The National Congenital Heart Disease Audit Database

Data Quality Audit for CONGENITAL HEART DISEASE

For Apr 2018 – Mar 2019

The Royal Hospital for Children, Queen Elizabeth University Hospital Glasgow

22 August 2019

performed by Lin Denne and Dr O Stumper

Summary

This validation visit, which has reviewed the congenital cardiac data for the years April – March 2018 - 19 has been fully funded by the NHS Scotland.

This visit was supported remotely by the NCHDA clinical audit nurse via a teleconference facility and; on site in person, by Dr O Stumper Consultant in congenital cardiology from Birmingham.

Prior to this congenital data review the data return to the NCHDA from the cardiac department of the Royal Hospital for Children at Queen Elizabeth University Campus Glasgow (RHS) indicated that some 533 procedures (252 surgical operations, 160 catheters, 55 others, 15 deaths), had been undertaken during the data collection year of April 2018 to March 2019 in patients aged 16 years or less.

As previously reported, procedures in patients aged over 16 years are mostly (but not all) undertaken in Glasgow at the Golden Jubilee National Hospital (GJH) and in Edinburgh at The Royal Infirmary. Whilst NCHDA received data from GJH in the past and have undertaken validations at that centre, no data have been received since April 2017 and no data are received from the Edinburgh Royal Infirmary. There is a 1.0WTE position of Information Manager for congenital cardiology based at GJH.

As at all the previous NCHDA visits, there is real time data input by clinicians using Heartsuite at RHS. HeartSuite is available at PCs throughout the congenital cardiac department.

There is a 1.0WTE post for a cardiac information manager at RHS. Since June 2015 it is reported that the role is divided into 2 jobs. There is a permanent 0.8WTE (32 hours per week) Information Manager (DBM) at RHS. The other is a 0.25 WTE role. 1 specific consultant clinician acts at Audit Lead for this data collection.

As previously reported, local validation of the previous weeks cardiology cases was commenced with the relevant clinicians in September 2007 and now takes place at the weekly MDT meetings. Validation of surgical cases takes place weekly with the consultant surgeons.

Actions Undertaken since the 2018 Validation Visit

1. At the time of this validation visit RHS were utilising HeartSuite 7.6.26. This application is suitable for the NCHDA 2018-19 dataset. During July 2019 HeartSuite was updated to 7.9.998
2. The surgical log book and catheter laboratory log book continue to be completed and internally verified regularly.

3. The DBM continues to complete additional data checks prior to upload with improved reverse validation procedures to ensure data quality. The inclusion of the primary key did improve these processes, however, it is reported that this identifier has been removed from some NICOR extracts and this has been difficult and time consuming.

4. RHS report that some code changes have impacted on previous procedures. These are:
   010110. Transposition of great arteries with concordant atrioventricular connections and ventricular septal defect;
   030223. Scimitar syndrome
   040413. Coronary sinus defect in left atrium: unroofed
   060204. Mitral annular hypoplasia
   060705. Atrioventricular septal defect (AVSD) with ventricular imbalance: dominant right ventricle, hypoplastic left ventricle,;
   060727. Atrioventricular septal defect (AVSD) with balanced ventricles
   091521. Unicuspid aortic valve;
   121777. Aortic valvar replacement using autologous pericardium constructed valve leaflets (Ozaki)
   094103. Anomalous origin of left coronary artery from pulmonary artery (ALCAPA)
   123548. Transluminal radiofrequency ablation procedure for arrhythmia;
   161001. Tracheal stenosis

5. RHS report that the field for Previous Procedures on the NCHDA database is limited to 12 values whereas previously this was one comma separated value. RHS comment that the most recent previous procedures are excluded.

6. RHS report that the comorbidity field may be recorded incorrectly this is due to a disparity in the definitions list and the HeartSuite code table.

7. Discussions following the second operator query raised at last year's audit have been resolved. The consultants identified that this information was being recorded to identify the nurse who was in theatre at that time.

8. RHS report that the Surgical complication is not uploading for 158065. Postprocedural prolonged pleural drainage (over 10 days). RHS report that this appears to be have been added as 158064. Prolonged pleural drainage > 7 days. An appropriate comment has been added to RHS data but these are not visible in the reverse download only on the procedure record.

9. The NCHDA Data Manager at RHS is presently working on a leaflet and opt out form with Medical Illustrations to comply with GDPR.

10. RHS have agreed a three monthly meeting for presenting PRAiS.

11. The RHS NCHDA Data Manager is presently 1.0WTE.

Consent for External Validation of Congenital Cardiac Patients Hospital Notes.

Since May 2018, the General Data Protection Regulation (GDPR) required that patients are made aware of how their data collected and used. As such, NCHDA now no longer requires a specific consent to examine hospital case notes. If a patient has expressed a wish not to allow their case notes to be examined by others not connected to their care, these wishes will be respected.

Data Quality Indicator Scores (DQI)

The overall DQI for the hospital is calculated to be (with previous years in parentheses) **99.5%** (99.5, 99.25, 98.5), with domain scores Demographics 1.0 (1.0 1.0 1.0) Pre Procedure .995 (1.0, .99, .98) Procedure .997 (1.0, .98, .96) and Outcome .99 (.98, 1.0, 1.0 .96).

Also, for this visit, a separate DQI calculation is being 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 RHS are:

Year of Visit	Data Years reviewed	Surgery DQI	Catheters DQI
2010	07-08	99%	97%
2011	08-09	95.25%	91.5%
2011	09-10	95.25%	95.5%
2012	10-11	95%	92%
2013(i)	11-12	96%	97%
2013(ii)	12-13	99%	99%
2014	13-14	97.5%	99.5%
2015	14-15	99.5%	96.5%
2016	15-16	98.75%	99.25%
2017	16-17	99.25%	99.75%
2018	17-18	99.5%	100%
2019	18-19	99.75%	99.5%

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 are identified accountable person/people for NCHDA data quality and information validity
Data Submissions are Timely and Accurate.

Introduction

The data return to NCHDA from the cardiac department of the Royal Hospital for Children Glasgow indicated that some 533 procedures (252 surgical operations, 160 catheters, 55 others, 15 deaths), had been undertaken in the data collection year 2018/2019 of which 20 records were selected for review.

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

On the day 20 sets were made available (19 Samples, 1 Reserves) covering 22 procedures, (15 operations and 7 catheters).

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

The Validation Team would again like to thank the Data Manager for the meticulous attention to detail in printing the relevant pages from the ePR during a very challenging period. This was of great assistance to the independent external clinician who was on site. The following observations during the case note audit;

1. The admission summary sheets that were seen were again found to be very helpful
2. The PICU/BADGER reports were generally very helpful and almost always recorded the date of extubation but not the exact time.
3. As previously reported, perfusion sheets were seen for almost all surgical patients.
4. The cardiac catheter sheets were fairly easy to locate and the data required for NCHDA were easy to identify.

5. It was noted that the discharge proforma appear to be prefilled prior to the actual discharge date

Review of the Catheter and Theatre Log Books 2018/2019

As previously reported, bound bespoke log books to record activity in both the cath labs and operating theatres were reinstated 2012 at RHS following a trial without them. The HeartSuite activity log is validated against the hospitals theatre management log OPERA and these books. OPERA is an all in one booking, scheduling and intraoperative data collection system. OPERA was not found to be such a comprehensive and accurate log of procedures as the bound log books and HeartSuite at earlier validation visits.

It was noted on several occasions in the hand written log book that the name of the operation performed did not always appear to accurately describe the actual procedure.

1. 0 surgical procedures were identified that may have been missed from the congenital submission
2. 2 surgical queries were identified in the submitted data.

For the 2018/2019 Cath Lab logbook review,

1. 2 submitted catheter records may have data errors in them

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 diagnosis and procedure coding will also be validated.

It is noted that under the General Data Protection Regulation of May 2018, that the data of deceased patients no longer requires consent for case note review.

15 patients were identified to have died following cardiac procedures during 2018/19. 10 of these deaths are reported to have occurred within 30 days of either a surgical or interventional catheter procedure. These10 case notes were made available for this review.

- All dates of death appear to be correct.
- There appears to be discrepancies on 2 records for complications

Casenote Audit

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

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	22	22		7	15
28	Proc Urgency	22	22		7	15
29	Unplanned Proc	2	2		-	2
30	Single Operator	5	5		5	-
31	Operator 1	22	22		7	15
32	Operator 1 Grade	22	22		7	15
33	Operator 2	17	17		2	15
34	Operator 2 Grade	17	17		2	15
35	Procedure Type	22	22		7	15
36	Sternotomy Sequence	13	13		-	13
37	Operation Performed	22	22		7	15
38	Sizing balloon used for septal defect	0	0		0	-
39	No of stents or coils	1	1		1	-
40	Device Manufacturer	9	9		4	5
41	Device Model	13	13		8	5
42	Device Ser No	12	13	1 incorrect	7/8	5
43	Device Size	12	12		8	4
44	Total Bypass Time	11	11		-	11
45	XClamp Time,	10	10		-	10
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	7	7		7	-
48	Cath Fluro Time,	7	7		7	-
49	Cath Fluro Dose,	7	7		7	-

	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	22	22		7	15
52	Post Proc Complications	1	2	1 unable to validate	1	0/1
53	Date of Discharge	22	22		7	15
54	Date of Death	2	2		-	2
55	Attribution of Death	1	1		-	1
56	Status at Discharge	22	22		7	15
57	Discharge Destination	22	22		7	15

Data Quality Indicator Assessment:

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

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 .995**	
	Card .99	**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** .997	
	Card .99	**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** .99	
	Card 1.0	**Surg** .99

This DQI is based upon the domain scoring below. The methodology for this DQI is provided in the paper The NCHDA – An Introduction to the Process.

Domain	2019 18-19	2018 17-18	2017 16-17	2016 15-16
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.995	1.0	.99	.99
Procedure	.997	1.0	.99	.98
Outcome	.99	.98	.99	1.0

Conclusions

On the whole the NCHDA data was accurate, well documented in the hospital electronic notes, and good quality.

The DQI score has yet again been maintained above 99% which is excellent and demonstrates that there continue to be robust methods and processes for clinical audit data quality maintenance and data collection at RHS. There were just 3 data discrepancies in 783 variables.

The Reviewers would again like to commend the dedication and conscientiousness of the DBM who has worked very many extra hours to ensure that only good quality complete data were submitted for the year 2018/2019. There have been a number of technical challenges with the NCHDA database also during this data collection period.

The bound operating theatre log books, as previously reported, are very well kept, being very neat and a concise record of activity. As previously reported, it was noted that on occasions the name of procedure performed appeared to be taken from the operating list for the day rather than completed at the end of the procedure with the precise description of the operation that had occurred. At times the descriptions of procedures in the cath labs appeared to be a little vague and imprecise.

As reported at the 2018 NCHDA Validation visit, the Validation Team are concerned to report that there still appears to be just a 1.0WTE DBM person in post dedicated to the NCHDA data collection at RHS. It is a recommended national standard, that in line with the New Congenital Heart Disease Review (NHSE July 2015) recommendation B32(L1) that each Specialist Surgical Centre must have a minimum of 1.0 WTE dedicated paediatric cardiac surgery/cardiology data collection manager, with at least 1.0 WTE assistant, responsible for audit and database submissions in accordance with necessary timescales. This is further underpinned by The Report of the Independent Review of Childrens Cardiac Services in Bristol (June 2016 Grey, Kennedy 1.22(2) and Ch17)

It is noted by the Reviewers that although Scotland is not subject to the NHSE Surgical Standards for Congenital Cardiac Surgery (2015), colleagues at RHS and National Services Scotland (NSD) requested a review and feedback on their service from NHSE in July 2019.

Validation of Deceased Patients Diagnostic and Procedure Coding

The congenital data manager at RHS receives data on all cardiac deaths in Scotland on a quarterly report. This enables prompt identification of any out of hospital deaths that may have occurred.

The were two minor discrepancies identified in the data of the deceased patients case note review.

Recommendations (as in 2014-18 and updated in 2019)

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 each of the following;

    a. Ensuring each patient/parent/guardian is given appropriate information in relation to how their data are recorded, stored and who it is share with in line with GDPR 2018.
    b. Input of the data for each diagnostic and therapeutic procedure at which point of the service delivery and it what time frame
    c. Ensuring the diagnosis reconciles with the procedure performed.
    d. Ensuring that radiation dosage is recorded in CG/cm^2
    e. Validity checking, 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
    f. Leading the local review (and how frequently and in which forum for both disciplines)
    g. Monthly running of PRAiS analysis and checking of congenital algorithm analysis
    h. Making timely submissions (monthly is recommended, quarterly is mandatory) and
    i. Timely reverse validation at RHS against an acknowledged 'gold standard' record of activity and procedures performed.
    j. Reviewing/Updating all of the SOPs at timely intervals

2. It is a recommended that in line with the New Congenital Heart Disease Review (NHSE July 2015) recommendation B32(L1) that there should be consideration given to ensuring that a minimum of 1.0 WTE dedicated paediatric cardiac surgery/cardiology data collection manager, with at least 1.0 WTE assistant, responsible for audit and database submissions in accordance with necessary timescales are in post.
3. As previously recommended, consider developing a standard discharge summary style for use throughout the cardiac department. Such a document should logically list all NCHDA pertinent information to that in-patient episode and previous interventions or operations.
4. To continue to develop training not only for the Cardiac Information Managers, 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