The National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit For the year 2018/19

Evelina London Children's and St Thomas' Hospitals

Guys & St Thomas NHS Foundation Trust (GSTT)

13 June 2019

performed by Lin Denne, and Dr S Arif

Summary and Overview

The Congenital NICOR data return, prior to this validation visit, from the combined Congenital Cardiac Department of Guy's and St Thomas' NHS Foundation Trust (GSTT) indicated that a total of 988 cases had been undertaken during the year 2017/18. These figures are broken down further below.

Year	Total	Surgery	Catheters	Others
2011/12	777	442	319	16
2012/13	830	488	327	15
2013/14	879	504	348	27
2014/15	980	491	422	67
2015/16	976	497	357	122
2016/17	998	494	390	114
2017/18	1006	620	290	96
2018/19	988	467	436	95

This validation visit has been fully funded by the Guys and St Thomas' NHS Foundation Trust. This visit was supported remotely by the NCHDA clinical audit nurse via a teleconference facility and on site in person by Dr S Arif Consultant in Congenital Cardiology from Birmingham.

The Trust has used HeartSuite for congenital cardiac data collection since January 2004. There is real time data entry by most clinicians and there is access to HeartSuite in all clinical areas. The Trust is now 'paper lite' and almost completely uses an electronic hospital note (e-Noting).

Additional Information and Actions Taken since the previous Validation Visit in 2018.

The NCHDA Review Team are also pleased to acknowledge the following actions implemented since the last visit.

1. The appointment of a dedicated ACHD data analyst.
2. Due to the late supply of datasets for 17/18 and18/19 by NICOR, the Trust were delayed in making submissions.

There were 1.8 WTEs Clinical Nurse Specialists in Audit and Research Data Management (CNSs) at the time of this validation visit who facilitated the congenital audit process, and an ACHD data manager who collaborates closely with the CNSs. As reported previously it is very clear that GSTT consider the matter of collecting good quality, accurate and validated information about patient procedural activity to be of the highest

importance and this has become embedded within the Trust culture. The data, once validated locally, are submitted electronically to National Congenital Heart Disease Audit (NCHDA) managed by NICOR.

Immediately following this validation visit took place, one of the CNS's moved to different role. Therefore at the time of this report there is just 1.0WTE CNS supporting the congenital paediatric data. There are plans in place to recruit a further 1.0WTE post.

As stated at the 2016 validation visit, log books for cardiac operating theatres and catheter laboratories are now electronic (Galaxy/Labyrinth). Combined printouts from both centres are reviewed and a single report on that validation is presented.

Consent for External Validation of Notes.

In May 2018 the General Data Protection Regulation became law in the UK.

At GSTT Foundation Trust there is now displayed and available in all places of patient activity, a leaflet that describes how the Organisation use and share patients personal information to deliver and improve healthcare. There is information in the leaflet that describes what information is kept, how safe it is and whom it may be shared with and whether it is anonymised or not. There is also information for patients who may wish to object to their data being shared and how to do this. Also in the document there is some information on patients' rights to access their medical data.

The overall DQI for the combined data and separate DQI for Surgery and for Catheters at GSTT

The DQI for the Trust is calculated to be (with the previous visit scores are in parentheses), **99.3%** (99, 96, 99.25,**)** The domain scores are as follows: Demographics 1.0 (1.0, 1.0, 1.0), Pre Procedure .99.3 (.96, .94, .98), Procedure .998 (1.0, .97, .99), and Outcome .98 (1.0, .93, 1.0).

This is based on 20 patients who underwent 14 catheter procedures and 11 operations during Apr-March 2018/19. 7 of these procedures were in patients with adult congenital heart disease. 1003 variables were checked and there were 5 queries or omissions identified.

On further review of the overall, when the cases were split into their surgery and catheter groups was;

Year of visit	Data Year Validated	Surgery	Catheters
2011	09/10	97.5%	99.25%
2011	10/11	96.75%	98.5%
2012	11/12	97%	98.75%
2013	12/13	97.5%	96.%
2014	13/14	98%	94.25%
2015	14/15	98.5%	98%
2016	15/16	99.25%	99.5%
2017	16/17	94.75%	97%
2018	17/18	98.75%	99.5%
2019	18/19	99.5%	98.75%

Review of the combined Cath Lab and Theatre Log Books at GSTT on the day revealed that no record have been missed from the data submission**.**

The body of this report is drawn from answers given on the NCHDA Pre Visit Questionnaire and from discussions on the day of the visit.

Technical Issues with Data Submission and Amendment

It should be noted that several NCHDA centres who also use HeartSuite have experienced difficulties with accessing and submitting and editing data to the NICOR database through 2017/18 and 2018/19.

Introduction

The NCHDA data return, prior to this validation visit, from the combined Congenital Cardiac Department of Guy's and St Thomas' NHS Foundation Trust indicated that a total of 988 cases had been undertaken during the year 2018/19. 20 cases were randomly selected for the case note review.

20 sets of notes were requested and a reserve list of 10 other cases was supplied approximately one month prior to this validation visit. On the day of the visit, no sets of notes from the sample were used from the Reserve list.

GSTT is now 'paper-lite'. It was reported at this visit that there are only two documents that remain in paper form. The perfusion record and the preoperative theatre check list. These two documents will become electronic within 12 months of this validation visit. The reviewers are very grateful to the two CNS's for Audit and Data Management for gathering together the ePR documents and reports and creating an individualised electronic NCHDA validation file for each of the patients whose procedures were being validated.

The accuracy of the NCHDA data return was then checked against each set of notes. The accuracy was recorded on a database to enable the (DQI) to be scored for each year being validated.

Review of the patient notes .

1. Perfusion records were seen in all of the notes of surgical patients where appropriate.
2. All individual patient files were meticulously ordered and this aided the review greatly.

Review of the Theatre and Cath Lab Activity Logs

As previously reported, all cardiac surgery is performed in St Thomas's Hospital. There are 4 cardiac operating theatres plus a hybrid operating room. All cath lab activity at Evelina London is recorded in a digital information system – Galaxy. Catheter lab activity in St Thomas' is recorded on Labyrinth. There are 5 cath labs at the St Thomas' site and 2 at Evelina London. One of these rooms is a dedicated MRI cath lab. Since mid-2018 a dedicated procedure room opened for use within the NICU, it has been used to facilitate PDA ligation surgery. Activity is recorded on Galaxy.

Bound paper theatre log books are no longer kept in the operating theatres. As reported in 2013-18, the Trust, in line with NHS & DH guidance is moving to E-records and has invested in NHS approved systems to record and log theatre activity - Galaxy. It is an approved audit tool for theatre activity and reflects the planned procedure using OPCS4.8 coding which in majority of cases will not cross reference accurately to EPCC coding used for the NCHDA national congenital cardiac audit. This is not something which is within the congenital cardiac service's control. Surgical notes (handwritten and typed) act as the gold standard of actual surgical procedure performed

The external visiting clinician was offered a printout from the electronic theatre log 'Galaxy' that is now used. The review revealed;

- 0 surgery procedures were identified that may have been missed from the data submission
- 4 submitted surgery records may have errors in them
- 0 catheter procedures were identified in the cath lab log book which may have been missed from the data submission
- 2 submitted catheter records were identified that may have errors in them
- 5 submitted diagnostic catheter records were identified that have no procedure coding and this is due to the dataset mismatch described above

The Trust is currently reviewing the cases identified above and will make new submissions or amend any errors where appropriate.

Septostomy cases performed outside of the catheter lab are recorded in a folder that is kept by the CNSs and this was seen on the day. The reviewers are pleased to note that these cases are being submitted to Congenital NCHDA.

Validation of Deceased Patients Diagnostic and Procedure Coding

This commenced with the validation of the 2013/14 data. The NCHDA 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.

14 congenital patients were noted on the data harvested for this visit to have died following a procedure. On the day 14 sets of data were made available. It was reported by the CNS's that there were 2 further deaths now reported. Both of these patients died more than 30 days following their procedures.

It is strongly recommended that if information regarding a date of death for a pre-existing congenital patient on the NCHDA database post discharge is, or becomes available this should be submitted to that individual's record in the NCHDA registry. However, this piece of information, once submitted to the NCHDA database is not always easily visible when the data are exported back to the centre.

Of the date the findings are;-

1. All dates of death were confirmed as correct
2. 1 element of a diagnosis string may be incorrect
3. 2 further post >30 day deaths had been identified by the CNS's but were not showing as dead on the extract used for this validation visit.

The Congenital NICOR pre visit Questionnaire was completed and returned prior to the validation visit. This confirmed 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

Casenote Audit

Case note audit based on 20 patients who underwent 12 operations and 9 catheter procedures

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		11	9
2	NHS Number	18	18		11	7
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	25	25		14	11
11	Previous Procedures	34	34		24	10
12	Patients Weight at Operation	25	25		14	11
13	Height	24	24		13	11
14	Ante Natal Diagnosis	2	3	1 absent	2	0/1
15	Pre Proc Seizures	25	25		14	11
16	Pre Proc NYHA	7	7		7	-
17	Pre Proc Smoker	7	7		7	-
18	Pre Proc Diabetes	7	7		7	-
19	Hx Pulmonary Dis	7	7		7	-
20	Pre Proc IHD	7	7		7	-
21	Comorbidity Present	25	25		14	11
22	Comorbid Conditions	12	12		5	7
23	Pre Proc Systemic Ventricular EF	25	25		14	11
24	Pre Proc Sub Pul Ventricular EF	22	23	1 absent	11/12	11
25	Pre-proc valve/septal defect/ vessel size	11	11		11	-
26	Consultant	25	25		14	11

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	25	25		14	11
28	Proc Urgency	25	25		14	11
29	Unplanned Proc	24	25	1 absent	14	10/11
30	Single Operator	1	1		1	-
31	Operator 1	25	25		14	11
32	Operator 1 Grade	25	25		14	11
33	Operator 2	24	24		13	11
34	Operator 2 Grade	24	24		13	11
35	Procedure Type	25	25		14	11
36	Sternotomy Sequence	10	10		-	10
37	Operation Performed	25	25		14	11
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	32	32		30	2
41	Device Model	32	32		30	2
42	Device Ser No	32	32		30	2
43	Device Size	30	30		-	1
44	Total Bypass Time	10	10		-	10
45	XClamp Time,	10	10		-	10
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	14	14		14	-
48	Cath Fluro Time,	12	12		12	-
49	Cath Fluro Dose,	12	12		12	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	11	11		-	11
51	Post Procedure Seizures	25	25		14	11
52	Post Proc Complications	2	2		-	2
53	Date of Discharge	25	25		14	11
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	25	25		14	11
57	Discharge Destination	23	25	2 incorrect	12/14	11

Data Quality Indicator Assessment:
The Overall Trust DQI = 99.3% Cardiology DQI = 98.75% Surgery DQI = 99.5%

Total Procedures = 25 Catheter Procs = 14 Surgery Procs = 11

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 .99.3**	
	Card .99	**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** .998	
	Card 1.0	**Surg** .99
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .98	
	Card .96	**Surg** 1.0

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.	**2019 18/19 data**	**2018 17/18 data**	**2017 16/17 data**	**2016 15/16 data**	**2015 14/15 data**
Demographics	1.0	1.0	1.0	1.0	.99
Pre Procedure	99	.97	.94	.98	.95
Procedure	.998	1.0	.97	.99	.97
Outcome	.98	1.0	.93	1.0	.99

Conclusions

On the whole the NCHDA data for congenital procedures was accurate, well-documented, good quality and was appropriately recorded in the Theatre and Cath Lab Management systems (Galaxy and Labyrinth) at GSTT. The Data Quality Indicator Score has been maintained above 99.3% which is excellent and demonstrates a continuing strong commitment to good quality verified clinical data. There appears to be a very robust culture of clinical audit embedded within the Trust. The Validation Team would like again, to commend the efforts of both of the CNSs and the ACHD Team in maintaining this at a time when there have been considerable technical challenges.

The Trust has developed and regularly reviews SOPs to inform the congenital data collection which further underpins this registry.

The Trust again reported to the validation team (as in 2015-18 site validations) that they have raised a considerable number of fault calls with the NCHDA Helpdesk, some of which are still to be resolved satisfactorily.

Recommendations

1. It is recommended that any Standard operating procedures should be reviewed and Updated in line with any changes to national audit process to ensure that details are current and clear as to **exactly who** is responsible for ;
    a. Input of the data for each procedure and at which point of the service delivery
    b. 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
    c. Reverse validation of the data submitted to NCHDA against locally held 'gold standard' clinical information systems in conjunction with clinician colleagues.
    d. Leading the local review (and how frequently and in which forum for both disciplines)
    e. Making timely submissions (monthly is recommended) where possible.
    f. Ensuring, where possible all manufacturers names, model and serial numbers are submitted for all implantable devices and valves.
    g. It is recommended that all staff connected with NCHDA audit should observe at least one other site validation per year.