458. Regional teams will continue to manage NHS England's relationships with the affected hospitals. This will include working closely with providers to support the development of:
- Locally appropriate care model including consideration of the role of level 2 care.
 - Capacity planning and development.
 - Transition planning.
 - Implementation of 'staff affected by change' policies across affected organisations including action to minimise redundancies.
 - Workforce planning and development.
 - Staff communication plans.
 - Patient communication plans.
 - Local media management.
459. Patients and their families have told us that changes to where their care is provided and to the staff providing their care can be unsettling, so we will ask the hospitals involved to look carefully at how this process is

managed if our proposals are implemented. We think the pattern set out in the standards for transition from children's to adult services may be helpful as this offers an opportunity to visit the new centre and meet the new staff in advance of the change happening. We will also ask them to maximise continuity in care so that as much as possible can remain familiar. We will ask for special attention to be paid to people with learning disabilities and their families because we know that change can be particularly difficult for this group.

460. We do not expect that changes of location in individual patient treatment will happen before spring 2018. We will ensure that there is no change to where care is provided until the new arrangements - the staff, estates and equipment – are in place and ready to provide that care. Detailed timelines are given in each of the recommendations that we expect to put before the Board.
461. We will reassure patients and their families that there will be no interruption in their care or reduction in the quality of their care if our proposals are implemented. Any changes will not happen overnight and we will ensure that patients and their families are kept informed throughout.

Managing the risks of change

462. From the beginning of NHS England's work a clear risk has been that continued uncertainty might compromise the safety, quality, resilience and viability of services until the future configuration of the service is established. Our work is motivated by the need to bring certainty to this specialty by completing the implementation of whatever recommendations were produced. Having agreed service standards therefore we now need to ensure that they are delivered. Once this has been done the specialty – hospitals providing services, clinicians delivering those services and patients using them – will have a new certainty about the future.
463. The way in which the system has coped with previous challenges provides assurance that the service is able to cope with such changes.
- In 2010 Oxford ceased to provide surgery during the Safe and Sustainable period and care of these patients was rapidly transferred to other centres, principally Southampton, without adverse consequences for patients.
 - In 2014 surgery was temporarily suspended at Leeds while an investigation was undertaken. This was an unplanned event. Centres from across the country provided support and patients needing urgent surgery were transferred to other centres for their operations.

- In 2015/16 there were restrictions on CHD admissions at Great Ormond Street and Newcastle due to a high number of patients on extra-corporeal life support which meant PICU beds were not available for surgical patients. Centres from across the country participated in regular frequent calls to manage this challenge and ensure that urgent surgical patients could be admitted at one of the other centres.

Using the standards to ensure services improve for patients

464. NHS England does not consider there to be a 'right number' of CHD surgery centres, nor that a certain number of centres must close. Rather, than reconfiguration, our aim is to ensure that every centre that offers CHD services meets the standards and, in doing so, provides the highest quality of care to patients on a sustainable basis. By setting standards that make clear what is required for an excellent service we have already seen improvements. For example, when NHS England completed its initial assessments, only seven centres had full out of hours cover for adults undergoing cardiology interventions (1 in 3 rota, specialist adult CHD interventionists); now all centres providing this service have full cover. Similarly, all now have full specialist adult cardiologist out of hours cover (1 in 4 rota). In addition, every centre now has consultant-led ward rounds seven days a week. These are important improvements that make a difference to the quality of care for patients. We have also seen increases in the number of specialist nurses and steady improvements in antenatal diagnosis of CHD; with targeted action becoming possible we expect to see more improvements.
465. The standards do not permit occasional and isolated practice (small volumes of surgery and interventional cardiology being undertaken in institutions that do not offer sufficient specialist expertise in this field). This has been of particular concern to patients and their representatives. We have worked with the hospitals involved and we are well on the way to completely eliminating occasional practice.
466. We are clear that all of the standards are important in ensuring excellent patient care and we are committed to ensuring that the NHS in England continues to work to see them all implemented in practice. A lot of the work we have done so far has concentrated on the challenge of meeting those standards that could not be met at every hospital working as they were. However, most of the standards are not of this type, and they can be met at every hospital with the right focus, attention and in some cases some extra investment. We are therefore putting in place a range of mechanisms to support the full implementation of all the standards.

Better information

467. Surviving surgery (or a cardiology intervention) is clearly vital for patients, but that is not the whole story when considering how good services are or

the quality of life they achieve for patients and their families. Unfortunately, to date, few other reliable measures have been available. To address that shortfall we have:

- Developed a measure of patients' experience of their own care.
- Worked with the relevant Clinical Reference Groups to introduce a dashboard that makes available a much wider range of measures of the quality of care than has ever been available before.
- Worked with the National CHD Audit to encourage reporting on a wider range of procedures and with a wider range of measures.
- Developed a research proposal to investigate longer term outcomes by diagnosis, which will now be commissioned by the Department of Health. This uses linked data from the national CHD audit and paediatric intensive care network databases, and other sources.

Networks

468. While most level 1 CHD surgical centres already have informal networks – the extent to which these networks have been developed varies. The standards place great emphasis on networks, and we believe they have a vital role to play in ensuring standards are met across the board. We will support the development of more formal operational delivery networks, including providing initial, pump-priming funding.

Peer review

469. The standards propose a system of inter-unit peer review where each centre will be required to provide evidence to show that it meets the standards. The emphasis is on improvement and learning from other centres. NHS England's Specialised Commissioning Quality Surveillance Team (QST) will support the development and delivery of a rolling peer review programme that will cover all of the standards at all hospitals.

PART SIX: CONCLUSIONS

470. Following the advice of patients and clinicians NHS England has developed standards for paediatric cardiac and adult congenital heart disease services.
471. It has consulted on proposals that aim to ensure that every patient should be confident that their care is being provided by a hospital that is able to meet the standards. To achieve this, we have proposed that in future we would only commission CHD services from hospitals that are able to meet the standards within required timeframes.
472. The recommendations that the Board is now expected to consider modify NHS England's original proposals, taking into account the views expressed in consultation, and the new proposals that have emerged.
473. The recommendations in this paper, if agreed, will further support us in moving towards full national compliance with the standards through:
- Commissioning Liverpool Heart and Chest Hospital NHS Foundation Trust to provide level 1 adult CHD services in the North West, with Manchester University Hospitals NHS Foundation Trust providing the full range of level 2 adult CHD services as an integral part of a North-West CHD Network;
 - Continuing to commission University Hospitals of Leicester NHS Trust to provide level 1 CHD services, conditional on achieving full compliance with the standards in line with their own plan to do so and demonstrating convincing progress along the way;
 - Backing the Royal Brompton and Harefield NHS Foundation Trust's ambitious new outline proposal for achieving full compliance with the standards and continuing to commission level 1 services from them in the meantime, conditional on demonstrating convincing progress along the way;
 - Continuing to commission Newcastle Hospitals NHS Foundation Trust to provide level 1 CHD services until at least March 2021, with further consideration to be given, by NHS England, to the future commissioning of both the Trust's advanced heart failure and transplant service and its level 1 CHD service;
 - Ceasing to commission level 2 CHD services, including cardiology interventions in adults with CHD, from Blackpool Teaching Hospitals NHS Foundation Trust, Imperial College Healthcare NHS Trust,

Nottingham University Hospitals NHS Trust, and University Hospital of South Manchester NHS Foundation Trust⁶³.

⁶³ University Hospital of South Manchester has now merged with Central Manchester University Hospitals to form Manchester University Foundation Trust. Under the recommendations the newly merged Trust would provide level 2 services from its Royal Manchester Infirmary site.

APPENDIX 1: BEST PRACTICE ASSURANCE

THE FIVE TESTS

1. This section sets out the evidence to demonstrate that NHS England has met the requirements of the Secretary of State's Four Tests (and the fifth test set by the Chief Executive of NHS England).

Test 1: A clear clinical evidence base

2. The evidence for the original proposals to implement the standards is essentially the same as the evidence for the standards themselves. That evidence is summarised here, having been refreshed prior to the launch of consultation.
3. The clinical evidence relating to service organisation in CHD was summarised for the NHS England Board⁶⁴ to inform its decisions in July 2015. This included a formal literature review commissioned from SchARR⁶⁵ and an examination of associations between a variety of factors and outcomes commissioned from NICOR.
4. Overall the Board heard that there is a body of evidence to support the challenging standards, some of it from academic studies, some inferential, some based on expert advice. The nature of the evidence is such however that it does not give precise answers to questions about the organisation of the service, or show what size is too small or what size is big enough, and neither can this data be extrapolated to show what improvements in outcomes might be expected. As a result it cannot tell us whether the benefits gained would outweigh the risks of change.
5. To avoid one of the pitfalls of Safe and Sustainable we have been very open about the limitations of the evidence base, and where we have therefore had to rely on judgement, and what the basis for that judgement is. We have published the minutes of every substantive discussion, bringing the debate into our various engagement groups. As a result, the vast majority of the proposed standards are uncontroversial and widely endorsed. But we readily concede that those standards where there has been most contention have been developed by listening to expert advice

⁶⁴ The 'Evidence base for the new standards & specifications' was included as Appendix 7 of the CHD paper considered by the NHS England Board at its meeting on 23 July 2015 and is available here: <https://www.england.nhs.uk/wp-content/uploads/2015/07/Item-4-CHD-Report.pdf>

⁶⁵ The report of SchARR's review (What evidence is there for a relationship between organisational features and patient outcomes in congenital heart disease services? A rapid review, Turner J, Preston L, Booth A, et al, University of Sheffield, 2014) was made available as part of the Reference Pack for the consultation on CHD standards available here: https://www.engage.england.nhs.uk/consultation/congenital-heart-disease-standards/user_uploads/reference-pack.pdf The research reported in this web report was commissioned and funded by the HS&DR programme as part of a series of evidence syntheses under project number 13/05/12.

and argument, not by proving that there is sufficient weight of evidence from research.

6. Additional evidence is provided in this paper to support the view that the proposed changes can be delivered without untoward effects on patient care based on the experience of ceasing to provide level 1 surgical services in Oxford.

Review of published evidence

7. We commissioned a review of the international literature⁶⁶ conducted by SchHARR at Sheffield University. Their report focussed on two questions:
 - What is the current evidence for the relationship between institutional and surgeon volume and patient outcomes and how is that relationship influenced by complexity of procedure and by patient case mix?
 - How are patient outcomes influenced by proximity to/co-location with other specialist clinical services (e.g. co-location of services such as specialist cardiac paediatric intensive care)?
8. The SchHARR literature review⁶⁷ identified a substantial number of studies reporting a positive relationship between volume and outcome and concluded that while the evidence demonstrates a relationship between volume and outcome in the majority of studies, this relationship is not consistent. The relationship is stronger for single complex conditions or procedures. It remains unclear whether the impact of volume on outcome is largely a consequence of higher volume units organising and providing a complex service with all the “right” components, or whether it remains an independent factor directly related to the advantages of dealing with a larger number of cases⁶⁸. The lack of any UK studies to contribute to the review indicates a serious gap in evidence relevant to service provision in the NHS.
9. Two additional publications^{69,70} on volume and outcomes (that were not included in the SchHARR review because they had not been published at

⁶⁶ Turner J, Preston L, Booth A et al, What evidence is there for a relationship between organisational features and patient outcomes in congenital heart disease services? A rapid review, School for Health and Related Research (SchHARR), University of Sheffield, 2014 available here:

<https://www.ncbi.nlm.nih.gov/pubmed/25642567>

⁶⁷ Ibid

⁶⁸ The evidence is equivocal – some studies found lower complication rates in high volume centres; others found no association between volume and complication rates. Two studies found low volume centres were associated with longer length of stay. Two studies also assessed costs and both found a relationship of higher costs associated with low volume centres.

⁶⁹ Kansey A , Ebels T, Schreiber C et al Association of Center Volume With Outcomes: Analysis of Verified Data of European Association for Cardio-Thoracic Surgery Congenital Database. *Ann Thorac Surg* 2014;98:2159–64

⁷⁰ Karamlou T et al. Surgeon and Center Volume Influence on Outcomes After Arterial Switch Operation: Analysis of the STS Congenital Heart Surgery Database. *Ann Thorac Surg* 2014;98:904–11.

the time it was written) have been reviewed by CAP. It concluded that they confirm that generally, greater volumes are associated with better outcomes. They do not, conflict with the findings of the SchAAR review; nor should they lead to changes in the volumes contained within the current set of standards. The study by Kansey et al was however notable in that it was based on European rather than American data.

10. The SchAAR review confirmed the findings of an earlier literature review⁷¹ carried out for Safe and Sustainable which found that the literature confirmed the association of volume with in-hospital mortality, but that precise recommendations on volume thresholds were difficult. This review also found that the relationship was stronger with increasing complexity.
11. While the data linking larger units with better outcomes is widely accepted, it is not clear over what range this relationship holds. Most of the published evidence comes from the US where units operate across a much wider size range. As a result of the banding of centres into small, medium and large, units bigger than 350 operations per year are classified as large. This means that while studies show better outcomes at larger centres, it is not possible from the published evidence to determine whether even bigger centres would be better still. Much of the published evidence considers only paediatric volumes, and it is also unclear how these numbers should be applied to services that deliver both paediatric and adult services. Our smallest units are currently undertaking around 300 operations annually (240 paediatric operations)⁷².
12. In the context of the NHS in England, while published evidence gives support to the view that units should undertake at least 350 paediatric operations per year, interpretation of this is complicated by analysis of UK outcomes which showed no significant association between annual centre volume and 30-day survival outcome⁷³. This complexity was recognised in our consultation document on the standards themselves⁷⁴ where we stated that “the evidence did not tell us the best size for a specialist surgical centre. As a result our Clinical Advisory Panel told us that ... the evidence was broadly supportive of the relationship between volumes and outcomes, but did not provide a compelling argument for change.”

⁷¹ Ewart E, The relationship between volume and outcome in paediatric cardiac surgery, PHRU Oxford, 2009

⁷² Sources: National Congenital Heart Disease Audit, NICOR data for 2013-14; NHS England analysis.

⁷³ Using data from 13 paediatric surgery centres, NICOR’s analysis of 12,186 episodes of care in paediatric heart surgery from April 2009 to March 2012 inclusive showed no significant univariate association between annual centre volume and 30-day survival outcome.

⁷⁴ Proposed congenital heart disease standards and service specifications: a consultation, NHS England, 2014 available here: https://www.engage.england.nhs.uk/consultation/congenital-heart-disease-standards/user_uploads/chd-consultation-doc-fin.pdf

13. The evidence from published literature can guide our thinking on the scale of services. But the arguments for size of surgical teams, individual surgeon caseload and our approach to subspecialisation are inferred, and relate to the resilience and reliability of systems rather than to outcomes.
14. Prior to consultation, a further review of the literature was undertaken to consider whether any new evidence has emerged since the Board's decision that should influence our proposals.
15. Two new studies, not previously considered, were identified. The studies reviewed appear to demonstrate an inverse association between volume and mortality after adjusting for patient risk factors and surgical case mix with the lowest surgical volume programmes showing significantly increased morbidity and mortality. One study retrieved also looked at hospitalization costs and concluded costs were lowest for the large volume providers.
16. Recent publications are generally indicative of a relationship between volume and outcomes. This is consistent with the findings of the SchARR report and the evidence review presented to the Board in July 2015. These additional studies did not cause us to consider that our original proposals should be changed.

Evidence from the national CHD audit

17. We have good data on post-operative mortality internationally and on 30 day mortality in this country from the National Congenital Heart Disease Audit run on behalf of NHS England by the National Institute for Cardiovascular Outcomes Research (NICOR).
18. However the best data relates only to children's services, and we have little information about longer term outcomes, morbidity or patient experience. Some believe that it is the lack of broader measures that hinders us in being able to show the benefits of larger scale services, arguing that 30 day mortality is a relatively insensitive indicator of good care. Without the data we cannot know the truth of this argument, but one of NHS England's objectives has been to develop proposals for a wider range of relevant timely metrics other than just 30 day mortality, to inform commissioners and support patient choice.
19. NICOR was asked to examine its data and to advise what this showed about service factors that could influence outcomes. Its analysis of UK outcomes showed no significant association between annual centre volume and 30-day survival outcome⁷⁵. It is unclear whether the sample

⁷⁵ Using data from 13 paediatric surgery centres, NICOR's analysis of 12,186 episodes of care in paediatric heart surgery from April 2009 to March 2012 inclusive showed no significant univariate association between annual centre volume and 30-day survival outcome.

size available is sufficiently powered to demonstrate such a difference even if it exists.

20. Although not yet in routine use, NICOR has, for the purposes of research projects, developed linkages with data on CHD patients while in a Paediatric Intensive Care Unit (PICU) using the Paediatric Intensive Care Audit Network (PICANET) database. This may in future become a routine feature of the national audit and help provide a richer picture of outcomes. NHS England does not at present have access to sufficiently granular PICANET data to conduct its own analysis of its usefulness in addressing service organisation factors.

Clinical expert advice

21. Many aspects of the standards could not be informed directly by published evidence because such evidence was not available. In these cases the review relied on the expert opinion of clinicians and service users. This approach was endorsed by Professor Sir Michael Rawlins, Chair of the Clinical Advisory Panel who said:

“In my experience, the amount of quantitative scientific evidence available to guide us in deciding how best to organise health services is often much less than we would like. In these circumstances we rely heavily on the views of experts, both specialist clinicians and those who are expert because of their experience of using the services in question. The views of experts, while qualitative rather than quantitative, are also valid and an important source of evidence in our deliberations.”

22. A particular and important example is the number of operations each surgeon should undertake each year. While two studies were reported by SchARR as suggesting a relationship between individual surgeon volumes and outcomes, these did not provide actual numbers for inclusion in the standards. The requirement in the proposed standards for a minimum of 125 operations per surgeon was based on the advice of the Society for Cardiothoracic Surgery, supported by the community of congenital cardiac surgeons themselves, and by the Royal College of Surgeons.
23. While not providing high quality independent evidence it was noted that similar numbers had been recommended by earlier reviews including the European Association for Cardio-Thoracic Surgery report⁷⁶ which recommended that each surgeon should perform 126 cardiac surgical procedures on adults or children and the Safe and Sustainable review⁷⁷

⁷⁶ Optimal Structure of a Congenital Heart Surgery Unit in Europe, Congenital Heart Surgery Committee on behalf of the European Association for Cardio-Thoracic Surgery, 2003

⁷⁷ Safe and Sustainable: A new vision for children’s congenital heart services in England, NHS Specialised Services, 2011 available here:

which recommended a minimum of 100 and ideally 125 paediatric operations per surgeon.

24. Surgeons were consistent in saying that they considered that individual case numbers were the single most important statistic to apply in terms of 'numbers', and there was very little argument against 125 being a helpful and achievable minimum standard.as each consultant surgeon could reasonably be expected to undertake at least 150 cases each year⁷⁸.
25. This illustrates the way in which expert clinical opinion influenced and shaped the standards. Expert advice was similarly influential in setting our requirements for surgical team size and for service interdependencies. The evidence and advice that contributed to these standards is described in detail in the 2015 Board paper.
26. Formally the review drew its clinical advice from four principal sources:
27. **The Standards Group** drew together congenital cardiac surgeons and cardiologists from all the level 1 centres in England (except Bristol which did not nominate a representative) together with representatives from Scotland and Wales, specialist nurse and psychologist representation and patient and public representatives. The Standards Group undertook the initial work of developing the standards, taking the paediatric standards developed for Safe and Sustainable and those previously developed for adult CHD services as a starting point.
28. **The Congenital Heart Services Clinical Reference Group** reviewed and commented on the standards before consultation and worked with the Standards Group after consultation to agree amendments to the standards in the light of comments received. The CRG set the timetable for achieving the standards and also drew up the service specifications.
29. **The Clinician Engagement Group** specifically established for the review to give broader engagement and chaired by Professor Deirdre Kelly, Birmingham Children's Hospital. This group included clinicians from every provider trust in England identified as providing any congenital heart surgery or cardiology intervention or with a specialist congenital cardiology centre, together with those from Wales, Scotland and Northern Ireland, providing specialist congenital heart services and relevant professional colleges and societies covering the main clinical professions and specialist groups involved in delivering care for congenital heart disease. This group had the most inclusive membership and advised the

http://www.webarchive.org.uk/wayback/archive/20130808112325/http://www.specialisedservices.nhs.uk/library/30/Safe_and_Sustainable_A_New_Vision_for_Childrens_Congenital_Heart_Services_in_England_Consultation_Document_1.pdf

⁷⁸ Barron D, Personal communication, 2014

Clinical Advisory Panel and Programme Board, through its chair, Professor Deirdre Kelly, on all clinical aspects of the review.

30. **The Clinical Advisory Panel**⁷⁹ was appointed to give independent and senior clinical advice to the review and in particular to the national medical director. While its membership included five practising CHD clinicians, it was an important principle that its membership was drawn more widely, both to ensure that the review benefitted from experience in other relevant specialties and to avoid such undue conflicts of interest as might arise had the panel been predominantly drawn from the CHD centres.
31. The Chair of the Panel, Professor Sir Michael Rawlins, then President of the Royal Society of Medicine, was appointed by the National Medical Director (Professor Sir Bruce Keogh). The panel's members were⁸⁰:

Member	Role / appointing organisation
Professor Sir Michael Rawlins	Chair
Royal Colleges and Specialist Societies	
Angie Martin	Royal College of Nursing representative on NHS England's Clinical Reference Group for Congenital Heart Services
Ms Carin Van Doorn	Chair of the Congenital Subcommittee of the Society for Cardiothoracic Surgery
Professor David Anderson	President, British Congenital Cardiac Association
Professor John Deanfield	Chair of Adult with Congenital Heart Disease Advisory Group
Dr Liam Brennan	President, The Royal College of Anaesthetists
Dr Mike Knapton	Deputy Medical Director, British Heart Foundation
Professor Neena Modi	President, Royal College of Paediatrics and Child Health
Dr Sarah Vause	Royal College of Obstetricians and Gynaecologists / British Maternal & Fetal Medicine Society representative

⁷⁹ A record of all the papers considered by the Clinical Advisory Panel and the minutes of its meetings are available here: <https://www.england.nhs.uk/commissioning/spec-services/npc-crg/chd/chd-review-2013-15/meetings/cap/>

⁸⁰ This is the membership of the panel convened to consider the consultation response and to advise on issues that had arisen during consultation. The membership of the panel changed over time as membership was linked to the post rather than the postholder. CAP membership during the development of the standards is described in the PCBC and in the records of its meetings referred to in note 88.

Member	Role / appointing organisation
NHS England Clinical Advisers	
Professor Deirdre Kelly	Chair of the review's Clinician Group
Dr Gale Pearson	Chair of NHS England's Clinical Reference Group for Paediatric Intensive Care
Professor Huon Gray	National Clinical Director for Cardiac Care, NHS England
Dr Jacqueline Cornish	National Clinical Director for Children and Young People, NHS England
Dr Trevor Richens	Chair of NHS England's Clinical Reference Group for Congenital Heart Services
Dr Vin Diwakar	Regional Medical Director, NHS England (London)

Evidence from experience of earlier changes to CHD services

32. We surveyed staff at centres where congenital heart surgery had previously been discontinued - Edinburgh, Cardiff and Oxford and centres where those patients now receive their surgical care. We were particularly interested in any learning from these centres about how to manage such a change effectively.
33. **Cardiff** was a small CHD service serving south Wales. In 1998 the CHD surgeon left and his replacement as a single handed practitioner was blocked by the Royal College of Surgeons. Between 1998 and 2001 patients requiring surgery were referred to Birmingham. In 2001 once improvements at Bristol were established, Cardiff established a partnership with Bristol and most patients are now referred there. A small number of patients with more complex conditions are still referred to Birmingham and some families choose to go there.
34. One of the paediatric cardiologists from Cardiff moved to Bristol. Another left. One paediatric cardiac anaesthetist took redundancy and the other two were re-deployed to adult cardiac surgery.
35. The level 2 specialist medical service has continued uninterrupted and has continued to grow. No adverse incidents were reported at the time but an adverse event may have been associated with low volume interventional practice as numbers fell. No patients are known to have been lost to follow-up. Patient feedback is positive. The current service is well regarded.
36. Bristol, Cardiff and NHS Wales commissioning meet annually to discuss activity and adverse events in a mortality/morbidity session.
37. Advice for managing change in future would be:

- Ensure so far as possible that local services improve and that only the location of surgery changes. That made it easier for Cardiff than closing a complete service and transferring it.
 - If services are reduced or closed staff should be relocated to the new centre and continue to see their historical patients there, or undertake outreach to their old centre (under the umbrella of the new, bigger service).
 - Take steps to ensure people with LD are not (and do not feel) disadvantaged. Listen to what they and their families say and try to meet their wishes.
 - Avoid the emergence of occasional practice at a level 2 centre by closely monitoring volumes of activity.
 - Ensure there are joint MDT meetings and high levels of communication between the teams including and seamless electronic links to be able to share clinical data and imaging.
 - Clinical nurse specialists working right across the network work as patient advocates and advisers and that can minimise concerns at the time of a change.
 - Provision of appropriate family accommodation and car parking is essential. This is really important to families a long way from home. Many are low-income families and need a great deal of social support.
 - Offer all patients from out-of-region an outpatient visit to come and meet the surgeons and the team prior to their operation (and include meeting the liaison nursing team and a visit to the wards, the ICU and other facilities. This can be extremely important for families to give them confidence and realise the value of being in a large specialist centre.
 - While there is a strain on families of moving further from home this is offset by the fact that they prefer to be in a centre that they have confidence in.
 - Good communication is critical and at the centre of that is the liaison nursing team and family support team. They are essential for dealing with questions and concerns.
 - An annual review of how arrangements are working is very helpful.
38. **Edinburgh** was a small CHD service. In 2000 the government decided, in the wake of Bristol, that there should only be a single surgical CHD service in Scotland and that this should be located in Glasgow which is the main population centre. From 2000 onwards all surgical and interventional patients receive their care in Glasgow, though a small

number of complex cases are referred to centres in England for specialist procedures. A small CHD cardiology service has continued in Edinburgh. Following retirement of one of the CHD cardiologists this is now a single handed practice and recruitment of a replacement has proved difficult.

39. Two doctors transferred to Glasgow. The surgeon re-deployed to adult cardiac surgery. There were no redundancies. No other staff transferred.
40. The service is on a much more sound footing now as a result of the decision to make the changes. The change was considered successful and has set a pattern for concentrating specialist services. Patients understood the change and are happy with the service.
41. No patients were lost to follow-up.
42. Advice for managing change in future would be:
 - Ensure that any decision to change services is very clear, and fully implemented to avoid the emergence of occasional practice.
 - Support staff to move with the service (particularly the surgeons) or be re-deployed.
 - Help staff to deal with their feelings about the change.
43. **Oxford** was a small to medium sized CHD service. In 2010 following the deaths of a number of babies surgery was immediately suspended and transferred to Southampton. Because of the urgency of the changes there were initial practical challenges but the service is now considered to be routine and straightforward. This is helped by the responsiveness of the Southampton team and by formal paediatric network arrangements between Oxford and Southampton.
44. Patients are now offered a choice of surgical centre recognising the wide geography served and roughly two thirds choose Southampton and one third choose London for surgery / intervention. Oxford provides the rest of the patient's care.
45. No staff transferred to Southampton. The staff changes evolved over time and there was no huge impact on staff. The surgeons moved elsewhere as did the paediatric anaesthetist who initially flagged the issues. There were no redundancies. Theatre staff were redeployed to adult cardiac surgery within the Trust.
46. While new patients accept the current arrangements, some patients who received their surgery at Oxford before these changes would prefer that Oxford was still a level 1 centre. The Trust Board has been clear that it would no longer be appropriate for Oxford to provide CHD surgery.

47. There was no effect on other services at Oxford. General paediatric surgery has increased at Oxford, following the move of patients requiring specialist care going to Southampton.
48. Advice for managing change in future would be:
- Ensure patients understand the change, the reasons for it, and that it is permanent.

Test 2: Strong patient and public engagement

49. Patient and public engagement has been a priority for NHS England's work on CHD from the very beginning. This has been evident in our approach to communications, participation and engagement/consultation.
50. We have published a regular blog on the NHS England website since the beginning of our work on CHD, providing the latest news, papers, discussions, meeting details and forthcoming events so that everything happening in our work was shared and freely available. The blog has been a tool of engagement particularly for those who are new to the review and we have encouraged those we meet at events to subscribe to the blog to keep up to date with the review.
51. The blog was originally written by John Holden, the Director responsible for the new review, subsequently by Will Huxter, the Senior Responsible Officer for the commissioning and implementation programme and most recently by John Stewart, lead Director for the programme. By June 2017, 52 blogs had been issued⁸¹. We continued this practice after the announcement of the proposals, and through consultation:
- 8 July 2016 – Action on Congenital Heart Disease services
 - 13 September 2016 – Next steps to meeting new national standards
 - 18 October 2016 – NHS England in 'listening mode' in preparation for consultation on Congenital Heart Disease proposals
 - 23 November 2016 - Why it's good to talk
 - 14 March 2017 – The voices of children and young people will be central to CHD consultation
 - 28 April 2017 – Extending the CHD consultation
 - 16 June 2017 – NHS England in listening mode
52. Over 250 subscribers receive an alert when the blog is published. Of these about 80% are patient and public - patients and their families,

⁸¹ Copies of John Holden's blogs may be read here: <https://www.england.nhs.uk/publications/blogs/john-holden/> and Will Huxter's blogs may be read here: <https://www.england.nhs.uk/commissioning/spec-services/npc-crg/chd/blogs/>

charities and patient support groups, members of the public, Healthwatch, elected representatives and so on. Many of the organisations pass on the information to their members so the reach of the blog is greater than just the number who subscribe.

53. Although primarily a news channel, the comments facility on the NHS England website has been used to establish a two way conversation with stakeholders.

Patient and public engagement in the development and agreement of the standards

54. The extensive work to engage with patients, families, the public and their representatives during the new CHD review is described in detail in the paper⁸² considered by the NHS England Board in July 2015.
55. In 2013 the review set up a Public and Patient Engagement and Advisory Group comprising representatives from national and local charities and support groups. The group met regularly throughout the lifetime of the review, sometimes as a discrete group, sometimes in joint meetings with the review's clinical and provider stakeholder groups. Over 50 groups were invited and many regularly took part. Some stakeholder groups in particular locations found it difficult to attend the meetings and in these cases we arranged bespoke sessions for briefing and dialogue. The group was chaired by Professor Peter Weissberg, from the British Heart Foundation.
56. Patient and public representatives were included in the groups that developed the standards.
57. During this phase of our work, Professor Weissberg represented the views of the Public and Patient Engagement and Advisory Group on the review's Programme Board.
58. The CRG, which includes three patient and public representatives was regularly briefed about the work of the review and contributed actively to its work.
59. In 2014 we undertook a national programme of engagement with children and young people with CHD involving nine events in cities across the country to ensure that we heard directly from children and young people themselves rather than only hearing their views mediated through parents, carers or charities. Over 100 children and 60 parents and carers attended the events and added their thoughts to what should be included in the standards of care.

⁸² See Appendix 6: 'Engagement with public, patients and their representatives' - of the CHD paper considered by the NHS England Board at its meeting on 23 July 2015 and available here: <https://www.england.nhs.uk/wp-content/uploads/2015/07/Item-4-CHD-Report.pdf>

60. We met a number of bereaved parents at our first meeting of patient and public representatives in 2013, and hearing about their experience led to the development of a new section in the standards relating to palliative care, end of life care and bereavement. We also travelled to Bristol to meet bereaved families and families of children whose outcomes had been less good than anticipated.
61. In 2014 we visited 14 hospitals providing level 1 CHD services and five providing level 2 CHD services and spoke to patients and their families. This included many who had not previously been involved with our work.
62. In addition to this ongoing work, in 2015 the standards were the subject of a full 12 week public consultation.
63. During consultation on the standards, we held 12 drop-in exhibitions in cities across England and Wales. We estimated that 400 - 500 people attended. As well as viewing posters and videos explaining the proposed standards, every attender had a conversation with a member of the review team. Many who attended were people with CHD or relatives of people with CHD. Many had not previously been involved with the work.
64. 459 responses were received to the consultation of which at least 237⁸³ were patients, the public or their representatives. A full report⁸⁴ of the consultation responses was prepared by an independent company, Dialogue by Design.
65. Consultation responses played an important role in finalising the standards and patient and public representatives continued to play a full part in this part of the process. Responses relating to particular standards were identified from Dialogue by Design's report and by a separate examination of responses by the programme team. The proposed standards were then annotated with all the related comments, and these were then reviewed by a specially convened group of clinicians and patient representatives (involving the two groups that had worked on the standards revision, the congenital heart services CRG and representatives of other related CRGs and known as the JSCRG). This group considered whether any changes were needed to the proposed standards in light of the comments received. Many minor changes were made to the standards. Some of these improved the drafting or removed ambiguity, others added important detail. A very small number involved material changes.

⁸³ 108 respondents could not be classified, either not answering the 'about you' question, preferring not to say who they were or answering 'other'.

⁸⁴ The report is available here: http://www.dialoguebydesign.co.uk/wp-content/uploads/2015/03/NHSEngland_CHD_Consultation_Final_Report_201503021.pdf

66. This activity is relevant to the consideration of patient and public involvement in the implementation of the standards because this earlier engagement in the development of the standards was always undertaken on the understanding that the standards were not an end in themselves, but that NHS England would in its role as national commissioner take action to ensure that the standards were met. Stakeholders would not have brought the energy and commitment so evident in their engagement had they suspected that the standards were simply an academic exercise.
67. Further, patients and their families themselves urged us to ensure that the standards would be implemented. While it was hoped that this could be achieved without major reconfiguration of services, it was always clear⁸⁵ that tough choices might be involved and that all providers would not be able to meet the standards unless there were changes to the way they worked.

Patient and public engagement in work to implement the agreed standards

68. The Board's decision to approve the standards in July 2015 brought to an end the new CHD review. From this time NHS England's work focussed on the implementation of the standards. At this point the governance and engagement arrangements of the review were reviewed and refreshed to ensure they were appropriate for this new phase of work.
69. Discussion with members of the Public and Patient Engagement and Advisory Group revealed that many did not want to continue to meet as a separate group, but rather preferred to meet with clinical and managerial stakeholders as a single group (as had happened on a number of occasions during the review's life).
70. New arrangements were therefore established to reflect the changed focus of the programme – to work as a commissioner to ensure that the standards were implemented. The new arrangements also recognised that a reduced intensity of meeting was appropriate for this stage of the work.
71. NHS England reviewed and then re-established its CRG arrangements (for all specialties) during 2016. When the congenital heart services CRG was re-launched its 'patient and public voice' arrangements returned to be in line with those for all other CRGs, and three representatives were appointed following an open application process.

⁸⁵ See for example part 5 of the consultation document 'Proposed CHD standards and specifications: a consultation' available here: https://www.engage.england.nhs.uk/consultation/congenital-heart-disease-standards/user_uploads/chd-consultation-doc-fin.pdf and paragraphs 94-103 of the CHD paper considered by the NHS England Board at its meeting on 23 July 2015 and available here: <https://www.england.nhs.uk/wp-content/uploads/2015/07/Item-4-CHD-Report.pdf>

72. As the patient and public group was no longer meeting, a new approach was taken to ensuring that the views of patients were heard by the Programme Board. In 2016, once the CRG was re-established, the three patient and public representatives from the CRG were invited to join the Programme Board and National Panel.
73. The main focus of NHS England's work since the standards were agreed has been with hospitals that provide the service, firstly to explore provider led solutions, and subsequently to assess whether existing providers meet the standards. In each of these pieces of work a National Panel has performed a pivotal role in assessing providers. We have included patient representatives in the panel both to ensure that the panel hears the service user perspective, and as guarantors of the process to other patient groups of the probity of the process. Initially, before the dissolution of the old CRG, two representatives were elected by the patient and public representatives on the CRG. Since the advent of the new CRG, all three patient and public representatives are members of the panel. While the role of the panel has been to assess providers and not to decide what action NHS England should take, the potential consequences of the assessments have always been clear to and discussed by members of the panel. The panel has met on five occasions during 2016. Reports⁸⁶ of the panel's work have been published on the NHS England website.
74. The CHD Implementation group (CHDI) was established to run alongside the assessment and service change processes and ensure that attention is given to all the standards and not just those that have been the subject of our formal assessment. Members of the review's Patient & Public Engagement and Advisory Group were invited to be part of this group, working with clinicians on this important agenda and have been active in the group's work from the beginning.
75. The membership of the CHDI Group is multi-professional clinical and patient groups and all levels of service delivery. To date, five CHDI Symposia have been held, focusing on Pregnancy, Living with CHD (split over 2 symposia), End of Life Care and Technology and Information Governance. Each session was attended by a group of around 40 people, with an average of 4 PPV members at each symposium. The group is chaired by CHD Programme Clinical Lead, Professor Kelly.

⁸⁶ The report of the National Panel on provider submissions is available here:

<https://www.england.nhs.uk/wp-content/uploads/2016/01/nhse-chd-report-national-panel.pdf>

The report of the National Panel assessment of centres against the standards is available here:

<https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/07/chd-national-panel-report.pdf>

76. The CHDI symposia programme is designed to cover all sections of the CHD standards and facilitate further joint work, such as development of professional networks and task specific Task and Finish Groups. It supports implementation of the standards by:
- supporting centres and networks to share learning;
 - focusing on cross provider issues; and
 - facilitating sharing of best practice.
77. Presentations and group work sessions are facilitated by the CHD Programme Team and invited speakers, with an online portal established to share symposium material and provide a forum for further discussion and sharing of resources.
78. We have held occasional virtual meetings with members of the review's PPVEAG to provide updates on progress with the assessment / service change work (20 April 2015 and 17 October 2016). We have also discussed with them plans for consultation and taken their advice on stakeholder engagement during consultation.
79. Prior to public announcement of the original proposals we called patient and public stakeholders who had previously engaged with our work, in areas potentially affected by change, ahead of our announcement of original proposals and personally briefed them. Following the announcement, on 29 July 2016, we held an 'all stakeholder' meeting to provide further briefing on the proposals.
80. Members of the NHS England team have visited centres providing CHD services. Whenever possible this has included meeting with patients and the public to explain and discuss the proposals.
- 16 September 2016 - Leicester Glenfield – Visit by Will Huxter, Jonathan Fielden and Jo Stringer to meet with clinicians, patients, local political representatives and stakeholders
 - 14 September 2016 - Royal Brompton – Visit by Will Huxter, Jonathan Fielden and Jo Stringer

Engagement with elected representatives

81. A briefing was provided to all top tier councils in England explaining the history of the CHD review and the proposals that had been made. The briefing also contained the offer of further briefing for Oversight Scrutiny Committees (OSCs) should they wish this. The briefing was circulated through the Centre for Public Scrutiny to all councils OSC officers; and a link to the NHS England website where the document is hosted was circulated to Health and Wellbeing Board members through the Local Government Association, via their Health and Wellbeing Board bulletin.

82. Members of the NHS England team have attended briefings and meetings with local government in areas affected by the original proposals:

Leicester City Council Health and Wellbeing Board – 18 August 2017

Royal Borough of Kensington and Chelsea OSC – 21 September 2017

Greater Manchester Joint Scrutiny Committee - 19 October 2017

83. Members of the NHS England team have given briefings and held discussions with MPs from areas affected by the original proposals.

Date / Meeting	MP	Party	Constituency
11 July 2016 meeting on NHSE Original proposals	Edward Argar	Conservative	Charnwood
	Jonathan Ashworth	Labour	Leicester South
	Andrew Bridgen	Conservative	North West Leicester
	Alberto Costa	Conservative	South Leicestershire
	Sir Alan Duncan	Conservative	Rutland and Melton
	Sir Edward Garnier	Conservative	Harborough
	Liz Kendall	Labour	Leicester West
	Nicky Morgan	Conservative	Loughborough
	David Tredinnick	Conservative	Bosworth
20 July 2016 meeting on NHSE original proposals	Victoria Borwick	Conservative	Kensington and Chelsea
	Nicky Morgan	Conservative	Loughborough
	Sarah Wollaston	Conservative	Totnes
	Lilian Greenwood	Labour	Nottingham South
29 November 2016 briefing on the future of CHD services in the East Midlands	Jon Ashworth	Labour	Leicester South
	Sir Edward Garnier	Conservative	Harborough
	Philip Hollobone	Conservative	Kettering
	Liz Kendall	Labour	Leicester West
	Nicky Morgan	Conservative	Loughborough
	David Mackintosh	Conservative	Northampton South
7 December 2016 briefing on the future of CHD services in London	Victoria Borwick	Conservative	Kensington and Chelsea
	Andy Slaughter	Labour	Hammersmith and Fulham

84. A briefing for MPs interested in the future of the CHD service in the North / North West was offered on 6 December 2016 with no uptake.
85. An email was sent on 23 November 2016 to MPs that have previously expressed an interest in the work on CHD services (201 recipients) to inform them of the delay to the launch of consultation. A link to the latest blog was provided.
86. Patient and public members of the programme board reviewed and commented on our plans for consultation activities, our communication

approach up to and through consultation and the materials to be used in consultation, including the consultation document.

87. A formal consultation with the public was held between February and July 2017⁸⁷.
88. Patient and public representatives have been involved thorough the National Panel in reviewing the consultation responses (as understood through the report on consultation).
89. We have continued to keep stakeholders informed of progress through the blog.

Test 3: Support for original proposals from clinical commissioners

90. Congenital heart disease is a specialised service, commissioned by NHS England rather than by CCGs. We have therefore considered that the most relevant clinical commissioners with whom to engage are those clinicians from the specialised service that work with NHS England to advise it on its commissioning approach.
91. In the first instance this would be the congenital heart services clinical reference group (CRG). In our work we supplemented the advice of the CRG with a variety of bespoke clinical engagement arrangements and these are described in more detail above.
92. The number of CHD patients seen by the average GP is small, and their involvement in shared care can be very limited. For example, between the two CCGs in Suffolk only 2 adults are admitted for CHD surgery in an average year.
93. CCGs do however commission level 3 services through local maternity, paediatric and cardiology contracts and this is important for the overall model of care that the NHS England Board agreed in the summer of 2015. We therefore made repeated attempts to identify representatives of CCGs to join the review's programme board. We approached NHS Clinical Commissioners on a number of occasions. We asked our regional teams to seek representatives through their collaborative commissioning arrangements. Although we were originally seeking two representatives, we were only able to find one.
94. From September 2014 Dr Cathy Winfield, Chief Officer for the Berkshire West CCG Federation joined the programme board. Dr Winfield was an active participant in the board's work for many months, but noting that the main focus of the board's work was a specialised service that would not be high on clinical commissioners' priorities it was agreed that Dr Winfield would become a non-attending member. Dr Winfield was involved in

⁸⁷ Our plans for engaging patients and the public in consultation are described below.

helping develop our thinking on level 3 services, joined more recently by Claire Herbert (Head of Policy and Delivery) from NHS Clinical Commissioners.

95. Members of the NHS England team have met and discussed the changes with CCG representatives / GPs in areas affected by change during visits to the affected hospitals and attendances at Health and Wellbeing Boards and Overview and Scrutiny Committees.
96. We notified all CCGs of consultation in the NHS England CCG bulletin and via NHS Clinical Commissioners. We arranged a webinar for CCGs though this did not prove a popular way of engaging. GPs attended a number of the consultation events.
97. The North West London group of CCGs, in their consultation response, stated that it was one of their core principles to centralise specialist services when it improves clinical outcomes and quality of care for our patients and therefore in principle they supported the concept proposed. They drew attention to the need for decisions to be clinically-led and evidence-based. While supporting the principle they also stated that they had not been able to identify the detail of the evidence that underpins the proposal, and that therefore they would need to be confident that in making its decision the NHS England Board had the full depth of evidence and assurance to support the proposed changes.
98. The Greater Manchester group of CCGs in their consultation response, stated that 'there is real urgency for NHS England to use their commissioning powers to drive joint, locally driven work on the future service model for the North West...Maternity services need special consideration. Manchester should be regarded as a Level 2 centre with the ability to undertake ASD closures and more complex interventional procedures, with the exception of those very complex procedures that require a congenital surgeon to be present'. 'As soon as feasible following the completion of the consultation and subsequent assessment of responses, we are keen that a final decision is reached and to agree the timescales for transition. This is particularly important given the current unavailability of a NW based adult surgical service'.
99. Will Huxter briefed the 19 January 2017 NHS Clinical Commissioners Board meeting on NHS England's original proposals for the future provision of congenital heart disease services in England and the proposed arrangements for public consultation on these proposals. The Board was broadly supportive of the rationale outlined for the proposed changes.

Test 4: Consistency with current and prospective need for patient choice

100. An important aim of the original proposals is to ensure that whichever centre a patient uses, they should receive care of the same high standard. A limited reduction in the number of centres providing level 1 services will not materially affect patients' opportunity to exercise choice, and will positively impact the quality of the choices available.
101. While a reduction in patient choice is inherent in the original proposals since these would involve a reduction in the number of providers of specialist CHD services, this is not inconsistent with assuring current and prospective need for patient choice. Services for patients with CHD are already concentrated in a limited number of centres.
102. We consider that there would be benefits to patients of limiting competition – such as the concentration of specialist services in regional centres or in providing services through a clinical network.
103. Competition between CHD centres was criticised by Verita⁸⁸ because of the potentially negative behaviours that this had produced that were not judged to be in the patient interest. 'We found that the Safe and Sustainable process put centres in competition with each other. This damaged the trust that some parents had in the neutrality of the advice given to them by those treating their children.' NHS England was directed in its work to seek to minimise these behaviours.
104. While competition may be reduced, choice for patients is affirmed and strongly supported. This is demonstrated, for example, in that a key aim of the Review was to improve the information available to patients in order to help them make informed choices about their care (for example paragraphs 66, 86 and 111 of the Final Report to the Board of 23 July 2015 and section H of the standards).
105. While most patients accept the advice of their referring doctor on the appropriate unit for their care, patient groups strongly support the right of patients to choose and this is reflected in section H of the standards:

H4(L1)	When referring patients for further investigation, surgery or cardiological intervention, patient care plans will be determined primarily by the availability of expert care for their condition. The cardiologist must ensure that parents, carers, children and young people are advised of any appropriate choices available as well as the reasons for any recommendations.
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⁸⁸ Leeds Teaching Hospitals NHS Trust, Overarching report about paediatric cardiac surgery – a report for NHS England (October 2014) available here: <https://www.england.nhs.uk/wp-content/uploads/2014/10/leeds-overarching-report.pdf>

H5(L1)	<p>Sufficient information must be provided to allow informed decisions to be made, including supporting parents, carers and young people in interpreting publicly available data that support choice. The following should also be described:</p> <p>other clinical specialties offered by alternative units, relevant to patients with co-morbidities;</p> <p>accessibility of alternative units;</p> <p>patient facilities offered by alternative units;</p> <p>outcomes at units under consideration; and</p> <p>consideration of the closest unit to the patient's home.</p>
H6(L1)	<p>Specialist Children's Surgical Centres must demonstrate that parents, carers and young people are offered support in obtaining further opinions or referral to another Specialist Children's Surgical Centre, and in interpreting publically available data that supports patient choice.</p>

Test 5: The requirement to demonstrate that sufficient alternative provision, including workforce, will be put in place alongside or ahead of bed closures.

106. Our impact assessment has provided a clear understanding of the alternative provision that will be needed if the proposals on which we have consulted were to be implemented. This includes the requirements for CHD care, the requirements for other services affected, the requirements for facilities, equipment and staff.
107. We have committed to ensuring that changes resulting from the Board's decisions will not happen until the hospitals providing care for more patients are ready to receive them.
108. We have also committed to ensuring on behalf of patients that there will be no interruption in their care or reduction in the quality of their care if the original proposals were implemented. Any changes will not happen overnight and we will ensure that patients and their families are kept informed throughout.
109. We also recognise, however, that it is likely to be increasingly difficult to maintain services at any centre where it is decided that level 1 services should not continue into the future. Under these circumstances it is likely that significant numbers of staff will seek to move to a more secure position ahead of the planned date for change at their centre. In addition some patients and their families may also seek a transfer to another centre ahead of the planned date for change at their centre. The recent

experience at Central Manchester has shown that under these circumstances unplanned service collapse is real risk. Managing this risk is the principal challenge of managing transition.

110. The Clinical Advisory Panel advised that national collaboration would be needed to:
- Reduce the risk of service collapse
 - Develop and deliver contingency plans in the event of service collapse
 - Manage supported change
 - Provide national oversight, management and commissioning
111. The National Panel endorsed the Clinical Advisory Panel's recommendation that national collaboration could help reduce the risk of service collapse. It saw a role for all level 1 CHD centres and for NHS England working together to provide this support. The clinical reference group could have a role in advising and national co-ordination.
112. Depending on the decisions taken by the Board, NHS England will work with professional associations, the CRG and all of the level 1 CHD centres to ensure that there is appropriate support to centres affected by change to manage transition in such a way that sufficient alternative provision, including workforce, will be put in place alongside or ahead of any changes to existing services.

LEGAL CONSIDERATIONS

113. In this section we consider compliance with the National Health Service Act 2006 and the Equality Act 2010.
114. In addition, this DMBC, our Equalities Impact Assessment, the proposals for consultation and our consultation document have all been subject to review by our legal advisers DAC Beachcroft LLP.

Compliance with sections 13C-13Q of the National Health Service Act 2006

115. **Section 13C Duty to promote NHS Constitution:** NHS England in its work on CHD has satisfied the duty to act with a view to securing that health services are provided in a way which promotes the NHS Constitution. This is demonstrated, for example, in the way that key elements of the NHS Constitution, notably putting patients and their families at the heart of the our work and a commitment to the highest standards of excellence and professionalism, are evident in the conduct of our work (see for example paragraph 21 of the Board paper of 18 July 2013 and section 11 of the PCBC).
116. **Section 13D Duty as to effectiveness, efficiency etc:** NHS England in its work on CHD has exercised its functions effectively, efficiently and

economically. The intended outcome of the new CHD review was improved and more efficient congenital heart disease services for patients through the introduction of standards of the highest possible quality delivered through networks which have the right staffing and skills and are designed to eliminate occasional practice. This is demonstrated, for example, in the discussions as to ensuring the highest possible quality within the available resources (see for example paragraph 15 of the Board paper of 18 July 2013 and paragraphs 17, 133 and 134 of the Final Report to the Board of 23 July 2015). The finance assessment undertaken in support of the Board's decision making in July 2015 and refreshed for this consultation confirms that:

- provider revenue costs of implementing standards should be covered by increasing income for increasing activity;
- any increased commissioner costs of CHD service over time, arising from activity growth, will be picked up from within the Prescribed Specialist Commissioning budget and that any additional requests for financial support from providers will not be supported by Prescribed Specialist Commissioning: and
- the capital costs of the changes have been identified by providers and will be met from existing allocations and/or charitable funds.

117. Section 13E Duty as to improvement in quality of services: NHS

England has carried out its work on CHD with a view to securing secure continuous improvement in the quality of services, in particular with a view to the outcomes achieved from the provision of services. This duty underpins the NHS England's work. This is demonstrated, for example, in the emphasis on the overriding need to improve congenital heart disease services and patient experience (see for example paragraphs 15 and 21 of the Board paper of 18 July 2013 and paragraphs 17, 84 and 134 of the Final Report to the Board of 23 July 2015). NHS England has continued its commitment to secure continuous improvement during our work on implementation of the standards. This is demonstrated, for example, in its consideration of the potential benefits of implementing its original proposals and the impact of doing so (see for example sections 5, 6.5, 7.7.2 and 7.7.3 of the PCBC).

118. Section 13F Duty as to promoting autonomy: NHS England in its work

on CHD has had regard to the desirability of securing, so far as consistent with the interests of the health service, that any other person exercising functions in relation to the health service or providing services for its purposes is free to exercise those functions or provide those services in the manner it considers most appropriate.

119. **Section 13G Duty as to reducing inequalities:** NHS England in its work on CHD has met its duty to have regard to the need to reduce inequalities between patients with respect to their ability to access health services and the outcomes achieved for them by the provision of health services. This is demonstrated, for example, in the mapping of patient journey times before and after its original proposals to show that existing patients of centres that no longer provided L1 services would not have longer journey times than those commonly experienced by other patients in England. Our work aims to improve quality for all patients. We have considered whether social inequality affects outcomes, and in the review of data undertaken by NICOR⁸⁹ and in our review of the literature for our Equality Impact Assessment we have found no evidence of a connection. The original proposals to improve care for children with CHD can be considered to be in line with the first principle of the Marmot Review to give every child the best start in life. The standards also respond to the views of patients about their care, and in requiring that they are appropriately involved in conversations about their own care, be provided information in an appropriate way and be offered choice, the standards can be considered to be in line with the second principle of the Marmot Review⁹⁰ to enable children, young people and adults to maximise their capabilities and have control over their lives
120. **Section 13H Duty to promote involvement of each patient:** NHS England in its work on CHD has discharged its duty to promote the involvement of patients, and their carers and representatives, in decisions which relate to the prevention or diagnosis of illness in the patients or their care or treatment. In particular, significant emphasis has been placed on the provision of improved information to help patients make informed choices and the importance of patient and public involvement and consultation.
121. **Section 13I Duty as to patient choice:** While a reduction in patient choice is inherent in the original proposals since these involve a reduction in the number of providers of specialist CHD services, this is not contrary to the duty because the duty requires that NHS England acts 'with a view to enabling patients to make choices with respect to aspects of health services provided to them'. This is demonstrated, for example, in that a key aim of the Review was to improve the information available to patients in order to help them make informed choices about their care (for example

⁸⁹ Nicholas O et al, Analysis of candidate risk factors in Paediatric Cardiac Surgery 30-day risk modelling: Ethnicity, Deprivation, Sex, Year, Volume, Distance from home, Weekday or weekend, NICOR, 2015

⁹⁰ Fair Society, Healthy Lives, the Strategic Review of Health Inequalities in England post-2010, The Marmot Review, 2010

paragraphs 66, 86 and 111 of the Final Report to the Board of 23 July 2015 and section H of the standards).

122. **Section 13J Duty to obtain appropriate advice:** NHS England in its work on CHD has complied with its duty to obtain appropriate advice that includes a broad range of professional expertise and has used evidence to support its conclusions. This is demonstrated, for example, the involvement of expert clinicians in the preparation of the standards and the documented explanations of how expert evidence and opinion was used (see for example paragraph 21 of the Board paper of 18 July 2013 and paragraphs 12, 13, 38 and 42 of the Final Report to the Board of 23 July 2015) and the involvement of expert clinicians in its assessment of providers of CHD services and in considering the impact of its original proposals on other interdependent services (see for example section 7.6.2 of the PCBC).
123. **Section 13K Duty to promote innovation:** NHS England in its work on CHD has complied with its duty to promote innovation in the provision of health services, including innovation in the arrangements made for their provision. This is demonstrated, for example, in its advocacy of innovative models of care in the provider led work on meeting the standards for example the way that multi-centre networks would have the opportunity to develop innovative approaches to meeting the standards that may not be available to individual centres working alone (see for example paragraph 25 of the Final Report to the Board of 23 July 2015), and in its consideration of innovative commissioning mechanisms (see for example paragraph 27 of the Final Report to the Board of 23 July 2015).
124. **Section 13L Duty in respect of research:** NHS England in its work on CHD has complied with its duty to promote research on matters relevant to the health service, and the use in the health service of evidence obtained from research. This is demonstrated, for example, in Section G of the standards sets out the expectations as regards participation of providers and networks in research. NHS England in its work on CHD has also discharged its duty to promote the use of evidence obtained from research in the health service in its use of research to inform both the standards and its original proposals. This is demonstrated, for example, in the conscious efforts of the Clinical Advisory Panel to ensure the latest research was taken into account (see for example paragraph 13 of the Final Report to the Board of 23 July 2015) and the commissioning of a refreshed evidence review in relation to its original proposals (see for example section 10.1.1 in the PCBC). NHS England has also given careful consideration to the potential impact on research (particularly at RBH) or implementing its original proposals.

125. **Section 13M Duty as to promoting education and training:** NHS England in its work on CHD has discharged its duty to promote education and training for relevant groups. This is demonstrated, for example, in the way it has identified areas requiring additional education and training and proposed remedial actions (see for example sonographer workforce and training, paragraphs 54, 55 and 129 of the Final Report to the Board of 23 July 2015). Section E of the standards sets out the expectations on providers and networks in relation to ongoing education and training. It is also demonstrated in the way that our assessment of the impact of its original proposals takes account of potential impact on training for CHD clinicians and proposes mitigations (see for example section 21 of the PCBC).
126. **Section 13N Duty as to promoting integration:** NHS England in its work on CHD has discharged its duty to act with a view to securing that health services are provided in an integrated way in relevant circumstances. This is demonstrated, for example, in the emphasis that has been placed on the opportunity available to NHS England as sole national commissioner of specialised services, to set national standards commissioned through a single model (see for example paragraph 20 of the Board paper of 18 July 2013) and the importance of service integration offered by the network service model (see for example paragraph 100 of the Final Report to the Board of 23 July 2015).
127. **Section 13O Duty to have regard to impact on services in certain areas:** NHS England in its work on CHD has discharged its duty to have regard to the likely impact of the Review on the provision of health services to persons who reside in an area of Wales or Scotland that is close to the border with England. This is demonstrated, for example, in our earlier consultation on standards which recognised that Welsh patients usually undergo congenital heart disease surgery in hospitals in England. Advice was taken from the Welsh Government on consultations in Wales and written materials were provided in Welsh at consultation events in Cardiff and Wrexham. Similarly our consultation documents recognise that there are individuals living in Wales, Scotland and Northern Ireland who use CHD services in England and steps were taken to make them aware of the consultation. The consultation materials were also translated into Welsh.
128. **Section 13P Duty as respects variation in provision of health services:** NHS England in its work on CHD has had regard for this duty and did not exercise its functions with the purpose of causing a variation in the proportion of services provided by persons of a particular description.

129. **Section 13Q Public involvement and consultation by the Board:** NHS England in its work on CHD has discharged its duty to secure that individuals to whom services are being or may be provided are involved (whether by being consulted or provided with information in other ways) in the planning of the commissioning arrangements by the Board, in the development and consideration of the original proposals by the Board for changes in the commissioning arrangements where the implementation of the original proposals would have an impact on the manner in which the services are delivered to the individuals or the range of health services available to them, and in decisions of the Board affecting the operation of the commissioning arrangements where the implementation of the decisions would (if made) have such an impact. This is demonstrated, for example, in the importance given to working with patient, clinical and organisational stakeholders and ensuring our work has been open, transparent and participatory (see for example paragraphs 16, 21, 25 and 26 of the Board paper of 18 July 2013 and paragraphs 10, 107 and Appendix 2 of the Final Report to the Board of 23 July 2015). In addition full public consultation has been carried out on two occasions: between September and December 2014 in relation to the standards; and between February and July 2017 on implementation of the standards.
130. Equality Act 2010 (including, in particular, the public sector equality duty at section 149 of the Equality Act 2010) and Children Act 2004: NHS England in its work on CHD has had regard for equality considerations and the need to safeguard and promote the welfare of children.
131. We undertook an Equalities Impact Assessment⁹¹ in relation to the proposed standards in order to be able to consider the particular impact of congenital heart disease on groups sharing each of the protected characteristics in the Equality Act 2010. In this document we also set out how this was addressed in the proposed standards.
132. We made efforts to engage with groups sharing the protected characteristics particularly affected by congenital heart disease⁹². We undertook specific engagement activities with children and young people. Charities working with people with learning disabilities and CHD were active members of our Patient and Public Engagement and Advisory Group. We heard from women with CHD who had been through pregnancy, and women who had conceived babies diagnosed with CHD both as individuals through our visits to CHD providers and our

⁹¹ The Equalities Impact Assessment was made available as part of the Reference Pack for the consultation on CHD standards available here: https://www.engage.england.nhs.uk/consultation/congenital-heart-disease-standards/user_uploads/reference-pack.pdf

⁹² See Appendix 6 of the CHD paper considered by the NHS England Board at its meeting on 23 July 2015 and available here: <https://www.england.nhs.uk/wp-content/uploads/2015/07/Item-4-CHD-Report.pdf>

consultation events, and through charities involved in our Patient and Public Engagement and Advisory Group. We made strenuous efforts to engage with people of south Asian ethnicity with CHD.

133. In addition full public consultation has been carried out on two occasions: between September and December 2014 in relation to the standards; and between February and July 2017 on implementation of the standards. Responses were from a wide variety of stakeholders, including patients, from across the country, and from individuals and groups representing individuals sharing the protected characteristics particularly affected by congenital heart disease⁹³. The views expressed in the 2014 consultation were then taken into account by the Board in reaching its decision.
134. We refreshed our Equalities Impact Assessment prior to consultation on the original proposals for change in order to be able to consider the particular impact of congenital heart disease on groups sharing each of the protected characteristics described in the Equality Act 2010. We have refreshed it again in light of the responses received in consultation (see **Annex 2**). In this document we also set out our proposed mitigations for these impacts.
135. As part of our impact assessment process we also asked hospitals that provide CHD services about equality and health inequality issues. The specific questions asked are shown in figure 2 below.

Figure 2: Equalities and health inequalities questions from the provider impact assessment

Equalities and health inequalities

Note: In considering equalities and health inequality impacts, please take into account the following characteristics: Age; Disability; Gender reassignment (including transgender); Marriage and civil partnership; Pregnancy and maternity; Race; Religion or belief; Sex; Sexual orientation; Carers; Other identified groups experiencing disadvantage and barriers to access and outcomes, including different socio-economic groups, geographical area inequality, income, resident status (migrants, asylum seekers).

- Are there issues relating to equalities and/or health inequalities that your Trust has identified in the delivery of your current service? Please provide the relevant assessment and evidence.
- If you have identified equalities and/or health inequalities issues, how are you addressing these? Is this approach effective?
- What effect, if any, would our proposals have on groups in your catchment population, sharing protected characteristics, if they were to be implemented? How could we mitigate those impacts?
- What effect, if any, would our proposals have on health inequalities in your catchment population, if they were to be implemented?
- For Trusts where we have proposed that level 1 services would no longer be

⁹³ See the report on consultation responses available here: http://www.dialoguebydesign.co.uk/wp-content/uploads/2015/03/NHSEngland_CHD_Consultation_Final_Report_201503021.pdf

<p>provided, if level 2 CHD services continued to be provided what effect would this have on any impacts on equalities and/or health inequalities?</p>
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136. Two hospitals identified potential equality / health inequalities impacts.
137. The Royal Brompton stated that although NHS England's original proposals were unlikely to impact on many of their patients with regard to gender, race or religion they did consider that they would have the following three impacts.
138. Create an unnecessary health inequality to pregnant CHD patients with a co-morbidity of pulmonary hypertension (due to the Royal Brompton being the only UK CHD centre which is designated to provide pulmonary hypertension services)
 - The concern that the proposals disproportionately affect pregnant CHD patients is considered in the integrated impact assessment accompanying this document in the section 'Pregnancy and maternity'. While other CHD centres do not deliver pulmonary hypertension services, all centres (as required by the standards) have a formal network relationship the national pulmonary hypertension service including joint referral and care protocols.
139. Increase the probability that a higher number of economically disadvantaged patients will find it harder to afford to attend outpatient clinics.
 - The concern that the proposals disproportionately affect people with low incomes is considered in the integrated impact assessment accompanying this document in the section 'Other equalities and inequalities issues identified in consultation'.
140. Dismantle the effective transition arrangements between children's and adults services which the Royal Brompton has developed over many years.
 - NHS England would not consider this an equality/inequality impact. While acknowledging the transition arrangements offered by the Royal Brompton, other providers of CHD services offer similar programmes.
141. Nottingham University Hospitals stated that it considered the original proposals likely to create a geographic inequality whereby the East Midlands would be the only English region without a level 1 Congenital Heart Unit. It stated that its experience of referring patients outside of the East Midlands is very poor indeed in relation to the timeliness of treatment. Nottingham University Hospitals were concerned that local patients always receive priority due to the pressure of work. In order to

ensure equity of care for these patients it considered that outpatient care would also need to be transferred to a level 1 centre.

- The concern that the proposals create a geographic inequality is considered in the integrated impact assessment accompanying this document in the section 'Other equalities and inequalities issues identified in consultation'.

142. As part of our consultation on the original proposals for implementing the standards we made strenuous efforts to ensure that we heard from groups sharing the following protected characteristics, as well as their families and carers: (1) children and young people; (2) people with learning disabilities; and (3) people from South Asian backgrounds. People sharing any of these three protected characteristics have been identified as disproportionately affected by CHD.

Proposals to implement standards for congenital heart disease services for children and adults in England - Consultation Document



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Proposals to implement standards for congenital heart disease for children and adults in England

Consultation Document

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Contents

Contents	4
Foreword	6
Background and context	8
The case for change	10
1.1 Ending uncertainty	12
1.2 Ending occasional practice	13
1.3 Resilient, sustainable services	14
Proposals for consultation	15
How our proposals were developed	22
1.4 Meeting the standards	22
Potential impact of implementing our proposals	25
Pre-consultation engagement and involvement	26
1.5 Engagement activity	26
Consultation	27
1.6 Why are we consulting?	27
1.7 How can I make my views known?	28
1.7.1 How to get involved	28
1.7.2 How to let us know your views	29
1.8 What happens next?	29
Appendix A: Consultation Questions	31
Appendix B: Summary of Impact Assessment	40
1.9 Impact on patients	40
1.10 Impact on CHD services	42
1.11 Impact on other services	43
1.11.1 Impact on other services: Paediatric Intensive Care	43
1.11.2 Impact on other services: Extracorporeal Membrane Oxygenation (ECMO)	44
1.11.3 Impact on other services: Specialist paediatric respiratory services	45
1.12 Workforce Impact	46
1.12.1 Provider organisations where level 1 services would be provided under the proposals: workforce impact	46
1.12.2 Provider organisations where level 1 services would no longer be provided under the proposals: workforce impact	46
1.13 Financial Impact	48
1.13.1 Provider organisations where level 1 services would be provided under the proposals: finance impact	48
1.13.2 Provider organisations where level 1 services would no longer be provided under the proposals: finance impact	49
Equalities and Health Inequalities	51
1.14 Age	51
1.15 Disability	52
1.16 Gender reassignment	52

1.17	Marriage and civil partnership	53
1.18	Pregnancy and maternity	53
1.19	Race.....	53
1.20	Religion or belief	54
1.21	Sex or gender.....	54
1.22	Sexual orientation	54
1.23	Asylum seekers and/or refugees.....	54
1.24	Carers	55
1.25	Those living with mental health issues	55
1.26	Other groups	55
Glossary		57

Foreword

In July 2016, NHS England published a set of proposals regarding the future commissioning of congenital heart disease (CHD) services for children and adults. They describe the actions which we, as commissioners, propose to take in order to ensure a consistent standard of care for CHD patients across the country, for now and for the future.

We propose to do this by implementing national service standards at every hospital that provides CHD services. The effect of our proposals, if implemented, will be that some hospitals will carry out more CHD surgery and catheter procedures, while others, which do not meet the relevant standards, will stop doing this work.

The standards describe services of the highest possible quality. They were developed by patients, and their families and carers, by surgeons and other specialist doctors and nurses, and were formally agreed by the NHS England Board in 2015. We acknowledged then that implementation of them would be a challenge for some hospitals. We also recognised that it might subsequently prove necessary to make tough choices when considering how to put them into practice.

The guiding principle for our work has always been ‘patients come first’. That principle remains at the forefront of our thinking today. It was patients, and their families/carers and representatives, as well as clinicians in the field, who told us – consistently – that the standards were only worth something if they were actually acted upon and met.

Now is the time for decisive action. We have an opportunity to future-proof CHD services, by ensuring that the standards are met. This will enable services to better cope with an increasing number of complex cases and make best use of advances in technology. We must not squander this opportunity. Equally, however, we must ensure that our commissioning decisions are informed by the views of patients and their families and carers, by clinicians and other hospital staff, and by other stakeholders.

We know that if our proposals are implemented, they will have an impact, not just on patients, but on this small number of hospitals, and some of the other services which they deliver, as well as on the staff working in them. We know that some of you are concerned about potentially longer journey times; having to travel greater distances for surgery; the availability of support and accommodation while away from home, and what might happen if there is an emergency. Thankfully, true emergencies in congenital heart disease are incredibly rare, but we recognise your concerns, and have tried to address them later in this document.

This is why we want to hear from you, during this public consultation, so that we can better understand how any changes might affect you and how we might support patients, hospitals and staff, during any future change. Before reading the rest of this consultation document, there are some important points which you might want to consider:

- No decisions about the future commissioning of CHD services have been taken. The proposals published in July were just that – proposals. If you can think of alternative ways in which the standards can be met, then we want to hear from you;
- This is not about saving money. You will already know that money is tight in the NHS, and the NHS has to live within its means. While implementing most of the standards will cost little, or nothing, we expect the overall amount of money spent on CHD care to increase in the future, driven by the growing number of patients living with this condition;
- These proposals are not about closing CHD units. We do not have a fixed number of hospitals providing CHD services in mind. This is about ensuring that every hospital providing a CHD service meets the standards. We have no view about the final number of hospitals which are able to do that;
- This is not about a short-term fix. We are focusing on the long-term resilience and sustainability of CHD services for generations to come.

Finally, we would like to acknowledge the significant time and effort which patients, parents, families, carers, and NHS staff have put into the various pieces of work which have been carried out during the past 16 years, all aimed at improving congenital heart disease services in England. We have all been at this a long time, and we recognise the cloud of uncertainty which hangs over these services as a result.

We need to put an end to this uncertainty, for everybody's sake. So, as you read this document, we hope that you will keep the future long-term stability of these important services in mind, and help us to reach a clear, and long-term, resolution, in the best interests of patients.



Will Huxter
Senior Responsible Officer for
CHD Commissioning and
Implementation Programme &
Regional Director for
Specialised Commissioning



Professor Huon Gray
National Clinical Director for Heart
Disease, NHS England & Consultant
Cardiologist, University Hospital of
Southampton

Background and context

“Sixteen years is a long time to wait. We have lost key consultant staff to posts abroad during that time, as they were not convinced that we were ever going to grasp this nettle. This is our last opportunity to make change happen. If we don’t grasp this opportunity now, we have to accept that ‘adequate’ is good enough”.

Professor Huon Gray
Consultant Cardiologist, University Hospital Southampton NHS Foundation Trust, and National Clinical Director for Heart Disease, NHS England

1. Congenital heart disease (CHD) refers to a heart condition or defect that develops in the womb, before a baby is born. There are many different forms of CHD, some more minor than others. Some people with CHD do not require any form of surgery or interventional procedure in the treatment of their condition; others require surgery before, or immediately after, birth. Thanks to advances in early diagnosis and medical advances, most babies born with CHD grow up to be adults, living full and active lives. CHD is common. It is estimated that between 5 and 9 in every 1000 babies born in the UK is born with CHD – this is around 5,500 to 6,300 babies each year. These figures will continue to increase if birth rates continue to rise, which leads to an increase in the number of operations and interventional procedures carried out on CHD patients each year.
2. Many congenital heart disease services work together in networks, so that neighbouring hospitals have good systems for referring patients, and for passing information back and forth. Networks help local services to work closely with specialist centres, to ensure that patients receive the care they need in a setting with the right skills and facilities, as close to home as possible.
3. Services are based around a three-tiered model of care with specialist surgical centres (Level 1) managing the most highly complex diagnostics and care, including all surgery and interventional cardiology. At the next level are specialist cardiology centres (Level 2), which provide the same level of specialist medical care as Level 1, but do not provide surgery or interventional cardiology (except for one, specific minor procedure – atrial septal defect (ASD) closures, more commonly known as ‘hole in the heart’ – at selected hospitals treating adults. These Level 2 hospitals focus on diagnosis, plus ongoing care and management of CHD. At Level 3 will be local cardiology services, which are services in local hospitals run by general paediatricians/cardiologists with a special interest in CHD. They will provide initial diagnosis and ongoing monitoring and care, including joint outpatient clinics with specialists from Level 1 and 2 hospitals. These services are commissioned by local Clinical Commissioning Groups (CCGs), and not by

NHS England. We are working with CCG commissioners to address the need for a more integrated approach to care across the three tiers.

4. Anybody who is familiar with the history of these services will know that publication of NHS England's proposals in the summer of 2016 represented the latest milestone in a very long journey, stretching back 16 years, to the publication of the report of a public inquiry into concerns about the care of children receiving complex cardiac surgery at Bristol Royal Infirmary. This was followed by the Safe and Sustainable review, launched by the Department of Health, in 2008. This review set out recommendations for a CHD service based on networks; with clinical standards for all hospitals designated to provide heart surgery for children, and a reduction in the number of NHS hospitals in England providing that heart surgery. Ultimately, these recommendations were not implemented, following intervention with the Secretary of State.
5. We know, from talking to stakeholders, that the failure to implement the recommendations of previous reviews has created uncertainty for patients and staff, and concerns raised during these, and other enquiries, have remained. However, despite the fact that previous reviews have not resulted in a coordinated programme of change, progress has been made. Outcomes for CHD surgery and interventional procedures across England are good, and compare well with other countries. We also know, from talking to patients and their families and carers in particular, that the quality of CHD care delivered in hospitals is very good. We have heard many, many positive stories about individual patient experiences, and recognise that each of those personal testimonies carries real weight, and shapes how people feel about the NHS service which has cared for, or saved the life of, their loved ones.
6. When NHS England took on responsibility for the commissioning of CHD services in 2013, we were aware of the impact that previous reviews had had, as described above, and were told by patients, families, doctors and nurses alike, that the best way to deal with these issues was through the development of service standards, setting out how a good CHD service should be set up, organised and run.
7. We worked with the different groups of stakeholders for more than two years, as part of the New Congenital Heart Disease Review, to create a set of quality and service standards that covered the entire patient pathway, from diagnosis, through treatment, and on into care at home and end of life care, to make sure that every child, young person and adult with CHD, in every part of the country, would receive the same high standard of treatment.
8. Surgeons told us how many operations should be done by each surgeon every year in order to maintain the surgeons' skills. Similarly, specialist doctors and nurses told us what medical care should be available by the bedside of a patient in a critical condition. Patient representatives led the work in developing the standards covering communication, facilities and bereavement. Additionally, for the first time ever, the transition from children's

services to adult services was included in the standards, to ensure that care is truly joined up.

9. The standards have never been considered as an end in themselves. They were developed in the full expectation that their implementation at every hospital in the country providing CHD services would be the means by which our work would be delivered, i.e:
 - securing best possible outcomes for all patients – not just reducing the number of deaths, but reducing disability caused by disease, and improving people's quality of life;
 - tackling variation, so that services are consistent in meeting standards, each of them offering 24/7 care, seven days a week, as part of a nationally resilient service;
 - improving patient experience, including provision of better information for patients, plus more consideration of access and support for families when they are away from home.
10. This review has been underpinned by principles of openness and transparency, and a need to engage as widely as possible, bringing patients, families, carers, patient representatives, and clinicians together, in the joint pursuit of an effective and equitable solution, in the interests of patients now, and in the future. Consensus across all groups was achieved on the content of the standards, and it became clear that NHS England, as the sole national commissioner of CHD services had a unique opportunity to drive service improvement, and reduce variation in access and quality, by implementing a set of nationally-agreed standards, governing a truly national service.

The case for change

11. The standards describe how to deliver CHD services of the very highest quality. We believe that implementation of these standards is the only way to ensure that patients are able to access care delivered to the same high standards, regardless of where they are treated. There is currently some variation as to where individual hospitals lie in meeting the standards, so care may vary, depending on where in England you access services.
12. We know, from talking to patients and their families/carers, that some people consider the care that they and their loved ones have experienced at a hospital to be the best there is. We do not wish to detract from that very personal experience, but it is not the same for everyone, and that simply is not fair.
13. Once all hospitals are meeting the standards, we can ensure that patients with CHD will be receiving the same levels of high quality care. For patients, and their families and carers, this means:
 - higher levels of support from specialist nurses and psychologists;

- improved communication and information, so that newly diagnosed patients have a better understanding of their condition; the care provided; treatment options; and how to take part in decisions about their own care;
- better managed transition from children's to adult services;
- improved palliative and end of life care, with specific standards focused on support for bereaved families and carers.

The above were all aspects of care which patients and patient groups told us were important, and are examples of the highest possible quality care, which we think should be available to all CHD patients, regardless of which hospital they attend.

14. For clinicians, and their teams, the broader benefits of meeting the standards will include:

- hospitals caring for people with CHD have the right staffing and skills mix, with no fewer than minimum staffing and activity levels, which support the maintenance of skills and expertise;
- improved resilience and mutual support provided by a networked model of care;
- enhanced opportunities for developing sub-specialisation;
- enhanced training and mentorship; sharing learning and skills; quality assurance and audit;
- elimination of isolated and occasional practice – this is when small volumes of surgery and interventional cardiology are undertaken in hospitals that do not offer specialist expertise in this field.

15. What we have described here are tangible benefits, things that will really make a difference to the care of patients with CHD, and to the teams caring for them. We believe that every patient receiving care for CHD should expect these highest possible standards of care, regardless of where they receive their treatment.

“From my perspective there are three main clinical advantages for having high-volume congenital cardiac surgical centres. Firstly, as an individual surgeon the more I do the better I become. There's lots of evidence for this in other surgical specialties, in particular showing that high volume centres reduce the number of post-operative complications and improving long-term quality of life. This also works for the whole team providing the care: the more the team does, the better they become, and this gives a huge opportunity for people to learn from each other in a large multidisciplinary setting.

And finally, higher surgical volumes enable specialisation in areas such as neonatal, congenital and device treatments. Importantly, these are all important for the next generation of surgeons coming up through the system - they will be less experienced when they become consultants than in the past - and they will need to fit into a large team to nurture them into becoming the surgeons of the future.”

**Mr Martin Kostolony - Head of Clinical Service - Cardiothoracic Surgery,
Great Ormond Street Hospital for Children NHS Foundation Trust**

16. Apart from the benefits achieved by meeting the standards themselves, there are some specific additional benefits associated with implementation of the standards:

1.1 Ending uncertainty

17. The long history of repeated reviews of CHD services has created uncertainty within the specialty, damaging relationships between hospitals; harming recruitment and retention of specialist staff; and reducing the resilience of services. Continued uncertainty affects recruitment and retention of congenital heart disease surgeons, a group in short supply and subject to international demand.
18. The 2014 report on CHD services at Leeds Teaching Hospitals NHS Trust¹ recommended that NHS England should act to dispel the “almost morbid sense of spectatorship and foreboding that hangs over these services”. Clear resolution is now needed to bring the stability the service needs to move forward.

¹ <https://www.england.nhs.uk/wp-content/uploads/2014/.../leeds-review.pdf>

1.2 Ending occasional practice

We have been calling for standards for adult congenital heart disease for many years and it is excellent that this has finally been achieved. Never before have the services for adults been designated and therefore occasional practice has happened. The introduction of these standards has already mainly eliminated that occasional practice and I am confident it will be a thing of the past, providing a much safer level of care and that is what these standards are all about.

Michael Cumper, Vice President, Somerville Foundation

19. Occasional and isolated practice (small volumes of surgery and interventional cardiology undertaken in hospitals without sufficient specialist expertise) has been a big concern, particularly for charities representing adults with CHD.
20. We asked every non-specialist hospital, where the data showed CHD procedures had taken place, to either cease occasional practice or take steps to meet the requirements of the standards, including minimum volume requirements. Most of these hospitals confirmed that the apparent occasional practice was due to coding errors. In other cases the practice had already stopped or steps were being taken to move this activity to an appropriate specialist Level 1 or Level 2 hospital. Some hospitals confirmed that they wished to be considered as specialist medical centres (Level 2), so we assessed them against the relevant standards
21. Occasional practice has largely been addressed through this process. Where the issue has not yet been resolved, it will be followed up by NHS England's regional teams.

1.3 Resilient, sustainable services

“We know that many people are very nervous about how the standards are moved forward, we must acknowledge those fears and support patients and families affected by any change but if we do not start to implement the new standards soon we will start to see a deterioration in the service.

We know that there are a growing number of children with highly complex conditions travelling through care. It is really important to make sure that there is a really strong service for them from the beginning of their lives, through their childhood and into adult services. They deserve nothing less.

Suzie Hutchinson, Chief Executive and Service Lead, Little Hearts Matter

22. Larger hospitals with bigger teams, more effectively networked with other hospitals, will be more resilient, providing an assurance of full 24-hour, seven- day care and a greater ability to cope with challenging events, for example the loss of a surgeon. We know, from talking to clinicians, that they feel best able to carry out their work when they are part of a team. Surgeons need the support of fellow surgeons, to provide cover for annual leave, and to step in when colleagues fall sick. They also need the support of an expert team around them. It is this kind of set-up that builds resilience in a service, and ensures that patients get access to the best possible care when they need it. The only way we can build this resilience is if we implement the standards.
23. The standards are – rightly – challenging, and it was acknowledged by the NHS England Board, when they were adopted, that it would be difficult for all hospitals to meet them, unless changes were made to the way in which those hospitals work. This is why the timeline for meeting some of the standards differs, as it was recognised that meeting some standards would take longer than others. For instance, the co-location of children’s CHD services with other children’s services might require physical changes to a hospital’s structure or layout.
24. Our proposals are described in detail on page 15. If they are implemented, in future, CHD services will only be provided by hospitals which already meet the standards required, or are likely to meet the standards within required timeframes as a result of the improvement plans they are putting in place.

“We fully support these standards. NHS England must ensure that the standards are applied for the benefit of patients, by ensuring that expertise is concentrated where it is most appropriate. The proposals put forward by NHS England in July 2016 should improve patient outcomes and help address variations in care currently provided”.

Royal College of Surgeons and the Society for Cardiothoracic Surgery (SCTS)

Proposals for consultation

25. At the heart of our proposals is our aim that every patient should be confident that their care is being delivered by a hospital that is able to meet the required standards. In order to achieve this, we propose that in future, NHS England will only commission CHD services from hospitals that are able to meet the standards within the required timeframes.
26. Three specific standards are relevant to our proposals:
 - Surgeon working requirements – the number of surgeons at each hospital, and the number of operations they each perform.
 - o The standards require that, for 2016, surgeons work in teams with a minimum of three surgeons, and in teams of at least four surgeons by April 2021. CHD surgeons are each required to carry out no fewer than 125 congenital heart operations a year (the equivalent of about three operations a week), averaged over a three-year period;
 - Service interdependencies, or co-location – the other services CHD patients depend upon, and which need to be on the same hospital site.
 - o The standards require that specialist children’s cardiac services are only delivered in settings where a wider range of other specialist children’s services are also present on the same hospital site. The standards require that certain paediatric specialties are within a 30-minute call to bedside range for April 2016, and co-located on the same site as children’s CHD services by 2019.
 - Interventional cardiology
 - o The standards require that for 2016, interventional cardiologists work in a team of at least three, and by April 2017 in teams of at least four, with the lead interventional cardiologist carrying out a minimum of 100 procedures a year, and all interventional cardiologists doing a minimum of 50 procedures a year.

27. The proposals on which we are consulting are, therefore:

Level 1 (surgical)

Proposal:

Surgery and interventional cardiology for adults would cease at **Central Manchester University Hospitals NHS Foundation Trust**. Central Manchester does not currently undertake surgery for children.

28. The standards require surgeons to be working in teams of three by April 2016, and in teams of four by April 2021. They also require each surgeon to be carrying out a minimum of 125 operations a year. Central Manchester University Hospitals NHS Foundation Trust has only one congenital heart surgeon, carrying out fewer than 125 congenital heart operations a year.

29. Interventional cardiology for adults at Central Manchester University Hospitals NHS Foundation Trust is already performed primarily by interventional cardiologists from Alder Hey Children's Hospital NHS Foundation Trust who travel to Manchester to see patients. Under our proposals, adult patients requiring surgery or interventional cardiology, who currently receive this level of care at Central Manchester University Hospitals NHS Foundation Trust, would be most likely to go to Liverpool Heart and Chest Hospital NHS Foundation Trust for surgery and/or interventional cardiology. All other care, with the exception of surgery and interventional cardiology, would continue to be provided in Manchester.

Proposal:

Surgery and interventional cardiology for children and adults would cease at **Royal Brompton and Harefield NHS Foundation Trust**.

30. The Royal Brompton and Harefield NHS Foundation Trust currently provides surgery and interventional cardiology for children and adults from the Royal Brompton Hospital. The agreed standards require a number of other specified services for children to be co-located by April 2019 on the same hospital site as surgical and interventional cardiology for children are provided from. The Royal Brompton Hospital does not have all of those required paediatric specialties on site, and does not have firm plans to do so. (These services are currently provided to the Royal Brompton's patients by Chelsea and Westminster NHS Foundation Trust). The Royal Brompton is therefore not able to meet that standard.

31. We are continuing to explore two avenues by which the Royal Brompton could continue to provide some, or all, Level 1 services by meeting all of the required standards:
- The hospital trust is exploring ways in which the paediatric co-location standards could be met by the required deadline of April 2019;
 - NHS England has raised with the Royal Brompton Hospital the potential for it to continue to provide Level 1 adult CHD services, including surgery. This would involve the hospital partnering with another Level 1 CHD hospital in London, that meets the required standards and that cares for children and young people. To date, the Royal Brompton Hospital has indicated that it does not support this approach, but it has not said that it would refuse to treat adults alone.
32. If a solution cannot be found then, under our proposals, children and adults who would currently be most likely to undergo CHD surgery and/or interventional cardiology at Royal Brompton and Harefield NHS Foundation Trust would still be able to receive their care in London, but would be most likely to go to Great Ormond Street Hospital for Children NHS Foundation Trust, Bart's Health NHS Trust or Guy's and St Thomas' NHS Foundation Trust if they required surgery and/or interventional procedures.

Proposal:

Surgery and interventional cardiology for children and adults would cease at **University Hospitals of Leicester NHS Trust**.

33. University Hospitals of Leicester NHS Trust performed 326 surgical procedures in 2015/16 which does not meet the minimum number of cases required by the standards. The hospital trust states that it is very close to meeting the requirement for an overall caseload of 375 operations for 2016/17, and has a growth plan in place to reach an overall caseload of 500 operations by 2021. NHS England does not consider these projections to be sound, and needs to see a more robust plan to support delivery of 375 cases now, and 500 cases by 2021. As of mid-January 2017, this plan has not been provided to us by the hospital trust.
34. The CHD service in Leicester lacks the capacity to deliver a full range of services as a fully independent centre, receiving clinical support for complex cases from surgical and cardiology colleagues in Birmingham. It has also transferred cases to Great Ormond Street Hospital for Children NHS Foundation Trust, and to Newcastle Hospitals NHS Foundation Trust. At this point in time, it is difficult to see how the hospital trust will be able to build up its resilience to ensure sustainable services for the future.

35. Similarly, University Hospitals of Leicester NHS Trust is at the margins of having enough interventional cardiology activity for its proposed team of three interventionists to meet the requirements of a lead interventionist carrying out a minimum of 100 procedures a year, and all interventionists doing a minimum of 50 procedures a year. While the hospital meets the April 2016 requirements, we need to see a credible plan which supports the development of a team of four interventionists by April 2017, and the associated activity that goes with that team.
36. Glenfield Hospital, which is part of University Hospitals of Leicester NHS Trust, and which is where the CHD service is located, has access to 24/7 paediatric gastroenterology and paediatric surgery, but does not have either of these services on site. The hospital originally proposed to achieve co-location of relevant paediatric specialties with its paediatric CHD service by 2019, through plans to build a new children's hospital, bringing all children's specialist services together on one site. However, the Trust has since developed an alternative plan that would involve moving paediatric cardiac services to the Leicester Royal Infirmary by 2019. We consider that the Trust's proposal to move paediatric cardiac Level 1 services to the Infirmary site would allow it to achieve full compliance with the co-location requirements, although the Trust would need to ensure that this move is achieved by the required deadline.
37. If we do not receive assurance that the hospital trust will meet the required standards then, under our proposals, children and adults who would currently be most likely to receive surgery and/or interventional cardiology at University Hospitals of Leicester would be likely to choose to receive their care at either Birmingham Children's Hospital NHS Foundation Trust or University Hospitals Birmingham NHS Foundation Trust. Some current Leicester patients would be likely to choose to receive care from Leeds Teaching Hospitals NHS Trust, if this was closer for them than Birmingham.
38. If our proposals are implemented, University Hospitals of Leicester NHS Trust could continue to offer Level 2 specialist medical services to children and adults, and we continue to discuss this option with the hospital trust. If the hospital carried on offering Level 2 CHD services, then the vast majority of patient care would continue to be offered in Leicester, and patients would only be required to travel elsewhere if they required surgery and/or interventional catheters. We continue to discuss this option with University Hospitals of Leicester NHS Trust.
39. It is important to note that change, such as that proposed above, has already taken place in CHD services without any adverse effects on patients. In 2010, Oxford stopped providing CHD surgery following the deaths of a number of babies. The hospital trust was carrying out more than 100 cases a year up until that time. Surgery was moved to Southampton. Surgeons employed at Oxford moved elsewhere, and there was no impact on other members of staff, who were all redeployed elsewhere within the hospital trust. Oxford is now part of a formal children's network, which means that patients can choose either Southampton or a hospital in London for surgery and/or

interventional catheters, but can have all of the rest of their CHD care in Oxford. One of the knock-on effects of the change was that children requiring specialist surgery are now transferred to Southampton, whilst general children's surgery at Oxford has increased, now that it has more capacity.

40. New patients accept referral to Southampton for surgery/interventional catheters as the norm, and, while some patients would prefer that Oxford were still offering Level 1 CHD surgery, the hospital trust Board made it clear that it would not be appropriate for the hospital to continue to provide CHD surgery. We do not use the Oxford illustration in any way to detract from the concerns that you might have about our proposals, but it does demonstrate that change such as this can take place with minimal impact, if well managed.

Surgery and interventional cardiology for adults and children would continue at **Newcastle upon Tyne Hospitals NHS Foundation Trust**.

41. While we are clear that all hospitals providing CHD services must meet the national CHD standards, we have had to propose a time-limited exception, or derogation, in the case of one particular hospital. Newcastle upon Tyne Hospitals NHS Foundation Trust does not meet the 2016 activity requirement and is unlikely to be able to meet the 2021 activity requirement. It also does not meet the 2019 paediatric co-location requirements or currently have a realistic plan to do so by April 2019. The CHD service for both children and adults is located at the Freeman Hospital, which is primarily an adult acute hospital. Relevant children's specialties – paediatric surgery, nephrology and gastroenterology – are located at the Great North Children's Hospital, which is part of the same hospital trust, but is not located on the same site. While the hospital trust meets the co-location requirement for 2016, i.e. bedside access within 30 minutes, it is unlikely to meet the full co-location requirement for 2019 for children's CHD surgery to be on the same site as other children's specialist services.
42. Newcastle upon Tyne Hospitals NHS Foundation Trust has a unique, strategic position in the NHS in England in delivering care for CHD patients with advanced heart failure, including heart transplantation and bridge to transplant. Advanced heart failure amongst people with CHD is increasing as a result of increased life expectancy, and treatment for people with this condition is dependent on CHD surgeons. Adult CHD patients with end stage heart failure have limited access to heart transplantation, and the unit in Newcastle is recognised as delivering more care to this group than other transplant centres nationally. This service is intimately connected to the CHD service and can only be delivered at a hospital providing Level 1 surgical services. No other provider currently has this capability so, while in principle it would be possible to commission these services from an alternative provider, the learning curve would be long and initially outcomes would not be as good.

43. In addition, the hospital trust is one of only two providing paediatric heart transplantation for the UK (the other is Great Ormond Street Hospital for Children NHS Foundation Trust in London).
44. While Newcastle does not meet these required standards now and is unlikely to be able to do so within the required timeframe, its role as one of only two national providers of critical heart transplantation and bridge to transplant services means that we need to consider retaining services at Newcastle despite the fact that it does not meet all the standards at present and is unlikely to do so within the required timeframes. The surgeons who perform CHD operations are the same surgeons carrying out heart transplants. If CHD surgery were moved elsewhere, the transplantation service could not be replaced in the short term without a negative effect on patients. For this reason, we are proposing to retain CHD services at Newcastle upon Tyne Hospitals NHS Foundation Trust.
45. This does not mean that change at Newcastle upon Tyne Hospitals NHS Foundation Trust will not happen in the longer-term. The hospital trust is required to meet the standards in the same way as all of the other Level 1 surgical centres. Timeframes for doing this may differ, but we will be working closely with the hospital trust to ensure that patients receiving CHD care at Newcastle upon Tyne Hospitals NHS Foundation Trust are not compromised in any way.
46. If our proposals were implemented, this would mean that, in future, Level 1 CHD surgical services would be provided by the following hospitals:
- **Alder Hey Children's Hospital NHS Foundation Trust** (children's services) and **Liverpool Heart and Chest Hospital NHS Foundation Trust** (adult service)
 - **Birmingham Children's Hospital NHS Foundation Trust** (children's services) and **University Hospitals Birmingham NHS Foundation Trust** (adult service)
 - **Great Ormond Street Hospital for Children NHS Foundation Trust** (children's services) and **Barts Health NHS Trust** (adult service)
 - **Guy's and St Thomas' NHS Foundation Trust** (children's and adult services)
 - **Leeds Teaching Hospitals NHS Trust** (children's and adult services)
 - **Newcastle upon Tyne Hospitals NHS Foundation Trust** (children's and adult services)
 - **University Hospitals Bristol NHS Foundation Trust** (children's and adult services)
 - **University Hospital Southampton NHS Foundation Trust** (children's and adult services)
47. Changes are also proposed to the provision of Level 2 specialist medical CHD care. In most cases, these proposals involve very small numbers of patients who might be impacted by that change. Whilst those changes are not the subject of this formal public consultation, we are very keen to talk to patients, their families/carers, and staff at affected hospitals, to better

understand the impact of any proposed change, and to hear their views about how we might limit that impact. We will be offering opportunities for stakeholders to talk to us about our proposals in relation to Level 2 services during this consultation period, so that we can discuss how we might support them to adjust to any changes in their care. You can find out about events in your area by visiting our [Consultation Hub](#)

48. If implemented, following our engagement with stakeholders, our proposals would result in the following changes at those hospitals that completed Level 2 self-assessments:

Level 2 (specialist medical services)

Proposals:

Specialist medical care and interventional cardiology should cease at **Blackpool Teaching Hospitals NHS Foundation Trust**

Specialist medical care and interventional cardiology should cease at **Imperial College Healthcare NHS Trust**

Specialist medical care and interventional cardiology should cease at **Nottingham University Hospitals NHS Trust**

Specialist medical care and interventional cardiology should cease at **Papworth Hospital NHS Foundation Trust**

Specialist medical care and interventional cardiology should cease at **University Hospital of South Manchester NHS Foundation Trust**

49. We are continuing to work with Papworth Hospital to consider whether it may be possible for the hospital trust to meet the required standards within the timeframes. At mid-January, there was a significant shortfall in terms of meeting the standards and a robust plan to address this had not been developed. Progress is being made, however. If the hospital trust can demonstrate that it is meeting the standards, or has a robust plan to do so, then we will review our proposal that Level 2 CHD services should cease to be provided at Papworth.

50. If our proposals for the hospitals listed above are implemented, this would mean that, in future, Level 2 CHD services would be provided by the following hospitals:

- **Brighton and Sussex University Hospitals NHS Trust** (adult service)
- **Central Manchester University Hospitals NHS Foundation Trust** (children's services)

- **Norfolk & Norwich University Hospitals NHS Foundation Trust** (adult service)
- **Oxford University Hospitals NHS Foundation Trust** (children's and adult services)

51. We continue to explore the potential for the provision of Level 2 specialist medical services at Central Manchester University Hospitals NHS Foundation Trust and University Hospitals of Leicester NHS Trust.

How our proposals were developed

1.4 Meeting the standards

52. The standards were agreed by NHS England's Board in July 2015, following a 12-week period of [public consultation](#). Once agreed, we started to look at how we might put the standards into practice. Patients and their families/carers, and patient representatives, told us early on that, while it was a good thing to have standards, they only really mattered if we ensured that they were met. Otherwise, they were a waste of time. That message is really important and has influenced our thinking throughout this process.
53. Initially we looked at whether the hospitals themselves, by working more closely together, could find new ways of working that would mean that the standards could be met across the country. However, this did not provide us with a solution that would give us a truly national CHD service.
54. It was decided, therefore, to look at each hospital individually, and ask them to complete a self-assessment to assess their compliance against a specific number of the standards. In deciding on which standards to focus on at this stage, we took advice from senior CHD clinicians, and from NHS England's Quality Surveillance Team, which has particular expertise in peer review. Collectively, the advice was to focus on those standards considered to be most closely and directly linked to measureable outcomes, and to effective systems for monitoring and improving quality and safety. This exercise was launched in January 2016, focusing on 14 specific requirements which covered 24 of the standards relating to children's care, as well as the corresponding adult standards.
55. The standards came into force on 1 April 2016. Each standard has an associated timeline for implementation, some of which are immediate, from April 2016, and some of which are longer. The timelines were set by NHS England's Congenital Heart Services Clinical Reference Group (CRG), which is made up of clinicians, patient representatives, commissioners and other experts, who felt that some of the changes required to meet the standards, such as the co-location of children's CHD services alongside other specialist children's services, could not be made overnight. They were also agreed by the NHS England Board in July 2015.

56. We asked each hospital whether it was able to meet the April 2016 standards. Where hospitals indicated that they could not meet that initial timescale, we set out development requirements to see them achieved by the end of the financial year (end of March 2017). These development requirements are being closely monitored via NHS contracts. We did not set out development requirements for Central Manchester University Hospitals NHS Foundation Trust, even though the hospital's assessment indicated that it was unable to meet the standards now, or in the future, as there was mutual recognition that the hospital would not be able to meet the requirements within the stated timeframe and would instead work with us to achieve any necessary changes in service delivery.

57. We considered two aspects of the standards to be of particular importance in terms of not just service quality, but for ensuring the resilience and safety of CHD services both for now, and for the future:

- Surgeon working requirements – the number of surgeons at each hospital, and the number of operations they each perform.

The standards require that, for 2016, surgeons work in teams with a minimum of three surgeons, and in teams of at least four surgeons by April 2021. CHD surgeons are each required to carry out no fewer than 125 congenital heart operations a year (the equivalent of about three operations a week); and

- Service interdependencies, or co-location – the other services CHD patients depend upon, and which need to be on the same hospital site. The standards require that specialist children's cardiac services are only delivered in settings where a wider range of other specialist children's services are also present on the same hospital site. The standards require that certain paediatric specialties are within a 30-minute call to bedside range for April 2016, and co-located on the same site as children's CHD services by 2019.

“125 really is a minimum number. It equates to three operations a week, per surgeon. Practice makes perfect, and 125 operations a year is considered the minimum to ensure that a newly appointed consultant surgeon acquires the skills they need across the differing surgical techniques. Some of the operations we do only come up once or twice a year, so ideally you would be doing at least four operations per surgeon each week, as that would result in 170-200 operations a year.

A surgeon doing too many, or too few, operations is not good. Either way can result in a poor performance when it matters, either through fatigue or a loss of skills. Individuals will, of course, vary in capability, but we must set a minimum standard in order to ensure that a surgeon has an acceptable level of skill refined and maintained through regular practice. Centres need to oversee the distribution of the work fairly, taking account of any specialist skills, to ensure that all surgeons have the opportunity to work at optimum levels.”

Professor David Anderson, Consultant Heart Surgeon and Professor of Children’s Heart Surgery, Guy’s and St Thomas’ NHS Foundation Trust, and President of the British Congenital Cardiac Association (BCCA)

58. Each set of returns from the hospitals was initially evaluated at a regional level by NHS England’s specialised commissioners, and then by a national panel, comprising patient representatives, clinicians, and commissioners, to ensure consistency of approach. The role of the regional and national panels was to assess each hospital’s ability to meet the standards, based on the evidence submitted by that hospital. A [report](#) of the panel’s work, and its assessments, was published by NHS England in July 2016.
59. In summary, the national panel found that as of May 2016, none of the hospitals providing CHD services met all of the standards tested. This was not unexpected, as the standards were aimed at ensuring that all services were brought up to the level of the best of existing practice. They were intended to be stretching, but realistic, and were focused on driving improvement.
60. The panel found that, with respect to Level 1 surgical services:
- Two hospitals – Birmingham Children’s Hospital NHS Foundation Trust and Great Ormond Street Hospital for Children NHS Foundation Trust – were very close to meeting all of the requirements, with robust and credible plans to meet the rest within the required timescale, i.e. end of March 2017. They were rated green/amber;

- Seven hospitals² were likely to meet all of the requirements within the required timescale with development of their plans. They were rated amber;
- Three hospitals were unable to meet the requirements now, and were unlikely to be able to do so within the required timeframe. They were University Hospitals of Leicester NHS Trust, Newcastle Hospitals NHS Foundation Trust, and the Royal Brompton and Harefield NHS Foundation Trust. They were rated amber/red;
- One hospital – Central Manchester University Hospitals NHS Foundation Trust – was not able to meet the requirements now, and was unlikely to be able to do so within the required timeframe. Manchester has fewer than 100 operations annually undertaken by a single surgeon, with interventional cardiology provided on a sessional basis. Appropriate 24/7 surgical or interventional cover is not provided. The national panel considered these arrangements to be a risk, and rated the centre red.³

61. As the national commissioner of congenital heart disease services, it was the responsibility of NHS England to consider the information provided to it by the national panel, and for deciding what action, if any, should be taken on the basis of that information.

62. The Specialised Services Commissioning Committee met at the end of June 2016, and considered the information provided to members by the national panel. The committee recognised that NHS England needed to take action to ensure that CHD patients, wherever they live in the country, have access to the same safe, stable, high quality services.

63. It was proposed that in future, NHS England would only commission CHD services from hospitals that are able to meet the full set of standards within the required timeframes (with the time-limited exception of Newcastle upon Tyne Hospitals NHS Foundation Trust, for the reasons set out in paragraphs 41- 45), and decided that, subject to appropriate public involvement and/or public consultation, a change in service provision would be appropriate. On the basis of the information received, NHS England then published its proposals on 8 July 2016.

Potential impact of implementing our proposals

64. We know, from talking to patients and their families, and carers; to clinicians and other hospital staff, and to other stakeholders, in the run-up to this consultation, that there are concerns about our proposals, and how implementation of them might affect them personally, or their jobs, or services, and the hospitals as a whole. We acknowledge that these are real

² Alder Hey, Leeds, University Hospitals Birmingham, Barts, Guy's & St Thomas', Bristol, and Southampton

³ Individual assessment reports for each of the CHD provider hospitals were published in September 2016 and can be found at <https://www.england.nhs.uk/commissioning/spec-services/npc-crg/chd/applying/>

concerns and we have listened carefully to all those who have spoken, or written to us during the pre-consultation period. We have tried to answer some very challenging questions as openly and honestly as we could.

65. To better understand these issues, we have undertaken a detailed impact assessment, looking at how, if our proposals are implemented, they might be delivered in practice, and to identify the consequences for patients, providers, commissioners and others.
66. All hospitals providing Level 1 and Level 2 CHD services were asked to review their services in light of NHS England's proposals. Their responses were considered first by NHS England's regional teams, and then a national panel was drawn together to review those submissions. The findings of that panel's review are summarised at Appendix B. A full impact assessment has been published alongside this document.

Pre-consultation engagement and involvement

67. Once the proposals were published, in July 2016, we entered a pre-consultation phase, which ran from July, right up until the start of formal consultation in February 2017.
68. The over-riding objective for NHS England during this period was to engage with hospitals providing CHD services – in particular, with those potentially affected by our proposals – to explore what the key issues were for them, in preventing them from meeting the standards, either for delivery in 2016, or the longer-term. Our aim throughout has been to maintain an open dialogue with the providers, so that we could work together to try and find alternative solutions to meeting the standards.

1.5 Engagement activity

69. Since July 2016, our regional and national teams have met regularly with managers and clinical teams at those hospitals currently providing CHD services and, in particular, with those whose current service will be affected if our proposals were to be implemented. As well as these more regular meetings, we also visited nine hospital trusts to talk specifically about our proposals, meeting with clinicians and managers, and touring the CHD facilities, including paediatric critical care and transplant units. Between July 2016 and January 2017 we visited:
- Royal Brompton and Harefield NHS Foundation Trust
 - University Hospitals of Leicester NHS Trust
 - Guy's and St Thomas' NHS Foundation Trust
 - Birmingham Children's Hospital NHS Foundation Trust
 - Great Ormond Street Hospital for Children NHS Foundation Trust
 - Barts Health NHS Trust
 - Newcastle Hospitals NHS Foundation Trust
 - University Hospitals Birmingham NHS Foundation Trust

70. In addition to talking to the hospital clinicians and managers, we have also taken the opportunity – whenever possible – to meet with staff on the CHD units, as well as with patients, families, carers and patient representatives. We met with patients, carers and patient representatives in Leicester and Newcastle-upon-Tyne, and attended a meeting of the North West Adult Congenital Heart Disease Forum in Liverpool. We will be meeting with patients and their families/carers and representatives in London during the consultation period.
71. We have also met with MPs, particularly those whose constituencies include one of the CHD units potentially most affected by our proposals, and have provided a written briefing about our proposals to all local authorities across England, and attended Overview and Scrutiny Committees and Health and Wellbeing Boards where invited.
72. We have responded to a significant volume of correspondence relating to our proposals for CHD services during this period, assessing and re-assessing information provided by the hospitals; answering Parliamentary correspondence and Freedom of Information requests, as well as more general correspondence from stakeholders associated with the hospitals who wrote to us expressing concerns and/or asking for more information about our proposals.
73. The discussions during the pre-consultation period were dominated by the theme of how an individual hospital might achieve compliance with the standards, as well as the level of impact which our proposals – if implemented - might have on a hospital, as well as on its staff and, most importantly, its patients and their families.

Consultation

1.6 Why are we consulting?

74. We know, from talking to patients, carers, patient representatives, hospital staff, and other stakeholders, that our proposals have caused some concern in certain areas of the country. We have tried, during the pre-consultation period, to address those concerns as best we can. However, we know that many of you remain concerned about what the future might look like in terms of your care, or that of your loved ones, or where you carry out your work.
75. Consultation is not a vote on whether or not our proposals should be implemented. Instead, it provides an opportunity for us to listen to people's views about our proposals, so that we can take them into account before any commissioning decisions are made. We have set out in this document some of the areas where we think our proposals could impact, or which people have told us could be impacted e.g. travel times for patients, and other hospital services. There may be other areas that we have not thought of, or alternative ways of meeting the standards which have not yet been explored. We need to hear about those now.

76. Consultation is open to everyone, not just those who have direct experience of CHD services.
77. The consultation is being run in accordance with [Cabinet Office guidance](#)
78. While our focus is on services for patients who are resident in England, we recognise that there are children and adults living in Wales, Scotland, and Northern Ireland, who use CHD services in England. We have agreed with our colleagues in the devolved nations that they will help support our consultation in making people aware of the consultation and how they can respond to it.
79. It is important that as many people as possible, with an interest in CHD services in England, have opportunity to contribute their views about the future of these important services.

1.7 How can I make my views known?

1.7.1 How to get involved

80. During consultation, there will be a number of opportunities for you to have your say about the future commissioning arrangements for CHD services.
81. Information about the different ways in which you can have your say is available at the NHS England [Consultation Hub](#). Consultation materials are also available here. We will be running a number of face-to-face events during the consultation period, which will enable us to tell you more about our proposals and provide you with an opportunity to ask us questions. We will also support charities, patient groups, clinicians, and provider hospitals to run their own events, and can provide materials to support this activity if required. To find out where, and when, your nearest event is taking place, and how to register to attend, please visit the [Consultation Hub](#)
82. Hard copies of the consultation document and response form can be made available. If you require a hard copy, please email us at england.congenitalheart@nhs.net
83. We will also be holding a number of webinars throughout the consultation period, which will enable you to learn more about our proposals, and ask us questions, without having to travel. Details about all of the forthcoming webinars, and how to join them, are available at the [Consultation Hub](#).

1.7.2 How to let us know your views

This is an opportunity to set the standards for the next generation. It has clearly taken a long time, and a lot of discussion, to get to where we are now.

There is a real opportunity to have standards that have been nationally agreed; that have been agreed by clinicians; by providers; by patient groups; and set up services that will benefit children and adults with congenital heart defects over the coming generations.

Jon Arnold
Chief Executive, Tiny Tickers

84. Consultation will run from Thursday 9 February 2017 to Monday 5 June 2017.

85. The full list of consultation questions can be found at Appendix A. For your response to be included in the analysis of this consultation, you need to ensure that we receive your response no later than 23.59 on Monday 5 June.

86. The online response form is located at our [Consultation Hub](#). Alternatively, you can send your response (whether on a response form, or as a letter) to:

Beverley Smyth
 Specialised Commissioning, NHS England
 4N08| Quarry House| Quarry Hill | Leeds | LS2 7UE

When you are replying, please let us know whether you are replying as an individual or whether your views represent those of an organisation. If you are replying on behalf of an organisation, please make it clear who the organisation represents and, where appropriate, how the views of the members were collated.

1.8 What happens next?

87. We have asked an independent company - Participate - to collate all of the responses we receive to the consultation and to produce an analysis of what respondents have said. The analysis will be published in due course and will include information about the number, type and other characteristics of the responses, giving us a good picture of the views expressed.

88. In coming to a decision, NHS England will consider the responses to the consultation and will adjust its proposals if we consider it appropriate to do so. We will take into account and balance all the main factors, including affordability, impact on other services, access and patient choice. Our

recommendations will then be considered by the relevant committees before a final decision is taken by the NHS England Board.

Appendix A: Consultation Questions

It is important, before answering the questions in our consultation survey, for you to ensure that you have read all of the information provided about each of the individual CHD provider hospitals potentially affected by our proposals, so that you understand the potential impact of our proposals on those hospitals, and the way in which service delivery might change, should our proposals be implemented.

Meeting the standards

1. In what capacity are you responding to the consultation?

- ☐ Current CHD patient
- ☐ Parent, family member or carer of a current CHD patient
- ☐ Member of the public
- ☐ CHD patient representative organisation
- ☐ Voluntary organisation / charity
- ☐ Clinician
- ☐ NHS provider organisation
- ☐ NHS commissioner
- ☐ Industry
- ☐ Other public body
- ☐ Other

If other – please specify:

2. In which region are you based?

- ☐ Not applicable/regional/national organisation
- ☐ England - North East
- ☐ England - North West
- ☐ England - Yorkshire and The Humber
- ☐ England - East Midlands
- ☐ England - West Midlands
- ☐ England - East of England
- ☐ England - London
- ☐ England - South East
- ☐ England - South West
- ☐ Scotland
- ☐ Wales
- ☐ Northern Ireland

3. NHS England proposes that in future Congenital Heart Disease services will only be commissioned from hospitals that are able to meet the full set of standards within set timeframes. To what extent do you support or oppose this proposal?

- ☐ Strongly support
- ☐ Tend to support
- ☐ Neither support or oppose
- ☐ Tend to oppose
- ☐ Strongly oppose

4. Please explain your response to question 3.

Three hospital trusts have been assessed as not able to fully meet the standards within set timeframes. NHS England therefore proposes that surgical (level 1) services are no longer commissioned from:

- **Central Manchester University Hospitals NHS Foundation Trust** (adult service)
- **Royal Brompton & Harefield NHS Foundation Trust** (services for adults and children); and
- **University Hospitals of Leicester NHS Trust** (services for adults and children).

5. Can you think of any viable actions that could be taken to support one or more of the trusts to meet the standards within the set timeframes?

Central Manchester University Hospitals NHS Foundation Trust and University Hospitals of Leicester NHS Trust

If Central Manchester and Leicester no longer provide surgical (level 1) services, NHS England will seek to commission specialist medical services (level 2) from them, as long as the hospitals meet the standards for a level 2 service. To what extent do you support or oppose this proposal?

- ☐ Strongly support
- ☐ Tend to support
- ☐ Neither support or oppose
- ☐ Tend to oppose
- ☐ Strongly oppose

Royal Brompton and Harefield NHS Foundation Trust

6. The Royal Brompton could meet the standards for providing surgical (level 1) services for adults by working in partnership with another hospital that provides surgical (level 1) services for children. As an alternative to decommissioning the adult services, NHS England would like to support this way of working.

To what extent do you support or oppose the proposal that the Royal Brompton provide an adult only (level 1) service?

- ☐ Strongly support
- ☐ Tend to support
- ☐ Neither support or oppose
- ☐ Tend to oppose
- ☐ Strongly oppose

Newcastle upon Tyne Hospitals NHS Foundation Trust

7. NHS England is proposing to continue to commission surgical (Level 1) services from Newcastle upon Tyne Hospitals NHS Foundation Trust, whilst working with them to deliver the standards within a different timeframe. To what extent do you support or oppose this proposal?

- ☐ Strongly support
- ☐ Tend to support
- ☐ Neither support or oppose
- ☐ Tend to oppose
- ☐ Strongly oppose

Travel

We know that some patients will have to travel further for the most specialised care including surgery if the proposals to cease to commission surgical (level 1) services from Central Manchester University Hospitals NHS Foundation Trust (adult service); Royal Brompton & Harefield NHS Foundation Trust (services for adults and children); and University Hospitals of Leicester NHS Trust (services for adults and children) are implemented.

8. Do you think our assessment of the impact of our proposals on patient travel is accurate?
- ☐ Yes
 - ☐ No

9. What more might be done to avoid, reduce or compensate for longer journeys where these occur?

Equalities and health inequalities

We want to make sure we understand how different people will be affected by our proposals so that CHD services are appropriate and accessible to all and meet different people's needs.

In our report, we have assessed the equality and health inequality impacts of these proposals. Do you think our assessment is accurate?

- ☐ Yes
- ☐ No

10. Please describe any other equality or health inequality impacts which you think we should consider, and what more might be done to avoid, reduce or compensate for the impacts we have identified and any others?

Other impacts

We want to make sure that the proposed changes, if they are implemented, happen as smoothly as possible for patients and their families/carers so it is important that we understand other impacts of our proposals.

11. Do you think our description of the other known impacts is accurate?

- ☐ Yes
- ☐ No

12. Please describe any other impacts which you think we should consider, and what more might be done to avoid, reduce or compensate for the impacts we have identified and any others?

Any other comments

13. Do you have any other comments about the proposals?

About you

14. Which age group are you in?

- ☐ Under 18
- ☐ 19 – 29
- ☐ 30 – 39
- ☐ 40-49
- ☐ 50 – 59
- ☐ 60-69
- ☐ 70-79
- ☐ 80+
- ☐ Prefer not to say

15. Please indicate your gender

- ☐ Male
- ☐ Female
- ☐ Intersex
- ☐ Trans
- ☐ Non-binary
- ☐ Prefer not to say

16. Do you consider yourself to have a disability?

- ☐ Yes
- ☐ No
- ☐ Prefer not to say

17. Please select what you consider your ethnic origin to be. Ethnicity is distinct from nationality.

White

- ☐ Welsh/English/Scottish/
Northern Irish/British
- ☐ Irish
- ☐ Gypsy or Irish Traveller
- ☐ Any other White
background

Asian or Asian British

- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi
- ☐ Any other Asian
background

Other ethnic group

- ☐ Chinese
- ☐ Any other ethnic group

Mixed

- ☐ White and Black
Caribbean
- ☐ White and Black African
- ☐ White and Asian
- ☐ Any other mixed
background

Black or Black British

- ☐ Black - Caribbean
- ☐ Black - African
- ☐ Any other Black
background

18. Please indicate your religion or belief

- | | |
|--------------------------------------|---|
| <input type="checkbox"/> No religion | <input type="checkbox"/> Muslim |
| <input type="checkbox"/> Buddhist | <input type="checkbox"/> Sikh |
| <input type="checkbox"/> Christian | <input type="checkbox"/> Atheist |
| <input type="checkbox"/> Hindu | <input type="checkbox"/> Any other religion |
| <input type="checkbox"/> Jewish | <input type="checkbox"/> Rather not say |

19. Please indicate the option which best describes your sexual orientation

- ☐ Heterosexual
- ☐ Gay
- ☐ Lesbian
- ☐ Bisexual
- ☐ Prefer not to say

Appendix B: Summary of Impact Assessment

89. The following section summarises key points from the provider impact assessment, and from the equalities and health inequalities impact assessment. It also summarises the likely financial impact on NHS England if our proposals are implemented. Documents setting out this detail in full have been published alongside this consultation document.

1.9 Impact on patients

90. A particular concern for some patients and their families is that they may face longer journeys to access Level 1 CHD services which will be inconvenient, and, they fear, carry a level of risk.
91. Our clinical advisers on NHS England's Congenital Heart Services Clinical Reference Group and Clinical Advisory Panel tell us that true emergencies are very rare. Thanks to advances in antenatal diagnosis, most congenital heart defects are detected while a baby is still in the womb, which enables the mother to give birth either at, or close to, an appropriate hospital providing CHD surgery to children. Even in those cases where CHD is not detected antenatally, and problems are spotted during or after delivery, surgery will often be planned over a period of a few days. If infants need to be moved from one hospital to another for emergency care, then ambulance services, local hospitals and specialist retrieval teams are well able to ensure that patients are stabilised before and during transfer so that the risks of long journeys are negligible.
92. We understand that patients feel safer having a hospital providing CHD surgery close by, but, given the relatively small number of congenital heart disease surgeons in England, this could never be the case for all patients. By implementing the standards, we are able to ensure that patients will receive their surgery in the best possible environment to achieve a good outcome. This is a delicate balance, but we believe that it outweighs the risk of additional journey time, given that emergencies in CHD patients are so rare.
93. Under the proposed model of care different journeys would only be required when patients need to undergo surgery or an interventional or other catheter procedure, and for some admissions. The CRG has advised that the distance travelled for surgery is less important than the distances travelled regularly for ongoing care.
94. Over the course of a lifetime, a person with CHD receives most of their care in an outpatient setting. This should not be affected by the proposed changes since outpatient care can be provided at hospitals providing Level 2 services, those offering Level 3 services, and in outreach clinics. In fact most patient care, apart from admission for a procedure, the pre-admission clinic, and a single follow-up outpatient visit, can be undertaken by Level 2 hospitals.
95. Where patients require more complex diagnostic tests, for most inpatient admissions and for surgery and almost all interventional cardiology procedures, patients and their families/carers will need to travel to a Level 1

hospital. In general we expect that patients would travel to their next nearest Level 1 hospital. For some patients this would mean a similar journey, for others, a longer journey than they would have at present.

96. Our modelling suggests that the impact on average journey times for patients is relatively modest:

- An increase in the average journey time of 11 minutes for adults who use Central Manchester.
- An increase in the average journey time of 14 minutes for children who use Leicester and 32 minutes for adults.
- Average journey times would stay much the same for patients who use the Royal Brompton, as most patients would be likely to continue to receive their care from one of the two other Level 1 hospitals in London.

97. Some patients would of course have longer journeys. However 90% of patients who would currently use University Hospitals of Leicester will still have a journey time of less than 1 hour and 45 minutes to their nearest surgical hospital and this is similar to the national picture and shorter than in some other parts of the country (for example the South West peninsula). Similarly, 90% of patients who would currently use Central Manchester University Hospitals would have a journey time of 64 minutes or less to their nearest surgical hospital, and, of the patients who would currently use the Royal Brompton Hospital, 90% will have a journey time of 85 minutes or less to their nearest surgical hospital.

98. We do, however, recognise that it is difficult for families to support patients in hospital at some distance from home. This is a problem faced by many families already, not just in CHD services, but in many other specialist services, which tend to be provided in a smaller number of hospitals across the country. Because of this, and based on the advice of patients and families, a number of standards were developed to make life easier in this situation - providing better information about where to eat and sleep; better facilities to prepare meals; provision of Wi-Fi; ensuring parking is easily accessible and parking charges affordable; and providing overnight accommodation for parents and carers.

99. Our equalities impact assessment showed that three groups of patients would potentially be more affected by the proposed changes:

- children and young people with CHD because most surgical and interventional procedures (around 7 in 10) occur in children and young people;
- people with CHD and learning disability (LD) because there is a higher likelihood of learning disability amongst people with CHD and people with learning disabilities and especially people with autistic spectrum disorder cope best when things are familiar, so changing settings and changing staff is more of an issue; and

- people of Asian ethnicity with CHD because people who are of Asian ethnicity have a higher incidence of CHD, and may be more likely to have more severe forms of the disease.

100. We will make available materials in different formats to assist people who are part of these groups to participate in the consultation, and will be talking directly to these groups during consultation so that we can better understand the potential impacts of our proposals and any steps we could take to minimise these.

1.10 Impact on CHD services

101. We have modelled the way in which patient flows may change if the proposals are implemented. The modelling assumes that a patient will go to their next nearest surgical hospital. There are clearly limitations to this approach which mean that the results should be treated as a guide rather than an exact representation of what will happen:

Hospital	Additional Operations	% increase
Birmingham - Children's Hospital	180	36%
University Hospitals Birmingham	45	45%
Liverpool Heart and Chest	90	N/A⁴
Leeds - General Infirmary	50	10%
Guy's and St Thomas'	200	40%
Great Ormond Street	220	31%
Barts	85	110%
Southampton	20	5%

102. Under this modelling, there would be little or no change to activity at Newcastle, Alder Hey or Bristol.

103. NHS England is working with the hospitals listed above to ensure that they would be ready and able to manage any increase in activity if the proposals are implemented. In each case we have received an assurance that if the changes go ahead, the hospital would increase its capacity – facilities, equipment, staffing – as necessary to be able to take the extra patients without any fall in service quality or rise in waiting times.

104. The aim of our proposals is to ensure that every provider that we commission to deliver CHD services meets the agreed standards. The standards were set to reflect the best evidence, expert advice and the

⁴ Liverpool Heart and Chest Hospital does not currently undertake CHD surgery.

experience of patients and families about what makes for the best services. We believe that making the changes we have proposed will ensure that no matter where they live, patients and their families will receive excellent care.

105. Services will also be more resilient and sustainable for the future. Under present arrangements services in some hospitals receive significant levels of support from other hospitals. Without this support, at best, these hospitals would not be able to offer their patients a full range of CHD services.
106. Bigger hospitals are generally more resilient. The provision of consistent care at all times of day and night throughout the year is more assured. Bigger teams are better able to cope when one of their number is unavailable or leaves. They are also better able to support the full range of surgical procedures and the development of very specialised practice.

1.11 Impact on other services

1.11.1 Impact on other services: Paediatric Intensive Care

107. Our assessment shows that if our proposals are implemented there will be an impact on paediatric intensive care (PIC) at University Hospitals of Leicester NHS Trust and the Royal Brompton and Harefield NHS Foundation Trust. The proposals affect only adult services at Central Manchester University Hospitals NHS Foundation Trust.

1.11.1.1 University Hospitals of Leicester: Paediatric Intensive Care

108. University Hospitals of Leicester has two paediatric intensive care units (PICUs), one at the Leicester Royal Infirmary and one at Glenfield Hospital (which supports CHD services). While we cannot pre-empt the decisions that NHS England will make on CHD services, or the findings and recommendations of its [Paediatric Critical Care & Specialised Surgery for Children Service Review](#), at this point we expect that Leicester would still provide PICU care for the East Midlands if our proposals are implemented, even if it no longer provides Level 1 cardiac surgery for children. This would be through a single PICU at the Royal Infirmary. We understand that, even if our proposals are not implemented and Leicester continues to provide Level 1 children's cardiac surgery, it plans to move this service from Glenfield to the Infirmary, which would be likely to lead to the closure at the Glenfield anyway (and a corresponding increase in capacity of PICU at the Infirmary). Accordingly, the future of the PICU at Glenfield is uncertain, whether or not NHS England's proposals on CHD are implemented, whereas the provision of the PICU at the Infirmary would be unaffected by the implementation of the proposals. The hospital trust does not share this assessment.

1.11.1.2 Royal Brompton: Paediatric Intensive Care

109. The Royal Brompton's PICU is largely dependent on the hospital's CHD service for children, because CHD accounts for 86% of the admissions. The hospital trust considers that its PICU would no longer be viable if the proposals are implemented, because paediatric cardiac patients are a large

proportion of its work and it would not have enough other patients to stay open. The national panel accepted that this was an accurate assessment. If the PICU at the Royal Brompton were to close, this would be expected to have an effect on their paediatric respiratory services, the only other clinical service for children offered by the Trust (see below).

1.11.1.3 Paediatric Intensive Care: wider implications

110. In order to ensure that there is still sufficient PICU capacity for CHD patients, NHS England will work with the other hospitals where increased paediatric cardiac surgery would be expected if our proposals are implemented (Birmingham Children's Hospital, Great Ormond Street, Leeds General Infirmary, St Thomas' - Evelina Hospital) to undertake the necessary planning and preparation to manage any increase in PICU capacity that would be needed for CHD patients.

111. If our proposals are implemented, there may also be an effect on the wider regional and national PIC system. NHS England has accelerated its Paediatric Critical Care & Specialised Surgery for Children Service Review, which will consider paediatric intensive care provision and paediatric transport. The critical care review aims to bring forward initial work looking at where paediatric critical care capacity is likely to be needed in future, with the first outputs coming through early in 2017. When the Board takes its decisions on the CHD proposals, it will therefore be able to take into account the impact on PIC for CHD patients in the wider regional and national context. The Paediatric Critical Care & Specialised Surgery for Children Service Review will then be able to pick up and deal with any wider implications for changes in PIC consequent upon the proposed CHD changes, as it considers the required capacity and distribution of PICU across the country as a whole.

1.11.2 Impact on other services: Extracorporeal Membrane Oxygenation (ECMO)

112. Extracorporeal Membrane Oxygenation (ECMO) is a technique that provides cardiac and/or respiratory support for very sick patients. When we use ECMO to support the lungs, supporting individuals with severe, potentially reversible respiratory failure, it is called 'respiratory ECMO'. When it is used to support the heart, it is called 'cardiac ECMO'.

1.11.2.1 Leicester: ECMO

113. Leicester provides cardiac and respiratory ECMO for children and is at present the only provider commissioned to offer mobile ECMO (which allows children to be transferred between hospitals on ECMO). It also provides cardiac and respiratory ECMO for adults. If our proposals were to be implemented, Leicester would no longer be able to provide cardiac or respiratory ECMO for children or mobile ECMO for children. Taken together this would affect around 55 children a year. It would no longer provide cardiac ECMO for adults with CHD. We would expect that Leicester could continue to provide adult respiratory ECMO, in a similar way to other hospitals

where services are supported by adult cardiac surgery services (not congenital cardiac).

1.11.2.2 Royal Brompton: ECMO

114. The Royal Brompton provides cardiac ECMO for children and cardiac and respiratory ECMO for adults. If our proposals were to be implemented, Royal Brompton would no longer be able to provide cardiac ECMO for children. This would affect around 15 children a year. It would no longer provide cardiac ECMO for adults with CHD. Adult respiratory ECMO provision at the Royal Brompton is the subject of a separate current procurement being undertaken by NHS England.

1.11.2.3 Central Manchester: ECMO

115. Central Manchester provides cardiac ECMO for adults with CHD. If our proposals were to be implemented, Central Manchester would no longer be able to provide cardiac ECMO for adults with CHD.

1.11.2.4 ECMO: wider implications

116. NHS England will work with the other hospitals, where increased paediatric cardiac surgery would be expected, if our proposals are implemented, (Birmingham Children's Hospital, Great Ormond Street, Leeds General Infirmary, and St Thomas' - Evelina Hospital) to undertake the necessary planning and preparation to manage any increase in paediatric cardiac ECMO capacity that would be needed for CHD patients.
117. If our proposals are implemented, there may also be a wider regional and national effect on ECMO services. NHS England has accelerated its Paediatric Critical Care & Specialised Surgery for Children Service Review, which will consider paediatric ECMO. When the NHS England Board makes its decision about the CHD proposals, it should, therefore, have greater clarity about the impact on ECMO for CHD patients in the wider regional and national context. The Paediatric Critical Care & Specialised Surgery for Children Service Review will then be able to pick up and address any wider implications for changes in children's ECMO services, as a consequence of the proposed CHD changes, as it considers the required capacity and distribution of children's ECMO across the country as a whole. We will re-commission appropriate levels of children's respiratory ECMO and mobile ECMO from an appropriate number of providers in the light of the recommendations of that review.

1.11.3 Impact on other services: Specialist paediatric respiratory services

118. As outlined above, the Royal Brompton considers it likely that its PICU would no longer be viable if our proposals are implemented, because paediatric cardiac patients are a large proportion of its work and it might not have enough other patients to stay open. The national panel accepted that this was an accurate assessment. The hospital trust considers that this would have a serious detrimental effect on children's respiratory services which also use the PICU.

119. The national panel considered that there would be an impact on paediatric respiratory services, if paediatric cardiac services and PICU were no longer provided by the Royal Brompton. NHS England's work focusses on congenital heart disease and has not examined paediatric respiratory services. The membership of the panel reflects that focus. Given this, it would not have been appropriate for the panel to undertake detailed assessment of this impact.

120. If a decision is taken that results in closure of the PICU at the Royal Brompton Hospital, NHS England will work with the hospital trust to understand and manage the impact on paediatric respiratory services. This could require a local service change process with further public engagement, potentially including full public consultation. There are alternative providers of specialist paediatric respiratory services in London.

1.12 Workforce Impact

1.12.1 Provider organisations where level 1 services would be provided under the proposals: workforce impact

121. The panel considered that hospitals that would gain more patients if the proposals were to be implemented were well placed to be able to expand their capacity to be able to provide that care. The recruitment of the necessary workforce for this increased activity was seen as potentially challenging for a number of these hospitals. Specifically, the recruitment of the PICU nurses necessary for the additional beds which would be required. The hospitals gaining significant activity believed that although challenging they had a good record of recruiting staff and would be able to recruit the necessary staff as long as they were given sufficient time prior to these proposals being implemented.

1.12.2 Provider organisations where level 1 services would no longer be provided under the proposals: workforce impact

122. Under our proposals some hospitals would no longer provide level 1 CHD services. In some cases this is likely to also affect the future of other linked services. For the staff delivering these services the potential implications include:

- employees being redeployed into other roles;
- the transfer of the contracts of employment of employees from one organisation to another;
- changes to the volume of work carried out by employees (either through increases or decreases in patient activity within the Trust they work for);
- employees working within the service being made redundant; and
- changes to the future workforce requirements to deliver the CHD standards and service specifications across the commissioned centres.

123. One of the key challenges both to current CHD services and to any future configuration is ensuring that there are sufficient staff with the necessary skills and experience to undertake this work across the country.
124. NHS England will work with provider organisations to ensure that staff are supported through any change process and redundancies are avoided wherever possible.
125. The national panel noted that experience at other hospitals where level 1 services have ceased – Edinburgh, Cardiff and Oxford – was that the majority of staff did not transfer to alternative providers of these services, but there were virtually no redundancies, with most staff being redeployed internally. It is reasonable to expect that many staff would seek to take up alternative roles within the relevant hospital trusts, rather than moving to another hospital. However, the panel noted that certain staff, such as CHD surgeons, would look to move to a Level 1 CHD hospital.

1.12.2.1 Impact on workforce at the Royal Brompton Hospital

126. The Royal Brompton identified approximately 430 WTE staff that it considered would be affected by the proposals, including those working as part of their CHD service, paediatric respiratory, paediatric intensive care and other services which will be impacted to a lesser extent. The hospital trust has estimated the cost of redundancies to be approximately £13.5m.
127. The panel was not able to take a view on the likelihood of all these staff being significantly impacted by the proposed changes; however, it was acknowledged that there would be a significant impact on the Royal Brompton's workforce, if the proposals were to be implemented. The panel noted that this impact would be reduced, were the Royal Brompton to continue providing adult-only Level 1.
128. NHS England has reviewed the hospital trust's assessment of the potential level of redundancy. Given that we expect that most patients using the Royal Brompton would transfer to alternative hospitals within three miles of the Royal Brompton with the scope for redeployment that would result, NHS England has a materially different view of possible redundancy costs. Internal redeployment is also likely to make a significant contribution to avoiding redundancy. We estimate that the costs could however be up to £1 – 1.5m. This estimate is highly sensitive to the degree to which staff can be redeployed.

1.12.2.2 Impact on workforce at University Hospitals of Leicester

129. University Hospitals of Leicester identified 153 WTE staff that would be directly affected by the proposals, including administrative and clerical staff, estates and ancillary, medical and dental and nursing and midwifery staff that work solely for East Midlands Congenital Cardiac Service. In addition to the staff directly affected, the hospital trust has also identified other roles, such as those working in theatres, imaging, outpatient care, catheter labs and intensive care that would be indirectly affected. University Hospitals of

Leicester considers it likely that many of its staff would prefer to take up posts elsewhere in the hospital trust if possible.

130. The panel was not able to take a view on the likelihood of all these staff being significantly impacted by the proposed changes; however, it was acknowledged that there would be a significant impact on the hospital trust's workforce, if the proposals were to be implemented. The panel noted that this impact would be reduced, were University Hospitals of Leicester to continue providing Level 2 specialist medical services.

131. NHS England considers it probable that most at risk staff will be redeployed and that therefore the costs of redundancy will be mitigated. We estimate that the costs could however be up to £1m. This estimate is highly sensitive to the degree to which staff can be redeployed.

1.12.2.3 Impact on workforce at Central Manchester University Hospitals

132. The hospital trust did not respond to the request to provide information on the potential impact of the proposals. The panel considered it likely that the impact on staff at Central Manchester University Hospitals would be considerably less than the other two hospitals as the scale of service reduction would be much smaller. Where staff are affected, close working between Central Manchester University Hospitals, Alder Hey Children's Hospital and Liverpool Heart and Chest Hospital should enable Central Manchester to ensure that staff are appropriately supported and that clear plans are made to enable staff who wish to transfer to a Level 1 hospital to do so.

1.13 Financial Impact

1.13.1 Provider organisations where level 1 services would be provided under the proposals: finance impact

1.13.1.1 Confirmation that revenue costs of implementing standards should be covered by increasing income for increasing activity

133. Trusts are paid for CHD services through tariff, which ensures that the money received is linked to patient activity. It is likely that there will be some economies of scale for providers linked with providing a higher volume of activity. As such the trusts which would gain activity under these proposals are confident of being able to fund this expansion through the income which would be associated with this extra activity.

134. The financial assessment undertaken in 2015 at the time the Board agreed the standards showed that additional income to hospital trusts resulting from growth in activity would be sufficient to fund the implementation of the standards. Growth predictions have been refreshed and continue to provide assurance that implementation of the standards will be affordable for providers.

1.13.1.2 Assessment of capital requirements at hospitals that would take additional patients under the proposals and the sources of this capital

135. NHS England asked hospitals providing CHD services whether there would be any capital implications if they were required to take additional patients if our proposals are implemented. NHS England has confirmed that no specific central funds will be made available.
136. Two hospital trusts indicated that they would need to source capital funds to accommodate additional activity: University Hospitals Birmingham (£4M) and Great Ormond Street (£6M). In both of these cases it is expected that the provider would be able to source the capital funding from existing allocations and/or charitable funds. This is being confirmed with NHS Improvement. No other provider indicated any requirement for capital funding, and the risk around capital funding requirement is minimal at this stage.

1.13.2 Provider organisations where level 1 services would no longer be provided under the proposals: finance impact

137. NHS England has assessed for each of the hospitals where it is proposed that level 1 congenital cardiac surgery is no longer provided what proportion of their income comes from caring for patients with congenital heart disease.

1.13.2.1 Impact on finances at Leicester

138. The overall contract value for specialised services at Leicester is approximately £234m. NHS England estimates that the financial effect of the proposed changes would be a reduction in income of around £14m (rather than the £19-20m estimate provided by the hospital trust). This is partly explained by a difference in view on the impact of the proposals on PICU. The hospital trust's estimate is based on an assumption that it would no longer be able to provide PICU services. The panel considered that there was no reason why PICU services could not continue at the Infirmary site even if the PICU currently located at the Glenfield site needed to close.
139. The loss of income to the hospital trust would, on the panel's assessment, represent between 1.6% and 2.2% of the hospital trust's total income, and between 6% and 8% of their total specialised services income. Some of this loss of income could be reduced if University Hospitals of Leicester continued to provide Level 2 specialist medical services. The loss of income to the hospital trust would also, to some extent, be offset by the reduction in the costs of providing the service.

1.13.2.2 Impact on finances at Central Manchester

140. The overall contract value for specialised services at Central Manchester is approximately £348m. The hospital trust did not respond to the request to provide information on the potential impact of the proposals. NHS England estimates that the financial effect of the proposed changes would be

around £1m. The loss of income to the hospital trust would therefore represent approximately 0.3% of their total specialised services income.

141. Some of this loss of income could be reduced if Central Manchester University Hospitals continued to provide Level 2 adult CHD services. The loss of income to the hospital trust would also, to some extent, be offset by a reduction in costs.

1.13.2.3 Impact on finances at the Royal Brompton:

142. The overall contract value for specialised services at Royal Brompton is approximately £226m. NHS England estimates that the financial effect of the proposed changes would be around £35m excluding the impact on paediatric respiratory services. The hospital trust's estimate of a £47m loss in income when paediatric respiratory services are taken into account appears to be broadly in line with NHS England's own estimate. The hospital trust estimates that the loss resulting from these proposals would be approximately 13% of its total income and 21% of its total specialised services income, which represents a significant financial and business challenge. The scale of loss reflects the impact on PICU and the potential impact on paediatric respiratory services.
143. Some of this loss of income could be reduced if the Royal Brompton continued to provide adult-only Level 1 surgical services, in partnership with a Level 1 paediatric hospital. Whilst adult Level 2 services to be provided at RBH would lessen the financial impact of the proposals on the Royal Brompton to a limited degree the vast majority of its CHD income relates to inpatient activity linked to a surgical or interventional procedure and therefore the Royal Brompton have identified just over £3m income from CHD activity not relating to surgery or catheter interventions. However, this almost totally related to paediatric services and as such if the Royal Brompton were to only offer adult Level 2 services, it is unlikely this would provide significant income to the Trust
144. The loss of income to the hospital trust would, to some extent, be offset by a reduction in costs. Data supplied by the Royal Brompton indicates that its provision of CHD services results in an overall net loss, and therefore although the loss of income is significant it may be that in the long term no longer providing these services is in the best financial interest of the hospital trust. The Royal Brompton has, however, stated that owing to the stranded costs associated with this service they estimate an adverse impact of over £7m per year to its bottom line if these proposals are implemented. The financial impact of the changes could be reduced if the Royal Brompton provided Level 1 services for adults.
145. We note that the Royal Brompton is an active partner in the North West London Sustainability and Transformation Planning process and has identified a number of potential areas for partnership working which could potentially contribute to the mitigation of any financial losses if our proposals are implemented.

1.13.2.4 Finance impact: NHS England

146. The cost of the CHD service to NHS England has been estimated at £175m pa (based on 2013/14 figures). Activity is projected to increase whether or not the new standards are implemented. As a result, we forecast that – in today's prices - by 2025/26 expenditure on CHD services will be between £186m and £207m depending on the level of activity growth. We therefore expect that the challenge for us as commissioners will be in meeting the costs of activity growth rather than any costs arising from meeting the standards, or costs arising from the proposed changes. There are no current plans to reduce the CHD budget (per capita or overall).
147. As commissioners of CHD services we pay hospitals for the majority of these services using the national tariff (price) per unit of activity. Were we to change the number of centres where care is provided, this would therefore have no impact on our expenditure on patient care. NHS England finance experts have advised that it is logical to assume that an improvement to clinical outcomes and the clinical, operational and administrative efficiency and geographical/estates consolidation that would result from implementation of our proposals should lead to reduction in unit cost of this service for providers.

Equalities and Health Inequalities

148. The CHD standards are intended to ensure that everyone with CHD gets the best possible care within available resources. Earlier analysis and engagement indicated that any proposed service change may differentially impact some Black and Ethnic Minority (BME) patients (those of Asian ethnicity), and those with a learning disability. In addition, services for CHD are of particular interest to children, and to the families and carers of children. We will be carrying out specific engagement activities with these groups during the consultation period.
149. We asked hospitals providing CHD services about any equalities or health inequalities as a consequence of our proposals being implemented. All responses submitted by the hospitals can be found in the Equalities and Health Inequalities Impact Assessment which has been published alongside this document.

1.14 Age

150. Our analysis shows that there has been an increase in demand for adult CHD care. More children now benefit from advances in treatment for CHD, and are therefore reaching adulthood. As more people survive with this condition, it is likely that the service will move from one that is centred on children, to one that is, in addition, treating a growing number of young people and adults. This has consequences for the way in which services are planned and delivered.

151. Most surgery and interventional cardiology for CHD happens early in life so our proposals, if implemented, will affect where care for children and young people will be delivered and will therefore impact children and young people. We will be talking directly to children and young people during the consultation period, and have also developed an Easy Read version of the consultation document to help younger children better understand our proposals.

1.15 Disability

152. Children and adults with CHD are at an increased risk of developing further difficulties. Many children with CHD experience delays in their development, for instance, taking longer to walk or talk. Some children will have a learning disability. Around 50% of children with Down's Syndrome have a congenital heart defect and around 60% of those children will require treatment in hospital.
153. Change for people with learning disabilities or on the autistic spectrum is more difficult. Any service change for this population can be more difficult and needs to be managed well. This is not unique to the CHD proposed service change; however careful consideration should be given to the management of change for these patients. The particular concern has been around the practical elements of change like travelling to a new location, and patients being treated by clinical teams in a location that they are not familiar with. For example, people with learning disabilities who allow clinicians that they know to work with them are more likely than people without learning disabilities to refuse the same treatment in an unfamiliar surrounding by unfamiliar people.
154. During consultation we will make special arrangements to gather the views of people with learning disabilities and their families and carers. We have also produced an Easy Read version of this consultation document to help parents and carers explain the proposals to people with learning disabilities. As part of our consultation we are asking people about the impact implementation of the proposals would have on people with learning disabilities and their families and carers and also for advice on dealing with any concerns.

1.16 Gender reassignment

155. We have not identified any specific evidence relating to gender reassignment (including transgender) and CHD. The standards and service specifications do not alter access or delivery of these services to people with this protected characteristic.

1.17 Marriage and civil partnership

156. We have not identified any specific evidence relating to marriage and civil partnership and CHD. (We do not think it appropriate or justified to assume that people who are married or in a civil partnership are more likely to be the parents or carers or in a family with a person with CHD). The standards and service specifications do not alter access or delivery of these services to people with this protected characteristic.

1.18 Pregnancy and maternity

157. Two distinct groups in this category may be affected by the proposed changes.

- Women with CHD who are pregnant
- Women who are pregnant carrying a baby with CHD

158. In both cases most maternity care is delivered through local maternity services at a hospital close to the woman's home. Arrangements will be made for the delivery of the baby that take account of the needs of both mother and child. This may be at the local obstetric unit or at an obstetric centre at or close to the specialist surgical centre. For some women, if the proposals are implemented it will mean that delivery will take place at an obstetric unit further from home

159. We believe that the proposed standards will have a positive impact on the experience and outcomes of women with CHD who are considering pregnancy, are pregnant or are receiving maternity care and on women who are pregnant carrying a baby with CHD. For the first time services will be nationally commissioned using common service specifications.

1.19 Race

160. Ethnicity is known to relate to the prevalence of certain diseases. The relationship between ethnicity and CHD is complex and may be confounded by cultural and religious factors. Research dating back to the 1980s⁵ and 1990s⁶ demonstrated higher prevalence among Asian communities in various UK cities including Manchester and Leeds, and in the West Midlands.

161. We looked at the recorded ethnicity of CHD patients at the three affected level 1 hospitals. All three trusts have a higher prevalence of South Asian patients than the average for the population and higher than the CHD patient group at other level 1 CHD hospitals:

⁵ Gatrad AR, Reap AP, Watson GH Consanguinity and complex cardiac anomalies with situs ambiguous, *Arch.Dis Child* 1984; 59: 242-5

⁶ Sadiq M, Stumper O, Wright JGC, de Giovanni JV, Billingham C, Silove ED Influence of ethnic origin on the pattern of congenital heart defects in the first year of life *Br Heart J* 1995; 73: 173-176

- CMFT has the highest prevalence of Asian population of the three providers that will be impacted by the service change at 15.9% compared to the average of 11.2% of all hospital trusts.
- UHL has a prevalence of 12.6% compared to the average of 11.2% of all hospital trusts.
- Royal Brompton has a prevalence of 12.1% compared to the average of 11.2% of all hospital trusts.

The data above shows that the changes will affect more people of Asian origin than the general population because of the higher incidence of CHD amongst people of Asian origin.

It is not straightforward to assess whether the proposed changes will affect people of Asian ethnicity differently from other groups. Implementation of the standards will ensure that everyone benefits from services provided to a consistent standard across the country. The consultation process will enable us to better understand the impact of the proposed changes by engaging with BME groups, and we will make special arrangements to gather the views of people of Asian ethnicity with CHD during the consultation period. We have produced a summary version of this consultation document in a number of Asian languages and the full document can be translated on request. We heard that religion and belief and culture could make it difficult for some people to engage with us in an open forum, and will therefore ensure that there are opportunities for people to engage with us on a one-to-one basis, via telephone interview, during the consultation period.

1.20 Religion or belief

162. We do not have any evidence that shows a particular impact of the proposed changes on people of differing religions and beliefs. It is envisaged that hospitals that would be expected to provide care for more patients, under our proposals, will review ethnic, religious and cultural mix of patient information in light of the standards and feedback of the communications, engagement and the independent consultation report

1.21 Sex or gender

163. We do not anticipate that the proposed changes will have a differential impact either by sex or gender of patient or carer.

1.22 Sexual orientation

164. We do not anticipate that the proposed changes will have a differential impact depending on sexual orientation.

1.23 Asylum seekers and/or refugees

165. We have not identified any specific evidence relating to asylum seekers and or refugees and CHD. Access to healthcare, understanding of the English health system and communication difficulties and cultural differences may be

relevant differences for asylum seekers and refugees but would not be specific to CHD services or the proposed changes.

1.24 Carers

166. We have heard how important it is for parents and carers to be supported, particularly when they are away from home. They told us about difficulties with finding their way around new hospitals, finding accommodation and eating balanced meals. They also told us about problems with car parking. These effects may be amplified if parents and carers have to travel to a new hospital. We also heard about the importance of having support for end of life for both children and adults. This means having identified support structures that encourage and enable open and honest communication with families and carers at that time. We have developed specific standards to address these issues.

Consultation will seek views from families and carers as well as from people with CHD. The consultation questions include open ended questions where families and carers will have the opportunity to share their experiences and concerns. This may include families and carers who would have compounded impacts of the proposed service changes.

1.25 Those living with mental health issues

167. In addition to medical problems, people living longer with CHD face psychological, sociological and behaviour challenges⁷. Since people with CHD are surviving longer into adulthood, the increasing population of adults with CHD also means there will be an increasing percentage of adult CHD patients that have mental health issues such as anxiety and depression.

168. We do not have any data to understand the percentage of people with mental health issues and CHD that would be impacted by the changes. However, we have heard during the 2016 preliminary stakeholder engagement that people with mental health issues may be differentially impacted by the proposed service changes. This will need further exploration during the consultation to understand the specific impact.

1.26 Other groups

169. We have not identified any specific evidence relating to the following groups and CHD:

- Alcohol and/or drug misusers
- Ex-service personnel/veterans
- Those who have experienced Female Genital Mutilation (FGM)
- Gypsies, Roma and travellers
- Homeless people and rough sleepers

⁷ [Int J Cardiol.](#) 2013 Dec 5;170 (1):49-53. doi: 10.1016/j.ijcard.2013.10.003. Epub 2013 Oct 11.

Sex workers

Trans people or other members of the non-binary community

Glossary

Adult Congenital Heart Disease	ACHD	This is also known as “grown-up congenital heart disease”, or “GUCH”.
Atrial Septal Defect	ASD	Most common type of ‘hole in the heart’
Bridge to heart transplant		The use of a ventricular assist device (VAD), or other form of circulatory assistance, to support the pumping action of a failing heart until a donor heart becomes available for transplantation. The technique is known as ‘bridge to transplant’.
Cardiologist		A doctor who specialises in investigating and treating diseases affecting the heart and some blood vessels.
Cardiothoracic:		Conditions affecting organs within the thorax, such as the heart, lungs and oesophagus.
Clinical Commissioning Groups	CCG	Groups of GP practices responsible for buying the majority of hospital and community-based health services for patients within their local communities
Clinical Reference Group	CRG	Groups of clinicians, patient representatives, commissioners and other experts, covering the full range of specialised clinical services, (such as cardiac), and providing clinical advice in support of NHS England’s direct commissioning function.
Clinician		Any health professional who is directly involved in the care and treatment of patients, for example, nurses, doctors, therapists, and midwives.
Co-location / service interdependencies		The other services required to provide optimum care of the whole patient, particularly when their conditions are complex or complications arise, and which need to be on the same hospital site.
Commissioning:		The process of buying health services, involving the assessment and understanding of a population’s health needs; the planning of services to meet those needs; securing services on a defined budget, and then monitoring of the services. Commissioning in the NHS in England is managed locally by CCGs, and nationally by NHS England.
Congenital Heart Disease	CHD	Refers to a range of birth defects that

		affect the normal workings of the heart.
Consultant		A senior doctor who is a specialist in a particular area of medicine
Diagnostics		Medical tests used to identify a medical condition or disease.
Extracorporeal Membrane Oxygenation	ECMO	A complex technique that provides cardiac and/or respiratory support for very sick patients
Gastroenterology		Area of medical specialism which deals with disorders of the abdomen, particularly the stomach and intestines.
Interventional cardiology		Various non-surgical procedures for treating cardiovascular disease, such as coronary angioplasty (inserting a tube with a balloon on the end to treat a narrowing or blockage in an coronary artery) or cardiac valve intervention.
Nephrology		Area of medical specialisation that deals with the physiology and diseases of the kidneys.
NHS England Board		The Board is the senior decision-making structure in NHS England and consists of a Chair and eight non-executive directors and four voting executive directors.
NHS England Clinical Advisory Panel	CAP	A group of experienced clinicians that is part of the CHD Review's governance structure.
Paediatric		A branch of medicine providing care for infants and children.
Paediatric Critical Care and Specialised Surgery for Children service review		NHS England national service review which will consider the provision of paediatric Intensive Care and paediatric transport in England
Paediatric Intensive Care	PIC	A highly specialist hospital ward that provides sick children with the highest level of medical care.
Referral		Sending a patient to a specialist, or between specialists, for expert care.
Service Standards		Sets out how NHS services should be set up, organised and run
Specialist		A clinician whose work is concentrated on a particular area of medicine.
Stakeholder		All individuals, parties or organisations with a particular interest in the organisation and delivery of particular clinical services, etc.
Sub-specialisation		Surgeons and cardiologists train generally in their specialty and, at the end of their training, will qualify as a

		consultant. Many will then sub-specialise in an area of particular expertise. These areas are known as sub-specialties.
Surgeon		A clinician who is qualified to practice surgery.
Time limited derogation		NHS England will put in place time limited exceptions (or derogations) allowing hospitals to continue providing essential quality services for their patients whilst working to meet more rigorous service specifications.
Whole time equivalent	WTE	A measure of staffing that takes account of both full time and part time workers.



Integrated Equalities Impact Assessment

August 2017

Contents

Introduction	3
Children, young people and their families	3
What we heard in consultation.....	4
Mitigating the impacts of the proposed changes	8
Pregnancy and maternity	11
What we heard in consultation.....	12
Mitigating the impacts of the proposed changes	14
People with learning disabilities	16
What we heard in consultation.....	17
Mitigating the impacts of the proposed changes	20
People of Asian ethnicity	22
What we heard in consultation.....	22
Mitigating the impacts of the proposed changes	25
Other equalities and inequalities issues identified in consultation.....	26
Appendix A: Healthcare Travel Costs Scheme (HTCS)	29

Introduction

1. As part of our preparation for consultation, we undertook a full Equality Impact Assessment¹ in relation to the original proposals.
2. This assessment found that the proposals could differentially impact some Black and Minority Ethnic (BME) patients (those of Asian ethnicity) and those with a learning disability. In addition, services for CHD are of particular interest to children and the families and carers of children.
3. In consultation we asked specific questions aimed at building our understanding of the nature of these impacts. In this paper we summarise the findings of our earlier assessment, report what we heard in consultation, provide our updated assessment and set out how NHS England proposes to deal with any potential negative effects of its proposals on people sharing a protected characteristic, dealing with each of the main groups in turn.
4. Respondents to the consultation perceived that the assessment of equality and health inequality impacts were inaccurate overall. Despite our having undertaken a full equalities and inequalities assessment and published it on our website alongside the consultation document, respondents called for a full EQIA to be undertaken. This suggests that, at least in some cases, the views of the accuracy of our earlier assessment were not based on an understanding of what that assessment said.

Children, young people and their families

5. Children and young people with CHD would be more affected by our original proposals because most surgical and interventional procedures (around 7 in 10) occur in children and young people. As a result the families or carers of these children and young people would also be affected.
6. The proposed changes at Manchester will have a very limited effect on children and young people as level 1 services in the North West are already provided in Liverpool. Our proposal to decommission services from Manchester relates only to adult services.
7. The proposals for change on which we consulted would affect children and young people at Leicester and the Royal Brompton who would previously have had their surgery or an interventional procedure done at these centres and under these proposals would need to travel to an alternative centre. In the case of Leicester the alternative centres are likely to be further away for many of those affected, in Birmingham or

¹ Equalities and Health Inequalities Assessment 2017 available at:
https://www.engage.england.nhs.uk/consultation/chd/supporting_documents/Equalities%20and%20Health%20Inequalities%20Impact%20Assessment.pdf

Leeds. As most patients from the Royal Brompton would still receive their care in London, journey times are largely unaffected.

8. A number of children and young people who would have had inpatient care for respiratory illnesses at the Royal Brompton would also be affected because the Brompton's Paediatric Intensive Care Unit (PICU) would no longer be viable. We are not able to assess the number affected because this would depend on the approach taken to managing the impact of the original proposals on paediatric respiratory services at the Royal Brompton. Further work would be undertaken by NHS England to clarify which patients would be affected and the necessary mitigations before any changes were implemented.
9. We have previously undertaken specific engagement activities with children and young people², and sought to ensure that the things that matter to them were reflected in the standards. We also took steps to ensure we heard from children and young people during the consultation on the original proposals for change to CHD services.
10. In consultation we provided an EasyRead version of the consultation document and also provided a website designed for children and young people's feedback. We promoted these through our charity stakeholders who work with young people; and used them at events to gather thoughts and opinions.
11. Where young people were present we used the animation to explain the consultation proposals and then used either drawing techniques or groups working to think about what they thought about these proposals and about what it might be like to go to another hospital, as well as what they would like to be there to make any change as good as it could be.
12. Drawings, writings, and verbal feedback were collected at events and fed into the consultation process.

What we heard in consultation

13. Only four responses were received via the main consultation survey from people aged 18 and under. However, the dedicated website received 43 responses from children and young people aged 11 to 17. Most responses were from those aged 17. The average age of respondents was 17 for male respondents and 10 for females. Most respondents related to Leicester and the Royal Brompton though not all received their follow-up care at these centres.
14. The following sets out the themes to have emerged from the young people with CHD survey.

² See Appendix 6: 'Engagement with public, patients and their representatives' - of the CHD paper considered by the NHS England Board at its meeting on 23 July 2015 and available here: <https://www.england.nhs.uk/wp-content/uploads/2015/07/Item-4-CHD-Report.pdf>

15. The majority of respondents knew about the original proposals. Many were very worried but some were positive about these proposals.
16. Those who were concerned felt the original proposals for the decommissioning of services would affect them a lot. Their concerns were:
 - They would have to wait longer for surgery and travel further for treatment and that would mean they and their parents would need to take more time off
 - They were worried about continuity of care: getting care from another centre would mean see a different consultant than they are used to; how would staff know the patients?
 - New people and places add to an already anxious time, thinking you may die or need more help.
 - Their usual consultant might move and replacing them could be difficult if the centre no longer does surgery.
 - Waiting times may increase as there are fewer hospitals and beds will decrease. Doctors would be over worked. The personal relationships with cardiologists would potentially decline due to high workloads. They did not want rushed appointments because the cardiologists are overburdened 'at the moment I can ask what questions I want and I feel important'.
 - Don't want hospitals to close as the others are too far away. They were concerned about not being able to receive treatment in time if they were poorly and the dangers of travelling further.
 - Don't want to be far away from home.
 - Appointments at hospitals further away would mean more time out of school and time off work for parents. A parent commented that closing services is not just about the logistics but the support networks that develop for families over time.
 - Would prefer their hospital to remain the same and changes to be at the others. 'Want my hospital to stay open as they saved me'.
 - Some saw a trade-off between better quality surgery, offset against having further to travel for check-ups.
17. Those who were positive about the original proposals said that:
 - The centre would become larger therefore have more experience to offer better care for people.
 - Bigger and better services improves care for all.
 - Not worried as long as they get the best care, no matter where it is.

18. Respondents whose surgical hospital is not one where change is proposed had mixed views about how the changes would affect them or their hospital. Their concerns related to additional demand, less personal service, increased waiting times and bed shortages. However, some highlighted that bigger centres meant better care for all.
19. Respondents advised what would help in managing any change:
 - Reassurance that they will continue to receive excellent support as a priority
 - Names of doctors and meeting the staff along with a tour of the hospital before admission.
 - Know where to go for care; clear information and clearly communicated to prevent worry.
 - Continuity of support;
 - Knowing capacity will be available
 - Care provided as close to home as possible
20. Respondents told us what they would consider high quality care wherever you live:
 - Important that good care is available everywhere but that may mean some individuals don't have such good care anymore.
 - Everybody expects high quality care.
 - Happy that better quality of care but not so happy as some people will have to travel further for check-ups
21. No comments appeared to have been made on the site by those with or on behalf of those with learning difficulties.
22. As part of the consultation, specific sessions for children and young people were held at the annual conference of a national charity³. 21 young people aged 11-18 years old and 10 children aged 8-11 years old were present in two separate sessions. They were shown the video from the children and young people website and then worked in groups to think through the implications of the original proposals.
23. Awareness of the original proposals prior to the meeting was not as high as amongst respondents to the website.
24. Participants expressed the following concerns about the original proposals:
 - Changing clinicians can be difficult and scary.

³ Little Hearts Matter, 18 March 2017

- Being in a different place further away from home could mean losing valued relationships (with staff and with other patients), might mean they did not have all their stuff and would make it harder for family to visit.
 - It would mean that some patients will have to travel long distances to have an operation and that costs of travel would rise.
 - There was a worry that the system would become more complex and harder to understand.
 - It was important that the new arrangements were safe.
25. Some participants agreed with the original proposals, others could see positives:
- 'People who go to small hospitals should go to big hospitals and the small hospitals shouldn't get any money'.
 - One did not see the longer journey as a problem – 'I like travelling' and saw it as 'a break from life'
 - The new hospitals would provide safer locations.
26. Participants advised what would help in managing any change:
- Overall they considered that it was important that the new hospital knew all about them in advance, that they got a chance to meet the new staff before the change happened and that if possible, their doctors would not change because they know them and are known by them. If the OP appointments were still in the same place that would make things better, but they were still worried if it meant some long journeys.
 - They told us they wanted: 'good health care; kind doctors; doctors who know me and understand my needs; friendly staff; help me understand more about my condition'.
 - Hospitals need to have good care, nice food, fun activities, enough beds.
 - Information was seen as very important so they could understand what was happening: 'I want full details about this matter; full details of all changes happening; to be told what is happening to my siblings; more knowledge for siblings and us'.
 - In relation to longer journeys, help with the travel and making sure the distance was appropriate.
 - One thought a trial period could help.
 - Lots of advice was given on ensuring a smooth transfer: meeting the people who would be looking after you before you actually transfer; speaking with people beforehand about your condition; staff getting to know the patients; get to know me; know you before you go there; making sure the doctors know exactly everything about the patient, 'so you don't have to explain it all';

transfer my information; no new tests should be required; nurses should go with the children to the new hospital / the nurses move with you; 'I have good relationships, so if I was changing I would want them to get to know me'; if people need to move: make them feel welcome; if you need to change hospital they should make you feel welcome.

- There should be more beds for siblings and more space: 'more Ronald McDonald houses for mums and dads; make it so the parents can stay with you; have more beds (for family members)'.
- 'Have the right toys and the right entertainment in the room; teenage room with stuff; acceptable toys and equipment; have more activities for siblings, family; have exciting things to do'.
- 'Better schools in hospital; don't give school work / homework'.
- There was a lot of concern about **how** things were explained: 'You HAVE to ensure that it's NOT patronising; have adult conversations; explain scientific terms; use easy to understand explanations (terminology); speak English not Jibber Jabber; patients and clinicians should be talking to each other; the doctors speak well, with a local accent; all the doctors should listen to what you want to say'.
- The attitudes of staff would be important: 'they need to be nice people - good doctors, nurses; people who aren't bossy, stressy, rude, or don't listen to you, and who don't have favourites; nice nurses / doctors; the doctors should be kind; they should give you the care that you need; give you support from the doctors'.
- Hospital food was seen as very important: 'food you like; nice food; a wide range of food.'
- The atmosphere should be relaxed and enjoyable.

Mitigating the impacts of the proposed changes

27. Many of the concerns expressed by children and young people are familiar from our consultation on the standards and as a result, many have been dealt with in the standards themselves. We also identified a number of issues we considered likely to affect children and young people in our pre-consultation equalities assessment. These are reflected below together with new thinking resulting from this most recent consultation.
28. Impact: Some children, young people and their families/carers will experience longer journeys for level 1 care.
29. Mitigation: The model of care is designed to give as much care as we can as close to home as possible. If the original proposals were implemented, and if inpatient stays and procedures are further from home, we will work with the remaining level 1 centres to ensure that outpatient care is

delivered through level 2 centres, level 3 services and outreach clinics: most outpatient care, except a small number of perioperative appointments should not require attendance at a level 1 centre.

30. Impact: Some children, young people and their families will experience stays at a level 1 centre further from home.
31. Mitigation: Reduce the impact of this and ensure appointments are made less difficult by ensuring that the facilities and information at their new level 1 centre meet the requirements for (amongst other things) providing better information about where to park, eat and sleep; better facilities to prepare meals; provision of Wi-Fi; ensuring parking charges are affordable; and providing overnight accommodation for parents and carers. If the original proposals were to be implemented we would ask their new level 1 centres to review these arrangements as a priority and ensure there is sufficient family accommodation to support the increased amount of patients. Where possible
 - Give as much notice to the patient, families and carers in advance to support planning e.g., for equipment management, family cover for other siblings and family members.
 - Timing of any appointments to be arranged in a one-stop clinic to avoid excessive amounts of time away from school and parents/families /carers away from work
 - Advise patients, families and carers about facilities to help support and manage their conditions e.g., support for learning and physical disabilities and learning difficulties.
 - Ensure care plans are defined and patients, families and carers have the opportunity, where possible to meet the Level 1 team at an outreach clinic and be offered a visit to the Level 1 centre prior to intervention.
32. Impact: Patients and their families have told us that changes to where their care is provided and to the staff providing their care can be unsettling.
33. Mitigation: We will ask the hospitals involved to look carefully at how this process is managed if our original proposals are implemented. We will ask them to make sure they communicate what is going to happen to patients and their families, clearly, in a way that children and young people can understand, in a timely way and through a variety of channels. We will ask them to maximise continuity in care so that as much as possible can remain familiar, for example continuing under the care of the same consultant and specialist nurse where possible. We think the pattern set out in the standards for transition from children's to adult services may be helpful. This describes a range of practices that could be usefully adapted

to the task of managing the transfer of patients from one hospital to another:

- the opportunity to visit the new centre and meet the new staff in advance of the change happening.
- specific responsibility to teams to co-ordinate the process lies with specialist nurses from the two hospitals
- a named key worker is nominated to act as the main point of contact and to provide information and support
- high quality information is transferred with the patient
- special consideration is given to the needs of children and young people with learning disabilities/difficulties
- psychological support is made available

34. The relevant standards are shown below:

I5(L1)	All young people requiring long-term congenital care undergoing transition must be seen at least once for consultation by an ACHD cardiologist and an ACHD Specialist Nurse in a specialist multidisciplinary team transfer clinic or equivalent. Clear care plans/transition passports must be agreed for future management in a clearly specified setting, unless the patient's care plan indicates that they do not need long-term follow-up.
I7(L1)	The Children's Cardiac Transition Nurse will work as a core member of the children's Cardiac Team, liaising with young people, their parents/carers, the Children's Cardiac Nurse Specialist, ACHD Specialist Nurse and wider multidisciplinary team to facilitate the effective and timely transition from the children's to adult services.
I8(L1)	All young people will have a named key worker to act as the main point of contact during transition and to provide support to the young person and their family. Peer to peer support should also be offered.
I9(L1)	All patients transferring between services will be accompanied by high quality information, including the transfer of medical records, imaging results and the care plan.
I11(L1)	The particular needs of young people with learning disabilities and their parents/carers must be considered, and reflected in an individual tailored transition plan.
I12(L1)	Young people must have the opportunity to be seen by a Practitioner Psychologist on their own. Psychological support must also be offered to parents/family or carers.

Pregnancy and maternity

35. There are two distinct subgroups to be considered within the maternity and pregnancy group:
 - a) Women with CHD who are pregnant or considering pregnancy
 - b) Pregnant women whose fetus has CHD
36. In both cases most maternity care is delivered through local maternity services at a hospital close to the woman's home. Arrangements will be made for the delivery of the baby that take account of the needs of both mother and child. This may be at the local obstetric unit or at an obstetric centre at or close to the specialist surgical centre. These requirements are described in the standards in section J - pregnancy and contraception; and section K - fetal diagnosis.
37. Implementation of the original proposals would affect the choice of place of delivery for both sets of women, and may mean that the appropriate place of delivery is further from home than would be the case currently.
38. Most antenatal care will continue to be delivered as it is now.
39. Our pre-consultation equalities impact assessment found that although pregnant women would be affected by the proposed changes, they were not considered to be affected to a greater degree than other current and future patients.
40. We believe that the proposed standards will have a positive impact on the experience and outcomes of women with CHD who are considering pregnancy, are pregnant or are receiving maternity care. For the first time services will be nationally commissioned, regionally delivered using common service specifications.
41. **Women with CHD who are pregnant or considering pregnancy.** The Clinical Advisory Panel advised that a small number of women (those where cardiac risk is high **and** in whom there is a high chance of needing urgent surgical or interventional cardiology procedure at the time of delivery) would need to deliver their babies at the level 1 centre or the linked nearby obstetric unit. If the proposals on which we consulted were implemented, this could mean a longer journey and potentially more time spent at a greater distance from home for those in the North West for whom Manchester is closer to home, and for those in the East Midlands for whom Leicester is closer to home.
42. The Clinical Advisory Panel advised that women with CHD who are pregnant rarely require surgery or interventional cardiology at or close to the time of delivering their baby. As a result the choice of place of birth will not be affected for most women with CHD, and most antenatal care, births and postnatal care will still be in local hospitals or level 2 centres. Place of

birth is agreed as part of preparing an individual care plan for each woman, and discussed at the MDT for higher risk patients.

43. **Pregnant women whose fetus has CHD.** The Clinical Advisory Panel advised that women carrying a baby with CHD would not all need to deliver at the level 1 centre or the linked nearby obstetric unit. Place of birth is agreed as part of preparing an individual care plan for each woman, and agreed between the level 1 centre, the specialist fetal-maternal unit, the local obstetric unit, the neonatal team, paediatricians and the parents. Only where a baby may require immediate postnatal catheter intervention or surgery, must the baby be delivered at the level 1 centre or the linked nearby obstetric unit.
44. If the original proposals were implemented this would affect those women in the East Midlands who would previously have delivered at Leicester because their baby needs urgent surgery or catheter intervention and for them will mean a longer journey and potentially more time spent at a greater distance from home.
45. Although not all mothers would need to deliver at the level 1 centre (or linked nearby obstetric unit) some may request to deliver here.
46. The Clinical Advisory Panel advised that increasing the rate of early diagnosis would facilitate appropriate decisions about place of birth, and reduce the chance of high risk deliveries taking place away from the level 1 centre.

What we heard in consultation

47. Some agreed that the proposed standards will have a positive impact on the experiences and outcomes of women with CHD who are pregnant, and for women who are pregnant and carrying a baby with CHD (where an antenatal diagnosis is made). However, respondents also agreed with the assessment that both women with CHD who are pregnant, and women who are pregnant and carrying a baby with CHD, will be impacted by the proposed changes. They expressed concerns about the impact of the original proposals on pregnant women:
 - The impact would be greater on pregnant women if they or their baby has CHD: travelling further, repeatedly, during pregnancy when already stressed and worried; separated from their family/community when their baby is born; longer to travel back for appointments post-natally.
 - Those pregnant women with CHD may have to travel further and need the intervention of three centres given the proposed configuration.
 - That the prospect of more difficult arrangements may alter their decision about whether to continue the pregnancy or not - families make decisions around whether to continue pregnancy, based not only on the problem with the fetus, but also the difficulty they will have in managing this after birth.

When this becomes more difficult many families see termination as their only option.

- Concern that service change could have negative impacts on a small number of babies who are born undiagnosed and in need of urgent intervention if they have to travel further to receive specialist treatment or if the baby is born outside of hospital because of rapid spontaneous labour
 - That early induction to avoid these problems also puts mother and baby at increased risk.
 - Longer distances will mean more women will have to choose between going home to fulfil other family responsibilities and providing milk to their very ill baby
 - That there will be an increased risk to high risk pregnancy patients.
48. Suggestions were made that some of these effects could be minimised through more outreach clinics for antenatal and postnatal review, multi-disciplinary team (MDT) discussion and greater use of telemedicine.
49. Respondents had a range of concerns about the proposed model of maternity care for women with CHD in NW England.
- Whether maternity care for congenital heart patients will continue at Manchester
 - How services in Liverpool would work and concern that as the model would involve several different hospitals (Liverpool Heart and Chest; Liverpool Women's; Alder Hey) this would be inherently less good, and potentially more risky than the current arrangements in Manchester. It would also mean more transfers for women and their babies and for the staff caring for them. There is also uncertainty as to how on-call obstetric arrangements would work if there was a need to cover multiple sites.
 - A concern that there has been too much focus on the availability of cardiac surgery for women with CHD at the time of delivery when this is very rarely needed.
50. A number of respondents said that co-location of maternity/neonatal services with the congenital heart disease service should be considered the gold standard. They call on NHS England to make this clear so that any new developments can build in such arrangements.
51. The recommendations of the most recent Confidential Enquiry were highlighted by some:
- 'Lack of co-location of obstetric and cardiac services jeopardises interdisciplinary working and communication'.
 - 'Inter-hospital referral of a sick pregnant or postpartum woman should be directed by the principle 'one transfer to definitive care'. It is unlikely to be

appropriate to move a sick antenatal woman to a facility without on-site obstetric cover’.

52. Access to other services sometimes needed by pregnant women with congenital heart disease (including cardiologists, cardiac physiologists, cardiac anaesthetists, intensivists, haematologists, renal physicians, hepatologists and diabetologists) was also highlighted.
53. The need to consider the impact on paediatric and neonatal transport services was also highlighted.
54. Other respondents express views about how services need to work when they are not all on the same site. This includes:
 - Ensuring that services are joined up with some of the same key individuals managing patients on both sites.
 - Good neonatal intensive care units, acute transport services, enough capacity at the Level 1 Specialist Children’s Surgical Centre, and a well-managed network.
 - The Royal College of Paediatrics and Child Health stated: ‘If neonatal and maternity services are not co-located with the children’s cardiac service, a robust neonatal critical care transport service must be in place to ensure safe passage for newborn babies to the children’s cardiac service.’

Mitigating the impacts of the proposed changes

55. Impact: The potential extra distance to be travelled with the decommissioning of centres will have a detrimental impact on either or both the mother and child with CHD.
56. Mitigation: Most antenatal and postnatal care will continue to be provided locally as now.
57. Central Manchester has acted as the maternity hub in the North West for women with CHD. If our original proposals were to be implemented Central Manchester would still have an important role in maternity care for women with CHD, working as part of a network of care with the level 1 centre and with agreed network referral guidelines. This role could be greater if Central Manchester met the standards for working as a level 2 specialist medical adult CHD centre. Under these arrangements, complex women would be discussed within a network multidisciplinary meeting to determine the best place for delivery. Only where women with CHD who are pregnant are likely to require surgery or interventional cardiology at or close to the time of delivering their baby would delivery at the level 1 centre be necessary.
58. Women with lower risk lesions could deliver closer to home as is current practice.

59. Impact: The care of babies with CHD not born at the level 1 centre (for example if not diagnosed antenatally or born outside of hospital because of rapid spontaneous labour) but needing urgent intervention could be compromised because transfer to the level 1 centre could take longer.
60. Mitigation: Local hospitals and ambulance services work closely with the level 1 and level 2 centres. Systems for managing these circumstances (which already exist) are already in place and well developed: contingency planning is part of birth plan (eg. setting out the steps that would need to be taken if the mother was to go into labour early).
61. Improvement in fetal scanning will support and help diagnose more children who have CHD. NHS England will continue to work to ensure that antenatal diagnosis is increased.
62. Impact: The impact of the changes on place of delivery for women with ACHD who would have had their babies at Central Manchester.
63. Mitigation: NHS England expects that Central Manchester would continue to play an important role in providing maternity care for women. We would expect that care for women with complex needs would be discussed within a network multidisciplinary team to determine the best place for delivery. Only women likely to require surgery or interventional cardiology, at or close to the time of delivering their baby, would need to deliver at the level 1 centre.
64. Impact: Lack of clarity about how maternity care will work in Liverpool with the involvement of multiple hospitals/Trusts.
65. Mitigation: The model of care for Liverpool if the original proposals were to be implemented is well developed and being further refined to provide full assurance to the Board.
66. It is worth noting that many women with CHD already receive their maternity care in Liverpool rather than Manchester (those for whom Liverpool is a closer centre and who do not require delivery at the level 1 centre) so that this is not the development of a whole new maternity service. Similarly, since the level 1 centre for paediatric cardiac in the north west is Alder Hey in Liverpool, delivery of babies with CHD that need to be delivered at or near the level 1 centre is already in Liverpool and the original proposals do not change these arrangements.
67. It is also worth noting that there are other level 1 centres in England (Birmingham; north London) where paediatric cardiac, adult CHD and maternity services are divided between different Trusts/hospitals and these systems function well with no evidence of less good care or outcomes.

People with learning disabilities

68. People with CHD and learning disability and learning difficulties⁴ would be more affected by our original proposals because there is an association between CHD and learning disability / difficulties, meaning that there is a higher likelihood of learning disability / difficulties amongst people with CHD.
69. Many children with congenital heart disease experience delays in their development. Some children with congenital heart disease also have learning disability / difficulties which are thought to be caused by a poor oxygen supply during early life, which affects the development of the brain. Natural intelligence is usually unaffected, but some children often perform well below the academic level they would be expected to reach.
70. In addition there is an association between Down's syndrome and CHD. Around 50% of children with Down's syndrome have a congenital heart defect and around 60% of children with Down's syndrome who are born with a heart defect require treatment in hospital.
71. Finally, there is an association between 22q11 deletion syndrome and CHD so that between 50 and 85% of individuals with 22q11DS have congenital heart disease. While there is a wide range of abilities in the 22q11DS population the vast majority of children will require educational support at some point as the intelligence of children with 22q11DS tends to be below average for their particular age group.
72. A greater proportion of people with learning disabilities die of disorders relating to congenital and chromosomal abnormalities (most commonly deaths reported as being due to Down's syndrome or congenital heart malformations) than the proportion of people in England and Wales as a whole.
73. People with learning disabilities or on the autistic spectrum tend to find change difficult. Any service change for this population needs to be managed well. This is not unique to the CHD proposed service change; however careful consideration should be given to the management of change for these patients.
74. The particular needs of people with CHD and LD are recognised throughout the standards. The standards address the particular needs of people with learning disability for example in requiring appropriate facilities, appropriate communication and individualised transition to adult services. There is also a requirement to work with the learning disability team and for CHD health professionals to include training on meeting the

⁴ In the UK both learning difficulty and disability are often used as interchangeable terms recognising there is a spectrum of conditions that fall within this bracket. This document will use learning disability (LD) to cover both terms.

needs of people with learning disability in their continuing professional development. Many other aspects of the standards will have a positive effect on the experience of people with learning disability and their families. Examples are: (standard C2) patients are cared for in an environment that takes account of the particular needs of people with a learning disability; that (standard E1) staff undertake CPD that includes working with people with LD; that (standard H15) the CHD team works closely with the LD team to ensure appropriate support is provided; and that (standard I11) the particular needs of young people with learning disabilities and their parents/carers must be considered, and reflected in an individual tailored transition plan.

75. We have worked closely with two charities with a particular interest in LD and CHD throughout: Down's Heart Group and Max Appeal. We have also been in regular contact with 22 Crew. We were able to meet with and hear from young people with LD during our engagement events for children and young people during the consultation on standards. Their views informed the standards. We have also sought their advice on the impact of the original proposals on this group, and on our approach to consultation.
76. An EasyRead version of the consultation material was created for CHD patients and families to enable those who did not wish or were unable to read full consultation materials. Advice from CHD specific learning disability charities was taken to ensure the EasyRead version enabled as many people to interact with the consultation as possible; an online webinar meeting was held rather than a physical meeting for families of those with CHD and learning difficulties. One respondent to consultation considered that more information should have been made available in an easy-read format.

What we heard in consultation

77. We asked consultation respondents whether they considered themselves to have a disability. 4% said that they did, but just over half of respondents either preferred not to say or did not answer this question. One respondent said that it was 'good that learning disabilities / autism have been considered'.
78. We asked charities that work with people with both CHD and learning disabilities about the potential impact of our original proposals on people with learning disabilities. Their concerns have centred on the practical elements of change like travelling to a new location, and patients being treated by clinical teams in a location that they are not familiar with. People with learning disabilities allow clinicians that they know to work with them and may refuse the same treatment in an unfamiliar surrounding by unfamiliar people. They told us that:

- People with LD and especially people with autistic spectrum disorder cope best when things are familiar, so changing settings and changing staff is more of an issue. Any changes / adjustments to current services are likely to cause concern to families affected by CHD. Hopefully with good information about the changes families will experience positive long term outcomes.
- 60% of those with any form of Q22 deletion will have an anxiety disorder of some kind, and this makes change and new experiences (as well as everyday experiences) particularly traumatic.
- Many patients/ families build good trusting relationships with their hospital teams, so any changes to those relationships will take time to re build confidence in the new teams looking after their care.
- We need to be able to let patients and their families / carers know what is going to happen very clearly including the practical details.
- Travel for people using wheelchairs or supportive aids is difficult. Children with autistic spectrum disorders often can't use public transport easily. So the issue of access and travel needs extra attention and support for people with learning disabilities and their families / carers
- The impact of a cancellation on a family of a patient with learning disabilities can be huge – so capacity at centres taking additional patients will need to be sufficient that cancellations can be minimised.
- Care and attention needs to be paid to any successful change and transition - visits with familiar staff to new units, new staff coming to meet a patient on familiar ground, arranging for visits prior to surgery or interventions to see where things will happen, what the ward looks like etc. can help.
- Discharge needs better planning and organisation so that travel doesn't mean that patients are arriving at their destination very late at night, and out of their regular schedule.
- Parents and carers need to be included in the planning each patient's needs.
- The following points need to be taken into consideration when planning and delivering any changes:
 - Consistency, changes to practices and continuity of care will be particularly important and co- location with services for other complex needs.
 - Communications with different teams may need more attention.
 - Travel arrangements and help with the cost of journeys as they may have restricted income.
 - Special attention to transitional processes to adult services.
 - They may require additional support and facilities whilst in hospital.

79. Respondents advised us of their views on the original proposals as they would affect people with learning disabilities:

- Changes could be particularly difficult for those affected by learning disabilities and complex needs; some family members may also be affected; difficulties could present both in inpatient stays and outpatient appointments; could disrupt family life; the distance and impact on the whole family would be greater.
- Could cause anxiety for a person with an LD e.g., a new environment; visits to hospital would add a further increase to the anxiety level; mental health of patients, families and carers will be affected.
- Parents with a child with chronic disabilities need to be with their child to advocate for them; longer time away from their parent/carer;
- Low income and disability go hand-in-hand – how would people afford the extra journey? As long as income benefits remain in place people should be ok; would travel be subsidised?
- Increased travel affects both the patient with LD and parents/carers (who may themselves have a disability). If those with a disability cannot drive, how would the poor public transport help the situation? Medical equipment may need to be carried with the patient/carer: how would this be managed on public transport? Taxis are expensive. Those patients and carers with disabilities may lose their jobs as they have to take more time off work and travel further. Therefore livelihoods could be at risk.
- Need to note that learning disabilities and difficulties are different
- Local units have learned an enormous amount from the Royal Brompton re the managing of disabilities and co-morbidities.
- If a person has CHD and a kidney problem they can't walk far and this could hinder them if the journey was longer.
- People may need to stop over if they have a long distance or early appointments.
- Outcomes for those with disabilities will need to be monitored.
- Co-location will reduce transfers between hospitals and reduce disabilities
- Choice is being taken away from those with disabilities
- Strain will be placed on the remaining centres to deal with for example Down's syndrome and complexity of cases
- Continuity of care is essential.
- Clinical Liaison Nurses offer support to patients, families/carers and teaching staff and often provide this at home and school, to help the care, management and capabilities of the patient. They are essential to support and at a Level 1 centre out of the East Midlands it is unlikely they will offer this support into the East Midlands.

Mitigating the impacts of the proposed changes

80. The following advises the potential impact and the proposed mitigations for the impacts, in respect of LD.
81. Impact: Changing settings and staff is more of an issue for people with LD especially being treated by different clinical teams in a location that they are not familiar with. People with learning disabilities allow clinicians that they know to work with them and may refuse the same treatment in an unfamiliar surrounding by unfamiliar people
82. Mitigation: We will ask the hospitals involved to look carefully at how processes are managed if our original proposals were to be implemented. We would ask them to maximise continuity in care so that as much as possible can remain familiar, for example continuing under the care of the same consultant where possible; Visits with familiar staff to new units; new staff coming to meet a patient on familiar ground; arranging for visits prior to surgery or interventions, to see where things will happen, what the ward looks like etc. can help. We think the pattern set out in the standards for transition from children's to adult services may be helpful. This emphasises the need to give special consideration to the needs of people with LD and describes a range of practices that could be usefully adapted to the task of managing the transfer of patients from one hospital to another:
- the opportunity to visit the new centre and meet the new staff in advance of the change happening.
 - specific responsibility to teams to co-ordinate the process lies with specialist nurses from the two
 - a named key worker is nominated to act as the main point of contact and to provide information and support
 - high quality information is transferred with the patient
 - special consideration is given to the needs of children and young people with LD
 - psychological support is made available
83. Impact: Travel for people using wheelchairs or supportive aids is difficult. Children with autistic spectrum disorders often can't use public transport easily.
84. Mitigation: We will continue to commission services to ensure that as much care as possible is as local as possible to minimise the number of longer journeys. Most outpatient care and investigations can be undertaken in level 2 centres, level 3 services and outreach clinics. We will also emphasise the need for good discharge planning so that travel doesn't mean that patients are arriving at their destination late in the

evening or at night, aiming to avoid undue disruption of their regular schedule.

85. We have and will continue to work with and inform ambulance commissioners and service providers to ensure they are aware of any proposed service change and the relative numbers and potential flow of patients.
86. Impact: The effect of a cancellation on a family of a patient with learning disabilities is bigger because of the difficulty of dealing with changes to what is expected and the level of planning and support that will have gone into the admission.
87. Mitigation: We will ensure that there is no decrease in overall capacity as a result of the proposed changes – we have assured ourselves that the hospitals that will receive more patients are able to expand their capacity accordingly: not just their facilities but also the additional staff needed. The standards (for example F14, F15 and F16) pay close attention to the issue of cancellations, particularly last minute cancellations, and these will be monitored locally and in performance management meetings with commissioners.
88. Impact: Information needs to be made available in a form that can be understood by all patients.
89. Mitigation: The standards address the particular needs of people with learning disability for example in requiring appropriate facilities, appropriate communication and individualised transition to adult services, for example:
90. Standard H7(L1): Information must be made available to parents and carers in a wide range of formats and on more than one occasion. It must be clear, understandable, culturally sensitive, evidence-based, developmentally appropriate and take into account special needs as appropriate. When given verbally, information must be precisely documented. Information must be interpreted or transcribed as necessary.
91. Standard H15(L1): The Children's Cardiac Nurse Specialist must make appropriate referrals as needed and work closely with the learning disability team to provide information and support to patients with learning disabilities. Support for people with learning disabilities must be provided from an appropriate specialist or agency.
92. Impact: Longer journeys will mean higher costs that will impact on those from low income families and single parents disproportionately
93. Mitigation: Local Trusts are able to reimburse those on low incomes through agreed government criteria. Help and support will be available from Patient Liaison Services (PALS). A link to the support available can

be found on the NHS website, which can be found here <http://www.nhs.uk/NHSEngland/Healthcosts/Pages/Travelcosts.aspx>

94. The full version, for ease, can be found in Appendix A.

People of Asian ethnicity

95. People who are of Asian ethnicity have a higher incidence of CHD, and may be more likely to have more severe forms of the disease. The most recent census data⁵ shows that in England and Wales 7.5% of the population is of Asian or Asian/British ethnicity whereas the proportion of admissions for CHD that are Asian or Asian/British is 11.2%. The proportion of admissions for CHD that are Asian or Asian/British is slightly higher at the hospitals where change has been proposed, so people of Asian ethnicity are slightly more likely to be affected by the original proposals than the population as a whole.

Proportion of admissions that are of Asian or Asian/British Ethnicity ⁶	
Central Manchester	15.9%
Leicester	12.6%
Royal Brompton	12.1%
England average	11.2%

96. Considerable efforts have been made to engage with BME groups before and during consultation. Consultation materials were provided in 5 languages (Urdu, Tamil, Gujarati, Hindi and Punjabi) for CHD patients and families from South Asian backgrounds, additionally all CHD clinicians were written to, to encourage patients of South Asian descent to contribute to the consultation and NHS England made the offer of translators available.
97. The recent consultation on commissioning and implementation of the standards demonstrated a wider engagement from BME groups than the consultation on standards with 9.4% of responses coming from people of Asian ethnicity. The most recent census data⁷ shows that in England and Wales 7.5% of the population is of Asian or Asian/British ethnicity.

What we heard in consultation

98. In terms of the impact upon the South Asian communities, it should be noted that 88% of those responding within the survey with this ethnic

⁵ ONS Census 2011: <https://www.ons.gov.uk/peoplepopulationandcommunity/culturalidentity/ethnicity>

⁶ Source: NCDR SUS 13/14 to 15/16 - This figure is based on the average number of people with a primary diagnosis of CHD and ethnic category H (Asian) who were recorded as having been admitted as an inpatient between the years 2013/14 and 2015/16. Those whose ethnic category was 'Not known' and 'Not stated' have been excluded (4672 of 26605 records)

⁷ Source: ONS Census 2011:

<https://www.ons.gov.uk/peoplepopulationandcommunity/culturalidentity/ethnicity>

background were from the Midlands & East region. Therefore, most comments mainly reflected the regional feedback for the Leicester area and the feeling that the potential loss of CHD services would unfairly impact upon the large South Asian community in that area.

99. It was felt that there is a need to consider language barriers, where English is not the first language for patients and where there may be the potential loss of support staff that can speak other languages (especially in the Leicester area).
100. In terms of religious beliefs, one respondent wondered whether the impact assessment should also consider religious beliefs.
101. The following outlines views expressed in consultation:
 - Given the evidence of higher incidence amongst South Asians - and the closure of the CHS services in those named areas - this proposal is effectively indirect discrimination against the south Asian community in those areas as per the definition in the Equalities Act 2010; there is a very high proportion of BME people living in Leicester (over 50%), the proposals seem to further knowingly create disadvantage to these families; the Asian community is disproportionately disadvantaged by the proposed closure of Leicester.
 - Using heat maps to demonstrate users of services for those patients by age, ethnicity, disability and distance travelled, will show a different picture.
 - There is a higher incidence of congenital heart defects in the BME community, therefore these proposals are discriminatory against a group on the basis of their ethnicity; this is a particular issue for Manchester and Leicester; you identify the Asian community as being at high risk for CHD.
 - Leicester has a high Asian population - this patient group & there family culture would be affected by the proposals
 - Have you considered the possible effect on the Black and Minority Ethnicity community of having to learn to understand what is happening, and where to go, if the CHD care was not locally integrated?
 - Gender has been disregarded in the report. Women are more likely to be caring roles, reduced financial opportunities and in some cases social opportunities. Women are more likely to have insecure, part time, low wage employment. Burden of responsibility can fall more heavily on mothers, daughters, wives. One woman can have to fulfil all roles and ensuing responsibilities at once. This can impact if they are patients or carers. Travel would not always be an easy option. Ethnicity has been mentioned but not applied to gender, the circumstances of women or men from certain ethnic groups may also restrict their social, economic and familial mobility. Leicester has a diverse cultural make up.

- Many congenital heart conditions affect whole families, and are likely to have an ethnicity bias of which the proposals to reduce the number of congenital heart centres will adversely affect due to the locations of the centres recommended for closure.
- Leicester has one of the largest Asian communities in the UK and it seems absurd that Glenfield is under threat. What other health threats to the Asian community will arise in the future - are these being investigated?
- Leicester has a strong Asian population. So does Manchester. The staff understand the cultural and religious requirements. I do not see that happening in other hospitals.
- Leicester has a very unique diverse population - our extended family. We have a large South Asian population, predominantly from India, Pakistan, Bangladesh and East Africa as well as an Afro-Caribbean population, and also in recent times people from Poland and Somalia. With this we also have a large white population from different parts of UK. This very diverse population has very unique needs which are met brilliantly and very effectively by the paediatric heart surgery team based at Glenfield hospital. It has taken a long time to understand these needs and excellent work in this area will be lost and hence patients will suffer. Surely, Glenfield at the forefront for the Asian community should be kept open. There must be other areas of research from this hospital which with help could bear fruit.
- The impact on the BME community needs to be properly considered, particularly in the context of the proposed closure UHL which has an above average proportion of people within the Asian population.
- Leicester has a younger than average population - hence a higher birth-rate. It has a significant Asian population at particular risk of CHD. Population growth has been amongst the younger age-groups against the trend of other areas.
- Socio-economic , cultural and race impact on outcomes and healthcare demand. The NW cover significant deprived areas and therefore the resources required would be different from other areas of the country.
- Support can be underestimated and this needs to be more seriously taken into consideration particularly when considering Asian families and those for whom English is not their first language; non-British families would suffer inequality as they are more unlikely to have a family support network to support parents and siblings.
- They are more likely to be affected and to remove the facility when it is likely they will need it most seems a paradox.
- In Leicester you have access to different language support staff and the local support services can support different ethnic background; the service from local council, religion, support from external services well established

- Understanding of English and in medical terminology, for those whose first language may not be English.
- Unacceptable extra costs for refugees and asylum seekers.
- Lead to vast disruption and patient care will be greatly affected. Patients get separated from their consultants, who not only know every inch about their condition but also have the patients trust, as well as their family who suffer from the same genetic mutation and then you lose all that family research and understanding of that particular gene mutation (this has happened to all my family members when NHS closed The Heart Hospital and moved to St Barts London). Genetic research will be affected as consultants move on.

Mitigating the impacts of the proposed changes

102. Impact: The centres where change is proposed are particularly attuned to the needs of patients of Asian ethnicity and this will be lost if those patients need to receive their care at another centre.
103. Mitigation: Although the proportion of Asian patients is slightly higher at the centres where change has been proposed, all the centres care for significant numbers of patients of Asian ethnicity and are able to meet their needs.
104. The standards address the communication needs of people who do not have English as a first language including the provision of interpreters. They also require that communication and information be culturally appropriate, and similarly the support provided at the time of bereavement. The service specification requires that the food and hydration provided meet any reasonable requirements arising from a service user's religious or cultural background. These were the only areas identified during the development of the standards, including the consultation process, which were considered to require a different approach depending on ethnicity.
105. Impact: Because the proportion of people of Asian ethnicity in the catchment of the hospitals is higher than for other centres, these proposals are discriminatory and in breach of the Equalities Act 2010.
106. Mitigation: We do not consider the original proposals to be discriminatory.
107. Firstly, although they are more likely to be impacted by the original proposals we do not have any evidence that people of Asian origin with CHD would be affected differently – we expect that the impact on people of Asian ethnicity will be comparable to that on any patient (current or future) of the centres where change has been proposed. This view was reinforced by the Clinical Advisory Panel which did not consider that people of Asian ethnicity would be differently affected if the original proposals were implemented.

108. Secondly, implementation of the standards is specifically designed to ensure that everyone benefits from services provided to a consistent standard wherever they live. So our original proposals advantage rather than disadvantage patients of Asian ethnicity currently receiving their care from hospitals assessed as not meeting key standards.

Other equalities and inequalities issues identified in consultation

109. Respondents to the consultation raised a number of other issues which they felt we should have considered in our equalities and inequalities assessment. Not all are considered to be equalities/inequalities according to the formal definitions, but we have summarised them in the following table and given our response.

Area of concern	What was said	Response
Travellers	Travellers are suspicious of change and therefore such changes may inadvertently disproportionately affect the named group	While not accepting this characterisation of travellers, the original proposals will ensure that travellers will be able to be confident of receiving high quality care wherever they access services.
Poverty	Those with low incomes will be disproportionately be impacted on with longer journeys and stays away from home. Visitors may be limited for a similar reason, causing further challenges for those with low income	Financial support for travel and where necessary overnight stays is available to those on low incomes. As much care as possible will continue to be delivered locally.
Rurality	The impact on those living in small villages with poor public transport will be greater and will affect those with low incomes more. This would be exacerbated for those with disabilities and or caring for someone with a range of comorbidities	As much care as possible will continue to be delivered as locally as possible. However, the nature of specialist services is that they cannot be provided in every town and village, and access to these services may be challenging for some, wherever they are provided. Although access to services (not just CHD care) is an issue for rural populations, rural areas often have a higher number of cars because of the need for private transport. Rurality is not necessarily associated with poverty, but financial support for travel and where necessary overnight stays is available to those on low incomes.
Geography	An East - West divide in	It is in the nature of specialist services is

Area of concern	What was said	Response
	<p>provision with a lack of a service on the East Coast from Newcastle to London.</p> <p>A postcode lottery where some areas have better access to services than others.</p>	<p>that they cannot be provided in every town and village. Level 1 CHD services are not provided in every region even now, for example there is no service in East Anglia or Wales. There is no evidence that outcomes are affected by distance from a level 1 centre. There is, however, evidence that the nature of the care offered by the centre does make a difference to outcomes and that is what is addressed by the standards.</p> <p>Although the continuation of services where they are is of great importance for some people, we have equally heard from many people that they would travel 'to the moon' to get access to high quality care, and this is evident in the support for the highly specialised transplant services that are provided in only two locations nationally.</p> <p>Our original proposals are the opposite of a post code lottery in that they ensure access to high quality services for everyone, regardless of where they live.</p>
Vulnerability & Age	<p>Long journeys and medications may be a challenge e.g., patients or carers on diuretics – given the number of times required to stop. People may not attend follow-ups – therefore impact on long-term care.</p>	<p>It is good news that more people with CHD are living to an older age. Adult CHD services are increasingly developing approaches to care for older patients. As much care as possible will continue to be delivered as locally as possible.</p> <p>Telemedicine, outreach and support through liaison nurses is advocated in the standards (See Standard A1/L3 re telemedicine usage).</p>
Integrated service impact	<p>The service proposed will impact on the other service provision e.g. for the Cystic fibrosis service, neuromuscular services; lack of PICU beds; research - if CHD services are decommissioned.</p>	<p>These issues have been addressed in detail by the National Panel and are covered in their impact assessment.</p>
Mental Health	<p>Increased stress with relationship changes with clinicians in other centres for patients, carers and families; post- traumatic stress for mothers due to</p>	<p>Some of these issues have been addressed above in our consideration of the impact on people with CHD and LD.</p> <p>The standards, once implemented will mean greater access to psychological</p>

Area of concern	What was said	Response
	<p>post -natal depression and having children with CHD. Potential longer waits for appointments and surgery. Social workers and liaison nurses are required as well as financial support to support patients and carers/families. Long-term condition – risk of family breakdown.</p>	<p>support for CHD patients and more specialist nurses. The standards require support for patients, carers and families and access to support groups - see standard H24 (L1).</p>

Appendix A: Healthcare Travel Costs Scheme (HTCS)⁸

If you are referred to hospital or other NHS premises for NHS specialist treatment or diagnostic tests by your doctor, dentist or other health professional, you may be able to claim a refund of reasonable travel costs under the Healthcare Travel Costs Scheme (HTCS).

The section below explains who is eligible for the scheme and how to make a claim. If you have questions about help with health costs, join the [Help with health costs team on Facebook](#), where the NHS Business Services Authority will respond to your queries Monday to Friday, 8am to 6pm.

Who can claim help with travel costs?

To qualify for help with travel costs under the HTCS, you must meet three conditions:

Condition one: At the time of your appointment, you or your partner (including civil partners) must receive one of the qualifying benefits or allowances listed below, or meet the eligibility criteria of the [NHS Low Income Scheme](#).

Condition two: You must have [a referral](#) from a healthcare professional for a specialist or to a hospital for further NHS treatment or tests (often referred to as "secondary care").

Condition three: Your appointment must be on a separate visit to when the referral was made. This applies whether your treatment is provided at a different location (hospital or clinic) or on the same premises as where your GP or other health professional issued the referral.

Children and other dependents

You can claim travel costs for your children if you are eligible for any of the benefits described under [condition one](#) and your child has been referred for treatment as outlined in [condition two](#) and [condition three](#). If your child is 16 or over, they may make their own claim under the Low Income Scheme.

Carers and escorts

You can claim travel costs for an escort, if your health professional says that it is medically necessary for someone to travel with you.

Some CCGs may accept claims for help with travel costs if you are the parent or guardian of a child under the age of 16 who you have to bring with you to your appointment.

These payments are made on the basis of the patient's eligibility for the scheme, irrespective of the escort's eligibility.

Who cannot claim help with travel costs?

You cannot claim help with travel costs if:

⁸ NHS Choice website <http://www.nhs.uk/NHSEngland/Healthcosts/Pages/Travelcosts.aspx>

- you are visiting someone in hospital; however, if you are a visitor in receipt of one of the qualifying benefits listed below, you may be able to receive assistance from [your local council](#)
- you are visiting your local GP, dentist or other primary care service provider for routine check-ups or other services, such as vaccinations or cervical cancer screening, as these are excluded from the scheme; urgent primary care services during out-of-hours periods (i.e. between 6.30pm and 8.00pm weekdays, at weekends or on bank holidays) are also excluded

What are the qualifying benefits and allowances?

You can claim help with travel costs if you or your partner (including civil partner) receive any of the following:

- Income Support.
- Income-based Jobseeker's Allowance.
- Income-related Employment and Support Allowance.
- Pension Credit Guarantee Credit.
- You are named on, or entitled to, an NHS tax credit exemption certificate. If you do not have a certificate, you can show your award notice. You qualify if you get child tax credits, working tax credits with a disability element (or both) and have income for tax credit purposes of £15,276 or less.
- You have a low income and are named on certificate HC2 (full help) or HC3 (limited help). To apply for this certificate, you should complete form HC1, which is available from your local hospital, Jobcentre Plus offices, or from the NHS print contract order line on 0300 123 0849.
- You receive [Universal Credit](#) and [meet the criteria](#).

Read more about the [NHS Low Income Scheme](#).

What form of transport can I use?

The NHS organisation handling your claim will base any refund on the basis of what would have been the cheapest suitable mode of transport for your circumstances, which can include your age, medical condition or any other relevant factors.

This means you should use the cheapest, most appropriate means of transport, which in most cases will be public transport. If you travelled by car and your claim was approved, you'll be reimbursed for the cost of fuel at the mileage rate used by [your local Clinical Commissioning Group \(CCG\)](#). You'll also be able to claim for unavoidable car parking and toll charges.

When using a taxi for transport, it is recommended that you agree this in advance with the hospital or CCG before you travel.

Patients in London may be able to claim congestion charges – Find information on the [Congestion Charge NHS Reimbursement Scheme](#) operated by Transport for London.

Help with travel costs before your appointment

In most cases, you are expected to pay for your travel and claim back the costs. The majority of payments are made on the day of your appointment by the cashier. However, if a cashier is not available, it is possible to claim in advance of travel or retrospectively, using the [HC5 \(T\) claim travel charges \(PDF, 347kb\)](#).

The HTCS also allows advance payments to help you attend your healthcare appointments – for example, if you do not have the money to get to your hospital appointment and you are on a low income or benefits.

Advanced payments may also be issued if you are attending a hospital or NHS clinic that does not have a cashier's office. Please contact the hospital or relevant CCG to check.

How do I claim a refund?

You should take your travel receipts, appointment letter or card, and proof that you are receiving one of the qualifying benefits (listed above) to a nominated cashier's office to claim your travel costs.

Nominated cashier offices will be located in the hospital or clinic that treated you. They are responsible for assessing your claim and making the payment directly to you.

In some hospitals, the name of the office that you need to go to may be different – e.g. the General Office or the Patient Affairs Office. If you are not sure, ask reception or [Patient Advice and Liaison Services \(PALS\)](#) staff where you should go.

If the hospital or clinic does not have a cashier facility, you can complete a [HC5 \(T\) form – claim travel charges \(PDF, 347kb\)](#) and post it to the address stated on the form. You can make a postal claim up to three months after your appointment has taken place.

**DMBC ANNEX 3: ASSESSMENT OF THE IMPACT OF IMPLEMENTING THE
PROPOSALS ON WHICH NHS ENGLAND CONSULTED**



**Impact Assessment: Implementing NHS
England's CHD Consultation Proposals**

Congenital Heart Disease Programme

September 2017

Contents

Introduction	4
Impact on hospitals where change was proposed	4
The impact of the proposal that surgery and interventional cardiology for adults should cease at Central Manchester University Hospitals NHS Foundation Trust.....	4
Impact of implementing the original proposal on journey times.....	4
Impact of implementing the original proposal on other providers	4
Impact on other services.....	5
Financial impact	6
The impact of the proposal that surgery and interventional cardiology for children and adults should cease at University Hospitals of Leicester NHS Trust.....	6
Impact of implementing the original proposal on journey times.....	6
Impact of implementing the original proposal on other providers	9
Impact of implementing the original proposal on other services.....	10
Financial impact of the original proposal.....	15
Impact of implementing the proposal that surgery and interventional cardiology for children and adults should cease at Royal Brompton & Harefield NHS Foundation Trust.....	16
Impact of implementing the original proposal on journey times.....	16
Impact of implementing the original proposal on other providers	16
Impact of implementing the original proposal on other services.....	18
Impact of the original proposal on research.....	21
Finance impact of the original proposal	21
Impact of implementing the proposal that surgery and interventional cardiology for children and adults should continue at Newcastle Hospitals NHS Foundation Trust (children's and adult services)	23
Impact of the original proposal on CHD services.....	23
Impact of the original proposal on patients	23
Impact of implementing the original proposal on other providers	23
Impact of implementing the original proposal on other services.....	23
Impact of the original proposal on workforce	24
Finance impact of the original proposal	24
Impact of the original proposals on patients.....	25
Impact of the original proposals on patients: journey times.....	25
What we heard in consultation.....	27

Mitigating the impact of the original proposals on journey times	28
Impact of the original proposals on patients: Inpatient stays	31
Mitigating the impact of the original proposals on inpatient stays.....	31
Impact of the original proposals on patients: Waiting times	32
Mitigating the impact of the original proposals on waiting times.....	32
Impact of the original proposals on services	33
Impact of the original proposals on other services	34
Mitigating the impact of the original proposals on Paediatric Intensive Care	35
Mitigating the impact of the original proposals on ECMO	39
Financial Impact of the Original Proposals	41
Confirmation that revenue costs of implementing standards should be covered by increasing income for increasing activity	41
Assessment of capital requirements at hospitals that would take additional patients under the proposals on which we consulted, and the sources of this capital	42
Financial impact at provider organisations where level 1 services would no longer be provided under the original proposals	43
Workforce Impact of the Original Proposals	45
Recruitment, retention and redundancy	45
Impact of the original proposals on training for clinical professionals.....	48
Impact of the original proposals on commissioners	50
Financial impact of the original proposals: NHS England	50

Introduction

1. NHS England has carried out a full assessment of the potential impacts of the proposals on which it consulted. In doing so it has taken account of the advice of the Clinical Advisory Panel, the work of the National Panel and the views expressed in consultation.
2. The assessment both identifies impacts and, where these are potentially negative, considers how these could be managed.
3. The assessment considers both the specific impacts associated with the hospitals where change has been proposed, and the cross-cutting impacts that could be felt more widely.
4. This confirms that the original proposals could be implemented by the NHS England Board and the impacts of doing so could be appropriately managed.

Impact on hospitals where change was proposed

The impact of the proposal that surgery and interventional cardiology for adults should cease at Central Manchester University Hospitals NHS Foundation Trust¹

Impact of implementing the original proposal on journey times

5. Based on our modelling², we would expect, if the original proposals were implemented, that in future around 96% of patients currently undergoing surgery at Central Manchester, would receive that care at Liverpool Heart and Chest Hospital. Our modelling suggests an increase in the average journey time of 11 minutes for adults who use Central Manchester.
6. Children in the North West already receive their level 1 CHD care in Liverpool, at Alder Hey Hospital.

Impact of implementing the original proposal on other providers

7. Liverpool Heart and Chest Hospital (LHCH) currently provides level 2 CHD services. Liverpool Heart and Chest does not currently have a level 1 adult CHD service. Under tLHCH would begin performing Level 1 services including surgery and interventional cardiology on adults for the first time. The number of patients involved, approximately 90 operations per year as well as the other related activity (interventional cardiology,

¹ On 1 October 2017 Central Manchester University Hospitals NHS Foundation Trust merged with University Hospital of South Manchester NHS Foundation Trust (UHSM) to form Manchester University NHS Foundation Trust. To avoid confusion and for purposes of continuity, this paper continues to refer to the Trust as Central Manchester.

² Our modelling is based on the assumption that patients would travel to their nearest level 1 centre. This assumption is made to aid planning. Patients' right to exercise choice is not affected.

diagnostics, outpatients etc.) will mean a significant change in the cohort of patients and activity levels.

8. The National Panel considered the scale and nature of this change to be a significant challenge for LHCH and therefore the most significant risk amongst hospitals gaining activity as a result of the original proposals.
9. LHCH provided further assurances of its readiness to implement the original proposals if that is the decision of the Board.
10. No significant increase in surgical activity would be expected at Alder Hey as a result of the original proposals. The direct impact on Alder Hey will therefore be minimal.
11. However, under the original proposals Alder Hey will form a joint level 1 centre with Liverpool Heart and Chest Hospital (which does not currently offer a level 1 adult CHD service) with a single surgical team. NHS England accepts the national panel's recommendations that Alder Hey would therefore need to act as the senior partner in the transition of Level 1 services from CMFT to Liverpool Heart and Chest in order to provide assurance for the continuation of the service at CMFT and support LHCH in the development of its service.

Impact on other services

ECMO

12. Central Manchester provided cardiac ECMO for adults with CHD. At the time of the current assessment it was no longer doing so because the level 1 adult CHD service previously provided by Central Manchester had been suspended by the Trust for an indefinite period.
13. If the original proposals were to be implemented, Central Manchester would no longer be able to provide cardiac ECMO for adults with CHD. NHS England would then work with the other hospitals, where increased adult congenital surgery would be expected (Liverpool Heart and Chest Hospital) to undertake the necessary planning and preparation to manage any increase in adult cardiac ECMO capacity that would be needed for CHD patients. These hospitals have already given an assurance that they would be able to expand their services to provide the necessary care for the patients currently cared for by Central Manchester, if the original proposals are implemented.

Maternity care for women with CHD in the North West

14. In its consultation response Central Manchester proposed that, if NHS England's original proposals were to be implemented, it should still have a role in caring for and delivering the babies of pregnant women with congenital heart disease, with a maternity hub remaining in Manchester,

because it believes the benefits of co-located services far outweigh that of having an ACHD surgeon on site.

15. The National Panel noted the advice of the Clinical Advisory Panel that:
‘...women with CHD who are pregnant rarely require surgery or interventional cardiology at or close to the time of delivering their baby. As a result the choice of place of birth will not be affected for most women with CHD, and most antenatal care, most births and most postnatal care will still be in local hospitals or level 2 centres. Place of birth is agreed as part of preparing an individual care plan for each woman, and discussed at the MDT for higher risk patients’.
16. It accepted therefore that Central Manchester could still have an important role in maternity care for women with CHD, working as part of a network of care with a level 1 centre and with agreed network referral guidelines. Under these arrangements, women with complex care needs would be discussed within a network multidisciplinary meeting to determine the best place for delivery. Women with lower risk lesions could deliver closer to home as is current practice.
17. If NHS England’s original proposals were to be implemented, this role could be greater if Central Manchester met the standards for working as an level 2 specialist medical adult CHD centre.

Financial impact

18. The overall contract value for specialised services (including CQUIN) at Central Manchester is approximately £348m. The Trust did not respond to the request to provide information on the potential impact of the original proposals. Prior to the launch of consultation, NHS England estimated that the financial effect of the proposed changes would be around £1m. The financial impact of this change is therefore not likely to have a significant impact on the Trust.
19. Some of this loss of income could be reduced if Central Manchester continued to provide level 2 adult CHD services. The loss of income to the Trust would also, to some extent, be offset by a reduction in costs.

The impact of the proposal that surgery and interventional cardiology for children and adults should cease at University Hospitals of Leicester NHS Trust

Impact of implementing the original proposal on journey times

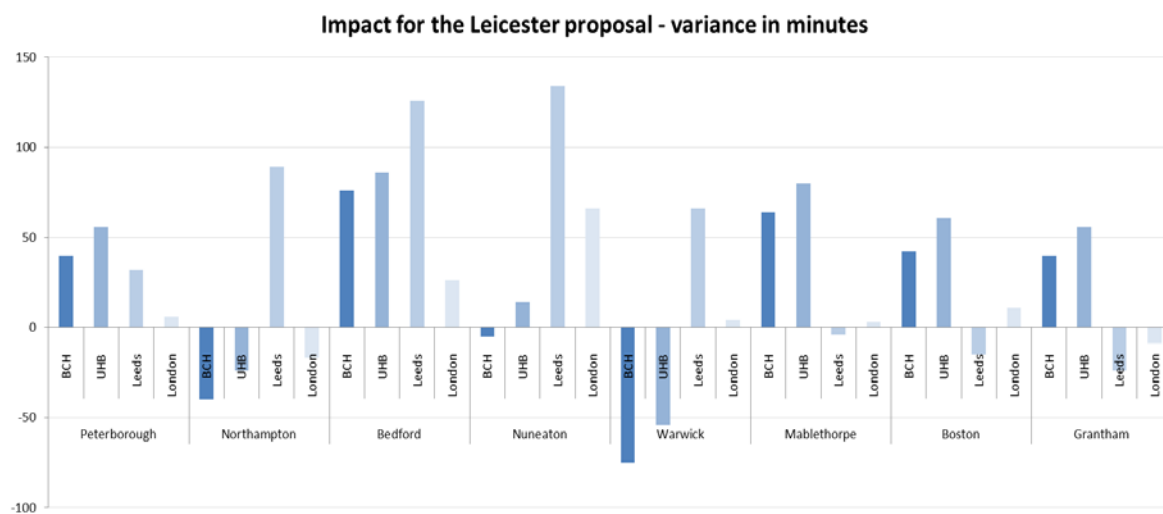
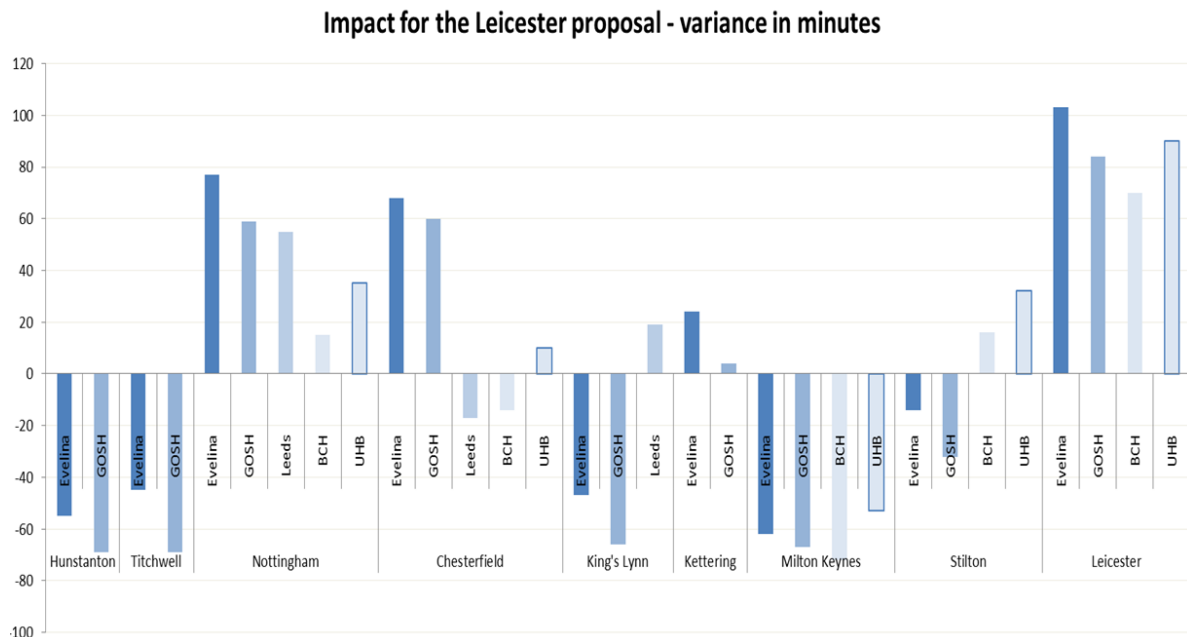
20. Based on our modelling³, we would expect, if the proposals on which we consulted are implemented, that in future around 76% of patients currently

³ Our modelling is based on the assumption that patients would travel to their nearest level 1 centre. This assumption is made to aid planning. Patients’ right to exercise choice is not affected.

undergoing surgery at Glenfield Hospital (part of UHL), would receive that care in Birmingham at Birmingham Children's Hospital and University Hospitals, Birmingham. A further 16% of surgery would be provided in Leeds at Leeds General Infirmary because this would be closer for some patients than Birmingham. Our modelling suggests an average increase in the average journey time of 13 minutes for children who use Leicester and 32 minutes for adults.

21. In consultation many respondents felt that the assessment of the impact of the original proposals on patient travel was not accurate. These comments were particularly heard from stakeholders in the East Midlands and members of the public.
22. NHS England undertook a sensitivity analysis which excluded from the travel time modelling those patients currently using Leicester for whom it is not the closest centre. Considering only those patients using UHL for whom it is their closest centre, if the original proposals were implemented, 90% of children would be within 1 hour 42 minutes of their nearest centre, an increase of 27 minutes while for adults, 90% would be within 1 hour and 44 minutes an increase of 31 minutes.
23. This analysis suggests that part of the reason why respondents may have felt that NHS England's modelling was not accurate was because they were only considering the impact on patients for whom Leicester is the closest centre.
24. We also note that where patients and their families travel by public transport rather than by car the effect of the original proposals can be quite different, with some journey times potentially falling.
25. We undertook some modelling of travel times by public transport for UHL patients to demonstrate this effect. Figure 1 below shows the potential change in journey time, if the original proposals were to be implemented, for patients in the Leicester notional catchment, when defined as being the closest level 1 CHD centre by road. This shows that, in practice the notional catchment would be different if modelled on the basis of public transport journey times, and that for a number of locations, other centres are already closer. When public transport journeys are taken into account, the impact of the original proposals on journey times could therefore be considered to be less than has previously been considered.

Figure 1: Difference in travel time by public transport from towns and cities within UHL's notional catchment if the original proposal was implemented⁴



⁴ The time to travel by public transport is calculated by using Google Maps. Thursday 31/08 8am is the journey start day and time. This analysis does not take into account various problems with public transport.



Impact of implementing the original proposal on other providers

26. If the original proposals on which we consulted are implemented they would be likely to result in significantly increased activity at Birmingham Children's Hospital. The number of patients involved, equivalent to 225 operations per year, is relatively large this represents a significant proportional increase in activity for Birmingham Children's of 45%.
27. Birmingham Children's Hospital is confident of its ability to increase its capacity sufficiently to provide the extra activity required under these proposals. The panel considered that it had provided very good evidence of having understood the scale of what would be required and of plans to increase capacity. Birmingham Children's did not identify any capital requirements in order to achieve this increase capacity.
28. The panel did not consider there to be any significant risks associated with Birmingham Children's Hospital increasing their capacity to meet the activity required by the original proposals but did note the challenges associated with the recruitment of staff, most notably PICU nurses, and the need for sufficient lead in time.
29. The original proposals would also be likely to result in increased activity at University Hospitals Birmingham (UHB). The number of patients involved is relatively modest, equivalent to 42 operations per year, although this represents a 66% increase in activity for UHB.

30. University Hospitals Birmingham (UHB) is confident of their ability to increase their capacity sufficiently to provide the extra activity required under these proposals. The panel considered that UHB had provided good evidence of having understood the scale of what would be required of them and of their plans to increase capacity.
31. University Hospitals Birmingham indicated that it would need to source capital funds of £6M to accommodate additional activity. It is expected that they would be able to source the capital funding from existing allocations and/or charitable funds. This is being confirmed with NHS Improvement.
32. The panel did not consider that there was any significant risk associated with UHB absorbing this additional activity.
33. Considered in the light of the scale of its overall adult cardiac service including ITU⁵ provision, the increased level of CHD activity it would absorb as a result of the proposed changes was not considered to be significant by the panel, which was therefore confident that any transition of activity would be able to be undertaken in a timely manner.
34. The original proposals would also be likely to result in increased activity at Leeds Teaching Hospitals. The number of patients involved, equivalent to 57 operations a year, is relatively modest and represents a small proportional increase in activity for Leeds of 14%.
35. Leeds Teaching Hospitals is confident of their ability to increase its capacity sufficiently to provide the extra activity required under these proposals. The panel considered that it had provided good evidence of having understood the scale of what would be required of it and of their plans to increase capacity.
36. Whilst the panel had some concerns relating to its ability to increase capacity in their cardiac ward, PICU and theatre they did not consider that these posed a significant risk to their ability to provide services for these additional patients.

Impact of implementing the original proposal on other services

Paediatric Intensive Care

37. Leicester has two paediatric intensive care units (PICUs), one at the Leicester Royal Infirmary and one at Glenfield. It is the Glenfield PICU which supports CHD patients who account for around 78% of its bed usage. If Leicester continues to provide level 1 paediatric cardiac surgery its plans for co-location involve the consolidation of the two PICUs at the Infirmary. The PICU at Glenfield will therefore close whatever decision is taken by NHS England.

⁵ Intensive Therapy Unit

38. Without predetermining the outcome of the national paediatric critical care review, at this point NHS England expects Leicester would still provide PICU care for the East Midlands if the original proposals on which we consulted are implemented, and even if it no longer provides level 1 paediatric cardiac surgery. The National Panel noted the Clinical Advisory Panel's view that it did not consider that the absence of CHD patients would threaten the viability of the service offered by the PICU at the Leicester Royal Infirmary. Other hospitals without CHD services offer PICU services at a similar scale without difficulty.
39. The National Panel accepted as reasonable NHS England's plans to re-provide PICU capacity if its original proposals were implemented.
40. ***Re-providing PICU capacity for CHD patients:*** NHS England will work with the other hospitals where increased paediatric cardiac surgery would be expected if the original proposals are implemented (Birmingham Children's Hospital, Leeds General Infirmary) to undertake the necessary planning and preparation to manage any increase in PICU capacity that would be needed for CHD patients.
41. ***Re-providing PICU capacity for respiratory ECMO patients:*** A significant proportion of the remaining usage of the Glenfield PICU is accounted for by patients on respiratory ECMO. NHS England would work with the other hospitals where increased paediatric respiratory ECMO would be expected if the original proposals were implemented, to undertake the necessary planning and preparation to manage any increase in PICU capacity that would be needed for these patients.
42. ***Re-providing PICU capacity for other patients:*** A small number of admissions to the Glenfield PICU are for other patient groups. NHS England would expect that these patients would in future still receive their care from UHL, but at the LRI PICU.

Paediatric Cardiac and Adult Congenital Cardiac ECMO

43. Leicester provides cardiac, respiratory and mobile ECMO for children. Taken together these services support around 55 children a year. It also provides cardiac ECMO for adults with CHD. If the original proposals were to be implemented, Leicester would no longer be able to provide cardiac ECMO for children; cardiac ECMO for adults with CHD; mobile ECMO for children; or respiratory ECMO for children.
44. The National Panel accepted as reasonable NHS England's plans to re-provide ECMO capacity if its original proposals were implemented.
45. ***Re-providing ECMO capacity for CHD patients:*** NHS England will work with the other hospitals, where increased paediatric cardiac and adult congenital surgery would be expected, if the original proposals are

implemented, (Birmingham Children's Hospital, Leeds General Infirmary, University Hospitals, Birmingham) to undertake the necessary planning and preparation to manage any increase in paediatric cardiac and adult congenital cardiac ECMO capacity that would be needed for CHD patients. These hospitals have already given an assurance that they would be able to expand their services to provide the necessary care for the patients currently cared for by UHL, if the original proposals are implemented.

46. ***Re-providing Paediatric Mobile ECMO:*** Paediatric ECMO transport can be placed into three categories:
- Conventional transport, whereby a critically ill child who has been accepted for ECMO support is transported to an ECMO centre in order to be cannulated and placed on ECMO. If the original proposals were implemented conventional transport could continue to be undertaken by existing transport teams.
 - Cannulation and mobile ECMO, whereby an ECMO team travels to a child, cannulates them onto ECMO support, and then transports them on ECMO to the ECMO centre.
 - Mobile ECMO transfer, whereby a child already on ECMO is moved from one ECMO centre to another for ongoing care.
47. Cannulation and mobile ECMO require specialist expertise including a consultant experienced in cannulation as well as perfusion nursing and medical input. The National Panel noted the Clinical Advisory Panel's confidence that mobile ECMO could be re-provided if one or more centres and/or retrieval services were commissioned to provide this service.
48. Glenfield Hospital is currently the only centre in England commissioned to provide paediatric and neonatal cannulation and mobile ECMO. This model of delivery, being reliant on a small group of staff within one service, is considered to be unsustainable in its present form. It is likely therefore that NHS England will re-procure this service within the next 18 months as part of the paediatric critical care review with the aim of creating greater service resilience.
49. Depending on the outcome of the CHD review, NHS England may seek one provider in the north and one in the south. The commissioning of two transport teams was also a recommendation of the work done by the Highly Specialised Commissioning Team in 2012/13 on the future delivery of paediatric respiratory and cardiac ECMO services. It is expected that some of the existing transport services would wish to tender for this as they have experience in transporting severely critically ill children who are not yet stabilised on ECMO, as well as those already on ECMO. These services already have the necessary retrieval competencies but would

need to develop the necessary ECMO competencies which includes 24/7 availability of staff who are able to cannulate and look after patients who are on ECMO.

50. If the CHD original proposals were implemented, at least one other commissioned respiratory ECMO centre would need to develop the appropriately skilled workforce and the necessary equipment to deliver this service, and this could not be achieved immediately. Taking this into account NHS England will examine the possibility of accelerating plans to tender the service as described above, to create a long term rather than a short term solution.
51. The future development of respiratory ECMO services (described below) could reduce, although not remove, the need for cannulation and mobile ECMO (as more centres would be able to cannulate).
52. ***Re-providing Paediatric Respiratory ECMO:*** Current service specifications stipulate that respiratory ECMO services must be co-located with children's cardiac surgery services. Should Glenfield's CHD services cease, these patients would need to be looked after in one of the other four commissioned paediatric respiratory ECMO centres (Great Ormond Street, Newcastle, Birmingham Children's and Alder Hey) or in an additional centre.
53. While the numbers are small, they represent around half of all the commissioned national paediatric and neonatal respiratory ECMO activity.
54. If the paediatric respiratory ECMO activity currently undertaken by Leicester were to be redistributed so that patients received this care from the nearest of the remaining paediatric respiratory ECMO centres, this would represent a significant increase in paediatric respiratory ECMO activity for some of these centres, especially Birmingham Children's. NHS England estimates that the change would be:
 - 15 patients, 103 bed days to Birmingham Children's compared to existing non-cardiac activity (2015) of 2 patients and 5 bed-days
 - 4 patients, 53 bed days to Great Ormond Street compared to existing non-cardiac activity (2015) of 16 patients and 63 bed-days
 - 6 patients, 56 bed days) to Alder Hey compared to existing non-cardiac activity (2015) of 2 patients and 26 bed-days
 - 2 patients, 16 bed days) to Newcastle compared to existing non-cardiac activity (2015) of 2 patients and 18 bed-days
55. Whilst redistributing paediatric respiratory ECMO activity in this way would mean that the care would be provided by centres already proficient in undertaking the intervention; we would need to work closely with those centres to reduce the likelihood of any decline in the currently excellent

outcomes reported nationally or any significant difference in the application of the eligibility criteria.

56. These centres already have the equipment, staff and infrastructure to deliver respiratory ECMO as currently commissioned. If the original proposals were to be implemented, it would take time to increase capacity and train staff at these centres, and potentially some investment. There would also likely be a need for additional paediatric critical care capacity in these centres.
57. NHS England will work with these hospitals to undertake the necessary planning and preparation to manage a timely increase in the paediatric respiratory ECMO capacity that would be needed if the original proposals were implemented.
58. There are recent precedents for ECMO centres scaling up rapidly; for example when Birmingham and Alder Hey changed from surge providers to permanent providers, or when Guy's and St. Thomas's Hospital developed its adult service over a short timeframe in association with the H1N1 epidemic in 2009.

Adult Respiratory ECMO

59. Leicester also provides adult respiratory ECMO. NHS England expects that Leicester could continue to provide adult respiratory ECMO, in a similar way to other hospitals where services are supported by adult cardiac surgery services (not congenital cardiac). The level of adult respiratory ECMO at Glenfield is at least comparable to the levels of activity at the four other adult respiratory ECMO centres and it is reasonable to assume that it could therefore still be provided on this basis.

Fetal cardiology and specialist obstetric services

60. The National Panel accepted that if the original proposals were implemented there would be an impact on Leicester's fetal cardiology service and that their high risk obstetric cardiology service could be affected including outpatient care, high risk deliveries in cardiac patients and inpatient antenatal care. These impacts would be minimised if Leicester provided a level 2 CHD service.
61. The National Panel noted the Clinical Advisory Panel's advice that all level 1 CHD services (and some level 2 services) offer an extensive fetal cardiology services and that fetal cardiology services would continue to be provided by other providers. If this did not happen Leicester's high risk obstetric service would need to access fetal cardiology support from another centre.

Financial impact of the original proposal

62. The overall contract value for specialised services (including CQUIN) at Leicester is approximately £234m. Prior to consultation, NHS England estimated that the financial effect of the proposed changes would be around £14m. The Trust's own estimate was £19-20m. This difference is partly explained by a difference in view on the impact of the original proposals on PICU. UHL's estimate is based on an assumption that it would no longer be able to provide PICU services. However, the National Panel would expect PICU services to continue at the Infirmary site even if the Glenfield PICU were to close. The loss of revenue to the Trust would therefore represent between 6% and 8% of their total specialised services income. Some of this loss of income could be reduced if UHL continued to provide level 2 services.

Impact of implementing the proposal that surgery and interventional cardiology for children and adults should cease at Royal Brompton & Harefield NHS Foundation Trust.

Impact of implementing the original proposal on journey times

63. Based on our modelling⁶, we would expect, if the original proposals on which we consulted are implemented that in future around 94% of patients currently undergoing surgery at the Royal Brompton would receive that care in London at Great Ormond Street Hospital, Barts Hospital or St Thomas' Hospital (including Evelina). Our modelling suggests that average journey times would stay much the same, as most patients would still get their care from one of the two other level 1 centres in London

Impact of implementing the original proposal on other providers

64. The proposals on which we consulted would be likely to result in significantly increased activity at Great Ormond Street Hospital. While the number of patients involved is relatively large, equivalent to 194 operations per year, this represents a more modest proportional increase in activity for Great Ormond Street of 28%.
65. Great Ormond Street Hospital is confident of its ability to increase capacity sufficiently to provide the extra activity required under these proposals. The panel considered that they had provided good evidence of having understood the scale of what would be required of them and of their plans to increase capacity.
66. Great Ormond Street indicated that it would need to source capital funds of £6M to accommodate additional activity. It is expected that they would be able to source the capital funding from existing allocations and/or charitable funds. This is being confirmed with NHS Improvement
67. Great Ormond Street identified that in order to provide the extra activity required by these proposals they would need additional PICU beds.
68. New capacity already under development will begin to be available from October 2017 and that capacity could be made available to support other centres in the event of unplanned service changes.
69. The panel did not consider there to be any significant risks associated with Great Ormond Street increasing their capacity to meet the activity required by the original proposals, but did note the challenges associated with the recruitment of staff, most notably PICU nurses, and the need for sufficient lead in time.

⁶ Our modelling is based on the assumption that patients would travel to their nearest level 1 centre. This assumption is made to aid planning. Patients' right to exercise choice is not affected.

70. The original proposals would be likely to result in significantly increased activity at Guy's and St Thomas'. While the number of patients involved, equivalent to 178 operations per year, is relatively large this represents a more modest proportional increase in activity for Guy's and St Thomas' of 36%.
71. Guy's and St Thomas' is confident of its ability to increase its capacity sufficiently to provide the extra activity required under these proposals. The panel considered that it had provided good evidence of having understood the scale of what would be required of it and of their plans to increase capacity. Guy's and St Thomas' did not identify any capital requirements in order to achieve this increase capacity.
72. Guy's and St Thomas' identified a need for both additional ward and PICU capacity in order to provide the additional activity modelled under these procedures. It has not identified the number of additional PICU and ward beds required because it is confident that the extra capacity to be provided under its planned expansion scheme will be sufficient. This will provide up to eleven ward beds and up to ten PICU beds by December 2017.
73. The panel did not consider there to be any significant risks associated with Guy's and St Thomas' absorbing the activity required by NHS England's original proposals. However, the panel did note that the most significant risk related to the workforce implications of the original proposals on Guy's and St Thomas' and its ability to recruit the appropriate staff, most notably PICU nurses.
74. The original proposals would be likely to result in increased activity at Barts. While the number of patients involved, equivalent to 85 operations per year, is relatively small, this still represents a doubling of activity for Barts. The panel recognised this scale of increase to be a significant challenge for Barts. Regional commissioners were assured of Barts' ability to increase their capacity sufficiently to provide the extra activity required under these proposals. The panel considered that Barts had a good track record in planning and delivering service expansions.
75. Considered in the light of the scale of its overall adult cardiac service including ITU provision, the increased level of CHD activity it would absorb as a result of the proposed changes was not considered to be significant by the panel, which was therefore confident that any transition of activity would be able to be undertaken in a timely manner.
76. The panel noted that Barts Health NHS Trust is in Financial Special Measures. Some adult CHD activity would be expected to transfer to Barts Health from Royal Brompton if the original proposals were implemented. The proposed expansion of CHD activity at Barts could

improve rather than worsen its financial position by increasing the activity at an existing facility.

77. There is available capacity in the PFI-financed Cardiac Centre on the St Bartholomew's site. Further development of cardiac services is in line with the Trust's strategic aims. Barts did not identify any capital requirements in order to achieve this increase capacity.
78. Barts is part of a joint level 1 centre with Great Ormond Street Hospital with a single surgical team. NHS England accepts the national panel's recommendations that Great Ormond Street would need to act as the senior partner in the scaling up of Level 1 services at Barts in order to provide assurance of the development of its service.
79. NHS England recognised that it would have an important role to play in supporting implementation if the original proposals were agreed.

Impact of implementing the original proposal on other services

Paediatric Intensive Care

80. The Royal Brompton's PICU is largely dependent on their paediatric CHD service, because CHD accounts for 84% of the admissions. The Trust considers that its PICU would no longer be viable if the original proposals on which we consulted are implemented, because paediatric cardiac patients are a large proportion of its work and it would not have enough other patients to stay open. The National Panel accepted that this was an accurate assessment. If the PICU at the Royal Brompton were to close, this would have an effect on their paediatric respiratory services, the only other clinical service for children offered by the Trust (see paragraph 86 and following below).
81. ***Re-providing PICU capacity for CHD patients:*** NHS England will work with the other hospitals where increased paediatric cardiac surgery would be expected if the original proposals were implemented (Great Ormond Street, St Thomas' - Evelina Hospital) to undertake the necessary planning and preparation to manage any increase in PICU capacity that would be needed for CHD patients. These hospitals have already given an assurance that they would be able to expand their services to provide the necessary care for the patients currently cared for by RBH, if the original proposals are implemented.
82. ***Re-providing PICU capacity for paediatric respiratory patients:*** If our original proposals were implemented and RBH also needed to cease to provide paediatric respiratory services, NHS England would work with the other hospitals where their paediatric respiratory patients would be expected to receive their care. Analysis of admissions to RBH's PICU shows that there have been, on average, over the period 2011-15, 105

PICU admissions each year for non-cardiac patients. Most of these patients were from London, East Anglia and the south east.

83. ***Re-providing PICU capacity for other patients:*** A small number of admissions to the Royal Brompton PICU are for other patient groups. NHS England would expect that these patients would in future receive their care from other PICUs in London and the south east.

ECMO

84. The Royal Brompton provides cardiac ECMO for children as well as cardiac and respiratory ECMO for adults. If the proposals on which we consulted were to be implemented, Royal Brompton would no longer be able to provide cardiac ECMO for children. This would affect around 15 children a year. It would no longer provide cardiac ECMO for adults with CHD.
85. ***Re-providing ECMO capacity for CHD patients:*** NHS England will work with the other hospitals where increased paediatric cardiac and adult congenital surgery would be expected, if the original proposals were implemented, (Great Ormond Street, Guys and St Thomas', Barts) to undertake the necessary planning and preparation to manage any increase in paediatric and adult congenital cardiac ECMO capacity that would be needed for CHD patients. These hospitals have already given an assurance that they would be able to expand their services to provide the necessary care for the patients currently cared for by RBH, if the original proposals were implemented.
86. ***Re-providing adult respiratory ECMO capacity:*** We would expect that the Royal Brompton could continue to provide adult respiratory ECMO, in a similar way to other hospitals where services are supported by adult cardiac surgery services (not congenital cardiac).

Specialist paediatric respiratory services

87. The circumstances at the Royal Brompton where paediatric cardiac and paediatric respiratory are the only children's services offered means that the original proposals will have an impact on paediatric respiratory services, if paediatric cardiac services and PICU were no longer provided by the Royal Brompton.
88. The Trust considers that this would have a serious detrimental effect on children's respiratory services which also use the PICU. The list of services offered by the paediatric respiratory services identified by the Brompton are:
- Cystic Fibrosis
 - Difficult asthma

- Primary Ciliary Dyskinesia
 - Neuromuscular diseases requiring Long-Term Ventilation
 - Interstitial lung diseases
 - Sleep services
 - Empyema and severe pneumonia
 - Specialist interventions for rare disease, e.g.lung biopsy
 - Thoracic surgery for congenital malformations
 - Thoracic cancer surgery
 - Bronchoscopy in infants and complex respiratory, ENT and cardiac conditions
89. The National Panel considered that while only a small number of children using paediatric respiratory services at the Royal Brompton would need to use the PICU, that continuing to run a specialist paediatric respiratory service without access to a PICU would be a lesser service. It considered that while it would be possible for the Royal Brompton to continue to run paediatric specialist respiratory services if the original proposals were implemented, it would not be in the best interests of children to do so.
90. The National Panel accepted the Clinical Advisory Panel's advice that the same arguments applied to children with respiratory illness and children with cardiac illnesses – children should have their care provided from a holistic children's environment with on-site access to the full range of paediatric specialties and services. If the original proposals were implemented the loss of paediatric cardiac and intensive care services from the Royal Brompton would mean that paediatric respiratory services were operating in an even more isolated adult environment.
91. The National Panel recommended that if the original proposals were to be implemented that NHS England should conduct a rapid review of paediatric respiratory services for London, East Anglia and the south east to develop alternative solutions. It noted the Clinical Advisory Panel's advice that relocating the whole service would be preferable to simply recommissioning additional capacity elsewhere. It also noted that panel's view that most aspects of the Royal Brompton's service could continue in the short term while this was done.
92. Specialist paediatric respiratory services are provided by a number of hospitals in England, including for example:
- Cystic fibrosis: King's, Great Ormond Street and Barts in London
 - Primary ciliary dyskinesia: a nationally commissioned service also provided at Southampton, Leicester, and Leeds.

Impact on fetal cardiology and specialist obstetric services

93. The National Panel considered that if the original proposals on which we consulted were implemented there would be a significant impact on the fetal cardiology service offered by the Royal Brompton. They also noted that the Trust considered that their work with the cardiac obstetric service at Chelsea and Westminster Hospital would no longer be viable. The National Panel considered that if the original proposals were implemented these services would be provided by the other level 1 and level 2 centres in London and the south east which also offered extensive fetal cardiology services.

Impact of the original proposal on research

94. The Royal Brompton considers that NHS England's original proposals, if implemented, would have a serious effect on the research that it undertakes, particularly in the field of adult CHD. It states that its work in this and related fields are highly regarded internationally and that the factors that underpin its successful research record could not be easily and quickly reproduced elsewhere.
95. This impact was not originally considered by the National Panel as NHS England's focus has been on improving direct patient care.
96. The National Panel accepted the Clinical Advisory Panel's advice that while the existing programmes of research would be disrupted, it considered that these could be undertaken at other centres and that research excellence is linked to individuals and teams rather than institutions. It noted the panel's advice that bringing services together at scale would enhance the environment for research and provide additional opportunities.

Finance impact of the original proposal

97. The overall contract value for specialised services (including CQUIN) at Royal Brompton is approximately £226m. Prior to the launch of consultation, NHS England estimated that the financial effect of the proposed changes would be around £35m excluding the impact on paediatric respiratory services. The Trust's estimate of a £47m loss in income when paediatric respiratory services are taken into account appears to be broadly in line with NHS England's own estimate. The Trust estimated that the loss resulting from these proposals would be approximately 13% of the Trust's total income and 21% of its total specialised services income, which represents a significant financial and business risk. The scale of loss is contributed to by the impact on PICU and the potential impact on paediatric respiratory services.

98. Some of this loss of income could be reduced if the Royal Brompton continued to provide either adult level 2 services and/or adult only Level 1 centres in partnership with a level 1 paediatric centre.
99. The loss of income to the Trust would also, to some extent, be offset by a reduction in costs. Data supplied by the Royal Brompton indicates that its provision of CHD services results in an overall net loss, and therefore although the loss of income is significant it may be that in the long term no longer providing these services is in the best financial interest of the Trust. The Trust stated that owing to the stranded costs associated with this service they estimate an adverse impact of over £7m per year to the Trust's bottom line if these proposals are implemented.

Impact of implementing the proposal that surgery and interventional cardiology for children and adults should continue at Newcastle Hospitals NHS Foundation Trust (children's and adult services)

- 100. If Newcastle continues to be commissioned to provide level 1 services until 2021 there would be no major changes to its services in the short term. Uncertainty would be increased because the decision makes plain that services may not continue unchanged in the long term, and this may impact staff recruitment and retention.
- 101. The increased uncertainty over the future of CHD and advanced heart failure and heart transplant services may affect the organisation's reputation, but the effect is likely to be limited because there is no specific threat to the future of these services. Any longer term reputational impact will be dependent on the commissioning decisions which are made.

Impact of the original proposal on CHD services

- 102. CHD services would continue to function as they currently do until 2021 though service levels may be affected if recruitment and retention are more difficult as a result of the decision.
- 103. Prior to 2021 the necessary mitigations and emergency arrangements are in place to provide the necessary assurances for these services in the short term.

Impact of the original proposal on patients

- 104. In the short term CHD services at Newcastle would be provided in the same way as now. Paediatric patients will continue to receive their CHD care from a hospital without the benefit of a holistic children's environment as required by the standards. Uncertainty about future care arrangements could affect clinician-patient relationships and the choices patients make. Journey times would be unaffected.
- 105. In the longer term, if the uncertainty impacts on the ability of Newcastle to recruit and retain the appropriate staff there is a risk that patients do not receive appropriate levels of care due to staff shortages. By 2021 the uncertainty should be fully resolved.

Impact of implementing the original proposal on other providers

- 106. No change is proposed to the level 1 service in Newcastle so other providers would be unaffected.

Impact of implementing the original proposal on other services

Advanced heart failure and heart transplant

- 107. Advanced heart failure and heart transplant services would continue to function as they currently do. There is a risk that the uncertainty over the

future commissioning of this service impacts the ability of Newcastle to continue to provide and develop this service, for example by affecting recruitment and retention making succession planning within the service more challenging.

Impact of the original proposal on workforce

108. Uncertainty for staff may be increased, potentially negatively affecting the attractiveness to both existing and future staff (retention and recruitment) and staff morale. It is difficult to predict the impact on recruitment and retention. There is a risk that Newcastle will find it more difficult to retain or recruit the necessary staff in the short term until a longer term commissioning decision is made by 2021.

Finance impact of the original proposal

109. Newcastle has identified a cost of £39.6m for its preferred option to achieve compliance with the paediatric co-location standards (building and fitting-out a new paediatric cardiac services centre on the RVI site). The Trust has engaged with NHS England and NHS Improvement regarding financial support for the substantial cost of co-location and submitted a bid for capital to NHSI in September 2017. This bid was supported by the Cumbria and North East STP. NHS England has previously stated that there is no new money to implement the standards. Costs of this order are likely to be considered poor value for money unless other benefits are also realised.
110. Newcastle would not be required to co-locate its service prior to a longer term commissioning decision being made by 2021. This limits the financial impact on the Trust in the short term.

Impact of the original proposals on patients

Impact of the original proposals on patients: journey times

111. A particular concern for patients and their families is that the cessation of level 1 services, as proposed in consultation, would, for some patients, mean longer journeys to hospital, where their care can only be provided by the level 1 centre, which will be inconvenient, and they fear, carry a level of risk.
112. We carried out detailed analysis of the impact of our original proposals on journey times. We used two measures to help understand this impact – the impact on average (median) journey times, and the impact on journey times for most people (90% of patients). Our original modelling showed a modest increase in average journey times for CHD patients across the country as a whole (an increase of 2-8 minutes), with the greatest impact on patients who currently use Leicester (an increase of 13-32 minutes). The impact on maximum journey time for 90% of patients across the country as a whole would be negligible, and again, greatest for patients who currently use Leicester (an increase of 14-26 minutes) – see Table 1 below.

Table 1: Travel time modelling if the proposals are implemented⁷

Going to	Current travel time - median (mins)	Future travel time - median (mins)	Change to median travel time	Current travel time for 90% patients (mins)	Future travel time for 90% patients (mins)	Change to travel time for 90% patients
<i>Paediatric</i>						
RBH	43m 00s	45m 15s	+2m 15s	1h 37m 19s	1h 24m 42s	-12m 37s
UHL	45m 40s	59m 01s	+13m 21s	1h 54m 46s	1h 41m 04s	-13m 42s
Paeds National	43m 41s	45m 34s	+1m 53s	1h 53m 27s	1h 50m 24s	-03m 03s
<i>Adult</i>						
CMFT	29m 05s	40m 06s	+11m 01s	59m 19s	1h 04m 18s	+4m 59s
RBH	47m 50s	46m 15s	-01m 35s	1h 43m 40s	1h 22m 35s	-21m 05s
UHL	41m 10s	1h 13m 18s	+32m 08s	1h 18m 28s	1h 44m 19s	+25m 51s
Adult National	41m 18s	49m 30s	8m 12s	1h 25m 55s	1h 25m 33d	-00m 22s

113. In consultation many respondents felt that the assessment of the impact of the original proposals on patient travel was not accurate. These comments were particularly heard from stakeholders in the East Midlands and members of the public.

⁷ Source – HES 2006/07 to 2014/15 and Google Maps API: These tables display current and potential future travel times for patients who have been admitted as inpatients based on car travel time as calculated by google maps. Both the median travel time and the maximum travel time for 90% of patients are displayed. Patient postcodes as recorded in HES have been used.

114. It is usually assumed that the great majority of patients use their closest centre and that each hospital has a clearly defined geographical catchment area. However, all centres lose some patients from their natural catchment and attract others from outside their natural catchment.
115. Our analysis shows that nationally 28% of patients do not currently go to their closest centre. In addition, many patients attend outpatients in one centre and are admitted to another, or have admissions at more than one centre.
116. Real world patient flows have more complexity than models are able to replicate, and this should be taken into account when interpreting predictions of changed patients flows. Modelling is useful for planning purposes but will not be a 100% correct prediction.
117. In the case of Leicester we estimate that between 2006/07 and 2014/15, a quarter of adult cases and nearly half of paediatric cases from within their notional catchment were admitted elsewhere, while 4% of adults and 23% of children admitted as an inpatient to their CHD service were from outside their notional catchment.
118. NHS England undertook a sensitivity analysis which excluded from the travel time modelling those patients currently using a centre which is not their closest. We considered that this model could be closer to the impact that people living within a notional catchment would have in mind, even though it is technically less accurate. Modelling in this way naturally shows a greater level of impact – see Table 2 below.

Table 2: Travel time modelling if the proposals are implemented – including only patients currently attending nearest providers⁸

Going to	Current travel time - median (mins)	Future travel time - median (mins)	Change to median travel time	Current travel time for 90% patients (mins)	Future travel time for 90% patients (mins)	Change to travel time for 90% patients
<i>Paediatric</i>						
RBH	32m 20s	40m 59s	+8m 38s	56m 12s	1h 00m 20s	+4m 08s
UHL	40m 51s	1h 00m 56s	+20m 05s	1h 15m 53s	1h 42m 52s	+26m 58s
National	37m 13s	39m 44s	+2m 32s	1h 23m 42s	1h 26m 02s	+2m 20s
<i>Adult</i>						
CMFT	24m 23s	42m 01s	+17m 38s	58m 12s	1h 06m 32s	+8m 20s
RBH	37m 00s	44m 08s	+7m 09s	56m 19s	1h 02m 25s	+6m 07s
UHL	40m 28s	1h 13m 28s	+33m 00s	1h 13m 13s	1h 44m 05s	+31m 05s
Adult National	32m 46s	39m 38s	+6m 52s	1h 14m 52s	1h 24m 06s	+9m 14s

⁸ This analysis excludes all patients who currently attend RBH, CMFT and UHL even though it is not their nearest level 1 centre. As this cohort of patients currently do not attend their nearest centre it seems reasonable that they may not in future. In addition excluding this cohort of patients enables the impact of the proposals on patients whose nearest centre is RBH, CMFT and UHL to be clearly presented.

119. Prior to consultation we had already asked for advice on whether longer journey times posed a risk to patients:

- Our clinical advisers have previously told us that true emergencies are very rare and that ambulance services, local hospitals and retrieval teams are trained to ensure that patients are stabilised before and during transfer so that the risks of long journeys are minimised.
- When NICOR analysed the outcomes of all paediatric cardiac surgery between 2009 and 2012 on our behalf, they found no link between 30-day outcome and distance from home to the tertiary centre.
- The CRG has advised that the distance travelled for surgery is less important than travelling continually for ongoing care.

What we heard in consultation

120. In consultation we asked about the impact of longer journey times. The most common themes⁹ overall were that:

- a risk assessment should be provided of the impact of additional travel times (especially taking into account public transport);
- consideration should be given to the potential stress on patients and families/carers;
- care should be provided closer to home by commissioning more Level 2 and Level 3 services;
- there was concern that increased travel times could result in deaths;
- there was concern that longer journeys would cause a reduction in family support;
- there was a view that longer journeys were disruptive if you have a child with a disability;
- cultural / rural / medical barriers to public transport should be considered;
- people should be made aware that the health benefits outweigh the travel issues;
- the impact on ambulance services of increased journeys should be considered; and
- the effect on children's education should be considered.

121. In terms of suggestions to reduce/avoid/compensate for longer travel times, the most common themes were:

- Compensation or hospital transport should be offered to patients/carers for longer journeys (especially for children with disabilities). Some

⁹ Extracted from replies to the question 'What more might be done to avoid, reduce or compensate for longer journeys where these occur?' The full analysis will be published in the report by Participate and published alongside the Board paper.

considered that the loss of patient/carer earnings should be taken into account, if they need to travel further.

- Alternative approaches to appointments were suggested including group appointments, all appointments clustered on one day, evening and weekend appointments when travel is sometimes easier and remote appointments by Skype.
- Ensuring adequate provision of patient/carer/family accommodation at low cost / Ronald McDonald house.
- More staff and resources would be needed at the remaining sites.
- Need low cost / free parking.
- Air ambulance should be used for critical cases.

Mitigating the impact of the original proposals on journey times

122. The Clinical Advisory Panel considered the risks associated with living further from a level 1 centre. They noted that:

- While journey times to the nearest level 1 centre would increase for some patients if the original proposals were implemented, the journey times for patients affected in this way would not be greater than those experienced by other patients elsewhere in the country, and there was no evidence that patients who currently are further from their level 1 centre, for example in the Channel Islands, have worse outcomes.
- There had been previous changes to CHD services in the UK which had the effect of increasing journey times to the nearest level 1 centre for some patients, including changes in Edinburgh, Cardiff, Oxford and Belfast, and there was no evidence that this had resulted in a worsening of outcomes.
- In other countries with internationally respected CHD services the distances to surgical centres may be much greater, and this provides reassurance services can be run safely in this way.
- Retrieval and ambulance services are trained in maintaining patients until they can receive definitive care.
- Care for patients with urgent needs can be delivered more locally at level 2 centres and local hospitals which are able to stabilise patients, taking advice from specialist level 1 centres in their network, prior to transfer for definitive care.
- The development of formal, managed networks (as described in the standards) with agreed shared protocols and lines of communication would support the safe operation of services.

123. Over the course of a lifetime, a person with congenital heart disease receives most of their CHD care in an outpatient setting. This should not

be affected by the proposed changes since outpatient care can be provided in clinics at level 2 and 3 centres and outreach clinics.

124. The Clinical Advisory Panel noted that level 2 centres would be more local for some than level 1 care. Most ongoing outpatient care could be delivered at level 2 centres and therefore if the original proposals were implemented this would make a big difference to the impact on patients of longer journey times to their closest level 1 centre. They also noted that while some urgent and emergency care for CHD might bypass level 2 centres, level 2 centres would still be able to provide care for non-cardiac emergencies and many cardiac complications (eg. arrhythmia management).
125. The following centres are expected to continue providing level 2 care:
- Brighton (adult only);
 - Cardiff (child and adult);
 - Norfolk and Norwich (adult only);
 - Oxford (child and adult); and
 - Papworth (adult only).
126. Depending on the decisions taken by the Board, under the proposals on which we consulted, the following centres would potentially provide level 2 services if they were to cease providing level 1 services:
- Central Manchester (child and adult); and
 - Leicester (child and adult).
127. Where patients require more complex diagnostic tests, for most inpatient admissions and for surgery and almost all interventional cardiology procedures, patients and their families/carers will need to travel to a level 1 centre. In general we expect that patients would travel to their next nearest centre. For some patients this will mean a similar journey.
128. Our modelling suggests that if the proposals on which we consulted were implemented, the impact on average journey times for patients would be relatively modest:
- An increase in the average journey time of 11 minutes for adults who use Central Manchester.
 - An increase in the average journey time of 14 minutes for children who use Leicester and 32 minutes for adults.
 - Average journey times would stay much the same for patients who use the Royal Brompton, as most patients would still get their care from one of the two other level 1 centres in London.

129. Some patients would of course have longer journeys. However 90%¹⁰ of patients who would have used Leicester would still have a journey time of less than 1 hour and 45 minutes to their nearest surgical centre and this is similar to the national picture and shorter than in some other parts of the country (for example the south west peninsula). Similarly, 90% of patients who have previously been seen in Manchester would have a journey time of 64 minutes or less to their nearest surgical centre, and for Royal Brompton patients, 90% would have a journey time of 85 minutes or less to their nearest surgical centre.
130. The number of patients affected by different journeys, and the number of journeys is difficult to estimate precisely. We expect it to be fewer than 950 each year because some patients have more than one operation within a year and patients sometimes have more than one operation during one admission.
131. Transfers between hospitals of very sick children (those requiring critical care) are undertaken by paediatric critical care transport services. These services cover the whole of England and are expected to be able to arrive at the referring hospital within three hours of the decision to retrieve the child. If the proposals on which we consulted were implemented, our modelling shows that 90% of children would be within 110 minutes of a level 1 surgical CHD centre – well within the three hour target. For children who would currently use Leicester, if the original proposals were to go ahead, 90% would be within 101 mins of their expected new centre.
132. The journey times - even for those patients furthest away from a surgical centre under the proposed new arrangements - would be no longer than those that are already experienced by some patients. For example, in the south west where patients from Penzance have journey times of over three hours to the Bristol centre, and those from Plymouth of around two hours. There is no evidence that outcomes are worse for patients from Cornwall than for the rest of the country. And these journey times are comparable to those from coastal Lincolnshire to Birmingham.
133. Distances to CHD centres are small in England compared with other parts of the world, for example Canada, Australia and the USA where much longer journey times are common and outcomes are considered good. Under the original proposals the great majority of patients – more than 9 in 10 – will still be less than two hours' drive from their nearest level 1 CHD centre.
134. So, many patients would have only modest rises in journey times when they attend the surgical centre, though for some journeys will be longer.

¹⁰ We use 90% rather than 100% because a number of patients choose not to use their closest centre and including their journey times would be misleading.

There is no evidence that greater distances are less safe, and most care, which is delivered in an outpatient setting, can still be delivered more locally. Overall, we consider that any negative impacts of longer journey times are outweighed by the benefits for all patients in terms of having access to more consistent, safe and high quality services.

Impact of the original proposals on patients: Inpatient stays

135. We recognise that it is difficult for families to support patients in hospital at some distance from home. This is a problem faced by many families already. The increased journey times for some patients and their families described above will exacerbate this issue for those patients and their families.

Mitigating the impact of the original proposals on inpatient stays

136. Because of this, and based on the advice of patients and families, a number of standards were developed to make life easier in this situation. This is particularly evident in section C – the standards relating to facilities - which sets requirements for (amongst other things) providing better information about where to park, eat and sleep; better facilities to prepare meals; provision of Wi-Fi; ensuring parking charges are affordable; and providing overnight accommodation for parents and carers:

C1(L1)	<p>There must be facilities in place to ensure easy and convenient access for parents/carers. Facilities and support include:</p> <ul style="list-style-type: none"> • accommodation for at least two family members to stay; • the ability for at least one parent/carer to stay with their child in the ward 24 hours per day (except when this is considered to be clinically inappropriate); • access to refreshments; • facilities suitable for the storage and preparation of simple meals; • facilities for parents/carers to play and interact with their child (and their other children); and • an on-site quiet room completely separate from general family facilities. <p>Family accommodation should be provided without charge.</p>
C3(L1)	<p>Children and young people must have access to general resources including toys, books, magazines, computers, free wifi and other age-appropriate activity coordinated by dedicated play specialist teams.</p>
C6(L1)	<p>Parents/carers will be provided with accessible information about the service and the hospital, including information about amenities in the local area, travelling, parking and public transport.</p>
C7(L1)	<p>If an extended hospital stay is required, any parking charges levied by the hospital or affiliated private parking providers must be reasonable and affordable.</p>

	Each hospital must have a documented process for providing support with travel arrangements and costs.
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137. The Clinical Advisory Panel advised that the NHS England Board should prioritise the early implementation of these (and other similar standards) at all hospitals. The panel also advised that NHS England should assess whether each level 1 centre was providing enough accommodation for family and carers.

Impact of the original proposals on patients: Waiting times

138. We recognise that there could be concern amongst patients and their families of centres that would under the original proposals provide care for more patients that rising numbers might mean longer waiting times.

Mitigating the impact of the original proposals on waiting times

139. Our impact assessment process has provided an assurance that these hospitals are well placed to expand their capacity accordingly, not just their facilities but also the additional staff needed.
140. The standards include a number that support the provision of timely care:

F12(L1)	Governance arrangements must be in place to ensure that when elective patients are referred to the multidisciplinary team, they are listed in a timely manner. Where cases are referred to the specialist multidisciplinary team meeting for a decision on management, they must be considered and responded to within a maximum of six weeks and according to clinical urgency.
F13(L1)	Admission for planned surgery will be booked for a specific date.
F14(L1)	All children/young people who have operations cancelled for non-clinical reasons are to be offered another binding date within 28 days.
F15(L1)	Specialist Children's Cardiology Centres and Local Children's Cardiology Centres must be informed of any relevant cancellations and the new date offered.
F16(L1)	Last minute cancellations must be recorded and discussed at the multidisciplinary team meeting.
F17(L1)	If a child/young person needing a surgical or interventional procedure who has been actively listed can expect to wait longer than three months, all reasonable steps must be taken to offer a range of alternative providers, if this is what the child/young person or parents/carers wish(es). Specialist Children's Cardiology Centres and Local Children's Cardiology Centres must be involved in any relevant discussions.

F18(L1)	When a Specialist Children's Surgical Centre cannot admit a patient for whatever reason, or cannot operate, it has a responsibility to source a bed at another Specialist Children's Surgical Centre, or Specialist Children's Cardiology Centre if appropriate.
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141. The new CHD dashboard reflects some of these standards and they will be subject to close monitoring during the transitional period if implementation of the original proposals is agreed. Data is submitted to the dashboard by each Trust on a quarterly basis and compared with the national average. Regional commissioners meet with providers to discuss performance and this will allow us to ensure that any adverse impacts are monitored and managed as the changes take place.

Impact of the original proposals on services

Impact of the original proposals on CHD services

142. The aim of the original proposals is to ensure that every provider that we commission to deliver CHD services meets the agreed standards. The standards were set to reflect the best evidence, expert advice and the experience of patients and families about what makes for the best services. We believe that making the changes we have proposed will ensure that no matter where they live, patients and their families will receive excellent care.
143. To inform our understanding of the impact of the proposed changes on CHD and other services, we modelled where patients would be likely to receive their care if the original proposals were implemented, and assuming that patients went to their nearest centre after the changes had been made. We used 'operations' as our currency in this modelling because we have the most accurate data for surgery, and because the centres involved would, from their own experience, be able to infer the related changes to the number of interventions, inpatient admissions, investigations and outpatient appointments that we could not model with any accuracy. The results are shown in Table 3 below.

Table 3: Patient flows if the original proposals were to be implemented – surgery 2016/17

Receiving Provider	From RBH			From CMFT			From UHL			Total redistributed		
	Adult	Paediatric	Total	Adult	Paediatric	Total	Adult	Paediatric	Total	Adult	Paediatric	Total
Alder Hey Children's NHS FT	0	1	1	0	0	0	0	11	11	0	12	12
Barts Health NHS FT	78	0	78	0	0	0	1	0	1	79	0	79
Birmingham Children's Hospital NHS FT	0	4	4	0	0	0	0	225	225	0	229	229
Great Ormond Street Hospital For Children NHS FT	0	194	194	0	0	0	0	5	5	0	199	199
Guy's and St Thomas' NHS FT	31	147	178	0	0	0	0	5	5	31	152	183
Leeds Teaching Hospitals NHS TRUST	1	1	2	3	0	3	9	48	57	13	49	62
Liverpool Heart and Chest NHS FT	1	0	1	88	0	88	0	0	0	89	0	89
The Newcastle Upon Tyne Hospitals NHS FT	0	0	0	0	0	0	0	0	0	0	0	0
University Hospital Southampton NHS FT	6	9	15	0	0	0	0	1	1	6	10	16
University Hospitals Birmingham NHS FT	2	0	2	0	0	0	42	0	42	44	0	44
University Hospitals Bristol NHS FT	3	2	5	0	0	0	0	3	3	3	5	8
Total	122	358	480	91	0	91	52	298	350	265	656	921

144. While there will be changes to the locations where CHD services are delivered, overall the capacity of CHD would be at least the same as now if the original proposals were implemented, as a result of ensuring that capacity is re-provided at hospitals that will need to care for more patients in future.
145. Services will also be more resilient and sustainable for the future. Bigger centres are generally more resilient. Under present arrangements services in some hospitals are significantly supported from other centres. Without this support, at best, these hospitals would not be able to offer their patients a full range of CHD services.
146. The provision of consistent care 24/7/365 is more assured at bigger centres. Bigger teams are better able to cope when one of their number is unavailable or leaves. They are also better able to support the full range of surgical procedures and the development of very specialised practice.

Impact of the original proposals on other services

Impact of the original proposals on Paediatric Intensive Care

147. Specialist paediatric intensive care services provide care for the very sick child including stabilisation, retrieval if necessary, and delivery of care in an appropriate paediatric intensive care facility. Paediatric intensive care is required for patients of other specialist paediatric services including paediatric cardiac. Level 1 paediatric surgical CHD centres are required by the standards to be located on the same hospital site as:

- Paediatric Intensive Care Unit (PICU): Level 3 paediatric critical care services, capable of multi-organ failure support (delivered in accordance with Paediatric Intensive Care Society Standards and NHS England's service specification for Paediatric Intensive Care).
 - High Dependency beds: Level 2, staffed by medical and nursing teams experienced in managing paediatric cardiac patients.
148. NHS England's impact assessment showed that if the original proposals were to be implemented there would be an impact on paediatric intensive care (PIC) provision at Leicester and Royal Brompton. If the original proposals were implemented, there may also be an effect on the wider regional and national PIC system.
149. The original proposals affect only adult services in Manchester, so PIC would not be affected.
150. The impact on PICU at specific hospitals that could be affected by the original proposals has already been considered earlier in this document.

What we heard in consultation

151. Respondents expressed concern about the impact of the original proposals on PICU capacity, and suggested that this should be assessed. Some suggested that the decision on CHD services should be delayed until NHS England's separate review of Paediatric Critical Care had reported.
152. The Clinical Advisory Panel expressed concerns about overall PICU capacity nationally and considered that NHS England should ensure that if it implemented its original proposals, they did not result in an overall reduction in PICU capacity. However, the panel recognised that it was not the job of the CHD review to address underlying problems within the PIC system nationally.

Mitigating the impact of the original proposals on Paediatric Intensive Care

153. The Clinical Advisory Panel recommended that, if NHS England were to implement its original proposals, it should ensure that the hospitals where additional patients would be treated would provide sufficient replacement PICU capacity as part of the increase in capacity needed for these patients.
154. To achieve this hospitals would need to:
- Develop plans that would deliver the expanded capacity in a timely way;
 - Develop operational policies that reflected the larger scale of the PICU;

- Be able to recruit the necessary staff, particularly because recruiting PICU nurses has been challenging for some centres. All centres where PICU capacity would need to expand should be asked to share their current PICU nurse vacancy rate to inform this; and
 - Have sufficient physical capacity and, where necessary, that the funding was available to achieve this.
155. The Clinical Advisory Panel noted that current understanding of the impacts of implementing NHS England's original proposals on patient flows was based on modelling that assumed affected patients would in future go to their next nearest centre. However, this should be interpreted only as an indicator of what would happen as a significant proportion of patients are not cared for at their closest centre.
156. The panel considered that in reaching its decisions NHS England would need to take account of its other reviews into neonatal and paediatric critical care and maternity services but should not delay its decision on CHD services until its separate review of Paediatric Critical Care had released its final report.
157. The panel heard that the early findings of the paediatric critical care review were that:
- there are patients currently being cared for in PICUs that do not need to be treated in such an intensive environment;
 - a large number of PICU beds are used by a small number of patients: these are likely to be children with long term, complex, needs who may benefit from alternative care settings; and
 - demand most often exceeds capacity during the winter and is mainly for lower levels of critical care.
158. Expanding PICU capacity directly was not considered to be the answer as experience suggested that any additional capacity would soon be used by less sick patients. Rather, the review's recommendations were expected to focus on how to ensure patients are treated in the right place, including developing level one and level two care, improving discharge arrangements for long term ventilated patients who may not need to be in a PICU, creating managed systems of care that allow patients to be stepped up and stepped down according to need, and introducing appropriate pricing mechanisms. The review is likely to revise current service specifications to support hospitals delivering all levels of critical care, including District General Hospitals in providing effective step down care for patients on their paediatric high dependency units (HDUs).

159. Should the original proposals be implemented, the review of paediatric critical care will need to take any impact on PICU into account in the regional implementation of its proposed new model of care.
160. The impact of implementing the original proposals on neonatal intensive care units (NICUs) would also need to be considered, though the panel noted that most babies born with CHD are managed in a PICU rather than an NICU, except for those born prematurely. Should the original proposals be implemented, the review of neonatal critical care will need to take into account any impact on the unit.

Impact of the original proposals on Extracorporeal Membrane Oxygenation (ECMO)

161. ECMO stands for Extra Corporeal Membrane Oxygenation and is a technique that provides respiratory and/or cardiovascular support to very sick patients.
162. ECMO gives us a way of putting oxygen into the blood, outside the body, and also of pumping the blood round the body when the body's own lungs or heart are failing. When we use ECMO to support the lungs it is called respiratory ECMO. When it is used to support the heart it is called cardiac ECMO.
163. ECMO for children is only provided in centres that also provide heart surgery for children. All of the CHD surgical centres are required by the standards to be able to provide cardiac ECMO for children.
164. Respiratory ECMO for children is currently provided by five centres in England: Alder Hey; Birmingham Children's; Great Ormond Street; Leicester; and Newcastle. There is also a paediatric respiratory ECMO centre at the Royal Hospital for Children in Glasgow.
165. On average in the past four years respiratory ECMO has been used in 74 children each year in England.
166. Of the centres in England, only Leicester is commissioned to retrieve patients on 'mobile' ECMO and this contributes to Leicester providing around half of all respiratory ECMO for children. The Glasgow centre also provides mobile ECMO.
167. Cardiac ECMO for adults is provided both by centres that provide CHD surgery for adults and by some centres that provide cardiac surgery for adults with other forms of heart disease.
168. All of the CHD surgical centres are required by the standards to be able to provide cardiac ECMO for adults with CHD.
169. Respiratory ECMO for adults is currently provided by five centres in England: Guy's & St Thomas'; Leicester; Papworth; Royal Brompton; and

South Manchester. There is also an adult respiratory ECMO centre at Aberdeen Royal Infirmary.

170. On average in the past five years respiratory ECMO has been used in around 220 adults each year in England. The number of cases has been rising but seems to be levelling off. This year the number of cases is expected to be over 260.
171. The respiratory ECMO service for adults is organised on a formal geographical network basis and all of the centres retrieve patients on 'mobile' ECMO from the referring hospitals in their networks. This approach minimises long transfers and balances the activity between the five centres so that Leicester provides around one fifth of respiratory ECMO in adults.
172. The Clinical Advisory Panel recognised that Leicester is the biggest provider of paediatric ECMO and that if we were to implement the proposals on which we consulted, there would therefore be a national impact.
173. The impact on PICU at specific hospitals that could be affected by the original proposals has already been considered earlier in this document.

What we heard in consultation

174. Respondents from the Midlands and East region raised concerns about the potential loss of ECMO services from UHL, which was seen by them as an international centre of excellence. The view was put forward that UHL's ECMO service should be regarded in the same light as Newcastle's transplant service and seen as a reason to continue commissioning CHD services from UHL, even if some standards are not met. There were concerns about where patients would receive this care in the future if it was not provided by UHL.
175. A standard response drawn up by supporters of the service at UHL (though submitted in this exact form by very few respondents) states:

'Crucial information needed to inform the consultation - The review into ECMO services is a crucial aspect of this consultation and it is inappropriate that the results of that review are not part of this consultation process...

...NHS England assumptions are that the current ECMO caseload for ECMO delivered by EMCHC¹¹ can easily and safely be delivered dispersed across the remaining cardiac surgical centres, all of whom in theory can undertake ECMO as it may be required after cardiac surgery.

¹¹ EMCHC – East Midlands Congenital Heart Centre (the service provided by UHL)

It is a huge assumption that the ECMO currently provided by EMCHC (over 50% of the UK requirements) will be able to be delivered by the units spread across the country. They are proposing to dilute ECMO practice whilst using concentration of cardiac surgical practice as a rationale for service reconfiguration...

...The assumption that there will be appropriately trained clinical and nursing staff available to deliver this specialist care across all of the units is severely challenged by the fact the majority of ECMO provided by EMCHC is provided for children with catastrophic respiratory and cardiac failure not related to cardiac surgery and in which other Level 1 centres have little or indeed no expertise. (This is currently evidenced by the fact the EMCHC ECMO team travel the country including to the current surgical centres to place patients in this situation on ECMO and bring them back to Glenfield for optimal expert care). Replicating this expertise will be as difficult as expecting all centres to deliver transplant surgery – the key rationale for the derogation being applied to Newcastle.'

176. One respondent stated that decisions about the future of cardiothoracic transplant and respiratory ECMO should be contingent on the final proposals for congenital heart services.

Mitigating the impact of the original proposals on ECMO

177. The optimal national model for provision of children's ECMO in the future will be considered as part of NHS England's Paediatric Critical Care & Specialised Surgery in Children Service Review. The maintenance of good outcomes will be a key consideration. The review is expected to consider the appropriate number of providers of children's ECMO, the case for minimum activity levels and the appropriate number of mobile ECMO providers.
178. While we cannot pre-empt the findings and recommendations of the Paediatric Critical Care & Specialised Surgery in Children Service Review, it is considered that the effects of redistributing paediatric ECMO activity could be mitigated by introducing a regionalised model of ECMO care. This is an emerging consideration in the paediatric critical care which would be implemented whether or not the CHD recommendations are taken forward. This approach builds on the work done by the Highly Specialised Commissioning Team in 2012/13 to develop a consensus on the future delivery of paediatric respiratory and cardiac ECMO services. That report made a number of recommendations, including:
- The model of ECMO care should be based on regional centres each covering a defined geographical area.

- Centres should work collaboratively to provide a national service and a 'buddying' system should be established to promote collaborative working.
 - Cardiac ECMO centres should conform to the same standards as those that provide both cardiac and respiratory ECMO and all centres should be able to at least initiate both forms of support prior to transfer to definitive care.
 - ECMO centres should be achieving a minimum annual volume of 20 ECMO cases per annum.
179. Within the paediatric critical care review, there is a growing clinical consensus that some centres not currently commissioned to provide respiratory ECMO, could cannulate patients onto ECMO and support them for a short time until transfer to one of the designated respiratory ECMO centres. Some existing cardiac ECMO centres have expressed a willingness to do this in a planned fashion in close collaboration with a designated respiratory ECMO centre. It is difficult, at this stage, to quantify the effects of this change in practice or the timescale over which it could take place. This will be addressed in the next stage of discussions between the paediatric critical care review and providers. Careful implementation would be needed to ensure that activity is not diffused across a larger number of units in such a way as to risk losing the expertise that has built up in the existing centres.
180. The Clinical Advisory Panel noted the expectation that if the original proposals were implemented, cardiac ECMO for children and for adults with CHD would be provided by the centres where these patients receive their CHD care. The panel advised that if NHS England were to implement its original proposals it should ensure that the hospitals where additional patients would be treated were able to provide sufficient replacement cardiac ECMO capacity as part of the increase in capacity needed for these patients. To achieve this hospitals would need to develop plans that would deliver the expanded capacity in a timely way.
181. The Clinical Advisory Panel noted the expectation that if the original proposals were implemented respiratory ECMO for children would be provided by the remaining four centres offering this service: Great Ormond Street, Newcastle, Birmingham Children's and Alder Hey. The panel advised that if NHS England were to implement its original proposals it should ensure that these hospitals would provide sufficient replacement ECMO capacity in a timely way.
182. The Clinical Advisory Panel noted the findings of the Paediatric Critical Care Review which advised that the rate of use of ECMO varied across the country, with an almost fourfold difference between the lowest and

highest utilisation rates. They noted that the review would be considering whether there is clinical justification for these variations, and this could change the capacity requirement for paediatric ECMO nationally.

183. The Clinical Advisory Panel was confident that mobile ECMO could be re-provided if one or more centres and/or retrieval services were commissioned to provide this service.

Financial Impact of the Original Proposals

Confirmation that revenue costs of implementing standards should be covered by increasing income for increasing activity

184. Trusts are paid for CHD services through tariff which ensures that the money received is linked to patient activity.
185. It is likely that there will be some economies of scale for providers linked with providing a higher volume of activity. As such the Trusts that would gain activity under these proposals are confident of being able to fund this expansion through the income which would be associated with this extra activity.
186. The financial assessment undertaken in 2015 at the time the Board agreed the standards showed that additional income to Trusts resulting from growth in activity would be sufficient to fund the implementation of the standards.
187. The minimal variation in growth expectations following the refresh of this modelling provides assurance that the analysis of affordability for providers within the current tariff structure remains robust. This is based on an assessment of the additional income providers will receive as a result of increased activity with the identifiable costs of meeting the standards.
188. The principal costs associated with achieving the proposed quality standards arise from increased levels of staffing and from establishing networks.
- Staffing: costs of additional congenital surgeons, paediatric cardiologists, paediatric nurse specialists and nurse educators.
 - Networks: costs include lead clinicians, lead nurses, network meetings etc.
189. Based on the current configuration of services the requirements of the standards would mean teams of four surgeons at each of the ten specialist surgical centres.
190. Although the exact number of CHD surgeons varies slightly over time, in May 2015 there were 37 surgeons practising in England at these 10

centres, so an increase of three surgeons would be required for all centres to have four.

191. We have used a working assumption that the estimated cost of an additional consultant (together with their associated supporting staff) is approximately £500k to estimate these additional costs.
192. Two growth scenarios have been tested. Scenario A assumes that the number of procedures per patient will stop growing and remain at current levels, with growth coming only from population change. Scenario B assumes that the number of procedures will continue to grow at the rate we have seen historically as well as population change. Under both scenarios, implementation of the standards would be affordable for providers.

Provider Cost Impact 2025/26	Scenario A (£000's)	Scenario B (£000's)
Income from Additional Activity at 100% Tariff (total forecast spend 2025/26 minus total spend 2013/14)	11,230	32,531
Cost of 3 additional surgeons (£500k per surgeon)	-1,500	-1,500
Specialist nurses (2 band 6 at 10 centres, £44k annual cost)	-880	-880
Psychologists (2 at 10 centres £43k annual cost)	-860	-860
Network Set-up Costs	-209	-209
Variable Cost Allowance @ 50% *	-5,615	-16,265
Remaining Income Available to Meet Other Costs	2,166	12,816
% Total Income Remaining	19%	39%

* Estimate of marginal costs of activity relating to non-pay

Assessment of capital requirements at hospitals that would take additional patients under the proposals on which we consulted, and the sources of this capital

193. NHS England asked providers whether there would be any capital implications if they were required to take additional patients if the original proposals were implemented. NHS England has confirmed that no specific central funds will be made available.
194. Two providers indicated that they would need to source capital funds to accommodate additional activity: University Hospitals Birmingham (£4M)

and Great Ormond Street (£6M). In both of these cases it is expected that the provider would be able to source the capital funding from existing allocations and/or charitable funds. This is being confirmed with NHS Improvement.

195. No other provider indicated any requirement for capital funding.

196. The risk around capital funding requirement is minimal at this stage.

Impact of the original proposals on finances at Barts Health NHS Trust:

197. Barts Health NHS Trust is in Special Measures. Barts is a joint level 1 centre with Great Ormond Street Hospital (GOSH), with GOSH providing the paediatric services. If the proposals on which we consulted were implemented, some adult CHD activity would be expected to transfer to Barts Health from Royal Brompton. This would bring a positive contribution to the Trust's bottom line.

198. There is available capacity in the PFI-financed Cardiac Centre on the St Bartholomew's site. Further development of cardiac services is line with the Trust's strategic aims.

Financial impact at provider organisations where level 1 services would no longer be provided under the original proposals

199. NHS England has assessed for each of the hospitals where it is proposed that level 1 congenital cardiac surgery is no longer provided what proportion of their income comes from caring for patients with congenital heart disease.

200. For centres which would no longer be commissioned to provide Level 1 services under the original proposals, whilst there has been a significant amount of work to understand the impact on revenue, more work will be needed to understand the overall net financial impact of these changes when costs are taken into account. There are likely to be some sunk costs associated with the cessation of this activity.

201. For each of the hospitals where it is proposed that level 1 congenital cardiac surgery is no longer provided NHS England has assessed what proportion of their income comes from caring for patients with congenital heart disease.

Impact of the original proposals on finances at Leicester

202. The overall contract value for specialised services (including CQUIN) at Leicester is approximately £234m. NHS England estimates that the financial effect of the proposed changes would be around £14m rather than the £19-20m estimate provided by the Trust. This is partly explained by a difference in view on the impact of the original proposals on PICU. UHL's estimate is based on an assumption that it would no longer be able

to provide PICU services. The panel considered that there was no reason why PICU services could not continue at the Infirmary site even if the Glenfield PICU needed to close. The loss of revenue to the Trust would therefore represent between 6% and 8% of their total specialised services income. Some of this loss of income could be reduced if UHL continued to provide level 2 services.

Impact of the original proposals on finances at Central Manchester

203. The overall contract value for specialised services (including CQUIN) at Central Manchester is approximately £348m. The Trust did not respond to the request to provide information on the potential impact of the original proposals. NHS England estimates that the financial effect of the proposed changes would be around £1m. The financial impact of this change is therefore not likely to have a significant impact on the Trust.
204. Some of this loss of income could be reduced if UHL continued to provide level 2 adult CHD services. The loss of income to the Trust would also, to some extent, be offset by a reduction in costs.

Impact of the original proposals on finances at The Royal Brompton

205. The overall contract value for specialised services (including CQUIN) at Royal Brompton is approximately £226m. NHS England estimates that the financial effect of the proposed changes would be around £35m excluding the impact on paediatric respiratory services. The Trust's estimate of a £47m loss in income when paediatric respiratory services are taken into account appears to be broadly in line with NHS England's own estimate. The Trust estimates that the loss resulting from these proposals would be approximately 13% of the Trust's total income and 21% of its total specialised services income, which represents a significant financial and business risk. The scale of loss is contributed to by the impact on PICU and the potential impact on paediatric respiratory services.
206. Some of this loss of income could be reduced if the Royal Brompton continued to provide either adult level 2 services and/or adult only Level 1 centres in partnership with a level 1 paediatric centre.
207. The loss of income to the Trust would also, to some extent, be offset by a reduction in costs. Data supplied by the Royal Brompton indicates that its provision of CHD services results in an overall net loss, and therefore although the loss of income is significant it may be that in the long term no longer providing these services is in the best financial interest of the Trust. The hospital trust stated that owing to the stranded costs associated with this service they estimate an adverse impact of over £7m per year to the Trust's bottom line if these proposals are implemented.

Workforce Impact of the Original Proposals

Recruitment, retention and redundancy

208. Workforce is a key element of any service provision within the NHS. Training, education and appropriate recruitment and retention of employees are essential to sustain service provision. One of the key challenges both to current CHD services and to any future configuration is ensuring that there is sufficient staff with the necessary skills and experience to undertake this work across the country.
209. The proposed changes may have a different impact on an organisation, depending upon the particular circumstances. The potential implications for workforce include (but are not limited to):
- employees working within the service being made redundant;
 - employees being redeployed into other roles;
 - the transfer of the contracts of employment of employees from one organisation to another;
 - changes to the volume of work carried out by employees (either through increases or decreases in patient activity within the Trust they work for); and
 - changes to the future workforce requirements to deliver the CHD standards and service specifications across the commissioned centres.
210. For individual employees, Trust policies will help inform the process(es) to be followed. Regional commissioners will work with local providers that may be affected by change to provide further detail on the programme at a local level.
211. Each organisation will need to consider what contracts are in place in respect of the relevant employees. Within the NHS, it is likely that most employees will be contractually covered by Agenda for Change or Consultant or Medical and Dental Staff terms and conditions of employment. Where staff work for a non-NHS organisation that is contracted/ commissioned to provide NHS services, they may be subject to alternative terms and conditions of employment.
212. It is expected that all NHS Trusts will have a policy identifying how they manage changes to the workforce which will outline their standard process when dealing with significant service change that could impact on employees. This would cover situations such as the decommissioning of a service and internal changes such as restructures, redundancies and / or changes in working patterns and terms and conditions.

213. The identification of employees potentially affected by any service change needs to be led by the service leads with input from their HR advisor. Identifying the employees in scope of any change will be an important part of delivering any service change and understanding the nature of the changed involved and what process needs to be carried out.
214. Employee representation will usually be encouraged through representatives of Trade Unions recognised by individual organisations; however each Trust will have its own arrangements in place. Early dialogue is recommended to ensure employees and their representatives are aware of the expected changes and what opportunities or impact this may result in for them.
215. TUPE - the Transfer of Undertakings (Protection of Employment) Regulations 2006 - offers protection to certain employees where the businesses or services they work in are being transferred from one organisation to another. In relation to the commissioning of CHD services, it may apply where employees work in organisations that have to date been commissioned (contracted) to provide CHD services that may now be decommissioned.
216. COSOP – the Cabinet Office Statement of Practice on Staff Transfers in the Public Sector – provides a similar level of protection to certain employees working in the public sector, or on contracts or services for the public sector, in circumstances where TUPE might not apply in strict terms to transfer their employment from one organisation to another. In such circumstances, COSOP operates so as to ensure that those employees are treated no less favourably than if TUPE applied.
217. If it is deemed that TUPE or COSOP applies then one possible consequence of this is that each organisation will need to consult with employees' representatives on what a transfer may mean to the affected employees.
218. If TUPE or COSOP does not apply, or depending on the circumstances, it may be appropriate to consider whether employees can be redeployed where people are displaced or posts are disestablished. In considering these opportunities it would be advisable for organisations to work collaboratively with the aim to ensuring scarce and/or highly specialist skills are retained.
219. Where the service that the employee works in is recommissioned at an alternative provider, local policies and any local agreements between employers may dictate the terms of any redeployment, for example, there may be applicable travel expenses policies etc.

220. A number of staff currently providing Level 1 CHD services would no longer provide these within their current Trust. Other centres will require additional staff in order to accommodate the additional activity.
221. Those centres who would gain additional activity under the original proposals, all stated a desire to work with the centres who would no longer be commissioned, to provide Level 1 services in order to maximise the possibility of retaining these skilled staff and minimising the impact of any changes.
222. NHS England would support TUPE and/or COSOP arrangements to enable staff affected by change to transfer their employment to other Level 1 centres requiring their skills.
223. Experience from previous CHD service changes shows that a number of staff, perhaps most, would prefer to be re-deployed within their current Trust, though TUPE would apply in these circumstances which would be expected to limit the choices available to staff.
224. This may create an additional challenge both for the centres gaining activity who may therefore find it more difficult to recruit the necessary staff for their additional activity and for the Trust no longer commissioned to provide Level 1 services which may not have appropriate roles for this workforce to move into.
225. Whilst this does represent a significant challenge to CHD services we anticipate that this can be managed with good planning, appropriate policies agreed between affected providers and sufficient lead times prior to changes being made, and appropriate structures and dialogue to support and protect staff affected by these changes.
226. The National Panel noted that experience at other centres where level 1 services have ceased – Edinburgh, Cardiff and Oxford – was that the majority of staff did not transfer to alternative providers of these services, but there were virtually no redundancies, with most staff being redeployed internally. It is reasonable to expect that many staff would seek to take up alternative roles within the Trust, rather than moving to another centre. However, the panel noted that certain staff, such as CHD surgeons, would look to move to a Level 1 CHD centre.
227. The panel considered that centres that would gain more patients if the original proposals were to be implemented were well placed to be able to expand their capacity to be able to provide that care. The recruitment of the necessary workforce for this increased activity was seen as potentially challenging for a number of these centres. Specifically, the recruitment of the PICU nurses necessary for the additional beds which would be required. The centres gaining significant activity believed that although challenging they had a good record of recruiting staff and would be able to

recruit the necessary staff as long as they were given sufficient time prior to these proposals being implemented.

228. A priority will be the development of a framework across organisations to ensure the best possible outcome for staff. The National Panel advised that all units are resourceful and where there is a shortfall in the staff available they were confident they will continue to find ways to recruit the necessary staff, including international recruitment where necessary.
229. Sufficient experienced staff within the service is vital key to good patient outcomes across the care pathway and therefore were these proposals to be implemented significant work would be required to ensure every effort was made to retain experienced staff, and ensure that every Level 1 centre maintained a highly skilled and experienced workforce.

Impact of the original proposals on training for clinical professionals

230. Concerns were raised by the Joint College of Physicians Training Board, that if NHS England's original proposals were to be implemented they would affect paediatric cardiology training because approximately 30% of paediatric cardiology training posts are currently allocated to University Hospitals Leicester or the Royal Brompton Hospital.
231. Health Education England (HEE) has advised that the 41 paediatric cardiology training posts are currently distributed as follows:

HEE local office	Hospital	Number of posts
South West	University Hospitals Bristol	4
North West	Alder Hey Children's NHS Foundation Trust	5
Wessex	University Hospital Southampton NHS Foundation Trust	4
Yorkshire & Humber	Leeds General Infirmary	3
West Midlands	Birmingham Children's Hospital NHS Foundation Trust	5
North East	Freeman Hospital	3
Pan-London / Oxford	Great Ormond Street	13
	Guy's and St Thomas (Evelina)	
	Royal Brompton	
	John Radcliffe Hospital	
East Midlands	University Hospitals of Leicester NHS Trust	4

	(Glenfield)	
Total		41

232. The distribution of trainee numbers has largely been historical, but in some cases Trusts have bid for additional posts, and this has allowed East Midlands and Wessex to increase numbers from 3 to 4.
233. There is no pre-existing formal process for re-distributing training posts in circumstances like these.
234. If the proposals on which we consulted were to be implemented, HEE has advised that trainees in the middle of their training, beyond ST4, would have to move. This would be less disruptive for London trainees who already rotate.
235. If UHL continued to provide level 2 services, HEE considers it likely, based on the paediatric cardiology curriculum, that it could still deliver the first year (ST4) of training, and under these circumstances, one trainee could remain at UHL. It considers it likely that the posts at the Royal Brompton would be reallocated to Evelina and Great Ormond Street and those at UHL would go to Birmingham Children's.
236. HEE told us that there is concern that there would not be sufficient training capacity in the remaining centres, especially as some centres already employ fellows¹² in areas such as cardiac catheterisation which could limit training opportunities.
237. We understand, however, that many centres did not get the number of training posts they would have liked and 'make up the numbers' with fellows (overseas or UK trainees trying to improve their chances of getting a numbered training place), general paediatricians or trainee PECs. Our clinical advisers tell us that it is unlikely that there would be any problem accommodating training posts from decommissioned units at the remaining centres.
238. The Royal Brompton at present is one of only 2 centres able to deliver training in Paediatric Electrophysiology and has trained 2 out of the last 4 UK Consultants appointed in this area. The loss of adult EP training at the Royal Brompton would also be a significant loss because of the centre's experience and the opportunity for training presented by its cohort of adult requiring complex EP support.
239. The Clinical Advisory Panel was reassured that if NHS England's original proposals were to be implemented paediatric cardiology training would be able to be provided at other centres. They noted that it would be

¹² Doctors in posts not recognised as part of a formal training scheme.

advantageous to trainees to receive their training at centres that met the standards including holistic paediatric care. The panel considered that electrophysiology training could be provided by other centres.

- 240. The Clinical Advisory Panel heard that the original proposals would not be expected to negatively affect congenital heart surgical training, nurse training or anaesthetist training.
- 241. They heard that overall there was a shortage of paediatricians overall and that concentrating care in fewer centres would therefore be expected to be helpful. The panel considered that training at a centre that meets the standards would be better for trainees.
- 242. Although not formally assessed HEE has advised that it will also be important that the number of Paediatricians with a Special Interest training posts available in Level 1 centres is maintained.

Impact of the original proposals on commissioners

Financial impact of the original proposals: NHS England

- 243. Specialist CHD services cost NHS England £175m a year in 2015/16, equivalent to 1.2% of the total specialised commissioning budget.
- 244. The financial impact for NHS England of the original proposals has also been considered. This was examined in detail at the time the Board approved the standards in July 2015. We have re-examined the basis of the financial assessment undertaken in 2015, refreshing our calculations with the latest data and confirmed that the main conclusions of that assessment are not changed. That is that implementing the standards is affordable for NHS England under tariff.
- 245. Many of the costs of providing services to the standards can be considered to be already within tariff funding because the standards describe ways of working/staffing levels that are already standard in a number of Trusts.
- 246. The main affordability challenge for commissioners would be the costs of activity growth. The original proposals do not change the number of people eligible for treatment, nor do they change the treatments offered to patients. Growth in activity is driven by an increasing population, increased longevity for CHD patients and advances in clinical practice. This is unaffected by the proposals on which we are planning to consult. NHS England will fund these additional costs, in line with national tariff and local price arrangements, from within the notified annual increase in the allocation for specialised services.

247. In developing and agreeing the CHD standards, NHS England has been clear throughout that no additional funding will be provided to meet the costs of provider improvements to deliver compliance with the standards.
248. There will however be a cost to establishing formal networks, but fewer multi-centre networks at wider scale may be more cost effective than asking every surgical centre to take on a bigger role through its local hub-and-spoke network arrangements. We have already given a commitment to pump prime the development of the new networks, with funding to come from a national top slice of CQUIN for specialised services that is already used to fund other Operational Delivery Networks.
249. Contracts with existing providers of CHD services for the 2018/19 period include specific reference to the original proposals, stating that we may as a result give notice on the back of our commissioning decisions following consultation.

DMBC ANNEX 4: A PAPER ON PAEDIATRIC CO-LOCATION PREPARED FOR THE ROYAL BOROUGH OF KENSINGTON AND CHELSEA, OCTOBER 2017



PAEDIATRIC CO-LOCATION

Introduction

NHS England's aim is 'that specialist children's cardiac services should only be delivered in settings where a wider range of other specialist children's services are also present on the same hospital site'. This is to ensure that children with cardiac disease receive holistic care in a child centred environment. Effective delivery of multi-organ care requires the input of the wider paediatric multidisciplinary team, not simply the individual clinical specialist. Our clinical advisers told us that, when co-located, the interaction between these teams on a daily basis is of significant benefit to patients. Although speed of response is important, continuing management and ready clinical dialogue from the multidisciplinary team is essential. Co-location is the standard of care in the majority of paediatric cardiac centres nationally and internationally as well as for other paediatric specialties.

What is co-location?

Co-location is a term used to describe a requirement that certain clinical services need to be provided on the same hospital site because they are dependent on each other for the provision of optimal care for patients.

Within the standards three different sets of interdependency are described:

- The relationship between paediatric cardiac services and other children's services and facilities.
- The relationship between adult CHD services and other adult services and facilities.
- The relationship between paediatric cardiac services and adult CHD services.

In earlier work on CHD services, co-location was imprecisely defined and this led to a variety of arrangements being considered acceptable even though the services were not on the same site. In NHS England's work the definition is clear. To be co-located requires three conditions to be met:

- services must be located on the same hospital site as level 1 paediatric cardiac services;
- services must function as part of the multidisciplinary team; and

- consultants from those services must be able to provide emergency bedside care (call to bedside within 30 minutes).

NHS England recognised that not all hospitals met all the co-location requirements at the time they were agreed, and so phased the introduction of the requirements, with some requirements applying immediately (from April 2016), some applying from six months later and some only after three years (from April 2019). This was based on the Clinical Reference Group's advice that this gave hospitals enough time to sort out any changes needed to be able to meet the requirements.

What do the paediatric standards require?

The standards describe the interdependencies with the full range of services that children with heart disease may need, but co-location is not required for every service. The services where co-location is required are:

From April 2016

Paediatric Cardiology

Paediatric Airway Team capable of complex airway management (composition of the team will vary between institutions).

Paediatric Intensive Care Unit (PICU): Level 3 paediatric critical care services, capable of multi-organ failure support (delivered in accordance with Paediatric Intensive Care Society Standards and NHS England's service specification for Paediatric Intensive Care). High Dependency beds: Level 2, staffed by medical and nursing teams experienced in managing paediatric cardiac patients.

Specialised paediatric cardiac anaesthesia

Perioperative extracorporeal life support (Non-nationally designated extracorporeal membrane oxygenation (ECMO))

From October 2016

The full range of non-invasive diagnostic imaging capabilities including CT and MRI scanning and suitable trained radiological expertise.

The range of cardiac physiological investigations must include Electrocardiography (ECG), Holter monitoring, event recording, tilt test, standard exercise testing, ambulatory blood pressure monitoring and pacemaker follow-up and interrogation, as well as standard, contrast, intraoperative, transoesophageal and fetal echocardiography.

There must be a 24/7 congenital echocardiography service with access to modern echocardiographic equipment, maintained to British Society of Echocardiography (BSE) standards, with a selection of probes suitable for all age groups, including suitable fetal echo probes, with facilities for advanced techniques including 3D and speckle tracking.

Specialist Children's Surgical Centres should be able to undertake cardio-pulmonary exercise testing (CPEX) and the six-minute walk test in children and adolescents; if not provided on site they must have access to these investigations.

Specialist Children's Surgical Centres must have access to Isotope Imaging. Radiological and echocardiographic images must be stored digitally in a suitable format and there must be the means to transfer digital images across the Congenital Heart Network.

Specialist Children's Surgical Centres must offer invasive diagnostic investigation and treatment, including:

- a. catheter intervention;
- b. electrophysiological intervention;
- c. pacemaker insertion and extraction; and
- d. cardiac surgical intervention, including the provision of extracorporeal support of the circulation and hybrid catheter/surgical treatment where clinically indicated).

These services must be available 24/7.

From April 2019

Paediatric Surgery

Paediatric Nephrology/Renal Replacement Therapy

Paediatric Gastroenterology

What is the issue at the Royal Brompton?

Paediatric surgery and paediatric gastroenterology are not co-located on the same site as the Royal Brompton's paediatric cardiac service, and until very recently the Trust had not presented firm plans for achieving the required co-location by April 2019.

The Clinical Advisory Panel advised that a solution must be found for the Royal Brompton that would ensure that children in future received their care from a holistic paediatric environment.

It is not the fact that certain services at the Royal Brompton are not co-located now that led to the original proposals but rather that the hospital had not developed a robust plan to address this shortfall.

We note, however, that as part of its response to NHS England's consultation the Trust has presented an alternative proposal which would allow these standards to be met following relocation of the service.

Why is paediatric co-location important?

Requiring paediatric cardiac services to be on the same site as other specialist children's services means that these children receive optimum care for any clinical problems that develop outside the heart (for example renal failure, the need for

specialist nutrition or any other multi-organ involvement) without the need for transfer to another hospital while critically ill. Co-location facilitates the input of the wider paediatric multidisciplinary team, and the interaction between this team on a daily basis and is of significant benefit to patients. Our clinical advisers told us that Congenital Heart Disease services being co-located with specialised paediatric services is important because it allows much closer working relationships to develop between paediatric cardiology specialists and the wider specialised paediatrics team to optimise clinical care of these patients. The requirement for full co-location is not only about faster response times but also about the relationships that develop between clinicians, about working as a wider multidisciplinary team, about culture and environment, and the way that all influences clinical care for the better.

NHS England's clinical advisers said that in their view it was not safe to care for children with complex conditions and co-morbidities (a high proportion of whom will need input from other specialties) in settings where other paediatric services were not on site. Having all tertiary specialties on one site means neither the child nor the specialist has to travel with the potential compromises involved in the care environment, access to the full team and equipment and timeliness of advice and intervention. This is important because many children with CHD have multiple medical needs and need input from other specialties.

Just as importantly, this also means that children with other diseases have access to the advice or care of a paediatric cardiologist.

The Clinical Advisory Panel has said: 'care for children should be provided in a holistic children's environment with on-site access to the full range of paediatric specialties and services. Isolated children's services are unacceptable; children's cardiac and respiratory services must be co-located within a hospital providing a broad range of paediatric specialties and services.' The National Panel endorsed the Clinical Advisory Panel's view and considered that this included meeting the co-location standards but was also about culture, environment and patient experience.

This is not just the view of NHS England or a small group of advisors. Examples of support for this view are given below.

In its consultation response, Little Hearts Matter, a charity supporting people with single ventricle heart conditions said:

'For far too long outcome has been measured purely by survival with excuses made for the poor outcome for children with complex disorders...Children with complex disorders are not just a heart in a bed. They require the skilled input of an array of clinicians because every organ in their system can be affected by their heart condition. This is needed in the acute short term swiftly by the bedside but also on a longer term basis as issues of childhood development, neurological conditions, gastroenterology complications and liver and kidney issues evolve. Cross condition care can be more effectively given in the same hospital which also allows for better joined up care.'

In response to the publication of NHS England's consultation on standards for congenital cardiac care, the Royal College of Paediatrics and Child Health said:

'We fully support these standards. We welcome the statement that specialist children's cardiac services should only be delivered in settings where a wider range of other specialist children's services are also present on the same hospital site. It is essential that other services required to provide optimum care for children, are based in the same hospital as children's cardiac services, particularly when a child's condition is complex or complications arise.'

The Children's Alliance, a strategic group of children's hospitals, told us:

'As providers of congenital heart disease services for children in England, we strongly endorse implementation of standards which ensure that specialist children's cardiac services are delivered in settings where a wide range of other specialist children's services are available on the same site. This is in line with accepted international practice and we consider this to be in the best interests of patients.'

Co-location of specialist children's cardiac services with, specialist paediatric surgery, renal, gastroenterology, neurology, respiratory and ENT services, supports a swift response to the bedside of a sick child; promotes regular interaction between specialist teams; and means that neither the child or the specialist has to travel between different sites, potentially compromising patient care. Implementation of the national standards provides us with a chance to ensure that all children, no matter where they receive their care, have access to consistent, high quality services, delivered in an environment best suited to meet their complex needs.'

FREQUENTLY ASKED QUESTIONS

Q: The paediatric co-location requirements were not part of the original standards and only introduced later. They were not properly agreed. This was never the intention of the paediatric standards group.

The paediatric co-location requirements now being implemented by NHS England were included in the standards from before the time that consultation on the standards took place, and they were only agreed by the Board of NHS England following full public consultation, and in the light of the responses to that consultation.

Dr Tony Salmon, Consultant Congenital Cardiologist, University Hospital Southampton, and Chair of the Paediatric Standards Group told us:

'When we set up the Paediatric Cardiac Standards Group we included representatives from all the centres around the country. It rapidly became clear that most of the group...were heavily influenced by the configuration and provision of services within their own centres. My personal view is that the time for arguing the case for co-location should be long passed. In the 1970s children were being treated and operated on by non-paediatric specialists, sometimes in adult facilities in District General Hospitals. There was a huge and successful move...to stop this practice and to get services together. Somehow, 40 years later we are questioning the validity of this direction of travel, asking what subspecialties we can do without on sites where one of the most complicated multidisciplinary services is undertaken. I think that it is possible only to fully appreciate the benefits of having all the paediatric subspecialties on site if you have them.

I believe that the long term aim should be for services to be co-located with Paediatric Cardiac Centres. I strongly urge NHSE to support centres to achieve this, and I hope that there are plans being developed along these lines. I am sure that this is key to ensure joined up care for the long term and will assist the continued development of paediatric cardiac services nationally'.

Q: There is no evidence that paediatric co-location will improve outcomes.

It is true that there is no published evidence that this change will improve outcomes. In fact we found no published evidence on this issue at all. That means that there is also no evidence to support the way the Royal Brompton currently arranges its services.

Early on in NHS England's work it was recognised that the amount of research available to guide service design is very limited. Commenting on the evidence, Clinical Advisory Panel chair Professor Sir Michael Rawlins, formerly Chair of The National Institute for Health and Care Excellence (NICE) and current Chair of the Medicines and Healthcare Products Regulatory Agency said:

'In my experience, the amount of quantitative scientific evidence available to guide us in deciding how best to organise health services is often much less than we would like. In these circumstances we rely heavily on the views of experts, both specialist clinicians and those who are expert because of their experience of using the services in question. The views of experts, while qualitative rather than quantitative, are also valid and an important source of evidence in our deliberations'.

The views of our expert clinical advisors, as described in this paper, have been clear. Children's heart services are best delivered in a holistic children's environment with on-site access to the full range of paediatric specialties and services.

Q: The Royal Brompton already meets the requirements in practice through its arrangements with Chelsea and Westminster Hospital.

A: It has been argued that co-location is unnecessary in light of arrangements that have been made between neighbouring hospitals. It is noted that the proximity of the two hospitals may mean that clinicians travelling from one hospital to another may have a similar distance to travel as clinicians within a large campus university hospital.

The National Panel's assessment has consistently been that the Royal Brompton's arrangements with Chelsea and Westminster do not meet the requirement of the standards. They meet the requirement as it exists currently for call to bedside response within 30 minutes. But they will not meet the requirement for full co-location that takes effect in 2019.

That is because, as already noted, these standards are about more than just responsiveness. The requirement for full co-location is also about the relationships that develop between clinicians, about working as a wider multidisciplinary team, about culture and environment, and the way that all influences clinical care for the better.

Q: Is this an exceptional requirement that has been imposed as part of this work but would not be usual elsewhere?

A: This way of working brings paediatric cardiac care into line with expectations in other specialist children's services. Most other specialist paediatric services expect to operate in a holistic child centred environment, including liver transplantation; bone marrow transplant; stem cell transplantation and haematology/oncology; end stage renal failure; high risk gastroenterology; and respiratory medicine. For many it is a national and international designation/accreditation requirement.

This approach will bring practice in England in line with the accepted international norm for paediatric cardiac services, in common with the following internationally recognised centres for paediatric cardiac care:

North America

USA

- Boston Children's
- Children's Hospital Philadelphia
- Washington Children's
- Texas Heart
- Chicago Memorial Children's Hospital
- Cincinnati Children's
- UCSF Benioff Children's Hospital
- Denver Children's Hospital
- CS Mott Children's Hospital, Ann Arbor
- Emory University, Atlanta
- Stanford University Hospital
- Johns Hopkins Baltimore
- University Wisconsin, Milwaukee

Canada

- Sick Kids Toronto
- Stollery Children's Hospital, Edmonton -
- Vancouver Children's
- Montreal Children's Hospital

Australasia

Australia

- Melbourne Children's
- Sydney Children's
- Lady Cilento Children's Hospital, Brisbane -

New Zealand

- Starship Children's Hospital, Auckland

Europe

Germany

- Berlin Herzzentrum
- Munich Herzzentrum
- University Hospital Sankt Augustin - Bonn

Netherlands:

- Leiden
- Utrecht
- Nijmegen
- Groningen

France

- Necker Enfants, Paris
- Haut Leveque, Bordeaux
- Chu Haute-pierre, Strasbourg
- Hopital Timone Enfants, Marseille

Italy

- Bambino Gesù, Rome
- San Donato, Milan
- Naples Children's Hospital
- Ancona Children's Hospital

Norway

- University Hospital Oslo

Sweden

- Karolinska University, Stockholm

Denmark

- Rigshospitalet

Poland

- Memorial Children's Warsaw



Clinical Advisory Panel Report:
Advice to the Congenital Heart Disease Programme
September 2017

Contents

Introduction	3
The Panel.....	3
A. Impact on Patients.....	5
Journey Times	5
Pregnancy and maternity.....	5
B. Impact on other services	8
Impact on Paediatric Intensive Care	8
Impact on other services: Extracorporeal Membrane Oxygenation (ECMO)	11
Impact on other services: Specialist paediatric respiratory services.....	12
Impact on fetal, maternity, neonatal and related services.....	14
Impact on the advanced heart failure service for CHD patients, including transplant, provided by Newcastle.....	15
C. Impact on research	17
D. Impact on training for clinical professionals	18
E. Other impacts.....	18
F. Alternative proposals for Royal Brompton	19
G. Pending co-location.....	20
H. Counting procedures	21
I. Implementation	21

Introduction

NHS England has set out proposals for congenital heart disease services and these have been subject to full public consultation.

The Clinical Advisory Panel was convened in order to give advice on a range of clinical issues in the light of consultation including issues raised by respondents to the consultation. It therefore looked at the impact of NHS England's original proposals on:

- Patients - the specific issues previously identified were longer journey times and the impact on pregnant women with CHD.
- Other services – focussing on Paediatric Intensive Care; Extracorporeal Membrane Oxygenation (ECMO); specialist paediatric respiratory services (at the Royal Brompton); fetal, maternity, neonatal and related services; and advanced heart failure service for CHD patients, including transplant (at Newcastle)
- Research at the Royal Brompton
- Training for clinical professionals
- Other impacts raised during consultation

The panel also considered alternative proposals that had been raised in consultation for the Royal Brompton.

Finally the panel looked at issues relating to implementation of NHS England's original proposals:

- Advice on the definitions of which procedures may counted in meeting the surgical and interventional cardiology standards
- Mitigation of any risks arising prior to paediatric co-location being achieved by all centres
- Managing the process of implementation

The panel was briefed on NHS England's pre-consultation impact assessment¹, responses to consultation and advice from groups convened on behalf of NHS England to provide further advice on the impacts of the original proposals.

The Panel

The Clinical Advisory Panel met on 25 August 2017 and was chaired by Professor Sir Michael Rawlins. The deputy chair was Professor Deirdre Kelly. Professor Kelly took over the chair of the meeting during discussions about Newcastle upon Tyne Hospitals to avoid any perception of a conflict of interest arising from Professor Rawlins' long association with the Freeman Hospital. Professor Rawlins took no part

¹ Available at:

https://www.engage.england.nhs.uk/consultation/chd/supporting_documents/NHS%20England%20Provider%20Impact%20Assessment%20Report.pdf

in the discussions relating to Newcastle. Similarly Ms Martin, as a current member of staff within the CHD service in Newcastle, took no part in discussions relating to Newcastle.

All members completed conflict of interest forms. These are available for inspection on request. They also declared their interests at the meeting.

Members of the panel present at the meeting were:

Member	Role / appointing organisation
Professor Sir Michael Rawlins	Chair
Royal Colleges and Specialist Societies	
Angie Martin	Royal College of Nursing representative on NHS England's Clinical Reference Group for Congenital Heart Services
Ms Carin Van Doorn	Chair of the Congenital Subcommittee of the Society for Cardiothoracic Surgery
Professor David Anderson	President, British Congenital Cardiac Association
Professor John Deanfield	Chair of Adult with Congenital Heart Disease Advisory Group
Dr Liam Brennan	President, The Royal College of Anaesthetists
Dr Mike Knapton	Deputy Medical Director, British Heart Foundation
Professor Neena Modi	President, Royal College of Paediatrics and Child Health
Dr Sarah Vause	Royal College of Obstetricians and Gynaecologists / British Maternal & Fetal Medicine Society representative
NHS England Clinical Advisers	
Professor Deirdre Kelly	Chair of the review's Clinician Group
Dr Gale Pearson	Chair of NHS England's Clinical Reference Group for Paediatric Intensive Care
Professor Huon Gray	National Clinical Director for Cardiac Care, NHS England
Dr Jacqueline Cornish	National Clinical Director for Children and Young People, NHS England
Dr Trevor Richens	Chair of NHS England's Clinical Reference Group for Congenital Heart Services
Dr Vin Diwakar	Regional Medical Director, NHS England (London)

A. Impact on Patients

Journey Times

A particular concern for patients and their families is that the cessation of level 1 services as proposed would, for some patients, mean longer journeys to hospital, where their care can only be provided by the level 1 centre, which will be inconvenient, and they fear, carry a level of risk.

NHS England's clinical advisers had previously told them that true emergencies are very rare and that ambulance services, local hospitals and retrieval teams are trained to ensure that patients are stabilised before and during transfer so that the risks of long journeys are minimised.

The NHS England's Clinical Reference Group² for congenital heart services had previously advised that the distance travelled for surgery is less important than travelling continually for ongoing care.

Pregnancy and maternity

In thinking about the impact of the original proposals on pregnant women, there are two distinct subgroups to be considered:

- Women with CHD who are pregnant or considering pregnancy
- Pregnant women whose fetus has CHD

Our pre-consultation equalities impact assessment³ suggested that although pregnant women would be affected by the proposed changes, they were not considered to be affected to a greater degree than other current and future patients.

Implementation of the original proposals would affect the choice of place of delivery for both sets of women, and may mean that the appropriate place of delivery would be further from home than would be the case currently.

The Panel's Advice

Key Consideration	Whether the risks for people who need urgent care are greater for those who live further away from a Level 1 centre and if so, how these could be minimised
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The panel noted that while journey times to the nearest level 1 centre would increase for some patients if the original proposals were implemented, the journey times for patients affected in this way would not be greater than those experienced by other

² Clinical Reference Groups are NHS England's system for obtaining clinical advice on its commissioning of specialised services.

³ Published at

https://www.engage.england.nhs.uk/consultation/chd/supporting_documents/Equalities%20and%20Health%20Inequalities%20Impact%20Assessment.pdf

patients elsewhere in the country, and there was no evidence that patients who currently are further from their level 1 centre, for example in the Channel Islands, have worse outcomes.

The panel also noted that there had been previous changes to CHD services in the UK which had the effect of increasing journey times to the nearest level 1 centre for some patients, including changes in Edinburgh, Cardiff, Oxford and Belfast, and there was no evidence that this had resulted in a worsening of outcomes. In other countries the distances to surgical centres may be much greater, and this provides evidence services can be run safely in this way.

Retrieval and ambulance services are trained in maintaining patients until they can receive definitive care.

Similarly, care for patients with urgent needs can be delivered more locally at level 2 centres and local hospitals which are able to stabilise patients, taking advice from specialist level 1 centres in their network, prior to transfer for definitive care.

The development of formal, managed networks (as described in the standards) with agreed shared protocols and lines of communication would support the safe operation of services.

Key Consideration	What further support could be given to patients and their families/carers who live further away from a Level 1 centre
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The panel noted that the standards already recognised that it is difficult for patients and their families when care is provided in a hospital at some distance from home, and based on advice from patients and their representatives were developed to make life easier in this situation by:

- Providing better information about where to park, eat and sleep;
- Providing better facilities to prepare meals;
- Providing free Wi-Fi;
- Ensuring parking charges are affordable; and
- Providing overnight accommodation for parents and carers.

The panel advised that the NHS England Board should prioritise the early implementation of these (and other similar standards) at all hospitals.

The panel also advised that NHS England should assess whether each level 1 centre was providing enough accommodation for family and carers.

Key Consideration	Whether the impact of the proposals on the following groups of patients would be felt to a greater extent or in a different way, and if so, what steps could be taken to minimise the impact:
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	<ul style="list-style-type: none"> • Children and young people with heart disease • People with learning disabilities and CHD • People of Asian ethnicity with CHD • Women with CHD who are pregnant or considering pregnancy and pregnant women whose fetus has CHD
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The panel considered that the primary impact of the original proposals on children and young people would be that all the clinical services they might need would be co-located and this would allow them to access these services in one place at one time.

The panel noted that change can be more difficult for people with learning disabilities and autistic spectrum disorder.

The panel did not consider that people of Asian ethnicity would be differently affected if the original proposals were implemented, and would not expect different considerations.

Considering women with CHD who are pregnant, the panel advised that a small number of women (those where cardiac risk is high, and in whom there is a high chance of needing urgent surgical or interventional cardiology procedure at the time of delivery) would need to deliver their babies at the level 1 centre or the linked nearby obstetric unit. For those in the North West for whom Manchester is closer to home, and for those in the East Midlands for whom Leicester is closer to home this will mean a longer journey and potentially more time spent at a greater distance from home.

The panel advised that women with CHD who are pregnant rarely require surgery or interventional cardiology at or close to the time of delivering their baby. As a result the choice of place of birth will not be affected for most women with CHD, and most antenatal care, births and postnatal care will still be in local hospitals or level 2 centres. Place of birth is agreed as part of preparing an individual care plan for each woman, and discussed at the MDT for higher risk patients.

Considering women carrying a baby with CHD the panel noted that not all would need to deliver at the level 1 centre or the linked nearby obstetric unit. Place of birth is agreed as part of preparing an individual care plan for each woman, and agreed between the level 1 centre, the specialist fetal-maternal unit, the local obstetric unit, the neonatal team, paediatricians and the parents. Only where a baby may require immediate postnatal catheter intervention or surgery, must the baby be delivered at the level 1 centre or the linked nearby obstetric unit.

If the original proposals are implemented this would affect those women in the East Midlands who would previously have delivered at Leicester because their baby needs urgent surgery or catheter intervention and for them will mean a longer journey and potentially more time spent at a greater distance from home.

The panel noted that while not all mothers would need to deliver at the level 1 centre (or linked nearby obstetric unit) some may request to deliver here.

The panel advised that increasing the rate of early diagnosis would facilitate appropriate decisions about place of birth, and reduce the chance of high risk deliveries taking place away from the level 1 centre. It advised that NHS England should take steps to ensure that antenatal diagnosis is increased. This would improve the experience of birth for parents. However, the panel noted that published evidence has not shown that increasing antenatal diagnosis leads to better physical outcomes.

Key Consideration	To what extent level 2 (specialist medical CHD) care provided at centres where level 1 care is no longer provided would address concerns around the impact on patients
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The panel noted that over the course of a lifetime, a person with congenital heart disease receives most of their CHD care in an outpatient setting. This should not be affected by the proposed changes since outpatient care can be provided in clinics at level 2 and 3 centres and outreach clinics.

The panel noted that level 2 centres would be more local for some than level 1 care. Most ongoing outpatient care could be delivered at level 2 centres and therefore if the original proposals were implemented this would make a big difference to the impact on patients of longer journey times to their closest level 1 centre. They also noted that while some urgent and emergency care for CHD might bypass level 2 centres, level 2 centres would still be able to provide care for non-cardiac emergencies and many cardiac complications (eg. arrhythmia management).

B. Impact on other services

The impact of service change at Newcastle on other patients and other services has not been assessed because the proposal is to continue to commission level 1 services from Newcastle. If a different direction emerged from the Board's discussions its impact would need to be considered and managed.

Impact on Paediatric Intensive Care

NHS England's impact assessment showed that if the original proposals were to be implemented there would be an impact on paediatric intensive care (PIC) provision at Leicester and Royal Brompton.

The original proposals affect only adult services in Manchester, so PIC would not be affected.

The Panel's Advice

Key	What would the impact on PICU services in centres that no longer
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Consideration	provide Level 1 care be if the original proposals were implemented and how could this be managed.
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The panel noted that Leicester has two paediatric intensive care units (PICUs), one at the Leicester Royal Infirmary and one at Glenfield (which supports CHD services, which accounts for slightly more than three quarters of its usage). The panel considered it likely that if the original proposals were implemented, the PICU at Glenfield would no longer be viable. However, it did not consider that the absence of CHD patients would threaten the viability of the service offered by the PICU at the Leicester Royal Infirmary, and noted that other hospitals without CHD services offered PICU services at a similar scale without difficulty.

The panel agreed with NHS England's assessment that the Royal Brompton's PICU would no longer be viable if the original proposals are implemented, because paediatric cardiac patients are a large proportion of its work and it would not have enough other patients to stay open.

The panel considered that if the PICU at the Royal Brompton were to close, it was reasonable to expect that at least some PICU staff, including nurses, would transfer to those centres where capacity would expand, because transport within London makes it feasible to transfer employer without moving house. The panel considered it unlikely that significant numbers of PICU nurses would transfer from Leicester to Birmingham or Leeds.

The panel noted that just as NHS England has modelled changes in CHD patient flows and therefore the associated requirements for increased PICU capacity, similar work would need to be done for non-CHD patients who currently use PICUs that would be affected by the original proposals. In practice because the panel expected that PICU care would still be delivered at Leicester Royal Infirmary, this was essentially an issue affecting non-CHD patients (including respiratory patients) who currently use PICU at the Royal Brompton.

Key Consideration	What would the impact on the national provision of PICU services be if the original proposals were implemented and how could this be managed.
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The panel expressed concerns about overall PICU capacity nationally and considered that NHS England should ensure that if it implemented its original proposals, they did not result in a reduction in PICU capacity.

The panel recommended that, if NHS England were to implement its original proposals, it should ensure that the hospitals where additional patients would be treated would provide sufficient replacement PICU capacity as part of the increase in

capacity needed for these patients. To achieve this, hospitals would need to develop plans that would deliver the expanded capacity in a timely way and:

- Develop operational policies that reflected the larger scale of the PICU. NHS England would need to work with hospitals to ensure that the expansions envisaged would not result in PICUs that were too big to be operationally effective.
- Be able to recruit the necessary staff, particularly because recruiting PICU nurses has been challenging for some centres - all centres where PICU capacity would need to expand should be asked to share their current PICU nurse vacancy rate to inform this.
- Have sufficient physical capacity and, where necessary, that the funding was available to achieve this.

The panel noted that current understanding of the impacts of implementing NHS England's original proposals on patient flows was based on modelling that assumed affected patients would in future go to their next nearest centre. However, this should be interpreted only as an indicator of what would happen as a significant proportion of patients are not cared for at their closest centre.

The panel recognised that it was not the job of the CHD review to address underlying problems within the PIC system nationally.

The panel considered that in reaching its decisions NHS England would need to take account of its other reviews into neonatal and paediatric critical care and maternity services but should not delay its decision on CHD services until its separate review of Paediatric Critical Care had released its final report.

The panel heard that the early findings of the paediatric critical care review were that:

- there are patients currently being cared for in PICUs that do not need to be treated in such an intensive environment;
- a large number of PICU beds are used by a small number of patients: these are likely to be children with long term, complex, needs who may benefit from alternative care settings; and
- demand most often exceeds capacity during the winter and is mainly for lower levels of critical care.

Expanding PICU capacity directly was not considered to be the answer as experience suggested that any additional capacity would soon be used by patients of lower acuity. Rather, the review's recommendations were expected to focus on how to ensure patients are treated in the right place, including developing level one and level two care, improving discharge arrangements for long term ventilated patients who may not need to be in a PICU, creating managed systems of care that allow patients to be stepped up and stepped down according to need, and introducing

appropriate pricing mechanisms. The review is likely to revise current service specifications to support hospitals delivering all levels of critical care, including for District General Hospitals in providing effective step down care for patients on their paediatric HDUs.

Should the original proposals be implemented, the review of paediatric critical care will need to take this into account in the regional implementation of its proposed new model of care.

The impact of implementing the original proposals on neonatal intensive care units (NICUs) would also need to be considered, though the panel noted that most babies born with CHD are managed in a PICU rather than an NICU, except for those born prematurely. Should the original proposals be implemented, the review of neonatal critical care will need to take this into account.

Impact on other services: Extracorporeal Membrane Oxygenation (ECMO)

Extra-Corporeal Membrane Oxygenation (ECMO) is a technique that provides respiratory and/or cardiovascular support to very sick patients. 'Respiratory' ECMO supports individuals with severe potentially reversible respiratory failure.

- All centres designated as level 1 CHD surgical centres are able to provide cardiac ECMO.
- Five centres in England are commissioned to provide paediatric/neonatal respiratory ECMO: Great Ormond Street, Newcastle, Leicester, Birmingham Children's and Alder Hey.
- Five centres in England are commissioned to provide adult respiratory ECMO: Papworth; South Manchester; Leicester; Guy's and St Thomas'; and Royal Brompton.
- Leicester is at the present the only provider commissioned to offer mobile ECMO (which allows children to be transferred between hospitals on ECMO).

The Panel's Advice

Key Consideration	What would the impact on ECMO (cardiac/respiratory; paediatric/adult; mobile) be in centres that no longer provide Level 1 care if the original proposals were implemented. What would the impact on the national provision of ECMO services be. How could these be managed.
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The panel noted NHS England's assessment that if the original proposals were implemented:

- Leicester would no longer be able to provide paediatric cardiac ECMO, paediatric respiratory ECMO or paediatric mobile ECMO or cardiac ECMO for adults with CHD. It would be able to continue to provide cardiac ECMO for adults with acquired heart disease and respiratory ECMO for adults.
- The Royal Brompton would no longer be able to provide paediatric cardiac ECMO or cardiac ECMO for adults with CHD. It would be able to continue to

provide cardiac ECMO for adults with acquired heart disease and respiratory ECMO for adults.

- Central Manchester would no longer be able to provide cardiac ECMO for adults with CHD. It would be able to continue to provide cardiac ECMO for adults with acquired heart disease.

The panel recognised that Leicester is the biggest provider of paediatric ECMO and that implementing the original proposals would have a national impact.

The panel noted the expectation that if the original proposals were implemented, cardiac ECMO for children and for adults with CHD would be provided by the centres where these patients receive their CHD care. The panel advised that if NHS England were to implement its original proposals it should ensure that the hospitals where additional patients would be treated would provide sufficient replacement cardiac ECMO capacity as part of the increase in capacity needed for these patients. To achieve this, hospitals would need to develop plans that would deliver the expanded capacity in a timely way.

The panel noted the expectation that if the original proposals were implemented respiratory ECMO for children would be provided by the remaining four centres offering this service: Great Ormond Street, Newcastle, Birmingham Children's and Alder Hey. The panel advised that if NHS England were to implement its original proposals it should ensure that these hospitals would provide sufficient replacement ECMO capacity in a timely way.

The panel noted the findings of the Paediatric Critical Care Review that the rate of use of ECMO varied across the country, with an almost fourfold difference between the lowest and highest utilisation rates. They noted that the review would be considering whether there is clinical justification for these variations, and this could change the capacity requirement for paediatric ECMO nationally.

The panel was confident that mobile ECMO could be re-provided, though not immediately. Other retrieval services had many of the necessary competencies and could develop an appropriately skilled workforce and the necessary equipment to deliver this service if commissioned to provide this service.

Impact on other services: Specialist paediatric respiratory services

The particular circumstances at the Royal Brompton, where paediatric cardiac and paediatric respiratory are the only children's services offered, means that NHS England's original proposals will have an impact on their paediatric respiratory service because of the effect on their PICU.

The Panel's Advice

Key Consideration	What would the impact on paediatric respiratory services at RBH be if the original proposals were implemented and how could this be
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	managed.
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The panel considered that while only a small number of children using paediatric respiratory services at the Royal Brompton would need to use the PICU, continuing to run a specialist paediatric respiratory service without access to a PICU would result in a diminished service.

The panel considered that while it would be possible for the Royal Brompton to continue to run paediatric specialist respiratory services if the original proposals were implemented, it would not be in the best interests of children to do so.

This is because the service would be less good compared to the current arrangements.

More importantly from the panel's perspective was that the same arguments applied to children with respiratory illness and children with cardiac illnesses, that children should have their care provided from a holistic children's environment with on-site access to the full range of paediatric specialties and services. If the original proposals were implemented the loss of paediatric cardiac and paediatric intensive care services from the Royal Brompton would mean that paediatric respiratory services was even more isolated, and operating in an adult focused environment.

The panel advised that if the original proposals were implemented NHS England would also need to assess the impact of additional journey times on children currently receiving specialist respiratory care from the Royal Brompton.

The panel identified a number of principles that it recommends NHS England should adopt when considering alternative ways of dealing with these impacts:

- Care for children should be provided in a holistic children's environment with on-site access to the full range of paediatric specialties and services. Isolated children's services are unacceptable; children's cardiac and respiratory services must be co-located within a hospital providing a broad range of paediatric specialties and services
- The solution should maintain the excellence and long term sustainability of service.
- The solution should be accessible to, and result in an equitable distribution of services for, the whole population served (London, East Anglia and the south east).
- The solution should fit strategically with plans for children's services across London.
- Ideally services should be provided in a vertically integrated model (integration of paediatric and adult care) but this is not as important as a horizontally integrated model (integration of specialist paediatric cardiac and respiratory services with the full range of paediatric specialties and services).

- Concerns of institutions, clinicians and researchers are secondary to the needs of children and their families.

The panel considered that if the original proposals were implemented, and recognising the high quality of this service, the best solution for paediatric respiratory services would be to move the respiratory service *en bloc* with the cardiac service to a single new hospital in order to preserve the strengths of these teams and the services they offer.

If it proved not to be possible to move the service *en bloc*, the panel considered that most aspects of the Royal Brompton's service could continue in the short term while a rapid review of paediatric respiratory services for London, East Anglia and the south east was undertaken and alternative solutions developed. This would need to be supported by developing an individual care plan for each child that took account of these arrangements. While redesigned care pathways could increase the number of providers and professionals involved in the child's care, particularly during times of crisis, the panel noted that the Royal Brompton does not have an A&E and therefore already operates a system of shared care with other hospitals.

Such a solution should only be short term because these services must (if the proposal is implemented) be moved to a holistic children's environment.

Impact on fetal, maternity, neonatal and related services

The national panel considered that if the original proposals were implemented there would be a significant impact on the fetal cardiology service offered by the Royal Brompton. They also noted that the Trust considered that their work with the cardiac obstetric service at Chelsea and Westminster Hospital would no longer be viable

The national panel noted that Leicester considered that if the original proposals were implemented there would be an impact on their fetal cardiology service (depending in part on whether they continued as a level 2 centre) and that their high risk obstetric cardiology service could be affected including outpatient care, high risk deliveries in cardiac patients and inpatient antenatal care.

The Panel's Advice

Key Consideration	What would the impact on fetal, maternity, neonatal and related services be if the original proposals were implemented and how could this be managed.
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The clinical panel considered that all level 1 CHD services (and some level 2 services) offer an extensive fetal cardiology service. These services could no longer be provided by the Royal Brompton or Leicester if the original proposals were implemented.

See also earlier section on impact on pregnant women with ACHD.

The panel advised that fetal cardiology services would continue to be provided by other providers. Fetal cardiology specialists from centres affected by the original proposals would be likely to move to these centres.

The panel advised that for pregnant women it was important that maternity services offered the full range of services needed by mother and baby, and that so far as is possible, mother and baby should not be separated. Services should be arranged in such a way as to avoid this.

All tertiary obstetric providers need access to fetal cardiology and clear pathways for patients.

The panel advised that in support of a whole life course approach NHS England should work towards geographical congruence for the various networks – congenital heart, neonatal and paediatric critical care and maternity.

The central role the Royal Brompton plays in fetal monitoring was discussed. It was noted by the panel that the clinicians in London would not disappear, but may move to other level 1 centres in and around London working within services that meet the standards.

The panel heard that there was evidence (not CHD specific evidence) that transferring sick babies has a negative effect on outcomes; this underlines the importance of managing the alignment of maternity, neonatal and cardiac networks. The panel noted that even where obstetric services and paediatric cardiac services are provided from within the same campus, ambulance transfers are sometimes necessary so this could not be avoided entirely. The panel advised that increasing the rate of fetal diagnosis and appropriate planning of place of birth would minimise unplanned transfers. It noted the earlier advice of the Royal College of Paediatrics and Child Health that: 'If neonatal and maternity services are not co-located with the children's cardiac service, a robust neonatal critical care transport service must be in place to ensure safe passage for newborn babies to the children's cardiac service.'

Impact on the advanced heart failure service for CHD patients, including transplant, provided by Newcastle

Newcastle has a unique role in delivering care for CHD patients with advanced heart failure including heart transplant and bridge to transplant. It is one of only two centres in the country to provide children's heart transplants (the other being Great Ormond Street). It also provides more heart transplants for adults with CHD than any other centre in the country. NHS England's clinical advisers have previously advised that these services can only be provided from a level 1 CHD surgical centre.

NHS England considers that this could not be replaced in the short term without a negative effect on patients and that it is therefore better to continue to commission level 1 CHD services from Newcastle, even though it does not currently meet either the paediatric co-location standards or the surgical activity standards that come into effect in 2019 and 2021 respectively, or have robust plans to do so.

The Panel's Advice

Key Considerations	<p>Whether Newcastle's advanced heart failure service, including heart transplant, could be replaced or moved elsewhere in the short term?</p> <p>Whether Newcastle's advanced heart failure service, including heart transplant, could continue to be offered at Newcastle if Newcastle no longer provided L1 paediatric cardiac services?</p> <p>Whether NHS England should continue to commission L1 paediatric cardiac services from Newcastle.</p> <p>What approach NHS England should take to this problem in the short term.</p>
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The panel noted the excellence of the service offered by Newcastle, and advised that this excellence must not be damaged or undermined. Ideally therefore a solution would be found that whereby Newcastle met the CHD standards and could therefore continue to provide both CHD and transplant services. The panel advised that the advanced heart failure; and bridge to transplant and transplant services could not be moved or replaced quickly. It would take time to replace these services and the proposed derogation would ensure continuing patient safety. The panel confirmed that these services could not be offered by a centre that was not a level 1 CHD surgical centre.

The panel advised that if NHS England were to continue commissioning L1 paediatric cardiac services from Newcastle patient outcomes should be monitored until either Newcastle meets the required standards or an alternative provider is commissioned.

The panel considered that while short term change was not possible, a longer term solution was needed.

The panel was concerned that allowing a level 1 CHD service to continue in the long term with only three surgeons would not be appropriate because it would not be in line with the principles set out by NHS England or be the right thing for patients with CHD.

The panel therefore considered that a 1 in 3 surgical rota at a transplant centre was particularly inappropriate because, of all cardiac surgical activity, transplantation demands the most work undertaken outside normal working hours and the operations themselves are long. As such a transplant service is very demanding for surgeons and requires a minimum of four surgeons to ensure acceptable rotas.

Succession planning and service resilience are also issues that favour such programmes being delivered as part of larger teams. To ensure sustainability, most, ideally all, of the surgeons should participate in the transplant programme.

The panel advised that demand for these services could be expected grow as more patients who have undergone procedures where heart failure is a predictable long term outcome survive into adulthood. Service planning had not yet fully taken these increases into account.

If NHS England concludes that Newcastle would not be able to reach the level of activity required to support a surgical team of four (as required by the standards) the panel advised that it should conduct a national review of the future of care for CHD patients with advanced heart failure including heart transplant and bridge to transplant.

The panel heard that in order to meet the CHD surgical activity requirement, hospitals would, in practice, need more than 500 operations per year, as had previously been discussed, because ensuring that every surgeon could undertake at least 125 operations, and that operations were assigned to an appropriate surgeon, would be difficult without enough operations to give some flexibility.

The panel advised that if NHS England concludes that Newcastle would not be able to reach this level of activity it should make clear that it is not supporting Newcastle in the long term. Under these circumstances the panel considered that it would then not be appropriate to press the Trust to achieve the 2019 co-location requirement if this involved significant disruption and/or cost. The panel acknowledged that a failure to give long term support could have a destabilising effect on Newcastle's service. If the service collapsed, it would *have* to be re-provided quickly. While Great Ormond Street might expand the capacity of its paediatric heart transplant programme, no other centre offered a transplant programme for adults with CHD, and this would need to be commissioned from an alternative centre.

C. Impact on research

NHS England accepts that the proposed changes would, if implemented, result in some disruption to the Royal Brompton's research programme.

The Panel's Advice

Key Consideration	What would the impact research at the Royal Brompton be if the original proposals were implemented and how could this be managed.
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The panel confirmed that if the original proposals were implemented this would lead to disruption of the Royal Brompton's research programme. They noted that this was particularly recognised for its extensive publication of research into long term outcomes in adult patients with CHD.

The panel advised that while the existing programmes of research would be disrupted these could be undertaken at other centres and that research excellence is linked to individuals and teams rather than institutions.

The panel advised that bringing services together at scale would enhance the environment for research and provide additional opportunities.

D. Impact on training for clinical professionals

Concerns were raised by the Joint College of Physicians Training Board, that if NHS England's original proposals were to be implemented they would affect paediatric cardiology training because approximately 30% of paediatric cardiology training posts are currently allocated to University Hospitals Leicester or the Royal Brompton Hospital.

The Panel's Advice

Key Consideration	What is the panel's advice in relation to the training of clinical professionals if the original proposals are implemented.
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The panel was reassured that if NHS England's original proposals were to be implemented paediatric cardiology training would be able to be provided at other centres. They noted that it would be advantageous to trainees to receive their training at centres that met the standards including holistic paediatric care. The panel considered that electrophysiology training could be provided by other centres.

The panel heard that the original proposals would not be expected to negatively affect congenital heart surgical training, nurse training or anaesthetist training.

The panel heard that overall there was a shortage of paediatricians overall and that concentrating care in fewer centres would therefore be expected to be helpful.

The panel considered that training at a centre that meets the standards would be better for trainees.

E. Other impacts

In consultation we asked 'Please describe any other impacts which you think we should consider, and what more might be done to avoid, reduce or compensate for the impacts we have identified and any others?'

The following additional impacts⁴ were identified by consultees:

- The impact on workforce: potential loss of staff and skills; difficulty recruiting; where will staff come from;
- Financial impact: the availability of capital funding to expand facilities in centres that would need to take more patients if the original proposals were to be implemented

⁴ Not a complete list of all replies to the question. I have extracted here only those answers directly answering the question, and excluded others. The full analysis will be published in the report by Participate and published alongside the Board paper.

- The impact on network working: how can outreach clinics be delivered and specialist nurses operate effectively across such large geographical networks? The need to share patient records.
- The impact on fetal medicine and the need to maintain seamless transfers of care.
- The impact on the ambulance service.
- The impact on local services: need better level 3 services and more paediatricians with expertise in cardiology (PECs).

The Panel's Advice

Key Consideration	Whether there are further clinical impacts that NHS England should take into account if the original proposals are implemented.
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The panel agreed that there would be an impact on workforce and that, outside London, nurses would be unlikely to move to a different town or city if a centre was no longer commissioned to provide level 1 services.

The panel did not consider that bigger networks would present a problem for the provision of outreach clinics or for specialist nurses. It noted that there were already examples of widely dispersed services of this kind. While larger networks could need more specialist nurses this could help reduce the need for patients to travel frequently to the level 1 centre.

The panel considered that impact on ambulance services was likely to be modest. However an increase in the amount of time ambulances were 'out of area' could be expected.

The panel advised that maintaining and developing level 2 services was important because of their role in supporting other specialties and not just for CHD patients.

F. Alternative proposals for Royal Brompton

A joint consultation response from the Royal Brompton and Guys and St Thomas's (on behalf of Kings Health Partners) was submitted that proposes a model for CHD services that brings together the existing RBH and GSTT services to deliver a joint, world class, service for all CHD patients from ante-natal to adulthood.

A response was also received from Chelsea and Westminster Hospital NHS Foundation Trust setting out proposals that would further develop the well-established and well integrated current clinical services and relationships between the CWFT and RBH. They argue that this would be the most practical and deliverable option; and would not incur the same level of risk as implementing NHS England's original proposals.

The Panel's Advice

Key Consideration	What the clinical risks and benefits of these alternative proposals are, and any further advice for NHS England as it considers these alternative proposals.
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The panel considered that sustaining the current arrangements at the Royal Brompton was not appropriate.

The panel advised that any solution needed to be a solution for all paediatric services currently delivered by the Royal Brompton and not just paediatric cardiac. The solution must also ensure that these children in future received their care from a holistic paediatric environment.

The panel considered that it would be possible to pursue a phased approach (as described in the RBH/GSTT proposal) that had the effect of separating paediatric cardiac and adult CHD services, but this should only be supported as a temporary transitional state, and the Royal Brompton's vertical integration should be maintained in the long term solution as this supports the whole life course approach.

The panel considered that if such a solution proved to be possible, a lift and shift solution was to be preferred because it supported the continuation of good service provision and kept established teams together.

The panel advised that it was appropriate to pursue a long term solution such as has been proposed for the Royal Brompton. Services are currently safe so pursuing a long term solution that can ensure that children receive their care in a holistic paediatric environment was considered to appropriate.

The panel advised that the National Panel should adopt a consistent approach to reviewing and assessing plans for change to meet the national standards at the Royal Brompton, Leicester and Newcastle.

G. Pending co-location

We are proposing that specialist children's cardiac services should only be delivered in settings where a wider range of other specialist children's services are also present on the same hospital site. This is recognised in the specific requirements in the standards for co-location of paediatric CHD care with paediatric surgery (D6); paediatric renal (D7); and paediatric gastroenterology (D9).

Full co-location is required by the standards 1 April 2019. However, some centres do not currently have paediatric CHD co-located with other tertiary paediatric services, and may not be co-located by the time required by the standards.

The Panel's Advice

Key Consideration	What actions can be taken by Trusts where full paediatric co-location has not yet been achieved to minimise clinical risks.
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The panel advised that at Trusts where full paediatric co-location has not yet been achieved appropriate working arrangements should be developed during the intervening period to support a safe and holistic approach to the care of children.

H. Counting procedures

Since the standards were approved, a number of factors have emerged that mean that further work has become necessary to define what procedures should be considered countable towards meeting the surgical and interventional cardiology activity standards.

In light of this NHS England considers that developing guidance on counting electrophysiology procedures should be deferred until a later time, but that these should not be included as countable procedures towards the interventional cardiology activity standards.

The panel heard that a simple count of the number of procedures undertaken by a surgeon is a very basic metric for assuring the maintenance of skills and that in future it was to be hoped that more sophisticated metrics would be developed to build on the existing standards.

The Panel's Advice

Key Consideration	Whether the recommendations set out for defining countable procedures for surgeons and interventional cardiologists are appropriate.
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The panel supported the sub-group's recommendations.

The panel agreed that, in future, further work should be undertaken to establish appropriate activity standards for electrophysiology practice. This should be part of a continuous process of audit and improvement activities to improve the quality of CHD services.

I. Implementation

If the original proposals are implemented, we do not expect that changes of location in individual patient treatment will happen before 2018. No changes will happen until the hospitals providing care for more patients are ready to receive them.

NHS England recognises that it will be increasingly difficult to maintain services at any centre where it is decided that level 1 services should not continue into the future.

The Panel's Advice

Key Consideration	How transition / implementation should be managed to minimise risks while maximising the benefits to patients.
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The panel considered that the plan must be implemented without further delay as the prolonged period of uncertainty has been destabilising and has an adverse impact on staff recruitment and maintenance of expertise.

The panel advised that the main risk of implementing the original proposals was the risk of unplanned service collapse before it was possible to execute a planned transfer of services.

The panel also highlighted the risk of not implementing the original proposals, which was that care for patients would not improve, and centres would not meet the standards even in the long term. The panel was also concerned that there was not enough surgical activity nationally to support ten centres meeting the surgical activity standards.

The panel advised that steps should be taken to learn from the experience in the North West.

The panel advised that national collaboration would be needed to:

- Provide national oversight, management and commissioning
- Manage supported change including monitoring an agreed set of metrics to assess the effect of any changes on the quality of care and outcomes
- Reduce the risk of service collapse
- Develop and deliver contingency plans in the event of service collapse

The panel considered that, if the original proposals were implemented, a buddying system could be a useful way of providing support both to centres that were decommissioned, and to centres where a significant step up was required.



National Panel Report

Post-Consultation Refresh of Assessments

September 2017

Contents

Introduction	4
Initial Assessment	4
The proposals.....	5
Pre-consultation Impact Assessment.....	7
Post-Consultation Review	8
The Panel's Assessment	10
NORTH REGION	11
Alder Hey Children's Hospital NHS Foundation Trust.....	11
Central Manchester University Hospitals NHS Foundation Trust.....	12
Leeds Teaching Hospitals NHS Trust	14
Liverpool Heart and Chest Hospital NHS Foundation Trust.....	15
Newcastle upon Tyne Hospitals NHS Foundation Trust	17
MIDLANDS AND EAST REGION	22
Birmingham Children's Hospital NHS Foundation Trust.....	22
University Hospitals Birmingham NHS Foundation Trust	23
Norwich and Norfolk University Hospital Foundation Trust (L2 adult only).....	24
Papworth Hospital NHS Foundation Trust (L2 adult only)	25
University Hospitals of Leicester NHS Trust.....	25
LONDON REGION	32
Barts Health NHS Trust	32
Great Ormond Street Hospital for Children NHS Foundation Trust	33
Guy's and St Thomas' Hospitals NHS Foundation Trust	35
Royal Brompton and Harefield NHS Foundation Trust.....	37
SOUTH REGION	45
Brighton and Sussex University Hospitals NHS Trust (L2 adult only).....	45
Oxford University Hospitals NHS Foundation Trust (L2 child and adult)	45
University Hospitals Bristol NHS Foundation Trust.....	45
University Hospital Southampton NHS Foundation Trust	47
Decision Making and Implementation.....	49
Decision Making.....	49
Developing implementation plans.....	49
Taking account of future demands	49
Unplanned service collapse	50

Ensuring all providers meet all standards.....	51
APPENDIX 1: Countable Procedures	52
APPENDIX 2: Interpretation of certain standards	55
Query 1 – Paediatric Gastroenterology	55
Query 2 – Adult Vascular	56
Query 3 - ACHD interventional specialist cardiologist staffing	57
APPENDIX 3: Paediatric Respiratory Services at Royal Brompton	59
APPENDIX 4: Research at Royal Brompton	67
Situation	67
Summary of research	67
High level claims.....	67
Analysis	72
Recommendations	72

Introduction

NHS England is the direct commissioner of congenital heart disease (CHD) services, as a prescribed specialised service. On 23 July 2015, the NHS England Board agreed new standards and service specifications for CHD services, with the expectation that in future all providers would meet the standards, leading to improvements in quality, patient experience and outcomes. The Board agreed a go-live date of April 2016 to begin implementation of the new standards, embedded in contracts with providers, with a standard-specific timetable giving up to five years to achieve full compliance.

Initial Assessment

In January 2016 a process to assess compliance with the standards was launched examining 24 paediatric standards (and the corresponding adult standards) considered to be most closely and directly linked to measurable outcomes (including the surgical and interdependency standards previously highlighted) and to effective systems for monitoring and improving quality and safety. These standards were organised as 14 requirements grouped into five themes:

1. Ensuring that paediatric cardiac / Adult CHD (ACHD) care is given by appropriate practitioners in appropriate settings
2. Ensuring that those undertaking specialist paediatric cardiac / ACHD procedures undertake sufficient practice to maintain their skills
3. Ensuring that there is 24/7 care and advice
4. Ensuring that there is effective and timely care for the management of co-morbidities
5. Assuring quality and safety through audit

Each set of returns was initially evaluated at a regional level by the NHS England specialised commissioning team, followed by a National Panel review to ensure a consistency of approach. The National Panel brought together NHS England staff from its national and regional teams with representatives from the Women and Children's Programme of Care Board and the Congenital Heart Services Clinical Reference Group.

The National Panel's work was considered by NHS England's Specialised Services Commissioning Committee (SSCC), at the end of June 2016. SSCC recognised that the status quo could not continue and that NHS England needed to ensure that patients, wherever they lived in the country, had access to safe, stable, high quality services. SSCC also recognised that achieving this within the current arrangement of services would be problematic.

SSCC determined that, subject to appropriate public involvement and/or consultation, a change in service provision was appropriate. As a result it was

proposed that in future NHS England would only commission CHD services from hospitals that are able to meet the standards within the required timeframes.

This National Panel then concluded its assessment of compliance with the standards, and the report of that assessment was published in July 2016. It showed that most hospitals were either very close to meeting the requirements, or were considered to be likely to meet them within the required timescales, with further development of their plans.

However, three of the hospitals - University Hospitals of Leicester NHS Trust, Newcastle upon Tyne Hospitals NHS Foundation Trust, and the Royal Brompton and Harefield NHS Foundation Trust - were unable to meet the requirements for April 2016, and were considered unlikely to be able to do so within the required timeframe.

One hospital – Central Manchester University Hospitals NHS Foundation Trust – was not able to meet the requirements now, was unlikely to be able to do so within the required timeframe, and the National Panel considered its current arrangements at that time to be a risk.

The National Panel's July 2016 assessment report is published at

<https://www.england.nhs.uk/commissioning/spec-services/npc-crg/chd/applying/>

The proposals

NHS England set out proposals for consultation in July 2016. The proposals would mean that, if agreed, in future:

- CHD level 1 services including surgery and interventional cardiology would be provided by the following hospitals:
 - **Alder Hey Children's Hospital NHS Foundation Trust** (children's services) and **Liverpool Heart and Chest Hospital NHS Foundation Trust** (adult service)
 - **Birmingham Children's Hospital NHS Foundation Trust** (children's services) and **University Hospitals Birmingham NHS Foundation Trust** (adult service)
 - **Great Ormond Street Hospital for Children NHS Foundation Trust** (children's services) and **Barts Health NHS Trust** (adult service)
 - **Guy's and St Thomas' NHS Foundation Trust** (children's and adult services)
 - **Leeds Teaching Hospitals NHS Trust** (children's and adult services)

- **University Hospitals Bristol NHS Foundation Trust** (children's and adult services)
- **University Hospital Southampton NHS Foundation Trust** (children's and adult services)
- Surgery and interventional cardiology for children and adults would also continue at **Newcastle upon Tyne Hospitals NHS Foundation Trust**. This recognises the Trust's unique role in delivering care for CHD patients with advanced heart failure including heart transplant and bridge to transplant and this could not be replaced in the short term without a negative effect on patients.
- If implemented, NHS England's proposals would result in the following changes at hospitals that currently provide level 1 (surgical) CHD services:
 - Surgery and interventional cardiology for adults would cease at **Central Manchester University Hospitals NHS Foundation Trust**.
 - Surgery and interventional cardiology for children and adults would cease at **Royal Brompton and Harefield NHS Foundation Trust**.
 - Surgery and interventional cardiology for children and adults would cease at **University Hospitals of Leicester NHS Trust**.
 - Through the consultation, NHS England also explored the potential for CHD level 1 (surgical) services for adults only to be provided the **Royal Brompton & Harefield NHS Foundation Trust** (partnering with another level 1 CHD hospital in London that is able to provide care for children and young people with CHD, and which meets the required standards).

Changes were also proposed to the provision of level 2 specialist medical CHD care. The proposals would mean that, if agreed, in future, and subject to meeting the requirements for level 2 provision:

- CHD level 2 (specialist medical) services would be provided by the following hospitals:
 - **Brighton and Sussex University Hospitals NHS Trust** (adult service)
 - **Central Manchester University Hospitals NHS Foundation Trust** (children's services)
 - **Norfolk & Norwich University Hospitals NHS Foundation Trust** (adult service)

- **Oxford University Hospitals NHS Foundation Trust** (children's and adult services)
- Through the consultation, NHS England also explored the potential for CHD level 2 (specialist medical) services to be provided at:
 - **Central Manchester University Hospitals NHS Foundation Trust** (adult service)
 - **University Hospitals of Leicester NHS Trust** (children's and adult services)

If implemented, the proposals would result in the following changes at hospitals that currently provide level 2 specialist medical CHD care (subject to further local engagement as appropriate):

- Specialist medical care and interventional cardiology would cease at **Blackpool Teaching Hospitals NHS Foundation Trust**
- Specialist medical care and interventional cardiology would cease at **Imperial College Healthcare NHS Trust**
- Specialist medical care and interventional cardiology would cease at **Nottingham University Hospitals NHS Trust**
- Specialist medical care and interventional cardiology would cease at **Papworth Hospital NHS Foundation Trust**
- Specialist medical care and interventional cardiology would cease at **University of South Manchester NHS Foundation Trust**

Through the consultation NHS England continued discussions with Papworth Hospital NHS Foundation Trust about its plans to meet the requirements to continue to provide specialist medical care and interventional cardiology.

The proposals were set out formally in NHS England's consultation document, published on 9 February 2017 at <https://www.engage.england.nhs.uk/consultation/chd/>.

Pre-consultation Impact Assessment

Prior to consultation NHS England undertook a detailed impact assessment considering the potential impact of its original proposals on patients and their families, on CHD services and other clinical services, and on hospital trusts, including financial implications. The aim of this impact assessment was:

- to understand how NHS England's original proposals could be delivered in practice;

- to identify the consequences of implementing the original proposals for patients, provider hospitals, commissioners and others; and
- to support planning of mitigations that may be needed to counter risks or address potentially negative consequences arising from implementing the proposed changes.

The pre-consultation impact assessment was published on 9 February 2017 at <https://www.engage.england.nhs.uk/consultation/chd/>.

Post-Consultation Review

Following the close of consultation, and to support the NHS England Board in its decision making, the National Panel was reconvened to refresh its earlier assessments. The aim of the National Panel's work was to:

- confirm the current (as at August 2017) assessment of each hospital providing level 1 and 2 CHD services against the standards;
- consider hospitals' progress in addressing the requirements set out in their improvement plan designed to address any shortfalls from meeting the standards;
- identify and assess the impacts of implementing NHS England's original proposals and any appropriate mitigations of these impacts; and
- consider any alternative proposals that have emerged during consultation: whether they would meet the standards and identify and assess the impacts of their implementation.

The National Panel met on 31 August 2017 with the following members present:

Chair

- Dr Vaughan Lewis, Regional Medical Director, Specialised Commissioning, NHS England, South and Chair of the CHD Programme Board;

Patient and Public Voice

- Michael Cumper, Patient Representative, Congenital Heart Services Clinical Reference Group;
- Suzie Hutchinson, Patient Representative, Congenital Heart Services Clinical Reference Group;

Clinical

- Professor Deirdre Kelly, CHD Programme Clinical Lead, NHS England;

- Professor Huon Gray, National Clinical Director for Heart Disease, NHS England;
- Dr Trevor Richens, Chair of the Congenital Heart Services Clinical Reference Group;

Specialised Commissioners (national team)

- Ben Parker, Project Development Manager, CHD Programme, NHS England;
- Cathy Edwards, Operational Delivery Director (National), Specialised Commissioning NHS England;
- Michael Wilson, Programme Director, CHD Programme, NHS England;
- Teresa Fenech, Director of Nursing and Quality Assurance, Specialised Commissioning, NHS England;

Specialised Commissioners (regional)

- Catherine O'Connell, Regional Director, Specialised Commissioning, NHS England, Midlands & East;
- Hazel Fisher, AD Programme of Care & NW London Locality Lead (London)
- Lesley Patel¹, Regional Nursing Director, Specialised Commissioning, NHS England, North;
- Linda Doherty, Regional Women and Children Programme of Care Manager, NHS England, South;
- Robert Cornall², Regional Director, Specialised Commissioning, NHS England, North.

This paper, which reports the National Panel's findings, should be read in conjunction with the July 2016 National Panel report setting out its initial assessment of each centre, and the National Panel report of November 2016 setting out its consideration at that time of how implementing the original proposals would affect each Trust, published

here: https://www.engage.england.nhs.uk/consultation/chd/supporting_documents/National%20Panel%20Assessment%20Report.pdf

¹ Ms Patel deputised for Mr Cornall prior to his arrival

² Mr Cornall was unable to attend the first part of the meeting

The Panel's Assessment

Following the pattern established in its earlier assessments, providers of CHD level 1 & 2 services were asked before and during the consultation process to provide evidence of their compliance with the standards: the April 2016 standards, the April 2017 (interventional cardiology) standards, the April 2019 (co-location) standards and April 2021 (surgical) standards.

Impact assessments were also refreshed taking account of any additional information that had emerged during consultation including views expressed in consultation.

NORTH REGION

Alder Hey Children's Hospital NHS Foundation Trust

Original Assessment

At the time of the original assessment, published in July 2016, Alder Hey was assessed as **Amber** – 'should be able to meet the April 2016 requirements with further development of their plans'.

Current Assessment (including progress and future plans for any standards not yet met – including 2019 and 2021 standards)

April 2016 / April 2017 ³requirements⁴: the National Panel assessed Alder Hey as **Green/Amber** – 'Meets most of the requirements and has good plans to meet the rest within max. 12 months'.

Alder Hey Children's Hospital must ensure that all interventional cardiologists meet the minimum requirements of 50 procedures per year.

April 2019 (paediatric co-location) requirements: the National Panel assessed Alder Hey as **Green** – 'Meets all the requirements'.

April 2021 (surgical activity, four surgeons) requirements: the National Panel assessed Alder Hey as **Amber** – 'Should be able to meet the April 2021 requirements with further development of their plans'.

The National Panel noted that NICOR reported that surgical activity⁵ at Alder Hey was:

394 for 2013/14

375 for 2014/15

357 for 2015/16

415 for 2016/17⁶

³ From April 2017 the standards require a 1:4 interventional cardiology rota as opposed to the 1:3 required in April 2016. Therefore during this exercise we assessed against the 1:4 requirement rather than the 2016 1:3 requirement.

⁴ Here and in subsequent assessment reports this refers to those requirements effective from April 2016 and April 2017 assessed by the panel.

⁵ Using the new definitions of countable surgical activity recommended by the countable procedures expert panel.

⁶ 2016/17 is unvalidated data subject to variation

The National Panel noted that the surgical team of a combined level 1 surgical centre in the North West would also undertake procedures currently undertaken at Central Manchester (approx. 90 per annum). Taken together the National Panel considered it reasonable to expect that the centre would be able to support a team of four surgeons each undertaking at least 125 operations a year from April 2021.

Impact of NHS England original proposals

No significant increase in surgical activity would be expected at Alder Hey as a result of the original proposals. The direct impact on Alder Hey will therefore be minimal.

However, under the original proposals Alder Hey will form a joint level 1 centre with Liverpool Heart and Chest Hospital (which does not currently offer a level 1 adult CHD service) with a single surgical team. The National Panel recommends that Alder Hey would therefore need to act as the senior partner in the transition of Level 1 services from CMFT to Liverpool Heart and Chest in order to provide assurance for the continuation of the service at CMFT and support LHCH in the development of its service.

Central Manchester University Hospitals NHS Foundation Trust

Original Assessment

At the time of the original assessment, published in July 2016, Central Manchester was assessed as Red – ‘Does not meet all the April 2016 requirements and is unlikely to be able to do so. Current arrangements are a risk.’

Current Assessment (including progress and future plans for any standards not yet met – including 2019 and 2021 standards)

At the time of the current assessment the level 1 adult CHD service previously provided by Central Manchester had been suspended by the Trust for an indefinite period. The National Panel did not consider that refreshing the earlier assessment was possible or appropriate.

The National Panel noted that NICOR reported that surgical activity⁷ at Central Manchester was:

99 for 2013/14

89 for 2014/15

88 for 2015/16

92 for 2016/17⁸

⁷ Using the new definitions of countable surgical activity recommended by the countable procedures sub-group.

Impact of NHS England original proposals

ECMO

Central Manchester provided cardiac ECMO for adults with CHD. At the time of the current assessment it was no longer doing so because the level 1 adult CHD service previously provided by Central Manchester had been suspended by the Trust for an indefinite period.

If the original proposals were to be implemented, Central Manchester would no longer be able to provide cardiac ECMO for adults with CHD. NHS England would then work with the other hospitals, where increased adult congenital surgery would be expected (Liverpool Heart and Chest Hospital) to undertake the necessary planning and preparation to manage any increase in adult cardiac ECMO capacity that would be needed for CHD patients. These hospitals have already given an assurance that they would be able to expand their services to provide the necessary care for the patients currently cared for by Central Manchester, if the original proposals are implemented.

Maternity care for women with CHD in the North West

In its consultation response Central Manchester proposed that, if NHS England's original proposals were to be implemented, it should still have a role in caring for and delivering the babies of pregnant women with congenital heart disease.

'For pregnant women with congenital heart disease, we believe the benefits of co-located services far outweigh that of having an ACHD surgeon on site. Therefore, the proposal would be that the existing model remains, with a maternity hub remaining in Manchester.'

The National Panel noted the advice of the Clinical Advisory Panel that:

'...women with CHD who are pregnant rarely require surgery or interventional cardiology at or close to the time of delivering their baby. As a result the choice of place of birth will not be affected for most women with CHD, and most antenatal care, most births and most postnatal care will still be in local hospitals or level 2 centres. Place of birth is agreed as part of preparing an individual care plan for each woman, and discussed at the MDT for higher risk patients'.

It accepted therefore that Central Manchester could still have an important role in maternity care for women with CHD, working as part of a network of care with a level 1 centre and with agreed network referral guidelines. Under these arrangements, women with complex CHD would be discussed within a network multidisciplinary meeting to determine the best place for delivery. Women with lower risk CHD could deliver closer to home as is current practice.

⁸ 2016/17 is unvalidated data subject to variation

Level 2 services in Manchester

If NHS England's original proposals were to be implemented, Central Manchester could have a greater role in maternity care if it met the standards for working as a level 2 specialist medical adult CHD centre.

The National Panel noted that Manchester had not been assessed against the level 2 standards. This would need to be completed. If the original proposals were implemented, developing and operating level 2 services would need the support of the level 1 centre, particularly given the suspension of services in Manchester.

Leeds Teaching Hospitals NHS Trust

Original Assessment

At the time of the original assessment, published in July 2016, Leeds Teaching Hospitals was assessed as **Amber** – 'Should be able to meet the April 2016 requirements with further development of their plans.'

Current Assessment (including progress and future plans for any standards not yet met – including 2017, 2019 and 2021 standards)

April 2016 / April 2017 requirements: the National Panel assessed Leeds as **Amber** – 'Should be able to meet the April 2016 and April 2017 requirements with further development of its plans'.

At the time of the current assessment although the Trust had agreed plans to ensure that all activity from Hull and East Yorkshire Hospitals is repatriated it had not implemented them. Assurances are still required from Leeds Teaching Hospitals that no CHD surgical or interventional activity is undertaken at Hull and East Yorkshire Hospitals.

At the time of the current assessment, although paediatric gastroenterology services are co-located with paediatric cardiac services, they are not provided 24/7. The Trust has co-located paediatric surgery with 24/7 availability. The National Panel was reassured by the emergency provision which was in place for gastroenterology however asked for assurances that formal arrangements are in place to provide 24/7 emergency bedside care within 30 minutes for gastrointestinal emergencies including gastrointestinal bleeding

April 2019 (paediatric co-location) requirements: the National Panel assessed Leeds as **Green** – 'Meets all of the requirements'.

April 2021 (surgical activity, four surgeons) requirements: the National Panel assessed Leeds as **Green/Amber** – 'Meets most of the requirements as of August 2017 and has good plans to meet the rest within max. 12 months'.

The National Panel noted that NICOR reported that surgical activity⁹ at Leeds was:

477 for 2013/14

497 for 2014/15

493 for 2015/16

422 for 2016/17¹⁰.

The National Panel considered it reasonable to expect that the centre would be able to support a team of four surgeons each undertaking at least 125 operations a year from April 2021 based on the activity levels across the years 2013/16. The National Panel noted the recent fall in activity. It also noted that there is some year on year variability at all centres. Regional commissioners would be asked to monitor activity in 2017/18 and if necessary ask the Trust to develop a plan to ensure that it meets the 2021 requirements.

Impact of NHS England original proposals

The original proposals would be likely to result in increased activity at Leeds Teaching Hospitals. The number of patients involved, equivalent to 50 operations a year, is relatively modest and represents a small proportional increase in activity for Leeds of 10%.

Leeds Teaching Hospitals is confident of their ability to increase its capacity sufficiently to provide the extra activity required under these proposals. The National Panel considered that it had provided good evidence of having understood the scale of what would be required of it and of their plans to increase capacity.

Leeds Teaching Hospitals did not identify any capital requirements in order to achieve this increase capacity.

Whilst the National Panel had some concerns relating to Leeds' ability to increase capacity in their cardiac ward, PICU and theatre the National Panel did not consider that these posed a significant risk to Leeds' ability to provide services for these additional patients.

Liverpool Heart and Chest Hospital NHS Foundation Trust

Original Assessment

At the time of the original assessment, published in July 2016, Liverpool Heart and Chest was assessed against the level 2 criteria. Assessment against the level 1

⁹ Using the new definitions of countable surgical activity recommended by the countable procedures sub-group.

¹⁰ 2016/17 data is unvalidated and subject to variation

criteria was not considered appropriate as it had not been working in this capacity and would not therefore have been expected to meet the criteria.

At level 2 it was assessed as Amber – ‘Should be able to meet the April 2016 requirements with further development of their plans.’

Current Assessment (including progress and future plans for any standards not yet met – including 2019 and 2021 standards)

At the time of the current assessment the Trust is not working as a level 1 centre so assessment against these standards was neither possible nor appropriate.

Impact of NHS England original proposals

Liverpool Heart and Chest Hospital (LHCH) currently provides level 2 CHD services. Liverpool Heart and Chest does not currently have a level 1 adult CHD service. Under the original proposals LHCH would begin performing Level 1 services including surgery and interventional cardiology on adults for the first time¹¹. The number of patients involved, equivalent to 90 operations per year will mean a significant change in the cohort of patients and activity levels.

The National Panel considered the scale and nature of this change to be a significant challenge for LHCH and therefore the most significant risk amongst hospitals gaining activity as a result of the original proposals.

The National Panel sought further assurances that Liverpool Heart and Chest understood the scale and nature of the challenge:

- Their understanding of the cohort of patients they would be caring for.
- The estates and equipment requirements they need to be able to provide the necessary care, what costs are associated with this and the sources of funds if needed.
- Their understanding of the workforce required and their plans for recruitment (and if needed for training).
- Their network approach – the way the relationship will work with Alder Hey, and with CMFT and the way that, jointly with Alder Hey they will support the NW network.
- The trajectory for launching the service – would this be phased or big bang, and how would they manage the transition.

¹¹ Although Liverpool Heart and Chest has reported CHD surgical procedures to NICOR, most of the procedures concerned were either aortic surgery (patients referred to an aortic specialist surgeon including referrals from CHD surgeons) or cases that do not require a CHD surgeon (based on the definitions of adult CHD surgery established before NHS England’s work in this area).

- Their communications plan (taking account of the negative views expressed by patients and other about the Liverpool Trusts' response to the collapse of the Manchester service).

The Trust provided further information. The National Panel considered that while this provided a greater level of assurance, more would need to be done to produce a fully developed model of care and describe the operational infrastructure necessary to deliver that care. It recommended that NHS England work with the Trusts in the North West to ensure that whatever decision it took, it could be confident that this could be delivered without undue delay and with a focus on patient rather than organisational needs.

Under the original proposals LHCH will form a joint level 1 centre with Alder Hey. The National Panel recommends that Alder Hey would therefore need to act as the senior partner in the transition of Level 1 services from CMFT to Liverpool Heart and Chest in order to provide assurance for the continuation of the service at CMFT and support LHCH in the development of its service.

Managing the risk of this change will require close working between CMFT, Alder Hey Children's Hospital and Liverpool Heart and Chest Hospital to ensure that they have a clear understanding of the activity LHCH will be required to undertake and the systems, facilities, staffing and capacity needed to manage this activity.

NHS England has recognised that it will have an important role to play in supporting implementation if the original proposals were to be agreed.

Newcastle upon Tyne Hospitals NHS Foundation Trust

Original Assessment

At the time of the original assessment, published in July 2016, Newcastle upon Tyne Hospitals was assessed as **Amber/Red** – 'Does not meet all the April 2016 requirements and is unlikely to be able to do so.'

Current Assessment (including progress and future plans for any standards not yet met – including 2019 and 2021 standards)

April 2016 / April 2017 requirements: the National Panel assessed Newcastle as **Amber** - 'Should be able to meet the requirements with further development of their plan'.

Newcastle upon Tyne Hospitals must ensure that their consultant interventional cardiology cover is provided solely by consultant interventional paediatric cardiologists.

April 2019 (paediatric co-location) requirements: the National Panel assessed Newcastle as **Amber** – ‘Should be able to meet the April 2019 requirements with further development of their plans’.

Paediatric cardiac services are not currently co-located with a full range of other paediatric specialist services. The Trust had carried out a scoping exercise to generate options for achieving co-location. As a result the Trust Board recommends that the best service would be achieved by moving both paediatric and adult services to one site at the RVI. The Trust was, however, concerned about the associated capital costs. While it was committed to achieving the requirement in principle, it considered it inappropriate to proceed without an assurance over the long term status of their CHD service, in light of its inability to meet the surgical activity requirement. If these plans to achieve co-location were to be implemented, the Trust expects that they would take time to complete, potentially beyond 2021.

April 2021 (surgical activity, four surgeons) requirements: the National Panel assessed Newcastle as **Amber/Red** – ‘Does not meet all the April 2021 requirements and is unlikely to be able to do so’.

The National Panel noted that NICOR reported that surgical activity¹² at Newcastle was:

391 for 2013/14

367 for 2014/15

324 for 2015/16

375 for 2016/17¹³

The National Panel noted that the Trust has enough surgical activity to support a team of three surgeons each undertaking at least 125 operations per year, and therefore meets the current requirement, which is in effect until March 2021.

The Trust reported that it does not consider it likely that it will have enough activity to be able to support a team of four surgeons each undertaking at least 125 operations a year from April 2021. The National Panel therefore considered it unlikely that this standard would be met.

Impact of NHS England original proposals

No significant increase in surgical activity would be expected at Newcastle as a result of the original proposals. The impact on Newcastle will therefore be minimal.

¹² Using the new definitions of countable surgical activity recommended by the countable procedures sub-group.

¹³ 2016/17 data is unvalidated and subject to variation

While noting that this meant that the original proposals posed a minimal risk at Newcastle, the National Panel considered that real risks did arise because Newcastle is unlikely to be able to meet the 2021 activity requirement.

Advanced heart failure including heart transplant and bridge to transplant services

The number of paediatric heart and lung transplants undertaken by Newcastle¹⁴ was:

- 2013/14: 12 paediatric heart transplants, 2 paediatric lung transplants and 10 ACHD heart transplants
- 2014/15: 21 paediatric heart transplants, 1 paediatric lung transplant and 7 ACHD heart transplants
- 2015/16: 19 paediatric heart transplants, 1 paediatric lung transplant and 5 ACHD heart transplants
- 2016/17: 17 paediatric heart transplants and 7 ACHD heart transplants

25 children received a long-term ventricular assist device at Newcastle between 1 April 2013 and 31 March 2016.

The National Panel endorsed the view, set out in the original proposals, that on balance it is better to continue to commission level 1 CHD services from Newcastle in the short term because of the Trust's pivotal role in delivering care for CHD patients with advanced heart failure including heart transplant and bridge to transplant services, which we are not assured could be replaced quickly without potential risk to patients.

This is in accord with the Clinical Advisory Panel's advice that the excellent advanced heart failure service offered to patients by Newcastle must not be damaged or undermined. The Clinical Advisory Panel agreed that these services could not be moved or replaced quickly, and that it would take time to plan and relocate these services. The proposed derogation would ensure continuing patient safety.

The Clinical Advisory Panel considered that while short term change was not possible, a longer term solution was needed. The Clinical Advisory Panel was concerned that allowing a level 1 CHD service to continue in the long term with only three surgeons would not be appropriate because it would not be in line with the principles set out by NHS England or be the right thing for patients with CHD. The National Panel agreed with these views. Furthermore, the Clinical Advisory Panel

¹⁴ For comparison heart transplant numbers at Great Ormond Street in the same period were:

2013/14: 15 paediatric and 3 ACHD

2014/15: 16 paediatric and 0 ACHD

2015/16: 15 paediatric 0 ACHD

noted that the unpredictable nature of the advanced heart failure work meant that the rota was more arduous than that in an equivalent CHD centre without an advanced heart failure service.

The National Panel agreed with the Clinical Advisory Panel (and the Trust) that in view of the time, effort, disruption and cost involved, it would be inappropriate to require the Trust to do the work necessary to achieve co-location if its CHD programme was not being supported in the long term. Any decisions on this work should therefore wait until after the NHS England Board had made its decisions.

Following on from this position, the National Panel identified two possible options:

- **Short to medium term derogation during which period a longer term solution should be developed.** The National Panel noted that a team of four surgeons would not be required by the standards until 2021, but that derogation would be needed for the paediatric co-location requirements if uncertainty over Newcastle's future remained. During this period consideration should be given as to whether alternative, innovative approaches could allow Newcastle to meet the surgical activity requirements, noting that the activity standards relate to individual surgeons and not to centres as a whole. The Clinical Advisory Panel advised that if Newcastle was unable to meet the activity requirements, NHS England should conduct a national review of the future of care for CHD patients with advanced heart failure including heart transplant and bridge to transplant. The National Panel considered that such a review would need to involve Newcastle (and other centres) in finding a solution. The National Panel noted that the impact assessments it had carried out related to the original proposals. Therefore if decommissioning of the level 1 service was considered a possibility by the review, impact assessments would need to be undertaken as part of this work.
- **Long term derogation.** This would give Newcastle the stability to continue to deliver both level 1 CHD services and advanced heart failure services including heart transplant and bridge to transplant. However, the National Panel, like the Clinical Advisory Panel, was concerned that such an approach would not be in line with the principles set out by NHS England or be the right thing for patients with CHD. The National Panel noted and accepted the Clinical Advisory Panel's view that accepting a 1 in 3 surgical rota at a transplant centre would not be appropriate because of all cardiac surgical activity, transplantation demands the most work undertaken outside normal working hours and the operations are lengthy. As such a transplant service is very demanding for surgeons and requires a minimum of four surgeons to ensure an acceptable rota.

The National Panel endorsed the Clinical Advisory Panel's view that that there was a risk that if NHS England's approach indicated only short term support for the CHD service continuing at Newcastle this could precipitate collapse of both CHD and advanced heart failure and cardiac transplantation services.

Concern has been expressed about the perceived dependence of the transplant service on one senior surgeon. The issue of service resilience was raised in the 2015 peer review of heart transplant services, however the 2016 report states that was 'confirmed as addressed at the 2016 visit through the recruitment of an additional surgeon'.

The National Panel considered that there could be an issue with the resilience of this service and asked for more information to be requested from the Trust.

MIDLANDS AND EAST REGION

Birmingham Children's Hospital NHS Foundation Trust

Original Assessment

At the time of the original assessment, published in July 2016, Birmingham Children's Hospital was assessed as Green Amber – 'Meets most of the requirements as of April 2016 and has good plans to meet the rest within max. 12 months.'

Current Assessment (including progress and future plans for any standards not yet met – including 2019 and 2021 standards)

April 2016 requirements: the National Panel assessed Birmingham Children's as **Green** – 'Meets all the requirements'.

April 2019 (paediatric co-location) requirements: the National Panel assessed Birmingham Children's as **Green** – 'Meets all of the requirements'.

April 2021 (surgical activity, four surgeons) requirements: the National Panel assessed Birmingham Children's as **Green** – 'Meets all of the requirements'.

The National Panel noted that NICOR reported that surgical activity¹⁵ at Birmingham Children's was:

514 for 2013/14

502 for 2014/15

503 for 2015/16

500 for 2016/17¹⁶

The National Panel noted that the surgical team of the combined level 1 surgical centre in Birmingham has sufficient surgical activity to support a team of four surgeons each undertaking at least 125 operations a year.

Impact of NHS England original proposals

The original proposals would be likely to result in significantly increased activity at Birmingham Children's Hospital. While the number of patients involved, equivalent to 180 operations per year, is relatively large this represents a more modest proportional increase in activity for Birmingham Children's of 36%.

¹⁵ Using the new definitions of countable surgical activity recommended by the countable procedures sub-group.

¹⁶ 2016/17 data is unvalidated and subject to variation

Birmingham Children's Hospital is confident of its ability to increase its capacity sufficiently to provide the extra activity required under these proposals. The National Panel considered that it had provided very good evidence of having understood the scale of what would be required and of plans to increase capacity. Birmingham Children's did not identify any capital requirements in order to achieve this increase capacity.

Birmingham Children's Hospital identified that in order to provide the extra activity required by these proposals it would need additional PICU and ward beds. It has identified a number of options for providing additional capacity for paediatric cardiac patients and is currently in the process of appraising these options. It is confident it would have this additional capacity in place by early 2018 but notes the significant challenge there will be in recruiting the necessary PICU nurses for this expansion. If the original proposals were to be implemented, Birmingham Children's Hospital would also be expected to need to take additional paediatric respiratory ECMO patients which would also require additional PICU capacity.

The National Panel did not consider there to be any significant risks associated with Birmingham Children's Hospital increasing their capacity to meet the activity required by the original proposals but did note the challenges associated with the recruitment of staff, most notably PICU nurses, and the need for sufficient lead in time.

University Hospitals Birmingham NHS Foundation Trust

Original Assessment

At the time of the original assessment, published in July 2016, University Hospitals Birmingham was assessed as **Amber** – 'Should be able to meet the April 2016 requirements with further development of their plans'.

Current Assessment (including progress and future plans for any standards not yet met – including 2019 and 2021 standards)

April 2016 / April 2017 requirements – **Amber** - 'Should be able to meet the April 2016 and 2017 requirements with further development of their plans.'

University Hospitals Birmingham must ensure that its ACHD interventionist performs a minimum of 50 procedures per year.

University Hospitals Birmingham must ensure that the centre is staffed by at least two interventional specialist cardiologists.

University Hospitals Birmingham must develop a 1:4 cardiologist rota.

April 2021 (surgical activity, four surgeons) requirements – **Green** - 'Meets all of the requirements as of August 2017'

The National Panel noted that NICOR reported that surgical activity¹⁷ at University Hospitals Birmingham was:

118 for 2013/14

86 for 2014/15

60 for 2015/16

64 for 2016/17¹⁸

The National Panel noted that the surgical team of the combined level 1 surgical centre in Birmingham has sufficient surgical activity to support a team of four surgeons each undertaking at least 125 operations a year.

Impact of NHS England original proposals

The original proposals would be likely to result in increased activity at University Hospitals Birmingham (UHB). The number of patients involved is relatively modest, equivalent to 45 operations per year, although this represents a 40% increase in activity for UHB.

UHB is confident of its ability to increase their capacity sufficiently to provide the extra activity required under these proposals. The National Panel considered that UHB had provided good evidence of having understood the scale of what would be required of them and of their plans to increase capacity.

UHB indicated that it would need to source capital funds of £6M to accommodate additional activity. It is expected that they would be able to source the capital funding from existing allocations and/or charitable funds. This is being confirmed with NHS Improvement.

The National Panel did not consider that there was any significant risk associated with UHB absorbing this additional activity.

Considered in the light of the scale of its overall adult cardiac service including ITU provision, the increased level of CHD activity it would absorb as a result of the proposed changes was not considered to be significant by the National Panel, which was therefore confident that any transition of activity would be able to be undertaken in a timely manner.

Norwich and Norfolk University Hospital Foundation Trust (L2 adult only)

Original Assessment

¹⁷ Using the new definitions of countable surgical activity recommended by the countable procedures sub-group.

¹⁸ 2016/17 data is unvalidated and subject to variation

At the time of the original assessment, published in July 2016, Norwich and Norfolk Hospital was assessed as **Green** – ‘meets all the requirements as of April 2016’.

Current Assessment

Regional commissioners provided an assurance that there had been no changes since the original assessment so Norwich and Norfolk was not reassessed.

Papworth Hospital NHS Foundation Trust (L2 adult only)

Original Assessment

At the time of the original assessment, published in July 2016, Papworth Hospital was assessed as **Red** – ‘has not demonstrated that it meets all of the requirements assessed and is unlikely to be able to do so. Current arrangements are a risk’.

Current Assessment (including progress and future plans for any standards not yet met – including 2017, 2019 and 2021 standards)

Current Assessment – **Green/Amber** - ‘Meets most of the requirements and has good plans to meet the rest within max. 12 months’.

Papworth must approve its memorandum of understanding with Guys and St Thomas’s. The National Panel understood this is due to be signed in October 2017.

Papworth must appoint a lead ACHD cardiologist. The National Panel understands that this post has Board level approval.

Papworth must ensure that it achieves co-location of its adult CHD services with adult vascular services (vascular surgery and interventional radiology). The National Panel noted that the new Papworth Hospital will open in September 2018 at which point all key specialties will be co-located on the same site.

Papworth has terminated its interventional activity in CHD patients. If it is successful in its bid to be accredited as a level 2 ACHD specialist medical centre it intends to develop proposals to reintroduce this service, subject to the support of the lead interventionist at Guys and St Thomas’ (the level 1 network centre) and regional commissioners, and demonstrating that it can meet the relevant standards.

University Hospitals of Leicester NHS Trust

Original Assessment

At the time of the original assessment, published in July 2016, University Hospitals of Leicester was assessed as **Amber/Red** – ‘Does not meet all the April 2016 requirements and is unlikely to be able to do so’.

Current Assessment (including progress and future plans for any standards not yet met – including 2019 and 2021 standards)

April 2016 and April 2017 requirements – **Amber** - ‘Should be able to meet the requirements with further development of its plans’.

At the time of the current assessment although the Trust had agreed plans to ensure that all ACHD interventional activity from Nottingham University Hospitals is repatriated this had not been implemented. Assurances are still required from University Hospitals of Leicester that no CHD interventional activity is undertaken at Nottingham University Hospitals.

University Hospitals of Leicester must ensure that all of its surgeons perform a minimum of 125 operations per year. The Trust does not currently have sufficient activity to meet the April 2016 standard requiring a team of three surgeons each performing a minimum of 125 procedures each year. Their growth plan suggested they would achieve this level of activity by 2019.

University Hospitals of Leicester must establish a 1:4 interventional cardiology rota. The Trust currently does not have four interventional cardiologists. The service is augmented by three interventional congenital cardiologists, who are employed elsewhere, but have contracts with University Hospitals of Leicester for their work at the Trust. The Trust plans to recruit additional interventional cardiologists this year to establish a substantive 1:3 rota and will increase this to 1:4 in the future. The National Panel noted the fragility of the current arrangements. It noted that under the revised definitions of interventional activity Leicester has sufficient activity to maintain a team of four interventional congenital cardiologists and therefore would be able to comply with this standard without requiring significant growth.

April 2019 (paediatric co-location) requirements – **Green/Amber** - ‘Meets most of the requirements and has good plans to meet the rest within max. 12 months’.

Paediatric cardiac services are not currently co-located with a full range of other paediatric specialist services. Leicester has developed a detailed plan to achieve paediatric co-location with the key paediatric specialties at the Leicester Royal Infirmary site, and that the funding for this has been secured. The National Panel noted that the timetable within the plan expected completion of the work necessary to be completed in July 2019. A timetable for the transfer of services and patients is not given. Nonetheless the National Panel considered that, assuming there was no significant slippage in delivery, this was an acceptable plan.

April 2021 (surgical activity, four surgeons) requirements - **Amber/Red** – ‘Does not meet all the April 2021 requirements and is unlikely to be able to do so’.

The National Panel noted that NICOR reported that surgical activity¹⁹ at University Hospitals of Leicester was:

299 for 2013/14

282 for 2014/15

323 for 2015/16

349 for 2016/17²⁰

Currently the Trust does not have enough surgical activity to support a team of three surgeons each undertaking at least 125 operations per year. Leicester has submitted a plan to achieve the 2016 and 2021 surgical activity requirements. The Trust's growth plan indicates that it plans to reach this volume of activity by 2019 and that it plans to have enough activity to be able to support a team of four surgeons each undertaking at least 125 operations a year from 2021.

The National Panel considered the growth plan to be optimistic. It was concerned that the plan did not give sufficient recognition to the role of either patient or physician choice or to the reputational attraction of the hospitals in Birmingham and London. The National Panel recognised that the continued uncertainty potentially made it difficult for Leicester to attract the best candidates, and that in turn, could have a negative effect on its attractiveness to patients and referring clinicians. It was concerned that there was not enough in the plan to change referring clinician preferences. This was of particular concern to the National Panel because the scale of the shortfall is considerable. Leicester is one of only two Level 1 centres yet to reach 375 operations per year. The National Panel was concerned that in order to succeed Leicester would need to move from a position where a high proportion of patients in its natural catchment at present receive their care elsewhere to a position where almost all these patients receive their care at Leicester.

The National Panel noted that NHS England had requested further assurances on the additional referrals identified within this plan, and considered this an appropriate way forward.

Impact of NHS England original proposals

Paediatric Intensive Care

Leicester has two paediatric intensive care units (PICUs), one at the Leicester Royal Infirmary and one at Glenfield (which supports CHD services, which accounts for 78% of its usage). If Leicester continues to provide level 1 paediatric cardiac surgery its plans for colocation involve the consolidation of the two PICUs at the Infirmary.

¹⁹ Using the new definitions of countable surgical activity recommended by the countable procedures sub-group.

²⁰ 2016/17 data is unvalidated and subject to variation

The PICU at Glenfield will therefore close whatever decision is taken by NHS England.

Without predetermining the outcome of the national paediatric critical care review, at this point NHS England expects Leicester would still provide PICU care for the East Midlands if the original proposals were implemented, and even if it no longer provides level 1 paediatric cardiac surgery. The National Panel noted the Clinical Advisory Panel's view that it did not consider that the absence of CHD patients would threaten the viability of the service offered by the PICU at the Leicester Royal Infirmary. Other hospitals without CHD services offer PICU services at a similar scale without difficulty.

The National Panel accepted as reasonable NHS England's plans to re-provide PICU capacity if its original proposals were implemented.

Re-providing PICU capacity for CHD patients: NHS England will work with the other hospitals where increased paediatric cardiac surgery would be expected if the original proposals were to be implemented (Birmingham Children's Hospital, Leeds General Infirmary) to undertake the necessary planning and preparation to manage any increase in PICU capacity that would be needed for CHD patients.

Re-providing PICU capacity for respiratory ECMO patients: A significant proportion of the remaining usage of the Glenfield PICU is accounted for by patients on respiratory ECMO. NHS England would work with the other hospitals where increased paediatric respiratory ECMO would be expected if the original proposals were implemented, to undertake the necessary planning and preparation to manage any increase in PICU capacity that would be needed for these patients.

Re-providing PICU capacity for other patients: A small number of admissions to the Glenfield PICU are for other patient groups. NHS England would expect that these patients would in future still receive their care from UHL, but at the LRI PICU.

Paediatric Cardiac and Adult Congenital Cardiac ECMO

Leicester provides cardiac and respiratory ECMO for children and mobile ECMO for children. Taken together these services support around 55 children a year. It also provides cardiac ECMO for adults with CHD. If the original proposals were to be implemented, Leicester would no longer be able to provide cardiac ECMO for children; cardiac ECMO for adults with CHD; mobile ECMO for children; or respiratory ECMO for children.

The National Panel accepted as reasonable NHS England's plans to re-provide ECMO capacity if its original proposals were implemented.

Re-providing ECMO capacity for CHD patients: NHS England will work with the other hospitals, where increased paediatric cardiac and adult congenital surgery would be expected, if the original proposals were to be implemented, (Birmingham

Children's Hospital, Leeds General Infirmary, University Hospitals, Birmingham) to undertake the necessary planning and preparation to manage any increase in paediatric cardiac and adult congenital cardiac ECMO capacity that would be needed for CHD patients. These hospitals have already given an assurance that they would be able to expand their services to provide the necessary care for the patients currently cared for by UHL, if the original proposals were implemented.

Re-providing Paediatric Mobile ECMO: Paediatric ECMO transport can be placed into three categories:

- Conventional transport, whereby a critically ill child who has been accepted for ECMO support is transported to an ECMO centre in order to be cannulated and placed on ECMO. If the original proposals were implemented conventional transport could be undertaken by existing transport teams.
- Cannulation and mobile ECMO, whereby an ECMO team travels to a child, cannulates them onto ECMO support, and then transports them on ECMO to the ECMO centre.
- Mobile ECMO transfer, whereby a child already on ECMO is moved from one ECMO centre to another for ongoing definitive care.

Cannulation and mobile ECMO require specialist expertise including a consultant experienced in cannulation as well as perfusion nursing and medical input. The National Panel noted the Clinical Advisory Panel's confidence that cannulation and mobile ECMO could be re-provided if one or more centres and/or retrieval services was commissioned to provide this service.

Glenfield Hospital is currently the only centre in England commissioned to provide paediatric and neonatal cannulation and mobile ECMO. This model of delivery, being reliant on a small group of staff within one service, is considered to be unsustainable in its present form. It is likely therefore that NHS England will re-procure this service within the next 18 months as part of the paediatric critical care review with the aim of creating greater service resilience.

Depending on the outcome of the CHD review, NHS England would be likely to seek one provider in the north and one in the south. The commissioning of two transport teams was also a recommendation of the work done by the Highly Specialised Commissioning Team in 2012/13 on the future delivery of paediatric respiratory and cardiac ECMO services. It is expected that some of the existing transport services would wish to tender for this as they have experience in transporting severely critically ill children who are not yet stabilised on ECMO, as well as those already on ECMO. These services already have the necessary retrieval competencies but would need to develop the necessary ECMO competencies which includes 24/7 availability of staff who are able to cannulate and look after patients who are on ECMO.

If the original proposals were implemented, at least one other commissioned respiratory ECMO centre would need to develop the appropriately skilled workforce and the necessary equipment to deliver this service, and this could not be achieved immediately. Taking this into account, NHS England would examine the possibility of accelerating plans to tender the service as described above, to create a long term rather than a short term solution.

The future development of respiratory ECMO services (described below) would be likely to reduce, although not remove, the need for cannulation and mobile ECMO (as more centres would be able to cannulate) whilst potentially increasing the number of mobile ECMO transfers.

Re-providing Paediatric Respiratory ECMO:

Current service specifications stipulate that respiratory ECMO services must be co-located with children's cardiac surgery services.

Should Glenfield's CHD services cease, these patients would need to be looked after in one of the other four commissioned paediatric respiratory ECMO centres (Great Ormond Street, Newcastle, Birmingham Children's and Alder Hey) or in an additional centre.

While the numbers currently treated at Leicester are small, they represent around half of all the commissioned national paediatric and neonatal respiratory ECMO activity.

If the paediatric respiratory ECMO activity currently undertaken by Leicester were to be redistributed so that patients received this care from the nearest of the remaining paediatric respiratory ECMO centres, this would represent a significant increase in paediatric respiratory ECMO activity for some of these centres, especially Birmingham Children's. NHS England estimates²¹ that the change would be:

15 patients, 103 bed days to Birmingham Children's compared to existing non-cardiac activity (2015) of 2 patients and 5 bed-days

4 patients, 53 bed days to Great Ormond Street compared to existing non-cardiac activity (2015) of 16 patients and 63 bed-days

6 patients, 56 bed days) to Alder Hey compared to existing non-cardiac activity (2015) of 2 patients and 26 bed-days

2 patients, 16 bed days) to Newcastle compared to existing non-cardiac activity (2015) of 2 patients and 18 bed-days

²¹ Figures based on estimated activity using historical data and do not necessarily reflect all the factors involved in determining where a patient should appropriately receive ECMO, and are therefore indicative only.

Redistributing paediatric respiratory ECMO activity in this way would mean that the care would be provided by centres already proficient in undertaking the intervention; it is expected that this would be less likely to result in any decline in the currently excellent outcomes reported nationally or any significant difference in the application of the eligibility criteria, as well as reducing requirements for additional staff training.

These centres are already commissioned to provide respiratory ECMO and already have the equipment, staff and infrastructure necessary to meet the existing requirements. If the original proposals were to be implemented, it would take time to increase capacity at these centres, and potentially some investment. There would also likely be a need for additional paediatric critical care capacity in these centres.

NHS England will work with these hospitals to undertake the necessary planning and preparation to manage a timely increase in the paediatric respiratory ECMO capacity that would be needed if the original proposals were implemented. There are recent precedents for ECMO centres scaling up rapidly; for example when Birmingham and Alder Hey changed from surge providers to permanent providers, or when Guy's and St. Thomas's Hospital developed its adult service over a short timeframe in association with the H1N1 epidemic in 2009.

Adult Respiratory ECMO

Leicester also provides adult respiratory ECMO. Leicester could continue to provide adult respiratory ECMO, in a similar way to other hospitals where services are supported by adult cardiac surgery services (not congenital cardiac). The level of adult respiratory ECMO at Glenfield is at least comparable to the levels of activity at the four other adult respiratory ECMO centres and it is reasonable to assume that it could therefore still be provided on this basis.

Fetal cardiology and specialist obstetric services

The National Panel accepted that if the original proposals were implemented there would be an impact on Leicester's fetal cardiology service and that their high risk obstetric cardiology service could be affected including outpatient care, high risk deliveries in cardiac patients and inpatient antenatal care. These impacts would be minimised if Leicester provided a level 2 CHD service.

The National Panel noted the Clinical Advisory Panel's advice that considered that all level 1 CHD services (and some level 2 services) offer an extensive fetal cardiology services and that fetal cardiology services would continue to be provided by other providers. If this did not happen Leicester's high risk obstetric service would need to access fetal cardiology support from another centre.

LONDON REGION

Barts Health NHS Trust

Original Assessment

At the time of the original assessment, published in July 2016, Barts Health was assessed as **Amber** – ‘Should be able to meet the April 2016 requirements with further development of their plans’.

Current Assessment (including progress and future plans for any standards not yet met – including 2017, 2019 and 2021 standards)

April 2016 / April 2017 requirements – **Amber** - ‘Should be able to meet the April 2016 and April 2017 requirements with further development of their plans’

Barts, working with Great Ormond Street, must establish a 1 in 4 interventional cardiology rota.

Barts, working with Great Ormond Street, must ensure that all of its surgeons perform a minimum of 125 operations per year.

Barts must provide further assurances that vascular services including surgery (or other surgeon competent to undertake vascular/microvascular repairs) and interventional radiology are co-located on the same site or that there are clear plans to co-locate this service.

April 2021 (surgical activity, four surgeons) requirements - **Green** - ‘Meets all of the requirements’

The National Panel noted that NICOR reported that surgical activity²² at Barts²³ was:

81 for 2013/14

67 for 2014/15

64 for 2015/16

86 for 2016/17²⁴

The National Panel noted that the surgical team of the combined level 1 surgical centre with Great Ormond Street has sufficient surgical activity to support a team of at least four surgeons each undertaking at least 125 operations a year.

Impact of NHS England original proposals

²² Using the new definitions of countable surgical activity recommended by the countable procedures sub-group.

²³ Data includes operations undertaken at University College Hospitals before the transfer of services.

²⁴ 2016/17 data is unvalidated and subject to variation

The original proposals would be likely to result in increased activity at Barts. While the number of patients involved, equivalent to 85 operations per year, is relatively small, this still represents a doubling of activity for Barts. The National Panel recognised this scale of increase to be a significant challenge for Barts. Regional commissioners were assured of Barts ability to increase their capacity sufficiently to provide the extra activity required under these proposals. The National Panel considered that Barts had a good track record in planning and delivering service expansions.

Considered in the light of the scale of its overall adult cardiac service including ITU provision, the increased level of CHD activity it would absorb as a result of the proposed changes was not considered to be significant by the National Panel, which was therefore confident that any transition of activity would be able to be undertaken in a timely manner.

The National Panel noted that Barts Health NHS Trust is in Special Measures. Some adult CHD activity would be expected to transfer to Barts Health from Royal Brompton if the original proposals were to be implemented. The proposed expansion of CHD activity at Barts will bring a positive contribution to the Trust bottom line by increasing income by greater use of an existing facility.

There is available capacity in the PFI-financed Cardiac Centre on the St Bartholomew's site. Further development of cardiac services is in line with the Trust's strategic aims. Barts did not identify any capital requirements in order to achieve this increase capacity.

Barts is part of a joint level 1 centre with Great Ormond Street Hospital with a single surgical team. The National Panel recommends that Great Ormond Street should act as the senior partner in the scaling up of Level 1 services at Barts in order to provide assurance of the development of its service.

NHS England recognised that it would have an important role to play in supporting implementation if the original proposals are agreed.

Great Ormond Street Hospital for Children NHS Foundation Trust

Original Assessment

At the time of the original assessment, published in July 2016, Great Ormond Street was assessed as **Green/Amber** – 'meets most of the requirements as of April 2016 and has good plans to meet the rest within max. 12 months'.

Current Assessment (including progress and future plans for any standards not yet met – including 2017, 2019 and 2021 standards)

April 2016 / April 2017 requirements – **Green/Amber** - ‘meets most of the requirements and has good plans to meet the rest within max. 12 months.’

Great Ormond Street must establish a 1 in 4 interventional cardiology rota.

Great Ormond Street must ensure that all of its surgeons perform a minimum of 125 operations per year.

April 2019 (paediatric co-location) requirements - **Green** - ‘Meets all of the requirements as of August 2017’

April 2021 (surgical activity, four surgeons) requirements - **Green** - ‘Meets all of the requirements as of August 2017’

The National Panel noted that NICOR reported that surgical activity²⁵ at Great Ormond Street was:

728 for 2013/14

717 for 2014/15

690 for 2015/16

695 for 2016/17²⁶

The National Panel noted that the surgical team of the combined level 1 surgical centre with Barts has sufficient surgical activity to support a team of at least four surgeons each undertaking at least 125 operations a year.

Impact of NHS England original proposals

The original proposals would be likely to result in significantly increased activity at Great Ormond Street Hospital. While the number of patients involved is relatively large, equivalent to 220 operations per year, this represents a more modest proportional increase in activity for Great Ormond Street of 31%.

Great Ormond Street Hospital is confident of its ability to increase capacity sufficiently to provide the extra activity required under these proposals. The National Panel considered that they had provided good evidence of having understood the scale of what would be required of them and of their plans to increase capacity.

Great Ormond Street indicated that it would need to source capital funds of £6M to accommodate additional activity. It is expected that they would be able to source the capital funding from existing allocations and/or charitable funds. This is being confirmed with NHS Improvement

²⁵ Using the new definitions of countable surgical activity recommended by the countable procedures sub-group.

²⁶ 2016/17 data is unvalidated and subject to variation

Great Ormond Street identified that in order to provide the extra activity required by these proposals they would need additional PICU beds for paediatric cardiac patients. If the original proposals were to be implemented, Great Ormond Street would also be expected to need to take additional paediatric respiratory ECMO patients which would also require additional PICU capacity. New capacity will begin to be available from October 2017 and that capacity could be made available to support other centres in the event of unplanned service changes.

The National Panel did not consider there to be any significant risks associated with Great Ormond Street increasing their capacity to meet the activity required by the original proposals, but did note the challenges associated with the recruitment of staff, most notably PICU nurses, and the need for sufficient lead in time.

Great Ormond Street is part of a joint level 1 centre with Barts. NHS England accepts the National Panel's recommendations that Great Ormond Street would need to act as the senior partner in the scaling up of Level 1 services at Barts in order to provide assurance of the development of its service.

Guy's and St Thomas' Hospitals NHS Foundation Trust

Original Assessment

At the time of the original assessment, published in July 2016, Guy's & St Thomas' was assessed as **Amber** – 'should be able to meet the April 2016 requirements with further development of their plans'.

Current Assessment (including progress and future plans for any standards not yet met – including 2017, 2019 and 2021 standards)

April 2016 / April 2017 requirements – **Amber/Green** - 'Meets most of the requirements and has good plans to meet the rest within max. 12 months'.

Guy's & St Thomas' must approve its memorandum of understanding with Papworth Hospital. The National Panel understood this is due to be signed in October 2017.

Guy's & St Thomas' must establish a 1:4 interventional cardiology rota.

April 2019 (paediatric co-location) requirements – **Green** - 'Meets all of the requirements as of August 2017'

April 2021 (surgical activity, four surgeons) requirements – **Green** - 'Meets all of the requirements as of August 2017'

The National Panel noted that NICOR reported that surgical activity²⁷ at Guy's & St Thomas' was:

534 for 2013/14

511 for 2014/15

513 for 2015/16

494 for 2016/17²⁸

The National Panel considered it reasonable to expect that Guy's & St Thomas' would have sufficient surgical activity to support a team of four surgeons each undertaking at least 125 operations a year by 2021. While this could be affected by changes to pathways for patients from Northern Ireland, this has been under discussion for a number of years. The National Panel considered that it should not take this into account without any certainty about when any change might take place, particularly given the potential impact of Brexit. In the event that the proposed changes become more certain, regional commissioners would ask the Trust to develop a plan to ensure that it meets the 2021 requirements.

Impact of NHS England original proposals

The original proposals would be likely to result in significantly increased activity at Guy's and St Thomas'. While the number of patients involved, equivalent to 200 operations per year, is relatively large this represents a more modest proportional increase in activity for Guy's and St Thomas' of 40%.

Guy's and St Thomas' is confident of its ability to increase its capacity sufficiently to provide the extra activity required under these proposals. The National Panel considered that it had provided good evidence of having understood the scale of what would be required of it and of their plans to increase capacity. Guy's and St Thomas' did not identify any capital requirements in order to achieve this increase capacity.

Guy's and St Thomas' identified a need for both additional ward and PICU capacity in order to provide the additional activity modelled under these procedures. It has not identified the number of additional PICU and ward beds required because it is confident that the extra capacity to be provided under its planned expansion scheme will be sufficient. This will provide up to eleven ward beds and up to ten PICU beds by December 2017.

The National Panel did not consider there to be any significant risks associated with Guy's and St Thomas' absorbing the activity required by NHS England's original

²⁷ Using the new definitions of countable surgical activity recommended by the countable procedures sub-group.

²⁸ 2016/17 data is unvalidated and subject to variation

proposals. However, the National Panel did note that the most significant risk related to the workforce implications of the original proposals on Guy's and St Thomas' and its ability to recruit the appropriate staff, most notably PICU nurses.

Alternative proposals

A joint consultation response from the Royal Brompton and Guys and St Thomas's (on behalf of Kings Health Partners) proposes a model for CHD services that brings together the existing Royal Brompton and Guys and St Thomas's services to deliver a joint service for all CHD patients from ante-natal to adulthood. More details and the National Panel's views are included under the Royal Brompton.

Royal Brompton and Harefield NHS Foundation Trust

Original Assessment

At the time of the original assessment, published in July 2016, the Royal Brompton was assessed as **Amber/Red** – 'does not meet all the April 2016 requirements and is unlikely to be able to do so'.

Current Assessment (including progress and future plans for any standards not yet met – including 2017, 2019 and 2021 standards)

April 2016 / April 2017 requirements – **Green/Amber** – 'Meets most of the requirements and has good plans to meet the rest within max. 12 months'.

Royal Brompton must ensure that all surgeons meet the minimum requirements of 125 operations per year. The National Panel was informed that this will be achieved when one of the surgeons retires at the end of 2017.

At the time of the current assessment, although the Trust has offered to undertake all interventional CHD activity from Imperial College Healthcare, this change has not been formally accepted by Imperial. Assurances are still required from the Royal Brompton that no CHD interventional activity is undertaken at Imperial as one of the hospitals within their network.

April 2019 (paediatric co-location) requirements – **Amber/Red** - 'Does not meet all the April 2019 requirements and is unlikely to be able to do so'

Paediatric surgery and paediatric gastroenterology are not co-located on the same site as the Royal Brompton's paediatric cardiac service.

The Trust has not presented firm plans for co-locating these services at its present site or by 2019. The National Panel noted that Royal Brompton's clinicians were working with clinicians from Guys and St Thomas's to develop joint protocols. The National Panel also noted that stronger multidisciplinary working had been demonstrated. However the National Panel also noted the Clinical Advisory Panel's

view that the current arrangements at the Royal Brompton were not viable and that a solution must be found that would ensure that children in future received their care in a holistic paediatric environment.

The Trust has presented an alternative proposal (see below 'Alternative Proposals') which would allow these standards to be met following relocation of the service. The National Panel considered that these plans are not yet sufficiently developed to provide an assurance that they could and would be delivered. Even if the plan was implemented as described, co-location would not be achieved until 2021/22.

April 2021 (surgical activity, four surgeons) requirements - **Green** - 'Meets all of the 2021 requirements'.

The National Panel noted that NICOR reported that surgical activity²⁹ at Royal Brompton was:

541 for 2013/14

516 for 2014/15

524 for 2015/16

475 for 2016/17³⁰

Impact of NHS England original proposals

Paediatric Intensive Care

The Royal Brompton's PICU is largely dependent on their paediatric CHD service, because CHD accounts for 84% of the admissions. The Trust considers that its PICU would no longer be viable if the original proposals were to be implemented, because paediatric cardiac patients are a large proportion of its work and it would not have enough other patients to stay open. The National Panel accepted that this was an accurate assessment. If the PICU at the Royal Brompton were to close, this would have an effect on their paediatric respiratory services, the only other clinical service for children offered by the Trust (see below).

Re-providing PICU capacity for CHD patients: NHS England will work with the other hospitals where increased paediatric cardiac surgery would be expected if the original proposals were implemented (Great Ormond Street, St Thomas' - Evelina Hospital) to undertake the necessary planning and preparation to manage any increase in PICU capacity that would be needed for CHD patients. These hospitals have already given an assurance that they would be able to expand their services to provide the necessary care for the patients currently cared for by RBH, if the original proposals were implemented.

²⁹ Using the new definitions of countable surgical activity recommended by the countable procedures sub-group.

³⁰ 2016/17 data is unvalidated and subject to variation

Re-providing PICU capacity for paediatric respiratory patients: If RBH also needed to cease to provide paediatric respiratory services (see below) NHS England would work with the other hospitals where increased paediatric respiratory care would be expected if the original proposals were implemented. Analysis of admissions to RBH's PICU shows that there have been, on average, over the period 2011-15, 105 PICU admissions each year for non-cardiac patients. Most of these patients were from London, East Anglia and the south east.

Re-providing PICU capacity for other patients: A small number of admissions to the Royal Brompton PICU are for other patient groups. NHS England would expect that these patients would in future receive their care from other PICUs in London and the south east.

ECMO

The Royal Brompton provides cardiac ECMO for children and cardiac and respiratory ECMO for adults. If the original proposals were to be implemented, Royal Brompton would no longer be able to provide cardiac ECMO for children. This would affect around 15 children a year. It would no longer provide cardiac ECMO for adults with CHD.

Re-providing ECMO capacity for CHD patients: NHS England will work with the other hospitals, where increased paediatric cardiac and adult congenital surgery would be expected, if the original proposals were implemented, (Great Ormond Street, Guys and St Thomas', Barts) to undertake the necessary planning and preparation to manage any increase in paediatric and adult congenital cardiac ECMO capacity that would be needed for CHD patients. These hospitals have already given an assurance that they would be able to expand their services to provide the necessary care for the patients currently cared for by RBH, if the original proposals are implemented.

Re-providing adult respiratory ECMO capacity: We would expect that the Royal Brompton could continue to provide adult respiratory ECMO, in a similar way to other hospitals where services are supported by adult general cardiac surgery services.

Specialist paediatric respiratory services

The circumstances at the Royal Brompton where paediatric cardiac and paediatric respiratory are the only children's services offered means that the original proposals would have an impact on paediatric respiratory services, if paediatric cardiac services and PICU were no longer provided by the Royal Brompton.

The Trust considers that this would have a serious detrimental effect on children's respiratory services which also use the PICU. The list of services offered by the Paediatric respiratory services identified by the Brompton are:

- Cystic Fibrosis

- Difficult asthma
- Primary Ciliary Dyskinesia
- Neuromuscular diseases requiring Long-Term Ventilation
- Interstitial lung diseases
- Sleep services
- Empyema and severe pneumonia
- Specialist interventions for rare disease, e.g.
- Lung biopsy
- Thoracic surgery for congenital malformations
- Thoracic cancer surgery
- Bronchoscopy in infants and complex respiratory, ENT and cardiac conditions

The National Panel accepted the Clinical Advisory Panel's advice that while only a small number of children using paediatric respiratory services at the Royal Brompton would need to use the PICU, that continuing to run a specialist paediatric respiratory service without access to a PICU would result in a less than optimal service. It considered that while it would be possible for the Royal Brompton to continue to run paediatric specialist respiratory services if the original proposals were implemented, it would not be in the best interests of children to do so.

The National Panel accepted the Clinical Advisory Panel's advice that the same arguments applied to children with respiratory illness and children with cardiac illnesses, that children should have their care provided in a holistic children's environment with on-site access to the full range of paediatric specialties and services. If the original proposals were implemented the loss of paediatric cardiac and paediatric intensive care services from the Royal Brompton would mean that paediatric respiratory services were operating in an even more isolated adult environment.

The National Panel recommended that if the original proposals were to be implemented NHS England should conduct a rapid review of paediatric respiratory services for London, East Anglia and the south east to develop alternative solutions. It noted the Clinical Advisory Panel's advice that relocating the whole service would be preferable to simply recommissioning additional capacity elsewhere. It also noted that Clinical Advisory Panel's view that most aspects of the Royal Brompton's service could continue in the short term while this was done.

Impact on fetal cardiology and specialist obstetric services

The National Panel considered that if the original proposals were implemented there would be a significant impact on the fetal cardiology service offered by the Royal Brompton. They also noted that the Trust considered that their work with the cardiac obstetric service at Chelsea and Westminster Hospital would no longer be viable. The National Panel considered that if the original proposals were implemented these services would be provided by the other level 1 and level 2 centres in London and the south east which also offered extensive fetal cardiology services.

Impact on research

The Royal Brompton considers that NHS England's original proposals, if implemented, would have a serious effect on the research that it undertakes, particularly in the field of adult CHD. It states that its work in this and related fields are highly regarded internationally and that the factors that underpin its successful research record could not be easily and quickly reproduced elsewhere.

This impact was not previously considered by the National Panel as NHS England's focus has been on improving direct patient care.

The National Panel accepted the Clinical Advisory Panel's advice that while the existing programmes of research would be disrupted, it considered that these could be undertaken at other centres and that research excellence is linked to individuals and teams rather than institutions. It noted the Clinical Advisory Panel's advice that bringing services together at scale would enhance the environment for research and provide additional opportunities.

The National Panel commissioned specific advice on this subject (see Appendix 4 below) which concluded that if NHS England were to decide to implement the proposals on which it consulted, consideration should be given to the potential for a planned and systematic transfer of research teams to support the preservation of research programmes. However, it also concluded that while such an approach may be viewed as attractive, highly successful academics can and do transfer between Universities, moving their research grants, programmes and research teams. Though this can be disruptive in the short term it is usually successful in the medium and long term.

Alternative proposals

The National Panel endorsed the Clinical Advisory Panel's view that any solution needed to be a solution for all paediatric services currently delivered by the Royal Brompton and not just paediatric cardiac. And the solution must ensure that these children in future received their care from a holistic paediatric environment. The National Panel considered that this included meeting the co-location standards but was also about culture, environment and patient experience. While the National Panel considered the current arrangements to be safe in the short term, in the long

term it could not support continued commissioning of paediatric cardiac services from the Royal Brompton site.

They also affirmed the view that while a vertically integrated model (integration of paediatric and adult care) is ideal, it could not obviate the need for a horizontally integrated model (integration of specialist paediatric cardiac and respiratory services with the full range of paediatric specialties and services) and a holistic children's environment. It is easier to manage the absence of vertical integration.

1. Royal Brompton providing an adult only (level 1) service

The National Panel's assessment, reported here, confirms that the Royal Brompton meets most of the ACHD level 1 standards assessed and has good plans to meet the rest within 12 months. However, the Panel noted that the ACHD service could not continue as a stand-alone service because it would not be able to meet all of the standards in this way, for example, supporting a team of four surgeons. However, as noted in NHS England's consultation the Royal Brompton could continue to provide surgical (level 1) services for adults by working in partnership with another hospital that provides surgical (level 1) services for children.

This option is not supported by The Royal Brompton.

We asked consultees to what extent they supported or opposed the proposal that the Royal Brompton provide an adult only (level 1) service as an alternative to decommissioning the adult services. Respondents from the London region disagreed with this proposal.

2. Bringing together existing services from the Royal Brompton and Guys and St Thomas's

A joint consultation response was received from the Royal Brompton and Guys and St Thomas's (on behalf of Kings Health Partners) that proposes a model for CHD services that brings together the existing RBH and GSTT services to deliver a joint, world class, service for all CHD patients from ante-natal to adulthood:

- delivery of CHD services for children (both those currently provided by GSTT and those from RBH) from new buildings of Evelina London. Services would move as soon as capacity is available, which should be by 2021/22 when further capital development at the Evelina London is completed.
- the joint development of a newly created specialist heart and lung centre on the Westminster Bridge campus. Adult services would be expected to move to the new specialist heart and lung centre at the Westminster Bridge Campus by the mid to late 2020s as this is completed.

The timing of moves would be subject to planning considerations.

The Trusts expect that this model would allow all standards to be met once co-location is achieved, as well as delivering benefits to patients through improved equity of access to specialist care, world class outcomes in a sustainable model and a leading research and education offering for the next generation of staff and therapies.

Noting that the Royal Brompton had been involved in discussions about this issue stretching back over years with many proposals emerging but none coming to fruition, the National Panel nonetheless considered that this proposal was very attractive, and although at a very early stage of development they considered that it should be supported and rapidly developed because the advantages of the proposed model, if it could be delivered, would be very significant. It recommended that NHS England consider supporting the development of more detailed plans.

Amongst these advantages of this solution is that it also addresses the parallel challenge for paediatric respiratory services, and that it facilitates keeping together the Royal Brompton's clinical and research teams.

3. Transferring the Royal Brompton's Paediatric Services to Chelsea and Westminster

A consultation response was received from Chelsea and Westminster Hospital NHS Foundation Trust setting out proposals that would further develop the established integration between the two Trust's services. It argues that this would be the most practical and deliverable option and would not incur the same level of risk as implementing NHS England's original proposals. This proposal builds on existing joint working and shared governance and minimise disruption of existing clinical, service and education relationships. The proposal describes two options:

Option 1 would create a single children's service for NW London at Chelsea and Westminster. This is Chelsea and Westminster's preferred option. This would see the transfer of inpatient paediatric cardio-respiratory and PICU services from RBH to the CWFT site. The Trust would expect this model to meet the national standards.

Option 2 would see additional Paediatric HDU (level 2) capacity at Chelsea and Westminster with the transfer from the Royal Brompton of patients for whom this is a suitable level of care (including Respiratory; Surgical: ENT, Cranio-Facial, Orthopaedics and others; 'Complex' surgical where underlying cardiac condition stable; and Post-operative cardiac but ventilation required). This partial and more incremental approach does not appear to meet the national standards.

What we heard in consultation

Few stakeholders were aware of these proposals as they emerged very late in the consultation period.

The Somerville Foundation, a charity that works with and on behalf of adults with congenital heart disease released a statement outlining its position on NHS England's original proposals relating to the Royal Brompton, which states:

'...The Brompton have also advised that it has plans to relocate the hospital onto the St Thomas' Hospital site that would enable it to comply with all the standards. We believe that 'derogation' (agreed delay to enable matters to be resolved) must be considered, as it has been for another unit...'

Imperial College Healthcare in its consultation did not directly comment on the new proposals outlined above, but stated their view that continuing to provide these services in north west London with closer collaboration between providers would benefit the people of north west London and the north west London health economy.

SOUTH REGION

Brighton and Sussex University Hospitals NHS Trust (L2 adult only)

Original Assessment

At the time of the original assessment, published in July 2016, Brighton & Sussex was assessed as **Green/Amber** – ‘meets most of the requirements as of April 2016 and has good plans to meet the rest within max. 12 months’.

Current Assessment (including progress and future plans for any standards not yet met – including 2019 and 2021 standards)

Current Assessment - **Amber** - ‘Should be able to meet the requirements with further development of its plans’.

The Trust must ensure that it has a lead specialist ACHD cardiologist who spends at least 0.8 WTE clinical time on ACHD.

Brighton has been meeting the interventionist activity requirement of at least 50 procedures per year with the inclusion of PFOs. The National Panel considered it reasonable to allow Brighton to continue its interventional activity until such time as a decision on commissioning PFOs had been reached. It was not clear to the National Panel whether the Trust would want to be a level 2 specialist medical ACHD centre if it were not able to undertake interventional activity. Regional commissioners would ask the Trust to confirm its intentions before making a decision on its status as a level 2 centre.

Oxford University Hospitals NHS Foundation Trust (L2 child and adult)

Original Assessment

At the time of the original assessment, published in July 2016, Oxford was assessed as **Amber** – ‘should be able to meet the April 2016 requirements with further development of their plans’.

Current Assessment (including progress and future plans for any standards not yet met – including 2017, 2019 and 2021 standards)

Current Assessment – **Green** - ‘Meets all of the requirements’

University Hospitals Bristol NHS Foundation Trust

Original Assessment

At the time of the original assessment, published in July 2016, Bristol was assessed as **Amber** – ‘should be able to meet the April 2016 requirements with further development of their plans’.

Current Assessment (including progress and future plans for any standards not yet met – including 2017, 2019 and 2021 standards)

April 2016 and April 2017 requirements – **Amber** – ‘Should be able to meet the requirements with further development of its plans’.

University Hospitals Bristol must ensure that all interventional cardiologists meet the minimum requirements of 50 procedures per year. The Trust has sufficient activity to meet the requirement that there be a 1 in 4 interventional rota but has six interventionists.

University Hospitals Bristol must provide further assurances that vascular services including surgery (or other surgeon competent to undertake vascular/microvascular repairs) and interventional radiology are co-located on the same site or that there are clear plans to co-locate this service.

University Hospitals Bristol must develop the capacity and capability to deliver cardiac ECMO for its adult CHD patients.

At present, although paediatric gastroenterology services are co-located with paediatric cardiac services, they are not provided 24/7. The Trust has co-located paediatric surgery with 24/7 availability. The National Panel was reassured by the emergency provision which was in place for gastroenterology however asked for assurances that formal arrangements are in place to provide 24/7 emergency bedside care within 30 minutes for gastrointestinal emergencies including gastrointestinal bleeding..

April 2019 (paediatric co-location) requirements – **Green** - ‘Meets all of the requirements.’

April 2021 (surgical activity, four surgeons) requirements – **Amber** - ‘Should be able to meet the requirements with further development of their plans’.

The National Panel noted that NICOR reported that surgical activity³¹ at Bristol was:

391 for 2013/14

409 for 2014/15

445 for 2015/16 455 for 2016/17³²

³¹ Using the new definitions of countable surgical activity recommended by the countable procedures sub-group.

³² 2016/17 data is unvalidated and subject to variation

The Trust meets the current surgical activity requirement with a team of three surgeons each undertaking at least 125 operations per year. The National Panel considered it possible that the centre would be able to support a team of four surgeons each undertaking at least 125 operations a year from April 2021 based on the activity levels across the years 2013/16. The National Panel noted the recent growth in surgical activity and that if this rate of growth continued it the Trust could meet the 2021 requirements. However, using historic national growth rates and considering the size of the Trust's natural catchment the National Panel considered that it was likely to be challenging to consistently meet the requirement. Regional commissioners would monitor activity and ask the Trust to develop a plan to ensure that it meets the 2021 requirements.

Impact of NHS England original proposals

No significant increase in surgical activity is expected at Bristol as a result of the original proposals. The impact on Bristol will therefore be minimal.

University Hospital Southampton NHS Foundation Trust

Original Assessment

At the time of the original assessment, published in July 2016, Southampton was assessed as **Amber** – 'should be able to meet the April 2016 requirements with further development of their plans'.

Current Assessment (including progress and future plans for any standards not yet met – including 2017, 2019 and 2021 standards)

April 2016 and April 2017 requirements – **Green/Amber** - 'Meets most of the requirements as of April 2016 and 2017 and has good plans to meet the rest within max. 12 months'

University Hospital Southampton must recruit an additional interventional cardiologist in order to establish a 1 in 4 rota. The National Panel noted that under the new definitions for counting interventional activity the Trust would be able to maintain a 1:4 rota and the Trust has agreed to appoint a fourth interventionist.

April 2019 (paediatric co-location) requirements – **Green** - 'Meets all of the requirements'

April 2021 (surgical activity, four surgeons) requirements – **Amber** - 'Should be able to meet the requirements with further development of its plans'.

The National Panel noted that NICOR reported that surgical activity³³ at Southampton was:

382 for 2013/14

367 for 2014/15

391 for 2015/16

431 for 2016/17³⁴

The Trust meets the current surgical activity requirement with a team of three surgeons each undertaking at least 125 operations per year.

The National Panel considered it possible that the centre would be able to support a team of four surgeons each undertaking at least 125 operations a year from April 2021 based on the activity levels across the years 2013/16. The National Panel noted the recent growth in surgical activity and that if this rate of growth continued the Trust could meet the 2021 requirements. However, using historic national growth rates and considering the size of the Trust's natural catchment the National Panel considered that it was likely to be challenging to consistently meet the requirement. Regional commissioners would monitor activity and ask the Trust to develop a plan to ensure that it meets the 2021 requirements.

Impact of NHS England original proposals

The modelling of patient flows which NHS England produced did not envisage significant activity flowing to Southampton as a result of these proposals.

The original proposals would be likely to result in increased activity at Southampton. The number of patients involved, equivalent to 20 operations per year, is relatively modest and represents a small proportional increase in activity for Southampton of 5%.

Southampton is confident of its ability to increase its capacity sufficiently to provide the extra activity required by the standards. Southampton did not identify any capital requirements in order to achieve this increase capacity.

The National Panel did not consider that there was any significant risk associated with Southampton absorbing this additional activity.

The National Panel considered that it had provided good evidence of having understood the scale of what would be required and of its plans to increase capacity. Work is already underway to expand PICU.

³³ Using the new definitions of countable surgical activity recommended by the countable procedures sub-group.

³⁴ 2016/17 data is unvalidated and subject to variation

Decision Making and Implementation

Decision Making

The National Panel advised that in reaching its decisions NHS England should recognise that there is no evidence of clinical detriment with increased travel time and that in its view consultation feedback indicates a willingness to travel to access high quality services.

They considered that co-location of paediatric CHD services with other children's services is of paramount importance.

They advised that the balance of risk for any decision needs to be considered, with patients' needs at the forefront of decisions.

The Clinical Advisory Panel highlighted the risk of not implementing the original proposals, which was that care for patients would not improve, and centres would not meet the standards even in the long term. The National Panel added that without a decision continued uncertainty would create problems for care provision.

Developing implementation plans

In consultation, a number of respondents referred to the need to develop a detailed implementation plan. The need to manage change in such a way as to avoid the loss of staff was particularly highlighted.

The National Panel noted that at this stage we have only very high level implementation plans as set out below. They asked the programme board to further consider and develop NHS England's implementation plan so that the Board could be assured that the organisation was in a position to implement its decisions once taken.

We have spoken to those hospitals which we expect would need to provide care for more CHD patients if the original proposals were implemented. They have looked at what they would need to do to increase the number of patients they care for and have assured us that they understand what is required and would be able to do what is needed to take the extra patients.

Taking account of future demands

The National Panel shared the Clinical Advisory Panel's concern that there is not currently enough surgical activity nationally to support ten centres that all meet the surgical activity standards. They noted that the number of procedures/operations required by the standards are a minimum and each service and operator should aspire to undertake more than the minimum figures to ensure compliance.

While there has been a year on year increase in the number of procedures (surgical and interventional, adult and paediatric) undertaken and activity levels have increased by almost 40% since 2003, they now appear to have largely stabilised over the last few years. Surgical activity at the level 1 centres in England for the last three years for which complete data is available was:

2013-14:- 4972

2014-15: - 4805

2015-16:- 4786

While overall growth in the number of surgical procedures may have slowed, demand for adult CHD services, with most care delivered in an outpatient setting, is expected to grow in the future as those with CHD live longer. If service change is under consideration the impact on adult services must be considered.

Unplanned service collapse

The Clinical Advisory Panel advised that the main risk of implementing the original proposals was the risk of unplanned service collapse before it was possible to execute a planned transfer of services. The National Panel noted that this was also a risk if decisions were not taken or deferred.

The Clinical Advisory Panel advised that steps should be taken to learn from the experience in the North West. It noted that the collapse of another service would be more difficult for the service to manage, both because a number of Trusts were already providing care for former patients of Manchester, and because of the scale of the challenge – Manchester being a much smaller centre than any of the centres that provide both paediatric and adult services.

The Clinical Advisory Panel advised that national collaboration would be needed to:

- Reduce the risk of service collapse
- Develop and deliver contingency plans in the event of service collapse
- Manage supported change
- Provide national oversight, management and commissioning

The Clinical Advisory Panel considered that, if the original proposals were implemented, a buddying system could be a useful way of providing support both to centres that were decommissioned, and to centres where a significant step up was required.

The National Panel endorsed the Clinical Advisory Panel's recommendation that national collaboration could help reduce the risk of service collapse. It saw a role for all level 1 CHD centres and for NHS England working together to provide this support. The clinical reference group could have a role in advising and national co-ordination.

Ensuring all providers meet all standards

The National Panel recognised that the decisions that the Board has to take on its original proposals are very important but that the process to date has focussed on selected standards. The National Panel recommended that NHS England take steps to ensure that, over time, all of the standards are met by all hospitals providing CHD care. It endorsed the following as key elements in bringing about improvement across all standards:

Contracts and improvement plans: All providers of CHD care are contractually required to meet NHS England's service standards by the CHD service specifications (Paediatric Cardiac E05/S/a and Adult CHD E05/S/b). Where a provider does not meet one or more of the standards, but the National Panel considers that they would be able to in future, an improvement plan with an agreed timetable should be agreed and made binding through a contract variation. Delivery against these plans should be monitored by regional commissioners in regular performance management meetings, and consolidated and reviewed nationally.

Better information: NHS England should continue to work with NICOR and the clinical reference group to ensure that a broader range of information is produced that can be used by providers and commissioners to measure quality and stimulate improvement, and guide patient choice.

Networks: Most level 1 CHD surgical centres already have informal hub and spoke networks – links with the hospitals that refer patients, to agree referral protocols and arrangements for working together. The extent to which these networks have been developed varies. NHS England should support and pump prime the development of more formal operational delivery networks.

Peer review: The standards propose a system of inter-unit peer review where each centre will be required to provide evidence to show that it meets the standards. NHS England's Quality Surveillance Team (QST) should support the development and delivery of a peer review programme, initially focused on the standards already assessed, but in future, through a rolling programme, expanding to cover every chapter of the standards.

APPENDIX 1: Countable Procedures

Report of an expert panel

In the summer of 2017 an expert panel was asked by the National Panel to make recommendations on the procedures which should be counted for assessing compliance with both the minimum surgical and interventional activity required by the CHD standards.

This panel had the following membership:

- Professor Deirdre Kelly, Chair of the CHD Implementation Group.
- Dr Tony Salmon; Consultant in Paediatric and Adult Congenital Cardiology, Southampton University Hospitals NHS Foundation Trust (Former Chair of CHD Paediatric Standards Group)
- Professor John Deanfield, Director, National Centre for Cardiovascular Prevention and Outcomes (Former Chair of ACHD Standards Group)
- Mr David Barron, Consultant Heart Surgeon at Birmingham Children's Hospital
- Dr Robin P Martin, Consultant Paediatric and Adult Congenital Cardiologist Bristol Royal Hospital for Children and Bristol Heart Institute
- Dr Graham Stuart, Consultant Cardiologist (Congenital Heart Disease), Bristol Heart Institute and Bristol Royal Hospital for Children
- Dr Rodney Franklin, Clinical Lead, NICOR National Congenital Heart Disease Audit and Consultant Paediatric Cardiologist, Royal Brompton & Harefield NHS Trust

The members of this panel were selected because of their involvement in the development of the standards and were the CHD specialist members of the New CHD review's Clinical Advisory Panel:

The recommendations from the panel on countable procedures are as follows:

Surgical Procedures

The relevant standard is as follows:

B10 (L1) Adult

“Congenital cardiac surgeons must work in teams of at least four surgeons, each of whom must be the primary operator in a minimum of 125 congenital heart operations per year (in adults and/or paediatrics), averaged over a three-year period. Only auditable cases may be counted, as defined by submission to the National Institute for Cardiovascular Outcomes (NICOR).”

B10 (L1) Paediatric states the same with the addition of the following sentence:

“VAD surgery and cardiac transplant surgery may also be counted.”

The panel recommends that the following definitions are agreed to ensure consistent application of the standard relating to minimum levels of surgical activity across all centres in country.

- Trainees – Where a trainee is operating under the supervision of a consultant the procedure is to be counted towards the consultant's activity. The trainee can continue to include this in their portfolio.
- Consultant dual operators – Where two consultants are undertaking a surgical procedure together only one surgeon can count this procedure.
- Cardiac ECMO (ECLS) – ECLS procedures which are not linked to an index procedure (defined as within 30 days of a previous procedure) can be included in a surgeon's minimum activity. (i.e. ECLS support for acute myocarditis, cardiomyopathy, bridge to transplant. Respiratory ECMO is not a countable procedure)
- VADS – Implantation of VADs can be included in a surgeon's minimum activity.
- Transplantation - Heart transplantation, Lung transplantation and Heart-Lung Transplantation can be included in a surgeon's minimum activity.
- Hybrid procedures – Hybrid procedures can be included in a surgeon's minimum activity.

Interventional Procedures

The relevant standards are as follows:

B17 (L1) Adult and B17 (L1) Paediatric

“Cardiologists performing therapeutic catheterisation in patients with congenital heart disease must be the primary operator in a minimum of 50 such procedures per year.

The Lead Interventional Cardiologist in a team must be the primary operator in a minimum of 100 such procedures per year, in each case averaged over a three-year period.”

B18 (L1) Adult and B18 (L1) Paediatric

“Each Specialist ACHD Surgical Centre must be staffed by a minimum of one expert electrophysiologist experienced in ACHD. There must be appropriate arrangements for cover by a competent person.”

B19 (L1) Adult and B19 (L1) Paediatric

“ACHD/Paediatric electrophysiology procedures must only be undertaken by an expert electrophysiologist experienced in the management of paediatric arrhythmias/arrhythmias with congenital heart disease.”

The panel recommends that the following definitions are agreed to ensure consistent application of the standards relating to minimum activity levels of interventional cardiology across all centres in country.

- Trainees – Where a trainee is performing an intervention under the supervision of a consultant interventional cardiologist the procedure is to be counted towards the consultant’s activity. The trainee can continue to include this in their portfolio.
- Dual interventional cardiologists – All interventionists (including the lead) must be the primary operator in a minimum of 50 procedures per year. Where two interventional cardiologists are undertaking a procedure together only one can count this procedure.
- Lead interventional cardiologist - The lead should perform a minimum of 50 procedures (as per the definition above) but the total of 100 could include cases where the lead has been supervising, or undertaking a procedure with, another consultant. The lead interventionist is to be defined by the centre and does not need to be their managerial lead.
- Hybrid procedures – Hybrid procedures can be included in an interventional cardiologist’s minimum activity.
- Diagnostic catheters – Currently these cannot be included in an interventional cardiologist’s minimum activity.
- Electrophysiology – Currently these cannot be included in an interventional cardiologist’s minimum activity.

APPENDIX 2: Interpretation of certain standards

A report of advice from the Congenital Heart Services Clinical Reference Group

The assessment of centres against standards inevitably throws up questions of interpretation when arrangements differ considerably from centre to centre. The National Panel sought clinical advice on the interpretation of three particular standards from the CHD members of the Clinical Advisory Panel. The Clinical Reference Group was asked for comment on the interpretations before final sign off by the National Panel.

Query 1 – Paediatric Gastroenterology

Standard D5, Level 1, Paediatric

The following specialties or facilities must be located on the same hospital site as Specialist Children's Surgical Centres. They must function as part of the multidisciplinary team. Consultants from the following services must be able to provide emergency bedside care (call to bedside within 30 minutes): **Paediatric Gastroenterology**

Specific request

Most centres meet the standard in a straightforward way. However a number of centres have paediatric gastroenterology services that are co-located but which do not provide 24/7 cover. When considering this issue a year ago the National Panel considered that in such cases, if paediatric surgery services were also co-located and provided 24/7 cover on site, this would be considered suitable mitigation.

The National Panel is now seeking advice on whether such an arrangement should be considered acceptable only while the hospital takes steps to ensure 24/7 cover by paediatric gastroenterology, or whether such an arrangement should be considered an acceptable interpretation of the standard and therefore be considered compliant in the long term. The National Panel discussed whether the requirement for 24/7 cover was specifically to manage GI bleeds or whether there were other issues to be considered.

Proposed interpretation

“Paediatric gastroenterology must be co-located on the same site; formal arrangements must be in place to provide 24/7 emergency bedside care within 30 minutes for gastrointestinal emergencies including gastrointestinal bleeding.”

Therefore an arrangement with co-located paediatric gastroenterology and 24/7 access to paediatric surgical services would be acceptable as long as the Trust had formal arrangements for providing 24/7 emergency bedside care within 30 minutes for gastrointestinal emergencies through its paediatric surgical team.

Query 2 – Adult Vascular

Standard D7, Level 1, Adult D7

The following specialties or facilities must be located on the same hospital site as Specialist ACHD Surgical Centres. They must function as part of the multidisciplinary team. Consultants from the following services must be able to provide emergency bedside care (call to bedside within 30 minutes): **Vascular services including surgery and interventional radiology.**

Specific request

Most centres meet the standard in a straightforward way. However a number of centres are part of vascular networks in which the vascular hub is on another site. In these circumstances vascular surgeons and interventional radiologists may be based at the L1 CHD centre, but not always. Interventional radiologists sometimes provide 24/7 cover on-site but not always. Full 24/7 cover with 30 minute response times is provided from the vascular hub.

The National Panel noted that the equivalent paediatric standard is different in three ways:

- Firstly the standard does not require a co-located service (while recognising this as the ideal). It does require a 30 minute response time 24/7.
- Secondly the standard makes no mention of interventional radiology.
- Thirdly the standard adds that the availability of another ‘surgeon competent to undertake vascular/microvascular repairs in children’ is an acceptable alternative.

Proposed interpretation

“Vascular services including surgery (or other surgeon competent to undertake vascular/microvascular repairs) and interventional radiology must be co-located on the same site; formal arrangements must be in place to provide 24/7 emergency bedside care within 30 minutes for vascular emergencies including vascular surgeons and interventional radiology.”

Therefore an arrangement with a co-located vascular service (which includes the necessary facilities, interventional radiology and a surgeon competent to undertake vascular/microvascular repairs) would be acceptable as long as the Trust had formal arrangements for providing 24/7 emergency bedside care within 30 minutes from a vascular surgeon if required.

Query 3 - ACHD interventional specialist cardiologist staffing

Standard B15, Level 1, Adult

Each Specialist ACHD Surgical Centre must be staffed by at least two interventional specialist cardiologists (ACHD or paediatrics), who may be included in the number referred to in standard B13(L1).

Note: B13 requires 4 WTE consultant specialist ACHD cardiologists.

Specific request

Standard B15 requires that there are at least two interventional specialist cardiologists on staff at each Specialist ACHD Surgical Centre.

The National Panel is seeking advice on the interpretation of standard B15. Specifically the interpretations which have been highlighted in bold.

The National Panel's initial view was that this standard was designed to ensure that each Specialist ACHD Surgical Centre **employs** at least **2 WTE** interventional specialist cardiologists who have been **trained in adult interventional cardiology and whose practice regularly includes adult interventional procedures**. The National Panel was mindful that how the standard was met would be different between centres, particularly between those where the whole CHD service is based on one site and those where paediatric and adult services are based on different sites.

Proposed interpretation

"Each Specialist ACHD Surgical Centre must be staffed by two interventional specialist cardiologists trained in adult CHD interventional cardiology and whose practice regularly includes adult CHD interventional procedures."

This can be achieved either through:

- **Option 1:** A joint adult and paediatric interventional cardiology team, of at least four congenital interventional specialist cardiologists, employed within the level 1 service (paediatric and adult), at least two of whom must have trained in adult congenital interventional cardiology and whose practice regularly includes adult congenital cardiac interventional procedures.
- **Option 2:** A separate adult congenital interventional cardiology team of at least two WTE congenital interventional specialist cardiologists, employed within the level 1 service (paediatric and adult), who have trained in adult congenital interventional cardiology and whose practice regularly includes adult congenital interventional procedures. These interventional specialists may be included in the minimum of four WTE consultant specialist ACHD

cardiologists required at each Specialist ACHD Surgical Centre (as required by standard B13(L1)Adult).

All interventionists must undertake a minimum of 50 congenital (including PFO) procedures each year. The lead interventionist must undertake a minimum of 100 procedures on people with CHD each year (including dual operator procedures or those where they are acting as a mentor as previously agreed). A shared lead interventionist across paediatric and adult services is acceptable, but this must be a role with real leadership authority and responsibility for the service as a whole and not merely be a way of ticking the box.

APPENDIX 3: Paediatric Respiratory Services at Royal Brompton

Recommendations from the panel examining potential impact of the original CHD proposals on Paediatric Respiratory and Cystic Fibrosis services at the Royal Brompton

Members:

- Dr Vinod Diwakar (**Chair**), Regional Medical Director, NHS England (London Region)
- Dr Iolo Doull, Consultant Respiratory Paediatrician, Children's Hospital for Wales, Cardiff
- Dr Peter-Marc Fortune, Consultant Paediatric Intensivist, Central Manchester University Hospitals; (via phone)
- Kathy Blacker, Accountable commissioner for Specialist Respiratory CRG;
- Nick Medhurst, Head of Policy, Cystic Fibrosis Trust
- Dr Penny Woods, Chief Executive, British Lung Foundation (not present at the meeting these recommendations were proposed and on leave during discussions on the recommendations. Steven Wibberley, Chief Operating Officer, British Lung Foundation, attended this meeting instead)

The views expressed in this paper are those of the members of the panel and do not necessarily reflect the views of the organisations they are employed by or represent.

Initial recommendations

Overall conclusion of the impact on RBH Cystic Fibrosis and paediatric respiratory services

The Royal Brompton Hospital delivers services for children with cystic fibrosis and a tertiary specialist service for children and young people with difficult asthma, interstitial and other rare lung diseases, primary ciliary dyskinesia, respiratory disorders related to neuromuscular disease, sleep disorders, and thoracic surgery for children with cancer and congenital lung and airway disease.

The service has a reputation for its experience in assessment and treatment, innovation and research which is supported by evidence.

The success of the service is based on the interrelationships between the individuals and the team and the colocation of outpatient, ambulatory, clinical investigation, inpatient, theatre and research facilities. It is a fully integrated service and therefore all of the components are interdependent on the others.

If CHD services are no longer commissioned at the Royal Brompton, NHS England has considered that there would not be sufficient activity to maintain the Royal

Initial recommendations

Brompton's PICU.

This expert panel has visited the Royal Brompton Hospital's Paediatric Respiratory and CF service, met with staff and patients, and reviewed information provided by the trust on the range and scope of services including details of clinical protocols and care pathways and how they interrelate with and utilise PICU. This includes relevant data on quality from CF Peer review and CF Registry data report.

Overall, the panel concludes:

1. The loss of the PICU would diminish the service offer for a relatively small group of the sickest and most vulnerable children and young people. Work would be required to redesign care pathways and could increase the number of providers and professionals involved in the child's care particularly during times of crisis.
2. Paediatric thoracic surgery could not continue on the Royal Brompton Hospital site
3. Paediatric intensive care and paediatric thoracic surgery are delivered in at least three other London trusts. A full assessment of the capacity of those organisations was not within the Terms of Reference of this panel though the panel noted that the number of patients affected is relatively small.
4. The majority of other patients under the CF and respiratory service could receive services at the current standard of service delivery with ongoing provision of paediatric high dependency care.
5. The Paediatric Respiratory and CF panel agreed with the National Panel (which reviewed the impact assessments relating to NHS England's CHD proposals) which said that while it might be possible to provide some aspects of paediatric respiratory services at the Royal Brompton & Harefield NHS Foundation Trust, this is not desirable. This is because:
 - a. The document *Commissioning Safe and Sustainable Specialised Paediatric Services: A Framework of Critical Inter-Dependencies* (Department of Health, London. 2008) considered that the co-location of paediatric respiratory services with PICU is desirable.
 - b. There are no logical arguments for the provision of a specialised and highly specialised CF and respiratory service without PICU in London. In other parts of England, CF centres are commissioned without PICU in order to ensure optimum access to service centres.
6. The inability to deliver the complex and specialist elements of the paediatric CF and respiratory service has the potential to lead to the decline of the service by

Initial recommendations

disrupting the current high performing professional relationships and the impact on recruitment of specialists to a less comprehensive service. This would also have in impact on RBH's major respiratory research centre and has the potential to result in the loss of a centre of research excellence. Future plans should aim to allow the paediatric CF and respiratory medicine team to build on the elements which contribute to their current high level of success.

7. The trust told the panel that paediatric anaesthesia service for respiratory patients is currently provided by paediatric anaesthetists who specialise in cardiac anaesthesia. The panel noted the experience of the team in managing the smaller number of highly complex respiratory patients. However the panel concluded that in other UK children's hospitals, anaesthetics for simple and complex respiratory patients are provided by consultant paediatric anaesthetists and do not usually require specialist paediatric cardiac anaesthetists. The proximity of services in London means that a service level agreement with appropriately skilled paediatric anaesthetists should be possible.

Comments on specific service lines

Cystic Fibrosis

1. *What would the impact of the CHD proposals be on this service?*

The NHSE Cystic Fibrosis (Children) service specification does not require co-located PICU.

Numbers of patients with CF who needed PICU are very low (10 patients over previous 3 years)

2. *Why would there be this impact? What (if any) mitigations or actions could be taken to reduce this impact?*

The loss of PICU would result in a small number of complex patients no longer being able to be cared for by RBH.

3. *Where activity could no longer be provided by RBH what alternatives are there?*

Any other CF centres with a PICU could provide care for the small volume of complex patients which could not be provided by RBH without a PICU. Kings or GOSH could be considered since these are CF centres with PICU in London.

Difficult Asthma – it was recognised that the team at RBH have an established international clinical and research track record and reputation in this field.

1. *What would the impact of the CHD proposals be on this service?*

Initial recommendations

The service could continue to be delivered in its current form without a PICU. RBH does not have an Emergency Department and told us that 4 patients with acute asthma had been transferred to RBH PICU in 3y (2014-6 inclusive).

They are a referral centre for severe asthmatics in the UK but these patients could be referred elsewhere.

The panel assessed RBH's protocols and concluded:

Stage 1 assessment would not be affected

Stage 2 assessment could continue as long as there was a HDU on site

Stage 3 assessment would not be affected

2. *Why would there be this impact? What (if any) mitigations or actions could be taken to reduce this impact?*

N/A

3. *Loss of PICU would impact small number of patients. Where activity could no longer be provided by RBH what alternatives are there?*

Other centres with PICU and paediatric respiratory medicine depending on where they are being referred from.

Primary Ciliary Dyskinesia

1. *What would the impact of the CHD proposals be on this service?*

Not affected at all by having PICU on site.

The national Service Specification for Primary Ciliary Dyskinesia (PCD) Diagnosis and Management Service (Children) says that specialist investigations (bronchoscopy, sputum induction) need to be provided by PCD centres. RBH estimates that 90-95% of all bronchoscopies could continue to be provided on the Royal Brompton Hospital site.

2. *Why would there be this impact? What (if any) mitigations or actions could be taken to reduce this impact?*

N/A

3. *Where activity could no longer be provided by RBH what alternatives are there?*

N/A

Interstitial lung disease – it was recognised that the team at RBH have an

Initial recommendations

established international clinical and research track record and reputation in this field and act as quaternary referral centre. Quaternary opinions are received for direct patient assessments, and for at a distance advice and guidance on biopsies, imaging, and other diagnostic assessments conducted at other tertiary centres

1. What would the impact of the CHD proposals be on this service?

These patients often require PICU either because they are very sick or require a lung biopsy. PICU backup would be required for RBH to continue to provide lung biopsies.

Most elements of this service could still be offered by RBH but the biopsies would need to be completed elsewhere and sent to RBH for review (this already happens).

RBH currently has 20 patients under active follow up. Small numbers of very sick patients could not be cared for by RBH. 10 patients required a PICU admission for lung biopsy in the last three years.

2. Why would there be this impact? What (if any) mitigations or actions could be taken to reduce this impact?

The loss of PICU would make lung biopsies and care for very sick patients unviable for RBH.

3. Where activity could no longer be provided by RBH what alternatives are there?

Other centres in London are believed to have the facilities required to care for this small group of children with rare and complex illnesses but the experience of the clinical team at RBH in this field is considered significant.

Sleep services

1. What would the impact of the CHD proposals be on this service?

The sleep service could continue to be delivered in its current form without a PICU. The trust told us that they conduct approximately 1000 sleep studies a year.

RBH cares for 156 patients on long term ventilation. Over 3y (2014-6), 10 patients were admitted to PICU, 6 with OSA and 4 with CCHS (mean LOS 8 days, longest 27d).

2. Why would there be this impact? What (if any) mitigations or actions could be taken to reduce this impact?

A small number of patients requiring recurrent PICU or HDU admissions could not be provided for by RBH without a PICU.

Initial recommendations

3. Where activity could no longer be provided by RBH what alternatives are there?

Other London centres with co-located PICU and paediatric respiratory medicine could provide this service.

Neuromuscular disease

1. What would the impact of the CHD proposals be on this service?

The specification of this service and the nature of the shared care arrangements with a paediatric neuromuscular or neurology centre was not clear from the information which was submitted. RBH does not have a collocated paediatric neuromuscular service. It appears that the majority of this is not acute but long term assessment and management for long term ventilation and sleep study which could continue without PICU.

The trust told us that the vast majority of the referrals are from secondary care. They previously received tertiary referrals from the neuromuscular team at GOSH and the Evelina, but numbers are much fewer since they expanded their respiratory NIV service.

On the basis of the information submitted, the panel inferred that the absence of a co-located PICU will not impact on this service other than for a small number of patients requiring repeated admissions to PICU. The trust said that in 2014-16 inclusive there were 8 patients who required PICU admission.

2. Why would there be this impact? What (if any) mitigations or actions could be taken to reduce this impact?

A small number of patients requiring recurrent PICU or HDU admissions could not be provided for by RBH without a PICU.

3. Where activity could no longer be provided by RBH what alternatives are there?

Other London centres with co-located PICU, paediatric respiratory medicine and paediatric neuromuscular could provide this service.

Surgical caseload

1. What would the impact of the CHD proposals be on this service?

Paediatric thoracic surgery could not continue on the Royal Brompton Hospital site.

Oncology: RBH described PICU activity relating to thoracic surgery for cancers (17 patients over 3y. The care pathway for patients with thoracic cancers between the

Initial recommendations

London cancer principle treatment centres and shared care centres was not clear.

Congenital lung and airway surgery: RBH has a shared care pathway with Chelsea and Westminster Hospital for antenatally diagnosed structural congenital lung disorders (11 patients over 3y were admitted to PICU). Surgery could not be conducted on the Royal Brompton Hospital site without co-located PICU or surgical NICU.

General Surgery, ENT and Dental: RBH listed surgical procedures which are required in patients with primary respiratory problems. They do not appear to require a co-located PICU and service level agreements are in place with Chelsea and Westminster Hospital for general paediatric surgery, dental, ENT. The trust told the panel that paediatric anaesthesia service for respiratory patients is currently provided by paediatric anaesthetists who specialise in cardiac anaesthesia. The panel noted the experience of the team in managing the smaller number of highly complex respiratory patients. However the panel concluded that in other UK children's hospitals, anaesthetics for simple and complex respiratory patients are provided by consultant paediatric anaesthetists and do not usually require specialist paediatric cardiac anaesthetists. The proximity of services in London means that a service level agreement with appropriately skilled paediatric anaesthetists should be possible.

2. *Why would there be this impact? What (if any) mitigations or actions could be taken to reduce this impact?*

Loss of thoracic surgical service and PICU would make any thoracic surgery unviable.

3. *Where activity could no longer be provided by RBH what alternatives are there?*

Paediatric thoracic surgery is provided by other London centres.

The care pathway for patients with thoracic cancers between the London cancer principle treatment centres and shared care centres was not clear and will need further work to determine how this service would be provided.

The care pathway for patients with antenatally diagnosed congenital lung lesions may be affected and further work on the requirement for co-located PICU or surgical NICU would be required in order to identify a suitable alternative care pathway.

Bronchoscopy

1. *What would the impact of the CHD proposals be on this service?*

RBH stated that 5-10% (8-16 cases per year) of bronchoscopies could not be

Initial recommendations

undertaken without a PICU backup. Therefore most of this activity would be unaffected.

The rest of this service could continue unaffected as long as there was HDU provision.

2. Why would there be this impact? What (if any) mitigations or actions could be taken to reduce this impact?

They would need an SLA with another provider to provide paediatric anaesthesia in order to RBH to continue providing these services.

3. Where activity could no longer be provided by RBH what alternatives are there?

Numerous other centres in London depending on where they were receiving their care.

APPENDIX 4: Research at Royal Brompton

The Impact of NHS England's Proposals for Congenital Heart Disease Services on Research at the Royal Brompton and Harefield NHS Foundation Trust

A report by Dr Michael Marsh, Medical Director, Specialised Commissioning, NHS England (London Region)

Situation

The Royal Brompton and Harefield NHS Foundation Trust has stated that it believes that the proposals for change to congenital heart disease (CHD) services on which NHS England has consulted would be damaging to its research programme in this field. Specifically, that the changes would be damaging because the research is unique, world leading and cannot be replicated elsewhere. The Trust has also asserted that other areas of research would also be negatively affected by the proposed changes because they are closely related and interlinked.

NHS England asked the Trust to submit detailed information to demonstrate details of the research and why it is unique to the Institute. The Trust provided a number of documents the main one title "RBH CHD Research NHSE 2017".³⁵

Summary of research

The evidence provided shows that over the past two decades RBH has made a significant and important contribution to the knowledge and academic development in the fields of paediatric and adult congenital heart disease. This has resulted in a large number of original articles, edited books and written chapters for a range of books.

High level claims

"The Trust produces more highly-cited publications in ACHD than any other Trust in the country, or anywhere else in the world."

"In the period 2012-2017, research from our team has led to the publication of more than 500 papers, nearly 300 of which were in journals with an impact factor >4. Eight books were edited and 61 book chapters authored"

"The research is clinical and has had a major impact in the UK and all over the world."

"Should CHD services be decommissioned from RBH, all paediatric and CHD services at the Trust would dissipated and research that involves both staff of the paediatric and ACHD services and patients squandered. The fragmentation of the above component parts would destroy the research that they currently produce."

³⁵ RBH CHD Research NHSE 2017 – Research and Education Programme in Paediatric and Congenital Heart Disease at the Royal Brompton Hospital August 2017.

The Trust supports this claim with a publication in the International Journal of Cardiology³⁶ (where 11 out of the 12 authors are associated with the Trust). The paper states that, taking into account numbers of papers and their perceived academic importance³⁷, London ranks it as the world leading research contributor, followed by Boston and Toronto. The Trust states that, within London, the Royal Brompton is the dominant contributor in this field with 49 highly cited papers in a number of prestigious scientific journals.³⁸

The RBH team has produced more than 500 academic papers in the period 2012-2017. The importance of the publications can be assessed to some degree by trying to consider the impact the publications have had in the field.

- Four publications have a very high impact with Impact Factor (IF)³⁹ of 72.4, though only one of these is an original article and the other 3 are letters;
- Two publications have an IF above 20 (28, 20.8);
- 57 have an IF between 10 – 19.9 (a mixture of articles, reviews and letters);
- 177 have an IF between 5 – 9.9;
- 150 have an IF between 2 – 4.9;
- 64 have an IF of less than 2; and
- 86 do not have a measured IF.

The full list of publications is provided in the Appendix 2.

Other publications

Between 2011 and 2017 RBH staff edited 8 books and contributed to 61 chapters in scientific books.

Details of academic staff

RBH staff involved in clinical and research activity come from a range of subspecialty areas including 40 working at consultant level as detailed below. The vast majority of these clinicians could be expected to work in the same clinical area following any implemented changes proposed by NHS England, and to continue their research interest. However, it is possible that if services at RBH were decommissioned not all RBH staff would end up working together in the same institution.

- **Paediatrics**
 - Fetal cardiology – 4 consultants
 - Paediatric cardiology – 10 consultants
 - Paediatric electrophysiology – 2 consultants

³⁶ Meeting the challenge: The evolving global landscape of adult congenital heart disease. Kempny et al IJC 2013;168:5182-5189.

³⁷ Measured by Impact Factor (IF).

³⁸ Research and Education Programme in Paediatric and Congenital Heart Disease and the Royal Brompton Hospital. Page 1.

³⁹ Impact Factor is a measure to try and show the relative importance of the paper in the field, the higher the IF the greater the perceived importance.

- Paediatric and congenital heart disease surgery – 5 consultants
- Paediatric Intensive care – 9 consultants
- Cardiac morphology – 2 consultants
- **Adults**
 - Adult congenital heart disease – 8 consultants

There are also a number of international fellows that come from units around the world to work at RBH in a research capacity with funding from their own employing institution. RBH has a long history of attracting independently funded research fellows and currently has six international research fellows from outside UK.

Grants held

RBH submitted information showing 19 current grants and fellowships from a number of funding bodies including the National Institute for Health Research, British Heart Foundation, Heart Research UK, Wellcome Trust and Department of Health, as well as other research charities and industry. However, 23 of the grants and fellowships cited are now past their funding dates.

The financial values of these grants was not shared. In the majority of cases the Lead or Sponsor of the grants was a University (including Imperial, UCL, Cambridge University, Queen's University Belfast and St. George's University Hospital) rather than RBH.

Outline research themes

The research programme has a number of different themes and the major ones are listed below. In certain areas RBH are widely recognised as leaders particularly in the fields of morphology⁴⁰, heart failure and pulmonary arterial hypertension (PAH) within the field of adult congenital heart disease. A lot of the research fields relate to the clinical services provided and it is stated that the research is intimately related to the clinical service. On a number of occasions the RBH documents state that NHSE current proposals do not include the transfer whole scale of the clinical services at Brompton, implying that if such a thing were to happen the detrimental effect on research would be mitigated.

- Cardiac morphology
- Adult congenital heart cardiology (ACHD)
- Prognostication in ACHD
- Pulmonary Artery Hypertension (PAH)
- Risk stratification in life-threatening arrhythmia and sudden cardiac death
- Adverse impact of pulmonary regurgitation
- Pregnancy and heart disease
- Arrhythmia
- Inherited cardiac conditions

⁴⁰ This deals with both the normal and abnormal structure and anatomy of the heart.

- Cardiomyopathy
- Channelopathy
- Aortopathy
- Genetics
- Fetal
- Other areas
- Kawasaki
- Surgery
- Paediatric critical care
- Studies in educational research
- Nursing and Allied Health Professionals research

Training and education

RBH is active in the arena of training and education. Though not research in itself, there is a close relationship between research and teaching and training. There is clear evidence that RBH had made significant contributions over a range of professions, at a range of levels from those in training to established consultants. In particular a large number of medical professionals have been trained in paediatric cardiology within the institution.

Leadership

Professionals that work at RBH in the field of congenital heart disease have played an important role in the leadership and development of the field of medicine. There is no reason to believe that the individuals concerned not be able to continue to do so, as it is based largely on their individual expertise.

Uniqueness of research

The Trust states that the uniqueness of its research success (both in terms of volume and influence of its research outputs) is based on multiple factors that would be *“difficult or impossible to replicate or recreate should CHD be decommissioned from the Trust”*.

They list the factors as:

- Its **vertical model**, allowing for seamless transition and lifelong (rather than separate paediatric and adult) patient care, research and training/education on a single site.
- The close working relationship with allied colleagues at **the National Heart and Lung Institute, Imperial College and Chelsea & Westminster Hospital (C&W)**
- **Heart Failure/Integrated Physiology** adult expertise with its novel application in ACHD, facilitating prognostication and optimal clinical care (World leadership position).

- ***Vertically integrated Arrhythmia services*** with joint working, MDTs and research allowing patients of any age to access the facilities and expertise in a large amenity
- ***Inherited Cardiac Conditions:*** integrated paediatric/adult cardiac services allowing familial holistic diagnosis and management with assimilated genetic services and on site accredited genetics laboratory with research facilities, academic staff and genetic scientist integration in clinical MDTs.
- The ***PAH (pulmonary hypertension) specialist designation in ACHD*** and discovery/advance in a previously neglected area of CHD, affecting up to 10% of patients.
- ***Tertiary High-Risk Obstetrics with joint clinical and research service*** (with colleagues from C&W Hospital/IC, Professors Phil Steer and Mark Johnson) to provide for patients with ACHD and/or PAH from the Royal Brompton and the rest of the country and advance understanding of this growing/challenging field.
- ***Strong and well developed fetal service; one of largest in the UK:*** with dynamic integrated links with Queen Charlotte's Hospital, St George's Hospital and C&W obstetric and fetal medicine centres.
- ***End-Stage CHD care, including Device Therapy and Transplantation in ACHD,*** in conjunction with our counterpart Harefield Hospital; current research focus on optimal timing for Transplantation (in conjunction with Newcastle) and impact of liver disease in outcomes.
- ***Delivery of world class paediatric and adult critical care:*** *contributes materially to continually maintained excellent clinical outcomes: participation in translational and clinical research endorses and fosters outstanding care.*
- Last but not least, ***Team Vision, Building and Chemistry towards making a national/global contribution*** in what is the most common inborn defect, namely congenital heart disease.

Why RBH considers NHS England's consultation proposals would be damaging to its research programme

The essential concern expressed by RBH is that the proposals as stated would lead to a break-up of the research and clinical teams in a piece-meal fashion. This would then result in a loss of the research teams and collaborations that have been established over many years.

The document submitted emphasises on a number of occasions that the NHS England proposals do not include the possibility that their 'paediatric or ACHD staff would be transferred collectively'.

They claim that the model of care with vertical integration of paediatric and adults, close integration of several academic and clinical institutes, expertise in a number of areas (heart failure, arrhythmias, inherited cardiac conditions, pulmonary

hypertension, critical care, fetal medicine and obstetrics) contribute to the uniqueness of the research success.

Finally they believe that the culture is important with a vision on making a national and international contribution.

Analysis

RBH has made a significant and important contribution to research in the field of paediatric and adult congenital heart disease over a prolonged period. Its research has had an important impact on clinical practice in the field of paediatric and adult congenital heart disease. RBH has a national and international reputation in the field of research and RBH staff make significant national and international contributions to the professional leadership in the field of paediatric and adult congenital heart disease.

RBH recognises the importance of close relationships between clinical teams, services and academic achievement. It attributes the success of its clinical service and research programme to the close collaboration between a large number of individuals and several institutes.

The RBH recognises the importance of the culture of an organisation in achieving academic excellence.

The features that the RBH believe are unique to making their research successful are important to academic success in many fields of medicine and are hence not unique to RBH, namely:

- integrated services across the field of concern;
- clinical excellence in different aspects of the field of medicine;
- effective close collaboration between universities and other institutes; and
- a culture focused on excellence and making a contribution nationally and internationally.

RBH suggests that any detrimental effects on research that the NHS England's consultation proposals may have on their research programme could be mitigated by collective transfer of teams rather than dissipation over a wide number of organisations. However, highly successful academics can and do transfer between Universities, moving their research grants, programmes and research teams. Though this can be disruptive in the short term it is usually successful in the medium and long term.

Recommendations

NHS England should recognise the significant contribution to research in this field that RBH has made over a prolonged period of time.

The concerns expressed by RBH regarding research should be acknowledged and noted.

If NHS England were to decide to implement the proposals on which it consulted, consideration should be given to the potential for a planned and systematic transfer of research teams. Developing such an approach would require RBH to work with senior academics at other research institutions and medical schools.

Proposals that involve planned and systematic transfer of clinical services would support the preservation of research programmes.

While such an approach may be viewed as attractive, highly successful academics can and do transfer between universities, moving their research grants, programmes and research teams. Though this can be disruptive in the short term it is usually successful in the medium and long term.