The National Congenital Heart Disease Audit

Procedures for
CONGENITAL HEART DISEASE

Data Quality Audit
For the year 2020/21

FINAL

Alder Hey Children's NHS Foundation Trust

9 September 2021

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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 782 therapeutic cardiac procedures had been undertaken during the 2020/2021 data collection year (surgery 345, catheters 344, others 91, Deaths 21) in patients with congenital heart disease. This represents a drop in procedural activity of 20.5% during the ongoing SARS-COV-2 pandemic. 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 2020:

- The NCHDA data collection standard operating procedure (SOP) is reviewed updated regularly and most recently to include the definitions outlined in the published NCHDA dataset manual.
- ACH report a new project due to start a major development of the existing cardiac database in the Summer 2021. It is envisioned to be a web-based system. This will include a tool for demographics data to be linked to the Trust Patient Administration System. This will improve the data quality and release auditor time to validate the clinical data.
- Theatre/Catheter (OR) Logbooks are regularly monitored by the Cardiac Audit Team. Results and Validation findings are fed back to OR and cath lab managers. The Theatre logbooks are annually internally clinically audited and presented at departmental Quality Assurance and Quality Indicator Meetings.
- It is also reported to the Review Team that towards the end of 2021, ACH expect a Patient Administrative System (PAS) upgrade called Meditech Expanse. This development includes a Digital Theatre logbook system.

Overview at ACH

As previously reported, some of the data entry and review is carried out by 2 Data Auditors who provide a total of 30 hours (2 x 0.4 WTE) per week. The combined Northwest Congenital Cardiac Network and Clinical Information Manager Posts (DBM) is currently a total of one 1.0 WTE role. The DBM role is responsible for supervising the data collection, auditing completeness and accuracy, and submission of data to the NCHDA registry. 2 individuals cover both of these roles to a total of 1.0WTE. The Senior

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Information Manager fulfils 0.6WTE (3 days) for ACH data management and the Assistant Information Manager works 0.4WTE (2 days).

As previously stated, 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 has been 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 as described elsewhere. 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.

Much more of the data are now input at the point of service.

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. Patients also now have a right to opt out of sharing their data outside the NHS Trust providing their care. If a patient has expressed a wish not to allow their case notes to be examined by others not connected to their care, these wishes will also be respected.

Data Quality Indicator

Data Quality Indicator (DQI) Score for ACH (with previous years in parentheses); **99.5%** (98.5, 98.5, 98). The domain scores are Demographics 1.0 (1.0 1.0 1.0). Pre Procedure 99 (95.25, .97, .94). Procedure .99 (99.75, .98, .997) and Outcome 1.0 (.99,.99, .99)

This is an excellent score.

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20 patients procedures were reviewed for the period April – March 2020/21. These patients had undergone 29 procedures, 20 operations and 9 catheter procedures. There were 1003 variables reviewed and 7 errors or discrepancies were identified.

The fields with the most discrepancies are:

Comorbidities	2 discrepancies
Duration and Radiation Data in a Hybrid procedure	3 discrepancies

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
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%
2021	21/20	99.5%	99%

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Introduction

Prior to the validation visit, the NCHDA data return from the Alder Hey Children's NHS Foundation Trust (ACH NHS Foundation Trust) indicated that 782 therapeutic cardiac procedures had been undertaken during the 2020/2021 data collection year (surgery 345, catheters 344, others 92, Deaths 21), in patients with congenital heart disease. As stated elsewhere, this represents a drop in procedural activity of 20.5% during the ongoing SARS-COV-2 pandemic.

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 DBMs 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 all visits since 2016, all procedure case notes reviewed had been prepared in separate A4 folders with much of the relevant documentation tabbed in chronological 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.
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. It should be noted that where the patient has only one functioning ventricle, it is only required to complete one of the fields for this.
4. The anaesthetic and operation records were fairly easy to find due to their colour (yellow and pink respectively) in the hospital case notes and the copies were also easy to identify.
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 that were seen.
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 always routinely recorded on the procedure reports that were seen 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 always appear to be included in the daily record entries or the procedure performed/description note.

Log Book Validation for Case Ascertainment

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Bound bespoke log books for Apr-Mar 2020/21 were presented for both the cath labs and operating theatres. It was noted that part of one operating room log book was not available as it had been locked in a cupboard for which the key was not available.

From the cath lab log books;

1. 0 procedures were identified in the log books that may have been missed from the data submissions
2. 3 submitted records may to have errors in the coding
3. 7 catheter records were not 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 submissions
2. 4 submitted records may have errors in them
3. 2 surgical records were not validated in the log books

During this part of the review, the external audit team were made aware that it is anticipated that an electronic log book is to be trialled in the Spring of 2022 with a view of going 'live' very soon afterwards.

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Validation of Data of Deceased Patients Data Entry in NCHDA

Commencing with the validation of the 2014/15 data at ACH, 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.

21 patients were identified to have died following cardiac procedures during 2020/21. 10 of these deaths are reported to have occurred within 30 days of either a surgical or interventional catheter procedure. These 10 case notes were made available for this review.

- 1 date of death may be incorrect.
- 4 records may have incomplete comorbidities listed
- 1 appears to have discrepancies in the previous procedures field
- 6 records may have incorrect completion of Field 4.09. Attribution of Death

It was not always possible to discern from the case notes seen, if patients who had died within 30 days were discussed with the coroner (when required), were discussed at an MDT and whether or not the death was related to the procedure.

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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		6	14
2	NHS Number	20	20		6	14
3	Surname	20	20		6	14
4	First Name	20	20		6	14
5	Sex	20	20		6	14
6	DOB	20	20		6	14
7	Ethnicity	20	20		6	14
8	Patient Status	20	20		6	14
9	Postcode	20	20		6	14
10	Pre Procedure Diagnosis	29	29	3 incomplete diagnoses	9	20
11	Previous Procedures	74	74		35	39
12	Patients Weight at Operation	29	29		9	20
13	Height	28	28		8	20
14	Ante Natal Diagnosis	3	3		2	1
15	Pre Proc Seizures	29	29		9	20
16	Pre Proc NYHA	-	-		-	-
17	Pre Proc Smoker	-	-		-	-
18	Pre Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre Proc IHD	-	-		-	-
21	Comorbidity Present	29	29		9	20
22	Comorbid Conditions	29	31	2 absent	3	26/28
23	Pre Proc Systemic Ventricular EF	29	29		9	20
24	Pre Proc Sub Pul Ventricular EF	24	24		8	16
25	Pre-proc valve/septal defect/ vessel size	-	-		-	-
26	Consultant	29	29		9	20

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	29	29		9	20
28	Proc Urgency	28	29	1 incorrect	9	19/20
29	Unplanned Proc	29	29		9	20
30	Single Operator	3	3		3	-
31	Operator 1	29	29		9	20
32	Operator 1 Grade	29	29		9	20
33	Operator 2	26	26		6	20
34	Operator 2 Grade	26	26		6	20
35	Procedure Type	29	29		9	20
36	Sternotomy Sequence	15	15		-	15
37	Operation Performed	29	29		9	20
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	2	3	1 absent	2	0/1
40	Device Manufacturer	6	6		4	2
41	Device Model	6	6		4	2
42	Device Ser No	6	6		4	2
43	Device Size	5	5		4	1
44	Total Bypass Time	15	15		-	15
45	XClamp Time,	14	14		-	14
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	8	9	1 absent	8/9	-
48	Cath Fluro Time,	8	9	1 absent	8/9	-
49	Cath Fluro Dose,	8	9	1 absent	8/9	-

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	17	17		-	17
51	Post Procedure Seizures	29	29		9	20
52	Post Proc Complications	3	3		-	3
53	Date of Discharge	29	29		9	20
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	29	29		9	20
57	Discharge Destination	29	29		9	20

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The Overall Trust DQI = 99.5%   Cardiology DQI = 99%   Surgery DQI = 99.5%

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		
	Overall	**Card**	**Surg**
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	1.0	1.0	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	**.99**	1.0	.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,**	.99	.975	.99
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	1.0	1.0	1.0

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DOMAIN	2021	2020	2019	2018
Demographics,	1.0	1.0	1.0	1.0
Pre Procedure	.99	.95	.97	.94
Procedure	.99	.997	.98	997
Outcome	1.0	.99	.99	.99

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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 excellent at 99.5% for the 20/21 data. This is another very good score. There were just 7 discrepancies in 1003 variables. The Reviewers are also pleased to note that is now 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. However the role of NCHDA Data Manager is split with NW Congenital Cardiac Network and the total WTE for NCHDA remains at 1.0 and does not appear to meet the recommendations of the New Congenital Heart Disease Review undertaken by NHSE (2016).

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 decreasing amount of the data appear to be input by the audit team still rather than the responsible clinical colleagues although it is acknowledged that this continues to improve. 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 of queries identified. All dates of death were correct. As stated elsewhere, it was not always possible to tell if patients who had died within 30 days were discussed with the coroner (when required), were discussed at an MDT and whether or not the death was related to the procedure

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Recommendations for ACH (2021)

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 and 1.0WTE assistant paediatric cardiac surgery/cardiology data collection manager. The recommended pay banding for the senior 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. 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. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data/Audit Managers at least monthly.
   f. Running the PRAiS (Paediatric Risk Analysis in Surgery) analysis tool monthly. This will inform the quarterly NHSE Dashboard reports.
   g. Ensuring that dates of death are reported for any ACH patient who has previously had a record submitted to the NCHDA
   h. Where a patient has died within 30 days of a procedure, documenting whether or not there was a discussion with the coroner (when required), was discussed at an MDT and whether or not the death was related to the procedure as these are NCHDA dataset items.
   i. Leading the local review (and how frequently and in which forum for both disciplines)

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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. 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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