The National Congenital Heart Disease Audit Database

Data Quality Audit for
CONGENITAL HEART DISEASE

Apr 2020 - Mar 2021

The Royal Victoria Hospital, Belfast

7 July 2021

performed by Dr A Narayanan and Lin Denne

FINAL

Summary

This congenital validation visit by NCHDA was funded by the Northern Ireland Health and Social Care Trust (HSCNI). The fiscal year reviewed is April to March 2020-2021. The validation was performed by 1 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 173 adult congenital heart disease procedures (surgery 25, catheters 148, 2 deaths) have been undertaken during the data collection year of April 2020 to March 2021 in patients with congenital heart disease. This represents a 5% increase in ACHD activity since the previous year. This is a year of pandemic SARS-COV-2 status where many centres have seen their activity drop in the region of 20% or more.

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 ROI is fully commissioned in (approximately) 2025 or later.

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 with the surgery and catheter data being collected on two different systems and being facilitated by 2 individuals.

At this review (for Apr 2020 – Mar 2021 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 have to be manually input to HeartSuite at the present time as the system is not connected to the trusts patient administration system (PAS).

FINAL

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.

Actions Implemented since the last Validation Visit in 2020:

- There are now regular meetings with the Lead Congenital Cardiologist and Surgeon to validate NCHDA data prior to submission.

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.

FINAL

Data Quality Indicator Scores (DQI)

The overall DQI for the centre is calculated to be (with previous year's in parentheses) **98%** (.967, 96, 95,**)** ,with domain scores Demographics 1.0 (1.0, 1.0, .97), Pre Procedure .985 (.92, 97, .92, .88,), Procedure .98 (.99, .97, 93,), and Outcome .97 (.96, .90, .98). This is based on 20 patients with adult congenital heart disease who underwent 23 procedures (6 operations and 17 catheters). There were 13 errors found in 961 variables.

This is an increase of 1.3%.

The fields causing the most errors are:

NYHA status documentation	2
Comorbidities	2
Number of stents or coils used	2

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
2013	12-13	98%	98.5%
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%

The NCHDA Previsit Questionnaire confirmed that there are 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

FINAL

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 173 adult congenital heart disease procedures (surgery 25, catheters 148, 2 deaths) have been undertaken during the data collection year of April 2020 to March 2021 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, 2 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.

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 is planned to start from approximately 2023.

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.

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. It was noted that some patients had their height measured in feet and inches rather than centimetres.
4. As previously reported the case notes were often not chronologically ordered and this considerably hindered the review process on occasions.
5. For patients who had had procedures as children at RVB, these case notes did not always appear to be included with their ACHD notes.
6. All relevant previous procedures should be included in the patient record submitted to NCHDA regardless of which country or city they have been performed.
7. It appeared that NYHA status is not always recorded as standard in all hospital records of patients
8. The Proforma created by the DBM for collecting the NCHDA dataset was seen in all case notes.

FINAL

Review of the Cath Lab and Theatre log books

Cath Lab

As previously reported the cath lab 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 6 Caths Labs at RVB and this centre is a designated PPCI centre.

Printouts from each cath lab were provided. These were ordered by date for each cathlab. It was again extraordinarily 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 patients 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. 1 submitted catheter record appears to have an error
2. 5 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.
3. 18 submitted catheter records were not validated on the information provided

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. 0 submitted record may have errors in them
2. 2 further procedures were identified that may be suitable for inclusion in the NCHDA

FINAL

Validation of Deceased Patients Diagnostic and Procedure Coding

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 2 deaths in ACHD patients who had had a therapeutic procedure during the 2020/21 data collection year.

The findings are:

- All dates of death were correct
- All submitted data were found to be correct
- The Attribution of Death field is incomplete for one patient

FINAL

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		17	6
11	Previous Procedures	15	16	1 absent	14/15	1
12	Patients Weight at Operation	23	23		17	6
13	Height	23	23		17	6
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	23	23		17	6
16	Pre Proc NYHA	21	23	2 incorrect	16/17	5/6
17	Pre Proc Smoker	23	23		17	6
18	Pre Proc Diabetes	22	23	1 incorrect	16/17	6
19	Hx Pulmonary Dis	23	23		17	6
20	Pre Proc IHD	23	23		17	6
21	Comorbidity Present	23	23		17	6
22	Comorbid Conditions	22	25	2 absent	18/19	5/6
23	Pre Proc Systemic Ventricular EF	23	23		17	6
24	Pre Proc Sub Pul Ventricular EF	23	23		17	6
25	Pre-proc valve/septal defect/ vessel size	9	9		9	-
26	Consultant	23	23		17	6

FINAL

	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	1	1		1	-
30	Single Operator	-	-		-	-
31	Operator 1	22	23	1 incorrect	17	5/6
32	Operator 1 Grade	23	23		17	6
33	Operator 2	23	23		17	6
34	Operator 2 Grade	23	23		17	6
35	Procedure Type	23	23		17	6
36	Sternotomy Sequence	6	6		-	6
37	Operation Performed	23	23		17	6
38	Sizing balloon used for septal defect	2	2		2	-
39	No of stents or coils	0	2	2 absent	0/2	-
40	Device Manufacturer	18	19	1 incorrect	16	2/3
41	Device Model	18	19	1 incorrect	16	2/3
42	Device Ser No	18	19	1 incorrect	15/16	3
43	Device Size	16	16		13	3
44	Total Bypass Time	6	6		-	6
45	XClamp Time,	6	6		-	6
46	Total Arrest	-	-		-	-
47	Cath Proc Time,	17	17		17	-
48	Cath Fluro Time,	17	17		17	-
49	Cath Fluro Dose,	17	17		16/17	-

	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	22	23	1 incorrect	16/17	6
52	Post Proc Complications	1	2	1 absent	-	½
53	Date of Discharge	23	23		17	6
54	Date of Death	1	1		1	-
55	Attribution of Death	0	1	1 incomplete	0/1	-
56	Status at Discharge	23	23		17	6
57	Discharge Destination	23	23		17	6

FINAL

Data Quality Indicator Assessment:

The Overall Trust DQI =   98% Cardiology DQI =   98.5%   Surgery DQI = 98%

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** 1.0	
	Card 1.0	**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 .98.5**	
	Card .98	**Surg** .99
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** .98	
	Card .99	**Surg** .96
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .97	
	Card .97	**Surg** .97

FINAL

Data Quality Indicator Assessment **2020-2021 data**:

The Overall Trust DQI = 98% Cardiology DQI = 98.5% Surgery DQI = 98%

DOMAIN	2021 20-21 data	2020 19-20 data	2019 18-19 data	2018 17-18 data
Demographics	1.0	1.0	1.0	.97
Pre Procedure	98.5	.92	.97	.92
Procedure	.98	.99	.97	.93
Outcome	.97	.96	.90	.98

FINAL

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.

The DQI of 98% has increased by 1.3% 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. There appears to be in the region of 160 ACHD procedures currently undertaken Belfast which makes it one of the smallest centres. Splitting the data collection between two different databases, CVIS for catheters and Dendrite Intellect for surgery, with 2 different individuals may unnecessarily risk compromising the integrity of the data by dividing this way. The data are then input manually to a 3rd 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.

It appears that at RVB that although the 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 spready equitably across the 2 clinical Divisions at this Trust who provide cardiovascular care.

The 2 individuals providing 0.25WTE each both have other much larger dedicated 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 and attention to detail.

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 3-5 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 DBMs promptly in a timely fashion but this does seem to be improving. The DBMs attendance at MDT

FINAL

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 was a minor discrepancy identified.

FINAL

Recommendations

1. It is strongly recommend 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.
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 supported 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

FINAL

4. It is recommended that the NCHDA DBM 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 under represented in recent years.
7. It is also recommended that both CNS/Data Managers have access to their own nhs.mail email address to enable secure discussion of sensitive information national secure collaboration platform for health and social care

FINAL