**The National Congenital Heart Disease Audit**

**Procedures for**

**CONGENITAL HEART DISEASE**

**Data Quality Audit**

**For the year 2016/17**

**Royal Liverpool Children’s Hospital NHS**

**Foundation Trust**

**21 June 2017**

*performed by Lin Denne, and Mr S Congou*

**Summary and Overview**

Prior to this Validation Visit, the data return from the Royal Liverpool Children’s Hospital Alder Hey (ACH NHS Foundation Trust) indicated that 869 therapeutic cardiac procedures had been undertaken during the 2016/2017 data collection year (surgery 405, catheters 270, others 194, Deaths 18) in patients with congenital heart disease. This validation visit has been fully funded by the Alder Hey Children’s NHS Foundation NHS Trust.

The NCHDA Validation Team are again grateful to the Service Manager for Cardiothoracic Services at ACH who made time to come and meet them.

**Update on actions reported by ACH to have been undertaken since last visit in June 2016:**

1. Following the retirement of an experienced cardiac auditor, the team has recruited a qualified clinical coder to the position of cardiac auditor. This is a permanent role at 16 hours per week.
2. The SOP is updated regularly and most recently to include the definitions outlined in the recently published NICOR dataset manual.
3. System developments – the Trust Business Intelligence Team will work with Cardiac Audit to develop Cardicare when NICOR release the specifications for the v6.0 dataset. The demographics data will be linked to the Trust Patient Administration System. This will improve the data quality and release auditor time to validate the clinical data.

**Overview at ACH**

As previously reported, data entry is carried out by 2 Auditors who provided a total of 30 hours (2 x 0.4 WTE) per week. The Cardiac Information Analyst (1 WTE) is responsible for supervising the data collection, auditing completeness and accuracy, and submission of data to the registry. The Deputy Head of Information (0.4 WTE) is the named Cardiac Data Manager for the Trust and oversees the registry; collaborating with the audit team and clinicians to ensure data accuracy.

**Congenital Data Collection at ACH**

As previously reported, from 2003, the data at ACH were collected on an electronic proforma in an Access Database; data entry has been carried out by 2 Auditors who received all cardiac notes on discharge, and data input was carried out by these personnel. Basic demographic data is obtained from the ACH Trusts Meditech system which is linked to an Access database designed by a former clinician at the hospital. There has been little or no technical support available for this database since 2004 and this is unchanged at the 2016 validation visit. This system is available to the Cardiac Department. The Cardiac Information Analyst runs ad hoc queries and makes the necessary data returns as required. Since the appointment of the Cardiac Data Manager in 2013, internal and external deadlines for data submission were met. A consultant surgeon has responsibility for the surgical data and its quality and works closely with the Audit Team.

In April 2014 -15 the surgeons commenced a series of pilots or trials of a new C-Cloud Cardiac Information System. This involves inputting data at the point of service. The Cardiologists also piloted the process and there have been a number of adjustments and retrials during this period. However there were a number of technical issues and logistical hold ups with this system and it has not yet been fully commissioned. ACH also moved location to a purpose built environment during the autumn of 2015 and this also impacted on any further developments.

**Consent for External Validation of Notes.**

Since 2006 informed consent has been required for external validation of any patients hospital notes. For cardiac surgery patients this consent is part of the consent for operation document. For cardiology patients this is recorded in a specially designed sticky label that is appended to the consent for procedure document.

**Data Quality Indicator**

The individual DQI for ACH (with previous years in parentheses) is **97.5%** (95.25,97.25 94.75). The domain scores are Demographics 1.0 (1.0 1.0 1.0). Pre Procedure . 96 (.91 .93 .88). Procedure .98 (.94, .99 .95 .95) and Outcome .96 (.96, .97 .96)

In addition to the overall DQI, the DQI for Surgery and Catheters where the sample are >5 records audited, is calculated as follows.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Data Year**  **Validated** | **Surgery** | **Caths** |
| **2009** | 07/08 | 96.25% | 91.75% |
| **2010** | 08/09 | 95.25% | 89.25% |
| **2011** | 09/10 | 91% | 96% |
| **2012** | 10/11 | 97.75% | 95.5% |
| **2013** | 11/12 | 94.25% | 96.25% |
| **2014(i)** | 12/13 | 96% | 92.75% |
| **2014(ii)** | 13/14 | 96% | 92.25% |
| **2015** | 14/15 | 96.5% | 98% |
| **2016** | 15/16 | 94% | 96.25% |
| **2017** | 16/17 | 97% | 99% |

**Introduction**

Prior to the validation visit, the NCHDA return from Liverpool Royal Children’s Foundation Trust indicated that some 869 therapeutic cardiac procedures had been undertaken during the 2016/2017 data collection year (surgery 405, catheters 270, others 194, Deaths 18).

20 sets of case notes were selected for review. A reserve list of 10 cases was also supplied and on the day, 3 case notes were used from the reserve list at ACH.

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 NCHDA Congenital Data Auditor and one external Consultant Congenital Cardiac Surgeon undertook the site audit at ACH.

As stated above, it is reported that the information system (C-Cloud) development has been discarded and a new system called Cardicare is being developed by the Trust. An electronic proforma continues to be used with the Cardiac Information Analyst monitoring the quality and completeness.

ACH are also moving towards using an electronic patient record system (EPR) and is now ‘paper-lite’ with most case notes being scanned to a Trustwide archive following patient discharge.

**Review of notes at ACH**

As at the 2016 validation visit, all procedure case notes reviewed had been prepared in separate A4 folders with much of the relevant documentation tabbed in order to validate the NCHDA data. The original case notes were also made available to facilitate further validation as required. The reviewers found this very helpful.

1. On the whole the files very well laid out but the hospital notes often did not appear to always be in chronological order and in some instances it appeared that the pages might be absent.
2. The anaesthetic and operation records were fairly easy to find due to their colour (yellow and pink respectively) in the patients hospital case notes.
3. As noted in previous reports, some anaesthetic records were not dated.
4. As previously reported, most of the surgeons appear to document bypass times on their typed reports. This was compared with the perfusionists record which is the NCHDA recommended standard source for this information. However, it was not always easy to locate the perfusion record and on some occasions this document was not found in the hospital notes of patients who had undergone procedures on cardiopulmonary bypass.
5. The explicit documentation of date and time of extubation was sometimes challenging to find in the hospital notes of surgical patients.
6. Also, as previously reported, occasionally some of the hand written clinical notes were not dated so it was difficult to identify exactly when a patient was discharged.
7. As previously reported, in the submitted records of patients who had undergone implanted device procedures, the description and identity label for these devices did not appear to be included in the daily record entries or the procedure description note.

**Log Book Validation for Case Ascertainment**

Bound bespoke  log books for Apr-Mar 2016/7 were presented for both the cath labs and operating theatres.

From the cath lab log books;

1. 4 submitted catheter records appear to be for DC conversions and these are not required for NCHDA and should be removed
2. 0 procedures were identified in the cath lab log books that may have been missed from the data submission

From the operating theatre log books;

1. 0 procedures were identified in the log books that may have been missed from the data submission

**Validation of Data of Deceased Patients Data Entry in NCHDA**

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. ACH declined to participate in this part of the data validation at the 2014 visit.

18 patients were noted in the NCHDA data submission to have died during the 2016/17 data collection year.  Each record was presented individually, in an A4 folder containing copies of various documents printed from the local electronic patient record system.

The findings were;-

* 6 records appear to have errors in the comorbidities field
* 1 preoperative weight may be incorrect
* It was noted particularly that the PICU discharge summary tended to use an array of local acronyms such as PIE, CRUS, ESBL etc.

**Security and Confidentiality**

As at all the previous visits, the Access system that was used for this data collection has been registered with the Trusts Data Protection Officer and there are tested procedures to ensure data backup and disaster recovery. The system is fully compliant with the Trusts policy on security and confidentiality. There are still (since 2004) no written procedures available to staff in all the areas where staff collect and manage data but there are written procedures in place for audit data collection activities. There is a proforma available which outlines the NCHDA Dataset. The Auditor and Information Analyst are confident that all patient data is consistently collected in all instances. This remains unchanged for the June 2017 NCHDA validation visit.

**Validation and Quality Assurance**

The Access database has validation routines built in to it but since 2006 some of these are no longer in force. Checking for duplicates is done but not data completeness or for invalid entries. These have to be done manually. The procedure to check for an NHS number without an 01 status indicator or for the validation algorithm for the NHS number, is done by the Trust PAS (Meditech) as the demographic data are input. This is unchanged since 2003.

Some validation rules built into the Cardicare system. For example the system only allows input of data/codes included in the NCHDA dataset.

Surgical data collection processes are audited on a regular basis. The audit staff routinely check data with other appropriate sources weekly. This is unchanged in June 2017. There is now regular validation of submitted data (reverse validation) and the PRAiS software is used regularly also.

**Training**

It is reported in the 2017 Pre Visit Questionnaire that there is now a documented training programme covering the recording clinical activity for staff and that there is central responsibility within the Trust for the identification of training needs and development and provision of training in data collection.

It is also reported in 2017 that clinicians do not enter any data.

As reported in 2008, an updated ICP proforma has been in use since 2007 to assist with collecting NCHDA relevant data. This is unchanged in June 2017.

**Communications**

As reported in 2011-16, there are established procedures for reissuing amended information following changes to the data and there are procedures to ensure timely collection and dissemination of activity data within the organisation and to NCHDA. There are established procedures for answering queries about the data or information produced from NCHDA. The NHS number is used on communications and appeared to be routinely present on patient identity labels.

**Accountability**

Dr R A Johnson (Consultant Congenital Cardiologist) and Mr Rafael Guerrero (Consultant Cardiac Surgeon) are the nominated persons within the Trust who have management responsibility for NCHDA data and they are the designated clinicians responsible for data quality and standards conformance in Cardiology and for Cardiac Surgery. It was reported in May 2007, that there were arrangements in place to give those staff responsible for data quality adequate influence over other staff whose actions affect data quality and appears unchanged in June 2017.

**Health Records Management**

On the whole most but not all of the information required by NCHDA can be found in the printed ePR notes, and the original hospital notes are also available for this to be done. As stated elsewhere in this report, the cardiologists have adapted their ICP to also reflect the NCHDA dataset more closely but this is not always completed as noted in the 2008-June 2016 reports

**Timeliness**

Internal reports are meeting agreed deadlines, the 2014-16 submission deadline was met.

It is also noted that there have again been extreme technical difficulties both locally and at NICOR with the physical submission of data.

**Completeness and Validity**

As at all the previous visits, transfer tables are available to ensure patient care events are defined correctly according to NCHDA classifications and includes a list of the acronyms, synonyms and abbreviations.

**Accuracy**

There is a data quality and audit programme in progress which includes checking data items against source documentation and this is undertaken by the Cardiac Auditor/Cardiac Information Analyst. The surgeons are reported to participate in the validation of diagnostic and procedure codes in surgery patients and there is increasing participation from some of the cardiologists. This is anticipated to continue to improve further during the year17/18.

**Casenote Audit:** 20 patients had 20 operations 12 therapeutic catheter procedures

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **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 | 31 | 32 | 1 incorrect element | 12 | 19/20 |
| 11 | Previous Procedures | 62 | 66 | 4 absent | 31/35 | 31 |
| 12 | Patients Weight at  Operation | 31 | 32 | 1 incorrect | 12 | 19/20 |
| 13 | Height | 26 | 28 | 2 incorrect | 11 | 15/17 |
| 14 | Ante Natal Diagnosis | 4 | 5 | 1 incorrect | 1 | 3/4 |
| 15 | Pre Proc Seizures | 32 | 32 |  | 12 | 20 |
| 16 | Pre Proc NYHA | - | - |  | - | - |
| 17 | Pre Proc Smoker | - | - |  | - | - |
| 18 | Pre Proc Diabetes | - | - |  | - | - |
| 19 | Hx Pulmonary Dis | - | - |  | - | - |
| 20 | Pre Proc IHD | - | - |  | - | - |
| 21 | Comorbidity Present | 17 | 17 |  | 6 | 11 |
| 22 | Comorbid Conditions | 31 | 31 |  | 11 | 20 |
| 23 | Pre Proc Systemic Ventricular EF | 31 | 32 | 1 incorrect | 12 | 19/20 |
| 24 | Pre Proc Sub Pul Ventricular EF | 27 | 39 |  | 12 | 15/18 |
| 25 | Pre-proc valve/septal defect/ vessel size | 4 | 4 |  | 4 | - |
| 26 | Consultant | 32 | 32 |  | 12 | 20 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 32 | 32 |  | 12 | 20 |
| 28 | Time Start | 32 | 32 |  | 12 | 20 |
| 29 | Proc Urgency | 32 | 32 |  | 12 | 20 |
| 30 | Unplanned Proc | - | - |  | - | - |
| 31 | Single Operator | 1 | 1 |  | - | - |
| 32 | Operator 1 | 32 | 32 |  | 12 | 20 |
| 33 | Operator 1 Grade | 32 | 32 |  | 12 | 20 |
| 34 | Operator 2 | 31 | 31 |  | 11 | 20 |
| 35 | Operator 2 Grade | 31 | 31 |  | 11 | 20 |
| 36 | Procedure Type | 32 | 32 |  | 12 | 20 |
| 37 | Sternotomy Sequence | 15 | 15 |  | - | 15 |
| 38 | Operation Performed | 32 | 32 |  | 12 | 20 |
| 39 | Sizing balloon used for septal defect | - | - |  | - | - |
| 40 | No of stents or coils | - | - |  | - | - |
| 41 | Device Manufacturer | 5 | 7 | 2 absent | 3 | 2/4 |
| 42 | Device Model | 6 | 7 | 1 absent | 3 | 3/4 |
| 43 | Device Ser No | 4 | 7 | 3 absent | 3 | 1/4 |
| 44 | Device Size | 6 | 6 |  | 3 | 3 |
| 45 | Total Bypass Time | 15 | 15 |  | - | 15 |
| 46 | XClamp Time, | 12 | 12 |  | - | 12 |
| 47 | Total Arrest | 0 | 1 | 1 absent | - | 0/1 |
| 48 | Cath Proc Time, | 11 | 12 | 1 absent | 11/12 | - |
| 49 | Cath Fluro Time, | 12 | 12 |  | 12 | - |
| 50 | Cath Fluro Dose, | 12 | 12 |  | 12 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation | 9 | 14 | 5 incorrect | - | 9/14 |
| 52 | Post Procedure Seizures | 32 | 32 |  | 12 | 20 |
| 54 | Post Proc Complications | 2 | 2 |  | - | 2 |
| 55 | Date of Discharge | 32 | 32 |  | 12 | 20 |
| 56 | Date of Death | 1 | 1 |  | - | 1 |
| 57 | Status at Discharge | 32 | 32 |  | 12 | 20 |
| 58 | Discharge Destination | 32 | 32 |  | 12 | 20 |

The Overall Trust DQI = 97.5% Cardiology DQI = 99% Surgery DQI = 97%

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 .96** | |
| **Card**  .97 | **Surg**  .95 |
| **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**  .99 | **Surg**  .98 |
| **Outcome**  Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination.  **Post Procedure Complications.** | **Overall** .96 | |
| **Card**  1.0 | **Surg**  .95 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **DOMAIN** | **2017** | **2016** | **2015** | **2014**  **(ii)** | **2014**  **(i)** |
| **Demographics**, | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 |
| **Pre Procedure** | .96 | .91 | .93 | .88 | .92 |
| **Procedure** | .98 | .94 | .99 | .95 | .95 |
| **Outcome** | .96 | 1.0 | .97 | .96 | .97 |

**Conclusions**

On the whole the NCHDA data were accurate and well documented in the theatre and cath lab log books that were seen. The patient information folders for each of the patients included in the Data Quality Indicator (DQI) analysis had been meticulously prepared by the Cardiac Information Analyst.

The DQI is 97.5% for the 16/17 data (95.25%, at the previous  validation).  This is a 2% increase in the DQI and a very good score.   There were 30 errors or omissions in  1035 variables.  There have again been some extreme technical challenges relating to timely data submission during the year 2016/17 that have affected almost every congenital centre.

As previously reported, it appears that there are still some challenges with developing and/or purchasing a cardiac information system that can be used at the point of service to capture data in real time at any location in within ACH. Currently there is an ‘in-house’ solution being developed.

There is still appears to be little or no contemporaneous input of data at each point of service in all clinical areas. A majority of the data appear to be input by the audit team rather than the responsible clinical colleagues.

There was less of the detail of implantable devices (manufacturer, model and serial number) absent from the submitted data this year but it remains a concern that these details do not always appear to be routinely included in the patients hospital notes.

There was also concern from Reviewers that on occasions the descriptions of procedures recorded as performed in the log books for the cath lab and operating theatres were not as specific as they could be.

**Validation of Deceased Patients Case Notes**

The NCHDA are grateful to the Medical Director for providing 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 a small number errors found as reported elsewhere. The Reviewers noted that in almost every PICU discharge summary examined there appeared to be a number of locally devised acronyms with no translation available.

**Recommendations for ACH (2017)**

1. If not already in place, it is recommended that Standard Operating Protocols are devised for the data collection, to include detailed guidance on and exactly **who** is responsible for each of the following;
   1. Ensuring consent for external validation of hospital notes is obtained prospectively from all patients with congenital heart disease
   2. Input of congenital patients NCHDA required dataset items and at which point of service delivery
   3. Encouraging every responsible clinician or allied professional to input data for each operation, diagnostic or catheter intervention at the point of the service delivery from admission to discharge and to own their data.
   4. Recording the knife to skin time for all surgical procedures where it can be validated (ie perfusion or anaesthetic record).
   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. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data Managers at least monthly.
   7. Running the PRAiS (Paediatric Risk Analysis in Surgery) analysis tool monthly. This will inform the quarterly NHSE Dashboard reports.
   8. Ensuring that dates of death are reported for any ACH patient who has previously had a record submitted to the NCHDA
   9. Leading the local review (and how frequently and in which forum for both disciplines)
   10. Making timely submissions (monthly is recommended) and
   11. Including details of manufacturer, model and serial numbers of all implantable devices the procedure record for each patient.
   12. Reviewing/Updating the SOP at timely intervals
2. In liaison with the person responsible for staff training and development in the Trust, regular training must be provided not only for the Auditors, but for all staff in the Department who may be involved with data input. This should include regular Quality Assurance and Governance training and visits to other centres who are involved in NCHDA data collection and submission.