The National Congenital Heart Disease Audit

Procedures for
CONGENITAL HEART DISEASE,
April 2024 – March 2025

Data Quality Audit

The Newcastle Upon Tyne Teaching Hospitals NHS Foundation Trust.

30 July 2025

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Summary

The NCHDA data return from the cardiac department of the Freeman Hospital for the data collection year 2024/25 indicated that 897 procedures (252 surgery, 608 catheters, 37 others, 7 deaths [within 30 days of a procedure]) had been undertaken in patients with congenital heart disease.

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 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 or experience.

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 10.50WTEs to cover all of the national cardiac data registries.

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 locally with the responsible clinicians, these data are submitted to the NCHDA database as .csv file.

Actions Reported since previous validation visit in 2024:

FRE report that internal processes have been reviewed and changes have been made relating to:

1. The timeliness of submissions to NICOR, the aim is monthly
2. More timely activity log book checks for operating rooms and catheter labs
3. The cross validation processes between the Data Manager (DM) and the Assistant Data Manager(ADM) and the tracking of procedures and their outcomes.
4. The processes for following up missing documentation / information

Data Quality Indicator (DQI)

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

There were 2 discrepancies identified in 998 data variables.

The calculation is based on the validation of 20 patients hospital notes who underwent 25 procedures (12 therapeutic catheter procedures and 13 surgical operations).

Separate DQI for Surgery and for Catheters

Since the 2009 cycle of visits commenced, as well as the overall DQI for each centre, the DQI for surgery and catheters is being calculated. It is recommended that a minimum number of 5 procedures in either group are required for the differential DQI calculation.

Year	Data Year Validated	Surgery	Caths
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%
2025	24/25	99.75%	99.5%

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

Data Maturity in 2025

This NHS Trust does not have a single unified digital health record system allowing the user to see **all** of the patient data in one document management system. Oracle Health Millenium e-records are used. There are still paper bound log books tracking operating room and catheter lab activity. Patient vital observations, clinic notes and some other charts are all still paper based and then scanned into Millenium.

Some clinical records are available on an application known as PowerChart and that is part of the Oracle Health Millenium e-health records application used at this Trust. This includes perfusion records.

This Trust also uses a Dentrite database to collect NCHDA data.

At least 3 different databases or information systems with specific user id and passwords are generally accessed to collect NCHDA data prior to submission as well as the paper bound log books for each catheter laboratory and operating room.

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 Sample notes were available on the day. Nil (zero) hospital notes were required from the Reserve list. As stated above, the Trust are mostly paper free using electronic health records that are part of the Oracle Health (previously known as Cerner Millennium) platform.

It has been previously reported that Surginet is used in the cardiothoracic operating theatres to record bookings and activity and is also part of the Oracle Health application. As stated in previous years, 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 2024/25 and harvested for this visit, indicated that 897 procedures (252 surgery, 608 catheters, 37 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 Specialty Trainee Congenital Cardiologist (ST7) from Dublin in person. There was 1 observer, the Clinical Registries Lead from NHS AGEM.

As stated elsewhere, 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 from paper-lite to paper free and it will be some time before that is totally achieved. The documents viewed were arranged as individual patient episode packs of printed pages from the ePR record. Where the Reviewers had further questions, the host DMs displayed screens from the live ePR as required.

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 and the range of adjectives used to describe function was wide and varied and open to interpretation.
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. This template, when seen was often incomplete or unfilled entirely.

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. The hand writing was often very difficult to read and some procedure descriptions were non specific and unclear 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 plans to move to using an electronic record of cath lab activity at this visit.

Due to time pressures the months of April 2024 – August 2024 only were validated. Therefore we are unable to state that case ascertainment for catheter procedures are complete for this centre.

1. 0 discrepancies were identified
2. 0 catheter records were identified that may have been missed from this submission
3. 361 submitted catheter records were not validated

<u>Registers Operating Theatres 1, 2, 3, + 4 were offered for review</u>.

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 or acquired or inherited heart disease.

It was reported to the Reviewers that there are no plans to move to using an electronic record of operating room activity at this visit. The Reviewers are aware that this Centre uses Oracle Health Millennium and Surginet which is part of this application can be used to record activity within the OR with training for all users.

1. 2 submitted records were identified that may have errors in them

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 2024-25. The Partial Risk Analysis in Surgery (PRAiS) sensitive fields were reviewed for each of the patients and the findings were:

- All dates of death were found to be correct.
- 3 records may have absent comorbidities.
- Detailed discharge summaries were seen and these included commentary of discussions with Medical Examiner and Coroners Office
- Death certificates were not seen but may not have been issued on the date of the visit.

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.

It was reported that currently the Congenital Data Manager is completing the field for Attribution of Death under guidance of a surgical colleague.

Casenote Audit – 20 patients who underwent 12 catheter and 13 surgical procedures

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
1	Hospital Number	20	20		10	10
2	NHS Number	20	20		10	10
3	Surname	20	20		10	10
4	First Name	20	20		10	10
5	Sex	20	20		10	10
6	DOB	20	20		10	10
7	Ethnicity	20	20		10	10
8	Patient Status	20	20		10	10
9	Postcode	20	20		10	10
10	Pre Procedure Diagnosis	25	25		12	13
11	Previous Procedures	109	109		52	57
12	Patients Weight at Operation	25	25		12	13
13	Height	24	24		12	12
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	9	9		12	13
16	Pre Proc NYHA	9	9		6	9
17	Pre Proc Smoker	9	9		6	9
18	Pre Proc Diabetes	9	9		6	9
19	Hx Pulmonary Dis	9	9		6	9
20	Pre Proc IHD	9	9		6	9
21	Comorbidity Present	25	25		12	13
22	Comorbid Conditions	36	36		15	21
23	Pre Proc Systemic Ventricular EF	25	25		12	13
24	Pre Proc Sub Pul Ventricular EF	19	20	1 incorrect	9	10/11
25	Pre-proc valve/septal defect/ vessel size	4	4		4	0
26	Consultant	25	25		12	13

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	25	25		12	13
28	Proc Urgency	25	25		12	13
29	Unplanned Proc	-	-		-	-
30	Single Operator	4	4		4	-
31	Operator 1	25	25		12	13
32	Operator 1 Grade	25	25		12	13
33	Operator 2	21	21		8	13
34	Operator 2 Grade	21	21		8	13
35	Procedure Type	25	25		12	13
36	Sternotomy Sequence	9	9		-	9
37	Operation Performed	25	25		12	13
38	Sizing balloon used for septal defect	3	3		3	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	11	11		8	3
41	Device Model	11	11		8	3
42	Device Ser No	11	11		8	3
43	Device Size	9	9		8	1
44	Total Bypass Time	9	9		-	9
45	XClamp Time,	8	8		-	8
46	Total Arrest	-	-		-	-
47	Cath Proc Time,	12	12		12	-
48	Cath Fluro Time,	12	12		12	-
49	Cath Fluro Dose,	12	12		12	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	9	9		-	9
51	Post Procedure Seizures	25	25		12	13
52	Post Proc Complications	3	4	1 incomplete	0/1	3
53	Date of Discharge	25	25		12	13
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	25	25		12	13
57	Discharge Destination	25	25		12	13

FRE NCHDA Report 2025

Data Quality Indicator Assessment:

The Overall Trust DQI = 99.6% Cardiology DQI = 99.5% Surgery DQI = 99.75%

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 .99**	
	Card 1.0	**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 1.0**	
	Card 1.0	**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** .99	
	Card .98	**Surg** 1.0

Data Quality Indicator Assessment by domain:

DOMAIN	2025	2024	2023	2022	2021
Demographics	1.0	1.0	1.0	.99	1.0
Pre Procedure	.99	.99	.997	.997	.995
Procedure	1.0	.997	.99	1.0	.997
Outcome	.99	1.0	1.0	.99	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 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 hours, 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.

As previously noted, the handwritten bound log books are very challenging to read as the standard of the writing can be poor and difficult to discern. Sticky labels to identify devices can also over lay the handwritten entries. When the patient record becomes digital 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 and 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 with only a very few discrepancies highlighted. 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 at least annually 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.
- and/or was discussed at an MDT and
- Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.
- Completing this field (Attribution of Death) in the NCHDA dataset as part of the Mortality and Morbidity meeting with the clinical team

g) Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data Managers at least monthly or whenever a data submission has been made to NCHDA.

h) Running the PRAiS (Paediatric Risk Analysis in Surgery) analysis tool monthly when possible. This will inform the quarterly NHSE Specialist Commissioning Dashboard reports.

i) Leading the local review (and how frequently and in which forum for both disciplines)

j) Making timely submissions, monthly is recommended or within 2 weeks of hospital discharge.

3. It is recommended to clearly identify in the bound log books for both cath lab and operating room congenital patients who undergo therapeutic cardiac procedures by non congenital colleagues. The use of a self inking stamp with the word CONGENITAL may be useful. It is suggested that this should be physically attached to the wall adjacent to the where the log books are completed at the end of each case.
4. It is specifically recommended that the use of Oracle Health SurgiNet be further explored as means of accurate and complete electronic data capture for NCHDA surgery procedures in the operating room and inclusion of ICD 10/11 and OPCS 4 coding be considered. This would really enhance clinical coding and help with the identifying patients with congenital heart disease.
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