**The National Congenital Heart Disease Audit Database**

**Data Quality Audit for**

**CONGENITAL HEART DISEASE**

**Apr 2016 - Mar 2017**

**Our Ladies’ Children’s Hospital, Crumlin, Dublin**

**15 November 2017**

*Performed by Dr R Franklin and Lin Denne*

**Summary**

This congenital validation visit by NCHDA is funded by the Republic of Ireland, Health Service Executive. The year reviewed is April to March 2016 - 2017. This is the sixth visit to Our Lady’s Children’s Hospital Crumlin. (OLCHC) All congenital cardiac centres in the UK participate in annual reviews of therapeutic procedures undertaken and further information on all of those centres can be found at the national audit website https://nicor5.nicor.org.uk/

Prior to the review of the hospital log books, the data return to NCHDA from the cardiac department of the Our Ladies’ Children’s Hospital (OLCHC) indicates that some 1068 procedures have been undertaken during the data collection year of April 2016 to March 2017 in patients with congenital heart disease aged up to 16 years.

As previously reported an access database of congenital procedures is maintained by the Cardiac Services Data Manager (DBM). Since February 2017 a further DBM post was recruited and there are now 2 DBMS providing 1.75WTEs to cover this congenital registry at OLCHC. The DBMs submit the data directly from the Access database to the live NCHDA Congenital Database via a CSV file.

As previously reported there is real time data entry to a number of different data bases by clinical staff with access in the operating theatre and the catheter lab as well as the ward areas in the Children’s Hospital. There is just one computer in the operating theatre and one in the cath lab to serve all the various databases.

As reported in 2014-16, a new cardiac information system is in the process of being commissioned, provided by Health Insights. At the time of this validation visit commissioning was almost completed and the system was about to go ‘live’ across the hospital imminently. The data fields for NCHDA are included within this information system.

There is no formal audit programme for congenital procedures and the case notes are used to check the data in the majority of the cases. Following local validity checking of the data held in the various databases, all relevant data are amalgamated into the Access database submitted electronically to NCHDA on an ongoing basis.

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

1. The consent for external validation of case notes is now part of a new hospital consent for operation form signed by parents and guardians.
2. The DBM attended the annual Contributors Meeting in March 2017
3. A second 1.0WTE congenital data manager has been appointed and had previously attended a UK validation visit as an observer
4. One congenital cardiologist one SpR in cardiac surgery have been assisting external clinicians at UK validation visits.

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

Consent for external validation of patient notes has been required since 1 April 2007 in UK and is a standard requirement in Republic of Ireland (ROI). This is a once only requirement for patients until they are 16 in the UK. From age 16 a further consent (once only) is required if the patient presents for further diagnostic or therapeutic procedures. Without consent from parents/patient/guardian external validation of hospital notes cannot take place.

As reported in 2012-16, the restrictions imposed by the ROI Information Commissioner do not allow any patient identifiers to be submitted to NCHDA other than date of birth (DOB) and gender. There has been an established method of pseudo identifiers created to enable data submission. However whilst this allows for specific procedures to be analysed by NCHDA and published on the NCHDA Public Portal it considerably hinders the physical process of external validation as each pseudo id has to be cross checked twice to ensure the correct patient and procedure has been identified. Theoretically it may be possible to confuse two records that have the same DOB and gender that have similar or the same procedures performed on the same day.

In March 2015 the NCHDA Clinical Auditor was informed by the Lead Clinician for OLCHC that it had been agreed that an appropriately worded clause would be included in the generic consent for operation form used at this Centre. This became practice from April 2016. However this consent was not always obtained initially and there were some patients or parents who had to be contacted by telephone prior to this validation visit in order to gain this permission to review their hospital notes.

The phone call for verbal consent was then followed up by a paper hard copy of the consent form in the post to the parents which is signed by the parent and returned to the DBMs and then filed in the hospital case notes.

Also as reported in 2012-16, in ROI there is no individual life time identifier issued to every individual similar to the NHS, CHI or HNC Number that is used in other UK countries. Therefore there is no independent source of death date for NCHDA to effectively track 1 year mortality in these patients. However during 2016 a unique identifier similar to the UK NHS Number is being gradually introduced throughout ROI.

The Validation Team are grateful to the CEO of OLCHC for giving permission for the deceased case notes to be reviewed. Patient deaths can impact on the Paediatric Risk Analysis in Surgery (PRAiS) that the NCHDA performs. It is therefore essential that these procedures and their coding are examined to ensure that it is correct and that any relevant comorbidities are correctly included.

Dr R Franklin undertook the validation visit on site and the NCHDA Clinical Data Auditor remotely accessing and supporting the review via Skype.

**Data Quality Indicator Scores (DQI)**

The overall DQI score is (with previous years in parentheses); **97%** (94.5, 97.25 96.5), with domain scores Demographics 1.0 (1.0, .99 1.0), Pre Procedure .92 (.85, .97 .92), Procedure .97 (.96, .94 .95,), and Outcome .99 (.97, .99 .99, ).

This is based on 20 patients who had 31 procedures (15 catheters, 16 operations). There were 36 errors or omissions in 961 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 OLCHC are:

|  |  |  |  |
| --- | --- | --- | --- |
| **Year of Visit** | **Data Years reviewed** | **Surgery DQI** | **Catheters DQI** |
| **2012** | 2011-12 | 92.5% | 92.75% |
| **2013** | 2012-13 | 98% | 96% |
| **2014** | 2013-14 | 96.25% | 96.5% |
| **2015** | 2014-15 | 97.25% | 96% |
| **2016** | 2015-16 | 94.25% | 95% |
| **2017** | 2016-17 | 96.75% | 97.5% |

Staff and Colleagues have completed the NCHDA pre visit questionnaire and 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 Our Ladies’ Hospital for Children had undertaken 1068 cases (surgery 396, catheters 443, others 229, deaths 20) in the data collection year 2016/2017 of which 20 cases were randomly selected for review*.*

20 sets of notes were requested (the Sample) and a reserve list of 10 further records (the Reserves) were also supplied in case any of the first 20 were irretrievable. On the day, 3 sets of case notes from the Reserves were required. 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 notes**

The Reviewers are extremely grateful to the DBMs who had clearly spent some considerable time marking many of the relevant documents in each case note that needed to be seen. This greatly aided the speed of the validation process.

The notes were mostly tidy and in chronological order.

1. As previously reported, some of the case notes seen were bulky, of several volumes and sometimes not in chronological order.
2. Ventricular function documentation was sometimes difficult to find in the hospital notes of surgical patients.
3. In the case notes seen, there are care pathway documents for catheter admissions and this greatly aided the review. These notes generally appeared to be well organised and the data easy to retrieve and validate. However, as previously reported in 2012-16, the actual catheter procedure report does not always include fluroscopy data or the names of both of the operators
4. The typed operation notes were easy to find and the green edged anaesthetic sheets were fairly easy to locate.
5. The perfusion record was present in all sets of surgical notes seen.

**Review of the Cath Lab log books**

There is 1 cath lab at OLCHC. 2 log books were made available to reviewers, the radiographers log and the nurses log. Generally originals are preferred for this part of the validation as it is difficult to know if photocopies are complete and there are not pages missing or data has been accidentally missed off the bottom of pages. It became apparent in the nurses log book that the pages for 2 dates were absent – the 29-31 March 2017. The radiographers log book was used for these dates.

The copies of the radiographers log book showed that patient identity labels were used mostly to indicate each patients case.

We would like to thank the DBM and colleagues who had marked the log books with the pseudo identifiers to aid the review.

As previously reported septostomies are often performed in other areas outside the cath lab ie NICU and there is not a log of these cases. However some septostomies have been included in the submission to NCHDA but it is not clear if it is all of all of these procedures.

1. TOE, Provocation Testing and DC conversion procedures are not required to be submitted to NCHDA at this time
2. 9 catheter procedures were identified that may have been missed from the data submission

**Theatre Log Books**

An electronic theatre management system (TMS Sapphire) is kept at OLCHC and print out of this was provided for the review. There is 1 dedicated congenital cardiac operating theatre at OLCHC.

1. 6 surgery entries in TMS were identified as possibly being missed from the data return
2. Delayed closure of sternum, debridements or wire removal procedures are not required to be submitted to NCHDA at this time
3. Pectus Repairs should be submitted in the category Thoracic

**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. The requirement for patient/parent/guardian consent to review the case notes is the same as for the congenital procedures and congenital IE review. In cases where it is unclear if this consent has been obtained during life, the Medical Director or CEO is asked for permission to undertake this review. The Validation Team are grateful to the CEO of OLHSC for giving this permission. 20 post procedural deaths were submitted in the data from OLS for the year 2016/17.

1. 3 records were identified that should be removed from NCHDA
2. 5 records appear to have incomplete comorbidities listed
3. 6 records appear to have an incomplete diagnoses string
4. 1 record appears to have previous procedures missing
5. 1 record may have incomplete procedure performed coding
6. 1 record appears to have incorrect complications submitted
7. 2 patients had incorrect weights recorded

**Casenote Audit**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  | | | | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 9 | 11 |
| 2 | NHS Number | - | - |  | - | - |
| 3 | Surname | 6 | 6 |  | 2 | 4 |
| 4 | First Name | 6 | 6 |  | 2 | 4 |
| 5 | Sex | 20 | 20 |  | 9 | 11 |
| 6 | DOB | 20 | 20 |  | 9 | 11 |
| 7 | Ethnicity | 20 | 20 |  | 9 | 11 |
| 8 | Patient Status | 20 | 20 |  | 9 | 11 |
| 9 | Postcode | 20 | 20 |  | 9 | 11 |
| 10 | Pre Procedure  Diagnosis | 30 | 31 | 1 incorrect | 15 | 15/16 |
| 11 | Previous Procedures | 29 | 32 | 3 absent | 12/13 | 17/19 |
| 12 | Patients Weight at  Operation | 31 | 31 |  | 15 | 16 |
| 13 | Height | 31 | 31 |  | 15 | 16 |
| 14 | Ante Natal Diagnosis | 5 | 5 |  | 2 | 3 |
| 15 | Pre Proc Seizures | 29 | 31 | 2 incorrect | 14/15 | 15/16 |
| 16 | Pre Proc NYHA | - | - |  | - | - |
| 17 | Pre Proc Smoker | - | - |  | - | - |
| 18 | Pre Proc Diabetes | - | - |  | - | - |
| 19 | Hx Pulmonary Dis | - | - |  | - | - |
| 20 | Pre Proc IHD | - | - |  | - | - |
| 21 | Comorbidity Present | 31 | 31 |  | 15 | 16 |
| 22 | Comorbid Conditions | 15 | 19 | 4 absent | 4/6 | 11/13 |
| 23 | Pre Proc Systemic Ventricular EF | 26 | 31 | 3 absent, 2 incorrect | 12/15 | 14/16 |
| 24 | Pre Proc Sub Pul Ventricular EF | 24 | 30 | 4 absent, 2 incorrect | 12/14 | 12/16 |
| 25 | Pre-proc valve/septal defect/ vessel size | 0 | 1 | 1 absent | 1 | - |
| 26 | Consultant | 31 | 31 |  | 15 | 16 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 31 | 31 |  | 15 | 16 |
| 28 | Time Start | 31 | 31 |  | 15 | 16 |
| 29 | Proc Urgency | 31 | 31 |  | 15 | 16 |
| 30 | Unplanned Proc | 31 | 31 |  | 15 | 16 |
| 31 | Single Operator | 4 | 11 | 7 incorrect | 4/11 | - |
| 32 | Operator 1 | 31 | 31 |  | 15 | 16 |
| 33 | Operator 1 Grade | 31 | 31 |  | 15 | 16 |
| 34 | Operator 2 | 28 | 28 |  | 12 | 16 |
| 35 | Operator 2 Grade | 27 | 28 | 1 incorrect | 12 | 15/16 |
| 36 | Procedure Type | 31 | 31 |  | 15 | 16 |
| 37 | Sternotomy Sequence | 11 | 11 |  | - | 11 |
| 38 | Operation Performed | 31 | 31 | 1 component absent | 15 | 16 |
| 39 | Sizing balloon used for septal defect | - | - |  | - | - |
| 40 | No of stents or coils | 1 | 1 |  | 1 | - |
| 41 | Device Manufacturer | 5 | 5 |  | 5 | - |
| 42 | Device Model | 5 | 5 |  | 5 | - |
| 43 | Device Ser No | 5 | 5 |  | 5 | - |
| 44 | Device Size | 3 | 3 |  | 3 | - |
| 45 | Total Bypass Time | 12 | 12 |  | - | 12 |
| 46 | XClamp Time, | 14 | 14 |  | - | 14 |
| 47 | Total Arrest | 0 | 0 |  | - | 0 |
| 48 | Cath Proc Time, | 15 | 15 |  | 15 | - |
| 49 | Cath Fluro Time, | 15 | 15 |  | 15 | - |
| 50 | Cath Fluro Dose, | 15 | 15 |  | 15 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation | 16 | 16 |  |  | 16 |
| 52 | Post Procedure Seizures | 29 | 31 | 2 incorrect | 15 | 14/16 |
| 54 | Post Proc Complications | 10 | 10 |  | 4 | 6 |
| 55 | Date of Discharge | 31 | 31 |  | 15 | 16 |
| 56 | Date of Death | 1 | 1 |  | 1 | - |
| 57 | Status at Discharge | 31 | 31 |  | 15 | 16 |
| 58 | Discharge Destination | 31 | 31 |  | 15 | 16 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 97% Cardiology DQI = 97.5% Surgery DQI = 96.75%

|  |  |  |
| --- | --- | --- |
| **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 .92** | |
| **Card**  .94 | **Surg**  .91 |
| **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** .97 | |
| **Card**  .96 | **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** .99 | |
| **Card**  1.0 | **Surg**  .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** | **2017**  **16-17** | **2016**  **15-16** | **2015**  **14-15** | **2014**  **13-14** |
| **Demographics** | 1.0 | 1.0 | .99 | 1.0 |
| **Pre Procedure** | .92 | .85 | .97 | .92 |
| **Procedure** | .97 | .96 | .94 | .95 |
| **Outcome** | .99 | .97 | .99 | .99 |

**Conclusions**

On the whole the Theatre log books/printouts appear to be of a good standard, accurate and precise. As previously reported the nurses and the radiographers log books from the cath labs were difficult to interpret with descriptions for the same patient episodes varying considerably at times. The DQI has increased and represents a very good validation result and the NCHDA Review Team would like to commend the DBMs for exceptional and conscientious efforts to ensure all the appropriate data were submitted. It is clear that many extra hours have been invested by the DBMs to maintain a demonstrably high DQI.

The Reviewers are delighted that OLCHC has increased the number of WTES to 1.75 to support this data collection and this has contributed to the increase in DQI. There were 961 variables reviewed and 36 discrepancies identified.

This is the sixth visit to OLCHC and the Reviewers are very pleased to report that there is now a process to obtain prospective consent for external validation of case implemented. This consent is essential for all parts of this review including validation of deceased patients records. The Validation Team are also grateful to the CEO of OLCHC for giving permission for the deceased case notes to be reviewed at this visit. Patient deaths can impact on the risk analysis that the NCHDA performs. It is therefore essential that these procedures, their dates and their coding are examined to ensure that it is correct and any comorbidities are correctly included.

A more formal process of data collection and review is slowly developing with steps set out to maintain a robust audit cycle. However it appears, as previously reported that some areas are still more proactive than others in supporting timely data review prior to submission to NCHDA.

It is recognised that there is now an individual identifier issued at birth in ROI and a developing national independent system of mortality tracking available in the ROI. It is reported to the NCHDA Validation Team that the DBMs continue to submit life status reports directly on to Lotus notes for patients who have died following surgical or interventional catheter procedures.

**Deceased Case Notes Review**

As reported elsewhere there were a small number of errors identified.

**Recommendations**

1. It is recommended that in liaison with the Lead Clinicians for cardiology and cardiac surgery, the congenital Database Managers should continue to regularly review the standard operating procedures (SOPs) to for this registry. Each SOP should clearly set out exactly **who** is responsible for and in what time frame the following should occur;
2. Ensuring consent for external validation of hospital notes is obtained from the patient/parent/guardian at first hospital attendance.
3. Input of the data for each episode and at which point of the treatment delivery
4. 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. It is recommended that this is done as soon after each patient treatment episode and again as soon after discharge from hospital as possible. Each clinician should be encouraged to ‘own’ their data
5. Leading the local review (and how frequently and in which forum),
6. Running the monthly PRAiS analysis
7. Making timely submissions (monthly is recommended, quarterly is mandatory) and
8. Timely reverse validation at OLHSC.
9. Updating life status as any dates of death become known
10. As previously, ensure that the primary diagnosis reconciles with the primary procedure performed and that this is consistently applied across each of the patients procedures
11. It is strongly recommended that the double data entry of records of procedural activity in the cath lab should be unified as soon as possible in order that they are an accurate description of exactly what procedure was performed. Currently neither appear to be particularly precise or clear.
12. 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.
13. It is recommended that consideration by the ROI Health Service Executive for the future funding to facilitate the annual validation process by NCHDA be given for each UK fiscal year.