**National Congenital Heart Disease Audit Report**

**On**

**Data Quality For Procedures for CONGENITAL HEART DISEASE for**

**April 2017 – March 2018**

 **At**

 **University Bristol Hospitals NHS Foundation Trust**

 **12 July 2018**

*performed by Lin Denne, and Dr J Bentham*

**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 1127 procedures (616 Surgery, 240 Catheters, 274 others, 5 deaths) for the year 2017/2018 were undertaken. These numbers include adult congenital procedures carried out at Bristol Royal Infirmary (BRI).

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 created a new congenital cardiac information team during 2014 and this is detailed below.

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**

Since 1 April 2007 patient consent is required for external validation of hospital case notes.

Since June 2012, this consent is 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.

**Data Quality Indicator (DQI)**

The DQI for the Trust is calculated to be (with the previous year in parentheses) **99%** (98.75, 98.6, 94.25) with domain scores Demographics 1.0 (1.0, 1.0 1.0) Pre Procedure .98 (.99, .95, .95, .85) Procedure .997 (.98, .99, .95) and Outcome .99 (.98, 1.0, .97).

There were 11 errors or omissions in a total of 1165 variables across 20 patients who underwent 31 procedures (17 catheter interventions, 14 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% |

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 2017 Validation Visit**

5 out of 6 recommendations made by NICOR have been fully implemented.

1. The data collection SOPs are still in place for both the paediatric and ACHD services. They are normally reviewed on an annual basis. A separate SOP has been developed for the fetal service which is currently being finalised.
2. Agreement from ACHD Theatres has been achieved to mark ACHD procedures with coloured dots in order to make them more easily identifiable.
3. The CARDDAS system information in the catheter laboratories has been replaced by the new system CCW which holds much more detailed lists of ICD10, OPCS and AEPC coding. This system will continue to be used as the electronic log of all ACHD cardiac catheter procedures. The Cardiac Data Team continue to liaise with the ACHD clinicians regarding the distinction of congenital and inherited cases as per ACHD SOP for data collection.
4. The two key members of the Cardiac Data Team are trained to produce the VLAD graphs using PRAiS method.
5. Training in information capture is custom made for each staff group and covers all the steps required in order to follow the data collection SOP. The Cardiac Data Manager is now in charge of the training programme which is being reviewed and improved several times a year 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 where NCHDA data is entered into HeartSuite. This is an ongoing process and will be continued on a permanent basis.

Changes in the Congenital Cardiac Information Team at Bristol:

Within the Cardiac Data Team the role of Assistant Data Manager was restructured into Cardiac Data Manager with the increase in banding from band 4 to band 5 with the reduction of hours from 1.0 WTE to 0.7 WTE. This was done in order to reflect the level of skill required to do this role and to meet the requirements of the NCHDA data submissions. As a result, the Cardiac Data Team now has the following members:

* Information Analyst & Clinical Data Manager band 6 (0.66 WTE)
* Cardiac Data Manager band 5 (0.8 WTE)
* Assistant Data Manager band 4 (0.4 WTE)
* Cardiac Data Quality and Audit Nurse band 5 (0.3 WTE)

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

Changes in UHBristol:

University Hospitals Bristol Trust is still in the process of 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 has been nearly completed for the paediatric congenital cardiac service. In the Bristol Heart Institute there were some issues with delays related to the scanning of patient notes.

**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 were undertaken in the data collection year April 2017 – March 2018. These numbers include adult congenital procedures carried out 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 2 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 mostly printed documents 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 anaesthetic and operation records were mostly easy to find
4. 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.
5. The time log of actions taken for adult patients undergoing electrophysiological procedures did not appear to be routinely present in the hospital records of these patients.
6. The PICU discharge summaries were very detailed and therefore extremely helpful in validating the perioperative data fields.
7. Perfusionists sheets were seen in most surgical patients records.

**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. 5 patients who had had therapeutic procedures during  the 2017/18 data collection year were noted to have died.  A file containing documents for each patient was made available that contained the procedural commentary and death summaries and in some cases the Coroners Reports.

* All dates of death were correct
* 3 procedure performed codes may be incorrect
* 3 records may have discrepancies 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

1. 0 of the submitted records for congenital surgery in the Bypass/Non Bypass category appear to have errors in them
2. 1 record was identified in the log books that may be suitable for submission to NCHDA
3. It was noted in the electronic record system that often the procedure descriptions were imprecise and it was difficult to know exactly what procedure had occurred.

**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 Centricity CARDASS system was made available  from BRI.  At the 2014 validation visit this is considered to be the ‘gold standard’ of recording of activity in the cath lab.  A printout was provided for the date range April 2017 – March 2018.

As previously reported, it was difficult to decipher some of the descriptions of procedures performed as they often appeared to be incomplete or rather vague.

1. The CARDASS printout was much easier to use than in previous years but some case descriptions appeared to be incomplete or truncated, it was not clear whether or not the cases were for ACHD patients or not in spite of a filter apparently being applied to the printout.
2. 2 submitted catheter records appear to have errors in them
3. 1 record was identified that may be suitable for inclusion in the NCHDA data submission
4. 7 submitted records were not identified in the log check in the NCHDA data submission

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 26 procedures (16 catheters and 10 operations)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **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 | 30 | 31 | 1 incorrect | 17 | 13/14 |
| 11 | Previous Procedures | 110 | 110 |  | 52 | 58 |
| 12 | Patients Weight atOperation | 31 | 31 |  | 17 | 14 |
| 13  | Height | 28 | 28 |  | 17 | 11 |
| 14 | Ante Natal Diagnosis | 2 | 2 |  | - | 2 |
| 15 | Pre Proc Seizures | 31 | 31 |  | 17 | 14 |
| 16 | Pre Proc NYHA  | 8 | 8 |  | 5 | 3 |
| 17 | Pre Proc Smoker | 8 | 8 |  | 5 | 3 |
| 18 | Pre Proc Diabetes | 8 | 8 |  | 5 | 3 |
| 19 | Hx Pulmonary Dis | 8 | 8 |  | 5 | 3 |
| 20 | Pre Proc IHD | 8 | 8 |  | 5 | 3 |
| 21 | Comorbidity Present | 16 | 19 | 3 incorrect | 6/7 | 10/12 |
| 22 | Comorbid Conditions | 39 | 43 | 4 incorrect | 16/18 | 23 |
| 23 | Pre Proc Systemic Ventricular EF | 31 | 31 |  | 16/17 | 25 |
| 24 | Pre Proc Sub Pul Ventricular EF  | 16 | 16 |  | 5 | 11 |
| 25 | Pre-proc valve/septal defect/ vessel size | 10 | 10 |  | 9 | 1 |
| 26 | Consultant | 31 | 31 |  | 17 | 14 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure + Time Start | 31 | 31 |  | 17 | 14 |
| 28 | Proc Urgency | 31 | 31 |  | 17 | 14 |
| 29 | Unplanned Proc | 31 | 31 |  | 17 | 14 |
| 30 | Single Operator | 31 | 31 |  | 17 | 14 |
| 31 | Operator 1 | 31 | 31 |  | 17 | 14 |
| 32 | Operator 1 Grade | 31 | 31 |  | 17 | 14 |
| 33 | Operator 2 | 24 | 24 |  | 10 | 14 |
| 34 | Operator 2 Grade | 24 | 24 |  | 10 | 14 |
| 35 | Procedure Type | 31 | 31 |  | 17 | 14 |
| 36 | Sternotomy Sequence | 10 | 11 | 1 incorrect | - | 10/11 |
| 37 | Operation Performed | 31 | 31 |  | 17 | 14 |
| 38 | Sizing balloon used for septal defect  | 1 | 1 |  | 1 | - |
| 39 | No of stents or coils | 3 | 3 |  | 3 | - |
| 40 | Device Manufacturer | 11 | 11 |  | 6 | 5 |
| 41 | Device Model | 11 | 11 |  | 6 | 5 |
| 42 | Device Ser No | 11 | 11 |  | 6 | 5 |
| 43 | Device Size | 10 | 10 |  | 6 | 4 |
| 44 | Total Bypass Time | 9 | 9 |  | - | 9 |
| 45 | XClamp Time, | 7 | 7 |  | - | 7 |
| 46 | Total Arrest | 2 | 2 |  | - | 2 |
| 47 | Cath Proc Time, | 17 | 17 |  | 17 | - |
| 48 | Cath Fluro Time, | 17 | 17 |  | 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  | 11 | 11 |  | - | 11 |
| 51 | Post Procedure Seizures  | 31 | 31 |  | 17 | 14 |
| 52 | Post Proc Complications | 7 | 7 |  | 1/2 | 5 |
| 53 | Date of Discharge | 31 | 31 |  | 17 | 14 |
| 54 | Date of Death | - | - |  | - | - |
| 55 | Attribution of Death | - | - |  | - | - |
| 56 | Status at Discharge | 31 | 31 |  | 17 | 14 |
| 57 | Discharge Destination | 31 | 31 |  | 17 | 14 |

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

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**.98 | **Surg**.98 |
| **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**1.0 | **Surg**.99 |
| **Outcome**Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination.**Post Procedure Complications.** | **Overall** .99 |
| **Card**.98 | **Surg**1.0 |

**Data Quality Indicator Assessment**

**The Trust DQI = 98.75%**

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**  | **2015****(14/15)** | **2016****15/16** | **2017****16/17** | **2018****17/18** |
| **Demographics** | 1.0 | 1.0 | 1.0 | 1.0 |
| **Pre Procedure** | .85 | .95 | .99 | .98 |
| **Procedure** | .95 | .997 | .98 | .997 |
| **Outcome** | .97 | 1.0 | .98 | .99 |

**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 (0.3WTE) has a clinical background. The Reviewers are concerned that BRC may still not have adequate personnel to support the NCHDA registry. From 2018 there has an extension to the NCHDA dataset that includes fetal diagnoses data points. 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.

From the CARDASS (the previous information system); a print out from BRI cath labs activity was provided. It was clear that a lot of cases were not congenital and descriptions of the procedures were truncated or cut off. As at the 2013-17 validation visits, it is very difficult to know whether or not there has been a full case ascertainment for therapeutic adult congenital procedures from the cath labs at BRI. There is an option to select ‘Congenital’ as procedure type when entering details of a case but it does not appear to be consistently used. Accuracy of descriptions of procedures performed and whether or not it was for congenital heart disease may have revenue implications. It is anticipated that the newer CCW information system in the cath labs will enable a more specific data collection to mirror those fields required by NCHDA and other cardiac audits.

**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;
2. Ensuring consent for external validation of hospital notes is obtained
3. Input of the data for each procedure and at which point of the service delivery
4. Input of fetal data and at which point of service delivery
5. 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
6. Leading the local review (and how frequently and in which forum for both disciplines)
7. Making timely submissions (monthly is recommended) and
8. Timely reverse validation with all relevant clinical teams
9. Monthly to quarterly PRAiS analysis as required
10. 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.
11. As recommended in 2011-17, it is suggested that consideration be given to identifying congenital procedures in the BRI theatre log books as the entries are made. A self inking stamp is used at some centres for this purpose.
12. Entries to the cath lab information system 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.
13. 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.
14. All staff who are involved with collecting, managing and validating NCHDA data should be fully trained in using the PRAiS software.
15. It is also recommended that the DBMs should visit with other centres that send congenital cardiac data to NCHDA.
16. 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.