**The National Congenital Heart Disease Audit**

**Data Quality Audit for**

**CONGENITAL HEART DISEASE Procedures**

**April 2017 - March 2018**

**University Hospital Southampton NHS Foundation Trust**

**25 July 2018**

*performed by Lin Denne and Dr H Bellsham-Revill*

**Introduction**

Prior to this validation visit, the data return to NCHDA from the Congenital Cardiac Department of University Hospital Southampton, indicates that some 832 procedures (507 surgical operations, 220 catheters, 105 others, 8 deaths) have been undertaken during the data collection year of 1 April 2017 to 31 March 2018.

Following the log book audit of cardiac theatres and cath labs 4 procedures were identified that may be suitable for inclusion in NCHDA. These cases were very promptly reviewed after the validation visit and any changes made.

This validation visit has been fully funded by the Southampton University NHS Foundation NHS Trust. This visit was supported remotely by the NCHDA clinical audit nurse via a teleconference facility and on site in person by Dr H Bellsham-Revill, Consultant Congenital Cardiologist from Evelina London.

**Congenital Audit Data Managers Role**

As previously reported SGH have at times struggled to establish a full complement of dedicated data managers who are specialist nurses with specific protected time to manage the congenital data collection; often splitting the role with catheter lab and or surgery scheduling. From 2012 until present there were up to 3 individuals covering 1.2 WTEs of the data manager roles.

As previously stated, many units have recognised the value and importance of these data and have a totally dedicated 2.0 WTEs or greater to provide congenital cardiac data management for the NCHDA and NHS England requests. NHSE may use NCHDA data to underpin CQUINs (Commissioning for Quality and Innovation) quarterly dashboards. As previously reported, NHSE require dashboards to be underpinned by PRAiS (Paediatric Risk Analysis in Surgery) software reports on a quarterly basis. In busy centres with high numbers of procedures, PRAiS is run on a monthly basis.

We also acknowledge that there have been long and protracted difficulties with data submission to a new web facing NCHDA database at NICOR. This has affected all centres.

There are now also much stricter controls on which data will be accepted by the database at the time that information is ready to be submitted and this has created an considerable burden for the data managers at all congenital centres.

**Actions Undertaken in response to the Recommendation of the 2017 Validation Visit**

No actions reported.

**Consent for External Validation of Hospital Notes**

This has been required by NCHDA since 1 April 2007. This is a once only requirement until the patient reaches 16 years of age. Patients aged over 16 are expected to give their own consent rather than a guardian or parent on their behalf. At Southampton there was initially a separate consent form, consisting of one sheet of paper that has been in use since the summer of 2007. This was available on the paediatric and adult congenital wards. There is a mechanism in place to capture consent from patients who require procedures as emergencies or out of hours. As previously reported, the paper form has now been replaced with a sticky label that is appended to the inside cover of the patients hospital notes.

20 Sample patients’ notes that were randomly selected for validation had either a signed consent form, label in or telephone consent for examination of their hospital notes. No sets of notes were required from the Reserve list to make the 20 casenote sample. These 20 patients had a total of 27 procedures, (12 catheters and 15 operations).

**The Data Quality Indicator Score (DQI)**

The DQI for the Trust is calculated to be (with previous years in parentheses) **98.75%** (99, 95.75 97.5,) with domain scores Demographics 1.0 (1.0, 1.0 .99) Pre Procedure .96 (98, .92 .95) Procedure .99 (997, .93 .97) and Outcome 1.0 (99, .98, .99). These are again very good scores. There were just 17 discrepancies identified in 966 variables.

**Separate DQI for Surgery and for Catheters**

On further review of the overall DQI for 2017/18, when the cases were split into their surgery and catheter groups the scores are:

|  |  |  |  |
| --- | --- | --- | --- |
| **Year of Visit** | **Data Reviewed** | **Surgery** | **Catheters** |
| **2009** | 2007-08 | 96.5% | 93.7% |
| **2010** | 2008-09 | 97.25% | 98.25% |
| **2011** | 2009-10 | 97.75% | 96.25% |
| **2012** | 2010-11 | 93.5% | 95.75% |
| **2013** | 2011-12 | 98.75% | 99.75% |
| **2013(Nov)** | 2012-13 | 95.6% | 95.4% |
| **2014** | 2013-14 | 98.25% | 98.25% |
| **2015** | 2014-15 | 98% | 97.5% |
| **2016** | 2015-16 | 98% | 93% |
| **2017** | 2016-17 | 99.25% | 99% |
| **2018** | 2017-18 | 98.25% | 99% |

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.

**Introduction**

The NCHDA data return indicates that the congenital cardiac department of Southampton University Hospital Trust has undertaken 832 procedures (507 surgical operations, 220 catheters, 105 others, 8 deaths) in the data collection year 2017/2018 of which 20 sets of case notes were randomly selected for review. Some of the hospital notes are now held digitally in an electronic patient record (ePR) and on occasions information was accessed via this system.

The Congenital Data Auditor for the NCHDA undertook the visit remotely with an external Consultant Congenital Cardiologist on site at SGH.

**Review of notes**

As stated above, 20 Sample sets of patient notes were requested for review, a further 10 sets were selected as Reserves in case any of the first 20 were unavailable. The case notes had been meticulously prepared for the validation, with each relevant document carefully identified with a sticky note. The accuracy of the NCHDA data return was then checked against each set of notes. The accuracy was then recorded to enable the Data Quality Indicator (DQI) to be scored.

1. As previously, the notes on the whole were tidy, but on occasions were not in chronological order.
2. Also as previously reported, the documentation of the NYHA status was not always clear in the hospital notes of ACHD patients.
3. As at the previous visits, the physical PICU and medical notes were colour edged green and blue respectively making them easy to locate.
4. The operation notes were also easy to locate as these are coloured pink.
5. Perfusion records were seen in all of the surgical patients notes at this visit.
6. Discharge information was variably found within ICP or within other areas of the patient notes.

**Review of the Log Books**

As in the previous visits, the Reviewers make the observation that the both the theatre and cath lab log books are bespoke volumes with ruled lines and columns for certain items of information. The entries are made in hand writing and at times it was difficult to identify exactly what procedure had taken place and whether or not it is for congenital heart disease. As in 2016-17. it is reported at this visit that there are no plans to move to electronic operating or cath lab log books.

**Review of the Theatre Log Books**

There are 5 cardiac theatres at SGH. Congenital cardiac surgery is mainly performed in Theatre 3 and Theatre B. Sticky labels with the patients name and case record number are used to identify patient episodes followed by hand written completion of the procedures performed and operators etc. There is also an additional column to identify the surgical specialty (ie congenital cardiac) from which the patient comes from.

1. 1 submitted  surgical records appear to have a coding error
2. 4 surgery procedures were identified that may have been missed from the data submission

**Cath Lab**

There are 4 catheter laboratories at SGH; 1,2, 3 and 4. Cath labs 1 and 2 are biplane. The reviewers are pleased to note that there is now a self inking stamp with the word ‘Congenital’ in use to help identify relevant procedures. The log books for all cath labs were made available to the Reviewers. All fields in the books seen are completed in hand written entries.

As noted in other mixed practice centres identifying adult congenital cases undergoing ablations and pacemakers can be a problem.

1. 6 submitted catheter records appear to have errors in them
2. 3 submitted  surgical records appear to have a coding error
3. 5 surgery procedures were identified that may have been missed from the data submission

**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 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.  In cases where it is unclear if this consent has been obtained during life, the Medical Director is asked for permission to undertake this process.  The Validation Team are grateful to the MD of Southampton General Hospital for giving this permission on the day of the validation visit.

8 deceased patients were identified in the data return for 2017-18 who had died within 30 days of an operation or therapeutic catheter procedure.

The PRAiS sensitive fields were reviewed for each of the 8 patients identified above and the findings were:

1. All dates of death were found to be correct.
2. 3 records may have missing additional diagnoses
3. 1 record may have a missing previous procedure
4. 3 records appear to have errors in the Comorbidity field
5. All dates of death were found to be correct.

**Casenote Audit**

20 patients who underwent 27 Procedures.15 operations and 12 theraputic catheter procedures

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  | | | | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 7 | 13 |
| 2 | NHS Number | 20 | 20 |  | 7 | 13 |
| 3 | Surname | 20 | 20 |  | 7 | 13 |
| 4 | First Name | 20 | 20 |  | 7 | 13 |
| 5 | Sex | 20 | 20 |  | 7 | 13 |
| 6 | DOB | 20 | 20 |  | 7 | 13 |
| 7 | Ethnicity | 20 | 20 |  | 7 | 13 |
| 8 | Patient Status | 20 | 20 |  | 7 | 13 |
| 9 | Postcode | 20 | 20 |  | 7 | 13 |
| 10 | Pre Procedure  Diagnosis | 27 | 27 | 2 incomplete | 12 | 15 |
| 11 | Previous Procedures | 36 | 37 | 1 absent | 11/12 | 25 |
| 12 | Patients Weight at  Operation | 27 | 27 |  | 12 | 15 |
| 13 | Height | 24 | 24 |  | 11 | 1 |
| 14 | Ante Natal Diagnosis | 2 | 2 |  | 1 | 15 |
| 15 | Pre Proc Seizures | 27 | 27 |  | 12 | 4 |
| 16 | Pre Proc NYHA | 8 | 8 |  | 4 | 4 |
| 17 | Pre Proc Smoker | 8 | 8 |  | 4 | 4 |
| 18 | Pre Proc Diabetes | 8 | 8 |  | 4 | 4 |
| 19 | Hx Pulmonary Dis | 8 | 8 |  | 4 | 4 |
| 20 | Pre Proc IHD | 8 | 8 |  | 4 | 4 |
| 21 | Comorbidity Present | 26 | 27 | 1 incorrect | 12 | 14/15 |
| 22 | Comorbid Conditions | 34 | 37 | 3 incorrect | 17 | 17/20 |
| 23 | Pre Proc Systemic Ventricular EF | 23 | 27 | 2 unable to validate, 2 incorrect | 11/12 | 12/15 |
| 24 | Pre Proc Sub Pul Ventricular EF | 23 | 27 | 1 unable to validate, 3 incorrect | 9/12 | 14/15 |
| 25 | Pre-proc valve/septal defect/ vessel size | 1 | 3 | 1 unable to validate, 1 incorrect | 1/3 | - |
| 26 | Consultant | 27 | 27 |  | 12 | 15 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure + Time Start | 27 | 27 |  | 12 | 15 |
| 28 | Proc Urgency | 27 | 27 |  | 12 | 15 |
| 29 | Unplanned Proc | 27 | 27 |  | 12 | 15 |
| 30 | Single Operator | 3 | 3 |  | 3 | - |
| 31 | Operator 1 | 27 | 27 |  | 12 | 15 |
| 32 | Operator 1 Grade | 27 | 27 |  | 12 | 15 |
| 33 | Operator 2 | 24 | 24 |  | 9 | 15 |
| 34 | Operator 2 Grade | 24 | 24 |  | 9 | 15 |
| 35 | Procedure Type | 26 | 27 | 1 incorrect | 12 | 14/15 |
| 36 | Sternotomy Sequence | 14 | 15 | 1 incorrect | - | 14/15 |
| 37 | Operation Performed | 26 | 27 | 1 incorrect | 12 | 14/15 |
| 38 | Sizing balloon used for septal defect | 1 | 1 |  | 1 | - |
| 39 | No of stents or coils | 2 | 3 | 1 incorrect | 2/3 | - |
| 40 | Device Manufacturer | 11 | 11 |  | 5 | 6 |
| 41 | Device Model | 11 | 11 |  | 5 | 6 |
| 42 | Device Ser No | 15 | 15 |  | 9 | 6 |
| 43 | Device Size | 12 | 12 |  | 7 | 5 |
| 44 | Total Bypass Time | 11 | 11 |  | - | 11 |
| 45 | XClamp Time, | 9 | 9 |  | - | 9 |
| 46 | Total Arrest | 0 | 0 |  | - | 0 |
| 47 | Cath Proc Time, | 12 | 12 |  | 12 | - |
| 48 | Cath Fluro Time, | 12 | 12 |  | 12 | - |
| 49 | Cath Fluro Dose, | 12 | 12 |  | 12 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 50 | Duration of Post Op Intubation | 12 | 12 |  | - | 12 |
| 51 | Post Procedure Seizures | 27 | 27 |  | 12 | 15 |
| 52 | Post Proc Complications | 3 | 3 |  | - | 3 |
| 53 | Date of Discharge | 27 | 27 |  | 12 | 15 |
| 54 | Date of Death | 3 | 3 |  | 1 | 2 |
| 55 | Attribution of Death | 3 | 3 |  | 1 | 2 |
| 56 | Status at Discharge | 27 | 27 |  | 12 | 15 |
| 57 | Discharge Destination | 27 | 27 |  | 12 | 15 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.75% Cardiology DQI = 99% Surgery DQI = 98.25%

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 .96** | |
| **Card**  .96 | **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** .99 | |
| **Card**  1.0 | **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** 1.0 | |
| **Card**  1.0 | **Surg**  1.0 |

**Data Quality Indicator Assessment**

**The Overall Trust DQI = 98.75%** (99, 97.5**,** 98,)

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.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **DOMAIN** | **2018** | **2017** | **2016** | **2015** | **2014** |
| **Demographic** | 1.0 | 1.0 | 1.0 | .99 | 1.0 |
| **Pre Procedure** | .95 | .98 | .92 | .95 | .96 |
| **Procedure** | .99 | .99 | .93 | .97 | .97 |
| **Outcome** | 1.0 | 1.0 | .98 | .99 | .99 |

**Conclusions**

On the whole the NCHDA data were accurate, well documented, and were appropriately recorded in the Theatre and Cath Lab log books that were seen

The Data Quality Indicator (DQI) is 98.75%. This is a very small decrease of 0.25% but is still an excellent achievement. This demonstrates a continued strong commitment to good quality verified clinical data. There appears to be a very robust culture of clinical audit embedded within the Trust. The Validation Team would like again, to commend the efforts of the CNSs (Data Managers) in maintaining this at time when there have been considerable technical challenges. The Reviewers would also like to particularly thank the CNSs for their very high standard of document preparation for this visit. This greatly assisted the process.

As previously reported, the handwritten entries in the cath lab and theatre log books while quite neat and well kept were sometimes very difficult to transcribe and it was impossible without further research to determine if some patients had congenital or acquired heart disease. The use of the Congenital stamp in the cath lab log book does help identify cases. The column in the theatre log books used to indicate the clinical specialty from which each patient comes from that was also very useful.

Care should be taken to ensure that diagnoses coding wherever possible reconciles with the procedure performed and explicit coding of balloon atrial septostomy will ensure that the Specific Procedure algorithm will count these procedures correctly.

**Deceased Patients Data Validation**

Case notes for all deceased patients were made available. There does not appear to be a regular cross check with NHS Strategic Tracking to identify out of hospital deaths of NCHDA patients.

As described above, there were a small number of errors identified and these have since been checked and rectified post visit.

**Recommendations.**

1. It is recommended that in liaison with the Lead Clinicians for cardiology and cardiac surgery, the CNSs/Congenital Data Manager(s), regularly review a standard operating procedure (SOP) to capture all data on congenital patients in a timely manner. The SOP should clearly set out exactly **who** is responsible for;
2. Ensuring consent for external validation of hospital notes is obtained prospectively from all patients with congenital heart disease 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 opting out is explained to patients/carers
3. Input of congenital patients NCHDA required dataset items and at which point of service delivery
   1. Encouraging responsible clinician input of the procedure data for each operation, diagnostic or catheter intervention at the point of the service delivery
   2. Recording the knife to skin time for all surgical procedures where it can be validated (ie perfusion or anaesthetic record).
   3. 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
   4. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the CNSs/Data Managers at least monthly.
   5. Running the PRAiS (Paediatric Risk Analysis in Surgery) analysis tool monthly. This will inform the quarterly NHSE Dashboard reports.
   6. Ensuring that dates of death are reported for any patient who has previously had a record submitted to the NCHDA by requesting and/or carrying out quarterly life status checks with NHS Strategic Tracking for SGH NCHDA patients
   7. Leading the local review (and how frequently and in which forum for both disciplines)
   8. Making timely submissions (monthly is recommended) and
   9. Including details of manufacturer, model and serial numbers of all implantable devices with each patient record for a procedure.
4. To ensure all staff collecting and submitting data have access to Lotus notes for the purpose of validation of data, communication from NCHDA of patient identifiable data etc. as previously recommended
5. It is recommended that all staff who are involved with collecting, reviewing and managing the NCHDA data should attend at least one external validation visit per year.
6. All senior trainees (ST6 and above) should be actively encouraged to volunteer to assist with external validation visits to other centres.