**The National Congenital Heart Disease Audit**

**Data Quality Audit**

**For years Apr 2015 - Mar 2016**

**Papworth Hospital NHS Foundation Trust**

**11 January 2017**

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**Summary**

Prior to the log book review on the day of the validation visit, the NCHDA data return from Papworth Hospital NHS Foundation Trust indicated that 87 (surgery 35, interventional catheters 52, diagnostic catheter procedures 0, other procedures 0, Deaths 2) had been undertaken in patients with congenital heart disease during the data collection year of 2015/2016. It was noted that no data for diagnostic catheter procedures, no data for implantable devices, diagnostic or therapeutic electrophysiological procedures had been submitted to NCHDA for the year under review.

This is the first NCHDA validation visit to Papworth Hospital (PAP). The audit year being reported is April – March 2015-16. Papworth is a specialist heart and lung hospital.

This visit has arisen following scrutiny by NHSE Commissioners following a review of congenital cardiac surgery services in England during 2015/16 and which centres should be undertaking such procedures and providing services to this population of patients.

On the day of this validation visit the Reviewers were informed by the clinicians at Papworth that all surgery on patients with congenital heart disease ceased on 1 April 2016.

Philips TOMCAT is the cardiac information system used at Papworth. It is designed to collect information on adult acquired cardiac disease procedures. It does not have a congenital heart disease module commercially available that includes the NCHDA dataset.

There is no individual with protected time and specific responsibility for congenital cardiac data at Papworth. There is a specifically designated Clinical Governance Manager supervising all of the data collection for cardiology and cardiac surgery at the time of this visit. There is a team of 3.0WTE who support the cardiac audits. The Deputy Clinical Governance Manager has access to the NCHDA Congenital Database.

**Actions on Recommendations Taken since Last Validation Visit**

1. None to report as this is the first validation visit.

**Patient Consent for External Validation of Case Notes**

Consent for external validation of hospital case notes by NCHDA has been required since 1 April 2007. There is no process at PAP to collect this consent currently as there has not been any previous validation visits.

Attempts were made to contact each of the 20 Sample patients and 10 Reserve patients via telephone to obtain a verbal consent. Where this consent was obtained, this was then annotated in the patients hospital case notes. On the day 19 patients were contacted successfully and gave their verbal consent.

Papworth are intending to launch Lorenzo as an electronic patient record (ePR) in June 2017. It is hoped that this ePR will incorporate the NCHDA dataset to underpin a more structured and appropriate process for this data collection.

The Data Quality Indicator (DQI) score for the Trust is calculated to be **83.5%** with domain scores Demographics 1.0 Pre Procedure .64 Procedure .81 and Outcome .89.

Separate DQI scores are being calculated for both catheters and surgery. A minimum number of 5 records are required in either group for this to be done. 19 patients had 8 operations and 11 catheter procedures in the 2015/16 sample. 1 patient was found to be missing a subsequent catheter procedure in the data submission. The DQI scores are;

|  |  |  |  |
| --- | --- | --- | --- |
| **Year of Visit** | **Data Year Validated** | **Surgery DQI** | **Catheter DQI** |
| 2017 | 15/16 | 84% | 82.25% |

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 the validation visit, the NCHDA return from Papworth Hospital NHS Foundation Trust indicates that 87 (surgery 25, interventional catheters 52, diagnostic catheterisation procedures 0, others 0, Deaths 2) had been undertaken in patients with congenital heart disease during the data collection year of 2015/2016.

20 sets of case notes were selected for review. The NCHDA Data Auditor and one external Consultant Cardiac Surgeon undertook the site audit. The Cardiac Head of Service, in collaboration with clinical colleagues completed the pre visit self assessment questionnaire.

A list of 20 sets of notes for the case note review were supplied by NCHDA in advance of the visit. Also included in this list were 10 further cases should any of the first 20 not be available or not have the required consent for external validation. On the day 12 were available from the Sample and 7 records were used from the Reserve list for the 2015/16 sample. The accuracy of the NCHDA data return was then checked against each set of notes and used to calculate the Data Quality Indicator (DQI) score.

**Review of notes**

The hospital notes for male patients are coloured blue and notes for females are pink. The majority of the hospital notes seen at this visit were tidy but not always in chronological order. In some hospital notes there were several copies of the same letter or discharge summary. It was generally very difficult and time consuming to validate the data but the reviewers would like to thank the Information Governance Staff for taking the time to book mark the more relevant documents.

1. The anaesthetic records were easy to identify due to their colour edge
2. The perfusion sheets were mostly seen but are not colour tabbed.
3. It was impossible to validate the endotracheal tube extubation time in the hospital notes as this did not appear to be routinely recorded in the hospital case notes.
4. Hand written operation notes were seen in the hospital notes
5. Hand written procedure notes for cath lab procedures were seen in the hospital notes.
6. It was not possible to validate any catheter fluroscopy data in the hospital case notes as these data are not included the procedure notes or integrated care pathways that were seen.
7. The adult care pathway is a well laid out, easy to follow document but often incomplete with fields left empty and this hindered the review.
8. The NHS number, is readily available on the Trust PAS, and was found in all sets of patient notes at this visit.
9. It was also noted that 1 surgical patient had had a subsequent pacemaker insertion and this procedure was absent from the data that PAP had submitted for the year 2015/16.

**Catheter Lab Log Book Review**

There are 5 cardiac catheter laboratories at Papworth Hospital. There are no separate or independent log of patient activity in these rooms other than the TOMCAT information collection system.

Copies of the activity logs from TOMCAT were prepared but with the patients identity and CRN redacted.

**Review of the theatre log books**

There are 5 cardiac operating theatres at Papworth Hospital. There is a separate independent log of patient activity in these rooms.

Copies of the activity logs from TOMCAT were prepared but with the patients identity and CRN redacted.

Following consultation with the Clinical Lead for NCHDA and another senior NCHDA Steering Committee member immediately prior to the visit,  it was felt the Reviewers should work to the accepted standards established during the previous 309 site validation visits and the absence of names and case record numbers precluded this.

It is clear from the data submitted to NCHDA for 2015/16 that there has not been full case ascertainment from this Centre and the Validation Team were unable to establish how many missing cases there may be. 3 procedures were identified to have been missed after all the 21 case notes (including the 2 deceased patients) had been examined.

**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 and procedure coding will also be validated.

The Validation Team are grateful to the Medical Director and Caldicott Guardian for giving permission to examine the hospital case notes of deceased patients.

2 post procedural deaths were submitted in the data from PAP for the year 2015/16.

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

* 1 deceased patient was noted to have 2 further procedures missing from the total data submitted to NCHDA for 2015/16.
* 1 record appears to have absent previous procedures
* 1 record appears to have an absent procedure code for the operation
* Both records appear to have an incomplete comorbidities field
* Both records appear to have incomplete fields for pre and post procedure seizures

**Security and Confidentiality**

The NCHDA system has been registered with the Trusts Data Protection Officer and there are tested procedures to ensure data backup and disaster recovery. The NCHDA system appears to be fully compliant with the Trusts policies on security and confidentiality. There are written procedures available to staff in all the areas where staff collect and manage data. There are procedures that include current relevant definitions for all relevant types of patient activity. There are processes in place to audit data collection activities and the audit team is confident that all patient data are consistently collected in all instances.

**Validation and Quality Assurance**

Formal validation routines are built into the Trusts system which includes checking for invalid entries and completeness of data items. These procedures are used for cardiology and surgical data input. The Trust has a direct linkage with the NHS Strategic Tracking System and this updates the hospital PAS system automatically with NHS Numbers. All demographic data interface with the local PAS. Data collection processes are audited regularly during a monthly meeting between the clinical team and the audit department to check and validate the data. This includes checking theatre lists, safer sleep (anaesthetic system), TOMCAT, EMR and patient case notes. In addition PAP have an annual Trust wide clinical coding audit, plus the annual BCIS, adult cardiac surgery and MINAP data review. Electronic discharge summaries are now used at this Trust.

**Training**

There is central responsibility within the Trust for the identification of training needs and development and provision of training in data collection. A documented training programme is provided covering all aspects of recording clinical activity on the NCHDA for all clinical staff involved in direct patient care.

**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. This is the first validation of NCHDA data at this Centre and due to the circumstances the actual submission date was somewhat delayed and at the time of this visit no data had been received in the congenital database relating to diagnostic catheterisation, any implantable devices or electrophysiological procedures for year under review. The Centre have made some submissions to NCHDA for the 2016/17 year. There are established procedures for answering queries about the data or information produced from NCHDA. The NHS Number is available on the Trusts’ PAS.

**Accountability**

There is someone within the Trust with management responsibility for the NCHDA system, Dr P Calvert and there is also someone with designated responsibility for data quality and standards conformance, the Deputy Clinical Governance Manager. There are also arrangements which give those staff responsible for data quality adequate influence over other staff whose actions effect data quality.

**Health Records Management**

On the whole most of the information required by NCHDA can be found in the hospital notes and the notes are available for this to be done. A majority of the data are collected in ‘real time’ at entry by the clinicians who perform the procedures.

**Timeliness**

There has been a reluctance to participate in the NCHDA in past years. This submission did not meet the deadline date of 2 May 2016. However the Centre is now making monthly submissions to NCHDA. It is reported that Q1 and Q2 have been successfully submitted for therapeutic cardiology procedures but there are no diagnostic or implantable device procedures submitted to NCHDA at the time of this validation visit. There may be some outstanding surgical cases also.

**Completeness and Validity**

Automated transfer tables are not available to ensure patient care events are defined correctly according to NCHDA classifications. Due to small numbers this is currently done at the monthly meeting with the clinical lead.

There are monthly internal targets for completeness of data within the Trust and these are mostly being met according to the responses in the previsit questionnaire at this validation.

**Accuracy**

There is a Health records annual audit. In addition there is an annual audit programme for the Trust which will include aspects of data quality. There is also an annual coding audit.

**Data Quality Indicator Assessment 2015 – 2016 (Apr- March)**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 19 | 19 |  | 11 | 8 |
| 28 | Time Start | 8 | 19 | 11 absent | 0/11 | 8 |
| 29 | Proc Urgency | 19 | 19 |  | 11 | 8 |
| 30 | Unplanned Proc | 0 | 0 |  | - | - |
| 31 | Single Operator | 1 | 1 |  | 1 | - |
| 32 | Operator 1 | 19 | 19 |  | 11 | 8 |
| 33 | Operator 1 Grade | 17 | 19 | 1 incorrect, 1 unable to validate | 9/11 | 8 |
| 34 | Operator 2 | 13 | 17 | 2 absent, 2 incorrect | 6/9 | 7/8 |
| 35 | Operator 2 Grade | 13 | 17 | 2 absent, 2 incorrect | 6/9 | 7/8 |
| 36 | Procedure Type | 19 | 19 |  | 11 | 8 |
| 37 | Sternotomy Sequence | 6 | 8 | 2 incorrect | - | 6/8 |
| 38 | Operation Performed | 18 | 19 | 1 incorrect, 2 others incomplete | 10/11 | 8 |
| 39 | Sizing balloon used for septal defect  | 1 | 2 | 1 absent | ½ | - |
| 40 | No of stents or coils | - | - |  | - | - |
| 41 | Device Manufacturer | 12 | 18 | 6 absent | 5/7 | 7/11 |
| 42 | Device Model | 13 | 18 | 5 absent | 5/7 | 8/11 |
| 43 | Device Ser No | 7 | 18 | 11 absent | 0/7 | 8/11 |
| 44 | Device Size | 14 | 18 | 4 absent | 3/7 | 11 |
| 45 | Total Bypass Time | 8 | 8 |  | - | 8 |
| 46 | XClamp Time, | 7 | 8 | 1 incorrect | - | 7/8 |
| 47 | Total Arrest | 0 | 1 | 1 absent | - | 0/1 |
| 48 | Cath Proc Time, | 0 | 11 | Unable to validate | 0/11 | - |
| 49 | Cath Fluro Time, | 0 | 11 | Unable to validate | 0/11 | - |
| 50 | Cath Fluro Dose, | 0 | 11 | Unable to validate | 0/11 | - |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation  | 0 | 0 | Unable to validate in case notes | - | 0 |
| 52 | Post Procedure Seizures  | 11 | 19 | 8 absent | 11 | 0/8 |
| 54 | Post Proc Complications | - | - |  | - | - |
| 55 | Date of Discharge | 19 | 19 |  | 11 | 8 |
| 56 | Date of Death |  |  |  | - | - |
| 57 | Status at Discharge | 19 | 19 |  | 11 | 8 |
| 58 | Discharge Destination | 19 | 19 |  | 11 | 8 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 83.5% Cardiology DQI = 82.25% Surgery DQI = 84%

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 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 .64** |
| **Card**.58 | **Surg**.72 |
| **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** .81 |
| **Card**.71 | **Surg**.89 |
| **Outcome**Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination.**Post Procedure Complications.** | **Overall** .89 |
| **Card**1.0 | **Surg**.75 |

**The Trust DQI = 83.5%**

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** | **2016****15/16** |
| **Demographics** | 1.0 |
| **Pre Procedure** | .64 |
| **Procedure** | .81 |
| **Outcome** | .89 |

**Conclusions**

On the whole the NCHDA data that were validated in the case note audit were well documented, of good quality and was mostly appropriately recorded. The Validation Team were impressed by the level of interest shown by colleagues in the on site part of the process throughout the day. It is clear that there is a strong clinical audit ethos embedded in the organisation and there have been steps taken to devise a process that includes the data collection for the NCHDA dataset going forward. The Validation Team would also like to thank the Deputy Information Governance Manager for doing much of the case note preparation in advance of the site visit.

However in the case notes seen there were empty data fields in the integrated care pathway documents that were relevant to NCHDA. Particularly in the Pre Procedure Domain. The overall Data Quality Indicator (DQI) score is low – 83.5% with two domains having the largest amount of missing or incorrect data being Pre Procedure and Procedure details. Of further concern is that it became apparent during the validation that local review of the data (reverse validation) submitted to NCHDA has not been taking place. This is an important part of the data review that should be done locally as it demonstrates exactly how data will be analysed by NCHDA and will highlight any coding errors or omissions quickly and easily.

As stated elsewhere the Reviewers were unable to undertake the log book review at PAP so it is not possible to establish if there has been full case ascertainment at this Centre for the year 2015/16. It was clear from the data submitted that no records for diagnostic cardiac catheter, electrophysiological studies, implantable devices or ablation procedures in patients with congenital heart disease had been submitted to NCHDA. It was apparent from 2 patients case notes reviewed that these individuals had undergone a further 3 procedures that had not been submitted to NCHDA either.

It was reported that it is anticipated that the new electronic patient record will incorporate all the NCHDA data set fields. The hospital are anticipating being paperless once the ePR is fully commissioned.

**Validation of Deceased Patients procedure details.**

As stated above both records reviewed had incomplete components. 1 record was missing 2 further procedures.

**Recommendations**

1. To urgently consider identifying a DBM with some protected time to manage the congenital cardiac data submission from Papworth Hospital. Ideally this individual should have a clinical background and IT skills.
2. If not already in place, it is recommended that Standard Operating Protocols are devised/amended for the congenital data collection, to include detailed guidance on and 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 congenital cardiac 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. Leading the local review (and how frequently and in which forum for both disciplines)
	5. Making timely submissions (monthly is recommended) and
	6. Timely reverse validation at Papworth Hospital against an acknowledged ‘gold standard’ record of activity and procedures performed.
	7. Reviewing/Updating the SOP at timely intervals
3. To consider the use of a self inking stamp as used at some centres with the word Congenital on it to mark each relevant entry in a bound paper log book as appropriate.
4. To ensure that fluoroscopy records on all catheter patients are retained in the patients notes. These data should include skin to skin time, fluro dose and fluro time.
5. To continue to develop training not only for the Audit Team but all staff who may be involved with data input. This could involve visiting other centres who return data to NCHDA and sharing ideas and experience.
6. To commence monthly data returns to NCHDA as soon as possible.
7. The NCHDA Contributors Meeting is on **Tuesday 14 March,** 13.00- 15.00 at The Waterfront in Belfast, NI. Data Managers and clinical leads are strongly recommended to attend this meeting
8. The next annual deadline for NCHDA data is **Monday 1 May 2017** for all 2016/17 data items.