



The National Congenital Heart Disease Audit Database

**Data Quality Audit for
CONGENITAL HEART DISEASE**

Apr 2019 - Mar 2020

The Royal Victoria Hospital, Belfast

14 October 2020

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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 2019-2020. 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 164 adult congenital heart disease procedures (surgery 44, catheters 118, others 2, no deaths) have been undertaken during the data collection year of April 2019 to March 2020 in patients with congenital heart disease.

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) 2022 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 2019 – Mar 2020 data), the majority of the data entry to HeartSuite was undertaken by the cardiology DBA 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).

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 2019:

- No actions were reported.
- There is now a CNS for Pulmonary Hypertension who facilitates the data collection for patients who undergo catheter procedures for approximately 0.2WTE
- Immediately prior to this site visit a CNS for adult cardiac surgery audit was nominated to assist with the collection of NCHDA data also

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) **96.75%** (96, 95.94.5), with domain scores Demographics 1.0(1.0, .97, 1.0), Pre Procedure .92 (.97, .92, .88,), Procedure .99 (.97, 93, .94), and Outcome .96 (.90, .98, .96,). This is based on 20 patients with adult congenital heart disease who underwent 20 procedures (6 operations and 14 catheters). There were 34 errors found in 877 variables.

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
2012	11-12	97.5%	96.25%
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%

The NCHDA pre visit Questionnaire from 2019 was reused for this visit. This 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

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 164 adult congenital heart disease procedures (surgery 44, catheters 118, others 2, no deaths) have been undertaken during the data collection year of April 2019 to March 2020 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, 6 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.

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. As previously reported the case notes were often not chronologically ordered and this considerably hindered the review process on occasions.
4. On occasions it was difficult to find cardiac echo reports that were contemporary with the episode being validated.

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 hospital records of patients
8. It was difficult at times to find records of xray time or the name of the second operator on the procedure sheets for patient who had undergone cath lab procedures.
9. The Proforma created by the DBM for collecting the NCHDA dataset was seen in all case notes.

Review of the Cath Lab and Theatre log books

Cath Lab

The cath lab are now using the CVIS (previously called TOMcat) system for electronic data. 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.

Bound printouts from each cath lab were provided this year. These were ordered by date for each cathlab. It was difficult at times to discern if a younger patient was having a procedure for congenital heart disease.

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. 4 submitted catheter records appear to have errors in them
2. 3 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. 1 submitted catheter record was not validated on the information provided
4. 1 submitted record was identified that does not appear to be for congenital heart disease.

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.



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1. 10 submitted records were identified for aortic valve replacement (AVR) that may fall outside the NCHDA algorithm for inclusion.
2. 0 submitted record may have errors in them
3. 2 further procedures were identified that may be suitable for inclusion in the NCHDA

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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 and procedure coding will also be validated.

No ACHD patients were reported in the data return to have died following procedures during the 2019/20 data collection year.

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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		20	3 incorrect elements	14	6
11	Previous Procedures	26	32	6 absent	15/20	11/12
12	Patients Weight at Operation	19	20	1 incorrect	13/14	6
13	Height	19	20	1 incorrect	13/14	6
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	20	20		14	6
16	Pre Proc NYHA	19	20	1 incorrect	14	5/6
17	Pre Proc Smoker	20	20		14	6
18	Pre Proc Diabetes	20	20		14	6
19	Hx Pulmonary Dis	19	20	1 incorrect	13/14	6
20	Pre Proc IHD	20	20		14	6
21	Comorbidity Present	19	20	1 incorrect	13/14	6
22	Comorbid Conditions	12	24	12 incorrect	13/14	9/10
23	Pre Proc Systemic Ventricular EF	20	20		14	6
24	Pre Proc Sub Pul Ventricular EF	19	20	1 incorrect	14	5/6
25	Pre-proc valve/septal defect/ vessel size	2	2		2	-
26	Consultant	20	20		14	6



	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	20	20			
28	Proc Urgency	20	20			
29	Unplanned Proc	19	20	1 incorrect		
30	Single Operator	3	3			
31	Operator 1	20	20			
32	Operator 1 Grade	20	20			
33	Operator 2	16	17	1 incorrect		
34	Operator 2 Grade	16	17	1 incorrect		
35	Procedure Type	20	20			
36	Sternotomy Sequence	6	6			
37	Operation Performed	20	20			
38	Sizing balloon used for septal defect	1	1			
39	No of stents or coils	1	1			
40	Device Manufacturer	13	13			
41	Device Model	13	13			
42	Device Ser No	12	13	1 absent		
43	Device Size	13	13			
44	Total Bypass Time	6	6			
45	XClamp Time,	5	5			
46	Total Arrest	0	0			
47	Cath Proc Time,	14	14			
48	Cath Fluro Time,	13	14	1 unable to validate		
49	Cath Fluro Dose,	13	14	1 unable to validate		

	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	20	20		14	6
52	Post Proc Complications	1	8	7 absent	0/6	½
53	Date of Discharge	17	20	3 incorrect	12/14	5/6
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	20	20		14	6
57	Discharge Destination	20	20		14	6



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Data Quality Indicator Assessment:

The Overall Trust DQI = 96.75% Cardiology DQI = 96.25% Surgery DQI = 97%

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	
<p><u>Demographics</u></p> <p>Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,</p>	Overall 1.0	
	Card 1.0	Surg 1.0
<p><u>Pre Procedure</u></p> <p>Pre procedure Diagnosis, Selected Previous Procedures, Patient Weight at Operation, Consultant, Antenatal Diagnosis, Pre Procedure Seizures, Comorbid Conditions,</p> <p>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,</p> <p>Note, the scores for his domain are affected by the selected previous procedure and pre procedure diagnosis</p>	Overall .92	
	Card .91	Surg .96
<p><u>Procedure</u></p> <p>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,</p> <p>Time Start, Procedure Urgency, Unplanned Procedure, Single Operator, Sizing Balloon Used, No of Stents/Coils, Device Mfr, Device Model, Device Ser No, Device Size,</p>	Overall .99	
	Card .97	Surg .99
<p><u>Outcome</u></p> <p>Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination.</p> <p>Post Procedure Complications.</p>	Overall .96	
	Card .97	Surg .9375



Data Quality Indicator Assessment **2019-2020 data:**

The Overall Trust DQI = 96.75% Cardiology DQI = 96.25% Surgery DQI = 97%

DOMAIN	2020 19-20 data	2019 18-19 data	2018 17-18 data	2017 16-17 data
Demographics	1.0	1.0	.97	1.0
Pre Procedure	.92	.97	.92	.88
Procedure	.99	.97	.93	.94
Outcome	.96	.90	.98	.96

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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 has increased by 0.75% to 96.75% which is a 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 there are two individuals looking after these data they are just 0.5WTE covering this important role.

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 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 DBM promptly in a timely fashion but this does seem to be 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 book 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



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they were for congenital heart disease was extremely difficult 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 post procedural deaths reported to NCHDA for this data collection year.

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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 may be necessary to whether or not the combined total 0.5WTE roles of the 2 DBMs adequately cover the remit of NCHDA when compared with 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

4. It is recommended that the DBM has access to the echocardiogram reports in order to validate these data.
5. 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.
6. 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.
7. 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.

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