The National Congenital Heart Disease Audit

Data Quality Audit for
CONGENITAL HEART DISEASE PROCEDURES
April – March 2018/2019

The Leeds Teaching Hospitals NHS Trust

4 July 2019

performed by Lin Denne and Dr A Bell,

Summary

The data return to the NCHDA made by the Congenital Cardiac Department of the Leeds Teaching Hospitals NHS Trust (LGI) and analysed 4 weeks prior to this visit, indicated that some 1203 procedures (417 operations, 677 catheters 109 others, 17 deaths) had been undertaken during the data collection year of 2018/2019.

This validation visit has been fully funded by the Leeds Teaching Hospitals NHS Trust. This site visit was undertaken by the NCHDA clinical audit nurse and Dr A Bell, Consultant Congenital Cardiologist from Evelina London.

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.

Since the completion of this validation visit the individual in the role of Database Manager has changed. The DBM referred to in this Report relates to the previous incumbent in that role. There was approximately 1 month of supported handover between the DBMs.

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 September 2017 validation visit.
LGI Report the following actions:

1. There continues to be a good level of engagement from the clinical staff to be responsible for their own data.
2. Monthly validation meetings are continue with the clinical team and the DM to ensure that all data is checked and signed off. This not only improves the quality of the data but also allows each individual to take ownership of their data.
3. Training is available and discussion of data on a monthly basis is now built into governance proceedings.
4. LGI are developing a Data Quality Tool to highlight any data errors according to the NCHDA Data Manual. This refreshes every 24 hours and is to be used in conjunction with Clinician validation.

Consent for External Validation of Notes.

Under the General Data Protection Regulation (GDPR) of May 2018, it is expected that patients will be made aware by all Organisations who care for them and produce data relating to their medical conditions to be open and transparent about how their data is being kept, used and who it is being shared with and how it may be disposed of. As such, 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 **98.25%** (99, 98. 97.75) with domain scores Demographics 1.0 (1.0, .99, .99) Pre Procedure .96 (.98, .95, .98) Procedure .97 (.96, .995, .96) and Outcome 1.0 (.99, .98, .98 .97).

There were just 20 discrepancies in 838 variables.

This DQI was based on the records of 20 patients who underwent 23 procedures (11 catheters and 12 operations).

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
2009	07/08	88.25%	96.25%
2010(i)	08/09	84.0%	96.0%
2010(ii)	09/10	88%	98.75%
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%

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 1203 procedures (417 operations, 677 catheters 109 others, 17 deaths) had been undertaken during the data collection year of 2018/2019 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 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. The pink operation note, when seen was very helpful in establishing exactly what procedure had been performed.
2. Also as previously documented, perfusion sheets were seen in the case notes of by- pass patients.
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 difficult to find a consistent place in the hospital notes where device labels are placed

<u>Review of the Log Books</u>

Cardiac Operating Theatres

The bespoke bound operating theatre ledgers for 3 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. 1 submitted surgical record appears to have an error in it
2. 4 records were identified from the log book that may have been missed from the congenital submission
3. 1 submitted record was not validated in the log books seen

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. 8 submitted catheter records appear to have errors in them
2. 0 procedures were identified in the cath lab log books which may have been missed from the data submission.
3. 10 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. The requirement for consent to validate these hospital data are the same as for the congenital procedures. Where there is no evidence that consent has been given the Medical Director is asked to give permission for the case note examination. The Validation Team are grateful to Chief Medical Officer for LGI for facilitating this.

17 patients who had had procedures during the 2018/19 data collection year were noted to have died. 4 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, however the date was noted to be incorrect for one of the multiple procedures for one patient
- 1 record appears to have incomplete comorbidities recorded in the data submitted to the NCHDA

- 1 record appears to have an absent post op complication

Case note Audit 2018/19 Data.

20 patients underwent 23 procedures (11 caths, 12 operations)

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

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	23	23		11	12
28	Proc Urgency	23	23		11	12
29	Unplanned Proc	1	1		-	1
30	Single Operator	0	0		-	-
31	Operator 1	23	23		11	12
32	Operator 1 Grade	23	23		11	12
33	Operator 2	23	23		11	12
34	Operator 2 Grade	23	23		11	12
35	Procedure Type	23	23		11	12
36	Sternotomy Sequence	12	12		-	12
37	Operation Performed	23	23	2 incorrect elements	11	12
38	Sizing balloon used for septal defect	0	0		0	-
39	No of stents or coils	1	2	1 incorrect	½	-
40	Device Manufacturer	9	11	1 incorrect, 1 unable to validate	7	2/4
41	Device Model	10	13	1 absent, 2 unable to validate	7	3/6
42	Device Ser No	10	13	1 absent, 2 unable to validate	7	3/6
43	Device Size	18	19	1 absent,	13	5/6
44	Total Bypass Time	12	12		-	12
45	XClamp Time,	12	12		-	12
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	12	12		-	12
51	Post Procedure Seizures	23	23		11	12
52	Post Proc Complications	1	1		-	1
53	Date of Discharge	23	23		11	12
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	23	23		11	12
57	Discharge Destination	23	23		11	12

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.25% Cardiology DQI = 98.5.% Surgery DQI = 97.75%

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,	**Overall .96**	
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	**Card** .95	**Surg** .97
Procedure Date of procedure, Operator 1, Operator 2 Cardiopulmonary Bypass used, Operator 1 grade,	**Overall** .97	
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** .99	**Surg** .94
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death,	**Overall** .99	
Status at Discharge, Discharge Destination. Post Procedure Complications.	**Card** 1.0	**Surg** 1.0

The Trust DQI = 98.25% (99, 98, 97.75**)**

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 Score	**2016**	**2017**	**2018**	**2019**
Demographics	.99	.99	1.0	1.0
Pre Procedure	.98	.95	.98	96
Procedure	.96	.995	.96	97
Outcome	.98	.98	.99	10

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 1.25% increase in the DQI to 99% which is another excellent achievement. In total there were just 10 errors or omissions in 1194 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. There have also again been some extreme technical challenges with the NCHDA database itself that has further impeded timely data submission during the year 2017/18 that have affected almost every congenital centre. It is acknowledged that the very late circulation of the final v6 NCHDA dataset in March 2018 was too late for LGI to update their 4D data collection system. Therefore this validation visit has reviewed the data using the v5.16 of the NCHDA dataset.

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