The National Congenital Heart Disease Audit Database

Data Quality Audit for CONGENITAL HEART DISEASE

Apr 2020 - Mar 2021

Glenfield Hospital
University of Leicester NHS Trust

7 September 2021

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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 328 (surgery 179, catheter 142, 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 2020/21. This represents a drop in procedural activity of 47% during the ongoing SARS-COV-2 pandemic as the congenital cardiac surgical service at this centre ceased for five months to enable priority to be given to patients requiring respiratory and ECMO support that this hospital also has particular expertise in.

The data for this visit was harvested in August 2021 and 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- 20, 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. This site visit was hosted at Glenfield Hospital.

Actions on Recommendations or Changes since Last Validation Visit in 2020.

GRL report the following actions:

- The congenital service was paused for 5 months (March - July 2020) during the first period of national lockdown to enable specific management of patients with SARS-COV-2 as described above.
- In August 2021, the congenital paediatric service relocated to Leicester Royal Infirmary while the adult congenital service remains at the Glenfield site. The Outcomes and Data Analyst and the DM remain located at the Glenfield site.
- Since the last visit GRL report that there are now more regular communications with surgical and catheter operators concerned to highlight and clean any gaps in the data. GRL also confirm that regular internal data checks and validations are performed.

- Prior the NCHDA submissions for 2020/21 GRL confirmed that there was a pre- submission data clean and where necessary data was referred back to the relevant surgeon or interventionist to approve.
- Post submission to Qreg5 (the NCHDA database) GRL confirmed that is their practice to extract the data back and reverse validate it.
- The GRL Data 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.
- In late 2020, a valued data clerk, retired and a member of the local clinical audit team has moved the role concerning NCHDA data collection and audit within the East Midlands Congenital Heart data team.
- GRL have confirmed that they would like to move to using ORMIS for surgical logging of activity and use it for validation and plans are being discussed on how to innovate this.

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 2021.

Data Quality Indicator (DQI) Score

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

This is very slight drop (0.25%) but nevertheless a very good score.

The hospital notes of 20 patients who had undergone 27 procedures (17 operations and 10 therapeutic catheter procedures. This amounted to 974 data points with 47 discrepancies that were identified.

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
2012	11/12	94.75%	91.75%
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%

The fields that appear where most discrepancies are occurring are:

Single Operator	10 discrepancies
Previous Procedures	8 discrepancies
Duration of Post Op intubation	5 discrepancies
Device Information	3 discrepancies
Discharge Destination	3 discrepancies

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 328 (surgery 179, catheter 142, 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 2020/21.

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 1 record was 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 information for patients. The original bound case note was also present in case of further queries or questions arising. As previously reported some of the older case notes were quite thick and bulky, untidy and not always in chronological order. Therefore making 1 copy of the relevant page for each piece of data for each episode being reviewed can expedite the time it takes to review a case note. The reviewers would like to again thank the congenital data manager for taking the time to book mark almost all of the relevant documents. The Reviewers are grateful to the consultant cardiologists and surgeons who made time to assist with navigating the packs of hospital notes during the review.

1. As previously reported, it was sometimes difficult to find documentary evidence of pre procedure echocardiograms from other hospitals in the patient notes.
2. Hand written 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. It was sometimes challenging to find explicit documentation of NYHA status for ACHD patients also.
5. Explicit documentation of the date and time of extubation was sometimes very difficult to find in the hospital notes of surgical patients.

6. 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.
7. As previously noted, the discharge sheet from ITU to the ward was useful.
8. Documentation of exact discharge destination was sometimes challenging to find
9. The Attribution of Death field should be completed whenever this information is available after a patient has died.

Review of the theatre log books

Following the intervention of the Medical Director in 2020, the log books from theatres 1, 2, 3 and 4 were offered for validation. At this validation visit in 2021, the theatre staff again declined to release the log books.

Over 10 weeks notice had been given of this site validation This is not acceptable. It is essential to enable the NCHDA validation team access to these activity logs in the room where they are based for the day to ascertain that all relevant cases have been submitted to this UK national registry as patient hospital case notes and other sensitive data.

Log books from theatres 1 and 8 were offered for validation. These are bespoke ledgers with wide ruled lines to comfortably place a patient's identity label and columns for various pieces of information pertaining to the procedure performed. As previously reported, the standard of data entry in these books was variable, at times extremely difficult to decipher and at others very simple and clear entries.

The electronic theatre management system ORMIS is also used at this centre and is being scrutinised simultaneously for accuracy along side the log books.

Review of the operating theatre log books for 2020/21 identified;

1. 4 of the submitted records for congenital surgery may have errors in them
2. 4 surgery procedures was identified that may have been missed from the data submission or may be in a log book that was reported as being 'absent', its location unknown.

Catheter Lab Log Book Review

Log books from cath labs Lab B and D was prioritised as this is used predominantly for congenital cardiac procedures. The log books are of a bespoke design are used in all labs. 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.

As reported elsewhere, it appears that the Audit Team 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. 7 submitted catheter records may have an error in them
2. 6 catheter procedures were identified in the log books that may be suitable for submission to NCHDA
3. 11 submitted records were not validated in the cath lab log books that were seen
4. It was also noted that there appears to be a paucity of ACHD EP and pacing procedures performed by adult cardiologists

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.

Five 30 day post procedural deaths were submitted in the data from GRL for the year 2020/21. The case notes were made available to the reviewers.

2 sets of hospital notes had been prepared and were made available and 3 sets of data were gathered from the ePR.

The following observations were made;

1. 2 records appear to have discrepancies in the Comorbid Codes submitted
2. 1 record may have incomplete complications recorded
3. All dates of death were confirmed as correct.
4. 4 records appear to have discrepancies in the discharge destination
5. 3 records appear to have discrepancies in the field for attribution of death

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 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		9	11
2	NHS Number	18	20	2 absent	7/9	11
3	Surname	20	20		9	11
4	First Name	20	20		9	11
5	Sex	20	20		9	11
6	DOB	20	20		9	11
7	Ethnicity	19	20	1 absent	9	10/11
8	Patient Status	20	20		9	11
9	Postcode	20	20		9	11
10	Pre Procedure Diagnosis	25	27	2 incorrect	8/10	17
11	Previous Procedures	61	69	8 absent	36/42	25/27
12	Patients Weight at Operation	26	27	1 incorrect	10	26/27
13	Height	25	25		10	15
14	Ante Natal Diagnosis	4	5	1incorrect	2	2/3
15	Pre Proc Seizures	27	27		10	17
16	Pre Proc NYHA	4	4		2	2
17	Pre Proc Smoker	3	4	1 incorrect	1/2	2
18	Pre Proc Diabetes	4	4		2	2
19	Hx Pulmonary Dis	4	4		2	2
20	Pre Proc IHD	4	4		2	2
21	Comorbidity Present	27	27		10	17
22	Comorbid Conditions	41	42	1 absent	19	22/23
23	Pre Proc Systemic Ventricular EF	27	27		10	17
24	Pre Proc Sub Pul Ventricular EF	26	26		10	16
25	Pre-proc valve/septal defect/ vessel size	1	1		1	-
26	Consultant	27	27		10	17

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date + Time Start	27	27		10	17
28	Proc Urgency	27	27		10	17
29	Unplanned Proc	1	1		-	1
30	Single Operator	0	10	10 incorrectly categorised	0/3	0/7
31	Operator 1	27	27		10	17
32	Operator 1 Grade	27	27		10	17
33	Operator 2	27	27		10	17
34	Operator 2 Grade	27	27		10	17
35	Procedure Type	27	27		10	17
36	Sternotomy Sequence	15	15		-	15
37	Operation Performed	26	27	1 incorrect	10	14/15
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	4	4		4	-
40	Device Manufacturer	7	7		5	2
41	Device Model	7	7		5	2
42	Device Ser No	6	7	1 absent	4/5	2
43	Device Size	4	5	1 absent	4/5	1
44	Total Bypass Time	12	13	1 absent	-	12/13
45	XClamp Time,	12	12		-	12
46	Total Arrest	-	-		-	-
47	Cath Proc Time,	8	10		8/10	-
48	Cath Fluro Time,	10	10		8/10	-
49	Cath Fluro Dose,	10	10		8/10	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	12	17	4 incorrect, 1 unable to validate	-	12/17
51	Post Procedure Seizures	27	27		10	17
52	Post Proc Complications	1	1		-	1
53	Date of Discharge	26	27	1 absent	8/10	17
54	Date of Death	1	1		-	1
55	Attribution of Death	0	1	1 absent	-	0/1
56	Status at Discharge	26	27	1 absent	9/10	17
57	Discharge Destination	24	27	2 incorrect, 1 absent	7/10	15/17

Data Quality Indicator Assessment:

The Overall Trust DQI = 94.5% Cardiology DQI = 92% Surgery DQI = 96%

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 .98**	
	Card .97	**Surg** .99
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 .96**	
	Card .94	**Surg** .97
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** .95	
	Card .92	**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** .89	
	Card .85	**Surg** .91

Data Quality Indicator Assessment

The Trust DQI = 94.5%

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	2018 17/18	2019 18/19	2020 19/20	2021 20/21
Demographics	.99	1.0	1.0	.98
Pre Procedure	.95	.89	.90	.96
Procedure	.94	.93	.98	.95
Outcome	1.0	.97	.91	.89

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 remains at 94.5% and is still a good score. This year (20/21) has been another challenging period for all NCHDA service providers due to the pandemic and many data managers who would be hospital based having to pivot to home based working.

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 clear that the use of the HeartSuite cardiac information system, with its inbuilt checks and balances is proving helpful with logging data completeness and accuracy.

It is also observed that GRL does not yet 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.

It is of concern that the current operating theatre management are unable to release the log books in time for site visit given 10 weeks notice of the date and the Reviewers had to move to a room within the theatre suite in order to complete this essential part of the audit. No other congenital hospital has ever had any difficulty with meeting this request. NCHDA site validation visits have been established for 20 years.

Also, as previously reported, reviewing of the hard backed cath lab log books 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.

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 coroner (when required), were discussed at an MDT and whether or not the death was related to the procedure

Recommendations (as in 2013-20)

1. 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 monthly 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) where possible and
    f) Devising a mechanism to identify capture dates of death in patients who have been discharged following a procedure
    g) Timely reverse validation at GRL against an acknowledged 'gold standard' record of activity and procedures performed.
    h) Updating these SOPs at timely intervals

2. To encourage clearer data entry in cath lab and operating log books to assist with identity of procedures in patients with congenital heart disease.
3. 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.
4. To have clear guidance on exactly where sticky labels from implanted devices should be located in the patients hospital case note.
5. To ensure that all relevant activity log books are available to the Reviewers in the room where they are based for the day.
6. To consider the layout and content of discharge/death summaries in relation to diagnosis and the chronology of procedures performed.
7. Encourage trainees at ST6 or above to volunteer to be the assisting clinician at external NCHDA validations to other Level 1 service providers.