National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit

The Great Ormond Street Hospital for Sick Children NHS Foundation Trust

26 May 2022

(to review data for year 2021-22)

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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 1040 procedures (526 surgical, 466 catheter, 48 others, 2 deaths within 30 days of a Specific Procedure) were undertaken during the data collection year Apr 2021 to March 2022. 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 the overarching patient information system at GOSH and 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; including a Data Quality and Information Manager and Trust wide, an Information Manager specific to NCHDA 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 2021

- No changes or actions were reported
- Following the national pandemic status in March 2020 almost all Audit and Information staff were pivoted to remote working and continue to do so at the time of this site visit with visits to the base office as required.

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 20 case notes from the Sample and nil from the Reserve list were used.

This DQI was based on the records of 20 patients who underwent 23 procedures (5 catheters and 18 operations).

Data Quality Indicator

The DQI for the Trust for this visit (previous year in parentheses) is calculated to be **99.25%** (98.5, 97.75, 93, 95,) with domain scores Demographics 1.0 (1.0 1.0 1.0) Pre-Procedure .98 (.97, .96, .92), Procedure .99 (.97, .96, .96), and Outcome 1.0 (1.0, .99, .84). These scores demonstrate a continued commitment to good quality and internally validated data.

There were just nine discrepancies identified in 828 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 five procedures in either group are required for the differential DQI calculation.

Year	Data Year Validated	Surgery DQI	Catheter DQI
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	92.5%	95%
2020	19/20	99%	95.75%
2021	20/21	99%	98.25%
2022	21/22	98.75%	100%

The body of this report is drawn from answers given on the NCHDA pre visit questionnaire and from discussions and actions 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 1040 procedures (526 surgical, 466 catheter, 48 others, 6 deaths within 30 days of a Specific Procedure) were undertaken during the data collection year Apr 2021 to March 2022.

The NCHDA auditor and one external Consultant Paediatric Cardiologist undertook the site visit.

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 2021-22

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. 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

Cardiac Operating Theatres

GOS moved to the EPIC healthcare information system in April 2019 and an extract from the electronic log book for the cardiac operating rooms and cath labs was provided on screen.

The findings were:

1. No errors were detected in the submitted catheter data
2. No extra catheter cases were identified
3. Two surgical procedures in the GOS electronic log were identified that may have been missed from the NCHDA submission.

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. 2 deaths that occurred within 30 days post procedure were submitted in the data from GOSH for the year 2021/22. 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
- All diagnostic, comorbidity and procedural coding was found to be correct.

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		5	15
2	NHS Number	18	18		5	13
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	19	19		5	15
9	Postcode	20	20		5	15
10	Pre-Procedure Diagnosis	23	23		5	18
11	Previous Procedures	33	34	1 incorrect	4	29/30
12	Patients Weight at Operation	23	23		5	18
13	Height	23	23		5	18
14	Ante Natal Diagnosis	2	2		-	2
15	Pre-Proc Seizures	23	23		5	18
16	Pre-Proc NYHA	-	-		-	-
17	Pre-Proc Smoker	-	-		-	-
18	Pre-Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre-Proc IHD	-	-		-	-
21	Comorbidity Present	23	23		5	18
22	Comorbid Conditions	40	40		3	37

23	Pre-Proc Systemic Ventricular EF	23	23		5	16/18
24	Pre-Proc Sub Pul Ventricular EF	22	22		5	14/17
25	Pre-proc valve/septal defect/ vessel size	-	-		-	-
26	Consultant	23	23		5	18

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	23	23		5	18
28	Proc Urgency	23	23		5	18
29	Unplanned Proc	2	2		-	2
30	Single Operator	0	0		5	18
31	Operator 1	23	23		5	18
32	Operator 1 Grade	23	23		5	18
33	Operator 2	23	23		5	18
34	Operator 2 Grade	23	23		5	18
35	Procedure Type	23	23		5	18
36	Sternotomy Sequence	14	17	3 incorrect	-	14/17
37	Operation Performed	23	23		5	18
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	-	-		-	-
40	Device Manufacturer	5	6	1 absent	¾	2
41	Device Model	6	6		4	2
42	Device Ser No	6	6		4	2

43	Device Size	5	5		4	1
44	Total Bypass Time	17	17		-	17
45	x Clamp Time,	17	17		-	17
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	5	5		5	-
48	Cath Fluro Time,	5	5		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	18	18		-	18
51	Post Procedure Seizures	23	23		5	18
52	Post Proc Complications	3	3		-	3
53	Date of Discharge	23	23		5	18
54	Date of Death	1	1		-	1
55	Attribution of Death	1	1		-	1
56	Status at Discharge	23	23		5	18
57	Discharge Destination	23	23		5	18

The Overall Trust DQI = 99.25% Cardiology DQI 100% Surgery DQI = 98.75%

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 .98**	
	Card 1.0	**Surg** .97
Procedure	**Overall .**99	

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,**	**Card** 1.0	**Surg** .98
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	2019 18/19	2020 19/20	2021 20/21	2022 21/22
Demographics	1.0	1.0	1.0	1.0
Pre-Procedure	.92	.96	.97	.98
Procedure	.96	.96	.97	.99
Outcome	.84	.99	1.0	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 a further 0.75% at this visit which is excellent. This has been another challenging year with many otherwise previously office-based colleagues now working remotely. 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 sometimes be difficult.

The logbook entries for both cath lab and operating room sometimes lacked specific detail of 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 Reviewers are grateful to the consultant intensivist who joined them.

Deceased Patients Procedure and Diagnosis data check.

The data were of very good quality and found to be correct.

Recommendations (as in July 2014-21)

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 extubating.
   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 virtually.
   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.