**The National Congenital Heart Disease Audit Database**

**Data Quality Audit for**

**CONGENITAL HEART DISEASE**

**Apr 2016 - Mar 2017**

**The Royal Victoria Hospital, Belfast**

**28 November 2017**

*performed by Dr A Magee and Lin Denne*

**Summary**

This congenital validation visit by NCHDA was funded by the Northern Ireland Health and Social Care Trust (HSCNI). The fiscal year reviewed is April to March 2016-2017. The validation was performed by 1 external consultant congenital cardiologist on site at RVB and supported remotely via Skype by the NCHDA Clinical Data Auditor.

Prior to the review of the hospital log books, the data return to NCHDA from the cardiac department of the Royal Victoria Hospital, Belfast (RVB) indicated that some 124 adult congenital heart disease procedures have been undertaken during the data collection year of April 2016 to March 2017 in patients with congenital heart disease.

Childrens heart surgery ceased at this Centre on 15 December 2014. Surgery and services for adult congenital heart disease (ACHD) patients (aged over 16 years) are being developed. As reported in 2015, it is likely in the short to medium term that paediatric cardiac surgery will be undertaken in London Birmingham and Dublin until the new children’s hospital in ROI is fully commissioned in 2020.

As stated previously, the submission of the congenital data across adult and paediatric cardiac services in RVB is being managed by a cardiac data manager (DBA). Since January 2016 the role of DBA has been undertaken on a part time basis of just 0.32 WTE by a clinical nurse specialist.

At the time of this data collection (Apr 2016 – Mar 2017), the majority of the data entry to HeartSuite is currently undertaken by the DBA from a completed proforma. As previously reported, access to HeartSuite is fully available in the Royal Childrens Hospital. HeartSuite is only available in the Royal Victoria Hospital, where procedures on adults with congenital heart disease take place, by individual user ID for relevant consultant clinicians and specialist nurses. Following local validity checking the data were submitted electronically to NCHDA on a monthly basis.

As before, all demographic data have to be manually input to HeartSuite at the present time as the system is not connected to the trusts patient administration system (PAS).

This centre have consistently maintained a very high standard of data quality due to the working relationships that the previous 0.5WTE DBA maintained with clinicians and managers within the cardiac domain and with NCHDA.

The unique identifier known as the Health + Care Number was launched in July 2004 and is now widely used in Northern Ireland and should be included in NCHDA data submissions. This identifier is similar to the NHS Number in England and Wales.

**Actions Implemented since the last Validation Visit in 2016**

1. Consent for external validation of hospital notes - consent forms are now available to clinicians in the outpatients clinics to enable prospective gathering of this permission. Cardiac Surgery patients also have this permission in writing on the operation consent form and clinic letters from that appointment.
2. The 0.32 WTE DBA attended the last Contributors Meeting at the SCTS conference in Belfast on 14 March 2017
3. It is hoped that a full time data manager will be recruited at RVB early in 2018.

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

Consent for external validation of patient notes has been required since 1 April 2007. It has been reported at previous validation visits that ACHD patients are asked for this consent on admission and not always at first contact with the hospital.

**Data Quality Indicator Scores (DQI)**

The overall DQI for the centre is calculated to be (with previous year’s in parentheses) **94.5%** (98.25% 98.75**,** 95.75,with domain scores Demographics 1.0 (.99 .99, 1.0), Pre Procedure .88 (.96, .98, .90), Procedure .94 (.98, .98 .94), and Outcome .96 (1.0 1.0, .99). This is based on 20 patients who underwent 24 procedures (4 operations and 20 catheters) There were 63 errors found in 946 variables.

Since 2009, 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 RVB are:

|  |  |  |  |
| --- | --- | --- | --- |
| **Year of Visit** | **Data Years reviewed** | **Surgery DQI** | **Catheters DQI** |
| **2011 (Mar)** | 08-09 | 97.25% | 98% |
| **2011 (Mar)**  | 09-10 | 98.25% | 98% |
| **2011 (Nov)** | 10-11 | 99% | 99% |
| **2012** | 11-12 | 97.5% | 96.25% |
| **2013** | 12-13 | 98% | 98.5% |
| **2014** | 13-14 | 96.75% | 95.25% |
| **2015** | 14-15 | 99.75% | 98.25% |
| **2016** | 15-16 | 98.25% | 98.5% |
| **2017** | 16-17 | 96.25% | 94% |

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

**Introduction**

Prior to the log book review by the NCHDA audit team, the data returned to NCHDA indicated that the cardiac department of the Royal Victoria Hospital had undertaken 124 cases (surgery 22, catheters 61, others 41, deaths 1) in the data collection year 2016/2017 of which 20 cases were randomly selected for review.

The NCHDA Congenital Audit Nurse and an external consultant congenital cardiologist undertook the site audit. As stated above, the consultant clinician was physically present on site and the NCHDA Congenital Audit Nurse supported the validation remotely via Skype.

20 sets of Sample notes were requested and a Reserve list of 10 further records were also supplied; in case any of the first 20 were irretrievable. On the day, 6 sets of notes was unavailable from the Sample therefore, 6 sets of case notes were required from the Reserve list. The accuracy of the NCHDA data return was then checked against each set of notes and then recorded on a database to enable the Data Quality Indicator (DQI) to be scored.

**Review of hospital case notes**

As at previous visits, the notes were mostly tidy and in chronological order.

1. The pink operation notes were easy to find and anaesthetic sheets were fairly easy to locate.
2. The perfusion record was present in all sets of surgical notes.
3. As previously reported the case notes were often not chronologically ordered and this considerably hindered the review process on occasions.
4. Documentation of NYHA status was not always clear in the hospital case notes
5. On occasions it was difficult to find cardiac echo reports that were contemporary with the episode being validated.
6. The Proforma created by the DBA for collecting the NCHDA dataset was seen in all case notes.

**Review of the Cath Lab and Theatre log books**

**Cath Lab**

The cath lab are now using the CVIS (previously called TOMcat) system for electronic data. There is no congenital module for any of the NCHDA specific data fields produced by the supplier of this system. There are 5 Caths Labs at RVB and this centre is a designated PPCI centre.

However, on this validation, bound log books were provided and used for this review as requested by the Review Team.

Please note that for EP patients aged over 18 years to be included in NCHDA, these patients must have been known and followed up during the years 0-16 years by the paediatric cardiology service.

1. 3 submitted catheter entries were not validated
2. 2 submitted catheter records may have errors in them
3. 2 submitted records may not be for congenital heart disease and if not should be deleted from NCHDA
4. 3 catheter procedures were identified that may be suitable to be included in NCHDA

**Theatre Log Books**

1bespoke bound and ruled log book that is a register of all cardiac theatre activity was made available for review. This is generally a very well-kept and neat log of all activity, patients identity labels are used for each entry and there is a good standard of precise descriptions of procedures undertaken.

1. 1 submitted record may have errors in it
2. 4 surgical entries may be for adult acquired valvular disease and if so these should be removed from NCHDA (age limit is <30 years unless previously known to congenital cardiac service).
3. 6 further procedures were identified that may be suitable for inclusion in the 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 any dates of death of deceased patients included in the year under review. The diagnosis and procedure coding will also be validated.

1 ACHD patient who had had a therapeutic procedure during  the 2016/17 data collection year was noted to have died.  The procedural and outcome documentation was made available to the Reviewers and all the case notes were made available also.

Immediately prior to this validation visit these case notes had been reviewed locally and it was found to be an erroneous entry.

**Casenote Audit**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 24 | 24 |  | 20 | 4 |
| 28 | Time Start | 24 | 24 |  | 20 | 4 |
| 29 | Proc Urgency | 24 | 24 |  | 20 | 4 |
| 30 | Unplanned Proc | 23 | 24 | 1 incorrect | 19/20 | 4 |
| 31 | Single Operator | 5 | 7 | 2 incorrect | 5/7 | - |
| 32 | Operator 1 | 23 | 24 | 1 incorrect | 19/20 | 4 |
| 33 | Operator 1 Grade | 24 | 24 |  | 20 | 4 |
| 34 | Operator 2 | 13 | 17 | 4 absent | 10/13 | 1/4 |
| 35 | Operator 2 Grade | 13 | 17 | 4 absent | 10/13 | 1/4 |
| 36 | Procedure Type | 23 | 24 | 1 incorrect | 19/20 | 4 |
| 37 | Sternotomy Sequence | 4 | 4 |  | - | 4 |
| 38 | Operation Performed | 23 | 24 | 1 incorrect | 20 | 4 |
| 39 | Sizing balloon used for septal defect  | 2 | 3 | 1 incorrect | 2/3 | - |
| 40 | No of stents or coils | 2 | 2 |  | 2 | - |
| 41 | Device Manufacturer | 12 | 12 |  | 20 | 2 |
| 42 | Device Model | 12 | 12 |  | 20 | 2 |
| 43 | Device Ser No | 12 | 12 |  | 20 | 2 |
| 44 | Device Size | 7 | 9 | 2 incorrect | 5/7 | 2 |
| 45 | Total Bypass Time | 4 | 4 |  | - | 4 |
| 46 | XClamp Time, | 3 | 4 | 1 incorrect | - | 3/4 |
| 47 | Total Arrest | 0 | 0 |  | - | - |
| 48 | Cath Proc Time, | 20 | 20 |  | 20 | - |
| 49 | Cath Fluro Time, | 19 | 20 | 1 incorrect | 19/20 | - |
| 50 | Cath Fluro Dose, | 18 | 20 | 2 incorrect | 29/20 | - |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation  | 3 | 4 |  | - | 3/4 |
| 52 | Post Procedure Seizures  | 24 | 24 |  | 20 | 4 |
| 54 | Post Proc Complications | 1 | 2 | 1 absent | ½ | - |
| 55 | Date of Discharge | 22 | 24 | 2 incorrect | 18/20 | 4 |
| 56 | Date of Death | - | - |  | - | - |
| 57 | Status at Discharge | 24 | 24 |  | 20 | 4 |
| 58 | Discharge Destination | 24 | 24 |  | 20 | 4 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 94.5% Cardiology DQI = 94% 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 .88** |
| **Card**.86 | **Surg**.98 |
| **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**.92 |
| **Outcome**Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination.**Post Procedure Complications.** | **Overall** .96 |
| **Card**.96 | **Surg**.95 |

Data Quality Indicator Assessment **2016-2017 data**:

The Overall Trust DQI = 94.5% Cardiology DQI = 94% Surgery DQI = 96.25%

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DOMAIN** | **2017****16-17****data** | **2016****15-16****data** | **2015****14-15****data** | **2014****13-14 data** |
| **Demographics**  | 1.0 | .99 | .99 | 1.0 |
| **Pre Procedure** | .88 | .96 | .98 | .90 |
| **Procedure** | .94 | .98 | .98 | .94 |
| **Outcome** | .96 | 1.0 | 1.0 | .99 |

**Conclusions**

On the whole the NCHDA data was accurate, well documented, good quality and was appropriately recorded in the relevant health records and log books. The NCHDA Review Team would like to particularly thank the clinical audit team for meticulously preparing all the sets of case notes.

However there is concern that the DQI has dropped 4.25%. This may be in part due to the role of data base administrator being restricted to 0.32WTE where until January 2017 it was 0.5WTE.

There have been difficulties with timely submission of ACHD data to NCHDA in the past and it is not clear how frequently these records are reverse validated with the relevant clinicians. As previously reported, this centre is likely to increase the numbers of ACHD procedures considerably in the next 2-5 year or more as the service is developed. There still appears to be difficulties at times with identifying ACHD cases to the DBA promptly. The DBA and other members for the clinical audit team do not appear to attend MDT meetings currently where potential interventions or operations are likely to be discussed.

As previously reported, The CVIS system used in the cath lab as the log book of activity still appears to contain some less accurate descriptions of what procedure has been performed and whether or not it is for congenital heart disease. This system is essentially designed for acquired heart disease and is not suitable for congenital heart disease.

There is a further planned extension to the NCHDA dataset to include Fetal Data. The next update of HeartSuite that is due imminently will include this.

**Validation of Deceased Case Notes**

As documented above there was one submitted record for a deceased patient. Upon local review it was confirmed that this was an erroneous entry.

**Recommendations**

1. It is recommended that Standard Operating Protocols are reviewed to ensure that they adequate and specifically support the congenital data collection, to include detailed guidance on ‘how to’ and exactly **who** is responsible for and in what timeframe for each of the following;

	1. Ensuring that the consent for external validation of hospital notes clause is obtained prospectively from all patients with congenital heart disease at first contact with RVB.
	2. Real time input of the data for each congenital diagnostic and therapeutic procedure at the point of the service delivery
	3. Validity and completeness checking, 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. Ensuring that all clinicians are encouraged to be responsible for their own their data where they are the operating or operative clinician and be involved in the local validation process
	5. Leading the local review (and in which forum for both disciplines)
	6. Making timely submissions of fully validated data (monthly is recommended) and
	7. Monthly reverse validation at RVB against an acknowledged ‘gold standard’ record of activity and procedures performed.
	8. Reviewing/Updating the SOP at timely intervals
	9. Capturing data on any out of hospital deaths of congenital patients
2. It is recommended that the proforma used to collect the NCHDA data items be incorporated in the care pathway documents in the patients hospital notes.
3. The NCHDA DBA and any members of the clinical audit team who assist with this data collection should make regular attendances at the MDT meetings. These meetings are an educational forum as well identifying future congenital cardiac patients and their procedures.
4. As part of the DBAs ongoing training and development, it is suggested that visits to other centres to view their procedures and practices is a valued and important exercise in maintaining good standards.