**The National Congenital Heart Disease Audit**

**Data Quality Audit for**

 **CONGENITAL HEART DISEASE PROCEDURES**

 **The Leeds Teaching Hospitals NHS Trust**

 **16 November 2017**

*performed by Lin Denne and Dr F Bu’Lock,*

**Summary**

The data return to the NCHDA made by the Congenital Cardiac Department of the Leeds Teaching Hospitals NHS Trust (LGI) and analysed 4 weeks prior to this visit, indicated that some 1167 procedures had been undertaken during the data collection year of 2016/2017.

This validation visit has been fully funded by the Leeds Teaching Hospitals NHS Trust. This visit was supported remotely by the NCHDA clinical audit nurse via Skype and on site in person by Dr F Bu’Lock, Consultant Congenital Cardiologist from Leicester.

Since June 2013 a dedicated 1.0WTE congenital Database Manager (DBM) has been in post. There is a nominated clinician with responsibility for this data and another who also had access to the NCHDA database. There is a further 1.0WTE administrative role that supports this registry.

As previously reported, the Congenital Cardiac Department at LGI uses a bespoke database (OSCAR 4D) and this is available at secretaries’ and clinicians’ desks within the Department and in the operating theatre where most congenital surgery is performed. There is an interface between OSCAR and the Trust PAS.

**Actions undertaken or changes to processes since the September 2016 validation visit.**

LGI Report the following actions:

1. There has been a greater engagement of the clinical staff to become more responsible for their own data.
2. Monthly validation meetings are now in place with the clinical team and the DM to ensure that all data is checked and signed off. This not only improves the quality of the data but also allows each individual to take ownership of their data.
3. A new upgraded database has been purchased and installed.
4. The appropriate individuals now have access to Lotus notes.
5. Perfusion records are routinely used as a reference point for appropriate data.
6. Training is available and discussion of data on a monthly basis is now built into governance proceedings.

**Consent for External Validation of Notes.**

Patients have been required to give their consent to allow external validation of their hospital notes since 1 April 2007. This process was established in 2000 at Leeds Teaching Hospitals NHS Trust using a separate paper form. As previously reported, immediately prior to the November 2013 validation, LGI designed and produced their own A5 size sticky label to indicate on the inside of the patients notes whether or not consent for external validation has been gathered.

LGI are moving towards an electronic patient record (ePR) and methods of capturing this piece of information electronically is currently being discussed and reviewed.

**Data Quality Indicator Score**

The overall DQI for the Trust (with the previous years in parentheses) is calculated to be **98%** (97.75, 9796.75,) with domain scores Demographics .99 (.99 1.0 1.0,) Pre Procedure .95 (.98, .92 .93) Procedure .995 (.96 .99 .97) and Outcome .98 (.98 .97 .97 .95).

There were just 19 errors in 1036 variables.

This DQI was based on the records of 20 patients who underwent 27 procedures (14 catheters and 13 operations).

**Individual DQI for Surgery and for Catheters**

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.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Data Year Validated** | **Surgery DQI** | **Catheter DQI** |
| **2009** | 07/08 | 88.25% | 96.25% |
| **2010(i)** | 08/09 | 84.0% | 96.0% |
| **2010(ii)** | 09/10 | 88% | 98.75% |
| **2012** | 10/11 | 95% | 96.25% |
| **2013** | 11/12 | 92% | 95.75% |
| **2013(ii)** | 12/13 | 94.25% | 96% |
| **2014** | 13/14 | 95.25% | 99% |
| **2015** | 14/15 | 97.25% | 96% |
| **2016** | 15/16 | 98.5% | 97.25% |
| **2017** | 16/17 | 99% | 97.5% |

The NCHDA pre visit Questionnaire was completed and returned prior to the validation visit. This 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 this validation visit, the NCHDA Data Return from the Paediatric Cardiac Department of the Leeds Teaching Hospitals NHS Trust indicated that 1167 (410 surgery, 482 catheters, 275 others, 14 deaths) procedures had been undertaken during the data collection year of 2016/2017 of which 20 cases were selected for review.

The Congenital Database Manager from LGI in collaboration with the nominated clinician for responsibility of these data and others completed the previsit questionnaire. Information on actions undertaken or changes to the local processes are mentioned above.

As previously reported and as stated above, the Department uses its own database to collect data (the Orion Software for Cardiology – OSCAR 4D). This database is connected to the hospital PAS. Access to this database is available throughout the department including the catheter labs and operating theatre where most congenital cardiac surgical procedures are undertaken. The consultants and their secretaries have access at their desks and input data. From the data that are input, a discharge summary is generated at time of discharge.

There is a detailed process (Standard Operating Protocol) for auditing data internally and reverse validating it once submitted to the NCHDA.

The Validation Team are extremely grateful to the Database Manager and the clinical team who organised and itemised many of the items in the case notes that the Review Team would need look at. This has been meticulously prepared.

A sample of 20 records with a reserve list of a further 10 was supplied prior to this validation.

On the day 18 records were made available from the sample and 2 records were used from the reserve list. All 20 records either had a signed consent form, consent label or a verbal consent noted for external validation of the related hospital notes. The Reviewers are also extremely grateful to the Chief Medical Officer for Leeds Teaching Hospitals NHS Foundation Trust for giving permission to view any hospital notes where it was unclear if there was informed patient/parent/guardian consent and it had not been possible (or inappropriate in the case of a deceased patient) to contact the family.

The accuracy of the NCHDA data return was checked against each set of notes. This was then recorded to enable the Data Quality Indicator (DQI) to be scored.

**Review of notes**

As described above, each set of notes was meticulously prepared with sticky post-it type labels identifying many of the pages the Validation Team needed to review. However many of the case notes see were very disorganised and not chronological.

1. The pink operation note, when seen was very helpful in establishing exactly what procedure had been performed.
2. Also as previously documented, perfusion sheets were seen in the case notes of by- pass patients.
3. Documentation of exactly when (date and time) a patient was extubated was at times difficult to find.
4. In some case notes there appeared to be a discrepancy between the electronic record and the paper records as to the exact date a patient was discharged from hospital.

**Review of the Log Books**

**Cardiac Operating Theatres**

The bespoke bound operating theatre ledgers for 3 theatres were made available.    Each entry of the log books seen is hand written.  As previously noted it is not always clear whether or not a procedure is for congenital heart disease. Some entries were blank where the name of the procedure performed should be given.

1. 12 submitted surgical records appear to have errors in them
2. 0  records were identified from the log book that may have been missed from the congenital submission

**Cardiac Catheter Lab Log Book Review**

There are 6 cath labs at this Centre.  The Validation Team were informed that most congenital procedures are performed in Lab 1, 2 and Lab 5.  The individual log books for each of these two cath labs were reviewed.   These books are A4 lined and ruled books.  As previously reported, it was quite difficult to identify whether or not a procedure is for congenital heart disease.  The findings are;

1. 11 submitted catheter records appear to have errors in them
2. 2 procedures were identified in the cath lab log books which may have been missed from the data submission.

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

Commencing with the validation of the 2013/14 data in 2014, 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 consent to validate these hospital data are the same as for the congenital procedures. Where there is no evidence that consent has been given the Medical Director is asked to give permission for the case note examination. The Validation Team are grateful to Dr Yvette Oade (Chief Medical Officer for LGI) for facilitating this.

14 patients who had had procedures during the 2016/17 data collection year were noted to have died.   The procedural and outcome documentation was made available to the Reviewers.

* 2 records appeared to have incomplete diagnoses coding
* 1 record appears to have an incorrect previous procedure submitted to the NCHDA
* 2 records appear to have an incorrect weight submitted
* 10 records appear to have incomplete comorbidities recorded in the data submitted to the NCHDA

**Case note Audit 2016/17 Data.**

20 patients underwent 27 procedures (15 caths, 13 operations)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 11 | 9 |
| 2 | NHS Number | 20 | 20 |  | 11 | 9 |
| 3 | Surname | 20 | 20 |  | 11 | 9 |
| 4 | First Name | 20 | 20 |  | 11 | 9 |
| 5 | Sex | 20 | 20 |  | 11 | 9 |
| 6 | DOB | 20 | 20 |  | 11 | 9 |
| 7 | Ethnicity | 18 | 20 |  | 11 | 9 |
| 8 | Patient Status | 20 | 20 |  | 11 | 9 |
| 9 | Postcode | 19 | 20 | 1 incorrect | 10/11 | 9 |
| 10 | Pre Procedure Diagnosis | 27 | 27 |  | 14 | 13 |
| 11 | Previous Procedures | 43 | 45 | 2 absent | 30/32 | 13 |
| 12 | Patients Weight atOperation | 27 | 27 |  | 14 | 13 |
| 13  | Height | 27 | 27 |  | 12/14 | 13 |
| 14 | Ante Natal Diagnosis | 2 | 2 |  | 1 | 1 |
| 15 | Pre Proc Seizures | 27 | 27 |  | 14 | 13 |
| 16 | Pre Proc NYHA  | 3 | 3 |  | 3 | 3 |
| 17 | Pre Proc Smoker | 3 | 3 |  | 3 | 3 |
| 18 | Pre Proc Diabetes | 3 | 3 |  | 3 | 3 |
| 19 | Hx Pulmonary Dis | 3 | 3 |  | 3 | 3 |
| 20 | Pre Proc IHD | 3 | 3 |  | 3 | 3 |
| 21 | Comorbidity Present | 25 | 27 | 2 incorrect | 13/14 | 12/13 |
| 22 | Comorbid Conditions | 29 | 33 | 4 incorrect | 15/18 | 14/15 |
| 23 | Pre Proc Systemic Ventricular EF | 25 | 27 | 2 incorrect | 14 | 11/13 |
| 24 | Pre Proc Sub Pul Ventricular EF  | 25 | 27 | 2 incorrect | 13/14 | 12/13 |
| 25 | Pre-proc valve/septal defect/ vessel size | 0 | 0 |  | - | - |
| 26 | Consultant | 27 | 27 |  | 14 | 13 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 27 | 27 |  | 14 | 13 |
| 28 | Time Start | 27 | 27 |  | 14 | 13 |
| 29 | Proc Urgency | 27 | 27 |  | 14 | 13 |
| 30 | Unplanned Proc | 27 | 27 |  | 14 | 13 |
| 31 | Single Operator | 2 | 3 | 1 absent | 2/3 | - |
| 32 | Operator 1 | 27 | 27 |  | 14 | 13 |
| 33 | Operator 1 Grade | 27 | 27 |  | 14 | 13 |
| 34 | Operator 2 | 24 | 24 |  | 11 | 13 |
| 35 | Operator 2 Grade | 24 | 24 |  | 11 | 13 |
| 36 | Procedure Type | 27 | 27 |  | 14 | 13 |
| 37 | Sternotomy Sequence | 11 | 11 |  | - | 11 |
| 38 | Operation Performed | 27 | 27 |  | 14 | 13 |
| 39 | Sizing balloon used for septal defect  | 3 | 3 |  | 3 | - |
| 40 | No of stents or coils | 3 | 3 |  | 3 | - |
| 41 | Device Manufacturer | 14 | 14 |  | 8 | 6 |
| 42 | Device Model | 14 | 14 |  | 8 | 6 |
| 43 | Device Ser No | 23 | 24 | 1 incorrect | 17/18 | 6 |
| 44 | Device Size | 24 | 24 |  | 18 | 6 |
| 45 | Total Bypass Time | 11 | 11 |  | - | 11 |
| 46 | XClamp Time, | 9 | 9 |  | - | 9 |
| 47 | Total Arrest | 2 | 2 |  | - | 2 |
| 48 | Cath Proc Time, | 14 | 14 |  | 14 | - |
| 49 | Cath Fluro Time, | 14 | 14 |  | 14 | - |
| 50 | Cath Fluro Dose, | 14 | 14 |  | 14 | - |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation  | 13 | 13 |  | - | 13 |
| 52 | Post Procedure Seizures  | 27 | 27 |  | 14 | 13 |
| 54 | Post Proc Complications | 2 | 3 | 1 incorrect | 0/1 | 2 |
| 55 | Date of Discharge | 26 | 27 | 1 incorrect | 14 | 12/13 |
| 56 | Date of Death | 1 | 1 |  | - | 1 |
| 57 | Status at Discharge | 27 | 27 |  | 14 | 13 |
| 58 | Discharge Destination | 27 | 27 |  | 14 | 13 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 98% Cardiology DQI = 97.5% Surgery DQI = 99%

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

|  |  |
| --- | --- |
| **DOMAIN** | **DOMAIN****Score** |
| **Demographics**Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status, | **Overall** .99 |
| **Card**.99 | **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 .95** |
| **Card**.94 | **Surg**.97 |
| **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** .995 |
| **Card**.99 | **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** .98 |
| **Card**.98 | **Surg**.985 |

**The Trust DQI = 98%** (97.75, 97, 96,**)**

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 Score** | **2014** | **2015** | **2016** | **2017** |
| **Demographics** | 1.0 | 1.0 | .99 | .99 |
| **Pre Procedure** | .93 | .92 | .98 | .95 |
| **Procedure** | .97 | .99 | .96 | .995 |
| **Outcome** | .97 | .97 | .98 | .98 |

**Conclusions**

On the whole the submitted NCHDA data were accurate, well documented, good quality and were appropriately recorded in the Theatre and Congenital Cath lab log books that were seen.

There has been a further 0.25% increase in the DQI to 97.75% which is another excellent achievement. In total there were just 19 errors or omissions in 1036 data variables. This demonstrates a strong commitment to good quality verified clinical data. There appears to be a very robust culture of clinical audit embedded within the Trust and the DBM has invested may hours overtime to achieve timely data submissions of a high quality. There have also again been some extreme technical challenges with the NCHDA database itself that has further impeded timely data submission during the year 2016/17 that have affected almost every congenital centre.

Again, the Validation Team are particularly grateful to the Congenital Data Manager for meticulously detailing the documents needed at this review. The Reviewers would also like to thank the Clinical Lead for Congenital Cardiology and other clinicians for making time to spend with the audit team throughout the day.

As previously reported, handwritten entries into log books will always be challenging to decipher and the Reviewers are aware that the Galaxy Theatre Information System is available in this Centre. This has been successfully used to replace the handwritten log books in at least one other large congenital cardiac centre as it is possible to record procedures using the OPCS codes that can be cross mapped to the Association of European Paediatric and Congenital Heart Disease (AEPC) coding that the NCHDA uses.

**Deaths**

As reported 14 patients who had had procedures during  the 2016/17 data collection year were noted to have died.

* A total of 14 discrepancies were identified to be reviewed and amended as necessary.
* All dates of death were found to be correct.

**Recommendations**

1. As previously, it is recommended that the local Standard Operating Protocols (SOPs) already devised for the congenital data collection, continue to be reviewed at regular intervals to ensure their fitness for the purpose they are required to address.
2. Also as previously recommended, it is suggested that greater attention to detail is used when recording procedures performed on patients with congenital heart disease in the operating theatre and cath lab log books. Until a fully electronic system is available the use of a self inking stamp with the word Congenital on it may help identify cases.
3. As previously recommended, consideration could be given to developing the GALAXY information system used in the operating theatres to include the accurate recording of the exactly which congenital operation was performed on each patient.
4. To keep a log of all procedures such as septostomies that occur outside the cardiac catheter laboratory.
5. In conjunction with the person responsible for training, it is suggested that regular Quality Assurance and Governance training should be available to the DBM. Visits to other centres who are involved in NCHDA data collection and submission are encouraged at least once, preferably twice annually.
6. Regular training updates should be provided for all staff who may be involved with data collection and input