The National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit For the year 2019/20

FINAL

Alder Hey Children's NHS Foundation Trust

13 October 2020

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Summary and Overview

Prior to this Validation Visit, the data return from the Alder Hey Children's NHS Foundation Trust (ACH NHS Foundation Trust) indicated that 983 therapeutic cardiac procedures had been undertaken during the 2019/2020 data collection year (surgery 399, catheters 462, others 122, Deaths 26) 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 September 2019:

- No actions reported
- Due to pandemic status audit staff have successfully pivoted to remote working

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 and Clinical Information Manager (DBM) (1.0 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. 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 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

From 2015 there was a cardiac information system used that allowed the dataset to be updated. This system is available to the Cardiac Department and is expected to undergo a further substantial development in the very near future. A consultant surgeon has responsibility for the surgical data and its quality and works closely with the Audit Team. The Cardiac and Clinical Information Manager can run ad hoc queries and made the necessary data returns as required.

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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.

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 Data Quality Indicator (DQI) Score for ACH (with previous years in parentheses) is; **98.5%** (98.5, 98, 97.5,). The domain scores are Demographics 1.0 (1.0 1.0 1.0). Pre Procedure 95.25 (.97, .94, .96). Procedure .99.75 (.98, .997, .98) and Outcome .99 (.99, .99, .96)

20 patients procedures were reviewed for the period April – March 2019/20. These patients had undergone 34 procedures, 18 operations and 16 catheter procedures. There were 1160 variables reviewed and 23 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 ACH are:

	Data Year Validated	Surgery	Caths
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%
2020	19/20	98.75%	98%

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Introduction

Prior to the validation visit, the NCHDA return from Alder Hey Children's NHS Foundation Trust indicated that some 983 therapeutic cardiac procedures had been undertaken during the 2019/2020 data collection year (surgery 399, catheters 462, others 122, Deaths 26) 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 Consultant in Congenital Cardiology undertook the site audit at ACH. The Congenital Auditor supported the visit remotely via MS Teams.

An electronic proforma continues to be used with the DBM 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 paper 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. MDT reports were not often seen. These often help the Reviewer's understand the course of events, decision making and previous history.
3. Documentary echocardiogram reports were very challenging to find.
4. The anaesthetic and operation records were fairly easy to find due to their colour (yellow and pink respectively) in the hospital case notes.
5. As noted in previous reports, some anaesthetic records were not dated.
6. The explicit documentation of date and time of extubation was sometimes challenging to find in the notes of surgical patients.

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7. Also, as previously reported, occasionally some of the handwritten clinical notes were not dated so it was difficult to identify exactly when a patient was discharged.
8. Caths in to caths out time does not appear to be routinely recorded on the procedure reports for patients undergoing procedures in the cath lab.
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 logbooks for Apr-Mar 2019/20 were presented for both the cath labs and operating theatres.

Cath Labs

One log book that covered the time period for 12 – 18 April 2019 was reported to be missing, its location unknown. The descriptions of procedures performed were not always clear as to what had actually happened.

From the cath lab log books;

1. 1 procedure was identified in the cath lab log books that may have been missed from the data submission
2. 8 submitted records may to have errors in the coding
3. 19 catheter records were not validated in the log books

Operating Rooms:

The log books from OR 4,5 and 6(hybrid) were offered to the Reviewer's. It was noted that in OR 4 log book the procedures were not always sequentially dated. Some handwriting made it very difficult to clearly discern what procedure had been performed.

From the operating theatre log books;

1. 1 procedure was identified in the log books that may have been missed from the data submission
2. 19 submitted records may have errors in them
3. 3 surgical records were not validated in the log books

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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.

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

- All dates of death appear to be correct.
- 3 records may have incomplete comorbidities listed
- 1 record may have discrepancies in diagnosis field
- 1 record may have a discrepancy in the previous procedures field

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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

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Casenote Audit

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		11	9
2	NHS Number	20	20		11	9
3	Surname	20	20		11	9
4	First Name	20	20		11	9
5	Sex	20	20		11	9
6	DOB	20	20		11	9
7	Ethnicity	20	20		11	9
8	Patient Status	20	20		11	9
9	Postcode	20	20		11	9
10	Pre Procedure Diagnosis	34	34	2 incomplete	16	18
11	Previous Procedures	94	96	1 absent	34	61/62
12	Patients Weight at Operation	34	34		16	18
13	Height	33	33		16	17
14	Ante Natal Diagnosis	6	6		4	2
15	Pre Proc Seizures	34	34		16	18
16	Pre Proc NYHA	-	-		-	-
17	Pre Proc Smoker	-	-		-	-
18	Pre Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre Proc IHD	-	-		-	-
21	Comorbidity Present	33	34	1 incorrect	15/16	18
22	Comorbid Conditions	41	46	5 absent	9/10	32/36
23	Pre Proc Systemic Ventricular EF	24	34	10 unable to validate	10/16	14/18
24	Pre Proc Sub Pul Ventricular EF	26	30	4 unable to validate	10/13	16/17
25	Pre-proc valve/septal defect/ vessel size	2	3	1 unable to validate	2/3	-
26	Consultant	34	34		16	18

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	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	34	34		16	18
28	Proc Urgency	34	34		16	18
29	Unplanned Proc	1	1		-	1
30	Single Operator	3	3		3	-
31	Operator 1	34	34		16	18
32	Operator 1 Grade	34	34		16	18
33	Operator 2	31	31		13	18
34	Operator 2 Grade	31	31		13	18
35	Procedure Type	34	34		16	18
36	Sternotomy Sequence	11	12	1 incomplete	-	11/12
37	Operation Performed	34	34		16	18
38	Sizing balloon used for septal defect	0	0		0	-
39	No of stents or coils	6	6		6	-
40	Device Manufacturer	9	9		8	1
41	Device Model	9	9		8	1
42	Device Ser No	9	9		8	1
43	Device Size	8	8		7	1
44	Total Bypass Time	10	10		-	10
45	XClamp Time,	9	9		-	9
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	16	16		16	-
48	Cath Fluro Time,	16	16		16	-
49	Cath Fluro Dose,	16	16		16	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	14	15	1 incorrect	-	14/15
51	Post Procedure Seizures	34	34		16	18
52	Post Proc Complications	2	2		2	-
53	Date of Discharge	34	34		16	18
54	Date of Death	2	2		-	2
55	Attribution of Death	2	2		-	2
56	Status at Discharge	34	34		16	18
57	Discharge Destination	34	34		16	18

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The Overall Trust DQI = 98.5% Cardiology DQI = 98% 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 .95**	
	Card .93	**Surg** .97
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 1.0	**Surg** .99
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

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DOMAIN	2020	2019	2018	2017
Demographics,	1.0	1.0	1.0	1.0
Pre Procedure	.95	.97	.94	.96
Procedure	.997	.98	997	.98
Outcome	.99	.99	.99	.96

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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 maintained at 98.5% for the 19/20 data. This is another very good score. There were just 23 discrepancies in 1160 variables. It is noted that as in 2019, 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 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. The Reviewers are pleased to report at this visit that there is an 'in-house' solution planned to be developed in the near future.

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. As previously reported, there appeared to be no standard method of documenting echo findings in the patient 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.

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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

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.

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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. It is recommended that a standard format reporting form be developed for echocardiograms.
5. 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.
6. 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.

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