Procedures for CONGENITAL HEART DISEASE For April – March 2020-2021

Data Quality Audit

Liverpool Heart and Chest Hospital NHS Foundation Trust

10 June 2021

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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 321 therapeutic cardiac procedures (254 catheters, 67 operations, 0 others, 7 deaths) had been undertaken during the 2020/2021.

Since 2017 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. At the time of this validation there were 6 ACHD consultant cardiologists at LHCH. 3 visiting consultant congenital cardiac surgeons from Alder Hey Children's Hospital operate at LHCH. There are 2 consultant electrophysiologists who undertake procedures on ACHD patient also.

For reasons of logistics and capacity, ACHD patients who require diagnostic cardiac catheterisation undergo these procedures at the Royal Liverpool Hospital which is adjacent to 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 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 was appointed in February 2020.

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 2020

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 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%

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

There were just 16 discrepancies in 916 variables.

This DQI is based on the records of 20 patients who underwent 22 procedures (18 interventional catheters and 4 operations).

The fields with the most discrepancies are:

Pre procedure systemic ventricular function	4 records
Pre procedure sup pulmonary ventricular function	6 records

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 321 therapeutic cardiac procedures (254 catheters, 67 operations, 0 others, 7 deaths) had been undertaken during the 2020/2021 data collection year in patients with congenital heart disease.

20 sets of case notes were selected for review. A Reserve list of 10 cases was supplied also and on the da. 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.

1. This was a little slower than when individual pages of ePR are printed and presented in folder for each patient. This directly impacted on the timeliness of the audit activities and the review of the activity log books was not completed.
2. It was not always clearly noted in either the .pdf documents or the ePR, whether or not two of the patients had had previous procedures performed in earlier adulthood or in childhood at other hospitals.
3. As noted in previously the documentation of ventricular function was not always easy to find

Review of the Log Books at LHCH

There are 9 operating rooms at LHCH. Log books of activity are now all electronic (digital). As previously noted it is not always clear whether or not a procedure is for congenital heart disease. The diagnoses descriptions were sometimes vague and imprecise such as 'congenital insufficiency'.

1. 1 submitted surgical record appears to have an error in it
2. 14 records were identified from the log book that may have been missed from the congenital submission.

Cath Lab Log Books

There are 5 cath labs at this Centre. One further cath lab is currently not being used. 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 were not always precisely described and sometimes it was difficult to discern if a patient had congenital or acquired heart disease.

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. A list of the records from Royal Liverpool Trust were included in this review of activity but it was not entirely clear if this was totally inclusive or not.

Due to time constraints the months of April to November 2020 only were audited. The findings are;

1. 8 submitted catheter records appear to have errors in them

2. 10 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
3. Some records appear to be labelled as ACHD and others not. It was unclear whether or not this labelling was accurate or precise due to lack of specificity of diagnoses descriptions.

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.

7 patients who had had procedures during the 2020/21 data collection year were noted to have died after their procedure. 5 of these deaths occurred within 30 days of the procedure and the PRAiS sensitive fields were examined. These fields are demographics, diagnosis, pre procedure weight, comorbidities, procedure performed and date of death.

The findings were;

- All dates of death were correct
- 2 records appear to have elements of the diagnosis coding absent

Case note Audit 2020/21 Data.

20 patients underwent 2x procedures (18 caths, 4 operations)

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		16	4
2	NHS Number	20	20		16	4
3	Surname	20	20		16	4
4	First Name	20	20		16	4
5	Sex	20	20		16	4
6	DOB	20	20		16	4
7	Ethnicity	20	20		16	4
8	Patient Status	20	20		16	4
9	Postcode	20	20		16	4
10	Pre Procedure Diagnosis	21	22	1 incorrect	17/18	4
11	Previous Procedures	45	48	3 absent	35/38	10
12	Patients Weight at Operation	22	22		18	4
13	Height	22	22		18	4
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	22	22		18	4
16	Pre Proc NYHA	21	22	1 incorrect	17/18	4
17	Pre Proc Smoker	22	22		18	4
18	Pre Proc Diabetes	22	22		18	4
19	Hx Pulmonary Dis	22	22		18	4
20	Pre Proc IHD	22	22		18	4
21	Comorbidity Present	21	22	1 incorrect	17/18	4
22	Comorbid Conditions	28	30	2 incorrect	24/26	4
23	Pre Proc Systemic Ventricular EF	18	22	1 absent, 3 incorrect	15/18	¾
24	Pre Proc Sub Pul Ventricular EF	15	21	6 incorrect	12/18	3
25	Pre-proc valve/septal defect/ vessel size	-	-		-	-
26	Consultant	22	22		14	4

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	22	22		18	4
28	Proc Urgency	22	22		18	4
29	Unplanned Proc	0	0		-	-
30	Single Operator	4	4		4	-
31	Operator 1	22	22		18	4
32	Operator 1 Grade	22	22		18	4
33	Operator 2	18	18		14	4
34	Operator 2 Grade	18	18		14	4
35	Procedure Type	22	22		18	4
36	Sternotomy Sequence	2	3	1 unable to validate	-	2/3
37	Operation Performed	22	22		18	4
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	12	12		8	4
41	Device Model	12	12		8	4
42	Device Ser No	11	12	1 incorrect	7/8	4
43	Device Size	10	11	1 incorrect	6/7	4
44	Total Bypass Time	3	3		-	3
45	XClamp Time,	2	2		-	2
46	Total Arrest	1	1		-	0
47	Cath Proc Time,	18	18		18	-
48	Cath Fluro Time,	18	18		18	-
49	Cath Fluro Dose,	18	18		18	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	3	3		-	3
51	Post Procedure Seizures	22	22		18	4
52	Post Proc Complications	1	1		1	-
53	Date of Discharge	22	22		18	4
54	Date of Death	1	1		1	-
55	Attribution of Death	1	1		1	-
56	Status at Discharge	22	22		18	4
57	Discharge Destination	22	22		18	4

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.75% Cardiology DQI = 98.75% Surgery DQI = 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	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 .96**	
	Card .96	**Surg** .98
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** .99	
	Card .99	**Surg** .98
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. Post Procedure Complications.	**Overall** 1.0	
	Card 1.0	**Surg** 1.0

The Trust DQI = 94.75% (93.5)

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	2021	2020	2019	2014
Demographics,	1.0	1.0	1.0	1.0
Pre Procedure,	.96	.95	.90	.93
Procedure	.99	.96	.89	.99
Outcome	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 third NCHDA visit to LHCH since being commissioned to provide Level 1 adult congenital cardiac services in July 2017. The Data Manager (DM) at this visit has been in this role within ACHD for just over 12 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 16 discrepancies in 916 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 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, this year, it appeared to transfer from document to document very slowly and this ultimately impacted on running of the day and it was not possible to review all of the log books. 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.

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 inconsistent at times.

Deaths

As documented above, there were some minor data elements that were incorrect but all other items 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 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 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) and
    l. Including details of manufacturer, model and serial numbers of all implantable devices with each patient record for a procedure.
    m. 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 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
4. 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.
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