**The National Congenital Heart Disease Audit**

**Procedures for**

**CONGENITAL HEART DISEASE**

**Data Quality Audit**

**For the year 2017/18**

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

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

**17 July 2018**

*performed by Lin Denne, and Dr K Gopaul*

**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 1006 cases had been undertaken during the year 2017/18. 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 |
| 2017/18 | 1006 | 620 | 290 | 96 |

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 Dr K Gopaul, ST7 in Congenital Cardiology from Leeds.

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 2017.**

The NCHDA Review Team are also pleased to acknowledge the following actions implemented since the last (2017) 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 had been required for external validation of all case notes since 1 April 2007.

In May 2018 the General Data Protection Regulation became law.

At GSTT Foundation Trust there is now displayed and available in all places of patient activity, a leaflet that describes how the Organisation use and share patients personal information to deliver and improve healthcare. There is information in the leaflet that describes what information is kept, how safe it is and whom it may be shared with and whether it is anonymised or not. There is also information for patients who may wish to object to their data being shared and how to do this. Also in the document there is some information on patients rights to access their medical data.

**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), **99%** (96, 99.25,97.5**)** The domain scores are as follows: Demographics 1.0 (1.0, 1.0 .99), Pre Procedure .96 (.94, .98 .95), Procedure 1.0 (.97, .99 .97), and Outcome 1.0 (.93, 1.0.98).

This is based on 20 patients who underwent 9 catheter procedures and 12 operations during Apr-March 2017/18. 5 of these procedures were in patients with adult congenital heart disease. 823 variables were checked and there were 9 queries or omissions identified.

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% |
| **2018** | 17/18 | 98.75% | 99.5% |

Review of the combined Cath Lab and Theatre Log Books at GSTT on the day revealed that 1 record may have been 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 years 2016 - 18. The final NCHDA web enabled dataset became available in early March 2018 left centres with a very short time to make adjustments. There have also been ongoing problems with editing submitted data. At the time of this validation visit this was still outstanding and there has been on going discussion between the CNS data managers at GSTT with the NICOR HelpDesk to find a resolution to the problems. It should be noted that several NCHDA centres who also use HeartSuite had experienced similar difficulties also.

**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 1006 cases had been undertaken during the year 2017/18. 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, 3 sets of notes from the sample were either irretrievable or there was no consent for external validation from the patient/parent, therefore 3 sets were used from the Reserve list.

GSTT is now ‘paper-lite’. It was reported at this visit that there are only two documents that remain in paper form. The perfusion record and the preoperative theatre check list. These two documents will become electronic within the next 12 months. The reviewers are very grateful to the two CNS’s for Audit and Data Management for gathering together the ePR documents and reports and creating an individualised electronic NCHDA validation file for each of the patients whose procedures were being validated.

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.

**Review of the patient notes** .

1. Perfusion records were seen in all of the notes of surgical patients where appropriate.

**Review of the Theatre and Cath Lab Activity Logs**

As previously reported, all cardiac surgery is performed in St Thomas’s Hospital. There are 4 cardiac operating theatres plus a hybrid operating room. 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. 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.

Bound paper theatre log books are no longer kept in the operating theatres. As reported in 2013-17, 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 surgery procedure was identified that may have been missed from the data submission
* 1 submitted catheter record appears to have a duplicate
* 0 catheter procedures  were identified in the cath lab log book which may have been missed from the data submission
* 2 submitted catheter records were identified that may have errors in them
* It was again noted that some procedure records are not recorded   in Galaxy, almost all of these were for ‘out of hours’ 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. 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 confirmed as correct
2. 1 element of a diagnosis string may be incorrect
3. 1 procedure performed code may be incorrect  
   The 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

**Casenote Audit**

Case note audit based on 20 patients who underwent 12 operations and 9 catheter procedures

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  | | | | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 9 | 11 |
| 2 | NHS Number | 20 | 20 |  | 9 | 11 |
| 3 | Surname | 20 | 20 |  | 9 | 11 |
| 4 | First Name | 20 | 20 |  | 9 | 11 |
| 5 | Sex | 20 | 20 |  | 9 | 11 |
| 6 | DOB | 20 | 20 |  | 9 | 11 |
| 7 | Ethnicity | 20 | 20 |  | 9 | 11 |
| 8 | Patient Status | 20 | 20 |  | 9 | 11 |
| 9 | Postcode | 18 | 18 |  | 9 | 9 |
| 10 | Pre Procedure  Diagnosis | 21 | 21 |  | 9 | 12 |
| 11 | Previous Procedures | 28 | 31 |  | 17/20 | 11 |
| 12 | Patients Weight at  Operation | 21 | 21 |  | 9 | 12 |
| 13 | Height | 21 | 21 | 2 incomplete | 9 | 12 |
| 14 | Ante Natal Diagnosis | 3 | 4 | 1 incorrect | 1 | 2/3 |
| 15 | Pre Proc Seizures | 19 | 21 | 3 absent | 9 | 12 |
| 16 | Pre Proc NYHA | 5 | 5 |  | 4 | 1 |
| 17 | Pre Proc Smoker | 4 | 5 | 1 incorrect | 4 | 0/1 |
| 18 | Pre Proc Diabetes | 5 | 5 |  | 4 | 1 |
| 19 | Hx Pulmonary Dis | 4 | 5 | 1 incorrect | ¾ | 1 |
| 20 | Pre Proc IHD | 5 | 5 |  | 4 | 1 |
| 21 | Comorbidity Present | 21 | 21 |  | 9 | 12 |
| 22 | Comorbid Conditions | 17 | 18 | 1 incorrect | 5 | 12/13 |
| 23 | Pre Proc Systemic Ventricular EF | 20 | 21 | 1 absent | 8/9 | 12 |
| 24 | Pre Proc Sub Pul Ventricular EF | 19 | 20 | 1 absent | 7/8 | 12 |
| 25 | Pre-proc valve/septal defect/ vessel size | 8 | 8 |  | 8 | - |
| 26 | Consultant | 21 | 21 |  | 9 | 12 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure + Time Start | 21 | 21 |  | 9 | 12 |
| 28 | Proc Urgency | 21 | 21 |  | 9 | 12 |
| 29 | Unplanned Proc | 21 | 21 |  | 9 | 12 |
| 30 | Single Operator | 21 | 21 |  | 9 | 12 |
| 31 | Operator 1 | 21 | 21 |  | 9 | 12 |
| 32 | Operator 1 Grade | 21 | 21 |  | 9 | 12 |
| 33 | Operator 2 | 21 | 21 |  | 9 | 12 |
| 34 | Operator 2 Grade | 21 | 21 |  | 9 | 12 |
| 35 | Procedure Type | 21 | 21 |  | 9 | 12 |
| 36 | Sternotomy Sequence | 8 | 8 |  | - | 8 |
| 37 | Operation Performed | 21 | 21 |  | 9 | 12 |
| 38 | Sizing balloon used for septal defect | 0 | 0 |  | 0 | - |
| 39 | No of stents or coils | 2 | 2 |  | 2 | - |
| 40 | Device Manufacturer | 8 | 8 |  | 7 | 1 |
| 41 | Device Model | 8 | 8 |  | 7 | 1 |
| 42 | Device Ser No | 8 | 8 |  | 7 | 1 |
| 43 | Device Size | 7 | 7 |  | 6 | 1 |
| 44 | Total Bypass Time | 8 | 8 |  | - | 8 |
| 45 | XClamp Time, | 8 | 8 |  | - | 8 |
| 46 | Total Arrest | 1 | 1 |  | - | 1 |
| 47 | Cath Proc Time, | 10 | 10 |  | 10 | - |
| 48 | Cath Fluro Time, | 8 | 8 |  | 8 | - |
| 49 | Cath Fluro Dose, | 8 | 8 |  | 8 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 50 | Duration of Post Op Intubation | 10 | 10 |  | - | 10 |
| 51 | Post Procedure Seizures | 21 | 21 |  | 9 | 12 |
| 52 | Post Proc Complications | 4 | 4 |  | 2 | 2 |
| 53 | Date of Discharge | 21 | 21 |  | 9 | 12 |
| 54 | Date of Death | 1 | 1 |  | - | 1 |
| 55 | Attribution of Death | 1 | 1 |  | - | 1 |
| 56 | Status at Discharge | 21 | 21 |  | 9 | 12 |
| 57 | Discharge Destination | 21 | 21 |  | 9 | 12 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 99% Cardiology DQI = 98.75% Surgery DQI = 99.5%

. Total Procedures = 21 Catheter Procs = 9 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 .96** | |
| **Card**  .95 | **Surg**  .98 |
| **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** 1.0 | |
| **Card**  1.0 | **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** 1.0 | |
| **Card**  1.0 | **Surg**  1.0 |

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**. | **2018**  **17/18**  **data** | **2017**  **16/17**  **data** | **2016**  **15/16**  **data** | **2015**  **14/15**  **data** | **2014**  **13/14**  **data** |
| **Demographics** | 1.0 | 1.0 | 1.0 | .99 | 1.0 |
| **Pre Procedure** | .97 | .94 | .98 | .95 | .91 |
| **Procedure** | 1.0 | .97 | .99 | .97 | .99 |
| **Outcome** | 1.0 | .93 | 1.0 | .99 | .98 |

**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. The Data Quality Indicator Score has increased to 99%, which is excellent and demonstrates a continuing 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 2015-17 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 continue to be regularly reviewed to ensure that details are current and clear as to **exactly who** is responsible for;
   1. Input of the data for each procedure and at which point of the service delivery
   2. 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
   3. Reverse validation of the data submitted to NCHDA against locally held ‘gold standard’ clinical information systems in conjunction with clinician colleagues.
   4. Leading the local review (and how frequently and in which forum for both disciplines)
   5. Making timely submissions (monthly is recommended)
   6. Ensuring, where possible all manufacturers names, model and serial numbers are submitted for all implantable devices and valves.
   7. It is recommended that all staff connected with NCHDA audit should observe at least one other site validation per year.
   8. Reviewing/Updating the SOP at timely intervals
2. It is recommended that Senior Trainees should be encouraged to volunteer to assist with validation visits to other centres.