The National Congenital Heart Disease Audit Database

Data Quality Audit for
CONGENITAL HEART DISEASE

Apr 2019 - Mar 2020

The Golden Jubilee National Hospital, Glasgow

10 November 2020

performed by Lin Denne and Dr K Jensen

Summary

This validation visit, that has reviewed the congenital cardiac data for the year April – March 2019-2020 has been fully funded by NHS Scotland. Validation visits did not take place during 2018 and 2019 due to lack of a data sharing agreement being agreed. The data submission for 2019-2020 had lmost all patient identifiable data removed except gender and CHI number.

This visit was supported remotely by the NCHDA clinical audit nurse via a MS Teams video conference facility and on site in person by Dr K Jensen Consultant Congenital Cardiologist from Newcastle.

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 181 interventional and surgical procedures had been undertaken during the data collection year of April 2019 to March 2020 in patients aged over 16 years.

The Validation Team are grateful to the Clinical Lead for making himself available for whole day and also the Senior Managers for attending the end of day feedback session. The hospital notes were meticulously prepared which was extremely helpful.

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' which is can cause a problem with the correct counting of catheter procedures.

As previously, the domestic hospital wide 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. Congenital users report that CaTHi is extremely difficult and cumbersome for the complex data. The CaTHi system provides a view of the information rather than stores data.

Also, as previously reported, due to the difficulties with using CaTHi for congenital data, 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 and when not working remotely is positioned close to the clinicians and their secretaries.

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.

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.

In addition it appears that the GJH HeartSuite software has not been updated to the latest version and this may impact on how the data are analysed for Specific Procedures and Activity that NCHDA publish annually. The lack of specific coding caused by the out of date software was not allowed to adversely impact on the DQI score.

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 2020. 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 the last Validation Visit in 2017:

- No new actions reported
- Due to the current pandemic status the IM has successfully pivoted from office based to remote working
- During this validation visit the Medical Director and Chief Operating Officer agreed that full patient identifying data should be submitted for this NCHDA registry forthwith.

Consent for External Validation of Congenital Cardiac Patients Hospital Notes.

The Golden Jubilee Hospital has a Data Sharing Agreement with NICOR who host the NCHDA dataset to submit these data.

Data Quality Indicator Scores (DQI)

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

The hospital notes for 20 patients who underwent 21 procedures (10 catheters and 11 operations). There were 802 variables and 12 discrepancies identified.

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%
2020	19-20	98%	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 181 cases (surgery 97, catheters 90, others 0, deaths 4) had been undertaken in the data collection year 2019/2020 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. Due to the absence of identifying data in the NCHDA submission this was a slow process due to constantly having to cross check with the patient names, date of birth and post code.

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. The typed surgical operation notes seen were clear and concise.
5. The anaesthetic form was easy to find
6. The perfusion sheets were seen for almost all surgical patients
7. As previously reported, cardiac catheter sheets were fairly easy to locate. The A5 sticky label completed by the Cath Lab staff with fluroscopy data was seen.
8. 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 previously the entry log of procedures performed, does not record the patient diagnosis and therefore it is not always clear if a patient had congenital heart disease.
2. 4 surgical cases were identified that may be suitable for inclusion in the NCHDA. Three appear to be for surgical electrophysiological procedures.
3. 1 submitted surgical record was not validated in OPERA
4. 4 submitted surgical records appear to have errors in them

Cath labs

CaTHi is the electronic record system used in the cathlab and patient diagnosis is included in this application.

1. 0 catheter records were identified that may be suitable for inclusion in NCHDA
2. 6 submitted catheter records appear to have errors in them.
3. 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.
4. As previously reported, there is no indication in 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.

4 post procedural deaths were submitted in the data from GJH for the year 2019/20. 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. During the validation visit the Reviewers were made aware that there is a check life status of all patients done approximately every 2 months.

1. All dates of death were found to be correct
2. 1 attribution of death may not be correct

Case Note 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		-	-
3	Surname	20	20		-	-
4	First Name	20	20		-	-
5	Sex	19	20	1 incorrect	8/9	11
6	DOB	20	20		9	11
7	Ethnicity	20	20		9	11
8	Patient Status	20	20		9	11
9	Postcode	19	20	1 incorrect	8/9	11
10	Pre Procedure Diagnosis	21	21		10	11
11	Previous Procedures	38	40	1 incorrect, 1 absent	21/22	17/18
12	Patients Weight at Operation	20	21	1 incorrect	9/10	11
13	Height	20	21	1 incorrect	9/10	11
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	21	21		10	11
16	Pre Proc NYHA	21	21		10	11
17	Pre Proc Smoker	21	21		10	11
18	Pre Proc Diabetes	21	21		10	11
19	Hx Pulmonary Dis	21	21		10	11
20	Pre Proc IHD	21	21		10	11
21	Comorbidity Present	20	21	1 incorrect	10	10/11
22	Comorbid Conditions	14	15	1 absent	10	4/5
23	Pre Proc Systemic Ventricular EF	21	21		10	11
24	Pre Proc Sub Pul Ventricular EF	19	20	1 incorrect	10	9/10
25	Pre-proc valve/septal defect/ vessel size	-	-		-	-
26	Consultant	21	21		10	11

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date and time of Procedure	21	21		10	11
28	Proc Urgency	21	21		10	11
29	Unplanned Proc	0	1	1 incorrect	0/1	-
30	Single Operator	2	2		10	11
31	Operator 1	21	21		10	11
32	Operator 1 Grade	21	21		10	11
33	Operator 2	19	19		8	11
34	Operator 2 Grade	19	19		8	11
35	Procedure Type	21	21		10	11
36	Sternotomy Sequence	11	11		-	11
37	Operation Performed	21	21		10	11
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	-	-		-	-
40	Device Manufacturer	12	12		7	5
41	Device Model	13	13		7	6
42	Device Ser No	13	13		7	6
43	Device Size	9	9		5	4
44	Total Bypass Time	8	8		-	8
45	XClamp Time,	7	7		-	7
46	Total Arrest	-	-		-	-
47	Cath Proc Time,	10	10		10	-
48	Cath Fluro Time,	10	10		10	-
49	Cath Fluro Dose,	10	10		10	-

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	11	11		-	11
51	Post Procedure Seizures	21	21		10	11
52	Post Proc Complications	-	-		-	-
53	Date of Discharge	19	21	2 incorrect	9/10	10/11
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	21	21		10	11
57	Discharge Destination	21	21		10	11

Data Quality Indicator Assessment:

The Overall Trust DQI = 98% Cardiology DQI = 98% 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**		
	Overall	**Card**	**Surg**
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	**.98**	.96	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	**.98**	.98	.976
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,**	.997	.99	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.**	.98	.975	.98

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	**2015** **14-15**	**2016** **15-16**	**2017** **16-17**	**2020** **19-20**
Demographics	.99	.99	1.0	.98
Pre Procedure	.86	.80	.98	.98
Procedure	.95	.93	.99	.997
Outcome	.98	.99	.99	.98

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 decreased by just 1% but nevertheless this is an excellent achievement. 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 are however, some continued technical difficulties relating to lack of interface between HeartSuite and the local electronic information systems. This has been further impacted by the insistence that patient identifiable data be stripped from the submission to NCHDA. This directly impacted on the time taken to complete every part of this review as all hospital notes with the full identities were made available to both the external clinician and shared via MS Teams with the clinical audit nurse.

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 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 2020 this is unchanged and has not been actioned.

It is also of concern that HeartSuite was not running the latest software and therefore there is a considerable risk that GJH data may be incorrectly analysed by NCHDA. Data analysis is run in R Code which is open source freeware and is available to all NHS Trusts. There does not appear to an analyst available to the IM to assist with running in house specific procedures and activity analyses for these NCHDA data. https://digital.nhs.uk/services/data-access-environment-dae/user-guides/using-rstudio-in-the-data-access-environment

This is the eighth annual NCHDA validation visit to GJNH and it is of real concern that there is still no specifically dedicated database that is 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. Congenital colleagues find CaThi cumbersome and time consuming to use for complex congenital heart disease data.

HeartSuite has not been updated to the latest NCHDA dataset for the 19/20 dataset ie the coding for Osaki and PEARS procedures were not present where they should be in up to date software versions.

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.

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 and as a priority, consider making HeartSuite available in every clinical area to facilitate timely data collection.
2. Ensure HeartSuite is updated to very latest dataset version.
3. 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.
4. 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;

    a. 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
    b. Real time input of the data for each congenital diagnostic and therapeutic procedure at the point of the service delivery
    c. 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
    d. 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
    e. Leading the local review (and in which forum for both disciplines)
    f. Making timely submissions of fully validated data (monthly is recommended) and
    g. Monthly reverse validation at GJNH against an acknowledged ‘gold standard’ record of activity and procedures performed.
    h. Reviewing/Updating the SOP at timely intervals
    i. Capturing data on any out of hospital deaths of congenital patients
    j. Providing access to HeartSuite to make timely software updates

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

10. To identify an individual to assist with the running R code analysis software for both Specific Procedures and Activity analyses and STAT score as required by the IM.