National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit

The Great Ormond Street Hospital for Sick Children
NHS Foundation Trust

20 May 2021
(to review data for year 2020-21)

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Summary

Prior to the theatre and Catheter lab logbook validation at this visit, the data submissions to NCHDA from the cardiac department of the Great Ormond Street Hospital for Sick Children (GOSH) indicated that a total of 977 procedures (535 surgical, 373 catheter, 66 others, 11 deaths) were undertaken during the data collection year Apr 2020 to March 2021. 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. Documents not printed were made available on EPIC by the DBM.

GOSH Overview

EPIC is now commissioned as the overarching patient information system at GOSH. EPIC is a complete information system that encapsulates all hospital and community care.

GOSH are now largely paperless to paper lite. Any printed 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 2020

- 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 and continue to do so at the time of this site visit.

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 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 31 procedures (13 catheters and 18 operations).

Data Quality Indicator

The DQI for the Trust for this visit (previous year in parentheses) is calculated to be **98.5%** (97.75, 93, 95, 99.5,) with domain scores Demographics 1.0 (1.0 1.0 1.0) Pre-Procedure .97 (.96, .92 .87, .99,), Procedure .9 7(.96, .96,.99), and Outcome 1.0 (.99, .84, .95). These scores demonstrate a continued commitment to good quality and internally validated data.

There were just 17 discrepancies identified in 970 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%
2021	20/21	99%	98.25%

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 977 procedures (535 surgical, 373 catheter, 66 others, 11 deaths) were undertaken during the data collection year Apr 2020 to March 2021.

The NCHDA auditor and one external Consultant Paediatric Cardiologist 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 2020-21

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 or highlighter on screen and this was of immense help.

1. Where documents were printed they were neat and tidy, and appeared in chronological order.
2. The anaesthetic and operation records were easy to find
3. In the operation notes that were seen, 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. Serial numbers of implanted devices were sometimes challenging to find in the ePR and on occasions the name of the device manufacturer appeared to be absent from a drop down 'pick' list.
6. As previously reported, in all electronic patient records 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 Logbooks

The EPIC healthcare information system includes electronic logbooks of activity. Both surgical and catheter lab episodes were exported to an Excel spreadsheet and printed out – this was reviewed against the submitted record of procedures.

The findings were:

1. No errors were detected in the submitted catheter data.
2. No extra catheter cases were identified.
3. One catheter record was identified for a patient marked as recently deceased but not yet updated in NCHDA database.
4. Three submitted surgical records may have errors in them.

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. Eleven post procedural deaths were submitted in the data from GOSH for the year 2020/21. Two of these deaths occurred within 30 days of a therapeutic procedure and these case notes were reviewed. As reported above, during the logbook check a further post discharge death was identified and this occurred more than 30 days after procedure.

Review of Deceased Patients Case notes

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

- All dates of death were correct
- All diagnostic, comorbidity and procedural coding was found to be correct
- It was noted that neither of these patients had Field 4.09 Attribution of Death completed yet.

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 regarding:

- 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

Case note Audit:

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		3	17
2	NHS Number	20	20		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	19	19		3	16
9	Postcode	20	20		3	17
10	Pre-Procedure Diagnosis	31	31		13	18
11	Previous Procedures	33	33		22	18
12	Patients Weight at Operation	30	31	1 unable to validate	12/13	18
13	Height	29	31	1 unable to validate, 1 incorrect	12/13	17/18
14	Ante Natal Diagnosis	4	4		-	4
15	Pre-Proc Seizures	30	31	1 incorrect	13	17/18
16	Pre-Proc NYHA	-	-		-	-
17	Pre-Proc Smoker	-	-		-	-
18	Pre-Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre-Proc IHD	-	-		-	-
21	Comorbidity Present	31	31		13	18
22	Comorbid Conditions	30	30		10	19/20
23	Pre-Proc Systemic Ventricular EF	30	31	1 incorrect	12/13	18
24	Pre-Proc Sub Pul Ventricular EF	29	31	1 incorrect, 1 absent	11/13	18
25	Pre-proc valve/septal defect/ vessel size	-	-		-	-
26	Consultant	31	31		13	18

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	31	31		13	18
28	Proc Urgency	31	31		13	18
29	Unplanned Proc	0	0		0	0
30	Single Operator	8	8		8	-
31	Operator 1	31	31		13	18
32	Operator 1 Grade	31	31		13	18
33	Operator 2	23	23		5	18
34	Operator 2 Grade	23	23		5	18
35	Procedure Type	31	31		13	18
36	Sternotomy Sequence	15	15		-	15
37	Operation Performed	31	31		13	18
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	0	1	1 absent	0/1	-
40	Device Manufacturer	2	6	4 absent	1/3	1/3
41	Device Model	4	6	2 absent	3	1/3
42	Device Ser No	4	6	2 absent	3	1/3
43	Device Size	1	1		1	-
44	Total Bypass Time	12	12		-	12
45	x Clamp Time,	9	9		-	9
46	Total Arrest	1	1		-	1
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	16	16		-	16
51	Post Procedure Seizures	31	31		13	18
52	Post Proc Complications	3	3		-	3
53	Date of Discharge	31	31		13	18
54	Date of Death	0	0		-	0
55	Attribution of Death	0	0		-	0
56	Status at Discharge	31	31		13	18
57	Discharge Destination	31	31		13	18

The Overall Trust DQI = 98.5% Cardiology DQI 98.25% 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 .97**	
	Card .95	**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 .**97	
	Card .98	**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** 1.0	
	Card 1.0	**Surg** 1.0

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	2018 17/18	2019 18/19	2020 19/20	2021 20/21
Demographics	1.0	1.0	1.0	1.0
Pre-Procedure	.87	.92	.96	.97
Procedure	.98	.96	.96	.97
Outcome	.95	.84	.99	1.0

Conclusions

Overall, 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 previously office-based colleagues now working remotely due to the pandemic status. This appears to have been a very successful transition.

The Reviewers find it helpful at site validations where it is possible for local colleagues both to understand the process in general and 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 logbook 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.

Deceased Patients Procedure and Diagnosis data check.

A very small number of discrepancies were identified as listed elsewhere in the report. Otherwise overall the data were of very good quality. One extra post discharge death was identified incidentally during the logbook checks. As reported elsewhere, this death had occurred more than 30 days after procedure.

Recommendations (as in July 2014-20)

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 either in person or vitually.
   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.