The National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit For the year April – March 2023-24

Alder Hey Children's NHS Foundation Trust

22 May 2024

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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 740 therapeutic cardiac procedures had been undertaken during the 2023/2024 data collection year (surgery 356, catheters 325, others 40, Deaths 10 within 30 days of a Specific Procedure), in patients with congenital heart disease. Following review of the catheter laboratory and operating room activity log books on the day of the validation visit, no other further procedures were identified.

This validation visit has been fully funded by the Alder Hey Children's NHS Foundation NHS Trust.

The NCHDA Validation Team are again grateful to the Service Manager for Cardiothoracic Services at ACH who spent the day with them.

ACH have undertaken the following action since last visit in September 2023:

- A new information system (Dendrite Clinical Systems) has been purchased. Planned go-live date is Q1 24/25. 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 Logbooks are regularly monitored by the Cardiac Audit Team. Results and Validation are then reported to the Theatre Manager. The Theatre logbooks are internally clinically audited and presented at the departmental Quality Assurance and Quality Indicator Meetings.
- A new Patient Administrative System upgrade called (Meditech Expanse) came into operation in Sept 2023.

Overview at ACH

Since April 2023 there has been a Senior Cardiac Information Manager 1.0WTE for NCHDA at this NHS Trust. In total, at the time of this visit there were 3 individuals providing 1.8WTEs

supporting the NCHDA data collection at Alder Hey Children's Hospital. None of these individuals have a clinical background.

As previously stated, the standard requirement as stated 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 Children's 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. As mentioned elsewhere, this system was available to the Cardiac Department and is now being replaced with Dendrite Intellect Information Database during Q1 of 2024/5.

Much of the data are reported to be input at the point of service currently and this practice will continue with Intellect.

Consent for External Validation of Notes.

Since May 2018, the General Data Protection Regulation (GDPR) 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); **99.6%** (98.75, 99.25, 99.5, 98.5). The domain scores are Demographics 1.0 (1.0, 1.0 1.0 1.0). Pre Procedure .996 (.99, .99, .99,). Procedure 1.0 (.97, .99, .99) and Outcome .99 (.99, .99, 1.0).

This is another excellent score.

20 patients procedures were reviewed for the period April – March 2023/24. These patients had undergone 26 procedures, 17 operations and 9 catheter procedures. There were 847 variables reviewed and 2 errors or discrepancies were identified.

Fields with the most discrepancies are:

Comorbid Conditions 1
Post Procedure Complications 1

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
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	20/21	99.5%	99%
2022	21/22	99.5%	98.5%

2023	22/23	99.25%	98.25%
2024	23/24	99.6%	100%

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 740 therapeutic cardiac procedures had been undertaken during the 2023/2024 data collection year (surgery 356, catheters 325, others 40, Deaths 10 within 30 days of a Specific Procedure), 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 Cardiac Surgery undertook the site audit at ACH.

ACH are using an electronic patient record system (ePR) and are now very '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 reviewers found this very helpful.

1. On the whole the files were very well prepared and well laid out.
2. Multidisciplinary or Joint Consultative Team (MDT/JCC) reports were seen in most packs of notes. These often help the Reviewer's understand the course of events, decision making and previous history.
3. The anaesthetic and operation records copies were easy to identify. Although it was noted that one operation note appeared to be either typed late or a late entry 12 months after the procedure.

4. When trying to validate the exact date and time of endotracheal extubation, it was noted on several occasions that the OR transfer sheet appeared to be incomplete in regard to ventilation status or plan.
5. The actual Sheath In/Sheath Out time was difficult to discern from the catheter record as the term Procedure Time is used without definition of what this actually is.
6. Over coding of procedures (such as the individual elements of Tetralogy Repair) rather than just using the one most appropriate over arching code may lead to incorrect counting of specific procedures and activity analysis.
7. As previously noted in 2023, when recording the amount of radiation used for procedures the unit of measurement should be the total dose in centigrays (cGy/cm$^{2)}$ and not miligrays (mGy/cm$^{2).}$
8. When entering pacemaker device details, it is not necessary to record the model and serial numbers of leads for NCHDA.
9. Loop recorder implant/explant plant procedures are no longer required for NCHDA
10. It would be really helpful to have a standard discharge format for all patients clearly documenting chronologically, the patients past history, procedures and the events of the current episode.
11. Also, as previously reported, occasionally some of the handwritten scanned clinical notes were not dated so it was difficult to identify exactly when a patient was discharged.

Log Book Validation for Case Ascertainment

Bound bespoke log books for Apr-Mar 2023/24 were presented for both the cath labs and operating theatres. 1 of the log books for the cath labs was missing, its location unknown.

The 1 cath lab log book findings are:

1. 0 procedures were identified in the log books that may have been missed from the data submissions
2. 16 submitted catheter procedures were not validated in the log books presumed to be in the absent or missing log book.

3. 4 submitted records do not appear to be for procedures required for NCHDA and should be deleted

From the operating theatre log books;

1. 0 procedure were identified in the log books that may have been missed from the data submissions
2. 6 surgical records were not validated in the log books,
3. As was noted in 2023, in one of the operating rooms used for cardiac surgery, that bowel surgery was also being performed on other days.

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.

19 patients were identified to have died following cardiac procedures during 2023/24. 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.

- All dates of death were found to be correct
- 1 record appears to have discrepancies in the comorbidities field
- 8 records appear to have incomplete fields for attribution of death

Documentation of whether or not there had been and discussion with the Coroner was seen and this is very helpful. No copies of the Death Certificates were seen. These can also be extremely helpful when undertaking this part of the review.

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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

Casenote Audit: based on 20 patients who underwent 1 catheter procedures and 1 operations

	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	26	26	1 incomplete	9	17
11	Previous Procedures	29	29		12	17
12	Patients Weight at Operation	26	26		9	17
13	Height	25	25		8	17
14	Ante Natal Diagnosis	6	6		3	3
15	Pre Proc Seizures	26	26		9	17
16	Pre Proc NYHA	-	-		-	-
17	Pre Proc Smoker	-	-		-	-
18	Pre Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre Proc IHD	-	-		-	-

21	Comorbidity Present	26	26		9	17
22	Comorbid Conditions	24	25	1 incorrect	6	18/19
23	Pre Proc Systemic Ventricular EF	26	26		9	17
24	Pre Proc Sub Pul Ventricular EF	24	24		8	16
25	Pre-proc valve/septal defect/ vessel size	2	2		2	-
26	Consultant	26	26		9	17

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	26	26		9	17
28	Proc Urgency	26	26		9	17
29	Unplanned Proc	-	-		-	-
30	Single Operator	3	3		3	-
31	Operator 1	26	26		9	17
32	Operator 1 Grade	26	26		9	17
33	Operator 2	23	23		6	17
34	Operator 2 Grade	23	23		6	17
35	Procedure Type	26	26		9	17

36	Sternotomy Sequence	14	14		-	14
37	Operation Performed	26	26		9	17
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	4	4		3	1
41	Device Model	4	4		3	1
42	Device Ser No	4	4		3	1
43	Device Size	3	3		3	-
44	Total Bypass Time	12	12		-	12
45	XClamp Time,	10	10		-	10
46	Total Arrest	-	-		-	-
47	Cath Proc Time,	9	9		9	-
48	Cath Fluro Time,	8	8		7/8	-
49	Cath Fluro Dose,	8	8		8	-

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	9	9		-	9
51	Post Procedure Seizures	26	26		9	17

52	Post Proc Complications	1	2	1 incorrect	-	½
53	Date of Discharge	26	26		9	17
54	Date of Death	1	1		-	1
55	Attribution of Death	1	1		-	1
56	Status at Discharge	26	26		9	17
57	Discharge Destination	26	26		9	17

The Overall Trust DQI = 99 6% Cardiology DQI = 100% Surgery DQI = 99.6 %
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.

<table>
<tr><th>DOMAIN</th><th colspan="2">DOMAIN Score</th></tr>
<tr><td rowspan="2"><u>Demographics</u>

Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,</td><td colspan="2">Overall 1.0</td></tr>
<tr><td>Card
1.0</td><td>Surg
1.0</td></tr>
<tr><td rowspan="2"><u>Pre Procedure</u>

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</td><td colspan="2">Overall .996</td></tr>
<tr><td>Card
1.0</td><td>Surg
.994</td></tr>
<tr><td><u>Procedure</u></td><td colspan="2">Overall 1.0</td></tr>
</table>

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,**	**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** .99 **Card** 1.0	**Surg** .99

DOMAIN	2024	2023	2022	2021
Demographics,	1.0	1.0	1.0	1.0
Pre Procedure	.996	.99	.99	.99
Procedure	1.0	.97	.99	.99
Outcome	.99	.99	.99	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 records 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 99.6% for the 23/234 data. This is another very good score. There were just 2 discrepancies in 847 variables. The Reviewers are pleased to report that the Dendrite Intellect is about to be launched at this Centre. However, the total WTE for NCHDA remains at 1.8WTE and does not meet the recommendations of the New Congenital Heart Disease Review undertaken by NHSE (2016).

As previously reported, the amount of the data that appear to be input by the audit team continues to decrease with a greater emphasis on clinician ownership of the data and input at point of service. It was noted that on some of the printed documents that were seen that dates of the entries were not always clear. It was also noted that data are kept on several different databases. This can prove challenging to the audit team who are not clinically trained when trying to validate procedure records.

It should be noted that NHSE now require NCHDA data to be submitted within 2 weeks of the date of procedure and it is likely that this clinical data team will need some further support to meet this requirement.

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. It was again as in 2023, further noted that in one of the operating rooms used for cardiac surgery, that bowel surgery was also being performed on other days.

It was of moderate concern that in some surgical cases the OR transfer documentation and the first entry on Badger the PICU information system did not always indicate the ventilation status or any plan to maintain adequate oxygenation of the patient.

The Reviewers are aware that there were preliminary discussions underway in 2023 around launching electronic activity log books for the cath labs and operating rooms. These are not date lined as yet in 2024.

Validation of Deceased Patients Case Notes

As reported above, there were a very small number of queries identified. All dates of death were correct. As stated elsewhere, there was more clearly dated documentation of conversations with a medical examiner or coroner, but it was not always possible to clearly identify whether or not the death was related to the procedures performed or another cause. It would be helpful to have a more detailed discharge/death summary and/or any documents created for presentation at Morbidity and Mortality meetings for these patients for this part of the Validation exercise and a copy of the Death Certificate.

Recommendations for ACH (as at 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 all of the 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. Enable the local audit team to access the Echo and RIS databases to ensure validated NCHDA data can be identified correctly. This is

particularly important in order to verify radiation dosage and exposure times.

g. Running the PRAiS (Paediatric Risk Analysis in Surgery) analysis tool monthly. This will inform the quarterly NHSE CQSSD 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. Where a patient has died within 30 days of a procedure, documenting whether or not there was a discussion with the local medical examiner or coroner (when required), was discussed at a Morbidity and Mortality review and whether or not the death was related to the procedure as these are NCHDA dataset items.
j. Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.
k. Leading the local review (and how frequently and in which forum for both disciplines)
l. Making timely submissions (monthly is required) and NICOR are now required by NCHDE to report each month all activity within 2 weeks of a procedure occurring.
m. Including details of manufacturer, model and serial numbers of all implantable devices the procedure record for each patient. Note that model serial numbers are not required for pacemaker leads
n. 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 Clinical Auditors, but for all staff in the Department who may be involved with data collection and 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, consideration could be given to 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.
6. DBMs should be encouraged each year to visit other NCHDA centres at site validation to gain peer support, education and share practice experience.