The National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit For the year 2018/19

Alder Hey Children's NHS Foundation Trust
Foundation Trust

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Summary and Overview

Prior to this Validation Visit, the data return from the Royal Liverpool Children's Hospital Alder Hey (ACH NHS Foundation Trust) indicated that 922 therapeutic cardiac procedures had been undertaken during the 2018/2019 data collection year (surgery 401, catheters 345, others 99, Deaths 22) in patients with congenital heart disease. This validation visit has been fully funded by the Alder Hey Children's NHS Foundation NHS Trust.

The NCHDA Validation Team are grateful to the Service Manager for Cardiothoracic Services at ACH who made time to come and meet them.

Update on actions reported by ACH to have been undertaken since last visit in June 2018:

- The Standard Operating Protocol is reviewed regularly and was updated to include the definitions outlined in the recently published NICOR dataset manual.

- System developments – the Trust Cardiac Audit Team are hoping to collaborate with the Business Intelligence Team to develop a new web based system. This will include dashboards for reporting of demographics data to be linked to the Trust Patient Administration System. This will improve the data quality and release clinical auditors' time to validate the clinical data.

- Theatre/Catheter Log books are now regularly monitored by the Cardiac Audit Team. Results and Validation are then reported to Theatre Management. .

Overview at ACH

As previously reported, data entry is carried out by 2 Auditors who provided a total of 30 hours (2 x 0.4 WTE) per week. The Cardiac Information and Clinical Data Manager (1 WTE) is responsible for supervising the data collection, auditing completeness and accuracy, and submission of data to the NCHDA registry. There is currently no 1.0WTE Assistant Cardiac Information Manager. This is a 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 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). 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

Congenital Data Collection at ACH

As previously reported, from 2003 until approximately 2015, the data at ACH were collected on an electronic proforma in an Access Database; data entry had been carried out by 2 Auditors who received all cardiac notes on discharge, and data input was carried out by these personnel. Basic demographic data was obtained from the ACH Trusts Meditech system that was linked to an Access database designed by a former clinician at the hospital. This system is available to the Cardiac Department. A Cardiac Information Analyst ran ad hoc queries and made the necessary data returns as required. Since the appointment of a Cardiac Data Manager in 2013, internal and external deadlines for data submission were met. From 2015 onwards that has been a development of a fully integrated cardiac information system, Cardicare. A consultant surgeon has responsibility for the surgical data and its quality and works closely with the Audit Team.

Much of the data are now input at the point of service however that have been several technical difficulties that have impacted further developments internally at ACH and with the NCHDA web enabled database. The latter has caused considerable delay in the data submission process for all NCHDA centres.

Consent for External Validation of Notes.

Since May 2018, the General Data Protection Regulation requires that patients are made aware of how their data are 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 individual DQI for ACH (with previous years in parentheses) is **98.5%** (98, 97.5, 95.25). The domain scores are Demographics 1.0 (1.0 1.0 1.0). Pre Procedure .97 (.94, .96, .91). Procedure .98 (.98, .98, .94) and Outcome .99 (1.0, .96, .97 .96)

20 patients procedures were reviewed for the period April – March 2018/19. These patients had undergone 25 procedures, 17 operations and 8 catheter procedures. There were 836 variables reviewed and 14 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 ACH are:

	Data Year Validated	***Surgery***	***Caths***
2009	07/08	96.25%	91.75%
2010	08/09	95.25%	89.25%
2011	09/10	91%	96%
2012	10/11	97.75%	95.5%
2013	11/12	94.25%	96.25%
2014(i)	12/13	96%	92.75%
2014(ii)	13/14	96%	92.25%
2015	14/15	96.5%	98%
2016	15/16	94%	96.25%
2017	16/17	97%	99%
2018	17/18	96.25%	95%
2019	18/19	98.75%	99%

Introduction

Prior to the validation visit, the NCHDA return from Liverpool Royal Children's NHS Foundation Trust indicated that some 922 therapeutic cardiac procedures had been undertaken during the 2018/2019 data collection year (surgery 401, catheters 345, others 99, Deaths 22) in patients with congenital heart disease.

20 sets of case notes were selected for review. A reserve list of 10 cases was also supplied and on the day. No case notes were required from the reserve list at ACH.

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

The NCHDA Congenital Data Auditor and one external Fellow in Congenital Cardiac Surgery undertook the site audit at ACH. The Congenital Auditor supported the visit remotely via Skype.

An electronic proforma continues to be used with the Cardiac Information Analyst monitoring the quality and completeness.

ACH are also moving towards using an electronic patient record system (EPR) and are now 'paper-lite' with most case notes being scanned to a Trustwide archive following patient discharge.

Review of notes at ACH

As at the 2016 validation visit, all procedure case notes reviewed had been prepared in separate A4 folders with much of the relevant documentation tabbed in order to validate the NCHDA data. The original case notes were also made available to facilitate further validation as required. The reviewers found this very helpful.

1. On the whole the files very well laid out but the hospital notes often did not appear to always be in chronological order and in some instances it appeared that the pages might be absent.
2. Documentary echocardiogram reports were very challenging to find.
3. In patients who were aged 16 or over, documentation of the ACHD risk fields, NYHA, diabetes, smoking, pulmonary disease and ischaemic heart disease were appeared to be almost absent.
4. The anaesthetic and operation records were fairly easy to find due to their colour (yellow and pink respectively) in the patients hospital case notes.
5. As noted in previous reports, some anaesthetic records were not dated.
6. As previously reported, most of the surgeons appear to document bypass times on their typed reports. This was compared with the perfusionists record which is the NCHDA recommended standard source for this information. However, it was not always easy to locate the perfusion record and on some occasions this document was not found in the hospital notes of patients who had undergone procedures on cardiopulmonary bypass.
7. The explicit documentation of date and time of extubation was sometimes challenging to find in the hospital notes of surgical patients.
8. Also, as previously reported, occasionally some of the hand written clinical notes were not dated so it was difficult to identify exactly when a patient was discharged.
9. As previously reported, in the submitted records of patients who had undergone implanted device procedures, the description and identity label for these devices did not appear to be included in the daily record entries or the procedure description note.

Log Book Validation for Case Ascertainment

Bound bespoke log books for Apr-Mar 2018/9 were presented for both the cath labs and operating theatres.

From the cath lab log books;

1. 2 procedures were identified in the cath lab log books that may have been missed from the data submission
2. 1 submitted record may to have errors in the coding
3. All submitted catheter procedures were validated in the log books

From the operating theatre log books;

1. 0 procedures were identified in the log books that may have been missed from the data submission
2. 8 submitted records may have errors in them
3. 10 surgical records were not validated in the log books

Validation of Data of Deceased Patients Data Entry in NCHDA

Commencing with the validation of the 2013/14 data, the National Congenital Heart Disease Audit will request to verify any dates of death of deceased patients included in the year under review. The diagnosis and procedure coding along with the Paediatric Risk Adjustment in Surgery (PRAiS) fields will also be validated.

22 patients were noted in the NCHDA data submission to have died during the 2018/19 data collection year. 10 of these patients died within 30 days of a therapeutic procedure. Each record was presented individually, in an A4 folder containing copies of various documents printed from the local electronic patient record system.

The findings were;-

- All dates of death appear to be correct.
- 2 records may have incomplete comorbidities listed
- 3 records may have discrepancies in the complication fields
- 3 records may have incomplete fields for attribution of death

The Congenital NICOR 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

Casenote Audit

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		8	12
2	NHS Number	20	20		8	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	25	25	X 2 absent elements	8	17
11	Previous Procedures	20	21	X 1 absent	7	13/14
12	Patients Weight at Operation	25	25		8	17
13	Height	24	24		8	16
14	Ante Natal Diagnosis	3	3		-	3
15	Pre Proc Seizures	25	25		8	17
16	Pre Proc NYHA	2	2		2	16
17	Pre Proc Smoker	2	2		2	-
18	Pre Proc Diabetes	2	2		2	-
19	Hx Pulmonary Dis	2	2		2	-
20	Pre Proc IHD	2	2		2	-
21	Comorbidity Present	25	25		8	17
22	Comorbid Conditions	40	41	1 incorrect	6	34/35
23	Pre Proc Systemic Ventricular EF	22	25	3 incorrect	6/8	16/17
24	Pre Proc Sub Pul Ventricular EF	22	25	3 incorrect	6/8	16/17
25	Pre-proc valve/septal defect/ vessel size	2	2		2	-
26	Consultant	25	25		8	178

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	25	25		8	17
28	Proc Urgency	24	25	1 incorrect	8	16/17
29	Unplanned Proc	2	2		-	2
30	Single Operator	1	1		1	1
31	Operator 1	24	25	1 incorrect	8	16/17
32	Operator 1 Grade	24	25	1 incorrect	8	16/17
33	Operator 2	23	24	1 incorrect	7	16/17
34	Operator 2 Grade	23	24	1 incorrect	7	16/17
35	Procedure Type	25	25		8	17
36	Sternotomy Sequence	12	12		-	12
37	Operation Performed	25	25		8	17
38	Sizing balloon used for septal defect	0	0		0	-
39	No of stents or coils	0	0		0	-
40	Device Manufacturer	5	5		1	4
41	Device Model	6	6		2	4
42	Device Ser No	6	6		2	4
43	Device Size	3	3		2	1
44	Total Bypass Time	9	9		-	9
45	XClamp Time,	9	9		-	9
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	8	8		8	-
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	14	14		-	14
51	Post Procedure Seizures	25	25		8	17
52	Post Proc Complications	2	3	1 absent	-	2/3
53	Date of Discharge	25	25		8	17
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	25	25		8	17
57	Discharge Destination	25	25		8	17

The Overall Trust DQI = 98.5% Cardiology DQI = 99% Surgery DQI = 98.75%

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 .97**	
	Card .955	**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** .98	
	Card 1.0	**Surg** .97
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

DOMAIN	2019	2018	2017	2016
Demographics,	1.0	1.0	1.0	1.0
Pre Procedure	.97	.94	.96	.91
Procedure	.98	997	.98	.94
Outcome	.99	.99	.96	1.0

Conclusions

On the whole the NCHDA data were accurate and well documented in the theatre and cath lab log books that were seen. The patient information folders for each of the patients included in the Data Quality Indicator (DQI) analysis had been meticulously prepared by the Clinical Information and Cardiac Data Manager with the assistance and support from the Clinical Audit Team.

The DQI is 98.5% for the 18/19 data (98%, at the previous validation). This is another increase in the DQI and a very good score. There were just 14 discrepancies in 836 variables. There have again been some extreme technical challenges relating to timely data submission during the year 2018/19 that have affected almost every congenital centre. It is also noted that there does not appear to be a dedicated assistant NCHDA data manager to support the Clinical Information and Cardiac Data Manager who has a very wide remit within the Clinical Information Domain.

As previously reported, it appears that there are still some challenges with developing and/or purchasing a cardiac information system that can be used at the point of service to capture all data in real time at any location in within ACH. Currently there is an 'in-house' solution planned to be developed.

A majority of the data appear to be input by the audit team still rather than the responsible clinical colleagues. It was noted that on some of the printed documents that were seen that dates of the entries were not clear or appeared to be missing. There appeared to be no standard method of documenting echo findings in the patient hospital notes. The extra risk data required for patients aged over 16 appeared to be un documented in some of the hospital notes seen.

There was less of the detail of implantable devices (manufacturer, model and serial number) absent from the submitted data this year but it remains a concern that these details do not always appear to be routinely included in the patients' hospital notes.

There was also as documented in previous reports, concern from Reviewers that on occasions the descriptions of procedures recorded as performed in the log books for the cath lab and operating theatres were not as specific as they could be.

Validation of Deceased Patients Case Notes

As reported above, there were a small number errors found as reported elsewhere. All dates of death were correct.

Recommendations for ACH (2019)

1. It is a recommended that in line with the New Congenital Heart Disease Review (NHSE July 2016) 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. The recommended pay banding for the data collection manager is contained in this document: https://www.hqip.org.uk/resource/national-congenital-heart-disease-audit-2013-2016/#.XiHWkojgqt8
   In addition the NHSE July 2016 recommend at least 1.0 WTE assistant data manager, 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 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 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 ACH 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. In liaison with the person responsible for staff training and development in the Trust, regular training must be provided not only for the Auditors, but for all staff in the Department who may be involved with data input. 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, 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.