The National Congenital Heart Disease Audit

Data Quality Audit for CONGENITAL HEART DISEASE PROCEDURES For April to March 2019-2020

The Leeds Teaching Hospitals NHS Trust

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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 1363 procedures (503 operations, 530 interventional catheters, 173 diagnostic catheters, 157 others, 28 deaths) had been undertaken during the data collection year of 2019/2020.

This validation visit has been fully funded by the Leeds Teaching Hospitals NHS Trust. This site visit was undertaken by Dr T Mukasa, Consultant Congenital Cardiologist from Leicester on site and the NCHDA Clinical Audit Nurse remotely via MS Teams.

Since June 2013 a dedicated 1.0WTE congenital Database Manager (DBM) has been in post. There is a nominated clinician with responsibility for this data and one other who also has access to the NCHDA database. There is a further 1.0WTE Data Analyst role that supports this registry.

It is also noted the LGI do not appear to meet 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.

As previously reported, the Congenital Cardiac Department at LGI uses a bespoke database (OSCAR 4D) 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 an interface between OSCAR and the Trust PAS.

Actions undertaken or changes to processes since the 2019 validation visit.

LGI Report the following actions:

1. The implementation of a new DQ tool developed by LGI Informatics team to help ensure more accurate submission of data to NCHDA.

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.

LGI are moving towards an electronic patient record (ePR) and methods of capturing this piece of information electronically is currently being discussed and reviewed.

Data Quality Indicator Score

The overall DQI for the Trust (with the previous years in parentheses) is calculated to be **99%** (98.25, 99, 98) with domain scores Demographics 1.0 (1.0, 1.0, .99) Pre Procedure .98 (.96, .98, .95) Procedure .98 (97, .96, .995) and Outcome 1.0 (1.0, .99, .98, .98).

There were just 7 discrepancies in 835 variables checked.

This DQI was based on the records of 20 patients who underwent 22 procedures (11 catheters and 11 operations).

Immediately prior to the validation taking place LGI had performed a further revalidation of their data against the data used for this visit and identified and corrected a number of 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.

	Data Year Validated	Surgery DQI	Catheter DQI
2012	10/11	95%	96.25%
2013	11/12	92%	95.75%
2013(ii)	12/13	94.25%	96%
2014	13/14	95.25%	99%
2015	14/15	97.25%	96%
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%

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.

Introduction

Prior to this validation visit, the NCHDA Data Return from the Paediatric Cardiac Department of the Leeds Teaching Hospitals NHS Trust indicated that 1363 procedures (503 operations, 530 interventional catheters, 173 diagnostic catheters, 157 others, 28 deaths) had been undertaken during the data collection year of 2019/2020 of which 20 cases were selected for review.

As previously reported and as stated above, the Department uses its own database to collect data (the Orion Software for Cardiology – OSCAR 4D). This database is connected to the hospital PAS. 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.

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 Database Manager, the Service Manager and the clinical team who organised and itemised many of the items in the case notes that the Review Team would need look at. These items and copies from the ePR had been meticulously prepared.

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 notes. This was then recorded to enable the Data Quality Indicator (DQI) to be scored.

Review of notes

As described above, each set of notes was meticulously prepared with sticky post-it type labels identifying many of the pages the Validation Team needed to review. However as reported in previous years, many of the case notes seen were very disorganised and not chronological.

1. It was noted on occasions that the primary diagnosis did not always reconcile with the procedure performed.
2. The pink operation note, when seen was very helpful in establishing exactly what procedure had been performed.
3. As previously documented, recording of exactly when (date and time) a patient was extubated was at times difficult to find.

4. In some case notes there appeared to be a discrepancy between the electronic record and the paper records as to the exact date a patient was discharged from hospital.
5. It was again difficult to find a consistent place in the hospital notes where device labels are placed

Review of the Log Books

Cardiac Operating Theatres

The bespoke bound operating theatre ledgers for 4 theatres were made available. Each entry of the log books seen is hand written. As previously noted it is not always clear whether or not a procedure is for congenital heart disease. Some entries were blank where the name of the procedure performed should be given.

1. 3 submitted surgical records were not validated in the log books

Cardiac Catheter Lab Log Book Review

There are 6 cath labs at this Centre. The Validation Team were informed that most congenital procedures are performed in Lab 1, 2 and Lab 5. The individual log books for each of these cath labs were reviewed. These books are A4 lined and ruled books. As previously reported, it was quite difficult to identify whether or not a procedure is for congenital heart disease. The findings are;

1. 0 procedures were identified in the cath lab log books which may have been missed from the data submission.
2. 8 records were not validated in the NCHDA data submission. This may be because it was unclear as to whether or not the patient had congenital heart disease in the log books.

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 the GDPR regulation of May 2018, the requirement for consent to validate this hospital data is no longer needed.

28 patients who had had procedures during the 2019/20 data collection year were noted to have died. 10 patients had died within 30 days of a therapeutic catheter intervention or surgical operation. These case notes were prioritised for the review. The procedural and outcome documentation was made available to the Reviewers.

- Dates of death in all patients were confirmed
- 2 records appear to have incomplete comorbidities recorded in the data submitted to the NCHDA

Case note Audit 2019/20 Data.

20 patients underwent 22 procedures (11 caths, 11 operations)

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		10	10
2	NHS Number	20	20		10	10
3	Surname	20	20		10	10
4	First Name	20	20		10	10
5	Sex	20	20		10	10
6	DOB	20	20		10	10
7	Ethnicity	20	20		10	10
8	Patient Status	20	20		10	10
9	Postcode	20	20		10	10
10	Pre Procedure Diagnosis	22	22		11	11
11	Previous Procedures	23	23		13	10
12	Patients Weight at Operation	22	22		11	11
13	Height	21	21		11	10
14	Ante Natal Diagnosis	2	3	1 incorrect	0/1	2
15	Pre Proc Seizures	22	22		11	11
16	Pre Proc NYHA	5	5		2	3
17	Pre Proc Smoker	5	5		2	3
18	Pre Proc Diabetes	5	5		2	3
19	Hx Pulmonary Dis	5	5		2	3
20	Pre Proc IHD	5	5		2	3
21	Comorbidity Present	22	22		11	11
22	Comorbid Conditions	45	47	2 incorrect	14	31/33
23	Pre Proc Systemic Ventricular EF	21	22	1 absent	10/11	11
24	Pre Proc Sub Pul Ventricular EF	21	22	1 absent	10/11	11
25	Pre-proc valve/septal defect/ vessel size	3	3		3	-
26	Consultant	22	22		11	11

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	22	22		11	11
28	Proc Urgency	22	22		11	11
29	Unplanned Proc	1	1		-	1
30	Single Operator	5	5		5	-
31	Operator 1	22	22		11	11
32	Operator 1 Grade	22	22		11	11
33	Operator 2	16	17	1 incorrect	6	10/11
34	Operator 2 Grade	16	17	1 incorrect	6	10/11
35	Procedure Type	22	22		11	11
36	Sternotomy Sequence	10	10		-	10
37	Operation Performed	22	22		11	11
38	Sizing balloon used for septal defect	0	0		0	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	10	10		8	2
41	Device Model	12	12		9	3
42	Device Ser No	11	12	1 incorrect	9	2/3
43	Device Size	10	10		9	1
44	Total Bypass Time	9	9		-	9
45	XClamp Time,	7	7		-	7
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	11	11		11	-
48	Cath Fluro Time,	11	11		11	-
49	Cath Fluro Dose,	11	11		11	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	10	10		-	10
51	Post Procedure Seizures	22	22		11	11
52	Post Proc Complications	4	4		2	2
53	Date of Discharge	22	22		11	11
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	22	22		11	11
57	Discharge Destination	22	22		11	11

Data Quality Indicator Assessment:

The Overall Trust DQI = 99% Cardiology DQI = 99.5% Surgery DQI = 99.25%

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	
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 .98**	
	Card .98	**Surg** .99
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** .98	
	Card 1.0	**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 = 99% (98.25, 99, 98**)**

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	2017	2018	2019	2020
Demographics	.99	1.0	1.0	1.0
Pre Procedure	.95	.98	96	.98
Procedure	.995	.96	97	.98
Outcome	.98	.99	10	1.0

Conclusions

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

There has been a further 0.75% increase in the DQI to 99% which is another excellent achievement. In total there were just 7 errors or omissions in 835 data variables. This demonstrates a strong commitment to good quality verified clinical data. There appears to be a very robust culture of clinical audit embedded within the Trust and the DBM has invested may hours overtime to achieve data of a high quality. However, the Reviewers are concerned that there appears to be no forward plan to increase the number of DBMs to meet the NHSe 2016 recommendations as the numbers of procedures are slowly increasing.

Again, the Validation Team are particularly grateful to the Congenital Data Manager for meticulously detailing the documents needed at this review at extremely short notice. 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.

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 centre 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

As detailed elsewhere, there were a very small number of discrepancies seen.

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 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 PRAiS2 (Paediatric 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
    j. Leading the local review (and how frequently and in which forum for both disciplines)
    k. Making timely submissions (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. It is recommended that consideration be given to recruiting a 1.0WTE data manager to support the ACHD practice at this centre as this expands.
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 operating theatre and cath lab log books.

4. 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.
5. To keep a log of all procedures such as septostomies that occur outside the cardiac catheter laboratory.
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