The National Congenital Heart Disease Audit

Procedures for
CONGENITAL HEART DISEASE,
April 2023 – March 2024

Data Quality Audit

The Newcastle Upon Tyne Teaching Hospitals NHS Foundation Trust.

10 July 2024

performed by Lin Denne and Dr S Arif

Summary

The NCHDA data return from the cardiac department of the Freeman Hospital for the data collection year 2023/24 that was extracted on 10 June 2024 indicated that 876 procedures (270 surgery, 575 catheters, 31 others, 7 deaths [within 30 days of a procedure]) had been undertaken in patients with congenital heart disease.

Following review of the catheter laboratory and operating room activity log books on the day of the validation visit, 32 patients procedural data were identified that had mistakenly been withheld from NCHDA prior to this site validation. 21 submitted procedures were identified that may not be for congenital heart disease and Newcastle upon Tyne University Hospitals NHS Foundation Trust (FRE) have reviewed these data and made the necessary amendments/deletions.

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

There is a Cardiothoracic Services Information Manager in post at this Trust whose remit covers all of the NICOR data collections. There have been several post holders in this role since 2018 and there was a further recruitment drive during 2023. There is a 1.0WTE individual Congenital Heart Disease (CHD) Data Manager (DM) dedicated to the NCHDA collection who has been in post since September 2023. Since February 2020 an assistant Data Manager post was created and appointed. Neither the DM or Assistant Data Manager have any previous clinical training.

While the reviewers are pleased to note that FRE has 2.0WTE dedicated individuals who look after the NCHDA paediatric data, 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.

There are 12 other members of the cardiac data team providing a total of 9.17WTE. This is currently extended to 10.67 WTE with agreed overtime and fixed-term contract arrangements.

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 2023:

1. There is a new CHD Data Manager in post since September 2023.

Data Quality Indicator (DQI)

The DQI for the Trust is calculated to be (with previous years in parentheses) **99.6%** (99.75, 99.5, 99.8,) with domain scores Demographics 1.0 (1.0, .99, 1.0,) Pre Procedure .99 (.997, .997, .99) Procedure .997 (.99, 1.0, 1.0) and Outcome 1.0 (1.0, .99, 1.0).

There were 5 discrepancies identified in 998 data variables.
The calculation is based on the validation of 20 patients hospital notes who underwent 26 procedures (15 therapeutic catheter procedures and 11 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
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%
2022	21/22	100%	99%
2023	22/23	99.9%	99.7%
2024	23/24	99.25%	99.8%

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 9 Reserves was sent to the cardiothoracic information manager. 20 sets of notes (14 Samples, 6 Reserves) were available on the day. The Trust are mostly paper free using electronic health records that are part of the Oracle Health (previously known as Cerner Millennium) platform. Surginet is used in the cardiothoracic operating theatres to record bookings and activity and is part of the Oracle Health application. Surginet, when programmed fully can accommodate both ICD 10 (diagnosis) and OPCS 4 procedure coding and this can be very useful when identifying procedures for congenital heart disease. However Surginet was not used to cross validate the surgical case ascertainment as detailed below. The paper bound logs books were used.

Introduction

As stated above, the NCHDA data return from the cardiac department of the Freeman Hospital for the year 2023/24 and harvested for this visit, indicated that indicated that 876 procedures (270 surgery, 575 catheters, 31 others, 7 deaths [within 30 days of a procedure]) had been undertaken in patients with congenital heart disease.

The Congenital Data Auditor for the NCHDA undertook the visit on site together with an external Consultant Congenital Cardiologist in person.

As stated elsewhare, 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. 2 records were rejected as upon examination were found to be for patients with acquired heart disease.

FRE are still in the process of going paper-lite and have mostly achieved this now. The documents were viewed on the ePR record or had been printed and made in to a bundle of bound notes.

Review of case notes

1. The case note bundles that had been printed from the ePR, had been meticulously prepared with highlighted text to identify many of the particular pages that the Reviewers needed to validate data.
2. As previously reported, the printed case notes were mostly in chronological order. The assistance of the local NCHDA Data Managers on the day was invaluable.
3. JCC or MDT meeting notes were seen in most sets of patient documents
4. As previously reported, echocardiography reports were seen in the case notes but did not always describe the percentage of function for each ventricle.
5. On occasions it was sometimes challenging to find documentation for complex patients who had undergone many previous procedures, listed chronologically.
6. As previously documented, there does not appear to be a consistently used template to always capture the data for the ACHD risk fields in the NCHDA dataset.

Review of Log Books for Operating Rooms and Cardiac Catheter Laboratories

Log books from Cath Labs 1-6 were offered for review.

As previously noted, the cath lab log books are bespoke bound volumes with ruled columns for various pieces of information which are completed by hand. Some procedure descriptions were non specific and unclear as to whether they were for congenital heart disease or not. 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. There still appears to be no confirmed plans as yet to move to using an electronic record of cath lab activity at this visit.

1. 0 discrepancies were identified
2. 19 records in the submitted data were identified that may not be for congenital heart disease and if not, these should be removed from the NCHDA registry

Registers Operating Theatres 1, 2, 3, + 4 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 and some entries appeared to lack clarity or specificity. As previously noted, it was extremely challenging at times to identify whether younger adult patients were having operations for congenital heart disease, acquired or inherited heart disease. Procedures for acquired or inherited heart disease should not be submitted to NCHDA unless the patient has previously been under the care of a paediatric or transition cardiologist. The exception is patients who are found to have bicuspid aortic valves and fit the guidelines and algorithm on pages 6+7 of the NCHDA Dataset Manual.

It was not known if there were any confirmed plans as yet to move to using an electronic record of operating room activity at this visit. As mentioned elsewhere, the Reviewers are aware that this Centre uses Oracle Health Millennium and Surginet to record activity within the OR.

1. 2 submitted records were identified that may have errors in them
2. 2 submitted records may not be for congenital heart disease and if so, should be removed from the NCHDA registry

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. 7 deaths within 30 days of a specific procedure for congenital heart disease were identified from the submitted data. for 2023-24. The Partial Risk Analysis in Surgery (PRAiS) sensitive fields were reviewed for each of the patients and the findings were:

1. 1 submitted record was found to be for acquired heart disease and this was discarded.
2. All dates of death were found to be correct

It is always helpful to have both the copies of detailed discharge summaries, including hospital death certificates and the detail of whether or not there had been a discussion with the Medical Examiner/Coroner and where completed, the Coroners Reports in each pack. This really does make this part of the review much more timely.

Casenote Audit – 20 patients who underwent 15 catheter and 11 surgical procedures

	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	26	26		15	11
11	Previous Procedures	79	81	2 absent	32	47/49
12	Patients Weight at Operation	25	26	1 incorrect	14/15	11
13	Height	25	25		14	11
14	Ante Natal Diagnosis	2	2		1	1
15	Pre Proc Seizures	26	26		15	11
16	Pre Proc NYHA	10	10		7	3
17	Pre Proc Smoker	10	10		7	3
18	Pre Proc Diabetes	10	10		7	3
19	Hx Pulmonary Dis	10	10		7	3
20	Pre Proc IHD	10	10		7	3
21	Comorbidity Present	26	26		15	11

22	Comorbid Conditions	44	45	1 absent	19	15/16
23	Pre Proc Systemic Ventricular EF	26	26		15	11
24	Pre Proc Sub Pul Ventricular EF	24	24		14	10
25	Pre-proc valve/septal defect/ vessel size	6	6		6	-
26	Consultant	26	26		15	11

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	26	26		15	11
28	Proc Urgency	26	26		15	11
29	Unplanned Proc	-	-		-	-
30	Single Operator	5	5		10	-
31	Operator 1	26	26		15	11
32	Operator 1 Grade	26	26		15	11
33	Operator 2	21	21		10	11
34	Operator 2 Grade	21	21		10	11
35	Procedure Type	26	26		15	11
36	Sternotomy Sequence	10	10		-	10
37	Operation Performed	25	26	1 incorrect	15	10/11

38	Sizing balloon used for septal defect	2	2		2	-
39	No of stents or coils	3	3		4	-
40	Device Manufacturer	12	12		10	2
41	Device Model	12	12		10	2
42	Device Ser No	12	12		10	2
43	Device Size	10	10		8	2
44	Total Bypass Time	11	11		-	11
45	XClamp Time,	11	11		-	11
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	6	6		-	6
51	Post Procedure Seizures	26	26		15	11
52	Post Proc Complications	3	3		-	3
53	Date of Discharge	26	26		15	11
54	Date of Death	1	1		1	-
55	Attribution of Death	1	1		1	-
56	Status at Discharge	26	26		15	11
57	Discharge Destination	26	26		15	11

Data Quality Indicator Assessment:

The Overall Trust DQI = 99.6% Cardiology DQI = 99.8% Surgery DQI = 99.25%

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 .99</td></tr>
<tr><td>Card
.995</td><td>Surg
.98</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 by domain:

DOMAIN	2024	2023	2022	2021	2020
Demographics	1.0	1.0	.99	1.0	1.0
Pre Procedure	.99	.997	.997	.995	.99
Procedure	.997	.99	1.0	.997	1.0
Outcome	1.0	1.0	.99	1.0	1.0

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 printed hospital case note bundles for each of the patients had been meticulously prepared by the Congenital Data Managers.

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 Managers have invested many extra hours some of which were outside those contracted, to ensure this. Care should be taken to only include adult patients who have previously been on a congenital heart disease management pathway who either may have previously had therapeutic procedures as children or been on active surveillance. Please see the NCHDA definition of 'Congenital" on p6 + p7 of the NCHDA Manual for further clarity.

As previously noted, as the patient record becomes more digitised in the operating rooms and catheter labs, it will be helpful to incorporate methods to enable quick and easy identity of NCHDA patients undergoing procedures by clinicians not directly associated with congenital heart disease. Such as general cardiologists undertaking pacemaker box changes or electrophysiological procedures.

FRE now has 2.0WTE dedicated individuals who look after the NCHDA data. Neither of these individuals have a clinical background and it should be noted that without clear documentation of previous procedures, it can be challenging to correctly accurately code these.

However, it should also 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.

Validation of Deceased Patients Case Notes

All data were found to be accurate and complete. As noted above, it was enormously helpful to have both the copies of detailed discharge summaries, including hospital death certificates and the detail of whether or not there had been a discussion with the Medical

Examiner/Coroner and where completed, the Coroners Reports in each pack. This really does make this part of the review much less time consuming.

Recommendations (unchanged since 2021)

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 continue to 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. Confirmation of antenatal diagnosis in ACHD patients who have a date of birth year of 1988 or later and underwent procedures during neonatal, infant or childhood years.
   f. Where a patient has died within 30 days of a procedure, documenting whether or not there was a discussion with the Medical Examiner or Coroner (when required), and whether or not the death was related to the procedure as these are NCHDA dataset items.
   g. Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.
   h. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data Managers at least monthly.
   i. Running the PRAiS (Paediatric Risk Analysis in Surgery) analysis tool monthly when possible. This will inform the quarterly NHSE Specialist Commissioning Dashboard reports.
   j. Leading the local review (and how frequently and in which forum for both disciplines)

   k. Making timely submissions (monthly is recommended or within 2 weeks of a procedure if possible as requested by NHSE)

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 Oracle Health SurgiNet be further explored as means of accurate and complete electronic data capture for NCHDA surgery procedures and inclusion of ICD 10/11 and OPCS 4 coding be considered. This would really enhance clinical coding.
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