National Congenital Heart Disease Audit Report

On

Data Quality For Procedures for CONGENITAL HEART DISEASE for
April 2019 – March 2020

At

University Bristol Hospitals NHS Foundation Trust

17 September 2020

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Summary

Prior to the Log Book Review, the combined data return to National Congenital Heart Disease Audit (NCHDA) from the Cardiac Directorate of Bristol Royal Children's Hospital (BRC) and Bristol Royal Infirmary (BRI) indicates that 1099 procedures (377 Surgery, 679 Catheters, 9 Hybrid, 34 others, 20 deaths) for the year 2019/2020 were undertaken. These numbers include adult congenital procedures carried out at Bristol Heart Institute (BHI).

This validation visit has been funded by the University Hospitals Bristol NHS Foundation Trust. Bristol Royal Children's Hospital is part of the UHBristol NHS Foundation Trust.

BRC have had a dedicated congenital cardiac information team since 2014. Real time data input by all clinicians is encouraged and is mostly undertaken.

Patient Consent for External Validation of Hospital Notes

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 and produce data relating to their medical conditions to 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 require individual patient informed consent.

Data Quality Indicator (DQI)

The DQI for the Trust is calculated to be (with the previous year in parentheses) **99.25%** (99.5, 99, 98) with domain scores Demographics 1.0 (.98, 1.0, 1.0) Pre Procedure .99 (997, 98, .99) Procedure 1.0 (.98, 997, .98) and Outcome .985 (1.0, 99, .98).

There were 5 errors or omissions in a total of 1114 variables across 20 patients who underwent 29 therapeutic procedures (19 catheter interventions, 10 operations).

As for the previous data validation cycles, separate DQI scores are being calculated for both catheters and surgery. A minimum number of 5 records are required in either group for this to be done and this was reached at BRC. The DQI scores are:

Year	Data Year Validated	Surgery DQI	Catheter DQI
2011(ii)	10/11	92%	98.25%
2012	11/12	91%	96.25%
2013	12/13	87%	96.5%
2014	13/14	98.25%	93.25%
2015	14/15	95%	94%
2016	15/16	99.25%	98.25
2017	16/17	99.25%	98%
2018	17/18	99.25%	99%
2019	18/19	98.75%	99.8%
2020	19/20	100%	99%

The body of this report is drawn from answers given on the NCHDA pre visit questionnaire and from discussions on the day of the visit.

Actions undertaken since 2019 Validation Visit:

1. The data collection SOPs are in place for both the paediatric and ACHD services. They are reviewed on a regular basis. Cardiac Data Team made monthly uploads to NCHDA in 19-20.
2. Coloured dots are used to distinguish adult congenital records from non-congenital in log books.
3. There have been reminders for clinical staff to make sure that hand-written notes are clear. In Bristol Heart Institute for catheter procedures new CCW electronic system replaced the older CARDDAS systemin 2018. CCW holds detailed lists of ICD10, OPCS and IPCC coding. This system continues to be used as the electronic log of all ACHD cardiac catheter procedures.
4. CCW procedure entries are improving over time (this process needs to continue). The Cardiac Data Team liaise with the ACHD clinicians regarding the distinction of congenital and inherited cases as per ACHD SOP for data collection.
5. Reporting of knife-to-skin times on catheter procedure logs for EP procedures at BHI still remains a challenge. There has been little progress made since last year. The overall accuracy of data on procedure logs requires further improvement.
6. Training sessions have been regularly provided for all new members of staff both at BRHC and BHI. HeartSuite training programme is custom made for each staff group and covers all the steps required to be done by those staff groups in order to follow the data collection SOP. The Cardiac Data Manager is in charge of the training programme which is being reviewed and improved on an ad-hoc basis whenever there is a change is NCHDA dataset, change of software or a change in internal processes. Whenever changes take place, existing staff are also offered refresher training sessions. Detailed step-by-step guidance documents and

shorter bullet point reminders are handed out to all new and existing members of staff and displayed in clinical areas. This is an ongoing process. In 19-20 Cardiac Data Manager was on maternity leave, so this responsibility was undertaken by Information Analyst and Clinical Data Manager.

Changes in the Cardiac Data Team:

One of the two Assistant Data Managers left the service. Their role will be covered by the other Assistant Data Manager who has now been recruited into the permanent role.

- Information Analyst & Clinical Data Manager band 6 (0.7WTE))
- Cardiac Data Manager band 5 (0.2WTE)
- Assistant Data Manager band 4 (1.0WTE)
- Cardiac Data Quality and Audit Nurse band 5 (0.15WTE)

As a result there are 4 members in the Cardiac Data Team making up 2.2 whole time equivalents.

Changes in UHBristol NHS Trust:

On discharge or completion of the appointment the patient's notes are immediately scanned onto an electronic patient record system 'Evolve'. The process of scanning all historical patient notes is now established in the paediatric cardiac service and usually there are no significant delays with notes being scanned. In BHI unfortunately there are delays related to the scanning of patient notes which sometimes results in delayed upload of certain records to NCHDA. The delays in scanning became worse recently during Covid-19 pandemic.

CCW system currently used in BHI is also being piloted by the paediatric service for generating procedure logs. This has not been established yet, so the old SENSIS system is currently used.

Paediatric cardiac service started to use a voice recognition system 'Big Hand' for producing some documents. This system is already widely used in BHI. However, the majority of documents in the paediatric service are currently generated within HeartSuite system.

Introduction

Prior to the validation visit the combined NCHDA return from the cardiac department of Bristol Royal Hospital for Children and Bristol Royal Infirmary indicated that 1099 procedures (377 Surgery, 679 Catheters, 9 Hybrid, 34 others, 20 deaths) were undertaken in the data collection year April 2019 – March 2020. These numbers include adult congenital procedures that are performed at Bristol Royal Infirmary.

20 Sample sets of case notes were selected for review on each day. A Reserve list of 10 was also supplied by NCHDA in case any of the first 20 were irretrievable or did not have consent for external validation. On the day no records were required from the Reserve list to replace those that were unavailable from the Sample. The accuracy of the NCHDA data return was then checked against each set of notes on each day.

One external Consultant in Congenital Cardiology undertook the patient notes audit on site at Bristol Royal Childrens Hospital. The NCHDA Data Auditor supported the visit remotely via a Webex connection. The DBM for Cardiac Services at BRC in collaboration with colleagues, completed the pre visit self assessment questionnaire.

Review of the notes

The patient case notes on the whole were mostly fairly tidy made up of very few traditional paper bound documents with others printed from the ePR. Many of the pages that were required to be seen by the Reviewers had been meticulously tabbed with sticky notes and this was very helpful. Where the hospital record was totally electronic the various pages required to be viewed for the audit had been printed out and arranged in neat bundles.

1. The Joint Clinical Conference discussion sheets were seen in almost all of the case notes and these were very detailed.
2. Cardiac echo reports were also seen and found to be very detailed.
3. The cardiac catheter procedure sheet was easy to locate and well laid out in the BRC hospital notes seen. Labels from implantable devices were often stuck to these sheets and this was useful for validation of these data.
4. The PICU discharge summaries were very detailed and therefore extremely helpful in validating the perioperative data fields.
5. As previously reported, in the discharge summaries of ACHD patients it was difficult at times to find the detail of the timeline of actions and interventions of an episode.
6. As previously reported, NYHA status did not appear to be routinely recorded in the hospital records of patients aged over 16 at admission clerking or outpatient pre admission appointments. This field is part of specific pre procedure risk assessment used in the NCHDA ACHD dataset.

Validation of Deceased Patients Diagnostic and Procedure Coding

Commencing with the validation of the 2013/14 data, the National Congenital Heart Disease Audit will request to verify any dates of death of deceased patients included in the year under review. The diagnosis and procedure coding along with the Paediatric Risk Adjustment in Surgery (PRAiS) fields will also be validated. 20 deceased patients were identified in the data return for 2019-20. Of these, 12 deaths occurred within 30 days of a therapeutic catheter or surgical procedure and these case notes were examined in closer detail. The PRAiS sensitive fields were reviewed for each of the patients and the findings were:

- All dates of death were correct
- 1 record may have a discrepancy in the diagnosis field
  2 records may have a discrepancy in the comorbidities field

It is reported by the DBM that there is now good communication with the specialist liaison nurses in regards to any post discharge deaths that may occur in the community. An annual query is also now run to compare life status with known NCHDA patients as a further check for patients who may have died post discharge.

Review of the Operating Theatre Log Books

Log books from BRC theatre 3 and one Hybrid room were made available. It was confirmed at this visit there are no plans to move to a totally electronic log book for the OR. BRI theatres 1, 2, 9 and Hybrid were offered for review. The log books that were reviewed are bound bespoke ledgers with large wide ruled lines for entries. However as previously reported it was not always clear exactly what procedure had been performed due to difficult to decipher handwritten noting.

1. 1 of the submitted records for congenital surgery may have a coding error
2. 0 records were identified in the log books that may be suitable for submission to NCHDA
3. 6 submitted records were not validated in the log book check
4. It was difficult to identify ACHD patient who may have undergone therapeutic procedures as there does not appear to be a standard way to indicate these patients in the logs.

Review of Cath Log Books

There is 1 paediatric catheter laboratory at BRC and 5 catheter laboratories at BRI. The log book for the paediatric catheter laboratory was made available. A printout from the CCW electronic information system was provided for BRI. This has replaced Centricity CARDASS system that was used previously. This is considered to be the 'gold standard' of recording of activity in the adult congenital heart disease cath labs. A printout was provided for the date range April 2019 – March 2020. CCW is much more detailed than the previous information system and there is the opportunity to use ICD10, and OPCS coding as well as the specific congenital cardiac coding that that is used by NCHDA

1. The CCW printout was fairly easy to use except where the names of procedures had been shortened.
2. It was not always clear whether or not the cases were for ACHD patients or not.
3. 3 submitted catheter records may have discrepancies in them
4. 0 record was identified that may be suitable for inclusion in the NCHDA data submission
5. 2 submitted records were not identified in the activity log check.

All queries raised at the time of the site visit have now been reviewed and amendments made as required.

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 in 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

	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	29	29		19	10
11	Previous Procedures	28	28		34	30
12	Patients Weight at Operation	-	-		19	10
13	Height	28	28		19	9
14	Ante Natal Diagnosis	18	18		-	-
15	Pre Proc Seizures	18	18		19	10
16	Pre Proc NYHA	17	18	1 incorrect	11/12	6
17	Pre Proc Smoker	28	28		12	6
18	Pre Proc Diabetes	18	18		12	6
19	Hx Pulmonary Dis	18	18		12	6
20	Pre Proc IHD	18	18		12	6
21	Comorbidity Present	16	16		11	5
22	Comorbid Conditions	50	50		34	16
23	Pre Proc Systemic Ventricular EF	29	29		18/19	10
24	Pre Proc Sub Pul Ventricular EF	25	26	1 incorrect	17/18	7
25	Pre-proc valve/septal defect/ vessel size	4	4		4	-
26	Consultant	29	29		19	10

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	29	29		19	10
28	Proc Urgency	29	29		19	10
29	Unplanned Proc	4	4		2	2
30	Single Operator	11	11		11	-
31	Operator 1	29	29		19	10
32	Operator 1 Grade	19	19		19	10
33	Operator 2	18	18		8	10
34	Operator 2 Grade	18	18		8	10
35	Procedure Type	10	10		19	10
36	Sternotomy Sequence	10	10		-	10
37	Operation Performed	29	29		19	10
38	Sizing balloon used for septal defect	4	4		4	-
39	No of stents or coils	-	-		-	-
40	Device Manufacturer	19	19		13	6
41	Device Model	19	19		13	6
42	Device Ser No	19	19		13	6
43	Device Size	10	10		5	5
44	Total Bypass Time	9	9		-	9
45	XClamp Time,	7	7		-	27
46	Total Arrest	2	2		-	3
47	Cath Proc Time,	18	18		18	-
48	Cath Fluro Time,	18	18		18	-
49	Cath Fluro Dose,	18	18		18	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	8	8		-	8
51	Post Procedure Seizures	29	29		19	10
52	Post Proc Complications	6	8	2 incorrect	0/2	6
53	Date of Discharge	29	29		19	10
54	Date of Death	1	1		-	1
55	Attribution of Death	1	1		-	1
56	Status at Discharge	29	29		19	10
57	Discharge Destination	29	29		19	10

The Overall Trust DQI = 99.25% Cardiology DQI = 99% Surgery DQI = 100%

This DQI is based upon the domain scoring below. The methodology for this DQI is provided in the paper The CCAD 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** .97	**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** .985	**Card** .97	**Surg** 1.0

Data Quality Indicator Assessment

The Trust DQI = 99.25%

This DQI is based upon the domain scoring below. The methodology for this DQI is provided in the paper The NCHDA CCAD Audit – An Introduction to the Process.

DOMAINS	2017 16/17	2018 17/18	2019 18/19	2020 19/20
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.99	.98	.98	.99
Procedure	.98	.997	.997	1.0
Outcome	.98	.99	1.0	.985

Conclusions

On the whole the NCHDA data are accurate, well documented, good quality and were appropriately recorded in the Theatre and Cath Lab logs books that were seen for BRC.

The Data Quality Indicator Score for this validation visit has remained excellent at 99%+ in what has been another extraordinarily challenging period due the pandemic situation. The DQI score is also now included in the NHSE CQINs quarterly dashboards for congenital heart disease.

The case note bundles were again meticulously prepared and this is of great assistance to the Reviewers. This Trust are now paper-lite with almost any paper notes that may be generated being scanned to the digital record very quickly after patient discharge.

As previously reported while the Reviewers are pleased to note that there now 4 individuals in post covering 2.2WTEs to support all of congenital heart disease data collection, just one of these individuals (0.2WTE) has a clinical background. The Reviewers are concerned that BRC may still not have adequately trained personnel to support the NCHDA registry.

As previously reported, it is very much hoped by the Clinical Audit Team that the new CCW information system will eventually enable a more specific data collection to mirror those fields required by NCHDA and the other cardiac audits. On this Review, using this print out, it appeared good quality but it became clear that shortening or truncating of names of procedures performed could cause difficulty in interpreting exactly what the procedure was and whether or not it should be included NCHDA.

Review of Deceased Patients case notes.

All data were found to be correct. Generally the documentation supplied for this part of the validation was very detailed with almost all records including a comprehensively written discharge or death summaries containing details of all cardiac diagnoses, previous cardiac procedures and comorbidities. In some instances the Coroners Report was also included.

Recommendations

1. It is recommended that the Standard Operating Protocols (SOPs) for the congenital data collection, (paediatrics and ACHD), continue to be reviewed to ensure that they include detailed guidance on and **exactly who** is responsible (and in what timeframe) for;
   i. Input of the data for each procedure and at which point of the service delivery
   ii. Input of fetal data and at which point of service delivery when this data collection goes 'live'
   iii. 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
   iv. Leading the local review (and how frequently and in which forum for both disciplines)
   v. Making timely submissions (monthly is recommended) and
   vi. Timely reverse validation with all relevant clinical teams
   vii. Monthly to quarterly PRAiS analysis as required
   viii. Ensuring that relevant case and procedural records and logs are extracted and printed from electronic sources (HeartSuite, ORMIS, CCW, MEDWAY etc) in advance to be easily accessible by the Auditors on the day of the visit.
   ix. Checking for any out of hospital deaths that may have occurred in the congenital cohort.

2. As recommended in 2011-19, it is suggested that consideration be given to identifying congenital procedures in the BRI theatre log books as the entries are made. Coloured dots may work and a self-inking stamp is used at some centres for this purpose very effectively.
3. It is recommended that care should be taken when hand writing entries of each procedure performed in log books to ensure clarity and specificity.
4. Entries to the cath lab information system CCW at BRI should continue to be reviewed monthly and if necessary staff given extra training to more specifically describe procedures performed and how to identify patients with adult congenital heart disease rather than inherited heart disease. Shortening of names of procedures should be avoided as this may lead to mis interpretation. The use of recognised clinical coding such as OPC, ICD10 and IPCC should be encouraged when it becomes available.
5. It is recommended that all staff connected with EP procedures should, in the cath lab, enable a recorded log of the times of events during the procedure and 'skin to skin' time.
6. It is also recommended that the DBMs should visit with other centres that send congenital cardiac data to NCHDA.
7. It is recommended that regular, training sessions and updates for all staff who may be involved with data input and should be part of the induction process for new staff. This should include adult congenital staff members, who may be working solely within the BRI.