**National Congenital Heart Disease Audit**

 **Procedures for CONGENITAL HEART DISEASE**

 **Data Quality Audit**

**The Great Ormond Street Hospital for Sick Children**

**NHS Foundation Trust**

**26June 2018**

**(to review data for year 2017-18)**

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**Summary**

Prior to the theatre and cath lab log book validation at this visits, the data submissions to NCHDA from the cardiac department of the Great Ormond Street Hospital for Sick Children (GOSH) indicated that a total of 1103 procedures (653 surgical 182 catheter, 268 others, 7 deaths) were undertaken during the data collection year Apr 2017 to March 2018. GOSH is one of the largest congenital centres that submit data to NCHDA.

This validation visit was funded by The Great Ormond Street Hospital for Children NHS Foundation Trust.

However, it became apparent during the log book check for full case ascertainment that there were possibly extra cases that had been thought to be successfully submitted but due to a number of technical difficulties appeared to be absent. It was not realised by the GOS team that these submissions had failed. These data had been submitted by a person who had since left the Trust and it was agreed that a return visit to validate the log books to check for case ascertainment would be undertaken by the NCHDA clinical data auditor and an external clinician later in 2018. The re-visit for the log book validation took place on 22 October 2018.

The Validation Team again wish to acknowledge the very thorough and meticulous preparation of each individual case note or file seen at this visit with each relevant document clearly identifiable.

Following the revisit a total of 1245 procedures (631 surgical 317 catheters, 297 others, 14 deaths) were validated to have been undertaken during the data collection year Apr 2017 to March 2018.

**GOSH Overview**

GOSH has used the TOMCAT data management system throughout its cardiac department since 2006. All clinical staff, surgeons, cardiologists, and technicians record clinical data in ‘real-time’ at the point of treatment. Following consultant clinician approval for each record, the data were submitted to NCHDA electronically.

As noted at the 2016 validation visit, the changes to the dataset meant that data collection was very challenging for GOSH to collect and submit. The TOMCAT system had not been upgraded to support the 5.13 version. This only happened in April 2017. The NCHDA dataset moved to v6 in April 2017. However this was not released until March 2018 and consequently many centres including GOS have a further, very challenging year.

Where possible, data has been collected from various other sources, but without a designated system for this, it has resulted and will continue to result, in missing/incomplete data for majority of the new data items. This may ultimately impact on the data quality.

In addition there are some data items in the new dataset which are not routinely recorded as part of GOSH clinical practice, and so going forward will continue to be missing from the data submissions. Great Ormond Street NHS Trust remain committed to collecting and submitting complete and accurate data for NCHDA.

The total number of Audit and Information WTE at GOSH is allocated to be 5.6WTE managed by a Principal Analyst and Information Lead. Each member of the audit team is trained to collect, validate and enter data for either cardiology or cardiac surgery as appropriate. Several members of the cardiac information team left their roles during early 2018 and a new team was being recruited at the time of the validation in June 2018.

**Electronic Patient Records**

GOSH are also in the process of moving from a paper based to electronic patient record. The Trust are currently ‘paper-lite’ with paper records being scanned to the ePR almost as soon as patients are discharged. It was reported at this validation visit that the next review in 2019 will be entirely based on an ePR.

**Consent for External Validation of Notes.**

Informed patient/parent/guardian consent for external validation of hospital notes has been required since 1 April 2007. This is a once only requirement until the patient reaches 16 years of age. Post 16 years, the patient may sign their own consent form. At GOSH, a separate consent form especially for cardiac patients used to be stapled into the generic form to enable this permission to be obtained. As in the 2017 validation visit, the Trusts solicitors advised that the generic consent form for operation was all that was required.

Where the consent for external validation of case notes was absent in the hospital records of deceased patients, the GOSH Solicitors gave permission on behalf of the Organisation to allow the validation of those notes to go ahead. The Validation Team acknowledge this with gratitude.

A total sample of 20 sets of notes are required and these are randomly selected from the data submission.

For this validation 19 case notes from the sample and 1 from the reserve list were used.

This DQI was based on the records of 20 patients who underwent 23 procedures (9 catheters and 14 operations).

**Data Quality Indicator**

The DQI for the Trust for this visit (previous year in parentheses) is calculated to be **95%** (99.5, 97, 99.25 99.5) with domain scores Demographics 1.0 (1.0 1.0 1.0) Pre Procedure .87 (.99, .94 .99), Procedure .98 (.99, .98 .99), and Outcome .95 (1.0, .95 1.0).

There were 35 errors or omissions in 747 variables audited

**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.

|  |  |  |  |
| --- | --- | --- | --- |
| **Year** | **Data Year****Validated** | **Surgery DQI** | **Catheter DQI** |
| **2009** | 07/08 | 95.25% | 95.5% |
| **2010** | 08/09 | 94.5% | 98.5% |
| **2011** | 09/10 | 94.5% | 99.5% |
| **2012** | 10/11 | 98.5% | 97% |
| **2013(i)** | 11/12 | 98% | 97.75% |
| **2013(ii)** | 12/13 | 99.25% | 98% |
| **2014** | 13/14 | 99.5% | 99.5% |
| **2015** | 14/15 | 99.5% | 99.75 |
| **2016** | 15/16 | 97.5% | 96.75% |
| **2017** | 16/17 | 99.75% | 98.75% |
| **2018** | 17/18 | 95.5% | 95% |

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.

**Actions Undertaken Following Previous Validation Visit in 2017**

It is reported that a new ePR (EPIC) is due to be launched early in 2019

**Introduction**

Prior to the validation visit, the NCHDA returns from the cardiac department of The Great Ormond Street Hospital for Sick Children indicate that 1103 procedures (653 surgical 182 catheter, 268 others, 7 deaths) were undertaken during the data collection year April 2017 to March 2018.

A total sample of 20 sets of notes are required and these are randomly selected from the submission for each year.

These 20 patients underwent 23 procedures (14 surgeries and 9 therapeutic catheter interventions).

The NCHDA auditor and one external ST7 in congenital cardiology undertook the site visit. The very recently appointed Information Lead supported the validation.

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

**Review of notes at GOS for 2017-18**

As mentioned above, the Validation Team would again like to congratulate the Centre on the most conscientious attention to detail in retrieving and preparing each set of case note documents printed from the ePR. Almost every relevant document that the reviewers needed to examine was carefully identified with a temporary sticky label and this was of immense help.

1. The notes were tidy, and were mostly in chronological order.
2. The anaesthetic and operation records were easy to find
3. It was noted that in patients who were non-bypass, that preoperative height was not always recorded.
4. Hand written operation notes were also seen, the typed operation note appears to form part of the final discharge summary.
5. The TOMCAT cardiac catheter sheets were also included in some records.
6. Perfusion records were seen and were clearly set out and helpful.
7. The number of patients who had undergone a catheter procedure in the sample was small (7) and in 1 of these records there appeared to be no typed physiologists report of the actual catheter fluroscopy (xray dose and xray time) for the procedure.
8. The information team also reported that on occasions it was difficult to identify and retrieve some of the cardiac catheter data from the ePR.
9. As previously reported, all sets of notes it was easy to find discharge summaries and in most cases both primary and secondary diagnosis was contained in the document.

**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.

The first 3 months (Apr-Jun 2017) were reviewed and it appears that there are:

1. 8 submitted surgical records appear to have errors in them such as absent procedure or diagnoses coding
2. 17  records from the log book that may have been missed from the congenital submission

Following the revisit to GOSH to validate the operating room log books on 22 October, the findings were:

1. 12 submitted surgery records appear to have errors in them
2. 7 submitted surgery records were not validated
3. 3 submitted surgical records appear to have duplicate entries
4. 8 procedures in the theatre log books may have been missed from this 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 two of these 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;

The first 3 months (Apr-Jun 2017) were reviewed and it appears that there are:

1. 3 submitted catheter records appear to have errors in them
2. 16 procedures were identified in the cath lab log books which may have been missed from the data submission.

Following the revisit to GOSH to validate the cardiac catheter laboratory log books on 22 October, the findings were:

1. 4 submitted catheter records appear to have errors in them
2. 5 submitted catheter records appear to have duplicate entries
3. 1 record was identified that may not be for congenital heart disease
4. 0 missed cases identified

**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 included in the year under review. The diagnosis and procedure coding will also be validated. 14 post procedural deaths were submitted in the data from GOSH for the year 2017/18. 7 of these deaths occurred within 30 days of a therapeutic procedure and these case notes were reviewed.

**Review of Deceased Patients Case notes**The procedural and outcome documentation was made available to the Reviewers.

* 1 record appeared to have incomplete diagnoses coding
* 2 records appear to have incorrect dates of death
* 1 record appears to have an incorrect weight submitted
* 3 records appear to have incomplete comorbidities recorded in the data submitted to the NCHDA
* Procedure performed coding appears to be correct

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;

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **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 | 20 | 20 |  | 9 | 11 |
| 10 | Pre Procedure Diagnosis | 23 | 23 |  | 9 | 11 |
| 11 | Previous Procedures | 13 | 25 | 13 absent | 6/10 | 8/15 |
| 12 | Patients Weight atOperation | 23 | 23 |  | 9 | 14 |
| 13  | Height | 23 | 23 |  | 9 | 14 |
| 14 | Ante Natal Diagnosis | 5 | 5 |  | 2 | 3 |
| 15 | Pre Proc Seizures | 23 | 23 |  | 9 | 14 |
| 16 | Pre Proc NYHA  | - | - |  | - | - |
| 17 | Pre Proc Smoker | - | - |  | - | - |
| 18 | Pre Proc Diabetes | - | - |  | - | - |
| 19 | Hx Pulmonary Dis | - | - |  | - | - |
| 20 | Pre Proc IHD | - | - |  | - | - |
| 21 | Comorbidity Present | 5 | 8 | 3 absent | 2/3 | 3/5 |
| 22 | Comorbid Conditions | 5 | 9 | 2 absent, 2 incorrect | 2/3 | 12/14 |
| 23 | Pre Proc Systemic Ventricular EF | 19 | 23 | 4 incorrect | 7/9 | 11/13 |
| 24 | Pre Proc Sub Pul Ventricular EF  | 18 | 23  | 4 incorrect | 7/9 | 11/13 |
| 25 | Pre-proc valve/septal defect/ vessel size | - | - |  | - | - |
| 26 | Consultant | 23 | 23 |  | 9 | 14 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure + Time Start | 23 | 23 |  | 9 | 14 |
| 28 | Proc Urgency | 23 | 23 |  | 9 | 14 |
| 29 | Unplanned Proc | 0 |  |  | - | - |
| 30 | Single Operator | 5 |  |  | 5 | - |
| 31 | Operator 1 | 23 | 23 |  | 9 | 14 |
| 32 | Operator 1 Grade | 23 | 23 |  | 9 | 14 |
| 33 | Operator 2 | 17 | 18 | 1 unable to validate | ¾ | 14 |
| 34 | Operator 2 Grade | 17 | 18 | 1 unable to validate | ¾ | 14 |
| 35 | Procedure Type | 23 | 23 |  | 9 | 14 |
| 36 | Sternotomy Sequence |  | 24 |  | - | 14 |
| 37 | Operation Performed | 23 | 23 |  | 9 | 14 |
| 38 | Sizing balloon used for septal defect  | 0 | 0 |  | - | - |
| 39 | No of stents or coils | 1 | 1 |  | 1 | - |
| 40 | Device Manufacturer | 3 | 3 |  | 1 | 2 |
| 41 | Device Model | 3 | 3 |  | 1 | 2 |
| 42 | Device Ser No | 3 | 3 |  | 1 | 2 |
| 43 | Device Size | 3 | 3 |  | 1 | 2 |
| 44 | Total Bypass Time | 14 | 14 |  | - | 14 |
| 45 | XClamp Time, | 13 | 13 |  | - | 13 |
| 46 | Total Arrest | 0 | 0 |  | - | 0 |
| 47 | Cath Proc Time, | 9 | 9 |  | 9 | - |
| 48 | Cath Fluro Time, | 0 | 4 | 4 absent | 0/4 | - |
| 49 | Cath Fluro Dose, | 4 | 4 |  | 4 | - |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 50 | Duration of Post Op Intubation  | 10 | 14 | 4 incorrect | - | 10/14 |
| 51 | Post Procedure Seizures  | 22 | 23 | 1 incorrect | 8 | 14 |
| 52 | Post Proc Complications | 5 | 5 |  | 1 | 4 |
| 53 | Date of Discharge | 23 | 23 |  | 9 | 14 |
| 54 | Date of Death | - | - |  | - | - |
| 55 | Attribution of Death | - | - |  | - | - |
| 56 | Status at Discharge | 23 | 23 |  | 9 | 14 |
| 57 | Discharge Destination | 23 | 23 |  | 9 | 14 |

The Overall Trust DQI = 95% Cardiology DQI = 95% Surgery DQI = 95.5%

This DQI is based upon the domain scoring below. The methodology for this DQI is provided in the paper the 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 .87** |
| **Card**.88 | **Surg**.87 |
| **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**.955 | **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** .95 |
| **Card**.97 | **Surg**.95 |

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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DOMAINS**  | **2015****14/15** | **2016****15/16** | **2017****16/17** | **2018****17/18** |
| **Demographics** | 1.0 | 1.0 | 1.0 | 1.0 |
| **Pre Procedure**  | .98 | .94 | .99 | .87 |
| **Procedure** | .99 | .98 | .99 | .98 |
| **Outcome** | 1.0 | .96 | 1.0 | .95 |

**Conclusions**

On the whole the NCHDA data that was seen was accurate, well documented, and of good quality. There is a strong culture of clinical audit in this centre and this is clearly demonstrated in the improvements in the data quality scores since 2009. The Validation Team would particularly like to commend the Cardiac Information Team for preparing each bundle of case notes with such conscientiousness and attention to detail.

The Data Quality Indicator Score has fallen slightly at this visit. However. the Reviewers would like to acknowledge that a considerable number of the established cardiac information and audit team members have changed within the 6 months prior to this validation visit and would commend the smooth running and organisation of the day and for the shorter return visit to review the log books for case ascertainment by the new team members.

The NCHDA Validation Team also recognise and appreciate that there has been a number of ongoing technical challenges with the new web facing NCHDA database and the late notice of dataset changes.    There are now much stricter controls on which data will be accepted by the database at the time that information is ready to submit to the database and this has created a considerable burden for the data managers at all congenital centres. Many centres were unable to meet the deadline for submission and at the time of this validation visit 3 centres had not submitted any data. It is fully anticipated by NCHDA that centres may experience a small drop in the data quality indicator as well.

It is reported that for the next NCHDA validation visit to review the 2018/19 data GOSH will have moved completely to an electronic record.

**Deceased Patients Procedure and Diagnosis data check.**

Some discrepancies were identified as listed elsewhere in the report. Otherwise on the whole the data were of good quality.

**Recommendations (as in July 2014-17)**

1. It is recommended that Standard Operating Protocols for the congenital data collection, are regularly reviewed to ensure that they include detailed guidance on and **exactly who** is responsible for;
	1. Ensuring prospective consent for external validation of hospital notes is obtained and all patients receive appropriate information on this prior to admission. That in line with the GDPR, all patients/parents and guardians are given full information of how their data are securely recorded, stored, where this information is shared and who with. And an opt out explained to patients/carers.
	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. Exporting data from NCHDA and running PRAiS analysis software each month with responsible clinician involvement.
	7. Making timely submissions (monthly is recommended) and
	8. Ensuring all manufacturers names, model and serial numbers are submitted for all implantable devices and valves.
	9. It is recommended that all staff connected with NCHDA audit should observe at least one other site validation per year.
	10. 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.