The National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit
For the year April – March 2023-24

Barts Health NHS Trust

Tuesday 1 October 2024

performed by Lin Denne and Dr M Johns

Summary

Prior to the theatre and cath lab logbook validation at this visit, the data submission to NCHDA from the department for Adult Congenital Heart Disease at Barts Health NHS Trust indicated that a total of 448 procedures (92 surgical, 358 catheter procedures, 0 others, and 2 deaths within 30 days of a specific procedure) were undertaken during the data collection year April 2023 to March 2024.

Following review of the catheter laboratory and operating room activity log books on the day of the validation visit, 17 additional procedures were identified and where found to be suitable were subsequently submitted to the Registry.

This validation visit has been fully funded by the Barts Health NHS Trust. The site visit was carried out on site in person by Dr M Johns, Specialty Trainee (ST8) in Congenital Cardiology from London and Liverpool and the NCHDA Audit Nurse.

In April 2015 The Heart Hospital cardiac unit moved to the St Bartholomew's' NHS foundation Trust site (SBH).

As previously reported, there are 9 consultant cardiologists at SBH that specialise or have an interest in adult congenital cardiology. There are 2 Congenital surgeons who undertake Congenital cardiac operations at SBH and who also practice at Great Ormond Street Hospital for Children which is in an adjacent NHS Foundation Trust.

Also, as previously reported at SBH, there is a 1.0. WTE Senior Clinical Nurse Specialist (CNS) for the National Adult Cardiac Surgery Audit (NACSA) registry and a 1.0WTE supporting data manager/analyst. These 2 individuals also have full responsibility with no particular time ring fenced to collect manage and quality control, NCHDA data. For NCHDA this also involves the internal validation with the responsible clinicians prior to submission.

The NHSE Standards Specification for Adult Congenital Heart Disease state (NHSE May 2016, B33L1) a dedicated 1.0WTE data collection manager should be responsible for ACHD audit and database submissions in accordance with necessary timescales

At SBH there is a specially created web-based Dendrite Intellect data collection system for NCHDA data. Data are collected in real time at the point of treatment.

Consent for External Validation of Notes.

Since May 2018, the General Data Protection Regulation has required that patients are made aware of how their data are collected and used. As such, NCHDA now no longer requires a specific consent to examine hospital case notes. If a patient has expressed a wish not to allow their case notes to be examined by others not connected to their care, these wishes will be respected.

A random list of case notes; 20 Samples and 10 Reserves were provided approximately 4 weeks prior to the Validation Visit. On the day all sets of case notes were made available from the Reserve list. These 20 patients had 22 procedures (5 operations and 17 catheter procedures)

Actions Undertaken Following Previous Validation Visit in 2023:

1. SBH report that the 2020-2023 NCHDA published outcome data has been reviewed which indicated a low denominator.
2. SBH also report that progress is being made with increasing surgical activity.
3. SBH would like to report that auditing the surgical outcomes data internally is now more frequent.

Data Quality Indicator

The DQI for the Trust for this visit (previous years in parentheses) is calculated to be **98.6%** (98.25, 98, 97.5) with domain scores Demographics .99 (1.0, 1.0, 1.0), Pre Procedure .97 (.95, .94, .96), Procedure .98 (.98, .98, .96, .95, and Outcome 1.0 (1.0, 1.0, .98,)

This represents another very good score. There were 880 variables reviewed for 20 patients who underwent 5 operations and 17 catheter procedures. 18 errors or discrepancies were identified. The Team were unable to validate 9 further fields relating to ventricular function

The fields where most discrepancies are:

Previous Procedures	4 discrepancies
Pre-Procedure Ventricular Function	2 discrepancies and a further 9 unable to validate

Since 2009, separate DQI scores are being calculated for both catheters and surgery. The DQI is calculated from the case note review only. A minimum number of 5 records are required in either group for this to be done.

Year of visit	Data year being validated	Surgery Procedures	Catheter Procedures
2015	**14/15**	**93.5%**	**95.25%**
2016	**15/16**	**91.75%**	**93.75%**
2017	**16/17**	**97.75%**	**96%**
2018	**17/18**	**100% (3 records only)**	**96.5%**
2019	**18/19**	**99%**	**95.75%**
2020	**19/20**	**99.25%**	**97.25%**
2021	**20/21**	**95.75%**	**97.75%**
2022	**21/22**	**98%**	**97.75%**
2023	**22/23**	**98.5%**	**98.25%**
2024	**23/24**	**98.5%**	**98.75%**

The NCHDA pre visit Questionnaire confirmed that there are good processes and procedures in place with 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.

Introduction

As previously stated, prior to the validation visit, the Congenital NCHDA return from the cardiac department at St Bartholomew's Hospital (SBH) indicate that a total of 448 procedures (92 surgical, 358 catheter procedures, 0 others, and 2 deaths within 30 days of a specific procedure) were undertaken during the data collection year April 2023 to March 2024.

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.

Review of notes at Barts Health NHS Trust

On the day 20 sets of case notes from the Sample list supplied were available and no sets of case notes were required from the Reserve list. The packs of hospital notes for each patient were a mix of paper records and printed documents from the ePR, prepared for the Validation Visit with all key data items indicated by temporary sticky notes to assist with finding information. SBH are 'paper-lite' with a mixture of electronic 'e' noting systems and with some retention of paper bound files. The paper notes that were seen were excellently prepared.

1. As previously, the NHS Number was found in the hospital notes seen at this visit as the DBM had printed out a registration document which has a field for this identifier.
2. As noted at previous validations, there does not appear to be consistent documentation of data items such as NYHA, diabetes, pulmonary or ischaemic heart disease in every set of the hospital notes but it is improving. These fields are part of the NCHDA dataset.
3. As reported in previous years, documentation of systemic and sub pulmonary ventricular function was variable and sometimes very difficult to identify and was often completely absent in the pre procedure hospital notes of patients who undergo catheter closure of a PFO.
4. For patients who have single ventricles it is only necessary to complete the field for systemic ventricular function.
5. As previously described, there does not appear to be consistent documentation of time of skin puncture to time of sheath removal (as opposed to time/time out of cath lab) in catheter procedures descriptions. although it was reported at the 2021-23 visits that this

data point is recorded in the cathlab information system Labyrinth. The Reviewers are grateful to a colleague who was able to access the Labyrinth system and provide these data as required during the case note examination.

6. The make, model and serial/lot number of any device left in the patient is required to be submitted to NCHDA. Details of soft materials such as patches or pacing wires are not required.
7. The labels of implanted devices were most very easy to find in the printed data presented from the ePR.
8. Regular reverse validation of data submitted to NCHDA is promoted as good practice and is an excellent way to gauge quickly and easily if data are correct, accurate and complete. It is important that this exercise is undertaken with the responsible consultants on a regular basis to encourage clinician ownership of the data.

Case Ascertainment validation

Both sets of electronic data (activity logs) supplied for the activity ascertainment are described below.

Review of the Theatre log books

There are reported to be 10 cardiac operating theatres at SBH. The local CNS for Cardiac Audit offered the Reviewers extracts from the electronic log books of activity as recorded on the local iWeb application.

As previously reported, it was difficult to scrutinise entries for younger patients whose procedures were not performed by known congenital surgeons as the diagnoses does not appear to be routinely recorded on each entry.

- 4 surgical records were identified that may be suitable for inclusion in NCHDA

Review of the Cath Lab Activity logs

There are reported to be 10 cardiac catheter labs at SBH. As at previous site validation visits, the Senior CNS for Cardiac Audit offered the Reviewers extracts from the log books of activity as recorded on the local iWeb application. It was difficult sometimes to identify

exactly what procedure had been performed on the date stated and whether or not it was for congenital heart disease.

- 13 catheter records were identified that may be suitable for inclusion in NCHDA. Many of these were for electrophysiology procedures such as radio frequency ablation or devices

The Senior CNS for Cardiac Surgery Audit which includes NCHDA at this centre, also checks the cardiac surgery lists daily for the known congenital surgeons planned activity.

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 the demographic, diagnostic and procedural data of deceased patients included in the year under review. The diagnosis and procedure coding will also be validated.

Two 30 day post procedural deaths were submitted in the data from SBH for the year 2023/2024. The Coroners Report or a detailed discharge summary were available for both deaths and were extremely helpful for this part of the data Review. The CNS for the NCHDA data confirmed that there are regular, at least quarterly, report enquiries run for life status of patients to enable timely record update of any out of hospital deaths.

1. All dates of death were correct
2. 1 record appears to have absent previous procedures and comorbidities
3. All other data appeared to be correct.

Discharge summaries were seen and documentation of the outcome of discussions with the local Medical Examiner or Coroner were also made available.

Case Note Audit 2024

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		15	5
2	NHS Number	20	20		15	5
3	Surname	20	20		15	5
4	First Name	20	20		15	5
5	Sex	20	20		15	5
6	DOB	20	20		15	5
7	Ethnicity	19	20	1 incorrect	14/15	5
8	Patient Status	20	20		15	5
9	Postcode	20	20		15	5
10	Pre Procedure Diagnosis	21	22	1 incorrect, 2 incomplete	17	
11	Previous Procedures	46	50	4 absent	32/36	
12	Patients Weight at Operation	21	22	1 incorrect	16/17	
13	Height	21	22	1 incorrect	16/17	
14	Ante Natal Diagnosis	-	-		-	
15	Pre Proc Seizures	22	22		17	5
16	Pre Proc NYHA	21	22	1 incorrect	17	4/5
17	Pre Proc Smoker	21	22	1 incorrect	17	4/5
18	Pre Proc Diabetes	22	22		17	5
19	Hx Pulmonary Dis	22	22		17	5

20	Pre Proc IHD	22	22		17	5
21	Comorbidity Present	22	22		17	5
22	Comorbid Conditions	24	26	2 incorrect	21	3/5
23	Pre Proc Systemic Ventricular EF	20	22	2 incorrect	17	5
24	Pre Proc Sub Pul Ventricular EF	21	21		17	4
25	Pre-proc valve/septal defect/ vessel size	7	7		7	-
26	Consultant	22	22		17	5

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	22	22		17	5
28	Proc Urgency	22	22		17	5
29	Unplanned Proc	-	-		-	-
30	Single Operator	5	5		5	-
31	Operator 1	22	22		17	5
32	Operator 1 Grade	22	22		17	5
33	Operator 2	17	17		12	5
34	Operator 2 Grade	17	17		12	5
35	Procedure Type	22	22		17	5

36	Sternotomy Sequence	4	4		-	4
37	Operation Performed	22	22		17	5
38	Sizing balloon used for septal defect	7	7		7	-
39	No of stents or coils	0	1	1 absent	0/1	-
40	Device Manufacturer	18	18		15	3
41	Device Model	19	19		15	4
42	Device Ser No	17	19	1 incorrect, 1 absent	13/15	4
43	Device Size	14	14		11	3
44	Total Bypass Time	4	4		-	4
45	XClamp Time,	4	4		-	4
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	17	17	1 incorrect	16/17	-
48	Cath Fluro Time,	16	16		16	-
49	Cath Fluro Dose,	16	16		16	-

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	3	3		-	3

51	Post Procedure Seizures	22	22		17	5
52	Post Proc Complications	-	-		-	-
53	Date of Discharge	22	22		17	5
54	Date of Death	1	1		1	-
55	Attribution of Death	1	1		1	-
56	Status at Discharge	22	22		17	5
57	Discharge Destination	22	22		17	5

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.6% Cardiology DQI = 98.75% Surgery DQI = 98.5%

<table>
<tr><th>DOMAIN</th><th colspan="2">DOMAIN Score</th></tr>
<tr><td rowspan="2"><u>Demographics</u>

Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,</td><td colspan="2">Overall .99</td></tr>
<tr><td>Card
.99</td><td>Surg
1.0</td></tr>
<tr><td rowspan="2"><u>Pre Procedure</u>

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</td><td colspan="2">Overall .97</td></tr>
<tr><td>Card
.98</td><td>Surg
.94</td></tr>
<tr><td><u>Procedure</u></td><td colspan="2">Overall .98</td></tr>
</table>

<table>
<tr><td>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,</td><td>Card
.98</td><td>Surg
1.0</td></tr>
<tr><td rowspan="2"><u>Outcome</u>

Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination.
Post Procedure Complications.</td><td colspan="2">Overall 1.0</td></tr>
<tr><td>Card
1.0</td><td>Surg
1.0</td></tr>
</table>

The Trust DQI = 98.6%

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.

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DOMAINS	2021	2022	2023	2024
Demographics	1.0	1.0	1.0	.99
Pre Procedure	.96	.94	.95	.97
Procedure	.96	.98	.98	.98
Outcome	.98	1.0	1.0	1.0

Conclusions

On the whole the NCHDA data were accurate, well documented and of good quality. The NCHDA Senior CNS and audit nurse and analyst are to be commended for the considerable time spent in preparing many documents for this validation. Especially where they have other much larger cardiac audit responsibilities outside of ACHD. These individuals have no ring fenced time to maintain NCHDA.

The overall DQI has been maintained at a very good standard and increased to 98.6% since the last NCHDA Validation. There were 18 discrepancies in 880 variables. However, 9 variables for ventricular function were unrecorded in patients with PFOs who would have passed through a specific MDT where this data could be captured and noted.

The Validation Team are aware that there is not any regular reverse validation (where the submitted data retrieved and reviewed) of the submitted data with the responsible clinicians. However, as stated in 2017 - 2019, there was an audit and quality process being devised as documented elsewhere to address this in particular and clinicians would be encouraged to take ownership of their data. The COVID pandemic clearly paused this further. It is not clear if this has been fully addressed since that time.

It should be noted that NICOR are now commissioned by NHSE to collect data within 2 weeks of a hospital procedure taking place and to publish these data quarterly within 2 weeks of quarter end. This is applicable across all NCAP Registries.

As previously reported, there does not appear to be consistent documentation yet of data items such as NYHA, diabetes, pulmonary or ischaemic heart disease in the hospital notes that are part of the NCHDA dataset for ACHD patients. This is improving gradually

Discharge dates were seen in all the patients daily narrative notes. There still does not appear to be consistently defined and itemised documentation of time of skin puncture to time of sheath removal in catheter procedures. As previously reported, xray dose and length of time of xray exposure are currently required fields for NCHDA and these were seen at this visit. Radiation exposure should be submitted in cGy CM^2 centigrays squared as required by

the NCHDA. However, if any gold standard data source is to be used to validate case ascertainment, it must include the patients names to make the process more timely.

Validation of Deceased Patients Demographic, Diagnostic and Procedure Coding

A very small number of discrepancies in the coding were identified but all other data appeared to be correct.

Recommendations

1. I It is strongly recommended that in line with the ACHD Specialist Surgical Standards (NHSE May 2016, B33L1) that the Senior CNS Audit Nurse and Data Analyst for NCHDA have ring 1.0WTE fenced time, to be responsible for ACHD data quality monitoring with responsible clinicians as well as database submissions in accordance with necessary timescales
2. It is recommended that Standard Operating Protocols when finalised, are regularly reviewed for the Congenital data collection, to include detailed guidance on and **exactly who** is responsible (and in what timeframe) for;
    a. Ensuring that in line with the GDPR, all patients/parents and guardians are given full information of how their data are securely recorded, stored and where or who this information is shared with. And opt out explained to patients/carers.
    b. Ensuring that patient who undergo catheter closure of PFO have data for function of both ventricles recorded in their MDT discussion documentation as these are required for NCHDA.
    c. Ensuring responsible clinician input of the procedure data for each operation, diagnostic or catheter intervention at the point of the service delivery and ownership of the data;
    d. Encouraging clear succinct description of the exact procedure performed in the digital log books used.
    e. Ensuring that radiation dose is recorded in cGY/CM^2
    f. Ensuring data fields that cannot be entered at the time of the procedure, such as extubation date and time and complications are completed as soon as possible and prior to discharge.
    g. 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
    h. Ensuring diagnosis coding reconciles with the procedure performed
    i. Recording of implanted device data and the placement of product labels in an agreed portion of the patients hospital record that can easily be validated.

j. Leading the local review with the Lead Clinician for Congenital Heart Disease (and how frequently and in which forum for both disciplines)
k. Where a patient has died within 30 days of a procedure, documenting whether or not there was a discussion with the 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.
l. Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.

m. Making timely submissions where possible, NHSE require within 2 weeks of a procedure and
n. Timely reverse validation together with the Clinical Lead for Congenital Cardiology and the responsible clinicians
o. Reviewing/Updating the SOP at timely intervals

3. It is recommended that there is a more robust method of identifying patients with congenital heart disease who undergo pacing or EP procedures with adult cardiologists are clearly identifiable in the ePR activity logs to enable more accurate and timely data capture.
4. It is recommended that the Congenital dataset fields should be set to mandatory in any of the data collection software used.
5. Documentation (either hard copy or on screen help) should be available to all staff in all areas where data are recorded real time.