The National Congenital Heart Disease Audit

Data Quality Audit for
CONGENITAL HEART DISEASE PROCEDURES
For April to March 2024-2025

The Leeds Teaching Hospitals NHS Trust

22 May 2025

performed by Lin Denne and Dr T Prendiville

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 1193 procedures (376 operations, 807 catheters, 10 others, 14 deaths within 30 days of a specific procedure) had been undertaken between April 2024 and March 2025.

Following review of the catheter laboratory and operating room activity log books seen on the day of the validation visit, 5 additional procedures were identified and where found suitable, were subsequently submitted to the Registry.

This validation visit has been fully funded by the Leeds Teaching Hospitals NHS Trust and was undertaken by Dr T Prendiville, Consultant in Congenital Cardiology from Dublin and the NCHDA Clinical Audit Nurse on site.

As previously reported, since June 2013 a dedicated 1.0WTE congenital Database Manager (DBM) has been in post. The current post holder has been in post since March 2024 and was previously involved with the NCHDA as a data analyst. There is a nominated clinician with responsibility for this data and one other who also has access to the NCHDA database. The 1.0WTE Data Analyst role that supports this registry was recruited in July 2024 and is in now in post. A further 1.0WTE data analyst has also been recruited during April 2025 but is not yet in post. This is a very positive development.

As noted since 2016, until this visit, LGI had not met 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.

The Congenital Cardiac Department at LGI uses a bespoke database (OSCAR 4D) to record all NCHDA relevant procedural activity 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 no complete interface between OSCAR and the Trusts' electronic patient record system (eHR – PPM+).

The PPM+ eHR (Patient Pathway Manager) is LGI's electronic health record. It is web based and internally designed and built by the NHS Trust. PPM+ is designed to consolidate data from disparate systems, both within the NHS Trust and also across local organisational boundaries. This allows clinicians to view a single patient record which includes city-wide information from a number of different organisations.

Actions undertaken or changes to processes since the 2024 validation visit:

- A new data analyst started in July 2024 and is receiving ongoing training.

- A further junior data analyst was recruited and started on 21 April 2025 and is about to begin training.

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.

At this visit in 2025, LGI are almost entirely paper free for patients' hospital notes.

Data Quality Indicator Score

The overall DQI for the Trust (with the previous years in parentheses) is calculated to be **98.75%.** Very well done in maintaining an excellent score.

The overall provisional DQI for the Trust (with the previous years in parentheses) is calculated to be **98.75%** (99.25, 99.6, 99.25) with domain scores Demographics 1.0 (1.0, 1.0, 1.0) Pre Procedure .98 (.997, .98, .97,) Procedure .99 (1.0, 1.0, 1.0) and Outcome .98 (.99, .99, .98)

There were 11 data discrepancies in 926 variables.

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 5 procedures in either group are required for the differential DQI calculation.

	Data Year Validated	Surgery DQI	Catheter DQI
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%
2023	22/23	99.5%	99.8%

2024	23/24	99.5%	99%
2025	24/25	98.25%	99.25%

The NCHDA pre visit Questionnaire indicates that there are still 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.

Digital Maturity 2025

As documented above, LGI does not yet have a fully digital electronic health record system that requires a single user ID and sign in process to access all health records to view the NCHDA applicable data. It is discreet in that it is supposed to only give each user the individual access to the various data that their role requires but in the case of the Data Managers this does not appear to have been fully recognised. The DBM user may need to log in to different domains within the electronic health record with different passwords to access some parts of the information system.

On average, each DBM user may need to log in and out to between 4 and 7 different parts of the electronic health records system at LGI to record, view or edit NCHDA data depending on level of access.

There are still some paper based systems such as operating room and cathlab activity log books used. Perfusion records are also paper based and scanned to attach to the electronic health record. It is reported that there are no plans to digitise the current data that are collected on paper.

Introduction

Prior to this validation visit, the NCHDA Data Return from the Congenital Cardiac Department of the Leeds Teaching Hospitals NHS Trust indicated that 1193 procedures (376 operations, 807 catheters, 10 others, 14 deaths within 30 days of a specific procedure) had been undertaken between April 2024 and March 2025.

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 does not interface with the hospital ePR. 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 almost completely ‘paper lite’ with almost all information recorded electronically in the electronic patient record (ePR) PPM+ and OSCAR.

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 Data Analyst and the clinical team who organised, collated and itemised many of the details in the parts of the ePR that the Review Team might would need look at. The day was well organised with digital files of images of documents for each patient containing copies of the ePR required to be viewed and the full live electronic patient records system PPM+ (ePR) available if the reviewers had further questions. The interchange between the 2 sets of data was much quicker this year than in previous years.

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

As noted above, these were individually prepared digital files from various electronic patient information systems. There was one file for each patient. The transition between pages and documents was very quick. This considerably speeded up the time needed to validate the patient’s hospital notes.

1. The operation note, when seen was very helpful in establishing exactly what procedure had been performed.
2. Specific detail of the exact date and time of extubation was often difficult to find. More often extubation was documented as happening 'overnight' or 'during the evening' in shift change/handover reports.
3. The DBM does not have access to PICANET to cross reference ventilation duration.
4. It was again noted that not all of the discharge summaries and/or clinic letters seen had a concise and chronological list of a patients previous procedures.
5. Discrepancies between the date of discharge recorded on the eHR and the discharge summary were noted.
6. 1 operation procedure code was found to be not quite correct and therefore had been excluded from the Specific Procedure analysis algorithm

Review of the Log Books

Cardiac Operating Theatres

The congenital cardiac operating theatres are numbered 3+10. There is 1 room that is hybrid and can be used as a cath lab or an operating room. The NCHDA Reviewers had been informed at previous validation visits that the activity log is a system known as Galaxy Data Web supplied by iSoft.

As previously documented, GALAXY is an operating room scheduling information system that also contains OPCS Classification of Interventions and Procedures (OPCS-4) and is a Fundamental Information Standard. OPCS is used to support operational and strategic planning, resource utilisation, (ie HES and HRG), performance management, reimbursement, research and epidemiology. It is used by NHS suppliers to build/update software to support NHS business functions and interoperability.

When OPCS4.6 is fully optimised within GALAXY it will provide accurate and timely identification of many of the congenital cardiac surgical cases that occur not only in the regular room but in other operating theatres, out of hours or those that may be performed by non-congenital cardiac surgeons. GALAXY can also be used in the cardiac catheter laboratories in the same way.

All users would require a little training in the importance of accurately coding and orientation to the OPCS coding used.

A spreadsheet of information from GALAXY was presented as a record of procedural activity.

1. As noted in 2023-4, the descriptions of procedures performed were sometimes absent, incomplete or very vague as the OPCS coding structure has not been used.
2. 0 procedures were identified in the log books that may have been missed.

Cardiac Catheter Lab Log Book Review

There are 6 cath labs at this Centre. The Validation Team were informed that almost all congenital catheter procedures were performed in the Hybrid Room for the year 2024/5. The individual paper bound log book in two volumes, for this room was provided along with the books from all the other cath labs. The information is largely handwritten around a patients hospital identity label.

It was noted that the log book for Lab 1 from February 2025, the log book for Lab 4 from September 2024 and the log book for Lab 5 from June 2024 were not made available.

These logs are A4 lined and ruled books. As previously reported, it was quite difficult sometimes to identify whether or not a procedure is for congenital heart disease. The handwriting was often difficult to decipher. The findings are;

1. 5 procedures were identified in the cath lab log book that may have been missed from the data submission.
2. 11 records were not validated in the NCHDA data submission.
3. 3 records may have discrepancies in them
4. 3 records may be for acquired heart disease and if so should be discarded.

As noted in 2023, ACHD EP and device procedures undertaken by non congenital cardiologists will not be captured by the CRM database as there is no appropriate coding or the data fields to do so. These procedures data should be captured in NCHDA with the correct congenital diagnostic and procedure coding and the responsible clinicians encouraged to be involved.

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 required.

14 patients who had had procedures during the 2024/25 data collection year were noted to have died within 30 days of a therapeutic specific procedure. The procedural and outcome documentation was made available to the Reviewers for these 14 patients.

- 1 record was discarded as was not for congenital heart disease
- Dates of death in all patients were confirmed
- There were 4 data queries noted.
- As noted in 2023/4, it was observed that finding documentation of discussion with the Medical Examiner/Coroner was not always seen.
- Death certificates were seen

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

Case note Audit 2024/25 Data.

20 patients underwent 26 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	24	24		13	11
11	Previous Procedures	54	60	3 absent, 3 incorrect	41/44	14/16
12	Patients Weight at Operation	24	24		13	11
13	Height	23	23		13	10
14	Ante Natal Diagnosis	4	4		-	4
15	Pre Proc Seizures	24	24		13	11
16	Pre Proc NYHA	6	6		4	2
17	Pre Proc Smoker	6	6		4	½
18	Pre Proc Diabetes	6	6		4	2
19	Hx Pulmonary Dis	6	6		4	2
20	Pre Proc IHD	6	6		4	2
21	Comorbidity Present	24	24		13	11
22	Comorbid Conditions	38	38		29	9
23	Pre Proc Systemic Ventricular EF	24	24		13	11
24	Pre Proc Sub Pul Ventricular EF	16	16		7	9
25	Pre-proc valve/septal defect/ vessel size	2	2		2	-
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	2	2		2	1
30	Single Operator	10	10		10	-
31	Operator 1	24	24		13	11
32	Operator 1 Grade	24	24		13	11
33	Operator 2	14	14		3	11
34	Operator 2 Grade	14	14		3	11
35	Procedure Type	24	24		13	11
36	Sternotomy Sequence	10	10		-	10
37	Operation Performed	23	24	1 incorrect	13	11
38	Sizing balloon used for septal defect	3	3		3	-
39	No of stents or coils	5	5		5	-
40	Device Manufacturer	14	14		12	2
41	Device Model	14	14		12	2
42	Device Ser No	14	14		12	2
43	Device Size	11	11		10	1
44	Total Bypass Time	10	10		-	10
45	XClamp Time,	9	9		-	9
46	Total Arrest	2	2		-	2
47	Cath Proc Time,	11	13	1 incorrect, 1 unable to validate	11/13	-
48	Cath Fluro Time,	11	11		11	-
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	9	11	X 2 incorrect	-	9/11
51	Post Procedure Seizures	24	24		13	11
52	Post Proc Complications	13	13		-	13
53	Date of Discharge	24	24		13	11
54	Date of Death	1	1		-	1
55	Attribution of Death	-	-		-	-
56	Status at Discharge	24	24		13	11
57	Discharge Destination	24	24		13	11

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.75%   Cardiology DQI = 98.25%   Surgery DQI = 98.25%

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**		
	Overall	**Card**	**Surg**
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	1.0	1.0	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	.98	.98	.975
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,	.99	.99	.99
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. Post Procedure Complications.	.98	1.0	.97

The Trust DQI = 98.75% (99.6, 99.5, .99, 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	2022	2023	2024	2025
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.98	.997	.995	.98
Procedure	1.0	1.0	.997	.99
Outcome	.99	.99	.98	98

Conclusions

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

As noted in previous years, it was not always clear in GALAXY (used in the OR) whether a procedure had taken place or had been postponed to another date. As reported above some entries for the name of the procedure were unfilled (blank) or very vague. This system does not appear to be optimised in regard to OPCS coding and it is not clear how this information is used or integrated into HES or HRG standards. If OPCS coding in GALAXY is used in the OR can be cross mapped to the Association of European Paediatric and Congenital Heart Disease (AEPC) coding that the NCHDA uses. GALAXY can also be utilised in the catheter laboratory.

The DQI from the Sample case notes seen is 98.75% which is an excellent achievement. In total there were just 11 discrepancies in 926 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 pleased to note that the increase in the number of DBMs to meet the NHSE 2016 recommendations. This will greatly support the other regular requirements of NHSE and Trust requirements at the local LGI level such as Specialist Services Commissioning Quality Dashboards.

Again, the Validation Team are particularly grateful to the Congenital DBM and Data Analyst 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.

It was noted that there are a number of EP and devices procedures in patients with ACHD being undertaken by cardiologists for adult acquired heart disease. As previously reported, the NCHDA DBM, while being able to capture these data locally, can have difficulties identifying them in a timely manner and the NCHDA field data are not necessarily noted in the ePR admission clerking as the clinicians may not be aware of this requirement. If ACHD procedures undertaken by cardiologists for acquired disease are coded correctly in ICD 10 and OPCS in GALAXY it will be somewhat easier to identify them in a timely manner to the NCHDA DBM.

Deaths

As detailed elsewhere, all data were found to be correct. 1 record was identified as non congenital heart disease.

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 all 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. Clear documentation of the exact date and time of ET tube extubation
   e. Ensuring the correct date of discharge is used on typed summaries
   f. 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
   g. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data Managers at least monthly.
   h. Running the PRAiS4.2 (Partial Risk Analysis in Surgery) analysis tool monthly. This will help inform the quarterly NHSE Dashboard reports.
   i. 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.
   j. Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.
   k. Including a copy of the MCCD in the patients notes would be helpful.
   l. Making timely submissions 2 weeks after a procedure where possible and within 2 weeks of each calendar month end at a minimum.
   m. Reviewing/Updating the SOP at timely intervals

2. A clear chronological listing of a patients previous procedures is always very helpful if included in standard discharge summaries and clinic letters.
3. As previously recommended, optimisation of GALAXY information system used in the operating theatres to include the accurate recording of exactly which congenital operation was performed together with OPCS 4.6 codes on each patient. OPCS codes can be cross mapped to NCHDA codes. If this is to be used a ‘gold standard’ record of activity.

4. To keep a log of all procedures such as septostomies that occur outside the cardiac catheter laboratory.
5. Clearer documentation of NYHA status together with the other ACHD risk fields would be helpful in the hospital records of all ACHD patients. Some NCHDA units have adapted their MDT discussion documents to include these fields.
6. In relation to adult cardiologists undertaking EP procedures in ACHD patients and capturing and identifying these data in the log books and electronic data systems used, it may be worth considering a regular liaison process with the CNS's for EP. Or with PPM+, enforcing a mandatory field question such as 'does this patient have congenital heart disease?'
7. In conjunction with the person responsible for training, it is suggested that regular Quality Assurance and Governance training should be available to the DBMs. Visits to other centres who are involved in NCHDA data collection and submission are encouraged at least once, preferably twice annually.
8. Consider a regular (2-3 monthly) reporting mechanism with the local IT Department to capture all NCHDA deaths in a timely manner.
9. Regular training updates should be provided for all staff who may be involved with data collection and input