Procedures for CONGENITAL HEART DISEASE For April – March 2021-2022

Data Quality Audit

Liverpool Heart and Chest Hospital NHS Foundation Trust

29 June 2022

performed by Lin Denne, and Dr B Grant

Summary and Overview

Prior to this Validation Visit, the data return from The Liverpool Heart and Chest Hospital (LHCH), indicated that 434 therapeutic cardiac procedures (334 catheters, 100 operations, 0 others, 3 deaths) had been undertaken during the 2021/2022.

Since 2018 LHCH has been commissioned to provide services for ACHD patients at Level 1. A full inpatient surgery and catheter interventions service commenced in December 2018. This is the fourth visit to LHCH since being commissioned as a Level 1 provider for Adult Congenital Heart Disease. At the time of this validation there were six ACHD consultant cardiologists at LHCH. Four visiting consultant congenital cardiac surgeons from Alder Hey Children's Hospital operate at LHCH and three visiting cardiac interventionists also visit from Alder Hey. There are two consultant electrophysiologists at LHCH who undertake procedures on ACHD patient also.

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 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 NICOR data are captured. As previously documented, there is a clinician lead.

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 over two years at the time of this validation.

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 2021

Due to pandemic SARS-COV 19, new ways of remote working have been devised to support the NCHDA data collection and submissions. Almost all clinical audit staff have pivoted to working remotely:

- NCHDA data manager has been working remotely since March 2020
- Almost all documents are available electronically and securely via EPR.
- Access to operating theatre/cath lab records is available remotely
- Microsoft Teams is fully utilised for clinical meetings.

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 minimum threshold was not reached in the surgery group for the case note review at LHCH.

Year of Visit	Data Reviewed	Surgery	Catheters
2010	2008-09	Insufficient Sample	86.5%
2011	2009-10	Insufficient Sample	87.75%

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%	99.25%

The overall DQI for the Trust is calculated to be (with previous years in parentheses) is 99.25**%** (98.75, 94.75 93.5). The individual Domain scores are as follows; Demographics 1.0 (1.0, 1.0 1.0), Pre Procedure .99 (.96, .95 .90) Procedure .99 (.99, .96 .89), Outcome .99 (1.0, .88 .95).
There were just 11 discrepancies in 1093 variables.

This DQI is based on the records of 20 patients who underwent 25 procedures (18 interventional catheters and 7 operations).

There were 11 discrepancies in 1093 data variables.

It was observed that three diagnoses had incomplete elements (additional parts).
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 434 therapeutic cardiac procedures (334 catheters, 100 operations, 0 others, 3 deaths) had been undertaken during the 2021/2022.

20 sets of case notes were selected for review. A reserve list of 10 cases was supplied also and on the day. No sets of case notes from this list were required at LHCH.

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 Consultant in congenital cardiac surgery undertook the site audit at LHCH. The NCHDA Clinical Auditor participated remotely using MS Teams.

As described elsewhere all data are input at the point of treatment in an ePR. This is used throughout the ACHD patient journey. 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 .pdf file of documents for each patient in the Sample and Reserve groups. No sets of case notes were required from the reserve list. The Validation Team reviewed each of 20 patients' files of electronic patient records.

It was noted that in this year's Sample cohort there were a number of younger ACHD patients with dates of birth in the later 1990's and very early 2000's. A proportion of these appeared to have unknown antenatal diagnosis fields but had had procedures at children. It would be helpful if the hospital where these early procedures were undertaken could be noted in the patients' medical record and this will assist with completing this field accurately in the NCHDA registry. NHCDA data managers at other congenital centres are always happy to liaise and assist with this.

1. This was a little slower than when individual pages of ePR are printed and presented in folder for each patient. It was not possible to screen share documents with the external reviewers. This directly impacted on the timeliness of the audit activities.

2. It did not always appear to be clearly noted in either the .pdf documents or the ePR, whether the younger ACHD patients had had previous procedures performed in earlier adulthood or in childhood at other hospitals.
3. As noted above, there was little noting of whether or not the younger ACHD patients had been fetally diagnosed.
4. As noted previously the documentation of ventricular function was not always easy to find and the NCHDA Data Manager at BHL does not appear to have access to the electronic echo cardiogram reporting system.
5. There were also some challenges with finding regular standard documentation of NYHA status in the patient's hospital records.

Review of the Log Books at LHCH

There are nine operating rooms and a hybrid room at LHCH. Log books of activity are now an all-electronic (digital) dashboard. As previously noted, and again in 2022 it is not always clear whether or not a procedure is for congenital heart disease. It would be helpful to incorporate and train the users of this dashboard to use the NCHDA codes as these would increase accuracy. It would also be helpful to have a mandatory field to indicate if a patient has congenital heart disease or not.

1. 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.
2. The label 'congenital insufficiency' is not useful for accurate NCHDA coding.
3. 23 submitted surgical records appear to have the wrong procedure type and may be Catheter EP.
4. 10 records were identified from the log book that may have been missed from the congenital submission.

Many of the 10 records identified that may have been missed from the submission appear to be for ACHD younger patients having aortic valve surgery but it is not clear whether or not they have congenital heart disease. 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 procedures as a paediatric patient.

Cath Lab Log Books

There are six cath labs (+ the hybrid room) currently in use at this centre. As previously reported, the activity of the cathlabs is 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. There is also bound book that is the log of congenital cardiac procedures. The Validation Team were informed that cath labs 1, 3 and 5 are the predominantly used rooms by the ACHD team. Some diagnostic catheters are done in adjacent Royal Liverpool Trust. It was not possible to check these for case ascertainment as no log this activity was available. The findings are:

1. Lack of specificity in entry field for diagnoses
2. No mandatory field to identify procedures in patients with congenital heart disease
3. Five submitted catheter records appear to have errors in them
4. 13 procedures were identified in the cath lab log books which may have been missed from the data submission. These are predominately for EP and pacing procedures
5. 62 records for diagnostic catheters were not validated.

Pre-Visit Questionnaire Assessment

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.

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.

Three patients who had had procedures during the 2021/22 data collection year were noted to have died. All deaths were more than 30 days of their procedure and therefore were not examined in close detail.

All dates of death, demographics, diagnostic, comorbidity, and procedural coding were correct.

Case note Audit 2021/22 Data.

20 patients underwent 25 procedures (18 caths, 7 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	25	25	3 have incorrect elements	18	7
11	Previous Procedures	76	76		68	8
12	Patients Weight at Operation	25	25		18	7
13	Height	25	25		18	7
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	24	25	1 incorrect	17/18	7
16	Pre Proc NYHA	24	25	1 incorrect	17/18	7
17	Pre Proc Smoker	25	25		18	7
18	Pre Proc Diabetes	25	25		18	7
19	Hx Pulmonary Dis	25	25		18	7

20	Pre Proc IHD	25	25		18	7
21	Comorbidity Present	25	25		18	7
22	Comorbid Conditions	46	47	1 incorrect	36/37	10
23	Pre Proc Systemic Ventricular EF	23	25	1 incorrect 1 unable to validate	16/18	7
24	Pre Proc Sub Pul Ventricular EF	23	24	1 unable to validate	16/17	7
25	Pre-proc valve/septal defect/ vessel size	5	5		5	-
26	Consultant	25	25		18	7

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	25	25		18	7
28	Proc Urgency	24	25	1 incorrect	1	7
29	Unplanned Proc	1	1		18	-
30	Single Operator	25	25		18	7
31	Operator 1	25	25		18	7
32	Operator 1 Grade	25	25		18	7
33	Operator 2	23	23		16	7
34	Operator 2 Grade	23	23		16	7

35	Procedure Type	24	25	1 incorrect	17/18	7
36	Sternotomy Sequence	6	6		-	6
37	Operation Performed	25	25		18	7
38	Sizing balloon used for septal defect	1	1		1	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	21	21		15	6
41	Device Model	23	23		15	8
42	Device Ser No	23	23		15	8
43	Device Size	15	15		8	7
44	Total Bypass Time	6	6		-	6
45	XClamp Time,	4	4		-	4
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	17	17		17	-
48	Cath Fluro Time,	16	17	1 incorrect	16/17	-
49	Cath Fluro Dose,	16	17	1 incorrect	16/17	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	6	6		-	7
51	Post Procedure Seizures	24	25	1 incorrect	18	6/7
52	Post Proc Complications	2	2		-	2
53	Date of Discharge	25	25		18	7
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	25	25		18	7
57	Discharge Destination	25	25		18	7

Data Quality Indicator Assessment:

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

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.

<table>
<tr><th>DOMAIN</th><th colspan="2">DOMAIN Score</th></tr>
<tr><td><u>Demographics</u>

Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status</td><td colspan="2">Overall 1.0</td></tr>
<tr><td></td><td>Card
1.0</td><td>Surg
1.0</td></tr>
<tr><td><u>Pre Procedure</u>

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</td><td colspan="2">Overall .99</td></tr>
<tr><td></td><td>Card
.98</td><td>Surg
1.0</td></tr>
<tr><td><u>Procedure</u></td><td colspan="2">Overall .99</td></tr>
</table>

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** .98	**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** 1.0	**Surg** .97

The Trust DQI = 99.25% (98.75)

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	2022	2021	2020	2019	2014
Demographics,	1.0	1.0	1.0	1.0	1.0
Pre Procedure,	.98	.96	.95	.90	.93
Procedure	.98	.99	.96	.89	.99
Outcome	1.0	1.0	.88	.95	.98

Conclusions

On the whole the submitted NCHDA data were accurate, well documented, good quality and were appropriately recorded in the electronic Theatre and Congenital Cath lab log books that were seen. This is the fourth 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 18 months. Shortly after the DM was appointed the COVID 19 pandemic was announced, and this role pivoted from being hospital based to being based remotely.

In total there were just 11 discrepancies in 1093 data variables. This demonstrates a very good commitment to provide good quality verified clinical data. There appears to be a robust culture of clinical audit embedded within the Trust and the DBM has invested many hours overtime to achieve data of good quality while being still relatively new to the post. The Data Quality Indicator (DQI) Score is excellent.

The Validation Team are particularly grateful to the Data Manager for meticulously detailing the documents needed at this review and grouping them together in individual electronic files for the reviewers to see. However, as in 2021, the digital system used to transfer from document to document was extremely slow and this ultimately impacted on running of the day. The reviewers would also like to thank the clinicians who visited them for making time to spend with the audit team throughout the day. We would also like to thank those individuals who made time to attend the validation feedback session via the MS Teams application.

As previously reported it was sometimes very difficult to find explicit documentation of right and left ventricular function for patient pre procedure. These data are required for every NCHDA entry. It was also challenging at times to find historical details of previous procedures that had been undertaken at other hospitals within a congenital paediatric service elsewhere.

The electronic log books, whilst easier to read, lacked specific diagnosis information and 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 little random and inconsistent at times.

Deaths

As documented above, all dates of death were accurate.

Recommendations

1. 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. 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 for each operation, diagnostic or catheter intervention at the point of the service delivery.
    d. Recording the knife to skin time for all surgical procedures where it can be validated (ie perfusion or anaesthetic record).
    e. 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.
    f. Recording implanted device details on the operation or intervention procedure note.
    g. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data Managers at least monthly.
    h. Running the NCHDA Activity Algorithm regularly using the R Code algorithm. This will help inform the quarterly NHSE Dashboard reports.
    i. Ensuring that dates of death are reported for any LHCH patient who has previously had a record submitted to the NCHDA.
    j. Leading the local review (and how frequently and in which forum for both disciplines).

k. Making timely submissions where possible (monthly is recommended).
l. Including details of manufacturer, model and serial numbers of all implantable devices with each patient record for a procedure.
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.
n. Reviewing/Updating the SOP at timely intervals

2. 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. 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.
3. 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.
4. 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
5. 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.
6. 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.
7. Regular training updates should be provided for all staff who may be involved with data collection and input