The National Congenital Heart Disease Audit Database

Data Quality Audit for CONGENITAL HEART DISEASE

Apr 2021 - Mar 2022

Glenfield Hospital
University of Leicester NHS Trust

11 August 2022

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Summary

Prior to the log book review on the day of the validation visit, the NCHDA data return from the Cardiac Department of Glenfield Hospital indicated that 488 (surgery 235, catheter 244, others 11, 4 deaths within 30 days of a procedure) procedures have been undertaken in patients with congenital heart disease during the data collection year of 2021/22.

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

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, this individual has responsibilities to other clinical areas and this role is not dedicated just to NCHDA.

As reported in 2011- 21, there is also a specifically identified data clerk role (DM) supervising the data collection for congenital cardiology who has access to the NCHDA Database and has time protected specifically for the NCHDA data registry. Neither of these individuals have a clinical background.

There is real-time data input in operating rooms and cath labs using the HeartSuite cardiac information system.

In August 2021, the paediatric congenital cardiac service moved location to Leicester Royal Infirmary while the ACHD service has remained at Glenfield Hospital within the same Trust. This site visit was hosted at Glenfield Hospital.

Actions on Recommendations or Changes since Last Validation Visit in 2021:

- Since August 2021, when the congenital paediatric service relocated to Leicester Royal Infirmary, the Outcomes and Data Analyst and the DM remain located at the Glenfield site.
- The GRL Database Manager has confirmed that the process of arranging regular meetings with the congenital surgeons and interventionists will become further embedded now that the congenital service is split over two sites.
- GRL have confirmed that they have moved to using ORMIS for surgical logging of activity and will use it for validation of activity going forwards.

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 2022 and paper bound hospital records continue to be used.

Data Quality Indicator (DQI) Score

The DQI score for GRL is (with previous years in parentheses): 96% (94.5, 94.75, 94.75) with domain scores Demographics 1.0 (.98, 1.0, 1.0, .99), Pre Procedure .93 (.96, .90 .89,) Procedure .94 (.95, .98, .93, .94,) and Outcome .97 (.89, .91, .97, 1.0).

This is an increase of 1.5% and a very good score.

We reviewed the hospital notes of 20 patients who had undergone 21 procedures (10 operations and 11 therapeutic catheter procedures. This amounted to 796 data points with 37 discrepancies that were identified.

The fields with the most discrepancies are:

Fluroscopy/xray dose and time	7 discrepancies
Comorbidities	6 discrepancies
ACHD risk fields	6 discrepancies
Previous Procedures	4 discrepancies
Implanted devices and their detail	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
2013	12/13	95.75%	90%
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%

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.

Introduction

Prior to the validation visit, the NCHDA return from the cardiac department of The Glenfield Hospital indicates that 488 (surgery 235, catheter 244, others 11, 4 deaths within 30 days of a procedure) procedures have been undertaken in patients with congenital heart disease during the data collection year of 2021/22

20 sets of case notes were randomly selected for review. The NCHDA Data Auditor was present on Zoom for the day and an external Consultant in Congenital Cardiology was present in person.

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 2 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 patients that would be audited. The original bound case note was 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 congenital data manager and data clerk for taking the time to assemble each pack. The Reviewers are also grateful to the consultant cardiologists and surgeons who made time to assist with navigating the packs of hospital notes during the review and to the recently appointed General Manager for Congenital Services for making time to attend the site validation.

1. As previously reported, it was sometimes difficult to find documentary evidence of pre procedure echocardiograms from other hospitals in the patient notes.
2. Handwritten details of catheter procedures were seen although some were missing the xray data. As previously reported, clinical audit staff do not appear to have access to the Radiology Information System (RIS) register for radiology to cross validate these items.
3. As previously noted, it was challenging to find any xray data in the case notes of ACHD patients who had undergone electrophysiological procedures.
4. As previously noted, for patients who had undergone implantation of devices there does not appear to be a standard place in the hospital notes for the product labels to be kept and these, when found were randomly placed in various part of the hospital file.
5. The discharge sheet from ITU to the ward was very useful.
6. Documentation of exact discharge destination was sometimes challenging to find

7. The Attribution of Death field should be completed whenever this information is available after a patient has died.

Review of the theatre log books

Since 2020 the operating room staff have been reluctant to release the bound log books for the review and this lead to the intervention of the Medical Director during one validation visit. This Trust use the electronic theatre management system ORMIS in all operating rooms at both sites and this was presented as the Trust gold standard for operating room activity at this site visit in 2022. 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. Therefore, it is difficult to know how complete and accurate ORMIS is at this time.

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 2021/22 identified;

1. 1 of the submitted records for congenital surgery may have errors in it
2. 1 of the submitted records for congenital surgery may have a duplicate entry
3. 6 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.

1 Log book from Glenfield was offered for review, cath 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.

The cath lab logbook from the Royal Infirmary is a much larger design similar to an operating room register and was much easier to navigate. However the standard of hand writing at times was still very difficult to decipher reliably.
It appears that the GRL Audit Team still do not have access to the Radiation Information System (RiS) to cross validate radiation dose and times or activity in general which may be helpful.

Following review of the catheter laboratory log books

1. 6 submitted catheter records may have an error in them
2. 15 catheter procedures were identified in the log books that may be suitable for submission to NCHDA
3. 38 submitted records were not validated in the cath lab log books that were seen

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, preoperative weight, procedure and complication coding will also be validated.

Four 30 day post procedural deaths were submitted in the data from GRL for the year 2021/22. The case notes were made available to the reviewers.

4 sets of data were gathered, mainly from the ePR.

The following observations were made;

1. 4 records appear to have discrepancies in the Comorbid Codes submitted
2. All dates of death were confirmed as correct.
3. 1 record appears to have a discrepancy in the description of severity of a complication
4. 1 record appears to have a discrepancies in the discharge date
5. 2 records appear to have discrepancies in the field for attribution of death and discharge destination

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

In 1 deceased patient it was challenging to clearly follow the timeline of events for patient who had two surgical episodes on consecutive days.

Casenote Audit

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		11	7
2	NHS Number	18	20		11	7
3	Surname	20	20		11	7
4	First Name	20	20		11	7
5	Sex	20	20		11	7
6	DOB	20	20		11	7
7	Ethnicity	19	20		11	7
8	Patient Status	20	20		11	7
9	Postcode	20	20		11	
10	Pre Procedure Diagnosis	20	21	1 incomplete, 1 missing an element	11	10
11	Previous Procedures	29	33	4 absent	24/25	6/7
12	Patients Weight at Operation	32	32		11	10
13	Height	32	32		11	10
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	21	21		11	10
16	Pre Proc NYHA	6	7	1 incorrect	5	½
17	Pre Proc Smoker	5	7	2 incorrect	3/5	2
18	Pre Proc Diabetes	7	7		5	2
19	Hx Pulmonary Dis	5	7	2 incorrect	3/5	2
20	Pre Proc IHD	6	7	1 incorrect	1/5	2
21	Comorbidity Present	19	21	2 incorrect	9/11	10
22	Comorbid Conditions	12	18	6 absent	3/6	8/10
23	Pre Proc Systemic Ventricular EF	19	21	2 incorrect	11	8/10
24	Pre Proc Sub Pul Ventricular EF	19	21	2 incorrect	11	8/10
25	Pre-proc valve/septal defect/ vessel size	4	5	1 incorrect	4/5	-

26	Consultant	21	21		11	10

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date + Time Start	21	21		11	10
28	Proc Urgency	21	21		11	10
29	Unplanned Proc	-	-		-	-
30	Single Operator	1	1		1	-
31	Operator 1	21	21		11	10
32	Operator 1 Grade	21	21		11	10
33	Operator 2	19	20	1 incorrect	9/10	10
34	Operator 2 Grade	19	20	1 incorrect	9/10	10
35	Procedure Type	21	21		-	10
36	Sternotomy Sequence	10	10		-	10
37	Operation Performed	21	21	1 incomplete element	11	10
38	Sizing balloon used for septal defect	2	2		2	-
39	No of stents or coils	1	1		1	-
40	Device Manufacturer	8	9	1 absent	¾	5
41	Device Model	8	9	1 absent	¾	5
42	Device Ser No	8	9	1 absent	3/4	5
43	Device Size	7	8	1 absent	3	4/5
44	Total Bypass Time	8	10	2 absent	-	8/10
45	XClamp Time,	9	10	1 absent	-	9/10
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	10	11	1 absent	10/11	-
48	Cath Fluro Time,	10	11	1 absent	10/11	-

49	Cath Fluro Dose,	6	11	5 absent	10/11	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	8	10		-	8/10
51	Post Procedure Seizures	21	21		11	10
52	Post Proc Complications	2	2		1	1
53	Date of Discharge	20	21	1 incorrect	10/11	10
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	21	21		11	10
57	Discharge Destination	21	21		11	10

Data Quality Indicator Assessment:

The Overall Trust DQI = 96% Cardiology DQI = 95.5% Surgery DQI = 96.25%

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.

DOMAIN	DOMAIN Score	
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	**Overall 1.0**	
	Card .99	**Surg** .81
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 .93**	
	Card .93	**Surg** .925
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** .94	
	Card .91	**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 .98	**Surg** .96

Data Quality Indicator Assessment

The Trust DQI = 96%

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	2019 18/19	2020 19/20	2021 20/21	2022 21/22
Demographics	1.0	1.0	.98	1.0
Pre Procedure	.89	.90	.96	.93
Procedure	.93	.98	.95	.94
Outcome	.97	.91	.89	.96

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 partly using digital electronic hospital records and partly paper.

The overall DQI score is 96% and increase of 1.5% which is excellent.

The Reviewers are pleased to report that there continues to be clinician involvement with validating the data locally prior to submission. This is an important part of the data review that should be done locally as it demonstrates exactly how data will be analysed by NCHDA and will highlight any coding errors quickly and easily. It is therefore essential that adequate support is provided for those that undertake this task.

It is also observed that GRL still does not appear to meet the recommendation 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 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 may use NCHDA data to underpin parts of the quarterly paediatric cardiac and ACHD/Transition and CQUINs dashboards for current and future activity.

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 did not 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 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), or discussed at an MDT and whether or not the death was related to the procedure

Recommendations (2022)

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
    c) Running PRAiS analysis software and completion of any monthly and quarterly Commissioner Dashboards 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 is recommended, quarterly is mandatory)
    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) Devising a mechanism to identify and capture dates of death in patients who have been discharged following a procedure

i) Timely reverse validation at GRL data against an acknowledged 'gold standard' record of activity and procedures performed.
j) Updating these SOPs at timely intervals

4. 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.
5. 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.
6. To have clear guidance on exactly where sticky labels from implanted devices should be located in the patient's hospital case note.
7. To consider the layout and content of discharge/death summaries in relation to diagnosis and the chronology of procedures performed.
8. Encourage trainees at ST6 or above to volunteer to be the assisting clinician at external NCHDA validations to other Level 1 service providers.