National Congenital Heart Disease Audit (NCHDA) Methodology

The National Congenital Heart Disease Audit (NCHDA) was set up in 2000 as the Central Cardiac Audit Database 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.

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.

This paper expands on description of methodology used for individual metrics in the Main Report by explaining processes used for data collection, validation & analysis and different statistical & risk models used for analysis and deriving outcomes. It is important to note that data from Scottish centres were excluded for all years throughout data analysis in the summary report this year.

1.1 CHD Activity (Procedural, Consultant, National Standards)

Although there remains no objective data to show the inverse relationship between paediatric cardiac surgery and mortality, 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. Previous analysis of the Congenital Audit data was not able to identify a statistically significant volume-outcomes relationship for UK centres undertaking paediatric cardiac procedures, although there was a definite trend to support better outcomes in larger centres. This supports the way that congenital heart centres have been commissioned in the UK over the last decade, not allowing NHS centre volumes to fall to the low numbers that can occur in other countries (including the USA). [1]

The NHS England national standards for manpower, related procedural volume and infrastructure are based on the expectation that this will ensure a consistent and sustainable service to help continue to improve the outcomes for paediatric and congenital heart patients of all ages as shown in QI Metric document Table 1.1.1.[2,3,4] Activity standards were set by NHS England in liaison with Society of Cardiothoracic Surgery (SCTS) with the aim to provide the best opportunity of achieving good outcomes for cardiac procedures in children and adults with CHD.
The exact nature of the procedure undertaken is also important for the standards and these ‘countable procedures’ were delineated by an NHS England-led subcommittee of congenital heart disease specialists in 2017.[2] Relatively minor operations, purely diagnostic catheter procedures and mechanical life support therapy used after CHD procedures are excluded. The NHS England review concluded that not all English centres treating children and adults fully met the current requirements. Hospitals undertaking congenital cardiac surgery were recommended to continue to work with specialist commissioners and to aim to meet the NHS England Standards.[5]

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.

Volume of activity is not the only consideration for good outcomes and there are other issues to consider. These include the sustainability of services, the numbers of support staff, the infrastructure needed and the frequency of on-call commitments. To better understand these factors within a quality assurance and improvement framework, the NHS England Quality Surveillance Team with senior congenital heart clinicians undertook peer review visits to all centres involved in tertiary level congenital heart services for children in England, Scotland, and Wales during 2019. This report, although complete, has not yet been published by NHS England.

A series of Qualitative Indicators have been developed to assess compliance with the CHD service standards[5] focussing on key areas of infrastructure and process that are indicative and relevant to delivering a robust and sustainable service, and that support improved clinical, and patient reported outcomes. These centre reviews should identify potential causes of variation in outcomes, which may be important for optimising the standard of care for those undergoing congenital heart procedures, providing an opportunity for sharing good practice across specialist centres as well as learning from centres with sustained better than predicted outcomes (see above).

Within the interactive report, CHD procedures are split by procedure type and divided into four age groups for children. Procedure types are categorised as surgery, cardiac catheter intervention, diagnostic cardiac catheter, and electrophysiology procedure. Similarly for children (aged 16 years and under) there are 4 age subgroups - neonate (birth to 30 days), infant (30 days to 1 year) and children (1 year to 16 years).

Extracorporeal membrane oxygenation (ECMO) is a form of mechanical circulatory support that can sustain or replace cardiac function. It is a type of life support intended for short to mid-term support. There are two main types of ECMO – venovenous (VV) and venoarterial (VA). For supporting cardiac failure, the venoarterial (VA) method is used and can be divided into 2 main categories:

1. Acute heart failure or augmented CPR: in cases where there is rapid decline in cardiac function or if patient in cardiac arrest does not recover from regular CPR. ECMO can be used to stabilise the patient, keep organs well perfused allowing the heart to either recover or allow time to transfer the patient to a specialist cardiac centre for further escalation therapy (bridge to

recovery or decision, implantation of a long-term mechanical support in form of ventricular assist device or transplantation). This can be defined as Primary ECMO, used as a bridging procedure and not as a rescue procedure after another CHD procedure.

2. Following CHD procedure: in cases where ECMO is connected to the patient following the operation, whether it was placed in the operating theatre or in the ICU and the indication was cardiac arrest, low cardiac output state, poor cardiac function, arrhythmia, residual or recurrent cardiac lesion, pulmonary including pulmonary hypertension, or sepsis. This can be defined as post-operative ECMO and reported as post-procedure complications.

1.2 Procedure Mortality (VLAD Charts, PRAiS2 and STAT risk models)

NCHDA focuses on improving the quality and safety of congenital cardiac procedures in children and adults. The ability to collect, analyse and report on procedural outcome data is a marker of quality assurance and safety assurance with possible in-house quality improvement measures undertaken following monthly within centre review of Variable Life Adjusted Displays (VLAD) charts. This identifies potential areas of concern or strengths, such as a 'cluster' of deaths, re-interventions, or survival of high-risk patients, thereby enabling improvements in patient safety and quality of care to be initiated.

However, there is increasing focus on outcome measures rather than mortality only. Outcome measures assess the effect of care on the health of patients, such as 30-day mortality and morbidity rates, length of stay, readmission rates, patient satisfaction, health-related quality of life, cost-effectiveness, and resource use.

The risk model (PRAiS2) essentially benchmarks the unit's outcomes against recent national outcomes in paediatric heart surgery accounting for all the important medical aspects of case mix complexity. A positive value (line going up) following an individual patient's operation indicates improved survival in comparison with what would be predicted based on that patient's congenital heart malformation and the presence of any associated cardiac and-or non-cardiac risk factors (so-called case mix). So, the estimated risk of death for a patient is small and this means that the VLAD will rise much more slowly for a run of survivors than it will fall for a run of deaths. Survival rates remain high, and the analyses show that the observed outcomes continue to be better than those predicted.

The VLAD chart national outcomes with surgical procedures represented by the orange 'VLAD chart' line, somewhat hidden by the re-intervention dots. The VLAD chart also displays all surgical or catheter-based re-interventions that occur within a 30-day episode of surgical. To note, when VLAD charts are displayed for within centre outcome review, the number of operations included is much smaller than this (depending on programme size this would be a few hundred rather than 8841 shown in the interactive report slide) and therefore the individual dots are easier to discriminate visually from the underlying blue alive-status line.

These displays, therefore, enable clinical teams to identify and review clusters of re-interventions following a review of VLAD charts within regular governance or morbidity conferences (usually monthly). Some of these will be planned re-interventions, but the focus by the centres will be on any unplanned additional procedures that are highlighted by the VLAD chart, and any learning or quality improvement measures that can be taken forward to avoid these in future. A full interpretation of the VLAD chart can be found **here.**

Although the VLAD trend and these crude mortality rates remain very good, it is important to note that both the risk model and assessment of life status (ONS) are based on mortality within 30 days of a surgical procedure and therefore does not account for the relatively few deaths, which occurred in hospital after 30 days. It is also an indication that the PRAiS2 model should be recalibrated. At present, recalibration is ongoing and PRAiS3 model is likely to be ready for implementation for report next year.

The interactive report slides also highlight that each centre's actual survival is significantly different from the predicted survival derived from the PRAiS2 model where the upper two zones (i.e., bright azure and azure) show higher and much higher than predicted survival and lower two zones (i.e., bright cyan and cyan) show lower and much lower than predicted survival. Paediatric cardiac surgical procedures are defined for this analysis as any cardiac or intrathoracic great vessel procedure carried out in patients under the age of 16 years, excluding lung transplant, extracorporeal and mechanical life support procedures, and minor/non-cardiovascular procedures.

The y-axis of the figure shows the survival ratio (actual survival/predicted survival) for all units, and the x-axis the number (in parentheses) of surgical 30-day episodes. The dot represents the actual performance of a unit. The shaded bars represent the alarm and alert control limits: three standard deviations (99.5%) and two standard deviations (97.5%) respectively. For centres that fall in these zones, there is evidence (at alert level) or strong evidence (at alarm level) to suggest that survival was lower or much lower than predicted by the PRAiS2 risk adjustment model (negative outlier) or was higher or much higher than predicted (positive outlier). The performance of units falling in or above the white area, indicates survival is the same, or above, that predicted by the model. It is important to note that as there are only 10 centres in the paediatric analysis this means that there is a 22.4% risk of at least one centre being beyond the alert limit and a 1% chance of being beyond the alarm limit by random chance (i.e., a false positive or negative outlier). For a more detailed, plain language explanation, see the **Understanding Children's Heart Surgery** website.

Adults who undergo surgery for congenital cardiac malformations represent over 20% of CHD surgical activity across the UK. The Congenital Audit has adapted the published adult congenital heart surgery mortality score methodology, as derived from the Society of Thoracic Surgeons–European Association for Cardio-thoracic Surgery (STAT) mortality score[6] for use as an aggregated assessment of 30-day survival for adults with congenital heart disease operated upon in the UK (currently the NCHDA do not receive adult congenital data from the Republic of Ireland). The coding system used by NCHDA and STAT system is the same (International Paediatric and Congenital Cardiac Code). The NCHDA cohort used was for all adults (16 years and older), who had undergone a surgical procedure (bypass, non-bypass & electrophysiology) at those centres undertaking over 30 procedures.

It is also important to understand that aortic valve surgery in older adults with CHD is often undertaken by surgeons who otherwise only operate on adults with acquired heart disease. Adult acquired surgical data and outcomes are submitted to the National Adult Cardiac Surgery Audit (NACSA), a separate Domain within NICOR. The Congenital Audit has arbitrarily set an upper age of 40 years for submission of data on individuals having aortic valve procedures, whilst data on older patients is submitted to the NACSA.

Using the STAT Specific Procedure allocation algorithm, each NCHDA surgical procedure category was allocated a STAT mortality rate, based on the postoperative outcomes of 12,513 adults with congenital heart disease (over 17 years of age, in hospital deaths) from 116 North American centres 2000/01 to 2012/13 within the Society of Thoracic Surgeons Congenital Heart Surgery Database here.

Although mortality here is based on historical outcomes of nearly 2 decades, the 30-day mortality is known to be low in this age group and is the only published comparable data at present on which to base our analysis. Where the Specific Procedure category had more than one STAT mortality rate the specific cases were identified and allocated specific STAT mortality rates according to the individual case procedure code. Using this process approximately 95% of all NCHDA adult procedures were captured. Where cases were excluded, this was generally because they did not fall into one of the STAT categories or it was not possible to map the specific procedure groups to a STAT category. Future reports will aim to incorporate a more detailed mapping exercise with group of clinicians to establish more sophisticated rules for inclusion and exclusion, as well as look to base these calculations on a more contemporaneous cohort of adult patients and their outcomes.

Mortality for the analysis was the usual externally validated NCHDA 30-day post-surgery outcome, as confirmed by the centre itself and the Office of National Statistics (ONS, part of NHS Digital). Cases with multiple procedures within 30 days of each other were treated in the same way as for the PRAiS methodology where the first procedure is used as the index procedure within the surgical episode. Subsequent analysis and generation of funnel plots for each centre used PRAiS2 methodology. The match of patient level data is acknowledged not to be perfect as the STAT mortality rate is based on hospital mortality (without external validation), whether before or after 30 days. Furthermore, in North America an adult is taken as over 18 years of age, whilst in NICOR the age cut off is at 16 years. However, these dissimilarities were judged to be relatively minor, and the differences between the patients themselves and congenital cardiac management strategies in North America and the UK were felt to be negligible.

1.3 Post-procedural Complications

Given the current excellent early survival rates for paediatric and congenital heart interventions, there has been agreement for some time by all stakeholders that this important safety outcome should be supplemented by a wider range of outcome measures. A recent 5-centre UK-based study was undertaken to prospectively measure the incidence of complications (also termed morbidities) following paediatric cardiac surgery and to evaluate the clinical and health-economic impact over the 6-months following surgery in 2015/16 to 2017/18. Clinicians involved included members of the NCHDA Domain Expert Group. Within this study, families and clinicians prioritised the following as principle postoperative events to monitor and define: unplanned re-intervention, feeding problems, renal replacement therapy, major adverse events, the need for extracorporeal life support, necrotising enterocolitis, post-surgical infection, and prolonged pleural effusion or chylothorax.[23] Independent significant risk factors for morbidity included neonatal age, complex heart disease and prolonged cardiopulmonary bypass and 6 months survival was less when morbidities were documented (88·2% compared to 99·3%) without a morbidity.[7]

For the purposes of the audit a complication is defined as an event or occurrence that is associated with a disease or a healthcare intervention, which is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome. A complication does not necessarily represent a breach in the standard of care that constitutes medical negligence or medical malpractice. In fact, the WHO has decided to call these *post-procedural disorders*, in an attempt to address this within the eleventh iteration of the International Classification of Disease (ICD-11). A procedure related complication is any complication (disorder), regardless of cause, occurring within 30 days after surgery or intervention in or out of the hospital. Procedural complications include both intra-procedural and post-procedural complications in this time interval.[8]

We also recognise that measurement of these variables is an area of ongoing development, and the NCHDA expert working 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 must be caution when drawing firm conclusions at present from any variance observed as a measure of performance.

The audit has reviewed and refined the definitions of all complications and the first results from this will be published in 2024. Detailed case-mix and specific procedure-adjusted analysis can then be undertaken to establish best-practice for benchmarking between centres.

1.4 Antenatal Diagnosis

Antenatal diagnoses require sophisticated ultrasonography equipment and highly skilled obstetric sonographers to acquire and interpret the images. Fetal cardiac screening is undertaken as part of the maternity service provided by local hospitals, and not at specialist congenital heart centres. This means that fetal cardiologists and the tertiary congenital cardiology centres listed in this report, do not have direct management of the obstetric sonographer team who undertake screening for CHD. A robust and swift referral system to fetal cardiologists is therefore also required following the finding of a possible fetal heart anomaly. A definitive diagnosis can then be made and a management pathway for the pregnancy agreed, along with appropriate counselling and support for the parents and the coordination of postnatal care.[9]

The proportion of infants detected with a heart anomaly requiring an intervention is over 50% in the latest NCHDA data, for babies with more complex lesions (such as hypoplastic left heart syndrome) antenatal detection is known to be much higher, around 80%, as such severe defects are easier to be seen by the obstetric sonographer. It is important to highlight that due to the great number of possible congenital heart disease diagnoses with a similarly large number of different therapeutic procedures, the four specific cardiac lesions reported do not account for the overall rate of antenatal diagnosis.

It is the NHS Fetal Anomaly Screening Programme that mandates the fetal echocardiographic views that sonographers use during screening. Originally this was simply the four chamber view and this was then expanded to left and right ventricular outflow tract (great arterial) views for detection of additional malformations such as transposition of the great arteries.[10] Most recently the three vessel and trachea views have been introduced as an aid to detect great arterial distal anomalies and disproportion.[10] Given this history, it is not surprising that antenatal detection

rates are much higher for babies with more severe, functionally single ventricle lesions (such as hypoplastic left heart syndrome), as such defects are more easily seen by the obstetric sonographer given a highly abnormal four chamber view.[11] Many important congenital heart malformations with great arterial abnormalities may have an entirely normal four chamber view and are therefore more difficult for the sonographers performing the screening scans to detect.

It is very important to emphasise that the NCHDA only publishes the success rate of antenatal detection of CHD by sonographers in those children who have survived pregnancy and have then required a procedure in infancy. These antenatal diagnosis rates of important CHD, in that they have required a procedure in infancy, are inevitably an underestimate of national and local prenatal detection success as they do not consider the four other possible outcomes following a fetal cardiac diagnosis:

- fetal death (spontaneous or termination of pregnancy)
- perinatal or postnatal death before an otherwise planned procedure was possible
- less severe malformations that have not required a procedure in infancy
- when a decision was made not to intervene on the infant due to the complexity of the heart abnormality or associated comorbidities such as severe chromosomal anomalies (compassionate care).

Of note, is that the specific lesions the NCHDA has focussed on would all expect to have procedures when a neonate or in infancy, unless designated for compassionate care. A further unknown factor is the likely small number of women who decide against antenatal sonographic screening for cultural and-or religious reasons – antenatal screening is not mandatory.

We have therefore described antenatal detection as ‘Procedures with Prenatal Diagnosis (PPD)’ in our reports.

NICOR has been working with Public Health England and the National Congenital Anomaly and Rare Disease Registration Service (NCARDS) to develop better measures to establish this, as well as developing an extension to the NCHDA dataset to include all those who have an antenatal diagnosis of CHD whatever their later outcome. It is hoped that direct linkage between the NCHDA database and NCARDS data would provide a comprehensive database to track diagnosis-based outcomes of all patients born with CHD, not just individuals who require a cardiovascular procedure.

Furthermore, we have tightened our methodology to ensure that patients were not counted more than once by ensuring that if an inter-unit transfer was made from one centre to another, that the infant was only counted once in terms of antenatal detection. In addition, rules about excluding any patients who had an isolated arterial duct procedure and were miscoded as having had an antenatal diagnosis were also excluded. These changes may partially explain the lower percentage increase seen than hoped for in comparison to previous years.

There are evidently a large number of regions who have scope for considerable improvement in detection rates. However, of importance is that most regions have many local screening centres sited within them, especially highly populated ones, such as the Thames Valley and London, with likely important centre-level variation in diagnostic rates within a region. Going forwards the NCHDA is planning to move away from regional reporting in England to reporting

antenatal detection rates along the geographic boundaries of Sustainability and Transformation Partnerships (STPs) and Integrated Care Systems (ICSs). Individual centres, however, should have a good grasp of how successful they are and be alerted of missed cases, mostly via links through their local fetal and paediatric cardiologist.

Many of the best regions in this three-year period have comparatively low volumes of these diagnoses. Again, it is worth emphasising that these rates do not account for inter-centre variation in the majority of regions, given the presence of several centres within their boundaries. As said, individual centres should have an understanding of how successful they are and of any missed cases, following feedback from their local fetal and-or paediatric cardiologist.

The continued major rises in detection rates in the last few years for transposition of the great arteries and tetralogy of Fallot, is attributable to the introduction of the mandatory 3-vessel and tracheal view in 2016 to the fetal cardiac sonographer protocol with the preceding 2-year national training programme.[12] However, it is also a tribute to individual local maternity centres introducing intensive training for their obstetric sonographers, often aided by the Tiny Tickers charity.

It is important to ensure that feedback mechanisms and links are in place between the Congenital Audit, the fetal cardiology community and antenatal ultrasound scanning departments to enable learning related to congenital heart cases which have not been detected. As previously, the NCHDA will facilitate this by passing on these results to the UK National Fetal Cardiology Group and Tiny Tickers Charity, enabling its members to target individual centres most in need of improvement for staff training and optimisation of ultrasonography equipment. Results will also be shared with the relevant Clinical Commissioning Groups (CCGs).

With considerable regional variations in diagnostic rates of congenital heart disease before birth, the NCHDA have been working to modify geographical analysis to fit in with contemporary regional boundaries aligned to ICB boundaries to map to PPD rates.[13]

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