**The National Congenital Heart Disease Audit**

**Procedures for**

**CONGENITAL HEART DISEASE**

**Data Quality Audit for April 2017 – March 2018**

**University Hospitals Birmingham NHS Foundation Trust**

**31 July 2018**

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**Summary**

Prior to this validation visit the combined Congenital NICOR data return from the Queen Elizabeth Medical Centre (UHB FT) indicated that some 126 (surgery 69, catheter 27, others 30, Deaths 3) procedures had been undertaken during the data collection year of 2017/18 on adults with congenital heart disease.

This validation visit has been fully funded by UHB NHS Foundation Trust. The external clinician assisting was an ST7 in Congenital Cardiology and was present on site in person. The NCHDA Clinical Audit Nurse was present via a combination of Skype and teleconference line.

20 sets of case notes are randomly selected from the submission from QEB. However, only 18 were made available on the day and no additional case notes had been requested from NCHDA.

This is the 14th successive external validation visit to UHB. As previously reported, the HeartSuite cardiac information is fully available at UHB but only appears to be used to review historic congenital cardiac surgical data. No congenital data are input to HeartSuite on the QEB site. The data for therapeutic interventional cardiology procedures are input directly to the NCHDA web Database at QEB.

Much of the data used on this validation visit is in the old v5.13 dataset format. NCHDA moved to a new dataset (v6 onwards) from 1 April 2017 and this should be used for all data submissions going forward.

The Queen Elizabeth University Hospital Birmingham (UHB/QEB) is a designated NHS England NHS Global Digital Exemplar. In August 2017 the electronic patient record system Oceano was launched.

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Of the 4 consultant cardiologists for adults with congenital heart disease at UHB, 2 consultants undertake interventional procedures.

Until 2013 one of the consultant cardiologists managed the catheter data collection, entry and submission to the NCHDA database. Since February 2013, there have been a number of individuals in post in a part time capacity (0.2WTE) attempting to manage these data. Since the July 2016 there has been a 1.0WTE dedicated individual to this data registry and also supports other functions such as NHSE CQiNs dashboard completion and NHSE activity reports etc. This individual has their own userid access to the Lotus Notes NCHDA database and NCHDA Web.

Data returns from QEB to NCHDA are now more timely. Most data that are submitted appear to be largely complete now where in the past data items such as surgical discharge information were absent. Monthly data submission is recommended.

There is very clear guidance on standards for data management in both paediatric and adult congenital surgical centres. Each Specialist ACHD Surgical Centre must have a dedicated congenital cardiac surgery/cardiology data collection manager, responsible for audit and database submissions in accordance with necessary timescales. (B33 L1 NHSE July 2015)

**Actions taken in response to the Recommendations at the June 2017 Validation Visit:**

1. It reported that there is now a Standard Operating Protocol in place to assist with and under pin the timely collection and management of the NCHDA dataset

**Consent for External Validation of Notes.**

Since 2006, informed patient consent is required for external validation of congenital cardiac patients hospital notes as the NCHDA is outside of Section 251 of the NHS Act (2006) Patients are therefore asked to give informed consent to allow their hospital case notes to be externally validated by the NCHDA.

As previously reported, at QEB/UHB there used to be an over arching clause in the generic consent form to allow external validation of a patients hospital case notes. However this clause was removed in 2012. There is no prospective collection of this consent from ACHD patients. Therefore each of the Sample and Reserve patients were contacted by telephone and a verbal consent requested and where possible, obtained. On the day 20 patients had been successfully contacted and their consent gained. However, 2 records were found to be for non congenital heart disease and were discarded.

**Data Quality Indicator**

The DQI for UHB is **94.5%** (92.5, 75,79). The Domain scores are; Demographics 1.0 (1.0, .92 .99), Pre Procedure .90 (.87, .56 .76), Procedure .96 (.96, .74 .975), Outcome .92 (.87 .79 .44 .54).

**Differential DQI for Surgery and Catheters**

As well as the overall DQI for each centre, DQI scores for surgery and catheters are being calculated. The scores are;

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Data Year Reviewed** | **Surgery** | **Catheters** |
| **2009** | 2007/08 | 80.75% | 98.75% |
| **2010** | 2009/09 | Insufficient sample | 92.5% |
| **2011** | 2009/10 | Insufficient sample | 88.25% |
| **2012** | 2010/11 | 87% (4 records) | 100% (1 record) |
| **2013** | 2011/12 | Insufficient sample | Insufficient sample |
| **2014(i)** | 2012/13 | 90% | 89% |
| **2014(ii)** | 2013/14 | 82.25% | 79.95% |
| **2015** | 2014/15 | 77% | 87.5% |
| **2016** | 2015/16 | 66.75% | 89.75% |
| **2017** | 2016/17 | 89.75% | 95.5% |
| **2018** | 2017/18 | 94.5% | 79.%% |

The body of this report is drawn from answers given on the NCHDA pre visit Questionnaire and from discussions on the day of the visit. This confirmed that there are some good processes and procedures in place in regard to Data Security and Management but further consideration is required to confer validity and quality assurance of data and training in Data Management.

The NHS Information Governance Training programme is used in the Trust.

There is or are identified accountable person/people for NCHDA data quality and information validity

Data Submissions are mostly timely but are not always accurate.

**Introduction**

Queen Elizabeth University Hospital (UHB FT) indicated that some 126 (surgery 69, catheter 27, others 30, Deaths 3) procedures had been undertaken during the data collection year of 2017/18 on adults with congenital heart disease.

These 20 sets of case notes represented 15 surgeries and 4 catheter procedures. 4 records were used from the Reserve list to replace the Samples that did not have verbal consent. This DQI is based on the case notes of 18/20 patients who underwent 19 procedures (4 therapeutic catheters and 15 operations) that had been submitted during the year April – March 2017/8. 2 case notes were discarded as they were found to be for non congenital heart disease and there were no other prepared reserve case notes.

818 variables were reviewed and 46 errors or omissions identified.

The accuracy of the NCHDA data return was then checked against each set of case notes to enable the Data Quality Indicator (DQI) to be scored.

**Review of the case notes at UHB**

This centre are moving to an electronic patient record (ePR) and where paper records were not available, some were reproduced on the request of the Validation Team from the EPR or made available on a computer screen. There were some files of paper hospital case notes were they were not complete as some documentation is always now stored digitally.

1. As reported at previous validations, there did not appear to be perfusion records filed in the case notes of the surgical patients that were reviewed. These are scanned to the ePR almost immediately after surgery.
2. As previously reported patients weights were sometimes difficult to find as the field for this data did not appear to be routinely completed on anaesthetic sheets.
3. As previously reported, operation notes did not always appear to include the name and grade of the second operator
4. As previously noted, it was not always clear what the NYHA status was of every patient and this is a required field for NCHDA.
5. It was also clear that previous procedures while being documented in the hospital notes are not being entered on the NCHDA database, such procedures as previous shunts or septostomy.
6. Recording of the exact day and time of extubation was not always clear in the paper notes or the ePR
7. Echo reports to assess ventricular function while available digitally weren’t not always easy to locate.
8. 1 patient whose case notes were reviewed was found to be missing a further procedure, for post surgical procedure permanent pacing system.

**Review of the Cath Lab Log Books at UHB**

At UHB, the separately kept congenital catheter log books that are kept in addition to the ledger described above were made available. These are bespoke printed and spiral bound A4 books that are neatly kept. The bound ledger from the cath labs in which all procedures are recorded was not made available.

1. 2 catheter records were identified that may be suitable for inclusion in NCHDA
2. 1 submitted catheter record appears to have an error or missing data
3. 1 submitted catheter record does not appear to be for congenital heart disease and if not should be removed.
4. It is again reported that no cath lab pacemaker or other implantable device procedures or diagnostic/therapeutic electrophysiological procedures in patients with congenital heart disease have been submitted to NCHDA.  It should be borne in mind that the following electrophysiological procedures are now among the NCHDA Specific Procedures that are analysed and published annually. In addition, NHSE require details of all activity on quarterly dashboards and if these data are missing, accurate activity analysis cannot be provided;-  
     
   Radiofrequency ablation for tachyarrthmias  
   Implantable cardioverter/defibrillator  
   Pacemaker implant  
   Biventricular pacing and CRT

**Review of the Theatre Log Books at UHB**

As from 2011 a new theatre suite at UHB became operational containing some 15 operating rooms. 3 of these are cardiac operating theatres. The log books for three of these theatres were offered for review, theatres 6,7 and 9.

As previously noted and unchanged in 2018, the Validation Team are aware that the Galaxy surgery information system is used in the operating theatres. If ICD 10 and OPCS codes are activated in this application, reports can be generated to identify all congenital cardiac procedures. The reviewers were also aware at this visit that Dendrite Intellect information software is used for collecting the adult acquired cardiac surgical data.

1. As previously reported, the standard of handwriting was sometimes quite variable and it was not always clear exactly what operation had been performed.
2. 1 record has been submitted with the incorrect procedure type and this needs to be resubmitted with the corrected field
3. 1 submitted record does not appear to be for congenital heart disease and if not should be deleted.
4. There were no submitted procedures for surgical pacemakers seen and these should be submitted to NCHDA if they occur.
5. 0  surgical cases were identified in the log books that may be suitable for inclusion in NCHDA.

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

This commenced with the validation of the 2014/15 data. The NCHDA 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.

It is strongly recommended that if information regarding a date of death for a pre-existing congenital patient on the NCHDA database post discharge is, or becomes available this should be submitted to that individual’s record in the NCHDA registry. However, this piece of information, once submitted to the NCHDA database is not always easily visible when the data are exported back to the centre.

3 congenital patients were noted on the data harvested for this visit to have died following a procedure.

The hospital case notes for all 3 patients were made available.

* all dates of death were confirmed
* 2 records had errors in the diagnoses coding
* 2 records had incomplete previous procedures listed
* 1 record had incomplete procedures coding
* 2 records did not have an attribution of death field completed

**Casenote Audit**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  | | | | **C** | **S** |
| 1 | Hospital Number | 18 | 18 |  | 4 | 14 |
| 2 | NHS Number | 18 | 18 |  | 4 | 14 |
| 3 | Surname | 18 | 18 |  | 4 | 14 |
| 4 | First Name | 18 | 18 |  | 4 | 14 |
| 5 | Sex | 18 | 18 |  | 4 | 14 |
| 6 | DOB | 18 | 18 |  | 4 | 14 |
| 7 | Ethnicity | 18 | 18 |  | 4 | 14 |
| 8 | Patient Status | 18 | 18 |  | 4 | 14 |
| 9 | Postcode | 18 | 18 |  | 4 | 14 |
| 10 | Pre Procedure  Diagnosis | 18 | 19 | 1 incorrect, 7 incomplete | 4 | 15 |
| 11 | Previous Procedures | 17 | 24 | 7 absent | ¾ | 14/20 |
| 12 | Patients Weight at  Operation | 19 | 19 |  | 4 | 15 |
| 13 | Height | 19 | 19 |  | 4 | 14/15 |
| 14 | Ante Natal Diagnosis | - | - |  | - | - |
| 15 | Pre Proc Seizures | 17 | 19 | 2 incorrect | 4 | 13/15 |
| 16 | Pre Proc NYHA | 17 | 19 | 2 incorrect | 4 | 13/15 |
| 17 | Pre Proc Smoker | 17 | 19 | 2 incorrect | 4 | 13/15 |
| 18 | Pre Proc Diabetes | 17 | 19 | 2 incorrect | 4 | 13/15 |
| 19 | Hx Pulmonary Dis | 18 | 19 | 1 incorrect | 4 | 13/15 |
| 20 | Pre Proc IHD | 18 | 19 | 1 incorrect | 4 | 13/15 |
| 21 | Comorbidity Present | 17 | 19 | 2 incorrect | 4 | 13/15 |
| 22 | Comorbid Conditions | 7 | 14 | 7 incorrect | 0/2 | 7/12 |
| 23 | Pre Proc Systemic Ventricular EF | 19 | 19 |  | 4 | 15 |
| 24 | Pre Proc Sub Pul Ventricular EF | 18 | 19 |  | ¾ | 15 |
| 25 | Pre-proc valve/septal defect/ vessel size | - | - |  | - | - |
| 26 | Consultant | 19 | 19 |  | 4 | 15 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure + Time Start | 19 | 19 |  | 4 | 15 |
| 28 | Proc Urgency | 19 | 19 |  | 4 | 15 |
| 29 | Unplanned Proc | 1 | 1 |  | - | 1 |
| 30 | Single Operator | 19 | 19 |  | 4 | 15 |
| 31 | Operator 1 | 18 | 19 | 1 incorrect | 4 | 14/15 |
| 32 | Operator 1 Grade | 19 | 19 |  | 4 | 15 |
| 33 | Operator 2 | 17 | 19 | 2 incorrect | 4 | 13/15 |
| 34 | Operator 2 Grade | 19 | 19 |  | 4 | 15 |
| 35 | Procedure Type | 19 | 19 |  | 4 | 15 |
| 36 | Sternotomy Sequence | 14 | 15 | 1 incorrect | - | 14/15 |
| 37 | Operation Performed | 19 | 19 |  | 3 | 15 |
| 38 | Sizing balloon used for septal defect | 3 | 3 |  | 1 | - |
| 39 | No of stents or coils | 1 | 1 |  | 5 | - |
| 40 | Device Manufacturer | 14 | 15 | 1 absent | 4/5 | 10 |
| 41 | Device Model | 14 | 15 | 1 absent | 4/5 | 10 |
| 42 | Device Ser No | 14 | 15 | 1 absent | 4/5 | 10 |
| 43 | Device Size | 14 | 15 | 1 absent | 4/5 | 10 |
| 44 | Total Bypass Time | 15 | 15 | 1 absent | - | 15 |
| 45 | XClamp Time, | 13 | 13 |  | - | 13 |
| 46 | Total Arrest | - | - |  | - | - |
| 47 | Cath Proc Time, | 3 | 4 | 1 incorrect | 3/4 | - |
| 48 | Cath Fluro Time, | 4 | 4 |  | 4 | - |
| 49 | Cath Fluro Dose, | 4 | 4 |  | 4 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 50 | Duration of Post Op Intubation | 12 | 15 | 3 incorrect | - | 12/15 |
| 51 | Post Procedure Seizures | 17 | 19 | 2 incorrect | 4 | 13/15 |
| 52 | Post Proc Complications | 2 | 2 |  | - | 2 |
| 53 | Date of Discharge | 18 | 19 | 1 incorrect | 4 | 14/15 |
| 54 | Date of Death | 1 | 1 |  | - | 1 |
| 55 | Attribution of Death | 0 | 1 | 1 incomplete | - | 0/1 |
| 56 | Status at Discharge | 0 | 1 | 1 incomplete | 4 | 14/15 |
| 57 | Discharge Destination | 19 | 19 |  | 4 | 15 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 94.5% Cardiology DQI = 79.5% Surgery DQI = 94.5%

|  |  |  |
| --- | --- | --- |
| **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 .90** | |
| **Card**  .91 | **Surg**  **.**89 |
| **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** .96 | |
| **Card**  .91 | **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** .92 | |
| **Card**  1.0 | **Surg**  .91 |

The DQI for UHB Foundation Trust congenital cardiology is based upon the domain scoring below. The methodology for this DQI is provided in the paper The NICOR Audit – An Introduction to the Process.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DOMAIN.** | **Score**  **2018** | **Score**  **2017** | **Score**  **2016** | **Score**  **2015** |
| **Demographics** | 1.0 | 1.0 | .92 | .99 |
| **Pre Procedure** | .90 | .87 | .56 | .76 |
| **Procedure** | .96 | .96 | .74 | .975 |
| **Outcome** | 1.0 | .87 | .79 | .44 |

**Conclusions**

On the whole the submitted NCHDA data were accurate, well documented, good quality and were appropriately recorded in the Theatre and Cath Lab log books that were seen. The DQI has risen by 2.25% this year making a total rise of 19.75% since the 2016 NCHDA Validation visit. This is excellent progress and clearly reflects how important the role of the NCHDA congenital data manager is and again the Reviewers congratulate UHB for recognising this.

The NCHDA surgical data from UHB are now input and submitted by the DBM which is again an excellent step forward.

There are still a few concerns. As reported in 2017, there appears to be no regular reverse validation of the congenital data with the responsible clinicians. Details on all implanted devices and valves are also now required, as well as more data on ACHD comorbidities. It was difficult to find explicit documentation of NYHA status in many patients hospital notes and in others it was clear that there had been previous cardiac procedures untaken in childhood that had not been recorded in the submitted data. Many of the NCHDA data fields are now included in the congenital cardiac NHS Commissioning for Quality and Innovation (CQINs) dashboard. Each congenital centres’ Data Quality Indicator Score (DQI) is also included in the quarterly dashboard. As previously reported the reviewers are also aware that the HeartSuite cardiac information is available at UHB and many of the ACHD patients transition from the adjacent paediatric service at Birmingham Childrens Hospital. However while the paediatric records are visible there is no ability to add continuing information on clinical interventions.

Data on electrophysiological and implantable pacemaker procedures undertaken in patients with congenital heart disease are also not being submitted to the NCHDA. This has been reported since QEB commenced congenital data submissions to NCHDA. It should be borne in mind that the following electrophysiological procedures are now among the NCHDA Specific Procedures that are analysed and the outcomes published annually;-  
  
Radiofrequency ablation for tachyarrthmias  
Implantable cardioverter/defibrillator  
Pacemaker implant  
Biventricular pacing and CRT

Not including these procedures in the NCHDA published data portrays a less than accurate representation of ACHD procedure activity at QEB.

**Validation of Case Notes of Deceased Patients.**

As mentioned elsewhere in this report there were a number of errors identified .

**Recommendations**

1. As previously, it is recommended as an immediate priority consideration, a cardiac information system that can accommodate all of the NCHDA dataset items should be identified and used to collect, validate and submit these data.
2. It is recommended that the Standard Operating Protocols devised for the congenital data collection, that describe in detail guidance on and exactly **who is responsible** for;
3. Ensuring prospective consent for external validation of hospital notes is obtained and all patients received appropriate information on this prior to admission 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.
4. Input of the data for each procedure and at which 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
6. Leading the local review (and how frequently and in which forum)
7. Making timely submissions (monthly is recommended) and
8. Timely reverse validation at QEB of the NCHDA dataset and reviewing Specific Procedures and activity as analysed by NCHDA.
9. Establishing who is responsible for notifying the DBM about dates of death of any ACHD patient.
10. Reviewing/Updating the SOP at timely intervals to reflect the needs of the Trust and the NCHDA
11. It is recommended that all Congenital Audit or Data Managers visit other congenital centres at least once annually to experience a validation from the external reviewers perspective, network with a colleague(s), trouble shoot and problem share.
12. Involve all clinically relevant staff in a review of audit data collection, review and quality initiatives
13. It is also recommended that the DBM and NCHDA Lead for QEB attend the annual NCHDA Contributors Meeting on Monday 11 March 2019 in London.