**The National Congenital Heart Disease Audit**

**Procedures for**

**CONGENITAL HEART DISEASE**

**Data Quality Audit**

**For the year 2017/18**

**Barts Health NHS Trust**

**Tuesday 7 August 2018**

*performed by Lin Denne and Mr D Barron*

**Summary**

Prior to the theatre and cath lab log book validation at this visit, the data submission to NCHDA from the cardiac department of the Adult Congenital Heart Disease unit Barts Health NHS Trust indicated that a total of 380 procedures (187 surgical, 113 catheter procedures, 80 others, 5 deaths) were undertaken during the data collection year April 2017 to March 2018.

This validation visit has been fully funded by the Barts Health NHS Trust. This visit was supported remotely by the NCHDA clinical audit nurse via a Skype facility and on site in person by Mr David Barron, Consultant in Congenital Cardiac Surgery from Birmingham.

As previously reported, until 2012, for the purposes of the NCHDA validation visits, the submission from this unit when it was at The Heart Hospital were combined with that of Great Ormond Street Hospital for Sick Children (GOSH). The workload was shared between these two sites over the subspecialty of congenital heart disease, with patients of adult age being treated at The Heart Hospital (THH) by the same surgeons as those at GOSH. Since 2013, to reflect the growing practice and numbers of procedures in patients with adult Congenital heart disease at THH, meaningful and useful information may now be derived from a completely dedicated review of a full 20 case note sample rather than a smaller portion of the combined cohort.

In April 2015 The Heart Hospital cardiac unit moved to the St Bartholomew’ NHS Trust site (SBH).

There are 5 consultant cardiologists at SBH that specialise in adult Congenital cardiology. There are 3 Congenital surgeons who visit to undertake Congenital cardiac operations at SBH who also practice at GOSH which is in an adjacent NHS Foundation Trust.

At the new SBH unit, there is a 1.0 WTE Clinical Nurse Specialist (CNS) for NCHDA cardiac audit and a data manager who coordinate the collection and submission of these data. These individuals also have full responsibility for the National Adult Cardiac Surgery Audit (NACSA) registry.

At SBH there was now a specially created data collection system for NCHDA and this went ‘live’ from March 2016 based on Dendrite Intellect which is web based. Data are collected in real time at the point of treatment.

**Consent for External Validation of Notes.**

Informed patient/parent/guardian consent for external validation of hospital notes has been required since 1 April 2007. This is a once only requirement.

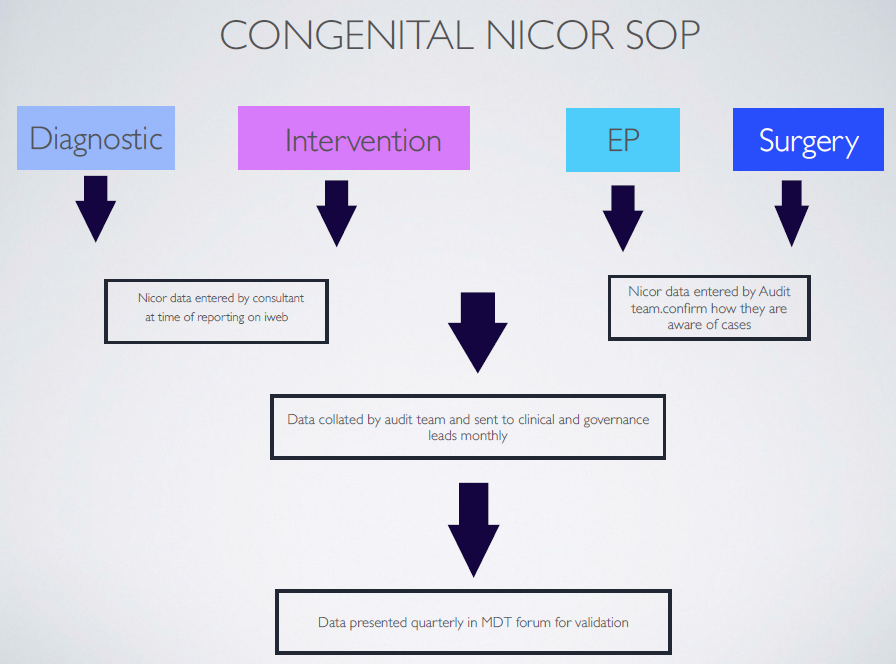
At SBH there is no current process for gaining this consent from patients prospectively. Therefore each of the selected patients in the Sample and Reserve groups were contacted by telephone and consent was requested. This was done by the Specialist Nurses for Adult Congenital Heart Disease. In some cases it was not possible to make contact with the patient.

The NCHDA Validation Team are grateful to Dr E Rowland, Senior Clinical Director, Cardiovascular CAG, for giving permission to review the hospital case notes that did not appear to have a verbal consent obtained.

A random list of case notes; 20 Samples and 10 Reserves were provided approximately 4 weeks prior to the Validation Visit. On the day 4 sets of case notes were made available from the Reserve list.   These 20 patients had 23 procedures (3 operations and 20 catheter procedures)

**Actions Undertaken Following Previous Validation Visit in 2017**

The Clinical Lead at SBH for the NCHDA data is with collaboration of colleagues, creating a Standard Operating Protocol for this data collection that currently highlights many of the recommended actions. This diagram supplied by the congenital clinical audit team below demonstrates the current drafting*:*



1. New consent forms will incorporate consent to patient data being reviewed by NCHDA
2. In the new SOP – it is anticipated that diagnostic and interventional cath operators will fill in NCHDA dataset whilst reporting. This is currently being piloted. The EP and surgical dataset will be completed by the CNS data management team within 4 weeks of the procedure
3. NHCDA data is now being sent to the SBH audit lead on a regular basis.
4. Outcomes are now being collected by the clinicians twice a month for validation.

**Data Quality Indicator**

The DQI for the Trust for this visit (previous years in parentheses) is calculated to be **96.5%** (96.75, 93.25%, 94.25) with domain scores Demographics 1.0 (1.0, .99, 1.0), Pre Procedure .94 (.94, .88, .83), Procedure .94 (.94, .89 .98), and Outcome .99 (.99, .97, .96).

Since 2009, separate DQI scores are being calculated for both catheters and surgery. The DQI is calculated from the case note review only. A minimum number of 5 records are required in either group for this to be done. However, only 3 surgical records were reviewed at this visit.

|  |  |  |  |
| --- | --- | --- | --- |
| **Year of visit** | **Data year being validated** | **Surgery** | **Catheter**  **Procedures** |
| **2013** | 11/12 | 94.75% | 94.75% |
| **2014(i)** | 12/13 | 96.5% | 93.5% |
| **2014(ii)** | 13/14 | 89% | 88.75% |
| **2015** | 14/15 | 93.5% | 95.25% |
| **2016** | 15/16 | 91.75% | 93.75% |
| **2017** | 16/17 | 97.75% | 96% |
| **2018** | 17/18 | 100% (3 records only) | 96.5% |

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 with 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**

Prior to the validation visit, the Congenital NCHDA return from the cardiac department at St Bartholomew’s Hospital (SBH) indicate that a total of 380 procedures (187 surgical, 113 catheter procedures, 80 others, 5 deaths) were undertaken during the data collection year April 2017 to March 2018.

The NCHDA clinical auditor and a Consultant in Adult Congenital Cardiac Surgery undertook this visit. The NCHDA clinical auditor participated remotely via a Skype link and the external clinician Mr D Barron attended SBH in person.

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

**Review of notes at Barts Health NHS Trust**

On the day 20 sets of case notes from the primary list supplied were available. 4 case notes were available from the Reserve list. The notes were prepared for the Validation Visit with some but not all key documents indicated by temporary sticky notes to assist with finding information. SBH are currently ‘paper-lite’ with a mixture of electronic ‘e’ noting systems and some retention of paper bound files.

1. As previously reported, the paper notes were rather untidy, not always in chronological order and occasionally rather chaotic.
2. The NHS Number was found in the hospital notes seen at this visit as the DBM had printed out a registration document which has a field for this identifier.
3. There is a care pathway for ACHD patients and this was most helpful for checking many of the pre procedure data fields.
4. However, it appears that the data for the 5 specific ACHD risk fields are not routinely recorded in the care pathway.
5. As previously reported, it was very difficult to find information on fluroscopy details in the patients hospital notes as this information is not routinely noted with the procedure report. In particular the data for the skin puncture to caths out time does not appear to be included either.
6. The labels of implanted products such as valves/pacemakers/coils were much easier to find the hospitals notes at this validation visit.
7. It is again reported that in some case notes it was difficult to find a detailed discharge summary and on occasions there were discrepancies on the eNotes and hand written records in respect to the actual date of discharge.
8. It was noted during the case note review that patients who had undergone electrophysiological procedures didn’t appear to have discharge summaries completed.

**Review of the Theatre log books**

There are reported to be 8 cardiac operating theatres at SBH and the log books were made available for theatre 8 as this is where most (but not all) congenital operations occur.   It was extremely difficult to clearly identify exactly what procedure had been performed and whether or not it was for congenital heart disease.

* 7 records were identified that may be suitable for inclusion in NCHDA
* 2 submitted records appear to have errors in them
* 1 submitted surgical record may not be for congenital cardiac surgery

**Review of the Cath lab log books**

There are reported to be 10 cardiac catheter labs at SBH and the log books were made available for labs 7 and 10.  These are mainly bespoke volumes with columns for information such as patients name, DOB, hospital number, operators details and the name and date of the operation performed.  It was again extremely difficult to identify exactly what procedure had been performed and whether or not it was for congenital heart disease.  There appears to be a number of abbreviations used to describe procedures in all the books seen with no transcription of what they actually mean.

* + 2 submitted catheter records may have errors in them
  + 55 submitted diagnostic or interventional catheter records were not validated in the log books
  + 9 records were identified in the catheter log books that may be suitable for inclusion in NCHDA

**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 the demographic, diagnostic and procedural data of deceased patients included in the year under review. The diagnosis and procedure coding will also be validated. 5 post procedural deaths were submitted in the data from SBH for the year 2017/2018.

1. All dates of death appear to be correct
2. 1 record had a previous procedure absent
3. 2 records appear to have incomplete comorbidities
4. 1 record appears to have incomplete procedure performed coding

All other data appeared to be correct.

Case Note Audit 2016

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  | | | | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 17 | 3 |
| 2 | NHS Number | 20 | 20 |  | 17 | 3 |
| 3 | Surname | 20 | 20 |  | 17 | 3 |
| 4 | First Name | 20 | 20 |  | 17 | 3 |
| 5 | Sex | 20 | 20 |  | 17 | 3 |
| 6 | DOB | 20 | 20 |  | 17 | 3 |
| 7 | Ethnicity | 20 | 20 |  | 17 | 3 |
| 8 | Patient Status | 20 | 20 |  | 17 | 3 |
| 9 | Postcode | 20 | 20 |  | 17 | 3 |
| 10 | Pre Procedure  Diagnosis | 23 | 23 | 3 incomplete | 17/20 | 3 |
| 11 | Previous Procedures | 40 | 41 | 1 absent | 40/41 | - |
| 12 | Patients Weight at  Operation | 23 | 23 |  | 20 | 3 |
| 13 | Height | 23 | 23 |  | 20 | 3 |
| 14 | Ante Natal Diagnosis | - | - |  | - | - |
| 15 | Pre Proc Seizures | 23 | 23 |  | 20 | 3 |
| 16 | Pre Proc NYHA | 22 | 23 | 1 incorrect | 19/20 | 3 |
| 17 | Pre Proc Smoker | 23 | 23 |  | 20 | 3 |
| 18 | Pre Proc Diabetes | 23 | 23 |  | 20 | 3 |
| 19 | Hx Pulmonary Dis | 21 | 23 | 2 incorrect | 11/20 | 3 |
| 20 | Pre Proc IHD | 23 | 23 |  | 20 | 30 |
| 21 | Comorbidity Present | 8 | 10 | 2 incorrect | 8/10 | 0 |
| 22 | Comorbid Conditions | 13 | 14 | 1 incorrect | 13/14 | 3 |
| 23 | Pre Proc Systemic Ventricular EF | 18 | 23 | 6 unable to validate | 14/20 | - |
| 24 | Pre Proc Sub Pul Ventricular EF | 17 | 23 | 7 unable to validate | 13/20 | 3 |
| 25 | Pre-proc valve/septal defect/ vessel size | 5 | 5 |  | 5 | - |
| 26 | Consultant | 23 | 23 |  | 20 | 3 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure + Time Start | 23 | 23 |  | 20 | 3 |
| 28 | Proc Urgency | 23 | 23 |  | 20 | 3 |
| 29 | Unplanned Proc | 23 | 23 |  | 20 | 3 |
| 30 | Single Operator | 19 | 19 |  | 16 | 3 |
| 31 | Operator 1 | 23 | 23 |  | 20 | 3 |
| 32 | Operator 1 Grade | 23 | 23 |  | 20 | 3 |
| 33 | Operator 2 | 19 | 19 |  | 16 | 3 |
| 34 | Operator 2 Grade | 19 | 19 |  | 16 | 3 |
| 35 | Procedure Type | 23 | 23 |  | 20 | 3 |
| 36 | Sternotomy Sequence | 2 | 2 |  | - | 2 |
| 37 | Operation Performed | 21 | 23 | 1 incorrect, 1 unable to validate | 18/20 | - |
| 38 | Sizing balloon used for septal defect | 4 | 4 |  | 4 | - |
| 39 | No of stents or coils | 0 | 0 |  | - | - |
| 40 | Device Manufacturer | 7 | 7 |  | 6 | 1 |
| 41 | Device Model | 7 | 7 |  | 6 | 1 |
| 42 | Device Ser No | 6 | 7 | 1 absent | 5/6 | - |
| 43 | Device Size | 2 | 2 |  | 2 |  |
| 44 | Total Bypass Time | 2 | 2 |  | - | 2 |
| 45 | XClamp Time, | 2 | 2 |  | - | 2 |
| 46 | Total Arrest | 0 | 0 |  | - | 0 |
| 47 | Cath Proc Time, | 11 | 20 | 8 incorrect, 1 unable to validation | 11/20 | - |
| 48 | Cath Fluro Time, | 18 | 20 | 2 absent | 18/20 | - |
| 49 | Cath Fluro Dose, | 17 | 20 | 2 incorrect, 1 unable to validate | 17/20 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 50 | Duration of Post Op Intubation | 2 | 2 |  | 2 | 2 |
| 51 | Post Procedure Seizures | 23 | 23 |  | 3 | 3 |
| 52 | Post Proc Complications | 0 | 1 | 1 incorrect | 0/1 | - |
| 53 | Date of Discharge | 23 | 23 |  | 3 | 3 |
| 54 | Date of Death | - | - |  | - | - |
| 55 | Attribution of Death | - | - |  | - | - |
| 56 | Status at Discharge | 23 | 23 |  | 3 | 3 |
| 57 | Discharge Destination | 23 | 23 |  | 3 | 3 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 96.5% Cardiology DQI = 96.5% Surgery DQI = 100%

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 .93** | |
| **Card**  .93 | **Surg**  1.0 |
| **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**  .94 | **Surg**  1.0 |
| **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**  .99 | **Surg**  1.0 |

**The Trust DQI = 96.5%**

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** | **2015** | **2016** | **2017** | **2018** |
| **Demographics** | 1.0 | .99 | 1.0 | 1.0 |
| **Pre Procedure** | .83 | .88 | .94 | .93 |
| **Procedure** | .98 | .89 | .94 | .94 |
| **Outcome** | .96 | .97 | .99 | .99 |

**Conclusions**

On the whole the NCHDA data were accurate, well documented and of good quality. As mentioned elsewhere, the case notes were a little chaotic at times. The NCHDA Validation Team are again grateful to Dr E Rowland, Senior Clinical Director at Bartshealth NHS Trust, for giving permission to review the hospital case notes that did not appear to have a patient signed consent form contained in them.

The overall DQI has dropped very slightly to 96.5% since the last NCHDA Validation but this is still a very good score. There were 41 errors or omissions in 951 variables.  There have also been some extreme technical challenges relating to timely data submission during the year 2017/2018 that have affected almost every congenital centre.

The Validation Team are aware that there is no regular reverse validation (where the submitted data retrieved and reviewed) of the data submitted to the NCHDA and the case notes are not always used to collect and/or validate data prior to submission. However, as stated in 2017, there is an audit and quality process being devised as documented elsewhere to address this in particular and clinicians will be encouraged to take ownership of their data.

As previously reported, there does not appear to be consistent documentation of data items such as NYHA, diabetes, pulmonary or ischaemic heart disease in the hospital notes that are part of the NCHDA dataset. It was very difficult to find echo reports in some patients hospital notes and patients who have undergone electrophysiological procedures didn’t always appear to have a discharge summary in the their hospital notes.

Discharge dates do not always appear to be recorded in the patients daily narrative notes and there does not appear to be consistent documentation of time of skin puncture to time of sheath removal in catheter procedures. Xray dose and length of time of xray exposure are currently required fields for NCHDA and it was difficult to find this information in the hospital records of patients who had undergone pacing or electrophysiological procedures.

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

4 records appear to have discrepancies in comorbidities or procedural coding but all other data appeared to be correct.

**Recommendations**

1. It is recommended that Standard Operating Protocols when finalised, are regularly reviewed for the Congenital data collection, to include detailed guidance on and **exactly who** is responsible (and in what timeframe) 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 op out explained to patients/carers.
3. Input of the NCHDA ACHD demographic, pre procedure, procedure and outcome data
4. Input of the data for each patients procedure and at which point of the service delivery
5. Recording of implanted device data and the placement of product labels in an agreed portion of the patients hospital record that can easily be validated.
6. 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
7. Leading the local review with the Lead Clinician for Congenital Heart Disease (and how frequently and in which forum for both disciplines)
8. Making timely submissions (monthly is recommended) and
9. Timely reverse validation together with the Clinical Lead for Congenital Cardiology and the responsible clinicians
10. Reviewing/Updating the SOP at timely intervals
11. Ensuring that relevant case and procedural records and logs are extracted and printed from electronic sources if used, in advance to be easily accessible by the Auditors on the day of the visit
12. As recommended in 2009, documentation (either hard copy or on screen help) should be available to all staff in all areas where data are recorded real time.
13. It is recommended that the Congenital dataset fields should be set to mandatory in any of the data collection software used.
14. Senior Trainees (ST6 and above) in ACHD should be encouraged to participate in both the SBH validation visit and assist with external visits to other centres.