**The National Congenital Heart Disease Audit Database**

**Data Quality Audit for**

**CONGENITAL HEART DISEASE**

**Apr 2017 - Mar 2018**

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

**24 July 2018**

*Performed by Mr A C McLean 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 2017 - 2018. This is the seventh 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/>

This validation visit has been fully funded by the Health Department of the Republic of Ireland.

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 1155 procedures (409 surgery, 434 catheters, 312 others, 16 deaths within 30 days of procedure) have been undertaken during the data collection year of April 2017 to March 2018 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 2014-17, a new cardiac information system has been commissioned, provided by Health Insights and this has been used since mid 2018.

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 2017**

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. Both DBMs attended the NCHDA Contributors meeting via teleconference on 3 July 2018

**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 2012-17, 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.

Since March 2015 it has 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 and has become further embedded during 2017-18. 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.

As in previous years, 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 2012-17, in ROI there was 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 was 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.

NICOR 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.

Mr A C McLean, Congenital Cardiac Surgeon from Glasgow 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); **98.25%** (97, 94.5, 97.25), with domain scores Demographics .99 (1.0, 1.0, .99), Pre Procedure .98 (.92 .85, .97), Procedure .97 (.97, .96, .94), and Outcome .99 (.99, .97, .99). This is another excellent score. Well done!

This is based on 20 patients who had 23 procedures (16 catheters, 7 operations). There were 11 errors or omissions in 756 variables.

**Separate DQI for Catheters and Surgery**

Since the 2009 cycle of visits commenced, as well as the overall DQI for each centre, the DQI for surgery and catheters is being calculated. It is recommended that a minimum number of 5 procedures in either group are required for the differential DQI calculation.

|  |  |  |  |
| --- | --- | --- | --- |
| **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% |
| **2018** | 2017-18 | 99% | 98% |

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 and used to provide the records for this validation visit, indicated that the cardiac department of the Our Ladies’ Hospital for Children had undertaken 1155 procedures (409 surgery, 434 catheters, 312 others, 16 deaths within 30 days of procedure) in the data collection year 2017/2018 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, 20 patients had 23 procedures (16 catheters, 7 operations).

5 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. There were 11 errors or omissions in 756 variables.

**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 occasionally 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 2012-17, 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.

The nurses log book showed that patient identity labels were used mostly to indicate each patients case.

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 these procedures.

1. As previously stated, TOE, Provocation Testing and DC conversion procedures are not required to be submitted to NCHDA at this time
2. 0 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. 2 submitted records were identified that may have errors in them
2. Delayed closure of sternum is 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 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.

**Review of Deceased Patients Case notes**16 patients were identified in the data return for 2017-18 to have died within 30 days of a cardiac operation or catheter intervention procedure. The PRAiS sensitive fields were reviewed for each record and the findings were:

1. 2 records appear to have incomplete comorbidities listed
2. 4 records appear to have an incomplete diagnoses string
3. 1 record appears to have previous procedures missing
4. 1 record may have incomplete procedure performed coding
5. 1 record may have incomplete complications listed

**Case Note Audit**

20 patients underwent 23 procedures. 7 operations and 16 therapeutic catheter procedures

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

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| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure + Time Start | 23 | 23 |  | 16 | 7 |
| 28 | Proc Urgency | 23 | 23 |  | 16 | 7 |
| 29 | Unplanned Proc | 0 | 0 |  | 0 | 0 |
| 30 | Single Operator | 1 | 1 |  | 1 | 0 |
| 31 | Operator 1 | 23 | 23 |  | 16 | 7 |
| 32 | Operator 1 Grade | 23 | 23 |  | 16 | 7 |
| 33 | Operator 2 | 22 | 22 |  | 15 | 7 |
| 34 | Operator 2 Grade | 22 | 22 |  | 15 | 7 |
| 35 | Procedure Type | 23 | 23 |  | 16 | 7 |
| 36 | Sternotomy Sequence | 7 | 7 |  | - | 7 |
| 37 | Operation Performed | 23 | 23 |  | 16 | 7 |
| 38 | Sizing balloon used for septal defect | 4 | 4 |  | 4 | - |
| 39 | No of stents or coils | 1 | 5 | 4 absent | 1/5 | - |
| 40 | Device Manufacturer | 12 | 12 |  | 12 | - |
| 41 | Device Model | 12 | 12 |  | 12 | - |
| 42 | Device Ser No | 12 | 12 |  | 12 | - |
| 43 | Device Size | 12 | 15 | 3 absent | 12/15 | - |
| 44 | Total Bypass Time | 6 | 6 |  | - | 6 |
| 45 | XClamp Time, | 6 | 6 |  | - | 6 |
| 46 | Total Arrest | 0 | 0 |  | - | 0 |
| 47 | Cath Proc Time, | 15 | 16 | 1 incorrect | 1516 | - |
| 48 | Cath Fluro Time, | 15 | 16 | 1 absent | 15/16 | - |
| 49 | Cath Fluro Dose, | 15 | 16 | 1 absent | 15/16 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 50 | Duration of Post Op Intubation | 6 | 6 |  | - | 6 |
| 51 | Post Procedure Seizures | 23 | 23 |  | 16 | 7 |
| 52 | Post Proc Complications | 0 | 1 | 1 incorrect | 0/1 | - |
| 53 | Date of Discharge | 23 | 23 |  | 16 | 7 |
| 54 | Date of Death | - | - |  | - | - |
| 55 | Attribution of Death | - | - |  | - | - |
| 56 | Status at Discharge | 23 | 23 |  | 16 | 7 |
| 57 | Discharge Destination | 23 | 23 |  | 16 | 7 |

**Casenote Audit**

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.25% Cardiology DQI = 98% Surgery DQI = 99%

|  |  |  |
| --- | --- | --- |
| **DOMAIN** | **DOMAIN**  **Score** | |
| **Demographics**  Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status, | **Overall .99** | |
| **Card**  1.0 | **Surg**  .96 |
| **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 .98** | |
| **Card**  .98 | **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** .97 | |
| **Card**  .96 | **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**  .98 | **Surg**  1.0 |

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**  **17-18** | **2017**  **16-17** | **2016**  **15-16** | **2015**  **14-15** |
| **Demographics** | .99 | 1.0 | 1.0 | .99 |
| **Pre Procedure** | .98 | .92 | .85 | .97 |
| **Procedure** | .97 | .97 | .96 | .94 |
| **Outcome** | .99 | .99 | .97 | .99 |

**Conclusions**

As previously reported, on the whole the Theatre log books/printouts appear to be of a good standard, accurate and precise. The DQI has increased by 1.25% to 98.25% and represents a very good validation result. 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.

There were 756 variables reviewed and 11 discrepancies identified.

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 where it was unclear if this consent had been gathered during life. 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 and NCHDA Web 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 information is given to each patient and consent for external validation of hospital notes is obtained from the patient/parent/guardian at first hospital attendance. That this consent is in line with the GDPR, and 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 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. 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.
12. 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.