The National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit For the year 2021/22

Barts Health NHS Trust

Wednesday 28 September 2022

performed by Lin Denne and Dr H Parry

Summary
Prior to the theatre and cath lab logbook validation at this visit, the data submission to NCHDA from the cardiac department of the Adult Congenital Heart Disease unit Barts Health NHS Trust indicated that a total of 398 procedures (82 surgical, 314 catheter procedures, 2 others, and 4 deaths within 30 days of a specific procedure) were undertaken during the data collection year April 2021 to March 2022.

This validation visit has been fully funded by the Barts Health NHS Trust. This visit was supported remotely by the NCHDA clinical audit nurse via a MS Teams facility and on site in person by Dr H Parry, Consultant in Congenital Cardiology.

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

There are seven consultant cardiologists at SBH that specialise in adult congenital cardiology. There are two 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.

At SBH there is a 1.0 WTE Clinical Nurse Specialist (CNS) for NCHDA cardiac audit and a data manager who coordinate the collection and submission of these data. These individuals also have full responsibility for the National Adult Cardiac Surgery Audit (NACSA) registry.

At SBH there is a specially created web-based Dendrite Intellect data collection system for NCHDA data. Data is 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 four weeks prior to the Validation Visit. On the day, one set 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 2021:

None reported

Data Quality Indicator

The DQI for the Trust for this visit (previous years in parentheses) is calculated to be **98%** (97.5, 98, 96.6) with domain scores Demographics 1.0 (1.0, 1.0, 1.0), Pre Procedure .94 (.96, .97, .925), Procedure .98 (.96, .95, .94), and Outcome 1.0 (.98, 1.0, 1.0).

This represents another very good score. Well done. There were 945 variables reviewed for 20 patients who underwent five operations and 17 catheter procedures. 30 errors or discrepancies were identified.

The fields where most discrepancies are:

Pre-Procedure Comorbidities	4
Pre-Procedure Ventricular Function	8
Catheter Procedure Time (Sheath in/out)	8

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 five records are required in either group for this to be done.

Year of visit	Data year being validated	Surgery Procedures	Catheter Procedures
2014(ii)	13/14	89%	88.75%
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%

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

Prior to the validation visit, the Congenital NCHDA return from the cardiac department at St Bartholomew's Hospital (SBH) indicate that a total of 398 procedures (82 surgical, 314 catheter procedures, 2 others, and 4 deaths within 30 days of a specific procedure) were undertaken during the data collection year April 2021 to March 2022.

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 19 sets of case notes from the sample list supplied were available. One set of case notes were available from the reserve list. The packs of hospital notes for each patient were mostly printed from the ePR and prepared for the Validation Visit with all key documents 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.

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 the hospital notes but it is improving. These fields are part of the NCHDA dataset.
3. Documentation of systemic and sub pulmonary ventricular function was variable and sometimes very difficult to identify in the pre procedure hospital notes of patients.
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 in catheter procedures descriptions. Although it was reported at the 2021 visit that this data point is recorded in the cathlab information system Labyrinth.
6. Discharge destination (for example home/other specialty in same hospital/convalescence) did not always appear to be recorded in the patients daily narrative notes.
7. The make, model and serial/lot number of any device left in the patient is required to be submitted to NCHDA.

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.

Case Ascertainment validation

Both sets of electronic data supplied for the activity ascertainment described below were without patient names. This made the validation very long and very challenging and at times cumbersome to cross reference activity recorded against what had been submitted. It is more helpful to the process to include patients' names.

Review of the Theatre log books

There are reported to be 10 cardiac operating theatres at SBH. The local Data Manager offered the reviewers extracts from the Cerner Millennium Surgery Scheduler (Surginet).

It was certainly much easier to check case ascertainment across multiple theatres for known congenital cardiac surgeons. However, 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. Descriptions of operations were often stated as 'other operative procedure' which was not very helpful.

- Three surgical records were identified that may be suitable for inclusion in NCHDA
- Two submitted surgery records appear to have errors in them.

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.

Review of the Cath lab logbooks

There are reported to be 10 cardiac catheter labs at SBH. The local CNS/Data Manager offered the reviewers extracts from the Gallery Partnership Labyrinth Cardiac Catheter Scheduler. This is essentially a booking system and does not appear to support OPCS or ICD10 codes. It was extremely difficult sometimes to identify exactly what procedure had been performed on the date stated and whether or not it was for congenital heart disease. Some patients appeared to have multiple entries.

- Four submitted catheter records may have errors in them
- Four records were identified in Labyrinth that may be suitable for inclusion in NCHDA
- Two records may be a procedure for acquired disease and if so, this should be removed from the NCHDA database.

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. Four post procedural deaths were submitted in the data from SBH for the year 2021/2022.

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

1. One record may have an incomplete previous procedure listing
2. Two records appear to have incomplete comorbidity fields
3. One record appears to have an incomplete listing of post op complications.

The Senior CNS for cardiac audit confirmed that regular six-monthly checks on the NHS Spine were undertaken to capture any out of hospital deaths of NCHDA patients.

Case Note Audit 2022

	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	20	20		15	5
8	Patient Status	20	20		15	5
9	Postcode	20	20		15	5
10	Pre Procedure Diagnosis	21	22	1 incomplete	16/17	5
11	Previous Procedures	44	44		35	9
12	Patients Weight at Operation	22	22		17	5
13	Height	22	22		17	5
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	22	22		17	5
16	Pre Proc NYHA	21	22	1 incorrect	16/17	5
17	Pre Proc Smoker	19	22	3 incorrect	15/17	4/5

18	Pre Proc Diabetes	22	22		17	5
19	Hx Pulmonary Dis	21	22	1 incorrect	17	4/5
20	Pre Proc IHD	22	22		17	5
21	Comorbidity Present	21	22	1 incorrect	16/17	5
22	Comorbid Conditions	18	22	4 absent	17/19	3/5
23	Pre Proc Systemic Ventricular EF	18	22	4 incorrect	14/17	4/5
24	Pre Proc Sub Pul Ventricular EF	18	22	4 incorrect	13/17	5
25	Pre-proc valve/septal defect/ vessel size	7	7		6/7	-
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	2	2		2	-
31	Operator 1	22	22		17	5

32	Operator 1 Grade	22	22		17	5
33	Operator 2	20	20		15	5
34	Operator 2 Grade	20	20		15	5
35	Procedure Type	22	22		17	5
36	Sternotomy Sequence	5	5		-	5
37	Operation Performed	21	22	1 incorrect	17	4/5
38	Sizing balloon used for septal defect	7	7		7	-
39	No of stents or coils	1	1		1	-
40	Device Manufacturer	16	16		15	1
41	Device Model	16	16		15	1
42	Device Ser No	16	16		15	1
43	Device Size	14	14		13	1
44	Total Bypass Time	5	5		-	5
45	XClamp Time,	5	5		-	5
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	9	17	8 incorrect	9/17	-
48	Cath Fluro Time,	16	17	1 incorrect	16/17	-
49	Cath Fluro Dose,	17	17		17	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	5	5		-	5
51	Post Procedure Seizures	22	22		17	5
52	Post Proc Complications	-	-		-	-
53	Date of Discharge	22	22		17	5
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	22	22		17	5
57	Discharge Destination	22	22		17	5

Data Quality Indicator Assessment:

The Overall Trust DQI = 98% Cardiology DQI = 97.75% Surgery DQI = 98%

<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 1.0</td></tr>
<tr><td>Card
1.0</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 .94</td></tr>
<tr><td>Card
.95</td><td>Surg
.94</td></tr>
<tr><td><u>Procedure</u></td><td colspan="2">Overall .98</td></tr>
</table>

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** .96	**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

The Trust DQI = 98%

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	2020	2021	2022
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.925	.97	.96	.94
Procedure	.94	.95	.96	.98
Outcome	1.0	1.0	.98	1.0

Conclusions

On the whole the NCHDA data were accurate, well documented and of good quality. The NCHDA CNS/Data Manager and analyst are to be commended for the considerable time spent in preparing many documents for this validation.

The overall DQI has been maintained at a very good standard and increased to 98% since the last NCHDA Validation. There were 30 discrepancies in 945 variables.

The Validation Team are aware that there is not any regular reverse validation (where the submitted data retrieved and reviewed) of the data submitted to the NCHDA and the case notes are not always used to collect and/or validate data prior to submission. 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-19 pandemic clearly paused this further. It is not known at this visit what the current status of this process is.

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. This is improving gradually. It was very difficult again to find echo reports in some patients' hospital notes and patients who have undergone electrophysiological procedures didn't always appear to have a detailed discharge summary in their hospital notes.

Discharge dates and destination did not always appear to be recorded in the patients daily narrative notes in the past, but this does appear to be more frequent at this visit. There still does not appear to be consistent documentation of time of skin puncture to time of sheath removal in catheter procedures. As previously reported, x-ray dose and length of time of x-ray exposure are currently required fields for NCHDA and it was again challenging to find this information in the hospital records of patients who had undergone pacing or electrophysiological procedures, although much of this data is reported to be recorded in Labyrinth. Surginet is an excellent operating room digital record, but clearer more succinct descriptions of the procedures actually performed should be used rather than the nonspecific 'other operative procedure'. However, if any gold standard data source is to be used to validate

case ascertainment, it must include the patient's names to make the process more timely and less cumbersome and unwieldy.

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. 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 responsible clinician input of the procedure data for each operation, diagnostic or catheter intervention at the point of the service delivery.
    c. Encouraging clear succinct description of the exact procedure performed in the digital log books used.
    d. Ensuring data fields that cannot be entered at the time of the procedure, such as intubation time and complications are completed prior to discharge.
    e. 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.
    f. Ensuring diagnosis coding reconciles with the procedure performed.
    g. Recording of implanted device data and the placement of product labels in an agreed portion of the patient's hospital record that can easily be validated.
    h. Leading the local review with the Lead Clinician for Congenital Heart Disease (and how frequently and in which forum for both disciplines).
    i. 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.
    j. Making timely submissions where possible (monthly is recommended) and
    k. Timely reverse validation together with the Clinical Lead for Congenital Cardiology and the responsible clinicians.
    l. Reviewing/Updating the SOP at timely intervals.

2. It is recommended that the Congenital dataset fields should be set to mandatory in any of the data collection software used.
3. Documentation (either hard copy or on-screen help) should be available to all staff in all areas where data are recorded real time.