Procedures for CONGENITAL HEART DISEASE For April – March 2019-2020

Data Quality Audit

Liverpool Heart and Chest Hospital NHS Foundation Trust

18 August 2020

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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 303 therapeutic cardiac procedures (225 catheters, 70 operations, 8 others, 6 deaths) had been undertaken during the 2019/2020.

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 4 ACHD consultant cardiologists at LHCH. 3 visiting consultant congenital cardiac surgeons from Alder Hey Childrens 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 have been required to be submitted to NCHDA.

Actions Taken Since Last Validation Visit

This Trust became a Level 1 service provider for ACHD in July 2018.

A new data manager was appointed in February 2020

Due to pandemic COVID 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.

Consent for External Validation of Notes.

Please note that 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%

The overall DQI for the Trust is calculated to be (with the 2019 results in parentheses) is **94.75%** (93.5). The individual Domain scores are as follows; Demographics 1.0(1.0), Pre Procedure .95 (.90) Procedure .96 (.89), Outcome .88 (.95).

There were 46 discrepancies in 1036 variables.

This DQI is based on the records of 20 patients who underwent 23 procedures (14 catheters and 9 operations).

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 303 therapeutic cardiac procedures (225 catheters, 70 operations, 8 others, 6 deaths) had been undertaken during the 2019/2020 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. 0 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 adult congenital cardiology 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 ePR. This is used throughout the ACHD patient journey.

During 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. 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. Catheter sheath in and out time was not always clearly recorded in the documents seen
2. As noted in 2019, documentation of ventricular function appeared to be recorded on a template for acquired cardiac disease and this does not include all the relevant data for NCHDA.

Review of the Log Books at LHCH

Log books for 8 operating theatres and 5 cath labs were made available. These are now all in an electronic format on a local application known as Carecube and were provided in printed sheets ordered by date.

Cath Lab Log Books

There are 5 cath labs at this Centre. The activity of the cathlabs are now collected digitally in CareCube. This is essentially a scheduling tool rather than a log of actual activity. 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 rooms used by the ACHD team. Some diagnostic catheters are done in adjacent Royal Liverpool Trust. It was not clear if these records were included in this review of activity or not. The findings are;

1. 3 submitted catheter records appear to have errors in them
2. 26 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. A further 26 records were not validated in the digital logs that were seen or the congenital log book.

Theatre Log Books

There are 9 operating rooms at LHCH. The bespoke bound operating theatre ledgers for theatres were made available for the time period until they became digital in October 2019. Each entry of the bound log books seen was hand written. As previously noted it is not always clear whether or not a procedure is for congenital heart disease.

1. 1 submitted surgical record appears to have an errors in it
2. 1 record was identified from the log book that may have been missed from the congenital submission
3. 1 record was identified in the submission that may not be a procedure for congenital heart disease.

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.

6 patients who had had procedures during the 2019/20 data collection year were noted to have died more than 30 days after their procedure. Due to time pressures these case notes were not reviewed. There were no deaths reported that occurred less than 30 days after a procedure.

Case note Audit 2019/20 Data.

20 patients underwent 23 procedures (14 caths, 9 operations)

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		12	8
2	NHS Number	20	20		12	8
3	Surname	20	20		12	8
4	First Name	20	20		12	8
5	Sex	20	20		12	8
6	DOB	20	20		12	8
7	Ethnicity	20	20		12	8
8	Patient Status	20	20		12	8
9	Postcode	20	20		12	8
10	Pre Procedure Diagnosis	22	23	1 incorrect	14	8/9
11	Previous Procedures	46	48	2 incorrect	31/33	15
12	Patients Weight at Operation	22	23	1 incorrect	14	8/9
13	Height	23	23		14	9
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	23	23		14	9
16	Pre Proc NYHA	23	23		14	9
17	Pre Proc Smoker	22	23	1 incorrect	13/14	9
18	Pre Proc Diabetes	23	23		14	9
19	Hx Pulmonary Dis	22	23	1 incorrect	14	8/9
20	Pre Proc IHD	22	23	1 incorrect	13/14	9
21	Comorbidity Present	21	23	2 incorrect	14	7/9
22	Comorbid Conditions	20	27	7 absent	14/18	6/9
23	Pre Proc Systemic Ventricular EF	23	23		14	9
24	Pre Proc Sub Pul Ventricular EF	21	23	1 incorrect, 1 absent	13/14	8/9
25	Pre-proc valve/septal defect/ vessel size	4	5	1 incorrect	4/5	-
26	Consultant	23	23		14	9

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	23	23		14	9
28	Proc Urgency	23	23		14	9
29	Unplanned Proc	23	23		14	9
30	Single Operator	1	1		0	1
31	Operator 1	23	23		14	9
32	Operator 1 Grade	23	23		14	9
33	Operator 2	22	22		14	8
34	Operator 2 Grade	20	22	2 incorrect	14	6/8
35	Procedure Type	23	23		14	9
36	Sternotomy Sequence	8	8			8
37	Operation Performed	23	23		14	9
38	Sizing balloon used for septal defect	0	0		-	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	18	20	2 absent	10	8/10
41	Device Model	18	20	2 absent	10	8/10
42	Device Ser No	21	23	2 absent	10	8/10
43	Device Size	19	19		12	7
44	Total Bypass Time	8	8		-	8
45	XClamp Time,	8	8		-	8
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	13	14	1 unable to validate	13/14	-
48	Cath Fluro Time,	12	14	1 unable to validate, 1 absent	12/14	-
49	Cath Fluro Dose,	13	14	1 absent	13.14	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	7	8	1 absent	-	7/8
51	Post Procedure Seizures	16	23	7 absent	7/14	9
52	Post Proc Complications	2	2		2	-
53	Date of Discharge	21	23	2 unable to validate	14	7/9
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	23	23		14	9
57	Discharge Destination	23	23		14	9

Data Quality Indicator Assessment:

The Overall Trust DQI = 94.75% Cardiology DQI = 94.25% Surgery DQI = 95%

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 .95**	
	Card .95	**Surg** .93
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** .96	
	Card .98	**Surg** .94
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. Post Procedure Complications.	**Overall** .88	
	Card .84	**Surg** .93

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	2020	2019	2014	2013
Demographics,	1.0	1.0	1.0	1.0
Pre Procedure,	.95	.90	.93	.74
Procedure	.96	.89	.99	.92
Outcome	.88	.95	.98	.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 second NCHDA visit to LHCH since being commissioned to provide Level 1 congenital cardiac services in July 2017. The Data Manager (DM) at this visit has been in this role within ACHD for just over 6 months. Shortly after the DM was appointed the COVID 19 pandemic was announced and this role pivoted from being hospital based to being home based.

In total there were just 46 discrepancies in 1036 data variables. This demonstrates a very good commitment to provide 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 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. The Reviewers would also like to thank the Clinical Lead for Congenital Cardiology and other clinicians 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.

It appeared that a template that is being used to record left ventricular function may be for acquired heart disease. This is not always helpful for the patient with congenital heart disease as the dataset requires information on both ventricles.

The use of abbreviations was noted and sometimes these were a little difficult to decipher.

As previously reported, handwritten entries into log books will always be challenging to decipher and the Reviewers are aware that the Galaxy Theatre Information System is available in this Centre. This has been successfully used to replace the handwritten log books in at least one other large congenital cardiac centres as it is possible to record procedures using the OPCS codes that can be cross mapped to the Association of European Paediatric and Congenital Heart Disease (AEPC) coding that the NCHDA uses.

Deaths

There were no deaths reported that occurred within 30 days of a procedure at this validation visit.

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. 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 logs.

3. As previously recommended, consideration could be given to developing the GALAXY information system used in the operating theatres to include the accurate recording of the exactly which congenital operation was performed on each patient.
4. 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.
5. Regular training updates should be provided for all staff who may be involved with data collection and input