NATIONAL CARDIAC AUDIT PROGRAMME

NATIONAL CONGENITAL HEART DISEASE AUDIT (NCHDA)

2021 Summary Report

NICOR

The National Institute for Cardiovascular Outcomes Research (NICOR)

NICOR is a partnership of clinicians, IT experts, statisticians, academics and managers who, together, are responsible for six cardiovascular clinical audits (the National Cardiac Audit Programme – NCAP) and a number of new health technology registries, including the UK TAVI registry. Hosted by Barts Health NHS Trust, NICOR collects, analyses and interprets vital cardiovascular data into relevant and meaningful information to promote sustainable improvements in patient well-being, safety and outcomes. It is commissioned by the Healthcare Quality Improvement Partnership (HQIP) with funding from NHS England and GIG Cymru/NHS Wales, and additional support from NHS Scotland.

Society for Cardiothoracic Surgery in Great Britain and Ireland (SCTS)

SCTS is an affiliated group of the Royal College of Surgeons of England and has charitable status. The Charity's objects are to enable surgeons to achieve and maintain the highest standards of surgical practice and patient care.

British Congenital Cardiac Association (BCCA)

The British Congenital Cardiac Association is a membership association that aims to support and represent all health professionals whose interest is in the practice or research of congenital heart disease in the adult or heart diseases in the fetus or child. The BCCA was approved as a charity in February 2017 with Charitable Incorporated Organisation status. The objectives of the BCCA are the advancement of health and education in all aspects of congenital cardiac diseases, in particular by: 1. Promoting the study and care of the fetus and child with heart diseases and the adult with congenital heart disease in the United Kingdom and Republic of Ireland; 2. Promoting and distributing study data pertaining to these problems and their prevention; 3. Promoting research in paediatric and congenital cardiology and to publish the useful results of such research; and 4. The improvement of knowledge of professionals, the public and the patients and their families of paediatric and congenital cardiology, through scientific and educational meetings.

Barts Health NHS Trust

With a workforce of around 17,000 people, Barts Health is a leading healthcare provider in Britain and one of the largest NHS Trusts in the country. The Trust's five hospitals – St Bartholomew's Hospital in the City, including the Barts Heart Centre, The Royal London Hospital in Whitechapel, Newham Hospital in Plaistow, Whipps Cross Hospital in Leytonstone and Mile End Hospital – deliver high quality compassionate care to the 2.5 million people of east London and beyond.

The Healthcare Quality Improvement Partnership (HQIP)

HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Its aim is to promote quality improvement in patient outcomes, and in particular, to increase the impact that clinical audit, outcome review programmes and registries have on healthcare quality in England and Wales. HQIP holds the contract to commission, manage and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP), comprising around 40 projects covering care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual projects, other devolved administrations and crown dependencies. www.hqip.org.uk

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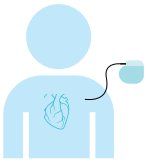
NCHDA AT A GLANCE

Data from the three-year period April 2017 to March 2020

12,393 congenital heart procedures in 2019/20; 8286 (67%) in children under 16

Number of treatments



66% increase in electrophysiology and pacemaker/ICD implant treatments in adults with congenital heart disease over 5 years; 22% increase in interventional procedures for this cohort

~15% reduction in paediatric cardiac surgical procedures in infants and children over 6 years

Complications after procedures

Low complications rates after paediatric cardiac surgical procedures:

2.4% life support, 1.2% unplanned pacemaker, 3.5% renal replacement therapy and 3.5% prolonged pleural drainage

Fluoroscopic screening

New data are provided on fluoroscopic screening times and radiation doses for a range of procedures. The work will help set reference standards for future audit.

Survival at 30 days

Despite this being one of the most complex areas of surgery, the UK and Republic of Ireland continue to have excellent outcomes with high survival and low mortality rates.

98.4% 30-day survival after paediatric cardiac surgical procedures

Dual consultant procedures

Two consultants operate where there are more complex lesions and this practice is also a key element of training or mentoring consultant colleagues.

11% dual consultant procedures for paediatric cardiac surgical procedures; 14% in neonates and 22% for transcatheter and electrophysiology procedures

Antenatal diagnosis

About 20–30% of congenital heart defects are severe, defined as being potentially life threatening and requiring surgery within the first year of life..

51% prenatal diagnosis for all infants requiring a procedure in the first year of life.

Executive summary

Congenital heart disease (CHD) is a heart condition or defect that develops in the womb before a baby is born, with CHD diagnosed in approximately 1 in 100 births.[1] Heart defects are the most common congenital anomaly in babies born in the UK and Ireland and they are the main cause of infant mortality due to a congenital anomaly.

Today, at least 80% survive to adulthood and the population of adults with congenital heart disease (ACHD) is rapidly increasing. Over one quarter of CHD patients will require an intervention during infancy, often as a matter of urgency, with procedural risks highest for neonates who present in poor condition.[2]

The goal of congenital heart disease services is therefore to diagnose heart disease as early as possible and the ideal is before birth, referred to as antenatal diagnosis, as well as to provide excellent continuity of care as they progress through childhood and into adulthood. By robust analysis of audit data and comparing patient outcomes, such as case-mix adjusted survival, the aim is to improve the quality of care received by patients from UK or Ireland hospital admission to discharge and ensuring they meet good practice standards.

The table below summarises the key messages from the Quality Improvement (QI) metrics within the National Congenital Heart Disease Audit (NCHDA).

KEY MESSAGES

	FOCUS OF ATTENTION	AUDIT FINDING
	**Procedural activity**	12,393 congenital heart disease procedures on children and adults reported to the NCHDA in 2019/20. There has been a 14-15% fall in surgical procedures over the last 6 years, especially for infants and children under 16 (the latter accounting for 8,286 procedures or 67% of all patients). Procedure numbers for adults with congenital heart disease (ACHD) have increased. There has been a continuous growth in pacing and electrophysiology procedures over the last ten years (now 2.6 times the level in 2010/11).
	**Surgical outcomes in children**	Overall outcomes after paediatric cardiac surgery continue to show a high 30-day survival rate of 98%. Unadjusted raw (crude) 30-day mortality rate in 2019/20 rose to 2% of the 3,731 surgical operations undertaken in children under 16 years of age but risk-adjusted analysis demonstrates outcomes that are better than expected.
	**Surgical outcomes in adults**	3,078 ACHD operations during 2017/20. Overall actual to predicted survival ratio was 1.001, with approximately 6% fewer deaths than predicted by the Society of Thoracic Surgeons–European Association for Cardio-thoracic Surgery (STAT) mortality model.

Dual consultant activity	Across all ages, dual consultant operators were involved in 11% of surgical procedures, 14% of neonatal operations and 22% of transcatheter or electrophysiology procedures. This supports outcomes that potentially could not be achieved by working alone for the most complex lesions, or when unexpected complications occur. It is also an important component of training and mentoring consultant colleagues.
Antenatal Diagnosis	Antenatal diagnosis for all infants requiring a procedure in the first year of life remains at 51% overall. There remains important variation between centres nationally that should be addressed by reviews of staffing, equipment and training.
Post-procedural complications	Post-procedure related complication rates for under-16s show some variation, including 2.4% requiring life support, 1.2% requiring an unplanned pacemaker, 3.5% with prolonged pleural drainage and 3.5% needing renal replacement therapy (including peritoneal dialysis). Measurement of complication rate variables is an area of ongoing development.
Data Quality Indicator	Overall DQI scores remain very good.
Case Study – Fluoroscopy	A case study aims to set reference standards by analysing use of radiation doses in commonly performed procedures across all paediatric centres and identifying factors leading to high inter-operator and inter-centre variability in total dosage use for the same procedures. Further analysis is needed to understand the variance identified but hospitals should focus on minimising radiation exposure to these complex patients, some of whom will require multiple procedures.

1 Introduction

The National Congenital Heart Disease Audit (NCHDA), a domain within the National Cardiac Audit Programme (NCAP), was set up in 2000 as the Central Cardiac Audit Database (CCAD for Congenital Heart Disease) to assess patient outcomes after therapeutic paediatric and congenital cardiovascular procedures (surgery, transcatheter and electrophysiological interventions) at all centres in the UK and the Republic of Ireland (since 2012) as well as the success of antenatal screening. The audit focuses on monitoring activity levels by compiling outcomes following congenital cardiovascular procedures with the aim to contribute to quality assurance (QA) and development of care.

In 2011, the audit moved from being part of the NHS Information Centre, to being one of six audits brought together under the auspices of the National Institute for Cardiovascular Outcomes Research (NICOR) and, in 2017, as a Domain within the National Cardiac Audit Programme (NCAP). Data submission is mandatory and is collected from all centres undertaking such procedures in children and adults.

The NCHDA dataset is designed by clinicians working in collaboration with two professional societies: the British Congenital Cardiac Association (BCCA) and the Society for Cardiothoracic Surgery in Great Britain and Ireland (SCTS). Members of the professional societies support the NCHDA Clinical Lead, together with representation from patients, allied health professionals, and commissioners all working together with the NCAP delivery team on the NCHDA Domain Expert Group (DEG) to help establish the direction of the audit programme.

1.1 Purpose & analytical scope of the Audit

The prevalence of congenital heart disease (CHD) has changed over the past decades.[1] In the UK, CHD is one of the most common types of birth defects, affecting about 8 per 1000 live births. Survival outcomes have significantly improved and consequently led to an increasing population of adults with congenital heart disease (ACHD). The main purpose of the National Congenital Heart Disease Audit (NCHDA) is to examine service delivery for, and outcomes of infants, children, adolescents and adults undergoing interventions for paediatric and congenital heart disease.

Patients, parents and carers, as well as clinicians and commissioners, are encouraged to review the information provided. This knowledge along with information received from the family doctor and heart specialist, can be used to make decisions on treatment options. Part of the audit data is also available for viewing via the website Understanding Children's Heart Surgery Outcomes, which aims to help make sense of the survival statistics provided.

The dataset for each NCAP audit broadly follows the 'clinical pathway' from patient admission to hospital discharge with the aim to review and reflect on the changing needs of congenital heart services. The dataset is also designed to address key elements of management of congenital heart disease:

- Treatment delivery – How is treatment delivered across the country, including the number of centres providing congenital heart services and the volume of procedures undertaken by each centre?
- Specific procedures – Which specific procedures are provided to treat children with heart disease and congenital heart disease from infancy to adults: surgery, transcatheter interventions and electrophysiological procedures?
- Clinical outcomes – What clinical outcomes are associated with these treatments and what are the steps to be taken to improve them?

Congenital heart disease (CHD) services are a relatively small specialty accounting for just over 1% of the NHS specialised commissioning budget.[3] Due to the relatively small number of cases involved with a large number of different procedures, the audit provides composite outcome analyses, to both allow meaningful comparison of units and minimise the risk of identifying individuals. This is in line with the Office for National Statistics (ONS) Confidentiality Guidance for publishing health statistics.

The NCHDA results cover three different time periods (financial years):

- 1 year: 2019/20 – data collected from April 1st 2019 – 31st March 2020
- 3 years: 2017/18 to 2019/20 – standard reporting

period for metrics related to the NCHDA in view of relatively small numbers of individual types of procedures

- 10 years: 2010/11 to 2019/20 – expanded from recent trends and is used to demonstrate longer-term variance as necessary.

This year the NCHDA reporting structure has been divided into two separate parts. The first part is the main summary report highlighting audit findings for the key QI metrics and key recommendations. The second part contains the supplementary report and provides descriptive narrative, which includes the methodology underpinning the main report analyses, detailed background for QI metrics and demographics, which you can find here.

Given the large number of different cardiac malformations with associated specific surgical and/or transcatheter procedures, relatively small variations in data quality can result in different conclusions about the quality of care. The NCHDA therefore uses a robust validation process to ensure that submitted data quality is of a high standard, being both accurate and pertinent, as well as ensuring all eligible patients are captured (case ascertainment).

The audit period to 31st March 2020 covers activity almost entirely before the COVID-19 pandemic, with data to suggest that there may have been a slight drop in activity in only the last 3 weeks of the audit period. The audit data need to be interpreted within that frame.[4]

1.2 Activity levels and trends

The quality improvement objectives of the NHCDA domain summary are based around three broad themes, which demonstrate the value and continued opportunities for quality improvement within the national audit. These are as follows:

- Safety – how can services be made safer? This includes ascertaining the number of different types of procedures undertaken by centres with respect to NHS England Standards, documenting trends in activity over the last 10 years. i.e. Procedural activity.
- Clinical effectiveness – are the best clinical protocols and treatments being used and is the care being delivered effectively? This focuses on the antenatal detection of CHD in patients who require a therapeutic procedure in infancy. i.e. Antenatal diagnosis.
- Patient outcomes – what can we do to improve patient outcomes? And how can we improve these? i.e. Procedure mortality and post-procedural complications.

There is limited information available regarding the associations of age, sex and ethnicity with the incidence of congenital heart disease. For a comprehensive contemporary analysis, data would be required for patients who do not undergo procedures as well as those who are included in this audit. Linkage to other sources of data or a specific prospective research study would be needed. A large enough study population would be required to adequately depict whether significant trends occurred after stratification into different demographic groups and to identify whether specific factors were associated with any observed trends.

Some preliminary analyses of procedural activity related to various age groups are provided in section 2.1. A key observation is a notable downward trend in surgical activity since a peak in 2013/14.

Regarding 10-year activity by sex, there is a slight predominance in procedural activity in males compared to females. The overall percentage of activity in both groups seems to be stable over time. Activity by ethnicity over the same period shows 69% of all procedures were undertaken in patients in one of the White ethnic groups and more procedures were performed in patients in Asian ethnic groups than in those from Black ethnic groups.[5] A more detailed analysis would be required to identify whether there was any evidence of inequitable opportunities for treatment.

1.3 NCHDA Quality Improvement (QI) Metrics

In 2020, NICOR introduced a range of data tools to aid hospital Quality Improvement programmes. These allow each hospital to look at how it currently compares with the national average as well as the best centres. If the information does not appear correct, this will give hospitals time to check their data and make appropriate corrections. This will improve the accuracy and transparency of the data provided to NICOR and information provided back to all the centres.

There is a strong focus of the NCAP and its six domains on identifying and communicating opportunities to raise the standards of care for patients. The data help hospitals and operators drive up quality of care by measuring processes and outcomes against achievable standards or

benchmarks. This ensures that high quality services are maintained (quality assurance) but provides a means to raise the standards of care over time by identifying changes in the way care is provided (quality improvement). These changes can then be monitored to determine whether outcomes and/or assessed quality of care are improved for patients or whether healthcare can be provided more efficiently.

This report includes analysis of selected QI metrics from the NCHDA which tell us about the following:

- Outcomes: through 30-day risk-adjusted mortality for 83 procedures in children and adults.
- Activity: The number of procedures (paediatric/adult) carried out across centres.
- Antenatal diagnosis: The number of patients requiring an intervention in infancy for various lesions.

1.4 List of codes for participating centres 2019/20

Code	Hospital
	Paediatric and Mixed Practice Hospitals
ACH	Alder Hey Children's Hospital, Liverpool
BCH	Birmingham Children's Hospital
BRC	Bristol Royal Hospital for Children
FRE	Freeman Road Hospital, Newcastle
GOS	Great Ormond Street Hospital for Children, London
GRL	Glenfield Hospital, Leicester
GUY	Evelina London Children's Hospital, London
LGI	Leeds General Infirmary
NHB	Royal Brompton Hospital, London
OLS	Our Lady's Children's Hospital, Dublin
RHS	Royal Hospital for Sick Children, Glasgow
SGH	Wessex Cardiothoracic Centre, Southampton General Hospital
	Adult centres
BHL	Liverpool Heart and Chest Hospital
GJH	Golden Jubilee National Hospital, Glasgow
HAM	Hammersmith Hospital, London
MRI	Manchester Royal Infirmary
NCR	Wolverhampton Lung & Heart Centre, New Cross Hospital
NGS	Northern General Hospital, Sheffield
PAP	Papworth Hospital, Cambridge
QEB	Queen Elizabeth Hospital, Birmingham
RAD	John Radcliffe Hospital, Oxford
RSC	Royal Sussex County Hospital, Brighton
RVB	Royal Victoria Hospital, Belfast
SBH	Barts Heart Centre, St Bartholomew's Hospital, London
STO	University Hospital of North Staffordshire, Stoke
UHW	University Hospital of Wales, Cardiff
VIC	Royal Victoria Hospital, Blackpool

2 Quality improvement metrics

2.1 Congenital Heart Disease Procedural Activity

Approximately 12,000 procedures in children and adults are submitted to the NCHDA every year. The volume of procedures carried out can be a significant factor in developing the necessary skills and infrastructure for treating patients with congenital cardiac malformations. As with the other audits, it is generally accepted that performance improves the more one practices a specific skill – 'practice makes perfect' – and professional societies, regulators and commissioners have recommended certain minimum volumes of activity at hospitals for particular services, including congenital heart disease, as set out in NHS England's 2016 Standards and Services Specification.[6, 7]

2.1.1 Overview of QI metric: Summary of procedures/volume of activity

QI Metric Description/Name	• **Procedural activity by age group and each centre** • **Catheter-based and surgical activity** • **Consultant activity**
Why is this important?	Activity standards were set out by NHS England to provide the best opportunity of achieving good outcomes for cardiac procedures in children and adults with CHD.
QI theme	Safety
What is the standard to be met?	NHS England Standards[6] require that: A centre's CHD surgeons work in a team of at least 3-4 and are required to perform at least 125 CHD 'countable' operations (all ages), per year (average over 3 years). A centre's interventional cardiologists work in a team of at least 3-4 with the lead interventional cardiologist carrying out a minimum of 100 interventional procedures a year, and all other interventional cardiologists do a minimum of 50 interventional procedures a year, averaged over 3 years. This equates to each centre performing 200-250 interventional catheter cases each year. Note that the standards exclude purely diagnostic catheter procedures from these activity numbers.
Key references to support the metric	The Society for Cardiothoracic Surgery, supported by the community of congenital cardiac surgeons themselves, and by the Royal College of Surgeons. Congenital Heart Disease Services: Decision Making Business Case November 2017: main document.[8] Congenital Heart Disease Services: Decision Making Business Case November 2017: Annex B, page 358 (Appendix 1, Annex 6).[9]
Numerator	NHSE countable surgical procedures – for neonate, child and adults.
Denominator	NHSE countable surgical procedures.

Trend	See Table 1 and Figure 2.1 and Figure 2. Paediatric activity showed a slight reduction of just over 2.5% in 2019/20 compared to the previous year (but there has been an overall 14-15% fall in paediatric surgical procedures since 2013/14). On the other hand, surgical activity in patients 16 years and older increased by 15%, with a similar increase in transcatheter procedures. While there was a 1.5% decrease in transcatheter activity, electrophysiological activity showed an increase by 10% in 2019/20 in children, continuing the overall upward trend in electrophysiological activity in patients with CHD.
Variance	See Figure 2.1. The reasons for the fall in surgical activity are not fully understood but may include changes in epidemiology, indications, complex surgical procedures replacing sequential staged procedures, other options for treatment and other factors.

2.1.2 Audit results: all Paediatric and CHD Procedures

In 2019/20, UK and Republic of Ireland centres submitted data on 12,393 procedures where 8,286 were paediatric cases and 4,107 were adult congenital heart cases as shown in Table 1 below. The expectation is that higher volumes will deliver a more consistent and sustainable service with the appropriate infrastructure to treat these complex patients born with a huge variety of cardiac malformations.

A full breakdown of 30-day outcomes by age group for all procedures (2017/18 to 2019/20) as well as a breakdown of activity for centres undertaking major congenital cardiac procedures (2017/20) for children and adults in the UK can be found here.

Table 1: CHD Activity by Age Group – All Procedures, 2019/20

PROCEDURES 2019/20			
	Procedures (All ages)	Procedures (Under 16 years)	Procedures (16 years and older)
Overall activity	**12,393**	**8,286**	**4,107**
Surgical procedure activity			
Surgery undertaken using cardiopulmonary bypass	4,106	3,080	1,026
Surgery undertaken without using cardiopulmonary bypass (including surgical EP)	955	876	79
Hybrid procedures	84	78	6
Primary ECMO	67	65	2
Ventricular Assist Device (VAD)	20	19	1
Total	**5,232**	**4,118**	**1,114**
Catheter procedure activity			
Interventional catheterisation procedures	3,861	2,397	1,464
Diagnostic catheter procedures	1,531	986	545
Total	**5,392**	**3,383**	**2,009**
Electrophysiological activity (non-surgical)			
Implantable Cardioverter Defibrillator (ICD)	164	45	119
Pacemaker procedures	440	127	313
EP ablation and EP diagnostic procedures	1,165	613	552
Total	**1,769**	**785**	**984**

Note: Activity numbers are those procedures agreed by NHS England to be 'countable' towards individual *operator activity. Primary Extracorporeal Membranous Oxygenation (ECMO), Ventricular Assist Devices (VAD), lung transplants and surgical electrophysiological (EP) procedures are counted as surgical activity for these calculations. Hybrid procedures are those with a combination of surgical and transluminal catheter interventions*

undertaken at the same time in the operating theatre. Primary ECMO procedure: the procedure is undertaken in isolation and not as a support operation after another congenital heart procedure (these are considered post-procedural complications); this excludes ECMO for primary respiratory failure.

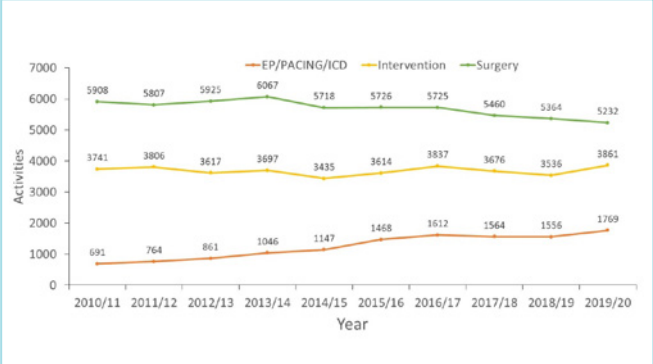
Table 2: Total number of cases categorised by type of procedure submitted to the NCHDA, 2010/11 – 2019/20

Year	Surgical	Hybrid	Interventional catheter & EP procedures			Diagnostic Catheter	Total
			EP/PACING	ICD	Intervention		
2010/11	5,902	6	627	64	3,741	—	10,340
2011/12	5,781	26	692	72	3,806	—	10,377
2012/13	5,909	16	777	84	3,617	—	10,403
2013/14	6,018	49	938	108	3,697	—	10,810
2014/15	5,656	62	1,031	116	3,435	—	10,300
2015/16	5,671	55	1,344	124	3,614	1,737	12,545
2016/17	5,677	48	1,457	155	3,837	1,879	13,053
2017/18	5,376	80	1,440	112	3,673	1,745	12,426
2018/19	5,288	74	1,416	133	3,519	1,634	12,064
2019/20	5,148	84	1,605	164	3,861	1,531	12,393
Total	56,426	500	11,327	1,132	36,800	8,526	114,711

Note: Primary Extracorporeal Membranous Oxygenation (ECMO), Ventricular Assist Devices (VAD) and lung transplants are counted as surgical activity for these calculations; interventional, Electrophysiology (EP)/Pacing and Implantable cardioverter-defibrillator (ICD) devices are counted as catheter procedures and were not collated separately until 2013/14. Hybrid procedures are those with a combination of surgical and transluminal catheter interventions undertaken at the same time in the operating theatre. Diagnostic catheter data were included in the dataset from 2015/16 onwards.

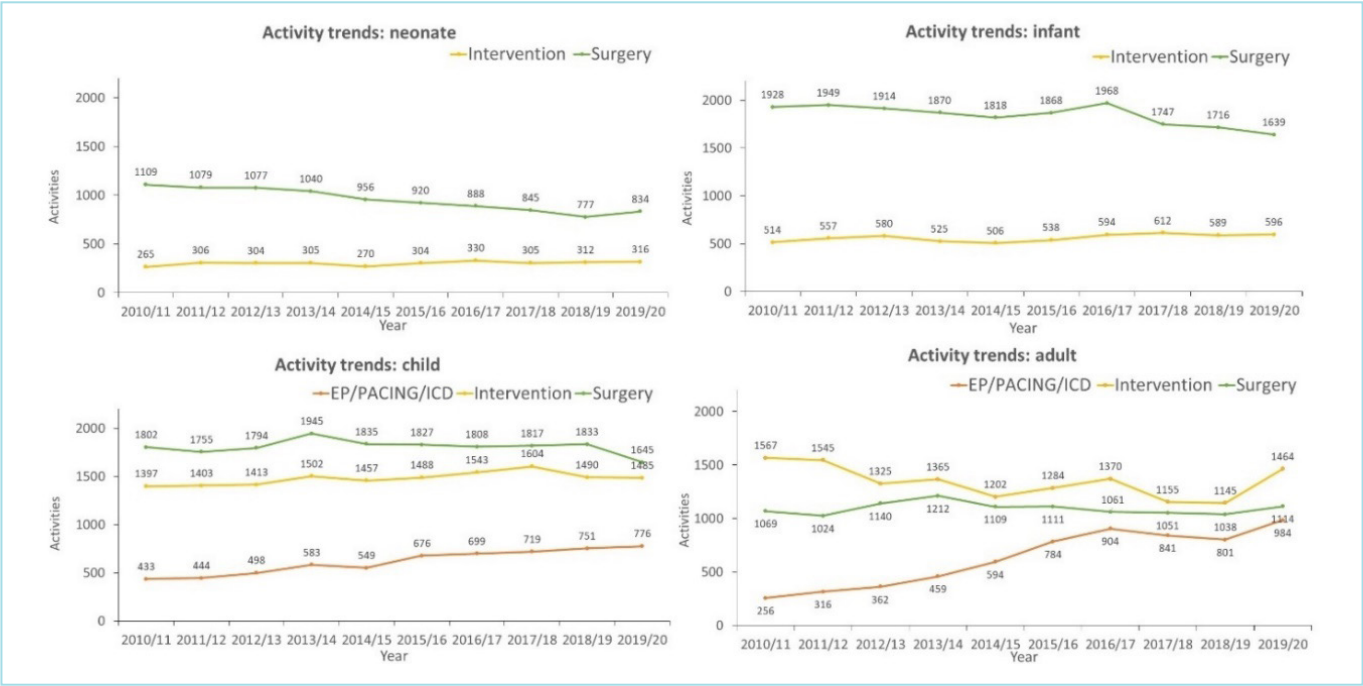
Table 2 and Figure 2.1 and Figure 2 show 10-year trends for CHD procedures, split by procedure type and divided into four age groups. Overall, surgical activity in the last six years has fallen by 14-15% in the UK and Republic of Ireland, with a 2.5% reduction in paediatric surgical activity in 2019/20 compared to the previous year. The reasons for the fall in surgical activity in the paediatric cohort are not fully understood. Although there has been a slight rise in interventional procedures, this does not on its own explain the changes seen. Whether, and to what extent, these observations are explained by a change in epidemiology, changes in indications, replacement of sequential staged procedures by more complex single procedures, other changes in treatment options or other factors requires further study. This may well have implications for the standards that have been set and requires further discussion.

Figure 2.1: 10-year trends of surgical, interventional catheter and electrophysiological procedures at all ages submitted to the NCHDA, 2010/11 – 2019/20



Note: for details of procedural inclusions and exclusions, see Table 3. 2010 = financial year 2010/11, etc.

Figure 2.2: 10-year trends of surgical, interventional catheter and electrophysiological procedures split into four age groups submitted to the NCHDA, 2010/11 – 2019/20



2.1.3 National standards and Consultant Activity

A key NHS England Standard, supported by the Society of Cardiothoracic Surgeons and BCCA, is that consultant congenital heart surgeons are expected to undertake a minimum of 125 congenital or paediatric cardiovascular operations on patients of any age each year (averaged over a three-year period).

For catheter interventions, it is 50 procedures each and 100 for the lead interventionist (noting that for the lead interventionist this can include dual scrubbing with a consultant colleague).[10] Further discussions are needed between the commissioners, the Professional Societies and NICOR to determine the appropriate timing of additional analyses to provide insights around contemporary volume-outcome relationships in UK practice and any implications for the current standards.

When calculating the number of procedures an individual consultant operator undertakes, there is a need to consider the scenario when there are two consultants scrubbed for the same patient (excluding a consultant scrubbing with a non-consultant trainee) as depicted in Table 3 and Table 4. Hybrid procedures require input by both a consultant surgeon and consultant catheter interventionist due to case or procedure complexity, such as atypical coronary anatomy when undertaking an arterial switch procedure, or with transcatheter valve implantation.

Table 3: Total number of surgical cases submitted to the NCHDA categorised by type of procedure and age group, illustrating the number of cases with two consultants operating at the same session, 2017/20

Hospital	All ages – dual/total		Neonates		Infants		Child		Adult	
Surgery (overall)	1,790/16,056	11.1%	338/2,356	14.3%	494/5,209	9.5%	540/5,288	10.2%	418/3,203	13.1%
Bypass	1,436/12,648	11.4%	250/1,486	16.8%	359/3,816	9.4%	437/4,377	10%	390/2,969	13.1%
Non-bypass	117/2,898	4%	35/743	4.7%	47/1,256	3.7%	22/691	3.2%	13/208	6.3%
Hybrid	197/237	83.1%	46/51	90.2%	82/92	89.1%	56/76	73.7%	13/18	72.2%
Primary ECMO	22/195	11.3%	6/75	8%	5/38	13.2%	11/78	14.1%	0/4	0%
Ventricular Assist Device (VAD)	18/78	23.1%	<3/<3	100%	<3/7	<42.8%	14/66	21.2%	<3/4	<75%

N.B. Data are suppressed where case numbers are less than three and secondary suppression has been applied where applicable to ensure anonymity of the patient data included in reporting.

Table 4: Total number of Catheter/Electrophysiology cases submitted to the NCHDA categorised by type of procedure and age group, illustrating the number of cases with two consultants operating at the same session, 2017/20

Hospital	All ages – dual/total		Neonates		Infants		Child		Adult	
Catheter / Electrophysiology (overall)	4,665/20,877	22.3%	339/992	34.2%	669/2,707	24.7%	1,600/9,037	17.7%	2,057/8,141	25.3%
Interventional	3,389/11,073	30.6%	310/870	35.6%	566/1,862	30.4%	986/4,577	21.5%	1,527/3,764	40.6%
Implantable Cardioverter Defibrillator (ICD)	70/412	17%	0/0		<3/3	<100%	36/130	27.7%	33/279	11.8%
Pacemaker procedures	127/1,225	10.4%	<3/<3	<100%	<3/4	<75%	66/373	17.7%	59/846	7%
EP & ablation & diagnostic EP	534/3,253	16.4%	0/0		<3/8	<37.5%	330/1,743	18.9%	203/1,502	13.5%
Diagnostic catheter	545/4,914	11.1%	28/120	23.3%	100/830	12%	182/2,214	8.2%	235/1750	13.4%

N.B. Data are suppressed where case numbers are less than three and secondary suppression has been applied where applicable to ensure anonymity of the patient data included in reporting.

The dual consultant operator data remain constant with over a fifth of all neonatal surgical and around a third of neonatal transcatheter interventions undertaken by two consultant operators, whilst this is the case in 10% of older children and adults having surgery [Figure 2.3 and Figure 2.4].

In adults, over a third of transcatheter interventions have dual consultant operators, with results similar to the previous year. For hybrid procedures, it is important to highlight that discrepancy in data entry by centres (i.e. either the procedure is misclassified as a hybrid or does not involve a consultant operator but a highly trained junior doctor) has led to dual consultant operators for hybrid procedures for all age groups being below the expected 100% (around 80%).

Figure 2.3: Percentage of patients of any age who had their procedure undertaken by two consultant operators, broken down by procedure type, 2017/20

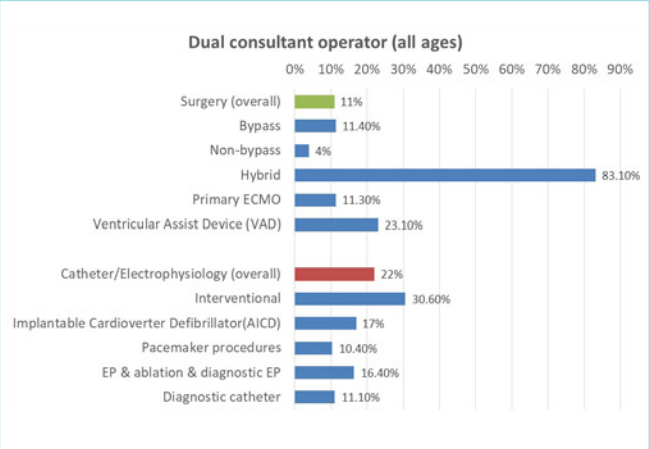
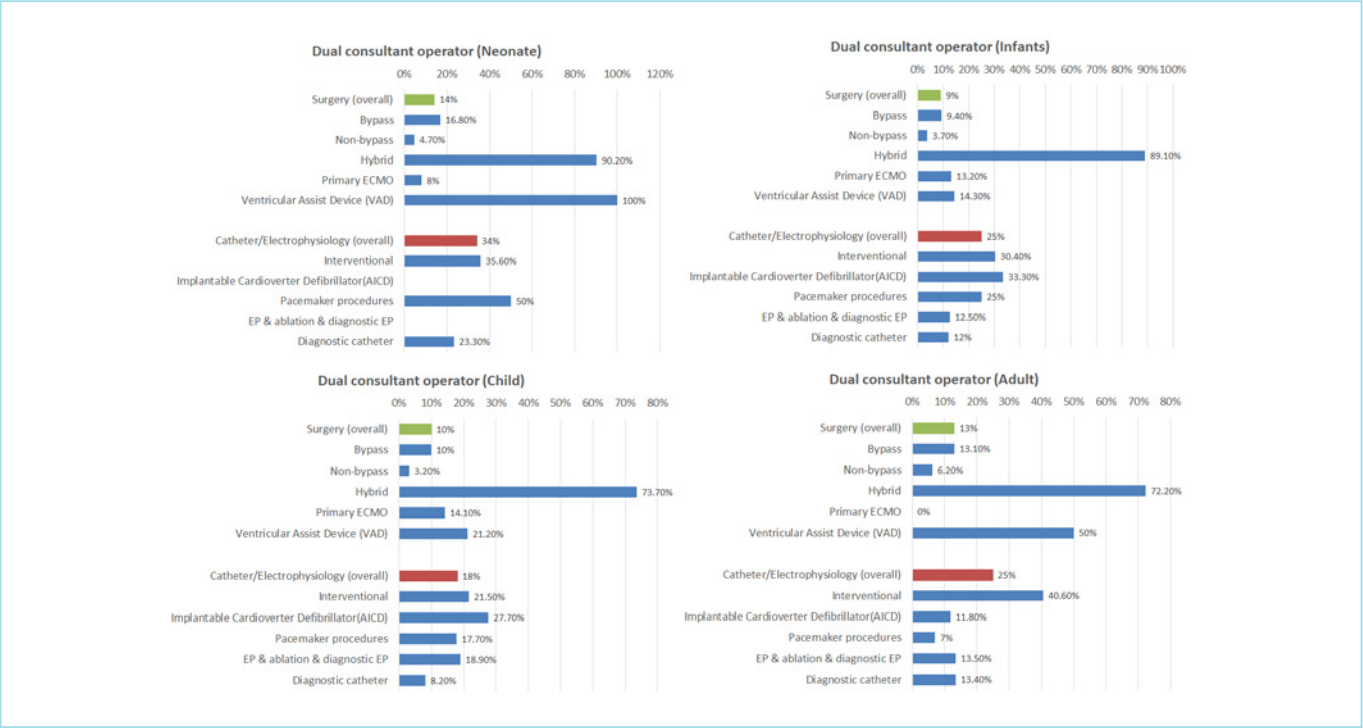


Figure 2.4: Percentage of patients who had their procedure undertaken by two consultant operators, broken down by procedure type and age, 2017/20



2.1.4 Provision of training for database managers regarding data quality on consultant operators

The methodology for collection of data for complex procedures is an area of ongoing development. The NCHDA will provide clear guidance for database managers on the definition of hybrid procedures so that data entry reflects dual consultant operators for all such procedures. The NCHDA will also update the data manual to capture different operator scenarios, thereby avoiding misclassified procedures and data entry errors. Further alerts will be set up within the software to highlight the errors and avoid any such discrepancy.

2.2 Procedural Mortality

Hospitals providing care for children and adults with CHD have low levels of 30-day mortality. Despite this being one of the most complex areas of surgery and lifesaving for congenital patients, the UK and Republic of Ireland continue to have excellent outcomes with high survival and low mortality rates. NCHDA uses two risk models for assessing outcomes:

1) Partial Risk Adjustment in Surgery (PRAiS) model for children;[11, 12]

2) Society of Thoracic Surgeons–European Association for Cardio-thoracic Surgery (STAT) mortality score for adults (over 16 years of age).[13]

2.2.1 Overview of QI metric: Summary of 30-day Mortality pertaining to aggregated and specific procedure outcomes, 2017/20

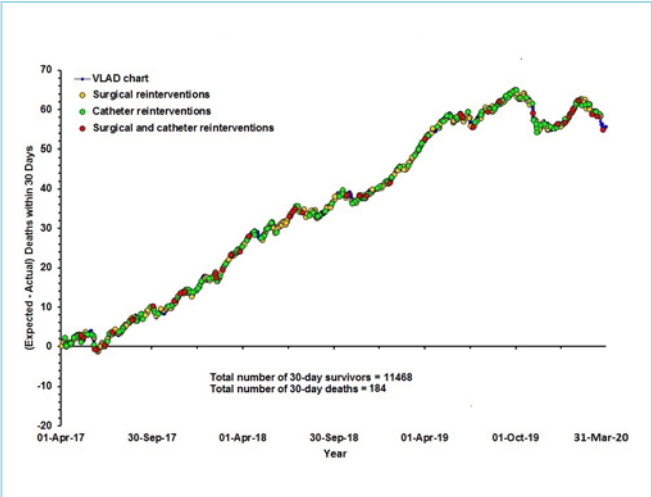
QI Metric Description/Name	Centre level risk-adjusted, and procedure-stratified, 30-day mortality following aggregated and specific CHD procedures in children and adults (16 years and over), using three year rolling cohorts of patients.
Why is this important?	Quality assurance following paediatric and congenital cardiac procedures to ensure safe service, and to initiate centre level quality improvement where negative variance detected. Exemplary centre level performance can be used as a benchmark for quality improvement initiatives at less well performing centres.
QI theme	Safety and Outcomes
What is the standard to be met?	30-day mortality at centre and procedure levels for 83 specific CHD procedures looking for negative deviation from averaged national performance. 30-day PRAiS2 risk adjusted mortality at centre level for aggregated surgical procedures in children looking for deviation (positive or negative) from average national performance. 30-day STAT risk adjusted mortality at centre level for aggregated surgical procedures in adults with CHD looking for deviation (positive or negative) from average national performance.
Key references to support the metric	Rogers L, Brown KL, Franklin RC, et al. Improving Risk Adjustment for Mortality After Pediatric Cardiac Surgery: The UK PRAiS2 Model. Ann Thoracic Surg 2017;104(1):211-219[11] Improving risk adjustment in the PRAiS model for mortality after paediatric cardiac surgery and improving public understanding of its use in monitoring outcomes[12] Fuller SM et al. Estimating Mortality Risk for Adult Congenital Heart Surgery: An Analysis of The Society of Thoracic Surgeons Congenital Heart Surgery Database. Annals Thor Surg 2015; 100 (5), 1728-1736.[13]
Numerator	Number of patients whose death is recorded by centre or ONS linkage.
Denominator	Total expected risk adjusted mortality.
Trend	Overall non-risk adjusted 30-day mortality has risen to 2.0% compared to last year but continues to remain low by international standards. This corresponds with changes depicted in the PRAiS2 derived VLAD chart [Figure 2.5].
Variance	No centre level outliers detected for 30-day mortality outcomes following any of the 83 specific procedures, or aggregated surgery in children or adults with CHD.

2.2.2 Audit results

30-Day Aggregate Survival after Surgery in Children

Specialist centres use Variable Life Adjusted Displays (VLAD), depicting the predicted minus the actual number of survivals at 30 days post-surgery, as well as re-interventions within 30 days of the surgery, to monitor their own outcomes [Figure 2.5]. The benchmarking in the VLAD is based on the Partial Risk Adjustment in Surgery (PRAiS) model, which was revised and improved in June 2016 (PRAiS2), as well as recalibrated using the 2009/10-2015/16 Congenital Audit outcomes, with improved statistical performance.[11]

Figure 2.5: Variable Life Adjusted Display (VLAD) Chart for all 12 paediatric centres in the UK and Republic of Ireland undertaking procedures in patients under 16 years of age, 2017/18 – 2019/20



The VLAD chart line in Figure 2.5 shows the national outcomes between 1 April 2017 and 31 March 2020 with two periods where the VLAD line drops. The number of deaths in the Q3 and Q4 quarters of 2019/20 reach 26 and 21, which are the highest and second highest quarterly rates between 2017/18 and 2019/20 and explains the plateau of the VLAD chart, but the results remain better than expected against the risk model.

Looking at this more closely we see that, based on the PRAiS2 risk model, 249 deaths were predicted compared to 184 actual deaths, a difference of 64 or 26% lower than the predicted number. But there is an increase in actual deaths in 2019/20 compared to 2018/19, which is reflected in Figure 2.6 (a).

These results will be monitored carefully. A continuous out-performing of a risk model raises questions about the calibration of that model. This is currently under review. Oscillations in the VLAD chart would be expected using a well-performing risk model. We will also be monitoring to determine whether outcomes have been maintained during the COVID-19 pandemic or whether they might have been affected by this.

Figure 2.6 (a): Trends in 30 days unadjusted mortality in children (under 16 years) after surgery over 10 years, 2010/11 – 2019/20

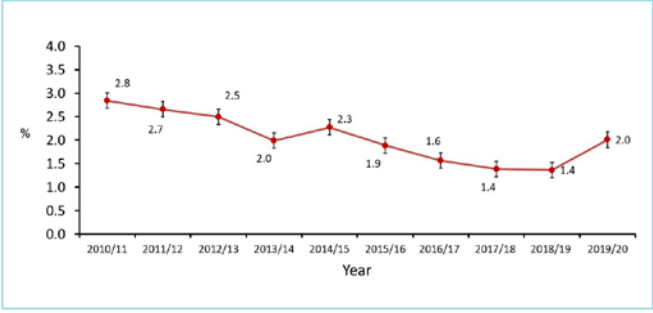


Figure 2.6 (b): Distribution of deaths in different risk groups, 2017/18 – 2019/20

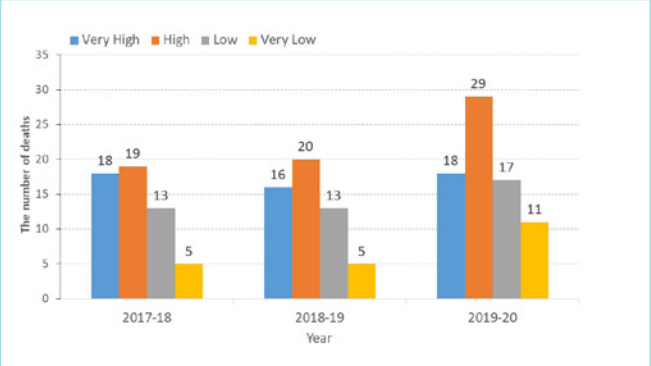
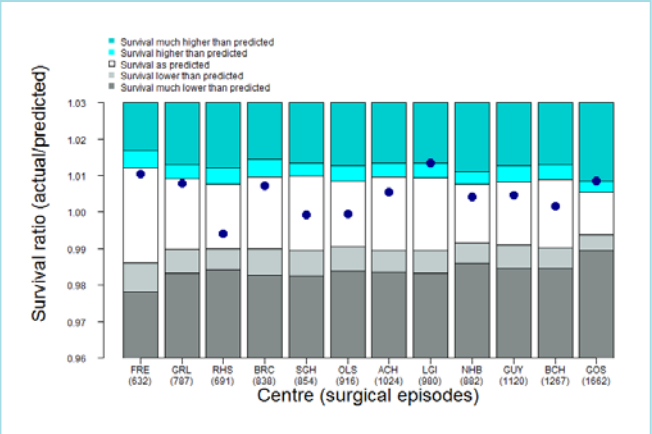


Figure 2.6 (a) shows the unadjusted raw (crude) mortality rates with a rise to 2.0% of 3,731 surgical operations undertaken in children under 16 years of age in 2019/20. The chi-squared test shows the crude mortality (2.0%; 75/3,731) in 2019/20 is significantly higher than 2017/18 (1.38%; 55/3,971) and 2018/19 (1.36%; 54/3,958). Although the analysis of the raw mortality data suggests an increase in mortality, the risk-adjustment results show that performance once adjusted for case mix remains better than expected. However, the levelling-off of results in 2018/19 depicted in the VLAD chart is noted and future results will be monitored carefully. Absolute numbers of deaths were higher in the very low, low and high risk groups but not the very high risk group [Figure 2.6 (b)]. Further analysis is required to determine whether there are any areas of concern, although the unit-specific results (see below) do not identify a problem at hospital level.

To understand the rise in crude mortality in 2019/20, in Figure 2.7 we show the distribution of deaths in 2019/20 compared to 2017/18 and 2018/19 where the y-axis is the absolute number of deaths. The definition of each risk group is outlined in reference 14.[14] The data depict that more higher-risk patients died (Q3 and Q4) in 2019/20 when compared to 2017/18 and 2018/19. To better understand this change, more in-depth data collection and analysis would be required.

Nevertheless, these outcomes still are amongst the best reported in the world, with comparable overall multicentre mortality at hospital discharge in North America in 2011-2014 of 3.2% (all ages) and a derived 2014-2017 rate of 2.8% (all ages).[15]

Figure 2.7: Actual vs Predicted Survival for all 12 centres undertaking cardiac procedures in patients under 16 years of age in the UK and Republic of Ireland, using PRAiS2 risk adjustment methodology, 2017/20



Note: Outcomes are adjusted for age, weight, diagnosis, comorbidities and procedures performed. Abbreviations: FRE, Newcastle, Freeman Hospital; GRL, Leicester, Glenfield Hospital; RHS, Glasgow, Royal Hospital for Sick Children; BRC, Bristol Royal Hospital for Children; SGH, Southampton, Wessex Cardiothoracic Centre; OLS, Dublin, Our Lady's Children's Hospital; ACH, Liverpool, Alder Hey Children's Hospital; LGI, Leeds General Infirmary; NHB, London, Royal Brompton Hospital; GUY, London, Evelina London Children's Hospital; BCH, Birmingham Children's Hospital; GOS, London, Great Ormond Street Hospital for Children.

Table 5: *Actual and Predicted Survival, using PRAiS2 Risk Adjustment methodology with average predicted risk per case, for all 12 units undertaking procedures in patients under 16 years of age, 2017/20*

Hospital	Centre Code	Surgical Episodes	Survivors	Deaths	Predicted Survival	Actual/ Predicted	Survival summary	Average Predicted Mortality Per Case
Newcastle Freeman Hospital	FRE	632	623	9	97.6%	1.011	as predicted	2.45%
Leicester Glenfield Hospital	GRL	787	778	9	98.1%	1.008	as predicted	1.91%
Glasgow Royal Hospital for Children	RHS	691	677	14	98.5%	0.994	as predicted	1.48%
Bristol Royal Hospital for Children	BRC	838	826	12	97.9%	1.007	as predicted	2.13%
Southampton Wessex Cardiothoracic Centre	SGH	854	835	19	97.9%	0.999	as predicted	2.14%
Dublin Our Lady's Children's Hospital	OLS	916	898	18	98.1%	0.999	as predicted	1.92%
Liverpool Alder Hey Hospital	ACH	1,024	1,004	20	97.5%	1.006	as predicted	2.49%
Leeds General Infirmary	LGI	980	970	10	97.7%	1.013	higher than predicted	2.34%

London Royal Brompton Hospital	NHB	882	872	10	98.5%	1.004	as predicted	1.55%
London Evelina London Children's Hospital	GUY	1,120	1,100	20	97.8%	1.005	as predicted	2.24%
Birmingham Children's Hospital	BCH	1,267	1,235	32	97.3%	1.002	as predicted	2.68%
London Great Ormond Street Hospital for Children	GOS	1,662	1,650	11	98.4%	1.008	higher than predicted	1.56%
Overall		11,652	11,468	184	97.9%	1.005		2.1%

The results in Figure 2.7 and Table 5 show that over the last 3 years, all centres have performed such that 30-day survival was as predicted or better than predicted, given the alert and alarm control limits, for aggregated outcomes after all surgical procedures in children (description linked to methodology here). Two centres performed 'higher' than predicted – Great Ormond Street Hospital, London and Leeds General Infirmary, Leeds. This is indicative of good performance and represents an opportunity for sharing optimal practice across specialist centres.

The Congenital Audit also calculates the average PRAiS2 risk adjusted mortality per patient operated upon at each of the 12 centres, as a way to understand the relative complexity of cases at each centre [Table 5, last column]. This shows significant variance between centres (Chi-Squared test, P value <0.001), from 1.48% to 2.68%, suggesting, for instance, that the two largest centres (Birmingham Children's Hospital and Great Ormond Street Hospital for Children) operate upon groups of patients with significantly different risk profiles of complex CHD and case-mix.

Some centres, for instance, such as Glasgow, are known to send many of their most complex patients to England for Norwood procedures. Having said this, the PRAiS2 model should largely take these differences into account. Future work for the Congenital Audit will include understanding case-mix proportions by centre and which procedures account for most of this variation.

2.2.3 30-Day Survival after 83 Specific Procedures

Survival at 30 days was analysed for 83 major surgical, transcatheter cardiovascular and electrophysiological interventions undertaken to treat congenital heart disease at any age (children and adults analysed separately), excluding minor and non-cardiovascular procedures. This has been a two-step increase from the 57 procedures reported in 2011/12 to 2013/14, to 72 procedures subsequently and the current 83 specific procedures reported since 2016/17.

Apart from two centres (Dublin Our Lady's Children's Hospital for balloon dilation and/or stenting of pulmonary veins and London Evelina Children's Hospital for transluminal systemic-to-pulmonary collateral artery (MAPCA) procedure), all other hospitals 30-day survival was better than the alarm (99.5%) and alert (97.5%) limits for all procedures. The results of these two centres fall in the alert category, but these relate to outcomes from previous years in the 3-year cycle as highlighted in our 2020 summary report. Both centres have been followed up for data accuracy with re-verification and re-analysis as both cases involved procedures for rare complex case-mix. Appropriate steps have been taken to ensure this does not represent issues around surgical competencies.

To see the volume and outcomes of activity for the different procedure categories and specific procedures for each congenital heart centre, click here. Funnel plots for each specific procedure are also available here. NICOR follows the Department of Health Outlier Policy[16] which sets out a process for providing assurance that all hospitals provide the expected quality of care. For details click here.

2.2.4 30-Day Aggregate Survival after Congenital Heart Surgery in Adults

Figure 2.8 illustrates the majority of work undertaken by centres for individuals between 20 and 50 years of age but there is a huge range from 16 years to over 80 years of age.

The box in each column for each centre represents the median of patient ages (middle bold line) and quartiles (1st and 3rd) instead of mean and standard deviations. The red line represents median age (i.e. 34 years old) across the 14 centres undertaking adult congenital surgical procedures in 2017/20. The box plots illustrate and compare the age distribution (skewness) of patients 16 years of age and older who have undergone CHD procedures. The exception is Great Ormond Street Hospital for Children, who, as the name suggests, do not take on operations in adults over 18 years of age.

Figure 2.8: Age distribution of adults undergoing surgery for CHD at the 14 centres undertaking over 30 procedures, 2017/20

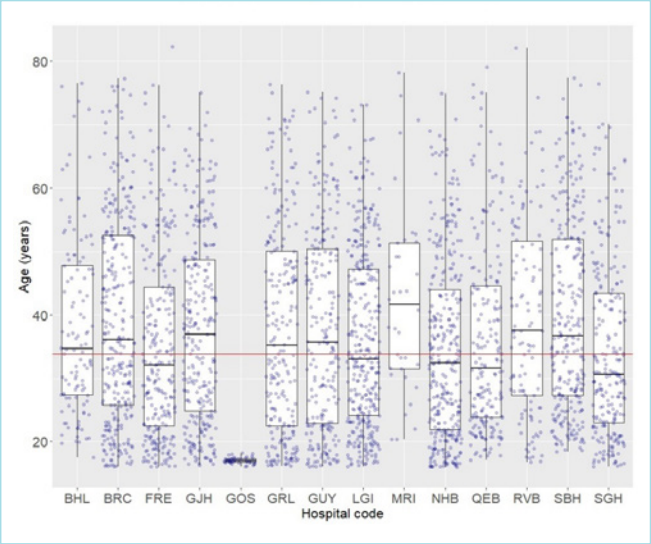


Figure 2.9: Actual vs Predicted Survival using STAT mortality score methodology for the 14 centres in the UK undertaking at least 30 congenital heart surgical procedures in patients aged 16 years and over, 2017/20

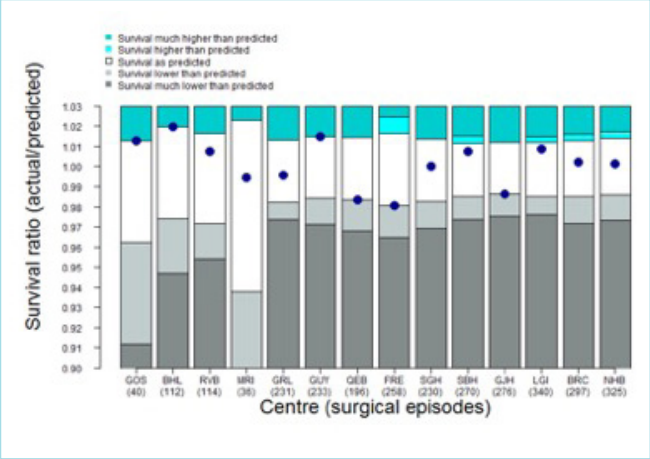


Table 6: Actual and Predicted Survival using STAT mortality risk methodology to give the average predicted risk of death per case centres undertaking at least 30 congenital heart surgical procedures in patients aged 16 years and over, 2017/20

Hospital	Centre Code	Surgical Episodes	Survivors	Deaths	Actual Survival	Predicted Survival	Actual / Predicted Survival	Average Predicted Mortality Per Case
London Great Ormond Street Hospital for Children	GOS	40	40	0	100.0%	98.7%	1.013	1.28%
Liverpool Heart and Chest Hospital	BHL	112	112	0	100.0%	98.1%	1.020	1.94%
Belfast Royal Victoria Hospital	RVB	114	11*	<3	>98.0%	98.4%	>1.00*	1.62%
Manchester Royal Infirmary	MRI	36	3*	<3	>94.4%	97.8%	>0.9**	2.25%
Leicester Glenfield Hospital	GRL	231	227	4	98.3%	98.7%	0.996	1.29%
London Evelina London Children's Hospital	GUY	233	233	0	100.0%	98.5%	1.015	1.47%
Birmingham Queen Elizabeth Hospital	QEB	196	190	6	96.9%	98.6%	0.984	1.44%
Newcastle Freeman Hospital	FRE	258	247	11	95.7%	97.6%	0.981	2.39%
Southampton Wessex Cardiothoracic Centre	SGH	230	227	3	98.7%	98.7%	1.000	1.33%
London Barts Heart Centre	SBH	270	26*	<3	>99.2%	98.5%	>1.00*	1.5%
Glasgow Golden Jubilee National Hospital	GJH	276	269	7	97.5%	98.8%	0.986	1.18%
Leeds General Infirmary	LGI	340	33*	<3	>99.3%	98.5%	>1.00*	1.46%
Bristol Royal Hospital for Children	BRC	297	293	4	98.7%	98.4%	1.002	1.58%
London Royal Brompton Hospital	NHB	325	320	5	98.5%	98.3%	1.002	1.69%
Other centres	—	120	120	0	100%	98.6%	1.011	1.44%
Overall		3,078	3,032	46	98.5%	98.4%	1.001	1.56%

Note: Adult surgical activity moved from Manchester Royal Infirmary hospital to Liverpool Heart & Chest hospital in 2018/19.

N.B. Data are suppressed where case numbers are less than three and secondary suppression has been applied where applicable to ensure anonymity of the patient data included in reporting.

The outcome results in Table 6 and Figure 2.9 show that there were 3,078 adult patients operated upon during 2017/20. The overall actual to predicted survival ratio was 1.001, and this year there were approximately 6% fewer deaths than predicted by the STAT mortality model, which predicted 49 deaths, whilst actual deaths were 46.

In comparison with 2017/20, this year's predicted mortality is lower than last year, and actual deaths are fewer than predicted deaths. All 14 centres that undertook more than 30 operative procedures in 2017/18 to 2019/20 performed such that 30-day survival was as predicted, given the alert and alarm control limits, after all surgical procedures in adults with congenital heart disease. In addition, there were no centre level outliers for any of the 44 specific surgical procedures analysed for 30-day mortality. This suggests that the outcomes are likely not to be outside the statistically acceptable limits used within the STAT risk-adjustment model.

The NCHDA will focus efforts on the development of new QI metrics, long-term outcomes by diagnosis, collaborative initiatives to reduce early morbidity, and patient reported outcome measures (PROMs). The success of these initiatives is partly dependent on securing analytical resources and funding for research outside the audit structure.

2.3 Post-procedural complications

We recognise that excellent early survival rates supplemented by a wider range of outcome measures help better evaluate longer-term clinical and health-economic impact following paediatric and congenital heart interventions.[17]

In April 2015, the NCHDA introduced separate data fields to capture post-procedural complications following surgery and transcatheter interventions (including electrophysiology), in anticipation of being able to analyse three years of data during the current analytical cycle. Post-procedure complication rates for children (less than 16 years of age) following 12,410 surgical procedures and 9,494 transcatheter interventions at 12 UK and Republic of Ireland centres during 2017/20 are reported.

We also recognise that measurement of these variables is an area of ongoing development, and the NCHDA Domain Expert Group is currently reviewing definitions of various complications and ensuring robust processes are in place to allow accurate and consistent coding by all centres. There has to be caution when drawing firm conclusions at present from any variance observed as a measure of performance. There are particular concerns about the consistency of reporting for neurological events and therefore, this year, the report has excluded publishing data on acute neurological events.

2.3.1 Overview of QI metric: Summary of post-procedural complications

QI Metric Description/Name	**Incidence of six post-procedural complications:** * **Use of extracorporeal life support** * **Need for renal replacement therapy (including peritoneal dialysis)** * **Unplanned need for a pacemaker** * **Prolonged pleural drainage** * **Need for emergency procedure following catheter intervention** * **Embolisation of transcatheter implanted device**
Why is this important?	Quality assurance with possible quality improvement recommendation(s) following investigation with aim to reduce inter-centre variance by drilling down at centre level (by age and specific procedure), to establish best practice to minimise the incidence of each complication by future benchmarking at CHD procedural level.
QI theme	Safety and Outcomes
What is the standard to be met?	No standards, but least incidence is usually optimal and this is usually dependent on patient's pre-operative cardiac status.

Key references to support the metric	Brown KL et al. Incidence and risk factors for important early morbidities associated with paediatric cardiac surgery in a UK population. J Thorac Cardiovasc Surg 2019: 158(4):1185-1196[17] Jacobs JP. Introduction – Databases and the assessment of complications associated with the treatment of patients with congenital cardiac disease. Cardiol Young 2008; 18(Suppl. 2):1–37[18] Brown KL, Pagel P, Brimmell R, Bull K, Davis P, Franklin RC et al. Definition of important early morbidities related to paediatric cardiac surgery. Card Young 2017; 27:747–756[19]
Numerator	Count of patients with a coded complication.
Denominator	Countable surgical procedures. It is important to highlight that there is lack of consistency in data collection from individual centres leading to considerable variation between centres for each complication.
Trend	5-year aggregate for individual hospitals planned in the future when enough data are accumulated.
Variance	Some inter-centre variance seen in the incidence of each complication. Detailed case-mix and specific procedure adjusted analysis of causation required in the future to establish best practice for benchmarking and well-defined data variables for complications.

2.3.2 Audit results

The analyses focussed on four surgical and two interventional catheter-related complications.

Table 7: Incidence of post-surgical use of extracorporeal life support in children under 16 years of age in the 12 UK and Republic of Ireland centres, 2017/20

Hospital	Centre code	No	Yes	Total	%
Birmingham Children's Hospital	BCH	1,305	26	1,331	1.95%
Bristol Royal Hospital for Children	BRC	888	17	905	1.88%
Dublin – Our Lady's Children's Hospital	OLS	969	21	990	2.12%
Glasgow – Royal Hospital for Sick Children	RHS	709	27	736	3.67%
Leeds General Infirmary	LGI	998	13	1,011	1.29%
Leicester – Glenfield Hospital	GRL	802	39	841	4.64%
Liverpool – Alder Hey Hospital	ACH	1,060	42	1,102	3.81%
London – Evelina Children's Hospital	GUY	1,138	19	1,157	1.64%
London – Great Ormond Street Hospital for children	GOS	1,760	33	1,793	1.84%
London – Royal Brompton Hospital	NHB	885	23	908	2.53%
Newcastle – Freeman Hospital	FRE	654	25	679	3.68%
Southampton University Hospital	SGH	890	12	902	1.33%
Total		12,058	297	12,355	2.40%

The overall rate of this important and impactful adverse event was 2.4% (range per centre 1.2-4.6%): neonatal 5.5% (128/2,337); infant 1.91% (95/4,965) child 1.45% (74/5,108). There is similar centre-related variability with the highest rates in Leicester (4.6%) and those with a national ECMO program (Liverpool and Newcastle, 3.7-3.8%), as shown in Table 7. This may reflect a lower threshold for resorting to mechanical support following surgery.

Post-operative ECMO is also well known to vary in usage based on procedure type as has been shown in the STS Registry[20] and in the NCHDA data highest postoperative ECMO rates were following repair of common arterial trunk with aortic arch obstruction at 35.3% (6/17) or without at 11.0% (8/73), heart transplantation at 14.3% (12/84), a Norwood procedure at 14.4% (39/270), and repair of anomalous coronary artery at 11.7% (7/60).

Table 8: Incidence of post-surgical use of renal replacement therapy (dialysis) in children under 16 years of age in the 12 UK and Republic of Ireland centres, 2017/20

Hospital	Centre code	No	Yes	Total	%
Birmingham Children's Hospital	BCH	1,305	26	1,331	1.95%
Bristol Royal Hospital for Children	BRC	833	72	905	7.96%
Dublin – Our Lady's Children's Hospital	OLS	979	11	990	1.11%
Glasgow – Royal Hospital for Sick Children	RHS	716	20	736	2.72%
Leeds General Infirmary	LGI	975	36	1,011	3.56%
Leicester – Glenfield Hospital	GRL	830	11	841	1.31%
Liverpool – Alder Hey Hospital	ACH	1,032	70	1,102	6.35%
London – Evelina Children's Hospital	GUY	1,102	55	1,157	4.75%
London – Great Ormond Street Hospital for Children	GOS	1,730	63	1,793	3.51%
London – Royal Brompton Hospital	NHB	882	26	908	2.86%
Newcastle – Freeman Hospital	FRE	656	23	679	3.39%
Southampton University Hospital	SGH	880	22	902	2.44%
Total		11,920	435	12,355	3.52%

The overall rate was 3.5% (range per centre 1.1-7.9%): neonatal 9.8% (229/2,337), infant 2.4% (120/4,965), child 1.7% (86/5,108). Similar to last year there is considerable inter-centre variability from under 1.5% (Dublin and Leicester) to 5-7% (Liverpool and Bristol), as shown in Table 8. This most likely reflects differing intensive care management practices with some units using high dose diuretic therapy compared to others with a lower threshold for instigating dialysis.

Further analysis with respect to length of stay and time to extubation is warranted to examine if there is a material difference in outcomes between centres using different strategies. The use of dialysis occurred most frequently following repair of common arterial trunk with 23.5% (4/17) or without arch obstruction at 20.5% (15/73), repair of complex transposition with arch obstruction 29.8% (14/47) or without arch obstruction 11.1% (6/54) in 20% of cases having a Norwood procedure 25.9% (70/270) or lung transplant 22.2% (4/18) and repair of total anomalous pulmonary venous connection at 12.3% (22/179).

Table 9: Incidence for the unplanned placement of a pacemaker following congenital cardiac surgery in children (under 16 years of age) in the 12 UK and Republic of Ireland centres, 2017/20

Hospital	Centre code	No	Yes	Total	%
Birmingham Children's Hospital	BCH	1,318	13	1,331	0.98%
Bristol Royal Hospital for Children	BRC	876	29	905	3.2%
Dublin – Our Lady's Children's Hospital	OLS	974	16	990	1.62%
Glasgow – Royal Hospital for Sick Children	RHS	720	16	736	2.17%
Leeds General Infirmary	LGI	1,003	8	1,011	0.79%
Leicester – Glenfield Hospital	GRL	836	5	841	0.59%
Liverpool – Alder Hey Hospital	ACH	1,087	15	1,102	1.36%
London – Evelina Children's Hospital	GUY	1,15*	<3	1,157	<0.17%
London – Great Ormond Street Hospital for Children	GOS	1,780	13	1,793	0.73%
London – Royal Brompton Hospital	NHB	902	6	908	0.66%
Newcastle – Freeman Hospital	FRE	668	11	679	1.62%
Southampton University Hospital	SGH	886	16	902	1.77%
Total		12,20*	15*	12,355	1.2*%

*N.B. Data are suppressed where case numbers are less than three and secondary suppression has been applied where applicable. An * represents a digit between 0 and 9. For example, 20* could be read as an integer between 200 and 209. Percentages have been adjusted accordingly. This process was conducted for data protection reasons, to ensure anonymity of the patient data included in reporting.*

Overall, there were 15* cases with a somewhat reassuringly low rate of about 1.21% (range per centre 0.5-3.2%): neonatal 0.4% (9/2,337), infant 1.1% (55/4,965), child 1.7% (86/5,108).

There was some inter-centre variability [Table 9], requiring more detailed case by case review, given that certain procedures are expected to be at much higher risk for this complication, such as left ventricular outflow tract surgery. Most frequent procedures were: repair of congenitally corrected transposition of the great arteries (double switch, or switch-Rastelli procedures) at 25% (6/24), and tricuspid (11.8%, 2/17) or mitral valve replacement (9.8%, 13/133).

Table 10: Incidence of prolonged pleural drainage (over 7-10 days) following congenital cardiac surgery in children under 16 years of age in the 12 UK and Republic of Ireland centres, 2017/20

Hospital	Centre code	No	Yes	Total	%
Birmingham Children's Hospital	BCH	1,251	80	1,331	6.01%
Bristol Royal Hospital for Children	BRC	872	33	905	3.65%
Dublin – Our Lady's Children's Hospital	OLS	943	47	990	4.75%
Glasgow – Royal Hospital for Sick Children	RHS	669	67	736	9.1%
Leeds General Infirmary	LGI	1,006	5	1,011	0.49%
Leicester – Glenfield Hospital	GRL	837	4	841	0.48%
Liverpool – Alder Hey Hospital	ACH	1,054	48	1,102	4.36%
London – Evelina Children's Hospital	GUY	1,130	27	1,157	2.33%
London – Great Ormond Street Hospital for Children	GOS	1,758	35	1,793	1.95%
London – Royal Brompton Hospital	NHB	874	34	908	3.74%
Newcastle – Freeman Hospital	FRE	675	4	679	0.59%
Southampton University Hospital	SGH	852	50	902	5.54%
Total		11,921	434	12,355	3.51%

Overall, there were 434 cases with a rate of 3.5% (range per centre 0.4-9.1): neonatal 3.6% (84/2,337); infant 2.6% (127/4,965), child 4.4% (223/5,108). There were again clear differences between centres with highest rates at Glasgow (9.1%) and Birmingham (6.1%), as shown in Table 10, requiring more detailed case by case review, given that certain procedures are expected to be at much higher risk for this complication, such as Fontan-type procedures (28.9%; 144/498) and lung transplant (55.6%; 1/18), as well as about 29.4% of those undergoing a Rastelli procedure (10/34) or repair of atrioventricular septal defect with tetralogy of Fallot 21.2% (7/33). As of last year, the Congenital Audit has changed the definition to be beyond 10 days of drainage to be in line with the definitions used by the national Congenital Heart Services Quality Dashboard.

Table 11: Incidence of the need for an emergency complication-related procedure (surgery or transcatheter) related to a transcatheter procedure in children under 16 years of age in the 12 UK and Republic of Ireland centres, 2017/20

Hospital	Centre code	No	Yes	Total	%
Birmingham Children's Hospital	BCH	1,028	10	1,038	0.96%
Bristol Royal Hospital for Children	BRC	775	8	783	1.02%
Dublin – Our Lady's Children's Hospital	OLS	1,334	10	1,344	0.74%
Glasgow – Royal Hospital for Sick Children	RHS	482	3	485	0.62%
Leeds General Infirmary	LGI	891	3	894	0.34%
Leicester – Glenfield Hospital	GRL	39*	<3	398	<0.5*%
Liverpool – Alder Hey Hospital	ACH	877	10	887	1.13%
London – Evelina Children's Hospital	GUY	585	7	592	1.18%
London – Great Ormond Street Hospital for Children	GOS	855	4	859	0.47%
London – Royal Brompton Hospital	NHB	1,079	8	1,087	0.74%
Newcastle – Freeman Hospital	FRE	47*	<3	474	<0.4*%
Southampton University Hospital	SGH	63*	<3	634	<0.3*%
Total		9,408	67	9,475	0.71%

*N.B. Data are suppressed where case numbers are less than three and secondary suppression has been applied where applicable. An * represents a digit between 0 and 9. For example, 20* could be read as an integer between 200 and 209. Percentages have been adjusted accordingly. This process was conducted for data protection reasons, to ensure anonymity of the patient data included in reporting.*

Overall, there were 67 cases with, again, a reassuringly low rate of 0.71% (range per centre 0.2-1.1): neonatal 1.9% (18/933), infant 1.4% (25/1,812), child 0.4% (24/6,749) [Table 11].

Most frequent procedures were not surprisingly neonatal radiofrequency pulmonary valve perforation-dilation (1 of 34 cases, 2.9%) and stent placement in the right ventricular outflow tract (16 of 205 cases, 7.8%), as both procedures may involve inadvertent perforation of the right ventricular or pulmonary outflow tracts. Stent placement to maintain arterial duct patency was also relatively high at 11.8% (24/204).

Table 12: Incidence of catheter-related device embolisation following or during a transcatheter procedure in children under 16 years of age in the 12 UK and Republic of Ireland centres, 2017/20

Hospital	Centre code	No	Yes	Total	%
Birmingham Children's Hospital	BCH	1,027	11	1,038	1.06%
Bristol Royal Hospital for Children	BRC	780	3	783	0.38%
Dublin – Our Lady's Children's Hospital	OLS	1,335	9	1,344	0.67%
Glasgow – Royal Hospital for Sick Children	RHS	48*	<3	485	<0.4*%
Leeds General Infirmary	LGI	887	7	894	0.78%
Leicester – Glenfield Hospital	GRL	394	4	398	1.01%
Liverpool – Alder Hey Hospital	ACH	878	9	887	1.01%
London – Evelina Children's Hospital	GUY	588	4	592	0.68%
London – Great Ormond Street Hospital for Children	GOS	85*	<3	859	<0.2*%
London – Royal Brompton Hospital	NHB	1,073	14	1,087	1.29%
Newcastle – Freeman Hospital	FRE	471	3	474	0.63%
Southampton University Hospital	SGH	630	4	634	0.63%
Total		9,404	71	9,475	0.75%

*N.B. Data are suppressed where case numbers are less than three and secondary suppression has been applied where applicable. An * represents a digit between 0 and 9. For example, 20* could be read as an integer between 200 and 209. Percentages have been adjusted accordingly. This process was conducted for data protection reasons, to ensure anonymity of the patient data included in reporting.*

Overall, there were 71 cases with, again, a reassuringly low rate of 0.75% (range per centre 0.2-1.2): neonatal 1.1% (10/933), infant 1.3% (24/1,812), child 0.5 (37/6,749). There was some inter-centre variability likely reflecting case complexity [Table 12], but also possibly the increasing use of the transcatheter route for closing a patent arterial duct in prematurely born neonates and infants (2.0%; 34/1665).

2.4 Antenatal diagnosis

About 20–30% of congenital heart defects are severe, defined as being potentially life threatening and requiring surgery within the first year of life.[1, 21, 22] Failure to recognise and promptly treat major congenital heart disease is associated with increased morbidity and mortality rates and is recognised as an important quality-of-care issue.[23] A goal of CHD services is to diagnose heart disease as early as possible and the ideal is before birth, referred to as antenatal diagnosis. The NCHDA collects data for babies antenatally diagnosed with cardiac defect undergoing an intervention in the first year of life and as these data do not represent the 'true' antenatal detection rates (as they exclude spontaneous intrauterine deaths, termination of pregnancy, non-intervention after birth and unrecognised death in community or non-tertiary centre) we have described antenatal detection against 'Procedures with Prenatal Diagnosis (PPD)' in this report.

Although at present there are no agreed international standards, the current aims of the Congenital Audit along with the National Fetal Cardiology Group are to achieve a PPD rate of at least 75% for all abnormalities but further discussion is required to determine whether different realistically achievable targets are needed for specific lesions. Poor antenatal diagnosis rates are associated with limited opportunity to counsel expectant patients and worse outcomes for babies.[24]

2.4.1 Overview of QI metric: Summary of level of Antenatal Diagnosis

QI Metric Description/Name	**Antenatal diagnosis of CHD in those requiring a procedure in infancy – overall and 4 specific diagnoses:** * **Hypoplastic left heart syndrome (HLHS)** * **Transposition of the great arteries with intact ventricular septum (TGA-IVS)** * **Tetralogy of Fallot (TOF)** * **Complete atrioventricular septal defect (cAVSD)**
Why is this important?	Antenatal diagnosis improves postnatal survival and morbidity after neonatal procedures. It also gives opportunities for parental counselling about the likely outcomes for their babies, investigations for associated extracardiac and genetic anomalies, and prenatal planning for the optimal place and method of delivery, as well as management in the perinatal period.
QI theme	Effectiveness and timeliness.
What is the standard to be met?	National fetal cardiology group recommendation for sonographers to: Achieve diagnosis PPD rate of at least 75% for all abnormalities where an intervention is undertaken in the first year of life; Achieve a high PPD rate of at least 75% for certain specific lesions where an intervention within hours of birth may be required.

Key references to support the metric	Gardiner HM, Kovacevic A, van der Heijden LB, et al. Prenatal screening for major congenital heart disease: assessing performance by combining national cardiac audit with maternity data. Heart. 2014 Mar; 100(5):375-382.[23] Holland BJ, Myers JA, Woods CR. Prenatal diagnosis of critical congenital heart disease reduces risk of death from cardiovascular compromise prior to planned neonatal cardiac surgery: a meta-analysis. Ultrasound Obstet Gynecol 2015;45:631–638.[24]
Numerator	Those with CHD who have an antenatal diagnosis and have had a countable procedure in infancy.
Denominator	Number of infants with CHD who underwent a therapeutic procedure in the first year of life, excluding patent arterial ductal and atrial septal defect closure procedures. It is important to highlight the denominator does not include spontaneous intrauterine deaths, termination of pregnancy, non-intervention after birth and unrecognised death in community or non-tertiary centre.
Trend	Ongoing improvement in PPD rates for infants requiring a cardiovascular procedure over the last 10 years across the UK and Republic of Ireland, as well as regional levels in England and Wales. The overall detection remains unchanged when compared to 2018/19.
Variance	Considerable regional variation remains between centres and their diagnostic success rate of CHD in those requiring a procedure in infancy.

2.4.2 Audit results

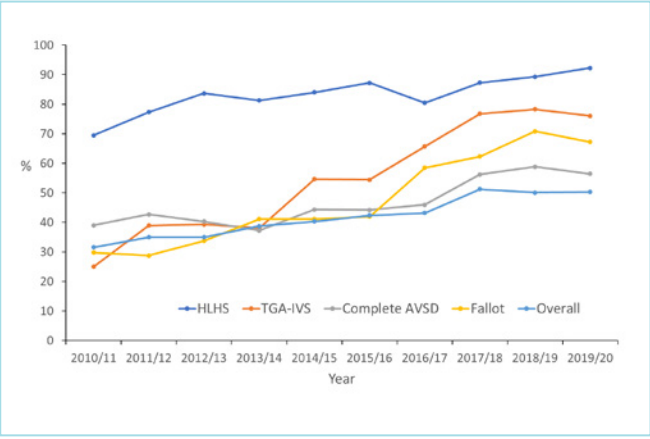
Overall detection of infants requiring a procedure

The latest audit data for 2019/20 show a continuing positive trend in PPD rates of all infants requiring a procedure with a successful antenatal detection [Table 13 and Figure 2.10]. The detection rate remains at 50% for all infants requiring a procedure in the first year of life [Figure 2.11].

Table 13: 10-year trend of proportion of patients undergoing procedures in infancy diagnosed antenatally, in the UK and Republic of Ireland, 2010/11 – 2019/20

Year	Overall diagnosis	Total	% Antenatally diagnosed
2010/11	680	2,154	31.6%
2011/12	737	2,106	35.0%
2012/13	780	2,230	35.0%
2013/14	843	2,175	38.8%
2014/15	852	2,114	40.3%
2015/16	915	2,159	42.4%
2016/17	953	2,208	43.2%
2017/18	1,173	2,292	51.2%
2018/19	1,014	2,025	50.1%
2019/20	1,015	2,017	50.3%

Figure 2.10: 10-year temporal trend in proportion of infants who underwent a procedure and were diagnosed antenatally, 2010/11 – 2019/20



Overall = any cardiac malformation; HLHS = hypoplastic left heart syndrome; TGA-IVS = transposition of great arteries with intact ventricular septum; Complete AVSD = complete atrioventricular septal defect; Fallot = tetralogy of Fallot.

However, there remains considerable regional variation in diagnostic rates for congenital heart disease before birth as shown in Table 14 ranging from below 40% to over 65% in different regions across the UK and RoI. Further work is ongoing to modify the geographical analysis to fit in with the contemporary regional boundaries.

The funnel plots below and on-line maps show graphically the regions where additional training for obstetric sonographers may be best targeted and which centres are performing best, given the caveats above that only continuing pregnancies are included of babies who have required an intervention in infancy.

To understand and improve rates of detection, several steps should be considered:

- Agreement on which pregnancies undergo sonographic evaluation;
- Mandatory training of the sonographers;
- Storage of specific cardiac views to allow internal and external review to encourage a learning process.

The NCHDA and its sponsoring professional societies will work with commissioners and the National Congenital Anomaly and Rare Disease Registration Service on these matters and to advise regions on steps to be taken to improve performance.

Figure 2.11: Overall 3-year PPD rates by region, 2017/20

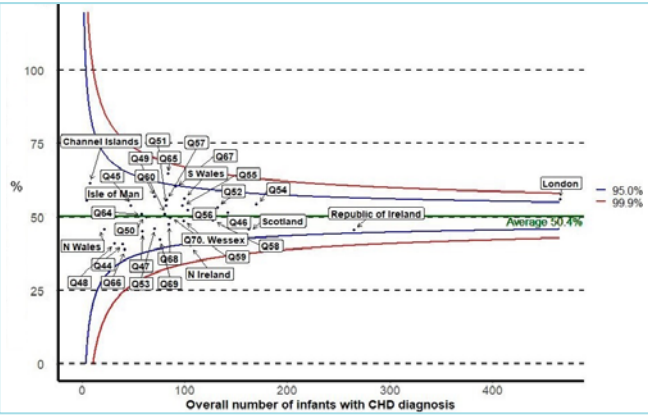


Figure 2.12: Overall 1-year PPD rates by region, 2019/20

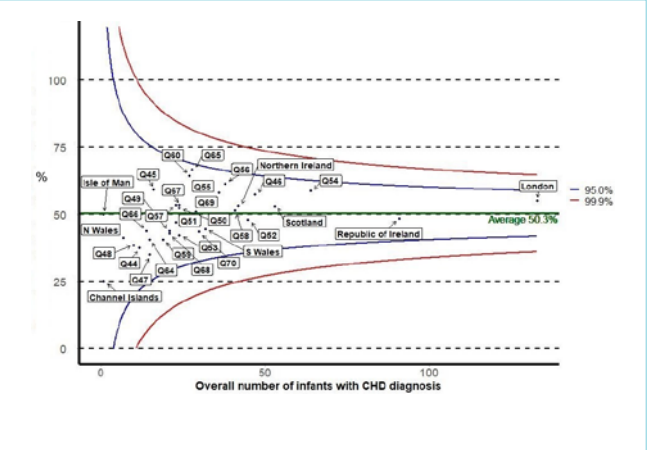


Table 14: Regional and national PPD rates for infants who underwent a procedure in the first year of life for any cardiac malformation in the UK and RoI, 2019/20

LAT	Overall diagnosis	Total	% Antenatally diagnosed
Channel Islands	<3	4	<75.0%
England	779	1522	51.2%
Isle of Man	<3	<3	<75.0%
Northern Ireland	42	79	53.2%
Republic of Ireland	91	188	48.4%
Scotland	53	100	53.0%
Wales	39	89	43.8%
Q44. Cheshire, Warrington and Wirral	12	32	37.5%
Q45. Durham, Darlington and Tees	16	27	59.3%
Q46. Greater Manchester	47	82	57.3%
Q47. Lancashire	15	43	34.9%
Q48. Merseyside	10	26	38.5%
Q49. Cumbria, Northumberland, Tyne and Wear	21	48	43.8%
Q50. North Yorkshire and Humber	24	46	52.2%
Q51. South Yorkshire and Bassetlaw	23	49	46.9%
Q52. West Yorkshire	45	94	47.9%
Q53. Arden, Herefordshire and Worcestershire	24	57	42.1%
Q54. Birmingham and the Black Country	64	109	58.7%
Q55. Derbyshire and Nottinghamshire	36	62	58.1%
Q56. East Anglia	38	62	61.3%
Q57. Essex	23	43	53.5%
Q58. Hertfordshire and the South Midlands	41	80	51.3%
Q59. Leicestershire and Lincolnshire	19	47	40.4%
Q60. Shropshire and Staffordshire	27	42	64.3%
Q64. Bath, Gloucestershire, Swindon and Wiltshire	15	37	40.5%
Q65. Bristol, North Somerset, Somerset and South Gloucestershire	28	42	66.7%
Q66. Devon, Cornwall and Isles of Scilly	14	32	43.8%
Q67. Kent and Medway	24	45	53.3%
Q68. Surrey and Sussex	21	49	42.9%
Q69. Thames Valley	29	57	50.9%
Q70. Wessex	30	69	43.5%
Q71. London	133	242	55.0%
T03. North Wales	7	17	41.2%
T04. South Wales	32	72	44.4%
Local Health Board 7A2	3	7	42.9%
Local Health Board 7A3	9	21	42.9%
Local Health Board 7A4	8	15	53.3%
Local Health Board 7A5	3	7	42.9%
Local Health Board 7A6	7	19	36.8%
Local Health Board 7A7	<3	<3	<75%
Overseas	6	26	23.1%
Unknown	3	7	42.9%
Total	1015	2017	50.3%

RoI = Republic of Ireland.

N.B. Data are suppressed where case numbers are less than three and secondary suppression has been applied where applicable to ensure anonymity of the patient data included in reporting.

Detection rates for individual cardiac malformations

Figure 2.13 to Figure 2.16 and Table 15 show that the detection rate of four individual cardiac lesions remains at a continued high diagnosis rate. For hypoplastic left heart syndrome, this has risen from about 70% ten years ago to over 90% this year. The improvement in TGA-IVS is particularly impressive due to incorporation of the 3-vessel and trachea (3VT) view into the fetal anomaly screening programme.

Table 15: 10-year detection rates for HLHS, TGA-IVS, complete AVSD and tetralogy of Fallot antenatally diagnosed and who underwent a procedure within 12 months of birth, 2010/11 to 2019/20*

Financial Year	HLHS		TGA-IVS		Complete AVSD		Tetralogy of Fallot	
	N	%	N	%	N	%	N	%
2010/11	66	69.5%	25	25.0%	57	39.0%	62	29.8%
2011/12	75	77.3%	30	39.0%	70	42.7%	57	28.8%
2012/13	82	83.7%	33	39.3%	58	40.3%	77	33.8%
2013/14	87	81.3%	32	38.1%	54	37.2%	102	41.1%
2014/15	79	84.0%	41	54.7%	63	44.4%	95	41.1%
2015/16	82	87.2%	49	54.4%	65	44.2%	94	42.0%
2016/17	66	80.5%	46	65.7%	74	46.0%	152	58.5%
2017/18	96	87.3%	53	76.8%	77	56.2%	180	62.3%
2018/19	67	89.3%	54	78.3%	80	58.8%	136	70.8%
2019/20	60	92.3%	38	76.0%	62	56.4%	135	67.2%

* Full table for individual lesions available here.

Figure 2.13 to Figure 2.16 show funnel plots depicting the PPD rates by region for the three years 2017/20 to 2019/20 for four CHD conditions (i.e. hypoplastic left heart syndrome, transposition of great arteries with intact ventricular septum, tetralogy of Fallot and complete atrioventricular septal defect (complete AVSD)) for those who underwent a cardiovascular procedure in the first year of life.

Figure 2.13: Hypoplastic left heart syndrome, 2017/20

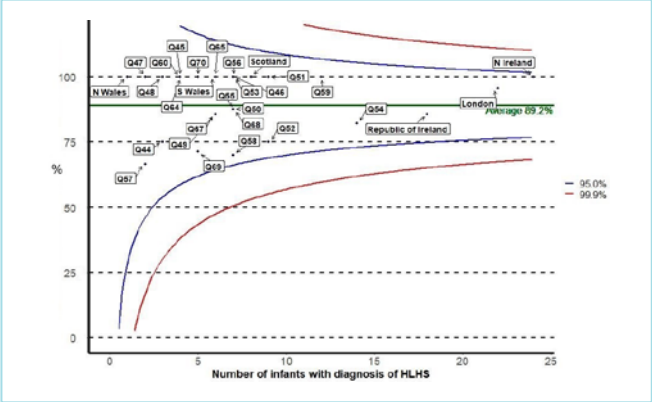


Figure 2.14: Transposition of great arteries with intact ventricular septum, 2017/20

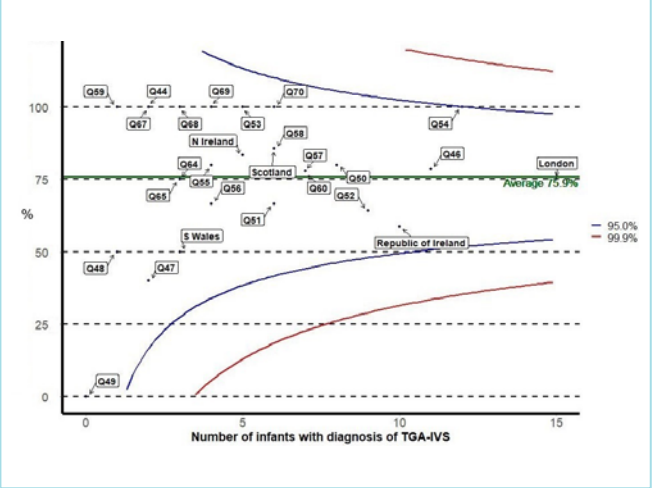


Figure 2.15: Tetralogy of Fallot, 2017/20

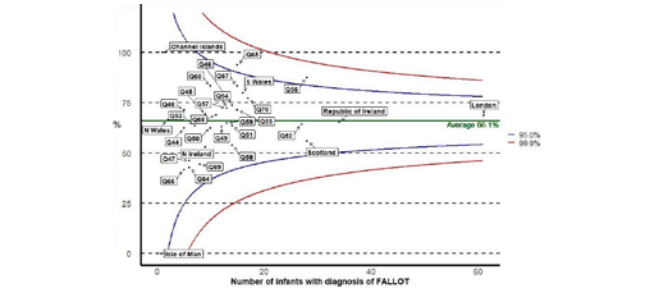
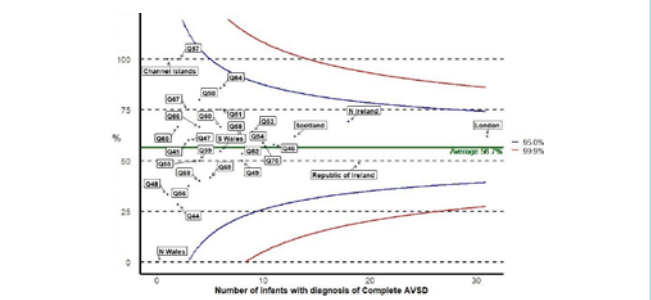


Figure 2.16: Complete atrioventricular septal defect (complete AVSD), 2017/20



2.4.3 Recommendation for those not achieving the standard

Hospitals should aim to increase the rate of antenatal diagnosis of conditions requiring intervention in the first year. Individual congenital heart disease networks should improve rates of antenatal diagnosis by reviewing staffing, infrastructure, education and training requirements.

2.5 Data Quality Indicator (DQI)

NCHDA validation includes a remote site validation process, which involves onsite assessment of data quality across 4 domains to produce a data quality indicator score for each centre assessed. The Data Quality Indicator score gives an indication of the quality of the data submitted by each mixed practice or paediatric centre against the expected NCHDA Standard.

2.5.1 Overview of QI metric: DQI scoring

QI Metric Description/Name	Data Quality Indicator Score
Why is this important?	Data Quality Indicator score gives an indication of the quality of the data submitted by each centre against defined NCHDA Standard
QI theme	Safety, Timely, Efficient, Effective
What is the standard to be met?	Good quality = >90% Excellent quality = >98%
Key references to support the metric	NCHDA annual reports 2018 and 2019. The conceptual basis for this DQI is explained in the 1998 -1999 Data Quality Indicator Methodology Paper (DoH). Clarke DR, Breen LS, Jacobs ML, Franklin RC, Tobota Z, Maruszewski B, Jacobs JP. Verification of data in congenital cardiac surgery. Cardiol Young 2008; 18 suppl 2: 177-185[25]
Numerator	Depends on number of procedures the random sample patients have had within a 12-month time period – can range from 20 – 35 procedures depending on complexity of sample.
Denominator	Depends on number of procedures the random sample patients have had within a 12 month time period – can range from 20 – 35 procedures depending on complexity of sample.
Trend	Overall Good to Excellent: 8 centres score 98% or more 7 centres score between 95 – <98% 2 centres score 90 – <95%
Variance	This is difficult to quantify due to variation in case mix and numbers of procedures and infrastructure support, and Trend (above) can be an indicator of this. Variance may also be due to inadequate, centre level, Database staff (Data Base Manager & support depending on size of centre), skillset, and in house software.

2.5.2 Audit results

Overall DQI scores remain very good. Of the two centres at the lower end of the scale this last year, these are either providers who are in the process of setting up a recently transferred service from another hospital or a centre that has had an information system change and new data manager. It is recommended that each Level 1 provider of congenital cardiac services meets the recommended staffing levels specified in NHSE New CHD Review 2016.[26] It is further suggested by the NCHDA that these senior data manager roles be scaled at Band 7 Agenda for Change with Band 6 for the assistant roles.

Table 16 shows the coloured DQI displaying overall DQI for centres and is RAG rated. It can be clearly seen using the RAG system that centres who score more than 98% overall are of an extremely high standard, green is good, amber is acceptable and red is a cause for concern.

Table 16: Overall DQI for all centres submitted to NCHDA for 5 years, 2014/15 to 2019/20.

Paediatric/Mixed Practice Hospitals	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	No. of WTE* 2019/20	NHSE Standards 2016 Requirement
Belfast Royal Victoria	98.75	98.25	94.50	*	*	*	see below	
Birmingham Children's Hospital	98.50	97.75	99.50	99.00	99.00	99.00	1.00	2 posts
Bristol Royal Children's Hospital	94.50	98.60	98.75	99.00	99.50	99.25	2.35	3 posts mixed practice
Dublin, Our Lady's Hospital	97.25	94.50	97.00	98.25	99.00	99.00	3.00	3 posts paeds only
Glasgow Royal Hospital for Sick Children	98.50	99.25	99.25	99.50	99,50	99.00	1.00	2 posts
Leeds General Infirmary	97.00	97.75	98.00	99.00	98.25	99.00	2.00	3 posts mixed practice
Leicester Glenfield Hospital	94.00	97.00	97.25	97.00	94.75	94.75	1.50	3 posts mixed practice
Liverpool Alder Hey Childrens Hospital	97.25	95.25	97.50	98.00	98.50	98.50	1.25	2 posts
London Evelina Childrens Hospital	97.50	99.25	96.00	99.00	99.40	97.75	3.00	3 posts mixed practice
London Great Ormond Street	99.50	97.00	99.50	95.00	93.00	97.75	1.00	1 post paeds only within a team of 5 in information department
London Harley Street Clinic	94.50	95.50	95.75	95.50	**	**		
London Royal Brompton & Harefield	99.00	99.25	99.25	99.00	87.50	95.75	2.00	3 posts mixed practice
Newcastle Freeman	97.25	97.50	99.00	98.75	99.00	99.75	1.00	3 posts mixed practice
Southampton Wessex Cardiothoracic Centre	97.50	95.75	99.00	98.75	98.75	98.25	1.50	3 posts mixed practice
Adult only Hospitals								
Belfast Royal Victoria	na	na	na	95.00	96.00	96.75	0.50	2 posts
Birmingham Queen Elizabeth Hospital	79.00	75.25	92.50	94.50	87.25	95.25	1.00	1 post
Glasgow Golden Jubilee	94.50	92.50	99.00	**	**	98.00	1.00	1 post
Liverpool Heart & Chest Hospital	****	****	****	****	93.50	94.75	1.00	1 post
London University College/St Bartholomew's	94.25	93.25	96.75	96.50	96.60	98.00	1.00	2 posts
Manchester Royal Infirmary	97.00	97.70	98.50	***	***	***	n/a	

Note: *WTE = Whole Time Equivalent Data Managers*

<90
90 to <95
95 to <98
>=98
* ACHD only
** No data submitted
*** Service transferred
**** New Service

2.5.3 Recommendation

In order to fully support the national clinical audit activity, it is recommended that all centres have provision of sufficient resources and processes in place including local information technology and software updates supporting NCHDA datasets for timely submission and data verification. This should also include supporting database managers to improve accuracy of data submission.

3 CASE STUDY REPORT: Standardising Cardiac Catheterisation radiation exposure in children with congenital heart disease

This is a case study exploring the variability in usage of total radiation dose (cGy/cm2) in cardiac catheter interventions in children (under 16 years of age) with congenital heart disease in all 12 UK centres.

3.1 Introduction

Cardiac catheter procedures can be used to understand the way the heart is working (diagnostic) or to carry out important treatments (interventions, pacing procedures and electrophysiology procedures). In the last 3 decades, the role of cardiac catheterisation in congenital heart disease has significantly expanded, not only being used as a diagnostic examination, but also having an important role in palliative and definitive treatments in over 50% of congenital heart disease patients.[27] Children and young adults are more radiosensitive to ionising radiation than the population as a whole and their longer lifespan provides more opportunity for long-term effects of ionising radiation to emerge. Ionising radiation is an important and necessary part of the care of children and young adults with congenital heart disease. Furthermore, the complexity, duration and number of catheter interventions in congenital heart disease patients have increased, consequently increasing the exposure to ionising radiation.[28]

The Ionising Radiation Medical Exposure Regulations (IR(ME)R, 2017) require hospitals to pay particular attention to medical exposure to radiation in children. There are no published diagnostic reference levels (DRLs) for congenital catheter procedures in children or established national standards that would allow centres to reference against. Using total radiation dose, which is recorded by most centres, this year the NCHDA sought to begin the process of helping centres fulfil these requirements and publish DRLs in a preliminary form. Data Analysis and Methodology:

The data analysed has shown a high variability in usage of total radiation dose (cGy/cm2) and screening time (minutes) nationally, which has made categorising centres difficult. Using box plots [Figure 3.1], we have displayed each centre variability/dispersion of radiation dose usage for the top seven specific procedure cohorts (i.e. Diagnostic catheter, PDA transluminal, ASD transluminal, ballooning pulmonary, ballooning aortic valve, PA ballooning, and stenting pulmonary artery) where each dot represents the usage of radiation dose; the vertical lines in the middle of the boxes represent average radiation doses used (median) by the centres and a red vertical line in each boxplot represents national average radiation dose (median) in the corresponding cohort. Several factors could contribute to this variation:

- Median age and weight of patients for each centre
- Use of single/multiple catheter labs with equipment with different radiation dose
- Age of imaging equipment[29]
- Consultant practice depending on experience and complexity of cases
- Optimising radiation exposure by controlling frame rate, area exposed, procedure complications, etc.
- Allowing trainees access to catheter labs and participating in procedures

Figure 3.1: *Total dose usage distribution of children undergoing the (top 7) seven catheter procedures by all 12 centres, 2017/20*

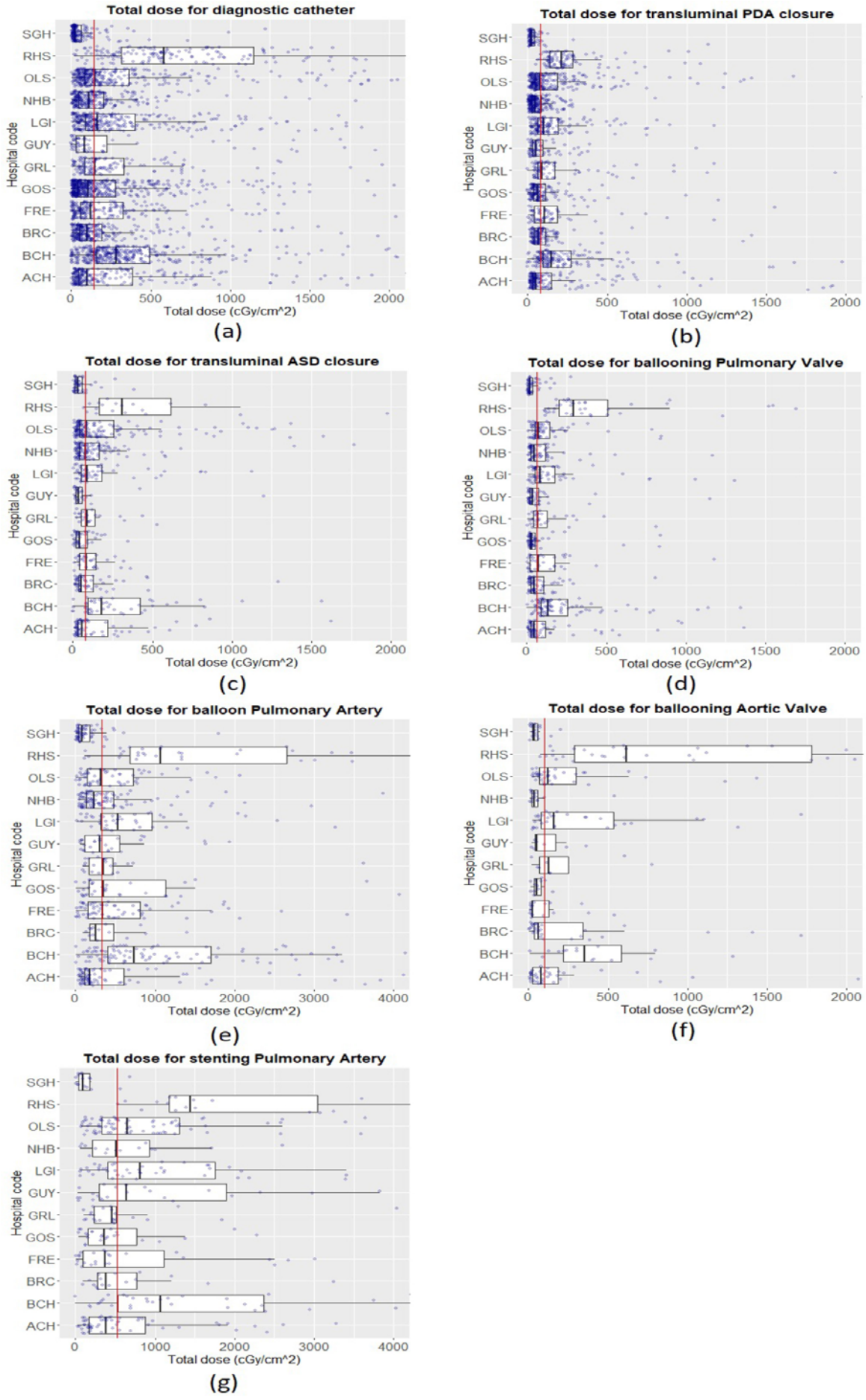
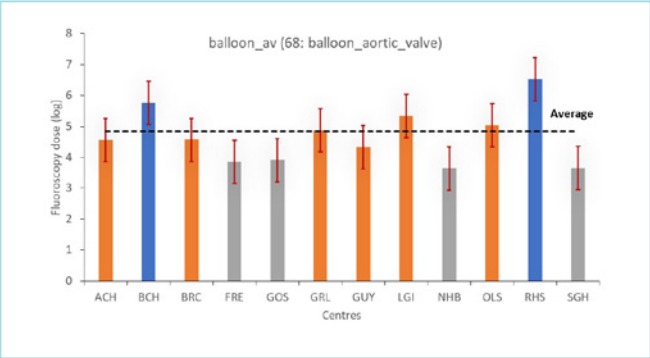


Figure 3.2 represents the usage of total dose (log scale) against the UK national average. The error bar represents the variability of total dose and dashed line the national average (log scale) with centres categorised into three different groups given their total dose usages, using a 98% confident interval for each cohort. The blue bars are group 1 centres (significantly higher than the national average of expected radiation dose), orange bars are group 2 centres (national average falling into the expected range of radiation dose), and grey bars are group 3 centres (significantly lower than the national average of expected dose).

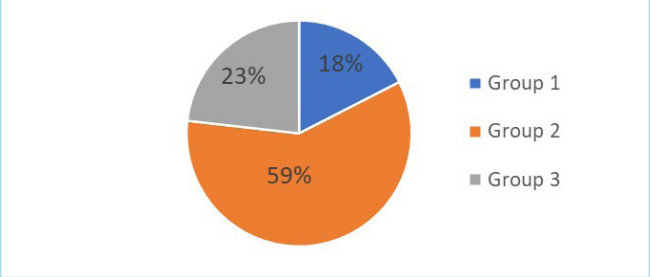
Figure 3.2: Bar chart of total dose by centres in ballooning aortic valve cohort



Note: The dashed line represents national average total dose usage (log scale) and error bars represent 98% confident interval for each centre. Different colours represent different groups of total dose usage where blue, grey and orange represent group 1, group 2 and group 3 respectively.

Figure 3.3 below shows an example of the ballooning aortic valve cohort with the percentage of each group identified in the cohort from the statistical point of view. It is important to highlight that the amount of dose usage by centres is an indicator of variability and not performance.

Figure 3.3: Percentage of fluoroscopy activity within the three groups for the ballooning aortic valve cohort.



3.2 Results

A total of 3,639 paediatric patients with congenital heart disease (age 16 years and under) were evaluated from 12 centres undergoing a diagnostic or interventional procedure between 2017/18 and 2019/20. The procedures with 'no qualifying codes' specific procedure category were excluded. Seven (top) procedures based on the highest fluoroscopy activity have been chosen to provide an opportunity for centres to perform a comparative evaluation. To allow centres to benchmark performance, the procedures selected were ones wherein more than 500 were undertaken nationally in the last three years.

Table 17 provides the demographic data and the characteristics of the population and procedure groups. Table 18 shows activity for all 12 centres in the UK and Republic of Ireland from 2017/18 to 2019/20 and Figure 3.4 highlights the top seven specific catheter procedures and fluoroscopic activity categorised by centre. In Figure 3.5 (a), we show the scatter plot between total dose (cGy/cm^2) and weight (Kg) where x-axis is patient weight and y-axis is corresponded total dose. Figure 3.5 (b) shows the scatter plot between screening time (minutes) and total dose (cGy/cm^2).

Due to the high variability and exponential growing usage of the total dose given the patient weight, we display this using a log scale (i.e., the patient weight growth from 1kg to 2kg is equivalent to the increase from 5kg to 10kg in the x-axis and the growth of total dose usage from 1 cGy/cm^2 to 100 cGy/cm^2 is equivalent to the increase from 100 cGy/cm^2 to 10000 cGy/cm^2 in the y-axis) as it is easier to reveal their relationship intuitively. It appears that there is linear relationship in the ratio of growth between the total dose usage and patient weight.

Table 17: Demographic data and characteristics of the procedures performed over 3 years in children aged 16 years and under at 12 centres nationally, 2017/20

	Total	Diagnostic	Interventional	7 top interventions
Patients (n)	3,639	1,146	2,771	2,904
Age (months)*	32	27	42	31
Weight(kg)*	13	14	12	13
Procedure time (min)*	55	47	59	47
Screening time (min)*	10	9	11	9
Total dose (cGy/cm2)*	146	140	148	121

** described in medians; n absolute number of patients.*

Table 18: Fluoroscopy activity summary for all 12 centres in the UK and Republic of Ireland, 2017/20

Hospital Code	ACH	BCH	BRC	FRE	GOS	GRL	GUY	LGI	NHB	OLS	RHS	SGH
Activity	973	1,263	767	727	1,071	493	505	1,092	1,180	1,493	575	587
Screening Time* (min)	9	12	11	10	7	14	14	11	10	10	11	8
Total dose* (cGy/cm2)	109	309	94	133	98	156	84	189	100	162	534	33

*Notes: 1) including procedure type 3. catheter intervention and 5. diagnostic catheter; 2) excluding Specific Procedure group "00:no_qualifying_codes"; 3) excluding Adult; 4) excluding small centres: BHL, GJH, HSC, RVB & STO; 5) Including >=500 centres and GRL (493); *5) median is used to present average screening time (min) and total dose (cGy/cm^2) by centre.*

Hospital name abbreviations: ACH – Liverpool Alder Hey Hospital; BCH – Birmingham Children's Hospital; BRC – Bristol Royal Hospital For Children; FRE – Newcastle Freeman Hospital; GOS – London Great Ormond Street Hospital for Children; GRL – Leicester Glenfield Hospital; GUY – London Evelina London Children's Hospital; LGI -Leeds General Infirmary; NHB – London Royal Brompton Hospital; OLS – Dublin Our Lady's Children's Hospital; RHS – Glasgow Royal Hospital for Children; SGH – Southampton Wessex Cardiothoracic Centre.

Figure 3.4: Fluoroscopic activity in percentage for all 12 centres in the UK and Republic of Ireland undertaking top 7 specific interventions in patients under 16 years of age, 2017/20

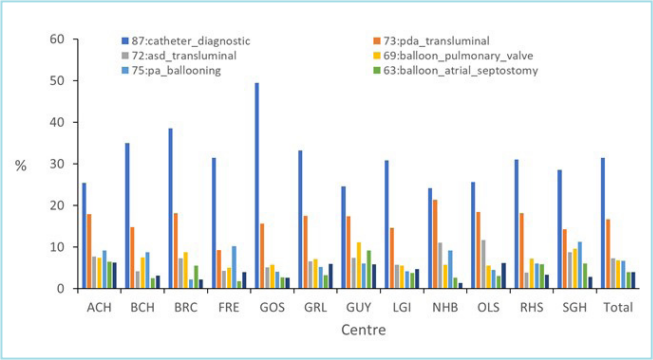


Figure 3.5 (a): Scatter plot between total dose (cGy/cm2) and weight (kg) by centres, 2017/20

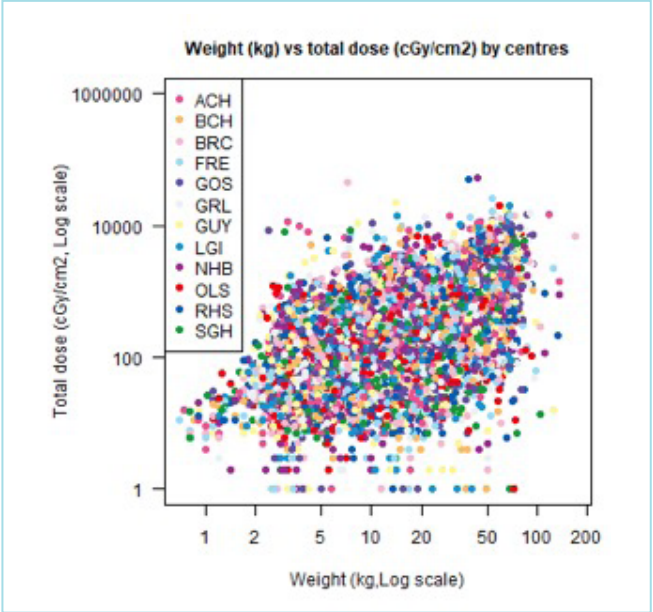
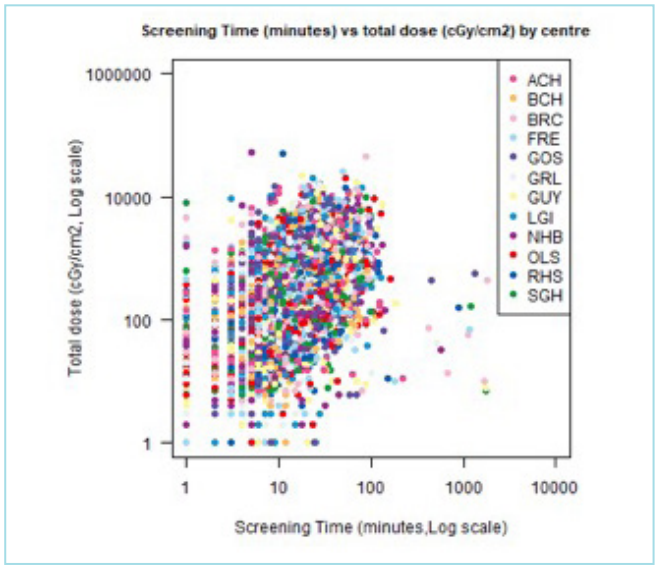


Figure 3.5 (b): Scatter plot between screening time (minutes) and total dose (cGy/cm2) by centres, 2017/20



Hospital name abbreviations expanded: ACH – Liverpool Alder Hey Hospital; BCH – Birmingham Children's Hospital; BRC – Bristol Royal Hospital For Children; FRE – Newcastle Freeman Hospital; GOS – London Great Ormond Street Hospital for Children; GRL – Leicester Glenfield Hospital; GUY – London Evelina London Children's Hospital; LGI -Leeds General Infirmary; NHB – London Royal Brompton Hospital; OLS – Dublin Our Lady's Children's Hospital; RHS – Glasgow Royal Hospital for Children; SGH – Southampton Wessex Cardiothoracic Centre.

3.3 Recommendations

The wide heterogeneity seen in congenital heart disease has been a major challenge for setting reference values leading to a lack of standardisation of radiation dosage and measurement units for diagnostic and interventional catheter procedures.[30] Furthermore, in recent years, the complexity and number of transcatheter procedures have increased.[28] Hence, it is important to protect patients and staff from cumulative exposure to ionizing radiation and its potential effects, making the need to establish reference data crucial.[31]

At the same time, one can also argue that a procedure could be done more safely with radiation rather than with echocardiography or a combination of the two would be better e.g. a good stent positioning and result might require more radiation than a mediocre result.

We hope that we will be able to provide referencing standards for commonly performed procedures that centres can use for dose reduction initiatives where possible, including in-house comparison of variance between individual operators. This reinforces the need for awareness of centres to ensure appropriate and updated imaging equipment and a well-developed controlled quality assurance programme for radiation safety. It is important to stress that radiation use should only be inferred by clinicians to look at their practice and what others are doing. The goal is to provide centres with DRLs that can be used to ensure what they are delivering is within a reasonable reference range.

Additional analysis is required to better demonstrate radiation doses and association to type of procedure, age & weight and screening times. This may help interventional cardiologists anticipate radiation doses for different case types and track these doses not only in terms of gross amount but also in terms of how much radiation above a planned dose was delivered.

4 Future direction

4.1 Data Completeness tools

The recent release of new data tools by NICOR will enable real time access to patient data that were not previously possible. The aim is to have more contemporaneous data available to hospitals with potential to transform patient care by enabling decision-making in a more timely, safe and effective manner. The QI tool will allow hospitals to compare themselves on a continuous basis for each QI metric with the national average as well as the best centres. The tool also allows for more autonomous management of the accuracy and completeness of hospital data.

4.2 New Quality Improvement metrics

With continued good performance in 30-day post-procedure outcomes, which is reassuring for patients, families and commissioners, the congenital heart disease community is now seeking new metrics and quality improvement initiatives, which can further improve care and life prospects. For instance, many adult congenital operations (aortic sub-speciality teams) are being established in adult acquired cardiac surgery, and efforts should be looked into combining internal databases within NICOR.

4.3 Review of Data variables

To supplement early survival rates with a wide range of longer-term outcome measures, NCHDA has been collecting data on post-procedure complications following paediatric and congenital interventions. The current definitions for these variables[14] have resulted in inconsistent data submission by individual centres leading to a huge variation in data for each complication. We recognise that measurement of these variables is an area of ongoing development, and NCHDA has therefore put together an expert working group to better define the variables.

4.4 Fetal Database

It has been a long-standing ambition to create a Fetal Database within NICOR with the aim to improve the information on antenatal diagnosis and outcome, linking to postnatal outcomes, thereby reporting national outcomes by congenital heart disease diagnosis rather than procedure. With the new NICOR database platform (QReg5) successfully implemented it will be possible to create a bidirectional data-sharing link between NCHDA and the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) to optimise data quality and full case ascertainment. The NCHDA is putting together a working group to define data variables and explore a funding stream for the project. The next steps would also be to explore ways of improving regional reporting and mapping using newly developed systems e.g. at ICS level.

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