**The National Congenital Heart Disease Audit**

**Procedures for**

**CONGENITAL HEART DISEASE**

**Data Quality Audit**

**For the year 2016/17**

**Evelina London Children’s and St Thomas’ Hospitals**

**Guys & St Thomas NHS Foundation Trust (GSTT)**

**7 November 2017**

*performed by Lin Denne, and Mr A Hoschtitzky*

**Summary and Overview**

The Congenital NICOR data return, prior to this validation visit, from the combined Congenital Cardiac Department of Guy’s and St Thomas’ NHS Foundation Trust (GSTT) indicated that a total of 998 cases had been undertaken during the year 2016/17. These figures are broken down further below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Year** | **Total** | **Surgery** | **Catheters** | **Others** |
| 2011/12 | 777 | 442 | 319 | 16 |
| 2012/13 | 830 | 488 | 327 | 15 |
| 2013/14 | 879 | 504 | 348 | 27 |
| 2014/15 | 980 | 491 | 422 | 67 |
| 2015/16 | 976 | 497 | 357 | 122 |
| 2016/17 | 998 | 494 | 390 | 114 |

For the purposes of the table above diagnostic procedures are grouped with Others. 5 missed procedures has been identified prior to this validation and these are included in the numbers above.

This validation visit has been fully funded by the Guys and St Thomas’ NHS Foundation Trust. This visit was supported remotely by the NCHDA clinical audit nurse via a teleconference facility and on site in person by Mr Andreas Hoschtitzky, Consultant Cardiac Surgeon from London.

The Trust has used HeartSuite for congenital cardiac data collection since January 2004. There is real time data entry by most clinicians and there is access to HeartSuite in all clinical areas. The Trust is moving towards a paper light mode of patient record increasingly using an electronic hospital note (e-Noting).

**Additional Information and Actions Taken since the previous Validation Visit in 2016.**

The NCHDA Review Team are also pleased to acknowledge the following actions implemented since the last (2016) visit.

1. Since last year Clinical Nurse Specialists for the Congenital Audit have established meetings with the surgeons to review their data on a monthly basis.
2. The CNS’s have produced new training guides for Heartsuite
3. The surgical team are responsible for recording post op complications during admission

There are 1.8 WTEs Clinical Nurse Specialists in Audit and Research Data Management (CNSs) who facilitate the congenital audit process, and an ACHD data manager who collaborates closely with the CNSs. As reported previously it is very clear that GSTT consider the matter of collecting good quality, accurate and validated information about patient procedural activity to be of the highest importance and this has become embedded within the Trust culture. The data, once validated locally, are submitted electronically to National Congenital Heart Disease Audit (NCHDA) managed by NICOR.

As stated at the 2016 validation visit, log books for cardiac operating theatres and catheter laboratories are now electronic (Galaxy/Labyrinth). Combined printouts from both centres are reviewed and a single report on that validation is presented.

**Consent for External Validation of Notes.**

Patient consent has been required for external validation of all case notes since 1 April 2007.

During 2010 a further revision was made to the consent process that uses a sticky label that is appended to the patients notes. This is approximately A5 in size, and clearly visible on the inside cover of the hospital notes. This process has remained unchanged and it was hoped that this could be assimilated into the new eNoting during 2015/16. However, due to technical challenges with the process it has been delayed and the Trust will be continuing with the sticky label in the immediate short term future. This challenge continues at the 2017 validation visit.

On the St Thomas’ Hospital site where the ACHD patients are cared for, a prospective collection of this consent was also started during 2010. Consent for external validation was recorded in the hospital notes in exactly the same way as for Evelina London.

**The overall DQI for the combined data and separate DQI for Surgery and for Catheters at GSTT**

The DQI for the Trust is calculated to be (with the previous visit scores are in parentheses), **96%** (99.25,97.5, 97**,)** The domain scores are as follows: Demographics 1.0 (1.0 .99 1.0), Pre Procedure .94 (.98 .95 .91), Procedure .97 (.99 .97 .99), and Outcome .93 (1.0.98 .98).

This is based on 20 patients who underwent 18 catheter procedures and 12 operations during Apr-March 2016/17. 11 of these procedures were in patients with adult congenital heart disease. 1130 variables were checked and there were 44 queries or omissions identified. 19 queries were identified in the ACHD records.

On further review of the overall, when the cases were split into their surgery and catheter groups was;

|  |  |  |  |
| --- | --- | --- | --- |
| **Year of visit** | **Data Year**  **Validated** | **Surgery** | **Catheters** |
| **2011** | 09/10 | 97.5% | 99.25% |
| **2011** | 10/11 | 96.75% | 98.5% |
| **2012** | 11/12 | 97% | 98.75% |
| **2013** | 12/13 | 97.5% | 96.% |
| **2014** | 13/14 | 98% | 94.25% |
| **2015** | 14/15 | 98.5% | 98% |
| **2016** | 15/16 | 99.25% | 99.5% |
| **2017** | 16/17 | 94.75% | 97% |

Review of the combined Cath Lab and Theatre Log Books at GSTT on the day revealed that 0 (nil) records were missed from the data submission**.** .

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.

**Technical Issues with Data Submission and Amendment**

There have been considerable numbers of technical issues both with HeartSuite software and the NCHDA Lotus Notes database during the year 2016 - 17. The Lotus notes database does not allow for direct editing of records as not all fields are visible this has led to the team to resubmit records. The final NCHDA web enabled dataset has not yet been released and will leave very little time to make adjustments. Centres (including GUY) have not been able to submit any congenital data for the year April 2017 – March 2018 yet. There have been ongoing problems with editing submitted data.

**Introduction**

The NCHDA data return, prior to this validation visit, from the combined Congenital Cardiac Department of Guy’s and St Thomas’ NHS Foundation Trust indicated that a total of 998 cases had been undertaken during the year 2016/17. 20 cases were randomly selected for the case note review.

20 sets of notes were requested and a reserve list of 10 other cases was supplied approximately one month prior to this validation visit. On the day of the visit, 5 sets of notes from the sample were either irretrievable or there was no consent for external validation from the patient/parent, therefore 5 sets were used from the Reserve list.

The accuracy of the NCHDA data return was then checked against each set of notes. The accuracy was recorded on a database to enable the (DQI) to be scored for each year being validated.

The hospital case notes had been meticulously prepared with sticky notes identifying almost every one of the documents that needed to be viewed. There was also access in the e-Noting electronic patient records for documents that are no longer in paper format.

**Review of the patient notes**

1. As reported previously, the paper notes on the whole were tidy, but were often not filed in chronological order.
2. The anaesthetic sheets were easy to find due to their colour (red edged), as at the previous visits.
3. As previously reported printed formal cath procedure notes were seen during the audit.
4. At previous validations, the A5 sticky label was used by the paediatric cardiologists to record seizure status and fluoroscopy data. This has now been incorporated in the discharge summary sheet.
5. Perfusion records were seen in all of the notes of surgical patients where appropriate.
6. It was easy to find details of date and time of extubation at this Validation visit.
7. It was noted that the device manufacturers name was not always present on the sticky label of implanted devices such as stents and coils. These labels are produced by the manufacturers themselves.

**Review of the Theatre Activity Log**

All cardiac surgery is performed in St Thomas’s Hospital. There are 4 cardiac operating theatres plus a hybrid operating room. Bound paper theatre log books are no longer kept in the operating theatres. As reported in 2013-16, the Trust, in line with NHS & DH guidance is moving to E-records and has invested in NHS approved systems to record and log theatre activity - Galaxy. It is an approved audit tool for theatre activity and reflects the planned procedure using OPCS4.7 coding which in majority of cases will not cross reference accurately to EPCC coding used for the NCHDA national congenital cardiac audit. This is not something which is within the congenital cardiac service’s control. Surgical notes (handwritten and typed) act as the gold standard of actual surgical procedure performed

The external visiting clinician was offered a printout from the electronic theatre log ‘Galaxy’ that is now used.

The review revealed;

1. 0 surgery procedures were identified that may have been missed from the data submission
2. 1 surgery record appears to have a duplicate entry
3. 1 record appears to be for acquired heart disease and this is not required for NCHDA
4. 12 submitted records appear to have an error in them

**Review of the Cath Lab Activity Logs at GSTT**

All cath lab activity at Evelina London is recorded in a digital information system – Galaxy or Labyrinth. Catheter lab activity in St Thomas’ is recorded on Labyrinth. The Audit Team were offered printouts from both electronic logs.

There are 5 cath labs at the St Thomas’ site and 2 at Evelina London. One of these rooms is a dedicated MRI cath lab. The Reviewers are grateful to the ACHD Analyst and ACHD Consultant who assisted with this*.*

1. 1 submitted catheter record appears to have a duplicate
2. 1 submitted catheter record appears to be for non-congenital heart disease and if so, should be deleted
3. 3 submitted records appear to have errors in them.
4. It was again noted that some catheter records are not recorded in Galaxy/Labyrinth, almost all of these were for ‘out of hours’ procedures or performed in the clinical areas (PICU/NICU).
5. 3 submitted records in the category ‘Other’ appear to be for catheter lab procedures

The Trust is currently reviewing the cases identified above and will make new submissions or amend any errors where appropriate.

Septostomy cases performed outside of the catheter lab are recorded in a folder that is kept by the CNSs and this was seen on the day. The reviewers are pleased to note that these cases are being submitted to Congenital NCHDA.

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

This commenced with the validation of the 2013/14 data. The NCHDA 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.

20 congenital patients were noted on the data harvested for this visit to have died following a procedure. 1 further ACHD death has been submitted after the initial harvest of the data. On the day 20 sets of data were made available.

It is strongly recommended that if information regarding a date of death for a pre-existing congenital patient on the NCHDA database post discharge is, or becomes available this should be submitted to that individual’s record in the NCHDA registry. However, this piece of information, once submitted to the NCHDA database is not always easily visible when the data are exported back to the centre.

Of the data reviewed for 20 patients the findings are;-

1. All dates of death were correct
2. 1 record appears to have a duplicate entry
3. 4 previous procedures appear to be absent
4. 3 comorbidities may be absent
5. 1 procedure performed code may be incorrect
6. 1 date of hospital discharge appears to be incorrect

Congenital NICOR 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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  | | | | | **C** | **S** |
| 1 | Hospital Number | | 20 | 20 |  | 11 | 9 |
| 2 | NHS Number | | 18 | 18 |  | 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 | | 20 | 20 |  | 11 | 9 |
| 8 | Patient Status | | 20 | 20 |  | 11 | 9 |
| 9 | Postcode | | 20 | 20 |  | 11 | 9 |
| 10 | Pre Procedure  Diagnosis | | 30 | 30 |  | 18 | 12 |
| 11 | Previous Procedures | | 50 | 59 | 9 absent | 35/41 | 12/18 |
| 12 | Patients Weight at  Operation | | 28 | 30 | 2 absent | 17/18 | 11/12 |
| 13 | Height | | 30 | 30 |  | 18 | 12 |
| 14 | Ante Natal Diagnosis | | 2 | 2 |  | 1 | 1 |
| 15 | Pre Proc Seizures | | 29 | 30 | 1 incorrect | 17/18 | 12 |
| 16 | Pre Proc NYHA | | 8 | 11 | 3 incorrect | 9 | 2 |
| 17 | Pre Proc Smoker | | 9 | 11 | 2 unable to validate | 9 | 2 |
| 18 | Pre Proc Diabetes | | 11 | 11 |  | 9 | 2 |
| 19 | Hx Pulmonary Dis | | 11 | 11 |  | 9 | 2 |
| 20 | Pre Proc IHD | | 10 | 11 | 1 incorrect | 9 | 2 |
| 21 | Comorbidity Present | | 30 | 30 |  | 18 | 12 |
| 22 | Comorbid Conditions | | 37 | 37 |  | 18 | 19 |
| 23 | Pre Proc Systemic Ventricular EF | | 29 | 30 | 1 incorrect | 17/18 | 12 |
| 24 | Pre Proc Sub Pul Ventricular EF | | 30 | 30 |  | 18 | 12 |
| 25 | Pre-proc valve/septal defect/ vessel size | | 8 | 10 | 2 unable to validate | 8/10 | -18 |
| 12 | Consultant | | 30 | 30 |  | 18 | 12 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 30 | 30 |  | 18 | 12 |
| 28 | Time Start | 30 | 30 |  | 18 | 12 |
| 29 | Proc Urgency | 30 | 30 |  | 18 | 12 |
| 30 | Unplanned Proc | 30 | 30 |  | 18 | 12 |
| 31 | Single Operator | 30 | 30 |  | 18 | 12 |
| 32 | Operator 1 | 30 | 30 |  | 18 | 12 |
| 33 | Operator 1 Grade | 30 | 30 |  | 18 | 12 |
| 34 | Operator 2 | 30 | 30 |  | 18 | 12 |
| 35 | Operator 2 Grade | 29 | 30 | 1 absent | 17/18 | 12 |
| 36 | Procedure Type | 29 | 30 | 1 absent | 17/18 | 12 |
| 37 | Sternotomy Sequence | 10 | 10 |  | - | 10 |
| 38 | Operation Performed | 30 | 30 |  | 18 | 12 |
| 39 | Sizing balloon used for septal defect | 1 | 1 |  | 1 | - |
| 40 | No of stents or coils | 4 | 4 |  | 4 | - |
| 41 | Device Manufacturer | 10 | 11 | 1 absent | 9 | ½ |
| 42 | Device Model | 11 | 12 | 1 absent | 9 | 1/3 |
| 43 | Device Ser No | 11 | 12 | 1 absent | 9 | 1/3 |
| 44 | Device Size | 8 | 9 | 1 absent | 7 | ½ |
| 45 | Total Bypass Time | 9 | 10 | 1 incorrect | - | 9/10 |
| 46 | XClamp Time, | 9 | 11 | 2 incorrect | - | 9/11 |
| 47 | Total Arrest | 2 | 2 |  | - | 2 |
| 48 | Cath Proc Time, | 18 | 18 |  | 18 | - |
| 49 | Cath Fluro Time, | 12 | 12 |  | 12 | - |
| 50 | Cath Fluro Dose, | 12 | 12 |  | 12 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation | 7 | 10 | 3 incorrect | - | 7/10 |
| 52 | Post Procedure Seizures | 28 | 30 | 2 absent | 18 | 10/12 |
| 54 | Post Proc Complications | 9 | 9 |  | 7 | 2 |
| 55 | Date of Discharge | 27 | 30 | 3 incorrect | 15/18 | 12 |
| 56 | Date of Death | 1 | 1 |  | 1 | - |
| 57 | Status at Discharge | 30 | 30 |  | 18 | 12 |
| 58 | Discharge Destination | 30 | 30 |  | 18 | 12 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 96% Cardiology DQI = 97% Surgery DQI = 94.75%

. Total Procedures = 30 Catheter Procs = 18 Surgery Procs = 12

|  |  |  |
| --- | --- | --- |
| **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 .94** | |
| **Card**  .94 | **Surg**  .94 |
| **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**  .99 | **Surg**  .95 |
| **Outcome**  Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination.  **Post Procedure Complications.** | **Overall** .93 | |
| **Card**  .95 | **Surg**  .90 |

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**. | **2017**  **16/17**  **data** | **2016**  **15/16**  **data** | **2015**  **14/15**  **data** | **2014**  **13/14**  **data** | **2013**  **12/13**  **data** |
| **Demographics** | 1.0 | 1.0 | .99 | 1.0 | 1.0 |
| **Pre Procedure** | .94 | .98 | .95 | .91 | .91 |
| **Procedure** | .97 | .99 | .97 | .99 | .98 |
| **Outcome** | .93 | 1.0 | .99 | .98 | .99 |

**Conclusions**

On the whole the NCHDA data for congenital procedures was accurate, well-documented, good quality and was appropriately recorded in the Theatre and Cath Lab Management systems (Galaxy and Labyrinth) at GSTT. Although the Data Quality Indicator Score has dropped slightly at this visit to 96%, this still 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. The Validation Team would like again, to commend the efforts of both of the CNSs and the ACHD Team in maintaining this at time when there have been considerable technical challenges.

The Trust has developed and regularly reviews SOPs to inform the congenital data collection which further underpins this registry.

As previously reported, the standard of data entry in the Galaxy Theatre Management System continues to improve on previous years but is still variable on occasions with the operation performed not reconciling with the actual procedure booked or vice versa. Where there are ‘out of hours’ cath lab or operating theatre procedures that do not get added to the Galaxy/Labyrinth information systems, there is an established protocol to capture these promptly.

The Trust again reported to the validation team (as in 2015-16 site validations) that they have raised a considerable number of fault calls with the NCHDA Helpdesk, some of which are still to be resolved satisfactorily.

**Recommendations**

1. It is recommended that any Standard Operating Protocols (SOP) that support the congenital data collection, should be regularly reviewed to ensure that details are current and clear as to **exactly who** is responsible for;
   1. Ensuring consent for external validation of hospital notes is obtained prospectively from all patients with congenital heart disease
   2. Input of the data for each procedure and at which point of the service delivery
   3. 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
   4. Reverse validation of the data submitted to NCHDA against locally held ‘gold standard’ clinical information systems in conjunction with clinician colleagues.
   5. Leading the local review (and how frequently and in which forum for both disciplines)
   6. Making timely submissions (monthly is recommended)
   7. Ensuring all manufacturers names, model and serial numbers are submitted for all implantable devices and valves.
   8. It is recommended that all staff connected with NCHDA audit should observe at least one other site validation per year.
   9. Reviewing/Updating the SOP at timely intervals
2. To encourage users to only place 1 procedure or 1 diagnostic code in each field when inputting data until the software supplier has finalised a resolution.
3. It is recommended that Senior Trainees should be encouraged to volunteer to assist with validation visits to other centres.