The National Congenital Heart Disease Audit

Procedures for
CONGENITAL HEART DISEASE

Data Quality Audit
For the year April – March 2024-25

Alder Hey Children's NHS Foundation Trust

1 July 2025

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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 884 therapeutic cardiac procedures had been undertaken during the 2024/2025 data collection year (surgery 409, catheters 419, others 56, Deaths 10/22 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, 2 further procedures were identified that may be suitable for inclusion in NCHDA.

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 most of the day with them.

ACH have undertaken the following action since last visit in September 2024:

- A new clinical information system (Dendrite Clinical Systems) went live Sept 24. This includes a demographics link to the Trust Patient Administration System (PAS).
- The operating theatre/catheter activity logbooks are regularly monitored by the Cardiac Audit Team. Results and Validation are then reported to Theatre Management. The Theatre logbooks are internally clinically audited and presented in the ACH departmental Quality Assurance and Quality Indicator Meetings.

Overview at ACH

As previously reported, 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). Participation in

NCHDA is a mandatory requirement and external validation is a compulsory requirement as set out in the NHSE Specialised Commissioning Specifications Document (2016) that supports the 2016 Review mentioned above.

Congenital Data Collection at ACH

As mentioned elsewhere, Cardiac Department are now using Dendrite Intellect Information Database since September 2024. All of the data managers are located very close to the clinicians and are able to seek quality and completeness guidance on procedures and their coding very easily.

Much of the data are reported to be input at the point of service.

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%** (99.6, 98.75, 99.25, 99.5,). The domain scores are Demographics .99 (1.0, 1.0 1.0 1.0). Pre Procedure .99 (99.5, .99, .99, .99,). Procedure 1.0 (1.0, .97, .99,) and Outcome .98 (.99, .99, .99).

This is another excellent score.

20 patients procedures were reviewed for the period April – March 2024/25. These patients had undergone 24 procedures, 16 operations and 8 catheter procedures. There were 841 variables reviewed and 6 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
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%
2025	24/25	98.75%	98.25%

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 884 therapeutic cardiac procedures had been undertaken during the 2024/2025 data collection year (surgery 409, catheters 419, others 56, Deaths 10/22 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 Specialty Trainee (ST4) in Congenital Cardiology 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. Documentation of ventricular function was sometimes difficult to discern. It would be more helpful for validation to describe the function of each ventricle separately.
4. The anaesthetic and operation records copies were easy to identify.
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 and 24, 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. 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.

Log Book Validation for Case Ascertainment

Bound bespoke log books for Apr-Mar 2024/25 were presented for both the cath labs and operating theatres. 1 log book for the OR was missing, its location unknown and another had been incorrectly labelled as belonging to a further OR.

From the cath lab log books;

1. 1 procedure was identified in the log books that may have been missed from the data submissions
2. 4 records in the submission may have discrepancies in them
3. 1 submitted catheter procedure was not validated in the log books
4. 1 submitted record does not appear to be for a procedure required for NCHDA and should be deleted

From the operating theatre log books;

1. 1 procedure was identified in the log books that may have been missed from the data submissions
2. 7 surgical records were not validated in the log books,
3. 10 submitted records may have discrepancies in them

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.

22 patients were identified to have died following cardiac procedures during 2024/25. 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
- 7 records appear to have discrepancies in one or more fields

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 (MCCD) were seen. This can also be extremely helpful when undertaking this part of the review. The DBMs do not currently attend Mortality and Morbidity Meetings but this may be helpful to do so in the future as a reminder and to encourage clinician completion of the Attribution of Death field in NCHDA.

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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

Digital Maturity (electronic health records) in 2025.

There is not a single unified digital health record system that allows user to see **all** of the patient data in one system and there are still some paper records kept such as observation charts, clinic notes etc at point of care. There are also bound paper log books used in both the operating rooms and catheter laboratories.

All patients health records are recorded on a mixture of both paper and a digital information system called Meditech Expanse. Meditech Expanse is a web-based electronic health record (EHR) system designed to improve patient care and streamline clinical workflows. It's a comprehensive platform that integrates patient data, enhances communication, and offers mobile-ready features for clinicians and patients.

NCHDA data are input to separate stand-alone information system (Dentrite Intellect) which is a web enabled system.

It is reported that for the complete NCHDA dataset data to be collected between 5 applications (each with unique user id and password control) have to be accessed.

The Trust have no plans to at this time to change any of the above methods or recording activity or patient medical records.

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		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	19	20	1 absent	6	14
8	Patient Status	20	20		6	14
9	Postcode	20	20		6	14
10	Pre Procedure Diagnosis	24	24		8	16
11	Previous Procedures	45	45		24	21
12	Patients Weight at Operation	24	24		8	16
13	Height	22	22		7	15
14	Ante Natal Diagnosis	5	5		4	1
15	Pre Proc Seizures	24	24		8	16
16	Pre Proc NYHA	-	-		-	-
17	Pre Proc Smoker	-	-		-	-
18	Pre Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre Proc IHD	-	-		-	-
21	Comorbidity Present	23	24	1 incorrect	7/8	16
22	Comorbid Conditions	29	29	2 incorrec	3/5	24
23	Pre Proc Systemic Ventricular EF	24	24		8	16
24	Pre Proc Sub Pul Ventricular EF	17	17		4	13
25	Pre-proc valve/septal defect/ vessel size	1	1		1	-
26	Consultant	24	24		8	16

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	24	24		8	16
28	Proc Urgency	24	24		8	16
29	Unplanned Proc	-	-		-	-
30	Single Operator	1	1		1	-
31	Operator 1	24	24		8	16
32	Operator 1 Grade	24	24		8	16
33	Operator 2	23	23		7	16
34	Operator 2 Grade	23	23		7	16
35	Procedure Type	24	24		8	16
36	Sternotomy Sequence	12	12		-	12
37	Operation Performed	24	24		8	16
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	8	8		8	-
41	Device Model	8	8		8	-
42	Device Ser No	8	8		8	-
43	Device Size	7	7		7	-
44	Total Bypass Time	12	12		-	12
45	XClamp Time,	11	11		-	11
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	13	13		-	13
51	Post Procedure Seizures	24	24		8	16
52	Post Proc Complications	4	4		-	4
53	Date of Discharge	23	24	1 incorrect	8	15/16
54	Date of Death	2	2		1	1
55	Attribution of Death	1	1		--	1
56	Status at Discharge	24	24		8	16
57	Discharge Destination	23	24	I incorrect	8	15/16

The Overall Trust DQI = 99% Cardiology DQI = 98.25% 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 .99**	
	Card 1.0	**Surg** .99
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 .99**	
	Card .97	**Surg** 1.0
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 1.0**	
	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** .98	
	Card 1.0	**Surg** .96

DOMAIN	2025	2024	2023	2022
Demographics,	.99	1.0	1.0	1.0
Pre Procedure	.99	.996	.99	.99
Procedure	1.0	1.0	.97	.99
Outcome	.98	.99	.99	.99

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 99% for the 24/25 data. This is another very good score. There were just 6 discrepancies in 841 variables. The Reviewers are pleased to report that the Dendrite Intellect has been launched and in use since September 2024. 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.

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.

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 still not date lined as yet in 2025.

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. The DBMs do not currently attend Mortality and Morbidity Meetings but this may be helpful to do so in the future as a reminder and to encourage clinician completion of the Attribution of Death field in NCHDA.

As previously reported, it may 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 PRAiS4.2 (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. This field could be completed at the Morbidity and Mortality review also.

k. Leading the local review (and how frequently and in which forum for both disciplines)

l. Making timely submissions (monthly is recommended).

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.