**The National Congenital Heart Disease Audit Database**

**Data Quality Audit for**

**CONGENITAL HEART DISEASE**

**Apr 2017 - Mar 2018**

**The Royal Victoria Hospital, Belfast**

**21 September 2018**

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**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 2017-2018. 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. A Specialist Congenital Audit Nurse who is a Congenital Data Manager (DBM) from another centre also supported the validation visit in person.

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 175 adult congenital heart disease procedures have been undertaken during the data collection year of April 2017 to March 2018 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 2022.

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 was undertaken on a part time basis of just 0.32 WTE by a clinical nurse specialist. Since March 2018 this role has been further trimmed to 0.2WTE with the surgery and catheter data being collected on two different systems and being facilitated by 2 individuals.

At the time of this data collection review (Apr 2017 – Mar 2018), the majority of the data entry to HeartSuite is was undertaken by the local DBM from a completed proforma. As previously reported, access to HeartSuite is fully available in the main cardiac points of service throughout the Hospital. HeartSuite is only available 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).

Prior to 2016 this centre consistently maintained an extremely high standard of data quality due to the working relationships that the previous 0.5WTE DBM 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 2017**

1. No actions were reported prior to the visit.

**Post visit** RVB reported the following changes/actions:

1. A new Data / Systems Manager appointed in early 2018.
2. A data collection form revised to coincide with changes to code changes such as ethnicities.
3. A patient consent form is now included in the care pathway within the hospital notes for all patients except those that undergo electrophysiology studies. A single consent form is used for those patients.
4. The new Data Manager has visited with the Evelina Hospital in London to look at the information collection processes.
5. Standard operating protocols have been written and formalised for the collection and validation of data for the Adult Congenital Heart Disease cardiac service at RVB.
6. Comprehensive user manual has been written for capturing and processing data on the Heart suite system aligned to the Adult Congenital Heart Disease service at RVB.

**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.

It should be noted that under GDPR 2018 regulation all patients/parents/guardians should receive fully documented information to keep on exactly how their data are collected, stored, to which Organisation submissions and of which data are made to and who may see this information. It is further advised that under GDPR there must be a clear option for the patient/parent/guardian to opt out of the NCHDA data collection and review process at any time. It is also suggested that under the GDPR, consent is no longer required to review the case notes of deceased patients if this has not been obtained during life.

**Data Quality Indicator Scores (DQI)**

The overall DQI for the centre is calculated to be (with previous year’s in parentheses) **95%** (94.5, 98.25% 98.75**)** ,with domain scores Demographics .97 (1.0, .99 .99), Pre Procedure .92 (.88, .96, .98,), Procedure .93 (.94, .98, .98), and Outcome .98 (.96, 1.0 1.0). This is based on 20 patients who underwent 22 procedures (8 operations and 14 catheter interventions). There were 56 errors found in 941 variables.

The fields causing the most errors are:

Previous Procedures with 15 missing
Operator 2 Grade with 7 discrepancies

Implanted Devices details with 6 missing data items

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% |
| **2018** | 17-18 | 96% | 93.5% |

The NCHDA pre visit Questionnaire completion was requested prior to the validation visit. However this does not appear to have been returned. Information on Data Security and Quality Assurance as covered by the PVQ was received post visit and appears later in this report on page 8.

**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 175 cases (surgery 95, catheters 41, others 39, deaths 1) in the data collection year 2017/18 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 together with a DBM from another congenital centre. 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, 3 sets of notes was unavailable from the Sample therefore, 3 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 many of the relevant pages has been tabbed with a sticky note..

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. For patients who had had procedures as children at RVB, these case notes did not appear to be included with their ACHD notes.
7. All relevant previous procedures should be included in the patient record submitted to NCHDA regardless of which country or city they have been performed.
8. The Proforma created by the DBM 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. It was reported at this visit that there are now 7 Caths Labs at RVB and this centre is a designated PPCI centre.

Bound printouts from each cath lab were provided.

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. 7 submitted records in the category ‘Other’ appear to be for catheter electrophysiology
2. 41 catheter procedures were identified that may be suitable to be included in NCHDA. Many of these appear to be for EP and pacing procedures

**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. 1 surgical entry may be for adult Marfans disease and these cases are not included in NCHDA.
3. 11 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 2017/18 data collection year was noted to have died.  Some but not all of the procedural and outcome documentation was made available to the Reviewers.

The full case notes were not made available for this part of the review. However some documentation was provided from the Surgeons PA and the surgeon was present and answered questions from the reviewers to assist with validating the fields required. Although ACHD procedures are not subject to the Paediatric Risk Assessment in Surgery (PRAiS), in the interest of equity across all congenital centres in this part of the audit, it is the PRAiS sensitive fields are reviewed and the finding are:

The date of death is correct
The attribution of death is correct
It appears the previous procedures fields are incomplete

Post visit the following information as covered in the Pre Visit Questionnaire was provided in regard to:

**Data Security and Management**

The Heart suite NCHDA system is registered with the Trusts Data Protection officer. The data/systems manager has management responsibility for the system. Robust backups are carried out by the Trust IT department with respect of the data contained on the system. Clinicians and administrative staff have unique logins and passwords to access the system which is available across the Belfast Trust.

Standard Operating Procedures and a comprehensive user guide for the Heart suite system has been written and aligned to the adult congenital service.

**Validation and Quality Assurance**

Formalised processes are in place for clinicians to validate and verify the information held on the NCHDA system. The data manager inputs the data to the system from a paper based pro-forma and sends clinicians a copy of their data to validate and verify as part of Quality Assurance. The data manager carries out reverse validation on the system and cross references data being input into the system with the PAS and CIVIS information system to ensure start times, doses, staff members etc are correct. Adult congenital cases performed in the Cath Lab are marked on the CIVIS system as Adult Congenital. The data manager cross references reports from the CIVIS system with the pro-formas to ensure cases are not missed. Similarly any patients aged less than 18 are checked with the lead clinicians if pro-formas have not been completed. Hospital numbers and HCN numbers (NHS numbers in Northern Ireland) are used to identify and reference patients.

**Training in Data Management**

Training is available to all staff regarding data management and data collection with the Heart suite system. A comprehensive user manual has been written along with standard operating procedures for guidance on data management processes and techniques.

**Information Governance Training**

Information Governance training is available for staff who user the Heart suite for collecting, storing and viewing information on the system. Standard operating procedures outline who is responsible and at what stage for collecting, inputting and validating information. A user guide has been developed to outline best practices in using the system in line with information governance requirements.

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

Data Submissions that are Timely and Accurate

**Casenote Audit**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 12 | 8 |
| 2 | NHS Number | 16 | 16 |  | 9 | 7 |
| 3 | Surname | 20 | 20 |  | 12 | 8 |
| 4 | First Name | 20 | 20 |  | 12 | 8 |
| 5 | Sex | 20 | 20 |  | 12 | 8 |
| 6 | DOB | 20 | 20 |  | 12 | 8 |
| 7 | Ethnicity | 20 | 20 |  | 12 | 8 |
| 8 | Patient Status | 16 | 20 | 4 incorrect | 9/12 | 7/8 |
| 9 | Postcode | 19 | 20 | 1 incorrect | 12 | 7/8 |
| 10 | Pre Procedure Diagnosis | 22 | 22 | 4 incomplete | 14 | 8 |
| 11 | Previous Procedures | 17 | 32 | 15 absent | 10/17 | 8 |
| 12 | Patients Weight atOperation | 22 | 22 |  | 14 | 8 |
| 13  | Height | 22 | 22 |  | 14 | 8 |
| 14 | Ante Natal Diagnosis | - | - |  | - | - |
| 15 | Pre Proc Seizures | 22 | 22 |  | 14 | 8 |
| 16 | Pre Proc NYHA  | 21 | 22 | 1 incorrect | 13/14 | 8 |
| 17 | Pre Proc Smoker | 20 | 22 | 2 incorrect | 13/14 | 7/8 |
| 18 | Pre Proc Diabetes | 22 | 22 |  | 14 | 8 |
| 19 | Hx Pulmonary Dis | 22 | 22 |  | 14 | 8 |
| 20 | Pre Proc IHD | 22 | 22 |  | 14 | 8 |
| 21 | Comorbidity Present | 8 | 11 | 3 incorrect | 6 | 2/5 |
| 22 | Comorbid Conditions | 9 | 13 | 2 incorrect | 5 | 5/8 |
| 23 | Pre Proc Systemic Ventricular EF | 21 | 22 | 1 incorrect | 14 | 7/8 |
| 24 | Pre Proc Sub Pul Ventricular EF  | 22 | 22 |  | 14 | 8 |
| 25 | Pre-proc valve/septal defect/ vessel size | 1 | 1 |  | 1 | - |
| 26 | Consultant | 22 | 22 |  | 14 | 8 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure + Time Start | 22 | 22 |  | 14 | 8 |
| 28 | Proc Urgency | 22 | 22 |  | 14 | 8 |
| 29 | Unplanned Proc | 21 | 22 | 1 incorrect | 14 | 8 |
| 30 | Single Operator | 5 | 6 | 1 incorrect | 6 | - |
| 31 | Operator 1 | 21 | 22 | 1 incorrect | 14 | 8 |
| 32 | Operator 1 Grade | 22 | 22 |  | 14 | 8 |
| 33 | Operator 2 | 17 | 18 | 1 incorrect | 10 | 8 |
| 34 | Operator 2 Grade | 11 | 18 | 7 incorrect | 10 | 4/8 |
| 35 | Procedure Type | 22 | 22 |  | 14 | 8 |
| 36 | Sternotomy Sequence | 7 | 8 | 1 incorrect | - | 7/8 |
| 37 | Operation Performed | 22 | 22 |  | 14 | 8 |
| 38 | Sizing balloon used for septal defect  | 2 | 2 |  | 2 | - |
| 39 | No of stents or coils | 0 | 2 | 2 absent | 2 | - |
| 40 | Device Manufacturer | 17 | 18 | 1 absent | 12 | 6 |
| 41 | Device Model | 15 | 18 | 2 absent, 1 unable to validate | 12 | 6 |
| 42 | Device Ser No | 24 | 25 | 1 absent | 19 | 6 |
| 43 | Device Size | 14 | 15 | 1 absent | 9 | 6 |
| 44 | Total Bypass Time | 7 | 8 | 1 incorrect | - | 7/8 |
| 45 | XClamp Time, | 7 | 8 | 1 incorrect | - | 6/7 |
| 46 | Total Arrest | - | - |  | - | 0 |
| 47 | Cath Proc Time, | 14 | 14 |  | 14 | - |
| 48 | Cath Fluro Time, | 13 | 14 |  | 13/14 | - |
| 49 | Cath Fluro Dose, | 13 | 14 |  | 13/14 | - |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 50 | Duration of Post Op Intubation  | 7 | 8 | 1 incorrect | - | 7/8 |
| 51 | Post Procedure Seizures  | 22 | 22 |  | 14 | 8 |
| 52 | Post Proc Complications | 2 | 2 |  | - | 2 |
| 53 | Date of Discharge | 21 | 22 | 1 incorrect | 14 | 7/8 |
| 54 | Date of Death | - | - |  | - | - |
| 55 | Attribution of Death | - | - |  | - | - |
| 56 | Status at Discharge | 22 | 22 |  | 14 | 8 |
| 57 | Discharge Destination | 22 | 22 |  | 14 | 8 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 95% Cardiology DQI = 96% Surgery DQI = 93.5%

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** .97 |
| **Card**.97 | **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 .92** |
| **Card**.95 | **Surg**.88 |
| **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** .93 |
| **Card**.92 | **Surg**.94 |
| **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**.95 |

Data Quality Indicator Assessment **2017-2018 data**:

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DOMAIN** | **2018****17-18****data** | **2017****16-17****data** | **2016****15-16****data** | **2015****14-15****data** |
| **Demographics**  | .97 | 1.0 | .99 | .99 |
| **Pre Procedure** | .92 | .88 | .96 | .98 |
| **Procedure** | .93 | .94 | .98 | .98 |
| **Outcome** | .98 | .96 | 1.0 | 1.0 |

**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.

The DQI has increased by 0.5% to 95%. However since January 2017 the role of data base administrator has been restricted to 0.2WTE. Prior to this it was 0.5WTE post.

The clinical practice has evolved to now being almost totally an ACHD service and this is still developing and expanding to include patients from ROI.

The data for ACHD catheter procedures and surgery are being input into separate unlinked information systems with separate individuals facilitating this. There appears to be in the region of 180 ACHD procedures currently undertaken Belfast which makes it one of the smallest centres. Splitting the data collection between two different databases, CVIS for catheters and Dendrite Intellect for surgery, with 2 different individuals may unnecessarily risk compromising the integrity of the data by dividing this way. The data are then input manually to a 3rd database, HeartSuite which contains many historic records of ACHD patients treatments and procedures as children.

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. The numbers of ACHD procedures are likely to rise in the next 2-5 years or more as the service is developed and timely reverse validation is considered essential practice to continually monitor accuracy and completeness. There still appears to be difficulties at times with identifying ACHD cases to the DBM promptly. The DBM and other members for the clinical audit team do not appear to attend MDT meetings currently which is the forum where potential interventions or operations are likely to be discussed and audit presentations made.

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. Dendrite Intellect is primarily used for acquired heart disease surgery and does not actively support the NCHDA dataset.

**Validation of Deceased Case Notes**

As documented above there was one submitted record for a deceased patient. The case notes provided were not complete but the PRAiS sensitive fields were validated with the help of one of the surgeons.

**Recommendations**

1. It is strongly recommend that as this centre is relatively small in terms of annual numbers of procedures performed, that there is one unified cardiac information system that is used to collect the NCHDA data. HeartSuite has been used since 2004 to collect the paediatric cardiac data and there is now a considerable archive. It would appear sensible to continue with this system as patients return for further procedures in adulthood.
2. 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 data submission and external validation of hospital notes clause is obtained prospectively from all patients with congenital heart disease and each patient/parent/guardian receives a description of data that is collected, how it is audited and the submission to Organisations such as NICOR or others.
	2. Real time input of the data for each congenital diagnostic and therapeutic procedure at the point of the service delivery in the cath labs and operating rooms.
	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. Regular monitoring of Specific Procedures allocation and Activity Analysis wither with R code or manually.
	9. Reviewing/Updating the SOP at timely intervals
	10. Capturing data on any out of hospital deaths of congenital patients
3. It is recommended that documentation to support patient/parent/guardian consent to participate in data submission and external validation of hospital notes that is given to each patient should include an ‘opt out’ clause should a patient/parent/guardian change their mind about participation.
4. It is recommended that NCHDA DBM and any members of the clinical audit team who assist with this data collection should regularly attend the MDT meetings. These meetings are an educational forum as well identifying future congenital cardiac patients and their procedures.
5. As part of the DBMs 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.