**The National Congenital Heart Disease Audit**

 **Procedures for**

 **CONGENITAL HEART DISEASE**

 **Data Quality Audit**

**For the year 2017/18**

 **Royal Liverpool Children’s Hospital NHS**

 **Foundation Trust**

 **15 October 2018**

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**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 815 therapeutic cardiac procedures had been undertaken during the 2017/2018 data collection year (surgery 398, catheters 203, others 214, Deaths 13) in patients with congenital heart disease. This validation visit has been fully funded by the Alder Hey Children’s NHS Foundation NHS Trust. The Validation was undertaken by an external consultant congenital cardiologist on site at Alder Hey and the NCHDA Clinical Auditor who was present via a Skype connection for the whole day.

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

**Update on actions reported by ACH to have been undertaken since last visit in June 2017:**

* The Standard Operating Protocol for NCHDA data collection is reviewed regularly and most recently updated to include the definitions outlined in the recently published NCHDA dataset manual.
* Information System developments – the Trust Business Intelligence Team have worked with Cardiac Audit to develop Cardicare when NCHDA released the specifications for the web facing v6.0 dataset.
* ACH report that development of a tool for demographics data to be linked to the Trust Patient Administration System is on going. This will improve the data quality and release auditor time to validate the clinical data.
* Following the departure of the Cardiac Data Manager, The experienced Cardiac Information Analyst-1.0 WTE to the service, is currently acting Cardiac Data Manager.

**Overview at ACH**

As previously reported, data entry is carried out by operators and 2 Auditors. The 2 auditor roles provide a total of 30 hours (2 x 0.4 WTE) per week. The Validation Team are pleased to report that the Cardiac Information Analyst (1.0 WTE) who previously was responsible for supervising the data collection, auditing completeness and accuracy, and submission of data to the registry, has now been appointed into the post of Cardiac and Clinical Data Manager. The role now includes overseeing the registry and collaborating with the audit team and clinicians to ensure data accuracy.

**Congenital Data Collection at ACH**

As previously reported, from 2003 until approximately 2015, the data at ACH were collected on an electronic proforma in an Access Database; data entry had been carried out by 2 Auditors who received all cardiac notes on discharge, and data input was carried out by these personnel. From 2015 onwards that has been a development of a fully integrated cardiac information system, Cardicare. A consultant surgeon has responsibility for the surgical data and its quality and works closely with the Audit Team.

Much of the data are now input at the point of service. The Cardiologists and the Surgeons piloted the process and there have been a number of adjustments and retrials. However there were a number of technical issues and logistical hold ups with this system was fully commissioned until 2017. ACH also moved location to a purpose built environment during the autumn of 2015 and this also impacted on the timeliness of this development.

**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.

It should be noted that under GDPR 2018 regulation all patients/parents/guardians should receive fully documented information to keep on exactly how their data are collected, stored, to which Organisation submissions and of which data are made to and who may see this information. It is further advised that under GDPR there must be a clear option for the patient/parent/guardian to opt out of the NCHDA data collection and review process at any time. It is also suggested that under the GDPR, consent is no longer required to review the case notes of deceased patients if this has not been obtained during life.

**Data Quality Indicator**

The individual DQI for ACH (with previous years in parentheses) is **98%** (97.5, 95.25,97.25). The domain scores are Demographics 1.0 (1.0 1.0 1.0). Pre Procedure .94 (.96, .91 .93). Procedure .997 (.98, .94, .99 .95) and Outcome .99 (.96, .97 .96)

20 patients procedures were reviewed for the period April – March 2017/18. These patients had undergone 25 procedures, 15 operations and 10 catheter procedures. There were 903 variables reviewed and 18 errors or discrepancies were identified.

Also, for this visit, a separate DQI calculation is being made for surgery and catheter procedures where there is a minimum of 5 records in either group at the case note validation.

The scores for ACH are:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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% |
| **2018** | 17/18 | 96.25% | 95% |

**Introduction**

Prior to the validation visit, the NCHDA return from Liverpool Royal Children’s Foundation Trust indicated that some 815 therapeutic cardiac procedures had been undertaken during the 2017/2018 data collection year (surgery 398, catheters 203, others 214, Deaths 13).

20 sets of case notes were selected for review. A reserve list of 10 cases was also supplied and on the day, 1 case note was 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

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 2016-17 validation visits, 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 were often not always in chronological order and in some instances it appeared that the pages might be absent.
2. Echocardiogram reports were sometimes difficult to find and it sometimes appeared that the specific left and right ventricular function percentages were not documented clearly.
3. The explicit documentation of date and time of extubation was sometimes challenging to find in the hospital notes of surgical patients.
4. 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.
5. 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 2017/8 were presented for both the cath labs and operating theatres.

**From the cath lab log books;**

1. 0 procedures were identified in the cath lab log books that may have been missed from the data submission
2. 7 submitted records may to have errors in their coding
3. 4 catheter records were not validated in the log books

**From the operating theatre log books;**

1. 1 procedure was identified in the log books that may have been missed from the data submission
2. 1 submitted record may have an error in it
3. 7 surgical records were not validated in the log books

**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.

13 patients were identified to have died following cardiac procedures during 2017/18. 5 of these deaths are reported to have occurred within 30 days of either a surgical or interventional catheter procedure. These 5 case notes were made available for this review.

* All dates of death appear to be correct.
* There appears to be discrepancies on 2 complication records

The 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

**Casenote Audit**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 10 | 10 |
| 2 | NHS Number | 20 | 20 |  | 10 | 10 |
| 3 | Surname | 20 | 20 |  | 10 | 10 |
| 4 | First Name | 20 | 20 |  | 10 | 10 |
| 5 | Sex | 20 | 20 |  | 10 | 10 |
| 6 | DOB | 20 | 20 |  | 10 | 10 |
| 7 | Ethnicity | 20 | 20 |  | 10 | 10 |
| 8 | Patient Status | 20 | 20 |  | 10 | 10 |
| 9 | Postcode | 20 | 20 |  | 10 | 10 |
| 10 | Pre Procedure Diagnosis | 25 | 25 |  | 10 | 15 |
| 11 | Previous Procedures | 28 | 30 | 1 absent, 1 incorrect | 3 | 25/27 |
| 12 | Patients Weight atOperation | 25 | 25 |  | 10 | 15 |
| 13  | Height | 25 | 25 |  | 10 | 15 |
| 14 | Ante Natal Diagnosis | 2 | 2 |  | - | 2 |
| 15 | Pre Proc Seizures | 25 | 25 |  | 10 | 15 |
| 16 | Pre Proc NYHA  | 1 | 1 |  | 1 | - |
| 17 | Pre Proc Smoker | 1 | 1 |  | 1 | - |
| 18 | Pre Proc Diabetes | 1 | 1 |  | 1 | - |
| 19 | Hx Pulmonary Dis | 1 | 1 |  | 1 | - |
| 20 | Pre Proc IHD | 1 | 1 |  | 1 | - |
| 21 | Comorbidity Present | 25 | 25 |  | 10 | 15 |
| 22 | Comorbid Conditions | 25 | 28 | 2 incorrect, 1 absent | 8 | 17/20 |
| 23 | Pre Proc Systemic Ventricular EF | 20 | 25 | 5 incorrect | 5/10 | 20 |
| 24 | Pre Proc Sub Pul Ventricular EF  | 18 | 24 | 6 incorrect | 5/10 | 18/19 |
| 25 | Pre-proc valve/septal defect/ vessel size | 5 | 5 |  | 4 | - |
| 26 | Consultant | 25 | 25 |  | 10 | 15 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure + Time Start | 25 | 25 |  | 10 | 15 |
| 28 | Proc Urgency | 25 | 25 |  | 10 | 15 |
| 29 | Unplanned Proc | 25 | 25 |  | 10 | 15 |
| 30 | Single Operator | 2 | 2 |  | 2 | - |
| 31 | Operator 1 | 25 | 25 |  | 10 | 15 |
| 32 | Operator 1 Grade | 25 | 25 |  | 10 | 15 |
| 33 | Operator 2 | 23 | 23 |  | 8 | 15 |
| 34 | Operator 2 Grade | 23 | 23 |  | 8 | 15 |
| 35 | Procedure Type | 25 | 25 |  | 10 | 15 |
| 36 | Sternotomy Sequence | 9 | 10 | 1 incorrect | - | 9/10 |
| 37 | Operation Performed | 25 | 25 |  | 10 | 15 |
| 38 | Sizing balloon used for septal defect  | 0 | 0 |  | 0 | - |
| 39 | No of stents or coils | 1 | 1 |  | 1 | - |
| 40 | Device Manufacturer | 7 | 7 |  | 6 | 1 |
| 41 | Device Model | 7 | 7 |  | 6 | 1 |
| 42 | Device Ser No | 7 | 7 |  | 6 | 1 |
| 43 | Device Size | 4 | 4 |  | 6 | - |
| 44 | Total Bypass Time | 10 | 10 |  | - | 10 |
| 45 | XClamp Time, | 10 | 10 |  | - | 10 |
| 46 | Total Arrest | 0 | 0 |  | - | 10 |
| 47 | Cath Proc Time, | 10 | 10 |  | 10 | - |
| 48 | Cath Fluro Time, | 10 | 10 |  | 10 | - |
| 49 | Cath Fluro Dose, | 10 | 10 |  | 10 | - |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 50 | Duration of Post Op Intubation  | 9 | 9 |  | - | 9 |
| 51 | Post Procedure Seizures  | 25 | 25 |  | 10 | 15 |
| 52 | Post Proc Complications | 7 | 8 | 1 absent | - | 7/8 |
| 53 | Date of Discharge | 25 | 25 |  | 10 | 15 |
| 54 | Date of Death | 1 | 1 |  | - | 1 |
| 55 | Attribution of Death | 1 | 1 |  | - | 1 |
| 56 | Status at Discharge | 25 | 25 |  | 10 | 15 |
| 57 | Discharge Destination | 25 | 25 |  | 10 | 15 |

The Overall Trust DQI = 98% Cardiology DQI = 95% Surgery DQI = 96.25%

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 .94** |
| **Card**.90 | **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** .997 |
| **Card**1.0 | **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** .99 |
| **Card**1.0 | **Surg**.99 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **DOMAIN** | **2018** | **2017** | **2016** | **2015** | **2014****(ii)** |
| **Demographics**, | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 |
| **Pre Procedure** | .94 | .96 | .91 | .93 | .88 |
| **Procedure** | 997 | .98 | .94 | .99 | .95 |
| **Outcome** | .99 | .96 | 1.0 | .97 | .96 |

 **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 98% for the 17/18 data. This is a further 0.5% increase in the DQI and a very good score.   There were 18 errors or omissions in 903 variables.  There have again been some extreme technical challenges relating to timely data submission during the year 2017/18 that have affected almost every congenital centre.

There appears to be growing contemporaneous input of data at each point of service in all clinical areas. This is an excellent development.

There was again 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.

As previously noted, there was 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. In particular it appeared on occasions that surgical pacemaker implants were not always recorded in the theatre log books and some pages appeared to be missing from the cath lab log books.

**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.

**Recommendations for ACH (2018)**

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 data submission and external validation of hospital notes is obtained prospectively from all patients with congenital heart disease and each patients parent/guardian receives a description of data that is collected, how it is audited and the submission to Organisations such as NICOR or others.
	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.