The National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit for April 2018 – March 2019

University Hospitals Birmingham NHS Foundation Trust

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Summary

Prior to this validation visit the combined Congenital NICOR data return from the Queen Elizabeth Medical Centre (UHB FT) indicated that some 148 (surgery 50, catheter 34, others 64, Deaths 4) procedures had been undertaken during the data collection year of 2018/2019 on adults with congenital heart disease.

This validation visit has been fully funded by UHB NHS Foundation Trust. The external clinician assisting was a Consultant Congenital Cardiologist from Liverpool. The NHCDA Clinical Auditor was also present on site for this validation visit.

20 sets of case notes are randomly selected from the submission from QEB.

This is the 15th successive external validation visit to UHB. As previously reported, the HeartSuite cardiac information is fully available at UHB but only appeared to be used to review congenital cardiac surgical data. No congenital data have been input to HeartSuite on the QEB site historically. The data for therapeutic interventional cardiology and congenital surgical procedures are input directly to the NCHDA web application at QEB. The Queen Elizabeth Hospital Birmingham (UHB/QEB) are a designated NHS England NHS Global Digital Exemplar. In August 2017 the electronic patient record system Oceano was launched.

It was reported that immediately prior to this visit that QEB have agreed to fully commission HeartSuite in all locations where ACHD patients are seen to allow the contemporaneous capture all data points within the NCHDA dataset.

Since February 2013, there have been a number of individuals in post in a part time capacity (0.2WTE) attempting to manage these data. Since mid 2016, there had been a 1.0WTE dedicated individual to this data registry who also supported other functions such as NHSE CQiNs dashboard completion etc. This individual left the post in November 2018.

QEB had been without a NCHDA Database Manager (DBM) of any sort for over 6 months of the 2018/19 data collection year. It was reported that immediately prior to this visit in 2019 that a 1.0WTE dedicated role had been approved and a part time incumbent that had been appointed in June 2019 had been successfully appointed into the whole time role. That DBM had been involved in the organising for this validation visit and involved in much of the capture of missed cases and data from earlier in the year during the part time role.

Of the 4 consultant cardiologists for adults with congenital heart disease at UHB, 2 undertake interventional procedures.

There is very clear guidance on standards for data management in both paediatric and adult congenital surgical centres. Each Specialist ACHD Surgical Centre must have a dedicated congenital cardiac surgery/cardiology data collection manager, responsible for audit and database submissions in accordance with necessary timescales. (B33 L1 NHSE July 2015). QEB was peer reviewed against these standards in June 2019.

Actions taken in response to the Recommendations at the 2018 Validation Visit:

1. The is now a 1.0WTE DBM in post
2. This DBM has attended 2 other external validation visits as part of a role induction process
3. HeartSuite information system is to be made available at every point of service delivery to enable contemporaneous data collection.

Consent for External Validation of Notes.

Since May 2018, the General Data Protection Regulation 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 but others not connected to their care, these wishes will be respected.

Data Quality Indicator

The DQI for UHB/QEB is **87.25%** (95.5, 92.5, 75). The Domain scores are; Demographics .96 (1.0, .92 .99), Pre Procedure . 85 (.87, .56 .76), Procedure .84 (.96, .74 .975), Outcome .84 (.87 .79 .44 .54).

122 discrepancies were identified in 921 variables.

Differential DQI for Surgery and Catheters

As well as the overall DQI for each centre, DQI scores for surgery and catheters are being calculated. The scores are;

	Data Year Reviewed	Surgery	Catheters
2009	2007/08	80.75%	98.75%
2010	2009/09	Insufficient sample	92.5%
2011	2009/10	Insufficient sample	88.25%
2012	2010/11	87% (4 records)	100% (1 record)
2013	2011/12	Insufficient sample	Insufficient sample
2014(i)	2012/13	90%	89%
2014(ii)	2013/14	82.25%	79.95%
2015	2014/15	77%	87.5%
2016	2015/16	66.75%	89.75%
2017	2016/17	89.75%	95.5%
2018	2017/18	94.5%	79.%%
2019	2018/19	87.0%	89.25%

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. This confirmed that there are some good processes and procedures in place in regard to Data Security and Management but further consideration is required to confer validity and quality assurance of data and training in Data Management. The NHS Information Governance Training programme is used in the Trust.

There is or are identified accountable person/people for NCHDA data quality and information validity. Data Submissions are not always accurate.

Introduction

Queen Elizabeth Medical Centre (UHB FT) indicated that some 148 (surgery 50, catheter 34, others 64, Deaths 4) procedures had been undertaken during the data collection year of 2018/2019 on adults with congenital heart disease.

These 20 sets of case notes represented 15 surgeries and 6 catheter procedures. No records were used from the Reserve list.

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

Review of the case notes at UHB

This centre are moving to an electronic patient record (ePR) and where paper records were not available, some were reproduced on the request of the Validation Team from the EPR or made available on a computer screen. There were some files of paper hospital case notes were they were not complete as some documentation is always now stored digitally.

1. As reported at previous validations, there did not appear to be perfusion records filed in the case notes of the surgical patients that were reviewed. These are scanned to the ePR almost immediately after surgery.
2. As previously reported patients weights were sometimes difficult to find as the field for this data did not appear to be routinely completed on anaesthetic sheets.
3. As previously reported, operation notes did not always appear to include the name and grade of the second operator
4. It was not always clear what the NYHA status was of every patient and this is a required field for NCHDA.
5. Recording of the exact day and time of extubation was not always clear in the paper notes or the ePR
6. Echo reports to assess ventricular function while available digitally were not always easy to locate.
7. The patient administration admission sheet did not always appear to be fully completed and as it is a carbon copy that is kept in the paper notes it was also sometime extremely difficult to read.

Review of the Cath Lab Log Books at UHB

At UHB, the separately kept congenital catheter log books that are kept in addition to a bound ledger were made available. The congenital catheter books are bespoke printed and spiral bound A4 books that are neatly kept.

It was reported to the Reviewers at the start of this part of the validation that a part of these volumes was missing, its location unknown. It was also apparent that the binding of one portion was missing and the remaining loose sheets were held together by a paper clip. The Reviewers found it difficult to ascertain whether or not pages were missing or lost from this bundle.

It was also reported that the formal bound log book for April to early September 2018 was missing, its location unknown.

1. 50 catheter records were identified that may be suitable for inclusion in NCHDA
2. 27 submitted records were not validated in the log books
3. 18 submitted catheter records appears to have an error or missing data
4. 1 submitted catheter record does not appear to be for congenital heart disease and if not should be removed.

It is again reported that no cath diagnostic/therapeutic electrophysiological procedures in patients with congenital heart disease have been submitted to NCHDA. It should be borne in mind that the following electrophysiological procedures are now among the NCHDA Specific Procedures that are analysed and published annually. In addition, NHSE require details of all activity on quarterly dashboards and if these data are missing, accurate activity analysis cannot be provided;-

Radiofrequency ablation for tachyarrthmias
Implantable cardioverter/defibrillator
Pacemaker implant
Biventricular pacing and CRT

Review of the Theatre Log Books at UHB

As from 2011 a new theatre suite at UHB became operational containing some 15 operating rooms. 3 of these are cardiac operating theatres. The log books for three of these theatres were offered for review, theatres 6,7 and 9.

As previously noted and unchanged in 2019, the Validation Team are aware that the Galaxy surgery information system is used in the operating theatres. If ICD 10 and OPCS codes are activated in this application, reports can be generated to identify all congenital cardiac procedures.

1. As previously reported, the standard of handwriting was sometimes quite variable and it was not always clear exactly what operation had been performed or if the patient had congenital heart disease.
2. 16 submitted records appear to have errors in them
3. 3 submitted records do not appear to be NCHDA collectable procedures and if not should be removed
4. There were no heart transplant procedures submitted for ACHD patients and these should be submitted to NCHDA if they occur.
5. 45 surgical cases were identified in the log books that may be suitable for inclusion in NCHDA.

6. There were no procedures submitted for the months of August and September 2018 but ACHD operations were recorded in the log books

Validation of Deceased Patients Diagnostic and Procedure Coding

This commenced with the validation of the 2014/15 data. The NCHDA 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. The requirement for patient/parent/guardian consent to review the case notes is the same as for the congenital procedures review.

It is strongly recommended that if information regarding a date of death for a pre-existing congenital patient on the NCHDA database post discharge is, or becomes available this should be submitted to that individual's record in the NCHDA registry. However, this piece of information, once submitted to the NCHDA database is not always easily visible when the data are exported back to the centre.

4 congenital patients were noted on the data harvested for this visit to have died following a procedure.

The hospital case notes for all 4 patients were made available.

- all dates of death were confirmed
- 2 records had errors in the diagnoses coding
- 2 records had incomplete previous procedures listed
- 1 record had incomplete comorbidity coding
- 1 record had incomplete procedures coding
- 1 record did not have an attribution of death field completed

Casenote Audit

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

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	21	21		6	15
	Proc Urgency	20	21	1 incorrect	5/6	15
29	Unplanned Proc	21	21		6	15
30	Single Operator	1	2	1 incorrect	1	0/1
31	Operator 1	19	21	2 incorrect	5/6	14/15
32	Operator 1 Grade	20	21	1 incorrect	6	14/15
33	Operator 2	17	20	1 incorrect, 2 absent	4/5	13/15
34	Operator 2 Grade	17	20	1 incorrect, 2 absent	5	12/15
35	Procedure Type	19	21	2 incorrect	6	13/15
36	Sternotomy Sequence	13	15	2 absent	-	13/15
37	Operation Performed	20	21	1 incorrect	6	14/15
38	Sizing balloon used for septal defect	1	4	2 incorrect, 1 unable to validate	¼	-
39	No of stents or coils	1	2	1 absent	½	-
40	Device Manufacturer	6	16	10 absent	3/6	7/10
41	Device Model	11	17	6 absent	4/7	7/10
42	Device Ser No	10	17	7 absent	4/7	7/10
43	Device Size	6	16	10 absent	3/6	7/10
44	Total Bypass Time	12	14	2 absent	--	12/14
45	XClamp Time,	12	14	2 absent	-	12/14
46	Total Arrest	-	-		-	-
47	Cath Proc Time,	5	6		5/6	-
48	Cath Fluro Time,	5	6		5/6	-
49	Cath Fluro Dose,	5	6		5/6	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	4	15	4 incorrect, 2 absent, 5 unable to validate	-	4/15
51	Post Procedure Seizures	20	21	1 absent	6	14/15
52	Post Proc Complications	2	6	1 incorrect, 3 absent	-	2/6
54	Date of Discharge	20	21	1 absent	6	14/15
55	Date of Death	1	1		-	1
56	Attribution of Death	1	1		-	1
57	Status at Discharge	21	21		6	15
58	Discharge Destination	21	21		6	15

Data Quality Indicator Assessment:

The Overall Trust DQI = 87.25% Cardiology DQI = 89.25% Surgery DQI = 87%

DOMAIN	DOMAIN Score	
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	**Overall .96**	
	Card .96	**Surg** .95
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 .85**	
	Card .82	**Surg** .86
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 .84**	
	Card .79	**Surg** .87
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .84	
	Card 1.0	**Surg** .795

The DQI for UHB Foundation Trust congenital cardiology is based upon the domain scoring below. The methodology for this DQI is provided in the paper The NICOR Audit – An Introduction to the Process.

DOMAIN.	Score 2019	Score 2018	Score 2017	Score 2016
Demographics	.96	1.0	1.0	.92
Pre Procedure	.85	.90	.87	.56
Procedure	.84	.84	.96	.74
Outcome	.84	.84	.87	.79

Conclusions

On the whole the submitted NCHDA data were accurate, well documented, good quality and were appropriately recorded in the Theatre and Cath Lab log books that were seen. The DQI has fallen by 7.25% since the 2018 NCHDA Validation visit. This should be seen in the context of no specific, dedicated data manager for NCHDA being in post for over 6 months of this data collection year. This demonstrates how critical this role is with congenital heart disease. The Reviewers congratulate the new DBM in grasping some of the complexities of this specialty so quickly and also recognise that several colleagues have been extremely supportive in ensuring this role is recruited.

The Reviewers would also like to thank the Deputy Director of Operations for making the time to meet with them during the validation visit.

There are still a few concerns. It appears that there is no regular reverse validation of the congenital data with the responsible clinicians. Details on all implanted devices and valves are required, as well as more data on ACHD comorbidities. Many of the NCHDA data fields are now included in the congenital cardiac NHS Commissioning for Quality and Innovation (CQINs) dashboard. Each congenital centres' Data Quality Indicator Score (DQI) is also included in the quarterly dashboard. The reviewers are also aware that the HeartSuite cardiac information is available at UHB and many of the ACHD patients transition from the adjacent paediatric service at Birmingham Childrens Hospital. However while the paediatric records are visible there has until now, been no ability to add continuing information on clinical interventions.

The Reviewers note that on occasions documentation on paper notes did not always appear to be completed with dates of entries apparently absent, and heights being recorded as surface areas. Also the names and status of second operators appeared to be absent at times. Details of dates and times of extubation were also difficult to find confirmatory documentation on.

There appeared to be no heart transplant procedures in patients with congenital heart disease reported from this centre for the year 2018/2019.

Validation of Case Notes of Deceased Patients.

There were a number of discrepancies identified as documented elsewhere in this report.

Recommendations

1. It is recommended as an immediate priority consideration, a cardiac information system that can accommodate all of the NCHDA dataset items should be identified and used to collect, validate and submit these data.
2. 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;
   a) Ensuring each patient/parent/guardian is given appropriate information in relation to how their data are recorded, stored and who it is shared with in line with GDPR 2018.
   b) Input of congenital patients NCHDA required dataset items and at which point of service delivery
   c) Encouraging every responsible clinician or allied professional to input complete data for each operation, diagnostic or catheter intervention at the point of the service delivery from admission to discharge and to own their data.
   d) Recording the knife to skin time for all surgical procedures where it can be validated (ie perfusion or anaesthetic record).
   e) 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
   f) Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data/Audit Managers at least monthly.
   g) Running the PRAiS (Paediatric Risk Analysis in Surgery) analysis tool monthly. This will inform the quarterly NHSE Dashboard reports.
   h) Ensuring that dates of death are reported for any QEB patient who has previously had a record submitted to the NCHDA
   i) Leading the local review (and how frequently and in which forum for both disciplines)
   j) Making timely submissions (monthly is recommended where possible) and
   k) Including details of manufacturer, model and serial numbers of all implantable devices the procedure record for each patient.
   l) Reviewing/Updating the SOP at timely intervals

3. It is recommended that all Congenital Audit or Data Managers visit other congenital centres at least once annually to experience a validation from the external reviewers perspective, network with a colleague(s), trouble shoot and problem share.
4. Involve all clinically relevant staff in a review of audit data collection, review and quality initiatives