National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit

The Great Ormond Street Hospital for Sick Children NHS Foundation Trust

9 May 2024

(to review data for year 2023-24)

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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 1057 procedures (574 surgical, 458 catheter, 25 others, 6 deaths within 30 days of a Specific Procedure,) were undertaken during the data collection year Apr 2023 to March 2024. GOSH is one of the largest congenital centres that submit data to NCHDA.

Following review of the catheter laboratory and operating room activity logs (EPIC Worklists) on the day of the validation visit, no additional procedures were identified for this Registry.

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 patient 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. When data are to be submitted to NCHDA there is a purposely designed and in built pre set export algorithm to collect NCHDA dataset fields from EPIC ready for submission to the national database.

Great Ormond Street NHS Trust remains committed to collecting and submitting complete and accurate data for NCHDA.

The Validation Team are aware there is currently 1.0WTE dedicated Cardiac Audit Data and information Manager for NCHDA only. This individual has many other add on roles and responsibilities in addition to the NCHDA data collection. The standard requirement as stated in the Congenital Heart Disease Review (NHSE May 2016; recommendation B32(L1) is that each Specialist Surgical Centre must have a minimum of 1.0 WTE dedicated paediatric cardiac surgery/cardiology data collection manager, with at least 1.0 WTE dedicated assistant, responsible for audit and database submissions in accordance with necessary timescales. This is further underpinned by The Report of the Independent Review of Children's Cardiac Services in Bristol (June 2016 Grey, Kennedy 1.22(2) and Ch17).

Actions Undertaken Following Previous Validation Visit in 2023:

- Timely submissions (monthly or within 2 weeks of a procedure is recommended) to the NCHDA Qreg5 database are being made.

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 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 **99.4%** (97, 99.25**,** 98.5,) with domain scores Demographics 1.0 (1.0 1.0 1.0) Pre Procedure .975 (.93, .98, .97, .96), Procedure 1.0 (.98, .99, .97), and Outcome 1.0 (985, 1.0, 1.0).

There were 7 discrepancies identified in 889 variables audited.

The bulk of the discrepancies were seen in the field for previous procedures.

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
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%
2023	22/23	97.25%	97.5%
2024	23/24	99.55	99.75%

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 1057 procedures (574 surgical, 458 catheter, 25 others, 6 deaths within 30 days of a Specific Procedure) were undertaken during the data collection year April 2023 to March 2024. The Reviewers were made aware during the visit that there is currently an NHS waitlist easing initiative in place for patients at GOS who require a surgical procedure. These operations are performed at a neighbouring private hospital that has theatre and paediatric ITU capacity.

The NCHDA auditor and one external Consultant Paediatric Cardiologist undertook the site visit. There were two data managers from other NCHDA centres in attendance as observers.

The accuracy of the NCHDA data return was 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 2023-24

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 data item in each relevant document that the reviewers needed to examine was carefully identified with a highlighter, 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. It was noted that one neonatal patient had a length (height) recorded as 34cms. This appears to be incorrect but has not been allowed to impact the DQI. Height/length is not a mandatory field for patients aged less than 2 years, but if the field is populated these data are validated.

4. In the operation notes that were seen, the typed procedure note appears to form part of the final discharge summary in surgical patients.
5. Perfusion records were seen and were clearly set out and helpful.
6. As previously reported, in the electronic patient records it was easy to find discharge summaries and, in most cases, both primary and secondary diagnosis was contained in the document. However, there did not always appear to be a standard format for details to be included in these narratives.

Review of the Cath lab and Operating Room Logbooks

As stated above, 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 discrepancies were detected in the submitted catheter or surgery data
2. It was noted that a small number of GOS surgical cases, as part of a waiting list initiative, are being undertaken at another hospital, some of the data fields are not fully complete.

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. 6 deaths that occurred within 30 days post procedure were submitted in the data from GOSH for the year 2023/24. 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 found to be correct
- 1 record may have an incomplete list of comorbidities.
- 2 records may have incomplete post codes

This year in 2024, it was noted that in most of the hospital notes seen in this part of the audit, that it was more clearly documented whether or not there had been a discussion with the local Medical Examiner or Coroner. However no copies of the Death Certificates were seen. These documents, if included in the hospital notes, are extremely helpful when undertaking this part of the review.

NCHDA Pre Visit Questionnaire.

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 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		8	12
2	NHS Number	16	16		6	10
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	20	20		8	12
10	Pre-Procedure Diagnosis	26	26		9	17
11	Previous Procedures	44	50	6 absent	2	42/48
12	Patients Weight at Operation	26	26		9	17
13	Height	26	26	1 incorrect in a neonate	9	17
14	Ante Natal Diagnosis	3	4	1 incorrect	0/1	3
15	Pre-Proc Seizures	26	26		9	17
16	Pre-Proc NYHA	-	-		-	-
17	Pre-Proc Smoker	-	-		-	-
18	Pre-Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre-Proc IHD	-	-		-	-
21	Comorbidity Present	26	26		9	17

22	Comorbid Conditions	31	31		7	24
23	Pre-Proc Systemic Ventricular EF	26	26		9	17
24	Pre-Proc Sub Pul Ventricular EF	20	20		4	16
25	Pre-proc valve/septal defect/ vessel size	2	2		2	-
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	3	3		-	3
30	Single Operator	0	0		-	-
31	Operator 1	26	26		9	17
32	Operator 1 Grade	26	26		9	17
33	Operator 2	26	26		9	17
34	Operator 2 Grade	26	26		9	17
35	Procedure Type	26	26		9	17
36	Sternotomy Sequence	16	16		-	16
37	Operation Performed	26	26		9	17
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	-	-		-	-
40	Device Manufacturer	8	8		6	2

41	Device Model	8	8		6	2
42	Device Ser No	8	8		6	2
43	Device Size	8	8		6	2
44	Total Bypass Time	12	12		-	12
45	x Clamp Time,	6	6		-	6
46	Total Arrest	-	-		-	-
47	Cath Proc Time,	8	8		8	-
48	Cath Fluro Time,	7	7		7	-
49	Cath Fluro Dose,	7	7		7	-

	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	26	26		9	17
52	Post Proc Complications	7	7		0	7
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 = 99.4% Cardiology DQI 99.75% Surgery DQI = 99.5%

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 .975**	
	Card .99	**Surg** .98
Procedure	**Overall 1.0**	

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** 1.0
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	2021 20/21	2022 21/22	2023 22/23	2024 23/24
Demographics	1.0	1.0	1.0	1.0
Pre-Procedure	.97	.98	.93	.975
Procedure	.97	.99	.98	1.0
Outcome	1.0	1.0	.985	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 Manager for preparing each bundle of case notes with such conscientiousness and attention to detail.

The Data Quality Indicator Score is excellent at this visit at 99.4%.

It is noted that there appears to have been a significant decrease in the numbers of whole time equivalent (WTE) posts supporting the NCHDA data collection to a total of 1.0WTE. As noted elsewhere in this report the recommended national Standard as stated in the Congenital Heart Disease Review (NHSE May 2016; recommendation B32(L1) is that each Specialist Surgical Centre must have a minimum of 1.0 WTE dedicated paediatric cardiac surgery/cardiology data collection manager, with at least 1.0 WTE dedicated assistant, responsible for audit and database submissions in accordance with necessary timescales.

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. It was not ideal that the location for this site visit was in a building across a busy road, away from the main clinical cardiac hub of the hospital.

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 NCHDA Data Manager had done as some of the cases were very complex.

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.

Deceased Patients Procedure and Diagnosis data check.

The data that were seen were of very good quality and found to be correct. There were just a few discrepancies relating to the fields for Discharge Destination and Attribution of Death.

Recommendations (as in July 2014-22)

1. It is strongly recommended that in line with the New Congenital Heart Disease Review National Standard (NHSE July 2016) recommendation B32(L1), that there should be a minimum of 1.0 WTE dedicated senior paediatric cardiac surgery/cardiology data collection manager and 1.0WTE assistant paediatric cardiac surgery/cardiology data collection manager in post.
2. It is recommended that in order to encourage more clinician engagement on the day of the site validation, that the room used for this review is as near to the clinical hub to enable colleagues to drop in as time permits.
3. It is recommended that Standard Operating Protocols for the congenital data collection, continue to be regularly reviewed to ensure that they include appropriate 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. To consider the layout and content of discharge/death summaries in relation to diagnosis and the chronology of procedures performed.
    j. Where a patient has died within 30 days of a procedure, documenting whether or not there was a discussion with the Medical Examiner or Coroner (when required), was

discussed at an MDT and whether or not the death was related to the procedure as these are NCHDA dataset items.

k. Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.

4. 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.

5. Reviewing/Updating the SOP at timely intervals

6. It is recommended that all Consultant Cardiac Clinicians encourage their Senior Trainees (ST6 and above) to volunteer to assist with validation visits to other centres.