National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit

The Great Ormond Street Hospital for Sick Children NHS Foundation Trust

8 May 2025

(to review data for year 2024-25)

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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 1003 procedures (502 surgical, 467 catheter, 34 others, 1 death within 30 days of a Specific Procedure) were undertaken during the data collection year Apr 2024 to March 2025. 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 electronic health record (EHR) EPIC. 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.

As previously stated, 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. Also as previously noted at this visit, 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 2024:

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

Consent for External Validation of Notes.

As previously stated, 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 0 from the Reserve list were used.

This DQI was based on the records of 20 patients who underwent 22 procedures (9 catheters and 13 operations).

Data Quality Indicator

The DQI for the Trust for this visit (previous year in parentheses) is calculated to be 99.75**%** (99.4, 97, 99.25) with domain scores Demographics 1.0 (1.0 1.0 1.0) Pre Procedure .99 (.975, .93, .98, .97), Procedure 1.0 (1.0, .98, .99), and Outcome 1.0 (1.0, 985, 1.0).

There were 3 discrepancies identified in 735 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%
2025	24/25	100%	99.3%

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 1003 procedures (502 surgical, 467 catheter, 34 others, 1 death within 30 days of a Specific Procedure,) were undertaken during the data collection year April 2024 to March 2025. The Reviewers were made aware during the visit that there was an NHS waitlist easing initiative in place for patients at GOS who require a surgical procedure during the earlier part of the data period under review. These operations are performed at a neighbouring private hospital that has theatre and paediatric ITU capacity.

The NCHDA auditor and one external Paediatric Cardiology Specialty Trainee (ST6) undertook the site visit. There was one data manager from another NCHDA centre in attendance as an observer.

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 2024-25

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. In the operation notes that were seen, the typed procedure note appears to form part of the final discharge summary in surgical patients.
4. Perfusion records were seen and were clearly set out and helpful.
5. 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, as previously reported, 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 catheter labs was provided on screen.

The findings were:

1. 6 discrepancies were detected in the submitted catheter data that may be procedures missed from the submission. Post visit the DBM has confirmed that these cases have been examined and those appropriate have now been submitted.
2. 8 discrepancies were found in the submitted surgery data that may be procedures missed from the submission. Post visit the DBM has confirmed that these cases have also been examined and those appropriate have now been submitted.
3. 99 submitted records may have pieces of data absent from fields in their submission: either because these patients were still an inpatient at the time of the data extract on 3 April, their inpatient episode had concluded but their digital file had not been completed, or the record had been and signed but had accidentally not been submitted.
4. It was noted that where other GOS surgical cases, as part of a waiting list initiative, are being undertaken at another hospital and these records had empty second operator fields in their entry. This information was submitted in the free text field of each relevant record.

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. 1 death that occurred within 30 days post procedure was submitted in the data from GOSH for the year 2024/25. These case notes were reviewed.

Review of Deceased Patients Case notes

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

- All data were found to be correct

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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

Digital Maturity 2025

As documented elsewhere, GOS use EPIC and as such all users have access to all relevant parts according to their role in health care at the Trust. This EHR has been in use since 2019 at GOSH and is an overarching patient information system that encapsulates all hospital and community care.

There are some paper records at the point of care such as for recording vital observations or clinical notes but these are scanned and added to the EHR in a timely manner.

All activity in the operating rooms and catheter labs are recorded in EPIC at the point of service. There are no bound log books. The NCHDA data fields are completed automatically and are internally validated prior to submission to the national database.

Case note Audit:

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		7	13
2	NHS Number	18	18		7	13
3	Surname	20	20		7	13
4	First Name	20	20		7	13
5	Sex	20	20		7	13
6	DOB	20	20		7	13
7	Ethnicity	20	20		7	13
8	Patient Status	20	20		7	13
9	Postcode	20	20		7	13
10	Pre-Procedure Diagnosis	22	22	1 element incorrect	9	13
11	Previous Procedures	39	41	2 absent	18/20	21
12	Patients Weight at Operation	22	22		9	13
13	Height	22	22		9	13
14	Ante Natal Diagnosis	2	2		-	2
15	Pre-Proc Seizures	22	22		9	13
16	Pre-Proc NYHA	-	-		-	-
17	Pre-Proc Smoker	-	-		-	-
18	Pre-Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre-Proc IHD	-	-		-	-
21	Comorbidity Present	22	22		9	13
22	Comorbid Conditions	12	12		7	5
23	Pre-Proc Systemic Ventricular EF	18	18		8	10
24	Pre-Proc Sub Pul Ventricular EF	22	22		9	13
25	Pre-proc valve/septal defect/ vessel size	-	-		-	-
26	Consultant	22	22		9	13

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	22	22		9	13
28	Proc Urgency	22	22		9	13
29	Unplanned Proc	-	-		-	-
30	Single Operator	2	2		2	-
31	Operator 1	22	22		9	13
32	Operator 1 Grade	22	22		9	13
33	Operator 2	18	18		7	13
34	Operator 2 Grade	18	18		7	13
35	Procedure Type	22	22		9	13
36	Sternotomy Sequence	11	11		-	11
37	Operation Performed	22	22		9	13
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	-	-		-	-
40	Device Manufacturer	7	7		6	1
41	Device Model	7	7		6	1
42	Device Ser No	7	7		6	1
43	Device Size	6	6		5	1
44	Total Bypass Time	11	11		-	11
45	x Clamp Time,	8	8		-	8
46	Total Arrest	0	0		-	-
47	Cath Proc Time,	9	9		9	-
48	Cath Fluro Time,	6	6		6	-
49	Cath Fluro Dose,	6	6		6	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	10	10		-	10
51	Post Procedure Seizures	22	22		9	13
52	Post Proc Complications	4	4		-	4
53	Date of Discharge	22	22		9	13
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	22	22		9	13
57	Discharge Destination	22	22		9	13

The Overall Trust DQI = 99.75% Cardiology DQI 99.3% Surgery DQI = 100%

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 .99**	
	Card .975	**Surg** 1.0
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 1.0**	
	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	2022 21/22	2023 22/23	2024 23/24	2025 24/25
Demographics	1.0	1.0	1.0	1.0
Pre-Procedure	.98	.93	.975	.99
Procedure	.99	.98	1.0	1.0
Outcome	1.0	.985	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 like to commend the Cardiac Information Manager for preparing each bundle of case notes again this year with such conscientiousness and attention to detail.

The Data Quality Indicator Score is excellent at this visit at 99.75%.

It is noted that there still appears to a lack of 1.0WTE whole time equivalent (WTE) posts supporting the NCHDA data collection. 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 are grateful to Dr Graham Derrick for making time to spend with them. It is very helpful at site validations where it is possible for local colleagues to participate, both to understand the process in general and to appreciate the accessibility in reverse of their own data systems. 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 catheter lab and operating room occasionally 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.

Recommendations (as in July 2014-24)

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.

l. Where GOS congenital operations have taken place in another hospital under a wait list initiative, the GMC number and name should be added manually to the data on the NCHDA database.

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.