**The National Congenital Heart Disease Audit**

**Procedures for**

**CONGENITAL HEART DISEASE**

**Data Quality Audit**

**Manchester Royal Infirmary (part of Central Manchester University Hospitals NHS Foundation Trust)**

**22 June 2017**

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**Summary and Overview**

Prior to this Validation Visit, the data return from Manchester Royal Infirmary (MRI) Foundation Trust, indicated that 353 cardiac procedures (surgery 89, catheters 142, others 122, deaths 2) had been undertaken during the 2016/17 data collection year in patients with congenital heart disease. MRI is part of the Central Manchester NHS Foundation Trust (CMFT).

As reported from January 2010 – June 2017 there had been a 1.0WTE congenital cardiac surgeon in post. There is also 1 further consultant cardiac surgeon with an interest in congenital cardiac surgery at MRI. There are 3 consultant cardiologists at MRI that specialise in adult congenital cardiology. 2 are full time consultants and 1 is part time. 2 further congenital interventional cardiologists from Alder Hey Childrens Hospital undertook therapeutic procedures in the cath lab at MRI on ACHD patients on a weekly basis. There is 1 further ACHD interventional cardiologist who undertook more complex therapeutic interventions. This individual visited MRI for 1 week on a prearranged basis until May 2017.

In June 2016 NHSE announced a public consultation on the future provision of congenital cardiac surgery in England and suggested that MRI may no longer be commissioned to undertake procedures in patients with congenital heart disease. This consultation is still ongoing and a final decision is expected during 2018. Following this uncertainty and difficulties with staff recruitment and retention, CMFT took the decision to cease level 1 congenital cardiac surgery in July 2017. These patients are now having procedures performed at either Freeman Hospital in Newcastle or Leeds General Infirmary.

**Overview at MRI**

As reported at the previous visits to MRI, the Cardex information system is used and available at every point of service throughout the hospital and there is real time entry of data. All staff have password protected secure IDs to access this system. Cardex is a locally developed information management system that has been in use since 1997. There are monthly meetings with the surgeons and the Clinical Governance Information team to validate 10 randomly selected sets of notes.

Since 2015, MRI have had a dedicated 1.0WTE person to support this data collection.

**Actions undertaken since the last validation visit in June 2016**

1. A weekly email with a list of previous weeks patients is sent to the ACHD team for confirmation whether ACHD or not
2. There is now earlier capture and entry of diagnosis and comorbidities at each clinic appointment
3. When the data are complete and ready for upload, the ACHD Information Coordinator uploads all data to NICOR, this was previously uploaded by MHC IT. This change in process has significantly decreased the number of duplicate records.
4. The electrophysiology team have improved their identification of Congenital cases
5. The trust coding team keep the hospital notes of all the patients identified with ACHD for collection and then process them through to the ACHD Information Coordinator to ensure all NCHDA data points are completed and accurate.
6. Continued re-assessment of case notes takes place to ensure completeness of data is at least 98%

**Consent for External Validation of Notes.**

This has been required since 1 April 2007. Without this consent in place data are not allowed to be externally validated. At MRI there is formal documentation to gather this consent which has been in place since August 2007. Where this consent was missing from a case note the Governance Information Staff attempted to contact the patients by Royal Mail and by telephone. The Validation Team are grateful to the Associate Medical Director of CMH FT for giving permission to use sets of hospital case notes where the all attempts to retrospectively contact the patients by Royal Mail and telephone had failed.

A random sample of 20 case notes were reviewed relating to 28 procedures to allow the Data Quality Indicator (DQI) to be calculated (20 catheter procedures, 8 surgery).

**Data Quality Indicator**

The DQI for MRI is calculated from the hospital notes review, with the previous year in parentheses, is calculated to be **98.5** (97.7**,** 95, 93.5)**.** The domain scores are Demographics .98 (.99 99, .99). Pre Procedure .99 (.98, .95 .87). Procedure .99 .(.985, 96 .98 .95) and Outcome .97 (.95, .98 .96 95).

Since 2009, at each validation visit, the DQI is being calculated separately for surgery and catheter procedures. The minimum threshold for this to be calculated is 5 records in either group.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Year validated** | **Surgery** | **Catheters** |
| **2012** | 10/11 | 92% | 94.75% |
| **2013** | 11/12 | 87.75% | 92.25% |
| **2014 (i)** | 12/13 | 93.75% | 93% |
| **2014 (ii)** | 13/14 | 97.75% | 92.25% |
| **2015** | 14/15 | 97.25% | 96% |
| **2016** | 15/16 | 97% | 96.75% |
| **2017** | 16/17 | 98% | 98% |

The body of this report is drawn from answers given on the NCHDA pre visit Questionnaire and from discussions on the day of the visit.

**Introduction**

Prior to this Validation Visit, the data return from Manchester Royal Infirmary (MRI) Foundation Trust, indicated that 353 procedures (surgery 89, catheters 142, others 122, deaths 2) had been undertaken during the 2016/17 data collection year in patients with congenital heart disease.

As mentioned elsewhere, 20 patients sets of case notes were selected for review who underwent a total of 28 procedures (8 surgery, 20 catheter procedures, 2 deaths). The accuracy of the NCHDA data return was then checked against each set of notes to enable the Data Quality Indicator (DQI) to be scored

The NCHDA Data Auditor and one external Consultant in Congenital Cardiology undertook the site audit at MRI.

**Review of case notes at MRI**

As in 2015-16, the hospital case notes had each been individually prepared with a coloured sticky note indicating many of the pages that the Reviewers needed to see and this was most helpful.

1. The JCC (Joint Cardiac Conference) meeting documents when seen were very detailed and helped to quickly establish the diagnoses and proposed action plan for a patient intervention or operation.
2. As previously reported, it was sometimes difficult to find a clear ending to an inpatient admission.
3. Hand written operation notes, consent forms and formal typewritten summaries were seen in most of the case notes.
4. It was noted on several occasions that the primary submitted diagnoses did not always reconcile with the procedure performed.
5. As previously reported, the orange labels sometimes seen in the notes and more regularly seen in the cath lab log books to indicate a congenital catheter procedure are very easy to spot due to the extremely vivid colour.
6. The sticky identity labels for implanted devices do not always appear to be in the patients hospital notes.
7. As noted at the 2008 visit, there is an ICP for cardiology but this often didn’t have all the fields completed
8. It was not always clear in the clinical notes exactly what the name of the 2nd operator was in the records of patients undergoing therapeutic electrophysiological procedures if there was one present.

**Review of the Catheter Log Books at MRI**

1. The cath lab log books for labs 1- 5 and the Hybrid room were offered for review.
2. The log book for lab 2 for the period Oct 2016 – January 2017 was absent, its location unknown.
3. As previously reported, the log books are a series of A4 hard back note books. Each page has 1 procedure on it.
4. As previously reported, the details are all hand written and often in a locally known shortened note form. There has been concern at previous visits about the ease of identifying exactly what procedure has taken place and this is unchanged at this visit.
5. As documented elsewhere, the congenital cardiologists have introduced a vivid orange label to identify congenital cardiac procedures and this was seen in many of the entries for both diagnostic and interventional procedures.
6. 2 submitted catheter records appear to have errors in them and these have been corrected post validation visit.
7. 15 procedures were identified in the cath lab log book which may have been missed from the data submission. Many of these were for implantable pacemakers or ICDs.
8. 76 submitted catheter records were not validated in the log books.

**Review of the theatre log books.**

The log books from theatres 1 and 3 were made available.

1. As previously reported, the theatre ledgers are A3 size, softly bound carbonised books. The entries are closely handwritten and at times very difficult to decipher exactly what procedure has taken place.
2. 6 surgery procedures were identified that may have been missed from the data submission
3. 3 of the submitted surgical records may have errors in them

**Validation of Data of Deceased Patients**

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, comorbidity and procedure coding will also be validated.

2 post procedural deaths were submitted in the data from MRI for the year 2016/17.

The procedural and outcome documentation as well as the hospital notes were made available to the Reviewers.

* 1 record appears to have an incomplete previous procedures listing
* All other data were found to be correct

**Data Security and Confidentiality**

As previously reported, the Cardex 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 fully compliant with the Trusts policy on security and confidentiality. Each staff member has a unique user ID and password. There are written procedures available to staff in all the areas where staff collect and manage data and there are processes in place to audit data collection activities. Training on the Cardex system is provided at induction for all staff and there is on going support. The Centre are confident that all patient data is consistently collected in all instances. This is unchanged in June 2017.

**Validation and Quality Assurance**

As at all the previous visits, there are validation routines built in to Cardex and these include checking for duplicates, data completeness and for invalid entries. The procedure to check for an NHS number without an 01 status indicator or for the validation algorithm for the NHS number, is done by the Trust PAS as the demographic data are input.

Reverse validation of submitted data (the retrieval of data submitted to NCHDA) against locally held records is now performed quarterly.

**Training**

There is central responsibility within the Trust for the identification of training needs and development and provision of training in data collection. The Trust use the NHS Key Skills Framework (KSF) to support staff training and to meet training needs. Training on the Cardex system is provided at induction for all staff and there is on going support. There is no formal training for the NCHDA data but this is provided informally within the Department. Any junior clinical staff are given formal training from the Audit Lead for ACHD.

There is ad hoc training for temporary staff and support is available. This is unchanged at the June 2017 NCHDA visit.

**Communications**

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 within the organisation and to NCHDA. There is also an established procedure for answering queries about the data or information produced from NCHDA, this is done on an ad hoc basis. The NHS number is used on communications but does not appear to be standard on patient identity labels. Again, this remains unchanged in June 2017.

**Accountability**

As at all the previous validation visits, there is a nominated person within the Trust who has management responsibility for NCHDA and there is a designated person responsible for data quality and standards conformance. There are arrangements in place to give those staff responsible for data quality adequate influence over other staff whose actions affect data quality.

**Health Records Management**

As at the previous visits, most of the information required by NCHDA can be found in the notes and the notes are available for this to be done.

**Timeliness**

As mentioned elsewhere there is a 1.0WTE support for this data collection and NCHDA are pleased to report that the deadlines for the last 4 years (2013-17) were met.

**Completeness and Validity**

As reported previously, there are transfer tables available to ensure patient care events are defined correctly according to NCHDA classifications and includes a list of the acronyms, synonyms and abbreviations. Internal targets for completeness of data are being met .

**Accuracy**

There is a data quality and audit programme in progress which includes checking data items against source documentation. Reverse validation of the submitted data to NCHDA takes place quarterly as the numbers of procedures have been modest. Clinical staff routinely participate in the validation of diagnostic and procedure codes and the ACHD clinical staff have monthly meetings with the Governance Information Team to review approximately 10 sets of randomly chosen patient notes.**Casenote Audit**

20 records covering 28 procedures (8 surgeries, 20 catheters)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  | | | | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 13 | 7 |
| 2 | NHS Number | 18 | 20 | 2 absent | 11/13 | 7 |
| 3 | Surname | 20 | 20 |  | 13 | 7 |
| 4 | First Name | 20 | 20 |  | 13 | 7 |
| 5 | Sex | 20 | 20 |  | 13 | 7 |
| 6 | DOB | 20 | 20 |  | 13 | 7 |
| 7 | Ethnicity | 20 | 20 |  | 13 | 7 |
| 8 | Patient Status | 20 | 20 |  | 13 | 7 |
| 9 | Postcode | 20 | 20 |  | 13 | 7 |
| 10 | Pre Procedure  Diagnosis | 28 | 28 |  | 20 | 8 |
| 11 | Previous Procedures | 84 | 85 | 1 absent | 74/75 | 10 |
| 12 | Patients Weight at  Operation | 28 | 28 |  | 20 | 8 |
| 13 | Height | 28 | 28 |  | 20 | 8 |
| 14 | Ante Natal Diagnosis | - | - |  |  | - |
| 15 | Pre Proc Seizures | 28 | 28 |  | 20 | 8 |
| 16 | Pre Proc NYHA | 28 | 28 |  | 20 | 8 |
| 17 | Pre Proc Smoker | 28 | 28 |  | 20 | 8 |
| 18 | Pre Proc Diabetes | 28 | 28 |  | 20 | 8 |
| 19 | Hx Pulmonary Dis | 25 | 28 | 3 incorrect | 17/20 | 8 |
| 20 | Pre Proc IHD | 26 | 28 | 2 incorrect | 18/20 | 8 |
| 21 | Comorbidity Present | 28 | 28 |  | 18 | 6 |
| 22 | Comorbid Conditions | 33 | 34 | 1 incorrect | 24/25 | 9 |
| 23 | Pre Proc Systemic Ventricular EF | 28 | 28 |  | 20 | 8 |
| 24 | Pre Proc Sub Pul Ventricular EF | 24 | 28 | 4 incorrect | 16/20 | 8 |
| 25 | Pre-proc valve/septal defect/ vessel size | - | - |  | - | - |
| 26 | Consultant | 28 | 28 |  | 20 | 8 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 28 | 28 |  | 20 | 8 |
| 28 | Time Start | 28 | 28 |  | 20 | 8 |
| 29 | Proc Urgency | 28 | 28 |  | 20 | 8 |
| 30 | Unplanned Proc | 28 | 28 |  | 20 | 8 |
| 31 | Single Operator | 8 | 8 |  | 8 | - |
| 32 | Operator 1 | 28 | 28 |  | 20 | 8 |
| 33 | Operator 1 Grade | 28 | 28 |  | 20 | 8 |
| 34 | Operator 2 | 20 | 20 |  | 12 | 8 |
| 35 | Operator 2 Grade | 20 | 20 |  | 12 | 8 |
| 36 | Procedure Type | 28 | 28 |  | 20 | 8 |
| 37 | Sternotomy Sequence | 8 | 8 |  | - | 8 |
| 38 | Operation Performed | 19 | 20 | 1 incorrect | 19/20 | 8 |
| 39 | Sizing balloon used for septal defect | - | - |  | - | - |
| 40 | No of stents or coils | - | - |  | - | - |
| 41 | Device Manufacturer | 27 | 27 |  | 15 | 12 |
| 42 | Device Model | 30 | 30 |  | 18 | 12 |
| 43 | Device Ser No | 30 | 30 |  | 18 | 12 |
| 44 | Device Size | 11 | 11 |  | - | 11 |
| 45 | Total Bypass Time | 8 | 8 |  | - | 8 |
| 46 | XClamp Time, | 8 | 8 |  | - | 8 |
| 47 | Total Arrest | - | - |  | 15/20 | - |
| 48 | Cath Proc Time, | 15 | 20 | 5 incorrect | 20 | - |
| 49 | Cath Fluro Time, | 20 | 20 |  | 20 | - |
| 50 | Cath Fluro Dose, | 20 | 20 |  | 20 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation | 5 | 8 | 3 incorrect | - | 5/8 |
| 52 | Post Procedure Seizures | 28 | 28 |  | 20 | 8 |
| 54 | Post Proc Complications | - | - |  | - | - |
| 55 | Date of Discharge | 27 | 28 | 1 incorrect | 19/20 | 8 |
| 56 | Date of Death | - | - |  | - | - |
| 57 | Status at Discharge | 28 | 28 |  | 20 | 8 |
| 58 | Discharge Destination | 28 | 28 |  | 20 | 8 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.5% Cardiology DQI = 98% Surgery DQI = 98%

|  |  |  |
| --- | --- | --- |
| **DOMAIN** | **DOMAIN**  **Score** | |
| **Demographics**  Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status, | **Overall** .98 | |
| **Card**  .98 | **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 .98** | |
| **Card**  .97 | **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** .99 | |
| **Card**  .98 | **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** .97 | |
| **Card**  .99 | **Surg**  .925 |

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** | **2016** | **2015** | **2014**  **(ii)** | **2014**  **(i)** |
| **Demographics,** | .98 | .99 | .99 | .99 | 1.0 |
| **Pre Procedure,** | .98 | .98 | .95 | .87 | .85 |
| **Procedure,** | .99 | .985 | .96 | .98 | .95 |
| **Outcome,** | .97 | .95 | .98 | .96 | .95 |

**Conclusions**

On the whole the NCHDA data was accurate and well documented in the theatre and cath lab log books. The reviewers again acknowledge that the adult congenital practice at MRI has grown considerably in the last seven years. This was the 10th consecutive validation visit to this centre. Throughout each of these visits every colleague has been immensely supportive of and engaged in the process; welcoming to the Review Teams and eager to participate in the validation visits.

The reviewers would like to also record their gratitude to the ACHD Information Coordinator and Information Governance Manager for meticulously identifying each document in all the hospital notes that the reviewers needed to see at this validation. There were just 19 errors or omissions in 1233 variables and as such reflects a very high standard of data quality.

It is reported that there were some occasional discrepancies in the dates of discharge on the printed forms used and the hand written entries in the hospital notes. On occasions the preoperative diagnosis for patients did not appear to completely reconcile with the procedure performed.

As previously reported, handwritten entries in the theatre log books were closely written and at times it was very difficult to decipher exactly what procedure had taken place. It was also difficult to identify whether or not the procedure performed was for congenital heart disease or not.

The number of electrophysiological (EP) and pacing procedures reported in patients with congenital heart disease in the NCHDA appears to be increasing also. It was noted that on some entries in the cath lab log books that patients aged less than 16 years of age were undergoing EP procedures. These patients should be included in the NCHDA submissions.

As previously noted, it is reported that currently Alder Hey Hospital in Liverpool provide some of the fetal service at St Marys Hospital that is part of the MRI/Central Manchester Hospitals campus. As reported in 2016, it is unclear whether or not there is a database to collect the fetal data and exactly who would be inputting the information. The number of foetuses seen, diagnosed with a possible congenital heart defect and referred are included in the NHSE quarterly dashboards required by Commissioners.

**Recommendations for MRI (unchanged from 2013-16)**

1. It is recommended that Standard Operating Protocols are devised for the congenital data collection, to include detailed guidance on and exactly **who** is responsible for and in what timeframe;
2. Ensuring consent for external validation of hospital notes is obtained
3. Input of the data for each procedure and at which point of the service delivery for:
   * 1. each therapeutic procedure, any therapeutic implantable device and
     2. diagnostic or therapeutic cardiac catheterisation
4. Devising a method of indicating or identifying operations for congenital heart disease in the operating theatre log books to aid easy recognition any cases missed from the data submission.
5. 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 in both surgery and cardiology disciplines
6. Leading the local review (and how frequently and in which forum for both disciplines)
7. Making timely submissions (monthly is recommended) and
8. Timely reverse validation at MRI against an acknowledged ‘gold standard’ record of activity and procedures performed.
9. Reviewing/Updating the SOP at timely intervals
10. As has been recommended on all previous visits, urgent consideration should be given to the use of a more formal theatre style log book in the cath lab would aid both internal and external validation.
11. To consider the inclusion of the NHS Number on the patient identity label.
12. In liaison with the person responsible for staff training and development in the Trust, regular training must be provided not only for the NCHDA Data Manager, but for all staff in the Department who may be involved with data input. This should include regular Quality Assurance and Governance training and visits to other centres who are involved in NCHDA data collection and submission.