**The National Congenital Heart Disease Audit**

 **Procedures for**

 **CONGENITAL HEART DISEASE,**

**April 2017 – March 2018**

 **Data Quality Audit**

**The Newcastle Upon Tyne Teaching Hospitals NHS Foundation Trust.**

 **9 August 2018**

*performed by Lin Denne and Dr J Dua*

**Summary**

The NCHDA data return from the cardiac department of the Freeman Hospital for the data collection year 2017/18 extracted on 4 August 2018, indicated that 964 procedures (329 surgery, 293, catheters, 342 others) had been undertaken in patients with congenital heart disease.

This validation visit has been fully funded by Newcastle upon Tyne University Hospitals NHS Foundation Trust.

As previously reported, there is a Cardiothoracic Services Information Manager post at this Trust whose remit covers all 6 of the NICOR data collections. This post was vacant at the time of this validation visit. There are a further 5 other members of the Cardiac Information Team at FRE covering 3.7 WTEs. There is a 1.0WTE individual dedicated to the NCHDA collection.

Data are entered into a Dendrite Intellect system at various points of service throughout the hospital, ie operating theatres, cath labs etc. When checked for accuracy, completeness and validity these data are submitted to the NCHDA database.

**Data Quality Indicator (DQI)**

The DQI for the Trust is calculated to be (with previous years in parentheses) **98.75%** (.99, 97.5%, 97.25) with domain scores Demographics 1.0 (1.0, 1.0 1.0) Pre Procedure .96 (.97, 97, .96) Procedure .99 (.995, .93 .9) and Outcome 1.0 (.99, 1.0 .96 .96).

The calculation is based on the validation of 20 patients hospital notes who underwent The calculation is based on the validation of 20 patients hospital notes who underwent 27 procedures (10 therapeutic catheter procedures and 17 surgical operations). There were just 13 discrepancies in 960 variables

**Separate DQI for Surgery and for Catheters**

On further review of the DQI when the cases were split into their surgery and catheter groups and the scores were;

|  |  |  |  |
| --- | --- | --- | --- |
| **Year** | **Data Year Validated** | **Surgery** | **Caths** |
| **2009** | 07/08 | 96% | 94.25% |
| **2010** | 08/09 | 97.50% | 97.25% |
| **2011** | 09/10 | 96.75% | 93.25% |
| **2012** | 10/11 | 97.75% | 95.60% |
| **2013** | 11/12 | 97% | 99% |
| **2014** | 13/14 | 97.25% | 95.50% |
| **2015** | 14/15 | 97.25% | 97% |
| **2016** | 15/16 | 98.5% | 97% |
| **2017** | 16/17 | 98.25% | 99% |
| **2018** | 17/18 | 98.25% | 99.75% |

The NCHDA 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

**Actions Reported and Undertaken since the July 2017 Validation:-**

1. The local NHCDA data collection and validation SOP is constantly being reviewed to ensure that clear guidance is given to all staff involved with the capture, input, validation and submission of data.
2. Input of data for each episode is now gathered locally at the point of procedure. The local database is web based and is accessible on all computers in the Trust if an individual has a valid username and password.
3. Data validation continues to be done constantly. Responsible Consultants are encouraged to be involved with this and take ownership of their data.
4. All data submitted to NICOR is reversed validated regularly.

**Consent for External Validation of Notes.**

This has been required since 2007 and is mandatory for every set of hospital notes selected in the NCHDA site validation. The generic consent form at the Freeman Hospital has been adapted to accommodate this with an itemised portion that requires an extra signature by the parent/patient or guardian and 2 tick boxes for ‘I agree or I do not agree statement to be ticked.

Prior to the visit a file with 20 case notes (the Sample) and 10 Reserves was sent to the cardiothoracic information manager. 20 sets of notes (13 Samples, 7 Reserves) were available on the day all of which had the necessary consent for external validation

**Introduction**

As stated above, the NCHDA data return from the cardiac department of the Freeman Hospital for the year 2017/18 and harvested for this visit in August 2018, indicated that 964 procedures had been undertaken in patients with congenital heart disease.

The Congenital Data Auditor for the NCHDA undertook the visit remotely via a Skype connection with an external Consultant Congenital Cardiologist on site in person.

As stated above, 20 sets of notes were requested. The accuracy of the NCHDA data return was then checked against each set of notes. The Specific Procedures algorithm grouping is also validated for the case notes seen.

**Review of case notes**

1. The case notes, had been meticulously prepared with sticky notes to identify many of the particular pages that the Reviewers needed to validate data.
2. As previously reported, the casenotes were mostly in chronological order but as stated above some were quite wieldy to handle. The assistance of the NCHDA Data Manager on the day was invaluable.
3. As previously reported, it was noted that on some of the typed operation notes that there did not appear to be a date of the operation or a summary history of previous procedures.
4. The detailed PICU summaries that were seen were again very helpful
5. As previously reported, printed catheter procedure data from Cathcore was seen.
6. It was further noted that on occasions the fluroscopy data for patients who have undergone electrophysiology procedures was not included in the procedure note. The NCHDA data manager does not have access to the cardiac technicians database where these data are kept.
7. It was also noted that the product labels for pacemakers do not always appear to be included in the hospital notes of patients who have these devices implanted
8. Almost all bypass patients appeared to have a perfusion sheet filed in their case note. This is the recommended information point to validated the perfusion data from.
9. As reported in 2014-17, the Trust is in the process of moving to E-records as part of the national strategy and on occasions the Cardiothoracic Information Manager was able to access letters and reports that did not appear to be filed in the case notes.
10. Echocardiography reports were seen in the case notes.

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

**Log books from Cath Labs 1- 6 were offered for review.** Labs 5 and 6 are used solely for Primary Percutaneous Coronary Interventions (PPCI) only. Time restraints prohibited review of the log books for lab 2,3,and 5.

The cath lab log books are bespoke bound volumes with ruled columns for various pieces of information which are completed by hand.  As previously reported, product identifying labels are also adhered to the relevant entry.  Sometimes the labels over lay the procedure descriptions.   This made it difficult on occasions  to identify if a procedure was for congenital heart disease or not or exactly what procedure had actually be performed.

1. 6 submitted records appear to have an error
2. 0 records were identified that may have been missed from the submission
3. Approximately 80 catheter procedures were not validated in the log book but this may be because they occurred in the cath labs for which the registers were not reviewed.

**Registers from Theatres 1 - 4 were offered for review**.

The log books are bespoke bound volumes with ruled columns for various pieces of information which are completed by hand.  As reported previously,  the legibility of the handwriting for some entries was quite poor, and in some entries there was no description of what procedure had been performed.  It was extremely challenging at times to identify whether younger adult patients were having operations for congenital heart disease or acquired or inherited heart disease.

1. 2 submitted records appear to have errors
2. 0 records were identified that may have been missed from the submission

**Validation of Deceased Patients Diagnostic and Procedure Coding**

Commencing with the validation of the 2013/14 data, the National Congenital Heart Disease Audit 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 as stated above. In cases where it is unclear if this consent has been obtained during life, the Medical Director is asked for permission to undertake this review. The Validation Team are grateful to the MD of Freeman Hospital for giving this permission. 6 deaths within 30 days of a procedure for congenital heart disease were identified from the submitted data. for 2017-18. The PRAiS sensitive fields were reviewed for each of the patients and the findings were:

All dates of death were found to be correct
No other discrepancies were identified

**Casenote Audit**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 6 | 14 |
| 2 | NHS Number | 20 | 20 |  | 6 | 14 |
| 3 | Surname | 20 | 20 |  | 6 | 14 |
| 4 | First Name | 20 | 20 |  | 6 | 14 |
| 5 | Sex | 20 | 20 |  | 6 | 14 |
| 6 | DOB | 20 | 20 |  | 6 | 14 |
| 7 | Ethnicity | 20 | 20 |  | 6 | 14 |
| 8 | Patient Status | 20 | 20 |  | 6 | 14 |
| 9 | Postcode | 20 | 20 |  | 6 | 14 |
| 10 | Pre Procedure Diagnosis | 27 | 27 |  | 10 | 17 |
| 11 | Previous Procedures | 29 | 31 | 2 absent | 10 | 21 |
| 12 | Patients Weight atOperation | 27 | 27 |  | 10 | 17 |
| 13  | Height | 27 | 27 |  | 10 | 17 |
| 14 | Ante Natal Diagnosis | 2 | 2 |  | - | 2 |
| 15 | Pre Proc Seizures | 27 | 27 |  | 10 | 17 |
| 16 | Pre Proc NYHA  | 8 | 10 | 1 absent, 1 incorrect | 1 | 7/9 |
| 17 | Pre Proc Smoker | 8 | 10 | 2 absent | 1 | 7/9 |
| 18 | Pre Proc Diabetes | 8 | 10 | 2 absent | 1 | 7/9 |
| 19 | Hx Pulmonary Dis | 8 | 10 | 2 absent | 1 | 7/9 |
| 20 | Pre Proc IHD | 8 | 10 | 2 absent | 1 | 7/9 |
| 21 | Comorbidity Present | 8 | 8 |  | 2 | 6 |
| 22 | Comorbid Conditions | 10 | 10 |  | 2 | 17 |
| 23 | Pre Proc Systemic Ventricular EF | 27 | 27 |  | 10 | 17 |
| 24 | Pre Proc Sub Pul Ventricular EF  | 27 | 27 |  | 10 | 17 |
| 25 | Pre-proc valve/septal defect/ vessel size | 1 | 1 |  | 1 | - |
| 26 | Consultant | 27 | 27 |  | 10 | 17 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 27 | 27 |  | 10 | 17 |
| 28 | Time Start | 27 | 27 |  | 10 | 17 |
| 29 | Proc Urgency | 27 | 27 |  | 10 | 17 |
| 30 | Unplanned Proc | 5 | 5 |  | 10 | - |
| 31 | Single Operator | 27 | 27 |  | 5 | 17 |
| 32 | Operator 1 | 27 | 27 |  | 10 | 17 |
| 33 | Operator 1 Grade | 27 | 27 |  | 10 | 17 |
| 34 | Operator 2 | 22 | 22 |  | 5 | 17 |
| 35 | Operator 2 Grade | 21 | 22 | 1 incorrect | 4/5 | 17 |
| 36 | Procedure Type | 27 | 27 |  | 10 | 17 |
| 37 | Sternotomy Sequence | 15 | 15 |  | - | 15 |
| 38 | Operation Performed | 27 | 27 |  | 10 | 17 |
| 39 | Sizing balloon used for septal defect  | 2 | 2 |  | 2 | - |
| 40 | No of stents or coils | 1 | 1 |  | 1 | - |
| 41 | Device Manufacturer | 17 | 17 |  | 7 | 10 |
| 42 | Device Model | 17 | 17 |  | 7 | 10 |
| 43 | Device Ser No | 24 | 24 |  | 14 | 10 |
| 44 | Device Size | 11 | 11 | 1 incomplete as Dendrite not adapted | 7 | 4 |
| 45 | Total Bypass Time | 13 | 13 |  | - | 13 |
| 46 | XClamp Time, | 13 | 13 |  | - | 13 |
| 47 | Total Arrest | 0 | 0 |  | - | 0 |
| 48 | Cath Proc Time, | 10 | 10 |  | 10 | - |
| 49 | Cath Fluro Time, | 10 | 10 |  | 10 | - |
| 50 | Cath Fluro Dose, | 10 | 10 |  | 10 | - |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation  | 12 | 12 |  | - | 12 |
| 52 | Post Procedure Seizures  | 27 | 27 |  | 10 | 17 |
| 54 | Post Proc Complications | 5 | 5 |  | 10 | 5 |
| 55 | Date of Discharge | 27 | 27 |  | - | 17 |
| 56 | Date of Death | - | - |  | - | - |
| 57 | Status at Discharge | - | - |  | 10 | 17 |
| 58 | Discharge Destination | 27 | 27 |  | 10 | 17 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.75% Cardiology DQI = 99.5% Surgery DQI = 98.25%

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 .97** |
| **Card**.99 | **Surg**.94 |
| **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** .99 |
| **Card**.99 | **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** 1.0 |
| **Card**1.0 | **Surg**1.0 |

**Data Quality Indicator Assessment by domain:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **DOMAIN** | **2018** | **2017** | **2016** | **2015** | **2014** |
| **Demographics** | 1.0 | 1.0 | 1.0 | 1.0 | .99 |
| **Pre Procedure** | .97 | .97 | .97 | .96 | .96 |
| **Procedure** | 99 | 99.5 | .93 | .97 | .96 |
| **Outcome** | 1.0 | 99 | 1.0 | .96 | .96 |

**Conclusions**

On the whole the NCHDA data was accurate, well documented, good quality and were appropriately recorded in the Cath Lab and Theatre log books. The hospital case notes for each of the patients included in the Data Quality Indicator (DQI) analysis had been meticulously prepared by the Congenital Data Manager.

Electronic log books are not yet in use at this centre. The DQI continues to be of a very high standard, which is excellent and demonstrates that the NCHDA data collection and audit processes in place to support it at this centre are working well.

As previously reported, data entry is now possible at a wider range of locations as each user has their own user ID and password to the information collection system Intellect.

NCHDA acknowledge that the data collection year 2017-18 was again fraught with technical challenges and thank every congenital centre for their patience while problems were resolved.

Some of the detail of implantable devices (manufacturer, model and serial number) was still difficult to find and it is of concern that these details did not always appear to be in included in the patients hospital notes and the congenital data manager does not have access to the database where much of the EP and Pacing data are recorded.

It was also noted that on some occasions that the diagnoses coding used did not always completely reconcile with the procedure performed.

As previously reported, there was also some difficulty in accurately identifying procedures for congenital heart disease in all of the log books seen. Some operating theatre and cathlab log book entries did not record what procedure was performed at all and in other records for young adult patients it was not clear whether or not the procedure being performed was for congenital, acquired or inherited heart disease.

**Validation of Deceased Patients Case Notes**

The NCHDA are grateful to the Medical Director for provided an over arching permission to examine these case notes where it was unclear if informed consent was not obtained during life.

As reported above, there were no errors found.

**Recommendations**

1. The standard operating procedures (SOP) for the NCHDA data collection should be reviewed to ensure that clear guidance is given on exactly how to capture all data on both paediatric and adult congenital cardiac patients in a timely manner. The SOP should clearly set out exactly who is responsible for;
2. Ensuring consent for external validation of hospital notes is obtained prospectively from all patients with congenital heart disease and that in line with the GDPR, all patients/parents and guardians are given full information of how their data are securely recorded, stored, where this information is shared and who with. And op out explained to patients/carers.
3. Input of congenital patients NCHDA required dataset items and at which point of service delivery
4. Encouraging responsible clinician input of the procedure data for each operation, diagnostic or catheter intervention at the point of the service delivery
5. Recording the knife to skin time for all surgical procedures where it can be validated (ie perfusion or anaesthetic record).
6. 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
7. Recording implanted device details on the operation or intervention procedure note.
8. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data Managers at least monthly.
9. Running the PRAiS (Paediatric Risk Analysis in Surgery) analysis tool monthly. This will inform the quarterly NHSE Dashboard reports.
10. Ensuring that dates of death are reported for any FRE patient who has previously had a record submitted to the NCHDA
11. Leading the local review (and how frequently and in which forum for both disciplines)
12. Making timely submissions (monthly is recommended) and
13. Including details of manufacturer, model and serial numbers of all implantable devices with each patient record for a procedure.
14. Reviewing/Updating the SOP at timely intervals
15. It is recommended that all NCHDA Data Managers visit another congenital centre on an annual basis to observe processes and practices, share experiences and network.
16. Attendance at the next NCHDA Stakeholders (QE11 Centre, London 10-12 March 2018)) by DBM and lead clinician for congenital heart disease