The National Congenital Heart Disease Audit Database

Data Quality Audit for CONGENITAL HEART DISEASE

For Apr 2019 – Mar 2020

The Royal Hospital for Children, Queen Elizabeth University Hospital Glasgow

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performed by Lin Denne and Mr M Nassar

Summary

This validation visit, which has reviewed the congenital cardiac data for the years April – March 2019 - 20 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 Mr M Nasser Consultant in congenital cardiac surgery from Newcastle.

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 502 procedures (241 surgical operations, 210 catheters, 49 others, 13 deaths), had been undertaken during the data collection year of April 2019 to March 2020 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.

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.

The standard requirement recommended in the Congenital Heart Disease Review (NHSE May 2016) 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 dedicated assistant, responsible for audit and database submissions in accordance with necessary timescales. This is further underpinned by The Report of the Independent Review of Children's Cardiac Services in Bristol (June 2016 Grey, Kennedy 1.22(2) and Ch17). The recommended banding for this role can be found in the NCHDA Annual Report 2013-16 p25 (Health Quality Improvement Partnership March 2018).

https://www.hqip.org.uk/resource/national-congenital-heart-disease-audit-2013-2016/#.XiHWkojgqt8

1 specific consultant clinician acts at Audit Lead for this data collection at RHS.

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.

The data manager reports that previously completed additional data checks prior to upload is now no longer available due to a change in HeartSuite's table structures this. This additional process improved the reverse validation procedures to ensure data quality.

RHS have also observed that:

- the comorbidity boolean field may be recorded incorrectly this is due to a disparity in the definitions list, HeatSuite and QReg5.
- HeartSuite continues to be unable to create the data transfer table correctly when procedures for a patient happen on the same day. Also, archiving old diagnoses is problematic and often records previous diagnosis when it has been archived.
- The previous procedures are difficult to check as the QReg5 order is different from the uploaded file.

Actions Undertaken since the 2019 Validation Visit:

1. Due to the prevailing pandemic status the DBM has pivoted to remote working with MDT and clinical audit meeting all occurring in an agile forum such as MS Teams audio visual format.
2. The surgical log book and catheter laboratory log book continue to be completed but internal verification has been reduced due to staff shortage and remote working.
3. Additional challenges this year have been the need to adapt quickly to changing circumstances. These range from standard software changes, end of life devices, poor connection speed and reduced logbook and paper internal validation.

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. RHS have a Data Sharing Agreement with NICOR who host NHCDA.

Data Quality Indicator Scores (DQI)

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

This is an excellent score. 20 patients procedures were reviewed for the period April – March 2019/20. These patients had undergone 28 procedures, 19 operations and 9 catheter procedures. There were 999 variables reviewed and 4 errors or discrepancies were identified.

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
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%
2020	19-20	99.25%	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 502 procedures (241 surgical operations, 210 catheters, 49 others, 13 deaths), had been undertaken during the data collection year of April 2019 to March 2020 in patients aged 16 years or less. 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 (17 Samples, 3 Reserves) covering 28 procedures, (19 operations and 9 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 were made 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 2019/2020

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.
3. 5 records in the submission were not validated with the log books

For the 2019/2020 Cath Lab logbook review,

1. 0 surgical procedures were identified that may have been missed from the congenital submission

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.

14 patients were identified to have died following cardiac procedures during 2019/20. 7 of these deaths are reported to have occurred within 30 days of either a surgical or interventional catheter procedure. These 7 case notes were made available for this review.

- All dates of death appear to be correct.
- 3 records may have discrepancies in the comorbidities field
- There appears to be discrepancies 3 records in the complications field

Although not part of the PRAiS analysis the Validation Team also check the field for Attribution of Death. 1 record may need further review and discussion in relation to this field.

The DBM receives regular updates of any patient aged less than 25 years who dies post discharge.

Casenote Audit

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		7	13
2	NHS Number	20	20		7	13
3	Surname	20	20		7	13
4	First Name	20	20		7	13
5	Sex	20	20		7	13
6	DOB	20	20		7	13
7	Ethnicity	20	20		7	13
8	Patient Status	20	20		7	13
9	Postcode	20	20		7	13
10	Pre Procedure Diagnosis	27	28	1 incomplete	8/9	19
11	Previous Procedures	74	74		21	53
12	Patients Weight at Operation	28	28		9	19
13	Height	27	27		9	18
14	Ante Natal Diagnosis	4	4		-	4
15	Pre Proc Seizures	27	28	1 incorrect	9	18/19
16	Pre Proc NYHA	-	-		-	-
17	Pre Proc Smoker	-	-		-	-
18	Pre Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre Proc IHD	-	-		-	-
21	Comorbidity Present	28	28		9	1
22	Comorbid Conditions	48	48		10	38
23	Pre Proc Systemic Ventricular EF	28	28		9	19
24	Pre Proc Sub Pul Ventricular EF	25	25		9	16
25	Pre-proc valve/septal defect/ vessel size	3	3		3	-
26	Consultant	28	28		9	16

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	28	28		9	19
28	Proc Urgency	28	28		9	19
29	Unplanned Proc	2	2		-	2
30	Single Operator	27	28	1 incorrect	8/9	19
31	Operator 1	28	28		9	19
32	Operator 1 Grade	28	28		9	19
33	Operator 2	25	25		6	19
34	Operator 2 Grade	25	25		6	19
35	Procedure Type	28	28		9	17
36	Sternotomy Sequence	17	17		-	19
37	Operation Performed	28	28		9	19
38	Sizing balloon used for septal defect	0	0		-	-
39	No of stents or coils	3	3		3	-
40	Device Manufacturer	12	12		7	6
41	Device Model	14	14		7	7
42	Device Ser No	14	14		7	7
43	Device Size	13	13		7	6
44	Total Bypass Time	12	12		-	12
45	XClamp Time,	9	9		-	9
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	9	9		9	-
48	Cath Fluro Time,	9	9		9	-
49	Cath Fluro Dose,	9	9		9	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	13	13		-	13
51	Post Procedure Seizures	0	0		-	-
52	Post Proc Complications	4	4		2	2
53	Date of Discharge	28	28		9	19
54	Date of Death	1	1		-	1
55	Attribution of Death	1	1		-	1
56	Status at Discharge	28	28		9	19
57	Discharge Destination	27	28	1 incorrect	9	18/19

Data Quality Indicator Assessment:

The Overall Trust DQI = 99% Cardiology DQI = 99.5% Surgery DQI = 99.25%

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 .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** .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** .98

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	2020 19-20	2019 18-19	2018 17-18	2017 16-17
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.99	.995	1.0	.99
Procedure	.997	.997	1.0	.99
Outcome	.99	.99	.98	.99

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 at 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 4 data discrepancies in 999 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 2019/2020. There have been a number of technical and practical challenges during this pandemic through this data collection period, not all of them yet resolved. It also appears that there is no analytic support identified to the DBM to run the R Code software for the Specific Procedures and Activity algorithms used by NCHDA. R Code is freeware and supported by the NHS. It is a specialist analytical programme that requires appropriate knowledge and expertise.

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 and 2019 NCHDA Validation visit, the Validation Team are concerned to report that there still appears to be just a 1.0WTE DBM post dedicated to the NCHDA data collection at RHS. As stated at the beginning of this report, 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 (2016), colleagues at RHS and National Services Scotland (NSD) opted to participate in the initial Review in 2015 and again sought feedback on their service from NHSE Panel in July 2019.

Validation of Deceased Patients Diagnostic and Procedure Coding

As reported above, there were just 6 discrepancies noted.

Recommendations (as in 2014-19 and updated in 2020)

1. 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.

2. 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

3. It is recommended that an R code experienced analytic individual be identified to assist the DBM with running ad hoc analysis algorithms for Specific Procedures and Activity.
4. 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.
5. 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