Proposed congenital heart disease standards and service specifications: a consultation

15 September 2014 to 8 December 2014

Reference Pack

This reference pack includes a selection of background information which may be useful to you in responding to the consultation. These documents are provided here for convenience. With the exception of the glossary of terms, all have been previously published on the NHS England website either as standalone reports or meeting papers. As some of these documents are under version control (for example terms of reference) they may be updated during the consultation period. The most recent version will always be posted on the NHS England website. This pack contains the most recent versions as published at 15 September 2014.

Contents

Abbreviations and Glossary

ACHD: Adult Congenital Heart Disease: This is also known as “grown-up congenital heart disease”, or “GUCH”.

Antenatal: Before birth; during or relating to pregnancy.

Antenatal scan: An ultrasound scan uses high frequency sound waves, which bounce off solid objects. This creates a screen image of the uterus and nearby organs, as well as the baby, the baby’s organs and the placenta.

Assessment: A series of tests that lead to a diagnosis.

BAME: Black Asian and Minority Ethnic.

BCCA: British Congenital Cardiac Association.

Cardiologist: A doctor who specialises in investigating and treating diseases of the heart.

Cardiothoracic: Conditions of the heart, lungs and oesophagus.

Care pathway: *(see definition for “protocol”).*

CHD: Congenital Heart Disease: refers to a range of birth defects that affect the normal workings of the heart.

CCG: Clinical Commissioning Group.

CCNS: Children’s Cardiac Nurse Specialist.

Children’s Cardiac Services: Include children’s CHD services as well as caring for children with other heart conditions.

Clinical Advisory Panel: CAP: a group of experienced clinicians that is part of the review’s governance.

Clinician: Any health professional who is directly involved in the care and treatment of patients, for example, nurses, doctors, therapists, and midwives.

Commissioning: The full set of activities that NHS England, local authorities and clinical commissioning groups (CCGs) undertake to make sure that services funded by them, on behalf of the public, are used to meet the needs of the individual fairly, efficiently and effectively.

Congenital heart network: Groups of CHD services working together to ensure a consistent approach to care, the sharing of information and a focus on improvement.

Consultant: A senior doctor who is a specialist in a particular area of medicine.

CPEX: Cardio-pulmonary exercise testing.

CQC: Care Quality Commission.

CRG: Clinical Reference Group**.**

CT: A computerised tomography scan uses X-rays and a computer to create detailed images of the inside of the body.

DNA: Did not attend.

Diagnostics: Medical tests used to identify a medical condition or disease.

EACVI: European Association of Cardiovascular Imaging.

ECG: Electrocardiography.

Echo: Echocardiogram: A non-invasive, high frequency ultrasound scan of the heart.

ECMO: Extracorporeal Membrane Oxygenation: It is a supportive measure that uses an artificial lung (the membrane) to oxygenate the blood outside the body (extracorporeal).

EP: Electrophysiology: A test of the heart's electrical activity which can be used to understand and treat fast or abnormal heart rhythms.

EPCC: European Paediatric Cardiac Code: A standardised audit code.

FASP: Fetal Anomaly Screening Programme.

FCNS: Fetal Cardiac Nurse Specialist.

Fetus: An unborn baby.

Follow-up care: Care provided after surgery or interventional procedures.

GP: General practitioner.

HES: Hospital Episode Statistics.

HOSC: Health Overview and Scrutiny Committee: (*see definition for "OSC"*).

Hospital trust: The organisation which runs one or more acute hospitals.

ICD: Implantable cardioverter defibrillator.

ICU: Intensive Care Unit.

Interdependencies: the relationship between CHD services and other specialist services**.**

Interventional cardiology: Various non-surgical procedures for treating cardiovascular disease such as when a catheter or other device is inserted through the skin into the central circulation and then into the heart.

IT: Information technology.

MDT: Multi-Disciplinary Team: A team involving many different professions e.g. doctors, nurses, therapists. MDT meetings bring together experts in different specialties to discuss the management of patients with a given condition or disease.

MRI: Magnetic resonance imaging is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body.

Murmur: An irregular or unusual sounding heartbeat. Not all children with a murmur have congenital heart disease.

NICE: National Institute for Health and Care Excellence.

NICOR: National Institute for Cardiovascular Outcomes Research.

NICU: Neonatal intensive care unit.

Non-interventional treatment: Preventing and managing potential and existing heart problems without surgery or having to insert devices through the skin.

ONS: Office for National Statistics.

Outcomes: change in the health of an individual, group of people or population which is attributable to an intervention or series of interventions.

Outpatient Clinic: Clinic at which patients receive treatment or care without needing to stay overnight.

OSC: Overview and Scrutiny Committee: A committee made up of local government councillors. It may also have representatives from voluntary organisations and patients' forums. It is concerned with issues of health service changes, health inequalities and strategic direction rather than how hospitals have performed against targets.

Paediatric: A branch of medicine providing care for children.

Patent ductus arteriosus: PDA: This means a baby has an additional (and abnormal) source of blood flow to the lungs. As a result, there is extra strain on the left-hand side of the heart, which has to collect and deal with the extra blood.

PEC: Paediatrician with expertise in cardiology.

PHE: Public Health England.

PICU: Paediatric intensive care unit.

Postnatal: The time period immediately after childbirth.

Protocol: The descriptions of the steps taken to care for and treat a patient. It is sometimes called an integrated care pathway. It identifies who carries out key parts of the care or treatment and where they should be delivered.

QALY: Quality-adjusted life year: A measure used in assessing the value for money of a medical intervention.

Referral: Sending a patient to a specialist for expert care.

ScHARR: University of Sheffield's School of Health Research and Related Studies.

Specialist: A clinician whose work is concentrated on a particular area of medicine.

Surgeon: A clinician who is qualified to practice surgery.

Surgical Unit: A centre at which surgery is provided.

Transition: An ongoing process, usually between the ages of 16 and 18, where a young person moves from children's to adult services.

Valves (of the heart): Valves allow blood to move forwards through the heart and prevent it flowing backwards into the previous chamber.

VC: Video conference.

WNB: Was Not Brought

WTE: Whole time equivalent: A measure of staffing that takes account of both full time and part time workers.

Draft financial impact assessment of draft new standards for paediatric cardiac and adult congenital heart disease services

Executive Summary

1. The aim of the new Congenital Heart Disease review is to ensure that services achieve the highest possible quality within the available resources. The available resources are not open-ended and it is the duty of the NHS to ensure both that it lives within its means and that it achieves the maximum value for every pound it spends.

2. New standards for congenital heart disease services are proposed for consultation. These will ensure consistent best practice across all providers in terms of how services should be organised and delivered but do not introduce new clinical interventions or change the threshold for treatment.

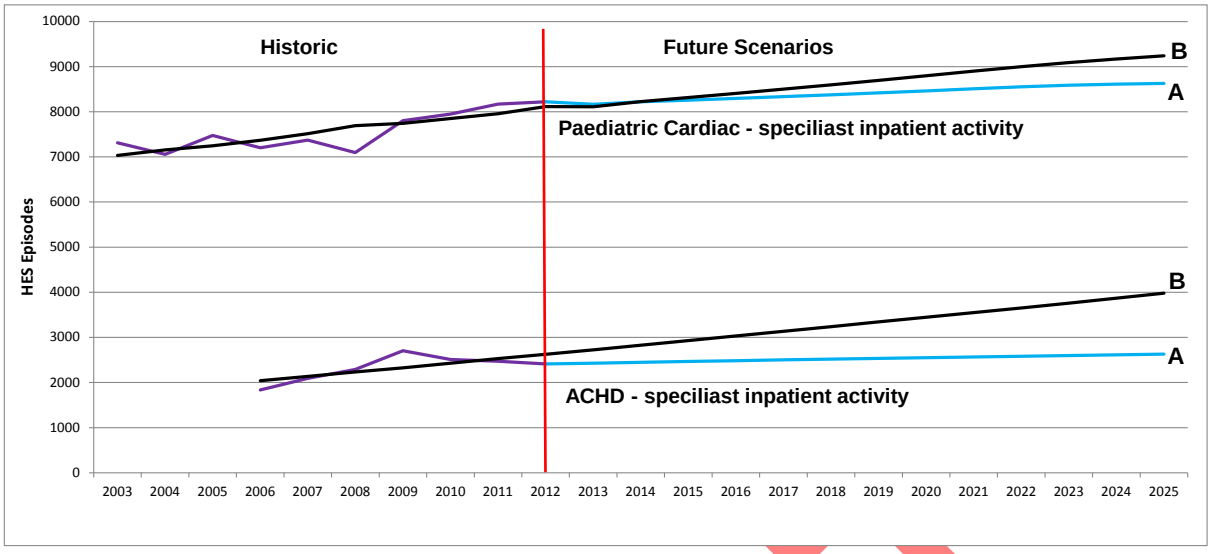
3. A detailed finance assessment has been prepared to understand the potential financial impact of the new standards on NHS England as the lead commissioner. Some consideration has also been given to provider impact, but this will be tested during consultation, and is in any case dependent on decisions about the implementation of the standards that will be taken in the future once the standards have been agreed.

4. In summary our assessment finds that CHD activity is expected to rise. We expect that the affordability challenge for commissioners will be in meeting the costs of overall growth, and that the additional costs of the standards should be affordable for providers within tariff income particularly given growth in activity. The costs to providers should be met by the additional funding they receive as activity levels increase, without causing the current tariff price paid per unit of activity to rise.

Activity

5. If recent trends continue it is expected that, whether or not new standards are introduced, activity will increase and, therefore, spending by commissioners, and thus income to hospitals, can be expected to increase. The graph below shows possible scenarios for future activity growth for paediatric cardiac and ACHD specialist inpatient care; Scenario A takes account of population growth only, Scenario B considers population growth and allows activity per head to increase as it has in the past.

6. This suggests that we should plan for between 0.4% and 1% more activity in children's CHD services and between 0.7% and 4% more activity in adult CHD services each year. The cumulative effect of this increase in activity is important to note. Using these levels would mean that by 2025 there would be an increase in activity between 5% and 14% in children's cardiac services and 10% and 67% in adult CHD services.



Current Spend

7. Current spend (based on SUS data for 2012/13, the most recent year available) on CHD services for both adults and children is estimated to be £110m. This estimate relies on a number of assumptions, but is based on the best data available, and is considered fit for purpose in assessing the likely financial impact of the proposed service standards.

Future Spend (Do Nothing)

8. Based on the activity modelling described above and the estimate of current spend, we forecast that in 2025/26 expenditure on CHD services will be between £117m and £140m depending on assumptions about growth.

9. By 2025/26 it is therefore expected that additional funding within a range of £7m to £30m will need to be made available to commission CHD services to meet increased activity levels based on current configuration of providers.

Future Spend (New specification)

10. We consider that the cost pressure for commissioners, arising from the standards, will not be materially different from those arising under the 'do nothing' scenario. This is for two main reasons:

11. Firstly, there is already a service specification for paediatric cardiac services which sets similar standards. Many of the costs associated with full implementation of the new standards are already inherent in the existing paediatric service specification, and some providers are already delivering them, therefore these standards are expected to be deliverable within the current tariff, and cannot be considered a new cost for commissioners. This includes many aspects of staffing (including additional congenital surgeons, paediatric cardiologists, paediatric nurse specialists and nurse educators) and the costs of establishing and running formal networks.

12. Secondly, for the majority of these services hospitals are paid by commissioners using the national tariff. Within this price is some funding for investment in services. Therefore as activity rises more funding becomes available for further investment. The new standards set out how this money should be spent rather than requiring specific funding of their own. We expect the costs of providing the service to the new standards to be met from this additional funding hospitals receive as activity levels increase, without causing the current price paid per unit of activity (tariff) to rise. This applies even for

those standards that are entirely new, for example the cost to providers of psychologists and adult specialist nurses. While these costs are material (at national level if not necessarily for individual providers who may already be meeting them) our estimates show that they would be covered by the additional income accrued by providers as a result of delivering increasing levels of activity.

Impact on patients and carers

13. The implementation of the new standards is not expected to result in new expenditure by either patients or their carers, and in some areas the standards should mitigate current expenditure. Any impacts arising from changes to services will be considered in a full assessment when implementation options have been developed.

Impact on providers

14. We estimate that the additional costs of the standard itself will be affordable for providers within tariff income given the estimated growth in activity under all scenarios modelled. It should be noted that the greatest increase in activity is expected in ACHD, that part of the specification which includes most wholly new standards, bringing the greatest increase in income. The projected increase in activity will provide an additional contribution to semi-fixed costs and overheads built into the current national tariffs. These funds could be directed in a way so as to meet the costs of the new standards.

15. Consideration of the impact on individual providers is not within the scope of this assessment. However, it is noted that the affordability position for any individual provider may differ from national affordability and provider differences such as number of procedures undertaken at individual centres will have an impact on their efficiency and affordability, and thus the overall cost of these services.

16. The standards include detailed expected implementation timescales set by the Clinical Reference Group. These recognise that some aspects of implementation cannot be achieved instantly. Timescales range from immediate to three years. As a result any cost impact on providers will be spread over a number of years.

17. In some cases there may be one-off costs associated with meeting the standards, particularly where providers need to consider how to achieve the interdependency standards. These costs will vary between providers. Estimating these costs is beyond the scope of this assessment. It is assumed that if the costs are uneconomical the provider will choose to not make the change and this will have an impact on future service provision and configuration. These consequences are outside the scope of this assessment, but will be considered when we assess implementation options.

18. We will use consultation as an opportunity to test with providers our understanding of the financial impact and the proposed timescale for implementation.

Benefits

19. In considering whether any increased costs represent good value it is important to consider what benefits come from the higher spending. Introducing the standards ensures that the NHS delivers higher quality and not just more activity. There will be wide-ranging benefits for patients, their families, NHS England and other commissioners, and also to provider organisations. These are summarised below:
    - The new standards will reduce variation and improve quality of care.
    - The standards will be clear, defined and credible enabling commissioners to take action where they are not being met.

- Occasional practice will be eliminated thereby addressing an obvious risk to patient safety.
- Providers will have clarity about the requirements of them, and after 14 years of service review this will enable them to plan for the future and direct investment appropriately.
- Relationships between providers will be improved by working as part of formal managed networks and will enable shared learning and peer review.
- Patients and their families will know what they should expect from their service providers and be empowered to raise questions where they feel this is not being met and/or to exercise patient choice.

20. As a result of reduced variation and improved quality of care from adopting the new standards we expect:
    - improvements in health outcomes and patient experience;
    - patients, their families and the public will be assured that the care they receive will be of a consistently high quality wherever they live in England;
    - commissioners will be assured of the quality of care and that additional expenditure for increased activity will be directed to services of increasing quality and not just quantity; and
    - providers will reduce their risk of litigation, see fewer complaints and resource-consuming investigations.

Conclusion

21. The proposed quality standards of care for CHD services will improve the quality of patient outcomes and patient and carer experience. They will ensure consistent best practice across all providers in terms of how services should be organised and delivered but do not introduce new clinical interventions or change the threshold for treatment.

22. Demand and activity is projected to increase to 2025/26 whether or not the new quality standards are implemented. The actual rate of increase will reflect population growth and potentially would exceed this should the recent trend interventions continue.

23. Commissioner spending will need to increase to meet the additional demand and activity.

24. Many of the costs of providing services to the standards are already within tariff funding because they are already included in the existing paediatric cardiac services specification.

25. Some additional costs will impact on providers to meet the requirement for the appropriate number of surgeons, specialist CHD nurses and psychologists. The additional activity and consequential commissioner spending will increase the income of providers and this is likely to cover, on average, the costs of the wholly new aspects of the standards for providers.

Recommendation

26. The approval for the consultation process for the new standards should proceed to the next stage as we do not expect the proposed standards would require material extra funding beyond that needed in the ‘Do Nothing’ scenario given current tariff and the projected increase in activity for both paediatric and adult CHD service.

Introduction

27. New standards for congenital heart disease services are proposed for consultation. These will ensure consistent best practice across all providers in terms of how services should be organised and delivered but do not introduce new clinical interventions or change the threshold for treatment.

28. In some areas of provider service delivery, additional costs will arise and these will be an additional cost to the NHS as a whole. Principally, these will relate to additional staff and an estimate of the costs of these has been made in order to gauge the relative magnitude and importance of these in relation to the overall service funding.

29. If recent trends continue it is expected that, whether or not new standards are introduced, activity will increase and therefore spending by Specialised Commissioning will need to increase accordingly.

30. Therefore:
    - The affordability challenge for commissioners will be in meeting the costs of overall growth.
    - The additional costs of the standard itself should be affordable for providers within tariff income particularly given growth in activity.

31. Some providers are currently delivering services to these standards within current tariff and therefore we are consulting on the basis that providing services in line with the proposed standards will not increase the tariff price paid by commissioners. We will seek a provider response on whether this assumption is viable. If providers consider that this cannot be done then we have to reflect this and we are therefore contingent on that response.

32. At this stage in the review, the purpose of this finance assessment is to consider how the proposals described in the main part of the consultation document could be funded, to help inform the responses from the consultees. Post-consultation, once a final set of standards have been agreed and recommended the implementation of them will be further considered and the preparation of a more detailed financial Business Case will be appropriate.

33. Costs and affordability relating to any individual provider will depend on how the final agreed standards are implemented, for which there may be many options. These options for service patterns and delivery are numerous and have not yet been developed therefore we cannot assess the impact at this stage. There is no expectation of a “Big Bang” approach. The implementation trajectory will reflect commissioners’ plans and affordability will be managed within the context of NHS financial planning frameworks.

34. The approach taken in this assessment is to consider the current and projected costs that are likely to be required from Specialised Commissioning budgets to meet expected demands using current tariff prices and future activity projections. Future changes in tariff prices reflecting wider system approaches to inflationary and other cost pressures as well as efficiency improvements have been excluded. For reasons stated above, the consideration of the net impact on providers is not within the scope of this assessment.

35. A significant proportion of these services are paid for via National Tariff. The National Tariff paid to providers covers both variable and fixed costs. For the purposes of this analysis, we have assumed that there will be economies of scale in the provision of this service and therefore an increase in activity will increase the contribution to the fixed overheads of the provider, which will not increase at

the same rate. An increase in activity will therefore provide an additional source of funds for providers to invest in the resources required to meet the standards set out in this consultation. The sufficiency of this funding will depend on the amount of additional activity, the proportion of the tariff consumed by variable costs and the level of investment required to meet the standards.

36. Consideration of the impact on individual providers is not within the scope of this assessment. However, it is noted that the affordability position for any individual provider may differ from national affordability and provider differences such as number of procedures undertaken at individual centres will have an impact on their efficiency and affordability, and thus the overall cost of these services.

Current CHD Commissioning Spend

37. The start point for an assessment of future activity and spend is the current estimated level of both. Establishing this has been hampered by a lack of nationally available data and consistency in the identification by commissioners and providers of the relevant activity and associated cost to commissioners.

38. The base period chosen is 2012/13 as this is the most recent full year for Secondary Uses Service (SUS) data is available.

39. The best information available to NHS England on total paediatric cardiac and adult congenital heart disease specialised activity and spend is that identified through SUS. NHS England is working on improved data flows in this area but this data represents the best estimate currently available. It is important to note that these estimates will underestimate total activity and spend on these services as they do not include spend on the following: high-cost devices (e.g. pacemakers), critical care (e.g. paediatric intensive care), any activity paid for by local prices, and adult CHD outpatient activity. There are also a number of caveats around the quality of the data that is included:

- *Coverage*: The Identification Rules (IR) are used to identify specialised activity within SUS data. However, not all specialised activity can be flagged by the IR, owing to a significant amount that either doesn't flow through SUS or requires cross-referencing with a range of external datasets (to which NHS England has extremely limited access).
- *Source*: Any SUS data underpinning this analysis has been sourced from the National Tariff-Mart extract, provided by the Health and Social Care Information Centre (HSCIC). This data is freeze data and may contain provider errors that have not been corrected during the reconciliation period. Any coding errors in provider-submitted fields and inconsistencies will remain.
- *Data Enhancements*: The NHS England Analytical Service has enhanced the SUS data to maximise quality and the amount of specialised activity identified. While improving the value of intelligence produced, these enhancements will result in difficulties reconciling the data back to national SUS extracts or local activity data processed by Data Services for Commissioners Regional Offices. Modifications have been applied to the IR to maximise the amount of activity that can be identified and designated as specialised, however these do not account for local deviations in the IR. The data has also been subjected to a light deduplicated algorithm, which removes a limited amount of erroneous data.

40. The SUS data for 2012/13 covers all spells for both procedural and non-procedural based CHD activity that have been paid via national tariff. For paediatric activity the data shows the figures for outpatient and inpatient episodes. However for adult activity, outpatient episodes for congenital heart disease are not separately identifiable from outpatient activity for other cardiac conditions. Therefore,

to provide an estimate of the activity, and thus commissioner expenditure, the following assumption has been used:

- The Paediatric activity information indicates that there are approximately 9 outpatient attendances for every inpatient spell.
- To reflect the fact that Adults are likely to have a lower incidence rate of attendances, we have assumed that the outpatient/inpatient ratios will be half the Paediatric rate, i.e. 4.5 attendances per inpatient spell.
- This translates to an estimate of 24,900 adult outpatient attendances.
- An average cost of £150 per attendance has been applied being 66% of the Paediatric cost.

41. An alternative population-based approach, following a long term condition model, is not possible as the number of adult patients in such a cohort cannot be identified from the data available.

42. The total National Tariff activity in 2012-13 has been summarised as:

	Outpatient	**Inpatient**	**Other (e.g. critical care)**
Paediatric cardiac	91,500	10,800	No national data
Adult congenital heart diseases	24,900 (assumption)	5,500	No national data

Note: figures rounded to nearest hundred.

43. The total National Tariff spend in 2012-13 has been summarised as:

£m	**Outpatient**	**Inpatient**	**Other (e.g. critical care)**
Paediatric Cardiac	20.5	62.1	No national data
Adult congenital heart disease	3.7	24.0	No national data
Total	24.2	86.1	No national data

Note: this baseline underestimates total spend on CHD services so as a result the increases in funding required may be higher than suggested above.

44. The costs to providers are not directly available. However, the National Tariffs are based on the full cost of providing their services including a share of all the overheads of the relevant organisation. The National Tariff should therefore reasonably represent the average costs incurred by providers.

45. From the limited information available it is clear that the current quality standards, as required by the existing paediatric CHD service specification have not been uniformly implemented by all providers. Where this is the case, providers may need to invest in staff and other resources in order to meet those elements of the standards that are defined by the resources required for a service, as opposed to those defined by outputs/outcomes. Providers cannot expect any additional income in the short term as the National Tariff is intended to reflect the current standards. The costs of compliance with existing standards would not be attributable to the proposed new service specification and standards.

Costs associated with the proposals

46. **Recurrent costs:**
The principal costs associated with achieving the proposed quality standards arise from increased levels of staffing and from establishing networks.

47. Many of these costs are already inherent in the existing paediatric service specification, and some providers already delivering them, therefore the associated are expected to be deliverable within the current tariff. This includes:

- **Staffing**: additional congenital surgeons, paediatric cardiologists, paediatric nurse specialists and nurse educators.
- **Networks**: most costs including lead clinicians, lead nurses, network meetings etc.

48. However, there may be some costs where not all providers are meeting current standards or the new standards introduce wholly new costs.

49. The principal additional cost to providers is the investment in increasing the number of surgeons and their medical teams to meet the standard of four surgeons per rota.

50. It is not possible to provide an exact estimate of the number of additional surgeons required. The number of surgeons at each individual provider would vary according to activity demands. Operative activity levels also vary considerably between surgeons. There may be changes in the way services are delivered that affects the number of surgeons required. However, based on the current configuration of services the requirement would mean teams of four surgeons at each of the ten specialist surgical centres that currently account for around 80% of paediatric and adult specialist inpatient activity. The IRP reported that in October 2012 there were 34 surgeons practising in England at these 10 centres, with a maximum of four surgeons at each centre at that time. This would therefore require an increase of six further surgeons. We have used a working assumption that the estimated cost of an additional consultant (together with their associated supporting staff) to be £500k (See Annex B) for the purposes of business planning, or £3m (£500k*6 additional surgeons) in this instance.

51. As has already been noted elsewhere, given the projected rise in activity levels, it can be assumed that additional staff will be needed and that the associated costs to providers would be met by the rise in income recovered by providers as a result of this higher activity (see ‘Future levels of activity and expenditure’ from paragraph 59 onwards). The way in which the standards have been written means that the number of surgeons is expected to rise only in line with rises in activity levels. Additional surgeons who were unable to meet the minimum activity levels required would not be supported.

52. Some of the costs of the proposed new standards are wholly new. This includes:
    - Psychologists
    - Adult CHD (ACHD) specialist nurses

53. Detailed costs have not been prepared because of the absence of an accurate baseline for comparison. It is known however that there is variation across providers in existing staffing levels. Commissioners would argue that: the increase in expenditure required by providers is modest in the context of overall spend; that this standard lifts all providers to the same levels of staffing achieved by the best; and, that any additional costs should be covered by providers as a result of higher activity levels (see ‘Future levels of activity and expenditure’ from paragraph 59 onwards).

54. For example, one of the new standards requires ACHD centres to have 4 specialist nurses. So the minimum additional staff for a provider is zero (if they already have four) or 4 (if they have none). Therefore, as an example, if we assume on average each provider may require 2 additional nurses at an annual cost of approx. £44,000 each, this would result in additional costs of 20 (2 at each of 10 centres) * £44,000= £880,000 (national cost to the system).

55. Further, another new standard requires Surgical Centres to employ a minimum of 1 WTE practitioner psychologist per 400 patients undergoing cardiac surgery each year. The costs of a further 20

Psychologists at approx. £43,000 each, would result in additional annual costs of £860,000 (national cost to the system).

Source of costs:
Nurse data - uses Band 6 data for specialists, based on banding information from NHS Careers
Psychologists - Qualified Allied Health Professionals

56. The implementation of the new standards is not expected to result in new expenditure by either patients or their carers under the current configuration of services. As previously stated any impacts arising from changes to services will be considered in a full assessment when implementation options have been developed.

57. **One-off costs:**

- **Co-location of paediatric services**: costs of ensuring paediatric CHD service is on the same site as other paediatric specialities – there are three centres where this is not currently the case and costs of meeting this requirement could be significant.

58. The costs associated with meeting this standard will vary depending on provider and what the barriers to this co-location have been in the past. As a result we have not been able to estimate this cost and will seek a response from providers during consultation.

Future levels of activity and expenditure

Future projections of activity

59. Based on evidence from data analysis, academic literature and speaking to clinicians, it is expected that the main drivers of CHD activity have been and will be:

a. Population growth (which is a function of birth rate, migration and life expectancy)
b. Increase in the proportion of patients who are of Asian and Black ethnicity for whom CHD is more likely to occur and in whom more serious manifestations of CHD are more common
c. Advances in medical techniques and new technology
d. Increased patient longevity and survival
e. Increased complexity and severity of patients considered for treatment (possibly also driven itself by 2, 3, 4 and 5 above)

60. We have used Hospital Episode Statistics (HES) data for the activity modelling, and this has been triangulated with data from the congenital audit run by the National Institute of Cardiovascular Outcomes Research (NICOR) where possible. This approach has been used for the following reasons:

- HES data is available for both Paediatric and Adult CHD, whereas NICOR's data on adults activity is incomplete.
- The Identification Rule (IR) definitions can be applied to HES, particularly for adults, and it is this definition that is used to calculate payments for specialised services through the National Tariff system and that will drive future levels of Specialised Commissioning funding.
- As with all HES data there is a risk that providers do not code activity in a consistent manner, though in this instance this is not considered to pose a significant threat to the validity of the data when considered at a national level.

61. Detailed analysis of historic trends in specialist inpatient activity for paediatric cardiac and adult CHD services (i.e. procedure-based activity; surgery and catheter interventions) has been used to identify a pattern of growth. This financial assessment considers all CHD activity which includes non-procedural based activity as well as activity which includes a surgical or catheter procedure, e.g. critical care, diagnostic tests and outpatient appointments. We have assumed that the relationship between specialist inpatient activity and all other CHD activity will remain stable and therefore the growth rates for all activity will follow the trend identified for specialist inpatient activity.

62. We have carried out scenario modelling based on Office of National Statistics (ONS) population projections and historic trends in activity per head of the patient population (see Annex C for details). This suggests that up to 2025:

63. Paediatric cardiac activity: 0.4% to 1% per annum up to 2025/6.

- Could be expected to grow by 0.4% per annum as a result of Population growth.
- Up to a further 0.6% per annum could be expected to arise from increasing activity per Head of Population.
  To note: These figures are very sensitive to ONS birth rate projections which have been previously underestimated. Therefore as a sensitivity we have considered ONS high projections. Under these we would be looking at 1% per annum as a result of population changes and up to a further 1% per annum could be expected to arise from increasing activity per Head of Population – giving a range of between 1% and 2% pa. This sensitivity is considered below in scenarios 1b and 2b.

64. Adult congenital activity increase will be between 0.7% and 4% per annum up to 2025/6.

- ACHD activity could be expected to grow by 0.7% annum as a result of Population growth.
- Up to a further 3.3% per annum could be expected to arise from increasing activity rates per Head of Population.

65. Assumptions:

- Population will grow as per ONS's 2012-based principal population projections (Scenario 1 and 2).
- Activity per head will continue to grow as it has in the past following a linear trend (Scenario 2 only).
- There will be no changes to Clinical Thresholds or Pathways arising from the implementation of the new quality standards (i.e. any changes will be at levels consistent with changes seen in the past).
- The current case mix of interventions will not change (for example, the relative proportion of surgical and cardiology interventions).

66. Adult congenital heart disease activity has grown more quickly than paediatric over recent years and is expected to continue to do so due to improved patient survival with children surviving into adulthood. As congenital heart disease is a lifelong condition these older patients continue to require care.

67. The Growth assumptions outlined above have been compared against National Planning assumptions for all specialised services in aggregate. The NHS belongs to the people: A call to action

was published in July 2013 and sets out projections of demand and costs for services to FY 2020/21. (Ref. section 6.1.10 and 6.2.5).

	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
Acute and Specialised Services Demographic Growth	1.7%	1.6%	1.6%	1.7%	1.7%	1.7%	1.6%
Specialised non-Demographic Growth	3.3%	3.3%	3.4%	3.2%	3.2%	3.3%	3.3%

68. The Demographic Growth assumptions used for National Planning (1.6% to 1.7% per year) are higher than the Population change growth rates indicated by the data for historic trends in specialist inpatient activity for paediatric cardiac and adult CHD services (Paediatrics 0.4%, ACHD 0.7%). This is because our figures are specific to paediatric cardiac and ACHD and account for the different levels of activity across age groups and the different population projections for each. For example, around 50% of paediatric inpatient activity occurs in those aged under 1 year. For this age group ONS projections forecast a fall rather than growth, so the population effect on paediatric activity is relatively low.

69. The non-Demographic Growth assumptions used for National Planning (3.2% to 3.4% per year) correlate well with the ACHD patterns (3.3% per year). The National Planning non-Demographic Growth rates are higher than the non-Demographic Growth rates for paediatric cardiac activity but are based on a less specific set of data. Our data suggests that for paediatric activity in the past population growth (specifically the unexpectedly high birth rates) accounted for more of the observed activity growth than non-demographic pressures, and more so than for adults.

70. Considering the above, we believe our activity projections and thus our assumptions about funding available are sufficiently prudent. Further, as our projection are lower than assumptions for specialised commissioning in general we are not expecting paediatric cardiac and ACHD services to become an increasing proportion of the total specialised commissioning budget.

71. Given the uncertainty over future growth rates, as described above, two scenarios have been developed, firstly where growth reflects only projected population growth and secondly where growth reflects the continuation of the average historic growth rates (2003/4-2012/13 for paediatric activity, 2006/7-2012/13 for ACHD activity – due to data issues). The historic trend has been broadly linear, and therefore the rate of growth in the future is assumed to be linear under both scenarios.

72. Scenario 1 – Population growth only

		Growth (per annum)	2012-13	2025-26
Paediatric	**Outpatients**	0.4%	91,500	96,400
	Inpatients	0.4%	10,800	11,400
Adult	**Outpatients**	0.7%	24,900	27,300
	Inpatients	0.7%	5,500	6,100

73. Scenario 2 – Population growth + Average historic growth rates

		Growth (per annum)	2012-13	2025-26
Paediatric	**Outpatients**	1.0%	91,500	104,100

	Inpatients	1.0%	10,800	12,300
Adult	**Outpatients**	4.0%	24,900	41,500
	Inpatients	4.0%	5,500	9,200

Future projections of spend

74. Applying our activity growth assumptions (from paragraph 59 above) to our estimate of baseline spend (from paragraph 37 above) allows us to generate our financial forecast for the adult congenital heart disease and paediatric cardiac specialised services from the perspective of commissioners paying for services under National Tariff.

75. This estimate considers only services paid for under National Tariff and in order to demonstrate more clearly the impact of activity growth, takes no account of deflation/inflation in National Tariff.

76. The following table presents a summary of estimates for baseline and projected commissioning spend by 2025/26 for the two activity growth scenarios presented.

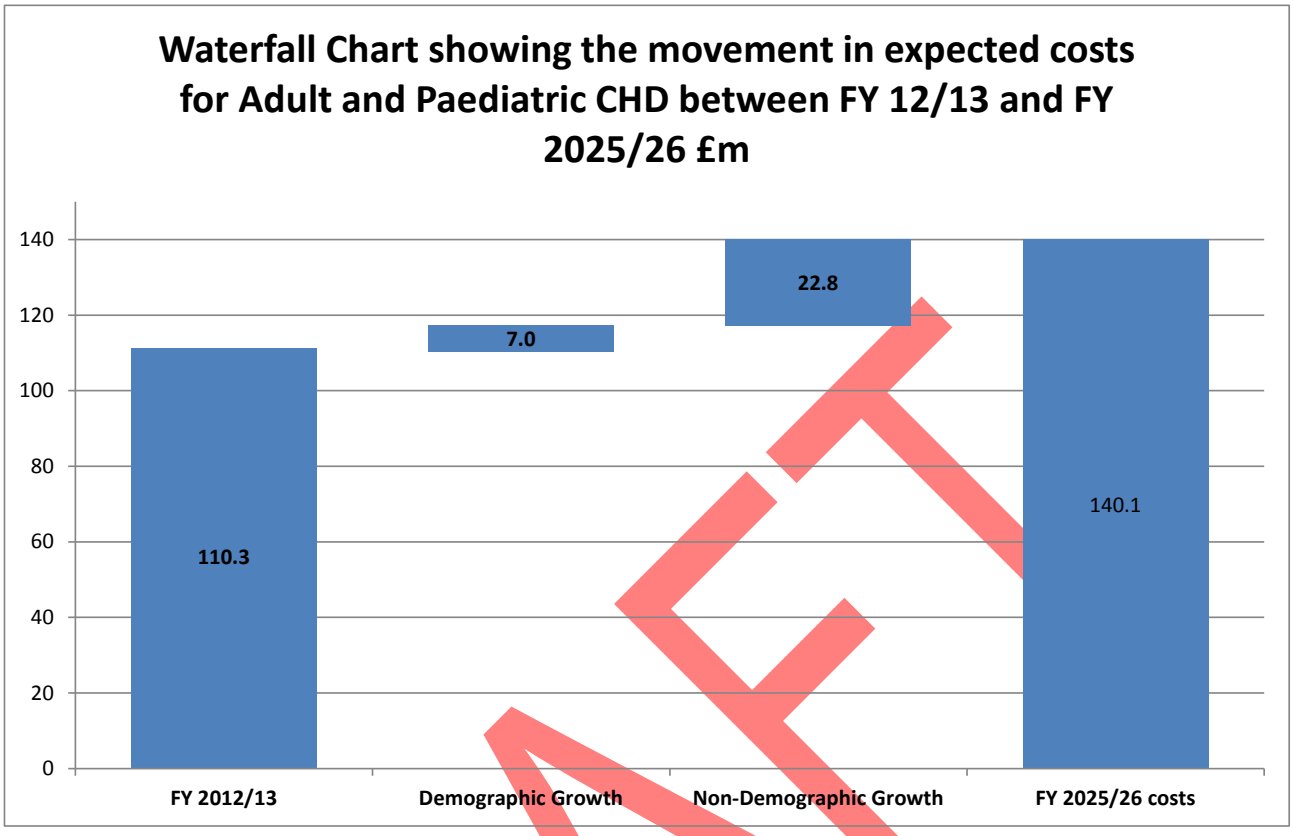
77. Scenario 1 – Population growth only

£m		**Growth (per annum)**	**2012-13**	**2025-26**
Paediatric	**Outpatients**	0.4%	20.5	21.6
	Inpatients	0.4%	62.1	65.4
Adult	**Outpatients**	0.7%	3.7	4.1
	Inpatients	0.7%	24.0	26.2
TOTAL			**110.3**	**117.3**

78. Scenario 2 – Population growth + Average historic growth rates

£m		**Growth (per annum)**	**2012-13**	**2025-26**
Paediatric	**Outpatients**	1.0%	20.5	23.3
	Inpatients	1.0%	62.1	70.7
Adult	**Outpatients**	4.0%	3.7	6.2
	Inpatients	4.0%	24.0	39.9
TOTAL			**110.3**	**140.1**

Figure 1: Waterfall Chart with movements in cost arising from Population and Non-population growth impacts under Scenario 2



79. The waterfall chart above presents the movements in costs for scenario 2.

80. For providers the financial impact in the intervening years will involve a linear increase for variable costs. The detail of the calculation of these spending projections is available in Annex A.

81. By 2025/26 it is expected that additional funding within a range of £7.0m to £29.8m will need to be made available to commission CHD services to meet increased activity levels based on current configuration of providers.

Affordability

82. Based on the information set out above we expect:

- The affordability challenge for commissioners will be in meeting the costs of overall growth.
- The additional costs of the standard itself should be affordable for providers within tariff income particularly given growth in activity.

83. This is discussed in more detail below.

84. **Affordability for commissioners:**
The implementation of the proposed quality standards is not currently estimated to result in new investment by commissioners, although this should be reconfirmed when implementation options have been developed. The affordability challenge for commissioners will be in meeting the costs of overall growth.

85. The increase in commissioner expenditure as modelled for the population plus historic growth model (Scenario 2) is significant and in common with other services, options to increase affordability may need to be considered and the impact evaluated.

86. These may include:
- additional Quality, Innovation, Productivity and Prevention (QIPP) schemes to reduce demand and reduce provider expenditure (e.g. Specialist Nurse-led follow-up); or
- commissioners to increase the share of their budgets that are directed to CHD; or
- measures to increase efficiency, such as reducing the number of networks (for example, creating multi-centre networks) or reducing the number of surgical centres.

87. **Affordability for providers:**
The additional costs of the standard itself should be affordable for providers within tariff income particularly given growth in activity.

88. The projected increase in activity will provide an additional contribution to semi-fixed costs and overheads built into the current National Tariff. These funds could be directed in a way so as to meet the costs of the new standards.

89. The table below shows that even with investment in the main expected costs, providers would still have significant remaining income as a result of rising activity to cover semi-fixed costs and some as yet unidentified costs of the proposed standards. As has been discussed, the position for any individual provider may be different but cannot be determined at this stage.

Table 1: Provider Cost Impact 2025/26

Provider Cost Impact 2025/26	1a £000's	1b £000's	2a £000's	2b £000's
Income from Additional Activity	7,000	14,000	29,800	42,700
Costs of 6 additional surgeons (£500k per Surgeon)	-3,000	-3,000	-3,000	-3,000
Variable Costs (30% of Tariff)	-2,100	-4,200	-8,940	-12,810
Remaining Income available for semi-fixed costs and proposed standards	1,900	6,800	17,860	26,890
Specialist Nurses (2 Band 6 at 10 centres £44k annual cost)	-880	-880	-880	-880
Psychologists (2 at 10 centres £43k annual cost)	-860	-860	-860	-860
Remaining to meet other costs	160	5,060	16,120	25,150

On average for each of 10 centres				
	£000's	£000's	£000's	£000's
Remaining Income available for semi-fixed costs and proposed standards	190	680	1,786	2,689
Specialist Nurses (2 Band 6)	-88	-88	-88	-88
Psychologists (2)	-86	-86	-86	-86
Remaining to meet other costs	16	506	1,612	2,515

Note: numbers may not sum due to rounding.

Scenarios:
1a - Population Growth only (principal paediatric pop growth)
1b - Population growth only (high paediatric pop growth) – sensitivity upper bound
2a - Population growth + historic activity increase (principal paediatric pop growth)
2b - Population growth + historic activity increase (high paediatric pop growth) - sensitivity upper bound

90. This allows for investment to meet other potential costs of:
- developing Education and Training and Networks
- offices and administrative support
- IT development and analytical support

91. The number of surgeons will only rise as and when activity rises because of the need to maintain surgical skills reflected in the standards. This means that there will be a lag between the increase in the activity and the surgical capacity, which further means that providers will have the additional income from that increased activity before they have to increase these staff costs.

92. Using scenario 2 at the highest rate of growth projected (Population and non-population growth), the table above demonstrates that under 2a, after costs for additional surgeons (estimated at £500k per Surgeon), Specialist Nurses and Psychologists are taken into account and the variable costs associated with the increased activity, on average each of the 10 specialist centres retains up to £1.6m to meet additional internal costs arising. As has been discussed, the position for any individual provider may be different but cannot be determined at this stage, currently around 20% of activity occurs outside of these specialist centres and this would need to be considered.

93. As well as finances other resources may be constrained: Specialist Consultants, Specialist Nurses and Psychologists are staff who have specific training and skills. Training costs and lead times for recruitment must be taken into account and discussions with Health Education England are expected to take place as part of provider implementation planning and development.

Efficiency and Value for Money

94. We expect the introduction of the new standards for CHD services to:
- increase the quality of care;
- improve health outcomes and patient experience;
- improve levers for commissioners to increase quality;

- improve clarity for providers as well as reduce adverse events and complaints;
- not change the expected number of interventions on the various clinical pathways;
- lead to more suitably trained Consultant Surgeons to undertake the additional activity; and
- ensure existing providers respond with improvements to quality of service delivery and to increase resources where necessary - the costs of which will be available to them from additional tariff income.

95. We do not expect this to require specific funding. We expect the costs to be covered through the estimated additional funding of £7m to £29.8m by 2025/26 to meet activity increases which will be cost pressure on commissioning budgets regardless of whether or not the standards are introduced.

96. A lack of suitable data on patient quality of life has not allowed a quality-adjusted life year (QALY) based calculation to undertake an economic assessment of the value of the proposed changes.

97. At this stage in the review, the purpose of this finance assessment is to consider how the proposals described in the main part of the consultation document could be funded, to help inform the responses from the consultees. Post-consultation, once a final set of standards have been agreed and recommended, the implementation of them will be further considered and the preparation of a more detailed financial Business Case will be appropriate. Implementation options could involve changes to the location, co-location and distribution of facilities and specialist staff for hospital-based CHD activity which would have an impact on the overall costs of the service. However, there would be additional costs and benefits to consider also, particularly on patients, and there would be non-recurrent costs of such a service change. As discussed above, the review is not yet at the stage of considering implementation options.

Benefits

Mechanism

98. The new standards will reduce variation and improve quality of care because:

- The standards define excellent care which is not currently being delivered consistently.
- The commissioners will have a means of contracting with providers on a consistent basis across the country.
- The standards will be clear, defined and credible enabling commissioners to take action where they are not being met.
- Occasional practice will be eliminated thereby addressing an obvious risk to patient safety.
- Providers will have clarity about the requirements of them, and after 14 years of service review this will enable them to plan for the future and direct investment appropriately.
- Relationships between providers will be improved by working as part of formal managed networks and will enable shared learning and peer review.
- Patients and their families will know what they should expect from their service providers and be empowered to raise questions where they feel this is not being met and/or to exercise patient choice.

Outcomes

99. As a result of reduced variation and improved quality of care from adopting the new standards we expect:

- improvements in health outcomes and patient experience;
- patients, their families and the public will be assured that the care they receive will be of a consistently high quality wherever they live in England;
- commissioners will be assured of the quality of care and that additional expenditure for increased activity will be directed to services of increasing quality and not just quantity; and
- providers will reduce their risk of litigation, see fewer complaints and resource-consuming investigations.

100. As can be seen from above, the new standards define how services should be organised and delivered; they do not define new clinical interventions or change the threshold for treatment. As a result it is difficult to quantify the direct impact on health outcomes. Further, the only reliable data available on health outcomes is the survival at 30 days post-procedure (surgery or catheter). We do not yet have robust information on survival at 1 year post-procedures or any other indicators of morbidity or educational attainment – work is underway to see what improvements can be made to the data and information available.

Conclusions

101. The proposed quality standards of care for CHD services will improve the quality of patient outcomes and patient and carer experience without changes to the existing patient pathways.

102. Demand and activity is projected to increase to 2025/26 whether or not the new quality standards are implemented. The actual rate of increase will reflect population growth and potentially would exceed this should the recent trend interventions continue.

103. Commissioner spending will need to increase to meet the additional demand and activity.

104. Many of the costs of providing services to the standards are already within tariff funding. Some additional costs will impact on providers to meet the requirement for the appropriate number of surgeons, Specialist CHD nurses and Psychologists.

105. The additional activity and consequential commissioner spending will increase the income of providers and this is likely to cover, on average, the costs of the wholly new aspects of the standards for providers.

Recommendations

106. The approval for the consultation process for the new standards should proceed to the next stage as we do not expect the proposed standards would require material extra funding beyond that needed in the ‘Do Nothing’ scenario given current tariff and the projected increase in activity for both paediatric and adult CHD services.

ANNEX A

Figure 2: Activity and Expenditure Forecast Population Growth

SCENARIO 1a - POPULATION GROWTH ONLY (paediatric low growth)														
ADULTS														
Year	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
Inpatients														
Population increase		*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Rate of intervention														
Total projected growth		*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Activity	5,534	5,573	5,612	5,651	5,691	5,730	5,771	5,811	5,852	5,893	5,934	5,975	6,017	6,059
Expenditure	£23,962,792	£24,130,532	£24,299,445	£24,469,541	£24,640,828	£24,813,314	£24,987,007	£25,161,916	£25,338,050	£25,515,416	£25,694,024	£25,873,882	£26,054,999	£26,237,384
Outpatients														
Population increase		*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Rate of intervention														
Total projected growth		*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Activity (est)	24,903	25,077	25,253	25,430	25,608	25,787	25,967	26,149	26,332	26,517	26,702	26,889	27,077	27,267
Expenditure	£3,735,450	£3,761,598	£3,787,929	£3,814,445	£3,841,146	£3,868,034	£3,895,110	£3,922,376	£3,949,833	£3,977,481	£4,005,324	£4,033,361	£4,061,595	£4,090,026
Total adult expenditure	£27,698,242	£27,892,130	£28,087,375	£28,283,986	£28,481,974	£28,681,348	£28,882,117	£29,084,292	£29,287,882	£29,492,897	£29,699,348	£29,907,243	£30,116,594	£30,327,410
PAEDIATRICS														
Year	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
Inpatients														
Population increase		*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*
Rate of intervention														
Total projected growth		*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*
Activity	10,839	10,882	10,926	10,970	11,013	11,058	11,102	11,146	11,191	11,236	11,280	11,326	11,371	11,416
Expenditure	£62,103,081	£62,351,493	£62,600,899	£62,851,303	£63,102,708	£63,355,119	£63,608,539	£63,862,974	£64,118,425	£64,374,899	£64,632,399	£64,890,928	£65,150,492	£65,411,094
Outpatients														
Population increase		*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*
Rate of intervention														
Total projected growth		*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*
Activity	91,498	91,864	92,231	92,600	92,971	93,343	93,716	94,091	94,467	94,845	95,225	95,605	95,988	96,372
Expenditure	£20,469,865	£20,551,744	£20,633,951	£20,716,487	£20,799,353	£20,882,551	£20,966,081	£21,049,945	£21,134,145	£21,218,681	£21,303,556	£21,388,770	£21,474,326	£21,560,223
Total paediatric expenditure	£82,572,946	£82,903,238	£83,234,851	£83,567,790	£83,902,061	£84,237,670	£84,574,620	£84,912,919	£85,252,570	£85,593,581	£85,935,955	£86,279,699	£86,624,818	£86,971,317
TOTAL EXPENDITURE	**£110,271,188**	**£110,795,367**	**£111,322,225**	**£111,851,776**	**£112,384,035**	**£112,919,017**	**£113,456,738**	**£113,997,211**	**£114,540,453**	**£115,086,478**	**£115,635,303**	**£116,186,942**	**£116,741,411**	**£117,298,727**

SCENARIO 1b - POPULATION GROWTH ONLY (paediatric high growth)														
ADULTS														
Year	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
Inpatients														
Population increase		*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Rate of intervention														
Total projected growth		*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Activity	5,534	5,573	5,612	5,651	5,691	5,730	5,771	5,811	5,852	5,893	5,934	5,975	6,017	6,059
Expenditure	£23,962,792	£24,130,532	£24,299,445	£24,469,541	£24,640,828	£24,813,314	£24,987,007	£25,161,916	£25,338,050	£25,515,416	£25,694,024	£25,873,882	£26,054,999	£26,237,384
Outpatients														
Population increase		*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Rate of intervention														
Total projected growth		*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Activity (est)	24,903	25,077	25,253	25,430	25,608	25,787	25,967	26,149	26,332	26,517	26,702	26,889	27,077	27,267
Expenditure	£3,735,450	£3,761,598	£3,787,929	£3,814,445	£3,841,146	£3,868,034	£3,895,110	£3,922,376	£3,949,833	£3,977,481	£4,005,324	£4,033,361	£4,061,595	£4,090,026
Total adult expenditure	£27,698,242	£27,892,130	£28,087,375	£28,283,986	£28,481,974	£28,681,348	£28,882,117	£29,084,292	£29,287,882	£29,492,897	£29,699,348	£29,907,243	£30,116,594	£30,327,410
PAEDIATRICS														
Year	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
Inpatients														
Population increase		*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*
Rate of intervention														
Total projected growth		*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*
Activity	10,839	10,947	11,057	11,167	11,279	11,392	11,506	11,621	11,737	11,854	11,973	12,093	12,214	12,336
Expenditure	£62,103,081	£62,724,112	£63,351,353	£63,984,866	£64,624,715	£65,270,962	£65,923,672	£66,582,909	£67,248,738	£67,921,225	£68,600,437	£69,286,442	£69,979,306	£70,679,099
Outpatients														
Population increase		*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*
Rate of intervention														
Total projected growth		*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*
Activity	91,498	92,413	93,337	94,270	95,213	96,165	97,127	98,098	99,079	100,070	101,071	102,081	103,102	104,133
Expenditure	£20,469,865	£20,674,564	£20,881,309	£21,090,122	£21,301,024	£21,514,034	£21,729,174	£21,946,466	£22,165,931	£22,387,590	£22,611,466	£22,837,580	£23,065,956	£23,296,616
Total paediatric expenditure	£82,572,946	£83,398,675	£84,232,662	£85,074,989	£85,925,739	£86,784,996	£87,652,846	£88,529,375	£89,414,668	£90,308,815	£91,211,903	£92,124,022	£93,045,262	£93,975,715
TOTAL EXPENDITURE	**£110,271,188**	**£111,290,805**	**£112,320,037**	**£113,358,975**	**£114,407,713**	**£115,466,344**	**£116,534,963**	**£117,613,667**	**£118,702,551**	**£119,801,712**	**£120,911,251**	**£122,031,265**	**£123,161,856**	**£124,303,125**

Figure 3: Activity and Expenditure Forecast Population Growth and Rate per Head Increase

SCENARIO 2a - POPULATION GROWTH + INCREASED INTERVENTION RATE (paediatric low growth)														
ADULTS														
Year	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
Inpatients														
Population increase		*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Rate of intervention		*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*
Total projected growth		*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*
Activity	5,534	5,755	5,986	6,225	6,474	6,733	7,002	7,282	7,574	7,877	8,192	8,519	8,860	9,215
Expenditure	£23,962,792	£24,921,304	£25,918,156	£26,954,882	£28,033,077	£29,154,400	£30,320,576	£31,533,400	£32,794,735	£34,106,525	£35,470,786	£36,889,617	£38,365,202	£39,899,810
Outpatients														
Population increase		*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Rate of intervention		*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*
Total projected growth		*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*
Activity (est)	24,903	25,899	26,935	28,012	29,133	30,298	31,510	32,771	34,081	35,445	36,863	38,337	39,871	41,465
Expenditure	£3,735,450	£3,884,868	£4,040,263	£4,201,873	£4,369,948	£4,544,746	£4,726,536	£4,915,597	£5,112,221	£5,316,710	£5,529,379	£5,750,554	£5,980,576	£6,219,799
Total adult expenditure	£27,698,242	£28,806,172	£29,958,419	£31,156,755	£32,403,026	£33,699,147	£35,047,112	£36,448,997	£37,906,957	£39,423,235	£41,000,164	£42,640,171	£44,345,778	£46,119,609
PAEDIATRICS														
Year	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
Inpatients														
Population increase		*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*
Rate of intervention		*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*
Total projected growth		*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*
Activity	10,839	10,947	11,057	11,167	11,279	11,392	11,506	11,621	11,737	11,854	11,973	12,093	12,214	12,336
Expenditure	£62,103,081	£62,724,112	£63,351,353	£63,984,866	£64,624,715	£65,270,962	£65,923,672	£66,582,909	£67,248,738	£67,921,225	£68,600,437	£69,286,442	£69,979,306	£70,679,099
Outpatients														
Population increase		*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*	*0.4%*
Rate of intervention		*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*	*0.6%*
Total projected growth		*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*
Activity	91,498	92,413	93,337	94,270	95,213	96,165	97,127	98,098	99,079	100,070	101,071	102,081	103,102	104,133
Expenditure	£20,469,865	£20,674,564	£20,881,309	£21,090,122	£21,301,024	£21,514,034	£21,729,174	£21,946,466	£22,165,931	£22,387,590	£22,611,466	£22,837,580	£23,065,956	£23,296,616
Total paediatric expenditure	£82,572,946	£83,398,675	£84,232,662	£85,074,989	£85,925,739	£86,784,996	£87,652,846	£88,529,375	£89,414,668	£90,308,815	£91,211,903	£92,124,022	£93,045,262	£93,975,715
TOTAL EXPENDITURE	**£110,271,188**	**£112,204,847**	**£114,191,081**	**£116,231,744**	**£118,328,764**	**£120,484,143**	**£122,699,958**	**£124,978,371**	**£127,321,625**	**£129,732,050**	**£132,212,068**	**£134,764,193**	**£137,391,040**	**£140,095,324**

SCENARIO 2b - POPULATION GROWTH + INCREASED INTERVENTION RATE (paediatric high growth)														
ADULTS														
Year	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
Inpatients														
Population increase		*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Rate of intervention		*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*
Total projected growth		*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*
Activity	5,534	5,755	5,986	6,225	6,474	6,733	7,002	7,282	7,574	7,877	8,192	8,519	8,860	9,215
Expenditure	£23,962,792	£24,921,304	£25,918,156	£26,954,882	£28,033,077	£29,154,400	£30,320,576	£31,533,400	£32,794,735	£34,106,525	£35,470,786	£36,889,617	£38,365,202	£39,899,810
Outpatients														
Population increase		*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Rate of intervention		*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*	*3.3%*
Total projected growth		*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*
Activity (est)	24,903	25,899	26,935	28,012	29,133	30,298	31,510	32,771	34,081	35,445	36,863	38,337	39,871	41,465
Expenditure	£3,735,450	£3,884,868	£4,040,263	£4,201,873	£4,369,948	£4,544,746	£4,726,536	£4,915,597	£5,112,221	£5,316,710	£5,529,379	£5,750,554	£5,980,576	£6,219,799
Total adult expenditure	£27,698,242	£28,806,172	£29,958,419	£31,156,755	£32,403,026	£33,699,147	£35,047,112	£36,448,997	£37,906,957	£39,423,235	£41,000,164	£42,640,171	£44,345,778	£46,119,609
PAEDIATRICS														
Year	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
Inpatients														
Population increase		*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*
Rate of intervention		*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*
Total projected growth		*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*
Activity	10,839	11,056	11,277	11,502	11,732	11,967	12,206	12,451	12,700	12,954	13,213	13,477	13,746	14,021
Expenditure	£62,103,081	£63,345,143	£64,612,045	£65,904,286	£67,222,372	£68,566,820	£69,938,156	£71,336,919	£72,763,657	£74,218,931	£75,703,309	£77,217,375	£78,761,723	£80,336,957
Outpatients														
Population increase		*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*
Rate of intervention		*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*
Total projected growth		*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*
Activity	91,498	93,328	95,195	97,098	99,040	101,021	103,042	105,102	107,204	109,349	111,536	113,766	116,042	118,362
Expenditure	£20,469,865	£20,879,262	£21,296,848	£21,722,784	£22,157,240	£22,600,385	£23,052,393	£23,513,441	£23,983,709	£24,463,384	£24,952,651	£25,451,704	£25,960,738	£26,479,953
Total paediatric expenditure	£82,572,946	£84,224,405	£85,908,893	£87,627,071	£89,379,612	£91,167,205	£92,990,549	£94,850,360	£96,747,367	£98,682,314	£100,655,960	£102,669,080	£104,722,461	£106,816,910
TOTAL EXPENDITURE	**£110,271,188**	**£113,030,577**	**£115,867,312**	**£118,783,826**	**£121,782,638**	**£124,866,351**	**£128,037,661**	**£131,299,356**	**£134,654,324**	**£138,105,549**	**£141,656,125**	**£145,309,251**	**£149,068,239**	**£152,936,519**

ANNEX B

Consultant Team cost estimate

Consultant Surgeon Team costs (Estimate) Annual Costs		
Medical Staff	WTE	£ 000's
Consultant	1	146
Merit Awards		30
Staff Grades	2	140
£70k per WTE		
Medical Secretary	1	28
Non-Pay costs		50
Travel, Office costs, IT equipment		
Outpatient Clinics		
Nursing staff		
Band 6	1	40
Band 5	1	30
Band 3	1	22
Admin support	0.5	14
Total	7.5	500

Cost include salaries and on-costs.

ANNEX C

Activity Analysis

There are two reliable national sources of data on paediatric cardiac and adult congenital heart disease (ACHD) inpatient activity. Both sources have some weaknesses and difficulties with interpretation and therefore this analysis draws on both sources, as appropriate, to triangulate the data and thus to increase confidence in our findings. The data sources used are:

- National Institute for Cardiovascular Outcomes Research (NICOR) Central Cardiac Audit Database (CCAD) which reports procedure numbers.
- Hospital Episode Statistics (HES) Admitted Patient Care (APC) which is derived from Secondary Uses Service (SUS) data and reports episodes of care.

Data for adult services is flawed from both sources:

- Although reporting has improved, not all units undertaking adult surgery/interventional cardiology report that activity to NICOR; and
- the way in which Hospital Episode Statistics (HES) activity is coded means it is not easy to distinguish CHD activity from other cardiac services.

While there are therefore concerns about the quality of data for ACHD activity the information presented is the best available and we consider it to be sufficiently robust for this purpose of informing this finance assessment.

Analysing this data we have found that:

- Paediatric activity has grown steadily by around 10% above population growth over the last 10 years.
- ACHD activity has grown by over 20% above population growth over the last 7 years, but is from a much lower base (so big % change may be small in absolute numbers).

	Paed Cardiac 2003-2012		ACHD 2006-2012	
	HES (0-18)	**NICOR (0-16)**	**HES (19+)**	**NICOR (17+)**
Activity growth	12%	14%	31%	N/A
of which population growth	3%	3%	6%	6%
gives remaining activity per head growth	10%	11%	24%	N/A

Note: figures may not sum due to rounding and compound affects

Paediatric activity growth has been mainly driven by growth in activity for those aged under 1 year old, which itself has been driven by growth in the birth rate. See table below.

	Paed Cardiac 2003-2012			
	HES (<1)	**NICOR (<1)**	**HES (1-18)**	**NICOR (1-16)**
Activity growth	36%	30%	0%	0%
of which population growth	21%	21%	2%	2%
gives remaining activity per head growth	13%	8%	-2%	-1%

Note: figures may not sum due to rounding and compound affects

We think the key demand drivers include technology/medical advances, increased patient expectations and clinician's willingness to treat, increased patient survival and for paediatric activity in particular the increasing % of patients who are of BME ethnicity (where there is some evidence of higher incidence and also of a greater proportion of serious anomalies). We think increased patient survival has been a significant driver of adult activity in the past and will continue to be.

Of the identified demand drivers the only one that can be separately modelled going forward is population growth (by age, sex and area). Modelling is based on ONS 2012 based projections. While this is the best information available these have not always been accurate in the past because of unanticipated changes to the population and birth rates.

The effect of all the other demand drivers over the last ten years is included in the historic trend in activity growth above population growth. This is not perfect, but it the best we can do under existing data constraints. We are confident that this represents a reasonable upper bound scenario for us to consider.

Therefore we have looked at two key scenarios for future activity:

- Scenario 1: Population growth only (England and Wales).
- Scenario 2: As for 1 but also allowing activity per head to increase at the same rate as it has in the past.

These scenarios suggest that up to 2025/6:

- Paediatric activity could be expected to grow by between **0.4%** and **1%** pa However, this is very sensitive to the birth rate projections which ONS has previously underestimated – under ONS' high variant projections expected growth would be between **1%** and **2%** pa.
- ACHD activity could be between **0.7%** and **4%** pa.

ANNEX D

Benefits and Value for Money

Improvements in health outcomes and patient experience

The below table sets out how each area of the new standards will improve patient outcomes and experience:

Standard	Impact on patient outcomes and experience
Section A: Networks	Hospitals and clinicians will work together locally, regionally and nationally to provide the best possible care for patients. Patients, their families and their carers will have a better experience as the services they receive will be more joined up and will work around the patients.
Section B: Staffing	Wherever patients receive their care, the centres will have the right staffing with the right skills, and if necessary will refer patients to another unit if they need more specialist care, or will bring in expert support. Occasional practice will be eliminated removing an obvious risk to patient safety.
Section C: Facilities	Patients, families and carers will be able to live as normally as possible during times spent in hospital.
Section D: Interdependencies	Wherever patients receive their care, all the experts they are likely to need are on site or available very quickly.
Section E: Education and training	Patients, families and carers will be cared for by staff who are appropriately trained in the skills needed to perform their jobs.
Section F: Governance and audit	Patients, families and carers will benefit from clearly organised systems focused on patient care and improved outcomes.
Section G: Research	Patients, families and carers will benefit from research that adds to the understanding of congenital heart disease now and in the future
Section H: Communication	Patients, families and carers will have a better understanding of congenital heart disease, the care provided and what the options are. They will also be encouraged to offer feedback and complain if they need to.
Section I: Transition	Young people will have the help and support they need as they grow up and move from children's into adult services.
Section J: Pregnancy and maternity	Patients will be able to make informed choices in relation to contraception, termination, pregnancy and maternity. Pregnant women who are at risk will be cared for in the most appropriate setting.
Section K: Fetal Diagnosis	Patients will receive the same high quality fetal anomaly screening wherever they live and will receive the support care, and information they need if an anomaly is suspected.
Section L: Palliative care	Patients, families and carers will receive all the support they need once on the end of life pathway whether that be in the hospital or in the community, including at home.

Section M: Dental	Patients who are at risk because of dental problems will be identified and treated.

Value for money

The above benefits section sets out why these new standards are important and the benefits we expect to see. Below summarises the key benefits identified and considers whether or not these would be realised under a 'do nothing' option and compares this with the expected costs.

	Do nothing	New standards
Benefits		
Improvements in health outcomes and patient experience	No - No mechanism to improve the quality of care	The standards define excellent care The commissioners will be able to contract with providers on a consistent basis and able to take action where they are not being met Providers will have clarity about the requirements of them which will enable them to plan for the future and direct investment appropriately Working as a network will enable provider peer review and sharing of ideas Occasional practice will be eliminated Patients and their families will know what they should expect from their service providers and be empowered to raise questions where they feel this is not being met and/or to exercise patient choice
Patients, their families and the public will be assured that the care they receive will be of a consistently high quality wherever they live in England	No – the service review would be unresolved and the position would be the same as it has been previously	
Commissioners will be assured of the quality of care and that additional expenditure for increased activity will be directed to services of increasing quality and not just quantity	No – No mechanism to improve the quality of care	
Providers will reduce their risk of litigation, see fewer complaints and resource-consuming investigations	No – No mechanism to improve the quality of care	
Costs		
Additional commissioner expenditure to fund activity growth	£7m to 29.8m by 2025/26	£7m to 29.8m by 2025/26

Draft national standards and service specifications for congenital heart disease services: draft equality analysis

Equality and diversity are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have given due regard to the need to:

- reduce health inequalities in access and outcomes of healthcare services, integrate services where this may reduce health inequalities;
- eliminate discrimination, harassment and victimisation; and
- advance equality of opportunity and foster good relations between people who share a relevant protected characteristic (as cited in the Equality Act 2010) and those who do not share it.

What are the intended outcomes of this work?

Congenital heart disease is a term for a range of birth defects that affect the normal workings of the heart. The treatment for congenital heart disease depends on the defect. Mild defects, such as a small ventricular septal defect (a hole in the heart), often do not need to be treated, as they may improve on their own and may not cause any further problems, or will just need regular monitoring by a cardiologist.

If the defect is significant and is causing problems, surgery (or sometimes a less invasive procedure) may be required. Modern surgical techniques can often restore most or all of the heart's normal function.

However, people with congenital heart disease often do need treatment over their life and, therefore, require specialist review during childhood and adulthood. This is because people with complex heart problems can develop further problems with their heart rhythm, muscle or valves over time.

The new Congenital Heart Disease review
The new Congenital Heart Disease (CHD) review ("the review") was set up in June 2013 to consider the whole lifetime pathway of care for people with CHD to achieve:

- the best outcomes for all patients, not just lowest mortality but reduced disability and an improved opportunity for survivors to lead better lives;
- tackling variation so that services across the country consistently meet demanding performance standards and are able to offer resilient 24/7 care; and
- excellent patient experience, which includes how information is provided to patients and their families, considerations of access and support for families when they have to be away from home.

The development of national standards to be applied through national service specifications is at the heart of the review's approach. This reflects the views of stakeholders from across the spectrum and is recognised in the review's objectives.

The review's six objectives:

1. **to develop standards to give improved outcomes, minimal variation and improved patient experience for people with CHD;**

2. to analyse demand for specialist inpatient CHD care, now and in the future;

3. to make recommendations on function, form and capacity of services needed to meet that demand, taking account of accessibility and health impact;

4. to make recommendations on the commissioning and change management approach including an assessment of workforce and training needs;

5. to establish a system for the provision of information about the performance of CHD services to inform the commissioning of these services and patient choice; and

6. to improve antenatal and neonatal detection rates.

Draft service standards and specifications

We are consulting on draft standards and specifications for CHD services for children and adults (there is currently a set of standards and a service specification in place for children's services but standards only exist in draft form for adults).

This equality analysis sets out the evidence we have considered as we have worked with others to develop these standards.

Draft standards

The draft standards cover the following:

- the network approach;
- staffing and skills;
- facilities;
- interdependencies;
- training and education;
- organisation, governance and audit;
- research;
- communication with patients;
- transition;
- pregnancy and contraception;
- fetal diagnosis;
- palliative care and bereavement; and
- dentistry.

We are producing standards and specifications which will enable commissioners to describe and commission an excellent service, within the available resource, and which

will help ensure that services are all meeting the same criteria and in doing this, reduce inequalities in CHD service provision and outcomes.

While some standards could have a bearing on how/where services are delivered (insofar as they make proposals as to surgeon numbers, caseloads and mixes, interdependencies and sub-specialisation), there is no predetermined outcome about the configuration of provider units. We await responses from the consultation to inform the final form of the standards, and the future consideration of the subsequent shape of services.

Scope of this equality analysis

It is important to stress that the work on objectives 2-6 above is **not** the subject of the current consultation or this equality analysis, but our future work will be informed by what we hear in consultation.

Future thinking on, for example, function, form and capacity will be subject to the equality duty, in so far as it relates to the configuration of services to meet demand. We will consider feedback to this consultation, alongside future evidence and where appropriate, further equality analyses would be produced. Furthermore, as the sole national Commissioner, NHS England will need to ensure monitoring of the duty as part of contract management with service providers.

We hope that this draft equality analysis will demonstrate the information that has informed our thinking so far, and provide an opportunity for stakeholders, and the general public alike, to share this and to enhance their own understanding and ours, by:

- **considering and commenting on the evidence we have included, and**
- **helping us to fill in the gaps.**

Who will be affected by this work?

It is estimated that across England and Wales between 5 and 9 in every 1,000 pregnancies are associated with some form of CHD based on information collected by the British Isles Network of Congenital Anomaly Registers (BINOCAR[1]). The number of babies born with CHD will increase if the total numbers of babies being born continues to rise[2]. 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 rates. But under their 'high' projections, ONS recognises that birth rates could rise.[3]

Because of improvements in treatment, people with CHD can now expect to live longer than ever before. Between 1979-1983 and 2004-2008, the number of deaths from CHD in children under 15 years fell by 83% in the UK[4]. 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 around children, to one that is treating a growing number

[1] *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

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

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

[4] *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

of young people and adults. Advances in paediatric cardiology, intensive care medicine, and cardiac surgery mean that the number of children with congenital heart disease (CHD) surviving into adulthood continues to increase. Hence, adults will constitute an ever-growing population [5], who will continue to have (often complex) health needs. For many defects treated in childhood, further problems can develop later in life that require medical care or further surgery[6].

As well as people with CHD, this work will affect their families and carers, all members of the multidisciplinary clinical teams who support patients with CHD, and hospital managers, in particular those with specialist CHD units. Paediatric cardiac services also care for children with acquired and inherited cardiac diseases (although CHD accounts for most of their work). These children and their families and carers will also be affected.

Evidence

Our evidence has come from a range of sources. Key sources of evidence for the review in general, and the standards in particular, have been advice from:

- patients;
- clinicians;
- provider leaders;
- academics and other experts; and
- the wider public through correspondence and responses to our blog.

We have gathered evidence from:

- our patients' and public, providers' and clinicians' engagement and advisory groups;
- the groups that have developed the draft CHD standards;
- the Clinical Advisory Panel;
- visits to 13 Trusts with specialist CHD units where we had the opportunity to meet staff and patients; and
- nine meetings across England with children and young people.

A report is available at http://www.england.nhs.uk/wp-content/uploads/2014/07/chd-cap-6.pdf.

To inform our thinking on standards and the other objectives of the review, we have put in place other pieces of work to gather evidence. This has been done in parallel with the work of the review's lead analyst who has been progressing work on Objective 2 (including interrogating Hospital Episodes Statistics (HES) data).

We have also commissioned a systematic literature review; and asked the National Institute for Cardiovascular Outcomes Research (NICOR) to investigate their data.

Systematic literature review (papers since 2003 or earlier if few papers)

[5] *Delivery of care for adult patients with congenital heart disease in Europe: results from the Euro Heart Survey,* Moons et al *(2006)* European Heart Journal 27, 1324–1330

[6] *Care and Treatment for congenital heart defects* (2011) American Heart Association http://heart.org/HEARTORG/Conditions/CongenitalHeartDefects

The independent systematic literature review, undertaken by The University of Sheffield, School of Health and Related Research (ScHARR) on our behalf, aimed to understand how organisational factors may affect patient outcomes focusing on:

- What is the current evidence for the relationship between institutional and surgeon volume and patient outcomes, and how is the 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 paediatric intensive care)?

National Institute for Cardiovascular Outcomes Research - data analysis

The National Institute for Cardiovascular Outcomes Research (NICOR) was asked to examine its data and to advise on what this showed about service factors that could influence outcomes. Although the final write-up of this work is not yet available, NICOR has kindly supplied a summary of the main findings and these have been incorporated in this paper.

NICOR run the Congenital Heart Disease Audit using patient information collected by the Central Cardiac Audit Database (CCAD). We asked them to consider whether the information collected could be used to further understand the relationship between certain organisational or patient factors and patient outcomes. NICOR have helped us understand better the association between 30-day mortality rates in relation to ethnicity and social deprivation.

We see the gathering of evidence as part and parcel of our continuing work.

To this end, we propose to hold further engagement and advisory meetings and targeted work with some groups that share protected characteristics: BAME communities; people with learning disabilities and adults with CHD.

In the following sections we consider what impact our proposed standards for congenital heart disease might have on each of the nine protected characteristics:

- Age
- Disability
- Gender reassignment
- Marriage and civil partnership
- Pregnancy and maternity
- Race
- Religion and belief
- Sex
- Sexual orientation

We have also considered carers and geographical variations.

Age

The draft standards are intended to ensure that everyone with CHD gets the best possible care within the available resource.

Changing CHD population

CHD related episodes by age and as percentage of total (2012/13 HES data)

Age band	Age	Episodes	% total
Neonate	0 to 30 days	1297	12%
Infant	30 to 365 days	2318	21%
Child 1 -16	1 to 16 years	4296	39%
Child 17-18	17 to 18 years	695	6%
Adult 19-64	19 to 64 years	1856	17%
Adult 65+	65 years+	600	5%
Unknown	N/A	25	0%

Note: includes all episodes in NHS England providers for all patients (not just England and Wales)

Mortality from CHD has decreased over the past 30 years; between 1979-1983 and 2004-2008, absolute numbers of deaths from CHD in children under 15 years declined by 83% in the UK[7]. As the birth prevalence of CHD is thought to have remained more stable over this time period[8], it can be inferred that a large part of this decline in mortality is due to improved survival. Knowles *et al*. found that while deaths rates in the first year of life have been reducing throughout the period studied, drops in mortality in all age groups has only been observed for birth cohorts originating after 1989[9].

There is a suggestion from our own analysis and what we have heard that there has been an increase in demand for adult congenital heart disease care, not just among people in their twenties (i.e. birth cohorts originating after 1989).

Whereas in the past, mortality rates were higher in the early days and months, now more children in the UK with CHD benefit from advances in paediatric cardiac surgery and intensive care, and receive treatment and reach adulthood. The greatest decline in deaths from congenital heart disease has occurred in those aged less than one year.

This means that in the future, as more people survive, we are likely to see the service moving from one that is centred around children to one that is treating a growing number of young people and adults, who will continue to have (often complex) health needs.

This has consequences for the way in which services are delivered (and what sort of services are delivered) for both children and young people (and their different needs and expectations) through to transition for young people into adult services.

[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

[8] *Temporal variability in birth prevalence of cardiovascular malformations* Wren C, Richmond S, Donaldson L (2000). Heart; 83: 414-9

[9] Op. cit.

For many defects treated in childhood, further problems can develop later in life which then require medical care or further surgery[10].

In *Children and young people: Statistics 2013*[11], the British Heart Foundation notes: 'Treatment of adults with congenital heart disease is relatively new as more children with congenital heart defects receive treatment and reach adulthood. As a result of the success of paediatric cardiology and cardiac surgery over the last four decades, it is thought that more adults with congenital heart disease will require medical care than children[12]' (page 15).

The report authors go on to highlight the importance of ensuring that facilities are adequate at transition.

Age and CHD: What we have heard during pre-consultation

Increasing need for adult congenital heart disease services
We have heard that there is a need for increasing capacity in adult congenital heart disease services and that some centres are expanding facilities and recruiting new staff.

Age-sensitive services
During pre-consultation, we have heard from patients, families and carers that services need to be age-sensitive and that effective transition is vital. This relates to effective and appropriate communication, but also to the facilities provided.

Young people have told us that they would like more information about sex and relationships and this needs to be away from parents – many teenagers are uncomfortable speaking about any of these things in front of their parents and some don't even like the idea of speaking with their regular doctors.

Our draft standards emphasise, in several places, the importance of open, honest communication in ways that are appropriate to the patient's needs. In addition we have also developed specific standards on:

- communication with patients;
- transition; and
- pregnancy and contraception.

We believe that the standards will have a positive impact on the experience and outcomes of all children and adults with CHD. For the first time services will be nationally commissioned using common service specifications across all ages.

We welcome more information/evidence.

[10] *Care and Treatment for congenital heart defects* (2011) American Heart Association http://heart.org/HEARTORG/Conditions/CongenitalHeartDefects
[11] *Children and young people: Statistics 2013* (2013) Townsend N, Bhatnagar P, Wickrama singhe K, Williams J, Vujcich D, Rayner M, British Heart Foundation: London
[12] *Task force on the management of grown up congenital heart disease of the European Society of Cardiology* (2003) European Heart Journal; 24: 1035-1084

Disability

The draft standards are intended to ensure that everyone with CHD gets the best possible care within the available resource.

Children and adults with congenital heart disease are at an increased risk of developing further problems. Many children with congenital heart disease experience delays in their development. For example, they may take longer to start walking or talking. They may also have lifelong problems with physical coordination.

Some children with congenital heart disease also have learning difficulties. These 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. This is because of problems such as:

- impaired memory;
- problems expressing themselves using language;
- problems understanding the language of others;
- low attention span and difficulty concentrating;
- poor planning abilities; and
- poor impulse control – acting rashly without thinking about the possible consequences.

Recent research has found that children who have had surgery for transposition of the great arteries have significant problems related to a concept known as theory of mind (TOM). TOM is the ability to understand other people's mental states and recognise that they may differ from your own. In other words, to recognise that everyone has their own set of desires, intentions, beliefs, emotions, perspective, likes and dislikes. In simple terms, TOM is the ability to see the world through another person's eyes. An inability to recognise other people's mental states can lead to problems with social interaction and behaviour in later life.

<u>Congenital heart disease as a complication of Down’s syndrome</u>
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.

Septal defects account for 9 out of 10 cases of congenital heart disease in people with Down’s syndrome. A septal defect is a hole inside one of the walls that separate the four chambers of the heart, often referred to as a ‘hole in the heart’.

Less common but serious types of congenital heart disease in people with Down’s syndrome include:

- tetralogy of Fallot (accounts for 6% of cases); and
- patent ductus arteriosus (accounts for around 4% of cases).

As noted above in relation to age, it is possible that in complex congenital heart disease cases, further problems (which could include a disability) will develop later in life that will require medical care or further surgery[13].

Disability and CHD: What we have heard during pre-consultation

We heard about the importance of ensuring the standards respect the needs of people with disabilities.

We have proposed standards that address the needs of all patients and have included particular standards that relate to learning disability, for example in relation to:

- communication with patients; and
- transition.

We believe that the standards will have a positive impact on the experience and outcomes of all children and adults with CHD, a number of whom have a disability. For the first time services will be nationally commissioned using common service specifications across all ages.

We welcome more information/evidence.

Gender reassignment (including transgender)

The draft standards are intended to ensure that everyone with CHD gets the best possible care within the available resource.

We have not identified any specific evidence relating to gender reassignment (including transgender) and CHD.

We welcome more information/evidence.

Marriage and civil partnership

The draft standards are intended to ensure that everyone with CHD gets the best possible care within the available resource.

We have not identified any specific evidence relating to marriage and civil partnership and CHD.

We welcome more information/evidence.

[13] *Care and Treatment for congenital heart defects* (2011) American Heart Association http://heart.org/HEARTORG/Conditions/CongenitalHeartDefects

Pregnancy and maternity

The draft standards are intended to ensure that everyone with CHD gets the best possible care within the available resource.

Cardiac disease is a leading cause of maternal death in pregnancy[14].

The Royal College of Obstetricians and Gynaecologists (RCOG) published a Good Practice guideline in 2011 which noted that pregnancy carries increased risks for women with congenital heart disease and particular efforts should be made to prevent any unwanted pregnancies. In particular teenage girls with congenital heart disease should have access to a specialist who can advise on contraception and later in life on preconception counselling. RCOG also noted the importance of ensuring that women with CHD:

- who go to their GP or midwife for advice are referred promptly to an appropriate high-risk pregnancy and heart disease team and see a cardiologist to establish how well the heart is working and discuss how pregnancy may impact their health.

- who want to become pregnant or who are pregnant visit their obstetrician and ideally should talk to them jointly with a cardiologist.

Fetal diagnosis
We are undertaking separate work (Objective 6) to improve fetal diagnosis of congenital heart disease.

Pregnancy and maternity and CHD: What we have heard during consultation

We have heard that there is a possibility that increased fetal diagnoses could in some cases increase terminations and reduce activity. But in other cases, it could increase the chance of survival and increase activity.

We have also heard that as a consequence of better care for people with congenital heart disease, more are going on to have their own children. This means that it is very important that there are close links between maternity services and ACHD services, and that deliveries are planned for safety.

We have developed specific standards on:
- pregnancy and contraception; and
- fetal diagnosis.

We believe that the proposed standards alongside our work to improve antenatal and neonatal detection rates (Objective 6) 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 using common service specifications.

We welcome more information/evidence.

[14] Royal College of Obstetricians and Gynaecologists (2011)

Race

The draft standards are intended to ensure that everyone with CHD gets the best possible care within the available resource.

CHD related episodes by ethnicity and as percentage of total (2012/3 HES data)

Ethnicity (%)	Specialist inpatient Episodes	Specialist inpatient Patients	ONS 2011 Census
Paediatric cardiac			
White	66%	66%	79%
Black	4%	4%	5%
White and Black	2%	1%	N/A
Asian	10%	10%	9%
White and Asian	1%	1%	N/A
Chinese and other	3%	3%	1%
Any other mixed	1%	1%	6%
Not Known	4%	4%	N/A
Not Stated	10%	11%	N/A
Ethnicity (%)	**Specialist inpatient Episodes**	**Specialist inpatient Patients**	**ONS 2011 Census**
ACHD			
White	79 %	79%	88%
Black	2%	2%	3%
White and Black	0%	0%	N/A
Asian	5%	5%	7%
White and Asian	0%	0%	N/A
Chinese and other	2%	2%	1%
Any other mixed	0%	0%	2%
Not Known	5 %	5 %	N/A
Not Stated	7%	7%	N/A

Note: ONS 2011 census do not use the same ethnic groups as HES so not directly comparable but give some sense of how the ethnic mix of activity for specialist inpatient CHD care compares to the general population of England and Wales.

The HES data above indicates that the majority of CHD episodes are among those patients classified as white, followed by those patients classified as Asian.

Ethnicity and prevalence

Research dating back to the 1980s[15] and 1990s[16] demonstrated higher prevalence among Asian communities in various UK cities including Manchester and Leeds, and in the West Midlands. In the 1980s research links were made between CHD and consanguinity in the Asian Muslim population. More recently in *Consanguinity and the risk of congenital heart*

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

[16] 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*

disease, (2012)[17] JT Shieh *et al.* undertook a systematic review of consanguinity in CHD, focusing on non-syndromic disease, with the methodologies and results from studies of different ethnic populations compared. They found that the majority of studies support the view that consanguinity increases prevalence of CHD, but found only three population-based studies controlled for potential socio-demographic confounding. The results suggested that the risk for CHD is increased in consanguineous unions in the studied populations, principally at first cousin level and closer.

For more precise risk estimates a better understanding of the underlying disease factors is needed. It has been suggested that we should consider whether and how to raise awareness of the risk of CHD within these communities.

Ethnicity and outcomes

We asked NICOR to see whether there was any link between ethnicity and the 30-day outcome after paediatric surgery. NICOR have used a 2009-12 dataset and a Partial Risk Adjustment in Surgery (PRAiS) model[18] recalibrated to evaluate the candidate risk factors for ethnicity. The PRAiS model assigns risk of death by 30 days after the first surgical operation (29 different specific procedures) in 30-day episodes of surgical management. NICOR's analysis of data from 13 paediatric surgery centres (12,186 episodes of care in paediatric heart surgery during April 2009 to March 2012 inclusive) showed that Asian ethnicity is associated with poorer outcomes (30-day post-operative mortality). This is a statistically significant finding. Other categories of ethnicity (Black, Chinese and Other) did not have statistically different risk from the Caucasian category.

Other factors beyond simple ethnicity may play a factor in this finding, such as deprivation and a higher incidence of consanguinity which is associated with more complex congenital heart disease and therefore less good outcomes.

Race and CHD: What we have heard during pre-consultation

We believe that the standards will have a positive impact on the experience and outcomes of children and adults from ethnic minorities with CHD. For the first time services will be nationally commissioned using common service specifications.

We welcome more information/evidence.

[17] Am J Med Genet A. 2012 May;158A(5):1236-41. doi: 10.1002/ajmg.a.35272. Epub 2012 Apr 9.

[18] (Sonya Crowe, Kate L. Brown, Christina Pagel, Nagarajan Muthialu, David Cunningham, John Gibbs, Catherine Bull, Rodney Franklin, Martin Utley, Victor T. Tsang**, Development of a diagnosis- and procedure-based risk model for 30-day outcome after paediatric cardiac surgery**, The Journal of Thoracic and Cardiovascular Surgery, Volume 145, Issue 5, May 2013, Pages 1270-1278, ISSN 0022-5223, http://dx.doi.org/10.1016/j.jtcvs.2012.06.023)

Religion or belief

The draft standards are intended to ensure that everyone with CHD gets the best possible care within the available resource.

We have not identified any specific literature relating to religion or belief and CHD.

Religion or belief and CHD: What we have heard during pre-consultation

We heard that religion and belief and culture could make it difficult for some people to engage with us in an open forum.

We welcome more information/evidence.

Sex

The draft standards are intended to ensure that everyone with CHD gets the best possible care within the available resource.

CHD-related episodes by gender and as percentage of total (2012/13 HES data)

Gender	**%**	**%**
Paediatric cardiac	**Episodes**	**Patients**
Male	56	55
Female	44	45
ACHD	**Episodes**	**Patients**
Male	50	50
Female	50	50

In terms of activity levels the HES data above shows that there are more episodes for males than females in paediatric cardiac procedures but the number evens out in adulthood.

In terms of outcomes, there is no evidence that outcomes differ by gender – based on analysis by NICOR – no statistical association between 30-day mortality and patient gender has been identified[19]. However, *Children and young people: Statistics 2013* (2013) notes that in children under five years of age, 3.5% of all deaths in boys and 4.8% of all deaths in girls are from congenital heart disease.

We have not identified any specific literature relating to gender and CHD.

Gender and CHD: What we have heard during pre-consultation

We did not identify any key messages about gender.

[19] Source: NICOR

We believe that the standards will have a positive impact on the experience and outcomes of children and adults of both sexes with CHD. For the first time services will be nationally commissioned using common service specifications.

We welcome more information/evidence.

Sexual orientation

The draft standards are intended to ensure that everyone with CHD gets the best possible care within the available resource.

We have not identified any specific evidence relating to sexual orientation and CHD.

Sexual orientation and CHD: What we have heard during pre-consultation

Young people have told us that they would like more information about sex and relationships and this need to be away from parents – many teenagers are uncomfortable speaking about any of these things in front of their parents and some don't even like the idea of speaking with their regular doctors. Our draft standards emphasise, in several places, the importance of open, honest communication in ways that are appropriate to the patient's needs.

We welcome more information/evidence.

Carers

The draft standards are intended to ensure that everyone with CHD gets the best possible care within the available resource.

It will be important to ensure that parents and carers of children with CHD have access to the information and any psychological support they might need.

Carers and CHD: What we have heard during pre-consultation

In addition, we have heard how important it is for parents and carers to be supported, particularly when they are away from home. They have told us about difficulties with finding their way round new hospitals, finding accommodation and eating balanced meals. They have also told us about problems with car parking.

We have also heard how important it is to have support for end of life and poor outcomes. 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 on:

- facilities; and
- palliative care and bereavement.

We believe that the standards will have a positive impact on the experience and outcomes for families and carers, ensuring that they are recognised and appropriately supported in their care of children and adults with CHD. For the first time services will be nationally commissioned using common service specifications.

We welcome more information/evidence.

Geographical variation

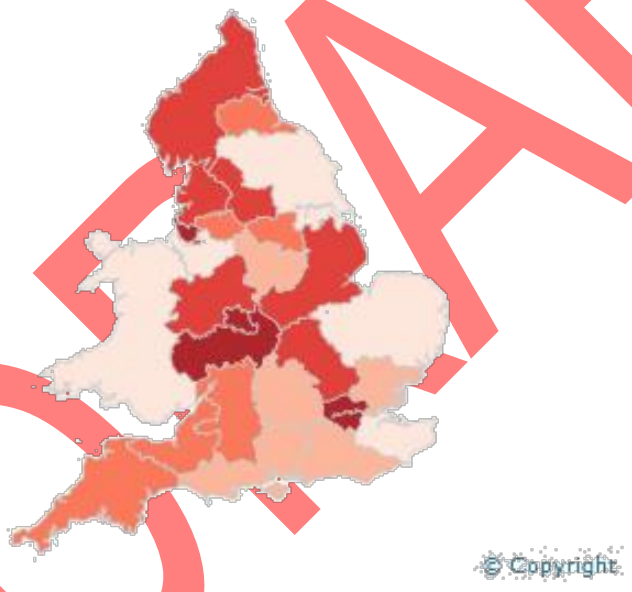
While not a protected characteristic, we have looked at CHD-related episodes (specialist inpatient activity) by area as percentage of total, and episodes per head of population (2012/3 HES data)

Area Team of patient residence	% of all specialist inpatient episodes	Specialist inpatient episodes per 100,000 (0-18) population	Specialist inpatient episodes per 100,000 (19+) population
Durham, Darlington and Tees	2%	60.0	4.9
Cumbria, Northumberland, Tyne and Wear	3%	69.0	3.9
Lancashire	3%	67.3	5.4
Greater Manchester	5%	63.1	6.3
Cheshire, Warrington and Wirral	2%	56.4	5.9
Merseyside	3%	72.4	10.5
West Yorkshire	4%	69.9	6.6
South Yorkshire and Bassetlaw	2%	59.8	3.4
North Yorkshire and Humber	2%	54.8	4.3
Leicestershire and Lincolnshire	3%	69.9	5.8
Hertfordshire and The South Midlands	5%	67.8	5.3
Derbyshire and Nottinghamshire	3%	59.7	5.1
Birmingham and The Black Country	6%	86.6	4.8
Shropshire and Staffordshire	3%	69.5	6.7
Arden, Herefordshire and Worcestershire	3%	72.2	5.7
East Anglia	4%	55.4	7.6
Essex	3%	59.5	3.9
London	16%	70.8	5.4
Kent and Medway	2%	53.7	4.5
Surrey and Sussex	4%	59.4	6.0
Thames Valley	3%	56.5	6.4
Wessex	4%	59.5	4.6
Bath, Gloucestershire, Swindon and Wiltshire	3%	59.8	8.8
Bristol, North Somerset, Somerset and South Gloucestershire	3%	63.9	6.9
Devon, Cornwall and Isles Of Scilly	3%	60.1	6.6

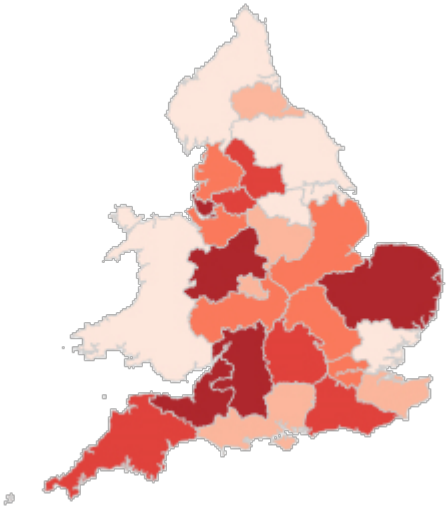
Wales	4%	52.6	2.0
Other (Scotland, N.I, Overseas etc.)	2%	N/A	N/A
Unknown	3%	N/A	N/A

The HES data above indicates that activity is fairly evenly spread across the country with the exception of London which has a much larger population, and Birmingham and Greater Manchester who are also slightly higher. However, once we account for different populations in each area we can see there is much more variation across the country in terms of relative activity. The episodes per 100,000 population show some differences from Wales at 52.6 and Kent and Medway at 53.7 to Merseyside at 72.4 to Birmingham and the Black Country at 86.6 (all paediatric services). In the case of adult services, the episodes per 100,000 population show differences from Wales at 2 and Essex at 3.9 to Bath, Gloucestershire, Swindon and Wiltshire at 8.8 and Merseyside at 10.5. This is demonstrated in the maps below; the darker the colour the higher the relative activity in that area.

Paediatric (0-18) 2012/13 HES specialist inpatient episodes per 100,000 population, by Area Team of patient residence (activity per head so controlled for different population sizes)



ACHD (19+) 2012/13 HES specialist inpatient episodes per 100,000 population, by Area Team of patient residence (activity per head so controlled for different population sizes)



Geographical variation and CHD: What we have heard during pre-consultation

The evidence we have received in relation to geographical variation has been limited. Where geography has been raised it has been in relation to how services are delivered now and how they might be delivered in the future. The focus has been on whether existing units will meet the standards and what it means to staff and patients if not; and travel times now and in the future.

We have noted the feedback we have received during pre-consultation on the concerns about how services will be delivered in the future, and will use this to inform our thinking in relation to future work on Objectives 3, 4 and 5.

We welcome more information.

Engagement and Involvement

Over the past 12 months we have been working with a wide range of stakeholders to develop the current draft standards. We have worked with and spoken to:

- children and young people with CHD and their parents and carers;
- adults with CHD and their parents and carers;
- groups representing people with CHD;
- clinicians and other members of the multidisciplinary team;
- providers; and
- local authorities and Healthwatch.

As well as regular meetings of formal engagement and advisory groups, we have undertaken visits to all specialist units, led by Professor Deirdre Kelly, Chair of the Clinician Group. During these visits, members of the new CHD review team had an opportunity to speak to clinical staff, and patients and their families. We also ran nine dedicated events for children and young people around the country.

The draft standards have been central to our engagement and involvement work from the outset and have informed the development of the draft service specifications. For the past year we have been working with experts to develop the draft standards, and then testing them out with our engagement and advisory groups and a wider audience.

We have adopted an approach of openness and transparency and all our papers are published on the NHS England Congenital Heart Disease Review website and John Holden's blog. Blog 23 contained the then-current version of the standards and so was open to everyone to see.

Launch of the consultation is the next step in the process and our work on engagement and involvement is ongoing. We plan to arrange four further regional visits during consultation and to do some targeted work with the stakeholders with an interest in the following protected characteristics:

- Age (specifically adults with CHD, with whom we have had less contact than children and young people)
- Disability (in particular, learning disability)
- Race

Summary of analysis

The evidence and engagement activity considered above has highlighted ways in which, subject to consultation and final agreement, our standards can help improve the way in which services are delivered to all those with CHD, including those in protected groups.

This is particularly so in relation to:

- Age
- Disability
- Pregnancy and maternity
- Race

The links between the standards and their impact on other protected groups is not so obvious. We hope to better understand how the standards might be used to support other protected groups through focused activities during the consultation – and also increase our understanding of the needs of adults with congenital heart disease.

The standards and the service specifications will, once agreed, set the framework through which CHD services will be delivered. It will be important for providers to ensure that they have regard to the equality duty in the provision of these CHD services.

Eliminating discrimination, harassment and victimisation

The draft standards apply to CHD services for children and adults – we currently only have agreed standards and a service specification for CHD services for children. The new draft

standards will ensure that everyone with CHD gets the best possible care whatever their age, thereby improving the consistency of our approach with adults.

Advancing equality of opportunity

The draft standards apply to CHD services wherever they are delivered in the country. They apply to all services (levels 1, 2 and 3). The draft standards will help ensure that all services are working to the same aims – and that people with CHD can receive a consistently high quality service.

Promoting good relations between groups

The standards will provide a consistent approach for all those with CHD in protected groups.

Our work to date has also enabled us to identify some areas that are common to all groups (and not solely applicable to CHD services) and improvements in these areas will benefit all:

- Effective communications
- Information sharing between professionals
- Transition

Evidence- based decision making

Our engagement and involvement to date has been invaluable in enabling us to develop the current draft standards and to hear from a wide range of people. It has at the same time allowed us to develop our thinking in relation to protected groups and to identify some gaps in relation to our understanding of whether people with CHD in some protected groups have a voice and are being heard.

Our work with children and young people and meeting patients and families at the hospitals we visited gave us a particular insight into issues around age (specifically children and young people, and the transition into adult services) disability, pregnancy and maternity, and race.

It has highlighted issues relating to three protected groups that would benefit from further consideration and research:

- How CHD services will develop to meet changing needs as the number of adults with CHD exceeds the number of children with CHD.

- The reason for the prevalence of CHD in some Asian communities and poorer outcomes at 30 days after first surgical procedure.

- How CHD services can best be developed to meet the needs of patients with a disability, in particular learning disability.

We are also keen during consultation to hear from people who can provide further evidence to inform our thinking in relation to those protected groups not mentioned above.

Sharing this draft equality analysis
As part of our assurance, this draft analysis will be shared with our programme board, the Specialised Commissioning Oversight Group, Programme of Care Board for Women and Children, the Clinical Priorities Advisory Group and the Directly Commissioned Services Committee.

The draft equality analysis will form part of the reference document that will accompany the consultation document, draft standards and service specifications.

As such it will be included in our communications and engagement activity at launch. We will send it to our engagement and advisory groups, our Clinical Advisory Panel and blog followers.

For your records **Name of person(s) who carried out this draft analysis:**	Penny Allsop
Name of Sponsor Director:	John Holden, Director of System Policy
Date analysis was completed:	August 2014
Review date:	TBC post-consultation

Congenital Heart Disease Activity Analysis: An update

Purpose

1. Objective 2 of the new congenital heart disease review is "to analyse demand for specialist inpatient congenital heart disease care, now and in the future".
2. The outputs of this work are an understanding of:
   a) current service provision and demand;
   b) future activity pressures that all else being equal will translate into future spend pressures; and
   c) future required capacity for specialist inpatient care services.
3. At this stage of the programme's work, the main focus is on how this informs the Financial Impact Assessment we are preparing for the Programme of Care (POC) Board and the Clinical Priorities Advisory Group (CPAG) as part of the assurance process to approve our consultation on standards.
4. **This paper asks the Programme Board to note the future activity pressures suggested by the analysis, to understand how they were derived and to agree that they form an appropriate basis for undertaking the Financial Impact Assessment.**
5. To note, further work may continue over the consultation period to further refine and sensitivity test our analysis particularly as we receive comments from interested parties; as a result, the numbers may change.

Analysis - Data

6. There are two reliable national sources of data on paediatric cardiac and adult congenital heart disease (ACHD) inpatient activity. Both sources have some weaknesses and difficulties with interpretation and therefore this analysis draws on both sources, as appropriate, to triangulate the data and thus to increase confidence in our findings. The data sources used are:
   - National Institute for Cardiovascular Outcomes Research (NICOR) Central Cardiac Audit Database (CCAD) which reports procedure numbers.
   - Hospital Episode Statistics (HES) Admitted Patient Care (APC) which is derived from Secondary Uses Service (SUS) data and reports episodes of care.
7. Data for adult services is flawed from both sources:
   - Although reporting has improved, not all units undertaking adult surgery/interventional cardiology report that activity to NICOR; and

- the way in which Hospital Episode Statistics (HES) activity is coded means it is not easy to distinguish CHD activity from other cardiac services.

8. While there are therefore concerns about the quality of data for ACHD activity the information presented in this report is the best available and we consider it to be sufficiently robust for this purpose.

Analysis - Results

9. The key findings from our analysis are summarised below:
    - Currently, around 65-75% of congenital heart inpatient activity is for 0-18 year olds.
    - Paediatric activity has grown steadily by around 10% above population growth over the last 10 years.
    - ACHD activity has grown by over 20% above population growth over the last 7 years, but is from a much lower base (so big % change may be small in absolute numbers).
    - We think the key demand drivers include technology/medical advances, increased patient expectations and clinician's willingness to treat, increased patient survival and for paediatric activity in particular the increasing % of patients who are of BAME ethnicity (where there is some evidence of higher incidence and also of a greater proportion of serious anomalies).
    - Of the identified demand drivers the only one that can be separately modelled going forward is population growth (by age, sex and area). Modelling is based on ONS projections. While this is the best information available these have not always been accurate in the past because of unanticipated changes to the population and birth rates.
    - The effect of all the other demand drivers over the last 10 years is included in the historic trend in activity growth above population growth.
    - Therefore we have looked at two key scenarios for future activity:
        - Scenario A: Population growth only (England and Wales).
        - Scenario B: As for A but also allowing activity per head to increase at the same rate as it has in the past.
    - These scenarios suggest that up to 2025/6:
        - Paediatric activity could be expected to grow by between 0.4% and 1% pa However, this is very sensitive to the birth rate projections which ONS has previously underestimated – under ONS' high variant projections expected growth would be between 1% and 2% pa.
        - ACHD activity could be between **0.7%** and **4%** pa.

Item 7 Annex A

New Congenital Heart Disease Review

NHS England

Activity Analysis Update

(slides 44 and 45, showing historic patient flows, have been amended / corrected since these slides were first published and circulated to the Programme Board. This was due to an issue in the software used to generate the maps not an issue in the actual data)

Jo Glenwright
John Buckell
Charles Keenan

Key Messages

- We have more confidence in paediatric activity data than ACHD activity data. NICOR data is good for paediatric activity (0-16), HES can do both paediatric and ACHD
- Currently, we think around 65-75% of congenital heart inpatient activity is for 0-18 year olds
- Paediatric activity has grown steadily by around 10% above population growth over the last 10 years, this is driven by growth in activity for children under the age of 1
- ACHD activity has grown by over 20% above population growth over the last 7 years, but is from a much lower base (so big % change may be small in absolute numbers)
- We think the key demand drivers include technology/medical advances, increased patient expectations and clinician's willingness to treat, increased patient survival and for paediatric activity in particular the increasing % of patients who are of BME ethnicity
- Some simple scenarios suggest that up to 2025:
  - **Paediatric activity could be expected to grow by between 0.4% and 1%pa (this is very sensitive to the birth rate projections – under ONS High projections it would be between 1% and 2% pa)**
  - **ACHD activity could be between 0.7% and 4% pa**

Item 7 Annex A

New Congenital Heart Disease Review

NHS England

Datasets, data issues and the definition of congenital heart disease activity

Joanna Glenwright
John Buckell
Charles Keenan

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We have data from NICOR and HES

NICOR data: Central Cardiac Audit Database (CCAD)

- NICOR provided us with data by for Adults and Children (0-16), by area team of residence, provider category (NHS England etc.), type of procedure (surgery or catheter), for financial years 2003/4 to 2012/13
- NICOR have a list of procedures they include, these are coded using EPCC* list
- NICOR data is reported by procedure, procedure type (including catheter vs surgery is verified as part of audit) * European Paediatric Cardiac Code

HES data: Admitted Patient Care (APC) data

- We extracted data from HES based on the presence of select OPCS codes in any of the procedure fields. For each episode extracted we have a variety of fields including, patient area of residence and provider, for financial years 1997/8 to 2012/13
- The list of procedures included is based on the existing Identification Rules (IR) used for paediatric cardiac (23B) (age 0-18) and ACHD (13X) (age 19+) and clinician advice. For adults in particular it is not clear that this identifies all of the relevant activity e.g. due to coding issues etc.
- HES data is reported by episode of care, catheter/surgery split is based on definition set of codes.

We have data from NICOR and HES

- For adult services both NICOR and HES data sources are flawed for different reasons:

1. not all adult activity is reported to the national database run by the National Institute for Cardiovascular Outcomes Research (NICOR), and

2. the generic nature of Hospital Episode Statistics (HES) means it is not easy to distinguish CHD activity from other cardiac services

- Given 2, we have struggled to come up with a definitive list of codes that we are certain capture the relevant activity in HES. After using a series of wider definitions that captured "too much" activity we have settled on using the procedure codes in the current IR – this should be at least of subset of actual activity. However, we have dropped one code L13.3 (arteriography of pulmonary artery) as this was significant outlier affecting the data and where it is used alone it is likely to be diagnostic rather than therapeutic intervention.

- Further, in our HES extract for ACHD we found that the coding of activity pre 2006/7 looked odd. 2006/7 is a significant year for the Payment by Results system which relies on this data to pay hospitals for the activity they do. Therefore we have not used any of the ACHD data pre 2006/7 as it was distorting our analysis.

- **As a result we have some concerns about the quality of data for ACHD activity and interpretation of any results should bear this in mind.**

We have data from NICOR and HES

- Because of the different databases, different coding classifications used (EPCC vs OPCS), different coding practices and different currencies (procedures vs episodes) it is not possible to know if the activity covered by each dataset is an exact match. The next slides test how well the two datasets compare…

2012/13 data for patients in England and Wales:

Age	NICOR (procedures)	HES (episodes)
Paediatric (0-16)	5,700	7,500
Paediatric (0-18)	N/A	8,200
ACHD (17+)	2,400 (3,000*)	3,100
ACHD (19+)	N/A	2,400

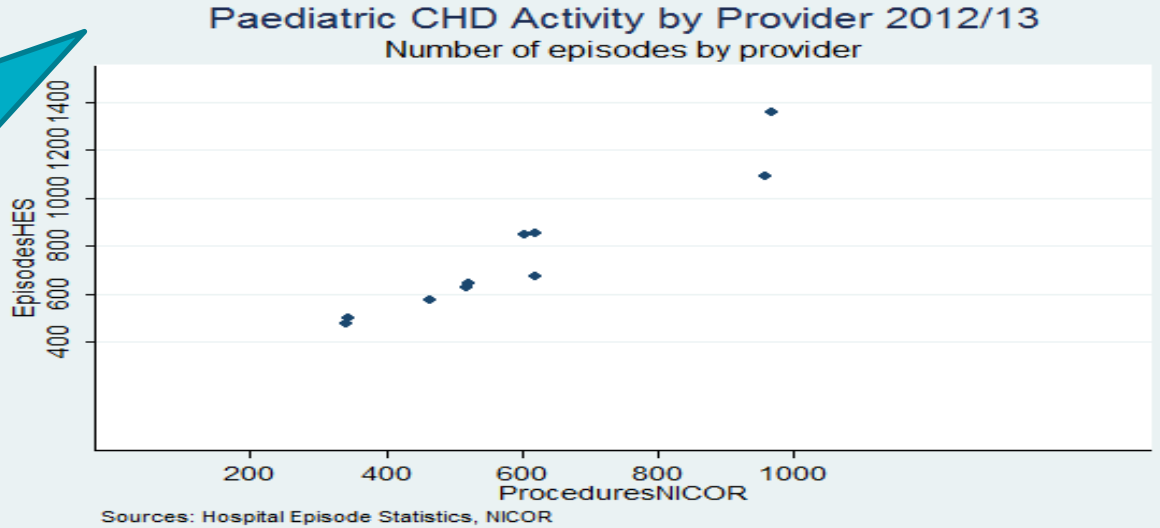
* Uplifted figure if we assume NICOR figure represents 80% of total
NICOR figures won't match website as only England and Wales residents treated in NHS E providers are included in figure above – website is all patients all reporting providers

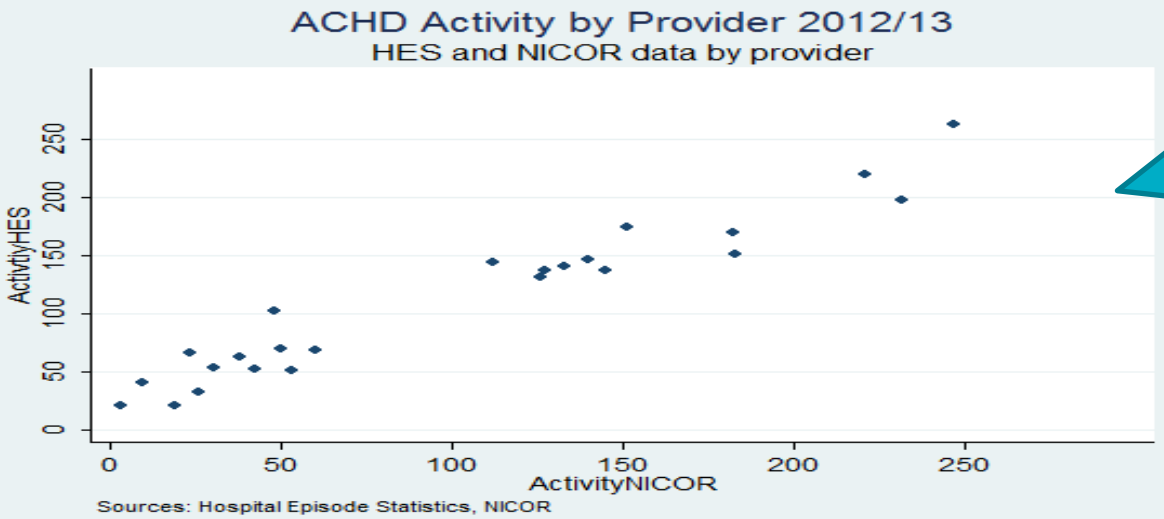
To note: definition of child vs adult. NICOR define a child as aged 0-16. The IRs for specialised commissioning define a child as aged 0-18. HES data is extracted on the latter, and will use this as the main definition going forward. Where using comparison with NICOR we compare activity for 0-16 only.

At provider level activity NICOR and HES data compare well

Paediatric (age 0-16 for comparison)
Strong results for rank correlation* and a correlation coefficient of 0.96

* Spearman's Rank and Kendall's Tau



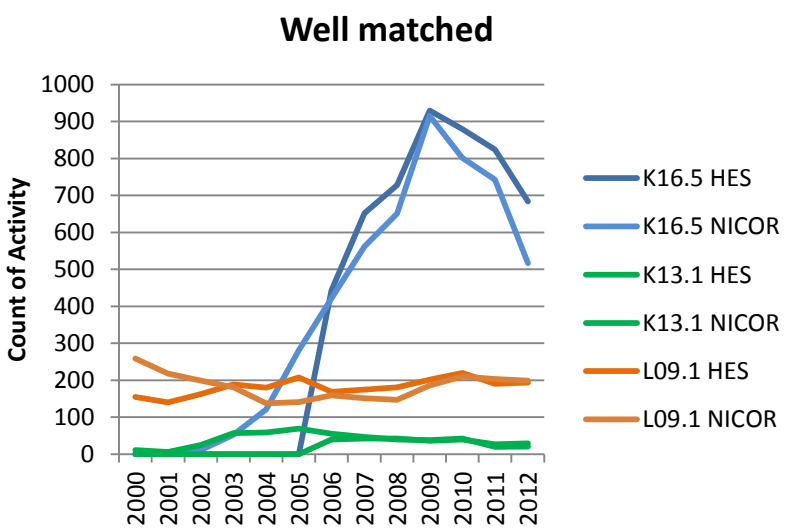


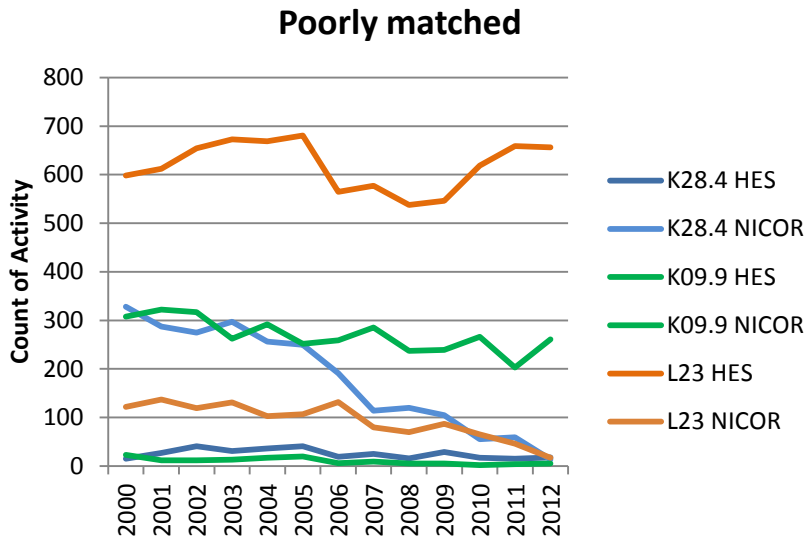
ACHD (age 17+ for comparison)
Strong results for rank correlation* and a correlation coefficient of 0.97

* Spearman's Rank and Kendall's Tau

At procedure level activity it is less clear

- Six procedures are chosen where the codes should map across the two data sets reasonably well; their activity is charted below for HES and NICOR
- Three of the procedures appear to have similar numbers and patterns in both data (left panel)
- Three appear to have very different numbers and patterns in both data (right panel)

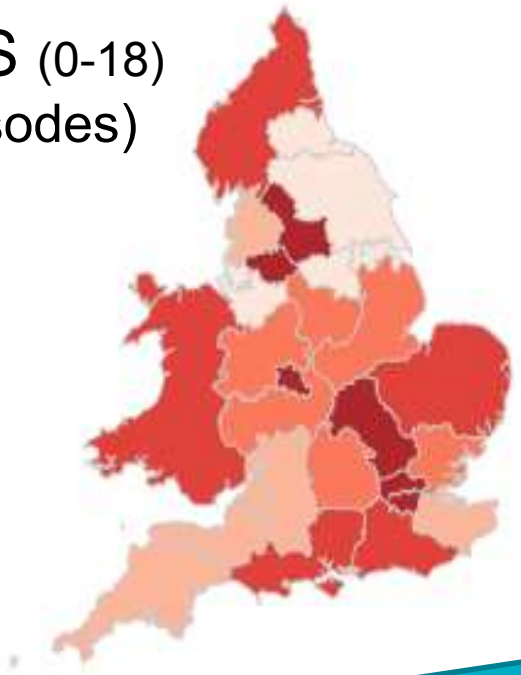


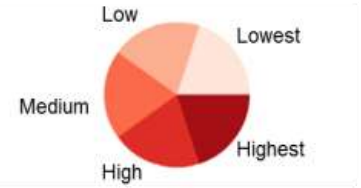


At Area Team of where the patient lives it looks OK

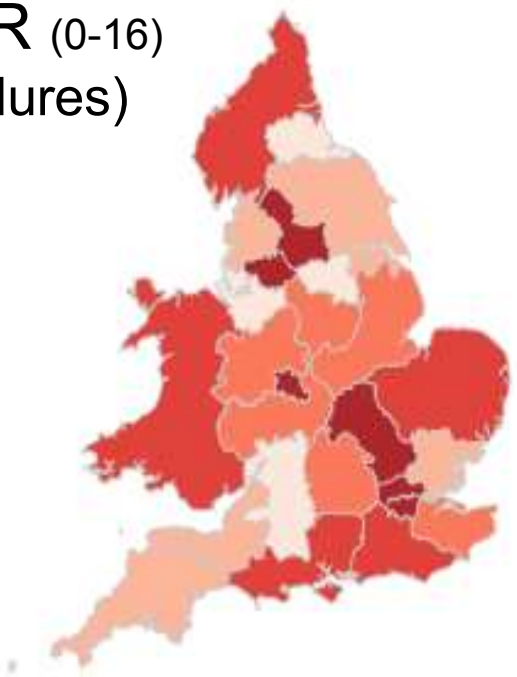
Paediatric 2012/13 activity by Area Team of patient residence

HES (0-18) (episodes)





NICOR (0-16) (procedures)

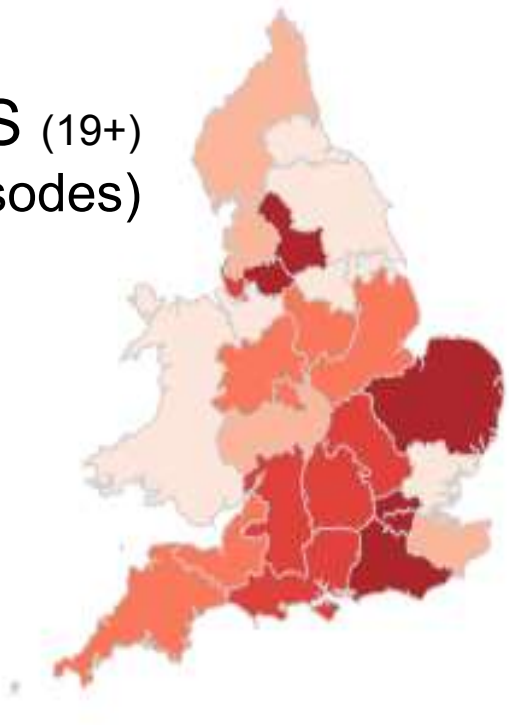


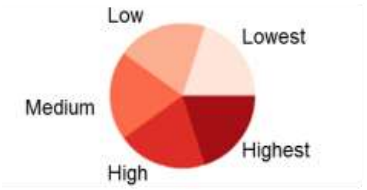
Similar patterns in which patient areas have the highest activity levels – paediatric activity 2012/13

At Area Team of where the patient lives it looks OK

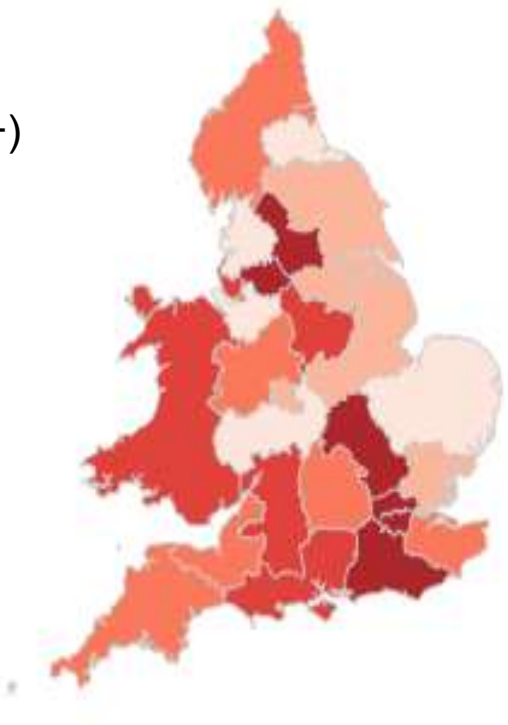
ACHD 2012/13 activity by Area Team of patient residence

HES (19+) (episodes)



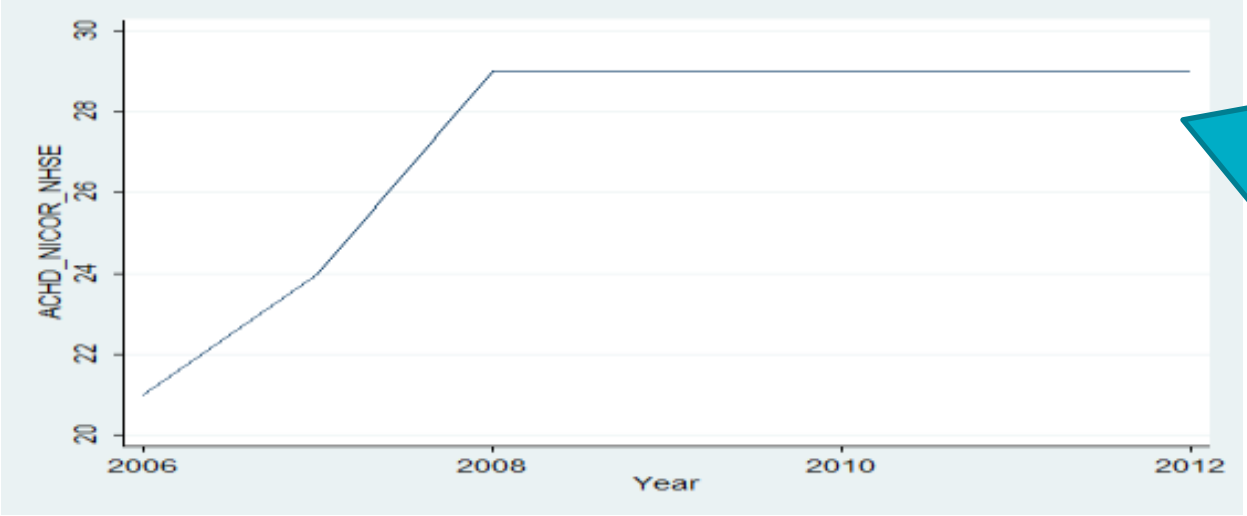


NICOR (17+) (procedures)



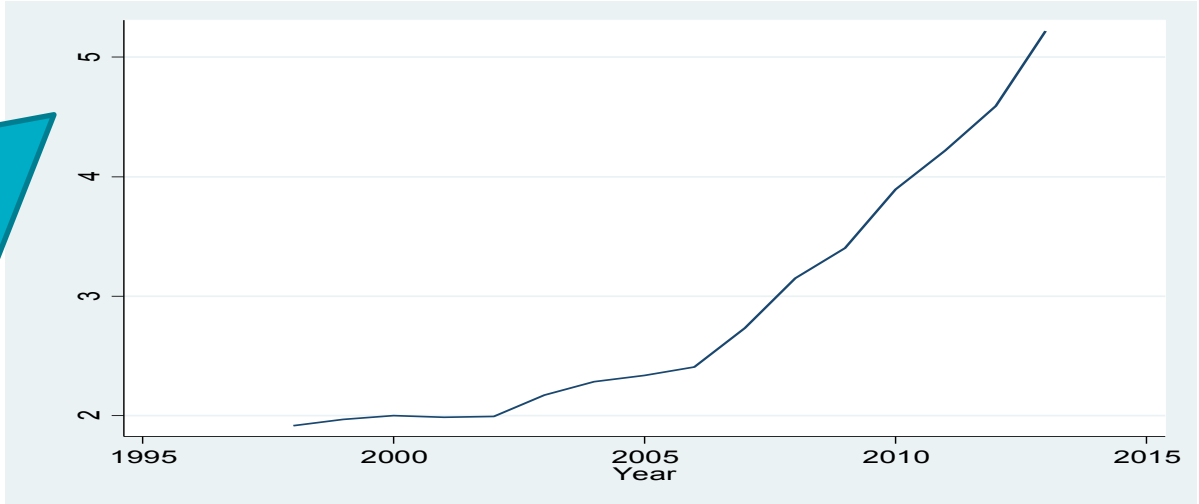
Similar patterns in which patient areas have the highest activity levels – ACHD activity 2012/13 - although comparison less reliable due to underreporting in NICOR data by some provider which **will bias certain areas.**

Both datasets may be affected by changes in reporting over time



NICOR ACHD data – not all NHS E and Wales providers report to NICOR but the number who do has increased over time from 21 in 2006/7 to 29 in 2012/13

HES data – Over time there have been changes in coding practice (especially with push to PbR payment in 06/07). The depth of coding has increased. For ACHD activity pre 2006/7 data was significantly distorted so has not been used.



This is a key caveat when considering past trends

Scope and coverage of the data and analysis:

Baseline year	2012/13
Population	England and Wales residents Paediatric = 0-18 (NICOR data only covers 0-16) Adult = 19+
Procedures included	NICOR: Surgical and catheter interventions reported to NICOR/CCAD congenital database HES: Procedures identified in the IRs and by clinicians as paediatric cardiac or ACHD procedures
Historic data	ACHD: 2006/07 -2012/13 Paeds: 2003/04– 2012/13
Projected data	• 2013-2025 (nationally) • 2013-2021 (sub nationally)
Projection Scenarios	• Population growth pressure only • Population growth plus continuation of historic trend
Sources	• NICOR CCAD database • HES APC data • ONS 2012 based projections for England • ONS 2011 based subnational projections by local authority

Item 7 Annex A

New Congenital Heart Disease Review

2012/13 baseline activity

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2012/13 is our baseline year

2012/13 data for patients in England and Wales:

Age	NICOR (procedures)	HES (episodes)
Paediatric (0-16)	5,700	7,500
Paediatric (0-18)	N/A	8,200
ACHD (17+)	2,400 (3,000*)	3,100
ACHD (19+)	N/A	2,400

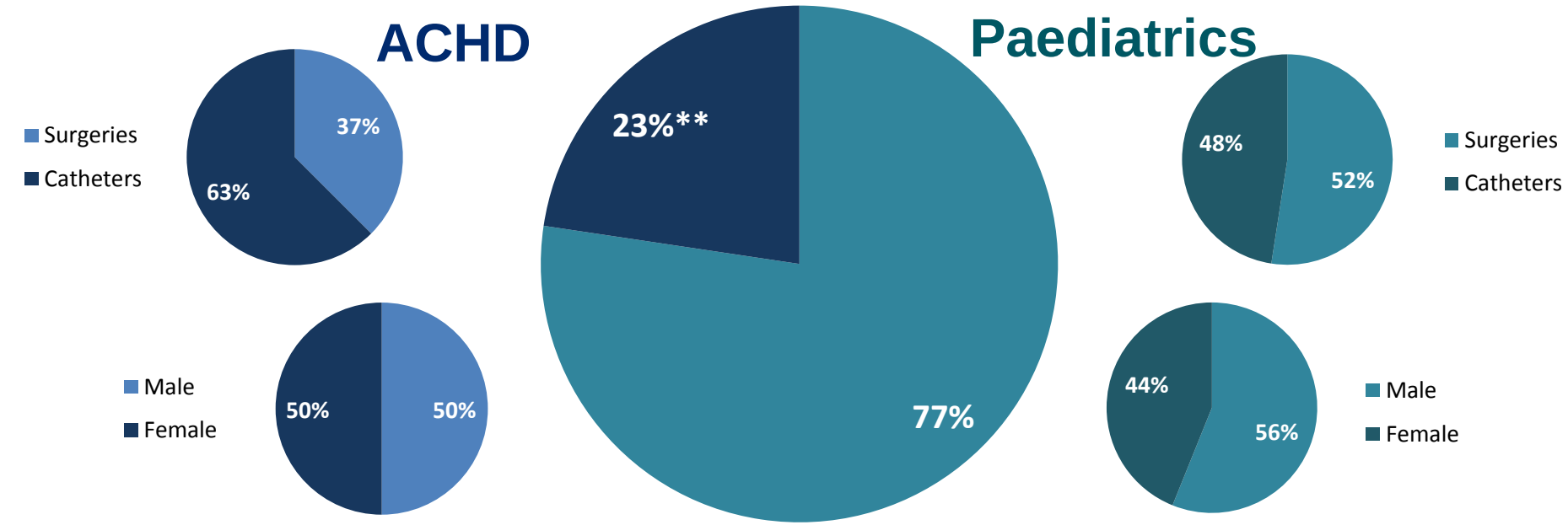
*Uplifted figure if we assume NICOR figure represents 80% of total

To note:
NICOR figures won't match website as only England and Wales residents treated in NHS E providers are included in figure above – website figures cover all patients for all reporting providers not just NHS England providers

In 2012/13…

Most episodes are for paediatrics (0-18), although the data could underestimate adult activity. According to our HES definition this activity is evenly split between catheters and surgeries, with more episodes for males rather than females

For adults most episodes are for catheter procedures and evenly split across males and females



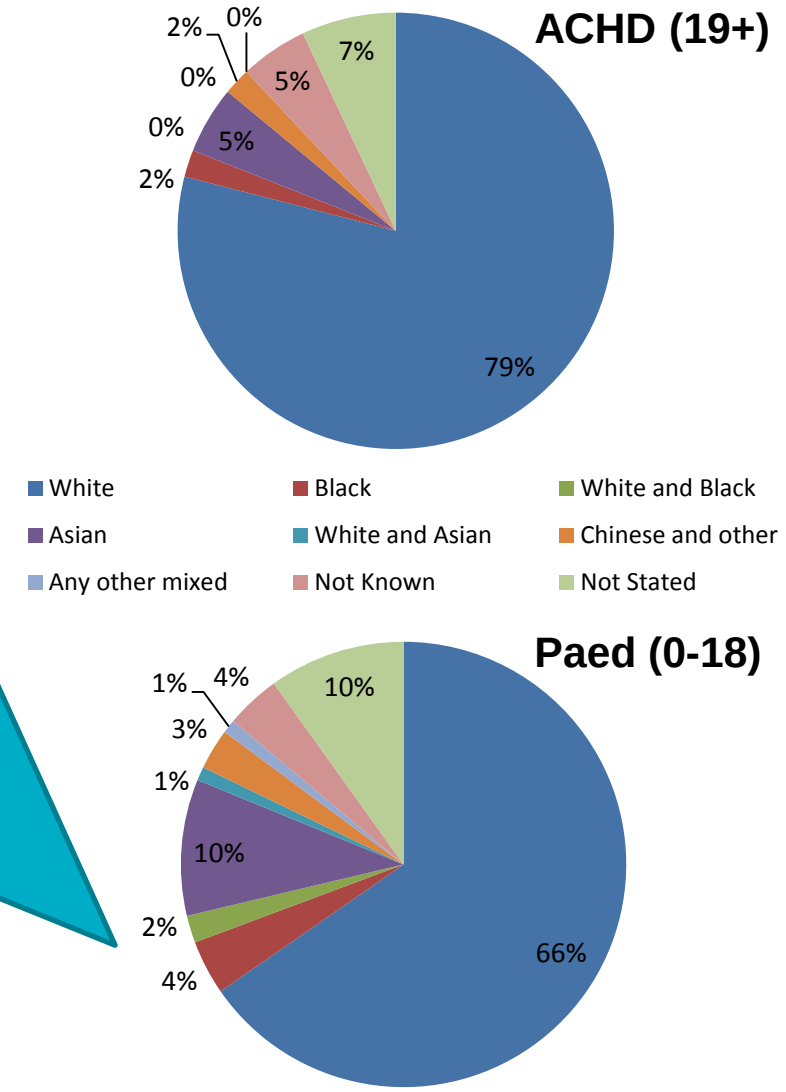
Source: HES data

** ACHD activity could be underestimated in the data. NICOR figures suggest activity for 17+= 34% so 19+ would be <34%

In 2012/13…

Ethnicity (%)	Episodes	England and Wales*
ACHD		
White	79%	88%
Black	2%	3%
White and Black	0%	N/A
Asian	5%	7%
White and Asian	0%	N/A
Chinese and other	2%	1%
Any other mixed	0%	2%
Not Known	5%	N/A
Not Stated	7%	N/A
Paed cardiac		
White	66%	79%
Black	4%	5%
White and Black	2%	N/A
Asian	10%	9%
White and Asian	1%	N/A
Chinese and other	3%	1%
Any other mixed	1%	6%
Not Known	4%	N/A
Not Stated	10%	N/A

A higher proportion of paed cardiac activity is for people from BME ethnic groups compared to ACHD activity, and for both it may be higher than the general population

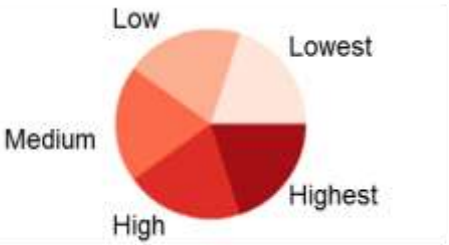


Source: HES data 2012/13 and ONS Census 2011

In 2012/13…

2012/3 activity (HES episodes) by area of patient residence

Paediatric (0-18)



ACHD (19+)

Activity varies by area of patient residence – some areas are "hotter" than others

In 2012/13…

Paed Cardiac Episodes	
GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST	1388
BIRMINGHAM CHILDREN'S HOSPITAL NHS FOUNDATION TRUST	1104
ROYAL BROMPTON AND HAREFIELD NHS FOUNDATION TRUST	917
ALDER HEY CHILDREN'S NHS FOUNDATION TRUST	859
GUY'S AND ST THOMAS' NHS FOUNDATION TRUST	700
UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION TRUST	684
LEEDS TEACHING HOSPITALS NHS TRUST	682
UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST	606
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST	529
THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST	518
OXFORD UNIVERSITY HOSPITALS NHS TRUST	59
OTHER PROVIDERS	560
TOTAL	8600*

ACHD Episodes	
PAPWORTH HOSPITAL NHS FOUNDATION TRUST	268
ROYAL BROMPTON AND HAREFIELD NHS FOUNDATION TRUST	166
UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION TRUST	164
UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST	151
LIVERPOOL HEART AND CHEST NHS FOUNDATION TRUST	146
LEEDS TEACHING HOSPITALS NHS TRUST	126
CENTRAL MANCHESTER UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	121
OXFORD UNIVERSITY HOSPITALS NHS TRUST	112
UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST	104
UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST	102
GUY'S AND ST THOMAS' NHS FOUNDATION TRUST	99
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST	81
THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST	80
IMPERIAL COLLEGE HEALTHCARE NHS TRUST	80
UNIVERSITY HOSPITAL OF NORTH STAFFORDSHIRE NHS TRUST	62
BRIGHTON AND SUSSEX UNIVERSITY HOSPITALS NHS TRUST	58
BARTS HEALTH NHS TRUST	56
UNIVERSITY HOSPITAL OF SOUTH MANCHESTER NHS FOUNDATION TRUST	55
KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST	54
OTHER PROVIDERS	370
TOTAL	2500*

11 Paed Cardiac providers and 19 ACHD providers provided more than 50 episodes of care according to our **HES** dataset

(* Figures include ALL patients treated by these providers not just patients from England and Wales)

New Congenital Heart Disease Review

In 2012/13…

Paed Cardiac - Procedures	
GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST	960
BIRMINGHAM CHILDREN'S HOSPITAL NHS FOUNDATION TRUST	930
GUY'S AND ST THOMAS' NHS FOUNDATION TRUST	620
ALDER HEY CHILDREN'S NHS FOUNDATION	610
ROYAL BROMPTON AND HAREFIELD NHS FOUNDATION TRUST	600
UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION TRUST	520
LEEDS TEACHING HOSPITALS NHS TRUST	510
UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST	450
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST	370
THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST	340
OXFORD UNIVERSITY HOSPITALS NHS TRUST	15
TOTAL	5900*

11 Paed Cardiac Providers and 25 ACHD providers in NHS England reported to **NICOR** that they provided relevant activity

(* Figures include ALL patients treated by these providers not just patients from England and Wales)

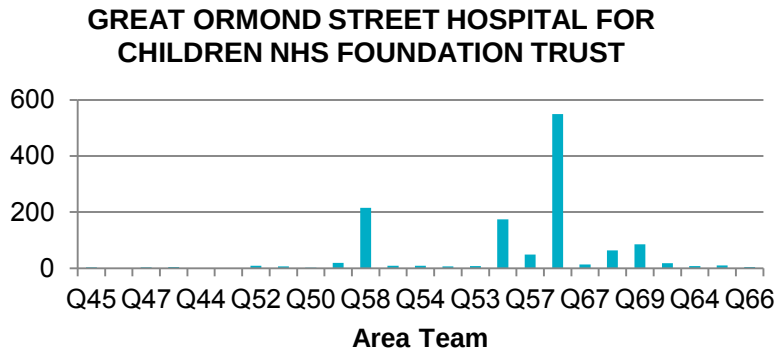
ACHD Procedures	
ROYAL BROMPTON AND HAREFIELD NHS FOUNDATION TRUST	250
LEEDS TEACHING HOSPITALS NHS TRUST	240
UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION TRUST	220
CENTRAL MANCHESTER UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	190
UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST	180
LIVERPOOL HEART AND CHEST NHS FOUNDATION TRUST	150
GUY'S AND ST THOMAS' NHS FOUNDATION TRUST (GUY)	150
THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST	140
UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST	130
UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST	130
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST	130
OXFORD UNIVERSITY HOSPITALS NHS TRUST	110
BRIGHTON AND SUSSEX UNIVERSITY HOSPITALS NHS TRUST	60
UNIVERSITY HOSPITAL OF NORTH STAFFORDSHIRE NHS TRUST	50
IMPERIAL COLLEGE HEALTHCARE TRUST	50
ST GEORGE'S HEALTHCARE NHS TRUST	50
GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST	40
GUY'S AND ST THOMAS' NHS FOUNDATION TRUST (St T)	40
BIRMINGHAM CHILDREN'S HOSPITAL NHS FOUNDATION TRUST	40
NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST	30
SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST	30
KINGS COLLEGE HOSPITAL NHS FOUNDATION TRUST	20
ALDER HEY CHILDREN'S NHS FOUNDATION TRUST	15
BLACKPOOL TEACHING HOSPITALS NHS FOUNDATION TRUST	<10
UNIVERSITY HOSPITALS COVENTRY AND WARWICKSHIRE	<10
THE ROYAL WOLVERHAMPTON NHS TRUST	<10
BASILDON AND THURROCK UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	<10
TOTAL	2500*

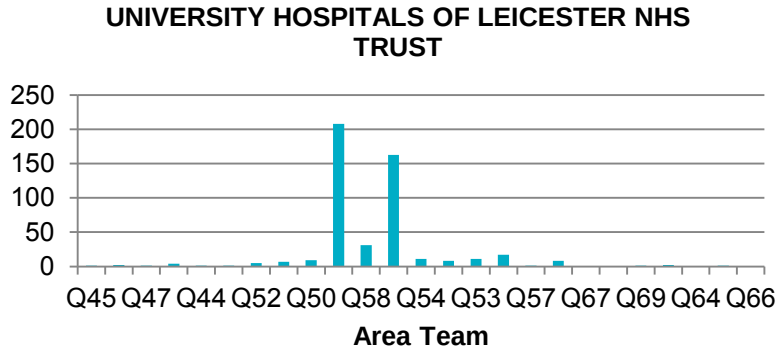
In 2012/13…

Paediatric activity by area of patient residence for different providers

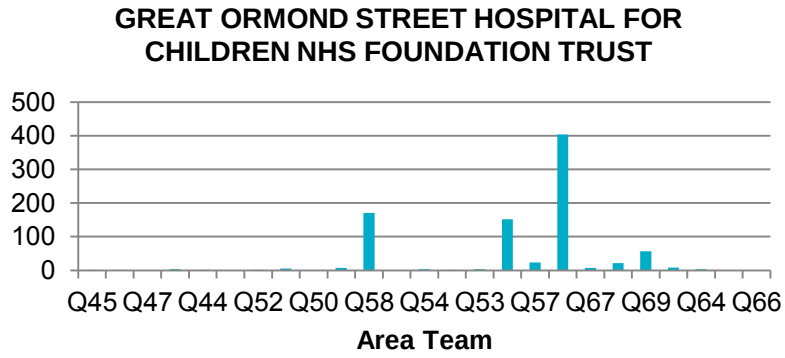
An example of how different providers have different "catchment" areas

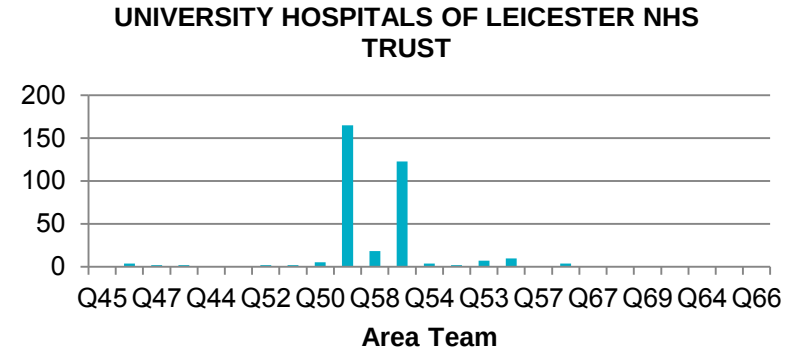
HES





NICOR





Similar patterns in both datasets

In 2012/13…

Paed Cardiac - HES		
OPCS code	*Procedure description*	*Count of episodes*
L02.2	Ligature of patent ductus arteriosus	1018
K63.1	Angiocardiography of combination of right and left side of heart	569
K10.4	Primary repair of defect of interatrial septum NEC	451
L03.1	Percutaneous transluminal prosthetic occlusion of patent ductus arteriosus	421
K61.1	Implantation of cardiac pacemaker system NEC	415
K11.2	Repair of defect of interventricular septum using pericardial patch	320
K11.1	Repair of defect of interventricular septum using prosthetic patch	305
L10.2	Repair of pulmonary artery using patch	294
K58.2	Percutaneous transluminal electrophysiological studies on conducting system of heart	290
K57.4	Percutaneous transluminal ablation of accessory pathway	274

ACHD - HES		
OPCS code	*Procedure description*	*Count of episodes*
K16.5	Percutaneous transluminal closure of patent oval foramen with prosthesis	665
K13.3	Percutaneous transluminal repair of defect of interatrial septum using prosthesis	332
K10.4	Primary repair of defect of interatrial septum NEC	188
L04.1	Pulmonary thromboendarterectomy	141
K10.2	Repair of defect of interatrial septum using pericardial patch	138
L13.2	Percutaneous transluminal embolisation of pulmonary artery	104
K16.6	Percutaneous transluminal chemical mediated septal ablation	72
L10.2	Repair of pulmonary artery using patch	52
L03.1	Percutaneous transluminal prosthetic occlusion of patent ductus arteriosus	50
K11.2	Repair of defect of interventricular septum using pericardial patch	43

2012/13 top 10 procedures by episode count according to our extract of HES data

In 2012/13…

Paed Cardiac (0-16) Procedures	
PDA closure (catheter)	574
PDA ligation (surgical)	373
VSD Repair	351
Radiofrequency ablation for supraventricular tachycardia	333
Tetralogy repair	306
Isolated coarctation repair	281
ASD closure (catheter)	251
Bidirectional cavopulmonary shunt	243
ASD repair	228
Pulmonary balloon valvoplasty	225

ACHD (17+) Procedures	
PFO closure (catheter)	506
ASD closure (catheter)	421
Pulmonary valve replacement	257
Radiofrequency ablation for supraventricular tachycardia	158
Aortic Valve Replacement - non Ross	149
ASD repair	106
Coarctation stenting	77
Aortic root replacement (not Ross)	55
Implantable Cardioverter Defibrillator	44
Transcatheter PVR	41

2012/13 top 10 procedures by count according to NICOR

(data taken from website 7th July 2014 – will include ALL patients and all providers not just NHS England)

In 2012/13…

From HES data:

Some episodes had a zero length of stay:

- 28% of episodes for Paediatric CHD patients
- 20% of episodes for ACHD patients

Of those episodes that covered at least one night, the average length of stay was around :

- 9 days for paediatric patients
- 8 days for ACHD patients

Item 7 Annex A

New Congenital Heart Disease Review

NHS England

Historic trends

Joanna Glenwright
John Buckell
Charles Keenan

THE NHS CONSTITUTION
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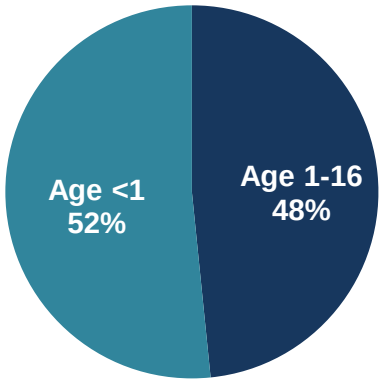
Historic trends: paediatric activity growth over time

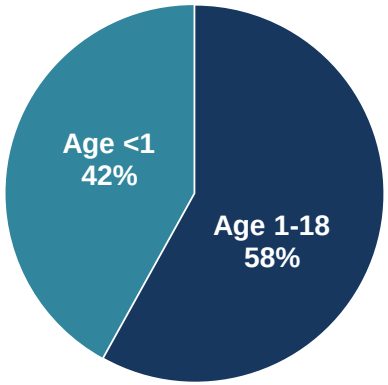
In the next slide we look at 2003/4 to 2012/13 growth in national paediatric activity over time

A significant % of paediatric activity is for children aged under 1 year (infants and neonates)

NICOR data (0-16)



HES data (0-18)



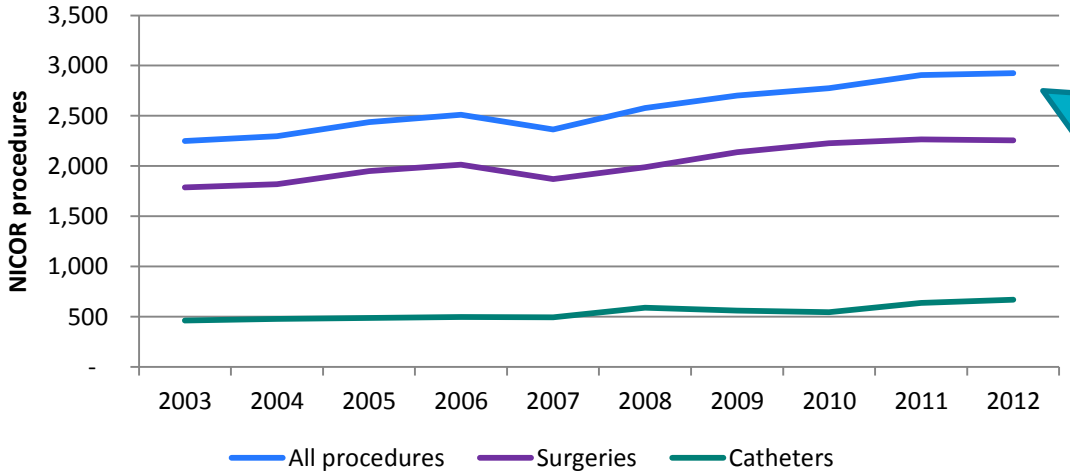
Therefore we consider paediatric activity growth over time by two groups:

1. aged under 1
2. aged 1+

Numbers may not sum due to rounding

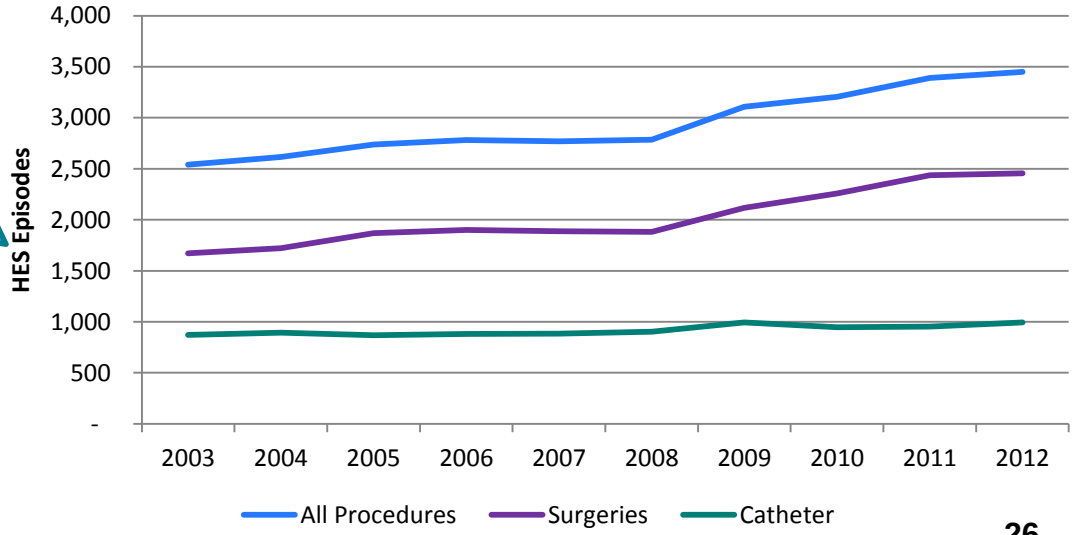
Historic trends: paediatric under 1 activity growth over time

2003/4 to 2012/13 growth in national paediatric under 1 activity over time



NICOR (<1) activity data counts reported procedure numbers – All procedures have increased steadily over time from around 2,200 in 2003/4 to 2,900 in 2012/13 (**30%**)

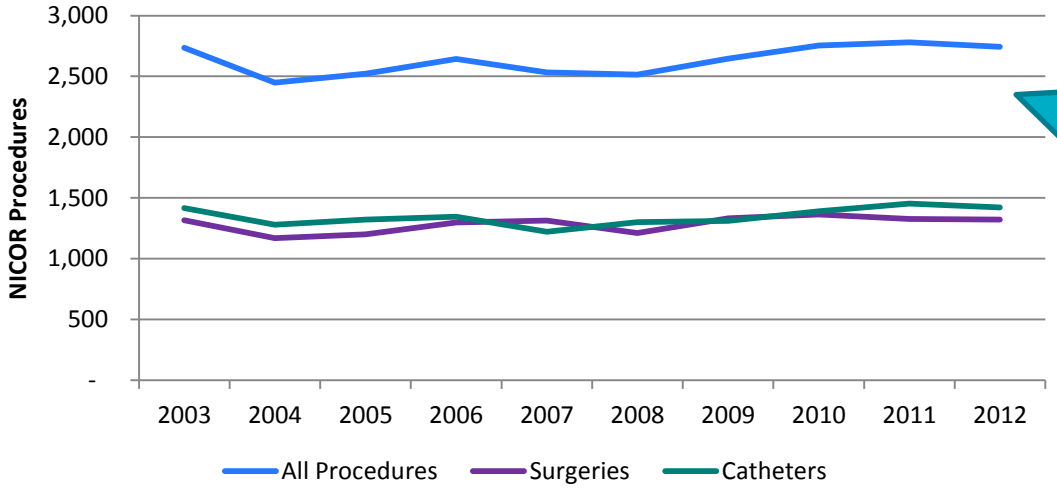
HES (<1) activity data counts episodes of care – Episodes for all procedures have increased steadily over time from around 2,500 in 2003/4 to 3,400 in 2012/13 (**36%**)



Numbers may not sum due to rounding

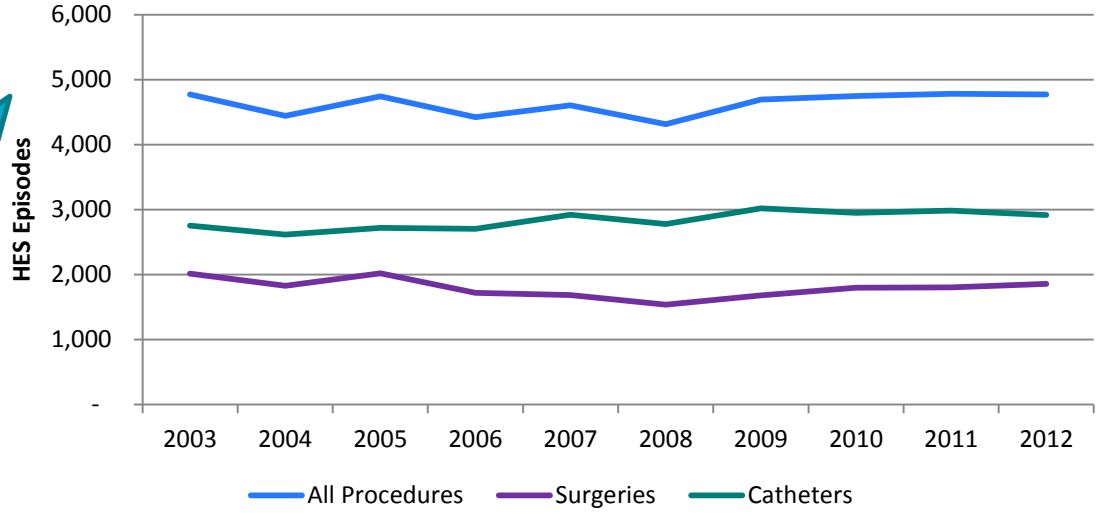
Historic trends: paediatric age 1 + activity growth over time

2003/4 to 2012/13 growth in national paediatric age 1+ activity over time



NICOR (1-16) activity data counts reported procedure numbers – All procedures have seen little change over the period, being around 2,700 in 2003/4 and 2012/13 (**0%**)

HES (1-18) activity data counts episodes of care – Episodes for all procedures have seen little change over the period, being around 4,700 in 2003/4 and 2012/13 (**0%**)

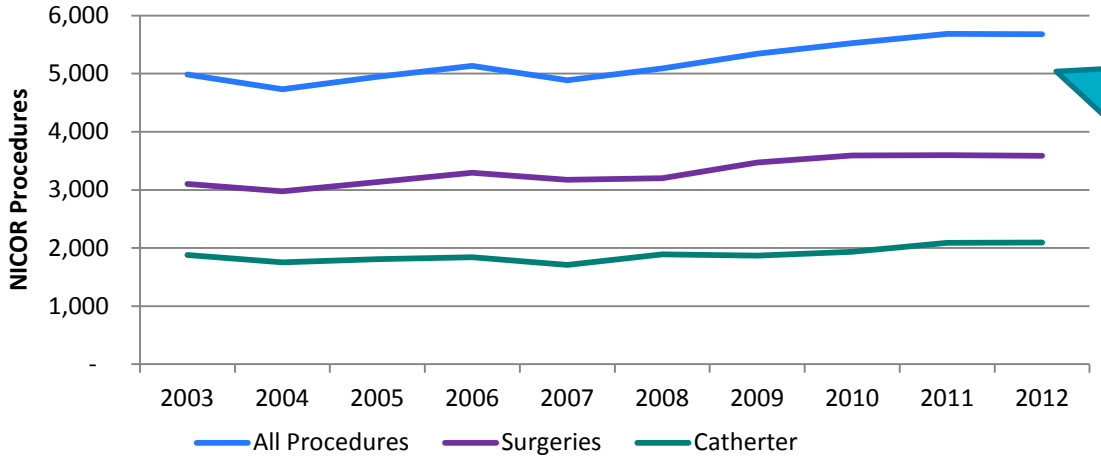


Numbers may not sum due to rounding

Driven by growth in activity for children aged under 1

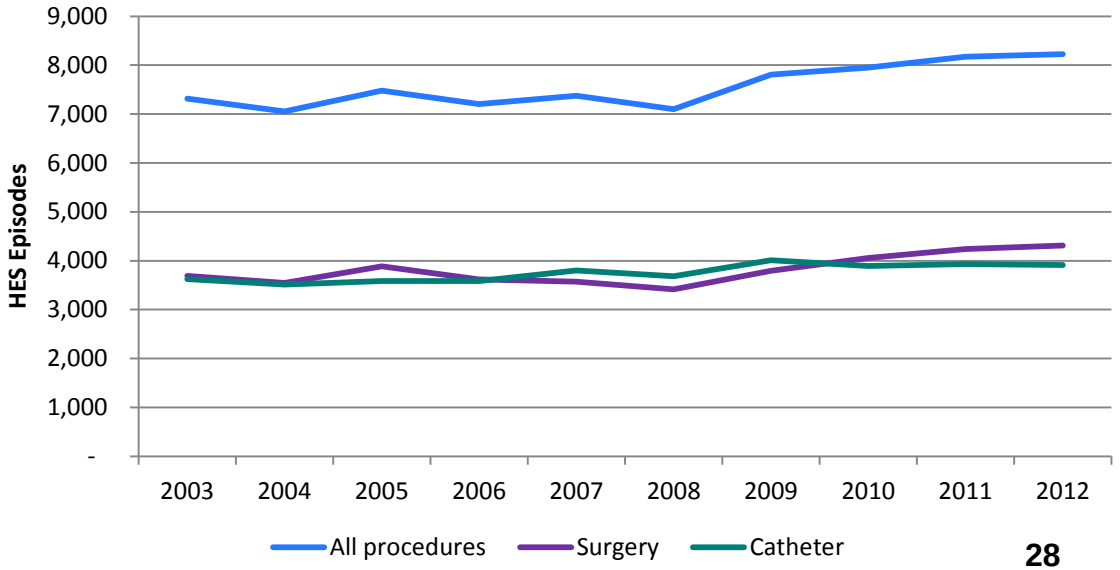
Historic trends: all paediatric activity growth over time

2003/4 to 2012/13 growth in national paediatric activity (all age) over time



NICOR (0-16) activity data counts reported procedure numbers – All procedures have increased steadily over time from around 5,000 in 2003/4 to 5,700 in 2012/13 (**14%**)

HES (0-18) activity data counts episodes of care – Episodes for all procedures have increased steadily over time from around 7,300 in 2003/4 to 8,200 in 2012/13 (**12%**)

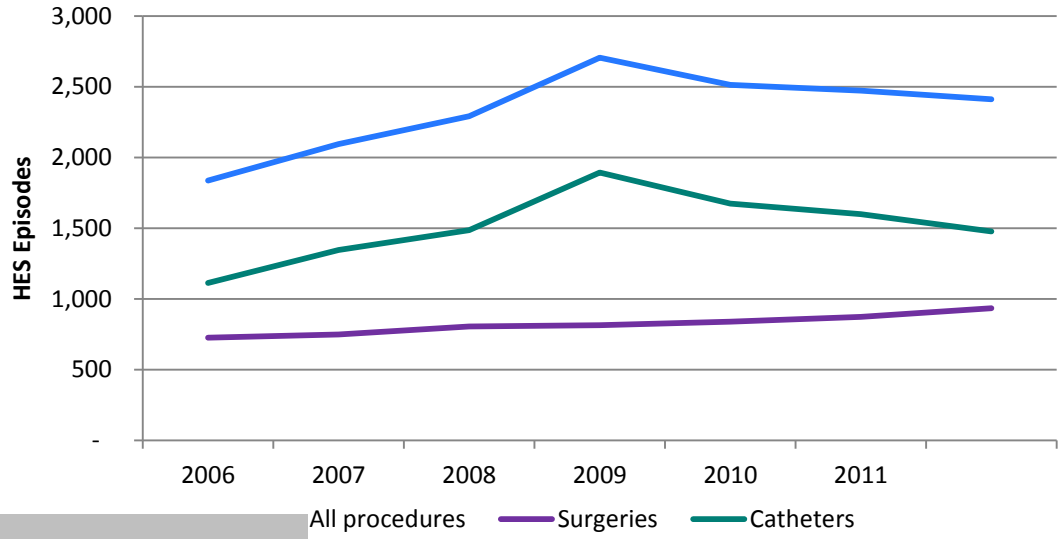


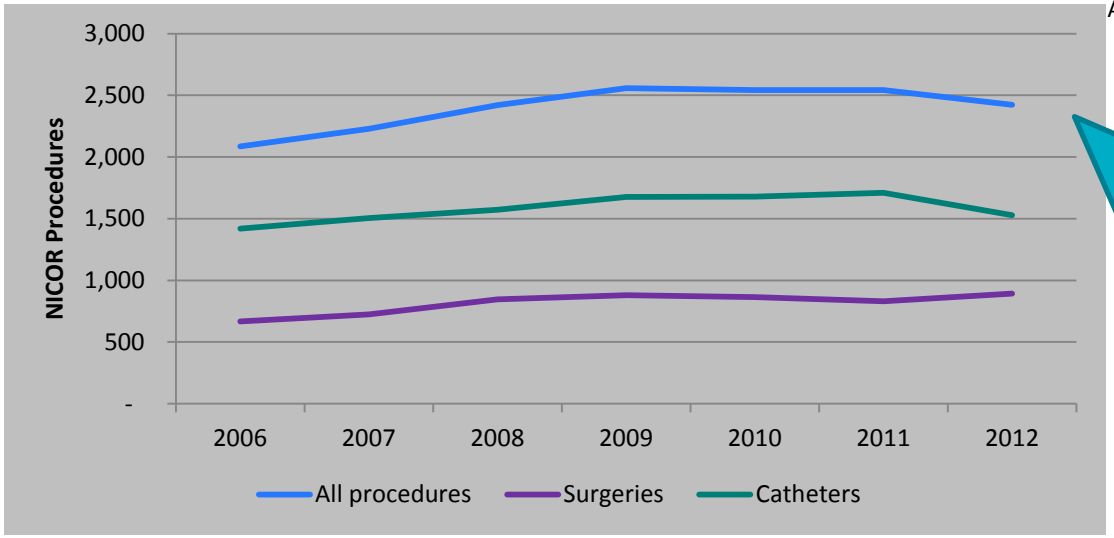
Numbers may not sum due to rounding

Historic trends: ACHD activity growth over time

2006/7 to 2012/13 growth in national ACHD activity over time

HES (19+) activity data counts episodes of care – Episodes have increased over time, mainly driven by increases in catheter procedures, from 1,800 in 2006/7 to 2,400 in 2012/13 (**31%**)

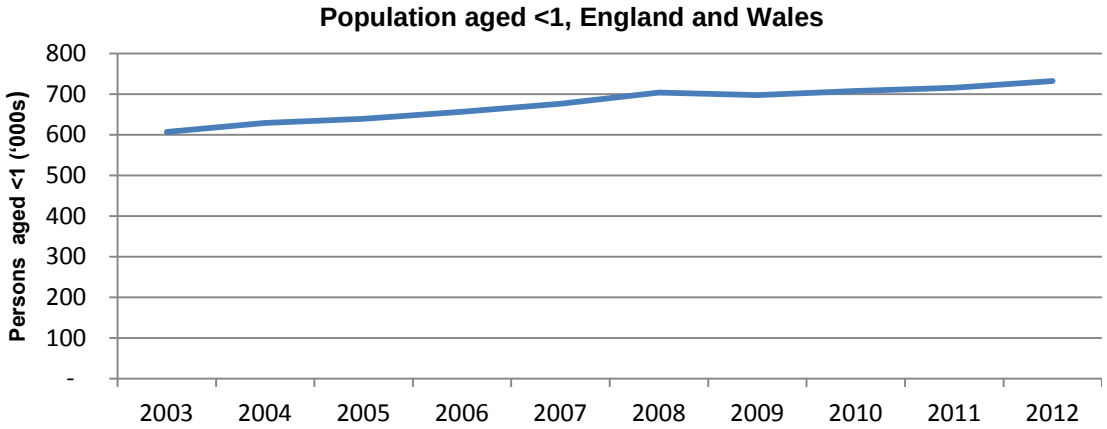




NICOR activity data counts reported procedure numbers – Over the last 10 years reporting has increased so the trend is distorted by this and cannot be used.

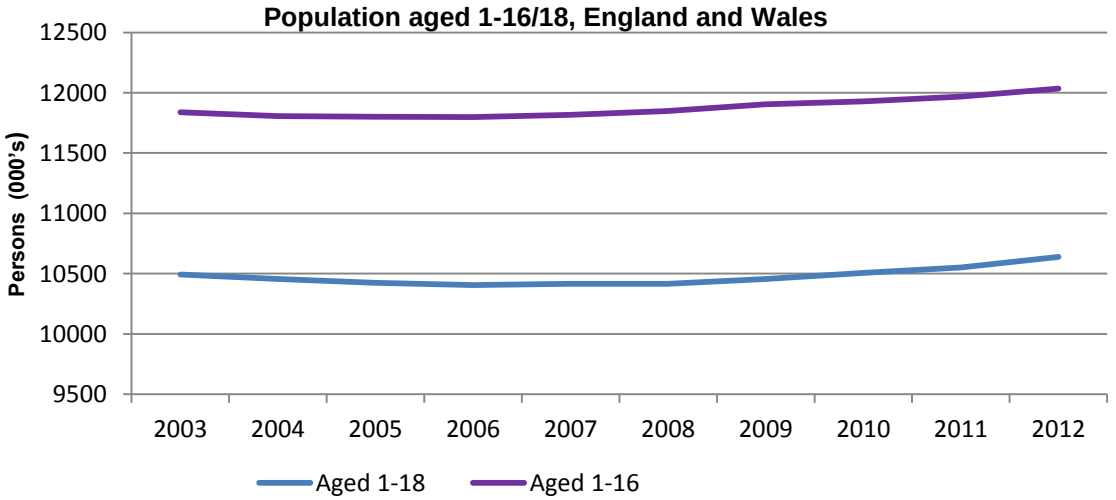
Historic trends: paediatric population growth (ONS data)

Paediatric population in total has grown over the last 10 years by around **3%,** but growth has varied by age within this

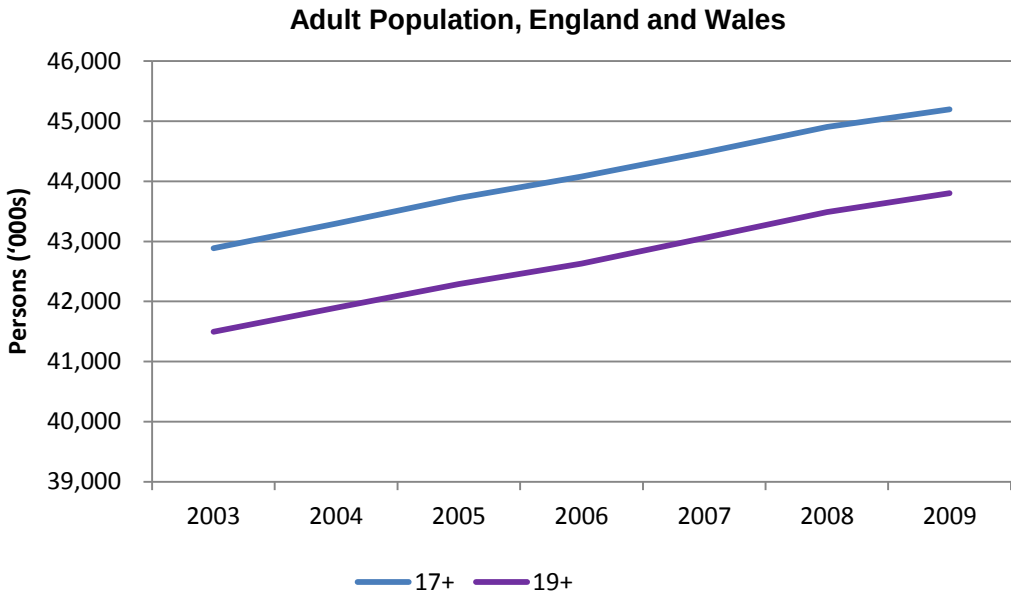


Over the last 10 years, the population aged under 1 has grown by **21%**

Over the last 10 years, the population of children over 1 has grown by **~2%**

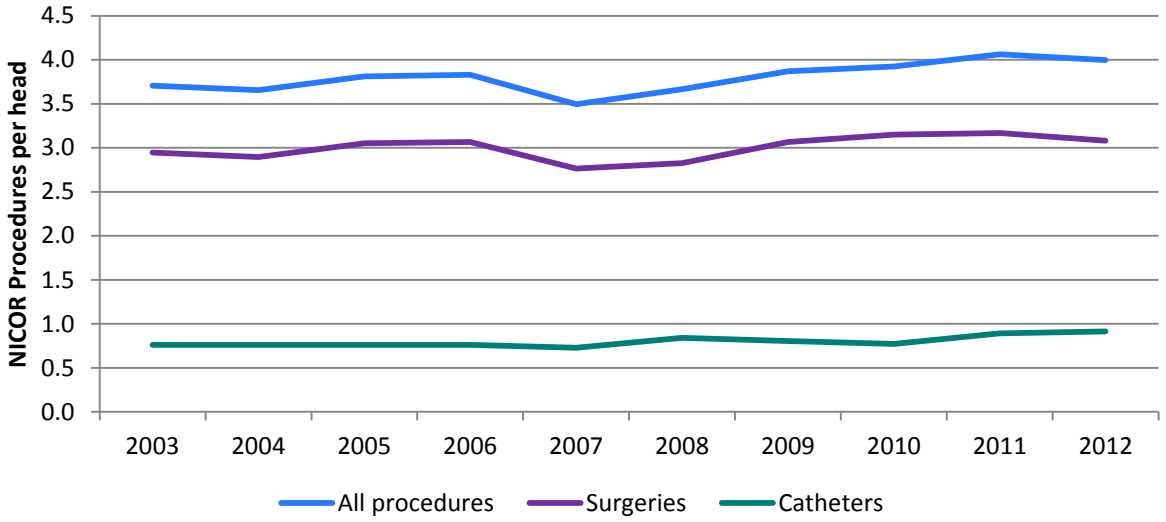


Historic trends: adult population growth (ONS data)



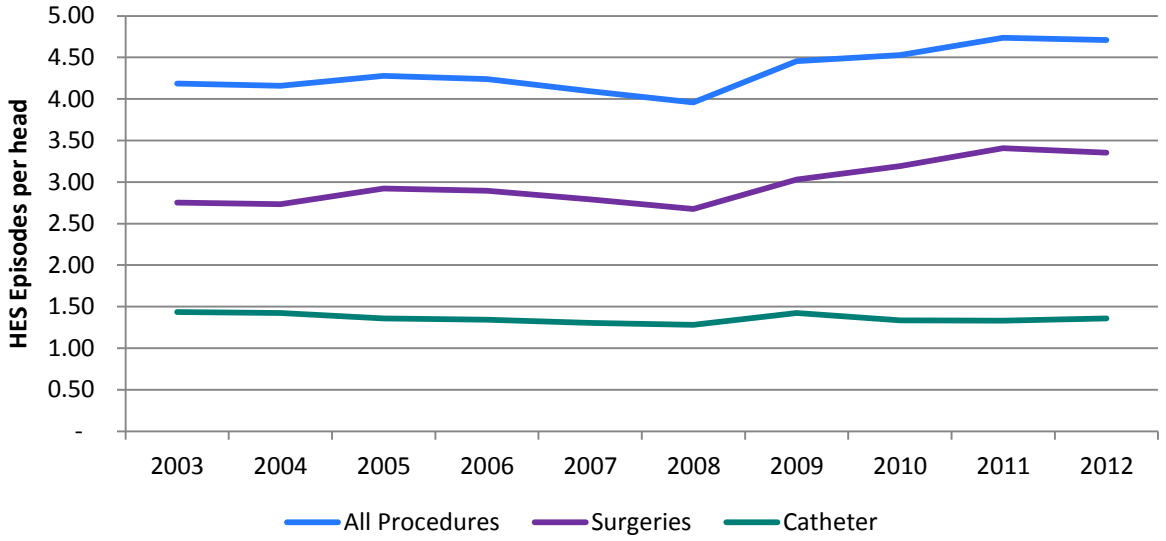
Adult population in England and Wales has grown over the last 7 years by around 6%

Historic trends: paediatric under 1 activity per head growth

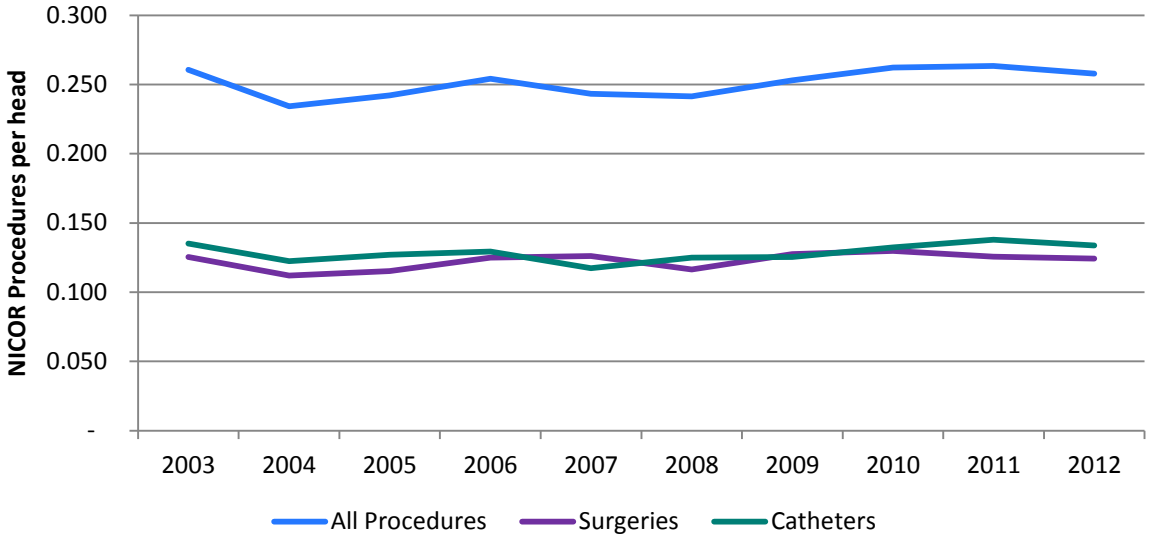


NICOR (<1) activity data – even once we have accounted for population growth there is still activity growth. Procedures per head of population grew by around **8%**

HES (<1) activity data – even once we have accounted for population data there is still activity growth. Episodes per head of population grew by around **13%**

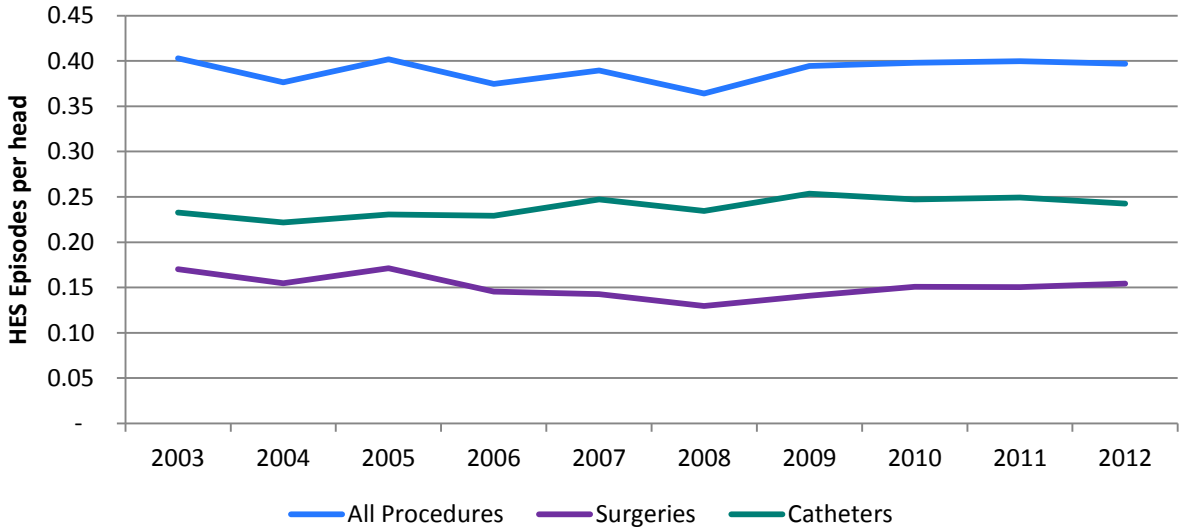


Historic trends: paediatric aged 1+ activity per head growth



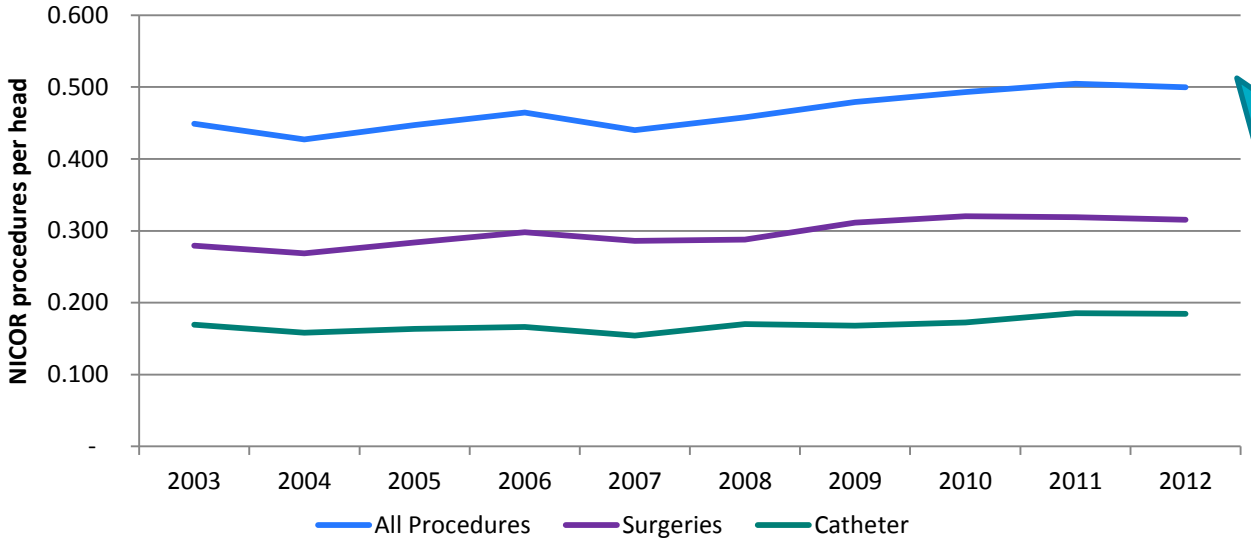
NICOR (1-16) activity data – once we have accounted for population growth activity look fairly stable with a slight decrease. Procedures per head of population grew by around **-1%**

HES (1-18) activity data – once we have accounted for population growth activity looks fairly stable with a slight decrease. Episodes per head of population grew by around **-2%**



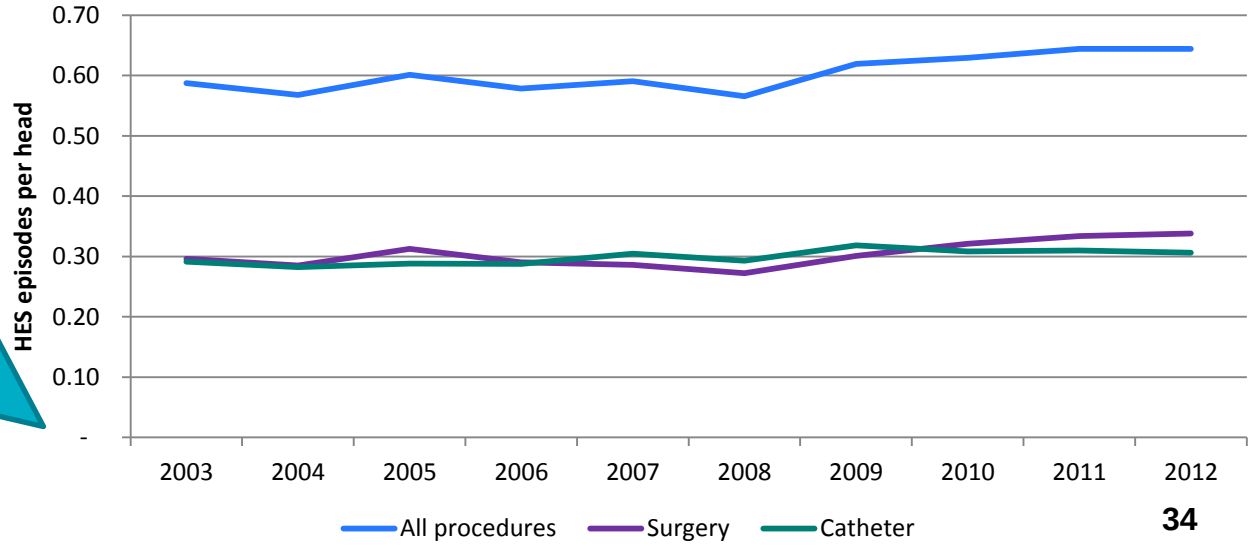
Driven by growth in activity for children aged under 1

Historic trends: all paediatric activity per head growth



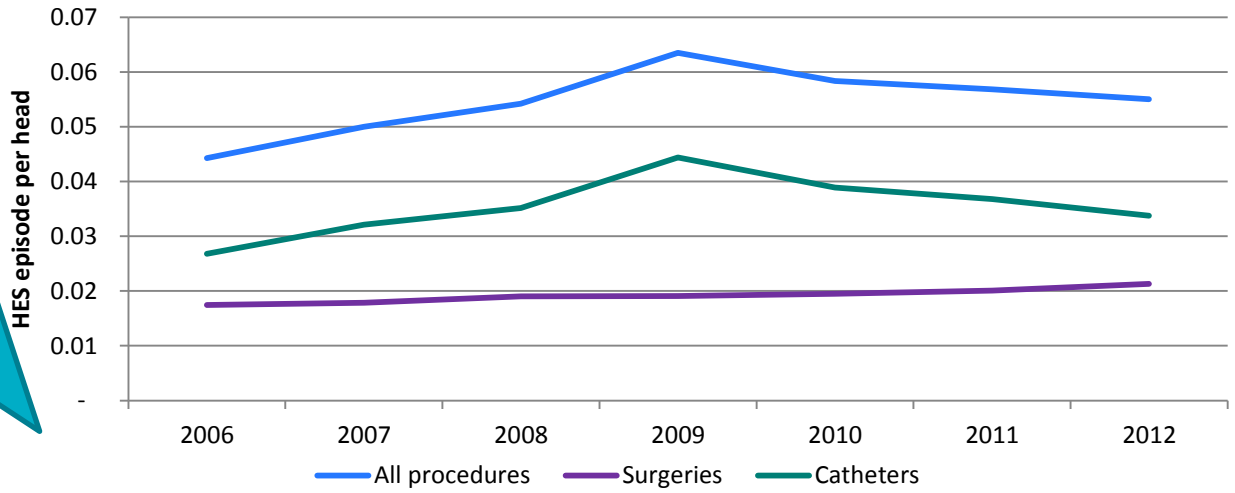
NICOR (0-16) activity data – even once we have accounted for population growth there is still activity growth. Procedures per head of population grew by around **11%**

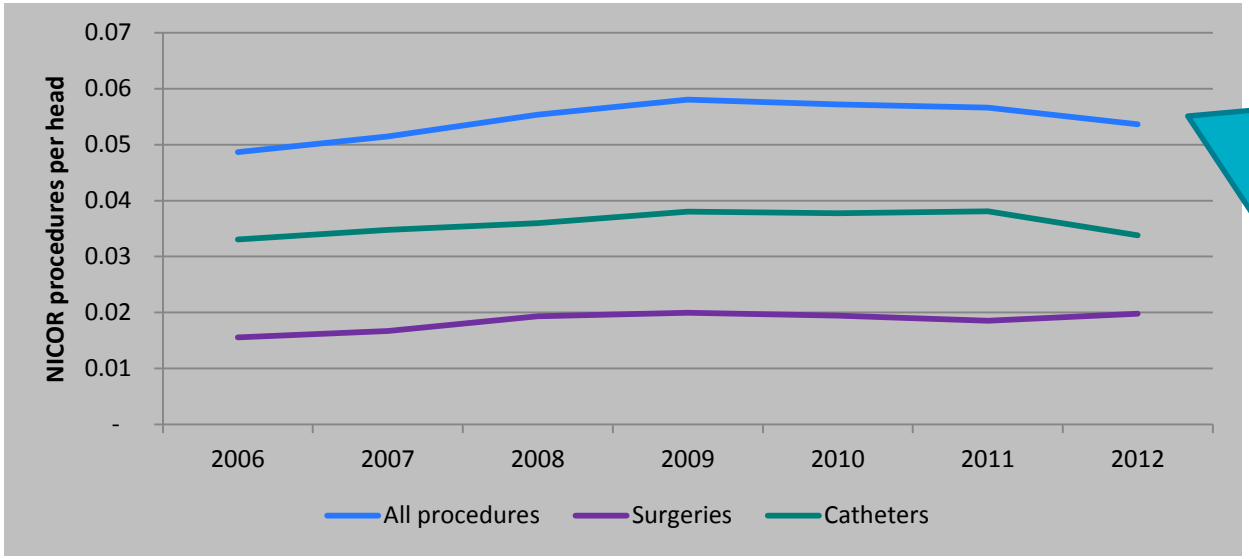
HES (0-18) activity data – even once we have accounted for population data there is still activity growth. Episodes per head of population grew by around **10%**



Historic trends: ACHD activity per head growth

HES activity data – even once we have accounted for population data there is still activity growth. Episodes per head of population grew by around **24%**





NICOR activity data counts reported procedure numbers – Reporting has increased over time so the trend is distorted by this and cannot be used.

Historic trends: activity growth summary

Summary of the historic pressures in Paediatric Cardiac and ACHD activity

	Paed Cardiac 2003-2012		ACHD 2006-2012	
	HES (0-18)	**NICOR (0-16)**	**HES (19+)**	**NICOR (17+)**
Activity growth	12%	14%	31%	N/A
of which population growth	3%	3%	6%	6%
gives remaining activity per head growth	10%	11%	24%	N/A

With Paediatric split out into under 1 and 1+ age groups

	Paed Cardiac 2003-2012			
	HES (<1)	**NICOR (<1)**	**HES (1-18)**	**NICOR (1-16)**
Activity growth	36%	30%	0%	0%
of which population growth	21%	21%	2%	2%
gives remaining activity per head growth	13%	8%	-2%	-1%

To note: numbers will not sum due to compounding effect and rounding

Historic growth by patient characteristic

Paed (0-18) 10 year change

Gender Changes	
Male	19%
Female	12%
Age Band Changes	
Neonate (0-30days)	32%
Infant (31-365 days)	32%
Child (1-16 yrs)	-5%
Child (17-18 yrs)	41%
Ethnicity band changes	
White	16%
Black	101%
White and Black	333%
Asian	102%
White and Asian	306%
Chinese	89%
Other	3%
Any other mixed	137%
Not Known	66%
Not Stated	-39%

ACHD (19+) 7 year change

Gender Changes	
Male	38%
Female	24%
Age Band Changes	
Adult 19-64	26%
Adult Over 65	49%
Ethnicity band changes	
White	37%
Black	10%
White and Black	267%*
Asian	59%
White and Asian	100%*
Chinese	0%
Other	141%
Any other mixed	-29%
Not Known	14%
Not Stated	-20%

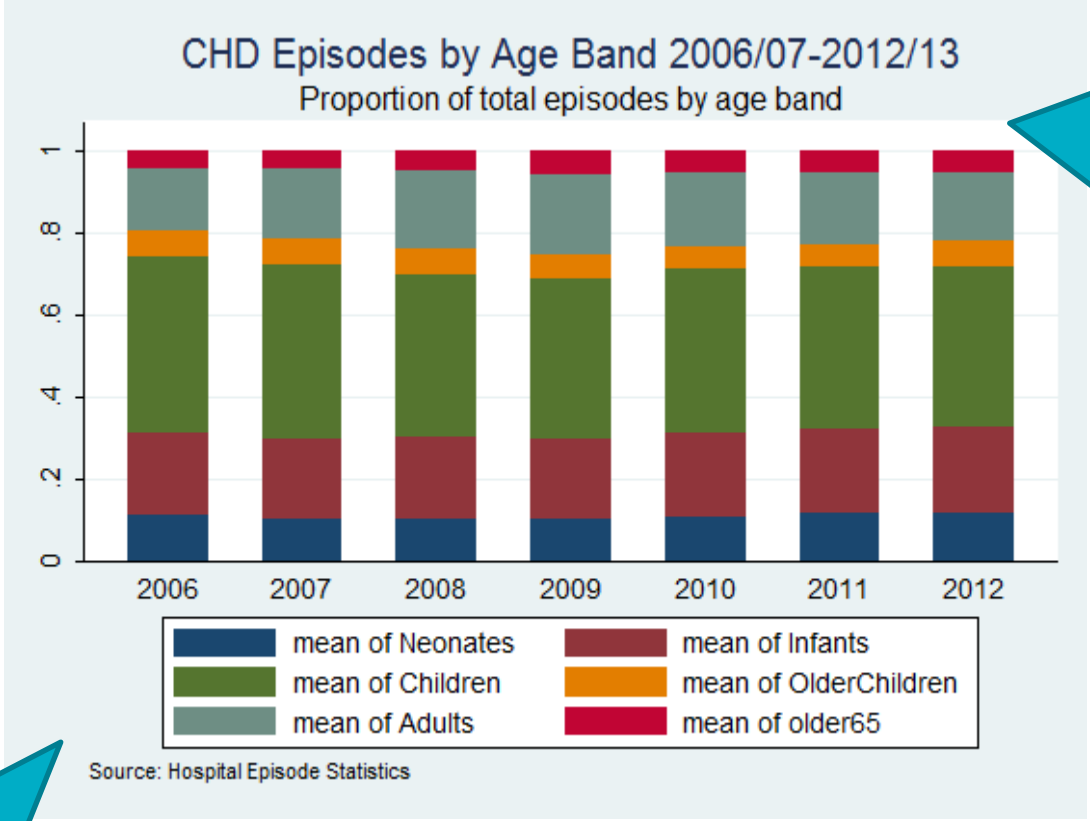
*very small numbers

Change in number of episodes with each patient characteristic between 2003/4 (Paeds) or 2006/7 (ACHD)and 2012/13 – interesting results circled. There has been higher growth in episodes for 17-18 yr. olds and over 65s, male episodes , BME paediatric episodes and Asian ACHD episodes.

See next slides for trends

Historic trends: activity by age

Neonate – 0-30 days
Infant – 30-365 days
Child – 1 – 16 years
Older child – 17-18 years
Adult - 19-64 years
Over 65 - 65+ years

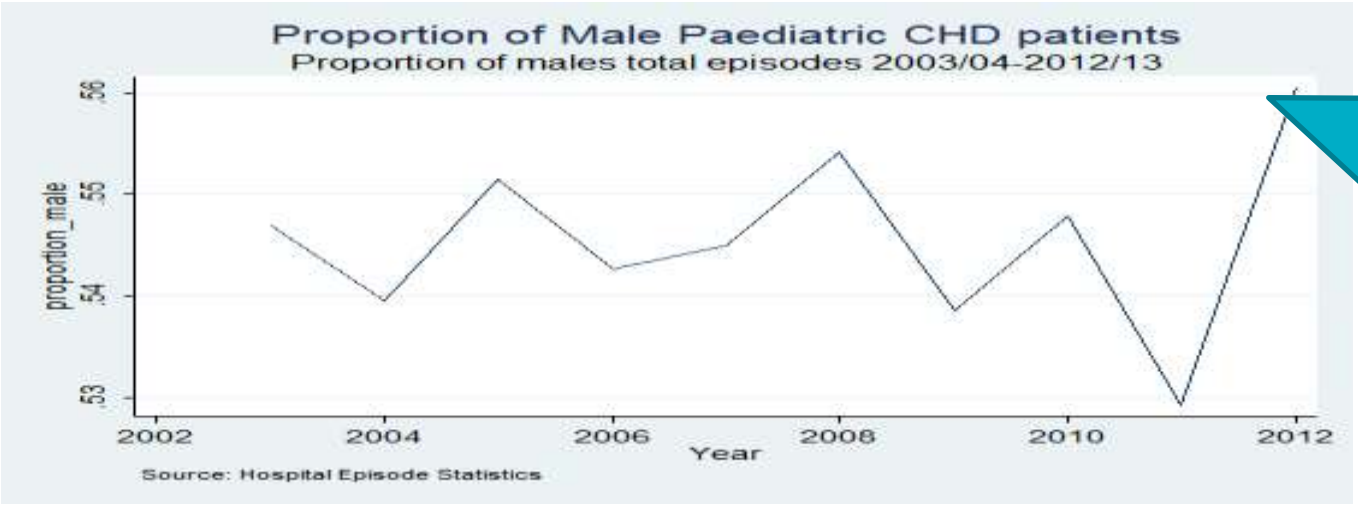


The % of episodes by age bands (neonate, infant, child, older child, adult, over 65) is stable over time with some increase in adults

Most activity is for the child and infant age groups but both adult groups are growing

We use a specific "older child" category to isolate the differences in the definition of child between NICOR (adults age 16+) and HES (adults age 18+)

Historic trends: activity by gender

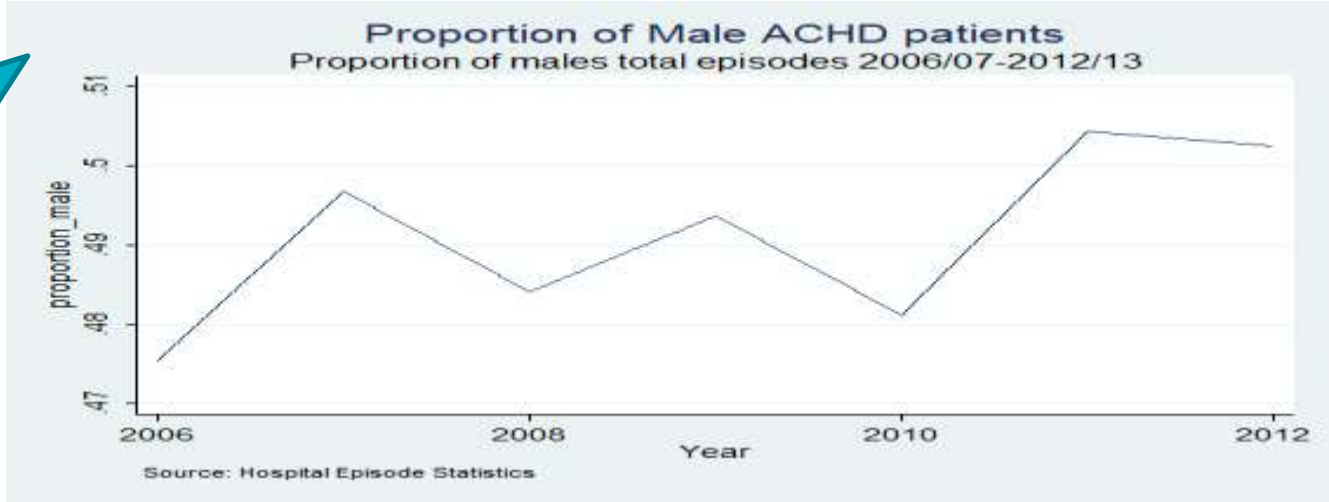


Paediatric activity - % of **males higher than females** in every year (males >50%)

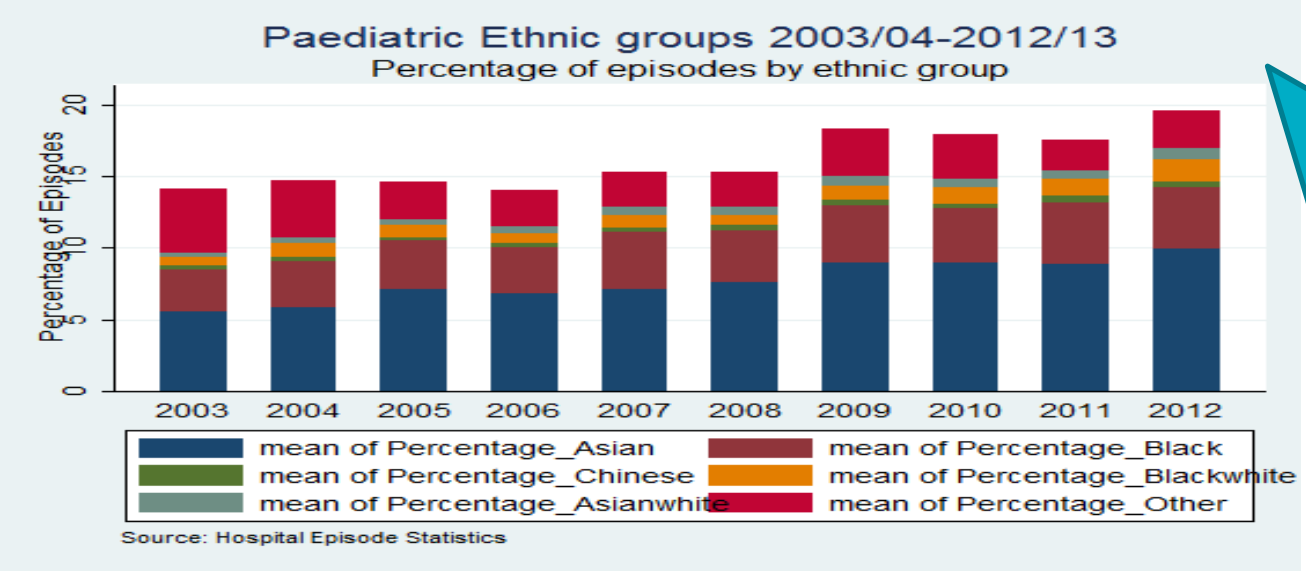
Range only 53%-55% - not much variation over time

ACHD activity - % of **females higher than males** in most years (males <50%)

Range 47%-51% - More variation than in Paeds activity



Historic trends: activity by ethnicity

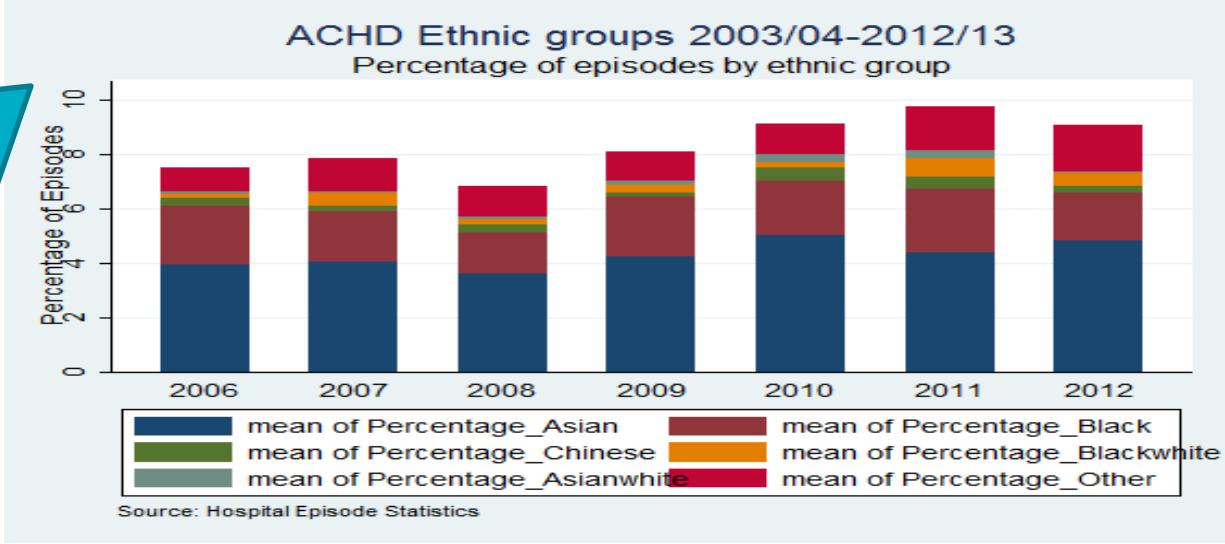


Paediatric activity:
% of activity for Asian, and Black ethnic groups has **increased** over time:

Asian from 6% to 10%
Black from 3% to 4%

ACHD activity:
% of activity for Asian ethnic groups has **increased slightly** over time but remains lower than for paediatric activity:

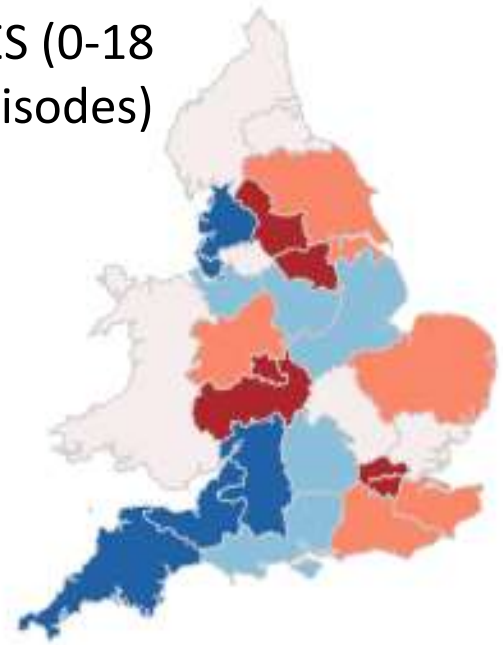
Asian from 4% to 5%



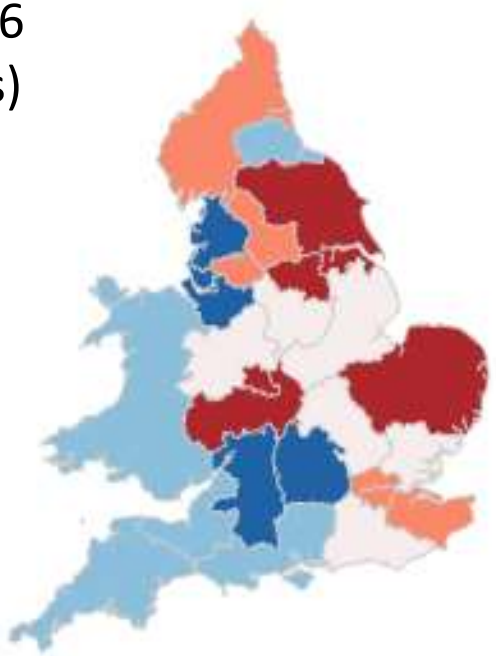
Historic trends: paediatric activity growth by area

2003/4 to 2012/13 growth in paediatric activity by area of patient residence

HES (0-18 episodes)



NICOR (0-16 procedures)

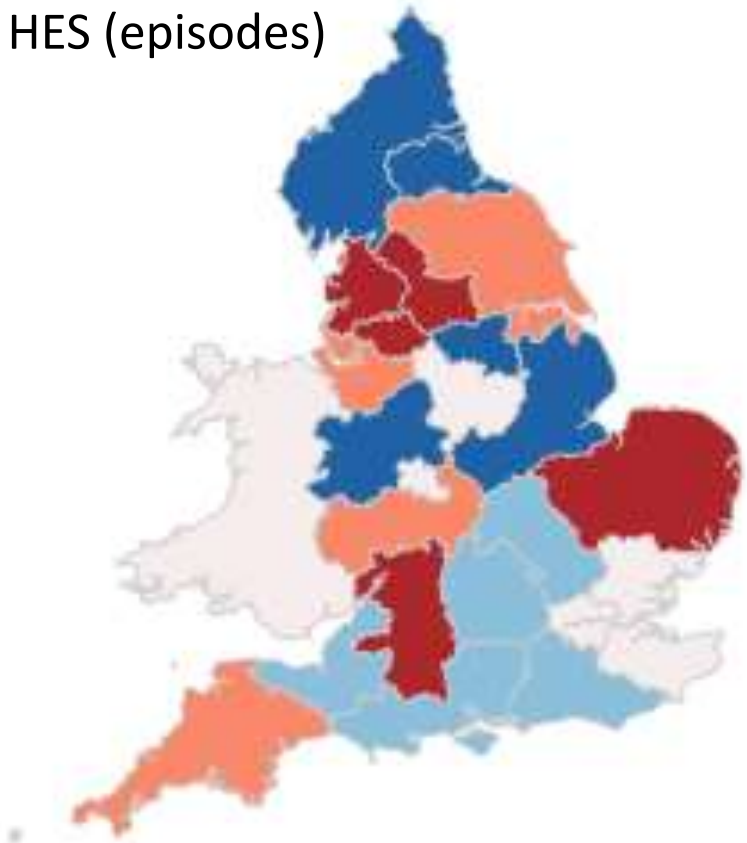


Heat Map:
Red = "Hot" = positive growth – higher growth darkest red
Blue = "Cold" = very low or negative growth – most negative growth darkest blue
NICOR and HES data suggesting similar "hot" and "cold" areas

Historic trends: ACHD activity growth by area

2006/7 to 2012/13 growth in ACHD activity by area of patient residence

HES (episodes)



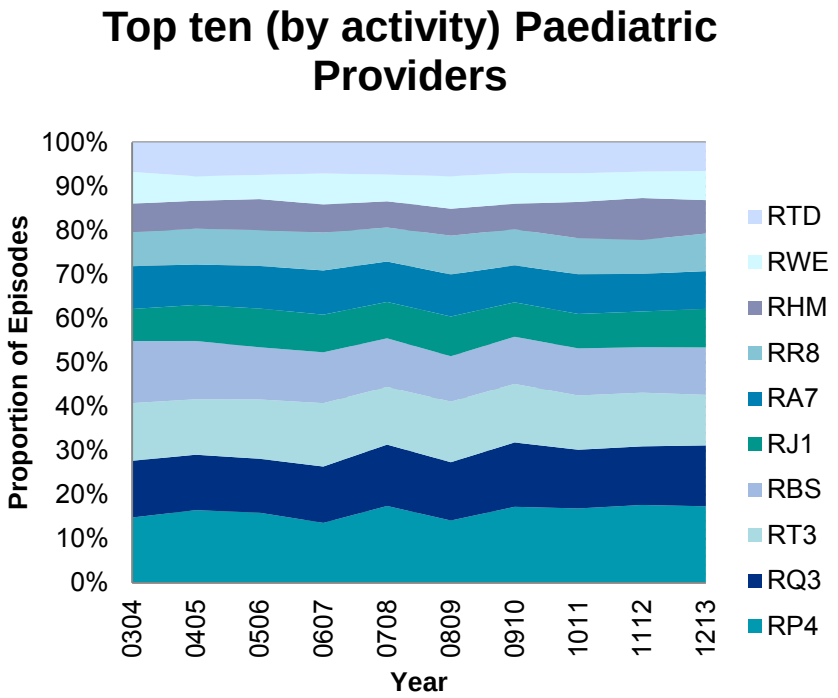
Heat Map:
Red = "Hot" = positive growth – higher growth darkest red

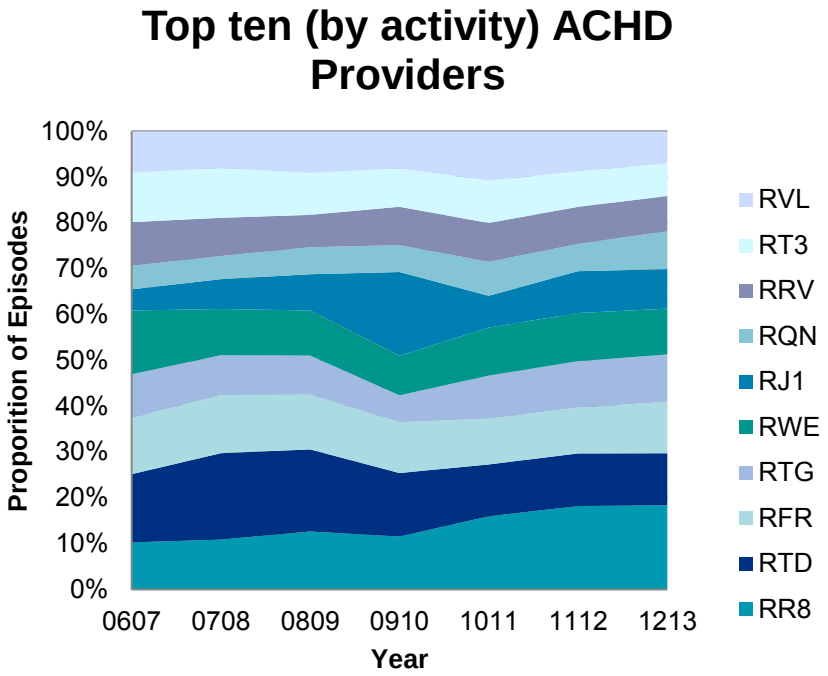
Blue = "Cold" = low or negative growth – most negative growth darkest blue

Cannot use NICOR data as geographical breakdown biased by changes in reporting over time.

Historic trends: activity by providers

Changes in “market share” of the top ten (by activity) providers over time





Share of the activity by provider is fairly stable over time

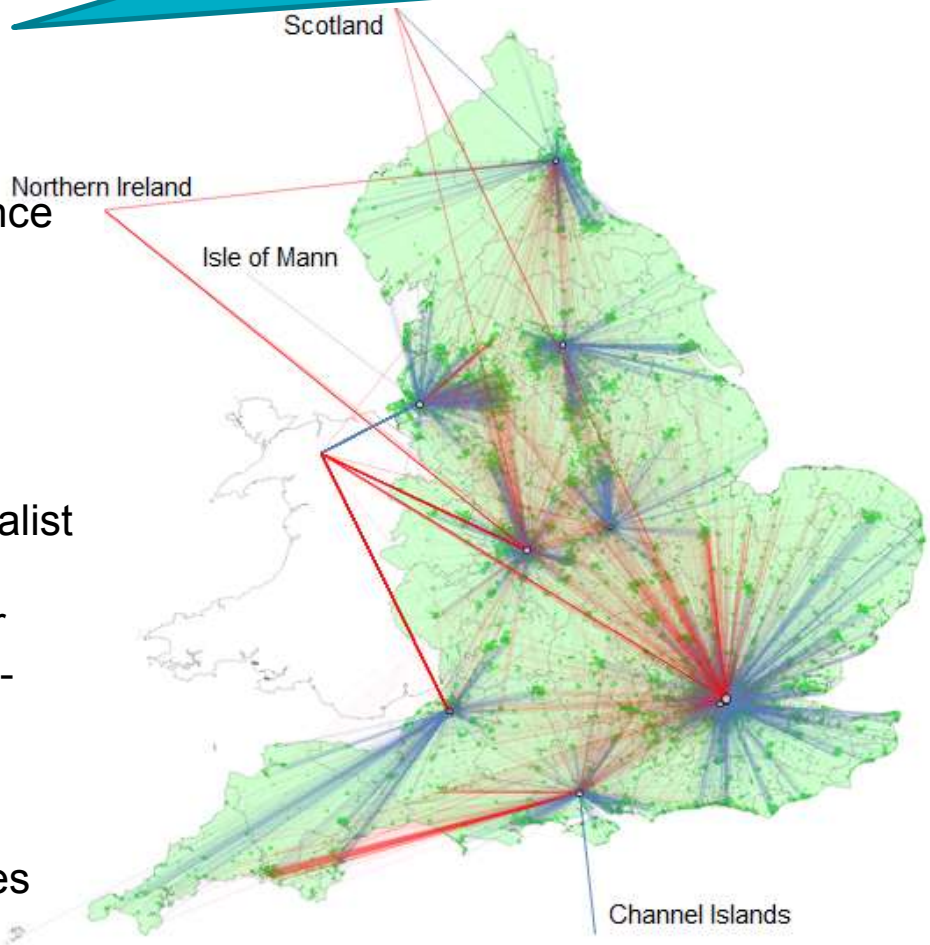
Share of the activity by provider is has changed over time

Historic trends: paediatric cardiac patient flows

Total episodes for the last 10 years by provider and patient residence. Different providers see patients from different areas.

Major Paediatric Providers

- 10 major centres
- 3 in London
- Lines denote activity flow from patient residence to provider
- Thickness of lines denote volume of activity
- Size of centroid denotes volume of provider activity
- Dark green areas are patient origins
- Most patients are going to their nearest specialist centre (as the crow flies -blue lines)
- Few centres are drawing patients from further than their nearest provider (as the crow flies - red lines)
- Only one point used for all activity from sites outside England
- Average distance per episode: 49km (excludes non England)
- Concentration ratio*, C_{10} = 0.91



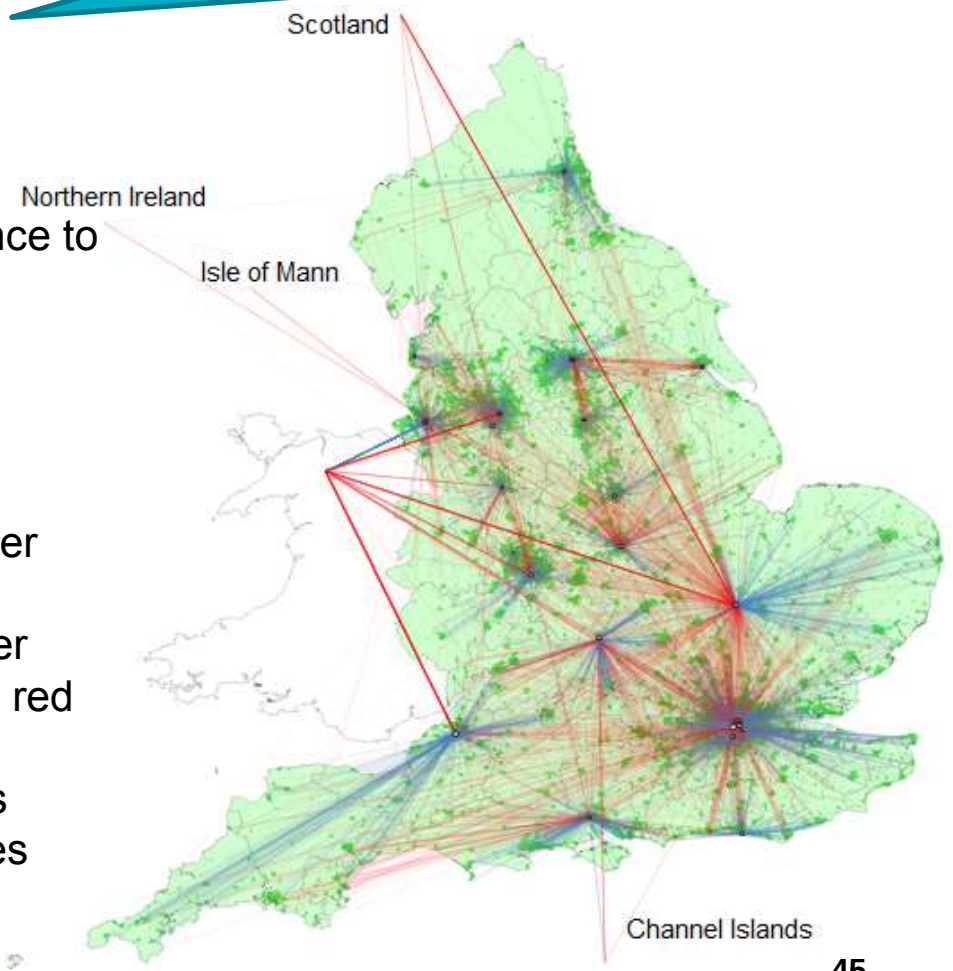
* the proportion of total activity provided by these centres over the last 10 years

Historic trends: ACHD patient flows

Total episodes for the last 7 years by provider and patient residence. Different providers see patients from different areas.

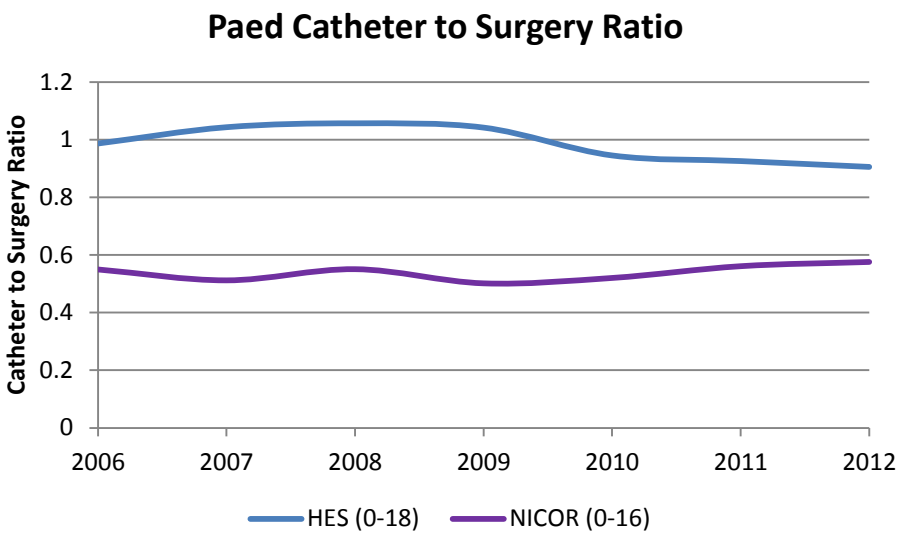
Major ACHD Providers

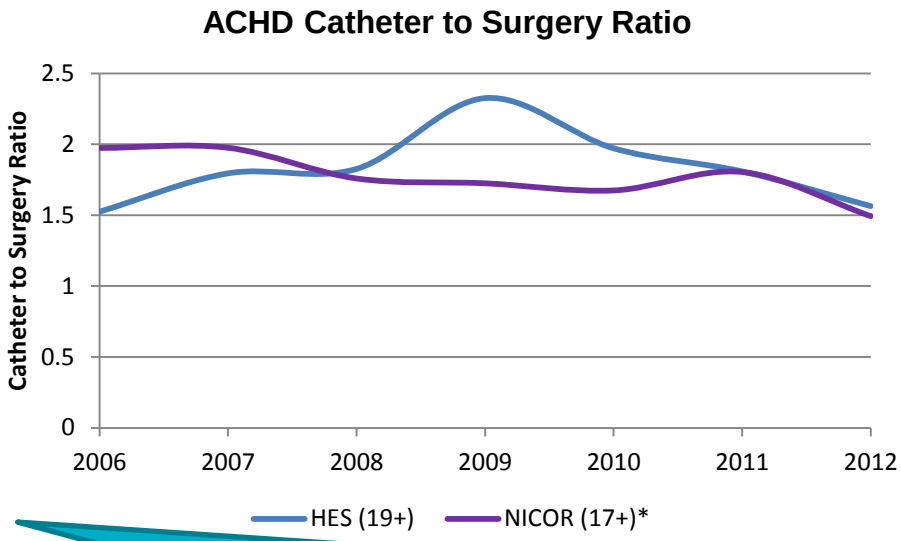
- Top 25 major centres
- 7 in London
- Lines denote activity flow from patient residence to provider
- Thickness of lines denotes volume of activity
- Size of centroid denotes volume of provider activity
- Dark green areas are patient origins
- Few patients are going to their nearest provider (as the crow flies - blue lines)
- Many centres are drawing patients from further than their nearest provider (as the crow flies - red lines)
- Only one point used for all activity from Wales
- Average distance per episode: 42km (excludes non England)
- Concentration ratio*, C_{25} = 0.92, C_{10} = 0.57



* the proportion of total activity provided by these centres over the last 7 years

Historic trends: Catheters vs Surgeries





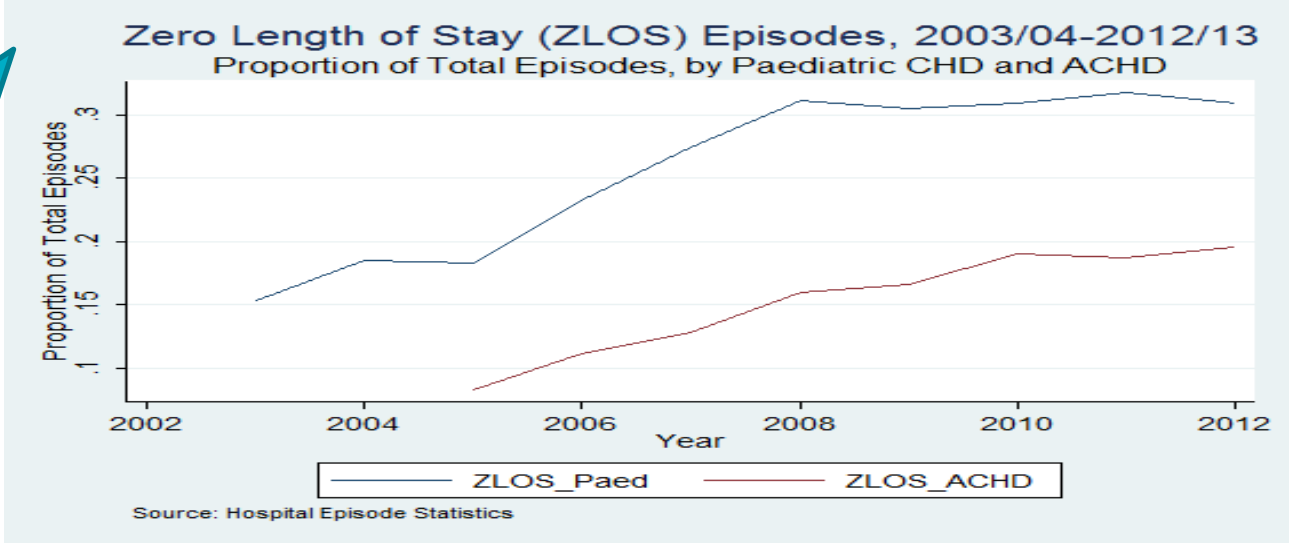
Paed: Both HES and NICOR suggest the catheter to surgery ratio has been stable over time. However, HES suggests a higher ratio than NICOR. This could be due to the differences in the two age groups (HES 0-18 vs NICOR 0-16)

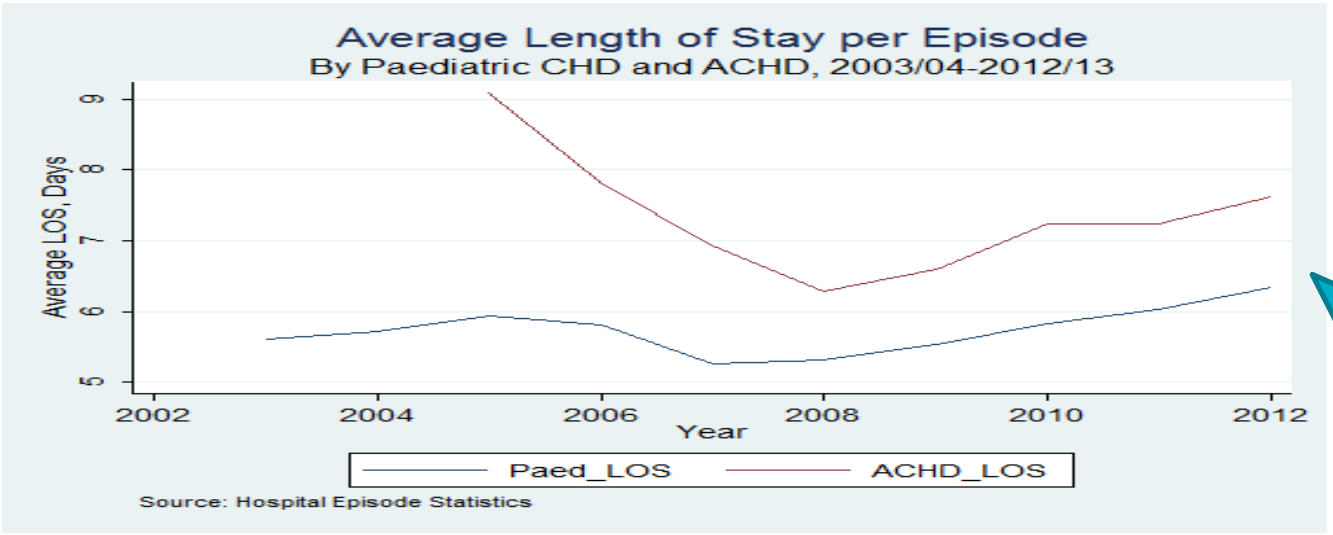
ACHD: Both HES and NICOR suggest a catheter to surgery ration of >1.5. There has been more variability over time according to HES. This could be changes in coding and difference in the two age groups (HES 19+ vs NICOR 17+)

To note: We have used a list of codes in HES to flag a procedure as a catheter – this is less reliable than NICOR who verify the procedures covered by the data. *For ACHD as NICOR data is missing for some provider the ratio may be bias depending on missing activity

Historic trends: Length of stay

Zero Length of Stay (LOS) episodes have been increasing as a proportion of the total number of episodes for both ACHD and Paediatric





For those episodes that are not zero LOS, the average LOS per episode looks to have declined for ACHD and looks to be fairly stable for Paediatric activity

Item 7 Annex A

New Congenital Heart Disease Review

NHS England

Activity Drivers

Joanna Glenwright
John Buckell
Charles Keenan

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We have investigated the possible drivers of activity

Levels of activity have changed over time and are different across patient resident areas beyond differences in population numbers

So we need to:

1. Understand what is driving the changes over time and the differences across the country

2. Make informed assumptions about what these drivers of activity are going to do in the future

To do this we have:

- ✓ Asked our clinician advisory group
- ✓ Reviewed academic literature
- ✓ Undertaken statistical analysis of HES data

What the clinician advisory group told us:

Factor	Relationship with activity	What has it done in the past?	What will it do in the future?
Population	Increased population = increased activity	Led to activity increases	Lead to activity increases
Patient longevity and survival	Increased longevity = increased activity	Led to activity increases	Lead to activity increases
Patient expectations and clinician willingness to treat	Increased expectations & willingness = increase activity	Led to activity increases	Lead to activity increases
Technology	Increased technology = increased activity	Led to activity increases	Lead to activity increases
Increased complexity of conditions	Increased complexity = increased activity	Led to activity increases	Lead to activity increases
Consanguineous relationships	Increased consanguinity = increased activity	Led to activity increases	Lead to activity increases
Maternal age	More mothers at edge of fertile age range = increased activity	Led to activity increases	Lead to activity increases
Deprivation	Increased deprivation = increased activity	Unclear	Unclear
Health tourism	Increased health tourism = increased activity	Unclear	Unclear
Early diagnosis and termination rates	Unclear	Unclear	Unclear

What some relevant literature suggests:

Driver of activity	References
Population	N/A
Patient longevity and survival	Hoffman, (1995), Wren (2001), Hoffman, Kaplan (2002), Billet (2007), Khairy (2010), Afalo et al (2011), Tutarel (2013), Mylotte (2014)
Patient expectations and clinician willingness to treat	Billet (2008), Irving (2011), Mylotte (2014)
Technology	Hoffman (1995), Wren (2001), Heart (2002), Marelli (2007), Khairy (2010), Irving (2011) ,Van der Linde at al (2011), 2013-CHD: International collaboration
Increased complexity of conditions	Wren (2001), Billet (2008)
Consanguineous relationships	Sadiq (1995), Sheridan (2013)
Maternal age	Reefhuis et al., (2004), Marelli (2007), Van der Linde at al (2011), Rankin (2012)
Deprivation	Sadiq (1995)
Health Tourism	N/A
Early diagnosis and termination rates	Wren (2001), Irving (2011), Rankin (2012), Sheridan (2013)
Other	Brown and Karunas (1972), Cullen et al., (1991), Jacobs (2000), Jenkins et al., (2007), Pinto (2007), Gilboa et al., (2010), Van der Linde at al (2011) Agay-Shay et al., (2013), Sheridan (2013), Zutphen et al., (2014)

The initial statistical analysis suggests:

We have applied a range of statistical techniques* to our HES data to investigate potential relationship between activity levels and possible “drivers”

For **paediatric** activity:

Covariate	Strong evidence	Some Evidence	Little Evidence	No findings	Association with activity	Relative Effect
Population	x				**Positive**	**Low**
Number of Diagnoses**	x				**Positive**	**High**
Age	x				**Negative**	**High**
Ethnicity: Asian	x				**Positive**	**Low**
Ethnicity: Black		x			**Positive**	**Low**
Ethnicity: Chinese			x		**Negative**	**Low**
Gender		x			**Positive**	**Low**
Time	x				**Positive**	**Low**

* A range of regression models: univariate and multivariate panel data models to look at data at Area Team level and hurdle models to look at patient level data, ** potential proxy for complexity but could be coding practice

The initial statistical analysis suggests:

We have applied a range of statistical techniques* to our HES data to investigate potential relationship between activity levels and possible "drivers"

For **ACHD** activity:

Covariate	Strong evidence	Some Evidence	Little Evidence	No findings	Association with demand	Relative effect
Population	x				**Positive**	**High**
Number of Diagnoses**	x				**Positive**	**High**
Age		x			**Positive**	**High**
Ethnicity: Asian			x		**Positive**	**Low**
Ethnicity: Black			X		**Positive**	**Low**
Ethnicity: Chinese			X		**Positive**	**Low**
Gender				x	**n/a**	**Low**
Time	x				**Positive**	**Low**

* A range of regression models: univariate and multivariate panel data models to look at data at Area Team level and hurdle models to look at patient level data** potential proxy for complexity but could be coding practice

Identified demand drivers but not quantified their effect

Based on the evidence considered we expect the main drivers of CHD activity are:

1. Population growth (which is a function of birth rate, migration and life expectancy)
2. Increasing proportion of patients who are of Asian and Black ethnicity
3. Technology and medical advances
4. Increased patient longevity and survival
5. Increased expectation (patients) and willingness (clinicians) to treat
6. Increased complexity and severity of patients (possibly also driven itself by 2,3,4 and 5 above)

All of these identified drivers are expected to continue to increase and drive up activity in the future

Item 7 Annex A

New Congenital Heart Disease Review

NHS England

Scenarios for future activity

Joanna Glenwright
John Buckell
Charles Keenan

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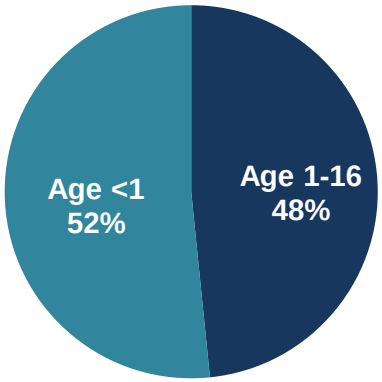
Future Activity Scenarios

- Of the identified demand drivers the only one that can reasonably be modelled going forward is population growth by age, sex and area
- The effect of all the other demand drivers over the last 10 years is wrapped up in the historic trend in activity
- Therefore we have looked at 2 key scenarios for future activity:
  - Scenario A: No change in procedures per head from 2012, only pressure is increase in number the population of England and Wales
  - Scenario B: As A but allow number of procedures per head to increase as it has in the past.

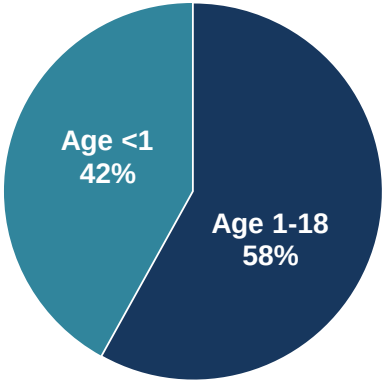
Future Activity Scenarios: Paediatric activity

As discussed a significant % of paediatric activity is for children aged under 1 year (infants and neonates)

NICOR data (0-16)



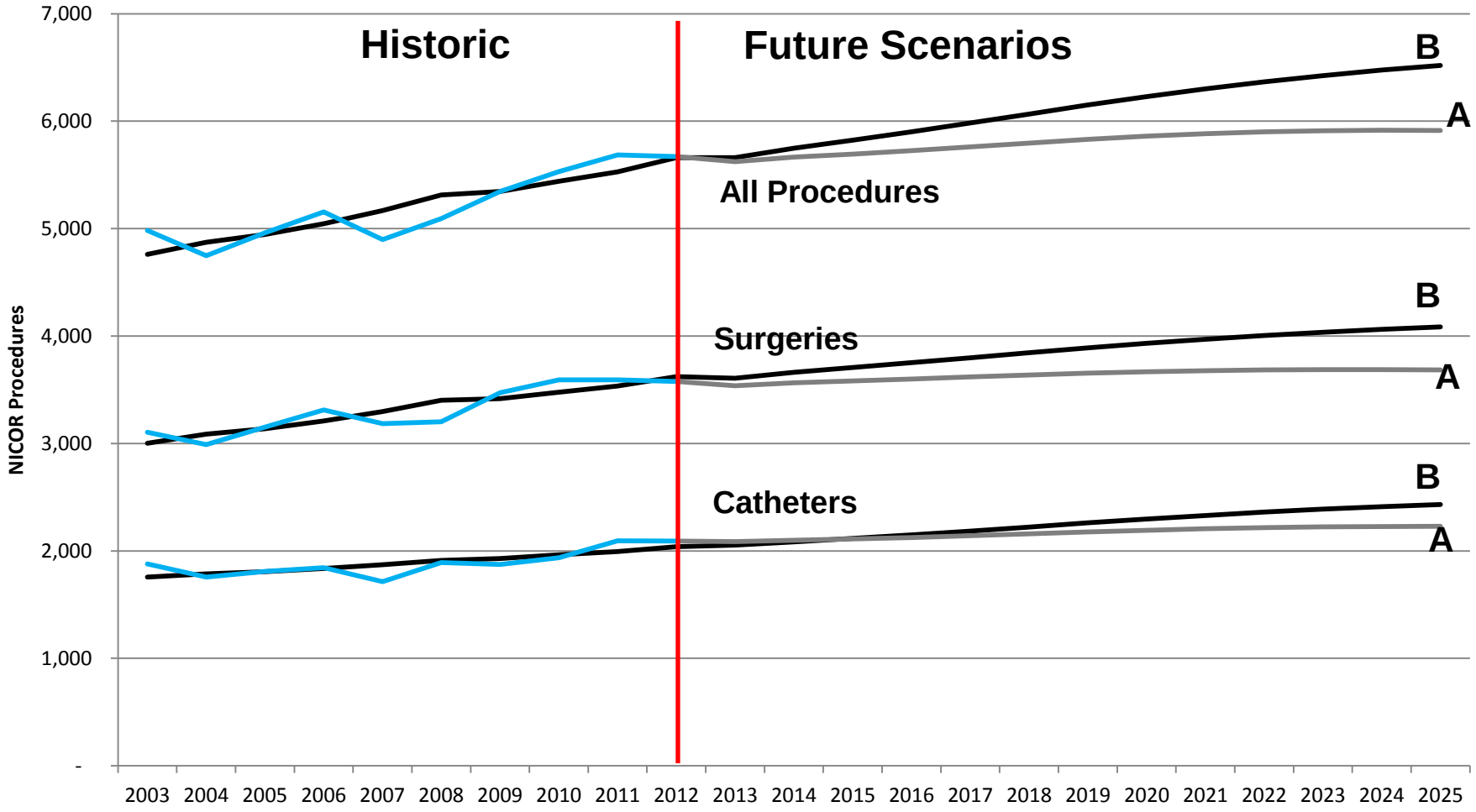
HES data (0-18)



As shown in previous slides activity trends differ significantly for those aged under 1 compared to those aged over 1, as do ONS population projections

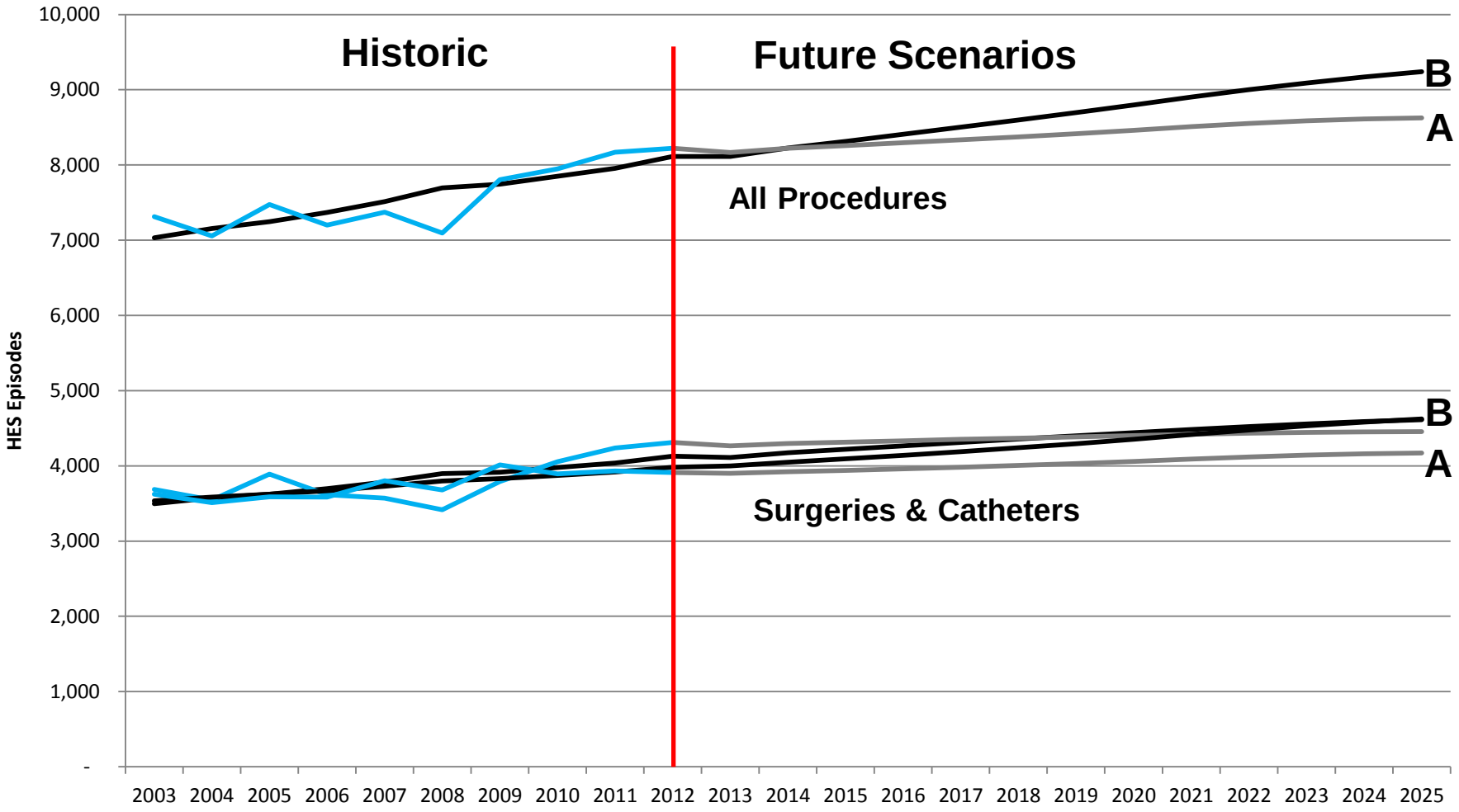
Therefore we have considered the future activity growth for these two groups separately and then brought them back together to give a total analysis for all paediatric activity

Future Activity Scenarios: paediatric (0-16) based on NICOR



NICOR data & ONS 2012 Principle Projections

Future Activity Scenarios: paediatric (0-18) based on HES



HES data & ONS 2012 Principle Projections

Using ONS Principal Population Projection

Future Activity Scenarios: paediatric activity pressure

	All Paed Cardiac (0-16) Procedure Based Activity – Based on ONS Principal Population Projections						
	2012/13 Baseline	Scenario A			Scenario B		
NICOR (0-16) CCAD data (procedures)							
Procedure Type	**2012/13**	**2025/26**	**13 yr growth**	**Per annum**	**2025/26**	**13 yr growth**	**Per annum**
All	5700	5900	4.3%	0.3%	6500	15.0%	1.1%
Surg	3600	3700	3.0%	0.2%	4100	14.2%	1.0%
Cath	2100	2200	6.5%	0.5%	2400	16.3%	1.2%
HES (0-18) APC data (episodes)							
Procedure Type	**2012/13**	**2025/26**	**13 yr growth**	**Per annum**	**2025/26**	**13 yr growth**	**Per annum**
All	8200	8600	4.9%	0.4%	9200	12.4%	0.9%
Surg	4300	4500	3.3%	0.3%	4600	7.0%	0.5%
Cath	3900	4200	6.7%	0.5%	4600	18.3%	1.3%

Baseline depends on activity currency and age group – HES episodes (0-18) vs. NICOR procedures (0-16)

Scenario A: Pressure is similar – it is driven by ONS population forecasts and the relative activity weight for each age group – around 3 - 7% up to 2025/26 or around **0.4% per annum**

Scenario B: Pressure is similar – around 10 – 15% up to 2025/26 or around **1% per annum**

To note: above calcs may not sum due to rounding and compound effects.

Using ONS High Population Projection

Future Activity Scenarios: paediatric activity pressure

	All Paed Cardiac (0-16) Procedure Based Activity – Based on ONS High Population Projections						
	2012/13 Baseline	Scenario A			Scenario B		
NICOR (0-16) CCAD data (procedures)							
Procedure Type	**2012/13**	**2025/26**	**13 yr growth**	**Per annum**	**2025/26**	**13 yr growth**	**Per annum**
All	5700	6500	14.8%	1.1%	7200	26.6%	1.8%
Surg	3600	4100	14.1%	1.0%	4500	26.5%	1.8%
Cath	2100	2400	16.1%	1.2%	2700	26.9%	1.9%
HES (0-18) APC data (episodes)							
Procedure Type	**2012/13**	**2025/26**	**13 yr growth**	**Per annum**	**2025/26**	**13 yr growth**	**Per annum**
All	8200	9400	14.5%	1.0%	10100	22.8%	1.6%
Surg	4300	4900	13.8%	1.0%	5100	18.6%	1.3%
Cath	3900	4500	15.3%	1.1%	5000	27.5%	1.9%

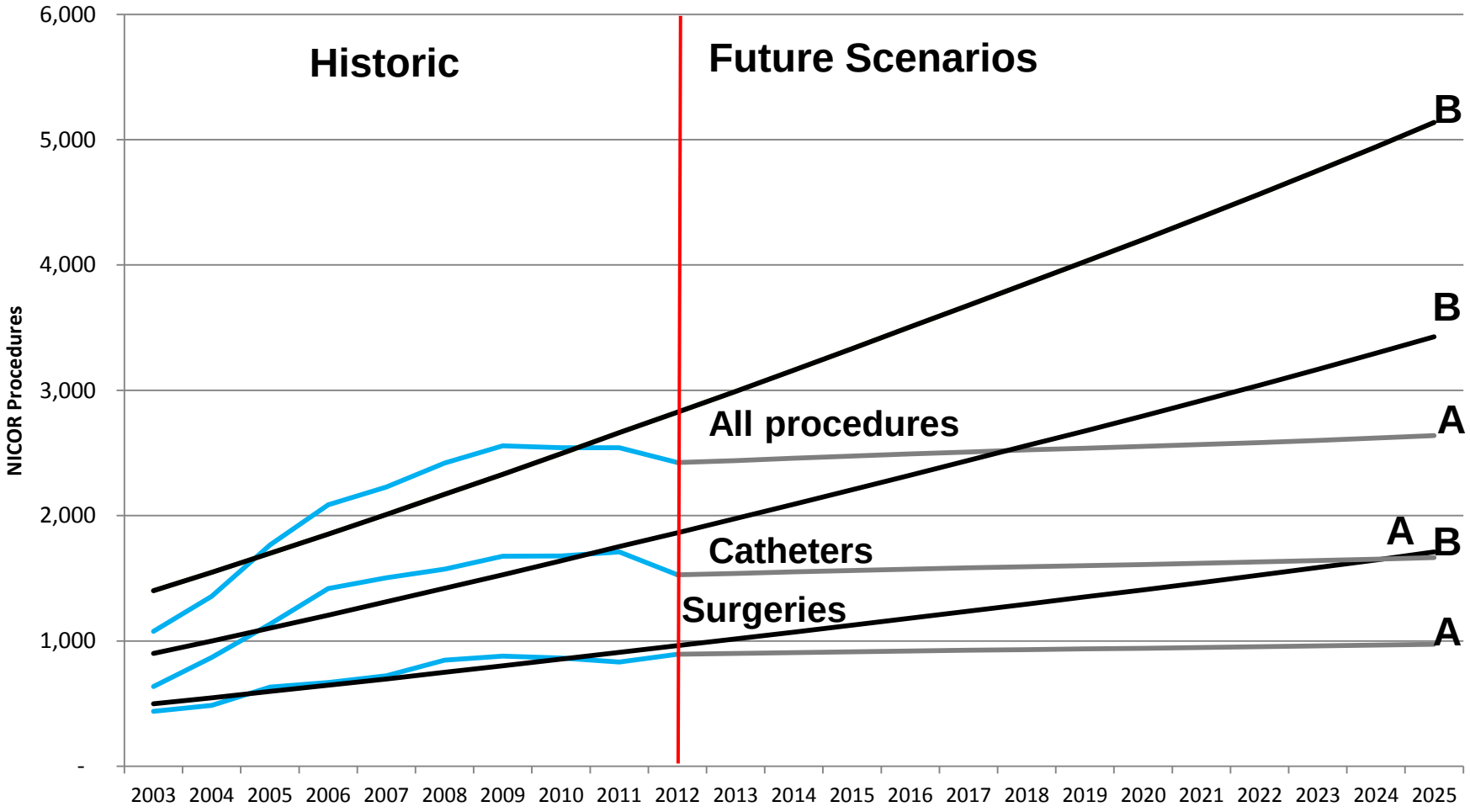
Baseline depends on activity currency and age group – HES episodes (0-18) vs. NICOR procedures (0-16)

Scenario A: Pressure is similar – it is driven by ONS population forecasts and the relative activity weight for each age group – around 15% up to 2025/26 or around **1% per annum**

Scenario B: Pressure is similar – around 20 – 25% up to 2025/26 or just under **2% per annum**

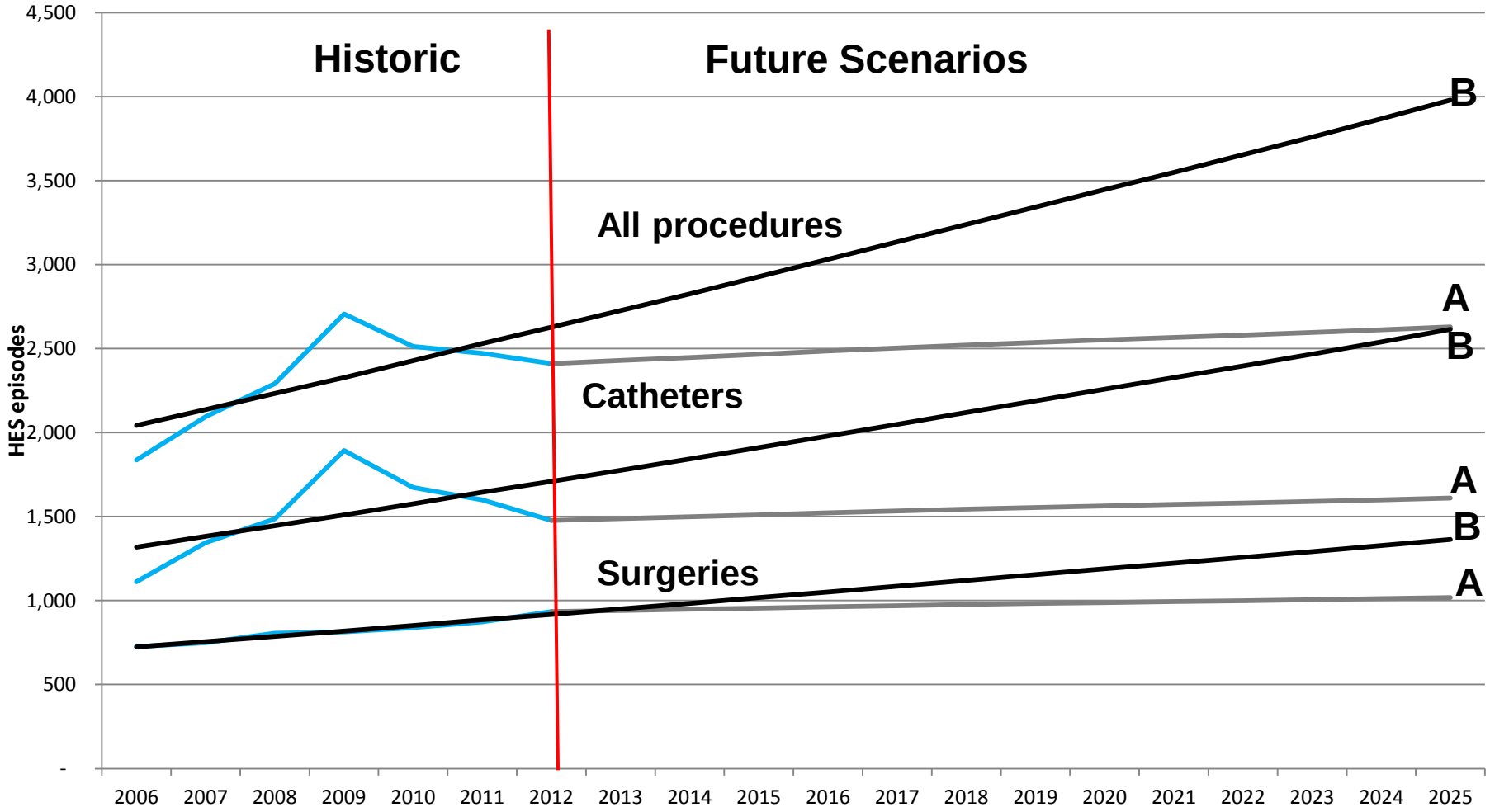
To note: above calcs may not sum due to rounding and compound effects

Future Activity Scenarios: ACHD 17+ based on NICOR data



NICOR ACHD data is affected by increases in the number of providers reporting over time so **Scenario B is distorted** by this and should not be used – included for completeness

Future Activity Scenarios: ACHD (19+) based on HES data



HES data and ONS 2013 Principle Projection

Using ONS Principal Population Projection

Future Activity Scenarios: ACHD (HES vs NICOR)

	ACHD Procedure Based Activity – Based on ONS Principal Population Projection						
	2012/13 Baseline	Scenario A			Scenario B		
NICOR (17+) CCAD data (procedures)							
Procedure Type	**2012/13**	**2025/26**	**13 yr growth**	**Per annum**	**2025/26**	**13 yr growth**	**Per annum**
All	2400	2600	8.9%	0.7%	5100	112.0%	6.0%
Surg	900	1000	8.9%	0.7%	1700	91.2%	5.1%
Cath	1500	1700	8.9%	0.7%	3400	124.1%	6.4%
HES (19+) APC data (episodes)							
Procedure Type	**2012/13**	**2025/26**	**13 yr growth**	**Per annum**	**2025/26**	**13 yr growth**	**Per annum**
All	2400	2600	9.0%	0.7%	4000	65.0%	3.9%
Surg	900	1000	9.0%	0.7%	1400	46.0%	3.0%
Cath	1500	1600	9.0%	0.7%	2600	77.0%	4.5%

Baseline numbers depends on activity currency and age – HES episodes 19+ vs NICOR procedures 17+. NICOR thought to cover around 80% of total

Scenario A: Pressure is driven by ONS population forecasts – around 9% up to 2025/26 or **0.7% per annum**

Scenario B: NICOR data unreliable due to reporting changes. But even for HES pressure is high and driven by catheter activity.
65-77% to 2025/26 or around **3-4% per annum**

To note: above calcs may not sum due to rounding and compound effect

From the Rt Hon Jeremy Hunt MP
Secretary of State for Health

Richmond House
79 Whitehall
London
SW1A 2NS

Tel: 020 7210 3000
Mb-sofs@dh.gsi.gov.uk

POC1_787312

Sir David Nicholson
Chief Executive
NHS England
Quarry House
Quarry Hill
Leeds
LS2 7UE

12 JUN 2013

Dear David,

"SAFE AND SUSTAINABLE REVIEW" OF CHILDREN'S CONGENITAL HEART SERVICES – INDEPENDENT RECONFIGURATION PANEL REPORT

As you know, I asked the Independent Reconfiguration Panel to undertake a full review of the proposals of the Safe and Sustainable Review of children's congenital heart services, following referrals to me from three local health overview and scrutiny committees.

The Panel has now submitted its report to me.

The report shows that the proposals of the Safe & Sustainable review clearly cannot go ahead in their current form. NHS England now needs to move forward on the basis of the IRP's recommendations, and the judgement of the court in the 'Save our Surgery' case - I understand that NHSE are withdrawing the appeal.

.

The challenge for NHS England is to determine how to take this forward as quickly and effectively as possible. You will be working with all interested parties to ensure that real progress is made as quickly as possible, always focused on the best outcomes for patients.

I would like NHS England to report back to me by the end of July on how you intend to proceed.

Yours ever

Jeremy

JEREMY HUNT

4W12
Quarry House
Quarry Hill
Leeds LS2 7UE
Tel: 0113 825 1104

Rt Hon Jeremy Hunt MP
Secretary of State for Health
Richmond House
79 Whitehall
London
SW1A 2NS

31 July 2013

Dear Secretary of State

New review of congenital heart disease (CHD) services

In your letter of 12 June about the "Safe and Sustainable" review, you asked NHS England to report back to you by the end of July setting out how we intend to take the process forwards.

I am pleased to enclose the paper which our Board considered at its meeting in public on 18 July, which sets out our thinking on the nature of the problem and the principles which must underpin our approach. In line with our commitment to transparency, a video recording of the Board's discussion is also available, at http://www.england.nhs.uk/2013/07/22/boardvids-180713/. Annex 1 of the Board paper describes an outline timetable for the work.

We have set ourselves the hugely ambitious challenge of an implementable solution within a year. This does not mean we think the job is easy; on the contrary, it is exceedingly difficult. We have a duty to patients now and to future generations to ensure the best possible quality of care within the available resource. That means best outcomes, a positive patient experience, and consistently high levels of safety.

We do not see this as a competition between providers to find "winners" and "losers". Instead, we want a single national service which sets high standards for the delivery of care, which are uniformly available to all NHS patients in England, wherever they live. Beyond this aspiration for a national service underpinned by national standards, we do not profess to know yet precisely what the answer is. We are very clear that the Independent Reconfiguration Panel's (IRP) report requires us, amongst other things, to look at children's and adults' services together, to look afresh at the demographic and other relevant data, to describe the entire pathway, and to properly involve all stakeholders throughout the work. So, we need a new process. Although the *Safe and Sustainable* conclusions cannot be implemented, there has nonetheless been some very good work during the past five years, with extensive involvement from clinicians and patient groups, to develop

standards and proposals for networks. As IRP suggests, this work needs to be completed. Once validated it will give us a platform for future work, but it does not in any way require us to reach the same conclusions as the previous process.

As we continue our initial discussions over the next few weeks, and begin to develop a proposition for debate in the autumn, there is bound to be speculation about the “answer” we have in mind. But having promised that we will listen before we act, I can assure you that we have no such prejudice. I welcome your support in reiterating this message.

We are still in an extended period of listening and we regularly publish the notes from our meetings to open the debate as widely as possible. I have established a committee of the Board to give this topic the focus it deserves, and Professor Sir Mike Rawlins will chair a clinical advisory panel to support our medical director Professor Sir Bruce Keogh in obtaining excellent clinical engagement and advice.

We are absolutely committed to achieve the service change required for these very vulnerable patients. We will exploit the full potential of NHS England as the sole national commissioner, and do so in a way that properly engages all interested parties, but at sufficient pace to mitigate the risks of further delay.
Yours sincerely

Professor Sir Malcolm Grant
Chair

NHSE180713

BOARD PAPER - NHS ENGLAND

Title: New review of congenital heart services

Clearance: Bill McCarthy, National Director: Policy

Purpose of paper:

- To describe the challenge facing NHS England in improving congenital heart disease services
- To outline early thinking on the way forward

Key issues and recommendations:

On 12 June 2013 the Secretary of State announced in Parliament that the safe and sustainable proposals for children's congenital heart services could not 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".

NHS England is the body responsible for commissioning specialised congenital heart services and for taking forward the process.

A new review is being established to consider the whole lifetime pathway of care for people with congenital heart disease (CHD), to ensure that services for people with CHD are provided in a way that achieves the highest possible quality within the available resources.

Actions required by Board Members:

- To note the proposals for conducting a review of congenital heart disease services

New review of congenital heart services

Summary

Following the outcome of judicial review, the report by the Independent Reconfiguration Panel (IRP) and the Secretary of State's announcements relating to the safe and sustainable review of children's congenital heart services, NHS England is now the responsible body for taking forward the process. A new review is now being established to consider the whole lifetime pathway of care for people with congenital heart disease (CHD).

The ambition of this review is to ensure that services for people with CHD are provided in a way that achieves the highest possible quality within the available resources:

- the best outcomes for all patients, not just lowest mortality but reduced disability and an improved opportunity for survivors to lead better lives.
- tackling variation so that services across the country consistently meet demanding performance standards and are able to offer resilient 24/7 care
- great patient experience, which includes how information is provided to patients and their families, considerations of access and support for families when they have to be away from home

We recognise that continued uncertainty is a risk to the service and unsettling for patients. We must therefore set ourselves the target of delivering the new review at pace. But we know that speed cannot be an excuse for imposing a top down solution or for running a process where people feel excluded from the real discussions, so we will be setting ourselves the additional challenge of achieving new levels of transparency and the highest levels of genuine participation. We know that this will need a new approach. We want to make sure that as well as mobilising NHS England's resources from right across the organisation, that we also work closely with partners and stakeholders to design the way forward.

By the end of September we will have established the new programme, co-designed a process for the work going forward and undertaken initial work on how to secure high quality resilient services.

By June 2014 working closely with stakeholders, we will have developed, tested and revised a proposition, undertaken work to identify a preferred approach to implementation, and completed the necessary preparatory work.

Background

1. Around eight out of every 1,000 babies have some form of congenital heart disease (CHD) – around 5,800 babies in 2011. The number of children born with CHD is expected to rise, as the birth rate rises. As technology and expertise continue to develop, it is possible to do more than ever before to improve their lives, so that more children with CHD are surviving to adulthood.
2. NHS cardiac surgery for children is currently provided by 10 hospitals in England. Specialist paediatric cardiology is also provided by a further three centres. Around 3,700 paediatric surgical procedures and 2,000 paediatric interventional cardiology procedures are carried out each year.

3. A recommendation for the concentration of medical and nursing expertise in a smaller number of centres of excellence was made as far back as 2001, in the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary. Since that time, there have been major improvements in outcomes, so that analysis of risk adjusted mortality for 2009-12, published this year by the National Institute for Cardiovascular Outcomes Research (NICOR), shows that no surgical unit has a mortality rate significantly above the "expected" rate, and on this evidence (for example, mortality rates alone) services are currently "safe".

4. For adults, around 850 surgical procedures and 1,600 interventional cardiology procedures are carried out each year and reported to NICOR by 25 hospitals in England, however a further 10 hospitals have undertaken procedures in recent years but not provided data to NICOR.

The safe and sustainable review

5. 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.

6. At the end of the four year programme, 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, covering:
   - the development of congenital heart networks,
   - service standards,
   - improving the collection, reporting and analysis of outcome data, and
   - 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.

7. 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.

8. The JR was decided on 7 March 2013, when the High Court declared that both the consultation process and the decision making process of the JCPCT were unlawful and quashed the decision to reconfigure surgical services. The judgement was based on a narrow point of process and the Court recognised "the compelling and urgent clinical case for the reform of existing paediatric congenital cardiac services" stating that the judgment should not be "construed as advocating a need to return to the start of the consultation process". Following legal advice, NHS England initially sought leave to appeal this decision but - in the light of the IRP's report and the Secretary of State's response (see below) - has since withdrawn this request.

9. The IRP were of the view that children and adults with CHD in England and Wales would benefit from services commissioned to national standards for the whole pathway of their care. They agreed that congenital cardiac surgery and interventional cardiology should only be provided by specialist teams large

enough to sustain a comprehensive range of interventions, round the clock care, training and research. However, the IRP concluded that the JCPCT's decisions were based on "flawed analysis of incomplete proposals and their health impact, leaving too many questions about sustainability unanswered and to be dealt with as implementation risks".

Addressing the IRP findings

10. 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".

11. The IRP's report highlighted the need to align the review of children's CHD services with ongoing work to consider the provision of adults' CHD services. Since the same surgeons operate on the same patients at different times in their lives, there are considerable dependencies between adults' and children's services, especially in the availability of surgical teams to provide 24/7 cover.

12. The IRP were also concerned that the while the Safe and Sustainable process received 75,000 responses to its public consultation, some stakeholders were nonetheless left feeling that their views were not fully heard or understood, or that they were not given all the information they needed to contribute fully. This in turn created, for some, the perception of a pre-determined outcome.

13. The IRP's report called for NHS England to develop a strategic framework for commissioning that reflects the complex interdependencies between specialised services provision and population need as a context within which any decisions about congenital heart services should be taken.

14. Importantly, neither the Courts, nor SofS nor IRP have questioned the need for change to ensure the resilience, sustainability and excellence of these services.

The challenge for NHS England

15. The challenge for NHS England is how to ensure that services for people with congenital heart disease are provided in a way that achieves the highest possible quality, within the available resources, now and for future generations:

    - Securing the best outcomes for all patients, not just lowest mortality but reduced disability and an improved opportunity for survivors to lead better lives.
    - Tackling variation so that services across the country consistently meet demanding performance standards and are able to offer resilient 24/7 care
    - Delivering great patient experience, which includes how information is provided to patients and their families, considerations of access and support for families when they have to be away from home

16. To do this, we need to develop a process which is as transparent and inclusive as it can be, particularly in the use of evidence and data. Almost as important as the thoroughness of our work will be the need to be seen to be engaging as widely as possible, bringing patients, clinicians and their representatives together

in the joint pursuit of an effective and equitable solution, in the interests of all service users now and in the future. What we do for CHD services will in some ways be seen as a template for whether and how NHS England undertakes other major service change in future.

17. It is widely acknowledged that the uncertainty which has been caused by recent developments is one of the greatest risks to the current delivery of the service. Patients and families are now unsure about precisely where and how they will receive treatment. Surgical centres are hamstrung in their planning, and recruitment and retention is made more difficult by the lack of a clear service model. This in turn creates a risk that the safety and quality of services may not be able to be maintained, that service levels could reduce or there could be unplanned closure(s). Charities, clinicians and other stakeholders gave a huge commitment to support change; many say they are demoralised, frustrated, exhausted and angry. Some doubt that there is the will to make the necessary changes happen.

18. These concerns need to be addressed as part of the new process. To support this measures designed to give commissioners early warning of any emerging concerns at units providing children's congenital heart services will be rolled out across the country, (and to adapt it to include adult services) accepting that it is still a developmental approach, and used as the basis of regular conversations between area teams and providers. A system will be established to ensure that aggregated information is regularly provided to the board committee.

19. In the light of all this, NHS England must bring forward an implementable solution within a year, ie by the end of June 2014. Given the complexity of the issues, the enlarged scope (children AND adults), the legitimate but differing views of stakeholders, and the need to build as much consensus wherever possible (in circumstances where some of the relationships have been badly bruised) this is a demanding but important ambition. We simply cannot re-run the previous process and hope to achieve a different outcome in a quarter of the time.

20. Instead, we must find ways to do this differently. As the sole national commissioner of specialised services NHS England has an opportunity not open to our predecessors. This creates a significant opportunity to drive service improvement including reduced variation in access and quality. We can focus on national standards for a national service, commissioned through a single model which enables us to drive change in the interests of patients.

Principles / Approach

21. We propose the following principles and approach:

- **Patients come first**: the new review must have patients and their families at its heart, with a relentless focus on the best outcomes now and for the future. That aim over-rides organisational boundaries.
- **Retaining what was good from earlier work**: although the JCPCT's decision on configuration of children's congenital heart services has been overturned, much else was developed as part of that process and the subsequent implementation programme including a model of care, service standards, and well-developed thinking about network working. Similarly standards for adult services have also been developed and are ready for

formal consultation. This work has had extensive clinical and patient input and has the potential to be applicable to whatever service configuration is decided. Therefore NHS England must work with stakeholders to determine how much of this work can be retained.

- **Transparency and participation**: NHS England is committed to openness, transparency and participation. We should work with user, clinical and organisational stakeholders to ensure that we develop an approach to take the work forward that is true to those values. Our work should be grounded in standards, rigour, honesty and transparency.
- **Evidence**: the IRP reflected criticism of the way in which Safe and Sustainable used evidence to support its conclusions. The new review will need to be clear about the nature and limitations of the available evidence, and about any intention to rely on expert opinion in the absence of evidence. Notwithstanding the comment above about "retaining what was good", we must have no preconceived notions about the outcome. Wherever there is an assumption it must be made explicit, and justified.

22. We have not attempted to develop a full plan describing how the work will be taken forward, because we want to take time to understand from stakeholders what was good and should be retained from the previous process and what did not work well. We believe however that it is likely that a standards driven process – developing, testing, adopting and applying best practice standards for every part of the pathway – has much to commend it, and we will be testing this with stakeholders.

Governance

23. The Board has established a committee which will provide formal governance of this work. The committee is chaired by Sir Malcolm Grant, Board Chairman, and includes Margaret Casely-Hayford and Ed Smith (non-executive directors), Sir Bruce Keogh (Medical Director), and Bill McCarthy (National Director for Policy). To support the committee, arrangements will be put in place for clinical, organisational and service user representation.

24. Bill McCarthy is the senior responsible officer for this work. John Holden (Director of System Policy) will co-ordinate the work within NHS England and ensure the full involvement of the many different stakeholders.

Stakeholder engagement and communications

25. We are drawing up a stakeholder engagement plan, based on how these stakeholders tell us they wish to be involved, and identifying the different groups, their preferred channels of communication and the key messages throughout the process. For example we know that some of the existing surgical centres have well established patient groups and using these channels may be one way to reach the majority of those most directly affected. For patients, families and their representatives we have sought expert external help from three charities - National Voices, Involve and Centre for Public Scrutiny (CFPS) – to help us design and implement effective and appropriate engagement. They can also

help us manage our risks (eg CFPS are experienced in working with oversight and scrutiny committees and can help us better understand the local government dimension). Due to their limited size these bodies are unable to be directly involved in the work but all have agreed to act in a mentoring capacity. For clinicians, Sir Bruce is convening a clinical advisory panel which will guide him throughout the process and will help design broader clinical engagement and address specific issues which may arise. He has identified the need for some international perspective on this work and will take some soundings from his international peers to determine how best international advice is provided.

26. Our communications will be as open and as often as possible – we have already initiated a fortnightly blog on the NHS England website where we will trail forthcoming meetings and provide a summary of recent progress and discussions. With the support of the NHS England Director of Communications and his team, we are also considering the potential for dedicated web pages, or other IT applications which allow documents and other information to be freely exchanged. We want to give anyone who is interested a simple and easy to use way to find out what is going on and to become involved. We will use social media as appropriate – and if our stakeholders find it helpful – to discuss and share information. We are also considering how we can address the needs of those who do not have access to the internet or do not use English as a first language.

Resources

27. We need to take this opportunity to review the resourcing of this work. It will be important to ensure that it is a priority for the whole organisation and that the resources of the whole organisation are appropriately mobilised to support the work. The cost of dedicated programme management and administrative support will be met from recycling funds previously reserved for the Safe and Sustainable process. The estimated annual cost of this support is £500k.

Conclusion

28. As the body responsible for commissioning specialised congenital heart services, NHS England is setting out ambitious plans to ensure that services for people with CHD are provided in a way that achieves the highest possible quality within the available resources. To achieve this, a new Congenital Heart review is being established to consider the whole lifetime pathway of care for people with CHD. The Board is asked to consider and comment on the proposed approach.

Bill McCarthy

National Director: Policy

July 2013

Annex 1: Programme Plan

Our indicative timetable is follows:

Phase 1 – up to October 2013

Co-design a process for the work going forward

- Take advice from external experts to help shape listening exercise *[done]*
- Review previous stakeholder input in order not to lose what has already been achieved; and check its continuing relevance with stakeholders *[under way]*
- Begin communications as per stakeholders preferences, eg blog, shared resources on webpage/sharepoint *[under way]*
- Agree approaches to participation, identify preferred communications channels

Establish the programme

- Establish governance, advisory and stakeholder arrangements *[under way]*
- Develop programme plan, update Board, secure agreement, update Secretary of State *[under way]*
- Identify resources *[underway]*

Initial work on how to achieve programme aims of higher quality services

- Agree with stakeholders what should be taken forward from previous processes
- Complete work on proposed paediatric cardiology standards *[underway]*
- Bring together adult and children's standards and agree process for approval and adoption *[underway]*
- Develop proposals for testing/implementing formal network arrangements *[underway]*
- Work with stakeholders to identify any fixed points and how these would influence service design. This is likely to include (but not be limited to) discussion of the provision of transplant services, the need for children's heart surgery and other tertiary paediatrics to be provided on the same site, and the need for children's and adults' surgery (and interventional cardiology) to be provided in close proximity
- Develop a "proposition" – not a list of sites, but a straw man of what a high quality and sustainable service looks like for adults and children, unconstrained by current configuration – the optimal model
- Consider and weigh, with legal advice, possible approaches for a managed process to translate these fixed points into firm proposals for structuring services, test with stakeholders, outline agreed process
- Establish the required capacity of the service in future years
- Set an ambitious timeline to have completed the work and be ready to implement.

Phase 2 – up to February 2014

Develop, test and revise the proposition

- Using multiple channels, including local and national clinically led events, engage on the clinical appropriateness and user acceptability of the proposition

- Benchmark existing provision against the proposition – considering access as well as service quality
- Test any emerging alternative proposals
- Review dependencies – eg for children, neonatal and paediatric intensive care (PICU) and retrieval services, extracorporeal membrane oxygenation (ECMO). While the IRP recommended that decisions about the future of transplant services and respiratory ECMO should be contingent on final proposals for congenital heart services, in practice the level of interdependency may mean that they need to be considered together
- Weigh alternative implementation approaches: early thinking suggests that some fixed points could constitute 'hurdle criteria' for potential providers within a commissioner led standards driven approach, however alternative approaches need to be considered including option appraisal and designation and provider led regional solutions.
- Agree revised proposition with clinical and patient groups

Phase 3 – up to June 2014

Preparation for implementation

Work in this phase will of course be dependent on the nature of the proposition developed and the measure of agreement with that approach.

- If the solution is for a national plan in which current centres continue/cease to provide surgery, then – subject to legal advice - there may need to be further full formal consultation. This could take the timeline for implementation beyond one year.
- If the solution is a commissioning approach to enforce a set of national standards which invites providers to cooperate to provide the service, any consultation could be undertaken sub-nationally as part of the development of tenders. Assuming local resolution and provider cooperation, the focus of this period would be on developing the tender exercise.

NHS England

New Congenital Heart Disease Review Board Task and Finish Group Terms of Reference

Information Reader Box

Directorate	
Medical	Commissioning Operations
Nursing	Commissioning Strategy
Patients & Information	Transformation and Corporate Operations
Finance	

Document Purpose	To describe the terms of reference of the New Congenital Heart Disease Review Board Task and Finish Group
Document Name	New Congenital Heart Disease Review Board Task and Finish Group Terms of Reference
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Contact Details (for further information)	Jennie Smith, Programme Co-ordinator england.congenitalheart@nhs.net NHS England Quarry House Quarry Hill Leeds LS2 7UE Direct Line: 0113 8248232

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New Congenital Heart Disease Review Board Task and Finish Group Terms of Reference

Version number: 2.0

First published: 24 October 2013

Updated: 01 September 2014

Prepared by: Michael Wilson, Programme Director

Contents

1 Purpose

1.1 The purpose of this document is to define the Terms of Reference for the 'Board Task and Finish Group (New Congenital Heart Disease Review)'.

2 Background

2.1 Following the outcome of judicial review, the report by the Independent Reconfiguration Panel (IRP) and the Secretary of State's announcements relating to the Safe and Sustainable review of children's congenital heart services, in summer 2013, NHS England established a new review to consider the whole lifetime pathway of care for people with congenital heart disease.

2.2 The aim of the review is to ensure that services for people with congenital heart disease are provided in a way that achieves the highest possible quality within the available resources:

- To secure the best outcomes for all patients, not just lowest mortality but reduced disability and an improved opportunity for survivors to lead better lives.
- To tackle variation so that services across the country consistently meet demanding performance standards and are able to offer resilient 24/7 care.
- To ensure great patient experience, which includes how information is provided to patients and their families, considerations of access and support for families when they have to be away from home.

2.3 The Task and Finish Group (referred to as "the Group" from here on in) has been established by the NHS England Board (referred to as "the Board" from here on in) to provide oversight to, and assure the development of, the new review of congenital heart disease services.

2.4 The Board has authorised the Group to provide strategic direction on behalf of the Board on all matters relevant to the new Congenital Heart Disease review.

2.5 The Group does not have permanency, and will exist until such time as the review has concluded and an implementable solution has been agreed. The high level programme plan and ambition of the organisation suggests that this will be June 2015.

3 Role and Responsibilities

3.1 The role of the Task and Finish Group is to:

- Provide strategic direction to the new congenital heart disease review on behalf of the Board;

- Provide assurance to the Board that the work of the review is aligned with the aims stated above and NHS England's other strategic priorities;

- Advise the Board on particular issues in relation to the review and also on any decisions which the Board may be required to make; and

- Where required, commission work and/or request further information from the Programme Board in order for the Group to fulfil its function.

3.2 The Task and Finish Group will be responsible for the following:

- Making arrangements for the proper governance of the review and its programme of work;

- Appointing a senior responsible owner for the programme;

- Taking decisions on the direction and running of the review;

- Ensuring that arrangements are in place to provide the group with clinical advice and the review with clinical leadership;

- Assuring the board that appropriate arrangements have been made for the engagement of stakeholders in the review;

- Resolving any issues and risks escalated by the Programme Board;

- Ensuring that the review is properly resourced including ensuring that the review is a priority for the whole organisation and that the resources of the whole organisation are appropriately mobilised to support the work;

- Making recommendations to the board on the actions to be taken as a result of the review, in particular decisions affecting the commissioning and delivery of congenital heart disease services; and

- At the end of Phase 3 (*preparation for implementation*), providing a recommendation to the Board in respect of ongoing governance arrangements in light of any decisions made and plans for implementation.

4 Membership

4.1 Core Membership

The core membership of the Task and Finish Group is as follows:

- Professor Sir Malcolm Grant, NHS England Chair (Chair);

- Ed Smith, NHS England Non-Executive Director;

- Margaret Casely-Hayford, NHS England Non-Executive Director;
- Professor Sir Bruce Keogh, National Medical Director;
- Ian Dodge, National Director: Commissioning Strategy and Chair of the Programme Board; and
- Professor Sir Michael Rawlins, Chair of the Clinical Advisory Panel.

4.2 **Additional attendees**

The additional attendance at the meetings is as follows:

- John Holden, Director of System Policy; and
- Secretariat.

4.3 On occasions when the Chair is unable to attend the meeting it will be chaired by a non-executive director.

4.4 The meeting will be quorate if three members are present, one of which must be a non-executive director and one, a national director.

4.5 Where members are unable to attend a meeting, deputies will not normally be appropriate. Where a member considers that a deputy may be appropriate this should be agreed with the Chair in advance. Such deputies in attendance will not count toward the meeting being quorate.

5 Frequency

5.1 The Task and Finish Group will meet at the end of each phase of the programme and on such occasions as the Chair shall deem necessary.

6 Secretariat

6.1 The Task and Finish Group Secretariat function will be provided by the new congenital heart disease review Programme Director.

7 Agenda and papers

7.1 The agenda and all papers will be normally be distributed via email to members and those in attendance in advance of the meeting by the new Congenital Heart Disease review team. The agenda and papers will be published on the NHS England website in advance of the meeting.

7.2 The actions to be taken will be recorded in the Task and Finish Group's minutes which will be circulated to all members of the Group.

7.3 The Chair is responsible for ensuring that the minutes of meetings, produced by the Secretariat, and any reports to NHS England accurately record the decisions taken, and, where appropriate, that the views of the individual group members have been taken into account. Once agreed by the Chair the minutes will be published on the NHS England website as outlined in the procedural rules document.

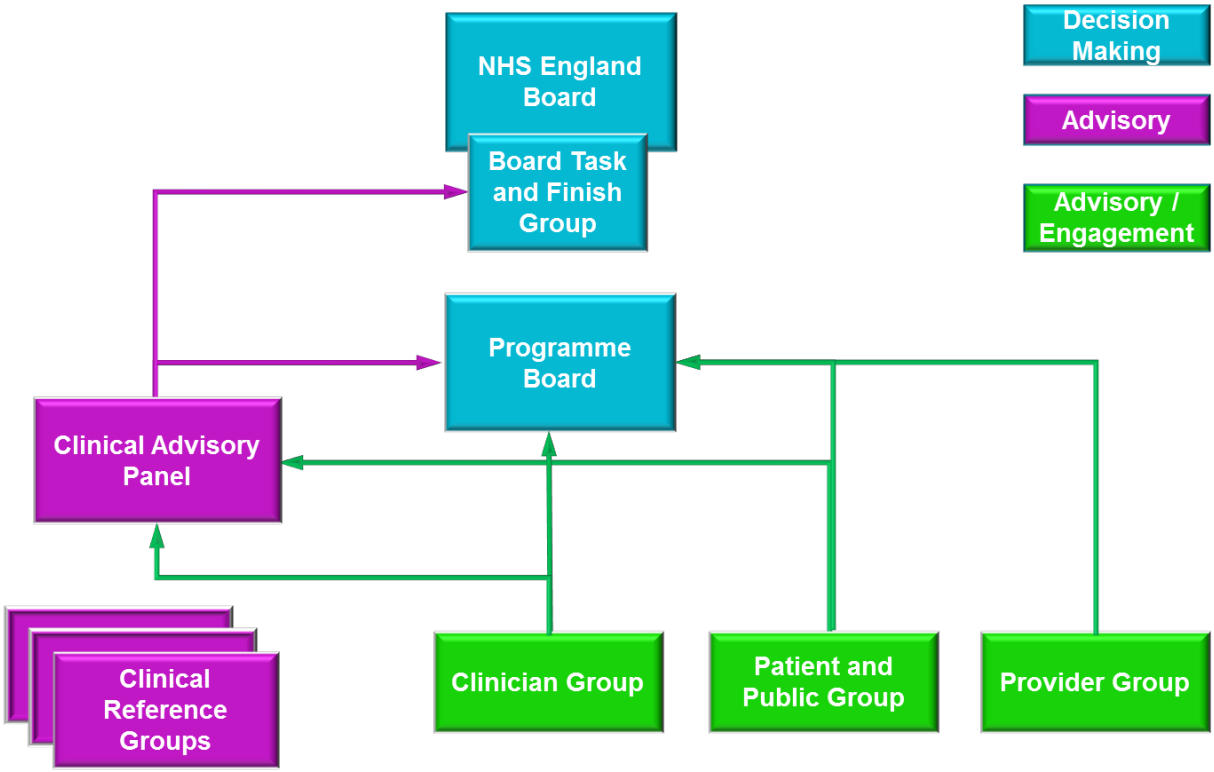
7.4 Minutes will be formally approved at the subsequent meeting (or by email where this would be more than one month later). Approved minutes will be published on the NHS England website.

8 Reporting line(s)

8.1 A report from the SRO on the work of the review will be provided at each board meeting.

8.2 The Group will make recommendations to the Board of any decisions requiring full Board approval and at the end of phase 3.

8.3 A diagram illustrating the governance structure is shown below:



9 Declaration of interests

9.1 Members must comply with the document *"Policy for managing potential conflicts of interest"* which details the approach and broad principles for the management of potential and perceived conflicts of interest, specifically in relation to the new Congenital Heart Disease review.

10 Public services values for members

10.1 Members must comply with the NHS England Standards of Business Conduct Policy at all times. Available here: http://www.england.nhs.uk/wp-content/uploads/2012/11/stand-bus-cond.pdf.

Published in electronic format only

NHS England

New Congenital Heart Disease Review Programme Board Terms of Reference

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Document Name	New Congenital Heart Disease Review Programme Board Terms of Reference
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Cross Reference	n/a
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Action Required	As described
Timing/Deadlines	See programme plan
Contact Details (for further information)	Jennie Smith, Programme Co-ordinator jennie.smith5@nhs.net NHS England Quarry House Quarry Hill Leeds LS2 7UE Direct Line: 0113 8248232

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New Congenital Heart Disease Review Programme Board Terms of Reference

Version number: 3.0

First published: 17 October 2013

Updated: 8 July 2014

Prepared by: Michael Wilson, Programme Director

Contents

1 Purpose

1.1 The purpose of this document is to define the Terms of Reference for the 'New Congenital Heart Disease Review Programme Board'.

2 Background

2.1 Following the outcome of judicial review, the report by the Independent Reconfiguration Panel (IRP) and the Secretary of State's announcements relating to the Safe and Sustainable review of children's congenital heart services, in summer 2013, NHS England established a new review to consider the whole lifetime pathway of care for people with congenital heart disease.

2.2 The aim of the review is to ensure that services for people with congenital heart disease are provided in a way that achieves the highest possible quality within the available resources:

- To secure the best outcomes for all patients, not just lowest mortality but reduced disability and an improved opportunity for survivors to lead better lives.
- To tackle variation so that services across the country consistently meet demanding performance standards and are able to offer resilient 24/7 care.
- To ensure great patient experience, which includes how information is provided to patients and their families, considerations of access and support for families when they have to be away from home.

2.3 The Programme Board has been established to support the SRO (Senior Responsible Owner) in managing all aspects of the review's work, taking day-to-day decisions on the running of the review. It is responsible for ensuring that the programme delivers its objectives, manages risk and for ensuring that there is a comprehensive and effective approach to stakeholder participation and involvement.

2.4 The Programme Board will have regard for the views of the provider group, the patient and public group, the clinician group and the clinical advisory panel.

2.5 The Programme Board will make recommendations to the Board Task and Finish Group.

3 Role and Responsibilities

3.1 The programme board will support the SRO (Senior Responsible Owner) in managing all aspects of the review's work, taking day-to-day decisions on the running of the review:

- Take overall responsibility for the effective running of the programme;

- Approve the:
  - Programme initiation document;
  - Programme plan and milestones;
  - Communications and engagement plan; and
  - Plan for evaluation.

- Agree significant variations to the programme plan;

- Monitor and manages programme progress;

- Provide visible leadership, direction and commitment to the programme, promoting effective communication of the programme's goals and progress;

- Ensure availability of essential programme resources;

- Report to the Board Task and Finish Group.

3.2 Ensure that the programme delivers its objectives:

- Develops standards to give consistent services, improved outcomes, and improved patient experience for people with CHD;

- Analyses the demand for specialist inpatient CHD care, now and in the future;

- Makes recommendations about the function, form and capacity of services needed to meet that demand and meet quality standards, taking account of accessibility and health impact;

- Makes recommendations on the commissioning and change management approach including an assessment of workforce and training needs;

- Establishes a system for the provision of information about the performance of CHD services to inform the commissioning of these services and patient choice;

- Improves antenatal and neonatal detection rates.

3.3 Manage risks and issues:

- Own risks and issues and develop proposals for mitigation / resolution;

- Ensure that all material risks and appropriate mitigating actions are recorded in the risk register;

- Escalate risks and issues to the Board Task and Finish Group as necessary.

3.4 Ensure that there is a comprehensive and effective approach to stakeholder participation and involvement.

4 Membership

4.1 The Chair of the Programme Board is the National Director: Commissioning Strategy as appointed by the Board Task and Finish Group, and has particular responsibility for providing effective leadership.

4.2 The Director of System Policy is the Vice Chair and is responsible for chairing Programme Board meetings and providing leadership if the Chair is unavoidably absent, or is not able to chair the meeting due to a conflict of interest for specific items on the agenda.

4.3 **Core Membership**
The core membership of the Programme Board is as follows:

- Ian Dodge, National Director: Commissioning Strategy (Chair);
- John Holden, Director of System Policy (Vice Chair);
- Wayne Bartlett-Syree, Assistant Head of Planning and Delivery (Specialised Commissioning;
- Eleri de Gilbert, Area Team representative, Area Team Director (South Yorkshire and Bassetlaw area team);
- Sam Higginson, Finance representative, Director of Strategic Finance;
- Chris Hopson, Chair of the review's Provider Group;
- Will Huxter, Regional Team representative, Head of Specialised Commissioning (London);
- Professor Deirdre Kelly, Chair of the review's Clinician Group;
- Professor Sir Bruce Keogh, National Medical Director;
- Michael Macdonnell, Head of Strategy, Specialised Commissioning Taskforce;
- Mr James Palmer, National Clinical Director, Specialised Services;
- Mr Daniel Phillips, Director of Planning, Welsh Health Specialised Services Committee;
- Linda Prosser, Area Team representative, Director of Commissioning (Bristol, North Somerset, Somerset and South Gloucestershire area team);
- Professor Sir Michael Rawlins, Chair of the Clinical Advisory Panel;
- Professor Peter Weissberg, Chair of the review's Patient and Public Group;
- Giles Wilmore, Director for Patient & Public Voice & Information;
- Michael Wilson, review Programme Director;
- Dr Cathy Winfield, (NHS Wokingham CCG); and
- one additional CCG representative, to be identified.

4.4 The meeting will be quorate if 10 members are present.

4.5 Where members are unable to attend a meeting, they may field a nominated deputy. Such deputies in attendance will count toward the meeting being quorate.

4.6 **Additional attendees**
The additional attendance at the Programme Board is as follows:

- Secretariat.

5 Frequency

5.1 The New Congenital Heart Disease Review Programme Board meeting will be held monthly and on such other occasions as the Chair shall deem necessary.

6 Secretariat

6.1 The Programme Board Secretariat function will be provided by the new congenital heart disease review team.

7 Agenda and papers

7.1 The agenda and all papers will be normally be distributed via email to members and those in attendance in advance of the meeting by the new Congenital Heart Disease review team. The agenda and papers will be published on the NHS England website in advance of the meeting.

7.2 The actions to be taken will be recorded in the Programme Board's minutes which will be circulated to all members of the Programme Board.

7.3 The Chair is responsible for ensuring that the minutes of meetings, produced by the Secretariat, and any reports to NHS England accurately record the decisions taken, and, where appropriate, that the views of the individual members have been taken into account. Once agreed by the Chair the minutes will be published in draft on the NHS England website.

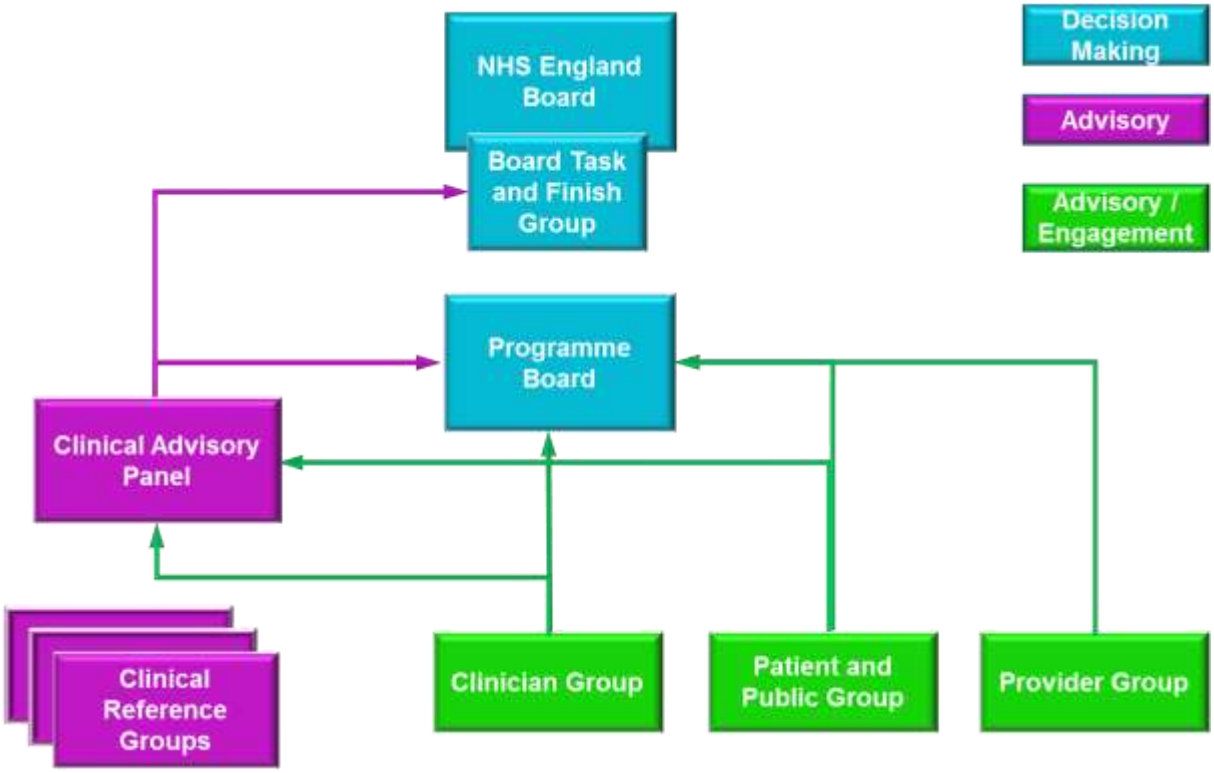
7.4 Minutes will be formally approved at the subsequent meeting. Approved minutes will be published on the NHS England website.

8 Reporting line(s)

8.1 A report will be provided by the SRO at each meeting of the Board Task and Finish Group on the work of the review.

8.2 The Programme Board will make recommendations to the Board Task and Finish Group of any decisions requiring full Board approval and at the end of phase 3.

8.3 A diagram illustrating the governance structure is shown below:



9 Declaration of interests

9.1 Members must comply with the document “Managing potential and perceived conflicts of interest” which details the approach and broad principles for the management of potential and perceived conflicts of interest, specifically in relation to the new Congenital Heart Disease review.

10 Public services values for members

10.1 Members must comply with the NHS England Standards of Business Conduct Policy at all times. Available here: http://www.england.nhs.uk/wp-content/uploads/2012/11/stand-bus-cond.pdf

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Children's Congenital Heart Services

NHS

Specialised Services

Children's Congenital Heart Services, Phase 2, Implementation

Clinical Implementation Advisory Group Standards Sub-group

Terms of Reference

Introduction

A joint committee of Primary Care Trusts (JCPCT), by virtue of delegated powers of decision making, made a final decision on the future configuration of children's congenital heart services in England in July 2012. Implementation will be planned and coordinated nationally, initially on behalf of NHS specialised commissioners, and from April 2013, on behalf of the NHS Commissioning Board. The JCPCT decision included establishing a number of congenital heart networks in England including the development of District Children's Cardiology Services and Children's Cardiology Centres *'for which standards will need to be developed'*.

This document sets out the Terms of Reference for the Clinical Implementation Advisory Group Standards Sub-group.

Programme Scope

- Improving the quality of care of children with suspected or diagnosed congenital heart disease, from the pre-natal period (including care of women whose unborn child has suspected or confirmed congenital heart disease) , through infancy, childhood and through transition to transfer into adult services
- Establishing seven children's congenital heart networks that cover the whole population of England and Wales
- Developing standards for Children's Cardiology Centres and District Children's Cardiology Services and commissioning these services as required in each network
- Ensuring the application of quality standards covering network working and the whole care pathway from prenatal screening and services through transition to transfer to adult services
- Commissioning of heart surgical services for children, that meet the specified quality standards, from the seven designated providers
- Decommissioning of heart surgical services for children from the four providers that were not designated
- Implementing new systems to improve the collection, analysis and reporting of outcome data

- Designating Birmingham Children's Hospital NHS Foundation Trust as a nationally commissioned provider of extracorporeal membrane oxygenation (ECMO) services for children with respiratory failure in place of the unit at University Hospitals of Leicester NHS Trust

The programme initiation document (PID) gives full details of programme scope (including what is not in scope), dependencies and linkages.

Programme Objectives

To ensure that:

1. Excellent care with a focus on the child and their family will be achieved by developing standards of care for the whole patient pathway from the pre-natal period (including care of women whose unborn child has suspected or confirmed congenital heart disease) through infancy, childhood and through transition to transfer into adult services, implemented through commissioning and monitored and managed by the networks.

2. Seven managed children's congenital heart networks are established covering the whole population of England, each with a specialist surgical centre.

3. The new model of care including local and regional cardiology services for children with congenital heart disease and a reduced number of specialist surgical centres is established.

4. Nationally commissioned ECMO services for children with respiratory failure are provided by Birmingham Children's Hospital NHS Foundation Trust in place of University Hospitals of Leicester NHS Trust.

5. Transition to the new system is managed safely and efficiently, and in such a way as to realise the benefits described in the PID, and clinical interdependencies and linkages are managed.

Sub-group purpose

To describe generic referral pathways for children with suspected congenital heart disease

To describe the core service offering for:

- District Children's Cardiology Services (DCCS)
- Children's Cardiology Centres (CCC)

To develop standards for cardiology services, building on the Safe and Sustainable standards across all settings including Specialist Surgical Centres, Children's Cardiology Centres and District Children's Cardiology Services.

To advise commissioners on the development of processes of self-assessment and peer review of services against the standards.

Sub-group deliverables

A paper describing the minimum service offering for DCCSs and CCCs, and referral pathways into and onwards from these services.

A document setting out standards document for cardiology services, across all settings including SSCs, CCCs and DCCSs.

A paper setting out proposals for self-assessment and peer review processes for DCCSs and CCCs.

Membership

All members of the Clinical Implementation Advisory Group Standards Sub-group are required to declare any professional or personal interests which may affect their contributions. These interests should be declared to the Clinical Implementation Advisory Group Standards Sub-group Chair and reviewed as and when they occur.

The group will be chaired by Dr Tony Salmon.

Member	Role
Dr Tony Salmon Chair	Consultant in Paediatric and Adult Congenital Cardiology, Southampton University Hospitals NHS Foundation Trust
Adam Tansey	Parent and Service User Representative, Keep the Beat
Dr Anjum Gandhi	Consultant Paediatrician, Heart of England NHS Foundation Trust
Colette Cochran	Paediatric Cardiac Nurse Specialist, Southampton University Hospitals NHS Foundation Trust
Dr David Mabin	Consultant Paediatrician with Expertise in Cardiology, Royal Devon & Exeter NHS Foundation Trust
Dr Dirk Wilson	Consultant Paediatric Cardiologist, Cardiff and Vale University Health Board
Dr Fiona Willcoxson	Consultant in Children's Cardiology, Leeds Teaching Hospitals NHS Trust
Dr Frances Bu'Lock	Consultant Paediatric Cardiologist, University Hospitals of Leicester NHS Trust
Gail Fortes-Mayer	Assistant Director, Specialised Commissioning, Midlands and East
Dr Ian Peart	Consultant Paediatric Cardiologist, Alder Hey Children's NHS Foundation

	Trust
Mr James Bruce	Consultant Paediatric Surgeon and Clinical Head, Royal Manchester Children's Hospital
Dr James Gnanapragasam	Consultant Paediatric Cardiologist, Southampton University Hospitals NHS Foundation Trust
Dr Janet Burns	Consultant Cardiologist, NHS Lothian
Dr Michael Burch	Director of Transplantation and Lead Cardiologist, Great Ormond Street Hospital for Children NHS Foundation Trust
Dr Milind Chaudhari	Consultant Paediatric and Adult Congenital Cardiologist, The Newcastle upon Tyne Hospitals NHS Foundation Trust
Dr Nick Archer	Consultant in Paediatric Cardiology, Oxford University Hospitals NHS Foundation Trust
Dr Owen Miller	Consultant in Paediatric & Fetal Cardiology, Guys and St Thomas' NHS Foundation Trust
Dr Rodney Franklin	Consultant and Lead Paediatric Cardiologist, Royal Brompton & Harefield NHS Foundation Trust
Dr Sara O'Curry	Consultant Clinical Psychologist specialising in Paediatric Cardiology, Great Ormond Street Hospital for Children NHS Foundation Trust
Suzie Hutchinson	Chief Executive, Little Hearts Matter
Dr Wilf Kelsall	Consultant Paediatric Cardiologist & Neonatologist, Cambridge University Hospitals NHS Foundation Trust
Michael Wilson	Implementation Programme Director

Individuals may also be invited as members, or co-opted for specific meetings, at the discretion of the Chair if it is considered that they will contribute specific expertise.

Linkages

The links between the work of the standards sub-group and the work of the other CIAG sub-groups, and other associated groups are managed through the CIAG Executive Group.

Accountability

The Clinical Implementation Advisory Group Standards Sub-group is accountable to the Children's Congenital Heart Services, Phase 2, Clinical Implementation Advisory Group.

Conduct of Meetings

The group will meet on a monthly basis as well as maintaining more frequent contacts as necessary by email and through conference calls.

Quorum is eight including the Chair.

Support

The Clinical Implementation Advisory Group Standards Sub-group will be supported by the programme team. This support will include support to chairs in preparing agendas, minute taking, venue booking and the development of working papers for groups.

NHS England

New Congenital Heart Disease Review Clinical Advisory Panel Terms of Reference

Information Reader Box

Directorate	
Medical	Commissioning Operations
Nursing	Commissioning Strategy
Patients & Information	Transformation and Corporate Operations
Finance	

Document Purpose	To describe the terms of reference of the New Congenital Heart Disease Review Board Task and Finish Group
Document Name	New Congenital Heart Disease Review Board Task and Finish Group Terms of Reference
Author	NHS England, Commissioning Strategy Directorate
Target Audience	General
Additional Circulation List	Website; Intranet
Description	Terms of Reference
Cross Reference	n/a
Superseded Document	n/a
Action Required	As described
Timing/Deadlines	See programme plan
Contact Details (for further information)	Jennie Smith, Programme Co-ordinator england.congenitalheart@nhs.net NHS England Quarry House Quarry Hill Leeds LS2 7UE Direct Line: 0113 8248232

Document Status

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New Congenital Heart Disease Review Clinical Advisory Panel Terms of Reference

Version number: 1.5

First published: 10 October 2013

Updated: 01 September 2014

Prepared by: Michael Wilson, Programme Director

Contents

1 Purpose

1.1 The purpose of this document is to define the Terms of Reference for the 'New Congenital Heart Disease Review Clinical Advisory Panel'.

2 Background

2.1 Following the outcome of judicial review, the report by the Independent Reconfiguration Panel (IRP) and the Secretary of State's announcements relating to the Safe and Sustainable review of children's congenital heart services, in summer 2013, NHS England established a new review to consider the whole lifetime pathway of care for people with congenital heart disease.

2.2 The aim of the review is to ensure that services for people with congenital heart disease are provided in a way that achieves the highest possible quality within the available resources:

- To secure the best outcomes for all patients, not just lowest mortality but reduced disability and an improved opportunity for survivors to lead better lives.
- To tackle variation so that services across the country consistently meet demanding performance standards and are able to offer resilient 24/7 care.
- To ensure great patient experience, which includes how information is provided to patients and their families, considerations of access and support for families when they have to be away from home.

2.3 The Clinical Advisory Panel has been convened to provide a full range of clinical advice and recommendations on all aspects of the new congenital heart disease review to the NHS England National Medical Director and to the NHS England Board, the Board Task and Finish Group and the Programme Board.

2.4 The constitution of the Panel ensures a broad and strategic perspective, from across a wide range of specialties as well as an international perspective, allowing the review to benefit from expertise, not limited only to congenital heart disease, but the broader system and the challenges of delivering clinical services.

3 Role and Responsibilities

3.1 **The role of the Clinical Advisory Panel is as follows:**

- To advise on how the programme should achieve the best clinical outcome for patients, and tackles variation so that services across the country consistently meet demanding performance standards and offer resilient 24/7 care.

- To advise on the metrics and information systems needed by NHS England as commissioners:
    - To measure outcomes (mortality, disability and quality of life).
    - To drive improvement.
    - To monitor the safety and quality of services.
- To advise on the evaluation of the work of the review.
- To support the National Medical Director in the design and implementation of an effective approach to clinical engagement.
- To advise on all clinical aspects of the programme including providing expert opinion on a range of specific issues, including quality assurance of supporting work.
- To provide clinical leadership to the programme, facilitate clinical discussions and to act as advocates for the programme.
- To advise on clinical workforce and training issues.
- To advise on how to align leading edge research and clinical practice.

3.2 The clinical advisory panel will have regard for the views of the clinical reference groups, the clinicians' group and the patient and public group.

4 Membership

4.1 The Chair and Members are appointed by the National Medical Director and the Chair has particular responsibility for providing effective leadership.

4.2 The Chair of the panel and the National Medical Director will nominate a Vice Chair from among the members, responsible for chairing the Panel meetings and providing leadership if the Chair is unavoidably absent or is not able to chair the meeting due to conflict of interest for specific items on the agenda.

4.3 The National Medical Director has advised that it is not intended that the Panel have a representative from every conceivable profession, speciality or geography. The programme has other means of achieving that (through the clinician group and the Clinical Reference Groups). Rather Panel members are asked to bring their professional experience and knowledge, but act in the wider interests of the service.

4.4 Members are selected for their personal expertise even when they may also be affiliated to specific stakeholder groups. As such they are appointed as individuals

to fulfil their role on the panel and it is expected that in their role as a member they will act in the public interest.

4.5 **Core membership**

- Professor Sir Michael Rawlins, President, Royal Society of Medicine (Chair);
- Mr Graham Cooper, Society for Cardiothoracic Surgery;
- Professor John Deanfield, Chair of Adult with Congenital Heart Disease Advisory Group;
- Professor Deirdre Kelly, Chair of the review's Clinician Group;
- Rob Martin, British Congenital Cardiac Association
- Dr Andy Mitchell, Regional Medical Director (London), (NHS England);
- Professor Pedro del Nido, International Advisor;
- Mr James Palmer, National Clinical Director for Specialised Services (NHS England);
- Dr Tony Salmon, Chair of the review's Standards Sub Group;
- Fiona Smith, Royal College of Nursing;
- Professor Terence Stephenson, Academy of Medical Royal Colleges;
- Graham Stuart, Chair of the Clinical Reference Group for Congenital Heart Services
- Dr J-P van Besouw, The Royal College of Anaesthetists;
- Professor Peter Weissberg, Chair of the review's Patient and Public Group;
- Professor Norman Williams, Royal College of Surgeons;

4.6 The meeting will be quorate if 10 members are present.

4.7 **Additional attendees**

The additional attendance at the meetings is as follows:

- Secretariat.

5 Frequency

5.1 The Clinical Advisory Panel meeting will be held every two months and on such occasions as the Chair shall deem necessary. The advice of the panel may also be sought via email between meetings.

6 Secretariat

6.1 The Clinical Advisory Panel Secretariat function will be provided by the new congenital heart disease review Programme Director.

7 Agenda and papers

7.1 The agenda and all papers will be normally be distributed via email to members and those in attendance in advance of the meeting by the new Congenital Heart Disease review team. The agenda and papers will be published on the NHS England website in advance of the meeting.

7.2 The actions to be taken will be recorded in the Clinical Advisory Panel's minutes which will be circulated to all members of the Group.

7.3 The Chair is responsible for ensuring that the minutes of meetings, produced by the Secretariat, and any reports to NHS England accurately record the decisions taken, and, where appropriate, that the views of the individual group members have been taken into account. Once agreed by the Chair the minutes will be published on the NHS England website as outlined in the procedural rules document.

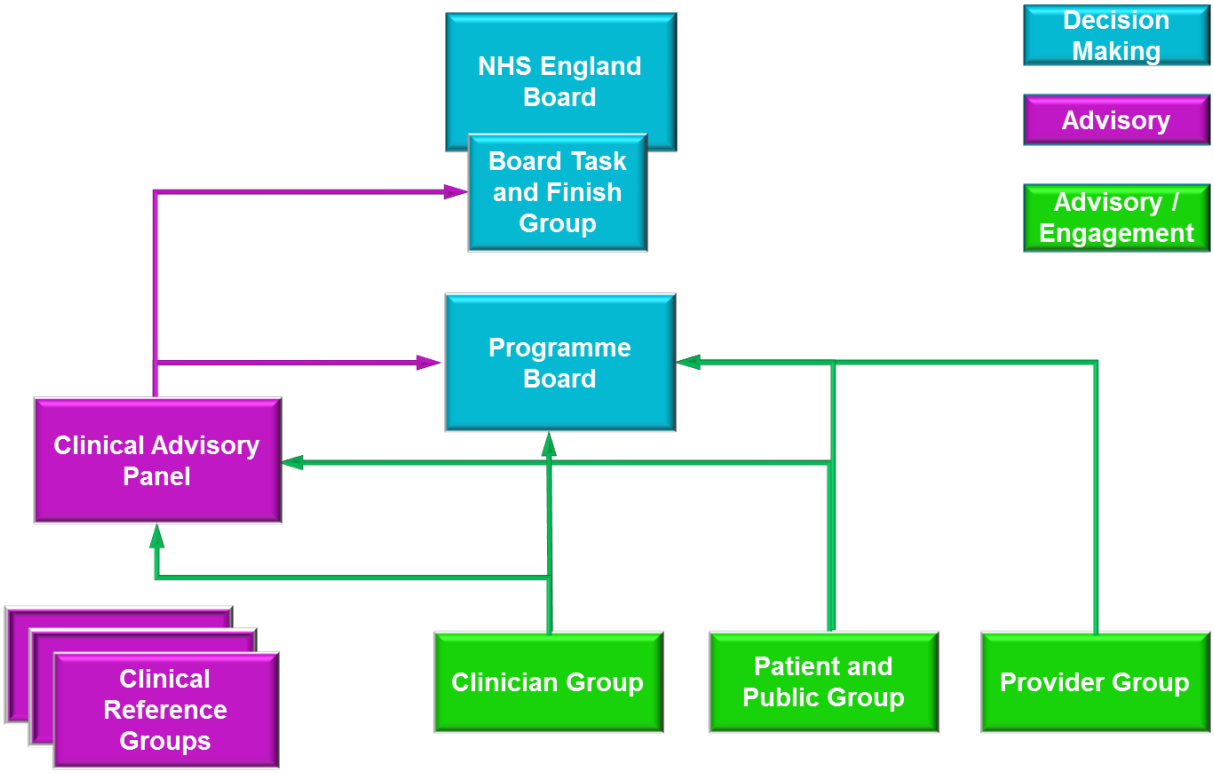
7.4 Minutes will be formally approved at the subsequent meeting (or by email where this would be more than one month later). Approved minutes will be published on the NHS England website.

8 Reporting line(s)

8.1 The Panel Chair will brief the National Medical Director after each meeting of the Clinical Advisory Panel.

8.2 The Panel Chair is a member of both the Task and Finish Group and the Programme Board.

8.2 A diagram illustrating the governance structure is shown on the next page:



9 Declaration of interests

9.1 Members must comply with the document *"Policy for managing potential conflicts of interest"* which details the approach and broad principles for the management of potential and perceived conflicts of interest, specifically in relation to the new Congenital Heart Disease review.

10 Public services values for members

10.1 Members must comply with the NHS England Standards of Business Conduct Policy at all times. Available here: http://www.england.nhs.uk/wp-content/uploads/2012/11/stand-bus-cond.pdf.

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Clinicians' Group

Terms of Reference

Purpose	
To facilitate engagement of, and advice from, clinicians providing congenital heart disease services in the new congenital heart disease review.	
Duties	
The Clinicians' Group will advise on all clinical aspects of the review. The group will provide advice based on its specialist experience. The Clinicians' Group will consider the impact of the review on the provision of clinical services. The Clinicians' Group will advise on the review's approach to clinical engagement. It will also advise on workforce and training issues. The Clinicians' Group advises the review's Clinical Advisory Panel and Programme Board through its Chair, Professor Deirdre Kelly and in turn this group is updated from the Programme Board and Clinical Advisory Panel.	
Members	***Attendees***
Professor Deirdre Kelly, Birmingham Children's Hospital (Chair) One clinician (nominated by the organisation's Chief Executive) from: • every English provider trust identified as providing any congenital heart surgery or cardiology intervention or with a specialist congenital cardiology centre. • Welsh, Scottish and Northern Irish hospitals providing specialist congenital heart services. Representatives from relevant professional colleges and societies covering the main clinical professions and specialist groups involved in delivering care for congenital heart disease. Representatives from the Clinical Reference Groups involved in delivering care for congenital heart disease.	John Holden, Director of System Policy Michael Wilson, Programme Director
Quorum	***Frequency***
n/a	Every two months.

Patient and Public Group

Terms of Reference

Purpose	
To facilitate engagement of, and advice from, service users and their representatives in the new congenital heart disease review.	
Duties	
The Patient and Public Group will advise on all aspects of the review that affect service users, helping to ensure that the review results in great patient experience (including the way information is provided to patients and their families, considerations of access and support for families, including when they have to be away from home). The Patient and Public Group will advise on the review's approach to patient and public engagement and provide a user perspective on emerging proposals. The Patient and Public Group will advise the review's Programme Board and the Clinical Advisory Panel through its Chair, Professor Peter Weissberg of the British Heart Foundation and in turn this group is updated from the Programme Board and Clinical Advisory Panel.	
Members	***Attendees***
Professor Peter Weissberg, British Heart Foundation (Chair) Two nominated representatives from each relevant national and local charity or support group	John Holden, Director of System Policy Michael Wilson, Programme Director
Quorum	***Frequency***
n/a	Every two months.

Provider Group

Terms of Reference

Purpose	
To facilitate engagement of, and advice from, organisations providing congenital heart disease services in the new congenital heart disease review.	
Duties	
The Provider Group will advise on all aspects of the review that affect service provision and the organisations that provide those services. The Provider Group will advise on organisational, financial and workforce issues, as well as implementation planning and risk mitigation. The Provider Group advises the review's Programme Board through its chair, Chris Hopson of the Foundation Trust Network and in turn this group is updated from the Programme Board.	
Members	***Attendees***
Chris Hopson, Chief Executive FTN (Chair) Chief Executives (or their nominees) from: • every English provider trust identified as providing any congenital heart surgery or cardiology intervention or with a specialist congenital cardiology centre • Welsh, Scottish and Northern Irish hospitals providing specialist congenital heart services.	John Holden, Director of System Policy Michael Wilson, Programme Director
Quorum	***Frequency***
n/a	Every two months.

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, O'Keeffe C, Campbell F, Jesurasa A, Cooper K, Goyder E*

School for Health and Related Research (ScHARR), University of Sheffield, UK

*Corresponding Author

Competing Interests: None Declared

Important

This web report has been created once the normal NIHR Journals Library peer and editorial review processes are complete. The report has undergone full peer and editorial review as documented at NIHR Journals Library website and may undergo rewrite during the publication process. The order of authors was correct at editorial sign-off stage.

A final version (which has undergone a rigorous copy-edit and proofreading) will publish in a forthcoming issue of the *Health Services and Delivery Research* journal.

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The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HS&DR editors have tried to ensure the accuracy of the authors' work and would like to thank the reviewers for their constructive comments however; they do not accept liability for damages or losses arising from material published in this web report.

This web report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HS&DR programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HS&DR programme or the Department of Health.

Abstract

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, O'Keeffe C, Campbell F, Jesurasa A, Cooper K, Goyder E*
School for Health and Related Research (ScHARR), University of Sheffield, UK

*Corresponding Author e.goyder@sheffield.ac.uk

Background: The purpose of this rapid evidence synthesis is to support the current NHS England service review on organisation of services for Congenital Heart Disease (CHD). The evidence synthesis team was asked to examine the evidence on relationships between organisational features and patient outcomes in CHD services, and specifically, any relationship between (1) volume of cases and patient outcomes and (2) proximity of co-located services and patient outcomes. A systematic review published in 2009 had confirmed the existence of this relationship but cautioned this was not sufficient to make recommendations on the size of units needed.

Objectives: To identify and synthesise the evidence on the relationship between organisational features and patient outcomes for adults and children with congenital heart disease.

Data sources: A systematic search of medical and health related databases (MEDLINE, EMBASE, CINAHL, Cochrane Library and Web of Science) was undertaken for 2009 – 2014 together with citation searching, reference list checking and stakeholder recommendations of evidence from 2003-2014.

Review methods: This was a rapid review so application of the inclusion and exclusion criteria to retrieved records was undertaken by one reviewer, with 10% double checked. Five reviewers extracted data from included studies using a bespoke data extraction form then used for evidence synthesis. No formal quality assessment was undertaken but the usefulness of the evidence was assessed together with limitations identified by study authors.

Results: Thirty nine papers were included in the review. No UK studies were identified and 36/39 (92.4%) only included outcomes for paediatric patients. Thirty two (82%) investigated the relationship between volume and mortality and 7 (18%) other service factors or outcomes. 90% were from the USA, 92.4% were multicentre studies and all were retrospective observational studies. Twenty five studies (64%) included all CHD conditions and 14 (36%) single conditions or procedures. Although the evidence does demonstrate a relationship between volume and outcome in the majority of studies, this relationship is not consistent. The relationship was stronger for single complex conditions or procedures. A mixed picture emerged revealing a range of factors as well as volume that influence outcome including condition severity, individual centre and surgeon effects and clinical advances over time. We found limited (7 studies) evidence about the impact of proximity and co-location of services on outcomes and about volume on non-mortality outcomes.

Limitations: This was a rapid review that followed standard methods to ensure transparency and reproducibility. The main limitations of the included studies were the retrospective nature, reliance on routine datasets, completeness and selection bias and lack of data on key clinical and service processes.

Conclusions: This review identified a substantial number of studies reporting a positive relationship between volume and outcome, but the complexity of the evidence requires careful interpretation. The heterogeneity of findings from observational studies suggests that, whilst a relationship between volume and outcome exists, this is unlikely to be a simple, independent and directly causal relationship. The effect of volume on outcome relative to the effect of other as yet undetermined health system factors remains a complex and unresolved research question.

Funding: The National Institute for Health Research HS&DR Programme

Word Count – 561 words

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List of Abbreviations

ACHD	Adult Congenital Heart Disease
ASO	Arterial switch operation
BTSP	Blalock Taussig Shunt Procedure
CHD	Congenital Heart Disease
CHSS	Congenital Heart Surgeon's Society
CI	Confidence Interval
CICU	Children's Intensive Care Unit
cPICU	Cardiac Paediatric Intensive Care Unit
EACTS	European Association for Cardio-Thoracic Surgery
ECMO	Extra Corporeal Membrane Oxygenation
HCUP	Healthcare Cost and Utilisation Project
HLHS	Hypoplastic Left Heart Syndrome
HS&DR	Health Services and Delivery Research
ICU	Intensive Care Unit
IRP	Independent Review Panel
JR	Judicial Review
LOS	Length of Stay
LTH	Large Teaching Hospital
MBTS	Modified Blalock-Taussig shunt
NHS	National Health Service
NIHR	National Institute of Health Research
NIS	Nationwide Inpatient Sample
OECD	Organisation for Economic Cooperation and Development
OHT	Orthotopic heart transplant
OR	Odds Ratio
OSHPD	Office of State-wide Health Planning and Development (California)
PA	Pulmonary Atresisia
PAIVS	Pulmonary Atresisia with Intact Ventricular Septum
PCCC	Paediatric Cardiac Care Consortium
PHIS	Paediatric Health Information System
RACHS-1	Risk Adjusted Classification on Congenital Heart Surgery
ROC	Receiver Operating Curve

ScHARR	School of Health and Related Research
SMR	Standardised Mortality Ratio
STS	Society of Thoracic Surgeons
TGA	Transposition of Great Arteries
UHC	University Health System Consortium
UNOS	United Network for Organ Sharing
VAD	Ventricular Assist Device
VSD	Ventricular Septal Defect

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HS&DR programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HS&DR programme or the Department of Health.

Scientific Summary

Background

This rapid evidence synthesis has been written in response to a request by NHS England to further examine the evidence around the delivery of congenital heart disease (CHD) services. The purpose of the evidence synthesis is to support the ongoing service review about how these services should be best organised. Prior work for the service review referred to a 2009 literature review which confirmed a relationship between volume and patient outcomes in CHD and highlighted the contributory effects of other system and process factors to this relationship. This rapid evidence synthesis has reassessed and updated the evidence base to examine what evidence there is for a relationship between organisational features and patient outcomes in CHD services.

Objectives

This rapid review focusses on two key organisational features – volume and proximity. The rationale for this is based on the hypothesis that there may be a relationship between the volume of CHD procedures (both by institution and by surgeon) and patient outcomes and the clinical conjecture that reconfiguration which includes the co-location (or increased proximity) of specialist services may be related to better patient outcomes. The research questions also reflect the view that mediating factors influence the relationship between patient outcomes and volume and proximity.

The research questions are as follows:

- 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)?

Methods

The rapid review was undertaken in twelve weeks. Our review aimed to identify key evidence of relevance to the review question and to extract and synthesise this evidence in a transparent and reproducible manner. A range of search methods was used to identify English language, peer reviewed evidence from 2003-2014 to address the research questions. Search methods included database searches, citation searches, evidence from topic experts and scrutiny of reference lists from key reviews and included evidence. Assessment of the search results according to the inclusion and exclusion criteria was undertaken by one reviewer and a 10% random sample checked by a second reviewer according to a pre-defined set of inclusion and exclusion criteria. Data extraction was undertaken in Excel using a purpose-specific data extraction form developed iteratively and tested extensively for this rapid review. Formal quality assessment was not undertaken; instead the usefulness of included studies to answering the review question and the generic and study specific limitations reported by study authors were critically assessed. Data were extracted and then tabulated in MSWord. Due to both the clinical and methodological heterogeneity of the included studies, a meta-analysis was not undertaken.

Results

A total of 39 studies were included in the review. Our database searches identified 2256 references from which 19 papers were included in the review. Supplementary search methods were used extensively. An additional 20 papers included in the review were identified via citation searching (2 papers), reference lists of published reviews (15 papers) and reference lists of included papers (3 papers).

No UK studies were identified and 36/39 (92.4%) only included outcomes for paediatric patients. Of the 39 included studies, 32 (82%) investigated the relationship between volume and mortality and 7 (18%) the relationships between other service factors and outcome or between volume and non-mortality outcomes. Eighteen of the 32 studies investigating the volume-mortality relationship included all CHD conditions and 14 focused on specific single or complex conditions and procedures. Thirty one of the 37 studies (84%) that used mortality as the primary outcome measured in-hospital mortality. Only 10 (27%) of the included studies measured mortality after discharge from hospital. Thirty five studies (90%) were from the USA, 92.4% were multicentre studies and all were retrospective observational studies.

Overall, we have found that although the evidence does demonstrate a relationship between volume and outcome in the majority of studies, this relationship is not consistent. Studies on single conditions or procedures were more likely to identify an effect of volume on mortality but these were focused on high risk conditions, such as Hypoplastic Left Heart Syndrome, and procedures, for example Norwood procedure. Even within these highly selected groups there was considerable variation in effect depending on procedure type and individual centre performance. It is possible that, for example, surgeon volume may be as important as centre volume for these complex cases. This updated and extended review confirms a pattern of studies supporting the existence of a volume and outcome relationship.

The findings from studies that did consider broader CHD populations were more equivocal. In some studies where an effect was identified, the effect was weak or only demonstrable for specific subgroups of patients. Overall, there was no clear indication that the evidence for the volume and mortality relationship was substantially stronger than the evidence for a no effect relationship in this group. The findings further highlight the complex relationship between volume and outcome and the range of other factors which also have an effect. Some of these, such as condition severity, are well established but the effect of association of processes, systems and individual clinical effects on outcome remain unknown.

We also included evidence from three studies on adult CHD of which one, that included transplant patients for a range of conditions in addition to CHD, was of limited value. The other two studies explored the effect of surgeon type in relation to outcome. Both studies found that adult CHD patients had better outcomes when operated on by paediatric surgeons in specialist children's centres.

We found limited evidence on the effects of proximity of other services on mortality or the impact of volume on non-mortality outcomes. There appears to be relatively little evidence from studies that attempt to measure the effect of related processes on outcome and this is an area for future development.

Some key themes emerged from our analysis.

1. **There are a range of factors which influence mortality in CHD and centre volume is only one of them.** Our data extraction identified 67 different variables used to adjust for risk in the included studies and the most influential risk factor for mortality is the severity of the condition.
2. **Medicine moves forward and clinical advances, training, increasing expertise and changes in service provision mean outcomes for CHD have also changed over time.** Five studies that analysed data over long time periods (approximately 10 years) measured changes in mortality over time and found that, irrespective of other factors including volume, mortality decreased over this time period. This occurred despite increasing complexity thus attesting to ongoing clinical improvement. This means the relevance of findings from historical data to contemporary services needs to be carefully considered.
3. **Although aggregated data may show a difference in mortality rates between low and high volume centres, such aggregation may mask between-centre variation.** Several included studies identified variation between centres with some low or medium volume centres performing equally as well as those with high volume. Such variation indicates that individual centre effects relating to training, management protocols, expertise and availability of services are also likely to influence outcomes.
4. **The evidence base available to guide UK decisions on service design and configuration for CHD is dominated by retrospective studies conducted within the USA and many of the studies have analysed centres with very small volumes of cases**. The extent to which the reported findings are generalisable and relevant to the UK setting is therefore limited. The organisation of services in the USA is very different to the UK and other countries where there has already been a degree of centralisation of CHD services. With centralisation comes a corresponding increase in volume as more cases are concentrated in fewer centres. 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 cases. The lack of any UK studies to contribute to the review indicates a serious gap in evidence relevant to service provision in the NHS.
5. **Despite the growing number of studies few studies have suggested what the optimum size of a CHD centre in terms of volume should be.** Less than half of the

included studies analysed volume as a continuous variable which would provide the most robust evidence from which to consider volume thresholds.

Limitations

This was a rapid review with limited second sifting and a modified quality appraisal that followed standard methods to ensure it was transparent and reproducible.

Many authors of studies included in the review take great care to point out the methodological limitations of their studies and caution against over-interpretation of their findings. Included studies are predominantly retrospective and observational in nature. Such design features make it very problematic when trying to establish a direct inverse relationship of cause (volume) to effect (mortality). All but 5 of the included studies used routine datasets as the source data including administrative, registry and voluntary datasets. With this comes consequent risks to data quality such as completeness, accuracy and selection bias. These sources also lack the data on key clinical and service processes needed to explain the associated effects of factors other than volume on outcome. The insights gained from study reports of a single condition or surgical procedure are important for an understanding of those conditions. Typically such reports bear little relation to overall surgical volume and therefore provide a limited contribution to the "evidence" that relates to optimal volumes for entire CHD services.

It is increasingly recognised that certain methods of investigation and analysis are unsuited to investigation of the volume – outcome question. Even though considerable advances in methodological approaches (e.g. complexity stratification) continue to be made, questions about the optimal configuration for volume/outcome debate remain unlikely to be resolved within the foreseeable future. This seems particularly the case given the absence of a comprehensive and accurate national database that provides sufficient information to account for risk, complexity and the effects of clinical care and service processes.

Conclusions

We have conducted a rapid review of the evidence on the relationship between volume and outcome and between other service factors and outcome for CHD. Overall, we found **a substantial number of studies reporting a positive relationship between volume and**

outcome, particularly for highly complex cases. However, the complexity of the evidence requires careful interpretation. A mixed picture emerged from the 39 included studies which increases our understanding of the complexity of this relationship and highlights variation in both methods and findings across individual studies, the potential effects of a range of other factors that may interact with volume and influence outcome and the methodological limitations imposed by the research approaches taken. Interpreting the evidence is particularly challenging due to a lack of information on clinical and service related processes in the literature. This lack of information means that the volume/outcome relationship is difficult to disentangle from other clinical and service processes and outcomes.

A clear evidence gap remains to be addressed with regard to: better understanding of the relationships between the wide range of organisational factors in CHD services; how these can potentially predict a number of outcomes of relevance to patients and families, and the causal pathways between organisational factors and outcomes. It is these questions that need to be answered and this requires the development of comprehensive, high quality clinical and administrative databases which collect information on a range of organisational factors and outcomes related to quality of care. There is scope to expand the existing NICOR database to capture more of this information. There is a clear need to conduct robust UK based studies and an enhanced database could then be used to conduct observational studies of the relationship between organisational factors, including volume, and outcomes that would have direct relevance to the NHS. Future research efforts directed to these tasks would be of considerable benefit to improving patient care for CHD.

Word Count - 2012

Plain English Summary

Some people have problems with the structure of the heart when they are born (Congenital Heart Disease - CHD). These problems need treatment during childhood and sometimes later when they become adults and it is important that they are cared for in a hospital where they will get the best possible specialist treatment for their condition.

For our review, we were asked to look at whether the treatment that patients receive and what happens to them as a result of this treatment (outcomes) are influenced by features of the hospital treating them. It is often thought that in hospitals where a lot of operations are done (both in the hospital and by individual surgeons), care for patients is better. It is also often thought that hospitals where key services are located together have better outcomes. We looked at published academic articles to provide this information.

We found 39 scientific studies that had investigated these features and analysed them to identify the key messages they contained. The main outcome studied was whether or not patients survived their surgery.

Our review found that whilst many of the studies show better patient outcomes when larger volumes of surgery are performed, this was not consistent and not all of the studies showed this. Where studies showed that there was a relationship between better patient outcomes and larger volumes of surgery, it was not clear why larger volumes led to better outcomes. More research is needed to try and better understand what other aspects of service affect outcome.

Word Count - 253 words

Chapter 1. Background

This rapid evidence synthesis has been written in response to a request by NHS England to further examine the evidence around the delivery of congenital heart disease (CHD) services. The purpose of the evidence synthesis is to support the ongoing NHS England service review about how CHD services should be best organised.

Services for children with CHD have been the subject of scrutiny for a number of years. In 2012, following an extensive review as part of the "Safe and Sustainable" work programme, a series of recommendations were made for the reconfiguration of cardiac services for this patient group[1]. The rationale for change was based on the view that clinical expertise was spread too thinly and that providing CHD surgery in a smaller number of units would ensure a critical mass of cases, access to associated specialist staff and the ability to provide a safe 24/7 emergency service. At the time of the review CHD surgery for children was carried out in 11 centres.

The "Safe and Sustainable" CHD review [1] recommended that CHD services be provided by 7 managed clinical networks centred around 7 units. However, these recommendations were challenged and subsequently the subject of a Judicial Review (JR) and an Independent Reconfiguration Panel (IRP) inquiry which concluded processes of the review were flawed. Consequently service reconfiguration was not implemented and these services are subject to a new review which will consider the whole lifetime pathway for CHD.

The JR and IRP identified a number of issues of concern with the "Safe and Sustainable" review process including the use and interpretation of the existing evidence base on surgical services for CHD and patient outcomes. In particular they questioned the reliance on evidence around the relationship between volume of cases and outcomes. A literature review undertaken in 2009 by Ewart [2] had examined this evidence in detail and, although confirming the existence of a relationship between volume and outcome, cautioned that this relationship alone was not sufficient to make recommendations on the size of units needed. The review was not able to identify any reliable evidence on the cut off points in terms of the minimum annual numbers of cases needed for a centre. The author also highlighted that likely

contributory effects of other system and process factors on the relationship between volume and outcome in the published literature were unclear.

As it is now almost 5 years since the Ewart review was published, it is timely to reassess the evidence base for CHD services to support the current service review. The purpose of this evidence synthesis in the form of a rapid review is to examine what evidence there is for a relationship between organisational features and patient outcomes in CHD services.

This rapid review of published research on the relationship between volume, proximity and patient outcomes is just one of the sources of evidence which has been commissioned to inform the NHS England CHD service review. The overall aim of this service review is to ensure that services for people with congenital heart disease are provided in a way that achieves the highest possible quality within the available resources. This will involve consideration of a very wide range of types of evidence including published research, but also audit and other service quality-related data from CHD services and information based on the experiences of clinicians, patients and families.

Chapter 2. Hypotheses tested in the review (Research Questions)

Due to the fact that this is a rapid review, the review is focussing on two key organisational features – volume and proximity. The rationale for this is based on the existing, evidence-based, consensus that there may be a relationship between the volume of CHD procedures (both by institution and by surgeon) and patient outcomes and the clinical consensus that reconfiguration which includes the co-location (or increased proximity) of specialist services may be related to better patient outcomes. The research questions also reflect the view that there are mediating factors that influence the relationship between patient outcomes and volume and proximity.

The research questions are as follows:

- 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/colocation with other specialist clinical services (e.g. co-location of services such as specialist cardiac paediatric intensive care)?

Chapter 3. Review methods

Rapid review methods

Due to the need to complete this review within a very short timeframe (twelve weeks including a three week protocol development stage) rapid review methods were used to ensure the efficient identification and synthesis of the most relevant evidence.

Rapid review methods are still in their relative infancy, in comparison to the more established systematic review. Harker and Kleijnen [3] examined a number of rapid reviews in order to develop understanding and definition of what a rapid review was. Rapid reviews are undertaken over a short time frame with a streamlined methodology. This streamlined methodology is a necessary compromise from a standard systematic review. Whilst they found considerable variation in the methodologies adopted by rapid reviews, acknowledging that there is not a "one size fits all" methodology, they advise "clear and transparent description and discussion of methodology utilised and acknowledge any limitations" (p.406). This advice has informed our choice of methods and report writing.

Our review did not attempt to identify **all** relevant evidence or to search **exhaustively** for all evidence that meets the inclusion criteria; the search approach aimed to identify the key evidence of most relevance to the review question.

The scope to both search for and review 'related evidence', reflecting the multiple dimensions of the topic, was considerable and thus was considered prohibitive within the timeframe given. The rapid review therefore focussed on the most relevant evidence from CHD services for children and adults. The rapid review was based on a proposed conceptual framework included in the study protocol. This allowed us to:

- Define the scope of the search strategy
- Define inclusion and exclusion criteria to specify what types of studies were to be included in the final report
- Construct summary tables of all included studies to present key information and findings

- Synthesise the evidence from the included studies

Protocol development

The protocol for the review was developed iteratively between ScHARR, NHS England and NIHR HS&DR. In addition, comments were sought from key stakeholders, who were part of the NHS England Clinical Advisory Panel for the Congenital Heart Disease review. The protocol development started on January 7th 2014 and was published on the NHS England website on February 10th 2014 [4].

Use of the conceptual framework

There is an extensive health services research evidence base documenting associations between a range of organisational factors, particularly factors related to location, nature and size of specialist facilities and outcomes, in both elective and emergency service provision. There is also a major field of research that has explored, both quantitatively and qualitatively, the impact of different aspects of service organisation and delivery which influence patient safety and may reduce the risk of adverse outcomes for patients. In order to make the relationship between this wider evidence base and the, relatively limited, scope of this commissioned rapid review more explicit, a logic model (or conceptual framework) was developed for the study protocol and this is included in Appendix One. This figure shows the relationship between the specific inclusion criteria for this review and the much wider context of factors of known relevance which were considered for inclusion in the review if there was relevant data within the included studies. This approach was chosen based on the need to both limit the scope of the review to the most relevant evidence, while not ignoring the very wide range of organisational, cultural and patient-related factors already known to be important predictors of outcome. The conceptual model was used to inform the literature search, development of inclusion and exclusion criteria, data extraction and evidence synthesis.

Literature searching

A range of search methods, as outlined below, were used in order to identify evidence to answer the rapid review research questions in a timely fashion:

- Stage One – Search of health and medical databases.
- Stage Two – Citation searching.
- Stage Three – Call for evidence from topic experts.
- Stage Four – Scrutiny of reference lists published reviews/key evidence.
- Stage Five – Scrutiny of reference lists of included papers.

The search process was undertaken with reference to the protocol, in particular the conceptualisation of the different subareas within which to identify relevant evidence.

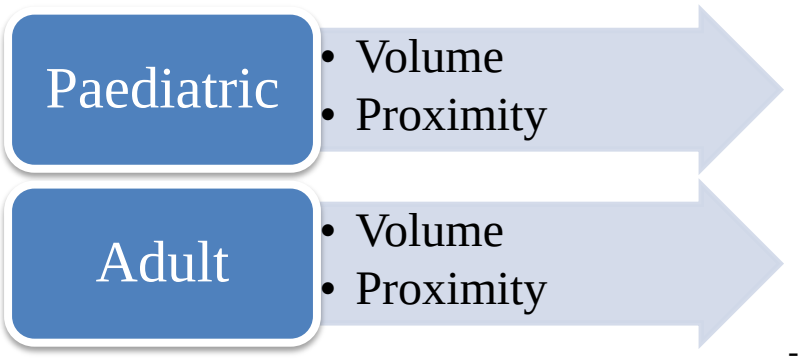

Figure 1 Conceptualisation of the evidence base

A systematic search of medical and health related databases (MEDLINE, EMBASE, CINAHL, Cochrane Library and Web of Science) was undertaken for the years 2009 – 2014 together with citation searching, reference list checking and recommendations from stakeholders to identify evidence for 2003-2014. The rationale for limiting the review to 2003-2014 was that this was in line with the dates used by Ewart and would limit the body of evidence to a manageable but meaningful number of studies.

Stage One- Search of health and medical databases

The starting point of our search strategy was Ewart [2]. We modified search terms from the previous review to capture a wider evidence base around the population (adults and children),

interventions (surgical and interventional) as well as outcomes (mortality, complications and related outcomes).

The search strategy used a combination of free-text and Medical Subject Headings (MeSH) and can be found in Appendix Two. The search was around key terms for the population (congenital heart disease), the intervening variables (volume and proximity) and outcomes (mortality, death, survival).

We searched MEDLINE and EMBASE via OVID SP, Cochrane Library via Wiley Interscience, Web of Science via Web of Knowledge and CINAHL via EBSCO. MEDLINE, EMBASE, CINAHL and the Cochrane Library are commonly considered the core databases for identifying evidence relating to clinical topics [5].

The search strategy was limited to 2009-2014 with the rationale that relevant evidence from 2003-2008 would be cited in later papers or in later reviews retrieved by the database search and therefore identified via Stages Two-Five.

The searches were undertaken in January 2014 and an update search was undertaken in March 2014. The search results were downloaded into Reference Manager where they were assessed for inclusion in the review. Additional detail on this process is available later in the methods section.

Stage Two – Citation searching

A search was undertaken to identify any published articles that have cited any of the articles included in the Ewart review [2]. This search was undertaken in Google Scholar, using the Publish or Perish software to manage the references identified. These references were then imported into Reference Manager.

We also undertook citation searching using included papers in areas not included within the scope of the original Ewart review [2] (i.e. adult and paediatric proximity and adult volume).

Stage Three –Call for evidence from topic experts

A call for evidence for potential inclusion in the review was made via the NHS England Congenital Heart Disease blog [4], directly at the NHS England Patient and Public group and via email to the NHS England Clinical Advisory panel. Evidence was forwarded to ScHARR via NHS England. Papers suggested by topic experts and the wider group of interested parties are listed in Appendix Two.

Stage Four –Scrutiny of reference lists of published reviews/key evidence

In order to identify additional published evidence that was not retrieved by the database searches, the team undertook scrutiny of reference lists of published reviews of services, guideline documents and reports as identified through Stages One, Two, Three and Five. Reviews that informed this stage of the search are listed in Appendix Two.

Stage Five - Scrutiny of reference lists of included papers

Reference lists of all papers identified for inclusion were examined. Any titles considered to be relevant were then scrutinised at abstract level via PubMed. Any relevant full papers were considered for inclusion by a reviewer. Where papers were identified for inclusion, their reference lists were subsequently checked.

Inclusion/Exclusion Criteria

The inclusion of studies in the review was according to the following table:

Table 1 Inclusion and Exclusion Criteria

Criteria	Inclusion	Exclusion
Population	Adults and children undergoing treatment (surgical or interventional) for congenital heart disease	
Intervention	Measurement of outcomes based	

Criteria	Inclusion	Exclusion
	on at least one of the following: volume of activity OR co-location with other related services	
Outcome	Patient outcomes	Process/service outcomes (these will only be included if studies report at least one patient outcome)
Study Type	Quantitative studies (observational evidence and evidence from trials) Publication Date 2003-2014. Published, peer reviewed evidence.	Qualitative evidence. Evidence from surveys of views/experiences. Editorials. Opinions. Non-English-language papers. Non OECD countries.

Assessment according to inclusion and exclusion criteria

References identified from Stages One and Two were downloaded into Reference Manager Version 12 to be sifted for inclusion in the review. All potential titles were examined for inclusion by one reviewer. Any titles that did not meet the inclusion criteria were excluded. Following the examination at title level , any remaining references were scrutinised at abstract level. For any references where possible inclusion was unclear a second reviewer independently examined the corresponding full-text.

Titles and abstracts of these citations identified by the searches were 10% checked by a second reviewer (and a check for consistency undertaken).

For Stages Three, Four and Five – References were checked following the same three stage process as for Stages One and Two (title, abstract, full text).

Assessment for inclusion of conference abstracts identified from all stages of the search was undertaken by one reviewer and checked by a second. Both reviewers assessed each conference abstract based on three criteria, namely:

- Whether the abstract fulfilled the inclusion criteria, in terms of the explanatory variables and outcomes.
- Whether the evidence in the abstract was already included within an already included paper
- Whether there was sufficient data in the abstract to be able to use the data in a meaningful manner to address the aims of the review.

Data extraction including development of the data extraction tool

The aim of the data extraction process was to focus on the most critical information for evidence synthesis rather than exhaustively extracting and critiquing all available information within individual papers. Due to the rapid nature of the review, data extraction was undertaken by five reviewers.

A standardised data extraction form was developed using the following process. The initial draft of the data extraction tool was designed as a comprehensive way to capture all relevant information from the studies on a broad range of factors related to congenital heart disease services that may affect patient outcomes following interventions. Four members of the ScHARR review team tested this initial draft on three studies [6-8].

It became apparent that these studies, which focussed on the relationship between volume and mortality, considered complexity of the underlying cardiac condition and other patient-level factors in their analysis, but did not include details of relevant organisational factors such as staffing and proximity of related services. Similarly mortality was the only outcome considered in these studies and other relevant outcomes such as morbidity, complications, length of stay and readmissions were not included.

The data extraction tool was therefore revised in the light of this initial data extraction. The revision also included reference to data tables included in other reviews in this area; Ewart[2] and Bazzani and Marcin[8]. The final layout was determined to explicitly include the following key details, in addition to the information included as standard on a data extraction form:

- Where data was obtained from a database, whether contribution to the database was voluntary (to indicate potential bias in reporting) and whether the purpose of

the database was administrative or clinical (to highlight the potential limitations of the details available)

- Whether volume was considered as a continuous or categorical variable and if categorical, what were the thresholds determined by the study for the different categories.
- The covariates used in the analysis
- In the quantitative assessment of the relationship between volume/ proximity and mortality, a breakdown of the crude association and the adjusted association (for casemix +/- other covariates).
- Where an association was identified, was the nature of this relationship (linear or non-linear)?

A sample data extraction form is available in Appendix Three.

Quality Assessment

Rather than using a standard checklist approach, instead, the focus was on an assessment of the overall usefulness of the included evidence in answering the research questions. The assessment of usefulness was made based on a number of factors which included:

- Whether the study adjusted for severity of condition
- Whether the study adjusted for age
- Whether the study was multi-centre.
- Whether the study included more than one intervention/condition.
- Whether contribution to the database used to collect the data was voluntary and whether data was collected comprehensively or collectively.

Assessment of the limitations of included studies was also undertaken using the limitations reported by study authors in the included studies.

Synthesis

Data were extracted and tabulated. This tabulation was used to inform the narrative synthesis in the Results section. A meta-analysis was not considered given that the review was a rapid review and there was considerable heterogeneity in the design, methods and setting of the included studies making the clinical value of such a formal statistical analysis open to debate.

Chapter 4. Studies included in the review

Results of the literature search

The full papers and conference abstracts identified as a result of the literature search are described in the following modified PRISMA diagram:

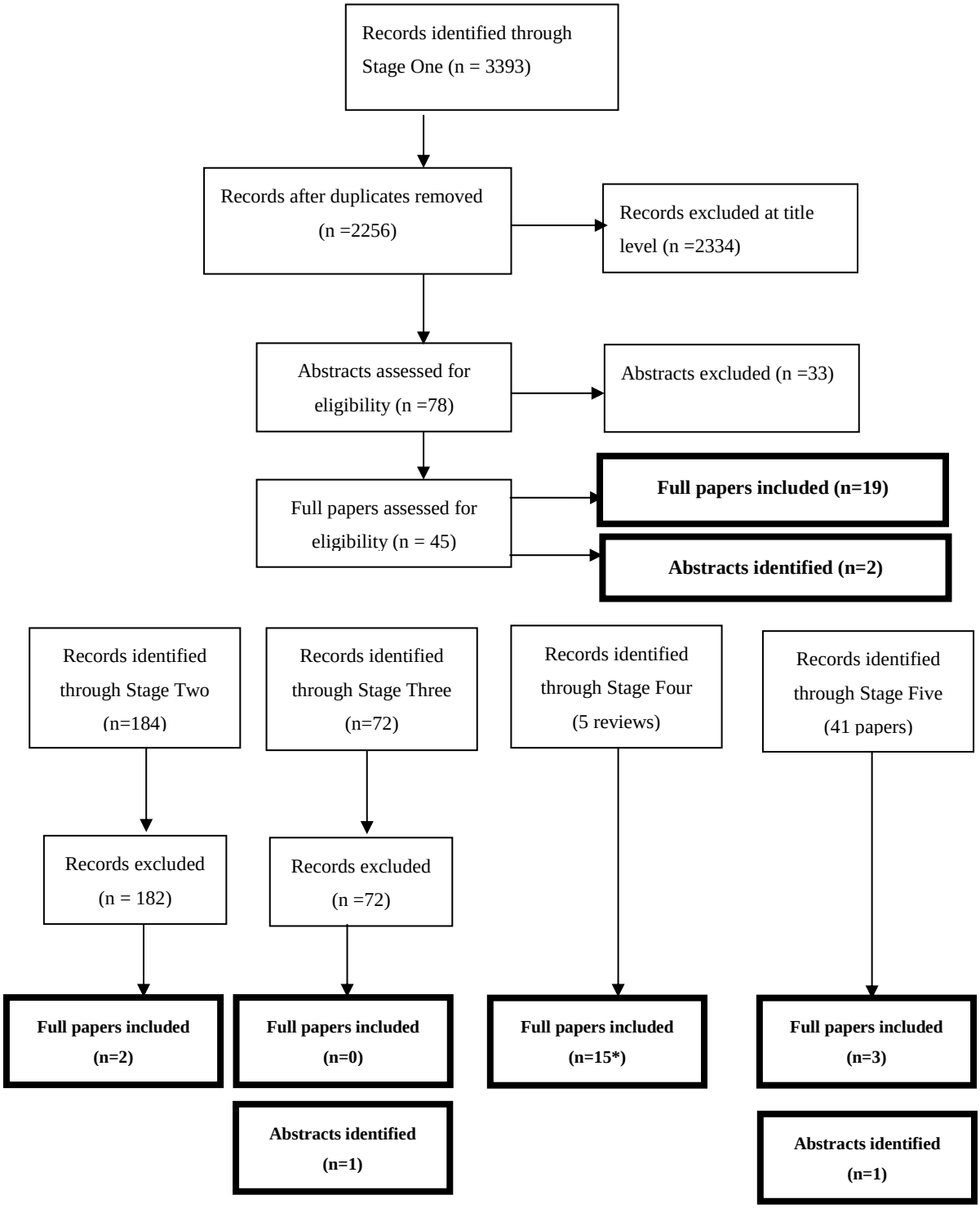

Figure 2 Modified PRISMA diagram

*This includes seven papers originally included in Ewart (2009) [2]

To summarise figure 2, 39 full journal articles and 4 conference abstracts met the inclusion criteria. Four additional abstracts met the inclusion criteria, however the evidence included in them was already included in a full paper. Upon scrutiny, the information included in the abstracts was insufficient for full data extraction and could not be used in a meaningful manner to address the aims of the review. Therefore a decision was made to data extract as much data as possible from these abstracts and include this information for reference in the report appendix but to not include this evidence in the analysis. The tables can be found in Appendix 3.

Second screening of retrieved references

In order to check the screening consistency of the single reviewer a second reviewer screened approximately 10% of the references (n=300). Reviewer 2 tagged as potential includes 5/292 (1%) references excluded by Reviewer 1, and tagged as probable excludes 1/8 (12.5%) references included by Reviewer 1. This gave a Kappa statistic of 0.77, generally acknowledged as good agreement. The three additional potential includes identified by Reviewer 2 were tenuous includes (two review articles potentially relevant as background, and an article for which only a title was available) while the one article tagged as "include" by Reviewer 1 and "exclude" by Reviewer 2 was subsequently checked for inclusion at the full text stage. Therefore it was unlikely that any relevant primary studies were overlooked in the 10% sample checked and this result can be extrapolated to the remainder of the screening process.

List of studies included in the review

Table 2 List of studies included in the review

Author and Year
Arenz et al (2011) [9]
Arnaoutakis et al (2012) [10]
Bazzani and Marcin (2007) [8]

Author and Year
Benavidez et al (2007) [11]
Berry et al (2007) [12]
Berry et al (2006) [13]
Burstein et al (2011) [14]
Chang et al (2006) [7]
Checcia et al (2005) [15]
Davies et al (2011) [16]
Dean (2013) [17]
Dinh and Maroulas (2010) [18]
Eldadah et al (2011) [19]
Fixler (2012) [20]
Gray et al (2003) [21]
Hickey et al (2010) [22]
Hirsch et al (2008) [23]
Hornik et al (2012) [24;25]
Karamlou et al (2013) [25]
Karamlou et al (2008) [26]
Karamlou et al (2010) [27]
Kazui et al (2007) [28]
Kim et al (2011) [29]
McHugh et al (2010) [30]
Mery (2014) [31]
Morales et al (2010) [32]
Oster et al (2011) [33]
Pasquali et al (2012a) [34]
Pasquali et al (2012b) [35]
Petrucci et al (2011) [36]
Pinto et al (2012) [37]
Sakata et al (2012) [38]
Seifert et al (2007) [39]
Tabbutt et al (2012) [40]

Author and Year
Vinocur (2013) [41]
Welke et al (2010) [42]
Welke et al (2009) [43]
Welke et al (2008) [6]
Welke et al (2006) [44]

List of conference abstracts included in the review

Table 3 List of conference abstracts included in the review

Author	Related to study
Karamlou et al (2014) [45]	27
Kochilas et al (2009) [46]	41
Scheurer et al (2011) [47]	14
Welke (2012) [48]	24

Chapter 5. Studies excluded from the review

A full list of the full text studies and conference abstracts excluded from the review is available in Appendix Two. In addition, the evidence suggested by topic experts and assessed for inclusion by the review team is also available in Appendix Two.

Chapter 6. Results of the review

Detailed summary tables of included papers are provided in Appendix Three. We also identified four relevant published conference abstracts and a summary of these is provided in Appendix Two for reference however we have not considered these in our analysis.

Characteristics of included studies

Thirty nine full papers were included in the review. The characteristics of these papers are summarised in Table 4.

Table 4 Summary of characteristics of included full papers

Study characteristics	Number (%)
Total number full papers included	39 (100)
Paediatric Volume and mortality relationship all conditions	18 (46)
Paediatric Volume and outcome relationship specific conditions/procedures	14 (36)
Variables other than volume or non-mortality outcomes	7 (18)
Country	
USA/Canada	35 (90)
Japan	2 (5)
Germany	1 (2.5)
Sweden	1 (2.5)
Multi-centre	36 (92.4)
Single centre	3 (7.6)
All CHD conditions/procedures	25 (64)
Single CHD condition/procedure	14 (36)
Data sources	
Voluntary (STS-CHD, HCUP-KIDS, PCCC, UHC)	21 (53
Involuntary/registry (PHIS, NIS, OSHPD, UNOS, Texas birth defects registry)	13 (33)
Study specific	5 (13)
Patient population	
All children (0-20)	22 (56.4)
Newborns and infants only	14 (36.9)
Adults	3 (7.6)
Outcomes measured	
Survival/mortality only	29 (74.5)
Survival/mortality and other outcomes	8 (20.5)

Other outcomes only (e.g. morbidity, complications)	2 (5)
Design	
Retrospective cohort	33 (82)
Cross-sectional analysis	5 (13)
Before and after	1 (2.5)

No UK studies were identified and 36/39 (92.4%) included only paediatric patients. The majority of studies (90%) were conducted in the USA and most were multicentre (92.4%). We have classified included studies in to three broad groups – those where the primary objective was to explore the relationship between volume of service and mortality outcome for a range of CHD conditions (18/39); those where the focus was on the relationship between volume and mortality outcome for specific single conditions or procedures (14/39) and those where the focus was on the impact of a variable other than volume or where non-mortality outcomes only were reported (7/39). For studies involving specific conditions or procedures these were mainly complex conditions - such asHypoplastic Left Heart Syndrome (HLHS), pulmonary atresia and -/ or procedures including Norwood Procedure, arterial switch operation (ASO), transposition of great arteries (TGA) and Blalock Taussig Shunt Procedure (BTSP) (10/14); heart transplant (2/14); Ventricular Septal Defect (VSD) repair cases only (1/14) and Ventricular Assist Devices (VAD) only (1/14).

Two studies included a paediatric CHD population as a subgroup in studies that examined a range of cardiothoracic procedures [38 28] and one a range of common paediatric operations [12]. For these studies only the findings related to the CHD population are reported here. Three procedure based studies for heart transplant [10 16] and VAD [32] included patients with conditions other than CHD.

The majority of studies used routine datasets (35/39) and of these voluntary clinical or mixed clinical and administrative data sources predominated (21/39) with 13 studies utilising involuntary administrative data. Descriptions of these datasets are provided in Appendix Four. Five studies used study specific data including one using data from a clinical trial [40].

Half of the studies included children of all ages (age range 0-20), 14/39 included only newborns and infants and 3 studies included adults.

Mortality was the primary outcome measure used with only two studies reporting morbidity outcomes only. The use of routine data is reflected in the types of study design used. There were no primary clinical trials with retrospective observational designs being the predominant feature. There was one before and after study assessing the impact of a paediatric cardiac intensive care unit [19].

Study populations and settings

Table 5 provides a summary of the dates, inclusion dates and study settings and sample sizes. Where reported, numbers of centres and centre volumes are included. In hospital mortality is death during the admission for the procedure.

Table 5 Summary of the dates, inclusion dates and study settings of included studies

	All (A) or Specific (S) cases[a]	Study period	Sample size[b] No. Centres	Lowest and highest reported centre volumes per year[c]	Mortality/survival endpoint
Arenz et al (2011) [9]	A	2006-9	1828	Single centre mean 457 cases per year	In hospital Within 30 days
Arnaoutakis et al (2012) [10]	S	2000 - 2010	18,226 141 centres	≤7 to >15 transplant cases	30 days 1 year
Bazzani & Marcin (2007) [8]	A	1998 - 2003	a)12,801 b)13,917	Lowest 20<75,>75 cardiac surgery cases	Within 30 days
Benavidez et al (2007) [11]	A	2000	10,032 100 centres	<150 to >450 CHD surgery admissions	Morbidity only
Berry et al (2007) [12]	S	2003	2301 113 centres	≤4 to ≥10 VSD repair cases	In hospital
Berry et al (2006) [13]	S	1997 and 2000	754 in 1997 880 in 2000	1 to 10 HLHS cases	In hospital
Burstein et al (2011) [14]	A	2007-9	20,922 47 centres	<150 to =>350 CHD surgery cases	In hospital
Chang et al (2006) [7]	A	1989-1999	25402 500 centres	≤100 cases to >100 cases CHD surgery cases	In hospital 30, 90 and 365 days
Checcia et al (2005) [15]	S	1998-2001	801 29 centres	<16 to >30 Norwood cases	In Hospital
Davies et al (2011) [16]	S	1992-2007	4647 136 centres	<19 to ≥63 transplants in preceding 5 years	In hospital One year
Dean (2013) [17]	S	1998 - 2007	1949 48	Not specified	In hospital mortality

	All (A) or Specific (S) cases[a]	Study period	Sample size[b] No. Centres	Lowest and highest reported centre volumes per year[c]	Mortality/survival endpoint
Dinh (2010) [18]	A	1985-2004	80,000 47 centres	Not specified	In hospital
Eldadah et al (2011) [19]	A	2004 - 2008	199 before 244 after	Single centre	In hospital
Fixler (2012) [20]	A	1996 - 2003	1213	Distance not volume	One year
Gray et al (2003) [21]	A	1992	284 admissions 261 patients 4 centres	47 to 85 complex CHD surgery cases	30 day post-operative
Hickey et al (2010) [22]	A	2005-2006	19,736 38 centres	47 to 764 CHD surgery cases	In hospital
Hirsch et al (2008) [23]	S	2003	547 74 centres	1 to 31 Norwood 1 to 24 ASO	In hospital
Hornik et al (2012) [24]	S	2000-2009	2,555 patients 53 centres	≤10 to >20 Norwood cases	In hospital
Karamlou et al (2013) [25]	A (ECMO only)	2000-2009	3867 207	Annual ECMO cases <15 to >30	In hospital
Karamlou et al (2008) [26]	A	1988-2003	30250	Not specified Continuous variable	In hospital
Karamlou et al (2010) [27]	S	1987-2000	2421 33 centres	1 to 47 (per surgeon) of 4 complex groups	In hospital
Kazui et al (2007)[28]	A	2000-2004	11,197 135	≤1-4 to >20 cases of open heart surgery of newborns & infants	In hospital
Kim et al (2011) [29]	A	2000 - 2008	97563 all CHD. 3061 adult 42 centres	<10 to >20 adults admitted for CHD surgery <200 to >400 all cases including children	In hospital
McHugh et al (2010) [30]	S	1998 - 2007	9187 118 centres	10-year study period:HLHS palliation procedures < 20 to >64 procedures	In hospital
Mery (2014) [31;49]	A	2004-2011	77,777 43 centres	Not volume	Complication only
Morales et al (2010) [32]	S	2006	187 67 centres	1 to >5 VAD placements	In hospital
Oster et al (2011) [33]	A	July 2006 -2008	49792 24112 subgroup 39 centres	Not specified Continuous variable	In hospital
Pasquali et al (2012a) [34]	S	2000-2009	2557 53 centres	≤10 to >20 Norwood cases	In hospital
Pasquali et al	A	2006-2009	35,776 patients	<150 to >350 CHD surgery	In hospital

	All (A) or Specific (S) cases[a]	Study period	Sample size[b] No. Centres	Lowest and highest reported centre volumes per year[c]	Mortality/survival endpoint
(2012b) [35]			68 centres	cases	
Petrucci et al (2011) [36]	S	2002-2009	1273 70 centres	Not specified	In hospital
Pinto et al (2012) [37]	A	2005- June 2006	271	Distance not volume. Single centre	Post discharge
Sakata et al (2012) [38]	A	2005-2009	13,074 220 centres	Not specified – CHD subgroup of 8 cardiothoracic procedures	30 days
Seifert et al (2007) [39]	A	2000	10,282	Not specified Continuous variable	In hospital
Tabbutt et al (2012) [40]	S	2005-2008	549 cases 15 centres	≤15 to >30 Norwood cases	In hospital 30 days
Vinocur (2013) [41]	A	1982 - 2007	10945 85023 subgroup 49 centres	≤10 to 500 CHD surgery cases	In hospital
Welke et al (2010) [42]	A	2000-2005	21,709 161 centres	Modelling	In hospital
Welke et al (2009) [43]	A	2002-2006	32,413 48 programs	<150 to ≥350 CHD surgery cases	In hospital
Welke et al (2008) [6]	A	1988 - 2005	55,164 307 centres	<200 to < 300 CHD surgery cases	In hospital
Welke et al (2006) [44]	A	2001 - 2004	12,672 procedures 11 centres	103 to 801 CHD surgery cases	In hospital

[a]All is where all conditions were included, specific is where selected conditions or procedures were included.

[b]Some papers report by operations or cases and others report by number of patients.

[c]Illustrates categories in included centres at lowest volume and highest volume where reported.

Most of the included studies were conducted after 2009 (29/39, 64%) with 14 studies conducted before 2009. The latter included the seven studies included in the Ewart review [2] and an additional seven studies identified as a consequence of our broader search strategy and inclusion criteria to include adult studies and those concerned with non-mortality outcomes or the impact of factors other than volume. Fifteen studies (38%) covered time periods of greater than five years. Just over half (8/14) of the studies for specific conditions or procedures, where case numbers will be smaller, utilised data from more than five years compared to 28% of studies where all conditions were included. Unsurprisingly there is a

marked difference in sample sizes between studies including all CHD conditions compared to those including highly selected populations based on single conditions or procedures and single centre studies. Where reported, there are also differences in the centre volumes with studies on specific conditions or procedures having lower volume thresholds. Within these 14 studies 9 included centres with 20 or fewer cases per year. For studies including all CHD cases 10/25 had centres with 200 or fewer cases per year and 5 of these had fewer than 100 cases per year including two studies with very low volume centres with less than 10 cases per year [41] [28].

The primary endpoint for measuring mortality outcome was within the post-operative period with 31/37 (84%) of studies reporting in hospital mortality. Seven studies measured mortality at 30 days and 4 up to one year.

Study analyses – adjustment for confounders and risk

The CHD population is highly complex and varied both in terms of the range of conditions it encompasses and the associated severity and risk of mortality for different conditions. Three CHD risk scores that take account of surgical complexity and associated risk of mortality have been developed- STS EACTS (Society of Thoracic Surgeons – European Assocation for Cardio Thoracic Surgery), RACHS 1 (Risk Adjusted Classification on Congenital Heart Surgery) and the Aristotle Complexity score – for risk adjustment in CHD. A detailed description of each score is provided in Appendix Four. Other risk scores do exist for CHD, but have not been used in the studies that have been included in the review. Outcome is also dependent on a range of patient, demographic and service factors that need to be taken into account in study analyses. We extracted details of all co-variates used in the analyses of each included study and identified 67 different types of co-variate (excluding subgroups within types). Thirty one (79%) of the studies included a co-variate that accounted in some way for condition. Of these 18 used a risk score for surgical complexity, 8 a condition descriptor, 3 a procedure descriptor and 2 an ICD-9-CM diagnostic code. Of other co- variates the most commonly used were age (18/39), co-morbidity (14/39), gender (13/39) and ethnicity (9/39). Some studies of highly selected groups of patients did not always adjust for common co-variates such as complexity (where a single condition was the subject) or age (where the study population were all neonates).

A detailed summary of the 32 co-variate types reported in at least 2 of the 39 included studies is provided in Appendix Four.

Overview of main findings

We have summarised the main findings of each included study in terms of whether a measurable effect of volume on mortality outcome was reported. Effect is defined as an inverse relationship between volume and mortality, that is, increasing volume results in decreasing mortality (or conversely low volume is associated with higher mortality). Where survival is reported the effect relationship is increasing survival with increasing volume and vice versa.which both only reported unadjusted mortality for a subpopulation of newborns and infants undergoing open heart surgery in larger studies of a range of cardiothoracic procedures. Kazui [28] reported an inverse relationship between volume and mortality with higher mortality in low volume centres and Sakata [38]found no relationship between volume and relationship for the CHD subgroup. Both reported wide variation in mortality rates across all volumes and both concluded that risk adjusted measures are needed to explore this relationship more robustly.

Relationship between volume and mortality for all CHD conditions

We identified 19 studies that examined the relationship between centre volume and mortality. A single centre study by Arenz [9] examined unit performance over four years using a composite measure including mortality but did not directly test the relationship between volume and mortality. Thirteen studies examined this relationship as the primary objective of the study, two examined the effect of adult CHD operative management in by paediatric services or surgeon and two examined the relationship as part of a more general study to identify risk factors for mortality or surgical performance. One study examined the relationship between volume and mortality and the impact of specialist nursing skills. A summary of the findings is given in Table 6. Note that the estimates of effect size are not comparable between studies due to different inclusion criteria (procedures, time periods, institutions), different definitions for volume categories, different definitions for mortality outcomes and adjustment for different confounding factors. Detailed analysis for each included study is available in Appendix 3.

Table 6 Effect of volume on mortality for all conditions – adjusted analyses

Study	Adjusted analysis of volume and mortality/survival outcome		Notes & Headline Message
	No effect detected [estimate of effect size and/or p value]	Effect detected [estimate of effect size and/or p value]	
Arenz (2011) 9	N/A	Basic and comprehensive performance score increased from 100% baseline to 124.9% and 132.9% respectively. Volume increased from 407%-487% over the same time period.	Composite measure of performance including mortality showed **performance over 3 years maintained despite increasing complexity and volume**
Bazzani and Marcin (2007) [8]		√ continuous Volume/Mortality OR = 0.86/ increase of 100 cases (95%CI 0.81-0.92) √ Categorical Volume/Mortality OR=0.75 (95% CI 0.55-1.02) in hospitals with >75 cases per year compared to hospitals with > 75 cases	Effect weaker using new expanded data set than replicated analysis of 4 previous studies. Effect lost by removing single highest volume centre. Scatter plot of volume vs outcome showed no clear cut off. **For each 100 patient increase in annual volume there was a 13.9% decrease in the odds of dying**
Dinh (2010) [18]		√ Mortality Linear decreasing dependency (mortality and volume) [1985-1989 (p=0.005) 1990-1994 (p =0.016), , 1995-1999 (p=0.043) 2000-2004 (p=0.045)]	Modelling study. Inverse relationship between volume and mortality. Small & medium sized centres higher mortality than high volume. **In small and medium sized centres the smaller the volume the higher the risk of dying.**

Study	Adjusted analysis of volume and mortality/survival outcome		Notes & Headline Message
	No effect detected [estimate of effect size and/or p value]	Effect detected [estimate of effect size and/or p value]	
Gray (2003) [21]	√ all patientsVolume/Mortality [ORs = 0.24, 0.12, 0.32 (p=0.0001)]		Comparison between 4 centres in one year **Differences in mortality in centres not consistent with smaller volume centres having lower mortality than the highest volume centre.**
Hickey (2010) [22]		√ Volume/Mortality **[**OR = 0.93/increase of 100 cases (95% CI 0.90-0.96;]	Also looked at effect of specialist nursing staff. **For each 100 patient increase in annual volume there was a 7% decrease in the odds of dying**
Kazui (2007)		√ **[**newborns OR=2.20 95% CI 0.95-5.09] √ Infants OR=3.69 95% CI 20.2-6.73	**Higher mortality in lowest volume centres compared to highest volume centres** for subgroup of cardiothoracic procedures **No adjustment for risk**
Oster (2011) [33]	√ [p=0.41 low risk, p=0.067 high risk]		SMR calculated from previous performance. Stratified cases no significance in low risk cases, borderline for high risk. **Previous hospital mortality was more significantly associated with future mortality than volume indicating factors other than volume have an effect.**
Pasquali (2012b) [35]		√ Continuous [OR= 1.10 95%CI 1.04-1.17 p=0.002] √ Categorical	Complex analysis comparing cases with and without complications. Association highest in cases of highest surgical risk. **Mortality greatest in low volume centres for all cases and those with complications.**

Study	Adjusted analysis of volume and mortality/survival outcome		Notes & Headline Message
	No effect detected [estimate of effect size and/or p value]	Effect detected [estimate of effect size and/or p value]	
Sakata (2012)	√ Pearson correlation co-efficient Newborns: -0.108 (p=0.273) Infants: -0.151 (p=0.149)		**No relationship between volume and mortality for subgroup of paediatric cardiothoracic procedures** **No adjustment for risk**
Vinocur (2013) [41]		√ [OR= 0.84/increase of 100 cases; 95% CI 0.78 to 0.90; p<0.0001]	Inverse relationship for each 100 cases added to volume. 10 fold decrease in mortality in teaching hospitals over time. **For each 100 patient increase in annual volume there was a 16% decrease in the odds of dying.**
Welke (2010) [42]	√ [only 8% hospital had minimum caseload required to detect 5% difference in mortality]		Compared case volumes with thresholds needed to detect 5% and doubling decrease in mortality. **Paediatric cardiac surgery operations are performed too infrequently or have mortality rates that are very low. Mortality rates are a poor measure for comparing hospital performance**.
Welke (2009) [43]	√ low difficulty operations [P = 0.29]	√ Difficult ops (Aristotle >3) [(OR= 2.41; p< 0.0001)]	**There is no relationship between volume and mortality for low difficulty operations but mortality decreases as volume increases for complex procedures.**
Welke et al (2008) [6]		√ Small/medium hospital vs. large hospitals [OR=1.85; 95%CI 1.56-2.20 and 1.48; 95% CI 1.24-1.77]	Age and complexity better predictors of mortality than volume. **Mortality rates significantly better for hospital performing >200 operations per year but volume mortality relationship was not linear with variability in different volume groups.**
Welke (2006) [44]	√ [Volume not predictor of mortality; c statistic 0.55]		**Mortality most associated with case-mix and not volume.**

Study	Adjusted analysis of volume and mortality/survival outcome		Notes & Headline Message
	No effect detected [estimate of effect size and/or p value]	Effect detected [estimate of effect size and/or p value]	
Karamlou (2008) [26]		√ [Non-paediatric v. paediatric surgeons OR = 4.5, 95% CI 2.1 to 9.5; More v.less paediatric CHD experience OR= 0.92, 95%CI 0.89 to 0.95; More v. less paediatric plus adult CHD experience OR =0.65, 95%CI 0.43 to 0.99]	Study looked at adult CHD surgery by paediatric surgeons. **Adult patients operated on by paediatric surgeons have lower mortality and this decreases further as surgeon volume increases.**
Kim (2011) [29]	√ total CHD volume [high volume (≥400) vs low volume (<200): adjusted OR 1.6 (CI not reported)]	√ Adult volume [high vs low adult CHD surgery volume (<10 cases annually); OR= 0.4; 95% CI 0.2 to 0.7]	Study looked at adult CHD in paediatric hospitals. **Adult CHD patients have lower mortality in the highest volume group compared to two lower volume groups**.
Studies identifying predictors of mortality or other indirect measures			
Chang (2006) [7]	no difference for post-discharge mortality]	√ [Total mortality (in hospital and post discharge) OR= 1.23, p<0.01	One risk factor for mortality examining a range of variables. **Lower volume hospitals had higher mortality for all cases combined (in hospital and post discharge) but no difference in post discharge only deaths**.
Seifert (2007) [39]		√ **[**highest v. lowest volume quartile OR =0.5 95% CI 0.35-0.71 p<0.001); middle quartile v.lowest OR =0.68, 95% CI 0.46-1.00, p=0.049]	Main objective was to assess gender effect on mortality. Volume used as one of a number of co-variates. **Mortality lower in highest volume centres and may be one factor influencing outcome**.

A number of studies detected no effect of volume on mortality. Oster [33] calculated standardised mortality rates from previous performance and found no strong effect with borderline significance for all cases and high risk cases and no effect for low risk cases and concluded it is whole hospital performance rather than volume that produces impact on outcome. Welke has conducted a series of studies examining the relationship between volume and mortality. The earliest [44] study found no effect of volume on mortality although complexity increased and mortality decreased over the study period. The 2008 study[6] found high volume hospitals performed better than other groups but complexity (RACHS-1) and age were better discriminators for mortality than volume which was only just significant (ROC curve area 0.5). This general relationship was repeated in the 2009 study [43] which found an inverse relationship between volume and mortality but this was only significant for high risk groups with no effect in low risk. The most recent study [42]examined the threshold needed to detect changes in mortality as a consequence of differences in volume and found that mortality was too low or individual procedures too rare to detect the true relationship between volume and performance.

Two studies included volume as a variable in broader studies designed to identify predictors of mortality in CHD but were not designed to explore this relationship as a primary objective. Chang [7] analysed the effect of a range of variables and found no association between volume and mortality for post discharge deaths but an association when inhospital deaths are included, and that age and procedure type were better predictors of mortality risk. The objective of the study by Seifert [39] was to examine the influence of gender on outcome. Volume was used as a co-variate in the analyses and an association between volume and outcome was detected but this was one of a number of variables that were also associated with increased risk of mortality. Both of these studies highlight that volume is just one factor influencing outcome.

Of studies reporting an effect of volume on outcome, Bazzani and Marcin [8] conducted a comprehensive set of analyses replicating four previous studies and developing a new model using a larger more contemporary dataset. A significant effect was found when volume was analysed as both a categorical and continuous variable with mortality decreasing for every 100 additional cases per year. However the effect detected was weaker than that reported in the previous studies and after sensitivity analysis in which the single highest volume hospital was removed the effect was reduced for the continuous analysis and disappeared for the

categorical analysis. Dinh & Maroulas [18] conducted a modelling study and found an inverse relationship between volume and mortality that held for both low and high risk patients in low and medium volume units and suggested this relationship was strong enough that it should be possible to identify a threshold for unit size.. The study by Gray [21] published in 2003 used data from a single year 10 years previously (1992). The study found no consistent relationship between volume and outcome in 4 centres with variable rates in the 3 lower volume centres compared to the highest suggesting there is also a centre effect but the relevance to current services is questionable. Pasquali [35] conducted a complex set of analyses examining the relationship between volume and mortality and mortality in patients with complications. An effect was found in the relationship between volume and mortality in all patients and those with complications where the effect was stronger. There was no difference in complication rates between high and low volume centres but low volume centres had higher mortality in patients with complications suggesting high volume hospitals may be better at managing complications. Vinocur [41;50] analysed data from a 25 year period (1982 – 2007) and found an inverse relationship between volume and mortality for every 100 extra cases/year. However the study also found that mortality decreased 10 fold over this time period indicating improving care and that individual centre effect contributed more to the risk model than volume. A number of studies used data over time period of 10 years or more and whilst these remain of value in contributing to the evidence base it is also the case that over time there has been substantial change in the management of CHD so relevance to current service provision or performance needs to be considered when interpreting results.

Two studies examined the effect of managing adult CHD in paediatric services or by paediatric surgeons. The study by Karamlou [26] found adults operated on by paediatric heart surgeons had lower mortality rates than those operated on by non-paediatric heart surgeons and was also associated with surgeon volume. Kim [29] examined the relationship between volume and mortality for adults undergoing operation in paediatric centres. They found no effect of total CHD volume on mortality but did find an effect of lower mortality in centres that had volumes of adult cases.

Relationship between volume and mortality for all selected conditions or procedures

We identified 14 studies of the relationship between volume and mortality for selected conditions or procedures. The findings are summarised in Table 7.

Table 7 Effect of volume on mortality for specific conditions/procedures – adjusted analyses

Study	**Adjusted analysis of volume and** and mortality/survival **outcome**		**Notes & Headline messages**
	No effect detected [estimate of effect size and/or p value]	**Effect detected** [estimate of effect size and/or p value]	
Arnaoutakis (2012) [10]		√ 30-day mortality: low vs high volume: OR= 1.9 95%CI 1.5 to 2.4; medium vs high volume: OR= 1.3 95% CI 1.1 to 1.5. 1-year mortality: low vs high volume: OR= 1.6 95% CI 1.3 to 1.9; medium vs high volume: OR= 1.2 95% CI 1.1 to 1.3.	Heart transplants including non-CHD (CHD only 3% of cases). **Mortality lower in high volume centres at 30 days and one year. High risk patients had higher mortality in low volume centres suggesting higher volume moderates the effect of risk.**
Berry(2007) [12]	√ Highest v lowest mortality rate 1.7% v 1.1% OR= 1.59 95% CI0.2-12.7		Surgery for VSD is a subgroup in a study of common paediatric operations. **No relationship between volume and mortality but VSD surgery concentrated in children's hospitalsresulted in better outcome**.
Berry (2006) [13]		√ **Low volume versus high volume** OR= 3.1 95% CI: 1.1– 8.3	HLHS. Effect in low (1-3 cases pa) quartile. Operation at teaching hospital was also an effect. **Comparing mortality in 4 volume groups found mortality was worse in the lowest volume group but no difference between the other 3 groups.**
Checcia (2005) [15]	√ surgeon P = 0.312	√ volume r2 =0.18, p= .02) Survival increased 4% (95% CI, 1%-7%) per 10 additional procedures	Norwood procedure. Number of cases per surgeon too small to detect an effect. **For each additional increase in volume of 10 cases per year there is a 4% improvement in survival**.

Study	**Adjusted analysis of volume and** and mortality/survival **outcome**		**Notes & Headline messages**
	No effect detected [estimate of effect size and/or p value]	**Effect detected** [estimate of effect size and/or p value]	
Davies (2011) [16]		√ OR = 1.60 95% CI, 1.13–2.24 for low-volume centres OR=1.24 95% CI, 0.92–1.67 for medium-volume centres compared to high volume centres.	Heart transplants including non-CHD Measure is observed v expected mortality **In low and medium volume centres mortality is worse than expected when compared to mortality in high volume centres.**
Hirsch (2008) [23]		√ Significant inverse associations for institutional volume/in-hospital mortality for Norwood procedure ($p \leq 0.001$) and ASO ($p = 0.006$).	Norwood v arterial switch. Inverse relationship of volume to mortality. **As volume of cases per year increases mortality decreases.**
Hornik (2012) [24]		√ continuous lower centre volume associated with higher inpatient mortality (p=0.03) Surgeon volume associated with higher inpatient mortality (p=0.02). √ categorical lowest vs highest category (OR =1.56 (1.05-2.31); p=0.03. Lowest v highest surgeon volume (OR= 1.6, 1.12-2.27;p=0.01).	Norwood. Analysed centre and surgeon volume. Effect held for both. **Both high volume centres and high volume individual surgeon caseload have lower mortality than low volume centres and low caseload surgeons**.

Study	**Adjusted analysis of volume and** and mortality/survival **outcome**		**Notes & Headline messages**
	No effect detected [estimate of effect size and/or p value]	**Effect detected** [estimate of effect size and/or p value]	
Karamlou (2010) [27]	√ Centre volume on adjusted mortality p=0.17 for Norwood and p=0.07 for PAIVS Surgeon total case volume p=0.4 Norwood	√ Centre volume impact on adjusted mortality p<0.001 for TGA and IAA Surgeon total case volume p=0.002 for TGA .	Complex CHD (4 groups). Centre and surgeon volume. Variable performance – good outcomes for one group didn't translate to all groups. **No relationship between centre or surgeon volume for Norwood and PAIVS but higher volume centres had lower mortality for TGA and IAA and higher surgeon volume had lower mortality for TGA only.**
McHugh (2010) [30]	Stage 2 medium volume compared to highest and stage 3 small volume compared to highest not significant but no values given	√Stage 1 small volume OR = 2.49 95% CI 1.51-4.07, medium volume OR=1.75 95% CI 1.23-2.49 compared to high volume 1998-2002 v 2003-7 OR-1.62 95% CI 1.16 – 2,27 Stage 2 small volume OR 2.09 95% CI 1.06-4.11 compared to highest volume Stage 3 medium volume OR=1.70 95% CI 1.13-2.57 compared to highest volume	HLHS. Longitudinal study so also looked at early v late era surgery. Late era also had an effect. **A complex pattern emerges with higher mortality in both small and medium volume centres compared to high volume centres for stage 1 but mixed results for stages 2 and 3. Mortality reduced over time independently of volume.**
Morales (2010) [32]		√ OR=0.07 95% CI0.02-0.24	Use of VAD – patients other than CHD. Effect was in large volume teaching hospitals v rest. **Placement of VAD at large volume teaching hospitals reduces the risk of mortality when compared to lower volume and non-teaching hospital**s.

Study	**Adjusted analysis of volume and** and mortality/survival **outcome**		**Notes & Headline messages**
	No effect detected [estimate of effect size and/or p value]	**Effect detected** [estimate of effect size and/or p value]	
Pasquali (2012a) [34]		√ volume as continuous variable p=0.04; categorical lowest vs. highest category >20; (OR = 1.54;95% CI 1.02-2.32; p=0.04) 3)	Norwood. Volume mortality effect but when volume adjusted for between centre variation remained. **Overall higher volumes are associated with lower mortality but there is variation in individual centre mortality rates that do not reflect this relationship. .**
Studies identifying predictors of mortality			
Dean (2013) [17]	√ stage 2 & 3 palliation	√ stage 1 palliation large vs small volume: OR= 0.57 (CI 0.45 to 0.71)	HLHS. Volume split is top 5 v rest (42). Volume is one variable examining a range of risk factors for mortality. **For stage 1 palliation mortality is lower in the highest volume centres but mortality in medium volume centres is not investigated. No relationship between volume and mortality for stages 2&3.**
Petrucci (2011) [36]	√ OR per 10-unit increase in average volume = 0.98 (95% CI, 0.85 to 1.13; p 0.78		BTSP. Total case volume and BTSP volume included. **No relationship between volume and mortality was found.**

Study	**Adjusted analysis of volume and** and mortality/survival **outcome**		**Notes & Headline messages**
	No effect detected [estimate of effect size and/or p value]	**Effect detected** [estimate of effect size and/or p value]	
Tabbutt (2012)[40]	√ mortality – no effect but values not reported	√ morbidity Renal failure – centre volume P=0.006, surgeon volume p=0.02 Sepsis – Centre volume P=0.003 Time to extubation – centre & surgeon volume P<0.001 Length of stay – centre volume P<0.001	Norwood. Centre and surgeon volume. **No relationship between volume and mortality was found but lower volume centres and surgeon procedures were associated with higher rates of morbidity outcomes and length of stay.**

Studies of the volume and mortality relationship were predominantly centred on complex and relatively rare conditions and associated procedures (9/14 studies). In general, these studies did demonstrate an effect of volume on mortality but the relationship is not straightforward. In 2 studies of HLHS palliation, Dean [17;51], found an effect for stage 1 palliation but not stage 2 and McHugh [30] also found the association between low volume and higher mortality was strongest for stage 1 with variable effects for stage 2 and 3. The study by Karamlou [27] looked at volume and outcome for 5 conditions and procedures and found the volume and outcome effect was only present for one group (TGA). Four of the six studies on Norwood procedure found an association between volume and mortality [15 23 24 34] and two found no association [27 40] although Tabbutt [40] did find that low volume was associated with higher morbidity and length of stay in hospital. A single study identifying risk factors for mortality after Blalock Taussig Shunt Procedure [36] found no relationship between volume and mortality with condition severity and weight being the most significant predictors for mortality.

One of the advantages of using these highly selected and standardised patient groups is that the potential effects of other factors on outcome may also be identifiable. Indeed the findings of these studies highlight this complexity. Highly specialised and complex surgery requires clinical expertise. Four studies also measured the effect of individual surgeon volume. For Norwood procedure Hornik [24] reported decreasing mortality with increasing surgeon volume, Tabbutt [40]found no effect of surgeon volume as did Checcia [15] although in the latter study it was acknowledged that the number of cases per surgeon may be too small to detect an effect. Karamlou [27] found increasing surgeon volume improved outcome but only for TGA and not for other groups within that study.

These studies also acknowledged the effect that individual institutions may have on mortality. The study by Karamlou [27] on 5 different but complex patient groups found that there was wide between centre variation in performance for the different conditions and that good performance for one condition was not necessarily translated to all conditions within a centre. McHugh [30] also identified substantial between centre variation and found that although overall there was an effect of higher mortality in low volume centres, there were also low and medium volume centres that were achieving good outcomes. Similarly the study by Pasquali [34] identified an effect of volume on outcome but volume only accounted for 14% of between

centre variation in risk of mortality indicating there are a range of other factors that are also having an impact.

Included studies also demonstrate the potential effects of changes in clinical advances and service provision. The study by McHugh [30] used data over a 10 year period and a dichotomised analysis of early and late era surgery found mortality improved over time. There has also been a move to centralisation or regionalisation of services also reflected in these studies. The primary objective of the study by Berry [13] was to assess the impact of management at teaching versus non-teaching centres and found over a 3 year period that stage 1 palliation surgery for HLHS in non-teaching hospitals reduced from 20% to 2%. In another study Berry [12] explored the relationship between volume and outcome for 4 common paediatric operations including repair of ventricular septal defect (VSD). For this subgroup no effect was detected between volume and mortality but VSD surgery was much more centralised to specialist children's hospitals than the other 3 operations which the author considered may have provided a protective effect. A study by Morales [32] of patients receiving a VAD found an effect of volume on mortality where comparator was not just high volume but high volume teaching hospitals versus other centres. We included 2 studies of cardiac transplant and both identified lower mortality rates in high volume hospitals. However, one study included only adults [10] and the other [16] focused on children and both included a range of conditions other than CHD. These studies add to the already substantial evidence on centralisation of transplant services but are of limited relevance to the evidence base on specialist paediatric CHD service provision.

Relationship between proximity and distance on mortality and volume on non-mortality outcomes

The provision of good CHD surgical care requires not just surgical expertise but also provision of the associated services that provide pre-and postoperative care. It has been suggested that the proximity of these services, for example by having them all available on one site rather than having to transfer patients at critical times for specialist care, may also be a factor that contributes to outcome in CHD. In addition, although the emphasis of volume on outcome is dominated by mortality, it can be argued that there may also be an effect on non-mortality patient outcomes such as morbidity and quality of life and service consequences

such as length of stay in hospital and associated costs. We identified seven studies that explored relationships other than volume and mortality for CHD. The findings of these studies are summarised in Table 8.

Table 8 Effect of proximity and distance on mortality and volume on non-mortality outcomes

Study	Impact on outcome		Notes & Headline messages
	No effect detected [estimate of effect size and/or p value]	**Effect detected** [estimate of effect size and/or p value]	
Effect of proximity of associated services or distance from specialist centres			
Burstein (2011) [14]	√ No overall difference between CICU & OICU OR= 0.88 95% CI 0.65-1.19	√ for STS-EACTS 3 OR =0.47 95% CI 0.25-0.86 in favour of CICU.	Paediatric Cardiac Intensive Care Unit v other ICU. **Overall there was no relationship between mortality rates and the type of ICU caring for patients but for one group of mid complexity cases mortality was lower in paediatric ICU**.
Eldadah (2011) [19]		√ Mortality declined from 3·5%) to 0·8%. p < 0.05	Paediatric Cardiac Intensive Care Unit before and after. Decrease in mortality and morbidity. **Outcomes following paediatric cardiac surgery improved after the introduction of a dedicated paediatric cardiac ICU.**
Karamlou (2013) [25]		√ highest category of volume for ECMO OR=0.51 95%CI 0.30-0.87; P < .01	ECMO case volume. Lowest mortality in patients requiring ECMO associated with highest ECMO volume centres. **Patients requiring ECMO have a lower mortality rate if they are cared for in units who manage a high volume of ECMO cases.**
Fixler (2012) [20]	√ mortality not significantly related to distance 50-100 miles vs. <50 miles: Hazard Ratio (HR) 0.83(0.57 to 1.22); for >100 miles vs. <50 miles: HR 1.08 (0.86 to 1.36).		Distance to cardiac centre not related to unadjusted first year survival. **The distance to a specialist cardiac centre does not appear to have any impact on mortality following CHD surgery.**
Pinto (2012)	√ mortality for those living 90-		Effect detected for adverse events in patients 90-300 minutes from

Study	Impact on outcome		Notes & Headline messages
	No effect detected [estimate of effect size and/or p value]	**Effect detected** [estimate of effect size and/or p value]	
[37]	300 min away vs those <90 min away HR 2.1; 95% CI 0.7 to 5.7.		centre but not for patients <90 minutes or >300 minutes. **The distance to a specialist cardiac centre does not appear to have any impact on mortality following CHD surgery.**
Effect of volume on non-mortality outcomes only			
Benavidez et al (2007) [11]		√ complications – Increased risk of death if complications OR=2.4, P<0.001	High volume hospitals had higher complications, higher complexity but lower mortality. **Patients with complications after CHD surgery have a higher mortality rate but this is reduced if they are cared for in high volume centres.**
Mery (2014) [31]		√ complications - highest volume quartile lower incidence of chylothorax OR= 0.49 95% CI 0.42 to 0.58 vs lowest volume	Chylothorax complication. **Patients cared for in lowest volume centres are more likely to develop this specific complication when compared to the highest volume centres.**

We identified two studies that specifically looked at proximity of associated specialist services and both examined the effect of a specialist cardiac paediatric intensive care unit (cPICU). In a multicentre study Burstein [14] compared care in cPICU with other ICU and found no effect on mortality except for STS-EACTS 3 level cases and primarily in patients undergoing atrioventricular repair and arterial switch operations suggesting that potential benefits may only be applicable to specific patient groups. Eldadah [19] conducted a single centre before and after study evaluating the impact of introducing a cardiac cPICU and found a reduction in mortality and a bigger effect in reducing morbidity (wound infection and chest re-exploration).

One study by Karamlou [25] explored the relationship between centre ECMO case volume and mortality in paediatric patients requiring ECMO and found a decreased mortality rate in the highest volume ECMO centres supporting the concept of regionalising highly specialist services.

In a related study discussed earlier Hickey [22] examined not only the effect of volume on mortality but also ICU nursing staffing and skill mix. They found no relationship between nursing staffing and skill mix and mortality but did find high nursing workload was associated with volume. They concluded it is possible that nursing staffing levels may already be above the threshold needed to detect an effect on mortality.

Two studies examined the relationship between distance from a specialist cardiac centres and mortality [20 37] and both found no relationship between distance and mortality although Fixler [20] found higher mortality in specific geographical areas where there was no identifiable cardiac centre. This effect may be as dependent on demographic factors as distance. Pinto [37] did find a higher rate of adverse events in one group although this was the mid distance (and not nearest or furthest) and the paper raised the possibility that the effect may be a consequence of follow up and monitoring policies related to proximity to a centre rather than distance itself.

We found two studies where the primary outcomes in relation to volume were complication rates. The study by Benavidez [11] primarily looked at complication rates although mortality rates were also measured. The main findings were that higher volume centres had higher complication rates but that lowest volume centres had higher mortality rates. They

acknowledged that this may be a consequence of better reporting of complications in high volume centres but also suggested that better mortality outcome, despite higher complication rates in high volume centres, may be because high volume centres are better at managing and rescuing patients with complications. The study by Mery [31;49] looked at risk factors for one specific complication – chylothorax – and found a relationship with a reduced rate of chylothorax in the highest volume centres compared to other centres. Nevertheless the same study also observed that some small volume centres had comparable complication rates to high volume again highlighting variability between centres.

A small number of the other studies we have included also examined non-mortality outcomes. In addition to the Eldadah [19]and Pinto [37] studies mentioned above, Tabbutt [40] and Davies [16] both found lower complication rates in high volume centres following Norwood procedure. Burstein [14], Berry [12] and Pasquali [35] all found no association between volume and complication rates. Karamlou [26] and Davies [16] both found low volume centres were associated with longer length of stay. Two studies [32 26] also assessed costs and both found a relationship of higher costs associated with low volume centres. Mery[31] found chylothorax complication increased both length of stay and costs. Although these variables were not explicitly tested in conjunction with volume in this study, this does provide some indication, given the relationship of lower complication rates in high volume units, that there is likely to be an association. There is a more substantial literature on costs and volume but this was outside the scope of our review.

Chapter 7. Discussion

Summary of the evidence about the relationship between volume and outcomes

The evidence reviewed did not include any UK studies and is predominantly based on outcomes in paediatric patients. Overall, we have found that although the evidence does demonstrate a relationship between volume and outcome in the majority of studies this relationship is not consistent. Instead there is a mixed picture with both effect and no effect being reported. Studies on single conditions or procedures were more likely to identify an effect of volume on mortality but, given that the focus of these studies were for populations of patients with complex conditions and associated surgical procedures that require highly specialised care and expertise, this in itself is unsurprising. The findings from these studies were not unequivocal as even within these highly selected groups there was considerable variation in effect depending on procedure type and individual centre performance. What these studies do indicate is the potential value of centralising or regionalising highly specialised services for very rare and complex cases. However, it cannot be assumed that comparable effects can be achieved for a much broader range of conditions and therefore used to define CHD centre volume. It is possible that surgeon volume may be as important as centre volume for these complex cases.

The findings from studies that did consider broader CHD populations were more equivocal. In some studies where an effect was identified, the effect was weak or only demonstrable for specific subgroups of patients. There was no clear indication that the evidence for the volume and mortality relationship was substantially stronger than the evidence for a no effect relationship in these broader groups. The findings further highlight the complex relationship between volume and outcome and the range of other factors which also have an effect. Some of these, such as condition severity, are well established but the effect of association of processes, systems and individual clinical effects on outcome remain unknown.

We also searched for evidence from studies on adult CHD but this only yielded 3 papers. One of these studies was concerned exclusively with cardiac transplantation for a range of

conditions not just CHD and so is of limited value other than to provide more general evidence of the potential value of centralising specialist services. The main focus of the other two studies was the effect of surgeon type and both found that adult CHD patients had better outcomes when operated on by paediatric surgeons in specialist children's centres. Karamlou [26] found outcome was associated with surgeon volume and Kim [29] found a similar association with adult procedure volume indicating the influence of expertise on outcome.

The previous systematic review conducted by Ewart [2] included studies published up until 2009. We have included studies considered by that review in this rapid review together with related studies published from 2009 to date. The review by Ewart included seven studies and concluded that whilst the evidence did suggest there is a relationship between volume and outcome it is likely that volume is a surrogate marker that encompasses other processes and system factors the effects of which are unknown. The additional evidence included in this review primarily adds further to our understanding of the complexity of the relationship between volume and outcome. Whilst there is now a larger number of studies reporting a relationship between volume and outcome, these studies also increase the evidence that this is unlikely to be a simple, independent and purely directly causal relationship. The effect of volume on outcome relative to the effect of other as yet undetermined health system factors remains a complex and unresolved research question.

Summary of the evidence about the relationship between proximity and outcomes and volume and non-mortality outcomes

We also attempted to identify studies that explored factors related to influencing outcomes in CHD other than the relationship between volume and mortality. This yielded only a small number of relevant papers. Two studies found sa benefit in terms of reducing mortality and morbidity in patients cared for in specialist intensive care units.One study identified lower mortality for patients requiring ECMO who were cared for in high volume ECMO units. Two studies on distance to specialist cardiac care found no relationship to mortality. Similarly we found only 2 studies where the primary objective considered the effect of volume on complications. However, a small number of the studies that examine the volume mortality relationship also measured morbidity as secondary outcomes. Such a small number of relevant studies do not provide a robust evidence base on related factors but collectively they do highlight that the overriding emphasis of research studies on CHD services has been

dominated by measurement of the relationship between volume and mortality and mainly short term, in hospital mortality. Care is the product of a complex set of processes of which volume of activity in any given centre or unit is only one contributor. There appears to be relatively little evidence from studies that attempt to measure the effect of related processes on outcome. The consequences of care, and hence outcomes, are also greater than may be captured by data on short term mortality. Long term mortality is also important, as are a range of other important short and long term outcomes for survivors including morbidity (for example complications) physical and neurological functioning and quality of life, and service consequences such as length of stay and costs, that seem to have received scant attention. As a consequence the available evidence base that can inform CHD service design is seriously limited and does not reflect the complex features and relationships that contribute to service provision.

What are the issues that have emerged from the evidence?

We have not conducted a systematic review but in assessing a broader topic range and more current literature we have identified some key themes.

1. There are a range of factors which influence mortality in CHD and centre volume is only one of them. In our data extraction we recorded variables within studies that were also identified as associated with mortality. This process revealed a wide range of patient, demographic and service factors that also have an impact on outcome. The most influential risk factor for mortality by far is the severity of the condition and the associated surgical complexity needed to treat that condition. Where an effect of volume on mortality was measured, in general this tended to be greater in high risk patients as illustrated by the studies on complex single conditions. This is further supported by some of the studies that included broader CHD populations. It is reasonable to assume that complex high risk surgery requires high level surgical expertise. A small number of studies have attempted to try to disentangle the effects of individual surgeon performance on outcome but with mixed results. This requires further exploration as this complex relationship of what has an effect – a high volume of complex procedures in a centre or a high volume of complex procedures by an individual surgeon – is still unclear. Furthermore, there is some evidence (Karamlou [27]) that it cannot be assumed that a high level of technical competence in one complex procedure translates across a range of conditions.

2. Medicine moves forward and clinical advances, training, increasing expertise and changes in service provision mean outcomes for CHD have also changed over time. Five studies that analysed data over long time periods (~10years) measured changes in mortality over time and found that, irrespective of other factors including volume, mortality decreased despite increasing complexity [18 44 41 30 8] illustrating ongoing clinical improvement. What this also means is that the relevance of findings from historical studies or more recent studies that have used historical data will not reflect current care and clinical improvements and so relevance to contemporary services needs to be considered. This observation also has implications for future research. The most recent study by Welke [42] attempted to establish the case volume thresholds needed to detect changes in mortality and concluded that some individual procedures occurred too infrequently or mortality rates were too low to reliably use mortality as a measure of between centre performance. If clinical advances continue to improve survival, this principle will need to be borne in mind.

3. Although aggregated data may show a difference in mortality rates between low and high volume centres, such aggregation may mask between-centre variation. The studies by Gray [21], Pasquali [34],Karamlou [27] and McHugh [30] all identified variation between centres with some low or medium volume centres performing equally as well as those with high volume. These studies acknowledged that there are likely to be other centre effects such as training, management protocols, expertise, teaching hospitals, availability of services composition of care teams and quality programmes that influence outcome. As a result it is unclear whether it is volume or these other effects that are influencing outcome.

4. **The evidence base available to guide UK decisions on service design and configuration for CHD is dominated by predominantly retrospective and uncontrolled studies conducted within the USA.** A noteworthy absence is the lack of any relevant large, well designed UK multicentre studies. The extent to which the reported findings are generalisable and relevant to the UK setting is therefore limited. In the USA services are organised very differently to the UK. Key differences include geography and therefore distances to specialist care; multiple providers of health care which means variation in organisation of services, for example numbers of units within different counties and states, and complex health service financing models. **many of the studies have analysed centres with very small volumes of cases** – for very rare complex cases the volume of cases may be

less than 5 a year and for broader CHD services some studies have included centres treating less than 20 cases a year.

Elsewhere and in line with other specialist services there has been a move to centralisation or regionalisation of CHD services, particularly in Europe ([52 53]). In the UK CHD services for children are already regionalised and so evidence on the relationship of very small volume centres on mortality has little relevance to decision making about services which are already highly centralised. However, CHD services for adults are less centralised, so decision making relating to service provision may be informed by evidence relating volume and outcomes.

It is axiomatic that, with this centralisation there is also a corresponding increase in volume as more cases are concentrated in fewer centres but centres will also be characterised by the range of factors associated with service provision discussed previously. It remains unclear whether the impact of volume on outcome is largely a consequence of higher volume units organising and providing a complex service and high quality service with all the "right" components that would be expected to reduce risk, or an independent factor directly related to the advantages of dealing with a larger number of cases. For example staff may have more experience of specific procedures and potential complications. It is the individual and combined effects of these complex factors on clinical outcomes for patients that remain to be unpicked. Without this better understanding the appropriate interpretation of the observed volume – outcome relationship remains unclear. There is also a lack of evidence about the effects of service factors such as proximity to specialist services and the impact of care on outcomes other than mortality.

5. Despite the growing number of studies on the relationship between volume and outcome few studies have suggested what the optimum size of a CHD centre in terms of volume should be. Less than half of the included studies analysed volume as a continuous variable (14/35 relevant studies) which would provide the most robust evidence from which to consider volume thresholds. Analyses conducted with volume as a categorical variable carry several limitations in informing decisions about volume thresholds both in terms of decisions about within study thresholds and the questionable robustness of the findings. This is particularly the case when comparisons have only been made between very high and very low volume centres only. Dinh [18] suggested the inverse relationship between volume and

outcome detected in their modelling study on 10 years of data was sufficiently robust to allow calculation of volume thresholds. However these authors did not go as far as identifying what this should be. Hirsch [23] suggested that a reasonable threshold for referral of children requiring Norwood procedure is centres doing at least 20 procedures a year and 10 procedures a year for arterial switch operation. Bazzani and Marcin [8] constructed scatter plots of volume against mortality and found no obvious threshold for centre volume. The review by Ewart [2] considered the data presented by Welke [15] and suggested a possible threshold of 200-250 cases per year. Welke[6] clearly expressed the view that volume is likely to be a surrogate for the processes and characteristics of care systems that produce outcomes and that centre specific quality measures would be more informative than volume thresholds . Pasquali [34] and Vinocur [41;50] concurred with this view and suggested that service design decisions should be guided by a range of individual centre performance measures and not volume. There are consistent and clear messages within the literature we have reviewed about the danger of viewing volume in isolation. Furthermore, included studies also caution concerning the likely but as yet poorly understood interaction of volume with the numerous other clinical and structural dimensions that contribute to delivering high quality services and hence good outcomes. Finally, questions still remain concerning what volume should be the item of consideration – is it whole service volume, complex procedure volume or individual surgeon volume that should direct decisions?

Methodological Limitations of the Included Studies

Quality assessment and methodological limitations

As this is a rapid review we have not conducted a quality appraisal of individual included studies. However, we have considered the collective methodological limitations of these studies in order to provide an overview of study quality and have assessed the usefulness of these studies in answering the research questions. Appendix Four provides a simple summary of key items for each paper that relate to the usefulness of studies on CHD services. Items relate to whether studies have conducted analyses that have adjusted for the two key risk factors for mortality, severity/complexity and age, whether they are single or multicentre studies and whether they included at least two CHD conditions or procedures. In summary, 37/39 studies adjusted for severity, 28/39 adjusted for age although some studies on specific

groups of patients were confined to specific age groups e.g. neonates, 35/39 were multicentre studies with just three single centre studies and 25/39 studies included a population with more than one condition or procedure.

Author assessments of study limitations

Many authors of included studies take great care to point out the methodological limitations of their studies and caution against over-interpretation of their findings. Included studies are predominantly retrospective and observational in nature. There were no prospective studies. Such design features make it very problematic when trying to establish a direct inverse relationship of cause (volume) to effect (mortality). Many of the source databases are limited in being primarily created for administrative purposes, for example claims data collection and billing [23 26 6 42 29 17;51]. As a consequence we can have little confidence in the clinical coding [42], although several studies seek to ascertain accuracy by comparing the coding for diagnosis with coding for the surgical procedure [42] in order to establish internal coherence and consistency.

Information bias might be introduced through "miscoding of information provided, missing data, or misinterpretation of data" [23]. Incompleteness of data is considered problematic – for example, even where records are available large numbers of surgeon identifiers may be missing [12]. Other data sources were voluntary which introduces problems of selection bias as they may be selective in their coverage [43 27 36 41]) or according to predefined membership or explicit criteria [40]. Changes or indeed inconsistency in institutional characteristics, such as coding for teaching status, may result in one hospital being coded differently across different points of an interrupted time-series [13]. Welke [6] considered that in large datasets errors in quality are likely to be random rather than systematic although it could also be argued that for data on rare conditions errors may then be systematic.

A key concern of this report relates not simply to the surgical performance of different size units but also to the personnel and structural characteristics of the observed surgical units. On these latter matters administrative source databases have little contextual data to offer [14]. Important contextual details are thought to include institutional factors such as team composition, individual surgeon training and experience, type of facility (e.g., freestanding children's hospital, general hospital), transfusion practices, infection control, and care

pathways [41]. Indeed several commentators also bemoan the lack of even basic clinical contextual details such as certain anatomic features [13] or accompanying non-surgical procedures. Critical details such as non-intervention, transfer to another institution, and preoperative mortality are frequently unavailable [15]. Furthermore some clinical data features rely on subjective judgement while perioperative details are frequently missing [36]. It is essential to recognise that not all in-hospital mortality will have an underlying surgical cause [39].

A further consideration occurs where the research question is deliberately prescribed i.e. where data relate to a single institution, a single year or, as with a substantial proportion of studies, to a single procedure. Data relating to a single institution is unlikely to be generalizable, particularly in the absence of details of the pattern of referrals to that location [37]. While analysing data from a single year circumvents concerns relating to structural changes or improvements in procedures over time [39] it carries the attendant danger of placing inordinate and inappropriate emphasis on an isolated timepoint. Finally, in the case of study reports of a single surgical procedure, the insights to be gained by a more extended examination of a discrete area of surgical practice involving typically more rare and complex conditions are outweighed, at least for the question that is the focus of this report, by neglecting overall surgical volume. Such studies thus provide a negligible contribution to the "evidence" that relates to optimal volumes for entire CHD services.
The well-reported characteristic of paediatric cardiac surgery as covering a wide range of conditions and associated procedures poses a further threat to accurate interpretation. While it is helpful to consider an overall portfolio of procedures the data for rare conditions necessarily involves small numbers of procedures [14]. Combining this statistical characteristic with the decreasing numbers of events of interest (i.e. mortality), particularly as cardiac surgical procedures improve, further limits the value of the reported results [33 42]. Numbers of procedures and numbers of deaths are particularly limited in low volume units meaning that low units are particularly vulnerable to even very small errors in the data.

With the ongoing development of methods for analysing the volume-outcome conundrum comes increasing recognition of the unsuitability of certain methods of investigation and analysis. For example recent papers carry almost universal acknowledgement of the inappropriateness of any analysis that does not take into account any adjustments for risk [38]

and complexity. Handling data on number of procedures as a continuous, rather than a categorical, variable is now considered essential while approaches that seek to establish a threshold that represents a step-wise change in outcome are frequently criticised for being unsophisticated and misleading [26].

It would be negligent to overlook the considerable advances in methodology that have occurred during the time period charted by these included studies. The increasing sophistication of the tools that seek to score for complexity are just one such example, as documented in Appendix Four. However while evolution and improvement of such tools and scores is to be welcomed such ongoing modification adds further to the complexity of a research area already characterised by considerable clinical heterogeneity. It is arguable whether the ongoing debates regarding the optimal configuration for volume/outcome are likely to be resolved in the absence of a comprehensive and accurate national database that provides sufficient information for risk stratification, complexity scoring and adequate contextual detail on clinical context as well as on structural and personnel related factors.

Chapter 8. Conclusions

We have conducted a rapid review of the evidence on the relationship between volume and outcome, and other service factors and outcome, for CHD. We found a large proportion of papers which analysed the relationship between volume and mortality for paediatric CHD surgery, but very limited evidence in relation to the other factors of interest, or for adult populations. It is noteworthy that so much evidence is available in what is a relatively small clinical specialty. No UK based studies or cross country comparions were identified. **This review identified a substantial number of studies reporting a positive relationship between volume and outcome, but the complexity of the relationship and of the evidence underpinning it requires careful interpretation**. The mixed picture emerging from the 39 included studies increases our understanding of the complexity of this relationship and highlights variation in both methods and findings across individual studies, the potential effects of a range of other factors that may interact with volume and influence outcome, and the methodological limitations imposed by the research approaches taken.

Even though our systematic, yet time-limited, searches have revealed a substantial volume of data on CHD outcomes, the existing data sources carry major limitations, particularly given the absence of information on clinical and service-related processes and outcomes, which are consistently recognised as important to patient care and patient safety. As a consequence, it is problematic to interpret the current evidence for the relationship between volume and outcome as the impact ofthis relationship may be having cannot be disentangled from the effects of other factors. The limitations of the rapid review approach means we could not consider conducting a meta-analysis of the evidence on volume and outcome but this is an option that could be considered and which may further enhance the evidence available. Further evidence review of the broader fields of cardiac surgery (rather than just CHD) may also contribute to identifying some of the clinical and service related processes and outcomes that may be relevant to CHD and provide a framework for future data collection and new studies.

The design, development and delivery of consistently good quality and safe services require an understanding of the complex components and interactions that constitute a service and how these influence patient outcome. There is a clear evidence gap that needs to be addressed

with regard to: better understanding of the relationships between the wide range of organisational factors in CHD services; how these relationships can potentially predict a number of outcomes of relevance to patients and families; and the causal pathways between organisational factors and outcomes. The development and validation of clinical and administrative databases which can be used for observational studies of the relationship between organisational factors and outcomes would clearly be a valuable resource. There is scope to expand the National Institute for Cardiovascular Outcomes Research (NICOR) database to consistently collectet information on a wider range of processes, organisational factors and outcomes related to quality of care that are not captured at present. It is our considered opinion that this should be the target at which future research efforts should be directed. This would support the design and conduct of UK studies and help address the clear lack ofevidence relevant to service provision in the NHS.

Chapter 9. Acknowledgements

The NIHR HS and DR team

The stakeholders who suggested evidence for inclusion in the review

Contributions of authors (listed in alphabetical order)

Dr Andrew Booth (Reader) undertook citation searches, contributed to the proposal writing, assessed evidence for inclusion in the review, proof read the final report, constructed summary tables, assessed the methodological limitations of the included studies and was the Chief Methodologist on the review.

Mrs Fiona Campbell (Research Fellow) undertook data extraction and contributed to the construction of summary tables.

Dr Katy Cooper (Research Fellow) undertook the double sifting and contributed to the proposal writing and construction of summary tables.

Professor Elizabeth Goyder (Professor of Public Health) was the senior lead on the project, contributed to the proposal writing and undertook the sifting of conference abstracts and construction of summary tables.

Dr Amrita Jesurasa (Honorary Clinical Lecturer in Public Health) undertook data extraction and report writing.

Dr Louise Preston (Research Associate) contributed to the proposal writing, designed and ran the literature search, contributed to report writing and managed the project.

Mr Colin O'Keeffe (Research Fellow) undertook data extraction and contributed to evidence synthesis through the production of summary tables and other key tables.

Ms Janette Turner (Senior Research Fellow) contributed to proposal writing, undertook data extraction and led on the evidence synthesis.

Chapter 10. Publications

There are currently no publications associated with this rapid review.

Chapter 11. References

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Chapter 12. Appendices

Appendix One – Final Protocol

Rapid Evidence Synthesis Proposal - What evidence is there on how organisational features affect patient outcomes in congenital heart disease services?

Background: This proposal has been written in response to a request by NHS England to further examine the evidence around the delivery of congenital heart disease (CHD) services. The purpose of the evidence synthesis is to support the ongoing review about how these services should be best organised.

Services for children with CHD have been the subject of scrutiny for a number of years. In 2012, following an extensive review as part of the "Safe and Sustainable" work programme, a series of recommendations were made for the re-configuration of cardiac services for this patient group (NHS Specialised services, 2012). The recommendations of "Safe and Sustainable" were challenged and were subsequently the subject of a Judicial Review (JR) and an Independent Reconfiguration Panel (IRP) who concluded that the processes of the review were flawed. Consequently service reconfiguration was not implemented. These services are subject to a new review which will consider the whole lifetime pathway for CHD.

The JR and IRP (IRP 2013) identified a number of issues of concern with the "Safe and Sustainable" process including the use and interpretation of the existing evidence base on delivery of surgical services for CHD and patient outcome. In particular they questioned the reliance on evidence around the relationship between volume of cases and outcomes. A 2009 literature review (Ewart, 2009) had examined this evidence in detail and, although confirming the existence of a relationship between volume and outcome, also cautioned that this relationship alone was not sufficient to make recommendations on the size of units needed as the effects of other contributory system and process factors to this relationship were unclear in the published literature.

Rapid review process: This is a rapid evidence synthesis which needs to be completed within a very short timeframe to produce a review which is relevant and timely. Therefore

rapid review methods will be used to ensure the efficient identification and synthesis of the most relevant evidence. The review will not attempt to identify all relevant evidence or to search exhaustively for all evidence that meets the inclusion criteria, although the proposed searching approach aims to identify the key evidence. Similarly the data extraction and quality assessment will focus on the most critical information for evidence synthesis rather than aiming to exhaustively extract and critique all the available information in individual papers. Given time and resource constraints, and the need to work in a transparent and reproducible manner, our review will focus on identifying and synthesising the key evidence as described below.

Purpose of review: The purpose of this literature review is to examine what evidence there is on how organisational features affect patient outcomes in congenital heart disease services.

Review questions: The literature review can be more specifically framed to focus on two key organisational features. The rationale for this is based on the existing, evidence-based, consensus that there may be a relationship between the volume of CHD procedures and patient outcomes and the clinical consensus that reconfiguration which includes the co-location (or increased proximity) of specialist services may be related to better patient outcomes. The questions are as follows:

1a. 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?

1b. How are patient outcomes influenced by proximity to/colocation with other specialist clinical services (e.g. co-location of services such as specialist cardiac paediatric intensive care)?

Scope: Clearly there is enormous scope to both search for and review related evidence as the subject area incorporates several different dimensions. The literature review will focus on evidence from CHD services for children and adults as this will be the most relevant. Evidence from other paediatric surgical services and evidence from general adult cardiac services may also be relevant to CHD services. Where there is limited evidence from the

CHD literature, the review will potentially consider the wider literature on these other clinically similar services as feasible and where relevant. Appendix 1 sets out our proposed conceptual framework to guide the review process.

This framework will allow us to:

- Define the scope of the search strategy
- Define inclusion and exclusion criteria to specify what types of studies will be included in the final report
- Construct summary tables of all included studies to present key information and findings
- Synthesise the evidence from the included studies

The report will not appraise the evidence in terms of how future services should be provided or make recommendations about service configuration.

Methods:

Search – Our initial approach will be to develop a search strategy based on the search strategy of Ewart et al (2009) with some modifications in order to capture a wider evidence base around the other explanatory factors (see conceptual framework) and a wider range of interventions (both adult and paediatric surgical and interventional cardiology services), within the time constraints of a rapid review. The search strategy is structured relevant terms as follows:

- Population = adults and children receiving treatment for congenital heart disease
- Intervention = organisational factors (based on volume and proximity)
- Outcomes = mortality, complications and related outcomes

The databases that will be searched are: MEDLINE, EMBASE, Cochrane Library, Web of Science (Science Citation Index and Social Science Citation Index) and CINAHL.

In addition to the database search as outlined above, we will also undertake the following to identify key evidence for the review:

- Liaison with topic experts.
- Citation searching on papers included in Ewart (2009) and other key papers identified by topic experts.
- Scrutiny of reference lists of included primary studies and relevant systematic reviews.
- Scrutiny of recent reviews of services and guideline documents for relevant peer reviewed evidence.

Inclusion and Exclusion Criteria – the evidence included in the review will be restricted to quantitative studies to ensure it addresses the key review questions and outcomes of interest. This is likely to be observational evidence; however there may be evidence from trials. The included evidence will be restricted to OECD countries only to ensure relative health system comparability. We will only include peer reviewed evidence published in order to ensure we are synthesising evidence which has already undergone methodological and expert scrutiny. We will limit the included evidence on the relationship between volume and outcome in paediatric cardiac surgery to 2009-2014 as evidence prior to 2009 is available in the Ewart review (Ewart 2009), which has undergone scrutiny through its inclusion in the "Safe and Sustainable" work programme. Other evidence will be included if published 2003-2014 in English to ensure the most recent relevant evidence is prioritised within the constraints of the rapid review process.

The inclusion criteria can be summarised as follows:

Population = adults and children undergoing treatment for congenital heart disease.
Intervention = the organisation of treatment based on at least one of the following: volume of activity and/or proximity to/co-location with other related services. Only studies including either volume or proximity factors will meet the inclusion criteria of the review.
Comparator = other methods of organisation of treatment (only studies with a comparator group will be included)
Outcome = patient outcomes. Studies reporting process outcomes will only be included if they report at least one patient outcome.

Data Extraction – Formal data extraction of included papers will be undertaken and will include both the explanatory factors outlined in the conceptual framework and any other factors identified by included studies, as well as patient outcomes. This may include data on:

Patient factors: Age of the patient casemix, range of the patient casemix.

Organisation: volume of activity (institutional volume and staff volume), specialisation (adult/children/both), sub specialisation (nature and complexity of procedures), size of specialist unit (number of staff, number of beds etc.), proximity to/co-location with other specialist clinical services, hospital/surgeon/nursing workloads, the health system that organisations operate in, timing of procedures and hospital/surgeon/nursing training/experience.

Outcomes: mortality, life expectancy, morbidity, quality of life, complications of treatment; and possibly processes such as length of stay and unplanned readmission rates. Data on process outcomes will only be extracted from studies which report at least one patient outcome. We anticipate that outcomes will be reported using measures such as relative risks, odds ratios and mean differences. Where possible, given the time and resource limitations, these will be reported, alongside confidence intervals. We will also check which way around the data is reported in terms of a)the intervention and comparator (for example high versus low volume and vice versa) and b) the outcome (for example mortality or survival). Where possible, outcomes will be converted so that they are all in the same direction for both of the above factors.

Quality Assessment - Rather than using a standard checklist approach, instead, the focus will be on an assessment of the overall quality and relevance of the evidence included in the review. The assessment of relevance will be made based on a number of factors which may include the study type, the country in which the research was undertaken, whether the research is single centre or multi centre, whether it included more than one procedure/intervention. The assessment of quality will be based on study type and other key factors. This process of quality and relevance assessment will allow readers of the rapid evidence synthesis to make an assessment of the hierarchy of relevance and quality of evidence included in the review.

Timelines:

Draft Proposal – 15 January 2014

Final Proposal – 24 January 2014

First draft report – 1 April 2014

Review Team:

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Appendix 1a Conceptual framework

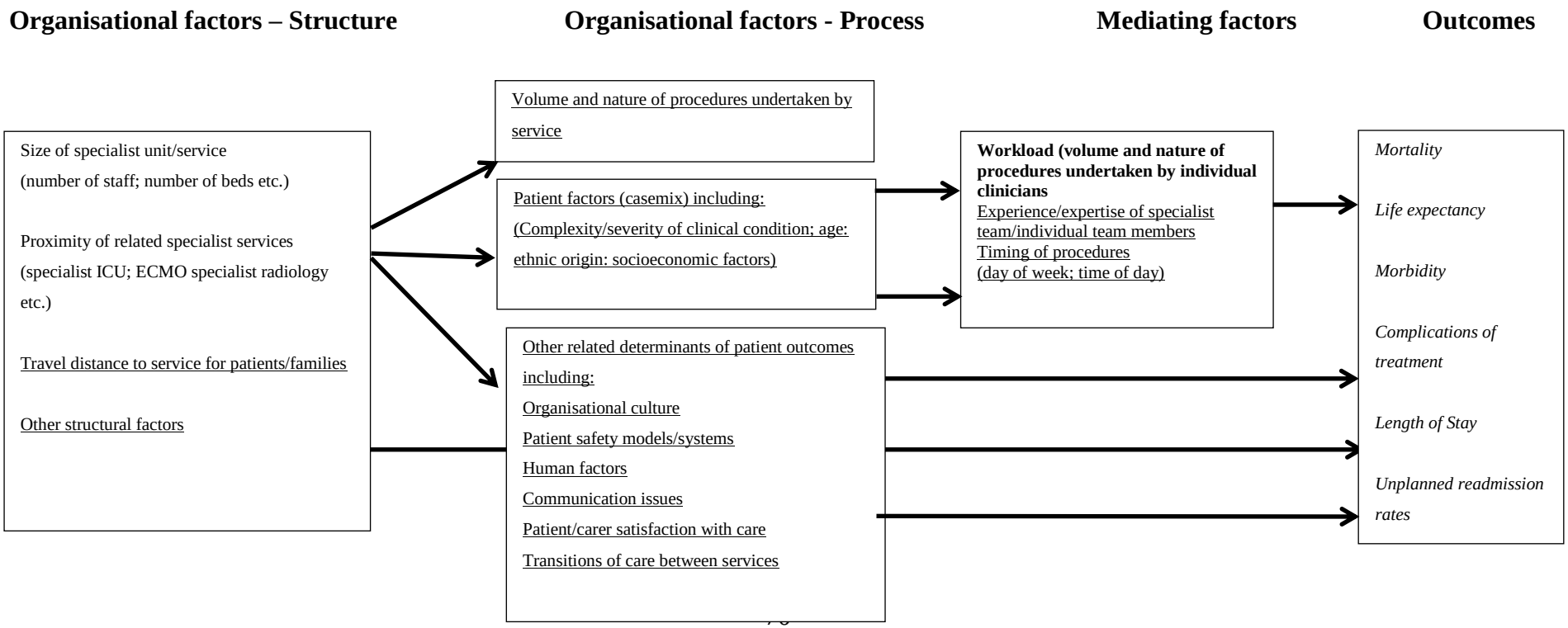
The proposed scope for a literature review on the organisational factors which may influence patient outcomes in surgical and interventional cardiology services for CHD in children and adults

Bold = Explanatory factors reported in included studies.

Underlined = Explanatory factors which may be reported in included studies. These factors may require evidence from beyond CHD.

Italics = Outcomes which may be reported in included studies.

(All relevant explanatory and outcome data will be extracted and reported as relevant – the model illustrates the potential breadth of included evidence)



Appendix 1b Proposed Search Strategy (based on Ewart 2009)

1. exp Child/ or exp Infant/ or exp Infant, Newborn/
2. (infan* or newborn* or neonat*).tw.
3. (child* or pediatric* or paediatric*).tw.
4. 1 or 2 or 3
5. thoracic surgery/
6. exp Cardiac Surgical Procedures/ or exp Cardiac Care Facilities/
7. ((heart or cardiac or cardiol* or thoracic or cardiothoracic) adj5 (surge* or procedure* or intervent* or defect*)).tw.
8. 5 or 6 or 7
9. 4 and 8
10. exp Heart Defects, Congenital/su, th [Surgery, Therapy]
11. Heart Diseases/cn [Congenital]
12. (congenital adj (heart or cardiac)).tw.
13. 9 or 10 or 11 or 12
14. workload/
15. Physician's Practice Patterns/
16. "Personnel Staffing and Scheduling"/
17. (caseload* or case load* or workload* or work load*).tw.
18. volume*.tw.
19. activit*.tw.
20. 14 or 15 or 16 or 17 or 18 or 19
21. ((proximity or close* or locat* or near or adult or pediatric or paediatric or child*) adj3 (facilit* or site or hospital* or service* or specialis* or specializ*)).tw.
22. (rationali* or streamlin* or centralis* or centraliz* or co-location or co-locate or (single adj site)).tw.
23. 21 or 22
24. exp Mortality/
25 Survival/
26 exp "Outcome Assessment (Health Care)"/ or exp Treatment Outcome/
27. (mortality or death or survival or outcome* or complication*).tw.

28. 24 or 25 or 26 or 27
29. 13 and (20 or 23) and 28
30. limit 29 to yr="2009 - 2014"

Appendix 1c: References

Ewart, H (2009) The Relation Between Volume and Outcome in Paediatric Cardiac Surgery. A Literature Review for the National Specialised Commissioning Group. Available from http://www.specialisedservices.nhs.uk/library/30/The_Relation_Between_Volume_and_Outcome_in_Paediatric_Cardiac_Surgery__A_Literature_Review_for_the_National_Specialised_Commissioning_Group_Henrietta_Ewart_Consultant_in_Public_Health_Medicine_PHRU_Oxford__September_2009.pdf

IRP (2013) Advice on Safe and Sustainable Proposals for Children's Congenital Heart Services. Available from http://www.hsj.co.uk/Journals/2013/06/12/g/h/f/IRP-Report.pdf.

NHS Specialised services (2012). Review of children's congenital cardiac services in England: July 2012. Available from (http://www.specialisedservices.nhs.uk/library/30/Safe_and_Sustainable_Review_of_Childrens_Congenital_Cardiac_Services_in_England_Decision_Making_Business_Case.pdf

Appendix Two - Literature Search

Appendix 2a Stage One – Database Search Strategy

MEDLINE via OVID SP (29th January 2014)

1. exp Child/ or exp Infant/ or exp Infant, Newborn/
2. (infan* or newborn* or neonat*).tw.
3. (child* or pediatric* or paediatric*).tw.
4. 1 or 2 or 3
5. thoracic surgery/
6. exp Cardiac Surgical Procedures/ or exp Cardiac Care Facilities/
7. ((heart or cardiac or cardiol* or thoracic or cardiothoracic) adj5 (surge* or procedure* or intervent* or defect*)).tw.
8. 5 or 6 or 7
9. 4 and 8
10. exp Heart Defects, Congenital/su, th [Surgery, Therapy]
11. Heart Diseases/cn [Congenital]
12. (congenital adj (heart or cardiac)).tw.
13. 9 or 10 or 11 or 12
14. workload/
15. Physician's Practice Patterns/
16. "Personnel Staffing and Scheduling"/
17. (caseload* or case load* or workload* or work load*).tw.
18. volume*.tw.
19. activit*.tw.
20. 14 or 15 or 16 or 17 or 18 or 19
21. ((proximity or close* or locat* or near or adult or pediatric or paediatric or child*) adj3 (facilit* or site or hospital* or service* or specialis* or specializ*)).tw.
22. (rationali* or streamlin* or centralis* or centraliz* or co-location or co-locate or (single adj site)).tw.
23. (Distance* or travel* or transport or regionali*).tw.
24. 21 or 22 or 23
25. exp Mortality/

26. Survival/

27. exp "Outcome Assessment (Health Care)"/ or exp Treatment Outcome/

28. (mortality or death or survival or outcome* or complication*).tw.

29. 25 or 26 or 27 or 28

30. 13 and (20 or 24) and 29

31. limit 30 to yr="2009 - 2014"

32. Limit to Humans and language=English

Cochrane Library via Wiley Interscience (29th January 2014)

#1 MeSH descriptor: [Child] explode all trees

#2 MeSH descriptor: [Infant] explode all trees

#3 infan* or newborn* or neonat*:ti,ab,kw (Word variations have been searched)

#4 child* or pediatric* or paediatric:ti,ab,kw (Word variations have been searched)

#5 #1 or #2 or #3 or #4

#6 MeSH descriptor: [Thoracic Surgery] explode all trees

#7 MeSH descriptor: [Cardiac Surgical Procedures] explode all trees

#8 MeSH descriptor: [Cardiac Care Facilities] explode all trees

#9 ((heart or cardiac or cardiol* or thoracic or cardiothoracic) near/5 (surge* or procedure* or intervent* or defect*)):ti,ab,kw (Word variations have been searched)

#10 #6 or #7 or #8 or #9

#11 #5 and #10

#12 MeSH descriptor: [Heart Defects, Congenital] explode all trees

#13 congenital near (heart or cardiac):ti,ab,kw (Word variations have been searched)

#14 #12 or #13

#15 #11 or #14

#16 MeSH descriptor: [Workload] explode all trees

#17 MeSH descriptor: [Physician Practice Patterns] explode all trees

#18 MeSH descriptor: [Personnel Staffing and Scheduling] explode all trees

#19 case load or caseload or work load or workload:ti,ab,kw (Word variations have been searched)

#20 volume or activity:ti,ab,kw (Word variations have been searched)

#21 #16 or #17 or #18 or #19 or #20

#22 ((proximity or close* or locat* or "near" or adult or pediatric or paediatric or child*) near/3 (facilit* or site or hospital* or service* or speciali*)):ti,ab,kw

#23 (rationali* or streamlin* or centrali* or co-location or co-locate or colocation or colocate or (single near/2 site) or distance* or travel* or transport or regionali*):ti,ab,kw

#24 #22 or #23

#25 MeSH descriptor: [Mortality] explode all trees

#26 MeSH descriptor: [Survival] explode all trees

#27 MeSH descriptor: [Outcome Assessment (Health Care)] explode all trees

#28 MeSH descriptor: [Treatment Outcome] explode all trees

#29 (mortality or death or survival or outcome* or complication*):ti,ab,kw

#30 #25 or #26 or #27 or #28 or #29

#31 #21 or #24

#32 #15 and #31 and #30 from 2009 to 2014

CINAHL via EBSCO

S25 (S22 AND S23 AND S24)

S24 (S14 OR S17)

S23 S9 OR S10

S22 S18 OR S19 OR S20 OR S21

S21 TX mortality or death or survival or outcome* or complication*

S20 MH outcome assessment

S19 MH survival

S18 MH mortality

S17 S15 OR S16

S16 TX (rationali* or streamlin* or centralis* or centraliz* or co-location or co-locate or (single site) or distance* or travel* or transport or regionali*)

S15 TX ((proximity or close* or locat* or near or adult or pediatric or paediatric or child*) N3 (facilit* or site or hospital* or service* or specialis* or specializ*))

S14 (S11 OR S12 OR S13)

S13 TX volume* or activit*

S12 TX caseload* or case load* or workload* or work load*

S11 MH workload

S10 TX congenital N1 (heart or cardiac)

S9 S5 AND S8

S8 S6 OR S7

S7 TX ((heart or cardiac or cardiol* or thoracic or cardiothoracic) N5 (surge* or procedure* or intervent* or defect*))

S6 MH thoracic surgery

S5 (S1 OR S2 OR S3 OR S4)

S4 TX child or pediatric or paediatric

S3 TX (infant* OR newborn or neonat*)

S2 MH infant

S1 MH child

Web of Science via Web of Knowledge

8 #6 AND #5 Refined by: PUBLICATION YEARS=(2013 OR 2010 OR 2012 OR 2009 OR 2011)

7 #6 AND #5

6 TITLE: ((caseload* or case load* or workload* or work load* or volume or activity or ((proximity or close* or locat* or adult or pediatric or paediatric or child*) near (facilit* or site or hospital* or service* or specialis* or specializ*)) or (rationali* or streamlin* or centralis* or centraliz* or co-location or co-locate or (single site) or distance* or travel* or transport or regionali*)))

5 #4 OR #3

4 #2 AND #1

3 TITLE: ((congenital NEAR (heart or cardiac)))

2 TITLE: (((heart or cardiac or cardiol* or thoracic or cardiothoracic) NEAR (surge* or procedure* or intervent* or defect*)))

1 TI=(infan* or newborn* or neonat* or child* or pediatric* or paediatric*)

Appendix 2b Stage Two – Citation Searching

Citation searches were conducted on Google Scholar (14th February 2014) for any references citing any of the following eight studies included in the Ewart review:

Bazzani and Marcin [8]

Chang et al [7]

Checchia et al [15]

Hirsch et al [23]

Tsang et al [54]

Welke et al [44]

Welke et al [6]

Welke et al [43]

184 individual citations (from an initial combined set of 366) remained following de-duplication and removal of non-English references

Appendix 2c Stage Three - Evidence suggested by stakeholders and reasons for inclusion/exclusion

Table 9 Evidence suggested by stakeholders and reasons for inclusion/exclusion

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
Jo Glenwright NHS England. 09/01/14	List of references from the Safe and Sustainable Review of Children's Congenital Cardiac Services. (Any references that are dated 2002 or earlier have not been included in this table for reasons of clarity).	Ewart (2009) [2]	LP	Exclude – Study Type - Review
		Caldarone and Al Radi (2008) [55]	LP	Exclude – Study Type – Discussion Paper
		Hilton et al (2005) [56]	LP	Exclude – Study Type – Discussion Paper
		Hirsch et al (2008) [23]	LP	Include (already identified by ScHARR)
		Hudsmith and Thorne (2007) [57]	LP	Exclude – Study Type - Review
		Lacour-Gayet et al (2004) [58]	LP	Exclude – Study Type – no data on outcomes
		Queensland Government (2006) [59]	LP/AB	Exclude – not peer reviewed. No original data on Volume-Mortality. Reports findings of earlier Mellis review and other international reviews e.g. Kennedy report. However these are pre 2003
		Reid et al (2004) [60]	LP	Exclude – Topic
		Welke et al (2007) [61]	LP	Exclude – Topic – no cardiac subgroup for

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
				CHD
		Welke et al (2008) [6]	LP	Include
Jo Glenwright NHS England 09/01/14	Additional References in Consultation Document	Commission for Paediatric Heart Interventions (2009) [62]	AB	Potentially relevant data on Volumes and Outcomes but has not been subject to peer review. Translation not freely available. Includes five relevant papers – two of which are full text exclude (Daenen et al, 2003, O'Brien et al 2007). One of which is an abstract exclude but use as source of evidence (Moons et al 2009). One of which is outside the date range of the review (Lundström N 2000) and one of which was already identified for inclusion (Welke et al 2009).
		Federal Ministry of Justice (2010) [63]	AB	Translation not freely available.
		Daenen et al (2003) [52]	AB	Provides suggested standards for number of procedures etc. Not evidence based standards but may be useful for discussion. No original data therefore exclude. Identifies a number of

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
				relevant references but all of these are outside the date range of the review.
		Analysis undertaken of the Hospital Episodes Statistics data by National Cancer Services Analysis Team, September 2010	LP	Exclude – not peer reviewed evidence
		The Royal College of Surgeons of England, Surgery for children: Delivering a first class service, London, July 2007	LP	Exclude – not peer reviewed evidence
		Ontario Ministry of Health and Long-Term Care (2002) [64]	AB	Considers volume data but no data on outcomes and has not been subject to peer review. Cites selected published evidence (but not within date range of the review).
		Welke et al (2009) [43]	LP	Include (already identified by ScHARR)

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
		Standard C9, National Specialised Commissioning Team, Safe and Sustainable: Children's Congenital Cardiac Services in England Service Standards, March 2010.	LP	Exclude – not peer reviewed evidence
John Wareing 04/03/2014		Giamberti et al (2009) [65]	AJ	Exclude – Data – Neither volume nor proximity appears to be variables under assessment in this study. It is an analysis of preoperative and operative factors and their relationship to outcome variables, one of which is mortality, in one institution. The preoperative factors are demographic and patient-level clinical factors. The conclusion in both the abstract and main paper that "Reoperations in ACHD... were associated with a low mortality rate if performed in a

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
				center with a considerable activity and a dedicated program" does not appear to relate to the results of the study.
		Kim et al (2011) [29]	LP	Include
John Wareing 03/03/2014	We note that the current list of references does not refer to pregnancy outcomes in women with congenital heart disease. Whilst there is limited literature on the subject the above reference contains specific a recommendation from the Cardiac disease chapter that ' Women with a known history of cardiac disease must be referred to consultant-led obstetric care in a maternity unit where there is a joint obstetric / cardiology clinic or a cardiologist with expertise in the care of	Centre for Maternal and Child Health (2011) [66]	LP	The chapter on Cardiac Disease was examined. There is no evidence in this chapter linking either volume or proximity to outcomes for pregnant women.

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
	women with heart disease.' The last sentence of this chapter examining maternal mortality is ' Some women with known heart disease before pregnancy are not offered or referred to appropriate multidisciplinary care in specialist units.' Heart disease has been the leading cause of maternal death in the last two triennial reports.			
Robert Craig 03/03/2014	Report commissioned by Royal Brompton & Harefield NHS Foundation Trust (RB&H) on the impact on RB&H of the proposed decommissioning of cardiac surgery under the 'Safe & Sustainable' Review (FH Partnership, January 2013). The report is marked 'strictly	Pasquali et al (2012) [34]	LP	Include (already identified by ScHARR)
		Welke et al (2012) [48]	LP	Include (conference abstract already identified by ScHARR)

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
	confidential' but was released to the IRP in January 2013. Pages 39-42 discuss the relationship between surgical volumes and outcomes.			
	Letter from Prof Pascal Vouhe (Paris) – undated, but received late 2012 – citing the 2003 EACTS paper on the 'Optimal structure of a congenital heart surgery department', which falls within the wider time horizon (2003-2014) identified in the ScHARR proposal.	Daenen (2003) [52]	LP	Exclude – paper about standards. Not evidence based.
Pedro Del Nido 21/02/2014		Hickey and Gavreau (2013) [67]	LP and project team	Exclude – topic – organisational factor under consideration is critical care nursing (i.e. clinical experience). There are no variables relating to either volume or proximity. Whilst skill mix of staff is a variable for data

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
				extraction, this would only be extracted when there is evidence about volume or proximity as the main organisational variable.
		Hickey et al (2011) [68]	LP and project team	Exclude – topic – organisational factor under consideration is staffing numbers and staffing ratios. There are no variables relating to either volume or proximity. Whilst skill mix of staff is a variable for data extraction, this would only be extracted when there is evidence about volume or proximity as the main organisational variable.
David Barron 14/02/2014		"Publications on the experience with reconfiguration in Sweden and Netherlands that would be important to trace"	LP	The literature search did not identify any publications from either of these countries that were peer reviewed evidence that included evidence on the relationship between either volume or proximity and outcomes.
		Karamlou et al (2014) [45]	LP	Include as conference abstract
		Pasquali et al (2012) [35]	LP	Include (already identified by ScHARR)

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
		Welke et al (2009) [43]	LP	Include (already identified by ScHARR)
		Oster et al (2011) [33]	LP	Include (already identified by ScHARR)
		Chang and Klitzner (2002) [69]	LP	Exclude – date
		Jenkins et al (1995) [70]	LP	Exclude – date
		Pasquali et al (2012) [34]	LP	Include (already identified by ScHARR)
		Tabbutt et al (2012) [40]	LP	Include (already identified by ScHARR)
		Hornik et al (2012) [24]	LP	Include (already identified by ScHARR)
		Karamlou et al (2013) [25]	LP	Include (already identified by ScHARR)
		Hughes et al (2013) [71]	EG	Exclude – population – not congenital heart disease
		Arnaoutakis et al (2012) [10]	LP	Include (already identified by ScHARR)
		Karamlou et al (2008) [26]	LP	Include (already identified by ScHARR)
		Lange et al (2013) [72]	EG	Exclude – no outcomes data reported in the paper
David Barron 27/02/14	Email in response to list of 22 references circulated via NHS England new CHD Review Blog	Welke et al (2009) [43]	LP	Include (already identified by ScHARR)
		Karamlou et al (2008) [26]	LP	
		Lange et al (2013) [72]	LP	Exclude – no outcomes data reported in the

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
	post of 24/02/14. References were 2009-2014 only.			paper
		Hughes et al (2013) [71]	EG	Exclude – population – not congenital heart disease
		Arnaoutakis et al (2012) [10]	LP	Include (already identified by ScHARR)
		Karamlou et al (2014) [45]	LP	Conference Abstract. Not identified by original search or in the list of references as abstract not obtained when the list was drawn up. Upon scrutiny of the reference, include in conference abstract table.
Bob Ward 13/02/2014	Included in letter supplied to ScHARR team, under paragraph 2	The German Heart Foundation (2011) [73]	AB	Exclude – relevant population but no data linking volume and outcome.
		Funkat et al (2012) [74]	AB	Table 3 reports Distribution of Units by number of procedures. However this is not linked to outcome anywhere within the report. Despite the high quality and completeness of the data, the report (published in a peer reviewed journal) is unable to address the volume/proximity-outcome question.

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
		Press statement 18.05.12 following inspection of RHSC Yorkhill by Sir Ian Kennedy's team.	LP	Exclude – not peer reviewed evidence
		Daenen et al (2003) [52]		Exclude – paper about standards. Not evidence based.
		Chang and Klitzner (2002) [69]	LP	Exclude – date
	Included in email	Pasquali et al (2012) [34]	LP	Include (already identified by ScHARR)
	"We recently came across some interesting data from 50 of the largest centres in USA - and have plotted the results in Excel. This shows scarcely any variation of volume and outcome"	http://health.usnews.com/best-hospitals/pediatric-rankings/cardiology-and-heart-surgery/data?sort_by=surgical_mortality (Accessed 15/02/2014)	LP	Exclude – this is not data from a peer reviewed source. The topic is relevant as it does link volume and outcome.
Bob Ward 06/03/2014	Link to two presentations given at the World Heart Congress, Cape Town,	Daenen et al (2003) [52]	LP	Exclude – paper about standards. Not evidence based.
		Dudley et al (2000) [75]	LP	Exclude – date

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
	2013(http://livestreamsa.co.za/wcpccs/presentations/?step=4&l_id=320&p_id=308&a_id=2090). Presentations include a number of references which were assessed for inclusion/exclusion	Halm et al (2002) [76]	LP	Exclude – date
		Hannan et al (1995) [77]	LP	Exclude – date
		Sowden et al (1995) [78]	LP	Exclude – date
		Ho (2000) [79]	LP	Exclude – date
		Sinzobahamvya et al (2010) [80]	LP	Exclude- Topic - relationship in question is costs for congenital heart surgery as related to the Aristotle Complexity Score.
		Pasquali et al (2012) [35]	LP	Include (already identified by ScHARR)
		Hornik et al (2012) [24]	LP	Include (already identified by ScHARR)
		Welke et al (2009) [43]	LP	Include (already identified by ScHARR)
		Welke et al (2012) [48]	LP	Include (already identified by ScHARR)
Ken Catchpole 10/02/2014	Extract from email "The hypothesis–suppo rted by the attached papers – is that performance in congenital heart surgery is defined by the interactions between people and systems"	Catchpole (2011) [81]	LP	Exclude – does not include evidence that links volume or proximity to outcomes.
		Catchpole et al (2007) [82]	LP	Exclude – does not include evidence that links volume or proximity to outcomes.
		Catchpole et al (2006) [83]	LP	Exclude – does not include evidence that links volume or proximity to outcomes.
		Catchpole et al (2007) [84]	LP	Exclude – does not include evidence that links volume or proximity to outcomes.

Source and Date	Type of evidence	Bibliographic Details	Reviewer ?	Outcome
		Wahr et al (2013) [85]	LP	Exclude – does not include evidence that links volume or proximity to outcomes.
		Carthey et al (2001) [86]	LP	Exclude – does not include evidence that links volume or proximity to outcomes.
		Catchpole et al (2005) [87]	LP	Exclude – does not include evidence that links volume or proximity to outcomes.

Appendix 2d Stage Four – References of reviews and other reports used as a source of evidence

Eggli et al (2010) [88]

Ewart (2009) [2]

Moons et al (2010) [89]

Queensland Government (2006) [59]

Tsang and Utley (2009) [54]

Appendix 2e List of full text excludes and reasons for exclusion

Table 10 List of full text excludes and reasons for exclusion

Ref ID	Bibliographic Information	Reviewer?	Reason
2771	Allen et al (2003) [90]	JT	Is about the efficacy of the referral process, rather than outcomes based on centre volume
2765	Ashburn et al (2003) [91]	FC	Comparison of institutions, insufficient data reported.
2168	Austin et al (2013) [92]	EG	Data on case-mix, single centre compared to database but no comparison of case mix or outcome data from any other centre (so zero mortality impossible to interpret - could have just been all very low risk -only say "20 different ops /"different complexity")
1411	Bennett (2010) [93]	Team	Paper looks at the influence of location of birth hospital on outcomes.
312	Boucek et al (2013) [94]	LP	Explanatory variables were the type of surgeon (no detail given on actual volume of procedures on children or adults) and the hospital (again no detail given on volume)
2612	Cabrera et al (2011) [95]	JT	ECMO and transportation.
2316	d'Udekem et al (2013) [96]	LP	Surgeon volume and center volume are not variables. Outcome measure is re-operation not mortality.
2584	Davies et al (2013) [97]	CO	No measure of volume or co-location of services – measure of regional factors.
1236	DeCampli (2011) [98]	LP	Data is via survey instrument therefore will not be sufficient to address the volume/proximity and outcome relationship.
2766	Dimick et al (2004) [99]	FC	The study reported mortality rates but no relationship with unit size was reported.
2772	Freeman et al (2014) [100]	CO	The population is a combination of 7 different diagnostic indications. While some of

Ref ID	Bibliographic Information	Reviewer?	Reason
			these 7 were CHD, the volume/mortality relationship was measured for the 7 indications as a whole.
1595	Giamberti et al (2009) [65]	AJ	Neither volume nor proximity appears to be variables under assessment in this study. It is an analysis of preoperative and operative factors and their relationship to outcome variables, one of which is mortality, in one institution. The preoperative factors are demographic and patient-level clinical factors. The conclusion in both the abstract and main paper that "Reoperations in ACHD… were associated with a low mortality rate if performed in a center with a considerable activity and a dedicated program" does not appear to relate to the results of the study.
626	Hannan (2011) [101]	LP	This is an article on the regulatory system. It is not an article that contains data on outcomes associated with explanatory variables – it just addresses how this data is collected.
2768	Jacobs et al (2012) [102]	CO	No analysis based on volume or proximity. Data analysis for benchmarking.
1463	Kang et al (2010) [103]	LP	Exclude as evidence is from an non OECD country
2770	Mahle et al (2008) [104]	JT	This is a descriptive paper – it reports volume but does not test the relationship between volume and outcome.
2	Mascio et al (2014) [105]	JT	Paper does not look at the relationship between volume and outcome, rather the relationship between volume and likelihood of using mechanical circulatory support.
2475	Morris et al (2014) [106]	Team	Paper looks at the influence of location of birth hospital on outcomes.
291	Nykanen et al (2013) [107]	EG	Conference Abstract .Methods paper with no data on volume or other organisational factors (states "risk and volume adjusted")
282	Raj et al (2011) [108]	EG	Conference Abstract .Not relevant – testing the hypothesis that CPR rates predict mortality
160	Rhee et al (2013) [109]	Team	Surgical experience cannot be used as a proxy for surgical volume.
158	Sinzobahamvya et al (2012) [110]	EG	Conference Abstract. Methods paper on impact of using "complexity score". Insufficient data on explanatory variables.

Appendix Three – Data Extraction

Appendix 3a List of criteria included on data extraction form

- Ref ID Study (Author, Year, Country)
- Aim of study
- Data source/type of data/study design
- Dates of study
- Sample size
- Population characteristics
- Unit characteristics
- Procedures included
- Definition of volume/proximity
- Type of risk adjustment (none, administrative data, clinical data, clinical data with robust prediction model)
- Covariates used
- Relation of volume/proximity to mortality
    - Crude
    - Adjusted (case mix +/- other)
    - Age-adjusted
    - Non-linear vs linear relationship
- Relation of other characteristics to mortality (covariates used)
- Other outcomes
- Comments
- Headline/key messages

Appendix 3b Study groupings

Table 11 Overview of study groupings

Group 1- Volume and mortality – All CHD conditions		**Group 2 - Volume and mortality – specific CHD conditions/ procedures**		**Group 3- Other – proximity, distance, non-mortality outcome.**
Arenz (2011) [9]	Welke et al (2009) [43]	Berry et al (2007) [12]		**Paediatric CHD, proximity**
Bazzani and Marcin (2007) [8]	Welke et al (2008) [6]	Berry et al (2006) [13]	**Adult cardiac volume**	Burstein et al (2011) [14]
Chang et al (2006) [7]	Welke et al (2006) [44]	Checcia et al (2005) [15]	Arnaoutakis et al (2012) [10]	Eldadah et al (2011) [19]
Dinh (2010) [18]		Davies et al (2011) [16]		Fixler (2012) [20]
Gray et al (2003) [21]	**Adult CHD, volume**	Dean (2013) [17;51]		Pinto et al (2012 [37]
Hickey et al (2010) [22]	Karamlou et al (2008) [26]	Hirsch et al (2008) [23]		
Kazui (2007) [28]	Kim et al (2011) [29]	Hornik et al (2012) [24]		**Other variables**
Oster et al (2011) [33]		Karamlou et al (2010) [27]		Benavidez et al (2007) [11]
Pasquali et al (2012b) [35]		McHugh et al (2010) [30]		Karamlou et al (2013) [25]
Sakata (2012) [38]		Morales et al (2010) [32]		Mery (2014) [31]
Seifert et al (2007) [39]		Pasquali et al (2012a) [34]		
Vinocur (2013) [41]		Petrucci et al (2011) [36]		
Welke et al (2010) [42]		Tabbutt et al (2012) [40]		

Appendix 3c Study Descriptive Tables

Table 12 Study Descriptive Tables – Group 1 - Volume and mortality – All CHD conditions

Author, Year, Country, Ref	**Study design**	**Population included**	**Data source and study dates**	**Sample size**
Arenz, 2011, Germany [9]	Longitudinal study	Paediatric patients undergoing any CHD surgery. Surgical closure of patent ductus arteriosus in premature new-borns and primary extracorporeal membrane oxygenation cannulation (ECMO) excluded.	International study developing a composite complexity score (Aristotle complexity score) and mortality data (2006-9)	1828 patients (single centre)
Bazzani and Marcin, 2007, USA [8]	Retrospective cohort (five separate analyses)	Paediatric cardiac surgery patients (<18 years) identified by diagnosis and procedure codes	California OSHPD Discharge database (1998-2003)	12,801 cases 4 analyses. 13,917 cases 1 analysis.
Chang, 2006, USA [7]	Retrospective cohort study	Infants and children undergoing Norwood operation, VSD closure, ASD closure	California OSHPD Discharge database (1989-1999)	25402 cardiac surgery cases from over 500 acute centres
Dinh & Maroulas, 2010 USA and	Retrospective cohort	Paediatric cardiac surgeries	PCCC Database (1985-2004)	Approximately 80,000 consecutive surgeries from 47

Author, Year, Country, Ref	Study design	Population included	Data source and study dates	Sample size
Canada [18]				small and medium size centres from different areas across the US and Canada
Gray, 2003, Sweden [21]	Cross sectional cohort	Primary or one -stage procedures, multi stage procedures and major procedures performed to correct earlier procedure failures or to treat major operative complications. Excluded heart transplants, group 1 procedures (closted heart procedures) and straightforward open heart procedures (e.g. open correction of primum and secundum atrial septal defects, simple ventricular septal defects).	Hospital medical records	284 admissions involving 261 patients from 4 centres
Hickey, 2010, USA [22]	Retrospective cohort (patient and staffing analysis)	Patients < 18 years, all hospital discharges indicating surgical repair of a congenital heart defect.	PHIS Database (2005-2006) for patient data.	19,736 congenital heart surgery cases from 38 paediatric centres

Author, Year, Country, Ref	Study design	Population included	Data source and study dates	Sample size
		Institutions < 25 cases in study period, heart transplants, premature infants or neonates with patent ductus arteriosus closure as only congenital heart surgery and cases that could not be assigned to a RACHS-1 risk category were excluded.	National Association of Children's Hospitals and Related Institution data (staffing data)	
Kazui, 2007, Japan [28]	Retrospective cohort	Open heart surgery in new-borns and infants	Survey data collected by Japanese Association for Thoracic Surgery (2000-2004)	11,197 open heart surgeries (N= 2611 in new-borns; N=8586 in infants)
Oster, 2011,USA [33]	Retrospective cohort	Children (0-18 years) undergoing surgery for CHD	Paediatric Health Information System (PHIS) database (2006- 2008)	49792 hospital encounters from 39 centres
Pasquali, 2012b,	Retrospective cohort	Children 0-18 undergoing cardio-	Society of Thoracic	35,7776 patients from 68

Author, Year, Country, Ref	Study design	Population included	Data source and study dates	Sample size
United States [35]		thoracic surgery	Surgeons Congenital Heart Disease (STS – CHD) database	centres
Sakata, 2012, Japan [111]	Retrospective cohort	New-borns and infants with CHD	Survey data collected by Japanese Association for Thoracic Surgery (2005-2009)	13,074 patients with CHD (2825 new-borns and 10,249 infants undergoing open heart surgery in 105 and 115 hospitals respectively)
Seifert, 2007, USA [39]	Retrospective cohort study	Ages 0-20 undergoing cardiac surgery (all procedures except closure of patent ductus arteriosis)	HCUP-KIDS (2000)	10282 patients
Vinocur, 2013, USA [41]	Retrospective cohort	All paediatric cardiac operations (except isolated ductal ligation in preterm infants weighting less than 2.5kg). Excluded centres outside North America, or centres	PCCC Database (1982 – 2007)	109475 operations for volume calculations and 85 023 admissions for detailed statistical analysis from 49 centres

Author, Year, Country, Ref	Study design	Population included	Data source and study dates	Sample size
		contributing incomplete data or performing fewer than 10 operations.		
Welke, 2006, USA [44]	Retrospective cohort	All paediatric cardiac surgical procedures that could be risk scored on RACHS-1	Study data collected from 29 Congenital Heart Surgeon's Society (CHSS) member institutions (2001-2004)	12,672 (out of 16,805 procedures = 76%) could be placed into RACHS-1 categories from 11 CHSS institutions
Welke, 2008, USA [6]	Retrospective cohort	Paediatric (<18y) cardiac operations identified by diagnosis and procedure codes	NIS database (1988 -2005)	55,164 operations from 307 hospitals
Welke, 2009, USA [43]	Retrospective cohort	Patients 18 years of age or less undergoing cardiac operation, which could be categorised by RACHS-1 or Aristotle risk categories. Patients weighing less than or equal to 2500g, undergoing patent ductus arteriosus ligation as primary	STS-CHD database (2002- 2006)	32,413 operations from 48 programs

Author, Year, Country, Ref	Study design	Population included	Data source and study dates	Sample size
		procedure or missing age and/or weight data were excluded.		
Welke, 2010, USA [42]	Retrospective cohort	Congenital cardiac surgical procedures performed on patients <18 years of age identified by ICD-9-CM diagnosis and procedure codes	Nationwide Inpatient Sample (NIS) Database (2000 to 2005)	21,709 operations from 161 hospitals

Table 13 Study Descriptive Tables – Group 1 - Volume and mortality – Adult CHD, volume

Author, Year, Country, Ref	Study design	Population included	Data source and study dates	Sample size
Karamlou, 2008, USA [26]	Retrospective observational study	Adults with CHD for open heart or thoracic aorta procedures	NIS (1988-2003)	30,250 operations
Kim, 2011, USA [29]	Retrospective cohort	Admissions ages 18-49 years with ICD-9-CM codes indicating at least one congenital heart surgery procedure. Excluded cardiac transplants, transcatheter interventions and pacemaker placements if it was the sole surgical procedure coded.	PHIS (2000-2008)	3061 from 42 centres

		Upper age limit was <50 years to minimize inclusion of acquired heart disease.		

Table 14 Study Descriptive Tables – Group 2 – Volume and mortality – specific conditions or procedures

Author, Year, Country, Ref	**Study design**	**Population included**	**Data source and study dates**	**Sample size**
Berry, 2006,USA [13]	Retrospective cohort study	Children with HLHS undergoing stage 1 palliation (mitral stenosis, aortic atresia/stenosis, or aortic hypoplasia systemic to pulmonary arterial shunt) Exclusions were right ventricle to pulmonary artery conduit (Sano modification, cardiac transplantation), Stage 2 surgical palliation or stage 3 surgical palliation	HCUP-KIDS Database (1997 and 2000)	754 in 1997 880 in 2000
Berry, USA, 2007 [12]	Retrospective cohort	Children 0-18 years having Ventricular Septal Defect (VSD) surgery with cardiopulmonary bypass	HCUP-KIDS database (2003)	2301 patients from general children's hospitals, children's hospitals within an adult teaching hospital or children's speciality hospitals

Author, Year, Country, Ref	Study design	Population included	Data source and study dates	Sample size
Checcia, 2005, USA [15]	Retrospective cohort	Principal diagnosis of HLHS and age on admission of 30 days or less undergoing Norwood Procedure	PHIS Database (1998-2001)	801 patients from 29 hospitals
Davies, 2011, USA [16]	Retrospective cohort	Paediatric heart transplants patients aged under 19 years	United Network for Organ Sharing (UNOS) Standard Transplant and Research Dataset (1992-2007)	4647 transplants from 136 centres
Dean, 2013, USA[17]	Retrospective cohort study	Patients with a diagnosis of HLHS undergoing three palliative procedures: stage 1 palliative (Norwood procedure with either Blalock-Taussig shunt or Sno modifications), stage 2 palliative procedure (Glenn procedure); stage 3 procedure (Fontan procedure)	University Health System Consortium (UHC) Database (1998-2007)	2761 patients
Hirsch, 2008, USA [23]	Cross-sectional analysis	Neonates undergoing either Norwood procedure for HLHS and ASO for d-	HCUP-KIDS database (2003)	547 patients with the diagnosis of d-TGA

Author, Year, Country, Ref	Study design	Population included	Data source and study dates	Sample size
		TGA		undergoing an ASO in 74 hospitals. 624 patients with the diagnosis of HLHS undergoing a Norwood procedure in 60 hospitals
Hornik, 2012, United States [24]	Retrospective cohort	Infants (median age 6 years) undergoing Norwood procedure	STS -CHD database (2000-2009)	2,555 patients, 53 centres and 111 surgeons
Karamlou, 2010,, Canada/USA [27]	Retrospective cohort	Four groups of neonates, either undergoing Norwood procedure or with one of three conditions: Transposition of Great Arteries (TGA); Interrupted Aortic Arch (IAA); Pulmonary Atresisia with Intact Ventricular Septum (PAIVS)	STS-CHD Database. Dates for each of four groups vary from 5 to 10 years' worth of data during years 1987-2000	Total 2421 (Norwood 710; TGA 829; IAA 474; PAIVS 408) from between 24 and 33 CHSS institutions
McHugh, 2010, USA [30]	Retrospective cohort	All paediatric hospital admissions with a diagnosis of HLHS. Included procedures were Stage 1-3 palliation	University Health System (UHC) Consortium	9187 hospital admissions (5416 patients) from 118 institutions; 1949 S1Ps were

Author, Year, Country, Ref	Study design	Population included	Data source and study dates	Sample size
		(S1P-S3P), Cardiac transplant, Biventricular repair, Coarctation of the aorta repair, Percutaneous valvuloplasty and Balloon atrial septostomy	Database (1998 to 2007)	performed at 48 institutions 1279 S2Ps were performed at 48 institutions 1084 S3Ps performed at 47 institutions
Morales, 2010, USA [32]	Retrospective cohort study	All patients aged 20 years or younger undergoing VAD discharged from hospital for cardiac conditions including cardiomyopathy (40%), CHD (21%), myocarditis (12%)	HCUP-KIDS Database (2006)	187 patients from 67 centres
Pasquali, 2012a, United States [34]	Retrospective cohort	Infants (median age 6 years) undergoing Norwood procedure regardless of underlying anatomy	STS -CHD database (2000-2009)	2,557 infants, 53 centres
Petrucci, 2011, United States [36]	Retrospective cohort	Neonates who received a modified Blalock-Taussig shunt with or without cardiopulmonary bypass, and with or without concomitant ligation of a patent ductus arteriosus; aged less than 30 days; Weight>1.5kg	STS -CHD database (2002-2009)	1273 operations from 70 hospitals

Author, Year, Country, Ref	Study design	Population included	Data source and study dates	Sample size
Tabbutt, 2012, USA [40]	Analysis of randomised controlled trial data	Children undergoing either Norwood procedure with right ventricular-pulmonary artery shunt (RVPAS) or modified Blalock-Taussig shunt (MBTS)	2005-8 (extracted from randomised controlled trial clinical and outcome data)	549 cases in 15 centres

Table 15 Study Descriptive Tables – Group 2 – Volume and mortality – specific conditions or procedures - Adult cardiac (not all CHD)

Author, Year, Country, Ref	Study design	Population included	Data source and study dates	Sample size
Arnaoutakis, 2012, USA [10]	Retrospective cohort	Adult (>18 years) orthotopic heart transplant (OHT) recipients	UNOS Standard Transplant and Research Dataset database (2000-2010)	18,226 OHT recipients at a total of 141 unique centres

Table 16 Study Descriptive Tables – Group 3 – Other – proximity, distance, non-mortality outcome - Paediatric CHD, proximity

Ref No.	Author, Year, Country	Study design	Population included	Data source (and study dates)	Sample size
1328	Burstein, 2011, USA	Retrospective cohort	Patients were 0-18 years. All CHD	Two data sources	20,922 patients from 47

Ref No.	Author, Year, Country	Study design	Population included	Data source (and study dates)	Sample size
	[14]	analysis of volume and proximity	related surgery except children weighing less than 2500g and undergoing patent ductus arteriosis ligation	1) STS-CHD database (patient data) 2) A survey of US ICU models in centres performing CHD surgery (Structural/service model data)	centres
1901	Eldadah, 2011, USA [19]	Before and after study (single centre) of proximity	All paediatric postop cardiac admissions to the general ICU and then to Cardiac ICU	Hospital records (September 2004 2008)	443 cases (199 with general ICU compared with 244 in the with Cardiac ICU)
2574	Fixler,2012, USA [20]	Retrospective cohort	Inclusion infants with estimated first-year mortality > 25%, having the diagnoses of HLHS, single ventricle, pulmonary valve atresia and intact ventricular septum (PAIVS),	Texas Birth Defects Registry (1996-2003)	1213 from multiple paediatric hospitals and birthing centres in Texas

Ref No.	Author, Year, Country	Study design	Population included	Data source (and study dates)	Sample size
			pulmonary valve atresia with ventricular septal defect, tricuspid atresia, interrupted aortic arch, Ebstein's malformation of the tricuspid valve, and truncus arteriosus, born in Texas. Exclusion: Infants with trisomy 13 and 18		
1202	Pinto, 2012, USA [37]	Cross-sectional cohort	Neonates < 30 days of age at the time of surgery undergoing congenital heart surgery. Patients who died before discharge from the surgical hospital or who had inoperable congenital heart disease and patients who underwent minor surgical procedures were excluded from the study.	Clinical data (2005 - 2006)	271 (status unknown for 15) from single large paediatric referral hospital

Table 17 Study Descriptive Tables – Group 3 – Other – proximity, distance, non-mortality outcome - Other variables

Ref No.	Author, Year, Country	Study design	Population included	Data source and study dates	Sample size
2471	Benavidez, 2007, USA [11]	Cross-sectional study	Congenital heart surgery admissions ages less than 18 years that could be assigned to a RACHS-1 risk category. Excluded transcatheter closure of atrial septal defects, ventricular septal defects, patent ductus arteriosus (PDA), and balloon atrial septectomy, vessel repair, or occlusion.	HCUP-KIDS Database (2000)	10,032 congenital heart surgical admissions from 100 centres
1006	Karamlou, 2013, United States [25]	Retrospective cohort	Paediatric patients (<20 years) undergoing ECMO of cardiac indication which could be scored on Risk Adjusted Classification on Congenital Heart Surgery (RACHS-1) risk categories.	HCUP-KIDS database (2000-2009)	4954 (86%) cardiac cases mapped to RACHS-1 categories.
3	Mery, 2014, USA [31]	Retrospective cohort study	All patients younger than 18 years who underwent congenital heart surgery	PHIS (2004-2011)	77,7777 patients included from 43 tertiary care paediatric hospitals

Appendix 3d Data Tables

Table 18 Data Tables – Group 1 - Volume and mortality – All CHD conditions

Author Date Country Ref.	**Main question/objective**	**Definition of volume/proximity**	**Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality**	**Key findings and messages**
Arenz (2011) Germany [9]	To measure if surgical performance changes over time in relation to complexity and case volume	None	**Volume/mortality** Relationship tested is for performance/ volume. Mortality is a characteristic of the performance score. Over 4 years basic and comprehensive unit performance increased from baseline 100% to 124.9% and 132.9% respectively. Volume increased from 407 to 487pa. Crude mean survival 97.5%. **Other variables associated with mortality:** Exponential relationship between comprehensive complexity score and	Paper does not correlate volume/outcome. It does show that as volume increases, so does complexity of cases but performance can be maintained and improved. Very complex cases are rare (1%)

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			early mortality (high complexity = high mortality)	
Bazzani and Marcin USA (2007) [8]	Replicated 4 previous studies and developed own model based on previous studies.	Volume treated as a continuous variable and then model re-run with annual volume dichotomised to 75 paediatric congenital open heart surgeries/ year. (California guidelines on minimum vol/ yr).	**Volume/mortality** **Unadjusted**: nonsignificant link for volume/mortality (OR, 1.00; 95% CI, 0.94 to 1.07). **Adjusted** Significant relationship for volume/mortality (OR = 0.86 per 100 patient increase in annual volume (95%CI 0.81-0.92). Equates to one fewer death per 200 operations performed). Removal of largest hospital reduced OR to 0.93:95%CI 0.82-1.05). Other 4 replicated	1. 100-patient increase in annual volume associated with 13.9% decrease in odds of mortality. 2. Weaker/less consistent volume-mortality relationship than reported previously 3. Association dependent on highly leveraged covariate patterns found in largest-volume hospital 4. Limitations of subanalysis in infants: exclusions used in analyses (i.e, patients with very low birth weight and patients

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
		Excluded hospitals<20 cases/yr	analyses found inconsistent relationship for volume/mortality. Significant relationship for volume/mortality only in children <30 days 0.97 (95%CI 0.95-0.97). Volume/mortality by surgical complexity only significant for level 4 complexity group. (OR=0.95). **Other variables associated with mortality:** Not reported **Other Outcomes:** Not reported	aged <3 months receiving certain surgical procedures) limit generalizability of findings to infant population as a whole. 5. Low-volume hospitals may already avoid specific surgeries they are ill-equipped to perform
Chang (2006) USA [7]	To characterize the epidemiology of post discharge death among infants and children undergoing cardiac surgery and to identify	Hospital average annual case volume used to define the hospitals as low volume (≤100 cases per year) and	**Volume/mortality** **Unadjusted:** Higher volume hospitals had higher rates of post-discharge mortality vs low-volume (0.64 versus 0.54). **Adjusted:** lower volume hospitals had	Findings suggest that predictors of mortality post-discharge may be different from risk factors for in-hospital mortality. In this population, lower hospital

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
	risk factors for early and late post discharge death.	high volume (>100 cases per year)	higher rates of combined in-hospital and post-discharge mortality (OR 1.23, p<0.01). No differences in post-discharge mortality. **Other variables associated with mortality:** Sex, race/ethnicity, home income, and hospital case volume were not significant predictors of post-discharge deaths. Risk factors for post-discharge death were young age and the type of surgery performed. Neonates and infants who undergo Norwood procedure, aortopulmonary shunt, total anomalous pulmonary vein repair (TAPVR), and truncus arteriosus	volume was associated higher overall mortality but did not show an effect on post-discharge mortality

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			repair are at high risk for postdischarge death	
Dinh 2010 USA and Canada [18]	To determine if hospital surgical volume is related to better patient outcomes in terms of in- hospital mortality, and whether there are differences for both high and low complexity pediatric cardiac procedures. To determine evidence for a hospital surgical volume threshold	Volume = continuous variable	**Volume/mortality** For 1985-1989 (p=0.005) and 1990-1994 (p = 0.0156), there is a **linear** decreasing dependency between the mortality risk and the volume. For the two consecutive periods, 1995-1999 (p=0.0426) and 2000-2004 (p=0.045), the decreasing dependency changes to a **power law.** The closer to the present year, the lower the mortality risk becomes. Threshold volume: after 1,000-1,200 surgeries for the period 1995-1999 and after 850 to 1,000 surgeries for the period 2000- 2004,	1. Identifies inverse relationship between in-hospital mortality and paediatric cardiac surgical volume in small and medium-sized centres. 2. Similar inverse relationship was found for both low and high complexity cases after stratifying the data by risk category using the Risk Adjustment for Congenital Heart Surgery (RACHS). 3. Given relationship, a threshold on volume to reach the lowest attainment of surgical mortality is suggested when is attainable.

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			the decreasing rate does not change drastically.	
Gray (2003) Sweden [21]	To conduct institutional comparison of risk adjusted 30 day post operative mortality.	Total number of admissions in 1992. Largest hospital used as a referent in analyses.	**Volume/mortality** **Unadjusted** ORs for three centres were 0.44, 0.27 and 0.39 (p=0.1130) **Adjusted** (for risk): ORs = 0.24, 0.12 and 0.32 (p=0.0001) Centres B and C had lowest risk adjusted mortality. Relationship for Group II and III admission volumes in individual centres/survival not linear.	Higher institutional volumes of complex procedures not consistently associated with increased survival. Adjusting for preoperative risk significantly altered institutional mortality ORs. Risk adjusted analysis addressed concerns that hospitals might be 'penalized' for treating patients with more complex disease.

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			Other variables associated with mortality: Not reported **Volume/other outcomes:** Not reported	
Hickey 2010 USA [22]	To examine the relationship of nurse staffing, skill mix, and Magnet* recognition to institutional volume and mortality for congenital heart surgery in children's hospitals. **Nationally recognized characteristic of excellent quality in*	Institution cardiac surgery volume = annual number of CHD procedures at each paediatric hospital over 2 years (2005-2006).	**Volume/mortality** **Adjusted:** Risk using RACHS-1, higher annual volume was associated with lower mortality; ORs corresponding to each increase of 100 cases = 0.93 (95% CI 0.90-0.96; P < 0.001) **Volume/other outcomes** No relationship between nursing skill mix and hospital volume, however,	After risk adjustment using RACHS-1 method, higher annual cardiac surgery volume associated with lower mortality Nursing characteristics varied in ICUs in children's hospitals treating congenital heart surgery but were not associated with mortality. ICU nurse staffing levels [in children's hospitals in study] may be above

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
	nursing and healthcare institutions		higher ICU worked hours per day was significantly associated with higher unit volume (r_s = 0.39, P = 0.027) **Other variables associated with mortality** No association for any nursing characteristics/ mortality (both univariate analysis and after risk-adjustment)	threshold to find difference for outcome of mortality.
Kazui et al 2007, Japan [28]	To investigate the relationship between hospital volume and outcome for 10 cardiac, lung, and oesophageal surgical procedures. Open heart surgery in	Categorical Newborn group; 1-4,5-9,10-19,≥20 cases pa Infant group; 1-4, 5-19, 20-49, ≥50	**Volume/mortality** **Unadjusted:** 1) Newborns - Centres with fewer than five cases per year had a mortality of 19.3% compared to 9.7% in centres with ≥ 20 cases (OR 2.20,95%CI 0.95–5.09). 2) Infants - Centres with fewer than five cases per	An inverse correlation was noted between hospital volume and operative mortality, although wide variations in clinical outcome among the very low-volume hospitals. Further analysis is warranted using risk-adjusted data

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
	newborns and infants of relevance		year had a mortality of 7.7% compared to 1.3% in centres with ≥ 50 cases (OR 3.69 ,95%CI 20.2–6.73)	
Oster (2011) USA [33]	To assess the relationships of a hospital's past adjusted in-hospital mortality and surgical volume with future in-hospital mortality after surgery for congenital heart disease	Surgical volume and SMR (SMR=observed number of deaths/expected number of deaths adjusted for surgery type) calculated for Jan 2004 to June 2006 and July 2006 to Dec 2008 separately.	**Volume/mortality** **<u>Unadjusted:</u>** a)inverse relationship between prior surgical volume and subsequent SMR (p=0.0089) b) prior hospital surgical volume was of borderline significance, with an increase in surgical volume of 40 cases annually corresponding to decrease in RR of inpatient mortality of 2.0% **<u>Adjusted:</u>** a) Prior hospital surgical volume was	After adjusting for multiple factors including prior hospital surgical mortality, prior surgical volume tended toward significant for higher-risk operations for CHD but was not significant for lower risk operations for CHD. Prior in-hospital mortality was significantly associated with future in-hospital mortality after surgery for CHD across all risk strata, even after adjusting for multiple factors including prior hospital surgical volume.

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			not significant for lower risk categories (p=0.4122) but was of borderline significance of higher risk categories (p=0.0678) **Other variables associated with mortality:** a) positive relationship between SMR from 2004-06 and 2006-08 (p=0.0002); for every 0.1 unit decrease in prior hospital SMR, 3.4% decrease in RR of inpatient mortality (p<0.0001) b) Adjusted for risk, prior risk adjust hospital SMR was significantly associated with future mortality for	Prior hospital mortality may be an appropriate consideration in the referral process - target quality improvement efforts and not just expansion efforts.

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			both lower risk RACHS-1 categories (p=0.0105 and higher risk categories (p=0.0015)	
Pasquali et al 2012b, USA [35]	Measurement of relationship between 1) centre volume and mortality; 2) centre volume and post-	Categorical and continuous variables for volume (four categories	**Volume/mortality** 1) **<u>Unadjusted:</u>** lower centre volume associated with a) higher mortality b) higher mortality in patients with complications	Lower mortality in high volume centres in part due to lower mortality in patients with a post-operative complication. Quality improvement should be aimed at both reducing complications, but also

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
	operative complications and 3) centre volume and in patient mortality due to post-operative complications	<150,150-250, 250-350 and >350)	2**) Adjusted:** CONTINOUS volume; lower centre volume significantly associated with a) higher inpatient mortality (OR 1.10 ;95%CI 1.04-1.17;p=0.002) b) higher mortality following post-operative complications (OR 1.10 ;95%CI 1.01-1.20;p=0.03) 3) **Adjusted:** CATEGORICAL volume showed lowest centre volume (<150) significantly associated with a) higher inpatient mortality (OR 1.60 ;95%CI 1.23-2.08;p=0.0004) and b) higher mortality following post-operative complications (OR 1.59 ; 95%CI 1.16-2.18;p=0.004). Significant association between	recognition and management of complications that occur.

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			volume/ mortality and mortality in patients with a complication in high risk groups only (RACHS categories 4-5) for both continuous and categorical data. **Volume/other outcomes** Lower volume not significantly associated with rate of complications (OR 1.07 ;95%CI 0.90-1.25;p=0.45)	
Sakata et al 2012, Japan [38]	Measurement of relationship between hospital volume and cardiothoracic outcome (30 day mortality).	Case volume calculated as mean number of cases per year for 5 years	**Volume/mortality** 1) Unadjusted analysis - no association between hospital volume and mortality at 30 days in either new borns or infants 2) Categorical analysis (unadjusted) showed; a)for infants hospitals with very small average volumes (1-4 cases	Wide variation in 30 day mortality between low/high volume hospitals. Need to evaluate performance in low volume hospitals using risk adjustment

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			pa) had significantly higher odds of dying vs. those with 20+; OR 2.46 (1.45-4.17) b) for newborns average volumes <50 significantly higher odds of dying vs. 50+;OR 3.54 (1.53-6.85)	
Seifert, USA, (2007) [39]	To determine if gender is a determinant of in-hospital mortality after CHD surgery and identify other associated factors	Annual number of paediatric cases used to calculate quartiles. Lowest quartile was reference.	**Volume/mortality** **Unadjusted**: Overall mortality rate was 4.5%; for 2nd, 3rd, 4th quartiles mortality was 4.6, 4.8, 3.6% respectively (p=0.003 for highest) **Adjusted** mortality was lower in highest volume quartile (OR 0.5 95%CI 0.35-0.71 p<0.001) as well as in middle quartile (OR 0.68, 95% CI 0.46-1.00, p=0.049), compared to lowest volume quartile.	Although study aims were to determine the relationship with gender, findings suggest hospital volume is independent predictor of in-hospital mortality

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			Other variables associated with mortality: **<u>Adjusted:</u>** female gender, no. of days between admission & operation; African American race; young age (neonates & <1year), pulmonary hypertension, and the Norwood procedure all associated with increased mortality	

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
Vinocur (2013) USA [41]	To analyse relationship of surgical volume and other risk factors on post-operative mortality in all operations performed for paediatric congenital heart disease over five time periods between1992-2007	Surgical volume modelled as continuous and categorical (divided into approximate tertiles)	**Volume/mortality** **Adjusted**: Significant inverse correlation between continuous volume measure/mortality (OR 0.84 per additional 100 operations/year; 95% CI 0.78 to 0.90; p<0.0001). Correlation varied by risk categories (no effect in risk category 1). Volume reduced variability of centre effect on mortality by 20.2%, although centre specific variation remained significant (p<0.0001). **Other variables associated with mortality:** Risk category, age at operations and time period contributed more to prediction of death after paediatric	Over study period RACHS-1 score remained best predictor of postoperative mortality. Increased surgical volume significant positive impact on postoperative mortality. The effect was clinically relevant (relative odds reduction generally 10-30%) but modest compared with that of other variables. Volume mortality relationship varied significantly by risk category (no effect at lowest risk) Volume is a relatively weak predictor of a centres mortality rate and volume should not be used in insolation to

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			cardiac surgery than centre volume, the centre random effect, or patient sex (comparing relative contributions to logarithmic likelihood ratio Chi square of each variable). **Adjusted**: postoperative mortality decreased more than 10 fold over study period (analysing surgical year as a categorical variable, 1982 vs 2007: OR 12.27; 95% CI 8.52 to 17.66; p=0.0001).	predict quality at the level of individual institutions.

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
Welke 2006 USA [44]	To evaluate whether published and widely quoted mortality rates for pediatric cardiac surgery accurately reflect current expectations. Hypothesises that (1) mortality rates at high-quality pediatric cardiac programs are lower than published national results despite (2) change in case mix with shift away from low complexity operations. Hypothesizes that,	Hospital volume - average number of RACHS-1 categorized procedures performed per year over 4 years of study. i. Volume evaluated as continuous variable. ii. Hospital volume categorized into terciles by dividing	**Volume/mortality** Several approaches used to define hospital volume/mortality: 1. **Unadjusted** mortality rates across volume groups compared using the X2 statistic for linear trend. 2. Discrimination of volume alone as predictor of mortality assessed by c statistic. Overall in-hospital mortality for categorized operations was 2.9%. No significant association for hospital surgical volume/mortality. Hospital volume poor predictor of mortality [c statistic of 0.55 (remaining poor when volume was divided into terciles c= 0.55)]. Hospital volume did not contribute significantly to predictive	Mortality was most related to case mix - Mortality rates declined, despite an increase in case mix complexity. Lack of association for hospital surgical volume/mortality suggests that other factors determine outcomes at high-quality institutions.

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
	unlike RACHS-1 category, hospital volume is poor discriminator of mortality.	sample into three relatively equal size hospital cohorts: low (<200 a year), medium (200 to 300 a year), and high (>300 a year).	value of multivariate model containing RACHS-1 category and adjusted for clustering within center. Ability of hospital volume by RACHS-1 category to predict mortality for each category (e.g. ability of category 4 volume to predict category 4 mortality), also poor. **Other variables associated with mortality:** Significant decrease in % of category 1 operations. Significant increases in category 2, 4, & 6 operations. Significant decreases in category 2, 3, 4, & 6 mortality rates: Mortality rates for category 1 (median, 0.0; 0.0-3.1) and category 2 (median, 0.8; 0.0-1.9)	

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			were low. Five centers had no deaths in category 1, two centers had no deaths in category 2. Slightly more variability in category 3 mortality rates (median, 3.0; range, 1.0-3.9) with one center outperforming the group mean. Mortality rate strongly influenced by case mix. Category 4 (median, 5.6; range, 0.0-18.2) mortality rates differed more, but owing to wider CIs (secondary to lower nos. of operations) only one center performed better than group mean. Greatest variation was for category 6 mortality (median, 16.7; range, 1.2-48.8); one center outperformed and one center underperformed group mean. When	

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			ranked by mortality rates for each RACHS-1 category, no center consistently best/worst performer. RACHS-1 category good discriminator of mortality (c = 0.77). **Volume/other outcomes:** Not reported	
Welke (2008) USA [6]	To determine the relationship between hospital surgical volume and mortality after pediatric cardiac surgery.	Volume evaluated as continuous variable. Then, volume groups created using following criteria: (1) natural cut points in the data, (2) previously studied volume	**Volume/mortality** In-hospital mortality by discharge disposition; paediatric cardiac surgical mortality adjusted for surgical volume, RACHS-1 risk category, patient age and year of operation. Mortality modelled for 1) volume alone & 2) volume/RACHS-1/patient age. **Unadjusted** mortality: very small hospitals no different from very large	1. Volume alone poor predictor of mortality 2. Casemix/age-adjusted mortality rates significantly better for hospitals performing >200/y vs. all other smaller volume categories of hospitals. 3. Non-linear relationship for volume/ mortality 4. Volume thresholds somewhat arbitrary

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
		thresholds, and (3) maintenance of a sufficient number of hospitals in each volume group to minimize impact of any individual hospital. All volume thresholds from 1 to 300 cases per year were investigated.	hospitals (OR 1.0; 95%CI 0.7-1.4). **Adjusted** for volume/year of operation, no difference very large vs very small hospitals in mortality (OR, 0.99; p=0.94). Small/Medium hospital significantly higher mortality vs very large hospitals (OR=1.47; 95% CI 1.25-1.73 and 1.29; 95%CI 1.10-1.52). Predictive value of volume/ mortality low (c = 0.6). Adjusting for volume, RACHS-1 and age, adjusted mortality large hospitals performed significantly better vs very small volume hospitals (OR, 1.88, p<0.01). Small/Medium hospital significantly higher mortality vs. large hospitals (OR=1.85; 95%CI 1.56-2.20 and 1.48; 95%CI 1.24-1.77).	5. Individual hospitals <200 ops/y with low mortality rates and a broad range of mortality rates within volume groups. 6. Patient's own risk characteristics/ level of disease burden accounts for majority of mortality risk. Impact of hospital volume may be small – volume a likely surrogate for process measures/ characteristics of systems that lead to better outcomes.

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			Predictive value of model on mortality was higher (C statistic =0.81) **Other variables associated with mortality:** Not reported **Volume/other outcomes** Not reported	

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
Welke 2009 USA [43]	To determine the association between pediatric cardiac surgical volume and mortality using sophisticated case-mix adjustment and a national clinical database.	Volume: No. of admissions for which the index operation was cardiovascular. (Surgical volumes: total no. of cardiovascular operations) Categorical - small, <150; medium, 150–249; large, 250–349; and very large, ≥350 cases per year. Categories chosen to ensure adequate	**Volume/mortality** Unadjusted overall mortality rate was 3.7%. With volume as *categorical* variable, unadjusted mortality rates did not differ significantly/consistently by volume groups. When mortality risk modeled as a function of program volume categories volume alone was poor predictor of mortality (c= 0.53),. Adjusted: Inverse relationship for overall surgical volume as continuous variable/[in-hospital] mortality (P < 0.002). No of programs is small, 95% CIs not sufficiently narrow. Mortality for small programs vs. very large programs significantly higher (OR, 1.51; P 1⁄4 .0005). Adjustment for	1. Overall unadjusted volume was a poor discriminator of mortality. 2. After adjustment for patient risk factors /surgical case mix, larger programs achieved superior results for more complex operations. 3. Relationship for volume/mortality complex, making volume a difficult choice as quality measure for paediatric cardiac surgery.

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
		sample size. Volume/ mortality explored as categorical, single continuous linear variables and to explore nonlinear volume effects.	patient risk factors/surgical case mix improved model substantially (c = 0.84). Sensitivity analysis: No substantial difference after removal of largest/2 largest/lowest mortality programs. **Other variables associated with mortality:** For low-difficulty operations (i.e. Aristotle difficulty ≤3.0), volume groups performed similarly (P = 0.29). For high-difficulty operations (i.e. Aristotle difficulty >3.0), small programs had substantially higher adjusted mortality relative to very high-volume programs (OR, 2.41; P < .0001). For Norwood procedure, very	

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			high- volume programs outperformed all other volume groups. (small vol 36.5% [23/63] vs v large vol 16.9% [81/479], P<.0001). **Volume/other outcomes:** None	

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
Welke, 2010, USA [42]	To demonstrate that case volumes and mortality rates present in pediatric cardiac surgery are too low to allow the use of mortality to[statistically] differentiate between hospitals.	Hospital annual surgical volumes = no of operations performed in a year. Actual volumes compared to thresholds necessary to detect doubling and a 5% increase in mortality rate.	**Volume/mortality** [1 tailed test:] If all RACHS cases aggregated, 167 operations needed to detect a 5% difference from the national mean mortality rate 4.2% = 15% of hospitals ≥ threshold. A median volume hospital, 61 operations/ year, would have to have a mortality rate of 15% to be statistically different from the national mean mortality rate. Similarly, to detect doubling of mortality rate for all RACHS-1 patients, 220 patients required and only 7.9% (n = 20) of hospitals met minimum caseload. [Similar results for 2 tailed test] Min case volumes necessary to detect	1. No hospital had a sufficient annual case volume to determine a doubling of or 5% increase in mortality for any individual operation and a minority of hospitals (0% to 5.6%) had sufficient volume to detect these differences for RACHS-1 categories. Pediatric cardiac surgery operations are performed too infrequently or have mortality rates that are too low to allow mortality based hospital quality comparisons

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			a 5% point increase in mortality: 71 for RACHS-1 category 1 to 588 for RACHS-1 category 5. Minimum hospital case volumes needed to detect a doubling of mortality ranged from 11 for RACHS-1 category 5 to 2,935 for RACHS-1 category 1	

Table 19 Data Tables – Group 1 - Volume and mortality – Adult CHD, volume

Author Date Country Ref No.	**Main question/objective**	**Definition of volume/proximity**	**Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality**	**Key findings and messages**
Karamlou 2008, USA [26]	To assess whether outcomes for adult CHD surgery vary between paediatric and non-paediatric surgeons	Volume defined as percentage of paediatric operations performed annually by a surgeon (continuous variable)	**Volume/mortality** **Unadjusted:** Overall in-hospital mortality for adult CHD patients 4.7%. Mortality lower in adult CHD operated on by paediatric surgeons (1.9%) vs. non-paediatric (4.8%). **Adjusted** (casemix +/- other): Higher in-hospital mortality for adult CHD cases operated on by non-paediatric surgeons vs. paediatric (OR 4.5, 95% CI 2.1 to 9.5, p<0.0001). Lower in-hospital mortality for adult CHD cases operated on by surgeons with greater paediatric CHD experience (OR 0.92, CI 0.89 to 0.95) or greater paediatric plus adult CHD experience (OR 0.65, CI	Lower adjusted mortality for adult CHD cases operated on by surgeons with greater paediatric CHD experience.

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			0.43 to 0.99). **Volume/other outcomes** Low annual percentage of paediatric heart cases associated with longer LOS and higher costs. **Other variables associated with mortality** Female sex, type of cardiac abnormality, co-morbid congestive heart failure, cardiovascular disease, renal failure and diabetes associated with higher in-hospital mortality.	
Kim (2011) USA [29]	To assess relationship between adult CHD surgery	Annual adult CHD surgical volume - low (<10), medium	**Volume/mortality** **Adjusted** (for age, complexity & other): high adult CHD surgery volume in paediatric hospitals (≥20 cases annually)	Adult CHD surgery associated with lower risk of inpatient mortality in paediatric hospitals with higher adult CHD surgery volumes. No relationship

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
	mortality and a) adult CHD surgery volume and b) total (adult and paediatric) CHD surgery volume	(10-19) or high (≥20). Total (adult + paediatric) CHD surgery volume - low (<200), medium (200-399) or high (≥400).	associated with lower risk of inpatient mortality vs low adult CHD surgery volume (<10 cases annually); OR 0.4; 95% CI 0.2 to 0.7. No association for total (adult and paediatric) CHD surgery volume/ adult CHD mortality: high volume (≥400) vs low volume (<200): adjusted OR 1.6 (CI not reported). **Other variables associated with mortality** **Adjusted:** older adults, male sex, government-sponsored insurance and higher RACHS-1 risk category associated with higher mortality.	for total (adult and paediatric) CHD surgery volume and adult CHD mortality.

Table 22 Data Tables – Group 2 – Volume and mortality – specific conditions or procedures

Author Date Country Ref No.	**Main question/objective**	**Definition of volume/proximity**	**Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality**	**Key findings and messages**
Berry (2006) USA [13]	To evaluate mortality of HLHS in children undergoing stage I surgical palliation in teaching and nonteaching hospitals.	Four volume categories based on annual HLHS stage I palliation volume. Median institutional stage I volume did not vary by teaching status in 1997; in 2000, teaching hospitals had a higher median volume vs. nonteaching	**Volume/mortality** **Unadjusted:** Low-volume hospitals performing stage I palliation for HLHS were associated with increased in-hospital mortality in 1997 (Range: 49% low-volume to 25% high-volume; p=0.03) and 2000 (Range: 47% low-volume to 19% high-volume; p=0.01). **Adjusted:** Mortality higher for low-volume vs. high-volume (OR: 3.1; 95% CI: 1.1– 8.3) in 1997; adjusted analysis not undertaken for year 2000. **Other variables associated with mortality** In 1997 but not in 2000, in-hospital mortality remained higher in nonteaching	Hospitals performing a low volume of stage I palliation were associated with increased adjusted mortality in 1997 (not assessed for year 2000). In-hospital mortality for stage I palliation higher in nonteaching hospitals in 1997.

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
		hospitals.	hospitals after controlling for stage I palliation hospital volume and condition-severity diagnoses	
Berry, USA, 2007 [12]	To describe hospital volumes for common paediatric speciality operations and evaluate outcomes from hospital volumes	Volume - number of annual surgical cases per hospital for operation type. Caseload quartiles calculated for each procedure and hospitals in lowest quartile designated as low volume.	**Volume/mortality** i. Crude ii. Adjusted (casemix +/- other) (not sure which!) In hospital mortality for VSD 2% overall and for volume lowest 1.1%, 2nd quartile 2.1%, 3rd quartile 3.1% and highest 1.7% iii. Age-adjusted iv. Non-linear vs linear relationship **Volume/other outcomes:** Not reported **Other variables associated with mortality** Complications - 1.7% for VSD (Quartiles low to high 0; 1.4%; 2.2%; 1.8%	No relationship for volume/mortality for VSD

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
Checcia et al 2005, USA [15]	To quantify the relative effects of institution and surgeon experience on patient outcome	Institutional volume measured as continuous and categorical variables. Categorical measure of institutional volume (for 4yr total case volume). Three groups 1) Low <16, 2) Medium 16-30, 3) Higher >30. Surgeon volume measured continuously.	**Volume/mortality** **Unadjusted:** a) Categorical hospital volume no relationship with mortality; b) Continuous hospital volume showed significant trend for increasing institutional volume (p=0.02) with mortality 2) Unadjusted surgeon volume/mortality: no significant trend for increasing surgeon volume/mortality (p=0.13) **Adjusted** for predictor variables: Lower risk-unadjusted mortality after Norwood procedure associated with higher institutional volume (r2 =0.18, p= .02) but not for number of procedures done by a surgeon/mortality (P=0.312). Survival after Norwood procedure increased 4% (95% CI, 1%-7%) per 10 additional procedures	Greater association for risk-unadjusted survival and institutional surgical volume of Norwood procedures vs individual surgeon volume. Small number of cases seen by most surgeons may mean inadequate power to detect surgeon effect. Data suggest that regionalisation of individual, high-risk procedure might improve outcome.

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			performed over 4-year study period per institution. **Other variables associated with mortality:** Not reported **Volume/other outcomes** Neither institutional/surgeon volume associated with average LOS in survivors or time to mortality in non-survivors	

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
Davies (2011) USA [16]	To assess the volume of paediatric heart transplants performed at each centre in the US over 10 year period (1998-2007) and estimate the influence of centre volume on outcomes.	Transplants assigned to one of 3 categories determined by the 25th and 75th percentiles of volume (based on the number of paediatric heart procedures in the previous 5 years at transplant centre). Categories were: high volume (≥63 procedures in the preceding 5	**Volume/mortality** **Unadjusted:** Postoperative mortality higher in low vs. high volume group (11.5% vs. 8.7%; OR 1.36; 95% CI 1.04 to 1.79). At one year, mortality remained highest in low volume group vs. high volume group (18.1% versus 12.9% OR 1.48, 95% CI 1.18 to 1.86). Long term mortality also higher (p<0.001). **Adjusted** (multivariate logistic regression): ORs for postoperative mortality were 1.60 (95% CI, 1.13–2.24) for low-volume centres (<19 transplants over 5 years) and 1.24 (95% CI, 0.92–1.67) for medium-volume centres (19 to 62 transplants over 5 years), compared to high volume centres.	Adjusted analysis (multivariate logistic regression) showed volume remained a significant predictor of postoperative mortality. The volume of transplants performed at any one centre has a significant impact on outcomes. Regionalization of care is one option for improving outcomes in paediatric cardiac transplantation.

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
		years), medium volume (19 to 62 transplants) or low volume (<19 transplants).	**Volume/other outcomes:** Patients at low-volume vs. high-volume centres more likely to: a) require a pacemaker (3.0% vs 0.7%, OR 4.60; 95% CI, 2.00–10.59) b) require additional operative procedures (16.9% vs 12.8%, OR 1.39, 95% CI, 1.10–1.75). Patient in high volume group had shorter LOS (21.9 days) after transplants vs. low-volume group (25.6 days, P = 0.02) or medium volume group (26.3 days, P = 0.0017).	
Dean (2013)	To investigate the effect of race,	For each of three surgical	**Volume/mortality** **Unadjusted:** For S1P in-hospital mortality	Identified other risk factors which might influence in-hospital mortality – for one

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
USA [17]	ethnicity and gender on the in-hospital mortality for 3 palliative procedures commonly used in the management of HLHS Procedures: stage 1, stage 2 and stage 3 palliation (S1P, S2P and S3P)	procedures, five institutions that performed most procedures are "large-volume institutions". The remaining institutions are "small volume institutions".	rate significantly lower at large-volume institutions vs. small volume institutions (23.6 vs 34.3% p<0.0001). For S2P the in-hospital mortality rate was similar to that at the small volume institutions (5.5 and 5.3% p=0.84). For S3P institutional surgical volume did not influence mortality. **Adjusted:** for other variables, surgical volume remained a significant risk factor for in-hospital mortality for S1P only: large vs small volume: OR 0.57 (CI 0.45 to 0.71) but not for S2P or S3P. **Other variables associated with mortality:** For S1P, mortality rate was also significantly higher for patients admitted from home vs. those born at or transferred to	procedure admission from home was a risk factor; for two procedures ethnicity was a significant predictor of mortality

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			institution performing the procedure. Ethnicity also significant risk factor for S1P and S2P (higher mortality for black and 'other' for S1P and black and Hispanic for S2P) but not for S3P. Racial differences in mortality for S2P only observed in lower-volume hospitals.	
Hirsch 2008 USA [23]	To determine the effect of institutional volume on hospital mortality for the Norwood and arterial switch operations (ASO) as representative high-complexity	Institutional volume as a continuous variable but for descriptive purposes, specific point estimates are highlighted on the continuum of data points	**Volume/mortality** Significant inverse associations for institutional volume/in-hospital mortality for Norwood procedure ($p \leq 0.001$) and ASO ($p = 0.006$). In-hospital mortality decreased for ASO as institutional volume increased. Mortality rates of 9.4% for institutions performing two ASOs/year, 3.2% for 10 ASOs/year, and 0.8% for 20 ASOs/year. For ASO, decreased in-hospital mortality greater	Inverse relation for in-hospital mortality/ institutional volume for both the ASO and the Norwood procedures.

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
	neonatal cardiac procedures.		with incremental increases in institutional volume for low-volume (0–10 ASOs/year) institutions with smaller effect as institutional volume increases. In- hospital mortality rates for hypoplastic left heart syndrome were 34.8% for two Norwood procedures/year, 25.7% for 10 Norwood procedures/year, and 16.7% for 20 Norwood procedures/year. For Norwood procedure, strong trend for decreasing hospital mortality with increasing institutional volume. Continuous nonlinear inverse relation suggests decreasing in-hospital mortality with increasing institutional volume. **Other variables associated with mortality:** No confounding for gender/race in either	

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			logistic regression model. **Volume/other outcomes:** Not reported	
Hornik et al 2012, USA [24]	Relative impact of 1) Surgeon volume 2) Centre volume on inpatient mortality following Norwood procedure	Centre and surgeon volume calculated as categorical and continuous variables. Centre volume 0-10, 11-20, >20 annual Norwood procedures. Surgeon volume 0-5, 6-10 , >10 annual procedures.	**Volume/mortality** **Adjusted:** 1) Centre volume (continuous variable): lower centre volume associated with higher inpatient mortality (p=0.03) 2) Centres with lowest category volume significantly increased risk of inpatient mortality vs highest category (OR 1.56 (1.05-2.31); p=0.03. 3) Surgeon volume (continuous) associated with higher inpatient mortality (p=0.02). 4) Lowest surgeon volume category significantly higher mortality vs. highest (OR 1.6, 1.12-2.27;p=0.01). 5) Adjusting for individual surgeon & centre	Centre and surgical volume significantly associated with inpatient mortality and both need to be taken into account when considering policy. Further study of factors in addition to volume need to be undertaken i.e. training, availability of personnel, composition of care teams

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			volume reduced impact of each variable. 6) Surgical volume did not impact significantly on outcome across three volume categories	
Karamlou, Canada/USA, 2010 [27]	To identify impact of institution and surgeon factors on 5 year survival from complex CHD surgery	5 domains for centre volume-total case volume over study period; total number of years procedure done for; cases per year per institution; rank order of cases and case velocity over time. Surgeon volume calculated	**Volume/mortality** i. **Unadjusted:** not reported ii. **Adjusted** (casemix +/- other) Institution experience only associated with an improvement in outcome for TGA. <50 TGA cases per year associated with increasing mortality. Improvement associated with arterial vs atrial switch (for arterial switch inc case velocity over time decreased mortality parameter estimate -0.06 and inversely related to total procedure time estimate -	Institution and surgeon experience not only factors influencing outcome in complex CHD. Overall no clear relationship for volumes/outcome. Excellence in one area not translated to others. Experience should be composite measure not just volume. One institution with improved Norwood outcomes had neutralised effect of low birth weight suggesting institutional management protocols may play a part.

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
		for same 5 domains for Norwood and TGA only	0.24. iii. Age-adjusted not reported - neonates only iv. Non-linear vs linear relationship **Other variables associated with mortality:** Not reported **Volume/other outcomes:** Institutional performance - considerable variation. Institutional excellence in some groups not translated to equally superior performance for others. Surgeon factors - increasing surgeon experience associated with improved survival for TGA as rank order of cases increased indicating potential learning curve.	

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
McHugh (2010) USA [30]	To assess the impact of institutional volume and surgical era for patients undergoing surgery for HLHS over a 10 year period (1998-2007).	Hospitals categorized as small (<20), medium (20-64), or large (>64) on no. of procedures for HLHS performed during the 10-year study period. Categories determined independently for S1P, S2P, and S3P.	**Volume/mortality** **Unadjusted: S1P cases: A**verage mortality rate among 6 large volume institutions (>64 S1P) = 22% (14–33%), for institutions with medium (n=16) volume = 32% (14–55%). Average mortality for small volume (n=26) institutions = 51% (0–100%). **Adjusted** (multivariate analysis): Surgery performed at smaller volume institutions vs. large institutions (OR = 2.5 vs. 1.8 for small- vs. medium-sized institutions). **S2 and S3 palliation**. Compared with large volume centres, small (but not medium) institutional volume was a risk factor for mortality for S2P (OR 2.09, CI 1.06–4.11).	Inverse relationship for institution surgical volume/mortality for S1P of HLHS. Large volume centres generally had low mortality rates. However large range of mortality rates present for medium-sized centres, and some smaller centres achieved excellent results.

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			However, medium (but not small) volume was associated with higher mortality for S3P (OR 1.70, CI 1.13– 2.57). **Other variables associated with mortality:** Operative mortality by surgical era (1998–2002 versus 2003– 2007) Newborn admissions (age <30 days) reduced from 43% in 1998 to 18% in 2007. Multivariate analysis showed surgery had higher odds of mortality in the first 5-year period (OR = 1.6).	

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
Morales, 2010 USA [32]	To characterise the use of Ventricular Assist Device (VAD) in children in the USA	For VAD high volume characterised as 5 or more procedures per year.	**Volume/mortality** i. **Unadjusted** Survival 89% in high volume large teaching hospital (LTH) v 61% in other hospitals. Survival not affected by hospital type (adult, children etc) ii. **Adjusted** (casemix +/- other) mortality for high volume LTH OR 0.07 (CI 0.02-0.24) (protective against mortality) **Volume/other outcomes:** Costs higher and LOS longer in children's hospitals but age VAD placed was younger. **Other variables associated with mortality:** Use of ECMO or need for congenital heart surgery before VAD associated with greater mortality	Increasing use of VAD may be best served in terms of outcomes and resource use by being centralized to high volume teaching hospitals.

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			ECMO and Acute Renal Failure both predictive of mortality Transplant highly associated with survival.	
Pasquali 2012a USA [34]	1) Evaluating whether risk status of patients impacts on relationship between centre volume and outcome 2) Extent to which differences in centre volume	Annual Norwood volume (continuous variable), Also categorical outcome with three categories of volume 0-10 annual Norwood procedures (34	**Volume/mortality** 1) **Unadjusted** categorical volume/inpatient mortality was significantly associated (p=0.037). 2) 2) **Adjusted:** (patient characteristics) centre volume remained significantly associated with inpatient mortality (volume as continuous variable p=0.04; categorical measure of volume 0-10 cases significantly higher risk of	Centre volume modestly associated with inpatient mortality (regardless of risk status pre-op), centre volume accounts for only a small proportion of between centre variation (Centre-specific risk adjusted outcome may be more appropriate than centre volume as marker of quality)

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
	account for between centre variation in outcome	centres), 11-20 (13 centres) , >20 (6 centres)	mortality vs. highest category >20; (OR = 1.54;95%CI 1.02-2.32; p=0.04) 3) 3) **Adjusted:** Risk for pre-operative showed volume relationship with mortality equal across all risk groups 4) **Adjusted:** mortality for each centre and % centre variation in mortality explained by volume =14% (adjusting for centre volume significant variation between centre inpatient mortality remained (p=0.001)	
Petrucci 2011, USA [36]	To identify potential risk factors (including centre volume) for morbidity and mortality in	Continuous only	**Volume/mortality** Relationship of centre volume to discharge mortality: OR per 10-unit increase in average MBTS volume of 0.98 (95% CI, 0.85 to 1.13; p 0.78). **Other variables associated with mortality:**	Mortality rate after the neonatal modified Blalock-Taussig shunt remains high, particularly for infants weighing less than 3 kg and those with the diagnosis of PAIVS**.** Patient specific factors play a more important role than

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
	neonates undergoing modified Blalock-Taussig shunt		Pre-op ventilation support; Weight of less than 3kg; Pre-op diagnosis of PAIVS all associated with increased risk of death.	system factors in this population
Tabbutt, 2012, USA [40]	To identify risk factors for mortality and morbidity after performance of the Norwood procedure for ventricular reconstruction	Centre volume defined as patients with single RV screened per centre per year. Categorised as ≤15, 16-20, 21-30, >30. Surgeon volume defined as patients with single RV scheduled for	**Volume/mortality** Mortality not related to centre or surgeon volumes in univariate or multi variate analysis. **Volume/other outcomes** Lower centre volume associated with renal failure, sepsis, time to extubation and length of ventilation, LOS. Lower surgeon volume associated with renal failure, time to extubation and length of ventilation, **Other variables associated with mortality:**	While centre and surgeon volume was not associated with mortality in this population, a range of patient and procedure related variables were associated with mortality. Lower centre and surgeon volume were associated with some causes of post-operative morbidity and poorer clinical outcomes.

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
		Norwood procedure screened per surgeon per year. Categorised as ≤5, 6-10, 11-15, >15.	Independent risk factors for mortality were lower birth weight, genetic abnormality, longer duration of deep hypothermic circulatory arrest (DHCA), extracorporeal membrane oxygenation (ECMO), open sternum procedures.	

Table 23 Data Tables – Group 2 – Volume and mortality – specific conditions or procedures - Adult cardiac (not all CHD), volume

Arnaoutakis (2012) USA [10]	To develop a recipient risk index predicting short-term mortality OHT. To examine the relationship between	Annual centre volume categorised as low (7 OHT procedures), medium (8-15) or high (>15)	**Volume/mortality** For orthotopic heart transplant (only 3% CHD; mean age 52): **<u>Unadjusted:</u>** mortality at 30 days: 4.6% (high-volume), 5.6% (medium-volume), 9.3% (low-volume). At 1 year: 11.6% (high-volume), 13.5% (medium-volume), 18.1% (low-volume).	For orthotopic heart transplant (3% CHD; mean age 52), adjusted 30-day and 1-year mortality was higher for medium and low-volume vs.

	institutional volume and recipient risk on post-OHT mortality **Note:** only 3% CHD; mean age 52		**<u>Adjusted</u>** (risk, age, other factors), medium and low-volume centres associated with higher mortality vs. high-volume centres. For 30-day mortality: low vs high volume: OR 1.9 (CI 1.5 to 2.4); medium vs high volume: OR 1.3 (CI 1.1 to 1.5). For 1-year mortality: low vs high volume: OR 1.6 (CI 1.3 to 1.9); medium vs high volume: OR 1.2 (CI 1.1 to 1.3). Effect more pronounced for high-risk patients. **Volume/other outcomes:** Post-operative complications, unadjusted data: Rates of cardiac reoperation and post-operative stroke were similar irrespective of volume. New-onset dialysis and drug-treated rejection in first year after transplant more common at low- and medium-volume centres. **Other variables associated with mortality:** **<u>Adjusted:</u>** Higher risk category (complexity etc), older age, longer allograft ischemic time associated with higher 30-day and 1-year mortality.	high-volume centres. Effect was more pronounced for high-risk patients.

Table 22 Data Tables – Group 3 – Other – proximity, distance, non-mortality outcome - Paediatric CHD, proximity

Author Date Country Ref No.	**Main question/objective**	**Definition of volume/proximity**	**Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality**	**Key findings and messages**
Burstein, 2011, USA [14]	To identify if there are differences in post-operative outcomes in children cared for in dedicated children's ICU (CICU) versus other ICU	Proximity - CICU "a stand-alone unit dedicated to care of paediatric patients with congenital and acquired heart disease". Volume - median number of operations per year stratified as <150; 150-249; 250-349; =>350	**Proximity/ mortality** In hospital mortality. i. Crude mortality – overall 3.8% (CICU 3.6% v OICU 4.1% p=0.04) ii. Adjusted - No overall difference between CICU & OICU OR 0.88 (95% CI 0.65-1.19); for STS-EACTS 3 OR 0.47 (95% CI 0.25-0.86) in favour of CICU. **Volume/other outcomes:** Crude and adjusted analysis showed no difference in length of stay or post-op complications. **Other variables associated with mortality:** STS -EACTS 3; CICU 2.2% v OICU 4.9% OR 0.47(95%CI 0.25-0.86)	A dedicated CICU does not appear to have an impact on mortality, LOS or post op complications following surgery for CHD. Potential benefits for specific subgroups of patients. Likely a complex pattern of structure, training, surgeon performance and protocols contribute to outcome

Author Date Country Ref No.	**Main question/objective**	**Definition of volume/proximity**	**Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality**	**Key findings and messages**
Eldadah 2011 USA [19]	To determine whether the designation of a separate, dedicated cardiac ICU affected outcomes (morbidity and mortality) for postoperative cardiac care in children	Proximity - introduction of an on-site dedicated paediatric cardiac care unit, instead of just general PICU. Volume not a variable as unchanged over time.	**Proximity/ mortality** Mortality declined from 7 of 199 (3·5%) to 2 of 244 (0·8%). p < 0·05. **Volume/other outcomes:** Morbidity declined as evidenced by: a decrease in wound infection; need for chest re-exploration; fewer children required resuscitation after introduction of CICU.	1. The designation of a specific area for postoperative cardiac care was instrumental in the accelerated improvement in patient care and a decline in morbidity and mortality. 2. Our study represents the experience of 1 hospital and 1 programme which may mean that it is not possible to duplicate these results in another institution.

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
Fixler (2012) USA [20]	To determine the effect of home distance to a cardiac centre, or having a Latin American–born parent, on first-year mortality in infants with severe CHD	Distances stratified as: 50 miles, 50–100 miles and >100 miles	**Proximity/ mortality** **Unadjusted**: First-year mortality not significantly related to distance to centre, for all patients or specific racial or ethnic categories. 50-100 miles vs. <50 miles: HR 0.83(0.57 to 1.22); for >100 miles vs. <50 miles: HR 1.08 (0.86 to 1.36). **Other variables associated with mortality:** **Unadjusted:** Ethnicity: No significant differences in overall first-year survival according to race/ethnicity or for Latin American-born parents. Survival lower for Hispanic vs white infants in specific high-risk subgroups: hypoplastic left heart syndrome (HLHS; p<.05) or pulmonary valve atresia and intact ventricular septum (PAIVS; p=0.10); no differences for black vs white infants. **Adjusted** (for CHD defect type): infant birthweight, gestational age, presence of extracardiac birth defects, and	Neither home distance to a cardiac centre nor race, ethnicity or parental birth country were related to unadjusted first-year survival. Survival was lower in Texas counties bordering Mexico (which have high rates of poverty) and in Hispanic infants with hypoplastic left heart syndrome.

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			residence in a county bordering Mexico were associated with higher risk of first-year mortality. Cases without identifiable cardiac centre (often in counties bordering Mexico) had higher unadjusted mortality.	
Pinto (2012) USA [37]	In neonates undergoing congenital heart surgery, to determine association between patient travel time and post-discharge mortality and adverse events	Distance to surgical centre calculated as car travel time from patient's primary residence	**Proximity/ mortality** Overall post-discharge mortality 8% (16/202). Those living 90-300 min away had non-significantly higher mortality (14.5%) vs those <90 min away (6.2%) or >300 min away (2.9%); p=0.09; limited by small numbers. **Adjusted** (complexity): post-discharge mortality for those living 90-300 min away non-significantly higher vs those <90 min away (HR 2.1; 95% CI 0.7 to 5.7). **Proximity/other outcomes** After discharge: 45% (n=49) unplanned readmission; 40% (n=43) unplanned cardiac reintervention; 21% (n=23) both.	Patients living 90-300 mins from centre were less likely to have unplanned readmissions or reinterventions vs. those living <90 mins away, though the relationship was non-linear (no difference for those >300 mins away).

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
			Adjusted (complexity): those living 90-300 min away less likely to have unplanned readmissions or unplanned cardiac reinterventions after discharge vs. those <90 min away (HR 0.5; 95% CI 0.2 to 0.9). No difference for >300 min vs. <90 mins (HR 1.1, 95% CI 0.6 to 2.1). **Other variables associated with mortality:** Non-white race independent predictor of post-discharge mortality.	

Table 23 Data Tables – Group 3 – Other – proximity, distance, non-mortality outcome - Other variables

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
Benavidez et al 2007, USA [11]	To examine association of an occurrence of complication during congenital heart surgery **admissions** on risk of death.	Categorical <150,150-299,300-449, >450 (CHD surgery cases per year)	**Volume/mortality** **Adjusted:** Volume adjusted for RACHS-1 casemix and other variables showed volume category <150 had significantly higher odds of death; OR 3.2 (CI 1.9 to,5.5; p<0.001) vs. reference category of ≥450 cases. Intermediate volumes had higher mortality vs. high volume: 150-299 vs. ≥450 cases: OR 1.8 (CI 1.1 to 3.0), 300-449 vs. ≥450 cases: OR 2.2 (CI 1.0 to 4.8). **Other variables associated with mortality:** Following significantly associated with death (adjusted for casemix & other): Any complications; RACHS-1 category 2-6; Younger age; Prematurity; Female gender; Black race.	Hospitals with <150 CHD surgical cases per year had three-fold higher adjusted odds of death vs hospitals with ≥450 cases. Hospitals with intermediate volumes had higher mortality vs those with high volumes.
Karamlou et al 2013, USA [25]	To measure the association between centre volume of cases of extracorporeal	Annual ECMO volume calculated as continuous variable and 3 categories <15,	**Volume/mortality** 1) **Unadjusted:** volume /mortality showed significantly higher mortality in lowest volume category vs highest volume category (49% vs 43%; p<0.015). 2) **Adjusted:** centres within highest category of volume for	Higher annual ECMO volume associated with improved outcomes in paediatric cardiac cases

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
	membrane oxygenation support (ECMO) and survival in patients requiring ECMO	15 to 30 and >30 patients/year.	ECMO associated with a significantly reduced in-hospital mortality (OR=0.51;95%CI 0.30-0.87; P < .01). **Other variables associated with mortality:** Older age significantly associated with risk of mortality.	requiring ECMO. Regionalization of care in which majority of cardiac ECMO support is provided should be considered.
Mery (2014) USA [31]	To determine the incidence, risk factors, current treatment strategies and outcomes of children with chylothorax after heart surgery.	Median annual RACHS procedure volume was calculated for each hospital and hospitals divided into quartiles according to cumulative median volumes. A similar analysis	**Volume/mortality** Not reported **Volume/other outcomes** Hospitals in highest volume quartile had significantly lower incidence of chylothorax after adjustment for procedure complexity and other covariates (OR 0.49; 95% CI 0.42 to 0.58) vs lowest volume hospitals. Even though hospitals with higher volume tended to have lower incidence of chylothorax, some low volume hospitals had similar incidence of chylothorax to the high volume centres. No significant association found for surgeon annual median volume/incidence	Hospitals in the highest quartile for volume had half the incidence of chylothorax of those in the lowest quartile after adjustment for procedure complexity. Development of chylothorax

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
		was done for median surgeon volume.	of chylothorax. **Other variables associated with mortality:** **Adjusted:** (age, procedure complexity, neck or upper vein thrombosis, and hospital volume), significant association for development of chylothorax/ length of the hospital stay (P<.0001) and in-hospital mortality (OR, 2.13; 95% CI,1.75-2.61).	consistently associated with greater risk of in-hospital mortality, even after adjustment for hospital volume. Differences in specific complication rates may therefore mediate relationship for volume/mortality. Unclear whether relationship is related to better preoperative selection, differences in postoperative patient care and

Author Date Country Ref No.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
				feeding protocols, differences in reporting between centres, or differences in surgical technique. May suggest certain practices, not identified in this study, prevalent in high-volume centres and some lower volume centres, are responsible for lower incidence of chylothorax.

Appendix 3e Conference Abstract Descriptive Table

Table 24 Conference Abstracts Descriptive Table

Study (author, Year, Country)	**Population Included**	**Data source**	**Study Dates**	**Sample size**
Welke et al (2012) USA [48]	Congenital Cardiac Operations performed on patients less than 18 years	Society for Thoracic Surgeons Congenital Heart Surgery Database	2005-2010	71745 operations, 197 surgeons at 85 hospitals
Scheurer et al (2011) USA [47]	Neonates undergoing Norwood	Pediatric Health Information System Database	2004-2008	2051 neonates who underwent Norwood at 29 freestanding Paediatric hospitals
Karamlou et al (2014) USA [45]	Neonates undergoing ASO for D transposition of the Great Arteries with or without VSD repair	The Society of Thoracic Surgeons Congenital Heart Surgery Database	2005-2012	2404 patients (84 centers, 155 surgeons)

Study (author, Year, Country)	Population Included	Data source	Study Dates	Sample size
Kochilas (2009) USA [46]	Children (pediatric cardiac procedures)	Pediatric Cardiac Care Consortium	2000-2004	22148 surgical procedures in 29 centers

Appendix 3f Conference Abstract Data Table

Table 25 Conference Abstracts Data Table

Author Date Country Ref.	**Main question/objective**	**Definition of volume/proximity**	**Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality**	**Key findings and messages**
Welke et al (2012) USA [48]	To test the hypothesis that surgeon volume is associated with mortality after accounting for hospital volume	Annual Volume Hospitals Low = less than 150, Medium = 150-249, High = greater than or equal to 250. Surgeons Low = less than 75, Medium = 75-124, High greater than or equal to 125.	Both surgeon and hospital volume inversely associated with mortality (p<0.0001). Surgeons - low versus high (OR 1.6/ 95% CI 1.3-1.9/p=0.0001. Hospitals low versus high (OR 1.4/95% CI 1.2-1.8 Low volume surgeons had higher adjusted mortality rates regardless of hospital volume. The addition of surgeon volume to the hospital volume models attenuated but did not mitigate the association of hospital volume with mortality (relative attenuation of OR 53% in low and 22% in medium volume hospitals.	Hospital and surgeon volume associated with in hospital mortality when adjusting for casemix

Author Date Country Ref.	Main question/objective	Definition of volume/proximity	Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality	Key findings and messages
Scheurer et al (2011) USA [47]	To expore the impact of dedicated pediatric intensive care units on high risk neonatal populations (after Norwood operation)	Presence or absence of CICU	Patients undergoing Norwood treated at hospital with CICU did not differ in terms of mortality (OR 0.91/95% CI 0.57-1.45), duration of mechanical ventilation (multiplication factor 0.85/95% CI 0.58-1.23) log ICU LOS (MF 0.95/95% CI 0.66-1.36) or log hospital LOS (MF 0.92 (95% CI 0.76-1.1). Centers with a CIU had decreased variability in outcomes (decreased median SD for: ventilation time 13vs18 hours p=0.04/ ICU LOS 19vs27days p=0.04/hospital LOS 22vs28 days p=0.13	Presence of CICU is not associated with better patient outcomes at free standing pediatric hospitals.
Karamlou et al (2014) USA [45]	Association of surgeon and center volume with early outcome following ASO	Categorical - Annual Center Volume 2 or 5 or 7 vs 10 cases. Annual Surgeon Volume 1 or 3 or 5 vs 6 cases.	Lower center volume (2 vs 10 cases OR 2.08 (95% CI 1.34-3.24)and lower surgeon volume (1 vs 6 cases OR 2.00 (95%CI 1.33-3.24) associated with composite endpoint (adjusted) Center volume + surgeon volume attenuated OR by 31%. Surgeon volume + center volume attenuated OR by 7%.	Surgeon and Center volume affect outcomes following ASO. Surgeon volume appears to be more important than center volume.

Author Date Country Ref.	**Main question/objective**	**Definition of volume/proximity**	**Results – Volume/proximity and mortality; volume/proximity other outcomes; other variables associated with mortality**	**Key findings and messages**
Kochilas (2009) USA [46]	Whether surgical volume is a determinant of center specific differences in surgical mortality for CHD	<100 procedures per year (9 centers). 101-200 (10). 201-290 (7), >290 (3)	Significant inverse relationship between in hospital mortality and surgical volume (p=0.0001). Similar results when grouping surgeries by risk category.	

Appendix Four- Supporting Evidence

Appendix 4a Data Source Description Table

Table 28 Data source description table

Database	Type	Database description
The Nationwide Inpatient Sample (NIS)	Administrative, involuntary	An administrative database developed by the Healthcare Cost and Utilisation Project (HCUP), NIS is the largest all-payer inpatient care database in the United States. It is a stratified, cross sectional sample taken from the State Inpatient database (SID) comprising approximately 20% of all community (non-Federal) hospital discharges in the US. It contains discharge data on approximately 8 million hospital stays between 1988 and 2011 from over 1000 hospitals, drawn from 46 states. The NIS contains both clinical and resource-use information including primary and secondary diagnoses; admission and discharge status; patient demographics; hospital characteristics; discharge status; severity and comorbidities.
The Society of Thoracic Surgeons Congenital Heart Surgery (STS-CHD) Database	Clinical registry, voluntary	This was set up to facilitate quality improvement and patient safety. The STS-CHD database is clinical register collecting operative, perioperative and outcomes information on all patients at participating institutions undergoing paediatric and congenital heart surgery from 1989 to the present day. Approximately 85% of all US paediatric heart surgery centres voluntarily participate in this database. This equates to outcomes data on >250,000 patients from 105 participating hospitals. Data quality and reliability are ensured through

Database	Type	Database description
		intrinsic verification of data and a process of site visits and data audits. Data collected includes patient demographics (including age, sex, weight and ethnicity), diagnoses, pre-operative risk factors including non-cardiac abnormalities, procedures undertaken, post-operative data and complications, and discharge status.
Healthcare Utilisation Project Kids' Inpatient Database (HCUP-KIDS) database	Predominately administrative with limited clinical data	Sponsored by the Agency for Healthcare Research and Quality, KID is the only national, all-payer database for inpatient paediatric care in the United States (represents 36 states). It contains a systematic random sample of paediatric discharges from all community, non-rehabilitation hospitals participating in the Healthcare Cost and Utilization Project (HCUP). The sampling frame for the KIDS is approximately 97% of all hospital discharges in the US and the sample of data approximates a 20 percent stratified sample of U.S. community hospitals. It contains data from approximately 8 million inpatient episodes and when weighting is applied it estimates data on over 40 million episodes. Hospitals are stratified by geographic region, location (urban vs rural), teaching status, bed size, and ownership/control (government vs private, not-for-profit status, etc.). Key data items collected include: primary and secondary diagnoses and procedures, admission and discharge status, patient demographics (e.g., sex, age, race, median income for ZIP Code), hospital characteristics (e.g., ownership, size, and teaching status), expected payment source, total charges, length of stay and severity and comorbidity measures.
The Paediatric Health	Administrative	PHIS is a large multi-centre administrative database containing inpatient, emergency department, ambulatory surgery and observational data from not-for-profit paediatric

Database	Type	Database description
Information System (PHIS)		tertiary care hospitals that are members of the Child Health Corporation of America (CHCA). Member hospitals contribute information on demographics, diagnoses, procedures, interventions and outcomes for all inpatient episodes. The database currently holds data on over six million inpatient episodes from 44 tertiary care centres. Forty-two of these hospitals also submit resource utilization data (e.g. pharmaceutical, imaging, and laboratory resources) into PHIS. Data is collected directly from each participating hospital's electronic medical and financial record systems. Data are subjected to reliability and validity checks between participating hospitals and the CHCA.
The Paediatric Cardiac Care Consortium (PCCC)	Clinical registry, voluntary	This database contains data from approximately 137,000 consecutive surgeries from up to 57 small and medium size (less or equal to 300 surgeries per year) centres from different areas across the US and Canada for the period 1982-2007. Founded in 1982 centres participate voluntarily and membership has varied over the time span with 35 centres contributing at least 10 years data. The PCCC prospectively collects detailed clinical data on cardiac operations (except isolated ductal ligation for prematurity). The PCCC classifies operations into 6 categories based on expected early mortality rates using the Risk Adjusted Classification for Congenital Heart Surgery, version 1 (RACHS-1), a validated and widely used system.
University Health System Consortium	Clinical database, voluntary	University Health System Consortium (UHC) is an alliance of 101 academic medical centres and 178 of their affiliated hospitals sharing diagnostic, demographic, procedural, and outcome data on all hospital discharges. The Clinical Data Base/Resource Manager

Database	Type	Database description
(UHC) Clinical Data Base		(CDB/RM) provides an expanded set of comparative data by combining patient encounter level and line-item transactional detail to yield information on patient outcomes and high-impact resource utilization.
The UNOS Standard Transplant and Research (STAR) Dataset	Clinical registry, involuntary	The United Network for Organ Sharing (UNOS) is an organisation that manages the organ transplant system, the Organ Procurement and Transplant Network (OPTN), in the United States. UNOS collects information on every organ donation and transplant event occurring in the U.S. since October 1, 1987 on a secure Internet-based transplant information database. The database allows individual centres to register patients for transplants, match donated organs to waiting patients and manage the time-sensitive, life-critical data of all patients, before and after their transplants. The STAR dataset contains data variables on transplant recipients collected on UNOS data forms and contain patient-level data for all kidney, pancreas, liver and thoracic transplant candidates and/or recipients. The dataset includes more than 500 variables from most UNOS forms, a number of calculated variables and extensive documentation of data variables.
California Office of Statewide Health Planning and Development (OSHPD) Discharge	Administrative and clinical registry, involuntary	This database includes data on all discharges collected from all licensed California hospitals (> 500 acute care hospitals), including inpatient, emergency care, and ambulatory surgery data, hospital emergency departments, and licensed stand-alone ambulatory surgery clinics in the state. OSHPD data contains ICD 9-CM discharge, diagnosis and procedure codes assigned by California hospitals to each individual discharge during the year. Among other variables, the data set includes primary procedure and diagnosis and up to 20 secondary

Database	Type	Database description
database		procedures and 24 secondary diagnoses.
Texas Birth Defects Registry	Population registry	The Birth Defects Epidemiology and Surveillance Branch of the Texas Department of State Health Services manage this population- based active registry. Data is collected from a variety of medical facilities in the state to identify instances of major birth malformations in offspring of Texas resident mothers (structural malformations and chromosomal disorders). Through these multiple sources of information, the Registry monitors all births in Texas (approximately 400,000 each year) and identifies cases of birth defects. Once identified, detailed demographic and diagnostic data are abstracted and entered into the electronic registry.

Appendix 4b Risk Adjustment for Congenital Heart Surgery (based on Jacobs 2012 [112])

Complexity stratification tools have seen increasing popularity in the analysis of outcomes associated with congenital and paediatric cardiac surgery, reflecting the fact that so many different distinct types of operations are performed. Since 2002, complexity stratification has been used extensively by The Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database and the European Association for Cardio-Thoracic Surgery (EACTS) Congenital Heart Surgery Database.

Aristotle Complexity score

The Aristotle Basic Complexity Score defines the complexity of an operation through three factors: potential for mortality, potential for morbidity, and technical difficulty of the operation.

When designed in 2000, the Aristotle Complexity Score was entirely based on subjective probability. This approach, based on the opinion of experts, was considered a good solution due to the limited amount of data available at that time. The Aristotle score evaluates basic surgical performance and more complex surgical performance through two complexity scores: 1) the basic complexity score (1.5—15 points), which is a procedure adjusted complexity comprising four levels of complexity, and 2) the comprehensive complexity score (1.5—25 points), which adds patient-adjusted complexity (0—10 points) to the procedure-adjusted complexity and comprises six categories.

Risk Adjustment for Congenital Heart Surgery (RACHS-1)

The Risk Adjustment for Congenital Heart Surgery (RACHS-1) is a mortality risk-adjustment methodology based on paediatric cardiac procedures for congenital heart disease. The method was created to adjust for differences in case mix when examining in-hospital death rates after congenital heart surgery. RACHS-1 was developed using a consensus approach involving a nationally representative panel of paediatric cardiologists and surgeons in the United States. The focus of RACHS-1 is on short term mortality after surgery with inpatient mortality as the indicator for this outcome, as it is easily available in administrative data and other data sets.

The RACHS-1 method involves the grouping of different cardiac procedures with similar risks for in-hospital mortality into six risk categories, several of which are stratified by age or diagnosis. The procedures are organised into the six categories to form an ordinal scale of increasing risk for inpatient mortality, where category 1 has the lowest risk of death and category 6 the highest. In instances where a patient is undergoing multiple cardiac surgical procedures, the procedures are placed in the category corresponding to the single highest risk procedure. The risk categories were created by consensus judgement of the panel primarily using common coding systems such as International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). The allocation of procedures was subsequently refined by using mortality data from two large multi-centre datasets. In order to measure case-mix as accurately as possible, the risk categories are usually included in multivariable models with other key variables such as age, prematurity, and the presence of a major non-cardiac structural anomaly, such as cleft lip/palate or anal atresia.

STS–EACTS Congenital Heart Surgery Mortality Categories (STS–EACTS categories)

The STS-EACTS Congenital Heart Surgery Mortality Score, an objective, empirically based index used to identify the statistically estimated risk of in-hospital mortality by procedure and to group procedures into risk categories. When modelled with three patient-level factors (age, weight, and preoperative length of stay) **STS EACTS** has a C-statistic of 0.816. The tool was developed using primarily objective data with minimal use of subjective probability. The risk of mortality prior to discharge from the hospital after cardiac surgery was estimated for 148 types of operative procedures by using actual data from 77,294 patients entered into the Congenital Heart Surgery Databases of the EACTS (33,360 patients) and the STS (43, 934 patients) between 2002 and 2007. Procedure-specific mortality rate estimates were calculated using a Bayesian model that adjusted for small denominators. Each procedure was assigned a numeric score (the STS-EACTS Congenital Heart Surgery Mortality Score). Claimed advantages of the STS/EACTS Mortality Score and Categories include that it is based on objective evidence, rather than expert opinion, that it is able to classify more procedures than RACHS-1 or Aristotle and that it demonstrates a higher correlation with outcome (observed mortality) by c-statistic.

Appendix 4c Table of covariates of included studies

Table 27 Covariates of included studies – patient factors

Patient Factors	
Age	[32,14,35,11,24,34,19,25,33,31,17,43,7,39,40,29,26,8]
Gender/Sex	[24,34,7,39,29,26,11,25,19,17,23,30,39]
Race/Ethnicity	[11,33,17,23,20,7,37,29,39]
Prematurity	[11,17,13,30]
Weight at surgery	[36,24,34,37,14,35,43]
Insurance status	[11,33,7,12]
Family income	[7,39]
Gestational Age	[40,10]

Table 28 Covariates of included studies – condition related

Condition related		
Cardiac Diagnosis	Congenital Heart Disease/single ventricle/double ventricle/ pulmonary atresia/intact ventricular septum/ aortic atresia/ Endocardial cushion defect / pulmonary venous	[16,36,13,30,24,34,36,14]

Condition related		
	return/arrhythmia/ Double outlet right ventricle/dominant ventricle	
Comorbidities/ Other non-cardiac abnormalities	Genetic syndrome/risk factor/abnormality/chromosomal anomaly	[14, 35, 24, 34, 33, 40, 29, 13, 30]
	Renal abnormalities	[32, 43, 36]
	Major non-cardiac structural anomaly	[11, 13]
ICD-9-CM diagnostic code		[8, 13]

Table 29 Covariates of included studies – procedure related

Procedure related		
Year (or era) in which procedure undertaken		[24, 34, 25, 43, 16, 17]
Surgical complexity	STS EACTS RACHS 1 Aristotle Basic Complexity Other	[9, 8, 35, 11, 19, 42, 37, 29, 43, 14, 8, 41, 34, 18, 33, 44, 21, 27, 22]
Procedure		[31, 33, 43, 15, 7]

Procedure related		
Admission Type - Planned or emergency		[17]; [39]; [12]; [8]
Pre-operative length of stay		[35]; [24]; [34] [43]
Ventilator use/support		[14]; [19]; [36]; [43]
Pre-operative – mechanical ventilation support		[24]; [36]; [34]
Use of ECMO		[25]; [40]; [32]
Characteristics of donor		[10]; [16]
Cardiopulmonary support/bypass		[19]; [8]
Acidosis		[43]; [36]
Postoperative - Sepsis		[14];[32]
Re-exploration of the chest/ Reoperative sternotomy		[16]; [19]

Table 30 Table of covariates of included studies – hospital factors

Hospital Factors	
Surgeon volume (including volume by procedure and volume by adult/pediatric)	[31]; [40]; [29]
Hospital Type (teaching or non teaching) (rural or urban)	[25]; [32]; [23]; [39]; [26]
Distance from patient home to hospital/travel time	[37]; [20]

Bed size of hospital	[31]; [25]

Appendix 4d Assessment of Relevance Table

Table 31 Assessment of Relevance table

	Adjusted for severity of condition?	**Adjusted for age?**	**Multi-centre?**	**Included > 1 intervention/condition?**
Arenz et al (2011) [9]	YES	YES	NO	YES
Arnaoutakis et al (2012) [10]	YES	YES	YES	NO
Bazzani and Marcin (2007) [8]	YES	YES	YES	YES
Benavidez et al (2007) [11]	YES	YES	YES	YES
Berry et al (2007) [12]	NO	NO	YES	NO
Berry et al (2006) [13]	YES	NO	YES	NO
Burstein et al (2011) [14]	YES	YES	YES	YES
Chang et al (2006) [7]	YES	YES	YES	YES
Checcia et al (2005) [15]	NO	NO	YES	NO
Davies et al (2011) [16]	YES	YES	YES	NO
Dean (2013) [17;51]	NO	NO	YES	NO
Dinh and Maroulas (2010) [18]	YES	YES	YES	YES
Eldadah et al (2011) [19]	YES	YES	NO	YES
Fixler (2012) [20]	YES	YES	NO	YES

	Adjusted for severity of condition?	Adjusted for age?	Multi-centre?	Included > 1 intervention/condition?
Gray et al (2003) [21]	YES	YES	YES	YES
Hickey et al (2010) [22]	YES	YES	YES	YES
Hirsch et al (2008) [23]	YES	NO	YES	NO
Hornik et al (2012) [24]	YES	YES	YES	NO
Karamlou et al (2013) [25]	YES	YES	YES	YES
Karamlou et al (2008) [26]	YES	YES	YES	YES
Karamlou et al (2010) [27]	YES	YES	YES	NO
Kazui et al (2007) [28]	NO	NO	YES	YES
Kim et al (2011) [29]	YES	YES	YES	YES
McHugh et al (2010) [30]	YES	NO	YES	NO
Mery (2014) [31]	YES	YES	YES	YES
Morales et al (2010) [32]	YES	NO	YES	NO
Oster et al (2011) [33]	YES	YES	YES	YES
Pasquali et al (2012a) [34]	YES	YES	YES	NO
Pasquali et al (2012b) [35]	YES	YES	YES	YES
Petrucci et al (2011) [36]	YES	NO	YES	NO

	Adjusted for severity of condition?	**Adjusted for age?**	**Multi-centre?**	**Included > 1 intervention/condition?**
Pinto et al (2012) [37]	YES	YES	NO	YES
Sakata et al (2012) [38]	NO	NO	YES	YES
Seifert et al (2007) [39]	YES	YES	YES	YES
Tabbutt et al (2012) [40]	YES	NO	YES	NO
Vinocur (2013) [41]	YES	YES	YES	YES
Welke et al (2010) [42]	YES	YES	YES	YES
Welke et al (2009) [43]	YES	YES	YES	YES
Welke et al (2008) [6]	YES	YES	YES	YES
Welke et al (2006) [44]	YES	YES	YES	YES

Clinical Advisory Panel review of proposed CHD standards

Introduction

The Clinical Advisory Panel (CAP) considered the proposed standards for CHD services at its meeting on 31 March 2014. Following discussion, and with a number of suggested amendments, CAP approved the standards for discussion with stakeholders prior to formal consultation.

This paper summarises views expressed during this pre-consultation period. In particular it reflects views from the review's Children and Young People Events, visits to CHD services across England and Wales, discussions with the review's three engagement and advisory groups and discussions at the CHD Clinical Reference Group. Some comments were also received via the NHS England website. In each case the paper seeks to accurately reflect what was said.

The views expressed are those of the individuals and groups concerned and not the official views of NHS England. Rather they are reported to aid the development of the proposed standards.

ScHARR was commissioned to undertake an independent review of the literature and its findings have been summarised at relevant points of this paper. Their work focused 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)?

The National Institute for Cardiovascular Outcomes Research was asked to examine its data and to advise on what this showed about service factors that could influence outcomes. Although the final write up of this work is not yet available, NICOR has kindly supplied a summary of the main findings and these have been incorporated in this paper.

Recommendation

CAP is asked to consider the standards in light of all these contributions and advise whether any amendments need to be made prior to full public consultation.

Section A: The network approach

Children and Young People Events

No specific comments

Visits to CHD services across England and Wales

On our visits to CHD services across England and Wales many centres told us that network working is what makes a difference

What makes networks work?

Networks only succeed when given a lot of time, energy and commitment. All parties have to want them to succeed.

Networks need to be managed and properly resourced - there are leadership, managerial and administrative costs.

Networks are about relationships built over the long term. Having named link consultants with good relationships with local PECs/CWSIs is crucial. Effective network working is very dependent on individual relationships.

Supporting PECs/CWSIs through outreach clinics, working alongside allows them to develop their skills.

Protocols, guidance and shared governance help reduce variation.

Telemedicine and information systems

Effective networks need shared information - clinical IT systems; videoconferencing; telemedicine. There were different views about the importance of being able to share scans.

Regional or national networking

Some centres consider that there is a role for network arrangements at a level above the hub and spoke model described in the standards. Regional networks would allow surgical centres to work more closely together and provide important quality assurance and mutual challenge, enhanced training and research opportunities. There was also support for a national network of surgical centres, and it was considered that developing this might be an NHS England / professional society joint venture.

We heard that some units are not speaking to each other – relationships had been OK but were damaged by the Safe and Sustainable process. Networking between distant centres is a bit better than it was, but with near neighbours it is still strained. This reduces opportunities to learn from each other.

Network boundaries, catchments, competition and choice

We heard concern in some places about boundary issues and how to ensure that each unit gets the ‘right number’ of patients to meet the minimum requirements of activity for its number of surgeons.

Transplant

A small percentage of CHD will require transplant and access to transplant is limited not just by the number of donors but also by professional views of the potential success.

Donation is the limiting factor with few donors from children. Most children who are transplanted receive adult hearts.

We were told that patients who get to adulthood with CHD will rarely get a transplant because whenever a heart becomes available there will always be other potential recipients in whom the operation would be simpler and in whom better long term outcomes are more likely.

Patient and Public Engagement and Advisory Group

The group emphasised the importance of effective communications between clinicians across networks and nationally.

The group considered that more attention needed to be given to transport and retrieval services (Embrace was raised as an example of best practice).

Provider Engagement and Advisory Group

The group asked for clarity about the proposed model for CHD networks. Were they operational delivery networks? There was a view that while ODN functions of shared pathways and joint working were being described other roles with a greater emphasis on sharing and learning to drive quality were also being described and this might be a different sort of network.

The group considered that it would be possible to describe quality driven relationships

Clinician Engagement and Advisory Group

Network boundaries, catchments, competition and choice

A subgroup considered the question of whether network boundaries should be managed or should emerge as a result of competition and choice. The group considered that unless boundaries were managed it would continue to damage relationships.

They considered that managed boundary networks would be more efficient and would drive costs down. The group therefore advised a more formal statement about this issue.

The group considered how boundaries could be set in a managed scenario (closest, shortest journey time) and how commissioners could enforce these arrangements, for example by not paying for activity where the boundaries were not respected.

Other members of the clinician group considered that patient choice must be allowed which implied competition.

The managed boundary model proposed led to units that would be similarly sized. Some considered that there was a case for at least some units to be larger. Others argued that if units all had to undertake at least 500 cases this meant that the decision not to have bigger units had in effect been taken.

Experience from trauma networks was that managed network boundaries had been effective and well accepted.

Transplant

A sub-group considered the approach to transplant taken in the standards.

They advised that the paediatric standards were fine.

Adults requiring transplant range from simple procedures that can be done in any of the transplant centres to complex patients who can only be done where there is special expertise that are almost all done in Newcastle. In the future we can expect more complex adult demand – a second centre may be required to do this work. There will also be a continued rise in the use of mechanical assist devices both as bridge to transplant and, in time, as destination therapy. Arrangements would also need to cover heart and lung transplant and not just heart transplant as demand for these procedures could be expected to rise.

The group identified a problem in applying the standards – the Newcastle centre is in a sparsely populated region where there won't be enough patients to meet the CHD activity requirements. The group advised that some sort of super network and intelligent commissioning will be needed if the CHD work is not to close the transplant service.

It was proposed that there should be a minor change in wording to differentiate between referral of simple rather than Complex patients:

The proposed adult standard (A2) which stated that *"each specialist ACHD centre must demonstrate formal working relationships with a cardiothoracic transplant centre staffed by transplant surgeons with a congenital practice"* has been modified to read *"each specialist ACHD centre must demonstrate formal working relationships with cardiothoracic transplant centres, including one staffed by transplant surgeons with a congenital practice"*

Clinical Reference Group

Network boundaries, catchments, competition and choice

There was discussion about network boundaries and pathways of care. The discussion noted that there would be a difficulty guaranteeing enough activity at some centres if network boundaries were not defined by commissioners but that the approach had also to recognise that competition/choice is allowed in the NHS and fixed boundaries would be anti-competitive. There was a view that network boundaries should take account of “normal expected” pathway flows. There was not general agreement that boundaries should be fixed.

Congenital networks

The CRG agreed that there should be combined CHD networks covering both children and adults. A clear definition of a “Network” is needed including descriptions of network leadership roles and responsibilities. There should be a single lead clinician across both aspects of the network.

Network development

There would be a need to define pathways of care from the outset recognising that the Network Functions will take time to establish.

Multidisciplinary Team

The MDT membership is not sufficiently defined. Need to define core members. The group proposed a minimum of three members - congenital cardiologist, congenital surgeon, specialist anaesthetist.

NHS England website – comments

Network boundaries, catchments, competition and choice

One comment stated that in order to attract and retain patients NHS specialised service providers have to listen and adapt to the changing needs of their patients. Those service providers which have implemented continuous improvements and change are those which naturally attract more patients and referring clinicians. This is not something that can be done nationally as the changes necessary often require local support and long term commitment. Any centre which is failing to attract enough patients to successfully employ enough staff to safely run its service and have successful succession planning has to look to itself and ask why. That centre needs to ask what is happening in those centres which are increasing their services naturally and ask what is it that they are doing that we are not.

ScHARR review

No specific comments

National Institute for Cardiovascular Outcomes Research review

No specific comments

Tier 2 Specialist Cardiology Centres

Children and Young People Events

No specific comments

Visits to CHD services across England and Wales

Where tier 2 paediatric services were running, units considered that they had a valuable role and were confident that as part of networks they could have a positive future.

Clinician Engagement and Advisory Group

The role of tier 2 specialist cardiology centres

A subgroup considered that the limitations on interventional cardiology in tier 2 ACHD centres were too inflexible and that there was the potential for these units to do more. This should be different for ACHD than paediatric CHD because adult cardiologists exist outside SSCs but do not for paediatrics. It was noted that the majority of adult ASD closure is currently undertaken outside specialist surgical centres and that the results are good.

They considered that the flexibility offered by the standard on electrophysiology was more appropriate - this requires that patients are discussed at the MDT. The group considered that this flexibility should be replicated for other forms of intervention / diagnostic catheters and that more should be allowed outside the surgical centre with network agreement. This might include ASD and PFO closure. They also recommended that arrangements for ASDs and PFOs should be consistent to reduce the risk of gaming. It was agreed that as a minimum BCS standards must be met including numbers of interventionists and numbers of procedures undertaken by each. The proposed tier 2 ACHD standards would also need to be met.

Clinical Reference Group

*Interventional cardiology in tier 2 specialist ACHD centres**

There was a discussion about the potential for interventional cardiology to be undertaken at tier 2 specialist ACHD centres, for example for the repair of ASDs. Currently the standards require that these are only undertaken at a specialist surgical centre, but interventionists from tier 2 centres (who have been appropriately trained and who meet the minimum volume thresholds) may undertake these procedures at the specialist surgical centre. The group considered that for this to be possible the level 2 unit would need to meet both the level 2 standards and the appropriate requirements for interventional cardiology services described in the tier 1 standards. The requirement for specialist congenital surgical back-up in particular was considered essential and surgical members of the group were of the view that congenital surgeons based at specialist surgical centres would not and could not provide this.

[nb. this record of CRG discussions is subject to ratification by the group]

Long term viability

The CRG expressed concerns about the viability of the Tier 2 Centres – both in achieving the standards on a sustainable basis and a concern that recruitment of high quality staff to these centres may present a problem.

Other issues

- Standards should affirm need for beds based on population/patient activity and provision should be aligned accordingly
- Standards should specify need for dedicated sonographer
- The standard on research needs to be stronger and include requirement for “national research”
- Where fetal diagnostics are provided in tier 2 centres, all staff must have the appropriate specialist expertise in fetal cardiology or refer onto the tier 1 service/specialist fetal centre

NHS England website – comments

No specific comments

ScHARR review

No specific comments

National Institute for Cardiovascular Outcomes Research review

No specific comments

Tier 3 Local Cardiology Centres / Local Hospitals

Children and Young People Events

Local A&E and paediatric services

- Local units find complex cases very difficult to manage and the parent needs to be the advocate which worries them - particularly if they can't be there all the time
- We heard about a situation when a local unit said her son 'was good for a child with CHD' but the parent knew that he 'wasn't right' - insistence on calling main centre who asked for a lung xray and both lungs had collapsed.
- Patient and the parents in particular have a big advocacy role but too often are not listened to - they are the experts and are seen as overly cautious by the doctors.
- Would be helpful if there was a way to flag these children on the system particularly for the local hospitals - a national database feels rather obvious - so that parents wouldn't be relied on - particularly in stressful situations.

Visits to CHD services across England and Wales

Local CHD Services

We heard about good work in many places to develop role of PECs/CWSIs.

Local tier 3 services are really important both to allow patients to receive more care locally and to ensure that specialist centres can focus on the most complex patients. The growth in the number of adult CHD patients makes the role of local centres even more important – specialists centres would be overwhelmed without the support of good local services.

We heard concerns in a number of places about whether CCGs would see local CHD services as a priority, and therefore a risk that they might not want to fund them.

Local A&E and paediatric services

We were told that local hospitals do not consistently deliver a good service to these patients / families

- Emergency admissions via A&E were cited as difficult
- Do not consistently contact specialist centres for advice
- Appear to not know what they are doing
- Act against the advice of the parents who are expert in their child’s condition
- Non specialist staff locally makes parents feel isolated and rely on the specialist centre
- Community and local hospital staff forget that the parents do become experts in their children's health and must be included in care decisions locally - they will know a lot more about the specific aspects of the child's care and 'what's right for their child'
- Many parents say they have to get aggressive to get care for their children locally, for concerns to be taken seriously, phoning surgeons and cardiac consultants desperately looking for them to influence the local care being given.
- Poor consistency in delivery of services close to home: community nurses, health visitors, GPs, prescribing specialist medication, blood tests
- Local hospitals are by passed in favour of specialist centres because of lack of faith in local hospitals to listen to them and call the specialist centre for advice

- Inconsistent GP involvement
- Because baby/child in the congenital heart system, children and babies (and post natal mothers) fall out of the normal health care/social system and struggle to get back in - health visitors, community nurses, midwives, GP's either aren't involved, aren't aware of the child, or are scared of the child and being involved in their health
- Once trust is lost in local DGHs very hard to get back, means parents are dependent on one hospital and surgeon/ specialist nurse and will travel great distances to get to the care they trust
- Unaware of what is available locally to support other family members – particularly siblings

We heard about a number of things that work well

- Open access to their local centres and therefore bypass A&E which has a positive impact
- Some hospitals have good links with the specialist centres and work with the parents as a partner in their child's care
- Handheld notes with patients history and medication that can be shared with other medics
- Experiences where the GP worked in partnership with the specialist centre to deliver local care
- Good IT across the network to support clinicians would be helpful to make these links work even better

Engagement and advisory groups

No specific comments

Clinical Reference Group

Commissioning

The CRG affirmed the importance of tier 3 services which offer the opportunity for many patients to avoid long journeys to specialist centres. However the CRG feels strongly that the activity which takes place in a tier 3 centre should be classified as "specialised" (outreach and PEC/CWSI). A PSAG submission would be required for this with a clear case for change with numbers and potential cost implications. The CRG does not feel that the tariff in tier 3 centres is sufficient to meet the standards.

Specific Standards

- Concern was expressed that the standards may be pitched too high, in a way that could deter some local hospitals from trying to deliver this type of service
- Is exercise testing a requirement in a tier 3 service?
- Archiving of documents needs to be the same across all 3 tiers.
- The group recommended that fetal diagnosis should only be undertaken in tier 3 units as part of an out-reach service.

NHS England website – comments

No specific comments

ScHARR review

No specific comments

National Institute for Cardiovascular Outcomes Research review

No specific comments

Section B: Staffing and skills

Children and Young People Events

Psychology and counselling

There should be a psychologist available for patients – someone to talk to (especially for older children). Genetics often have a counsellor – this should be available to all

It would be good to have someone non-medical in the hospital to talk to – counsellor or youth worker

Specialist Nurses

There should be more Liaison nurses on each ward – they are stretched too thin but a wonderful resource.

Cardiac liaison nurses play an essential role and are seemingly overworked

Play and clowns

Every hospital should have Clown Doctors – children love it – great form of entertainment

Could there be a play therapist on site that could be commissioned?

Practicalities

Where possible there should be a male nurse on each ward

Staff need to be easily identifiable so you know who to talk to – on the uniform, or by colour coding, or a sign in the ward

Patients should be told when there is a shift change so they know there will be a new nurse to look for

Competence

Staff should not be doing procedures they are not trained to do

Clinician mobility

Mobility of staff/doctors/surgeons needs to be encouraged – the current system seems to work in the opposite way

Private practice

Parents wanted to know how we work out whether time that is being spent in private practice is calculated when looking at work ratios. Also need to look at the ratio of people to patients.

Visits to CHD services across England and Wales

Specialist nurses

The role of the specialist nurse is absolutely pivotal for patients. Their role encompasses system navigation, counselling and support, problem resolution, educator. In some places it was noted that because numbers were limited the service that nurse specialists could offer was limited.

Should have liaison nurse in outpatients.

Surgeon numbers and minimum activity levels

Surgeons have mixed views about whether the minimum number of surgeons in a team should be three or four. This was not simply conditioned by the scale of their own unit.

Surgeons who advocate for larger surgical teams are not usually motivated by concerns for out of hours arrangements or work life balance considerations. Rather the number of surgeons is used as a proxy for the scale of the unit – perceived advantages being greater subspecialisation within surgical teams, better supporting facilities and staffing, more attractive units for recruitment, greater opportunities for training and research. These are not seen as ends in themselves but as important contributors to higher quality services that will improve outcomes.

Surgeons recognised the importance of being able to access specialist advice and support from other centres. Strained relationships mean that some centres will not contact some other centres. Where surgeons had experience of being asked to assist a colleague at another hospital it had often proved to be frustratingly difficult to sort out the HR clearances needed to do so.

Surgeons all supported a minimum of 125 operations. They told us that this must be seen as a minimum. They are clear that this is a more important determinant of surgical quality than the number of surgeons in a team and that increasing the number of surgeons in a team must never be at the expense of minimum levels of activity. Some surgeons consider that maintaining skills is not just about numbers but also about case mix so some considered that in counting a distinction should be made between short and long procedures.

Some were sceptical that more than a minority of operations are dual surgeon operating so this counting issue could be unimportant.

Some thought that senior surgeons don't need to do so much surgery to maintain skills and that they could do more adult work but would still be competent to tackle paediatric work because of their accumulated experience.

Out of hours

The need for out of hours emergency surgery in this specialty is low (except for transplant centres) so is not considered especially onerous. However it is important that on call arrangements ensure the prompt availability of a surgeon with the skills to deal with whatever problem presents. This is not just a matter of the number of surgeons in a team – the degree of subspecialisation in their surgical practice matters as does the availability of other surgeons when needed. Out of hours these arrangements seem usually to be informal. An alternative approach is to ensure that all surgeons practice across the whole age range.

We heard that most emergencies are arrhythmias. Some difficult arrhythmias might need the ability to bring in a full highly skilled team out of hours to diagnose and manage with interventional techniques.

Scale of units matters to the extent that any unit needs to have sufficient scale to be able to offer the full range of services out of hours that might present as an emergency to that unit out of hours.

Psychology and counselling

Proposals that will ensure greater availability of psychologists are welcome. This must be reflected in the adult standards and not just children’s.

We were told that there is a need to connect with social workers to make sure families they are getting benefits they need. In one centre we heard from a specialist social worker who also offered counselling and psychological support.

Play

Play specialists are vital to ensure the child's development does not stop because they are in hospital

Recruitment and retention

Recruitment is challenging in some specialties and some locations. Specific initiatives beyond traditional recruitment practices have been successful.

Specific concerns –

- Nursing – recruitment and retention of highly skilled and qualified nurses is critical and hard but we heard about a number of successful, less traditional approaches; the supply of paediatric nurses was a concern; turnover is high in London – people come for the experience then move on; the availability of PICU nurses was often seen as a capacity limiting factor; nurses are not a mobile workforce so any closures could mean a serious loss of experience and skill to the system; nurses are less flexible now because trained specifically for either paediatric or adult nursing.
- Cardiac surgery – retention was seen to have been adversely affected by the uncertainty. Given the small numbers involved staffing was seen as precarious.
- Scientists, cardiac technicians, physiologists – widespread concerns that curriculum changes resulting from modernising scientific careers meant that appropriate Masters level training is no longer available.
- Cardiologists – concern about whether it will be possible to attract high quality cardiologists to work in level 2 units, particularly in paediatrics.

Clinician engagement and advisory group

One member stated that changing the number of cases to 100 would make little difference to the surgeons but a lot of difference to the networks.

One member stated that it is wrong, especially for adults, to count all cases as equal - some are much more complex.

Provider engagement and advisory group

Recruitment and retention

Attracting cardiologists into Tier 2 services is challenging

There may be different staffing issues in and outside London. Retention seems much more difficult in London – it is more difficult to fill vacancies at lower pay bands in London. It may be easier to fill medical vacancies in London. Competition between units will lead to more staff moves, as some posts are on higher Agenda for Change bandings than others. The group saw value in a dialogue about bandings.

The draft standards propose new requirements for psychologists. While recognising that there is huge variability in availability, there was a concern that resolving this would bring a financial pressure.

There has been little investment in adult services and so it is proving difficult to fill vacancies. This is exacerbated by the fact that there are no standards for adult congenital heart specialists. Need to look at what happened with nursing 10 or 15 years ago - need to link to universities nationally to deliver an adult congenital course.

There may be an issue with ECHO as training has changed and people don't have the same skill set. There is a four year gap because of *Modernising Scientific Careers* – need to look at numbers going in to training as well as bandings. The review team could talk to HEE about the increasing demand for specialists at a time when they are moving towards generalised training rather than specialist. There may be an opportunity to introduce a new training module to Modernising Scientific Careers.

Mobility of staff

The group noted it would be possible to look at getting a passport. In addition, it may be possible to reach agreement for surgeons along the lines of locums in the standards.

Clinical Reference Group

Surgeon numbers and minimum activity levels

The CRG discussed the appropriate size of surgeon teams. The surgeons were less concerned about this issue than the need to ensure that each surgeon undertakes enough procedures to maintain competence.

They noted that if numbers of surgeons and activity levels were set then network boundaries should be fixed to ensure that these levels are achieved. The timetable for reaching the activity levels required could be critical for some centres that don't reach these levels now but might in 10 years time.

There was agreement that in order to provide on call continuity, cover and back up for illness etc, at least three surgeons at each centre should be an immediate requirement. They noted that most surgeons also agree that four surgeon teams are ideal.

The minimum number of procedures per surgeon is an appropriate standard, and 125 an appropriate minimum.

Out of hours

Given the spread of sub-specialisation which is likely to increase CRG surgeons considered that the number of surgeons was not the only issue. Arrangements needed to ensure the availability of surgeons with the required skills: neonatal surgery (the most frequent out of hours emergencies), complex congenital operations and establishing cardiac ECMO. Emergencies out of hours are however rare.

Specialist nurses

The group considered that the number of specialist nurses in each network should be based on population to ensure that the number would rise in networks with bigger catchments.

Psychology

The group considered that a more prescriptive statement of required psychologist staffing was needed in the adult standards.

NHS England website – comments

Succession planning

One comment from a former congenital heart surgeon stated that larger teams of surgeons was better for succession planning - departure of the senior surgeon through retirement, illness or moving abroad, could lead to significant interruption in continuity of the service. It takes several years to integrate a new surgeon in to the team because new consultants will not have undertaken most of the major procedures when they are appointed. During that period they cannot play a full part in the on-call service.

Two other commenters considered that succession planning was a matter that should be managed by each Trust without the need for a national review to sort it out. Those Trusts that wished to continue to provide a CHD service have to show that they are able to plan and meet all the needs of running the services.

One commenter noted that this approach seemed overly focused on just one individual whereas surgeons work as part of a team and each member of that team provides a crucial role to the individual patients.

ScHARR review

Relationship between volume and outcome - mortality

This review identified a substantial number of studies reporting a positive relationship between volume and outcome. While many of the studies show better patient outcomes when larger volumes of surgery are performed, this was not consistent and not all of the studies showed this.

The relationship between volume and outcome is unlikely to be a simple, independent and directly causal relationship, *but rather be a marker for other process and system factors.* Welke clearly expressed the view that volume is likely to be a surrogate for the processes and characteristics of care systems that produce outcomes and that centre specific quality measures would be more informative than volume thresholds. Pasquali and Vinocur concurred with this view and suggested that service design decisions should be guided by a range of individual centre performance measures and not volume. There are consistent and clear messages within the literature reviewed about the danger of viewing volume in isolation. Furthermore, included studies also caution concerning the likely but as yet poorly understood interaction of volume with the numerous other clinical and structural dimensions that contribute to delivering high quality services and hence good outcomes. With centralisation comes a corresponding increase in volume as more cases are concentrated in fewer centres. 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 cases. The lack of any UK studies to contribute to the review indicates a serious gap in evidence relevant to service provision in the NHS.

Despite the growing number of studies on the relationship between volume and outcome few studies have suggested what the optimum size of a CHD centre in terms of volume should be.

ACHD

Two studies found that adult CHD patients had better outcomes when operated on by paediatric surgeons in specialist children's centres.

Two studies suggest a relationship between individual surgeon volumes and outcomes for adults with CHD -one study found outcome was associated with surgeon volume. Another found a similar association with adult procedure volume indicating the influence of expertise on outcome.

Complex conditions

Studies on single conditions or procedures were more likely to identify an effect of volume on mortality but these were focused on high risk conditions, such as Hypoplastic Left Heart Syndrome, and procedures, for example Norwood procedure. Even within these highly selected groups there was considerable variation in effect depending on procedure type and individual centre performance. It is possible that, for example, surgeon volume may be as important as centre volume for these complex cases. Hirsch suggested that a reasonable threshold for referral of children requiring Norwood procedure is centres doing at least 20 procedures a year and 10 procedures a year for arterial switch operation. These studies indicate the potential value of centralising or regionalising highly specialised services for very rare and complex cases.

Relationship between volume and outcomes other than mortality

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.

Relationship between distance from specialist centre and outcome

Two studies examined the relationship between distance from a specialist cardiac centre and mortality and both found no relationship between distance and mortality.

National Institute for Cardiovascular Outcomes Research review

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

No association was shown with distance from home.

Section C: Facilities

Children and Young People Events

Teens and young adults

- There need to be forms of entertainment for all ages not just younger children (toys etc. in the waiting room) – to be used as more of a distraction than anything else.
- The playroom needs to be staffed as long as possible so children and young people can have more access to entertainment.

Environment

- The rooms are boring and clinical – they need more of a personality (less intimidating)
- Cleanliness is paramount in all areas of the hospital – for all staff, parents and families
- Facilities for the parents could do with some improvement.

Food

- The standard of food in hospitals needs to be higher – it's when you most need good, healthy, balanced food.
- One parent felt there should not be a McDonalds/Burger King in a heart unit – people are too easily tempted by fast food and it's a main cause/contributor of obesity/heart disease. (other parents had differing views)
- There needs to be a wider variety of food especially for people with:
    - Allergies
    - Intolerances
    - Religious restrictions
- It would be good if the canteen was open later – especially for parents who need to stay overnight in the hospital
- It would be good to have a kitchen on all wards so parents can bring food from home rather than buying everyday
- It would be good if there was somewhere that families can eat together (not fast food)

WiFi

- There needs to be 24 hour access to Wi-Fi for all patients (both in and out) not only for entertainment purposes but so that older children can keep up with school work easily if they have to miss school for operations etc.
- It would also allow siblings to occupy themselves whilst at/waiting at the hospital. It could also benefit parents massively - they would have the opportunity to keep up with work or other family members during their time at the hospital.
- It could also be used as a way of keeping in touch with friends and family whilst in hospital – phones often have no signal in the hospital so Skype/Facebook/messenger programmes would be helpful.

Accessibility

- There needs to be a space where children can put out of use wheelchairs
- There must be easy access for ambulances at the hospitals

Transport

- Not all hospital buses are wheelchair accessible (re: pavements and curbs)
- There isn't enough disabled parking
- It's very expensive to park
- Discount [on parking] is great but needs to be better advertised

School

- Wi-Fi is vital so that children can keep up with school work
- It would be great to run Skype lessons
- There should be a teacher that children can talk to about school work

Visits to CHD services across England and Wales

- The availability of good facilities makes a huge difference to patient and family experience.
- Specific facilities for teenagers and young adults (clinical and social) could be better developed.
- Hospitals should provide a "how to find us/about us" booklet with where to park/eat/sleep in case you use a hospital in a different city – local knowledge is invaluable.
- It is expensive to live in the hospitals – it is expensive to eat in the hospitals.

Engagement and advisory groups

No specific comments

Clinical Reference Group

No specific comments

NHS England website – comments

No specific comments

ScHARR review

No specific comments

National Institute for Cardiovascular Outcomes Research review

No specific comments

Section D: Interdependencies

Children and Young People Events

No specific comments

Visits to CHD services across England and Wales

When done well, the relationship between maternity services, fetal and paediatric cardiology, fetal medicine, NICU and ACHD cardiology can make a real difference both to the care delivered and to patient experience.

Having services for children and adults all on one site was considered by some to improve efficiency and to promote the sharing of expertise. Having services in the same location is not enough – they must work together with patient needs at the centre. Too often this is not the case in practice. Communication between specialties is not uniformly good

Children with multiple morbidities need access to a range of specialties. It is not always possible to predict which other specialities will be needed. A lot of children require input not from just another specialist medical team but also from nurse specialists, therapists, dietician and so on. If a patient has to wait several days for an opinion that is not considered to be good care or a good service.

Paediatric and adult CHD services must work closely together. There can often be beneficial learning across the age groups. Links are also needed with acquired cardiologists, aortic and mitral surgeons.

Critical care (both childrens and adults)

Capacity in PICU and ITU is often the pinch point. This is mostly about nurses not about estates

Standards for ICU may not be in scope but its importance can’t be ignored

Clinician engagement and advisory group

One member suggested that the co-location standards had been set in a collegiate way 'to make sure that everyone can meet them' and there was not enough ambition.

Patient and Public Engagement and advisory group

Considered that co-location with antenatal care was important.

Noted that the delivery of the response times envisaged in the interdependency standards would need robust agreements between hospitals;

Provider engagement and advisory group

Expressed a concern that the CHD interdependency standards no longer followed DH guidance that was still used for other specialties.

Suggested that hospital activity data could be used to show how often other specialties were involved in the care of CHD patients, though it was also noted that the use of other services tended to be strongly influenced by their relative availability.

Noted that services can be next door to each other and not speak to each other – it is about having positive relationships.

Recommended that if triple co-location (ie. childrens CHD with other tertiary children's services, adult CHD with other adult tertiary services, children's CHD with adult CHD) is ideal, this is made clear in the standards.

Clinical Reference Group

Vascular surgery – it was noted that there are no paediatric vascular surgeons and also that in some hospitals other surgeons with suitable expertise are used instead, so recommended that the standard suggested should be amended to require paediatric experience and should say: 'vascular surgeon or other surgeon competent to undertake vascular/micro vascular repairs.'

Paediatric Neurosurgery – the group considered the original standard proposed prior to amendment by CAP was more appropriate i.e. 30 minutes to telephone advice / four hours for bedside care or transfer of care.

NHS England website – comments

No specific comments

ScHARR review

The review found limited evidence on the effects of proximity of other services on mortality or the impact of volume on non-mortality outcomes. One multicentre study compared care in a cardiac PICU with other ICU and found no effect on mortality except for STS-EACTS 3 level cases and primarily in patients undergoing atrioventricular repair and arterial switch operations suggesting that potential benefits may only be applicable to specific patient groups. A second study conducted a single centre before and after study evaluating the impact of introducing a cardiac cardiac PICU and found a reduction in mortality and a bigger effect in reducing morbidity (wound infection and chest re-exploration).

National Institute for Cardiovascular Outcomes Research review

No specific comments

Section E: Training and education

Children and Young People Events

- Parents reported finding that new SHOs and other trainees need to understand better that there is a person not just a procedure. They can be so focused on getting the procedure correct they don't think about listening to the young person and understanding their unexpected expertise
- History taking with new clinicians can be laborious - so standard forms and some kind of hand held records - filofax record - portable record - like the red book - electronic would be preferable

Visits to CHD services across England and Wales

No specific comments

Engagement and advisory groups

No specific comments

Clinical Reference Group

No specific comments

NHS England website – comments

No specific comments

ScHARR review

No specific comments

National Institute for Cardiovascular Outcomes Research review

No specific comments

Section F: Organisation, governance and audit

Children and Young People Events

- Patients should not have to pay for files/patient information to be transferred from one hospital to another
- There need to be stronger links between GPs, hospitals, workplaces and schools so everyone is on the same page regarding the care of the patient

Visits to CHD services across England and Wales

One centre had a highly developed internal data analysis system used to drive quality improvement.

Patient and public engagement and advisory group

It was suggested that an unacceptable number of operations were being cancelled at short notice, causing distress to patients and families. But other group members argued that there is always a risk, in any health system, that surgical capacity will be required to perform more clinically urgent work.

Clinical Reference Group

The CRG considered that while it would take some time to develop robust documented clinical governance frameworks (standard F1) this should be tackled urgently.

The CRG noted that standard F2 requires national reporting of adverse incidents but this does not exist at the moment, though the CRG agrees is extremely important. The methodology for reporting incidents regionally or nationally will need to be agreed and a national system for sharing serious incidents/learning established. The Network function in this regard is not clear.

The CRG discussed alternative models to Peer Review that were effective but potentially less resource intensive.

NHS England website – comments

No specific comments.

ScHARR review

No specific comments.

National Institute for Cardiovascular Outcomes Research review

No specific comments.

Section G: Research

Children and Young People Events

No specific comments.

Visits to CHD services across England and Wales

Many centres emphasised the importance of research and their association with academic institutions. Only some made an explicit link between this and driving improvements in services and outcomes for patients.

Engagement and advisory groups

No specific comments.

Clinical Reference Group

No specific comments.

NHS England website – comments

No specific comments.

ScHARR review

No specific comments.

National Institute for Cardiovascular Outcomes Research review

No specific comments.

Section H: Communication with patients

Children and Young People Events

Communication

- Doctors and nurses need to improve their communication skills
- Communication training should be provided throughout career – like medical training
- From the start they need to establish who they need to talk to – parents/patient
- The way doctors and nurses speak to people with disabilities needs to be improved
- Communication needs to be age specific – knowing your audience
- Get down to the child's level when they are on the bed /chair
- There needs to be more honest communication about the diagnosis
- There needs to be some kind of patient information summary page on the front of each file – so patients don't have to repeat themselves for every clinician
- Children (along with the above point) should have an 'I like/I don't like page that describes their preferences to improve patient experience
    - eg: If I am quiet and not making eye contact then I will be feeling anxious – please come back later
    - eg: I don't like to take my medicine with milk
    - eg: I don't like breakfast so please don't wake me up
- There needs to be a better process for handling delays/cancellations
- There needs to be a register/recording of cancelled operations – re: patients and clinicians
- It's massively beneficial when doctors explain things using diagrams/visual aids/models
- Communication between hospitals is poor and parents become the lynch pin as they are there 24/7 with the child
- Communication standard would be helpful - named consultant for the local area hospitals to refer to
- Life is controlled by fear, ward rounds need more respect for the parents - with personality, apologies and learning to say sorry.
- Patients and parents lose confidence in the staff, parents become neurotic - trust is low when things go wrong
- Need clarity about how to raise complaints or give feedback
- Names on the beds should include mums, dads and guardians – "my name is not "mum"".
- One consultant was intimidating at first but this is a style the family got used to and they have a very good relationship with the consultant now.
- Explain the diagnosis better
- Need a care plan that is common throughout the country

Information

- Need to offer more information to patients – especially regarding transition, consultations and how to live with congenital heart disease.
- Consultation letters that come through are too complicated – they need a glossary or to offer trusted websites for more information
- Patients are unaware to whom you can direct your questions at the Trust

- There needs to be a clear hierarchy within the hospital and a formal process for complaints
- There needs to be a national (or regional at least) register for people with congenital heart disease
- Misdiagnosis is a huge problem for many people with congenital heart disease – local hospitals/GPs need to be aware of symptoms and when necessary they need to refer patients to a specialist centre as soon as possible
- Communicate to patients that there are things they can do whilst in hospital – learning, reading, helping others
- Workshops for children on 'how the heart works' or something similar would be good so they know what's going on from a younger age and can take responsibility for their own care as well
- There needs to be more information given to young people about sex, drugs, alcohol, relationships, contraception, the possibility of children – this needs to be away from parents completely – many teenagers are uncomfortable speaking about any of these things in front of their parents and some don't even like the idea of speaking with their regular doctors

Pre-op and Post-op care

- There needs to be more support for patients post op – not only dealing with medical issues but also things like depression/anxiety – a psychologist would be good at this point
- Much more explanation about what to expect, post surgical, all about the procedures so people are prepared
- Even individual words matter - parents who are told to say 'Goodbye' to children going to surgery find this very distressing. "Goodnight" has been used as a replacement in some places

Out of hospital

- Follow on care very limited when leaving hospital
- Helping parents prepare for real life - preparation for life stages, schools, what do you say and how do you say it, thinking about making decisions about children and what they can do
- Working out how to get insurance for things like holidays

Visits to CHD services across England and Wales

The review team heard that children are individuals and this needs to be taken into consideration rather than applying a blanket rule – this particularly applies to people with special needs / learning difficulties

Choice

Patient choice was considered controversial by some. Some centres strongly affirmed the right of patients to make informed choices about where they would receive their care. Others favoured significantly constraining choice either because they considered that cardiologists knew where patients would get the best care and would refer accordingly or because constraining choice would make it possible to guarantee activity levels at surgical centres.

Inpatients

Where children have multiple medical needs parents are sometimes left to navigate specialties with no-one in overall control.

When parents don't attend ward rounds and information from the ward round is not passed on they start to feel that they are not being told everything

Communications between departments in a hospital and between clinicians and patients/parents need urgent and thorough improvement - it casts a shadow on good aspects of the care. The review team were told that it's important for the specialist centres to get communication right: – between departments – pharmacy, dietetics, other specialties, and between nursing staff.

This works well when a clinician takes the lead for an individual patient.

Outpatients

When parents see a new doctor they have to explain the child's history again. The clinician may disagree with the last consultation - unsettling for patients.

Facilities not always children / special needs friendly.

Multiple visits sometimes close together to see several specialties are not satisfactory.

It is very helpful when there is a liaison nurse at all clinic appointments

Patients and parents get a lot of complex information at outpatient clinics. It is helpful when everything written down (including medications) to share with health professionals

Discharge from hospital

Transition between hospital and community care is patchy and scary - going from very supported to completely 'on your own'. It helps when hospital and community services connect before discharge and the hospital uses whatever means are available to communicate with local services – eg., red book, email discharge letter to GP, TTO letter.

Arranging to meet community staff in the hospital before discharge – handover meeting with hospital and community staff and family – is also helpful.

Some parents and grandparents had been trained to do CPR so they felt comfortable taking baby home

Being discharged late in the day (whilst waiting for reviews, medications and so on) is bad.

Parents taking a small baby home with a congenital heart disease need a lot of support.

Poor communication between the specialist centre and local services causes unnecessary distress for patients. Arriving home with a new baby after several months in hospital means you have missed some basic things like: registering for child benefit, hearing tests, red book. Red book has a section for complex health needs – not always completed in the hospital – would be a good means of communication.

Parents rely on nurse specialists to liaise with the schools to help the teachers understand the child's condition and therefore what the child is able to do

Provider engagement and advisory group

It was noted that the Somerville Foundation do a survey with patients in adult centres to check that services are addressing expectations. A similar survey for children's services would be helpful.

Clinical Reference Group

Ensure where it refers to patients in the adult standards that carer is added: patient/carers

Top of page 3 – add to standard as follows:

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 patients *and carers* are advised of any appropriate choices available *(including transplantation)* as well as the reasons for any recommendations

H 10 – Should state "plain language" not plain English

NHS England website – comments

No specific comments

ScHARR review

No specific comments

National Institute for Cardiovascular Outcomes Research review

No specific comments

Section I: Transition

Children and Young People Events

The review team heard that in some cases experiences of transition had been unsatisfactory

- Not enough discussion – need someone to talk to who's been through it/has experience with CHD
- Not enough information given to patients about the transition period
- The Information offered comes in the form of a huge booklet which is daunting to read through
- Process so far poor - no conversations about transition, wasn't going to happen till 21 then suddenly with 2 weeks' notice child was moved without finally seeing the paediatric consultant all rather 'hush, hush'
- Very annoyed when their child was asked whether the old consultant didn't like him as had not said goodbye or anything.
- Poor experience with the cardiac liaison nurse.
- Transition needs to be dealt with better - helping them talk in grown up terms, understanding the technical language, designing the service for young adults.

The review team heard a number of ideas for improving transition

- Needs to be a slow introduction from one to the other – meet the staff first and get to know the building/ward in advance
- There can't be an age limit – each patient is different – some should move early, others late, others never.
- Parents know how it should be done with a slow set up to transition and with the old and new doctor preparing. They can see that things should be different from how they are. and understood that it should be different to how it was
- Needs to be a better guide to transition so that all parties know what to expect.
- With children & adults who have more complex needs there needs to be more support to know how to manage the system, social and health care gets very complicated.
- As children and young people get older they may need support to make their own decisions.
- Transition is difficult if you have other specific problems and managing this in transition is difficult.
- A lot more support is needed to enable transition and it needs to be tailored to the child's specific needs.
- Transition should depend on the individual rather than the age of the person
- Some considered it had been helpful to be at a hospital where the consultants look after adults as well as children
- In a unit offering both paediatric and adult services, parents appreciate the ability to retain the contacts with consultants and the clinicians that they have been involved with.
- Be good to think about how parental involvement is managed within transition
- Managing the transition and engagement with the parents as they get used to a different level of involvement in adult care and different facilities.
- Also needs to be a transition for parents - it's a big change for them as well

- Young adults need lifestyle advice, need to be able to talk to the cardiac liaison nurses about how manage a teen/young adult life about managing their condition.
- When everything is planned around school, and the consultant has explained the handover and families know how many meetings there will be with both teams and when they will go over to adult care, then transition is less worrying.

A lot of people talked about the 'in between' nature of being a teen or young adult and the need for a different approach and distinct facilities

- Transition was an issue for the young people 14 + - stuck between 2 worlds
- The review team heard about a young person who was admitted to an adult cardiac ward with mostly much older men, which was considered totally inappropriate for a young person of 18 who looks no more than 11.
- There should be a transition/young person's ward
- There is a need for something in the middle - teenage services.
- Need help finding further education opportunities, limbo of being over 16 in the educational system.
- Expectations of involvement are high from parents but older teens and young adults often have different ideas.
- Facilities need improving for young adults - like staying in the familiar surroundings in paeds but paeds not set up to deal with large bodies, having quiet spaces away from babies etc
- An older teen in paeds is an oddity.

Some people told us about the particular difficulties of transition for young people with learning difficulties

- For families of young people with learning difficulties transition from paediatric care to adult care was expected to be very difficult as the things they enjoy were more paediatric based

Visits to CHD services across England and Wales

Transition was one of the most talked about subjects. Many centres had made efforts to improve the management of transition. It seems likely that too many patients are still lost to follow up at this stage.

Patients and their families often found the prospect of transition daunting and the experience unsatisfactory. This is only partly to do with the management of transition. Often the problem is the nature of adult services which are organised very differently to children's services, the experience of which can come as a shock.

Transition is especially difficult for patients with learning difficulties. A more flexible approach is needed for these patients and better support for them and their families are needed in adult services.

The review team were told that the CHD standards need to connect with what is happening in transition nationally

Joint working of adult and paediatric teams helps smooth transition for patients, and has the advantage that the clinicians will already know the patient and that the plans will have been developed for care beyond transition.

The review team heard from patients that their relationship with their consultant and nursing staff is very important so transition requires time to build up the trust with new people.

A number of things can help young people transition well:

- Dedicated transition nurses
- Young adult clinics
- Transition days
- To be able to speak to someone who has already gone through it if you want (buddy system)
- Meeting the new consultant and ward staff before transition
- Teenage and young adult wards

Those who had been through transition urged that children and young people were told early about their condition and not to wait until transition as this was an added stress at that time.

Engagement and advisory groups

No specific comments

Clinical Reference Group

Standards need to include further wording regarding flexibility for older children e.g. those with learning disabilities in the paediatric setting to ensure appropriately timed transition.

NHS England website – comments

No specific comments

ScHARR review

No specific comments

National Institute for Cardiovascular Outcomes Research review

No specific comments

Section J: Pregnancy and contraception

Children and Young People Events

No specific comments

Visits to CHD services across England and Wales

As care of patients with CHD has improved, pregnancy is becoming more commonplace, emphasising the importance of a close relationship between maternity and ACHD services, and the importance of decisions about place of delivery and the levels of CHD cardiology support available.

Clinician engagement and advisory group

A sub-group made a number of editorial improvements to the proposed standards:

- The first section should be re-titled ‘Family Planning Advice’
- The standards for adult services use the word co-located to mean ‘Women should be cared for at an obstetric unit at or close to (within 30 minutes) the network specialist surgical centre’. This should be spelled out in the standard.
- Standard J11 refers to a maternal medicine specialist. An obstetrician with a specialist interest in maternal medicine would also be an alternative.
- Standard J12 should also mention the obstetrician and midwife as members of the MDT.

Clinical Reference Group

No specific comments

NHS England website – comments

No specific comments

ScHARR review

No specific comments

National Institute for Cardiovascular Outcomes Research review

No specific comments

Section K: Fetal diagnosis

Children and Young People Events

One parent said that she was glad that she didn't know until birth – she didn't want to be made to make decisions.

Visits to CHD services across England and Wales

Improving rates of fetal diagnosis

Rates of fetal diagnosis vary considerably.

National standards for screening programme to look for CHD at 18-20 weeks were only introduced in 2010. Many places have not yet fully implemented 2010 standards. Some units are struggling just to offer the 20 week scan consistently at all.

New standards are expected next year that will improve detection rates. But standards alone will not solve things. There also needs to be:

- Training for sonographers:
    - There needs to be training and support for sonographers.
    - Sonographer training is underfunded.
    - Can't just do it once - needs regular top up.
    - Feedback on success rates can be helpful
- National anomaly register:
    - Need a national register to know how we're doing.
    - Able to audit performance of units and provide targeted training with scarce resource

Wales has achieved higher levels than many parts of England and there may be important learning.

Ultrasound scanning is packaged within the obstetric tariff. Incentives are not aligned to support improved practice.

The fetal network is really important and needs to be closely linked. A number of services emphasised the importance of close working with in house and neighbouring local fetal medicine clinicians emphasised

CHD detection is a good marker for the overall quality of the ultrasound service.

Diagnosis and support before birth

A lot of parents spoke about their experiences of finding out that their children had congenital heart disease. Parents were sometimes informed as a result of antenatal screening and sometimes the diagnosis was made after the child’s birth.

- The review team heard that it was important that enough time and support were given for decision making and planning for delivery.
- The wait between 20 week scan where an anomaly is suspected and specialist scan is a hard time

- The scariest time is when you're pregnant – parents support each other because they know how other people feel
- The review team heard from one parent whose diagnosis changed after more sophisticated tests she was told it might be one thing and she could terminate the pregnancy, then at the next scan there was another diagnosis
- Specialist nurses are very important at this time – easy access is very important. Where detection was in local fetal unit there was not always access to the specialist nurse until after the birth.
- Parents liked the opportunity to speak to other parents and see other children with the same diagnosis
- Parents agreed that they liked to be able to speak to a variety of people including hospital staff, charities and other parents to be able to get as much information as possible.

The review team also spoke to people whose diagnosis was missed antenatally who said that it is not good to miss the diagnosis antenatally. Antenatal detection offers parents the opportunity to speak to relevant people in the health service and to prepare for the birth, to visit the neonatal and paediatric critical care areas and meet the surgeons before birth

Neonatal detection

Experiences when the diagnosis was made after birth were distressing for parents. Where mothers suspected their baby was "not right" they were made to feel neurotic and "fobbed off" in encounters with the health service before the condition is detected. Some of these parents reported that they were told that the symptoms they were describing were characteristics of a normal baby.

This experience was not replicated in the specialist centres where their concerns were taken seriously and acted upon quickly.

Screening for women with CHD

The review team heard that one stop clinics for the high risk women works well

Engagement and advisory groups

No specific comments

Clinical Reference Group

Current standards require that women with a suspected or confirmed fetal cardiac anomaly are seen by a fetal cardiology specialist within five working days of referral and if possible within two days. PPE reps advised that five days is too long from a patient perspective. Similarly having to wait 48 hours for contact with a specialist nurse feels far too long and every effort should be made to limit the wait.

The group also agreed that the ideal would be for women to be able to see both the fetal medicine and fetal cardiology specialists on the same day (while recognising that this may sometimes be difficult to organise and should not be allowed to introduce delay into the process).

NHS England website – comments

No specific comments

ScHARR review

No specific comments

National Institute for Cardiovascular Outcomes Research review

No specific comments

Section L: Palliative care and bereavement

Children and Young People Events

One mother expressed frustration that during the care of her daughter the term palliative care was being used and no one explained what it meant - 'we're not stupid people - but it wasn't a word we were used to. We asked a nurse what it meant as we had heard it several times. The nurse went quiet and then said she would get a 'doctor'.

Visits to CHD services across England and Wales

No specific comments

Provider engagement and advisory groups

It was agreed that units could start using these standards immediately and that this could give useful feedback and on how they work in practice.

It was noted that the Leeds review and local follow up has produced some good work on culture and communications. The families are keen that lessons are learned and that this work informs future thinking. The offer was made to share this with the group.

Clinical Reference Group

No specific comments

NHS England website – comments

No specific comments

ScHARR review

No specific comments

National Institute for Cardiovascular Outcomes Research review

No specific comments

Section M: Dental

Children and Young People Events

No specific comments

Visits to CHD services across England and Wales

The development of dental standards was welcomed.

Engagement and advisory groups

No specific comments

Clinical Reference Group

No specific comments

NHS England website – comments

No specific comments

ScHARR review

No specific comments

National Institute for Cardiovascular Outcomes Research review

No specific comments

Other issues

PICU

- Inconsistent nurse staffing means that parents feel the need:
    - to be at every handover
    - to tell the nurse about their child at hand over
    - not leave their child – days are very long and there is no chance of doing anything normal like washing their clothes
- Maternity / lactation care is missed as the focus is on the baby.
- The mother would like to be at baby's bedside (particularly difficult in Children's hospitals not on the same site)
- Inconsistent approach to parent involvement in caring for their child – some fully involved in feeds, nappy changing, bathing and others not, therefore are unprepared for the lower staffing levels on the ward
- Step down from critical care wards can be difficult - parents not always informed of or prepared for the ward routine on arrival eg., expectations are they have to provide more hands on care and either don't know that they have to do it, or have not been involved on the PICU and therefore don't know how to do it
- Parents can be up all night and need somewhere to catch a bit of sleep in the day without leaving the hospital

Some things that help are:

- Getting parents involved with baby's care as early as possible
- Communication following ward rounds where parents are not present

Inherited conditions

- The review team were told that inherited conditions cannot be ignored as they use the same resources as CHD.

Care for adults with CHD

- Adult CHD will be enormous in the next 30 years. Must build a network approach because just can't handle it all within a single centre. The need is not for more surgical centres as the big bulk of work is OP and imaging. That needs to be excellent across the network.
- ACHD intervention numbers seem to be steady but ACHD surgery has risen steadily and it would be even higher if there was enough ITU capacity to bring the patients in. 60% of operations are re-dos, many have already had multiple operations. Even those that are not re-dos are not easy because after a life time of abnormal circulation it will be harder to repair than it would have been if done as a child.
- Interventions however need specialist skills and shouldn't be dispersed.
- Follow up probably manages to see 95% of complex patients but there are probably hundreds of less complex patients not being seen regularly.

- Expanded team as part of a strategic plan to cope with rising demand.
- Nurse led OP clinics
- Challenges are: Geography, IT, shared records, growth
- Embedding ACHD service within adult CV services gives open access to other adult cardiology as patients get older for arrhythmia, ischaemia etc.
- Patients find adult services difficult partly because adult services have gaps or the full range of services they need are not all available in one site.

Support groups

Where there was no specific support group associated with a unit, parents felt the lack keenly.

- There needs to be better promotion of support groups (a lot of parents and families weren't even t aware of the groups that are available at their trusts)
- It would be good if doctors recommended support groups to families – all the options or specific to the family's needs
- More away days and in hospital activity days should be available to patients and siblings
- It would be great if there was a 'Buddy Scheme' where you could meet older people who have gone through the same or similar things to you – volunteering
- There needs to be stronger connections between charities/support groups and the wards.
- Support networks essential for knowledge and support
- The whole experience can be very isolating
- Other young people with their parents (particularly those who had had diagnosis later in life 10 +) wanted to connect with young people like them that had been through the process of before
- Parents also wanted to connect - it appears that parents with very small children are instantly linked to the charity and support circuit - less so with teenagers
- Would be helpful to have more of a support network.
- It would be good if appointments were grouped by age so that you can meet people of a similar age while at hospital

Continuity of care

- Having the same consultant/surgeon is very important
- Getting to know and being known by hospital staff makes hospital life easier
- Dosing advice is different at local hospitals – there needs to be continuity in all areas
- When doctors give different views and opinions

Life

Many of the children and young people that we met stressed that for them, the most important thing whilst in hospital is maintaining some level of normality. They wanted us to know that even though they have congenital heart disease, they have to stay in hospital and they need to have different procedures and operations throughout their lifetime, all they really want is what everyone wants, to enjoy the life they have.

So, where possible, the hospital/NHS/staff should try and facilitate that through:

- Eating with your family

- Exercising/playing sports
- Seeing/making friends
- Playing/chatting
- Learning – school, studies, exams
- Having boyfriends/girlfriends
- Watching television/listening to the radio
- Having access to social media/internet/online resources
- Home comforts

Ethnicity

NICOR's analysis of data from 13 paediatric surgery centres (12,186 episodes of care in paediatric heart surgery during April 2009 to March 2012 inclusive) showed that Asian ethnicity is associated with poorer outcomes (30 day post-operative mortality). This is a statistically significant finding.

Other categories of ethnicity (Black, Chinese and Other) did not have statistically different risk from the Caucasian category.

Other factors beyond simple ethnicity may play a factor in this finding, such as deprivation and a higher incidence of consanguinity which is associated with more complex congenital heart disease and therefore less good outcomes.

Paper NHS071414

BOARD PAPER - NHS ENGLAND

Title: Update from the Board Task and Finish Group on the new congenital heart disease review.
From: Rosamond Roughton, Interim National Director: Commissioning Strategy
Purpose of paper: • To provide an update on the work of the Board Task and Finish Group for the new congenital heart disease review.
Actions required by the Board: The Board is asked to: • note the key issues; and • note the progress of the new congenital heart disease review to date ("One year on" - Annex C).

Update from the Board Task and Finish Group on the new congenital heart disease review

Background

1. The purpose of this paper is to provide an update to the NHS England Board on the progress of the new congenital heart disease (CHD) review since the last update to the Board on 24 January 2014.

Board task and finish group

2. The purpose of the Board task and finish group is to:

- provide strategic direction to the new congenital heart disease review on behalf of the NHS England Board;
- provide assurance to the Board that the work is aligned with the stated aims of the review and NHS England's other strategic priorities;
- advise the Board on particular issues in relation to the review and also on any decisions which the Board may be required to make; and
- where required, commission work and / or request further information from the review's programme board in order for the group to fulfil its function.

3. Since the paper was written for the NHS England Board meeting on 24 January 2014, the Board Task and Finish Group (the "Group") met on 7 January 2014 and 15 April 2014. The minutes of both meetings are attached as Annex A and Annex B to this paper.

Key issues

4. When the Group met on 15 April 2014, members noted that the best case scenario for public consultation on the new set of standards for the whole lifetime pathway of care was July 2014. Since that meeting and following further work, the new CHD review team have concluded that the new timeline for the start of public consultation is now September 2014. Though the Group has not met again at the time of writing this paper, members have received an update on the revised timeline and will discuss this in more detail at their next meeting on 23 June 2014.

Recommendations

5. The Board is asked to note the Task and Finish Group's report on progress of the new congenital heart disease review and in particular the paper "One Year On" at Annex C.

John Holden
Director of system policy
July 2014

Minutes of the Board Task and Finish Group held on 7 January 2014

Present:

- Mr Ed Smith, Non-Executive Director (Deputy Chair)
- Ms Margaret Casely-Hayford, Non-Executive Director
- Mr Bill McCarthy, National Director: Policy
- Professor Sir Michael Rawlins, Chair of the Clinical Advisory Panel

Apologies:

- Professor Sir Malcolm Grant (Chair)
- Professor Sir Bruce Keogh, National Medical Director

In attendance:

- Mr John Holden, Director of System Policy
- Mr Michael Wilson, Programme Director
- Penny Allsop (Secretariat)

Item	Agenda Item
1	**Welcome and Apologies**
	The Deputy Chair welcomed everyone to the meeting and the apologies were noted.
2	**Note of the last meeting**
	The notes of the last meeting were agreed. The Group recognised the importance of transparency, and emphasised the need for papers and notes of its meetings to be made public.
3	**Action log**
	Actions in progress were considered. Action 5: The Group recognised the importance of distinguishing between evidence and judgment and was encouraged that the new review team are commissioning an independent evidence review. On this basis this action was closed. Action 7: The Group recognised the importance of this piece of work but understood that it cannot be undertaken at this stage. It was agreed that the action will be closed on this log, but will be tracked elsewhere so that it is addressed at the appropriate time. Action 8: This action related to the work as originally envisaged. The new review is focused on continual engagement and so the Group agreed to close this action. Actions 15 and 19: The Local Government Association is keen to be kept up to date about the new review, but does not consider that it would be feasible to set up a national overview and scrutiny committee. The action was closed. Action 16. See item 4. Action closed. Action 17: The review team undertook to produce guidance on completing the agreed conflict of interest declarations

Item	Agenda Item
ACTION	**Update action log as per discussion.**
ACTION	**Produce guidance on completing the agreed conflict of interest declaration form.**
4	**DRAFT Policy for managing conflicts of interest**
	Action 16: The draft policy for managing conflict of interest was agreed, subject to there being a clear reference in the policy to the need to publish a register of interests.
ACTION	**A clear reference to be added to the policy for managing conflicts of interest regarding the publication of the register of interests.**
5	**Programme Stocktake**
	The Group received a presentation on progress to date (slides attached here). The Group acknowledged the size of the task and also the history involved. Specifically, the Group: • supported the focus on standards and recognised the important contributions of the Standards Group and the Clinical Implementation Advisory Group; • was pleased to hear that the new review team has commissioned an analysis of future demand of CHD services up to 2025, but recognised that there may be some limitations due to the way in which CHD is coded, particularly in adults; and • recognised the importance of the work on antenatal and neonatal detection rates. Recognising that the current focus of work is on standards and not the form of services, it was noted that it would be important to speak to Monitor in advance of any scenario planning/modelling and that it would be critical to engage with the Competition and Markets Authority. The Group discussed the importance of recruitment and retention of surgeons and asked the new review team as a matter of urgency to speak to the Royal College of Surgeons about training. The Group agreed the timetable as set out in the presentation, but urged the new review team to look at what work could be done in parallel, including scenario planning on what form services could take, without prejudice to any future public consultation. The Group asked the new review team to set out a more complete timetable as quickly as possible.
ACTION	**Engage with both Monitor and the Competition and Markets Authority in advance of any scenario planning / modelling.**
ACTION	**The new review team to speak to the Royal College of Surgeons about training, as a matter of urgency.**
ACTION	**The new review team to look at what work could be done in parallel, including scenario planning on what form services could take, without prejudice to any future public consultation.**

Item	Agenda Item
ACTION	**The new review team to set out a more complete timetable as quickly as possible.**
6	**Update from the Programme Board**
	Bill McCarthy noted that he has undertaken to ensure that the new review is adequately resourced. The Group supported this as a high priority programme for NHS England.
7	**Update from the Clinical Advisory Panel**
	Professor Sir Michael Rawlins (Chair of the Clinical Advisory Panel) provided a verbal update on the second meeting of the review's Clinical Advisory Panel (18 December 2013). The Clinical Advisory Panel (CAP) comprises a range of clinicians from within and outside the CHD community. The meetings to date have been a success and the members of the CAP are getting to grips with the issues. The Group recognised the importance of CAP and suggested that Professor Sir Malcolm Grant might be invited to a future meeting.
ACTION	**Professor Sir Malcolm Grant to be invited to a future meeting of the Clinical Advisory Panel.**
8	**Highlight report**
	The report was accepted.
9	**Any other business**
	There was no other business
Date of next meeting	Wednesday 12 February 2014, 10:30am – 12pm, Maple Street, LONDON ***[THIS MEETING WAS SUBSEQUENTLY CANCELLED]***

Minutes of the Board Task and Finish Group held on 15 April 2014

Present:

- Professor Sir Malcolm Grant (Chair)
- Professor Sir Bruce Keogh, National Medical Director
- Mr Ed Smith, Non-Executive Director
- Ms Margaret Casely-Hayford, Non-Executive Director
- Mr Bill McCarthy, National Director: Policy
- Professor Sir Michael Rawlins, Chair of the Clinical Advisory Panel

In attendance:

- Mr John Holden, Director of System Policy
- Lauren Phillips (Secretariat)

Item	Agenda Item
1	**Welcome and Apologies**
	The Chair welcomed everyone to the meeting.
2	**Note of the last meeting**
	The notes of the last meeting were agreed (7 January 2014).
3	**Declarations of Interest**
	The Chair advised the Board Task and Finish Group that at the time that the National Institute for Cardiovascular Outcomes Research (NICOR) was established he was the President and Provost of University College London (UCL). Professor Sir Bruce Keogh advised the Board Task and Finish Group that at the time NICOR was established he was the Professor of Cardiac surgery at UCL.
4	**Action log**
	All actions in progress were considered. Professor Sir Malcolm Grant confirmed that he would be attending part of the next meeting of the Clinical Advisory Panel on 18 June 2014. (Action 28)
5	**Update and Assurance Process**
	John Holden pointed out that though the Board Task and Finish Group had not met since 7 January 2014, as the meeting scheduled for February 2014 had been cancelled, John had circulated a note to members of the Group in the interim period to update them on progress. John introduced the item “Update and Assurance Process” which described

Item	Agenda Item
	the review's work and proposed approach for the key NHS England assurance groups. John explained that this is the slide set / paper that would be considered at the both the Women and Children's Programme of Care Board meeting on 29 April 2014 and the Clinical Priorities Advisory Group (CPAG) meeting on 30 April 2014. John drew the Task and Finish Group's attention to the following slides: **Slide 8: Engagement and Advisory Groups** The Board Task and Finish Group discussed what could be interpreted by "interdependencies", for example integrated, co-located, networked and agreed it was important to be really clear about what the review meant when it used the term. John confirmed that to date there had been a lot of consensus from the engagement and advisory groups about the importance of the standards based approach. He also explained that the review was now operating on a more stable basis than the situation which had been inherited. The Board Task and Finish Group noted that the large amount of engagement with those groups had put the review into a good position to move onto the next phase. John explained that through discussions with Local Government, NHS England's patient voice team and representative faith groups, there had been some further suggestions for engagement with people from Black, Asian and Minority Ethnic (BAME) groups who are disproportionately affected by congenital heart disease. The Board Task and Finish Group noted that further engagement work was required was required for BAME groups. **Slides 10, 11 and 12: Review methodology, evidence and assessing capacity** John explained that the review's intention was to develop a single set of standards for the whole pathway of care which sets out the ideal. Alongside that the team is currently carrying out analytical work to understand current and future demand and the implications for capacity requirements. This will be used with the other evidence, for example the work with NICOR, intelligence from the Trust Visits and the literature review. The Board Task and Finish Group requested that further detail and options relating to the recommendations on function, form and capacity of future services and the commissioning model should be brought back to a future meeting for a more detailed discussion. **Slides 29 and 30: Consultation timeline** John explained that the current best-case scenario is that the 12 week full public consultation could begin in July 2014.

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	John noted that it was impossible to know how many responses to consultation would be received, though noted that the *Safe and Sustainable* consultation received approx. 75,000. As such, the current timeline had allowed 3 months for the analysis of any consultation responses, to amend the standards / specifications and, if necessary go back through the NHS England specialised commissioning governance. John explained that under the current arrangements, 6 months notice was to be given to providers which would mean that the new specification would not be commissioned until 2015/16. The Board Task and Finish Group acknowledged that this did not necessarily prevent NHS England encouraging providers to implement some changes and improvement to services during the notice period. **Slide 31: Proposed pre-consultation engagement activity** The Board Task and Finish Group noted with approval the proposed pre-consultation engagement activity. **Slides 34 – 40: (CPAG) assurance process** John explained that the review team intended to attend a meeting of CPAG at the end of April 2014 to provide a briefing on the work to date, clarify their assurance requirements and explain and test the review's proposed approach. John explained that slides 35 – 40 were framed around the standard CPAG template (those assurances the review must satisfy CPAG on) as follows: 1. **Governance and decision-making** CPAG requires assurance that the review had been though the appropriate governance (both the review's own 'governance and also the NHS England specialised commissioning governance). 2. **Stakeholder testing** CPAG requires assurance that the review's stakeholders are familiar with the standards and that they believe a consultation is necessary. 3. **Financial impact** (see below) 4. **Equality analysis** CPAG requires a statement outlining the review's approach to equalities. Following discussion, the Board Task and Finish Group confirmed that it supported the review's proposed approach to assuring the CPAG on governance and decision-making, stakeholder testing and equality analysis. John drew the Board Task and Finish Group's attention to the work in relation to the **financial impact** (slides 38 and 39) and made the following points: • The review is consulting on ideal and aspirational standards. • It is unlikely that any current provider will be able to satisfy every

Item	Agenda Item
	single part of the new standards. • Affordability, value for money and deliverability are important considerations, however a full / detailed financial impact analysis which takes into account potential changes to delivery of service, cannot be completed at this stage. The intention however is to provide some high level analysis now about the potential impact of this work, including a baseline of current spend and likely future cost drivers. The Board Task and Finish Group discussed and agreed that ideally the high-level financial impact analysis should set out: • the best sense of the overall financial envelope at the present; • those standards which, because they are extending the scope, will inevitably cost more (for example pre-natal screening); and • those standards which are about improvements to existing services and therefore may potentially incur additional cost or even create reductions in cost due to better organisation or smarter processes. Standards must describe a high quality service but this did not of itself guarantee a "blank cheque" for every possible change. The Board Task and Finish Group discussed the relationship between costs and tariff and John confirmed that the current time lag between cost collection and tariff change is 3 years. The Board Task and Finish Group agreed that a meeting should be scheduled between Malcolm Grant, Bill McCarthy and John Holden to further discuss the approach to assurance. The Task and Finish Group agreed that it was important to provide a line of sight to the NHS England Board via an update to the meeting on 3 July 2014, including all the progress to date and current expected timescales for the review.
ACTION	**Further engagement required with Black, Asian and Minority Ethic (BAME) groups.**
ACTION	**Discussion to be scheduled at a future meeting of the Board Task and Finish Group regarding the recommendations of function, form and capacity of future services and the commissioning model.**
ACTION	**Malcom Grant, Bill McCarthy and John Holden to meet to discuss assurance requirements.**
ACTION	**An update to be provided to the NHS England Board in July 2014, detailing the progress to date.**
6	**Feedback from the engagement and advisory groups**
	The feedback from the review's engagement and advisory groups was noted.

Item	Agenda Item
7	**Update from the Programme Board**
	Bill McCarthy (Chair of the review's Programme Board) provided a verbal update on the last meeting of the review's Programme Board. Bill confirmed that following the recent business planning round, further financial resourcing had been secured for the new CHD review programme for 2014/15. Bill noted that in response to requests from the review's Patient and Public Group for a specific session on safety concerns, John Stewart (NHS England), Ted Baker (Care Quality Commission) and Nigel Acheson (NHS England) had attended the last meeting of the Patient and Public Group on 27 March 2014 to discuss this. The Board Task and Finish Group noted that the next meeting of the review's Programme Board was scheduled for 16 April 2014.
8	**Update from the Clinical Advisory Panel**
	Professor Sir Michael Rawlins (Chair of the review's Clinical Advisory Panel) provided a verbal update on the third meeting of the review's Clinical Advisory Panel (31 March 2014). This meeting had focussed on the latest iteration of the draft standards and the associated "knotty issues". The Board Task and Finish Group noted that the next meeting of the review's Clinical Advisory Panel was scheduled for 18 June 2014.
9	**Highlight report**
	The Board Task and Finish Group noted the highlight report and requested sight of the risk mitigation associated with the key risks on the highlight report.
ACTION	**Latest iteration of review's Programme Board risk register to be circulated to the Board Task and Finish Group.**
10	**Any other business**
	There was no other business.
Date of next meeting	TBC

One Year On: progress of the new congenital heart disease (CHD) review

Executive summary

The review has made progress against all of its objectives. In particular, the development of a single coherent set of standards provides the platform for commissioning an excellent service, and will help determine whether providers are able to meet our requirements. But commissioning an excellent service is not just about the location of surgical units. Our work to date will enable us to describe expectations of the service for the whole lifetime pathway of care; to set out a detailed understanding of current and future demand and the drivers which affect it; to make information readily available on the quality of service; and to improve outcomes by ensuring earlier and better diagnosis.

We had hoped to be consulting on standards by this point, but we have more work to do. The review has managed a constant tension between acting with enough pace to mitigate the risks of "limbo" (whereby investment is withheld, recruitment is difficult, service developments are stalled) versus taking enough time to give all stakeholders the opportunity to shape the future. "Safe and Sustainable" took four years and had a net cost of £6m, but in the end the conclusions were not implemented because of concerns about the process. We are mindful of this and - despite the clamour for a quick solution – have resisted the temptation to take short-cuts in our process, our engagement or in our own internal assurance.

The next steps in this work are to consult on and agree the standards and specification, complete the analytical work, and develop the functions & form and commissioning & change model. At that point we will be able to make recommendations to the NHS England Board. We expect that by the end of the 2014/15 financial year this will cease to be a dedicated "task and finish" project, and implementation will be mainstreamed as part of NHS England's wider commissioning of specialised services.

Introduction – an "implementable solution within a year"

In June 2013 the Secretary of State announced that he accepted the recommendations of the Independent Reconfiguration Panel (IRP), and was therefore setting aside the outcome of the "Safe and Sustainable" review of children's congenital heart surgery. The work had been led by a committee, acting on behalf of all primary care trusts, which no longer existed. He therefore asked NHS England, as the organisation now responsible for commissioning these services, to undertake a new review, learning the lessons of experience to date, including Judicial Review findings and the report of the IRP.

The Board of NHS England, meeting in public in July 2013, discussed the issue (see link to paper). It was recognised that the new review was a vital opportunity to secure lasting improvements for some of the most vulnerable NHS patients. Reviewing such a high profile and sensitive service would be seen as a test of the way in which the emergent NHS England conducted itself, and our commitment to patient and public engagement, clinical leadership in every aspect of our work, and evidence-based decision making. The

Board recognised the difficulties of conducting the review in a climate where trust had broken down and relationships needed to be rebuilt, but was nonetheless concerned about the risks to the congenital heart service due to continuing uncertainty and "limbo". Therefore the Board set an ambition that there should be an "implementable solution within a year". We have now reached the one year anniversary of the Board's challenge, and this paper describes the progress that has been made and what remains to be done.

Overall approach – six objectives

Stakeholders – especially patient groups and clinicians - told us from the start that to have any kind of constructive dialogue, we should "take closure off the table". In other words, we must find a way to discuss the issues without pre-supposing that some units must cease to provide services. Many told us that the threat of closure had led to an adversarial approach during the previous review, both in terms of engagement in the review, and even in the way that surgical centres behaved towards each other, to the detriment of patients. More positively, many stakeholders told us that the key to a successful outcome would be to build consensus around a set of standards, but that the standards should not be "fudged" – i.e. they should objectively describe the optimal model of care, without regard for the current service arrangements.

At the same time, it became apparent to us that we needed a comprehensive understanding of historic activity, and the current and anticipated volume of services. Alongside a new set of standards for the whole pathway care - from fetal through children and adults - this would help us to understand the capacity requirements and the cost implications. Analysis of the historic data could help us to identify any relationship between the way services are organised and the outcomes for patients. In turn, the standards and capacity requirements would allow us to start to describe the functions and form of a congenital heart disease service for all patients in England, including issues not dealt with by the standards like access and geographical distribution. Taking all these points together, we were satisfied that we could legitimately "take closure off the table". We considered that in the absence of compelling, prima facie evidence that closing units was the only way to secure high quality services for the future, that the new review should have an open mind, develop standards of care and follow the evidence as it emerged. Once we had agreed the standards, examined the data and other evidence, and considered functions & form, only then could we have a meaningful dialogue with potential providers about how to meet our requirements, and whether any reconfiguration would be necessary.

NHS England is a commissioning organisation and this strategic review is the front end of a commissioning process – defining the need, and considering the options. Provider organisations told us they wanted to understand and to help shape the approach to commissioning and change – any reconfiguration resulting from the review would affect all those involved and have implications for workforce, teaching, and of course for interdependent clinical services. Even if reconfiguration were not required, it was highly likely that providers would need to make changes to be compliant, and to network effectively.

Finally, patient and public stakeholders, strongly endorsed by clinicians, told us they wanted better real time information to understand how the service was faring, to provide a quality safeguard and to inform patient choice. They argued that current data was overly-

focused on one metric, for "30 day mortality" (i.e. post-operative survival), which showed that in the past decade (since the Kennedy Inquiry at Bristol in 2000) surgical outcomes had levelled up significantly so that across England these outcomes were now world-leading. But mortality is not the only indicator of good care, and does not reveal enough about other outcomes. They also told us that a really good service does not begin at the point that surgery takes place; it begins with early and accurate detection and diagnosis, through improved rates of antenatal detection, supplemented by improved neonatal detection.

In January 2014 our Board was asked to consider and agree a set of six objectives for the review, which captured all of these different strands of work (see link to paper). Progress against the six objectives would be the measure by which we could demonstrate progress against the Board's ambition for an "implementable solution".

The following six objectives were agreed:

> **Objective 1:** to develop standards to give improved outcomes, minimal variation and improved patient experience for people with congenital heart disease;
>
> **Objective 2:** to analyse the demand for specialist inpatient congenital heart disease care, now and in the future;
>
> **Objective 3:** to make recommendations about the function, form and capacity of services needed to meet that demand and meet quality standards, taking account of accessibility and health impact;
>
> **Objective 4:** to make recommendations on the commissioning and change management approach including an assessment of workforce and training needs;
>
> **Objective 5:** to establish a system for the provision of information about the performance of congenital heart disease services to inform the commissioning of these services and patient choice; and
>
> **Objective 6:** to improve antenatal and neonatal detection rates.

Range of services covered by the review

Our Board had already decided, in July 2013, that the new review should encompass both adults and children's services, recognising that in practice they were inextricably linked, through shared staff including surgeons. Stakeholders – especially clinicians - told us this "child and adult" approach was essential, but it was a significant departure from "Safe and Sustainable", which had been asked to look at children's services only. This meant that without doing anything else, our work was already much broader in scope than the previous review. And there were more detailed questions of scope to be answered, for example whether and how to take account of interdependencies between services. It was important to get the balance right before asking the Clinical Advisory Panel (Chaired by Professor Sir Michael Rawlins) to consider and advise on the review's scope, because too broad a scope would make the review undeliverable; too narrow might mean that important dependencies were overlooked. Therefore we consulted our stakeholders for comment, and through this process we formally agreed the scope of our work on standards.

Similarly, one of the most powerful messages we heard from our early meetings with patient groups was that the CHD service sometimes failed patients and families at their lowest ebb, when there was a poor outcome, or during palliative care, or following bereavement. This was about treating people with compassion and dignity, rather than a question of the technical skills of the clinicians involved. So, almost from our first meeting with patients, we decided that there should be a dedicated chapter in our new standards to deal with palliative care and bereavement. And throughout the standards there are references to the importance of open, honest communication. Finally, we have been clear that NHS England's focus is on commissioning services for the population normally resident in England. However, congenital heart surgery for patients resident in Wales invariably takes place in England, and so we have been factoring this in to our work, and considering where appropriate the relatively smaller cross-border flows with the other devolved administrations.

Openness, engagement and decision making

We began our work in June 2013 by meeting the national patients' charities, to get an overall perspective on the challenge. This immediately triggered concerns amongst local charities and patient support groups that their views were not being sought and would not be respected by the national charities. It was clear that relationships between some of the charities and patient groups had been left strained following the "Safe and Sustainable" process.

Our early meetings with stakeholders were focused on giving everyone a chance to say what they felt about the recent history and their hopes for the future. This was essential to the constructive working relationship we have now, based on a programme of regular engagement events with three different groups each chaired by an independent representative of the group concerned. (Patient and Public Group chaired by Professor Peter Weissberg, Medical Director at the British Heart Foundation; Clinicians' Group chaired by Professor Deirdre Kelly, Consultant Paediatric Hepatologist at Birmingham Children's Hospital NHS Foundation Trust; and Provider Group chaired by Chris Hopson, Chief Executive of the Foundation Trust Network). We have sought to involve every constituency in these groups – every charity and patient support group, clinicians and managers from every hospital delivering specialist congenital heart care, and every linked speciality. We make sure that we offer all three groups a broadly similar programme so that there is consistent and comprehensive sharing of information, but we also adapt the agendas to reflect whatever those groups wish to discuss. Every meeting has its own character. All are robust in their debates and appropriately challenging to NHS England. They never allow us to forget that these are real issues that need to be resolved.

For local government and Healthwatch representatives we have held a national plenary meeting (in Birmingham) and subsequently an update via WebEx; we have also attended Overview and Scrutiny Committee hearings around the country to explain the work of the review. We have attended two all-party parliamentary briefing sessions, and supported Department of Health ministers to answer numerous Parliamentary Questions. We have also attended various professional conferences – for example the national association of critical care managers. Over the Easter School Holidays in April 2014 we ran nine regional events around the country, specifically designed to hear from children and young people. Over 100 young people and their families told us their stories. And we have just completed a series of visits to every specialist congenital heart unit in the country, led by

the chair of our clinicians' engagement and advisory group. As part of these visits we were able to hear from and talk to front-line clinicians, patients and their families and hospital managers, giving us a much richer understanding of their achievements and challenges. There is more work to do – especially to hear from adults with CHD, from black, Asian and minority ethnic groups, from people with learning disabilities and from bereaved families, all of whom have been relatively under-represented in our work to date. But as a result of this extensive engagement we feel we are in a good position to consult on a set of standards, and that there will be no surprises for any of our constituencies.

The IRP report into "Safe and Sustainable" observed that there were perceptions of a lack of openness, and a suspicion that outcomes were pre-determined. The diagram at Figure 1 shows the governance arrangements we have established for this review, and in particular how our decisions are made, and how the different engagement and advisory groups feed in to the decision making process. We have shared this widely so that there is no confusion about the route by which the ultimate decisions are made – in particular, the pre-eminence of the NHS England Board and its "Task and Finish Group" (chaired by Professor Sir Malcolm Grant) dedicated to this project. But for reasons of simplicity and clarity the diagram does not attempt to show the full complexity of the governance arrangements which must be satisfied in order to consult on the new service standards, which require the involvement of a Programme of Care Board; the Specialised Commissioning Oversight Group; the Clinical Priorities Advisory Group; and the Directly Commissioned Services Committee of the main Board. Successfully navigating this governance without undue delay is one of the main challenges we face in consulting on standards in September 2014.

One of the defining features of our work over the last year has been the approach we have taken to openness and transparency. In addition to involving the widest possible range of stakeholders, we have tried to make sure that everything we do is open to scrutiny, with a conflicts of interest declaration being widely rolled out, and a publications policy where the default is always that we publish everything. This is logistically difficult and can create tensions – often we are doing our "thinking out loud", and in public, and we are robustly challenged on ideas which have merely been floated, not finalised. But on balance the approach has been quite liberating. We publish all significant material, whether it is correspondence, agendas, meeting papers or minutes. We produce a blog every fortnight (there have been 25 in the year from June 2013) in which we describe what is happening and what is forthcoming, and we always feedback what we have heard and what we have done about it.

Progress update against the objectives

- **Objective 1 - standards**

  From the beginning of the review's work, stakeholders told us that the best way to improve services was through clear service standards, uniformly applied. The creation of NHS England as a single national commissioner of specialised services presents an opportunity to drive high standards consistently in a way not open to our predecessors. Under the leadership of Professor Deirdre Kelly and with extensive cooperation from a range of clinical experts and patient representatives, a single coherent set of standards has been developed that describes the whole patient pathway from fetal diagnosis through children's services and adult services including transition and pregnancy. This builds on two discrete sets of pre-existing standards,

and a third which was underway; all have been fully reviewed, refreshed and further developed. There is an increased emphasis on good communication with patients and their families and a new section covering end of life care and bereavement. Responding to the challenge set by Professor Sir Bruce Keogh, the standards aim to describe an excellent service, not just best fit with current practice. This has been a lengthy, complex and testing exercise, to harmonise a large number of standards which had previously been organised and expressed in different ways, and grappling with some of the most "knotty" issues. The draft standards will be subject to full public consultation later this year: our target date has slipped from July 2014 to September 2014 and we have been criticised for the delay, which is due to the production of the consultation materials, and the challenge of clearing the internal assurance process referred to above. One issue to be tested in consultation will be the potential trade-offs required if, in meeting the standards at all specialist units, the standards were to be considered unaffordable. Possible approaches could include a longer timetable, commissioning from fewer units (to achieve economies of scale), lowered expectations for those standards associated with higher costs, or focusing on a smaller set of "must do" standards.

The standards, once agreed, will form the basis of NHS England's service specification which we use for contracting. The standards will be challenging and it is not expected that any provider meets all the standards currently. Some of the standards will be developmental, so a timetable for reaching them will be set out. The Clinical Reference Group (CRG) responsible for congenital heart services has worked with the new CHD review team to develop the draft service specification and timetable for developmental standards. Once agreed, the specification will become the basis for NHS England's commissioning of CHD services and all providers will be expected to meet the standards.

In addition to the work described on developing standards for CHD services, the review will work with colleagues from NHS England and the relevant CRGs to develop standards for extra corporeal life support services (including extracorporeal membrane oxygenation) and referral pathways and criteria for CHD patients who could benefit from cardiac transplant.

- **Objective 2 - analysis**

In order to commission CHD services effectively, NHS England needs to understand the demand for services now and in future. Clinicians and hospitals providing CHD services have told us that they expect the growth in paediatric activity seen over the last ten years to continue in future. The number of adult patients with CHD is now believed to exceed the number of children with CHD for the first time, and the number of adult patients is expected to continue to rise.

For adult services we have two sources of data available on current inpatient activity, but both are flawed for different reasons. Not all adult activity is reported to the national database run by the National Institute for Cardiovascular Outcomes Research (NICOR), and the generic nature of Hospital Episode Statistics (HES) means it is not easy to distinguish CHD activity from other cardiac services. No comprehensive assessment of expected changes in future years has previously been available for both children and adults. The review's analytical team has worked with clinicians, NICOR and NHS England's lead commissioners from national and area teams to define a set of procedure codes that most accurately describe CHD

inpatient activity. Data from the NICOR database and the HES data set are being analysed and compared to give the best understanding possible of current activity as well as trends over the last ten years. By the end of July 2014 we aim to have the first evidence-based projections of activity for children's and adults' services, modelling two different scenarios for growth (population only, and population plus other factors). The emerging analysis already confirms our understanding that beyond those centres providing specialist CHD services, a larger number are involved in providing care for adult patients, mostly undertaking lower numbers of procedures, which raises questions about the incidence of "occasional practice". Our public and patient stakeholders representing adult patients have told us this is a significant concern for them.

- **Objectives 3 and 4 – function, form & capacity and commissioning & change**

  The review will move beyond standard-setting and activity analysis to make recommendations for the shape of the CHD service of the future. It will also consider possible approaches to commissioning those services to ensure that everyone has access to excellent services that meet the service standards, and that occasional practice is eliminated. The preparatory work is already underway, but we cannot pre-judge the outcome of the standards and analytical work. The review is working with colleagues from across NHS England to develop an approach that helps to inform similar work on other specialised services.

  Engagement with our provider leaders' group has highlighted the importance of any change programme taking account of research, training and workforce implications, and the need to have some explicit recognition of the cost of any substantial change. We intend to describe the necessary components of a commissioning approach to facilitate the emergence of regional, collaborative, provider-led solutions, including the potential for the development of formal joint approaches that also meet the necessary requirements of competition and choice.

  The standards will establish some important parameters for future services including the minimum levels of surgical and interventional activity required (because of the requirements for teams of surgeons and interventionists and minimum activity requirements for each of these groups to assure continued competence). This will be taken into account along with considerations of access, changing demand, affordability and other parameters in making these recommendations.

- **Objective 5 – better information**

  The IRP in its review of the work of "Safe and Sustainable" noted that high quality, accessible and understandable information to inform decision making was lacking. The review will therefore ensure that better information is available for commissioners and to inform patient choice.

  As a first step, we have worked with lead commissioners from regional teams to institute the use of a children's congenital heart "transition dashboard". This was originally specified to manage risks in the period when it was expected that "Safe and Sustainable" would be implemented. Despite implementation not taking place, the transition dashboard still provides a mechanism to test the current health of the system, by collecting specific information on defined aspects of the children's congenital heart services in England. And in line with other specialised services, the

CRG for Congenital Heart Service has developed a quality dashboard covering a range of measures, which will be the enduring approach to real time quality monitoring. Although the quality dashboard has been introduced for 2014/15, it has been agreed that the transition dashboard will remain in situ until further notice.

The review is also working with NICOR to consider how the information it produces can be improved. We will work with them to consider how a wider range of outcomes (beyond mortality) could be reported. We will also work with them to develop ways of presenting the information which would be easier for patients to interpret and allow them to make informed choices.

- **Objective 6 – early detection**

  Abnormalities of the heart are the most common congenital defect and yet rates of diagnosis before and immediately after the baby is born are not as high as they could be. Clinicians tell us that earlier diagnosis can lead to better outcomes throughout a patient's lifetime, more informed choice, better managed births and better experience for families.

  The review has brought together a wide range of stakeholders with an interest in early diagnosis to better understand the reasons for current low antenatal detection rates and to develop plans for addressing these. Early work suggests that better training and support for ultra-sonographers undertaking antenatal scans will be important. We will work with Health Education England (HEE), providers and third sector partners to consider how this, and other potential issues, could be addressed.

  Stakeholders have also told us that the lack of a consistent, national database for recording all congenital defects is a further significant problem. Without this it is not possible to be sure about the rate of antenatal diagnosis. We are in discussion with Public Health England (PHE) who will be developing and implementing a new national database which is expected to be functional by April 2015.

  The National Screening Council (NSC), now part of PHE, recently consulted on the efficiency of pulse oximetry, a simple test to measure oxygen saturation levels in new born infants which can help to identify potential congenital heart problems. The evidence was not conclusive and so the NSC has announced that it will be running a pilot programme to better assess the effectiveness of pulse oximetry and the related implications if it were to be specified as part of the new-born infant physical examination (NIPE). This will help to address longstanding concerns in this area, and the review will stay close to this work as we are very supportive of the evidence-based approach.

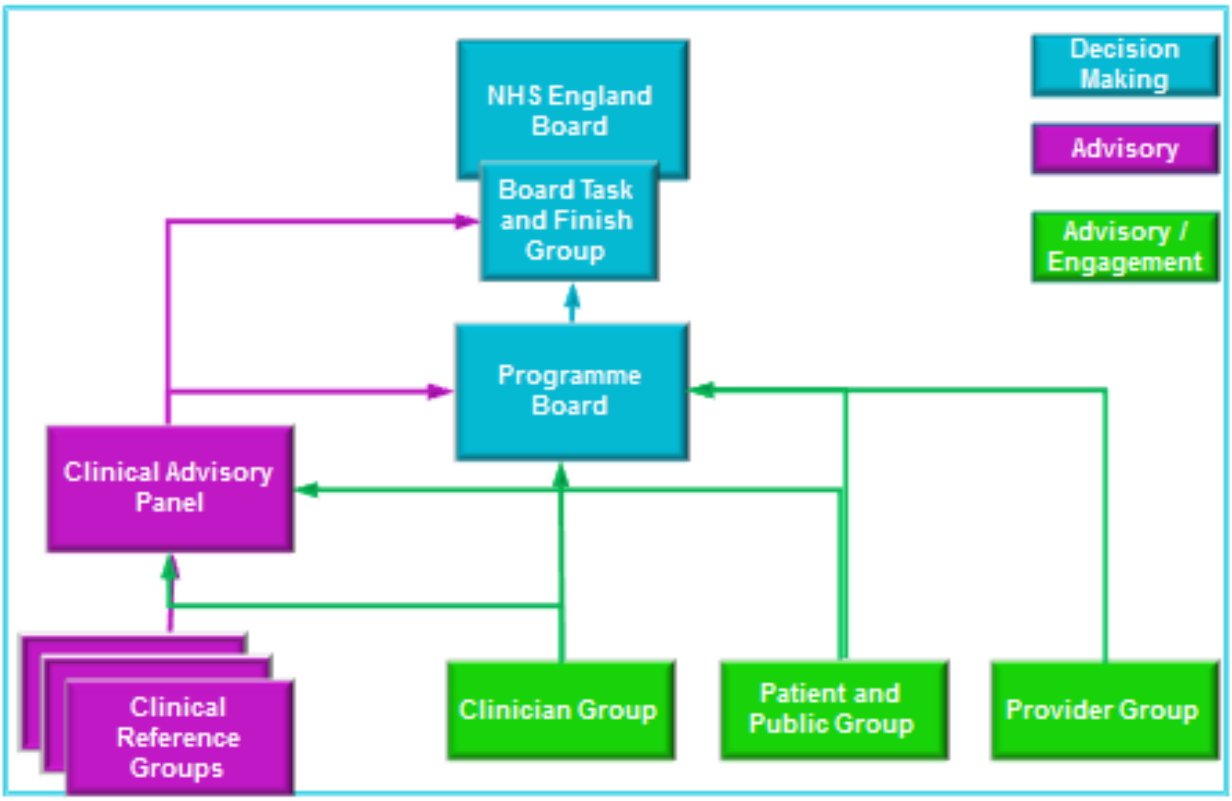
Conclusion and next steps

The review has taken seriously the Boards' ambition for an implementable solution to be delivered within one year. Early work with stakeholders made clear that the scope of the review needed to be wider than originally envisaged and that a new approach would need to be developed, retaining what was useful from earlier processes (e.g. the work on standards for children's surgical centres) but with no pre-conceptions about a particular "answer". The review also needed to rebuild trust, and this has been successful because in large part it was not rushed. In the year since we were asked to take on this challenge,

NHS England has invested significant time and effort in working with public and patients (and their representatives), clinicians from provider organisations and national bodies, and provider leaders. We have been very open in our processes and maintained a constant account of what we are doing, publishing all relevant documentation at every step of the way. Taken together, these factors have made it hard to meet the ambitious timeline originally envisaged.

Good progress has however been made on all of the review's objectives, especially in the development of standards for the whole lifetime pathway. Plans are well advanced to consult on these standards, but there remain significant risks, and our current expectation is that consultation could commence in September 2014, subject to approval by NHS England's internal assurances processes. This could then mean that the review would be able to make recommendations to the NHS England Board on all six objectives at the end of the financial year.

Figure 1: Decision making, advice and engagement



Scope and Interdependencies

Introduction

1. The new Congenital Heart Disease (CHD) review has been established to consider the whole lifetime pathway of care for people with congenital heart disease. In order to conduct the review and to ensure that there is a manageable programme of work it is necessary to define its scope in more detail.

2. Patients, clinicians and the public have been asked to advise on what services and conditions should be included in the scope of the new review. Approximately 40 responses were received (these will be made available to the Task and Finish Group in hard copy for reference).

3. NHS England originally proposed three categories (in scope; out of scope; to be determined). It was apparent from the responses received that not enough explanation had been given to respondents which had led to some misunderstanding of the concept of scope. It was also apparent that the reality is more complicated than a simple 'in' or 'out'. There are multiple, complex interdependencies, so this paper recommends a less binary, more nuanced approach that explains how the review relates to a range of other services and conditions, rather than simply declaring them to be either 'in' or 'out' of scope. At the same time, it is important to define the boundaries in such a way that there is a realistic prospect of completing the review and avoids mission creep.

4. A paper was written for the Clinical Advisory Panel summarising stakeholder responses. Members were also provided with the full original responses for reference. The panel met on 15 October 2013 and considered the scope of the review. This paper reflects that group's recommendations.

5. It will also be necessary to consider the relationship of the review to the devolved administrations and the potential impact on services for congenital heart disease offered in those countries and used by their populations. Cross-border flows are significant and need to be taken into account. The NHS in each of the devolved administrations will therefore be asked to agree their relationship to the review and appropriate channels of communication.

Summary recommendations

6. In summary the panel recommends that:

   A. The heart of the review should be the whole lifetime pathway of care for people with congenital heart disease, and specifically congenital heart disease services.

   B. There are a number of clinical conditions which while not CHD receive their care wholly or mainly from congenital heart services. The standards for services for these conditions should not be reviewed as part of the review (though the standards being developed may address aspects of the service). However, patients

who fall within this category use congenital heart services and should be able to participate in the review.

C. There are a number of services beyond congenital heart services that CHD patients may use. Some of these services are reliant on clinical support or backup from CHD specialists. The standards for these services should not be reviewed as part of the review. However, the use of these services by congenital heart disease patients should be considered by the review, including the definition of clinical pathways and referral routes. Any impact of changes recommended by the review on these services should be considered prior to decisions being taken and during implementation. Patients and specialists from these services should be able to participate in the review.

Detailed recommendations

7. Based on these principles, the Clinical Advisory Panel recommends that:

In scope

8. The heart of the review should be the whole lifetime pathway of care for people with congenital heart disease, and specifically congenital heart disease services. This means:

a) Improving the quality of care of people with suspected or diagnosed congenital heart disease (including those with congenital heart arrhythmias or arrhythmias in the context of congenital heart disease) along the whole patient pathway:

- Fetal and neonatal diagnosis of CHD
- Specialist obstetric care (including both care of women whose unborn child has suspected or confirmed CHD and care of pregnant women with CHD)
- Care for babies, children and young people
- Transition from children's services to adult services
- Care for adults
- End of life care

b) Cardiac and respiratory extracorporeal membrane oxygenation (ECMO) for children and young people.

c) Care and support for families suffering bereavement and / or poor outcomes from surgery or other intervention for congenital heart disease.

d) The review covers all care for congenital heart disease commissioned by the NHS for people living in England.

Interdependencies

9. There are a number of clinical conditions which while not CHD receive their care wholly or mainly from congenital heart services. The standards for services for these conditions should not be reviewed as part of the review (though the standards being developed may address aspects of the service). However, patients who fall within this category use congenital heart services and should be able to participate in the review. This means:

    a) Children and young people with acquired heart disease
    b) Children and young people with inherited heart disease (for which a separate service specification has already been developed).

10. There are a number of services beyond congenital heart services that CHD patients may use. Some of these services are reliant on clinical support or backup from CHD specialists. The standards for these services should not be reviewed as part of the review. However, the use of these services by congenital heart disease patients should be considered by the review, including the definition of clinical pathways and referral routes. Any impact of changes recommended by the review on these services should be considered prior to decisions being taken and during implementation. Patients and specialists from these services should be able to participate in the review. This means:

    a) Neonatal, paediatric and adult intensive care unit (ICU) services, and transport and retrieval services.
    b) Other interdependent clinical services (for example other tertiary paediatric services).
    c) Mechanical circulatory support for adults including cardiac ECMO and VAD.
    d) Complex tracheal surgery.
    e) Heart transplant and bridge to transplant services for children and young people.
    f) Heart transplant for adults.

Out of scope

11. Adults with inherited heart disease
    It was recommended that this group be excluded from the review because these patients do not receive their care from congenital heart services.

12. Adult respiratory ECMO
    It was recommended that this service should be excluded from the review because it is not dependent on congenital heart services, and operates independently of ACHD services.

13. Local maternity services
    It was recommended that local maternity services should be excluded from the review. Rather, the review should include specialist cardiac obstetric care (see 7a) above).