**The National Congenital Heart Disease Audit Database**

**Data Quality Audit for**

**CONGENITAL HEART DISEASE**

**Apr 2016 - Mar 2017**

**The Golden Jubilee National Hospital, Glasgow**

**24 November 2017**

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**Summary**

This validation visit, that has reviewed the congenital cardiac data for the year April – March 2016-17 has been fully funded by NHS Scotland.

This visit was supported remotely by the NCHDA clinical audit nurse via a Skype video conference facility and on site in person by Dr A Tometzki, Consultant Congenital Cardiologist from Bristol.

Prior to this congenital data review the data return to the NCHDA from the cardiac department of the Golden Jubilee National Hospital (GJH) indicated that some 214 interventional and surgical procedures had been undertaken during the data collection year of April 2016 to March 2017 in patients aged over 16 years.

Therapeutic and diagnostic implantable devices and electrophysiological therapeutic and diagnostic procedures performed in patients with known congenital heart disease are included in this data collection. As previously reported, due to operational requirements endocardial pacemaker implant procedures are performed in the operating theatre by consultant cardiologists rather than in the cardiac catheter laboratory at this centre. It was apparent at the 2012-16 validation visits that these procedures are being categorised at ‘non-bypass’.

The possibly incorrect categorisation of these procedures has further implications as these cases are now amongst the 72 Specific Procedures that are analysed and published by NCHDA. The following procedures that are not always being correctly reported are Radiofrequency ablation for Tachyarrhythmia, Implantable Cardioverter Defibrillator, and Pacemaker implants.

As previously, the domestic cardiac data collection system used at GJH is CaTHi – a bespoke Cardiac and Thoracic Information system (via a Clinical Portal). This is for acquired heart disease and has been developed within the Golden Jubilee Hospital. There is no specific module within CaTHi to record the congenital cardiac data fields required by NCHDA. CaTHi does not interface with the congenital cardiac database – HeartSuite. The CaTHi system provides a view of the information rather than stores data.

Also, as previously reported, there is no real time data entry, at the point of service delivery by responsible clinicians into a specific information system that holds the complete NCHDA Dataset. HeartSuite is available to one individual only – the Scottish Adult Congenital Cardiac (SACCs) Manager.

The 1.0WTE SACCs Information Manager (IM) for congenital cardiology based at GJH is positioned close to the clinicians and their secretaries. This post has been occupied by number of individuals in the 36 months prior to this validation visit. Combined with this there has been a catalogue of technical issues, some related to the local IT service and others specifically related to HeartSuite that have hindered timely data submission.

The Validation Team would particularly like to commend the current IM for the meticulous preparation of the case note documentation for this visit and the preparation of the printed material from OPERA. Adult congenital heart disease is a complex specialty and the current IM has no previous clinical background*.*

As reported above, there is no real time data input by clinicians at GJH to HeartSuite. HeartSuite is available at the desk of the SACCs IM only and not in the Cath Labs or operating theatres or any other clinical areas. There is no link between the hospitals patient information or administration system (PAS) and HeartSuite. Following completion of a proforma by the clinicians, all data are input manually by the IM to HeartSuite. As previously reported, there is no automated data linkage between the national Scottish paediatric cardiac service in an adjacent hospital Trust (Royal Hospital for Sick Children at Queen Elizabeth University Hospital) and the ACHD service at GJNH to enable fast and efficient information access during transition for patients from the paediatric to the adult service. This is unchanged in 2017. Both of these centres use the HeartSuite Information System to collect and submit congenital cardiac data. There are known to be 2 hospital centres in England, one is paediatric only the other provides the transition and adult congenital cardiac service, in adjacent NHS Trusts that both use HeartSuite that have linked their databases to meet strict NHS and local Information Governance Standards satisfactorily.

**Actions Taken following February 2017 Validation Visit**

1. There are now quarterly internal data validations by the information manager.
2. Intubation times were an issue at the Nov 2016 validation. The information manager now keeps records of all intubation times in the form of screenshots from the in-house ITU system ‘Centricity’ to ensure this data is input correctly.
3. All catheter procedures now have the sheath in and sheath out times taken from the procedural print out sheet instead of online systems to improve accuracy.

**Consent for External Validation of Congenital Cardiac Patients Hospital Notes.**

This has been required by The NCHDA since 1 April 2007. In June 2014, an additional clause was added to the generic consent for operation form that requires an additional signature and this appears to work well. The Validation Team are grateful to the Medical Director for giving permission to review sets of case notes where there appeared to be no patient consent for external validation present.

**Data Quality Indicator Scores (DQI)**

The overall DQI for the hospital is calculated to be (with previous years in parentheses) **99%** (92.5, 94.5 97.5), with domain scores Demographics .98 (.99, .99 1.0), Pre Procedure .99 (.80, .86 .95), Procedure .99 (.93, .95 .95) and Outcome .99 (.90, .98 1.0).

Also, a separate DQI calculation is made for surgery and catheter procedures where there is a minimum of 5 records in either group at the case note validation*.*

The scores for GJH are:

|  |  |  |  |
| --- | --- | --- | --- |
| **Year of Visit** | **Data Years reviewed** | **Surgery DQI** | **Catheters DQI** |
| **2012** | 10-11 | 90% | 92.5% |
| **2013(i)** | 11-12 | 96% | 91.5% |
| **2013(ii)** | 12-13 | 93% | 97.75% |
| **2014** | 13-14 | 98.5% | 95.25% |
| **2016(i)** | 14-15 | 95.25% | 94% |
| **2016(ii)** | 15-16 | 93.25% | 92% |
| **2017** | 16-17 | 99% | 99% |

The NCHDA 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.

**Introduction**

The data return to The NCHDA from the cardiac department of the Golden Jubilee National Hospital, Glasgow indicated that 214 cases (surgery 97, catheters 57, others 60, deaths 3) had been undertaken in the data collection year 2016/2017 of which 20 records were selected for review.

As stated above, 20 sets of patient notes were requested for review for each year, a further 10 sets were selected as a reserve in case any of the first 20 were unavailable on each day.

On the day 20 sets were made available and all were from the Sample group. These 20 patients underwent 25 procedures (13 operations and 12 cardiac catheter procedures). 3 of the 10 cardiac catheter procedures had been incorrectly categorised as ‘Other’ instead of ‘Catheter Intervention’.

The accuracy of the NCHDA data return was then checked against each set of notes to enable the Data Quality Indicator (DQI) to be scored.

**Review of case notes**

As reported elsewhere, the hospital notes had been meticulously prepared. This hospital is now operating a ‘paper lite’ electronic patient record. All paper entries in a case note are scanned to an electronic information system upon discharge of the patient from hospital. The case notes reviewed were a mixture of original paper documents and documents reprinted from the ePR.

The Validation Team made the following observations during the case note audit;

1. As previously reported, the patient notes on the whole were clearly labelled with the patients name and hospital number, were in good chronological order, clearly set out and tidy.
2. As previously reported, it was noted that in some of the correspondence from the physicians that was seen, this often listed the previous procedures which was helpful but did not appear to be a routine occurrence.
3. As previously reported, the printed care pathway documents were helpful when the data fields were completed but in some cases they were not and this hindered the reviewers at times.
4. NYHA status recording appeared to be variable in the case notes reviewed.
5. The typed surgical operation notes seen were clear and concise.
6. The anaesthetic form was easy to find
7. The perfusion sheets were seen for almost all surgical patients
8. As previously reported, cardiac catheter sheets were fairly easy to locate. The A5 sticky label completed by the Cath Lab staff with fluroscopy was data seen.
9. As previously reported the discharge summaries did not always appear to have the actual date of discharge documented, it appeared it was often an estimated date of discharge as it appears to be a pre prepared document.

**Review of the Catheter and Theatre Log Books**

As reported previously, formal hand written log books are not kept in the operating theatres or cath labs. A print out from the electronic booking and theatre management system (OPERA) which is also used as a log of procedures performed was supplied by the cardiac Information Manager. The HeartSuite activity log is validated against this.

**Theatre Log Books**

1. As reported in 2012-16, generally the entries of procedures performed, as listed in the theatre management printout, did not always appear to be accurate descriptions of exactly what procedure had taken place and whether or not the patient had congenital heart disease.
2. 16  surgical cases were identified that may be suitable for inclusion in the NCHDA
3. 1 submitted surgical record was not validated in OPERA
4. 4 submitted surgical records appear to have errors in them

**Cath labs**

1. 39 catheter records were identified that may be suitable for inclusion in NCHDA
2. 2 submitted catheter records were not validated in OPERA
3. As for the surgery entries in OPERA, it was not always clear exactly what specific procedure had been undertaken or whether or not it was for congenital heart disease but some cases were clearly for congenital heart disease
4. As previously reported, some descriptions of diagnoses were not specific and it was impossible to gauge whether or not the procedure performed was for congenital heart disease or not.
5. As previously reported, there is no indication in OPERA if any EP procedures are for congenital heart disease or not.

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

Commencing with the validation of the 2014/15 data, the National Congenital Heart Disease Audit wish to verify any dates of death of deceased patients included in the year under review. The demographic, diagnosis and procedure coding are also validated. The requirement for patient/parent/guardian consent to review the case notes is the same as for the congenital procedures review. In cases where it is unclear if this consent has been obtained during life, the Medical Director is asked for permission to undertake this review. The Validation Team are grateful to the MD of GJH for giving this permission.

3 post procedural deaths were submitted in the data from GJH for the year 2016/17. It is reported at this visit that there is no standard mechanism for informing the IM of any out of hospital deaths that may occur.

1. 2 records appear to have incomplete previous procedures listed
2. 2 records appear to have complications absent from the submitted records
3. 1 record has incomplete comorbidities

**Case Note Audit**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  | | | | **C** | **S** |
| 1 | Hospital Number | 20 | 20 |  | 11 | 9 |
| 2 | NHS Number | 20 | 20 |  | 11 | 9 |
| 3 | Surname | 20 | 20 |  | 11 | 9 |
| 4 | First Name | 20 | 20 |  | 11 | 9 |
| 5 | Sex | 20 | 20 |  | 11 | 9 |
| 6 | DOB | 20 | 20 |  | 11 | 9 |
| 7 | Ethnicity | 20 | 20 |  | 11 | 9 |
| 8 | Patient Status | 20 | 20 |  | 11 | 9 |
| 9 | Postcode | 120 | 20 |  | 11 | 9 |
| 10 | Pre Procedure  Diagnosis | 24 | 25 | 1 incorrect | 11/12 | 13 |
| 11 | Previous Procedures | 18 | 18 |  | 12 | 13 |
| 12 | Patients Weight at  Operation | 25 | 25 |  | 15 | 13 |
| 13 | Height | 25 | 25 |  | 12 | 13 |
| 14 | Ante Natal Diagnosis | - | - |  | - | - |
| 15 | Pre Proc Seizures | 25 | 25 |  | 12 | 13 |
| 16 | Pre Proc NYHA | 25 | 25 |  | 12 | 13 |
| 17 | Pre Proc Smoker | 24 | 25 | 1 incorrect | 11/12 | 13 |
| 18 | Pre Proc Diabetes | 25 | 25 |  | 12 | 13 |
| 19 | Hx Pulmonary Dis | 24 | 25 | 1 incorrect | 11/12 | 13 |
| 20 | Pre Proc IHD | 24 | 25 | 1 incorrect | 11/12 | 13 |
| 21 | Comorbidity Present | 25 | 25 |  | 12 | 13 |
| 22 | Comorbid Conditions | 19 | 21 | 2 incorrect | 7/9 | 12 |
| 23 | Pre Proc Systemic Ventricular EF | 24 | 24 |  | 11 | 13 |
| 24 | Pre Proc Sub Pul Ventricular EF | 24 | 24 |  |  | 13 |
| 25 | Pre-proc valve/septal defect/ vessel size | 1 | 1 |  | 1 | - |
| 26 | Consultant | 25 | 25 |  | 12 | 13 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 27 | Date of Procedure | 25 | 25 |  | 12 | 13 |
| 28 | Time Start | 25 | 25 |  | 12 | 13 |
| 29 | Proc Urgency | 25 | 25 |  | 12 | 13 |
| 30 | Unplanned Proc | 23 | 25 | 2 incorrect | 12 | 11/13 |
| 31 | Single Operator | 4 | 4 |  | 4 | - |
| 32 | Operator 1 | 25 | 25 |  | 12 | 13 |
| 33 | Operator 1 Grade | 25 | 25 |  | 12 | 13 |
| 34 | Operator 2 | 21 | 21 |  | 8 | 13 |
| 35 | Operator 2 Grade | 21 | 21 |  | 8 | 13 |
| 36 | Procedure Type | 25 | 25 |  | 12 | 13 |
| 37 | Sternotomy Sequence | 13 | 13 |  | - | 13 |
| 38 | Operation Performed | 25 | 25 |  | 12 | 13 |
| 39 | Sizing balloon used for septal defect | 1 | 2 | 1 absent | 1/2 | - |
| 40 | No of stents or coils | 0 | 0 |  | - | - |
| 41 | Device Manufacturer | 7 | 7 |  | 3 | 4 |
| 42 | Device Model | 7 | 7 |  | 3 | 4 |
| 43 | Device Ser No | 7 | 7 |  | 3 | 4 |
| 44 | Device Size | 7 | 7 |  | 3 | 4 |
| 45 | Total Bypass Time | 12 | 13 | 1 incorrect | - | 12/13 |
| 46 | XClamp Time, | 12 | 13 | 1 incorrect | - | 12/13 |
| 47 | Total Arrest | - | - |  | - | - |
| 48 | Cath Proc Time, | 12 | 12 |  | 12 | - |
| 49 | Cath Fluro Time, | 12 | 12 |  | 12 | - |
| 50 | Cath Fluro Dose, | 12 | 12 |  | 12 | - |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|  |  |  |  |  | **C** | **S** |
| 51 | Duration of Post Op Intubation | 13 | 13 |  | - | 13 |
| 52 | Post Procedure Seizures | 25 | 25 |  | 12 | 13 |
| 54 | Post Proc Complications | 3 | 3 |  | 1 | 2 |
| 55 | Date of Discharge | 25 | 25 |  | 12 | 12/13 |
| 56 | Date of Death | - | - |  | - | - |
| 57 | Status at Discharge | 25 | 25 |  | 12 | 13 |
| 58 | Discharge Destination | 25 | 25 |  | 12 | 13 |

Data Quality Indicator Assessment:

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

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 .98** | |
| **Card**  .97 | **Surg**  1.0 |
| **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**  .99 | **Surg**  .98 |
| **Outcome**  Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination.  **Post Procedure Complications.** | **Overall** .99 | |
| **Card**  1.0 | **Surg**  .985 |

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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Domain** | **2014**  **13-14** | **2015**  **14-15** | **2016**  **15-16** | **2017**  **16-17** |
| **Demographics** | 1.0 | .99 | .99 | 1.0 |
| **Pre Procedure** | .95 | .86 | .80 | .98 |
| **Procedure** | .95 | .95 | .93 | .99 |
| **Outcome** | 1.0 | .98 | .99 | .99 |

**Conclusions**

On the whole the NCHDA data was accurate, well documented in the hospital notes, in the printed pages of the ePR, and good quality. The DQI has increased by 6.5% which is an excellent acheivement. There is no doubt that the role of Congenital Cardiac Information Manager is a very important one and critical to timely, relevant and accurate data collection processes. There have been 4 different congenital cardiac information managers at this centre in 36 months and this had seriously impacted on the DQI scores of the previous 2 years. There are however, continued technical difficulties relating to lack of interface between HeartSuite and the local electronic information systems.

As previously, the Validation Team would again particularly like to thank the current IM who has clearly worked hard to grasp the basics of a complicated clinical specialty and for the meticulous preparation of the hospital notes and for preparing the printouts from OPERA of the cath lab and operating theatre procedures. This individual is also tasked with managing data for the Scottish national adult congenital registry (SACCS) but has no defined hours (WTEs) for either role.

There is still no real time or point of service data entry at this centre by the responsible clinicians as there are no access points in the cardiac catheter laboratory of operating theatres to the HeartSuite information database that holds the complete NCHDA dataset. The data are solely input retrospectively from a proforma completed by the clinicians and passed to the IM who is not clinically experienced but is now located within or immediately close to the consultant clinicians offices and is well supported by clinical colleagues. The Reviewers understood in November 2016 that that may be a number of licenses available at GJH to make access to HeartSuite available in the clinical areas and in November this was unchanged.

This is the seventh annual NCHDA validation visit to GJNH and it is of real concern that there is still no specifically dedicated database available to collect this information in ‘real time’ at the point of service. As reported in 2012-16, CaTHi the local domestic patient information system does not interface with HeartSuite and does not contain the NCHDA dataset.

As at the previous validations, it was clear that many previous procedures that had been undertaken when ACHD patients has accessed a paediatric cardiac service as children and may have been undertaken at the Royal Hospital for Sick Children in Glasgow (RHS). HeartSuite is the cardiac information collection system used at RHS which is sited in an adjacent NHS Trust. This was discussed at the November 2016 validation visit but there still appears to be minimal advances in linking these 2 systems. The ability to link 2 HeartSuite databases to meet with both NHS and local Information Governance standards at adjacent NHS Trusts has been proven and is now active between 2 NHS Trusts in England.

The Validation Team again note that there appears to be an overall paucity of electrophysiological and implantable device procedures in patients with congenital heart disease reported from this centre.

It is important to ensure that **all** relevant information relating to procedures undertaken on patients with congenital heart disease are as robustly recorded as is possible and the reviewers noted again at this validation that some of the surgical procedures were now prefixed GUCH but this did not appear to be consistently used.

**Recommendations**

1. To urgently consider making HeartSuite available in every clinical area to facilitate timely data collection.
2. To expedite the link from the GJNH HeartSuite with RHS at QE University HeartSuite to enable the intervention and operation records of congenital patients who are transitioning and have already transitioned available to all relevant staff.
3. As previously it is recommended that Standard Operating Protocols (SOPs) are regularly reviewed for the congenital data collection, to ensure they include detailed guidance on and exactly **who** is responsible for each of the following;
   1. Ensuring that the consent for external validation of hospital notes clause is obtained prospectively from all patients with congenital heart disease at first contact with GJH
   2. Real time input of the data for each congenital diagnostic and therapeutic procedure at the point of the service delivery
   3. Validity and completeness checking, 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. Ensuring that all clinicians are encouraged to be responsible for their own their data where they are the operating or operative clinician and be involved in the local validation process
   5. Leading the local review (and in which forum for both disciplines)
   6. Making timely submissions of fully validated data (monthly is recommended) and
   7. Monthly reverse validation at GJNH against an acknowledged ‘gold standard’ record of activity and procedures performed.
   8. Reviewing/Updating the SOP at timely intervals
   9. Capturing data on any out of hospital deaths of congenital patients
4. To include the time (as well as date) of extubation on the printed ICU care pathways
5. To ensure the patients primary presenting diagnoses reconciles with the procedure performed.
6. To ensure that endocardial pacemakers that are implanted in the operating room by the cardiologists are submitted in the category ‘Catheter Intervention’ rather than ‘Non Bypass’ to give a more accurate portrayal of catheter type procedures as analysed by NCHDA.
7. To ensure that diagnostic electrophysiological procedures are submitted.
8. To clearly document the exact date of hospital discharge in the narrative notes.
9. To continue to develop training not only for the Cardiac Information Manager, but all staff who may be involved with data management. This should involve visiting other centres who return data to NCHDA and sharing ideas and experience