Procedures for
CONGENITAL HEART DISEASE
For April – March 2023-2024

Data Quality Audit

Liverpool Heart and Chest Hospital NHS Foundation Trust

23 May 2024

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Summary and Overview

Prior to this Validation Visit, the data return from The Liverpool Heart and Chest Hospital (LHCH), indicated that 540 therapeutic cardiac procedures were performed in patients with congenital heart disease during the data collection year of 2023-24. These are broken down as follows: Surgery 79, Catheters 458, Others 3, Deaths within 30 days of a Specific Procedure 0 (zero)

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Following partial review of the catheter laboratory and operating room activity log books on the day of the validation visit, 51 additional procedures were identified that may be suitable for submission and subsequently were submitted to the Registry where they were found to be appropriate.

Since 2018 LHCH has been commissioned to provide services for ACHD patients at Level 1. A full in patient surgery and catheter interventions service commenced in December 2018. This is the fifth visit to LHCH since being commissioned as a Level 1 provider for Adult Congenital Heart Disease. At the time of this validation there were 7 ACHD consultant cardiologists at LHCH.   4 visiting consultant congenital cardiac surgeons from Alder Hey Children's Hospital operate at LHCH and 3 visiting cardiac interventionists also visit from Alder Hey, supported by a structural interventional cardiologist based at LHCH whom is also trained in CHD intervention. There is one ACHD cardiologist whom is an electrophysiologist and device implanter supported by one electrophysiologist with an interest in ACHD EP.

For reasons of logistics and capacity, ACHD patients who require diagnostic cardiac catheterisation undergo these procedures by a consultant congenital cardiologist at the Royal Liverpool University Hospital which is adjacent LHCH.

This external validation visit is fully funded by Liverpool Heart and Chest Hospital NHS Foundation Trust.

Overview at LHCH

There is an extremely strong, well established and embedded clinical audit culture at this Centre. As previously reported, data entry is at the point of treatment by clinician and throughout the centre using the Trust ePR. The demographic data for congenital procedures are identified from the Trust Patient Administration System and a separate data collection is then undertaken to ensure all relevant congenital NCHDA data are captured. As previously documented, there is a clinician lead. Prior to the NCHDA Data Manager being able to validate the data and check the completeness, the clinical coders complete the ICD10 and OPCS coding.

Both the cardiology and surgery parts of the congenital data collection are managed by a 1.0WTE Data Manager who has been in post for just 3 months at the time of this validation. This role has been held by 3 different people over 2 years. None of these individuals have had or have any clinical background.

Pacing and EP data are submitted to CRM. However, any therapeutic pacing or EP procedures in patients with congenital heart disease are required to be submitted to NCHDA.

Actions Taken Since Last Validation Visit in 2023:

- No actions reported
- New NCHDA Data Manager in post from February 2024

Consent for External Validation of Notes.

Since May 2018, the General Data Protection Regulation required that patients are made aware of how their data are 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.

Data Quality Indicator (DQI)

Since 2009 at each validation visit, the DQI is being calculated separately for surgery and catheter procedures. The minimum threshold for this to be calculated is 5 records in either group.

The overall DQI for the Trust is calculated to be (with previous years in parentheses) is **90.5%** (98.5, 99.25, 98.75). The individual Domain scores are as follows; Demographics 1.0 (.99, 1.0, 1.0 1.0), Pre Procedure .83 (.98, .99, .96, .95) Procedure .86 (.99, .99, .99,), Outcome .93 (.98, .99, 1.0,).

There has been a drop of 8% since the last validation site visit. There were 113 discrepancies in 1005 variables. This DQI is based on the records of 20 patients who underwent 23 procedures (18 interventional catheters and 5 operations).

The fields with the most discrepancies are:

Previous Procedures	22 discrepancies
ACHD Risk Fields for smoking, diabetes, NYHA etc	14 discrepancies
Implanted Device Details	15 discrepancies

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.

Year of Visit	Data Reviewed	Surgery	Catheters
2012	2010-11	Insufficient Sample	94.75%
2013	2011-12	Insufficient Sample	91%
2014	2012-13	Insufficient Sample	97.5%
2019	2018-19	92.75%	94%
2020	2019-20	95%	94.25%

2021	2020-21	Insufficient Sample	98.75%
2022	2021-22	99.25%	99%
2023	2022-23	99.25%	99%
2024	2023-24	92.75%	92.25%

The body of this report is drawn from answers given on the Congenital NICOR pre visit Questionnaire and from discussions on the day of the visit.

Introduction

Prior to the validation visit, the Congenital NICOR return from Liverpool Heart and Chest Hospital indicated that 540 therapeutic cardiac procedures were performed in patients with congenital heart disease during the data collection year of 2023-24. As previously stated, these are broken down as follows: Surgery 79, Catheters 458, Others 3, Deaths within 30 days of a Specific Procedure: 0.

20 sets of case notes were selected for review. A Reserve list of 10 cases was supplied also and on the day. 1 set of case notes from this list were required at LHCH to replace a patient who did not have congenital heart disease..

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

The Congenital NCHDA Data Auditor and one external Specialty Trainee (ST6) in Congenital Cardiology undertook the site audit at LHCH.

As described elsewhere most data are input at the point of treatment to a digital ePR. This is used throughout the ACHD patient journey. The information describing diagnoses and procedure performed are than translated into coded data ICD10 and OPCS 4.10 and entered into hospital information systems by clinical coders. It is only then that NCHDA Data Manager is able to access the data and add the very specific descriptions of congenital cardiac diagnoses, comorbidities and procedures used in this specialty from the AEPC Short Code List v6.1. Once complete, the data are then submitted manually via the NICOR NCHDA data portal.

In 2012 LHCH moved from using paper based hospital notes to using electronically held data collection systems.

Review of notes at LHCH

The DBM had prepared an electronic file of documents for each patient in the Sample and Reserve groups. The Validation Team reviewed each of 20 patients' files of electronic patient records.

There were also 20 folders of copies of these documents from the ePR, 1 for each patient being reviewed. These were filled with many sheets of the printed ePR.

It was again noted that in the Sample cohort there were a number of ACHD patients who appeared to have had procedures as children.   It would be helpful if the hospital where these early procedures were undertaken could be noted in the patients records to assist with completing this field accurately in the NCHDA registry. Recording previous procedures also informs risk attached to current and future procedures. Data managers at other congenital centres are always happy to liaise and assist with this.

1. There appeared that there was little noting of whether or not the younger ACHD patients had been antenatally diagnosed.
2. Patients who are isomeric should always have the specific code for left or right isomerism in their diagnoses as well as any other congenital cardiac anomalies.
3. There was also some challenges with finding regular standard documentation or template of NYHA status in the patients hospital records along with the 4 other specific ACHD risk fields
4. There did not appear to be a method of imaging/storing copies of echocardiograms and their reports from referring hospitals when a patient was transferred to LHCH. The images should stored on PACS or ISCV.
5. The OR handover sheet to ITU was often incomplete or completely unfilled

6. Some of the cath lab check list documents seen were also completely unfilled
7. It was most difficult to ascertain the exact sheath in/sheath out time for catheter procedure patients. This is translated to the procedure time that is required for NCHDA.
8. As previously reported, for patients who had undergone surgical procedures, it was not easy to find the data for date and time of extubation that is logged on the ITU documentation.

Review of the Log Books at LHCH

Due to the unusually large amount of time that was required to validate the case note data (5.5 hours) the review of the log books was allocated as 1 hour to OR and 1 hour to cath lab in order to provide at least 30 – 60 minutes feedback and discussion with the colleagues at LHCH.

Therefore the months of April – December 2023 were reviewed in the operating room logs.

There are 5 cardiac operating rooms and a hybrid room at LHCH. Log books of activity are now an all electronic (digital) dashboard. As previously noted from 2022 and 2023 it is not always clear whether or not a procedure is for congenital heart disease. The diagnoses descriptions were sometimes vague and imprecise and it is not clear if any coding structure is consistently used by the individuals completing this record. The label ‘congenital insufficiency’ is not useful for accurate NCHDA coding. As previously stated in 2022-2023, It would be helpful to incorporate and train the users to use the NCHDA codes and descriptions as these would increase specificity and accuracy and to have a mandatory field to indicate if a patient has congenital heart disease or not would be extremely helpful.

1. 14 surgical records from April – December 2023 may have errors in them
2. 12 records were not validated
3. 28 records were identified from the log book that may have been missed from the congenital submission.

Many of the 28 records identified appear to be younger patients having aortic valve surgery but it is not clear whether or not they have congenital heart disease. The ACHD aortic valve algorithm is part of the NCHDA Data Manual (page 7) and assists with identifying these patients correctly. Inherited heart disease is not part of the NCHDA registry unless a patient has previously been followed up by a paediatric cardiology service and undergone a therapeutic procedure.

Cardiac Catheter Lab Log Book Review

Due to the time pressure described above and the lack of specific diagnosis or procedure descriptions, the months of April to June 2023 were reviewed in the 1 hour available.

There are 6 cath labs (+ the hybrid room) at this Centre. As previously reported, the activity of the cathlabs are now collected digitally in CareCube. This is essentially a scheduling tool rather than a log of actual activity.

The diagnoses are not always precisely described and sometimes it was extremely difficult to discern if a patient had congenital or acquired heart disease. There is no mandatory field to identify whether or not a procedure is for congenital heart disease. A diagnosis of ASD appeared to be frequently used but the procedure performed did not seem to reconcile with this diagnosis.

A diagnosis of coarctation was seen in several patients entries but the procedure performed did not reconcile with that diagnosis. Several dates of death were seen to be noted in this log within 30 days of a catheter procedure but it was not clear if the patient had been diagnosed with congenital heart disease or not.
Diagnostic catheters are mostly done at the adjacent Royal Liverpool University Trust. It was not possible to check these for case ascertainment as no log this activity was available. The findings are;

1. 4 submitted catheter records for April – June 2023 appear to have errors in them
2. 23 procedures were identified in the cath lab log books between April 2023 – June 2023 which may have been missed from the data submission. These are predominately for EP and pacing procedures
3. 389 records were not validated, many of these were for diagnostic catheters, due to lack of time

Pre Visit Questionnaire Assessment

The NCHDA pre visit Questionnaire was not completed and returned prior to this visit and the Validation Team are unable to confirm that if there are any changes to the previously good processes and procedures in place in regard to:

Maintain 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.

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 GDPR regulation there is now no requirement for consent to validate these hospital data.

No deaths in patients who had had procedures submitted for the during the 2023/24 data collection year were noted to have died within 30 days of a Specific Procedure.

Case note Audit 2023/24 Data.

20 patients underwent 22 procedures (16 caths, 6 operations)

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		15	5
2	NHS Number	20	20		15	5
3	Surname	20	20		15	5
4	First Name	20	20		15	5
5	Sex	20	20		15	5
6	DOB	19	20		15	5
7	Ethnicity	20	20		15	5
8	Patient Status	20	20		15	5
9	Postcode	20	20		15	5
10	Pre Procedure Diagnosis	22	23	1 absent, 3 missing key elements	18	5
11	Previous Procedures	60	82	22 absent	49/65	11/17
12	Patients Weight at Operation	18	23	2 incorrect, 3 absent	13/18	5
13	Height	18	23	2 incorrect, 3 absent	13/18	5
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	23	23		18	5
16	Pre Proc NYHA	20	23	2 incorrect, 1 absent	15/18	4/5
17	Pre Proc Smoker	20	23	3 absent	15/18	5

18	Pre Proc Diabetes	20	23	3 absent	15/18	5
19	Hx Pulmonary Dis	18	23	3 absent, 2 incorrect	15/18	5
20	Pre Proc IHD	20	23	3 absent	15/18	5
21	Comorbidity Present	20	23	2 incorrect, 1 absent	16/18	4/5
22	Comorbid Conditions	29	37	1 incorrect, 7 absent	28/35	1/2
23	Pre Proc Systemic Ventricular EF	19	23	2 unable to validate, 1 incorrect	14/18	5
24	Pre Proc Sub Pul Ventricular EF	14	20	1 unable to validate, 4 incorrect	9/14	4/5
25	Pre-proc valve/septal defect/ vessel size	-	-		-	-
26	Consultant	23	23		18	5

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	23	23		18	5
28	Proc Urgency	23	23		18	5
29	Unplanned Proc	-	-			-
30	Single Operator	2	2		2	-

31	Operator 1	23	23		18	5
32	Operator 1 Grade	23	23		18	5
33	Operator 2	19	21	2 incorrect	16	2/5
34	Operator 2 Grade	19	21	2 incorrect	16	2/5
35	Procedure Type	22	23	1 incorrect	19/18	5
36	Sternotomy Sequence	5	5		-	5
37	Operation Performed	23	23	3 elements absent	18	5
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	-	-		-	-
40	Device Manufacturer	10	15	5 absent	7/10	3/5
41	Device Model	10	15	5 absent	7/10	3/5
42	Device Ser No	10	15	5 absent	7/10	3/5
43	Device Size	13	13		8	5
44	Total Bypass Time	5	5		-	5
45	XClamp Time,	5	5		-	5
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	12	18	4 incorrect, 2 absent	12/18	-
48	Cath Fluro Time,	13	17	4 absent	13/17	-
49	Cath Fluro Dose,	15	17	2 absent	15/17	-

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	4	5	1 incorrect	-	4/5
51	Post Procedure Seizures	23	23		18	5
52	Post Proc Complications	0	6	6 absent	0/6	-
53	Date of Discharge	23	23		18	5
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	23	23		18	5
57	Discharge Destination	23	23		18	5

Data Quality Indicator Assessment:

The Overall Trust DQI = 90.5% Cardiology DQI = 92.5% Surgery DQI = 92.75%

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.

DOMAIN	DOMAIN Score	
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	**Overall 1.0**	
	Card	**Surg**
	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	**Overall .83**	
	Card	**Surg**
	.815	.88
Procedure	**Overall** .86	

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** .935	**Surg** .866
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. Post Procedure Complications.	**Overall** .93	
	Card .94	**Surg** .96

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	**2024**	**2023**	**2022**	**2021**	**2020**
Demographics,	1.0	.99	1.0	1.0	1.0
Pre Procedure,	.83	.98	.98	.96	.95
Procedure	.86	.99	.98	.99	.96
Outcome	.93	.98	1.0	1.0	.88

Conclusions

On the whole the submitted NCHDA data were accurate, well documented, good quality but did not appear to be always appropriately recorded in the electronic Theatre and Congenital Cath lab log books that were seen. This is the sixth NCHDA visit to LHCH since being commissioned to provide Level 1 adult congenital cardiac services in July 2018. The Data Manager (DM) at this visit has been in this role within ACHD for just over 3 months. As noted above, there have been 3 post holders in this role with two years.

In total there were 113 discrepancies in 1005 variables. This has been a drop of 8% in the Data Quality Indicator Score for verified clinical information. In previous years there appeared to be a robust culture of clinical audit embedded within the Trust and it was reported to the Reviewers at this visit that there have been some key changes in staff that collect and process audit and activity information data. The Data Quality Indicator (DQI) Score in previous year has been:

Year	Score %
2024	90.5
2023	98.5
2022	99.25
2021	98.75

The Validation Team are particularly grateful to the new Data Manager for detailing some of the documents needed at this review and grouping them together in individual files for the Reviewers to see and for printing them. The Reviewers would also like to thank the clinicians and Clinical Nurse Specialist who visited them during the day. We would also like to thank the Chief Operating Officer and Medical Director who made time to attend the validation feedback session in person and discuss the findings.

As previously reported it was sometimes very difficult to find explicit documentation of the specific ACHD risk fields. These data are required for every NCHDA entry. It was also challenging at times to find detailed and documentation regarding the exact previous procedures that had been undertaken at other hospitals within a congenital paediatric service elsewhere.

It was also noted that the NCHDA Data Manager does not have automatic access to enable contemporaneous NCHDA congenital coding checks for procedures performed but has to wait until the clinical coding has been done. There is very little inter relation between clinical coding (ICD10 and OPCS) and NCHDA. NHSE now requires congenital procedures data to be submitted within 2 weeks of an operation or cath lab procedure.

The electronic log books, were quite challenging to read, and often lacked specific diagnosis information that could be reconciled with the procedure performed. Therefore it was difficult to discern whether or not a patient was undergoing a procedure for congenital heart disease or not. The labelling of procedures as ACHD appeared to be a very random and inconsistent or absent. Several patient entries see appeared to have dates of death entered within 30 days of a procedure. OPCS and ICD 10 codes were seen in the electronic log books but not NCHDA codes.

Deaths

No deaths had been identified in the submitted data or the case note Sample seen.

Recommendations

1. Consider embedding the NCHDA Dataset v6.1 in Trust ePR access in the areas where ACHD patients are seen such as in Out Patients, wards, operating rooms and cath labs to enable real time data entry with correct coding and descriptions of diagnoses, comorbidities, previous procedures and the procedure performed. This will enable improved quality and accuracy of the data collected for this often high risk complex cohort of patients.

2. 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. That in line with the GDPR, 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 op out explained to patients/carers.
    b. Identifying who is responsible for the input of congenital patients NCHDA required dataset items and at which point of service delivery
    c. Encouraging responsible clinician input of the procedure data and coding for each operation, diagnostic catheter or catheter intervention at the point of the service delivery
    d. Recording sheath in and sheath out time for cath lab procedures.
    e. Recording the knife to skin time for all surgical procedures where it can be validated (ie perfusion or anaesthetic record).
    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. Recording implanted device details on the operation or intervention procedure note.

h. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data Managers at least monthly.
i. Running the NCHDA Activity Algorithm regularly using the R Code algorithm. This will help inform the quarterly NHSE Dashboard reports.
j. Ensuring that dates of death are reported for any LHCH patient who has previously had a record submitted to the NCHDA
k. Leading the local review (and how frequently and in which forum for both disciplines)
l. Making timely submissions where possible (within 2 weeks of procedure performed in recommended) and
m. Recording date and time of any discussion with a medical examiner/coroner in the case of a patient death with in 30 days of a therapeutic procedure for congenital heart disease and considered completion of the Attribution of Death field.
n. Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.
o. Reviewing/Updating the SOP at timely intervals

3 Also as previously recommended, it is suggested that greater attention to detail is used when recording procedures performed on patients with congenital heart disease in the electronic operating theatre and cath lab activity logs. Training staff to use the terms in the NCHDA dataset would be helpful. The use of the term ‘congenital insufficiency’ is not precise enough to confirm whether or not a patient has congenital heart disease as defined by the NCHDA ACHD algorithm.

4 It would also be helpful to document the dates chronologically of previous congenital procedures a patient may have had as a paediatric patient and whether or not they were antenatally diagnosed.

5 If possible, adapt the electronic e noting to include a template for the specific ACHD risk fields for NYHA, Smoking, Pulmonary Disease, Ischaemic Heart Disease and Diabetes etc

6 It is suggested that consideration be given to the possibility of a congenital colleague attending the aortic valve MDTs to assist with identifying ACHD patients and ensuring that the correct data are submitted to NCHDA

7 It is further suggested that the BHL NCHDA data manager attends the ACHD MDT to assist with identifying patients who may have future surgery or catheter investigations or interventions in a timely manner. This will also contribute to the DBMs ongoing ACHD education.

8 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.

9 Regular training updates should be provided for all staff who may be involved with data collection and input

LHCH NCHDA Validation Report 2024