**The National Congenital Heart Disease Audit (NCHDA)**

**Data Quality Audit for Congenital Procedures**

**For the years Apr-Mar 2017/18**

**The Harley Street Clinic**

**10 July 2018**

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**Summary**

Prior to the Log Book Review, the data return to the NCHDA from the Cardiac Department of The HCA Harley Street Clinic (HSC) indicates that 113 therapeutic cardiac procedures (79 surgery, 26 therapeutic catheter procedures, 8 others, and 0 deaths) had been undertaken in children and adults with congenital heart disease during the data collection year from Aril 2017 to March 2018..

As previously reported, Dendrite Intellect is the information collection system used at HSC and throughout all the other 6 hospitals run by HCA in London. There is a team of clinical analysts who support the 3 HCA hospitals that undertake cardiac procedures, reporting data for NACSA, NAPCI, CRM and NCHDA locally and externally. There is 1 part time external clinician (0.2WTE) who reviews the quality of the clinical data coding prior to submission to NCHDA.

As previously reported, since January 2008 the cardiac catheter laboratory staff have been involved in collecting and inputting interventional catheter data. 1 resident specialist surgeon reviews and amends the surgical data prior to submission. As previously reported it appears that the Consultant clinicians do not have access to Dendrite in the operating theatres or the catheter labs. Therefore, there is no direct data entry by the responsible clinicians at the point of service at either location.

There are a number of congenital cardiac surgeons and congenital cardiologists who undertake cardiac procedures on congenital patients in the cardiac catheter laboratories at HSC.

As in 2009-17, HCA do not have a direct link with the NHS Strategic Tracing Service for rapid identification of NHS Numbers for patients who are UK residents. However, the Organisation do have an N3 (NHS standard secure broadband) connection. It appears that 24 records (21% of the total) in the 2017/2018 cohort appear to have a UK residential postcode but none has an NHS Number contained in the record submitted to the NCHDA. It is reported at this visit that this is being addressed by HCA.

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

Since 1 April 2007 patient consent is required for external validation of hospital case notes. Without patient consent, external validation of hospital notes cannot take place.

HCA (HSC) took full responsibility for validation consent to enable audit of the selected hospital notes. The reviewers are grateful to the Director of Clinical Services who is the local Caldicott Guardian for facilitating this.

**Actions taken since the last validation visit in 2017**

1. No actions were reported on the Previsit Questionnaire

**Data Quality Indicator Score**

20 patients were randomly selected for the case note review to derive the Data Quality Indicator Score. These 20 patients had undergone 21 procedures (10 operations, 11 cardiac catheter procedures).

The overall DQI HSC (with the previous years in parentheses) is calculated to be **95.5%** (95.75, 94.5,94.5**,** 95.75), with domain scores Demographics .95 (.99, .97 .99) Pre Procedure .95 (.94, .92 93) Procedure .94 (.90, .94 .89 .94) and Outcome .98 (1.0, .95 .97).

There were 39 errors or omissions in 809 variables.

As in 2009-17, separate DQI scores are being calculated for surgery and catheter procedures. A minimum of 5 cases from each group are required in the random sample. The separate DQI score’s at HSC are;

|  |  |  |  |
| --- | --- | --- | --- |
| **Year Visited** | **Data Year Validated** | **Surgery DQI %** | **Catheter DQI %** |
| **2009** | 07/08 | 86.25% | Insufficient sample |
| **2010** | 08/09 | 91.25% | 90.5% |
| **2011(i)** | 09/10 | 95% | 92% |
| **2011(ii)** | 10/11 | 97.5% | 95% |
| **2012** | 11/12 | 93.75% | 98% |
| **2013** | 12/13 | 94.75% | 96.5% |
| **2014** | 13/14 | 96.5% | 94.5% |
| **2015** | 14/15 | 96.5% | 86% |
| **2016** | 15/16 | 95.5% | 93.5% |
| **2017** | 16/17 | 97.75% | 93.25% |
| **2018** | 17/18 | 96.25% | 95% |

The body of this report is drawn from answers given in the NCHDA pre visit questionnaire and from discussions on the day of the visit.

**Introduction**

As stated in the Summary above, prior to the Log Book Review, the data return to Congenital NCHDA from the Harley Street Clinic that was used for this validation visit indicated that 113 therapeutic cardiac procedures (79 surgery, 26 therapeutic catheter procedures, 8 others, and 0 deaths) had been undertaken in children and adults with congenital heart disease during the data collection year from Aril 2017 to March 2018..

20 Sample sets of case notes were randomly selected. A further Reserve list of cases was supplied in case any of the first 20 were unavailable. On the day, 1 Reserve case note was used to replace those that were unavailable in the Sample. The NCHDA Clinical Data Auditor and one external Consultant in Congenital Cardiology undertook the site audit on the day. The NCHDA Clinical Data Auditor was present for the whole day via Skype.

The Regulatory Compliance Lead at HSC, in collaboration with clinical colleagues completed the pre visit self-assessment questionnaire.

**Review of the notes**

As previously reported, the hospital notes of patients are routinely scanned into the hospital electronic patient record system Meditech after final live discharge. The hospital notes of deceased patients are scanned. For this visit all of the original paper bound case notes were still available to view and where necessary parts of the EPR were accessible to enable viewing if required.

As previously, almost all of the case notes had been prepared with small sticky notes indicating documents that the Reviewers needed to see. Some data were only available on the electronic data systems.

The numerical indices for GMC number and name were submitted for each consultant which is excellent.

1. As in previous years, perfusion sheets were available in the bypass patients hospital notes seen.
2. Also, as previously reported, fluroscopy data sheets were seen in almost all the catheter procedure hospital notes but were often sparsely completed. It was also not clear whether the total time calculated was from skin puncture to sheath removal or total time in the cath lab. NCHDA require skin puncture to sheath removal in minutes.
3. It was unclear on some the cath lab procedure reports exactly how the fluroscopy dose had been calculated.
4. As previously reported, it was not always clear in the hospital notes (handwritten or electronic ICIP) exactly (date and time) when a patient was extubated. The typed operation notes seen were mostly very detailed and outlined the previous procedures a patient may have had.
5. Written notes on ventricular function data were often seen in the hospital records but were submitted as ‘unknown’ in the NCHDA data. Patients with single ventricles only need to have one of the ventricular fields (systemic) completed.
6. It again became clear during the case note review that the Paediatric Risk Analysis in Surgery (PRAiS) software has not been used at HSC since the 2016 Validation visit.

**Cath lab log book review:**

As in previous years, the log books from 3 cath labs were offered for review. These are bespoke bound volumes with ruled lines and named columns for recording various information including fluoroscopy data and predominantly used by the radiography staff. As previously reported, it is noted that there is an ink stamp in use that says ‘CONGENITAL’ and this was helpful in enabling the identification of cases more speedily.

1. As previously reported the descriptions of procedures were not always easy to read or decipher as on occasions the CONGENITAL stamp is not always used consistently.
2. 3 catheter case was identified that may have been missed from the submission.
3. 1 submitted catheter record appears to have an error in the procedure performed field
4. 15 submitted catheter records appeared to be for patients with a UK post code but had no NHS Number.

A list of the above cases has been provided to the HSC DBM for local review and consideration for submission to congenital NCHDA.

**Review of the Operating Theatre Log Books**

There are 4 operating theatres used for congenital surgery at HSC. A copy of the electronic logs from MediTech for these theatres were offered for the review. This appears to be a theatre booking system and is an integral part of the EPR.

1. 4 records were identified that may be suitable for inclusion in the NCHDA.
2. 4 records were identified that may have errors or omissions in them.
3. 10 submitted surgical records appear to be for patients with a UK residential post code but had no NHS Number

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

Commencing with the validation of the 2013/14 data in 2014, the National Congenital Heart Disease Audit wish to verify any dates of death of deceased patients included in the year under review. The data fields that are included in the PRAiS analysis are validated for both paediatric cardiac and ACHD patients.

The requirement for consent to validate these hospital data are the same as for the congenital procedures review. Where there is no evidence that consent has been given the Medical Director is asked to give permission for the case note examination. The Validation Team are grateful to the Director of Clinical Services for facilitating this.

Zero (nil) deaths in post procedural congenital cardiac patients were noted in the 2017/2018 data.

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

However, it is of concern that reverse validation of the submitted data to NCHDA against locally held data had not been undertaken and the risk analysis PRAiS, has also not be run.

**Casenote Audit 17/18**

20 patients underwent 2x procedures (11 operations, 10 catheter procedures)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  | | | | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 9 | 11 |
| 2 | NHS Number | 0 | 8 | 8 Absent | 0/5 | 0/3 |
| 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 | 21 | 21 |  | 10 | 11 |
| 11 | Previous Procedures | 27 | 27 |  | 19 | 8 |
| 12 | Patients Weight at  Operation | 21 | 21 |  | 10 | 11 |
| 13 | Height | 19 | 19 |  | 10 | 9 |
| 14 | Ante Natal Diagnosis | 1 | 1 |  | 1 | 1 |
| 15 | Pre Proc Seizures | 21 | 21 |  | 10 | 11 |
| 16 | Pre Proc NYHA | 9 | 10 | 1 absent | 4/5 | 5 |
| 17 | Pre Proc Smoker | 8 | 10 | 1 absent, 1 incorrect | 4/5 | 4/5 |
| 18 | Pre Proc Diabetes | 9 | 10 | 1 absent | 4/5 | 5 |
| 19 | Hx Pulmonary Dis | 9 | 10 | 1 absent | 4/5 | 5 |
| 20 | Pre Proc IHD | 9 | 10 | 1 absent | 4/5 | 5 |
| 21 | Comorbidity Present | 20 | 21 | 1 incorrect | 4/5 | 5 |
| 22 | Comorbid Conditions | 4 | 6 | 2 absent | 4/5 | 5 |
| 23 | Pre Proc Systemic Ventricular EF | 19 | 21 | 2 incorrect | 9/10 | 11 |
| 24 | Pre Proc Sub Pul Ventricular EF | 19 | 20 | 1 incorrect | 10 | 9/10 |
| 25 | Pre-proc valve/septal defect/ vessel size | 6 | 8 | 2 incorrect | 6/8 | - |
| 26 | Consultant | 21 | 21 |  | 10 | 11 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure + Time Start | 21 | 21 |  | 10 | 11 |
| 28 | Proc Urgency | 21 | 21 |  | 10 | 11 |
| 29 | Unplanned Proc | - | - |  | - | - |
| 30 | Single Operator | 7 | 9 | 2 incorrect | 6/8 | 0/1 |
| 31 | Operator 1 | 21 | 21 |  | 10 | 11 |
| 32 | Operator 1 Grade | 21 | 21 |  | 10 | 11 |
| 33 | Operator 2 | 12 | 14 | 1 incorrect, 1 absent | 2/3 | 9/11 |
| 34 | Operator 2 Grade | 12 | 14 | 1 incorrect, 1 absent | 2/3 | 9/11 |
| 35 | Procedure Type | 21 | 21 |  | 10 | 11 |
| 36 | Sternotomy Sequence | 11 | 11 |  | - | 11 |
| 37 | Operation Performed | 21 | 21 |  | 10 | 11 |
| 38 | Sizing balloon used for septal defect | 1 | 1 |  | 1 | - |
| 39 | No of stents or coils | 3 | 3 |  | 3 | - |
| 40 | Device Manufacturer | 12 | 12 |  | 10 | 2 |
| 41 | Device Model | 12 | 12 |  | 10 | 2 |
| 42 | Device Ser No | 10 | 17 | 7 absent | 8/15 | 2 |
| 43 | Device Size | 9 | 10 | 1 absent | 7/8 | 2 |
| 44 | Total Bypass Time | 10 | 11 | 1 incorrect | - | 10/11 |
| 45 | XClamp Time, | 10 | 11 | 1 incorrect | - | 10/11 |
| 46 | Total Arrest | 2 | 3 | 1 incorrect | - | 2/3 |
| 47 | Cath Proc Time, | 10 | 10 |  | 10 | - |
| 48 | Cath Fluro Time, | 9 | 9 |  | 9 | - |
| 49 | Cath Fluro Dose, | 8 | 9 | 1 absent | 8/9 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **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 | 21 | 21 |  | 10 | 11 |
| 52 | Post Proc Complications | 2 | 3 | 1 absent | - | 2/3 |
| 53 | Date of Discharge | 21 | 21 |  | 10 | 11 |
| 54 | Date of Death | - | - |  | - |  |
| 55 | Attribution of Death | - | - |  | - |  |
| 56 | Status at Discharge | 21 | 21 |  | 10 | 11 |
| 57 | Discharge Destination | 21 | 21 |  | 10 | 11 |

Data Quality Indicator Assessment:

The Overall DQI = 95.5% Cardiology DQI = 95% Surgery DQI = 96.25%

|  |  |  |
| --- | --- | --- |
| **DOMAIN** | **DOMAIN**  **Score** | |
| **Demographics**  Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status, | **Overall .95** | |
| **Card**  .93 | **Surg**  .97 |
| **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 .95** | |
| **Card**  .94 | **Surg**  .96 |
| **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** .94 | |
| **Card**  .93 | **Surg**  .96 |
| **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**  1.0 | **Surg**  .96 |

**Data Quality Indicator Assessment**

**The Trust DQI = 95.5%**

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** | **2018**  **17/18** |
| **Demographics** | .98 | .99 | .97 | .99 | ..95 |
| **Pre Procedure** | .96 | .93 | .92 | .94 | .95 |
| **Procedure** | .94 | .89 | .94 | .90 | .94 |
| **Outcome** | .95 | .97 | .95 | 1.0 | .98 |

**Conclusions**

On the whole the NCHDA data that has been submitted are accurate, well documented, good quality and was appropriately recorded in the Cath Lab and Meditech logs. There have been a number of personnel changes in the area of compliance and governance at HSC and the new team are working hard to build on past achievements.

The NCHDA Team are very pleased to report that the prospective gathering of consent for external validation of patients hospital notes while slightly delayed from 2016, is to be embedded in the admission procedures together with the collection of NHS Numbers for patients who are UK residents. The NHS Number is essential for accurate mortality tracking. The 30 day and 1 year mortality for 83 specific procedures are published on the Congenital public website and are therefore in the public domain.

As previously reported there appears to be no contemporaneous NCHDA procedural data input by responsible clinicians at the point of service in the operating theatre or cath labs. Other more junior staff appear to be doing this task. As previously reported, there are entries in the hospital records but these often do not include radiation dose or time or skin to skin time which are required for the NCHDA validation. Where electronic entries from the ICIP ITU information system were made available it was not always easy to find nor was it very clear what the exact time scale of events were such as extubation of the ET tube.

It is still of considerable concern that the responsible clinicians are not involved in the reverse validation of their data after it has been submitted to NCHDA. The Reviewers are also concerned that the PRAiS risk analysis for surgery has not been used in this centre for approximately 24 months and it is recommended that it is run at least quarterly or more frequently depending on volume of procedures undertaken.

It also appears that congenital data from HCA are submitted quarterly in arrears. Whilst this has been acceptable in the past, it may be prudent to review this as NCHDA are likely to be moving to quarterly reporting during 2018/19.

A printout of the HSC Meditech System was provided for the operating theatre log book check. This was not clear to read at times and some of the descriptions recorded of the procedures performed did not appear to reconcile completely with the data that had been submitted to the NCHDA. The use of the self inking stamp to mark congenital interventions in the cath lab log book again aided the identity of such cases but as previously, it was noted that it was not always consistently used.

**Validation of Deceased Patients data.**

* No post procedural deaths have been reported by HSC for 2017/18

**Recommendations (as in 2017-17)**

1. The NCHDA recommends that each congenital centre has 1.0WTE dedicated data manager and an at least 1.0WTE assistant responsible for audit and database submissions per 400 procedures undertaken. This recommendation is in accordance with the congenital cardiology Standards published as part of the NHS England new Congenital Heart Disease review (July 2015).
2. It is recommended that any Standard Operating Protocols for the congenital data collection are reviewed regularly to ensure that they, include detailed guidance on and exactly **who** is responsible for and in what timeframe;
   1. Ensuring consent for external validation of hospital notes is obtained prospectively from all patients with congenital heart disease in line with GDPR 2018
   2. Input of congenital patients NCHDA required dataset items and which point of service delivery
   3. Identifying and collecting the NHS Number for any UK resident, who is a congenital cardiac patient at HSC and that it is included in the data submission
   4. Encouraging responsible clinician input of the procedure data for each operation or catheter intervention at the point of the service delivery
   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 DBM at least quarterly.
   7. Regular running of PRAiS risk analysis software. In high volume NHS centres this is required monthly.
   8. Ensuring that dates of death are reported for any HSC 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 with each patient record for a procedure.
   12. Reviewing/Updating the SOP at timely intervals
3. It is also recommended that all congenital cardiac audit data personnel, should visit with other centres that submit congenital cardiac data to NCHDA.