**The National Congenital Heart Disease Audit Database**

**Data Quality Audit**

**for**

**Apr 2016 - Mar 2017**

**Royal Brompton & Harefield NHS Foundation Trust**

**3 and 4 May 2017**

*performed by Lin Denne, and Mr S Mussa*

**Summary**

Prior to this validation visit, the data return to NCHDA from Royal Brompton & Harefield NHS Foundation Trust (RBH) for the data collection year 2016/17 indicated that some 1466 procedures (469 surgery, 634 catheterisations, 363 others, 12 deaths) had been undertaken in children and adults with congenital heart disease. These procedures take place at both Royal Brompton and Harefield Hospitals.

This validation visit was fully funded by the Royal Brompton & Harefield NHS Foundation Trust.

As reported at all previous visits, data were input to the Dendrite information system by consultant and junior medical staff. This system is ‘web enabled’ and is called INTELLECT. Computer terminals are available in a variety of different clinical locations including operating theatres and catheter laboratories and real time data input is expected. There is one single dedicated 1.0WTE Quality and Safety Lead for Congenital Heart Disease on the RBH site; who monitors the data for completeness and circulates information to all relevant clinicians on a monthly basis on data quality

The Reviewers again recognise that the Trust is well advanced in its move towards full electronic records and fully support and encourage this process, noting that systems must continue to be in place to ensure complete and accurate identification of patients for submission to NCHDA. RBH have moved from ‘paper lite’ to almost being paper free at this visit in May 2017.

The Quality and Safety Lead for Congenital Heart Disease had printed off the relevant documents from the ePR that held the data that was to be audited and high lighted many of these data items*.* Therefore, it was easy to find the majority of data required. Access to the ePR was also provided in case the Reviewers wished to scrutinise any other documents.

**Consent for External Validation of Notes.**

As previously reported, since February 2011, this centre has started to use a modified version of their generic patient registration form to include a clause to accommodate consent for external case note validation. This page had been printed for each of the records seen on the day. The Validation Team are again grateful to the Medical Director of the Trust for giving permission to review any case note that did not appear to have any consent for external review contained in it.

**Feedback on Actions Implemented following the last NCHDA Validation Visits in 2016**

* Due to the uncertainty generated by the CHD review, the 1.0WTE Clinical outcomes Officer post was vacant from July 2016 to April 2017.
* A full time Clinical Outcomes Officer/MDT coordinator has now been appointed and commenced in post at the beginning of May 2017
* Junior Drs will are being encouraged to volunteer to participate in external audit visits
* The Quality and Safety Lead attended the NCHDA Contributors Meeting in Belfast in March 2017
* The Trust continues to submit data to the NCHDA every month two weeks in arrears

**Data Quality Indicator**

The DQI for the Trust is calculated to be **99.25%** (99.25, 99, 98, at previous visits). The Domain scores for this visit are; (with previous years in parentheses) Demographics 1.0 (1.0 1.0 1.0), Pre Procedure .99 (.99 .995 .96), Procedure .98 (.99 1.0 .98) and Outcome .99 (.99 .98 .98). This DQI demonstrates again a consistently high standard of data collection and validation within the Trust.

As well as the overall DQI for each centre, the DQI for surgery and catheters is being calculated. On review of the DQI when the cases were split into their surgery and catheter groups the scores are;

|  |  |  |  |
| --- | --- | --- | --- |
| **Year of visit** | **Data year being validated** | **Surgery** | **Therapeutic Catheter Interventions** |
| **2009** | 07/08 | 98.25% | 97% |
| **2010** | 08/09 | 98% | 96% |
| **2011** | 09/10 | 97.25% | 99.5% |
| **2012** | 10/11 | 97.75% | 98% |
| **2013(i)** | 11/12 | 99.75% | 98.25% |
| **2013(ii)** | 12/13 | 97.86% | 96.43% |
| **2014** | 13/14 |  99.25% | 96.25% |
| **2015** | 14/15 | 98.75% | 97.75% |
| **2016** | 15/16 | 99.5% | 98.75% |
| **2017** | 16/17 | 99.25% | 98.75% |

The body of this report is drawn from answers given on the NICOR pre-visit Questionnaire (PVQ).

**Introduction**

Prior to this validation visit, the data return to NCHDA from Royal Brompton & Harefield NHS Foundation Trust for the data collection year 2016/17 indicated that some 1466 procedures (469 surgery, 634 catheterisations, 363 others, 12 deaths) had been undertaken in children and adults with congenital heart disease, of which 20 cases were randomly selected for the case note review. These procedures take place at both Royal Brompton and Harefield Hospitals

The NICOR Data Auditor and one Post CCT Fellow in congenital cardiac surgery undertook the site audit.

20 sets of notes were requested (the Sample). A list of 10 records (the Reserves) was also supplied in case any of the Sample were unavailable. On the day of the validation 19 Sample case notes were made available to the Reviewersand 1 case note from the Reserves was used.The accuracy of the NCHDA data return was then checked against each set of notes in order to calculate the Data Quality Indicator (DQI).

 **Review of notes**

Of the 20 patient’s case notes that were reviewed, there were a total of 29 procedures (16 catheters, 13 operations).

1. As previously, the notes were very tidy, and meticulously prepared for the visit
2. As noted in earlier Validation Reports, the standard of completion of the care pathway documents was extremely good.
3. The NHS Number was present in all notes and is included on the patients identity label.
4. Perfusion records were seen in all the case notes of bypass patients
5. Of the 13 surgical case notes reviewed, it was noted that all had a typed surgical summary. This is a commendable practice and tremendously aided the data review.

**Theatre & Catheter Lab Records and Review of the Catheter Laboratory Log Books**

As previously reported ICIP is the electronic theatre management system in place at both Royal Brompton & Harefield Hospitals. Extracts were made available from both sites.

1. No surgery queries were raised

Across both sites, the radiologists use a customised electronic data collection tool (Radiology Information System or RIS) in the catheterisation laboratories. This has been adapted for the collection of all catheter intervention and diagnostic data, rather than just for radiology. Infoflex is a database that is used in the cath labs to collect information on electrophysiology activity and PACEnet is a data base used in the cath labs to collect information on all pacing procedures. COGNOS is the software used to extract data and run reports. The only congenital catheter interventions taking place at Harefield site are some closures of PFOs in adults. This activity is easily picked up from the COGNOS reports.

1. The Quality and Safety Lead has identified a record missed from the submission immediately prior the validation visit
2. 6  submitted catheter records appeared to have errors in them
3. As noted previously,  the descriptions of procedures in RIS did not always  accurately portray exactly what had actually taken place or whether the patient had a diagnosis of congenital heart disease.
4. When reviewing PACEnet it was sometimes quite difficult to know whether or not a patient having a procedure had congenital heart disease or not.

As noted previously it is of great assistance when reviewing these documents if a single consistent approach to identifying NCHDA procedures within log books (electronic or hand written) that can be used across both hospital sites.

**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 notified to them from the hospital under 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 is asked for permission to undertake this review. The Validation Team are grateful to the MD of the Royal Brompton and Harefield NHS Foundation Trust for giving this permission. 12 post procedural deaths were submitted in the data for the year 2016/17.

All data on the deceased patients was readily available and concise. All patients were discussed in the local mortality meetings and a summary of the findings were available for review. All of the cases were very complex and were investigated fully at local level. A further example of very good clinical and audit practice at the Royal Brompton & Harefield NHST Foundation Trust.

1. 1 record appears to have an absent comorbidity
2. All dates of death were correct.

**Security and Confidentiality (Data Management)**

As in all the previous Reports, the NCHDA system has been registered with the Trusts Data Protection Officer and there are tested procedures to ensure data backup and disaster recovery. The system is also fully compliant with the Trusts policies on security and confidentiality. The information system is run on its own dedicated server. Each user has their own unique login to the Dendrite INTELLECT system and is reminded of their responsibilities in regard to confidentiality. There is a full security module and audit trail, built into the system. Login details are supplied to users after training, where security and confidentiality are discussed. This is unchanged at the time of this visit in 2017.

**Coverage (Data Management)**

As previously reported, there are written procedures available to staff in all areas where data are collected and managed and this also includes current relevant definitions and technical documents relating to the NCHDA can be found on the website**.** All staff are taken through the database during induction training, and reminders are in place in theatres and catheter labs. Dr Maria Serrato is the Quality and Safety Lead for Congenital Heart Disease and she monitors and reports on data completeness and accuracy on a continuous basis. Dr Serrato checks all entries against the electronic log books (caseviewer and AGFA downloads) . Dr Franklin (Clinical lead) and Consultant Paediatric Cardiologist is always on hand to resolve queries. Lorenzo is the new patient administration system and interfaces with the NHS Summary Care Record sometimes referred to as the NHS Spine.

The Centre is confident that all data is consistently collected in all instances as all procedures are cross-checked with the electronic log books for catheterisation laboratory and theatre systems. Data are collected in ‘real time’ at the point of service.

**Quality Assurance**

As in all the previous NCHDA Reports, formal validation routines are built into the system. Checks for invalid entries and completeness of data items and for duplicates are done by the Quality and Safety Lead for Congenital Heart Disease.

The Trust has a HL7 feed from Lorenzo, both Lorenzo and Intellect check the NHS number parameters to ensure compliance. NHS numbers are routinely checked with the NHS Tracing (NSTS) service and are now included in the patient identity labels.

There is a process of a continuous audit, with a final monthly quality and safety reports; weights, perfusion data, intubation times and final outcome are 100% validated against ICIP and Lorenzo data. The consultants are circulated their data at the end of each month and the clinical audit lead runs a final validation every month. There are 3 levels of validation:

* First by the Quality and Safety Lead for CHD
* By the Consultants
* By the Clinical Audit Lead

Every single entry is validated against all electronic available resources. This is unchanged in 2017.

**Training**

There is central responsibility within the Trust for identifying, developing and provision of training in data collection. There is training provided by the Quality & Safety Office for data submitted to national audits. There is also a documented training programme covering all aspects of recording clinical activity in the NCHDA. The training programme covers NCHDA clinical classifications, the uses and importance of data both locally and nationally as well as security and confidentiality. The training programme is for all staff who have responsibility for collecting and managing data appropriate to their role. The Quality and Safety Lead for Congenital Heart Disease undertakes procedures for validating and correcting data. Each Consultant is responsible for the provision of data on their patients and the Consultant and Specialist Registrar do all the data entry and have been trained to perform this. Temporary staff do not enter data. The Quality and Safety Lead for the NCHDA at RBH oversees the process and management of the data. Locums and temporary staff do not enter data. This is unchanged since the previous visits.

**Communications**

As at all the previous visits, there are established procedures for reissuing amended information following changes to the data and there are procedures to ensure timely collection and dissemination of activity data with the organisation and to the NCHDA. Monthly reports are produced for the Directorates.

There are also established procedures for answering queries about the data or information produced from the NCHDA. The NHS number was widely seen on patient documentation throughout the visit.

**Accountability**

As before at the previous NCHDA visit, the Quality and Safety Lead for Congenital Heart Disease has management responsibility for the NCHDA system. There are designated people (Lead Consultant/ /Quality and Safety Lead for Congenital Heart Disease) who are jointly responsible for data quality and standards conformance. There is a service level agreement between Children’s Services and Quality & Safety that gives those staff responsible for data quality adequate influence over other staff whose actions affect data quality. The Quality and Safety Lead for Congenital Heart Disease is a senior member of the Q&S team and is fully supported by the Clinical Director, Directors of Paediatrics and the Heart Division and Clinical Audit Lead . This is endorsed by the Medical Director & Responsible Officer, Dr Richard Grocott-Mason.

**Health Records Management**

All the information required by NCHDA can be found in the notes, the ePR is available if needed, for this to be done and can be used for this purpose if required. There is ‘real time’ data entry at the point of service by clinicians. This is unchanged in 2017.

**Timeliness**

The Trust moved from a quarterly schedule of submissions to the NCHDA to monthly in 2014. All internal deadlines for data preparation, submission and validation are being met. While quarterly submissions are the minimum standard required for NCHDA, the more frequent submission are again, highly commended. RBH aim to submit all NCHDA data at the end of each month two weeks in arrears.

* The RBH Quality and Safety report is always published the second Friday after the end of the month
* The NCHDA data forms part of the paediatric dashboard presented at the governance day which takes place between the second and third week of the month

**Completeness and Validity**

As at the previous visits, the EPCC coding is available to ensure patient care events are defined correctly according to NCHDA classifications and include a list of the acronyms, synonyms and abbreviations. All clinical staff are familiar with these.

Internal targets for completeness are at approximately 90% within one month of the procedure and this has been maintained at the 2017 visit.

**Accuracy**

As previously reported, there is a very robust data quality and audit programme in progress which includes checking data items as discussed above under Coverage. The Quality and Safety Lead for Congenital Heart Disease reviews all entries against hospital notes and/or electronic records at least monthly. All consultants are asked to check their data against their own records prior to submission to NCHDA and the Lead Clinician for the NCHDA validates all entries prior to monthly submission to the NCHDA.

**Case Note Audit**:

Patient’s notes were audited covering 16 catheter interventions and 13 operations.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 12 | 8 |
| 2 | NHS Number | 19 | 19 |  | 12 | 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 | 20 | 20 |  | 12 | 8 |
| 9 | Postcode | 20 | 20 |  | 12 | 8 |
| 10 | Pre Procedure Diagnosis | 29 | 29 |  | 16 | 13 |
| 11 | Previous Procedures | 61 | 61 |  | 36 | 25 |
| 12 | Patients Weight atOperation | 27 | 29 | 1 incorrect, 1 unable to validate | 15/16 | 12/13 |
| 13  | Height | 29 | 29 |  | 16 | 13 |
| 14 | Ante Natal Diagnosis | 4 | 4 |  | 2 | 2 |
| 15 | Pre Proc Seizures | 29 | 29 |  | 16 | 13 |
| 16 | Pre Proc NYHA  | 6 | 6 |  | 5 | 1 |
| 17 | Pre Proc Smoker | 6 | 6 |  | 5 | 1 |
| 18 | Pre Proc Diabetes | 6 | 6 |  | 5 | 1 |
| 19 | Hx Pulmonary Dis | 6 | 6 |  | 5 | 1 |
| 20 | Pre Proc IHD | 6 | 6 |  | 5 | 1 |
| 21 | Comorbidity Present | 29 | 29 |  | 16 | 13 |
| 22 | Comorbid Conditions | 12 | 12 |  | 10 | 2 |
| 23 | Pre Proc Systemic Ventricular EF | 29 | 29 |  | 16 | 13 |
| 24 | Pre Proc Sub Pul Ventricular EF  | 22 | 22 |  | 14 | 8 |
| 25 | Pre-proc valve/septal defect/ vessel size | 3 | 3 |  | 3 | - |
| 26 | Consultant | 29 | 29 |  | 16 | 13 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 29 | 29 |  | 16 | 13 |
| 28 | Time Start | 29 | 29 |  | 16 | 13 |
| 29 | Proc Urgency | 29 | 29 |  | 16 | 13 |
| 30 | Unplanned Proc | 29 | 29 |  | 16 | 13 |
| 31 | Single Operator | 29 | 29 |  | 16 | 13 |
| 32 | Operator 1 | 29 | 29 |  | 16 | 13 |
| 33 | Operator 1 Grade | 29 | 29 |  | 16 | 13 |
| 34 | Operator 2 | 25 | 25 |  | 12 | 13 |
| 35 | Operator 2 Grade | 22 | 25 | 3 absent | 10/12 | 12/13 |
| 36 | Procedure Type | 29 | 29 |  | 16 | 13 |
| 37 | Sternotomy Sequence | 13 | 13 |  | - | 13 |
| 38 | Operation Performed | 29 | 29 |  | 16 | 13 |
| 39 | Sizing balloon used for septal defect  | 1 | 1 |  | 1 | 1 |
| 40 | No of stents or coils | 8 | 9 | 1 absent | 8/9 | - |
| 41 | Device Manufacturer | 24 | 25 | 1 absent | 18/19 | - |
| 42 | Device Model | 24 | 25 | 1 absent | 18/19 | 6 |
| 43 | Device Ser No | 24 | 25 | 1 absent | 18/19 | 6 |
| 44 | Device Size | 22 | 23 | 1 absent | 18/19 | 6 |
| 45 | Total Bypass Time | 11 | 11 |  | - | 11 |
| 46 | XClamp Time, | 9 | 9 |  | - | 9 |
| 47 | Total Arrest | 0 | 0 |  | - | 0 |
| 48 | Cath Proc Time, | 15 | 16 |  | 15/16 | - |
| 49 | Cath Fluro Time, | 15 | 16 |  | 15/16 | - |
| 50 | Cath Fluro Dose, | 15 | 16 |  | 15/16 | - |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation  | 12 | 13 | 1 absent | - | 12/13 |
| 52 | Post Procedure Seizures  | 29 | 29 |  | 16 | 13 |
| 54 | Post Proc Complications | 3 | 3 |  | 1 | 2 |
| 55 | Date of Discharge | 29 | 29 |  | 16 | 13 |
| 56 | Date of Death | 1 | 1 |  | - | 1 |
| 57 | Status at Discharge | 29 | 29 |  | 16 | 13 |
| 58 | Discharge Destination | 29 | 29 |  | 16 | 13 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 99.25%, Cardiology DQI = 98.75%, Surgery DQI = 99.5%

This DQI is based upon the domain scoring below. The methodology for this DQI is provided in the paper: The NICOR 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 .99** |
| **Card**.99 | **Surg**.99 |
| **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** .98 |
| **Card**.96 | **Surg**.995 |
| **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**.985 |

This DQI is based upon the domain scoring below. The methodology for this DQI is provided in the paper The NICOR Audit – An Introduction to the Process.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DOMAIN** | **2017****May****16/17** | **2016****Oct****15/16** | **2015****Oct****14/15** | **2014****May****13/14** |
| **Demographics** | 1.0 | 1.0 | 1.0 | 1.0 |
| **Pre Procedure** | .99 | .99 | .955 | .96 |
| **Procedure** | .98 | .99 | 1.0 | .98 |
| **Outcome** | .99 | .99 | .98 | .98 |

**Conclusions**

This validation visit occurred 2 days after the final submission date for 2016-17 data and the Validation Team would like to commend the Quality and Safety Lead not only for the attention to detail in the preparation of the case notes, which greatly enhanced this part of the Review, but for managing singlehandedly the timely data collection, quality management and then submission of these data for the largest Congenital NHS Centre in the UK. It is also recognised that a large number of extra hours had been invested by the Quality and Safety Lead to ensure that the data that were submitted were complete and accurate prior to submission to NCHDA.

On the whole the NCHDA data were very well documented, high quality and were appropriately recorded in the electronic printouts seen at this validation visit. However, as mentioned in previous validation reports, the precise descriptions of the procedures performed and whether or not it was for congenital heart disease were often not recorded but this is improving. As previously reported, the data manager (Dr Serrato) is actively involved in validation of the data and in resolving discrepancies. The overall quality of the electronic notes and data submission is to be commended. The PICU discharge summaries and the inpatient discharge letters were of great help during the Review.

The availability of electronic theatre and catheter lab registries is very useful and expedites the time needed to perform this task. The Reviewers were informed that NCHDA patients are flagged within the system and would recommend that robust procedures are in place to check the reliability of this flagging system as the Trust moves forward with electronic records. However, as stated above it was often not clear to the Reviewers whether or not a procedure was being performed for congenital heart disease.

The Reviewers are delighted to report that RBH, as one of the largest congenital centres in the UK that has maintained an excellent standard of data quality >5 years, that a further 1.0WTE member of staff has been recruited to support this data collection. The high standards of data quality may well be compromised without at least one additional staff member to support not only the NCHDA, but also the various related NHSE monthly and quarterly activity analyses and ‘dashboard’  requests.

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

Just 1 query was raised with these data and all of the dates of death were found to be correct.

**Recommendations**

1. To continue to strive to meet the New Congenital Heart Disease Review (NHSE July 2015) recommendation B32(L1) that each Specialist Surgical Centre must have a minimum of 1.0 WTE dedicated paediatric cardiac surgery/cardiology data collection manager, with at least 1.0 WTE assistant, responsible for audit and database submissions in accordance with necessary timescales. This is further underpinned by The Report of the Independent Review of Childrens Cardiac Services in Bristol (June 2016 Grey, Kennedy 1.22(2) and Ch17 ) These should fulfil dedicated roles to meet the growing demands of the NCHDA data collection and NHSE with no other ‘add on’ parts.
2. It is recommended that the Standard Operating Protocols for this data collection are regularly reviewed to ensure ongoing consistently good data standards. .
3. It is recommended to maintain the scheduled monthly submissions to NCHDA. More frequent submissions are welcomed but are not mandatory.
4. It is recommended that the Quality and Safety Lead attends the NCHDA Contributors Meeting in Glasgow during 18-20 March 2018.
5. It is recommended that all staff involved with managing and collecting NCHDA data undertake an annual visit to another congenital centre to observe the validation processes and practices and share experiences with colleagues.