The National Congenital Heart Disease Audit

Procedures for
CONGENITAL HEART DISEASE,
April 2020 – March 2021

Data Quality Audit

The Newcastle Upon Tyne Teaching Hospitals NHS Foundation Trust.

21 July 2021

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Summary

The NCHDA data return from the cardiac department of the Freeman Hospital for the data collection year 2020/21 indicated that 617 procedures (233 surgery, 349, catheters, 35 others, 15 deaths [within 30 days of a procedure]) had been undertaken in patients with congenital heart disease. This represents a drop in procedural activity of 27% during the ongoing SARS-COV-2 pandemic.

This validation visit has been fully funded by Newcastle upon Tyne University Hospitals NHS Foundation Trust.

As previously reported, there is a Cardiothoracic Services Information Manager post at this Trust whose remit covers all 6 of the NICOR data collections. There are a further 6 other members of the Cardiac Information Team at FRE covering 6.0WTEs. There is a 1.0WTE individual Data Manager (DM) dedicated to the NCHDA collection and in February 2020 an assistant data manager was created and appointed.

Data are entered into a Dendrite Intellect system at various points of service throughout the hospital, ie operating theatres, cath labs etc. When checked for accuracy, completeness and validity these data are submitted to the NCHDA database.

Actions Reported since previous validation visit in 2020:

1. None reported

Data Quality Indicator (DQI)

The DQI for the Trust is calculated to be (with previous years in parentheses) **99.8%** (99.75, 99, 98.75, .99) with domain scores Demographics 1.0 (1.0, 1.0 1.0) Pre Procedure .9 (.99, .985, .96,) Procedure 1.0 (1.0, .99, .99,) and Outcome 1.0 (1.0, .99, 1.0).

There were 2 discrepancies in 827 data variables.

The calculation is based on the validation of 20 patients hospital notes who underwent 23 procedures (15 therapeutic catheter procedures and 8 surgical operations).

Separate DQI for Surgery and for Catheters

On further review of the DQI when the cases were split into their surgery and catheter groups and the scores were;

Year	Data Year Validated	Surgery	Caths
2012	10/11	97.75%	95.60%
2013	11/12	97%	99%
2014	13/14	97.25%	95.50%
2015	14/15	97.25%	97%
2016	15/16	98.5%	97%
2017	16/17	98.25%	99%
2018	17/18	98.25%	99.5%
2019	18/19	99%	99%
2020	19/20	100%	99.5%
2021	20/21	100%	99.6%

The NCHDA pre visit Questionnaire was completed and returned prior to the validation 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

Consent for External Validation of Notes.

Since May 2018, the General Data Protection Regulation (GDPR) 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.

Prior to the visit a file with 20 case notes (the Sample) and 10 Reserves was sent to the cardiothoracic information manager. 20 sets of notes (16 Samples, 4 Reserves) were available on the day. The Trust are currently using mixed paper and electronic patient hospital notes.

Introduction

As stated above, the NCHDA data return from the cardiac department of the Freeman Hospital for the year 2020/21 and harvested for this visit, indicated that 617 procedures (233 surgery, 349, catheters, 35 others, 15 deaths [within 30 days of a procedure]).

The Congenital Data Auditor for the NCHDA undertook the visit remotely via a MS Teams connection with an external Consultant Congenital Cardiologist on site in person. 1 NCHDA data manager from another centre joined the validation remotely as an observer.

As stated above, 20 sets of notes were requested. The accuracy of the NCHDA data return was then checked against each set of notes. The Specific Procedures algorithm grouping is also validated for the case notes seen.

FRE are still in the process of going paper-lite. Some documents were viewed on the electronic patient record or had been printed and added to the hospital paper bound notes. The paper case notes were often large and bulky.

Review of case notes

1. The case notes, had been meticulously prepared with sticky notes to identify many of the particular pages that the Reviewers needed to validate data.
2. As previously reported, the case notes were mostly in chronological order but as stated above some were quite wieldy to handle. The assistance of the local NCHDA Data Manager on the day was invaluable.
3. As previously reported, echocardiography reports were seen in the case notes but did not always describe the percentage of function for each ventricle.
4. On occasions it was sometimes challenging to find documentation for complex patients who had undergone many previous procedures listed chronologically.

Review of the Cath Lab and Theatre Log Books

Log books from Cath Labs 1,2, and 3 were offered for review.

The cath lab log books are bespoke bound volumes with ruled columns for various pieces of information which are completed by hand. As previously reported, product identifying labels are also adhered to the relevant entry. Sometimes the labels over lay the procedure descriptions. This made it difficult on occasions to identify if a procedure was for congenital heart disease or not or exactly what procedure had actually been performed. It was not known if there were any plans to move to using an electronic record of cath lab activity at this visit.

1. Approximately 22 catheter procedures were not validated in the log book. This may be because they occurred in the cath labs for which the registers were not reviewed or it is unclear whether or not procedures are for patients with congenital heart disease.

Registers Operating Theatres 1, 2, 3 and 19 were offered for review.

The log books are bespoke bound volumes with ruled columns for various pieces of information which are completed by hand. As reported previously, the legibility of the handwriting for some entries was quite poor. It was extremely challenging at times to identify whether younger adult patients were having operations for congenital heart disease or acquired or inherited heart disease.

1. 0 records were identified that may have been missed from the submission

During the validation, the reviewer's learned that Cerner SurgiNet is used in the operating rooms at FRE to record procedural activity. This resource may be a useful to accurately identify cases that occur in other operating rooms in future years but the entries do not appear to include details of the patient diagnosis.

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. The requirement for patient/parent/guardian consent to review the case notes is as stated above. 13 deaths within 30 days of a procedure for congenital heart disease were identified from the submitted data. for 2020-21. The PRAiS sensitive fields were reviewed for each of the patients and the findings were:

All dates of death were found to be correct and no data discrepancies were identified.

It is reported that the Summary Care Record is checked for NCHDA patient life status on a regular bi monthly basis.

It was not always possible to discern from the case notes seen, if patients who had died within 30 days were discussed with the coroner (when required), were discussed at an MDT and whether or not the death was related to the procedure.

Casenote Audit

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		13	7
2	NHS Number	20	20		13	7
3	Surname	20	20		13	7
4	First Name	20	20		13	7
5	Sex	20	20		13	7
6	DOB	20	20		13	7
7	Ethnicity	20	20		13	7
8	Patient Status	20	20		13	7
9	Postcode	20	20		13	7
10	Pre Procedure Diagnosis	20	20		15	8
11	Previous Procedures	23	23		32	4
12	Patients Weight at Operation	36	36		15	8
13	Height	23	23		15	7
14	Ante Natal Diagnosis	2	2		1	-
15	Pre Proc Seizures	23	23		15	8
16	Pre Proc NYHA	-	-		-	-
17	Pre Proc Smoker	-	-		-	-
18	Pre Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre Proc IHD	-	-		-	-
21	Comorbidity Present	23	23		15	8
22	Comorbid Conditions	54	55	1 absent	29/30	15
23	Pre Proc Systemic Ventricular EF	23	23		15	8
24	Pre Proc Sub Pul Ventricular EF	22	22		14	8
25	Pre-proc valve/septal defect/ vessel size	2	2		2	-
26	Consultant	23	23		15	8

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure	23	23		15	8
28	Time Start	23	23		15	8
29	Proc Urgency	-	-		-	-
30	Unplanned Proc	2	2		2	-
31	Single Operator	23	23		15	8
32	Operator 1	23	23		15	8
33	Operator 1 Grade	21	21		15	8
34	Operator 2	21	21		13	8
35	Procedure Type	23	23		13	8
36	Sternotomy Sequence	7	7		-	7
37	Operation Performed	23	23		15	8
38	Sizing balloon used for septal defect	3	3		3	-
39	No of stents or coils	6	6		6	-
40	Device Manufacturer	11	11		11	1
41	Device Model	13	13		13	1
42	Device Ser No	13	13		13	1
43	Device Size	12	13	1 absent	12/13	1
44	Total Bypass Time	8	8		-	8
45	XClamp Time,	8	8		-	8
46	Total Arrest	1	1		-	1
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	8	8		-	8
51	Post Procedure Seizures	23	23		15	8
52	Post Proc Complications	8	8		3	5
53	Date of Discharge	23	23		15	8
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	23	23		15	8
57	Discharge Destination	23	23		15	8

Data Quality Indicator Assessment:

The Overall Trust DQI = 99.8%   Cardiology DQI = 99.6%   Surgery DQI = 100%

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 .995**	**Card** .99	**Surg** 1.0
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 .997**	**Card** .995	**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 by domain:

DOMAIN	2021	2020	2019	2018	2017
Demographics	1.0	1.0	1.0	1.0	1.0
Pre Procedure	.995	.99	.985	.97	.97
Procedure	.997	1.0	.99	99	99.5
Outcome	1.0	1.0	.99	1.0	99

Conclusions

On the whole the NCHDA data was accurate, well documented, good quality and were appropriately recorded in the Cath Lab and Theatre log books. The hospital case notes for each of the patients included in the Data Quality Indicator (DQI) analysis had been meticulously prepared by the Congenital Data Manager.

Electronic log books are not yet in use at this centre. The DQI continues to be of an excellent standard, and demonstrates that the NCHDA data collection and audit processes in place to support it at this centre are working well.   It is clear that the Data Manager has invested many extra hours some of which were without a nominated assistant outside those contracted, to ensure this.

The Reviewers are pleased to report that FRE now has 2.0WTE dedicated individuals who look after the NCHDA data. However, it should be noted that it is a recommended standard of the New Congenital Heart Disease Review (NHSE May 2016 for Level 1 ACHD services (B33L1) that each centre providing these services must also have a dedicated congenital cardiac surgery/cardiology data collection manager, responsible for ACHD data and data submissions in accordance with necessary timescales.

As previously reported, data entry is now possible at a wider range of locations as each user has their own user ID and password to the information collection system Intellect.

NCHDA acknowledge that the data collection year 2020-2021 has been difficult in the environment of a pandemic and thank every congenital centre for their dedicated and conscientious contribution to this registry.

It was also noted that on some occasions that the diagnoses coding used did not always completely reconcile with the procedure performed.

As previously reported, there was also some difficulty in accurately identifying procedures for congenital heart disease in all of the log books seen. Some operating theatre and cathlab log book entries did not record what procedure was performed at all and in other records for young adult patients it was not clear whether or not the procedure being performed was for congenital, acquired or inherited heart disease. The Validation Team became aware during this visit that the electronic activity and data capture system Cerner SurgiNet that encapsulates preoperative, intraoperative and perioperative information is used in the operating rooms at FRE.

Validation of Deceased Patients Case Notes

All data were found to be accurate and complete. It was noted however that there did not always appear to be a detailed death or discharge summary for patients who had died in hospital and no Coroners Reports were seen. As stated above, it was not always possible to tell if patients who had died within 30 days were discussed with the coroner (when required), were discussed at an MDT and whether or not the death was related to the procedure

Recommendations

1. It is suggested that in line with the ACHD Specialist Surgical Standards (NHSE May 2016, B33L1) a dedicated data collection manager is recruited, to be responsible for ACHD audit and database submissions in accordance with necessary timescales
2. The standard operating procedures (SOP) for the NCHDA data collection should be reviewed to ensure that clear guidance is given on exactly how to capture all data on both paediatric and adult congenital cardiac patients in a timely manner. The SOP should clearly set out exactly who is responsible for;
   a. Input of congenital patients NCHDA required dataset items and at which point of service delivery
   b. Encouraging responsible clinician input of the procedure data for each operation, diagnostic or catheter intervention at the point of the service delivery and particularly data that cannot be entered at the time of the procedure, such as intubation time and complications prior to discharge.
   c. Validity checking and completeness 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 diagnosis coding reconciles with the procedure performed
   e. Where a patient has died within 30 days of a procedure, documenting whether or not there was a discussion with the coroner (when required), was discussed at an MDT and whether or not the death was related to the procedure as these are NCHDA dataset items.
   f. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data Managers at least monthly.
   g. Running the PRAiS (Paediatric Risk Analysis in Surgery) analysis tool monthly. This will inform the quarterly NHSE Dashboard reports.
   h. Leading the local review (and how frequently and in which forum for both disciplines)
   i. Making timely submissions (monthly is recommended)

3. It is recommended to clearly identify in log books for both cath lab and operating room congenital patients who undergo therapeutic cardiac procedures by non congenital colleagues.
4. It is recommended that the use of Cerner SurgiNet be explored as means of accurate and complete electronic data capture for NCHDA surgery procedures
5. It is recommended that all NCHDA Data Managers visit another congenital centre on an annual basis to observe processes and practices, share experiences and network.
6. Attendance at the next NCHDA Stakeholders (venue and date tbc) by DBM and lead clinician for congenital heart disease