**The National Congenital Heart Disease Audit**

**Procedures for**

**CONGENITAL HEART DISEASE**

**Data Quality Audit for April 2017 to March 2018**

**Birmingham Children’s Hospital NHS Foundation Trust**

**13 August 2018**

**Professor R Tulloh and Lin Denne**

**Summary**

Prior to this validation visit the Congenital NICOR data return from the Birmingham Children’s Hospital NHS Foundation Trust (BCH) indicated that some 1084 (surgery 568, catheter 336, others 180, deaths 32) procedures had been undertaken during the data collection year of 2017/2018 on children with congenital heart disease.

20 sets of case notes are randomly selected from the BCH submission (the Sample) with a further 10 randomly selected as reserves. 6 case notes were used from the reserve list to replace those unavailable in the sample. A combined total of 29 procedures were reviewed, 15 therapeutic catheter procedures and 14 operations.

The HeartSuite information system continues to be used at Birmingham Children’s Hospital to collect and manage all congenital cardiac data.

This validation visit has been fully funded by the Birmingham Women’s and Children’s NHS Foundation NHS Trust. This visit was supported remotely by the NCHDA clinical audit nurse via a teleconference facility and on site in person by Professor R Tulloh, Consultant Congenital Cardiologist from Bristol.

**BCH Overview**

There is an overall Cardiac Information Manager at BCH. Since October 2010, there has been a 1.0WTE audit facilitator post for congenital heart disease. There is a further 1.0WTE post within the cardiac information department that provides support for a number of audits and registries as well as NCHDA.

**Actions taken since the 2017 Validation Visit**

1. The Information Manager at BCH has continued to update the NCHDA Data Manual that is used by all congenital centres (NCHDA v5)
2. The Data Manual is now available within HeartSuite
3. BCH continue to routinely review their data collection and validation processes and are undertaking the development of a more streamlined data submission process that will make monthly data submissions possible – to be implemented this year once the NICOR Congenital platform Qreg5 is fully commissioned and is available.

**Consent for External Validation of Notes.**

As previously reported, in early 2008, BCH modified their Trust wide consent form to include consent to external validation of hospital notes. The patient/parent/guardian is required to tick a box and sign a hand written clause agreeing to external validation. However under GDPR regulations patients/parents/guardians are recommended to be given written information detailing exactly how their data are to be collected and used, where the data are kept and where these data may be submitted to as well as external validation. In addition to this it is also recommended that there is a clear opt out clause should a patient decline or change their mind.

**Data Quality Indicator**

The preliminary individual DQI score for BCH is **99%** (99.5, 97.75, 98.5) The domain scores are; Demographics 1.0 (.99, 1.0, 1.0), Pre Procedure .99 (.99, 96, 96), Procedure .997 (1.0, .97 1.0), and Outcome .98 (1.0, .98 .98,).

This is based on 20 patients who underwent 29 therapeutic procedures (15 catheters and 14 operations. 1017 data variables were validated and 6 discrepancies identified.

This represents another excellent DQI score.

**Separate DQI for Surgery and Catheters**

Since the 2009 cycle of visits commenced, as well as the overall DQI for each centre, the DQI for surgery and catheters is being calculated. It is recommended that a minimum number of 5 procedures in either group are required for the differential DQI calculation.

|  |  |  |  |
| --- | --- | --- | --- |
| **DQI** | **Data Year Reviewed** | **Surgery** | **Catheters** |
| **2009** | 2007-08 | 98.5% | Sample too small |
| **2010** | 2008-09 | 88.75% | 92.75% |
| **2011** | 2009-10 | 94% | 98.25% |
| **2012** | 2010-11 | 94.5% | 98.75% |
| **2013** | 2011-12 | 95.75% | 94.25% |
| **2014(i)** | 2012-13 | 98% | 98% |
| **2014(ii)** | 2013-14 | 96.75% | 97% |
| **2015** | 2014-15 | 98.5% | 98% |
| **2016** | 2015-16 | 98.75% | 96.75% |
| **2017** | 2016-17 | 100% | 99.5% |
| **2018** | 2017-18 | 98.75% | 99% |

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.

**Introduction**

The NCHDA data return, prior to checking the theatre and cath lab log books, indicated that the combined cardiac departments of the Birmingham Children’s Hospital have undertaken some 1084 (surgery 568, catheter 336, others 180, deaths 32) procedures in the data collection year of 2017/2018 on children with congenital heart disease.

The Information Manager and Audit Facilitator, in collaboration with colleagues completed the pre visit self assessment questionnaire at BCH.

The accuracy of the NCHDA data return was then checked against each set of notes to enable the Data Quality Indicator (DQI) to be scored.

The Congenital Data Auditor for the NCHDA undertook the visit remotely with an external Consultant Professor in Congenital Cardiology.

**Review of notes**

1. The notes had again been meticulously prepared by the Congenital Audit Team
2. The relevant clinical records were highlighted in the casenotes and therefore very easy to find
3. The NHS number was always easily available on the individual patients labels.

**Review of the Cath Lab and Theatre Log Books**

Paper log books have not been kept at BCH for over a decade and an electronic Operating Room Information System (ORMIS) is used in both the cath labs and operating theatres. A spreadsheet of all cases ordered by date for the period under review was provided on a screen for the visiting clinician to review.

**Cath Labs**

1. As previously reported, the descriptions of procedures in ORMIS often do not always accurately portray the exact procedure performed.
2. 3 submitted records appear to have duplicate entries
3. 0 records were identified that may be suitable for inclusion in NCHDA

**Operating Theatres**

1. As reported at the  2014-17 validation visits, the surgical procedures appear to be gradually getting more accurately described than previously.
2. 0  surgical records were identified that may be suitable for inclusion in NCHDA

**Validation of Dates of Death and Procedure Coding of Deceased Patients**

This commenced with the validation of the 2014/15 data. The NCHDA wish to verify any dates of death of deceased patients included in the year under review. The diagnosis and procedure coding will also be validated. The requirement for patient/parent/guardian consent to review the case notes is the same as for the congenital procedures review.

32 congenital patients were noted on the data harvested for this visit to have died following a procedure. 15 of these deaths occurred within 30 days of a catheter intervention or surgical procedure.

It is recommended that if information regarding a date of death for a pre-existing congenital patient on the NCHDA database post discharge is, or becomes available this should be submitted to that individual’s record in the NCHDA registry. However, this piece of information, once submitted to the NCHDA database is not always easily visible when the data are exported back to the centre.

Of the data reviewed for 15 patients the findings are;-

* 2 records appear to have incomplete comorbidities
* All dates of death were correct

**Casenote Audit**

Data Quality Indicator Assessment:

The Overall Trust DQI = 99% Cardiology DQI = 99% Surgery DQI = 98.75%

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  | | | | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 9 | 11 |
| 2 | NHS Number | 18 | 18 |  | 8 | 10 |
| 3 | Surname | 20 | 20 |  | 9 | 11 |
| 4 | First Name | 20 | 20 |  | 9 | 11 |
| 5 | Sex | 20 | 20 |  | 9 | 11 |
| 6 | DOB | 20 | 20 |  | 9 | 11 |
| 7 | Ethnicity | 20 | 20 |  | 9 | 11 |
| 8 | Patient Status | 20 | 20 |  | 9 | 11 |
| 9 | Postcode | 20 | 20 |  | 9 | 11 |
| 10 | Pre Procedure  Diagnosis | 29 | 29 |  | 15 | 14 |
| 11 | Previous Procedures | 87 | 89 | 2 absent | 59/60 | 29 |
| 12 | Patients Weight at  Operation | 29 | 29 |  | 15 | 14 |
| 13 | Height | 29 | 29 |  | 15 | 14 |
| 14 | Ante Natal Diagnosis | 4 | 4 |  | 1 | 3 |
| 15 | Pre Proc Seizures | 29 | 29 |  | 15 | 14 |
| 16 | Pre Proc NYHA | - | - |  | - | - |
| 17 | Pre Proc Smoker | - | - |  | - | - |
| 18 | Pre Proc Diabetes | - | - |  | - | - |
| 19 | Hx Pulmonary Dis | - | - |  | - | - |
| 20 | Pre Proc IHD | - | - |  | - | - |
| 21 | Comorbidity Present | 6 | 7 | 1 incorrect | ½ | 5 |
| 22 | Comorbid Conditions | 13 | 13 |  | 7 | 6 |
| 23 | Pre Proc Systemic Ventricular EF | 5 | 5 |  | 4 | 1 |
| 24 | Pre Proc Sub Pul Ventricular EF | 24 | 25 | 1 unable to validate | 16 | 8/9 |
| 25 | Pre-proc valve/septal defect/ vessel size | 5 | 5 |  | 5 | - |
| 26 | Consultant | 29 | 29 |  | 15 | 14 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure + Time Start | 29 | 29 |  | 15 | 15 |
| 28 | Proc Urgency | 29 | 29 |  | 15 | 15 |
| 29 | Unplanned Proc | 29 | 29 |  | 15 | 15 |
| 30 | Single Operator | 3 | 3 |  | 3 | 3 |
| 31 | Operator 1 | 29 | 29 |  | 15 | 15 |
| 32 | Operator 1 Grade | 29 | 29 |  | 15 | 15 |
| 33 | Operator 2 | 26 | 26 |  | 12 | 12 |
| 34 | Operator 2 Grade | 26 | 26 |  | 12 | 12 |
| 35 | Procedure Type | 29 | 29 |  | 15 | 15 |
| 36 | Sternotomy Sequence | 13 | 13 |  | - | - |
| 37 | Operation Performed | 29 | 29 |  | 15 | 15 |
| 38 | Sizing balloon used for septal defect | 0 | 1 | 1 incorrect | 0/1 | - |
| 39 | No of stents or coils | 2 | 5 | 2 absent, 1 incorrect | 2/5 | - |
| 40 | Device Manufacturer | 14 | 14 |  | 7 | 7 |
| 41 | Device Model | 14 | 14 |  | 7 | 7 |
| 42 | Device Ser No | 14 | 14 |  | 7 | 7 |
| 43 | Device Size | 11 | 11 |  | 5 | 6 |
| 44 | Total Bypass Time | 14 | 14 |  | - | 14 |
| 45 | XClamp Time, | 11 | 11 |  | - | 11 |
| 46 | Total Arrest | 4 | 4 |  | - | 4 |
| 47 | Cath Proc Time, | 15 | 15 |  | 15 | - |
| 48 | Cath Fluro Time, | 15 | 15 |  | 15 | - |
| 49 | Cath Fluro Dose, | 15 | 15 |  | 15 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 50 | Duration of Post Op Intubation | 10 | 11 | 1 incorrect | - | 10/11 |
| 51 | Post Procedure Seizures | 29 | 29 |  | 15 | 14 |
| 52 | Post Proc Complications | 8 | 8 |  | 3 | 5 |
| 53 | Date of Discharge | 27 | 29 | 2 incorrect | 14/15 | 13/14 |
| 54 | Date of Death | 1 | 1 |  | - | 1 |
| 55 | Attribution of Death | 1 | 1 |  | - | 1 |
| 56 | Status at Discharge | 29 | 29 |  | 15 | 14 |
| 57 | Discharge Destination | 29 | 29 |  | 15 | 14 |

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**  .99 | **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 1.0** | |
| **Card**  .995 | **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** **.98** | |
| **Card**  .99 | **Surg**  .97 |

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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DOMAIN.** | **Score**  **2018** | **Score**  **2017** | **Score**  **2016** | **Score**  **2015** |
| **Demographic** | 1.0 | .99 | 1.0 | 1.0 |
| **Pre Procedure** | .99 | .99 | .96 | .96 |
| **Procedure** | .997 | 1.0 | .97 | 1.0 |
| **Outcome** | .98 | 1.0 | 1.0 | .98 |

**Conclusions**

On the whole the NCHDA data were again of very good quality. The Data Quality Indicator (DQI) is remains in the very high nineties at 99% and this is an excellent score. This also further demonstrates that there continues to be robust processes in place to ensure good quality data standards are maintained.

As reported previously, it is very clear that BCH NHS Trust consider the matter of collecting good quality, accurate and validated information about patient procedural activity to be of the highest importance and this has become embedded within the culture of the Cardiac Department. There were just 8 errors or omissions in 1017 variables. The Validation Team would particularly like to recognise the level of conscientiousness displayed by the Congenital Audit Facilitators and their colleagues in preparing the hospital notes and various printed sheets so meticulously.

Again, as reported in previous years, the standard and accuracy of the information recorded in ORMIS for surgery appears to continue to improve since the 2014 visits, however it is still poor in places for the catheter procedures. It was impossible to clearly identify exactly what catheter procedure had actually been performed in some of the entries and therefore to validate numbers and details of cardiac catheterisations performed in particular.

Within the review of the case notes for patients who became deceased within 30 days of their procedures, 2 queries raised across 15 patients variables. These data are part of the PRAiS risk adjustment analysis that used by NCHDA.

**Recommendations**

1. As previously recommended, it is recommended that consideration be given to obtaining informed consent from parent/guardian/patient for external case note review at initial outpatient consultation or first hospital attendance. It is also recommended that parents/patients/guardians are given written details of exactly how their data are collected, protected and stored and to where it may be submitted and for what purpose. This is in line with GDPR 2018. There should also be an opt out clause included.
2. It is recommended that the Standard Operating Protocols for the congenital data collection, review and reverse validation procedures continue to be reviewed on a regular basis to ensure that they contain detailed guidance on exactly which data are required and in what time frame.
3. As recommended previously, continue to educate and train staff to improve the accuracy of the procedural information recorded on ORMIS in order to make it more robust for identifying exactly what procedures have been performed and for retrieving the appropriate revenue.
4. Ensure that all data fields for each minor or excluded record are completed.
5. It is recommended that the congenital audit facilitators should be encouraged to observe a validation visit at another congenital cardiac centre as part of an annual training and development programme.