The National Congenital Heart Disease Audit

Procedures for
CONGENITAL HEART DISEASE,
April 2018 – March 2019

Data Quality Audit

The Newcastle Upon Tyne Teaching Hospitals NHS Foundation Trust.

31 July 2019

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Summary

The NCHDA data return from the cardiac department of the Freeman Hospital for the data collection year 2018/19 extracted on 12 July 2019, indicated that 901 procedures (345 surgery, 455, catheters, 101 others, 15 deaths) had been undertaken in patients with congenital heart disease. Under the usual protocol for a NCHDA validation visit, these data would have been harvested 4 weeks prior to the review date. Due to time constraints at FRE, and at their request this harvest was deferred for 10 days to allow a last minute internal data quality checks to be completed.

This validation visit has been fully funded by Newcastle upon Tyne University Hospitals NHS Foundation Trust.

As previously reported, there is a Cardiothoracic Services Information Manager post at this Trust whose remit covers all 6 of the NICOR data collections. There are a further 6 other members of the Cardiac Information Team at FRE covering 6.0WTEs. There is just 1.0WTE individual dedicated to the NCHDA collection.

Data are entered into a Dendrite Intellect system at various points of service throughout the hospital, ie operating theatres, cath labs etc. When checked for accuracy, completeness and validity these data are submitted to the NCHDA database.

Actions Reported since previous validation visit in 2018:

None reported at this visit.

Data Quality Indicator (DQI)

The DQI for the Trust is calculated to be (with previous years in parentheses) **99%** (98.75, .99, 97.5%) with domain scores Demographics 1.0 (1.0, 1.0 1.0) Pre Procedure .985 (.96, .97, 97) Procedure .99 (.99, .995, .93) and Outcome .99 (1.0, .99, 1.0 .96).

The calculation is based on the validation of 20 patients hospital notes who underwent 22 procedures. (10 therapeutic catheter procedures and 12 surgical operations). There were 7 discrepancies in 869 variables

Separate DQI for Surgery and for Catheters

On further review of the DQI when the cases were split into their surgery and catheter groups and the scores were;

Year	Data Year Validated	Surgery	Caths
2009	07/08	96%	94.25%
2010	08/09	97.50%	97.25%
2011	09/10	96.75%	93.25%
2012	10/11	97.75%	95.60%
2013	11/12	97%	99%
2014	13/14	97.25%	95.50%
2015	14/15	97.25%	97%
2016	15/16	98.5%	97%
2017	16/17	98.25%	99%
2018	17/18	99.75%	98.25%
2019	18/19	99%	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

Consent for External Validation of 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 but others not connected to their care, these wishes will be respected.

Prior to the visit a file with 20 case notes (the Sample) and 10 Reserves was sent to the cardiothoracic information manager. 20 sets of notes (13 Samples, 7 Reserves) were available on the day all of which had the necessary consent for external validation

Introduction

As stated above, the NCHDA data return from the cardiac department of the Freeman Hospital for the year 2018/19 and harvested for this visit on 12 July, indicated that 901 procedures had been undertaken in patients with congenital heart disease.

The Congenital Data Auditor for the NCHDA undertook the visit remotely via a Starleaf connection with an external Consultant Congenital Cardiac Surgeon on site in person.

As stated above, 20 sets of notes were requested. The accuracy of the NCHDA data return was then checked against each set of notes. The Specific Procedures algorithm grouping is also validated for the case notes seen.

FRE are in the process of going paper-lite. Some documents were viewed on the electronic patient record or had been printed and added to the hospital paper bound notes. The paper case notes were often large and bulky.

Review of case notes

1. The case notes, had been meticulously prepared with sticky notes to identify many of the particular pages that the Reviewers needed to validate data.
2. As previously reported, the casenotes were mostly in chronological order but as stated above some were quite wieldy to handle. The assistance of the NCHDA Data Manager on the day was invaluable.
3. As previously reported, it was noted that on some of the typed operation notes that there did not always appear to be a date of the operation or a summary history of previous procedures.
4. The detailed PICU summaries that were seen were again very helpful
5. As previously reported, printed catheter procedure data from Cathcore was seen.
6. It was further noted that on occasions the fluroscopy data for patients who have undergone electrophysiology procedures was not included in the procedure note.
7. It was also noted that the product labels for pacemakers do not always appear to be included in the hospital notes of patients who have these devices implanted
8. As reported in 2014-18, the Trust is in the process of moving to E-records as part of the national strategy and on occasions the Cardiothoracic Information Manager was able to access letters and reports that did not appear to be filed in the case notes.
9. Echocardiography reports were seen in the case notes but did not always detail the percentage of function for each ventricle.

Review of the Cath Lab and Theatre Log Books

Log books from Cath Labs 1,2, and 3 were offered for review.

The cath lab log books are bespoke bound volumes with ruled columns for various pieces of information which are completed by hand. As previously reported, product identifying labels are also adhered to the relevant entry. Sometimes the labels over lay the procedure descriptions. This made it difficult on occasions to identify if a procedure was for congenital heart disease or not or exactly what procedure had actually be performed.

1. 1 record was identified that may have been missed from the submission
2. Approximately 76 catheter procedures were not validated in the log book but this may be because they occurred in the cath labs for which the registers were not reviewed.

Registers from Theatres 1, 2, 3 and 4 were offered for review.

The log books are bespoke bound volumes with ruled columns for various pieces of information which are completed by hand. As reported previously, the legibility of the handwriting for some entries was quite poor, and in some entries there was no description of what procedure had been performed. It was extremely challenging at times to identify whether younger adult patients were having operations for congenital heart disease or acquired or inherited heart disease.

It was also of concern that the operating room staff apparently declined to make the register available for operating room 19 where in the past it has been. A photocopy was offered but this is not an acceptable alternative as pages maybe accidentally missed, not copied in full or be in incomplete for other reasons.

1. 0 records were identified that may have been missed from the submission
2. 68 records were not validated in the log books that were made available for this review

Validation of Deceased Patients Diagnostic and Procedure Coding

Commencing with the validation of the 2013/14 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. The requirement for patient/parent/guardian consent to review the case notes is as stated above. 11 deaths within 30 days of a procedure for congenital heart disease were identified from the submitted data. for 2018-19. The PRAiS sensitive fields were reviewed for each of the patients and the findings were:

1. All dates of death were found to be correct
2. 1 record may have a discrepancy in the Comorbidity field
3. 1 record may have a discrepancy in the Procedure Urgency field

It is reported that the Summary Care Record is checked for NCHDA patient life status on a regular basis but that does not appear to be networking between the NCHDA data manager and the Liaison Nurses who may be aware of other out of hospital deaths outside of England or Wales

Casenote Audit

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
1	Hospital Number	20	20		8	12
2	NHS Number	19	19		7	12
3	Surname	20	20		8	12
4	First Name	20	20		8	12
5	Sex	20	20		8	12
6	DOB	20	20		8	12
7	Ethnicity	20	20		8	12
8	Patient Status	20	20		8	12
9	Postcode	20	20		8	12
10	Pre Procedure Diagnosis	22	22		10	12
11	Previous Procedures	34	34		14	12
12	Patients Weight at Operation	22	22		10	20
13	Height	22	22		10	12
14	Ante Natal Diagnosis	3	3		2	1
15	Pre Proc Seizures	22	22		10	12
16	Pre Proc NYHA	10	10		10	12
17	Pre Proc Smoker	10	10		5	5
18	Pre Proc Diabetes	10	10		5	5
19	Hx Pulmonary Dis	9	10	1 incorrect	4/5	5
20	Pre Proc IHD	10	10		5	5
21	Comorbidity Present	8	9	1 absent	5	¾
22	Comorbid Conditions	8	9	1 absent	5	3/4
23	Pre Proc Systemic Ventricular EF	22	22		10	12
24	Pre Proc Sub Pul Ventricular EF	19	20	1 incorrect	9	10/11
25	Pre-proc valve/septal defect/ vessel size	0	0		--	-
26	Consultant	22	22		10	12

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure	22	22		10	12
28	Time Start	22	22		10	12
29	Proc Urgency	0	0		0	O
30	Unplanned Proc	1	1		1	-
31	Single Operator	22	22		10	12
32	Operator 1	22	22		10	12
33	Operator 1 Grade	21	21		9	12
34	Operator 2	21	21		9	12
35	Procedure Type	11	11		10	12
36	Sternotomy Sequence	22	22		-	11
37	Operation Performed	1	1		10	12
38	Sizing balloon used for septal defect	2	2		1	-
39	No of stents or coils	13	13		2	-
40	Device Manufacturer	13	13		6	7
41	Device Model	13	13		6	7
42	Device Ser No	12	13	1 absent	6	6/7
43	Device Size	10	11	1 absent	5	5/6
44	Total Bypass Time	7	7		-	11
45	XClamp Time,	0	0		-	7
46	Total Arrest	10	10		-	0
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	22	22		10	12
52	Post Proc Complications	3	3		-	3
53	Date of Discharge	21	22	1 incorrect	9/10	12
54	Date of Death	1	1		-	1
55	Attribution of Death	1	1		-	1
56	Status at Discharge	22	22		10	12
57	Discharge Destination	22	22		10	12

Data Quality Indicator Assessment:

The Overall Trust DQI = 99% Cardiology DQI = 99% 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**	
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 .985**	
	Card .99	**Surg** .98
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** .99	
	Card 1.0	**Surg** .987
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 .975	**Surg** 1.0

Data Quality Indicator Assessment by domain:

DOMAIN	2019	2018	2017	2016	2015
Demographics	1.0	1.0	1.0	1.0	1.0
Pre Procedure	.985	.97	.97	.97	.96
Procedure	.99	99	99.5	.93	.97
Outcome	.99	1.0	99	1.0	.96

Conclusions

On the whole the NCHDA data was accurate, well documented, good quality and were appropriately recorded in the Cath Lab and Theatre log books. The hospital case notes for each of the patients included in the Data Quality Indicator (DQI) analysis had been meticulously prepared by the Congenital Data Manager.

Electronic log books are not yet in use at this centre. The DQI continues to be of a very good standard, and demonstrates that the NCHDA data collection and audit processes in place to support it at this centre are working well. It is clear that the Data Manager has invested many extra hours without a nominated assistant outside those contracted, to ensure this.

However, it should be noted that it is a recommended of the New Congenital Heart Disease Review (NHSE May 2016) B32(L1) that each Level 1 Paediatric Specialist Congenital Cardiac Surgery 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. In the same NHSE review for Level 1 ACHD services (B33L1) it is also recommended as a standard that each centre providing these services must also have a dedicated congenital cardiac surgery/cardiology data collection manager, responsible for ACHD audit and database submissions in accordance with necessary timescales.

As previously reported, data entry is now possible at a wider range of locations as each user has their own user ID and password to the information collection system Intellect.

NCHDA acknowledge that the data collection year 2018-19 was again fraught with technical challenges and thank every congenital centre for their patience while problems were resolved.

Some of the detail of implantable devices (manufacturer, model and serial number) was still difficult to find and it is of concern that these details did not always appear to be in included in the patients hospital notes and the congenital data manager does not have access to the database where much of the EP and Pacing data are recorded.

It was also noted that on some occasions that the diagnoses coding used did not always completely reconcile with the procedure performed.

As previously reported, there was also some difficulty in accurately identifying procedures for congenital heart disease in all of the log books seen. Some operating theatre and cathlab log book entries did not record what procedure was performed at all and in other records for young adult patients it was not clear whether or not the procedure being performed was for congenital, acquired or inherited heart disease.

Validation of Deceased Patients Case Notes

As reported above, there were a very small number of discrepancies identified. The Reviewers also became aware that there does not appear to be mechanism for outreach or network nurses to liaise with the DBM in relation to congenital patients who may die following discharge.

Recommendations

1. It is suggested that in line with the New Congenital Heart Disease Review (NHSE May 2016) recommendation B32(L1); further recruitment of a 1.0WTE assistant data manager for paediatric congenital heart disease is considered.
2. Also in line with the ACHD Specialist Surgical Standards (NHSE May 2016, B33L1) it is recommended a dedicated data collection manager, responsible for ACHD audit and database submissions in accordance with necessary timescales
3. The standard operating procedures (SOP) for the NCHDA data collection should be reviewed to ensure that clear guidance is given on exactly how to capture all data on both paediatric and adult congenital cardiac patients in a timely manner. The SOP should clearly set out exactly who is responsible for;
    a. Input of congenital patients NCHDA required dataset items and at which point of service delivery
    b. Encouraging responsible clinician input of the procedure data for each operation, diagnostic or catheter intervention at the point of the service delivery and particularly data that cannot be entered at the time of the procedure, such as intubation time and complications
    c. Recording the knife to skin time for all surgical procedures where it can be validated (ie perfusion or anaesthetic record).
    d. 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
    e. Recording implanted device details on the operation or intervention procedure note.
    f. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data 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 FRE 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) and
    k. Including details of manufacturer, model and serial numbers of all implantable devices with each patient record for a procedure.
    l. Reviewing/Updating the SOP at timely intervals
    m. Liaising with network and outreach clinics in regard to out of hospital deaths of NCHDA patients

4. It is recommended that all NCHDA Data Managers visit another congenital centre on an annual basis to observe processes and practices, share experiences and network.

5. Attendance at the next NCHDA Stakeholders (venue and date tbc) by DBM and lead clinician for congenital heart disease