**National Congenital Heart Disease Audit**

 **Procedures for CONGENITAL HEART DISEASE**

 **Data Quality Audit**

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

**NHS Foundation Trust**

**8 June 2017**

**(to review data for year 2016-17)**

*performed by Lin Denne and Dr M Harris*

**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 1360 procedures (676 surgical 360 catheter, 324 others, 32 deaths) were undertaken during the data collection year April 2016 to March 2017. GOSH is one of the largest congenital centres that submit data to NCHDA.

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.

**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, so GOSH have had a second year of data collection and submission without a functional database for the most part.

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. In addition some data has been submitted which has not been through a thorough internal validation process that GOSH have been accustomed to for the previous dataset version. 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.

As of 01.06.17, there remains some procedures that GOSH have been unable to submit due to problems with the csv upload. GOSH will work with the NICOR Helpdesk to resolve these.

As discussed and agreed prior to the validation visit GOSH provided a full summary of the procedures in question on the morning of the visit so that the whole years data can be validated.

The recent international cyber attack (May 2017) has also meant data could not be submitted during week commencing 15th May as had been planned. GOSH have also had problems with Lotus Notes and the new data fields not uploading via the csv file.

The total number of Audit and Information Personnel 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.

**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.

**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. For this years’ 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 11 case notes from the sample and 9 from the reserve list were used. These 20 patients underwent 27 procedures (20 surgeries and 7 therapeutic catheter interventions).

**Data Quality Indicator**

The DQI for the Trust for this visit (previous year in parentheses) is calculated to be 99.5%(97, 99.25 99.5 99) with domain scores Demographics 1.0 (1.0 1.0 1.0) Pre Procedure .99 (.94 .99 1.0), Procedure .99 (.98 .99 .99), and Outcome 1.0 (.95 1.0 .99). There were 6 errors or omissions in 947 variables audited.

As for the previous data validation cycle, 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 and this was reached at GOS.

|  |  |  |  |
| --- | --- | --- | --- |
| **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% |

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**

No actions were reported by the Centre, however GOS comment (as above):

* As noted at 2015 – 16 validation visits, the changes to the NCHDA dataset has meant data has been very challenging to collect and submit as the TOMCAT system was not updated until April 2017 to support this and at the time of the validation visit there are still some outstanding issues.

**Introduction**

Prior to the validation visit, the NCHDA returns from the cardiac department of The Great Ormond Street Hospital for Sick Children indicate that 1360 procedures (676 surgical 360 catheter, 324 others, 32 deaths) were undertaken during the data collection year April 2016 to March 2017.

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 27 procedures (20 surgeries and 7 therapeutic catheter interventions).

The NCHDA auditor and one external congenital cardiologist undertook the site visit. The Principal Analyst and Information Lead. from GOSH completed the pre visit self assessment questionnaire in collaboration with clinical colleagues.

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 2016-17**

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 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 Theatre log books at GOS**

The log books from 2 theatres were offered for review.

1. 1  surgical case was identified in the log books that may be suitable for inclusion in NCHDA.
2. 2 submitted surgical records in  the log book review may either contain errors in the  coding or be incorrectly categorised in the Procedure Type field
3. 1 duplicate surgical record was identified
4. It was noted that Hybrid procedures were entered in both surgery and catheter submissions and this is not correct.  These records should be submitted once in the category Hybrid. These problems were due to technical difficulties with the csv upload and being addressed with the NICOR IT Helpdesk.

**Review of the Cath Lab log books at GOS**

The log books for 2 cath labs were offered for review. This is the nurse’s record book/diary.

1. The NCHDA reviewers identified 2 catheter cases that may be suitable for inclusion in the NCHDA.
2. 1 submitted catheter record may have an error in the procedure coding
3. GOSH had identified 5 further catheter procedures that had been accidentally missed from this submission
4. It was noted that Hybrid procedures were entered in both surgery and catheter submissions and this is not correct.  These records should be submitted once in the category Hybrid. These problems were due to technical difficulties with the csv upload and are being addressed with the NICOR IT Helpdesk.
5. As previously reported pacemaker procedures were identified in the surgical submission that had actually be entered in the catheter log book not the theatre log book

The centre is currently reviewing these records and will make the appropriate resubmissions if necessary.

**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. 32 post procedural deaths were submitted in the data from GOSH for the year 2015/16. 11 of these patients had undergone either thoracic procedures or had post heart transplant ventricular biopsies at least 12 months after the original operation.

23 files relating to patients who had undergone procedures included in the NCHDA Specific Procedures algorithm were created especially for this data validation were made available containing documentation of demography, pre procedure coding, procedure and outcome coding.

1. 1 submitted record may have an incomplete comorbidity listing
2. All other data were found to be correct

**Security and Confidentiality (Data Management)**

As previously reported, the NCHDA dataset is embedded in TOMCAT and has been registered with the Trust’s Data Protection Officer. There are tested procedures to ensure data backup and disaster recovery. TOMCAT is fully compliant with the Trust’s policies on security and confidentiality. Each user has their own unique user ID and password and the system is backed up each night. This is unchanged at the 2017 validation.

Written procedures are available to staff in all the areas where staff collect and manage data. There are also built in validation controls on TOMCAT forcing users to complete the NCHDA minimum dataset. As previously reported, there is an extensive data quality programme in place carried out by the Information Team. This includes weekly validation of data entered into TOMCAT against Cath and Theatre log books and more recently validation against other clinical sources. Activity is also checked against the Trust PiMS system weekly.

Training guides are available for all relevant NCHDA modules on TOMCAT- this did not include updates for version 5.13 of the dataset in 2016/17. 2016/17 was the second year where TOMCAT was not configured to collect the new version of the dataset. The upgraded version of TOMCAT was released from 1st April 2017.

**Validation and Quality Assurance**

As at the previous NCHDA visits, formal validation routines are built into TOMCAT which includes checking for invalid entries and completeness of data items. These procedures are used when data are input. There is a check for duplicates, and for the NHS number validation algorithm as they are imported from the hospital PAS system automatically. Data collection staff routinely check data with the appropriate source and data collection processes are audited weekly as noted above. Regular authorisation checks take place to audit activity and to review completeness and accuracy of all TOMCAT procedures. It is not possible to authorise a TOMCAT record until NCHDA data is complete.This includes NCHDA data items and non NCHDA data items.

**Training**

Data collection for specialised data sets such as NCHDA is divisional responsibility.

Previously training was provided to all staff required to use the TOMCAT system at time of induction. This has ceased to exist. This has been flagged internally as an issue. It had been proposed that Training will be provided via a Trust IT e-learning initiative going forward but this has yet to be rolled out. This will be addressed in conjunction with the upgrade to TOMCAT to allow collection of dataset version 5.13.

NCHDA data fields are mandatory in TOMCAT meaning all data has to be input before Consultants can authorise records.

TOMCAT is designed to collect data contemporaneously. All staff performing cardiac caths and surgery are made aware of this. Clinicians are not able to authorise a treatment episode unless all data are complete. Training on IPCC coding is provided by the clinicians.

**Communications**

As at the previous visits, it is reported that there are established procedures for reissuing amended information following changes to the data if requested in writing and there are procedures to ensure timely collection and dissemination of activity data within the organisation and to NCHDA. All queries come to the West Division Clinical Information Team whom have extensive knowledge of the data/information from NCHDA. All data requestors have to complete a data request form, with details logged for reference and requestors must acknowledge awareness of data protection responsibilities.

Timeliness of collection and dissemination of data within the organisation has continued to improve and on occasions information is available in ‘real-time’. Frequency of reporting to NCHDA was erratic during 2013 to Apr 2016 due to the previously documented extreme staffing and then technical difficulties with TOMCAT.

Queries are not re-issued unless specifically requested. Incomplete or un-validated data is not generally distributed. The only exception would be data issued internally which is accompanied by a relevant health warning.

Patient identifiable information is never issued outside of the organisation with the only exception being NCHDA and PICANet. The NHS Number is now used on communications internally, is now included on the patient label and was also seen on correspondence.

Timeliness of collection and dissemination of data within the organisation has continued to improve over recent years and we are now able to disseminate information weekly in real time. Despite TOMCAT not being able to support the new dataset for NCHDA in 2016/17, GOSH were able to submit data quarterly to NCHDA.

**Accountability**

Mr Ben Davies has management responsibility for the NCHDA system and Vicky Banks, Principal Analyst & Clinical Information Lead,Charles West Division, is responsible for data quality and standards conformance. There are arrangements that give those staff responsible for data quality adequate influence over other staff whose actions affect data quality. This is unchanged at the 2017 visit.

**Health Records Management**

As previously reported, On the whole, all the information required by NCHDA can be found in the notes as seen on this validation visit but they are not used or referred to, during data collection. There are some items of the new dataset which are reported to be not routinely collected or part of GOSH clinical practice. The subjectivity of some of the new data items also remain a cause for concern for GOS.

**Timeliness**

NCHDA acknowledge again, that considerable effort has been put into improving data quality and timeliness of procedure reporting and authorisation. GOSH aim to continue to submit data to NCHDA in quarterly amounts.

For 2016/17, data was submitted quarterly despite not having a database in place to collect the dataset, but the end of year submission was slightly delayed. This was due to a number of reasons:

As reported above, the recent international cyber attack meant data could not be submitted w/c 15th May 2017 as was planned and problems with Lotus Notes and new data fields not uploading via the csv file.

Internal deadlines are being met.

**Completeness and Validity**

As in 2008, transfer tables are available in TOMCAT to ensure patient care events are defined correctly according to NCHDA classifications and include a list of the acronyms, synonyms and abbreviations. However, as mentioned above, TOMCAT did not fully accommodate the NCHDA Dataset v5.1 and information has to be kept on various other databases.

At the previous validation visits in 2013-16, there were internal targets for completeness of data which were being met. The current internal target is to enter all data contemporaneously or at least within 2 weeks of the procedure date. Discharge data is completed within 1 week of the patient leaving hospital. This remains the same in 2017.

**Accuracy**

The West Division Clinical Information Team at GOSH continue to implement an extensive data quality improvement programme to ensure completeness and accuracy of data for all surgical and cath procedures is of the highest quality. This has been extended and will continue to grow to incorporate the new dataset items where possible.

The West Division Clinical Information Team at GOSH continue to work with consultant clinicians and Specialist Registrars in training to ensure records for all procedures are complete and validated and no record may be completed and authorised without a clinician password. This also remains unchanged in 2017.

Casenote Audit;

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 5 | 15 |
| 2 | NHS Number | 16 | 16 |  | 5 | 13 |
| 3 | Surname | 20 | 20 |  | 5 | 15 |
| 4 | First Name | 20 | 20 |  | 5 | 15 |
| 5 | Sex | 20 | 20 |  | 5 | 15 |
| 6 | DOB | 20 | 20 |  | 5 | 15 |
| 7 | Ethnicity | 20 | 20 |  | 5 | 15 |
| 8 | Patient Status | 20 | 20 |  | 5 | 15 |
| 9 | Postcode | 20 | 20 |  | 5 | 15 |
| 10 | Pre Procedure Diagnosis | 27 | 27 |  | 7 | 20 |
| 11 | Previous Procedures | 36 | 36 |  | 14 | 12 |
| 12 | Patients Weight atOperation | 27 | 27 |  | 7 | 20 |
| 13  | Height | 24 | 26 | 2 incorrect | 7 | 27/29 |
| 14 | Ante Natal Diagnosis | 3 | 3 |  | - | 3 |
| 15 | Pre Proc Seizures | 27 | 27 |  | 7 | 20 |
| 16 | Pre Proc NYHA  | 3 | 3 |  | 2 | 1 |
| 17 | Pre Proc Smoker | 3 | 3 |  | 2 | 1 |
| 18 | Pre Proc Diabetes | 3 | 3 |  | 2 | 1 |
| 19 | Hx Pulmonary Dis | 3 | 3 |  | 2 | 1 |
| 20 | Pre Proc IHD | 3 | 3 |  | 2 | 1 |
| 21 | Comorbidity Present | 27 | 27 |  | 7 | 20 |
| 22 | Comorbid Conditions | 27 | 27 |  | 5 | 22 |
| 23 | Pre Proc Systemic Ventricular EF | 26 | 27 | 1 incorrect | 7 | 20 |
| 24 | Pre Proc Sub Pul Ventricular EF  | 26 | 26 |  | 6 | 20 |
| 25 | Pre-proc valve/septal defect/ vessel size | 0 | 0 |  | - | - |
| 26 | Consultant | 27 | 27 |  | 7 | 20 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 27 | 27 |  | 7 | 20 |
| 28 | Time Start | 27 | 27 |  | 7 | 20 |
| 29 | Proc Urgency | 27 | 27 |  | 7 | 20 |
| 30 | Unplanned Proc | 27 | 27 |  | 7 | 20 |
| 31 | Single Operator | 2 | 2 |  | 2 | - |
| 32 | Operator 1 | 27 | 27 |  | 7 | 20 |
| 33 | Operator 1 Grade | 27 | 27 |  | 7 | 20 |
| 34 | Operator 2 | 25 | 25 |  | 5 | 20 |
| 35 | Operator 2 Grade | 25 | 25 |  | 5 | 20 |
| 36 | Procedure Type | 27 | 27 |  | 7 | 20 |
| 37 | Sternotomy Sequence | 15 | 15 |  | - | 15 |
| 38 | Operation Performed | 27 | 27 |  | 7 | 20 |
| 39 | Sizing balloon used for septal defect  | 0 | 0 |  | 0 | - |
| 40 | No of stents or coils | 0 | 0 |  | 0 | - |
| 41 | Device Manufacturer | 5 | 5 |  | 2 | 3 |
| 42 | Device Model | 5 | 5 |  | 2 | 3 |
| 43 | Device Ser No | 5 | 5 |  | 2 | 3 |
| 44 | Device Size | 5 | 5 |  | 2 | 3 |
| 45 | Total Bypass Time | 15 | 15 |  | - | 15 |
| 46 | XClamp Time, | 14 | 14 |  | - | 14 |
| 47 | Total Arrest | 1 | 1 |  | - | 1 |
| 48 | Cath Proc Time, | 6 | 7 | 1 unable to validate | 6/7 | - |
| 49 | Cath Fluro Time, | 6 | 7 | 1 unable to validate | 6/7 | - |
| 50 | Cath Fluro Dose, | 6 | 7 | 1 unable to validate | 6/7 | - |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation  | 16 | 16 |  | - | 16 |
| 52 | Post Procedure Seizures  | 27 | 27 |  | 7 | 20 |
| 54 | Post Proc Complications | 6 | 6 |  | - | 6 |
| 55 | Date of Discharge | 27 | 27 |  | 7 | 20 |
| 56 | Date of Death | - | - |  | - | - |
| 57 | Status at Discharge | 27 | 27 |  | 7 | 20 |
| 58 | Discharge Destination | 27 | 27 |  | 7 | 20 |

The Overall Trust DQI = 99.5% Cardiology DQI = 98.75% Surgery DQI = 99.75%

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 .99** |
| **Card**.99 | **Surg**.99 |
| **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** .99 |
| **Card**.965 | **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 NCHDA Audit – An Introduction to the Process.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DOMAINS**  | **2014****13/14** | **2015****14/15** | **2016****15/16** | **2017****16/17** |
| **Demographics** | 1.0 | 1.0 | 1.0 | 1.0 |
| **Pre Procedure**  | 1.0 | .98 | .94 | .99 |
| **Procedure** | .99 | .99 | .98 | .99 |
| **Outcome** | .99 | 1.0 | .96 | 1.0 |

**Conclusions**

On the whole the NCHDA data was accurate, well documented, and of very 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 Principal Analyst and Information Lead again for preparing each bundle of case notes with such conscientiousness and attention to detail.

The Reviewers are pleased to report that, although there were delays in data reporting and extensive data cleaning, and local and NICOR technical difficulties, quarterly submissions were made to NCHDA. It was reported to the Validation Team that all relevant parties were informed. The Centre also have difficulties with lack of TOMCAT software support and as such the latest additions to the NCHDA dataset v5.01 have not been included until April 2017. NCHDA is likely to move to quarterly reporting in the next 12 months and the need for an effective information collection system will be essential.

In spite of 2016-17 being yet again a very challenging year at GOS the data quality score has has increased by 2.5% which is excellent.

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

1. 1 submitted record may have an incomplete comorbidity listing
2. All other data were found to be correct

**Recommendations (as in July 2014-16)**

1. If not already in place, it is recommended that Standard Operating Protocols are devised 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 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.
3. As recommended in 2010, it is suggested that clearer (neater and more specific) documentation of exactly what procedure was undertaken in all the catheter laboratory and operating theatre log books is made.