The National Congenital Heart Disease Audit

Procedures for
CONGENITAL HEART DISEASE

Data Quality Audit
For the year 2019/20

Barts Health NHS Trust

Thursday 24 September 2020

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Summary

Prior to the theatre and cath lab log book 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 439 procedures (92 surgical, 311 catheter procedures, 36 others, 3 deaths) were undertaken during the data collection year April 2019 to March 2020.

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 Alan Magee, Consultant in Congenital Cardiology.

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

There are 5 consultant cardiologists at SBH that specialise in adult congenital cardiology. There are 2 Congenital surgeons who visit to undertake Congenital cardiac operations at SBH who also practice at Great Ormond Street Hospital for Children which is in an adjacent NHS Foundation Trust.

At the new SBH unit, 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 was now a specially created data collection system for NCHDA and this went 'live' from March 2016 based on a Dendrite Intellect database that is web based. 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 2 sets of case notes were made available from the Reserve list. These 20 patients had 20 procedures7(6 operations and 13 catheter procedures)

Actions Undertaken Following Previous Validation Visit in 2019:

- It was reported that there is now a new MDT template in use to facilitate a more complete NCHDA data capture.
- ACHD clinicians now attend the MDT for patients with aortic valve disease to facilitate identity of late presentation of previously unknown ACHD patients at SBH.

Data Quality Indicator

The DQI for the Trust for this visit (previous years in parentheses) is calculated to be **98%** (96.6, 96.5, 96.75) with domain scores Demographics 1.0 (1.0, 1.0, 1.0), Pre Procedure .97 (.925, .93, .94), Procedure .95 (.94,.94, .94), and Outcome 1.0 (1.0, .99, .99).

This represents a very good score. Well done. There were 807 variables reviewed for 20 patients who underwent 7 operations and 13 catheter procedures. 21 errors or discrepancies were identified.

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
2013	11/12	94.75%	94.75%
2014(i)	12/13	96.5%	93.5%
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%

The NCHDA pre visit Questionnaire from 2018 was reused for this validation visit. This 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 439 procedures (92 surgical, 311 catheter procedures, 36 others, 3 deaths) were undertaken during the data collection year April 2019 to March 2020.

The NCHDA clinical auditor and a Consultant in Congenital Cardiology undertook this visit. The NCHDA clinical auditor participated remotely via MS Teams and the external clinician Dr Magee was on site at SBH in person.

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 primary list supplied were available. 7 case notes were available from the Reserve list. The notes were prepared for the Validation Visit with some but not 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 reported, the paper notes were rather untidy, not always in chronological order.
2. 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.
3. There does not appear to be consistent documentation of data items such as NYHA, diabetes, pulmonary or ischaemic heart disease in the hospital notes yet but it is improving. These fields are part of the NCHDA dataset.
4. Where there were several entries in the hospital notes for preoperative heights and weights of patients, this appeared at times to be very variable around the same date of operations and interventions. It was difficult sometimes to gauge which was the correct measurement.
5. Discharge dates do not always appear to be recorded in the patients daily narrative notes.

6. As previously reported, there does not appear to be consistent documentation of time of skin puncture to time of sheath removal in catheter procedures
7. Xray dose and length of time of xray exposure are required fields for NCHDA and it was difficult to find this information in the hospital records of patients who had undergone pacing or electrophysiological procedures.
8. Make, model and serial/lot number of any device left in the patient is required to be submitted to NCHDA
9. 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.

Review of the Theatre log books

There are reported to be 10 cardiac operating theatres at SBH. The request to view the bound log books was declined by the OR Manager. So 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.

- 3 records were identified that may be suitable for inclusion in NCHDA
- 2 submitted records appear to have errors in them
- 1 submitted surgical record may not be for congenital cardiac surgery
- 2 records submitted in the surgical categories were not validated
- 7 records submitted for surgery appear to be incorrectly categorised and should catheter EP procedures.

Review of the Cath lab log books

There are reported to be 10 cardiac catheter labs at SBH. The request to view the bound log books was declined by the Cath Labs Manager. So the local Data Manager offered the Reviewers extracts from the Labyrinth 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.

Due to time pressures, the Reviewers looked at the months of April 2019 to (and including) September 2019 but this was extremely time consuming.

- 2 submitted catheter records may have errors in them
- Records submitted for 1 October to 31 March 2020 were not validated due to time pressures and difficulty with deciphering Labyrinth.
- 7 records were identified in Labyrinth that may be suitable for inclusion in NCHDA

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. 3 post procedural deaths were submitted in the data from SBH for the year 2019/2020.

1. 1 record may have an incomplete previous procedure listing
2. 2 records appear to have incomplete comorbidity fields

Case Note Audit 2020

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

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	20	20		13	7
28	Proc Urgency	20	20		13	7
29	Unplanned Proc	0	0		-	-
30	Single Operator	4	4		4	-
31	Operator 1	18	20	2 incorrect	11/13	7
32	Operator 1 Grade	20	20		13	7
33	Operator 2	16	17	1 incorrect	8/9	7
34	Operator 2 Grade	17	17		9	7
35	Procedure Type	20	20		13	7
36	Sternotomy Sequence	5	5		-	5
37	Operation Performed	20	20		13	7
38	Sizing balloon used for septal defect	4	4		4	-
39	No of stents or coils	1	2	1 absent	½	-
40	Device Manufacturer	10	10		7	3
41	Device Model	13	13		10	3
42	Device Ser No	13	13		10	3
43	Device Size	8	8		6	2
44	Total Bypass Time	6	6		-	6
45	XClamp Time,	5	5		-	5
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	8	13	7 unable to validate	6/13	-
48	Cath Fluro Time,	11	11		11	-
49	Cath Fluro Dose,	11	11		11	-

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	6	6		-	6
51	Post Procedure Seizures	20	20		13	7
52	Post Proc Complications	0	0		-	-
53	Date of Discharge	20	20		13	7
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	20	20		13	7
57	Discharge Destination	20	20		13	7

Data Quality Indicator Assessment:

The Overall Trust DQI = 98% Cardiology DQI = 97.25% Surgery DQI = 99.25%

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 .97**	
	Card .96	**Surg** .97
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** .95	
	Card .93	**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

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.

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DOMAINS	2017	2018	2019	2020
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.94	.93	.925	.97
Procedure	.94	.94	.94	.95
Outcome	.99	.99	1.0	1.0

Conclusions

On the whole the NCHDA data were accurate, well documented and of good quality. As mentioned elsewhere, the case notes were a little chaotic at times.

The overall DQI has been maintained at a very good standard and increased to 98% since the last NCHDA Validation. There were just 21 discrepancies in 807 variables.

The Validation Team are aware that there is no 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 is an audit and quality process being devised as documented elsewhere to address this in particular and clinicians will be encouraged to take ownership of their data.

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 discharge summary in the their hospital notes.

Discharge dates do not always appear to be recorded in the patients daily narrative notes and there does not appear to be consistent 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 it was again challenging to find this information in the hospital records of patients who had undergone pacing or electrophysiological procedures.

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 op out explained to patients/carers.
   b. Input of the NCHDA ACHD demographic, pre procedure, procedure and outcome data
   c. Input of the data for each patients procedure and at which point of the service delivery
   d. 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.
   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. Leading the local review with the Lead Clinician for Congenital Heart Disease (and how frequently and in which forum for both disciplines)
   g. Making timely submissions where possible (monthly is recommended) and
   h. Timely reverse validation together with the Clinical Lead for Congenital Cardiology and the responsible clinicians
   i. Reviewing/Updating the SOP at timely intervals
   j. Ensuring that relevant case and procedural records and logs are extracted and printed from electronic sources if used, in advance to be easily accessible by the Auditors on the day of the visit

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