National Congenital Heart Disease Audit Report

On 14 May 2019

Data Quality For Procedures for CONGENITAL HEART DISEASE for April 2018 – March 2019

At University Bristol Hospitals NHS Foundation Trust

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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 1088 procedures (597 Surgery, 268 Catheters, 223 others, 12 deaths) for the year 2018/2019 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 Childrens Hospital is part of the UHBristol NHS Foundation Trust.

BRC have had a dedicated congenital cardiac information team since 2014.

Since the implementation of HeartSuite in the cath-labs and theatres at Bristol Royal Children's Hospital (BRC) and BRI in December 2003, real time data input by all clinicians is encouraged and is mostly undertaken.

Patient Consent for External Validation of Hospital Notes

From 1 April 2007 – May 2018 informed signed patient consent was required for external validation of hospital case notes.

Since June 2012, this consent has been incorporated into the Trustwide consent form and is either obtained at the pre admission clinic for elective patients or at the time of admission from congenital patients who undergo emergency or out of hours procedures.

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) **99.5%** (99, 98.75, 98.6,) with domain scores Demographics .98 (1.0, 1.0 1.0) Pre Procedure .997 (98, .99, .95, .95) Procedure .98 (997, .98, .99) and Outcome 1.0 (99, .98, 1.0).

There were 8 errors or omissions in a total of 1046 variables across 20 patients who underwent 29 therapeutic procedures (18 catheter interventions, 11 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
2009	07/08	92.5%	95%
2010	08/09	95%	95.75%
2011(i)	09/10	91.75%	96.75%
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%

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 2018 Validation Visit

Recommendations from previous validation visit:

5 out of 7 recommendations made by NICOR have been fully implemented (and are being implemented on an ongoing basis). Recommendations 4 and 6 have not been implemented to a satisfactory standard in 18-19.

1. Recommendation 1: The data collection SOPs are in place for both the paediatric and ACHD services. They are reviewed on an annual basis. A separate SOP has been developed for the fetal service and is incorporated with fetal SOP. Cardiac Data Team made monthly uploads to NCHDA in 18-19.

2. Recommendation 2: Coloured dots are used to distinguish adult congenital records from non-congenital in log books.
3. Recommendation 3: CARDDAS system has been replaced by the new system CCW which holds much more detailed lists of ICD10, OPCS and IPCC coding. This system will continue to be used as the electronic log of all ACHD cardiac catheter procedures. The Cardiac Data Team liaise with the ACHD clinicians regarding the distinction of congenital and inherited cases as per ACHD SOP for data collection. Further work is required to improve CCW entries.
4. Recommendation 4: Record keeping of EP procedure times sometimes remains poor with knife-to-skin times missing from procedure logs. Further liaison between Cardiac Data Team and BHI is required to improve this.
5. Recommendation 5: The key members of Cardiac Data Team are trained in using PRAiS software.
6. Recommendation 7: 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. 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.

Changes in the Congenital Cardiac Information Team at Bristol May 2019:

The Cardiac Data Manager is taking maternity leave from May 2019 to summer 2020. The maternity leave will be partially covered by a new Assistant Data Manager, at Agenda for Change (AfC) NHS Band 4 for 30 hours per week. Other members of the Cardiac Data Team are:

- Information Analyst & Clinical Data Manager band 6 (25 hpw)
- Assistant Data Manager band 4 (30 hpw)
- Assistant Data Manager band 4 (15 hpw)
- Cardiac Data Quality and Audit Nurse band 5 (11.5 hpw)

As a result there are still 4 members in the Cardiac Data Team making up 2.2 whole time equivalents. However, the overall team will be less experienced in 2019-20.

Changes in UHBristol:

UHBristol Trust is moving towards ‘paper light’ record keeping for all hospitals. This involves having a paper copy of patient’s notes only during an in-patient admission or an outpatient appointment. 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 nearly complete for the paediatric cardiac service and it is reported that there are no significant delays with notes being scanned. In BHI it is reported that there are some delays related to the scanning of patient notes which sometimes results in delayed upload of certain records to NCHDA.

CARDDAS system in the Bristol Heart Institute (BHI) was replaced by and application called CCW in spring 2018. CCW holds much more detailed lists of ICD10, OPCS and IPCC coding compared to the old CARDDAS system.

JCC discussions in BHI are no longer documented on HeartSuite. All documentation has been moved to UHBristol electronic patient record (ePR) Medway system.

In the paediatric cardiac service there are plans to start using a voice recognition system ‘Big Hand’ for producing documents currently generated within HeartSuite system, however there are no specific timescales for this change.

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 1088 procedures (597 Surgery, 268 Catheters, 223 others, 12 deaths) were undertaken in the data collection year April 2018 – March 2019. 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 Skype 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. As previously reported, the time log of actions taken (including sheath in to sheath out times) for adult patients undergoing electrophysiological procedures did not appear to be routinely present in the hospital records of these patients. These data are required to be validated.
5. The PICU discharge summaries were very detailed and therefore extremely helpful in validating the perioperative data fields.
6. Perfusionists sheets were seen in most surgical patients records but it was not always easy to identify the total bypass time, cross clamp and circulatory arrest times
7. 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.

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. 12 deceased patients were identified in the data return for 2018-19. Of these, 8 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 comorbidities field

There was some discussion in relation to identifying out of hospital deaths of patients following procedures for congenital heart disease and how this may be reviewed to ensure all deaths are appropriately reported.

Review of the Operating Theatre Log Books

Log books from BRC theatre 3 and one Hybrid room were made available. 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 hand written noting.

1. 3 of the submitted records for congenital surgery in the Bypass/Non Bypass category appear to have errors in them

2. 6 records were identified in the log books that may be suitable for submission to NCHDA

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 2018 – March 2019. 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. However it became clear that the names of procedures performed were often shortened to acronyms not necessarily recognised by the external auditors.

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

Casenote Audit. 20 patients had 2 procedures (1 catheters and 1 operations)

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
1	Hospital Number	20	20		12	8
2	NHS Number	20	20		12	8
3	Surname	20	20		12	8
4	First Name	20	20		12	8
5	Sex	20	20		12	8
6	DOB	20	20		12	8
7	Ethnicity	20	20		12	8
8	Patient Status	20	20		12	8
9	Postcode	20	20		12	8
10	Pre Procedure Diagnosis	29	29		18	11
11	Previous Procedures	54	54		44	10
12	Patients Weight at Operation	29	29		18	11
13	Height	27	27		18	9
14	Ante Natal Diagnosis	5	5		3	2
15	Pre Proc Seizures	29	29		18	11
16	Pre Proc NYHA	8	9	1 incorrect	8	0/1
17	Pre Proc Smoker	9	9		8	1
18	Pre Proc Diabetes	9	9		8	1
19	Hx Pulmonary Dis	9	9		8	1
20	Pre Proc IHD	9	9		8	1
21	Comorbidity Present	13	13		6	7
22	Comorbid Conditions	26	26		9	17
23	Pre Proc Systemic Ventricular EF	27	29	1 incorrect, 1 unable to validate	18	9/11
24	Pre Proc Sub Pul Ventricular EF	23	27	2 incorrect, 2 unable to validate	17/18	6/9
25	Pre-proc valve/septal defect/ vessel size	4	4		4	-

26	Consultant	29	29		18	11

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	29	29		18	11
28	Proc Urgency	29	29		18	11
29	Unplanned Proc	3	3		2	1
30	Single Operator	8	8		8	-
31	Operator 1	29	29		18	11
32	Operator 1 Grade	29	29		18	11
33	Operator 2	25	25		14	11
34	Operator 2 Grade	25	25		14	11
35	Procedure Type	29	29		18	11
36	Sternotomy Sequence	11	11		-	11
37	Operation Performed	29	29		18	11
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	3	3		3	-
40	Device Manufacturer	24	24		19	5
41	Device Model	24	24		19	5
42	Device Ser No	23	24	1 absent	18/19	5
43	Device Size	6	6		4	2
44	Total Bypass Time	8	8		-	8
45	XClamp Time,	8	8		-	8
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	16	16		16	-
48	Cath Fluro Time,	14	14		14	-
49	Cath Fluro Dose,	14	14		14	-

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	9	9		-	9
51	Post Procedure Seizures	29	29		18	11
52	Post Proc Complications	8	8		1	7
53	Date of Discharge	29	29		18	11
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	29	29		18	11
57	Discharge Destination	29	29		18	11

The Overall Trust DQI = 99.5% Cardiology DQI = 99.8% Surgery DQI = 99.75%

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 .98**	**Card** .997	**Surg** .95
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** .997	**Card** .996	**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

Data Quality Indicator Assessment

The Trust DQI = 99.5%

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	2016 15/16	2017 16/17	2018 17/18	2019 18/19
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.95	.99	.98	.98
Procedure	.997	.98	.997	.997
Outcome	1.0	.98	.99	1.0

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 challenging period with considerable and severe technical difficulties not only with HeartSuite but with the NCHDA web facing database itself. 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.

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. There is an extension to the NCHDA dataset that includes fetal diagnoses data points although the start date for this data submission has not yet been confirmed. These data are included in the NHSE quarterly Dashboards. The means to record and submit this information may impact on the current personnel supporting the NCHDA registry although it is envisaged that fetal nurses and cardiologists will participate in the data submission.

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. However, it is not completely clear exactly how post procedural out of hospital deaths of patients with congenital heart disease are accurately identified in a timely manner.

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 2011-18, 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.