The National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit For the year 2019/20

Evelina London Children's and St Thomas' Hospitals

Guys & St Thomas NHS Foundation Trust (GSTT)

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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 934 cases had been undertaken during the year 2019/20. This number of procedures 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
2019/20	934	418	472	43

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 Lead and the NCHDA Clinical Audit Nurse via a video conference facility MS Teams.

Due to the pandemic status this is a pilot study to assess the feasibility and practicability of a totally remote method of NCHDA data validation. The clinical audit nurses and analytic team at GSTT were all remotely interacting and facilitating all parts of this validation. All team members have equal remote access to required data systems and data bases.

3 data managers from other NCHDA centres joined the MS Teams video conference to observe this visit.

The GSTT NHS Trust are in the process of merging congenital cardiac services with an adjacent Trust and it is anticipated that numbers of procedures in both paediatric and ACHD patients will slowly increase as expanded facilities become available.

The GSTT 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 very 'paper lite' and almost completely uses an electronic hospital note (e-Noting).

Actions Taken since the previous Validation Visit in 2019.

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

1. Appointment of Deputy Senior CNS as a replacement following staff promotion
2. Since March 2020 due the pandemic status, the congenital clinical audit and research service has pivoted to mainly remote working alternating with periods of redeployment

There were 2.0 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 a 1.0WTE ACHD data manager who collaborates closely with the CNSs.

Data are primarily input to all systems by clinical colleagues with Consultants and Senior Trainees completing the HeartSuite data at the point of service.

The Centre have a well established embedded culture in clinical audit and all colleagues are encouraged to own their data. Almost all data are collected contemporaneously and reviewed within a described timeframe by the CNS's. Discrepancies are immediately referred back the responsible colleague(s) for urgent review and amendment. Data from this centre are generally submitted within 2-4 weeks of patient discharge.

The data, once validated locally, are submitted electronically to National Congenital Heart Disease Audit (NCHDA) managed by NICOR.

GSTT have been compiling digital data in the manner described and using a number of systems that inter locate for the last 5 years of NCHDA site visits.

Since 2016 the log books for cardiac operating theatres and catheter laboratories have been fully electronic (Galaxy/Labyrinth).

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. The document also contains 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), **97.75%** (99.3, 99, 96**)** The domain scores are as follows: Demographics .99 (1.0, 1.0, 1.0), Pre Procedure .94 (.993, .96, .94), Procedure .99 (.998, 1.0, .97), and Outcome .99 (.98, 1.0, .93).

This is based on 20 patients who underwent 23 procedures (10 catheter interventions and 13 operations). 13 patients were from the ACHD cohort.

There were 24 discrepancies in 933 variables.

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	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%
2020	19/20	99%	97%

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.

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 934 cases had been undertaken during the year 2019/20. 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.

Prior to the visit the CNS's had compiled a digital file of each page from the relevant information system for each patient record. Each patient had their own folder of documents. HeartSuite was only used and shared on screen where the data were not already in the patient folder and were not recorded on any other digital system at GSTT. This was only in exceptional circumstances such as an echo report not detailing ventricular function for both chambers.

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

Review of the digital patient notes on the shared screens.

It must be highlighted that preparing the individual patient folders required meticulous and structured planning, effort and time from the local team to facilitate an efficient flow of the validation process.

All GSTT hosts were very responsive to requests from the Reviewers to check other digital case note documentation when requested. Where print was small, this was magnified for the Reviewers to see.

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.

The Trust, in line with NHSE & DH guidance in moving to E-records and has invested in NHS approved systems to record and log theatre activity – Galaxy Dataweb. It is an approved audit tool for theatre activity and reflects the planned procedure using OPCS4.9 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. Digital surgical notes (handwritten and typed) act as the gold standard of actual surgical procedure performed.

The electronic operating theatre and cath lab records from the Galaxy (OR) and Labyrinth (Cath Labs) were made available for the time period under review. These documents in the form of excel spreadsheets, were shared on screen and each record was checked.

- 31 surgery procedures were identified that may have been missed from the data submission
- 2 submitted surgery records may have errors in them
- 14 submitted records for surgery were not validated in Galaxy
- 0 submitted catheter records were identified that may have errors in them
- 23 catheter procedures were identified in the cath lab log book which may have been missed from the data submission. 13 of these records had been identified by the CNS's immediately prior to the visit.
- 42 submitted catheter procedures were not validated in the shared log books that were screened.

- A further 36 records were identified in the procedure type 'Other' and these were found to mostly for EP/Pacing procedures and should be recategorised as Electrophysiology Catheter.

The Trust have reviewed the cases identified above and have made new submissions or amendments where appropriate.

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. The requirement for patient/parent/guardian consent to review the case notes is the same as for the congenital procedures review.

19 congenital patients were noted on the data harvested for this visit to have died following a procedure. 7 of these fell within 30 days of a therapeutic procedure. On the day 7 sets of digital data were made available on shared screens.

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 data reviewed the findings are;-

- All dates of death were confirmed as correct
- 1 further post >30 day death had been identified by the CNS's after the data extract for this site visit had been made
- 5 records may have discrepancies in the field for Comorbidities

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		8	12
2	NHS Number	20	20		8	12
3	Surname	20	20		8	12
4	First Name	20	20		8	12
5	Sex	20	20		8	12
6	DOB	20	20		8	12
7	Ethnicity	20	20		8	12
8	Patient Status	20	20		8	12
9	Postcode	19	20	1 incorrect	7/8	12
10	Pre Procedure Diagnosis	23	23		10	13
11	Previous Procedures	59	59		26/43	14/16
12	Patients Weight at Operation	23	23		10	13
13	Height	23	23		10	13
14	Ante Natal Diagnosis	1	1		-	1
15	Pre Proc Seizures	23	23		10	13
16	Pre Proc NYHA	13	13		6	7
17	Pre Proc Smoker	13	13		6	7
18	Pre Proc Diabetes	13	13		6	7
19	Hx Pulmonary Dis	13	13		6	7
20	Pre Proc IHD	13	13		6	7
21	Comorbidity Present	23	23		10	13
22	Comorbid Conditions	33	34	1 absent	11	22/23
23	Pre Proc Systemic Ventricular EF	23	23		10	13
24	Pre Proc Sub Pul Ventricular EF	20	20		8	12
25	Pre-proc valve/septal defect/ vessel size	6	6		6	-
26	Consultant	23	23		10	13

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	23	23		10	13
28	Proc Urgency	23	23		10	13
29	Unplanned Proc	-	-		-	-
30	Single Operator	23	23		10	13
31	Operator 1	23	23		10	13
32	Operator 1 Grade	23	23		10	13
33	Operator 2	23	23		10	13
34	Operator 2 Grade	23	23		10	13
35	Procedure Type	23	23		10	13
36	Sternotomy Sequence	11	11		-	11
37	Operation Performed	23	23		10	13
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	8	8		6	2
41	Device Model	8	8		6	2
42	Device Ser No	6	7	1 incorrect	5/6	1
43	Device Size	7	7		6	1
44	Total Bypass Time	8	9	1 incorrect	-	8/9
45	XClamp Time,	9	9		-	9
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	9	10	1 incorrect	9/10	-
48	Cath Fluro Time,	10	10		10	-
49	Cath Fluro Dose,	10	10		10	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	13	13		-	13
51	Post Procedure Seizures	23	23		10	13
52	Post Proc Complications	4	4		4	0
53	Date of Discharge	22	23	1 incorrect	10	12/13
54	Date of Death	1	1		-	1
55	Attribution of Death	1	1		-	1
56	Status at Discharge	23	23		10	13
57	Discharge Destination	23	23		10	13

Data Quality Indicator Assessment:
The Overall Trust DQI = 97.75% Cardiology DQI = 97% Surgery DQI = 99%
. Total Procedures = 23 Catheter Procs = 10 Surgery Procs = 13

DOMAIN	DOMAIN Score	
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	**Overall .99**	
	Card .99	**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 .94**	
	Card .90	**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** .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** .99	
	Card 1.0	**Surg** .985

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.	**2020 19/20 data**	**2019 18/19 data**	**2018 17/18 data**	**2017 16/17 data**	**2016 15/16 data**
Demographics	.99	1.0	1.0	1.0	1.0
Pre Procedure	.94	99	.97	.94	.98
Procedure	.99	.998	1.0	.97	.99
Outcome	.99	.98	1.0	.93	1.0

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. A high Data Quality Indicator Score has been maintained above 97% 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 infrastructure and location challenges.

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

GSTT have clearly made a strong and early commitment to move to entirely electronic record keeping. The electronic log books were first trialled alongside bound logs at the 2014 site visit. For the last 4 years of on site validation visits data have been presented digitally for the patient records and in A3 size print outs from the cath labs (Labyrinth) and operating log books (Galaxy).

The digital presentation of documentation via MS Teams with the external clinician and NCHDA Clinical Auditor remotely connected worked very well for this annual NCHDA validation. This level of connectivity was maintained throughout the day.

The Trust would like to note that they have raised concerns regarding data produced by NICOR that remain unresolved for instance using out of data postcode data that results in extra work at unit level.

The Trust would also like to state that they do not believe that it is good practice for NICOR to ask for unvalidated data to be issued to them for use in analysis. The Trust confirms that at no point will the Organisation support the use of unvalidated data for the production of any reports.

Recommendations

1. It is recommended that any Standard Operating Protocols (SOP) that support the congenital data collection, should continue to be regularly reviewed 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.