The National Congenital Heart Disease Audit

Data Quality Audit for CONGENITAL HEART DISEASE PROCEDURES For April to March 2021-2022

The Leeds Teaching Hospitals NHS Trust

31 August 2022

performed by Lin Denne and Dr D Cullington,

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, indicating that there were 948 procedures (304 operations, 636 catheters, 8 others, 10 deaths within 30 days of procedure) has been undertaken between April 2021 and March 2022.

This validation visit has been fully funded by the Leeds Teaching Hospitals NHS Trust. This site visit was undertaken by Dr D Cullington, Consultant Congenital Cardiologist from Liverpool 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. At the time of this visit the Data Analyst role was vacant and shortly afterwards an appointment was made into this post.

As has been previously reported, 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 noted, 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 Patient Administration System (PAS).

Actions undertaken or changes to processes since the 2021 validation visit:

None reported.

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 being considered.

Data Quality Indicator Score

The overall DQI for the Trust (with the previous years in parentheses) is calculated to be **99.25%** (.99, 99, 98.25,) with domain scores Demographics 1.0 (1.0, 1.0, 1.0) Pre Procedure .98 (.97, .98, .96,) Procedure 1.0 (1.0, .98, 97,) and Outcome .99 (.98, 1.0, 1.0).

There were just six data discrepancies in 971 variables checked.

This DQI was based on the records of 20 patients who underwent 24 procedures (13 catheters and 11 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 five procedures in either group are required for the differential DQI calculation.

	Data Year Validated	Surgery DQI	Catheter DQI
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%
2022	21/22	99.75%	99%

The NCHDA pre visit Questionnaire used for the 2021 site validation 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.

No changes were reported at the 2022 site visit.

Introduction

Prior to this validation visit, the NCHDA Data Return from the Paediatric Cardiac Department of the Leeds Teaching Hospitals NHS Trust indicated that 948 procedures (304 operations, 636 catheters, 8 others, 10 deaths within 30 days of procedure) were undertaken during the data collection year April 2021 – March 2022.

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.

The Congenital Cardiac Department at LGI is largely 'paper lite' with almost all information recorded electronically in an electronic patient record (ePR).

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 local congenital DBM, the Service Manager and the clinical team who organised, collated and itemised many of the details in the case notes that the Review Team might would need look at. These items and copies from the ePR had been meticulously prepared.

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 hospital notes. This was then recorded to enable the Data Quality Indicator (DQI) to be scored.

Review of notes

These were individually prepared digital files from various electronic patient information systems. There was one file for each patient. There were a small number paper notes available also for patients whose data was completely digitised:

1. It was noted on a few occasions that the primary diagnosis did not always reconcile with the procedure performed.
2. The operation notes, when seen was very helpful in establishing exactly what procedure had been performed.
3. It was again noted that some of the discharge summaries and/or clinic letters seen did list a patient's previous procedures and this is very helpful.
4. As previously reported, specific documentation of NYHA was not always easy to find in the patient notes of ACHD patients
5. The data fields 2.08 and 2.09 (for ventricular function) were sometimes a little challenging to validate. It should be noted that functional status is required for each of the ventricles in this dataset. These fields are not currently included in the MDT/JCC proforma.

Review of the Log Books

Cardiac Operating Theatres

The bespoke bound operating theatre ledgers for 4 theatres and 1 hybrid room that can be either an operating room or a cath lab, were made available. 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 was not validated in the log books
3. 7 procedures were identified in the log books that may have been missed.

It was reported that there are no plans as yet to use electronic log books in the operating rooms but the reviewers are aware that the Galaxy electronic patient record system is used at LGI and this can accommodate OPCS coding of procedures.

Cardiac Catheter Lab Log Book Review

There are six cath labs at this Centre. The Validation Team were informed that most congenital procedures are performed in the Hybrid Theatre and Lab 5. The individual log books for each of these cath labs/rooms 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. 16 procedures were identified in the cath lab log books that may have been missed from the data submission.
2. One of the submitted records may not be for congenital heart disease and if not, should be deleted.
3. 41 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 the procedure occurred in another cath lab that was not available for the reviewers, or that the record was not clearly identifiable as being for congenital heart disease.

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 wises 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.

10 patients who had had procedures during the 2021/22 data collection year were noted to have died within 30 days of a therapeutic procedure. The procedural and outcome documentation was made available to the reviewers for these 10 patients.

- Dates of death in all patients were confirmed
- The attribution of death may be incorrect in one record.

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

Case note Audit 2021/22 Data

20 patients underwent 24 procedures (13 caths, 11 operations)

	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	23	24		12/13	11
11	Previous Procedures	70	71	1 component absent	47/48	23
12	Patients Weight at Operation	24	24		13	11
13	Height	23	23		12	11
14	Ante Natal Diagnosis	1	2	1 incorrect	0/1	1
15	Pre Proc Seizures	24	24		13	11
16	Pre Proc NYHA	11	12	1 incorrect	6/7	5
17	Pre Proc Smoker	12	12		7	5
18	Pre Proc Diabetes	12	12		7	5
19	Hx Pulmonary Dis	12	12		7	5
20	Pre Proc IHD	12	12		7	5
21	Comorbidity Present	24	24		13	11

22	Comorbid Conditions	45	46	1 absent	23	20/21
23	Pre Proc Systemic Ventricular EF	24	24		13	11
24	Pre Proc Sub Pul Ventricular EF	20	20		11	9
25	Pre-proc valve/septal defect/ vessel size	3	3		3	-
26	Consultant	24	24		13	11

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	24	24		13	11
28	Proc Urgency	24	24		13	11
29	Unplanned Proc	3	3		1	2
30	Single Operator	3	3		3	-
31	Operator 1	24	24		13	11
32	Operator 1 Grade	24	24		13	11
33	Operator 2	21	21		10	11
34	Operator 2 Grade	21	21		10	11
35	Procedure Type	24	24		13	11
36	Sternotomy Sequence	11	11		-	11
37	Operation Performed	24	24		13	1111

38	Sizing balloon used for septal defect	2	2		2	-
39	No of stents or coils	1	1		1	-
40	Device Manufacturer	14	14		6	8
41	Device Model	14	14		6	8
42	Device Ser No	14	14		6	8
43	Device Size	9	9		4	5
44	Total Bypass Time	10	10		-	10
45	XClamp Time,	9	9		-	9
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	13	13		13	-
48	Cath Fluro Time,	12	12		12	-
49	Cath Fluro Dose,	12	12		12	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	10	10		-	10
51	Post Procedure Seizures	24	24		13	11
52	Post Proc Complications	2	2		-	2
53	Date of Discharge	24	24		13	11
54	Date of Death	1	1		1	-
55	Attribution of Death	0	1	1 incorrect	0/1	-
56	Status at Discharge	24	24		13	11
57	Discharge Destination	24	24		13	11

Data Quality Indicator Assessment:

The Overall Trust DQI = 99.25% Cardiology DQI = 99% Surgery DQI = 99.75%

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	
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 .98**	
	Card .98	**Surg** .99
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 1.0**	
	Card 1.0	**Surg** 1.0

Outcome	**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** .98	**Surg** 1.0

The Trust DQI = 99.25% (.99, 99, 98.25**)**

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	**2019**	**2020**	**2021**	**2022**
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	96	.98	.97	.98
Procedure	97	.98	1.0	1.0
Outcome	10	1.0	.99	.99

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 99.25% which is an excellent achievement. In total there were just six discrepancies in 971 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. 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 DBM 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, all data were found to be correct with only one discrepancy identified.

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:
    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 and ensuring any discussions with a local Medical Examiner or Coroner are clearly documented.
    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 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. To clearly document function of each ventricle in the echocardiogram reports.
6. Clearer documentation of NYHA status would be helpful in the hospital records of ACHD patients.
7. 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.
8. Regular training updates should be provided for all staff who may be involved with data collection and input.