The National Congenital Heart Disease Audit Database

Data Quality Audit for CONGENITAL HEART DISEASE
Apr 2021 - Mar 2022

The Royal Victoria Hospital, Belfast

21 June 2022

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Summary

This congenital validation visit by NCHDA was funded by the Health and Social Care Trust for Northern Ireleand (HSCNI). The fiscal year reviewed is April 2021 to March 2022. The validation was performed by one external consultant congenital cardiologist on site at Belfast Health and Social Care Trust (RVB) and supported remotely MS Teams by the NCHDA Clinical Data Auditor.

Prior to the review of the hospital log books, the data return to NCHDA from the cardiac department of the Royal Victoria Hospital, Belfast (RVB) indicated that some 134 adult congenital heart disease procedures (surgery 32, catheters 101, 1 other, 0 deaths) have been undertaken during the data collection year of April 2021 to March 2022. This is a 23% drop in activity in ACHD activity since the previous visit in July 2021.

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) 2025 or later.

As previously reported, prior to 2015, the submission of the congenital data across adult and paediatric cardiac services in RVB is 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 two individuals.

As in 2021, and at this review (April 2021 - March 2022 data), the majority of the data entry to HeartSuite was undertaken by two Specialist Nurses (one for cardiology and one for surgery) 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 were submitted electronically to NCHDA on a monthly basis by an information manager/analyst within the IT Department.

As before, all demographic data has 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 and 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.

Actions Implemented since the last Validation Visit in 2021:

- There are regular structured meetings with the Lead Congenital Cardiologist and Surgeon to validate NCHDA data prior to submission have continued and are now well embedded in the audit process.
- The Health and Social Care Trust for Northern Ireland has commissioned the all-encompassing digital information and patient record system EPIC. Discussions continue regarding integration of the NCHDA Dataset and its planned inclusion when EPIC is launched. The prospective launch data is not yet known.

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.

Data Quality Indicator Scores (DQI)

The overall DQI for the centre is calculated to be (with previous year's in parentheses) 98.75**%** (.98, .967, 96), with domain scores Demographics .99 (1.0, 1.0, 1.0), Pre Procedure .97 (.985, .92, 97, .92), Procedure .99 (.98, .99, .97) and Outcome 1.0 (.97, .96, .90). This is based on

20 patients with adult congenital heart disease who underwent 21 procedures (6 operations and 15 catheters). There were 13 errors found in 909 variables.
This is an increase of 0.75% which is fantastic.

The fields causing the most errors are:

Previous Procedures	3 discrepancies
Comorbidities	3 discrepancies
Name and grade of second operator	2 discrepancies

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

Year of Visit	Data Years reviewed	Surgery DQI	Catheters DQI
2014	13-14	96.75%	95.25%
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%

The NCHDA pre visit 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 134 adult congenital heart disease procedures (surgery 32, catheters 101, 1 other and 0 deaths) during the data collection year of April 2021 to March 2022 in patients with congenital heart disease.

The NCHDA Congenital Audit Nurse and an external consultant congenital cardiologist undertook the site audit. As stated above, the consultant clinician was physically present. The NCHDA Congenital Audit Nurse supported the validation remotely via MS Teams.

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, five sets 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.

As reported in 2021, RVB is starting the process of moving from paper hospital notes to an electronic patient record (ePR). From there it is planned that the Trust will progress to EPIC which is an all-encompassing electronic health care record that connects primary, secondary, tertiary care and related activity in one package. This process was planned to start from approximately sometime during 2023. It would be helpful if the very specific AEPC coding that NCHDA uses is embedded into EPIC.

Review of hospital case notes

As at previous visits, the hospital notes are almost entirely paper bound and were mostly tidy and many of the relevant pages has been tabbed with a sticky note. This was extremely helpful. Where reports were available on electronic systems, these were made available to the reviewers on screen in the room.

1. The pink operation notes were easy to find and anaesthetic sheets were fairly easy to locate.
2. The perfusion record was present in all sets of surgical notes.

3. As previously reported the case notes were sometimes not chronologically ordered and this hindered the review process on occasions.
4. For patients who had had procedures as children at RVB, these case notes did not always appear to be included with their ACHD notes.
5. All relevant previous procedures should be included in the patient record submitted to NCHDA regardless of which country or city they have been performed.
6. The Proforma created by the CNS/DBMs for collecting the NCHDA dataset was seen in all case notes.
7. It was noted that the CNS/DBM who looks after the cardiology data does not have access to the database that stores echocardiogram (echo) data and their reports.

Review of the Cath Lab and Theatre log books

Cath Lab

As previously reported the catheter (cath) labs are 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 six Cath Labs at RVB and two cath labs at the City Hospital where some congenital procedures such as pacemaker box changes 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 cath lab. It was again very difficult at times to discern if a younger patient was having a procedure for congenital heart disease. It did not appear that concise recording was made of the patient's diagnosis.

Please note that 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.

1. One submitted catheter record appears to be a duplicate entry.
2. Three catheter procedures were identified that may be suitable to be included in NCHDA.

These appear to be for EP and pacing procedures and there is no indication in the information provided whether or not these patients have congenital heart disease. One of the procedures appears to be a post operative complication for a patient who was part of the hospital case note review.

Theatre Log Books

One bespoke bound and ruled log book that is a register of all three 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. It was noted that throughout the NCHDA surgical submission the start time was always 00.00. It should be noted that the actual knife to skin time is the start time that is required for this field.

1. One submitted record may have a duplicate
2. Zero further procedures were identified that may be suitable for inclusion in the NCHDA.

Validation of Deceased Patients Diagnostic and Procedure Coding

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 diagnosis, comorbidity, preoperative weights and procedure coding are also validated.

RVB reported zero deaths in ACHD patients who had had a therapeutic procedure during the 2021/22 data collection year.

It was confirmed during the visit that regular checks are made for out of hospital deaths in the NCHDA cohort.

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	19	20	1 incorrect	13/14	6
10	Pre Procedure Diagnosis	21	21	3 incomplete	15	6
11	Previous Procedures	13	16	3 absent	16	6
12	Patients Weight at Operation	21	21		15	-
13	Height	21	21		15	6
14	Ante Natal Diagnosis	-	-		-	6
15	Pre Proc Seizures	21	21		15	-
16	Pre Proc NYHA	20	21	1 incorrect	14/15	6
17	Pre Proc Smoker	21	21		14/15	6
18	Pre Proc Diabetes	21	21		14/15	6

19	Hx Pulmonary Dis	21	21		14/15	6
20	Pre Proc IHD	21	21		15	6
21	Comorbidity Present	21	21		15	6
22	Comorbid Conditions	28	31	3 absent	23/25	5/6
23	Pre Proc Systemic Ventricular EF	21	21		15	6
24	Pre Proc Sub Pul Ventricular EF	20	21	1 incorrect	15	5/6
25	Pre-proc valve/septal defect/ vessel size	9	9		9	-
26	Consultant	21	21		15	6

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	21	21		15	6
28	Proc Urgency	21	21		15	6
29	Unplanned Proc	-	-		-	-
30	Single Operator	2	3	1 incorrect	2/3	-
31	Operator 1	21	21		15	6
32	Operator 1 Grade	21	21		15	6

33	Operator 2	16	17	1 incorrect	10/11	6
34	Operator 2 Grade	16	17	1 incorrect	10/11	6
35	Procedure Type	21	21		15	6
36	Sternotomy Sequence	6	6		-	6
37	Operation Performed	21	21		15	6
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	7	7		7	-
40	Device Manufacturer	17	17		14	3
41	Device Model	17	17		14	3
42	Device Ser No	17	17		13	3
43	Device Size	13	13		-	-
44	Total Bypass Time	6	6		-	6
45	XClamp Time,	6	6		-	6
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	15	15		15	-
48	Cath Fluro Time,	15	15		15	-
49	Cath Fluro Dose,	15	15		15	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	5	6	1 incorrect	-	5/6
51	Post Procedure Seizures	21	21		15	6
52	Post Proc Complications	1	1		-	1
53	Date of Discharge	21	21		15	6
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	21	21		15	6
57	Discharge Destination	21	21		15	6

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.75% Cardiology DQI = 98.75% Surgery DQI = 99%

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.

DOMAIN	DOMAIN Score	
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status	**Overall .99**	
	Card .99	**Surg** 1.0
Pre Procedure 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	**Overall .97**	
	Card .98	**Surg** .96
Procedure 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**	**Overall .**99	
	Card .98	**Surg** 1.0

Outcome 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 **2021-2022 data**:

The Overall Trust DQI = 98.75% Cardiology DQI = 98.75% Surgery DQI = 99%

DOMAIN	**2022 21-22 data**	**2021 20-21 data**	**2020 19-20 data**	**2019 18-19 data**
Demographics	.99	1.0	1.0	1.0
Pre Procedure	.97	98.5	.92	.97
Procedure	.99	.98	.99	.97
Outcome	1.0	.97	.96	.90

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 team for meticulously preparing all the sets of case notes. This greatly enables the process of the case note examination.

The DQI of 98.75% has increased by 0.75% which is another very good score.

As previously reported, the data for ACHD catheter procedures and surgery are being input into separate unlinked information systems with separate individuals facilitating this. As previously noted, splitting the data collection between two different databases, CVIS for catheters and Dendrite Intellect for surgery, with two different individuals may unnecessarily risk compromising the integrity of the data by dividing this way. The data are then input manually to a third database, HeartSuite which contains many historic records of ACHD patients treatments and procedures as children.

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 looking after these data, they are just 0.5WTE in total, covering this important role and the funding of this role is not spread equitably across the two clinical Divisions at this Trust who provide cardiovascular care.

The two individuals providing 0.25WTE each have other much larger dedicated 1.0WTE clinical roles and it appears that NCHDA data is 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 meets the NHS Mail standard DCB 1596.

It was also reported to the reviewers that the whole of Northern Ireland expect to migrate to the EPIC clinical information system. This is an overarching data management system for both tertiary, primary and secondary medical care.

The numbers of ACHD procedures are likely to rise in the next three to five years or more as the service is developed and timely reverse validation is considered essential practice to continually monitor accuracy and completeness. There still appears to be difficulties at times with identifying ACHD cases to the CNS/DBMs promptly in a timely fashion but this is reported as improving. The DBMs 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 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. This system is essentially designed for acquired heart disease and is not suitable for congenital heart disease. The description of procedures undertaken and whether or not they were for congenital heart disease was extremely difficulty to identify. Dendrite Intellect is primarily used for acquired heart disease surgery and does not actively support the NCHDA dataset.

Validation of Deceased Case Notes

As documented above there were no deceased patients in this year cohort. It was confirmed that regular electronic data checks are made on life status for NCHDA patients.

Recommendations

1. It is strongly recommended that as this centre is relatively small in terms of annual numbers of procedures performed, that there is one unified cardiac information system that is used to collect the NCHDA data. HeartSuite has been used since 2004 to collect the paediatric cardiac data and there is now a considerable archive. It would appear sensible to continue with this system as patients return for further procedures in adulthood. It is also recommended that a method or either transferring these data from HeartSuite to EPIC or keeping a permanent accessible archive once the new data collection system is fully commissioned.
2. It is recommended that the role of NCHDA data manager/CNS for this registry is specifically 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).
3. 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 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 (monthly is recommended) 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.

4. 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.
5. 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.
6. 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.
7. 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.