The National Congenital Heart Disease Audit Database

Data Quality Audit for CONGENITAL HEART DISEASE

Apr 2018 - Mar 2019

Glenfield Hospital
University of Leicester NHS Trust

25 June 2019

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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 615 (surgery 365, catheter 299, others 22, 8 deaths within 30 days of a procedure) procedures have been undertaken in patients with congenital heart disease during the data collection year of 2018/19. The data for this visit was harvested in June 2019.

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 that post was vacant from March – August 2018 and very little data were submitted in that time.

As reported in 2011-18, there is also a specifically designated data manager (DM) supervising the data collection for congenital cardiology who has access to the NCHDA Database.

The Data and Outcomes Analyst and the Data Manager do not have a clinical background. There is real-time data input using the HeartSuite cardiac information system.

Actions on Recommendations Taken since Last Validation Visit in 2018.

GRL report the following actions:

1. HeartSuite is now the primary data collection system for the NCHDA audit, replacing the previous PATS / Intellect system.
2. The new Data and Outcomes Analyst came into post during August 2018 however, there was a considerable delay arranging the correct access to the national database due to slow response times by NICOR helpdesk.
3. Processes for reporting on activity; quality controlling the information being entered and subsequently passed to NCHDA continue to be reviewed.
4. HeartSuite continues to be used to improve the MDT process and subsequent reporting of activity. This has the effect of ensuring more complete and accurate diagnoses are coded for patients who subsequently have a surgical or catheter procedure.
5. There is a weekly liaison with surgical and catheter teams to review the accuracy and completeness of coding. These systems have been adapted for use with the HeartSuite system and GRL are continually reviewing these.

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 2019.

Patient Consent for External Validation of Case Notes

Since May 2018, the General Data Protection Regulation 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.

The DQI for the Trust is calculated to be (with previous years in parentheses) it is(with previous years in parentheses); **94.75%** (97, 97.25, 97, 94) with domain scores Demographics 1.0 (.99, 1.0, 1.0 1.0), Pre Procedure .89 (.95, .93, .93, .84,) Procedure .93 (.94, .97, .99 .96) and Outcome .97 (1.0, .99, .99, .96).

We reviewed the hospital notes of 20 patients who had undergone 25 procedures (14 operations and 11 therapeutic catheter procedures. This amounted to 946 data points with 61 discrepancies 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. 20 patients had 10 operations and 11 interventional catheter procedures in the sample. The DQI scores are;

Year of Visit	Data Year Validated	Surgery DQI	Catheter DQI
2009	07/08	90%	94%
2010	08/09	93.75%	96.%
2011(i)	09/10	95.75%	91.25%
2011(ii)	10/11	97.75%	89.5%
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%	94.5%
2019	18/19	94.25%	96%

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 615 procedures (surgery 365, catheter 299, others 22, 8 deaths within 30 days of a procedure) have been undertaken in patients with congenital heart disease during the data collection year of 2018/19.

20 sets of case notes were selected for review. The NCHDA Data Auditor and an external ST7 in Congenital Cardiology undertook the site audit 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. On the day 5 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 a mixture of traditional folio type card bound paper files and a few printed packs of information for those patients whose records were almost entirely electronic. As previously reported some of the older case notes were quite thick and bulky, untidy and not always in chronological order. It was generally a little challenging and time consuming to validate the data but 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 cardiologist who made time to assist with navigating the hospital notes during the review.

1. As previously reported, the anaesthetic records were easy to identify due to their colour (blue edged) as well as the perfusion sheet (red edged).
2. It was sometimes difficult to find documentary evidence of pre procedure echocardiograms from other hospitals in the patient notes.
3. Hand written details of catheter procedures were seen although some were missing the xray data. Clinical audit staff do not appear to have access to the RIS register for radiology to cross validate these items.
4. It was challenging to find any xray data in the case notes of ACHD who had undergone electrophysiological procedures.
5. 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 file.

6. As previously reported in 2018, the single operator field is for procedures where there is one (1) operator only and this appears to be have been incorrectly interpreted in some submitted data.
7. As previously noted, the discharge sheet from ITU to the ward was useful.
8. 1 patient in the case note review was found to have a surgical procedure absent from the NCHDA data submission.

Review of the theatre log books

Log books from theatres 1, 2, 3 and 4 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 validation team were made aware that the log book for operating theatre 3 from April – August 2018 is missing, its location unknown.

The electronic theatre management system ORMIS is also used at this centre but it is not known how complete or accurate this is.

Review of the operating theatre log books for 2018/19 identified;

1. 14 of the submitted records for congenital surgery in the Bypass/Non Bypass category appear to have errors in them
2. 9 submitted records were not validated in the log books
3. 9 surgery procedures was identified that may have been missed from the data submission or may be in the log book that was missing
4. 3 submitted surgical records may not be for congenital heart disease and if so should be deleted from NCHDA

Catheter Lab Log Book Review

Sue to time constraints it was not possible to validate all of the log books from all 6 cath labs (A,B, C, D, E and F). Lab b 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.

The months of April to May 2018 were reviewed in the time remaining.

Following review of the catheter laboratory log books for lab B for April – May 2018/19

1. 7 submitted catheter records appear to have errors in them or absent diagnosis
2. 2 records appear to be duplicated
3. 6 procedures were identified in the cath lab log books which may have been missed from the data submission for April to May 2018.
4. The catheter data submitted for June 2018 to March 2019 procedures were not validated in the log books due to time constraints.

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.

Eight 30 day post procedural deaths were submitted in the data from GRL for the year 2018/19. All case notes were made available to the reviewers.

1. 1 record appears to have no diagnosis coding
2. 7 records appear to have discrepancies in the Comorbid Codes submitted
3. All dates of death were confirmed as correct.
4. 1 record appears to have discrepancies in the mode of discharge and discharge status

There does not appear to be a standard death summary report including full medical history in the case notes that were seen for this part of the review at GRL.

Casenote Audit

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		9	11
2	NHS Number	20	20		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	20	20		9	11
8	Patient Status	20	20		9	11
9	Postcode	20	20		9	11
10	Pre Procedure Diagnosis	21	25	3 absent, 1 incomplete	8/11	12/14
11	Previous Procedures	58	67	9 absent	21/26	37/41
12	Patients Weight at Operation	23	25	1 absent, 1 incorrect	11	12/14
13	Height	22	23	1 absent	10	12/13
14	Ante Natal Diagnosis	3	3		-	3
15	Pre Proc Seizures	25	25		11	14
16	Pre Proc NYHA	2	3	1 incorrect	1	½
17	Pre Proc Smoker	0	3	2 incorrect, 1 unable to validate	0/1	0/2
18	Pre Proc Diabetes	2	3	1 unable to validate	1	½
19	Hx Pulmonary Dis	2	3	1 unable to validate	1	½
20	Pre Proc IHD	2	3	1 unable to validate	1	1/2
21	Comorbidity Present	24	25	1 incorrect	10/11	14
22	Comorbid Conditions	20	23	3 absent	5/7	15/16
23	Pre Proc Systemic Ventricular EF	22	25	2 incorrect, 1 unable to validate	11	11/14
24	Pre Proc Sub Pul Ventricular EF	22	25	2 incorrect, 1 unable to validate	11	11/14
25	Pre-proc valve/septal defect/ vessel size	2	2		2	-
26	Consultant	25	25		11	14

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date + Time Start	25	25		11	14
28	Proc Urgency	25	25		11	14
29	Unplanned Proc	25	25		11	14
30	Single Operator	14	25	11 incorrect	10/11	4/14
31	Operator 1	24	25	1 incorrect	11	13/14
32	Operator 1 Grade	24	25	1 incorrect	11	13/14
33	Operator 2	21	24	2 absent, 1 incorrect	8/10	13/14
34	Operator 2 Grade	21	24	3 absent	8/10	13/14
35	Procedure Type	25	25		11	14
36	Sternotomy Sequence	12	13	1 incorrect	-	13
37	Operation Performed	25	25		11	14
38	Sizing balloon used for septal defect	1	1		1	-
39	No of stents or coils	1	3	2 absent	1/3	-
40	Device Manufacturer	14	14		7	7
41	Device Model	14	14		7	7
42	Device Ser No	13	14	1 incorrect	7	6/7
43	Device Size	13	13		7	6
44	Total Bypass Time	12	12		-	12
45	XClamp Time,	11	11		-	11
46	Total Arrest	0	0		-	-
47	Cath Proc Time,	9	11	2 unable to validate	9/11	-
48	Cath Fluro Time,	11	11		11	-
49	Cath Fluro Dose,	11	11		11	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	12	14	2 incorrect	-	12/14
51	Post Procedure Seizures	25	25		11	14
52	Post Proc Complications	1	2	1 absent	-	½
53	Date of Discharge	25	25		11	14
54	Date of Death	1	1		-	1
55	Attribution of Death	1	1		-	1
56	Status at Discharge	25	25		11	14
57	Discharge Destination	25	25		11	14

Data Quality Indicator Assessment:

The Overall Trust DQI = 94.75% Cardiology DQI = 96% Surgery DQI = 94.25%

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 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 .89**	
	Card .90	**Surg** .88
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** .93	
	Card .937	**Surg** .92
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 1.0	**Surg** .96

Data Quality Indicator Assessment

The Trust DQI = 94.75%

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	2016 15/16	2017 16/17	2018 17/18	2019 18/19
Demographics	1.0	1.0	.99	1.0
Pre Procedure	.93	.93	.95	.89
Procedure	.99	.97	.94	.93
Outcome	.96	.99	1.0	.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.

The overall DQI score has decreased a little but this is still a good score as this has been another challenging period for all NCHDA service providers. As in the 2013-18 validation visits, most of the data errors or omissions are concentrated in the Pre Procedure Domain.

As reported in 2018 the new Data and Outcomes Analyst does not have a clinical background and needs support with 'sense' checking of data prior to submission as well as when the monthly PRAiS analysis is run. 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.

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 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 discussed above, more frequent local scrutiny of the data will assist with identifying errors or discrepancies in these data.

Recommendations (as in 2013-17)

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) Ensuring that all patients/parents and guardians are given full information of how their data are securely recorded, stored, where this information is shared and who with. And that opting out is explained to patients/carers
    b) 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.
    c) 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
    d) Running PRAiS analysis software monthly and completion of any monthly and quarterly Commissioner Dashboards as required.
    e) Leading the local review (how frequently and in which forum for both disciplines) and encouraging clinician ownership of the data.
    f) Making timely submissions (monthly is recommended, quarterly is mandatory) where possible and
    g) Devising a mechanism to identify capture dates of death in patients who have been discharged following a procedure
    h) Timely reverse validation at GRL against an acknowledged 'gold standard' record of activity and procedures performed.
    i) 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 consider the layout and content of discharge/death summaries in relation to diagnosis and the chronology of procedures performed.

6. Encourage trainees at ST6 or above to volunteer to be the assisting clinician at external NCHDA validations to other Level 1 service providers.