**The National Congenital Heart Disease Audit Database**

**Data Quality Audit for**

**CONGENITAL HEART DISEASE**

**Apr 2016 - Mar 2017**

**Glenfield Hospital**

**University of Leicester NHS Trust**

**20 November 2017**

*Performed by Lin Denne and Dr L Orchard*

**Summary**

Prior to the log book review on the day of the validation visit, the NCHDA data return from the Cardiac Department of Glenfield Hospital indicated that 683 (surgery 348, catheter 226, others 9, deaths 7) procedures have been undertaken in patients with congenital heart disease during the data collection year of 2016/17. The data for this visit was harvested in July 2017.

This visit has been fully funded by Leicester Teaching Hospitals NHS Trust.

Since November 2014 has been a Data and Outcomes Analyst who is responsible for submitting the data to the NCHDA.

As reported in 2011-16, there is also a specifically designated data manager (DM) supervising the data collection for congenital cardiology who has access to the NCHDA Database.

The Data and Outcomes Analyst and the Data Manager do not have a clinical background.

As reported in 2009-15, there is opportunity for real time data input to a PATS database by all clinicians immediately following a procedure. Attention is again drawn to the NCHDA definition of the term ‘congenital’ on the public web portal for guidance.

**Actions on Recommendations Taken since Last Validation Visit in 2016.**

GRL report the following actions:

1. In June 2017 GRL launched HeartSuite as their main data collection system for the NCHDA audit, replacing the previous PATS / Intellect system.
2. Processes for reporting on activity; quality controlling the information being entered and subsequently passed to NCHDA have been completely overhauled.
3. HeartSuite is now being used to improve the MDT process and subsequent reporting of activity. This has the effect of ensuring more complete and accurate diagnoses are coded for patients who subsequently have a surgical or catheter procedure.
4. There is a weekly liaison with surgical and catheter teams to review the accuracy and completeness of coding. These systems have been adapted for use with the HeartSuite system and GRL are continually reviewing these.

GRL also report some issues that may have an effect on the Data Quality Indicator:

1. Some NHS numbers are missing in HeartSuite. It is understood to be a technical ‘bug’. Manually entering the NHS number has no effect as the change is overwritten when the record is next accessed. GRL are working with the suppliers to address this and other issues with patient demographic data.
2. GRL have moved back to paper notes (from a system of scanned electronic notes). However, this has the implication that some notes can be difficult to track down, especially for patients being seen elsewhere in the hospital system.

**Electronic Patients Records at GRL.**

As mentioned above since the NCHDA validation visit in 2015, GRL have implemented and then paused an electronic records storage and retrieval system.

**Patient Consent for External Validation of Case Notes**

Consent for external validation of hospital case notes by NCHDA has been required since 1 April 2007. As previously reported, it is planned that patients who attend the congenital outpatients clinic at Glenfield are to be routinely asked to consent to external data validation of their records. Adult congenital patients are also seen in this clinic and, on the whole consent from these patients is also gained. The Centre are not confident that all relevant patients consent for external validation is captured.

The DQI for the Trust is calculated to be (with previous years in parentheses) **97.25%** ( 97, 94,90, 94,) with domain scores Demographics 1.0 (1.0 1.0 1.0 .99 .) Pre Procedure .93 (.93, .84 .775, .81) Procedure .97 (.99 .96 .90,.99) and Outcome .99 (.99, .96 .95, .975).

Since 2009, 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. 20 patients had 17 operations and 12 interventional catheter procedures in the sample. The DQI scores are;

|  |  |  |  |
| --- | --- | --- | --- |
| **Year of Visit** | **Data Year Validated** | **Surgery DQI** | **Catheter DQI** |
| 2009 | 07/08 | 90% | 94% |
| 2010 | 08/09 | 93.75% | 96.% |
| 2011(i) | 09/10 | 95.75% | 91.25% |
| 2011(ii) | 10/11 | 97.75% | 89.5% |
| 2012 | 11/12 | 94.75% | 91.75% |
| 2013 | 12/13 | 95.75% | 90% |
| 2014 | 13/14 | 94% | 85.5% |
| 2015 | 14/15 | 92.5% | 97% |
| 2016 | 15/16 | 97% | 97.25% |
| 2017 | 16/17 | 94% | 98% |

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.

**Introduction**

Prior to the validation visit, the NCHDA return from the cardiac department of The Glenfield Hospital indicates that 683 (surgery 348, catheter 226, others 9, deaths 7) had been undertaken in patients with congenital heart disease during the data collection year of 2016/2017.

20 sets of case notes were selected for review. The NCHDA Data Auditor supported the validation remotely via Skype and an external Consultant in Congenital Cardiology undertook the site audit in person.

A list of 20 sets of notes for the case note review were supplied by NCHDA in advance of the visit. Also included in this list were 10 further cases should any of the first 20 not be available or not have the required consent for external validation. On the day 4 records were used from the reserve list. The accuracy of the NCHDA data return was then checked against each set of notes and used to calculate the Data Quality Indicator (DQI) score.

**Review of notes**

The case notes reviewed at this visit were a mixture of traditional folio type card bound paper files and a few printed packs of information for those patients whose records were almost entirely electronic. As previously reported at other visits; some of the older case notes were quite thick and bulky, untidy and not always in chronological order. It was generally a little challenging and time consuming to validate the data but the reviewers would like to again thank the congenital data manager for taking the time to book mark almost all of the relevant documents. The Reviewers are grateful to the consultant cardiologist who made time to assist with navigating the hospital notes during the review.

1. As previously reported, the anaesthetic records were easy to identify due to their colour (blue edged) as well as the perfusion sheet (red edged).
2. Hand written details of catheter procedures were seen also but not all noted fluroscopy details or recorded the manufacturer and serial numbers of implanted devices.
3. As previously noted, the discharge sheet from ITU to the ward was useful.
4. It was not always easy to find a preoperative echo report as this detail was often included in clinic letters or other documentation.
5. It was occasionally challenging to find details of a patients pre operative height.

**Catheter Lab Log Book Review**

The log books from 6 cath labs (A,B, C, D, E and F) were offered. Log books of a bespoke design are used in all labs. Each case performed is recorded as one full entry with column headings clearly indicating what information is required. As previously reported, the space to record data is quite narrow and made auditing extremely difficult and time consuming to decipher on occasions.

Following review of the catheter laboratory log books for 2016/17

1. 11 submitted catheter records appear to have errors in them
2. 1 record for VSD closure in a post myocardial infarction patient was identified and this should be removed from NCHDA as this is acquired heart disease
3. 1 record appears to be for a TOE only and this is not required for NCHDA
4. 103 submitted catheter records were not validated in the log books
5. 6 procedures were identified in the cath lab log books which may have been missed from the data submission.

**Review of the theatre log books**

Log books from theatres 1, 2, 3 and 4 were offered for validation. These are bespoke ledgers with wide ruled lines to comfortably place a patient’s identity label and columns for various pieces of information pertaining to the procedure performed. As previously reported, the standard of data entry in these books was variable, at times extremely difficult to decipher and at others very simple and clear entries. After the visit the NCHDA Data Auditor was made aware the electronic theatre management system ORMIS is used at this centre.

Review of the operating theatre log books for 2016/17 identified;

1. 8 of the submitted records for congenital surgery in the Bypass/Non Bypass category appear to have errors in them
2. 2 submitted records may be in the wrong category/procedure type
3. 0 surgery procedures were identified that may have been missed from the data submission
4. 1 submitted surgical record appears to be for an adult with Marfan Syndrome.  Procedures for adults with Marfan Syndrome are not included in NCHDA

**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 the same as for the congenital procedures review. 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 Glenfield General Hospital for giving this permission. 7 post procedural deaths were submitted in the data from GRL for the year 2016/17.

6 case notes were made available. 1 case note was missing, its location unknown but some clinical information such as letters were made available. There does not appear to be a standard death summary report including full medical history for congenital deceased patients at GRL.

1. 1 record appears to be for a post MI VSD and this is not an NCHDA procedure and should be deleted.
2. 1 record appears to have an incomplete diagnosis
3. 1 record appears to have an incorrect pre-operative weight recorded in the submitted record
4. 3 records  appears to have errors or omissions in the Comorbid Codes submitted
5. 1 record appears to have an incorrect operation performed code

**Casenote Audit**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  | | | | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 14 | 16 |
| 2 | NHS Number | 20 | 20 |  | 14 | 16 |
| 3 | Surname | 20 | 20 |  | 14 | 16 |
| 4 | First Name | 20 | 20 |  | 14 | 16 |
| 5 | Sex | 20 | 20 |  | 14 | 16 |
| 6 | DOB | 20 | 20 |  | 14 | 16 |
| 7 | Ethnicity | 20 | 20 |  | 14 | 16 |
| 8 | Patient Status | 20 | 20 |  | 14 | 16 |
| 9 | Postcode | 20 | 20 |  | 14 | 16 |
| 10 | Pre Procedure  Diagnosis | 22 | 23 | 1 incorrect | 17 | 5/6 |
| 11 | Previous Procedures | 45 | 46 | 1 absent | 27 | 18/19 |
| 12 | Patients Weight at  Operation | 22 | 23 | 1 u/a to validate | 17 | 5/6 |
| 13 | Height | 22 | 23 | 1 u/a to validate | 17 | 5/6 |
| 14 | Ante Natal Diagnosis | 2 | 2 |  | - | 2 |
| 15 | Pre Proc Seizures | 22 | 23 | 1 incorrect | 17 | 5/6 |
| 16 | Pre Proc NYHA | 6 | 6 |  | 2 | 4 |
| 17 | Pre Proc Smoker | 6 | 6 |  | 2 | 4 |
| 18 | Pre Proc Diabetes | 6 | 6 |  | 2 | 4 |
| 19 | Hx Pulmonary Dis | 5 | 6 |  | 2 | 2/4 |
| 20 | Pre Proc IHD | 6 | 6 |  | 2 | 4 |
| 21 | Comorbidity Present | 21 | 23 | 2 incorrect | 15/17 | 4 |
| 22 | Comorbid Conditions | 24 | 25 | 1 absent | 13/14 | 11 |
| 23 | Pre Proc Systemic Ventricular EF | 19 | 23 | 1 u/a to validate, 3 incorrect | 13/17 | 5/6 |
| 24 | Pre Proc Sub Pul Ventricular EF | 18 | 23 | 1 u/a to validate, 4 incorrect | 12/17 | 4/6 |
| 25 | Pre-proc valve/septal defect/ vessel size | 3 | 4 | 1 u/a to validate | - | 3/4 |
| 26 | Consultant | 23 | 23 |  | 17 | 6 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 23 | 23 |  | 17 | 6 |
| 28 | Time Start | 23 | 23 |  | 17 | 6 |
| 29 | Proc Urgency | 23 | 23 |  | 17 | 6 |
| 30 | Unplanned Proc | 2 | 2 |  | 2 | - |
| 31 | Single Operator | 2 | 2 |  | 2 | - |
| 32 | Operator 1 | 23 | 23 |  | 17 | 6 |
| 33 | Operator 1 Grade | 23 | 23 |  | 15 | 6 |
| 34 | Operator 2 | 20 | 20 | 2 incorrect | 15 | 6 |
| 35 | Operator 2 Grade | 28 | 20 |  | 17 | 4/6 |
| 36 | Procedure Type | 23 | 23 |  | 17 | 6 |
| 37 | Sternotomy Sequence | 4 | 5 | 1 incorrect | - | 4/5 |
| 38 | Operation Performed | 22 | 23 | 1 incorrect | 3 | 5/6 |
| 39 | Sizing balloon used for septal defect | 3 | 3 |  | 2 | - |
| 40 | No of stents or coils | 2 | 2 |  | 7 | - |
| 41 | Device Manufacturer | 9 | 10 | 1 absent | 7 | 2/3 |
| 42 | Device Model | 10 | 11 | 1 absent | 8 | 2/3 |
| 43 | Device Ser No | 10 | 11 | 1 absent | 8 | 2/3 |
| 44 | Device Size | 9 | 10 | 1 absent | 8 | 1/2 |
| 45 | Total Bypass Time | 6 | 6 |  | - | 6 |
| 46 | XClamp Time, | 3 | 3 |  | - | 3 |
| 47 | Total Arrest | 0 | 0 |  | - | 0 |
| 48 | Cath Proc Time, | 14 | 15 | 1 incorrect | 15 | - |
| 49 | Cath Fluro Time, | 14 | 15 | 1 incorrect | 15 | - |
| 50 | Cath Fluro Dose, | 15 | 15 |  | 15 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation | 4 | 5 | 1 incorrect | - | 4/5 |
| 52 | Post Procedure Seizures | 23 | 23 |  | 17 | 6 |
| 53 | Post Proc Complications | 0 | 0 |  | -- | - |
| 55 | Date of Discharge | 23 | 23 |  | 17 | 6 |
| 56 | Date of Death | - | - |  | - | - |
| 57 | Status at Discharge | 23 | 23 |  | 17 | 6 |
| 58 | Discharge Destination | 23 | 23 |  | 17 | 6 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 97.25% Cardiology DQI = 98% Surgery DQI = 94%

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 .93** | |
| **Card**  .945 | **Surg**  .90 |
| **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** .97 | |
| **Card**  .99 | **Surg**  .90 |
| **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**  1.0 | **Surg**  .96 |

**Data Quality Indicator Assessment**

**The Trust DQI = 97.25%**

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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DOMAINS** | **2014**  **13/14** | **2015**  **14/15** | **2016**  **15/16** | **2017**  **16/17** |
| **Demographics** | 1.0 | 1.0 | 1.0 | 1.0 |
| **Pre Procedure** | .775 | .83 | .93 | .93 |
| **Procedure** | .90 | .97 | .99 | .97 |
| **Outcome** | .95 | .96 | .96 | .99 |

**Conclusions**

On the whole the NCHDA data were accurate, well documented, of good quality and were appropriately recorded in the Theatre and Cath Lab log books.

The overall DQI score has increased by a further 0.25% on the 2016 score to 97.25%. This is an extremely good score as this has been a challenging period as GRL have found themselves under scrutiny by NHSE Commissioners following a review of congenital cardiac services in England. As in the 2013-16 validation visits, most of the data errors or omissions are concentrated in the Pre Procedure Domain but in a far smaller number than previous years. There were a total of 31 errors or omissions in 876 variables.

The Data and Outcomes Analyst does not have a clinical background and needs support with ‘sense’ checking of data prior to submission as well as when the monthly PRAiS analysis is run. The Reviewers are pleased to report that there appears to be more clinician involvement now with validating the data locally prior to submission. This is an important part of the data review that should be done locally as it demonstrates exactly how data will be analysed by NCHDA and will highlight any coding errors quickly and easily. It is therefore essential that adequate support is provided for those that undertake this task. It is clear that the use of the HeartSuite cardiac information system, with its inbuilt checks and balances is proving helpful with logging data completeness and accuracy.

As previously stated it should also be borne in mind that NHSE may use NCHDA data to underpin parts of the quarterly paediatric cardiac and ACHD/Transition and CQuINs dashboards for current and future activity.

As previously reported, reviewing of the hard backed cath lab log books was at times extremely difficult due to the rows for each record entry being so very closely drawn and the hand writing difficult to decipher. It was also clear to the reviewers at times that what was actually recorded in the cath lab log books did not accurately portray the procedure that was performed. 103 submitted records were unvalidated in the cath lab log books.

**Review of Deceased Patients Diagnostic and Procedural Coding**

As discussed above, more frequent local scrutiny of the data will assist with identifying errors or mistakes such a missing comorbid conditions, diagnoses or coding for procedures performed.

**Recommendations (as in 2013-16)**

1. It is recommended that any Standard Operating Protocols devised for the congenital data collection, should be regularly reviewed to ensure that they include detailed guidance on ‘how to’ and exactly **who** is responsible for and in what timeframe for each of the following;
2. Ensuring consent for external validation of hospital notes is obtained
3. Input of the data for each relevant procedure and identifying at which point of the service delivery this should be done. Ideally this should be ‘real time’.
4. Validity checking for completeness and the time intervals for feedback to responsible clinicians on this along with a clear time scale and line of responsibility for rectifying any omissions or errors in both surgery and cardiology disciplines
5. Running PRAiS analysis software monthly and completion of any monthly and quarterly Commissioner Dashboards as required.
6. Leading the local review (how frequently and in which forum for both disciplines) and encouraging clinician ownership of the data.
7. Making timely submissions (monthly is recommended, quarterly is mandatory) and
8. Timely reverse validation at GRL against an acknowledged ‘gold standard’ record of activity and procedures performed.
9. Reviewing/Updating these SOPs at timely intervals
10. To encourage clearer data entry in cath lab and operating log books to assist with identity of procedures in patients with congenital heart disease.
11. To develop training for all other staff who may be involved with data input. This could involve visiting other centres who submit data to NCHDA and for sharing ideas, knowledge and experience.
12. To have clear guidance on exactly where sticky labels from implanted devices should be located in the patients hospital case note.