



The National Congenital Heart Disease Audit

Data Quality Audit for CONGENITAL HEART DISEASE PROCEDURES For April to March 2020-2021

The Leeds Teaching Hospitals NHS Trust

4 July 2021

performed by Lin Denne and Mr M Nassar,

Summary

The data return to the NCHDA made by the Congenital Cardiac Department of the Leeds Teaching Hospitals NHS Trust (LGI) and harvested prior to this visit, indicated that some 1215 procedures (409 operations, 649 catheters, 155 others, 17 deaths) had been undertaken during the data collection year of 2020/2021. This represents an approximate 11% drop on 19/20 activity most likely impacted by the SARS-COV-2 pandemic creating different ways of working.

This validation visit has been fully funded by the Leeds Teaching Hospitals NHS Trust. This site visit was undertaken by Mr M Nassar, Consultant Congenital Cardiac Surgeon from Newcastle on site and the NCHDA Clinical Audit Nurse remotely via MS Teams.

As previously reported, since June 2013 a dedicated 1.0WTE congenital Database Manager (DBM) has been in post. There is a nominated clinician with responsibility for this data and one other who also has access to the NCHDA database. There is a further 1.0WTE Data Analyst role that supports this registry.

It is also noted the LGI do not appear to meet the NHSE Surgical Standards (2016) recommended standard for staffing of the data managers roles. The standards recommend 1.0WTE data manager and 1.0WTE assistant data manager for paediatric congenital services and 1.0WTE data manager for ACHD services.

As previously reported, the Congenital Cardiac Department at LGI uses a bespoke database (OSCAR 4D) and this is available at secretaries' and clinicians' desks within the Department and in the operating theatre where most congenital surgery is performed. There is an interface between OSCAR and the Trust PAS.

Actions undertaken or changes to processes since the 2019 validation visit.

LGI Report the following actions:

- There is now a data quality (DQ) tool in full use and is used regularly and before each submission to ensure as many errors as possible are identified and corrected. This has helped to ensure smoother submission to the NCHDA database.
- LGI congenital clinicians have agreed to start an internal audit twice a year where a trainee doctor will review the coding alongside the congenital Database Manager.
- This will enable and support learning for both the database manager and the supporting analyst.

Consent for External Validation of Notes.

Under the General Data Protection Regulation (GDPR) of May 2018, NCHDA now no longer require individual patient informed consent.



LGI are moving towards an electronic patient record (ePR) and methods of capturing this piece of information electronically is currently being discussed and reviewed.

Data Quality Indicator Score

The overall DQI for the Trust (with the previous years in parentheses) is calculated to be **99%** (99, 98.25, 99) with domain scores Demographics 1.0 (1.0, 1.0, 1.0) Pre Procedure .97 (.98, .96, .98,) Procedure 1.0 (.98, 97, .96,) and Outcome .98 (1.0, 1.0, .99).

There were just 6 data discrepancies in 837 variables checked.

This DQI was based on the records of 20 patients who underwent 23 procedures (14 catheters and 9 operations).

Individual 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.

	Data Year Validated	Surgery DQI	Catheter DQI
2013	11/12	92%	95.75%
2013(ii)	12/13	94.25%	96%
2014	13/14	95.25%	99%
2015	14/15	97.25%	96%
2016	15/16	98.5%	97.25%
2017	16/17	99%	97.5%
2018	17/18	98.25%	99.5%
2019	18/19	97.75%	98.5%
2020	19/20	99.25%	99.5%
2021	20/21	98.75%	99.25%



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The NCHDA pre visit Questionnaire confirms 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.

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Introduction

Prior to this validation visit, the NCHDA Data Return from the Paediatric Cardiac Department of the Leeds Teaching Hospitals NHS Trust indicated that 1215 procedures (409 operations, 649 catheters, 155 others, 17 deaths) had been undertaken during the data collection year of 2020/2021.

As previously reported and as stated above, the Department has used its own database to collect data (the Orion Software for Cardiology – OSCAR 4D) for over 20 years. This database is connected to the hospital PAS. Access to this database is available throughout the department including the catheter labs and operating theatre where most congenital cardiac surgical procedures are undertaken. The consultants and their secretaries have access at their desks and input data. From the data that are input, a discharge summary is generated at time of discharge.

There is a detailed process (Standard Operating Protocol) for auditing data internally and reverse validating it once submitted to the NCHDA.

The Validation Team are extremely grateful to the NCHDA audit team, the Service Manager and the clinical team who organised and itemised many of the details in the case notes that the Review Team would need look at. These items and copies from the ePR had been meticulously prepared. This centre is increasingly but not totally 'paper-lite' and there are still some paper hospital notes.

A sample of 20 records with a reserve list of a further 10 was supplied prior to this validation.

On the day 20 records were made available from the sample and no records were used from the reserve list.

The accuracy of the NCHDA data return was checked against each set of notes. This was then recorded to enable the Data Quality Indicator (DQI) to be scored.

Review of notes

As described above, each set of notes was meticulously prepared with sticky post-it type labels identifying many of the pages the Validation Team needed to review.

1. It was noted on a few occasions that the primary diagnosis did not always reconcile with the procedure performed.
2. The pink operation note, when seen was very helpful in establishing exactly what procedure had been performed.
3. In some case notes there appeared to be a discrepancy between the electronic record and the paper records as to the exact date a patient was discharged from hospital.
4. It was noted that some of the discharge summaries and/or clinic letters seen did list a patients previous procedures and this is very helpful.

5. Specific documentation of NYHA was not always easy to find in the patient notes of ACHD patients

Review of the Log Books

Cardiac Operating Theatres

The bespoke bound operating theatre ledgers for 4 theatres were made available. 1 theatre is hybrid and can be used as a cath lab. Each entry of the log books seen is hand written. As previously noted it is not always clear whether or not a procedure is for congenital heart disease. It was again noted that some entries were blank where the name of the procedure performed should be given.

1. 1 submitted record may have an error
2. 1 submitted record may not be congenital heart disease
3. 0 procedures were identified in the log books that may have been missed.

Whilst it was unclear if there was planned to move to electronic theatre log books the Reviewers are aware that GALAXY a theatre management system is used at the this centre. This system is essentially for booking operations but there are facilities within the application to record OPCS codes and cross map these to the NCHDA Dataset as another congenital centre has successfully achieved this.

Cardiac Catheter Lab Log Book Review

There are 6 cath labs at this Centre. The Validation Team were informed that most congenital procedures are performed in Lab 1, 2 and Lab 5. The individual log books for each of these cath labs were reviewed. These books are A4 lined and ruled books. As previously reported, it was quite difficult to identify whether or not a procedure is for congenital heart disease. The findings are;

1. 1 procedures was identified in the cath lab log books that may have been missed from the data submission.
2. 3 of the submitted records may have errors in them
3. 5 records were not validated in the NCHDA data submission. This may be because they were cases such as balloon septostomy that might have been performed in another place or that the record was not clearly identifiable as being for congenital heart disease.

It is reported that there are no plans yet to use electronic log books in the cath lab.

Validation of Deceased Patients Diagnostic and Procedure Coding

Commencing with the validation of the 2013/14 data in 2014, 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. Under the GDPR regulation of May 2018, the requirement for consent to validate this hospital data is no longer needed.

17 patients who had had procedures during the 2020/21 data collection year were noted to have died. 6 patients had died within 30 days of a therapeutic catheter intervention or surgical operation. These case notes were prioritised for the review. The procedural and outcome documentation was made available to the Reviewers.

- Dates of death in all patients were confirmed
- 2 records appear to have the incorrect data option for the field for Attribution of Death in the data submitted to the NCHDA

The DBM at LGI confirmed that life status reports on congenital patients are requested and run on a regular basis to enable accurate tracking of LGI NCHDA patients.

Case note Audit 2020/21 Data.

20 patients underwent 22 procedures (11 cath, 11 operations)

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		14	6
2	NHS Number	20	20		14	6
3	Surname	20	20		14	6
4	First Name	20	20		14	6
5	Sex	20	20		14	6
6	DOB	20	20		14	6
7	Ethnicity	20	20		14	6
8	Patient Status	20	20		14	6
9	Postcode	20	20		14	6
10	Pre Procedure Diagnosis	23	23		14	9
11	Previous Procedures	45	47	2 incorrect	34/36	11
12	Patients Weight at Operation	2	2		14	9
13	Height	23	23		13	9
14	Ante Natal Diagnosis	2	2		2	-
15	Pre Proc Seizures	5	5		4	9
16	Pre Proc NYHA	5	5		4	1
17	Pre Proc Smoker	5	5		4	1
18	Pre Proc Diabetes	5	5		4	1
19	Hx Pulmonary Dis	5	5		4	1
20	Pre Proc IHD	5	5		4	1
21	Comorbidity Present	23	23		14	9
22	Comorbid Conditions	42	45	3 incorrect	33	9/12
23	Pre Proc Systemic Ventricular EF	21	23	2 unable to validate	12/14	9
24	Pre Proc Sub Pul Ventricular EF	17	19	2 unable to validate	10/12	7
25	Pre-proc valve/septal defect/ vessel size	6	6		6	-
26	Consultant	23	23		14	9



	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	23	23		14	9
28	Proc Urgency	23	23		14	9
29	Unplanned Proc	-	-		-	-
30	Single Operator	4	4		4	-
31	Operator 1	23	23		14	9
32	Operator 1 Grade	23	23		14	9
33	Operator 2	19	19		10	9
34	Operator 2 Grade	19	19		10	9
35	Procedure Type	23	23		14	9
36	Sternotomy Sequence	9	9		-	9
37	Operation Performed	23	23		14	9
38	Sizing balloon used for septal defect	2	2		2	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	10	10		10	-
41	Device Model	10	10		10	-
42	Device Ser No	13	13		13	-
43	Device Size	11	11		11	-
44	Total Bypass Time	8	8		-	8
45	XClamp Time,	6	6		-	6
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	16	16		16	-
48	Cath Fluro Time,	15	15		15	-
49	Cath Fluro Dose,	15	15		15	-



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	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	8	8		-	7/8
51	Post Procedure Seizures	23	23		14	9
52	Post Proc Complications	2	2		2	-
53	Date of Discharge	23	23		14	9
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	23	23		14	9
57	Discharge Destination	23	23		14	9



Data Quality Indicator Assessment:

The Overall Trust DQI = 99% Cardiology DQI = 99.25% Surgery DQI = 98.75%

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	
<u>Demographics</u>	Overall 1.0	
Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	Card 1.0	Surg 1.0
<u>Pre Procedure</u>	Overall .97	
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	Card .97	Surg .97
<u>Procedure</u>	Overall 1.0	
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 1.0	Surg 1.0
<u>Outcome</u>	Overall .99	
Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. Post Procedure Complications.	Card 1.0	Surg .98



The Trust DQI = 99% (99, 98.25, 99)

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.

DOMAIN Score	2018	2019	2020	2021
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.98	96	.98	.97
Procedure	.96	97	.98	1.0
Outcome	.99	10	1.0	.99

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Conclusions

On the whole the submitted NCHDA data were accurate, well documented, good quality and were appropriately recorded in the Theatre and Congenital Cath lab log books that were seen.

The DQI is 99% for the second consecutive year which is an excellent achievement. In total there were just 6 discrepancies in 835 data variables. This demonstrates a strong commitment to good quality verified clinical data collection. There appears to be a very robust culture of clinical audit embedded within the Trust and the DBM has invested many hours overtime to achieve data of a high quality. However, the Reviewers are concerned that there appears to be no forward plan to increase the number of DBMs to meet the NHSE 2016 recommendations.

Again, the Validation Team are particularly grateful to the Congenital Data Team for meticulously detailing the documents needed at this review. The Reviewers would also like to thank the Clinical Lead for Congenital Cardiology, the surgeons and other clinicians for making time to spend with the audit team throughout the day.

As previously reported, handwritten entries into log books will always be challenging to decipher and the Reviewers are aware that the Galaxy Theatre Information System is available in this Centre. This has been successfully used to replace the handwritten log books in at least one other large congenital cardiac centre as it is possible to record procedures using the OPCS codes that can be cross mapped to the Association of European Paediatric and Congenital Heart Disease (AEPC) coding that the NCHDA uses.

Deaths

As detailed elsewhere, there were a very small number of discrepancies seen.

Recommendations

1. As previously, it is recommended that the local Standard Operating Protocols (SOPs) already devised for the congenital data collection, continue to be reviewed at regular intervals to ensure their fitness for the purpose they are required to address ie:
 - a. Ensuring that all patients with congenital heart disease, in line with the GDPR, and 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 opting out explained to patients/carers as well.
 - b. Input of congenital patients NCHDA required dataset items and at which point of service delivery
 - c. Encouraging responsible clinician input of the procedure data for each operation, diagnostic or catheter intervention at the point of the service delivery
 - d. 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
 - e. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data Managers at least monthly.
 - f. Running the PRAiS2 (Paediatric Risk Analysis in Surgery) analysis tool monthly. This will help inform the quarterly NHSE Dashboard reports.
 - g. Ensuring that dates of death are reported for any LGI patient who has previously had a record submitted to the NCHDA
 - h. Making timely submissions (monthly is recommended) and
 - i. Reviewing/Updating the SOP at timely intervals
2. It is recommended that consideration be given to recruiting a 1.0WTE data manager to support the ACHD practice at this centre as this expands.
3. As previously recommended, consideration could be given to developing the GALAXY information system used in the operating theatres to include the accurate recording of the exactly which congenital operation was performed on each patient.
4. To keep a log of all procedures such as septostomies that occur outside the cardiac catheter laboratory.
5. In conjunction with the person responsible for training, it is suggested that regular Quality Assurance and Governance training should be available to the DBM. Visits to other centres who are involved in NCHDA data collection and submission are encouraged at least once, preferably twice annually.
6. Regular training updates should be provided for all staff who may be involved with data collection and input



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