The National Congenital Heart Disease Audit Database

Data Quality Audit for CONGENITAL HEART DISEASE
Apr 2023 - Mar 2024

The Royal Victoria Hospital, Belfast

3 September 2024

performed by Dr A Magee and Lin Denne

Summary

This congenital validation visit by NCHDA was funded by the Health and Social Care Trust for Northern Ireland (HSCNI). The fiscal year reviewed is April to March 2023-2024. The validation was performed by an external consultant congenital cardiologist on site at Belfast Health and Social Care Trust (RVB) together with the NCHDA Clinical Data Auditor.

Prior to the review of the hospital log books, the data return to NCHDA from the adult congenital cardiac department of the Royal Victoria Hospital, Belfast (RVB) indicated that some 163 adult congenital heart disease procedures (surgery 37, catheters 127, 0 others, 2 deaths within 30 days of a Specific Procedure) have been undertaken during the data collection year of April 2023 to March 2024.

Following review of the catheter laboratory and operating room activity log books on the day of the validation visit, 22 additional procedures were identified and where found suitable were subsequently submitted to the Registry.

Children's heart surgery ceased at this Centre in December 2014. Surgery and services for adult congenital heart disease (ACHD) patients (aged over 16 years) continue. As previously reported in 2015, it is likely in the medium term that paediatric cardiac surgery will be undertaken in London Birmingham and Dublin until the new children's hospital in Republic of Ireland (ROI) is fully commissioned in (approximately) 202/6.

Prior to 2015, the submission of the congenital data across adult and paediatric cardiac services in RVB was being managed by a cardiac data manager/administrator (DBA). Since then a number of individuals have supported the smaller data collection and in March 2018 this role had been further trimmed to 0.2WTE (1 day per week) with the surgery and catheter data being collected on two different systems and being facilitated by 2 individuals. Both of these individuals are Clinical Nurse Specialist (CNSs) within other larger sub specialties, one for adult cardiothoracic surgery and the other for Pulmonary Hypertension. There is a further non clinical data analyst who supports both NCHDA and the cardiothoracic NACSA registry.

Since 2021, the majority of the data entry to HeartSuite is undertaken by the two Specialist Nurses (CNSs identified above) from a completed proforma. As previously reported, access to HeartSuite is fully available in the main cardiac points of service throughout the Hospital. HeartSuite is only available by individual user ID for relevant consultant clinicians and specialist nurses. Following local validity checking, the data are submitted electronically to NCHDA on a monthly basis.

As before, all demographic data have to be manually input to HeartSuite at the present time as the system is not connected to the Trusts' patient administration system (PAS).

The unique identifier known as the Health + Care Number has been used since July 2004 and is now widely seen in Northern Ireland and should be included in NCHDA data submissions. This identifier is similar to the NHS Number in England and Wales.

Electronic Health Record (EHR) - EPIC

In 2020 the Health and Social Care Trust for Northern Ireland commissioned the all-encompassing digital information and patient record system EPIC. The local name for this project is Encompass. It was again highlighted at this visit that there needs to be an agreed method of archiving the congenital data gathered over the last 40-50 years to make it accessible to EPIC. EPIC was launched in Belfast on 6 June 2024. Other parts of Northern Ireland are launching EPIC at slightly different times.

Actions Implemented since the last Validation Visit in 2023:

- Continue to build a more structured approach to data collection and resolving queries – this includes dedicated time with the clinicians to discuss cases.
- With EPIC ''go live' training resources and workflow, SOPs will need to reviewed and updated.
- RVB anticipate a period where submissions are delayed as staff familiarise themselves with EPIC and EPIC build issues are resolved despite training and data managers having engaged with the EPIC team prior to the go live date.

Patient Consent for External Validation of Case Notes

Since May 2018, the General Data Protection Regulation required that patients are made aware of how their data collected and used. As such, NCHDA now no longer requires a specific consent to examine hospital case notes. If a patient has expressed a wish not to allow their case notes to be examined by others not connected to their care, these wishes will be respected as part of the GDPR Opt Out. Currently there does not appear to be one generic consent form used across the whole NHS Trust that covers all specialties that describes exactly how patients data are used either for research nationally or internationally, or national/ international clinical audit. This inevitably leads to retrospective consent gathering for some patients whose data is part of NCHDA registry in particular.

Data Quality Indicator Scores (DQI)

The overall DQI for the centre is calculated to be (with previous year's in parentheses) **99.4%** (99, 98.75, .98**)** ,with domain scores Demographics 1.0 (1.0, .99, 1.0), Pre Procedure .98 (.96, .97, .985), Procedure .997 (1.0, .99, .98), and Outcome 1.0 (1.0, 1.0, .97).

This is based on 20 patients with adult congenital heart disease who underwent 23 procedures (6 operations and 17 catheters). There were 9 errors found in 985 variables.

The fields causing the most errors are:

Comorbidities 2 discrepancies

Previous Procedures 2 discrepancies

Since 2009, a separate DQI calculation is being made for surgery and catheter procedures where there is a minimum of 5 records in either group at the case note validation. The scores for RVB are:

Year of Visit	Data Years reviewed	Surgery DQI	Catheters DQI
2015	14-15	99.75%	98.25%
2016	15-16	98.25%	98.5%

2017	16-17	96.25%	94%
2018	17-18	93.5%	96%
2019	18-19	91.25%	99%
2020	19-20	97%	96.25%
2021	20-21	98%	98.5%
2022	21-22	100%	98.75%
2023	22-23	99.25%	98.75%
2024	23-24	98.5%	99.75%

The NCHDA Previsit Questionnaire confirmed that there continued to be good processes and procedures in place in regard to:

Data Security and Management
Validation and Quality Assurance
Training in Data Management
Information Governance Training
There is or are identified accountable person/people for NCHDA data quality and information validity
Data Submissions are Timely and Accurate

Introduction

Prior to the log book review by the NCHDA audit team, the data returned to NCHDA indicated that the cardiac department of the Royal Victoria Hospital had undertaken some 163 adult congenital heart disease procedures (surgery 37, catheters 127, 0 others, 2 deaths) have been undertaken during the data collection year of April 2023 to March 2024.

The NCHDA Congenital Audit Nurse and an external consultant congenital cardiologist undertook the site audit in person.

20 sets of Sample notes were requested and a Reserve list of 10 further records were also supplied; in case any of the first 20 were irretrievable. On the day, 1 set of case notes were required from the Reserve list. The accuracy of the NCHDA data return was then checked against each set of notes and then recorded on a database to enable the Data Quality Indicator (DQI) to be scored.

Review of hospital case notes

Photocopies and screen shots for the hospital notes and electronic records were neatly prepared alongside the hospital paper note folders for each patient reviewed. All were very well prepared and clearly labelled. This was extremely helpful. Where reports were available on electronic systems, these were made available to the reviewers on a laptop computer in the room.

1. The operation notes were easy to find, and generally very detailed, and anaesthetic sheets were fairly easy to locate.
2. The perfusion record was present in all sets of surgical notes.
3. For patients who had had procedures as children at RVB, these case notes did not always appear to be included with their ACHD notes. It was also reported at this visit, that sometimes there was difficulty in retrieving this in a timely manner when required.
4. All relevant previous procedures should be included in the patient record submitted to NCHDA regardless of which country or city they have been performed.

5. As previously reported, there still does not appear to be one uniform proforma that collects all the ACHD risk fields that are part of the NCHDA registry. This was particularly noticeable in the hospital records for patients undergoing EP procedures.
6. It was also noted that at times they may be a variance in the units used to record the amount of radiation used in catheter lab procedures. Centigrays - cGy per m2 is the unit required by NCHDA not mGy (milligrays).

Review of the Cath Lab and Theatre log books

Cath Lab

As previously reported and during the data collection year under review, the cath lab were using the CVIS system for electronic data collection. There is no congenital module for any of the NCHDA specific data fields produced by the supplier of this system. It was reported at this visit that there are now 6 Caths Labs at RVB and 2 cath labs at the City Hospital where some congenital procedures may be performed by clinicians from RVB. RVB is a designated PPCI centre.

Printouts from each cath lab were provided. These were ordered by date for each cathlab. It was again very difficult at times to discern if a younger patient was having a procedure for congenital heart disease. As previously reported, there is no recording of the patients diagnosis in CVIS.

It should always be noted that generally for EP or pacing patients aged over 18 years to be included in NCHDA, these patients must have been known and followed up during the years 0-16 years by a paediatric cardiology service. However from time to time there may be exceptions to this.

1. 1 submitted catheter record appears to have an error in it.
2. 15 catheter procedures were identified that may be suitable to be included in NCHDA.

Theatre Log Books

1 bespoke bound and ruled log book that is a register of all 3 cardiac theatres activity was made available for review. This is generally a very well-kept and neat log of all activity, patients identity labels are used for each entry and there is a good standard of precise descriptions of procedures undertaken.

1. 1 submitted surgery record appears to have an error in it.
2. 4 further procedures were identified that may be suitable for inclusion in the NCHDA

Validation of Deceased Patients Diagnostic and Procedure Coding in NCHDA

Validation of Deceased Patients Diagnostic and Procedure Coding in NCHDA

Commencing with the validation of the 2013/14 data, the National Congenital Heart Disease Audit wish to verify any dates of death of deceased patients included in the year under review. The demographics, diagnosis, comorbidity, preoperative weights and procedure coding are also validated.

Medical Examiner

Since early in 2024 the NHS in England and Wales required all acute NHS Trusts to set up an Office of Medical Examiner

These positions are staffed by a team of medical examiners, supported by medical examiners officers.

The role of these offices is to examine deaths to:

- agree the proposed cause of death and the overall accuracy of the medical certificate of cause of death (MCCD) with the doctor completing it
- discuss the cause of death with bereaved families and relatives and establish if they have questions or any concerns with care before death
- act as a medical advice resource for the local coroner
- identify cases for further review under local mortality arrangements and contribute to other clinical governance processes.

The Health Service in Northern Ireland at the time of this validation visit, has not set up the office of Medical Examiner.

RVB reported 2 deaths in ACHD patients who had had a therapeutic procedure during the 2023/24data collection year. The hospital notes were made available for examination.

- The hospital case notes that were made available all data were checked and found to be correct.
- Death Certificates were seen
- It was confirmed during the visit that regular checks are made for out of hospital deaths in the NCHDA cohort.

Currently any congenital cardiac deaths are discussed at the Trust Mortality and Morbidity meetings and recorded as appropriate.

Casenote Audit

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		14	6
2	NHS Number	20	20		14	6
3	Surname	20	20		14	6
4	First Name	20	20		14	6
5	Sex	20	20		14	6
6	DOB	20	20		14	6
7	Ethnicity	20	20		14	6
8	Patient Status	20	20		14	6
9	Postcode	20	20		14	6
10	Pre Procedure Diagnosis	23	23	2 elements absent	17	6
11	Previous Procedures	32	34	1 absent, 1 incorrect	28/30	4
12	Patients Weight at Operation	23	23		17	6
13	Height	-	-		17	6
14	Ante Natal Diagnosis	23	23		-	-
15	Pre Proc Seizures	23	23		17	6
16	Pre Proc NYHA	23	23		17	6
17	Pre Proc Smoker	22	23	1 incorrect	17	5/6
18	Pre Proc Diabetes	23	23		17	6
19	Hx Pulmonary Dis	22	23	1 incorrect	17	5/6
20	Pre Proc IHD	23	23		17	6

21	Comorbidity Present	23	23		17	6
22	Comorbid Conditions	29	31	1 absent, 1 incorrect	20/21	9/10
23	Pre Proc Systemic Ventricular EF	22	23	1 incorrect	17	5/6
24	Pre Proc Sub Pul Ventricular EF	22	23	1 incorrect	17	5/6
25	Pre-proc valve/septal defect/ vessel size	2	2		2	-
26	Consultant	23	23		17	6

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	23	23		17	6
28	Proc Urgency	23	23		17	6
29	Unplanned Proc	22	23	1 absent	17	5/6
30	Single Operator	6	6		6	-
31	Operator 1	23	23		17	6
32	Operator 1 Grade	23	23		17	6
33	Operator 2	17	17		17	6
34	Operator 2 Grade	17	17		17	6
35	Procedure Type	23	23		27	6

36	Sternotomy Sequence	6	6		-	6
37	Operation Performed	23	23		17	6
38	Sizing balloon used for septal defect	1	1		1	-
39	No of stents or coils	1	1		1	-
40	Device Manufacturer	15	15		11	4
41	Device Model	15	15		11	4
42	Device Ser No	15	15		11	4
43	Device Size	10	10		6	4
44	Total Bypass Time	6	6		-	6
45	XClamp Time,	6	6		-	6
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	17	17		17	-
48	Cath Fluro Time,	16	16		16	-
49	Cath Fluro Dose,	16	16		16	-

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	6	6		-	6

51	Post Procedure Seizures	23	23		17	6
52	Post Proc Complications	2	2		1	1
53	Date of Discharge	23	23		17	6
54	Date of Death	1	1		-	1
55	Attribution of Death	1	1		-	1
56	Status at Discharge	23	23		17	6
57	Discharge Destination	23	23		17	6

Data Quality Indicator Assessment:

The Overall Trust DQI = 99.4% Cardiology DQI = 99.75% Surgery DQI = 98.55%

This DQI is based upon the domain scoring below. The methodology for this DQI is provided in the paper The CCAD Audit – An Introduction to the Process.

<table>
<tr><th>DOMAIN</th><th colspan="2">DOMAIN Score</th></tr>
<tr><td rowspan="2"><u>Demographics</u>

Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,</td><td colspan="2">Overall 1.0</td></tr>
<tr><td>Card
1.0</td><td>Surg
1.0</td></tr>
<tr><td rowspan="2"><u>Pre Procedure</u>

Pre procedure Diagnosis, Selected Previous Procedures, Patient Weight at Operation, Consultant, Antenatal Diagnosis, Pre Procedure Seizures, Comorbid Conditions,
Height, Pre Procedure NYHA, Pre Procedure Smoker, Pre Procedure Diabetes, Previous Pulmonary Disease, Pre Procedure Ischaemic Heart Disease, Comorbidity Present, Pre Procedure Systemic Ventricular Ejection Fraction, Pre Procedure Sub Pulmonary Ejection Fraction, Pre Procedure valve/septal defect/vessel size,

Note, the scores for his domain are affected by the selected previous procedure and pre procedure diagnosis</td><td colspan="2">Overall .98</td></tr>
<tr><td>Card
.99</td><td>Surg
.95</td></tr>
<tr><td><u>Procedure</u></td><td colspan="2">Overall .997</td></tr>
</table>

Date of procedure, Operator 1, Operator 2 Cardiopulmonary Bypass used, Operator 1 grade, Operator 2 grade, Operation performed, Sternotomy sequence, Bypass Time, CircArrest, XClamp Time, Cath Proc Time, Cath Fluro Time, Cath Fluro Dose, **Time Start, Procedure Urgency, Unplanned Procedure, Single Operator, Sizing Balloon Used, No of Stents/Coils, Device Mfr, Device Model, Device Ser No, Device Size,**	**Card** 1.0	**Surg** .99
<u>Outcome</u> Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** 1.0 **Card** 1.0	 **Surg** 1.0

Data Quality Indicator Assessment **2023-2024 data**:

The Overall Trust DQI = 99.4% Cardiology DQI = 99.75% Surgery DQI = 98.5%

DOMAIN	2024 23-24 data	2023 22-23 data	2022 21-22 data	2021 20-21 data
Demographics	1.0	1.0	.99	1.0
Pre Procedure	.98	.96	.97	98.5
Procedure	.997	1.0	.99	.98
Outcome	1.0	1.0	1.0	.97

Conclusions

On the whole the NCHDA data was accurate, well documented, good quality and was appropriately recorded in the relevant health records and log books. The NCHDA Review Team would like to particularly thank the clinical audit nurses and analyst for meticulously preparing all the sets of case notes. This greatly enables the process of the case note examination.

The DQI of 99% has increased by 0.4% which is another very good score. Having well supported individuals with congenital cardiac knowledge and experience greatly enhances not only the quality of the data but the completeness and timeliness of submissions as well.

As previously reported, the data for ACHD catheter procedures and surgery were being input into separate unlinked information systems with separate individuals facilitating this. The data were then input manually to a 3rd database, HeartSuite which contains many historic records of ACHD patient's treatments and procedures as children. Now that RVB are using EPIC as a total eHR it is essential that all the historic data are preserved and fully available to the new data system when required. EPIC is an overarching data management system as described above that may be used for tertiary, primary and secondary medical care. In Northern Ireland it is not currently being used in primary care although GPs can access records on a read only basis.

The New Congenital Heart Disease Review (NHSE May 2016) recommendation B33(L1) is that each Specialist ACHD Surgical Centre must have a minimum of 1.0 WTE dedicated cardiac surgery/cardiology data collection manager, responsible for audit and database submissions in accordance with necessary timescales.

As reported since 2020 at RVB, that although there are two individuals (both CNSs) looking after these data they are barely 0.5WTE in total, covering this important role and the funding of this role does not appear to be spread equitably across the 2 clinical Divisions at this Trust who provide cardiovascular care.

The 2 individuals providing 0.5WTE have other much larger dedicated 1.0WTE clinical roles and it appears that NCHDA data is still considered a minor add-on activity when it is a complex and very detailed dataset that demands a considerable concentration, specific knowledge of cardiology and in particular knowledge of congenital cardiology terms, processes and procedures as well as great attention to detail. Neither of the CNS/DBMs have access to a secure email address such as NHSmail and it is not known if this NHS Trust is compliant with the NHS Mail standard DCB 1596.

The numbers of ACHD procedures may rise in the next 3-5 years as the service develops further. Timely reverse validation is considered essential practice to continually monitor accuracy and completeness. There still appears to be difficulties at sometimes with identifying ACHD cases to the CNSs promptly in a timely fashion but this is reported as improving. The CNSs' attendance at MDT meetings may help with identifying patients who are considered for interventions or operation and may be admitted in the future.

As previously reported, The CVIS system was used in the cath lab as the log of activity still appears to contain some less accurate descriptions of what procedure has been performed and whether or not it is for congenital heart disease. For instance it appears that there some younger patients having angioplasty procedures, but it is not known if these are individuals with congenital heart disease or not. This system is essentially designed for acquired heart disease and is not suitable for congenital heart disease. It is acknowledged that EPIC will now be used as the activity log from June 2024 and it is hoped that it will lead to better more accurate descriptions of procedures performed as well as diagnoses if the worklist application is used.

Dendrite Intellect was primarily used for acquired heart disease surgery and does not actively support the NCHDA dataset. ACHD data collection in EPIC, if properly utilised amongst the users in the design should make this much more efficient.

Validation of Deceased Case Notes

As documented above there were 2 deceased patients in this years cohort who had died within 30 days of a procedure. All submitted data were confirmed as correct and there is a local mortality and morbidity process in place to discuss post procedural deaths.

It was confirmed that regular electronic data checks are made on life status for NCHDA patients.

Recommendations

1. It is strongly recommended that as a priority, included in forward planning for the congenital cardiac module of Encompass that a method of either transferring historic data from HeartSuite to EPIC or keeping a permanently accessible archive once the new data collection system is fully commissioned.
2. It is strongly recommended that the NCHDA CNSs and any other interested professional associates regularly liaise with other congenital centres data managers and clinical colleagues to learn from their experiences and get on going peer support with the transfer to and then using EPIC in the congenital heart disease arena. The Level 1 centres are Guys & St Thomas's NHS Foundation Trust (mixed paediatric/ACHD) and Great Ormond Street NHS Foundation Trust. A Level 2 NCHDA ACHD centre is Manchester Royal Infirmary.
3. It is recommended that the role of NCHDA data manager/CNS for this registry is specifically documented and defined as 1.0WTE and appropriately and equitably financially supported and remunerated by both care divisions within RVB that provide cardiovascular care to meet the NHSE Standards (2016) minimum recommendation B33(L1). NICOR is now commissioned to publish NCHDA data quarterly within 2 weeks of end of each quarter.
4. It is recommended that Standard Operating Protocols are reviewed regularly to ensure that they adequately and specifically support the congenital data collection, to include detailed guidance on 'how to' and exactly **who** is responsible for and in what timeframe for each of the following;

    a. Ensuring all NCHDA patients are made aware of how their data are protected, stored and used and GDPR option for 'opt out' explained
    b. Real time input of the data for each congenital diagnostic and therapeutic procedure at the point of the service delivery in the cath labs and operating rooms, particularly data which cannot be entered at the time of the procedure, such as intubation time and complications

c. Validity and completeness checking, and the time intervals for feedback to responsible clinicians on this with a clear time scale and line of responsibility for rectifying any omissions or errors in both surgery and cardiology disciplines
d. Ensuring that all clinicians are encouraged to be responsible for their own their data where they are undertaking procedures and be involved in the local validation process
e. Leading the local review (and in which forum for both disciplines)
f. Making timely submissions of fully validated data, NHSE requires data to be submitted within 2 weeks of a procedure where possible (monthly within 2 weeks of month end, submission is essential) where possible and
g. Monthly reverse validation at RVB against an acknowledged 'gold standard' record of activity and procedures performed.
h. Regular monitoring of Specific Procedures allocation and Activity Analysis with R code or manually.
i. Reviewing/Updating the SOP at timely intervals
j. Capturing data on any out of hospital deaths of congenital patients
k. When post procedural deaths occur during an inpatient stay, documenting any date and outcome of conversations with the Medical Examiner or Coroner in the deceased hospital notes as these are NCHDA dataset requirements.
l. Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.

2. It is recommended that the NCHDA CNS/DBMs and any members of the clinical audit team who assist with this data collection should regularly attend the MDT meetings. These meetings are an educational forum as well identifying future congenital cardiac patients and their possible procedures.
3. It is also recommended to consider if there was ACHD clinician representation at MDTs for other allied cardiac specialties such as aortic valve disease, to identify whether or not a patient meets the ACHD criteria to be included in the registry..
4. As part of the DBMs ongoing training and development, it is suggested that visits to other centres to view their procedures and practices is a valued and important exercise in maintaining good standards.

5. All congenital clinicians (ST6 to Consultant) should be encouraged to volunteer to assist with at least one NCHDA validation as RVB has been very underrepresented in recent years.
6. It is also recommended that both CNS/Data Managers have access to their own email address or similar that meets the NHS Mail Standard 1596 compliance to enable secure discussion of sensitive information on a secure collaboration platform for health and social care colleagues.
7. RVB should be aware that from April 2025 the Partial Risk Analysis in Surgery v4 (PRAiS 4) will be used to review all surgery cases up to age 18 years. This is essentially used in paediatric centres but there may now be overlap in ACHD centres where any 16-18 year old patients with congenital heart disease undergo surgical procedures.