National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit

The Great Ormond Street Hospital for Sick Children
NHS Foundation Trust

05 June 2019
(to review data for year 2018-19)

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Summary

NCHDA Report – GOS - 2019

Prior to the theatre and cath lab log book validation at this visits, the data submissions to NCHDA from the cardiac department of the Great Ormond Street Hospital for Sick Children (GOSH) indicated that a total of 1290 procedures (766 surgical, 322 catheter, 202 others, 18 deaths) were undertaken during the data collection year Apr 2018 to March 2019. GOSH is one of the largest congenital centres that submit data to NCHDA.

This validation visit was fully funded by The Great Ormond Street Hospital for Children NHS Foundation Trust.

The Validation Team again wish to acknowledge the very thorough and meticulous preparation of each individual case note or file seen at this visit with each relevant document clearly identifiable.

GOSH Overview

GOSH has used the TOMCAT data management system throughout its cardiac department since 2006. All clinical staff, surgeons, cardiologists, and technicians record clinical data in 'real-time' at the point of treatment. Following consultant clinician approval for each record, the data were submitted to NCHDA electronically.

As noted at the 2016-18 validation visits, the changes to the dataset meant that data collection was very challenging for GOSH to collect and submit. The TOMCAT system had not been upgraded to support the v6 version of the NCHDA dataset as a new information system is being commissioned (EPIC). EPIC is complete information system that encapsulates all hospital and community care.

As in previous years, where possible, data has been collected from various other sources, but without a designated system for this, it has resulted in missing/incomplete data for majority of the new v6 dataset items. This may ultimately impact on the data quality. Great Ormond Street NHS Trust remains committed to collecting and submitting complete and accurate data for NCHDA.

The total number of Audit and Information WTE at GOSH is allocated to be 5.6WTE managed by a Principal Analyst and Information Lead. Each member of the audit team is trained to collect, validate and enter data for either cardiology or cardiac surgery as appropriate. Several members of the cardiac information team left their roles during early 2018 and a new team has been recruited.

During 2019 GOSH will commence using EPIC information system for data collection and submissions.

Actions Undertaken Following Previous Validation Visit in 2018

- Complications and Activity are now reviewed at the weekly mortality and morbidity meetings

Consent for External Validation of Notes.

From 1 April 2007 – May 2018 informed signed patient consent was required for external validation of hospital case 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 that all information relating to their medical conditions will 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 requires individual patient informed consent.

A total sample of 20 sets of notes are required and these are randomly selected from the data submission.

For this validation 19 case notes from the Sample and 1 from the Reserve list were used.

This DQI was based on the records of 20 patients who underwent 26 procedures (5 catheters and 21 operations).

Data Quality Indicator

The DQI for the Trust for this visit (previous year in parentheses) is calculated to be **93%** (95, 99.5, 97, 99.25) with domain scores Demographics 1.0 (1.0 1.0 1.0) Pre Procedure .92 (.87, .99, .94 .99), Procedure .96 (98, .99, .98), and Outcome .84 (.95, 1.0, .95).

There were 56 discrepancies identified in 846 variables audited

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.

Year	Data Year Validated	Surgery DQI	Catheter DQI
2009	07/08	95.25%	95.5%
2010	08/09	94.5%	98.5%
2011	09/10	94.5%	99.5%
2012	10/11	98.5%	97%
2013(i)	11/12	98%	97.75%
2013(ii)	12/13	99.25%	98%
2014	13/14	99.5%	99.5%
2015	14/15	99.5%	99.75
2016	15/16	97.5%	96.75%
2017	16/17	99.75%	98.75%
2018	17/18	95.5%	95%
2019	18/19	92.6%	95%

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

Prior to the validation visit, the NCHDA returns from the cardiac department of The Great Ormond Street Hospital for Sick Children indicate that 1290 procedures were undertaken during the data collection year April 2018 to March 2019.

The NCHDA auditor and one external Consultant Cardiac Surgeon undertook the site visit. The NCHDA clinical auditor supported the site visit via Skype.

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

Review of notes at GOS for 2018-19

As mentioned above, the Validation Team would again like to congratulate the Centre on the most conscientious attention to detail in retrieving and preparing each set of case note documents printed from the ePR. Almost every relevant document that the reviewers needed to examine was carefully identified with a temporary sticky label and this was of immense help.

1. The notes were tidy, and were mostly in chronological order.
2. The anaesthetic and operation records were easy to find
3. Hand written operation notes were also seen, the typed operation note appears to form part of the final discharge summary.
4. The TOMCAT cardiac catheter sheets were also included in some records.
5. Perfusion records were seen and were clearly set out and helpful.
6. Although the time of a patients extubation appeared to be recorded, the date was often not clear.
7. The information team also reported that on occasions it was difficult to identify and retrieve some of the cardiac catheter data from the ePR.
8. As previously reported, all sets of notes it was easy to find discharge summaries and in most cases both primary and secondary diagnosis was contained in the document.

Review of the Log Books

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. 4 submitted surgical records appear to have errors in them
2. 4 submitted records were not validated in the log books
3. 3 records from the log book that may have been missed from the congenital submission

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. There appears to be one log book for all cath labs at this validation where previously each cath lab had its own log book. One log book was offered for validation. This book had ruled outline for different pieces of information such patient demographics and procedure performed and by whom. 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. 5 procedures were identified in the cath lab log books which may have been missed from the data submission.
3. 3 submitted records were not validated
4. 1 record was identified that should be removed as NCHDA do not collect data on TOE only procedures.

Validation of Deceased Patients Diagnostic and Procedure Coding

Commencing with the validation of the 2013/14 data, 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. 18 post procedural deaths were submitted in the data from GOSH for the year 2018/19. 11 of these deaths occurred within 30 days of a therapeutic procedure and these case notes were reviewed.

Review of Deceased Patients Case notes

The procedural and outcome documentation was made available to the Reviewers.

- All dates of death were correct
- 1 record appeared to have incomplete diagnoses coding
- 1 record had an incomplete list of previous procedures
- 4 records appear to have incomplete comorbidities recorded in the data submitted to the NCHDA
- 4 records may have discrepancies in the procedure performed coding
- The field 4.09 Attribution Of Death which is part of this NCHDA dataset was unfilled. This may be due to a technical difficulty.

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;

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		3	17
2	NHS Number	19	19		3	17
3	Surname	20	20		3	17
4	First Name	20	20		3	17
5	Sex	20	20		3	17
6	DOB	20	20		3	17
7	Ethnicity	20	20		3	17
8	Patient Status	20	20		3	17
9	Postcode	20	20		3	17
10	Pre Procedure Diagnosis	26	26	1 missing component	5	20/21
11	Previous Procedures	22	24	2 absent	6/8	16
12	Patients Weight at Operation	25	26	1 incorrect	65	20/21
13	Height	26	26		5	21
14	Ante Natal Diagnosis	3	6	3 incorrect	-	3/6
15	Pre Proc Seizures	24	26	1 absent, 1 incorrect	5	19/21
16	Pre Proc NYHA	-	-		-	-
17	Pre Proc Smoker	-	-		-	-
18	Pre Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre Proc IHD	-	-		-	-
21	Comorbidity Present	24	26	2 absent	5	19/21
22	Comorbid Conditions	14	16	2 absent	3/5	11
23	Pre Proc Systemic Ventricular EF	23	26	3 absent	5	19/21
24	Pre Proc Sub Pul Ventricular EF	19	26	4 incorrect, 2 absent	5	15/21
25	Pre-proc valve/septal defect/ vessel size	-	-		-	-
26	Consultant	26	26		5	21

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	26	26		5	19/21
28	Proc Urgency	24	26	2 absent	5	19/21
29	Unplanned Proc	22	26	4 absent	5	17/21
30	Single Operator	25	26	1 incorrect	5	20/21
31	Operator 1	26	26	1 unable to validate	4/5	21
32	Operator 1 Grade	26	26		5	21
33	Operator 2	24	25	1 unable to validate	¾	21
34	Operator 2 Grade	24	25	1 unable to validate	¾	21
35	Procedure Type	26	26		5	21
36	Sternotomy Sequence	16	17	1 unable to validate	-	16/17
37	Operation Performed	26	26	1 procedure unable to validate	5	21
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	0	1	1 absent	0/1	-
40	Device Manufacturer	2	2		2	-
41	Device Model	2	2		2	-
42	Device Ser No	1	2	1 unable to validate	½	-
43	Device Size	2	2		-	-
44	Total Bypass Time	15	15		-	15
45	XClamp Time,	11	11		-	11
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	4	5	1 unable to validate	4/5	-
48	Cath Fluro Time,	3	5	2 absent	3/5	-
49	Cath Fluro Dose,	5	5		5	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	7	20	10 incorrect, 1 absent, 2 unable to validate	-	7/20
51	Post Procedure Seizures	16	26	10 absent	4/5	12/21
52	Post Proc Complications	-	-		-	-
53	Date of Discharge	25	26	1 incorrect	4/5	21
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	26	26		5	21
57	Discharge Destination	26	26		5	21

The Overall Trust DQI = 93% Cardiology DQI = 95% Surgery DQI = 92.6%

This DQI is based upon the domain scoring below. The methodology for this DQI is provided in the paper the 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 .92**	
	Card .925	**Surg** .915
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 .94	**Surg** .97
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .84	
	Card .95	**Surg** .82

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.

DOMAINS	2016 15/16	2017 16/17	2018 17/18	2019 18/19
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.94	.99	.87	.92
Procedure	.98	.99	.98	.96
Outcome	.96	1.0	.95	.84

Conclusions

On the whole the NCHDA data that was seen was accurate, well documented, and of good quality. There is a strong culture of clinical audit in this centre and this is clearly demonstrated in the improvements in the data quality scores since 2009. The Validation Team would particularly like to commend the Cardiac Information Team for preparing each bundle of case notes with such conscientiousness and attention to detail.

The Data Quality Indicator Score has fallen slightly at this visit. However. the Reviewers would like to acknowledge that a considerable number of the established cardiac information and audit team members have changed within the 6-12 months prior to this validation visit and would commend the smooth running and organisation of the day by the new team members.

The Reviewers find it helpful at site validations for local colleagues both to understand the process in general and also to appreciate the accessibility in reverse of their own data systems; for instance that for regular interventional caths it might be quite easy to find the product codes for implants if they are on the cath form but that for hybrid procedures this can be difficult. That the log book entries for both cath lab and operating room sometimes lacked clarity on what procedure has been done and, if it was for congenital heart disease. The hierarchy order of entries appeared a little random at times which may reflect how data is entered but may also affect what ends up being submitted to NCHDA. So particularly for the people doing procedures and entering the data its quite informative to be present during a validation for a short while. It also very much helps to have someone local around when looking through the notes even when they have been as well marked up as the GOS team had done as some of the cases were very complex.

The NCHDA Validation Team also recognise and appreciate that there has been a number of ongoing technical challenges with the web facing NCHDA database and the late notice of dataset changes. There are now much stricter controls on which data will be accepted by the database at the time that information is ready to submit to the database and this has created a considerable burden for the data managers at all congenital centres. Many centres were unable to meet the deadline for submission and at the time of this validation visit 2 centres had not submitted any data. It is fully anticipated by NCHDA that centres may experience a small drop in the data quality indicator as well.

It is reported that for the next NCHDA validation visit to review the 2019/20 data GOSH will have moved completely to an EPIC complete electronic health record.

Deceased Patients Procedure and Diagnosis data check.

A very small number of discrepancies were identified as listed elsewhere in the report. Otherwise on the whole the data were of good quality.

Recommendations (as in July 2014-18)

1. It is recommended that Standard Operating Protocols for the congenital data collection, are regularly reviewed to ensure that they include detailed guidance on and **exactly who** is responsible for;
   a. Input of the data for each procedure and at which point of the service delivery particularly data that cannot be entered at the time of the procedure such at intubation time and complications.
   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 (where possible) 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. Exporting data from NCHDA where possible and running PRAiS analysis software each month with responsible clinician involvement.
   f. Making timely submissions (monthly is recommended) when the NCHDA Qreg5 database becomes available and
   g. Ensuring all manufacturers names, model and serial numbers are submitted for all implantable devices and valves.
   h. Ensuring the date is clearly stated as well as the time of extubation.
   i. It is recommended that all staff connected with NCHDA audit should observe at least one other site validation per year.
   j. Reviewing/Updating the SOP at timely intervals

2. It is recommended that Senior Trainees should be encouraged to volunteer to assist with validation visits to other centres.