The National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit for April 2020 to March 2021

Birmingham Children's Hospital NHS Foundation Trust

20 July 2021

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Summary

Prior to this validation visit the Congenital NICOR data return from the Birmingham Children's Hospital NHS Foundation Trust (BCH) indicated that some 793 (surgery 386, catheter 372, others 35, [deaths 9 within 30 days]) procedures had been undertaken during the data collection year of 2020/2021 on children with congenital heart disease. This represents a drop in procedural activity of approximately 20% during the first SARS-COV-2 pandemic year.

20 sets of hospital case notes are randomly selected from the BCH submission (the Sample) with a further 10 randomly selected as reserves. 5 case notes were used from the reserve list to replace those unavailable in the sample. A combined total of 25 procedures were reviewed, 12 catheters and 14 operations.

The HeartSuite information system continues to be used at Birmingham Children's Hospital to collect and manage all congenital cardiac data.

This validation visit has been fully funded by the Birmingham Women's and Children's NHS Foundation NHS Trust. This visit was supported remotely by the NCHDA clinical audit nurse via a Zoom and MS Teams video conference facility and on site in person by Dr G Derrick Consultant Congenital Cardiologist from London.

BCH Overview

There is an overall Cardiac Information Manager at BCH. The current IM was appointed in November 2020. There has been a 1.0WTE audit facilitator post for congenital heart disease at BCH since October 2010 and at the time of this visit this post was vacant and in the process of recruitment. There is a further 1.0WTE post within the cardiac information department that provides support for a number of audits and registries as well as NCHDA. BCH also have a Research Nurse part time (just under 0.5WTE per week) who assists in this Audit.

Actions taken since the 2020 Validation Visit

1. A new individual has been appointed as the Cardiac Information Manager.
2. Refresher training has taken place for Cardiac Interventionists and Registrars, highlighting key fields that are sometimes missed in order to try and eliminate any absent data
3. Standard Operating Protocol's have been updated to support timely collection of good quality accurate data.
4. The Surgery logbook has been amended to try and eliminate any missing data from key fields.

Data Quality Indicator

The individual DQI score for BCH is **99.5%** (99, 99, 99.5,) The domain scores are; Demographics 1. 0(1.0, 1.0, 1.0), Pre Procedure .98 (.985, .97, .99), Procedure 1.0 (1.0, .997, .997), and Outcome 1.0 (.97, 1.0, .98). There were 4 data discrepancies identified in 858 variables.

This represents another excellent DQI score.

Separate DQI for Surgery and Catheters

Since the 2009 cycle of visits commenced, as well as the overall DQI for each centre, the DQI for surgery and catheters is being calculated. It is recommended that a minimum number of 5 procedures in either group are required for the differential DQI calculation.

DQI	Data Year Reviewed	Surgery	Catheters
2012	2010-11	94.5%	98.75%
2013	2011-12	95.75%	94.25%
2014(i)	2012-13	98%	98%
2014(ii)	2013-14	96.75%	97%
2015	2014-15	98.5%	98%
2016	2015-16	98.75%	96.75%
2017	2016-17	100%	99.5%
2018	2017-18	98.75%	99%
2019	2018-19	99.5%	98.5%
2020	2019-20	99%	99%
2021	2020-21	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 is or are identified accountable person/people for NCHDA data quality and information validity
Data Submissions are Timely and Accurate.

Introduction

The NCHDA data return, prior to checking the theatre and catheter lab log books, indicated that the combined cardiac departments of the Birmingham Children's Hospital have undertaken some 793 (surgery 386, catheter 372, others 35, [deaths 9 within 30 days]) procedures had been undertaken during the data collection year of 2020/2021 on children with congenital heart disease.

The Information Manager in collaboration with colleagues completed the pre visit self assessment questionnaire at BCH.

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

Review of notes

1. The notes had again been meticulously prepared by the Congenital Audit Team
2. The relevant clinical records were highlighted in the case notes and therefore very easy to find
3. The NHS number was always easily available on the individual patients labels.
4. As previously reported, documentation of ventricular function was sometimes difficult to find and it was noted that a variety of adjectives were sometimes used to describe the findings instead of approximate percentage of performance.
5. 1 surgical patient who was noted to have had two procedures 36 hours apart, had both operation reports written on the same sheet of paper.

Review of Log Books for Operating Rooms and Cardiac Catheter

Paper log books have not been kept at BCH for over a decade and have been replaced by Operating Room Information System (ORMIS) in both the cath labs and operating theatres. A spreadsheet of all cases ordered by date for the period under review was provided on a screen for the visiting clinician to review.

The findings were:

1. 0 records were identified that may be suitable for inclusion in NCHDA
2. 1 surgical record may not be for a procedure that is included in NCHDA
3. 1 submitted surgical record may have an error it
4. 1 submitted catheter record may need be changed to procedure type 'Hybrid'
5. 2 submitted catheter records may have errors in them

Validation of Dates of Death and Procedure Coding of Deceased Patients

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.

BCH identify out of hospital deaths either from the local information system as its updated and/or from running regular queries on the NHSE Strategic Tracking System. For non NHS patients or patients from Scotland or N Ireland, the Information Team liaise with those colleagues as required.

9 deceased patients were identified in the data return for 2020-21 who had died within 30 days of their therapeutic procedure. The PRAiS sensitive fields were reviewed for each of the patients and the findings were:

- 1 patient may have an incorrect procedure code
- 1 patient may have an incorrect date of death

Casenote 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		9	11
3	Surname	20	20		9	11
4	First Name	20	20		9	11
5	Sex	20	20		9	11
6	DOB	20	20		9	11
7	Ethnicity	20	20		9	11
8	Patient Status	20	20		9	11
9	Postcode	20	20		9	11
10	Pre Procedure Diagnosis	25	25	1 incomplete	11	14
11	Previous Procedures	33	33		16	17
12	Patients Weight at Operation	25	25		11	14
13	Height	23	23		11	12
14	Ante Natal Diagnosis	3	3		1	2
15	Pre Proc Seizures	25	25		11	14
16	Pre Proc NYHA	-	-		-	-
17	Pre Proc Smoker	-	-		-	-
18	Pre Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre Proc IHD	-	-		-	-
21	Comorbidity Present	25	25		11	14
22	Comorbid Conditions	28	29	1 absent	6	22/23
23	Pre Proc Systemic Ventricular EF	25	25		11	14
24	Pre Proc Sub Pul Ventricular EF	26	26		11	13
25	Pre-proc valve/septal defect/ vessel size	1	3	1 unable to validate, 1 incorrect	1/3	-
26	Consultant	25	25		11	14

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time start	25	25		11	14
28	Proc Urgency	25	25		11	14
29	Unplanned Proc	2	2		-	2
30	Single Operator	3	3		11	1
31	Operator 1	25	25		11	14
32	Operator 1 Grade	25	25		9	14
33	Operator 2	22	22		9	13
34	Operator 2 Grade	22	22		11	13
35	Procedure Type	25	25		11	14
36	Sternotomy Sequence	11	11		-	11
37	Operation Performed	25	25	2 incomplete	11	14
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils				2	-
40	Device Manufacturer	8	8		7	1
41	Device Model	8	8		7	1
42	Device Ser No	8	8		7	1
43	Device Size	7	7		7	-
44	Total Bypass Time	10	10		-	10
45	XClamp Time,	10	10		-	10
46	Total Arrest	3	3		-	3
47	Cath Proc Time,	11	11		11	-
48	Cath Fluro Time,	11	11		11	-
49	Cath Fluro Dose,	11	11		11	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	10	10		-	10
51	Post Procedure Seizures	25	25		11	14
52	Post Proc Complications	5	5		1	4
53	Date of Discharge	25	25		11	14
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	25	25		11	14
57	Discharge Destination	25	25		11	14

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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 .98**	
	Card .98	**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 1.0**	
	Card 1.0	**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** 1.0	
	Card 1.0	**Surg** 1.0

DOMAIN.	Score 2021	Score 2020	Score 2019	Score 2018
Demographic	1.0	1.0	1.0	.99
Pre Procedure	.98	.985	.97	.99
Procedure	1.0	1.0	.997	1.0
Outcome	1.0	.97	1.0	1.0

Conclusions

On the whole the NCHDA data were of very good quality. The Data Quality Indicator (DQI) has remained at 99.5% and this is another excellent score. This also further demonstrates that there are robust processes in place to ensure good quality data standards are maintained.

It is very clear that BCH NHS Trust consider the matter of collecting good quality, accurate and validated information about patient procedural activity to be of the highest importance and this has become embedded within the culture in the Cardiac Department. There were just 4 discrepancies in 858 variables. The Validation Team would particularly like to recognise the level of conscientiousness displayed by the Cardiac Information Manager and colleagues in preparing the hospital notes and various printed sheets so meticulously. This is a very large task to perform in particular when there is no assistant data manager currently in post to support these tasks.

It is reported that clinicians input much of the NCHDA data to HeartSuite in the first instance. However it is not always clear that colleagues are always involved in reverse validating their own data.

As previously reported, the standard and accuracy of the information recorded in ORMIS for surgery appears to continue to improve since the 2014 visit, however it is still a little poor in places for the catheter procedures. It was a little difficult at times to clearly identify exactly what catheter procedure had actually been performed in some of the entries.

Within the review of the deceased patients data there were 2 queries raised.

BCH have confirmed that all inconsistencies raised at this visit have been internally reviewed and amended where appropriate.

Recommendations

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. It is recommended that Standard Operating Protocols for the data collection, to include detailed guidance on and exactly who is responsible for each of the following be regularly reviewed to ensure they fit the correct purpose. IE;
    i. 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.
    ii. Input of congenital patients NCHDA required dataset items and at which point of service delivery
    iii. 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.
    iv. Recording the knife to skin time for all surgical procedures where it can be validated (ie perfusion or anaesthetic record).
    v. 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
    vi. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data/Audit Managers at least monthly.
    vii. Running the PRAiS (Paediatric Risk Analysis in Surgery) analysis tool monthly. This will inform the quarterly NHSE Dashboard reports.
    viii. Ensuring that dates of death are reported for any BCH patient who has previously had a record submitted to the NCHDA
    ix. Leading the local review (and how frequently and in which forum for both disciplines)
    x. Making timely submissions (monthly is recommended where possible) and
    xi. Including details of manufacturer, model and serial numbers of all implantable devices the procedure record for each patient.

3. In liaison with the person responsible for staff training and development in the Trust, regular training should be provided not only for the NCHDA Data Managers, but for all staff in the Department who may be involved with data input and validation. This should include regular Quality Assurance and Governance training and visits to other centres who are involved in NCHDA data collection and submission.
4. As previously recommended, to 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. All trainees (ST6 and above) should be encouraged to volunteer to participate in a NCHDA site validation visit as an external colleague to gain insights to the importance of maintaining good standards in data collection and quality management.