**National Congenital Heart Disease Audit Report**

**On**

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

**April 2016 – March 2017**

 **At**

 **University Bristol Hospitals NHS Foundation Trust**

 **01 November 2017**

*performed by Lin Denne, and Dr O Stumper*

**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 1189 procedures (453 Surgery, 452 Catheters, 284 others, 20 deaths) for the year 2016/2017 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.

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. As previously reported, there appears to be an ongoing problem with more than 1 diagnoses or procedure occurring in 1 field.

**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) **98.75%** (98.6, 94.25, 96.5) with domain scores Demographics 1.0 (1.0, 1.0 1.0 .97) Pre Procedure .99 (.95, .95, .85 .92) Procedure .98 (.99, .95 .95) and Outcome .98 (1.0, .97 .99).

There were 16 errors or omissions in a total of 960 variables across 20 patients who underwent 26 procedures.

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. 20 patients had 10 operations and 16 interventional catheter procedures. 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% |

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 2016 Validation Visit**

1. Significant changes took place within the Cardiac Data Team. An additional part-time Assistant Data Manager has been recruited for 15 hours per week. As a result, in 2017-18 Bristol Cardiac Data Team will have 4 members of staff at a total of 2.37 whole time equivalents (WTEs).
2. It is reported by BRC, that the paediatric and ACHD Standard Operating Protocols for data collection and validations were both reviewed and amended to reflect the changes in NCHDA dataset for 17-18. The overall level of data accuracy as recorded by clinicians has been fairly steady throughout the year but still requires further improvement. As recommended by NICOR at 2016 validation visit a SOP has been created for the collection of the fetal dataset.
3. A new process was introduced for collection of the new fetal dataset from April 17. The mandatory data items are collected by the clinical and admin staff within the Fetal Cardiology Team based at St Michael’s Hospital supported by the Cardiac Data Team based at Bristol Royal Hospital for Children. Currently the data items are being recorded on internal electronic sources and will be submitted to NICOR as soon as the web-based specialised software is available.
4. The system of weekly audits of patient notes by Cardiac Data Quality and Audit Nurse proved very successful and the vast majority of patient notes are audited against the HeartSuite data prior to being submitted to NICOR. This applies to both surgical and catheter procedures for paediatric and ACHD patients.
5. UHBristol Trust is currently in the process of moving towards ‘paper light’ record keeping for all hospitals. 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 and is in progress in the ACHD service.
6. There has been a change in the electronic theatre system in 16-17. The previous ‘Medway’ system has been replaced with ‘Bluespear’ theatre system and therefore it is thought to be best to postpone the use of the electronic theatre system as a bespoke log for surgical procedures. The paper theatre log books are still currently in use in the paediatric congenital cardiac service.

**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 1189 procedures (453 Surgery, 452 Catheters, 284 others, 20 deaths) were undertaken in the data collection year April 2016 – March 2017. 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 no records was required from the Reserve list to replace any 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 hospital notes on the whole were mostly fairly tidy made up of some traditional paper bound documents with some 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 due to their colour (red edged and pink typed respectively)
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 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 notes.
7. As previously reported, the explicit location (ie home or another hospital) to which a patient was discharged to was not always clear in the discharge summaries.

**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 patients who had had therapeutic procedures during  the 2016/17 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
* No other errors or omissions were identified.

**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. 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 but it is reported that the book that includes March 2017 is missing and its location unknown.  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 2016 – March 2017.

As with the electron surgical information system, 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. At least 8 submitted catheter records appear to have errors in them
3. 3 records were identified that may be suitable for inclusion in the NCHDA data submission

All queries raised at the time of the site visit have now been reviewed and amendments made as required.**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 |  | 15 | 5 |
| 2 | NHS Number | 20 | 20 |  | 15 | 5 |
| 3 | Surname | 20 | 20 |  | 15 | 5 |
| 4 | First Name | 20 | 20 |  | 15 | 5 |
| 5 | Sex | 20 | 20 |  | 15 | 5 |
| 6 | DOB | 20 | 20 |  | 15 | 5 |
| 7 | Ethnicity | 20 | 20 |  | 15 | 5 |
| 8 | Patient Status | 20 | 20 |  | 15 | 5 |
| 9 | Postcode | 20 | 20 |  | 15 | 5 |
| 10 | Pre Procedure Diagnosis | 26 | 26 |  | 16 | 10 |
| 11 | Previous Procedures | 45 | 45 |  | 31 | 14 |
| 12 | Patients Weight atOperation | 26 | 26 |  | 16 | 10 |
| 13  | Height | 24 | 24 |  | 16 | 8 |
| 14 | Ante Natal Diagnosis | 3 | 3 |  | 2 | 1 |
| 15 | Pre Proc Seizures | 26 | 26 |  | 16 | 10 |
| 16 | Pre Proc NYHA  | 6 | 7 | 1 incorrect | 5 | ½ |
| 17 | Pre Proc Smoker | 7 | 7 |  | 5 | 2 |
| 18 | Pre Proc Diabetes | 7 | 7 |  | 5 | 2 |
| 19 | Hx Pulmonary Dis | 7 | 7 |  | 5 | 2 |
| 20 | Pre Proc IHD | 7 | 7 |  | 5 | 2 |
| 21 | Comorbidity Present | 26 | 26 |  | 16 | 10 |
| 22 | Comorbid Conditions | 20 | 20 |  | 14 | 6 |
| 23 | Pre Proc Systemic Ventricular EF | 25 | 26 | 1 incorrect | 16 | 9/10 |
| 24 | Pre Proc Sub Pul Ventricular EF  | 21 | 22 | 1 incorrect | 15 | 6/7 |
| 25 | Pre-proc valve/septal defect/ vessel size | 6 | 6 |  | 6 | - |
| 26 | Consultant | 26 | 26 |  | 16 | 10 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 26 | 26 |  | 16 | 10 |
| 28 | Time Start | 26 | 26 |  | 16 | 10 |
| 29 | Proc Urgency | 26 | 26 |  | 16 | 10 |
| 30 | Unplanned Proc | 26 | 26 |  | 16 | 10 |
| 31 | Single Operator | 2 | 2 |  | 2 | - |
| 32 | Operator 1 | 24 | 26 | 2 incorrect | 14/16 | 10 |
| 33 | Operator 1 Grade | 25 | 26 | 1 incorrect | 15/16 | 10 |
| 34 | Operator 2 | 22 | 24 | 2 incorrect | 12/14 | 10 |
| 35 | Operator 2 Grade | 23 | 24 | 1 incorrect | 13/14 | 10 |
| 36 | Procedure Type | 26 | 26 |  | 16 | 10 |
| 37 | Sternotomy Sequence | 8 | 8 |  | - | 8 |
| 38 | Operation Performed | 26 | 26 |  | 16 | 10 |
| 39 | Sizing balloon used for septal defect  | 1 | 1 |  | - | 1 |
| 40 | No of stents or coils | 2 | 2 |  |  | 2 |
| 41 | Device Manufacturer | 11 | 11 |  | 11 | - |
| 42 | Device Model | 11 | 11 |  | 9 | 2 |
| 43 | Device Ser No | 11 | 11 |  | 9 | 2 |
| 44 | Device Size | 5 | 5 |  | 3 | 2 |
| 45 | Total Bypass Time | 8 | 8 |  | - | 8 |
| 46 | XClamp Time, | 6 | 7 | 1 absent | - | 6/7 |
| 47 | Total Arrest | 1 | 1 |  | - | 1 |
| 48 | Cath Proc Time, | 16 | 16 |  | 16 | - |
| 49 | Cath Fluro Time, | 15 | 16 | 1 incorrect | 15/16 | - |
| 50 | Cath Fluro Dose, | 16 | 16 |  | 16 | - |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation  | 6 | 6 |  | - | 6 |
| 52 | Post Procedure Seizures  | 26 | 26 |  | 16 | 10 |
| 54 | Post Proc Complications | 6 | 8 | 1 incorrect, 1 absent | 16 | 6/8 |
| 55 | Date of Discharge | 26 | 26 |  | 16 | 10 |
| 56 | Date of Death | 1 | 1 |  | - | 1 |
| 57 | Status at Discharge | 26 | 26 |  | 16 | 10 |
| 58 | Discharge Destination | 26 | 26 |  | 16 | 10 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.75 Cardiology DQI = 99.25 Surgery DQI = 98

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**1.0 | **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 .98** |
| **Card**.97 | **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** .98 |
| **Card**1.0 | **Surg**.96 |

**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**  | **2014****(13/14)** | **2015****(14/15)** | **2016****15/16** | **2017****16/17** |
| **Demographics** | 1.0 | 1.0 | 1.0 | 1.0 |
| **Pre Procedure** | .92 | .85 | .95 | .99 |
| **Procedure** | .95 | .95 | .997 | .98 |
| **Outcome** | .99 | .97 | 1.0 | .98 |

**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 98.75% in what has been another challenging period with considerable severe technical difficulties not only with HeartSuite but with the NCHDA database itself. The DQI score is also now included in the NHSE CQINs quarterly dashboards for congenital heart disease.

As previously reported while the Reviewers are pleased to note that there now 4 individuals in post covering 2.7WTEs 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 adequate personnel to support the NCHDA registry. From 2018 there will be 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 print out from BRI cath labs that 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 2013-16 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.

**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;
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, CARDASS, MEDWAY etc) in advance to be easily accessible by the Auditors on the day of the visit.
11. As recommended in 2011-16, 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 (CARDASS) 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. All staff who are involved with collecting, managing and validating NCHDA data should be fully trained in using the PRAiS software.
14. It is also recommended that the DBMs should visit with other centres that send congenital cardiac data to NCHDA.
15. 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.