The National Congenital Heart Disease Audit Database

Data Quality Audit for CONGENITAL HEART DISEASE PROCEDURES

Apr 2023 - Mar 2024

Glenfield Hospital
University of Leicester NHS Trust

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Summary

Prior to the log book review on the day of the validation visit, the NCHDA data return from the East Midland Congenital Cardiac Department of Leicester Hospitals NHS Foundation Trust indicated that that 549 (surgery 282, catheter 258, others 9, 6 deaths within 30 days of a procedure) procedures have been undertaken in patients with congenital heart disease during the data collection year of 2023/24.

This visit has been fully funded by Leicester Teaching Hospitals NHS Foundation Trust.

Following review of the catheter laboratory and operating room activity log books on the day of the validation visit, 13 additional procedures were identified for local review and where found to be congenital cardiac procedures were submitted to the Registry.

Since November 2014 there has been a Data and Outcomes Analyst role and the post holder is responsible for submitting the data to the NCHDA. However, as previously reported, this individual has responsibilities to other clinical areas and this role is not dedicated to, and has no protected time for NCHDA.

As reported in 2011- 23, there is also a specifically identified data clerk role (DM) supervising the data collection for congenital cardiology and has some time protected specifically for the NCHDA data registry. Neither of these individuals have a clinical background. The DM does not have access to the NCHDA database.

There is real-time data input in operating rooms and cath labs using the HeartSuite cardiac information system. However, it appears that not all clinicians fully the complete the clinical aspects for the data all the time.

From August 2021, the congenital cardiac service was divided across two sites within the Trust. The paediatric congenital cardiac service moved location to Leicester Royal Infirmary where other paediatric services are co-located. The ACHD service has remained at Glenfield Hospital within the same Trust. This site visit was hosted at Glenfield Hospital. This NHS Trust continues to use predominantly paper hospital case notes.

Actions on Recommendations or Changes since Last Validation Visit in 2023:

- None reported

Electronic Patients Records at GRL.

As previously reported in 2015, GRL have implemented and then paused an electronic records storage and retrieval system. This remains the same in 2024 and paper bound hospital records, sometimes in large volumes, continue to be used.

Data Quality Indicator (DQI) Score

The DQI score for GRL is (with previous years in parentheses); **96.75%** (97.75, 96. 94.5) with domain scores Demographics 1.0 (.99, 1.0, .98, 1.0), Pre Procedure .94 (.98, .93, .96) Procedure .96 (.98, .94, .95) and Outcome .97 (.96, .97, .89,). This is a decrease of 1.0 %.

We reviewed the hospital notes of 20 patients who had undergone 22 procedures (13 operations and 9 therapeutic catheter procedures.
This amounted to 850 data points with 31 discrepancies that were identified.

The fields with the most discrepancies are:

Comorbidities	5 discrepancies
Ventricular Function	5 discrepancies
Implanted Device Details	5 discrepancies
Pre Procedure Diagnosis	4 discrepancies

Since 2009, separate DQI scores are being calculated for both catheters and surgery. A minimum number of 5 records are required in either group for this to be done. The DQI scores are;

Year of Visit	Data Year Validated	Surgery DQI	Catheter DQI
2014	13/14	94%	85.5%
2015	14/15	92.5%	97%
2016	15/16	97%	97.25%
2017	16/17	94%	98%
2018	17/18	97%	94.8%
2019	18/19	94.25%	96%
2020	19/20	95%	94%
2021	20/21	96%	92%
2022	21/22	96.25%	95.5%
2023	22/23	97.25%	99%
2024	23/24	98%	95%

As in 2023, a pre visit Questionnaire was supplied and return requested but had not been received prior to the site visit. Therefore, it was not possible to comment on the 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 validation visit, the NCHDA return from the cardiac department of The Glenfield Hospital indicates that that 549 (surgery 282, catheter 258, others 9, 6 deaths within 30 days of a procedure) procedures have been undertaken in patients with congenital heart disease during the data collection year of 2023/24.

The NCHDA Clinical Data Auditor and a post CCT Registrar in Congenital Cardiology were present in person for this site validation visit. A Data Manager for NCHDA from another centre attended as an observer and also assisted with the case notes and case ascertainment validations.

A list of 20 sets of notes for the case note review were supplied by NCHDA in advance of the visit. Also included in this list were 10 further cases should any of the first 20 not be available. On the day 3 records were used from the reserve list. The accuracy of the NCHDA data return was then checked against each set of notes and used to calculate the Data Quality Indicator (DQI) score.

Review of notes

The case notes reviewed at this visit were printed packs of the information for each of the patients that would be audited. The printouts were from a mixture of the Trusts ePR – Nervecentre an iCloud based system that has been in use at GRL since 2019 and the original bound case note that were also present in case of further queries or questions arising, however these were often not in chronological order of events. The reviewers would like to again thank the Data and Outcomes Analyst and DM for taking the time to assemble each pack. The Reviewers are also grateful to the local consultant cardiologist and consultant surgeon who both spent most of the day with them to assist with navigating the packs of hospital notes and discuss issues arising during the review and to the Service Manager and Lead Nurse for the EMCH Network for making time to attend the site validation.

1. The photocopied packs of selected pages from the hospital notes were well organised and prepared with key data fields identified. The complete hospital case notes were nearly all available when the Reviewers needed to access them.

2. It was observed that there still appears to be a large number of adjectives used to describe ventricular function
3. The discharge sheet from ITU to the ward, when seen, was very useful.
4. It was challenging at times to find the explicit information of the date and time of extubation as the ITU vital observations charts do not appear to always be kept with the narrative hospital notes and narrative documents were sometime vague on this information
5. The template for documentation of the ACHD risk fields required for NCHDA was often only partly completed or completely blank.
6. It was also challenging to find reporting of ventricular function in the hospital notes of ACHD patients.
7. It appears that one particular clinician may not be completing all of the diagnoses fields
8. Some of the day case patients whose notes were validated, did not appear to have a discharge summary in their hospital file.
9. The Attribution of Death field should be completed whenever this information is available after a patient has died. It is important that this is discussed in the appropriate forum and completed by the lead clinicians.

Review of the theatre log books

The electronic theatre management system ORMIS that is used in operating rooms at both sites was presented. This is essentially a theatre booking system and does not have any fields for clinical diagnosis or recognised clinical diagnostic coding. It also does not have any clinical procedural coding system within its function to accurately record exactly what operation has been performed only the name of the scheduled procedure which may be something quite different from the actual procedure performed. Therefore it is difficult to know how complete and accurate ORMIS is at this time or to know how the Trust uses the information collected.

It is acknowledged that there is flexibility within ORMIS to load OPCS4.9 procedure coding and this, when used correctly after suitable education and training, will add to the accuracy of the data being collected.

Review of ORMIS for 2023/24 identified;

1. 25 of the submitted records for congenital surgery may have errors in them
2. 1 of the submitted records for congenital surgery may have a duplicate entry
3. 2 submitted records may not be countable procedures for NCHDA and if not, should be removed
4. 3 surgery procedures were identified that may have been missed from the data submission as it was not always clear exactly what procedure had been performed or whether or not the patient had congenital heart disease.

Catheter Lab Log Book Review

As stated above, the paediatric service moved from Glenfield Hospital to the Royal Infirmary in August 2021. It is reported that there is one dedicated paediatric cathlab at the Royal infirmary. ORMIS is used to collect cathlab activity data at Leicester Royal Infirmary.

1 bound paper Log book from Glenfield was offered for review, cathlab B. There are 5 other cath labs at Glenfield and these books were not made available. The log book is of a bespoke design is used in all labs at Glenfield. Each case performed is recorded as one full entry with column headings clearly indicating what information is required. As previously reported, the space to record data is quite narrow and made auditing extremely difficult and time consuming to decipher on occasions. The handwriting was often unclear and acronyms were used with no transcription table available in the front of the log books making it very difficult to understand exactly what procedure had taken place. There was no clear indication or method to indicate whether or not a procedure was for a patient with congenital heart disease.

Following review of the Glenfield catheter laboratory log books and ORMIS from LRI:

1. 53 submitted catheter records may have an error or unfilled field in them
2. 10 catheter procedures were identified in the logs that may be suitable for submission to NCHDA

3. 1 submitted record was not validated in the cath lab log books/ORMIS that were seen

As in previous years it was again observed that there appears to be a smaller than expected number of electrophysiology and other EP procedures such as Pacing, reported from GRL in the NCHDA data. This may be due to these procedures being performed in other cath labs for which the books were not seen. It was also reported that these cases may be being performed by non congenital colleagues and the NCHDA audit team are not aware of.

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 all dates of death of deceased patients included in the year under review. These are post procedural deaths. The diagnosis, comorbidity, pre operative weight, procedure and complication coding will also be validated.

Six 30 day post procedural deaths were submitted in the data from GRL for the year 2023/24. Photocopies from the case notes were made available to the reviewers. Some volumes of hospital notes were also available to the Reviewers.

5 of 6 sets of data from the hospital notes were seen. 1 set of notes were not made available.

The following observations were made;

1. All dates of death in were confirmed as correct in the case notes seen.
2. All 5 records examined appeared appear to have a discrepancy in the Attribution of Death field
3. It is reported that the completion of this data for NCHDA is not discussed at the mortality meeting
4. There also appears to be a small number of discrepancies in a number of fields of all the deceased records that were seen.
5. Documentation of discussion with the Medical Examiner/Coroner was seen in most sets of hospital notes
6. It was noted that in the hospital notes for ACHD deceased patients, it was very difficult to find any detailed discharge/death summary.

Casenote Audit

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		8	12
2	NHS Number	20	20		8	12
3	Surname	20	20		8	12
4	First Name	20	20		8	12
5	Sex	20	20		8	12
6	DOB	20	20		8	12
7	Ethnicity	20	20		8	12
8	Patient Status	20	20		8	12
9	Postcode	20	20		8	12
10	Pre Procedure Diagnosis	18	22	2 absent, 2 missing primary components	7/9	11/13
11	Previous Procedures	34	35	1 incorrect	20	14/15
12	Patients Weight at Operation	21	22	1 incorrect	9	12/13
13	Height	22	22		9	13
14	Ante Natal Diagnosis	3	4	1 incorrect	-	¾
15	Pre Proc Seizures	22	22		9	13
16	Pre Proc NYHA	8	8		3	5
17	Pre Proc Smoker	8	8		3	5
18	Pre Proc Diabetes	8	8		3	5
19	Hx Pulmonary Dis	8	8		3	5
20	Pre Proc IHD	8	8		3	5
21	Comorbidity Present	22	22		9	13

22	Comorbid Conditions	27	31	5 incorrect	12/14	14/17
23	Pre Proc Systemic Ventricular EF	20	22	2 incorrect	8/9	12/13
24	Pre Proc Sub Pul Ventricular EF	17	20	3 incorrect	5/8	12
25	Pre-proc valve/septal defect/ vessel size	3	3		3	-
26	Consultant	22	22		9	13

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date + Time Start	22	22		9	13
28	Proc Urgency	22	22		9	13
29	Unplanned Proc	-	-		-	-
30	Single Operator	2	2		2	-
31	Operator 1	22	22		9	13
32	Operator 1 Grade	22	22		9	13
33	Operator 2	20	20		7	13
34	Operator 2 Grade	20	20		7	13
35	Procedure Type	22	22		9	13
36	Sternotomy Sequence	11	11		-	11

37	Operation Performed	21	22	1 incorrect	8/9	13
38	Sizing balloon used for septal defect	2	2		2	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	8	9	1 absent	6	2/3
41	Device Model	8	9	1 absent	6	2/3
42	Device Ser No	8	9	1 absent	6	2/3
43	Device Size	8	9	1 absent	6	2/3
44	Total Bypass Time	10	11	1 absent	-	10/11
45	XClamp Time,	9	9		-	9
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	7	9	2 absent	7/9	-
48	Cath Fluro Time,	7	9	2 absent	7/9	-
49	Cath Fluro Dose,	8	9	1 absent	8/9	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	11	11		-	11
51	Post Procedure Seizures	22	22		9	13
52	Post Proc Complications	0	3	3 absent	0/3	-
53	Date of Discharge	22	22		9	13
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	22	22		9	13
57	Discharge Destination	22	22		9	13

Data Quality Indicator Assessment:

The Overall Trust DQI = 96.75% Cardiology DQI = 95% 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 .94**	
	Card .93	**Surg** .945
Procedure	**Overall** .96	

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** .95	**Surg** .97
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** .92	**Surg** 1.0

Data Quality Indicator Assessment

The Trust DQI = 96.75%

This DQI is based upon the domain scoring below. The methodology for this DQI is provided in the paper The NCHDA Audit – An Introduction to the Process.

DOMAINS	2021 20/21	2022 21/22	2023 22/23	2024
Demographics	.98	1.0	.99	1.0
Pre Procedure	.96	.93	.98	.94
Procedure	.95	.94	.98	.96
Outcome	.89	.96	.96	.97

Conclusions

On the whole the NCHDA data were accurate, well documented, of good quality and were appropriately recorded in the Theatre and Cath Lab log books. This centre is still using paper hospital case notes and digital electronic records for recording procedural activity in the operating rooms and some catheter laboratories.

The overall DQI score is 96.75%. This is a decrease of 1% on the 2023 score.

The Reviewers are pleased to note that there continues to be some clinician involvement with validating the data locally prior to submission. However, it became clear that amongst some clinicians there appears to be a lack of ownership of the data causing fields to be unfilled or unchecked in the appropriate forums. Local validation is an important part of ensuring only complete, good quality data are collected. Reverse validation – that is exporting submitted data to NCHDA back to the local forum for the data review should be done on a regular basis as it demonstrates exactly how data will be analysed by NCHDA and will highlight any coding errors quickly and easily. It is essential that adequate support is provided for the current Information and Data Managers, who are not clinically trained, who undertake a vast majority of this task, to do this equitably with all clinicians.

It is again observed that GRL still does not meet the standards outlined within with the New Congenital Heart Disease Review (NHSE July 2015) recommendation B32(L1) that there should be consideration given to ensuring that a minimum of 1.0 WTE dedicated paediatric cardiac surgery/cardiology data collection manager, with at least 1.0 WTE assistant, responsible for audit and database submissions in accordance with necessary timescales are in post. The same Review also recommends (point B33L1) a dedicated 1.0WTE data collection manager to be responsible for ACHD audit and database submissions in accordance with necessary timescales. The congenital paediatric service has relocated to Leicester Royal Infirmary in summer 2021 leaving the ACHD service at its present location at Glenfield.

As previously stated it should also be borne in mind that NHSE now require monthly data submissions or within 2 weeks of a procedure where possible. No NCHDA data for Q1 of

24/25 were received at the time of this validation visit. It should also be noted that NHSE may use NCHDA data to underpin parts of the quarterly paediatric cardiac and ACHD/Transition and CQUINs dashboards for current and future activity provision.

As noted by the Reviewers when validating above, and as in previous years, in the activity ascertainment, that there is a lack of procedures for electrophysiology and devices implantation from GRL.

Also, as previously reported, reviewing of the hard backed cath lab log book from Glenfield was at times extremely difficult due to the rows for each record entry being so very closely drawn and the hand writing difficult to decipher. It was also clear to the reviewers at times that what was actually recorded in the cath lab log books and ORMIS did not always accurately portray the procedure that was performed.

Using ORMIS for the theatre ascertainment validation was useful but it is clear that there still needs to be much more clarity in describing the actual procedures performed and also using OPCS 4.9 codes would be helpful in ensuring accuracy of the data entries. The procedure performed should reconcile with the presenting diagnosis of the patient.

Review of Deceased Patients Diagnostic and Procedural Coding

As reported above, there were a small number of queries identified. All dates of death that were validated, were correct. As stated elsewhere, it was not always possible to tell if patients who had died within 30 days were discussed with the Medical Examiner or Coroner (when required) and discharge/death summaries for ACHD patients were very hard to find in the hospital notes that were provided.

It was agreed during this part of the validation visit that the data fields for these patients and in particular the field for Attribution of Death, it would be most appropriate to discuss its completion at monthly mortality meetings

The Reviewers were also made aware that there is no process to regularly report and inform the NCHDA Data Managers of any out of hospital patient deaths.

Recommendations (unchanged from2022)

1. It is strongly recommended that in line with the New Congenital Heart Disease Review National Standard (NHSE July 2016) recommendation B32(L1), that there should be a minimum of 1.0 WTE dedicated senior paediatric cardiac surgery/cardiology data collection manager and 1.0WTE assistant paediatric cardiac surgery/cardiology data collection manager in post. The recommended pay banding for the senior data collection manager is contained in this document: https://www.hqip.org.uk/resource/national-congenital-heart-disease-audit-2013-2016/#.XiHWkojgqt8
2. It is also strongly recommended that in line with the recommendation within with the New Congenital Heart Disease Review National Standard (NHSE July 2015, point B33L1), that there should be a 1.0WTE dedicated data collection manager that is responsible for ACHD audit data and database submissions in post to facilitate data collection, data validity and submission to NCHDA.
3. It is recommended that any Standard Operating Protocols devised and/or reviewed for the congenital data collection, should be done regularly to ensure that they include detailed guidance on 'how to' and exactly **who** is responsible for and in what timeframe for each of the following;

    a) Input of the data for each relevant procedure and identifying at which point of the service delivery this should be done, particularly data that cannot be input at the time of procedure such as intubation duration and complications.

    b) Validity checking for completeness and the time intervals for feedback to responsible clinicians on this along with a clear time scale and line of responsibility for rectifying any omissions or errors in both surgery and cardiology disciplines. Monthly face to face meetings with all clinicians are recommended.

    c) Running PRAiS analysis software and completion of any monthly and quarterly NHSE Commissioner Dashboards or data returns as required.

d) Leading the local review (how frequently and in which forum for both disciplines) and encouraging clinician ownership of the data.
e) Making timely submissions (monthly or within 2 weeks of a procedure)
f) Clearly documenting the date of any discussion with the local Medical Examiner/Coroner and its outcome following a patient death post procedure.
g) Documentation of the attribution of death as this is an NCHDA required data field.
h) Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.
i) Devising a mechanism to identify and capture dates of death in patients who have been discharged following a procedure
j) Timely reverse validation at GRL data against an acknowledged 'gold standard' record of activity and procedures performed.
k) Updating these SOPs at timely intervals

4. To encourage a more restricted list of adjectives to describe right and left ventricular function to match with the NCHDA Dataset Requirements. See NCHDA Data Manual pages 28 and 29. https://www.nicor.org.uk/datasets/supporting-data-set-documentation
5. To encourage clearer data entry in cath lab and operating log books/electronic data bases to assist with identity of procedures in patients with congenital heart disease.
6. To develop training for all other staff who may be involved with data input. This could involve visiting other centres who submit data to NCHDA and for sharing ideas, knowledge and experience.
7. Provide access to RIS (or CRIS) for NCHDA Data Managers to enable capture of xray dose and times if not clear in the patients hospital records.
8. To have clear guidance on exactly where sticky labels from implanted devices should be located in the patients hospital case note.
9. Encourage trainees at ST6 or above to volunteer to be the assisting clinician at external NCHDA validations to other Level 1 service providers.

10. For local NCHDA Data/Information Managers to attend and observe a validation visit to another centre annually.