The National Congenital Heart Disease Audit

Procedures for
CONGENITAL HEART DISEASE

Data Quality Audit
For the year 2018/19

Barts Health NHS Trust

Tuesday 7 August 2019

performed by Lin Denne and Dr H Bellsham Revell

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 400 procedures (99 surgical, 271 catheter procedures, 30 others, 5 deaths) were undertaken during the data collection year April 2018 to March 2019.

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 Skype facility and on site in person by Dr Hannah Belsham Revell, Consultant in Congenital Cardiology from London.

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

There are 5 consultant cardiologists at SBH that specialise in adult congenital cardiology. There are 3 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 7 sets of case notes were made available from the Reserve list. These 20 patients had 21 procedures (6 operations and 15 catheter procedures)

Actions Undertaken Following Previous Validation Visit in 2018:

- It was reported that there is now a new MDT template in use to facilitate a more complete NCHDA data capture.

Data Quality Indicator

The DQI for the Trust for this visit (previous years in parentheses) is calculated to be **96.6%** (96.5, 96.75, 93.25%) with domain scores Demographics 1.0 (1.0, 1.0, .99), Pre Procedure .925 (.94, .94, .88), Procedure .94 (.94, 94, .89), and Outcome 1.0 (.99, .97, .96).

There were 40 discrepancies in 867 variables.

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	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%

The NCHDA pre visit Questionnaire was completed and returned prior to the 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 400 procedures (99 surgical, 271 catheter procedures, 30 others, 5 deaths) were undertaken during the data collection year April 2018 to March 2019.

The NCHDA clinical auditor and a Consultant in Adult Congenital Cardiac Surgery undertook this visit. The NCHDA clinical auditor participated remotely via a Skype link and the external clinician Dr Bellsham Revell attended 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 and occasionally rather chaotic.
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 that 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 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 8 cardiac operating theatres at SBH and the log books were made available for theatre 8 as this is where most (but not all) congenital operations occur. It was noted that the log book that covered April to June 2018 was missing, its location unknown. It was extremely difficult to clearly identify exactly what procedure had been performed and whether or not it was for congenital heart disease.

- 3 records were identified that may be suitable for inclusion in NCHDA
- 3 submitted records appear to have errors in them
- 1 submitted surgical record may not be for congenital cardiac surgery
- 23 records submitted in the surgical categories were not validated and some of these may be incorrectly categorised

Review of the Cath lab log books

There are reported to be 10 cardiac catheter labs at SBH and the log books were made available for labs 2, 7 and 10. These are mainly bespoke volumes with columns for information such as patients name, DOB, hospital number, operators details and the name and date of the operation performed. It was again extremely difficult to identify exactly what procedure had been performed and whether or not it was for congenital heart disease. The handwriting of entries was also very difficult to decipher at times. There appears to be a number of abbreviations used to describe procedures in all the books seen with no transcription of what they actually mean.

- 7 submitted catheter records may have errors in them
- 134 submitted diagnostic or interventional catheter records were not validated in the log books that were seen
- 24 records were identified in the catheter log books 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. 2 post procedural deaths were submitted in the data from SBH for the year 2018/2019.

1. 1 date of death appears to be incorrect
2. 1 record appears to have incomplete complications fields

All other data appeared to be correct.

Case Note Audit 2019

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
1	Hospital Number	20	20		14	6
2	NHS Number	20	20		14	6
3	Surname	20	20		14	6
4	First Name	20	20		14	6
5	Sex	20	20		14	6
6	DOB	20	20		14	6
7	Ethnicity	20	20		14	6
8	Patient Status	20	20		14	6
9	Postcode	20	20		14	6
10	Pre Procedure Diagnosis	21	21		15	6
11	Previous Procedures	20	26	6 absent	20/25	0/1
12	Patients Weight at Operation	21	21		15	6
13	Height	21	21		15	6
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	21	21		15	6
16	Pre Proc NYHA	17	21	4 incorrect	11/15	6
17	Pre Proc Smoker	16	21	5 incorrect	11/15	5/6
18	Pre Proc Diabetes	21	21		15	6
19	Hx Pulmonary Dis	21	21		15	6
20	Pre Proc IHD	19	21	2 incorrect	13/15	6
21	Comorbidity Present	6	7	1 incorrect	¾	3
22	Comorbid Conditions	6	7	1 absent	¾	3
23	Pre Proc Systemic Ventricular EF	21	21		15	6
24	Pre Proc Sub Pul Ventricular EF	16	20	4 incorrect	13/15	4/5
25	Pre-proc valve/septal defect/ vessel size	4	4		4	-

26	Consultant	21	21		15	6

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	21	21		15	6
28	Proc Urgency	21	21		15	6
29	Unplanned Proc	2	2		2	-
30	Single Operator	21	21		15	6
31	Operator 1	21	21		15	6
32	Operator 1 Grade	21	21		15	6
33	Operator 2	16	17	1 incorrect	10/11	6
34	Operator 2 Grade	15	17	1 incorrect	9/11	6
35	Procedure Type	21	21		15	6
36	Sternotomy Sequence	6	6		-	6
37	Operation Performed	21	21		15	6
38	Sizing balloon used for septal defect	1	1		1	-
39	No of stents or coils	4	5	1 absent	4/5	-
40	Device Manufacturer	14	14		10/11	3
41	Device Model	14	14		11	3
42	Device Ser No	12	14	2 absent	9/11	3
43	Device Size	10	10		9	2
44	Total Bypass Time	6	6		-	6
45	XClamp Time,	6	6		-	6
46	Total Arrest	-	-		-	-
47	Cath Proc Time,	10	15	5 unable to validate	10/15	-

48	Cath Fluro Time,	12	15	2 unable to validate	12/15	-
49	Cath Fluro Dose,	12	15	3 incorrect	12/15	-

	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	21	21		15	6
52	Post Proc Complications	-	-		-	-
53	Date of Discharge	21	21		15	6
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	21	21		15	6
57	Discharge Destination	21	21		15	6

Data Quality Indicator Assessment:

The Overall Trust DQI = 96.6% Cardiology DQI = 95.75% Surgery DQI = 99%

<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 .925</td></tr>
<tr><td>Card
.91</td><td>Surg
.96</td></tr>
<tr><td rowspan="2"><u>Procedure</u>
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 colspan="2">Overall .94</td></tr>
<tr><td>Card
.92</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 = 96.6%

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	2016	2017	2018	2019
Demographics	.99	1.0	1.0	1.0
Pre Procedure	.88	.94	.93	.925
Procedure	.89	.94	.94	.94
Outcome	.97	.99	.99	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 of 96.6% since the last NCHDA Validation. There were 40 discrepancies in 867 variables. There has again been some extreme technical challenges relating to timely data submission during the year 2018/2019 that have affected almost every congenital centre.

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 and 2018, 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 of data items such as NYHA, diabetes, pulmonary or ischaemic heart disease in the hospital notes that are part of the NCHDA dataset. It was very difficult 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 difficult 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. As recommended in 2009, documentation (either hard copy or on screen help) should be available to all staff in all areas where data are recorded real time.
4. It is recommended that the Congenital dataset fields should be set to mandatory in any of the data collection software used.
5. Senior Trainees (ST6 and above) in ACHD should be encouraged to participate in both the SBH validation visit and assist with external visits to other centres.