National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit

The Great Ormond Street Hospital for Sick Children
NHS Foundation Trust

06 October 2020
(to review data for year 2019-20)

performed by Lin Denne and Mr S Stoica

Summary

NCHDA Report – GOS - 2020

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 1069 procedures (582 surgical, 421 catheter, 65 others, 12 deaths) were undertaken during the data collection year Apr 2019 to March 2020. 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

Since April 2019 EPIC is now commissioned as the over arching patient information system at GOSH. As noted at the 2016-19 validation visits, the changes to the dataset meant that data collection was very challenging for GOSH to collect and submit. The previous TOMCAT system had not been upgraded to support the v6 version of the NCHDA dataset. EPIC is a complete information system that encapsulates all hospital and community care.

GOSH are now largely paperless to paper-lite. Many of the documents seen at this visit were reprinted from digital sources such as the ePR.

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.

Actions Undertaken Following Previous Validation Visit in 2019

- No changes or actions were reported
- Due to the national pandemic status almost all Audit and Information staff were pivoted to remote working in March 2020.

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 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 18 case notes from the Sample and 2 from the Reserve list were used.

This DQI was based on the records of 20 patients who underwent 26 procedures (9 catheters and 17 operations).

Data Quality Indicator

The DQI for the Trust for this visit (previous year in parentheses) is calculated to be **97.75%** (93, 95, 99.5, 97) with domain scores Demographics 1.0 (1.0 1.0 1.0) Pre Procedure .96 (.92 .87, .99, .94), Procedure .96 (.96,.99, .99), and Outcome .99 (.84, .95, 1.0).

There were 25 discrepancies identified in 883 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
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%
2020	19/20	99%	95.75%

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 1069 procedures (582 surgical, 421 catheter, 65 others, 12 deaths) were undertaken during the data collection year Apr 2019 to March 2020.

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

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 2019-20

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. Each individual file of notes were neat and tidy, and were mostly in chronological order.
2. The anaesthetic and operation records were easy to find
3. Hand written operation notes were also printed, the typed operation note appears to form part of the final discharge summary.
4. Perfusion records were seen and were clearly set out and helpful.
5. The information team also reported that on occasions it was difficult to identify and retrieve some of the cardiac catheter data from the ePR.
6. Serial numbers of implanted devices were sometimes challenging to find in the ePR.
7. 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 Cath lab and Operating Room Log Books

As GOS moved to the EPIC healthcare information system in April 2019 and this includes log books of activity, an extract from the electronic log book for the cardiac operating rooms and cath labs was provided.

The findings were:

1. No errors were detected in the submitted data
2. No extra cases were identified.
3. 51 submitted catheter records appear to have an error in them
4. 0 procedures were identified in the cath lab log books which may have been missed from the data submission.
5. 4 records were not validated in the electronic log books

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. 12 post procedural deaths were submitted in the data from GOSH for the year 2019/20. 8 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
- 2 records appear to have incomplete previous procedure coding
- 3 records appear to have incomplete comorbidities recorded in the data submitted to the NCHDA

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		5	15
2	NHS Number	20	20		5	15
3	Surname	20	20		5	15
4	First Name	20	20		5	15
5	Sex	20	20		5	15
6	DOB	20	20		5	15
7	Ethnicity	20	20		5	15
8	Patient Status	20	20		5	15
9	Postcode	20	20		5	15
10	Pre Procedure Diagnosis	26	26		9	17
11	Previous Procedures	22	26	4 absent	6/8	16/18
12	Patients Weight at Operation	24	26	2 incorrect	8/9	11/17
13	Height	24	24		9	15
14	Ante Natal Diagnosis	6	6		-	6
15	Pre Proc Seizures	26	26		9	17
16	Pre Proc NYHA	1	1	1 unable to validate	0/1	-
17	Pre Proc Smoker	1	1	1 unable to validate	0/1	-
18	Pre Proc Diabetes	1	1	1 unable to validate	0/1	-
19	Hx Pulmonary Dis	1	1	1 unable to validate	0/1	-
20	Pre Proc IHD	1	1	1 unable to validate	0/1	-
21	Comorbidity Present	26	26		9	17
22	Comorbid Conditions	17	19	2 absent	11	8
23	Pre Proc Systemic Ventricular EF	25	26	1 unable to validate	9	16/17
24	Pre Proc Sub Pul Ventricular EF	21	21		9	12
25	Pre-proc valve/septal defect/ vessel size	1	1		1	-
26	Consultant	26	26		9	17

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	26	26		9	17
28	Proc Urgency	26	26		9	17
29	Unplanned Proc	1	1		-	1
30	Single Operator	3	3		3	-
31	Operator 1	26	26		9	17
32	Operator 1 Grade	26	26		9	16/17
33	Operator 2	23	23		6	16/17
34	Operator 2 Grade	23	23		6	17
35	Procedure Type	26	26		9	17
36	Sternotomy Sequence	17	17		-	17
37	Operation Performed	26	26		9	17-
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	1	1		1	-
40	Device Manufacturer	5	9	4 absent	3/7	2
41	Device Model	8	9	1 absent	6/7	2
42	Device Ser No	6	9	3 absent	4/7	2
43	Device Size	6	6		5	1
44	Total Bypass Time	15	15		-	15
45	XClamp Time,	14	14		-	14
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	8	9	1 unable to validate	8/9	-
48	Cath Fluro Time,	7	9	2 unable to validate	7/9	-
49	Cath Fluro Dose,	9	9		9	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	16	17	1 incorrect	-	16/17
51	Post Procedure Seizures	26	26		9	17
52	Post Proc Complications	10	10		2	8
53	Date of Discharge	26	26		9	17
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	26	26		9	17
57	Discharge Destination	26	26		9	17

The Overall Trust DQI = 97.75% Cardiology DQI = 95.75% Surgery DQI = 99%

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 .96**	
	Card .92	**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** .96	
	Card .91	**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** .99

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	2017 16/17	2018 17/18	2019 18/19	2020 19/20
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.99	.87	.92	.96
Procedure	.99	.98	.96	.96
Outcome	1.0	.95	.84	.99

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 increased by 4.75% at this visit which is excellent. This has been a challenging year with many otherwise officebased colleagues now working remotely due to the pandemic status.

The Reviewers find it helpful at site validations where it is possible 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 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.

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 2014-19)

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.