The National Congenital Heart Disease Audit

Procedures for
CONGENITAL HEART DISEASE

Data Quality Audit
For the year April – March 2021/22

Alder Hey Children's NHS Foundation Trust

28 July 2022

performed by Lin Denne, and Dr B Grant

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 795 therapeutic cardiac procedures had been undertaken during the 2021/2022 data collection year (surgery 347, catheters 386, others 64, Deaths 17), 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 again grateful to the Service Manager for Cardiothoracic Services at ACH who made time to come and meet them.

No actions were reported by ACH to have been undertaken since last visit in September 2021

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. At the time of this site visit, 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 Information Manager fulfilled 0.6WTE (3 days) for ACH data management and the Assistant Information Manager works 0.4WTE (2 days). In total, at the time of this visit there were 4 individuals providing 1.8WTEs supporting the NCHDA data collection at Alder Hey Children's Hospital. None of these individuals have a clinical background.

Since this visit took place, both the Clinical Information Manager and the Assistant Information Manager have left their posts in August and November 2022 respectively. The Trust are considering recruitment options. No data had been submitted to the NCHDA registry for the collection year April 2022 to March 23 at the time of this visit.

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 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 during 2022 - 5. It was reported at the time of this visit, that 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 could 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 (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); 99.25**%** (99.5, 98.5, 98.5, 98). The domain scores are Demographics 1.0 (1.0, 1.0 1.0 1.0). Pre Procedure 99 (.99, 95.25, .97). Procedure .99 (.99, 99.75, .98) and Outcome .99 (1.0, .99,.99,)

This is another excellent score.

20 patients' procedures were reviewed for the period April – March 2021/22. These patients had undergone 30 procedures, 17 operations and 13 catheter procedures. There were 1071 variables reviewed and 7 errors or discrepancies were identified.

The fields with the most discrepancies are:

Post procedure complications 2 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
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%
2022	21/22	99.5%	98.5%

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 795 therapeutic cardiac procedures had been undertaken during the 2021/2022 data collection year (surgery 347, catheters 386, others 64, Deaths 17), 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 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 Trust wide 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. Multidisciplinary or Joint Consultative Team (MDT/JCC) 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. 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.
6. Catheter into catheter 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.
7. 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

Bound bespoke log books for Apr-Mar 2021/22 were presented for both the cath labs and operating theatres. It was noted that one operating room log book for (room 4) was not available for the entire year under review and it appeared that its' location was unknown.

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. 3 submitted records may to have errors in the coding
3. The handwritten entries on the whole were easier to decipher this year but there are still some entries that were very difficult to read.

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. 3 submitted records may have errors in them
3. Approximately 95 surgical records were not validated in the log books, presumed to be in the absent or missing log book. These patients were cross referenced with the Trust electronic patient record and were found to have had a procedure. However,

the descriptions of these procedures was often without detail of exactly what operation had been performed.

It appears at times that in the submitted data, there is a tendency to over code procedures ie it is not necessary to code the individual parts of a Tetralogy of Fallot Repair or a Norwood procedure. Where appropriate for a Norwood procedure it is acceptable to add the code for a Sano shunt if that is used.

During the 2021 site validation at 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. It was reported at this visit that this was delayed and was to be done at a later date but there was no specific timeline for this.

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.

17 patients were identified to have died following cardiac procedures during 2021/22. Three of these deaths are reported to have occurred within 30 days of either a surgical or interventional catheter procedure. These 3 case notes were made available for this review.

- One record appears to have discrepancies in the previous procedures field
- all dates of death were correct
- all other data were found to be correct.

It was noted that most of the hospital notes did document whether or not there had been a discussion with the local Medical Examiner or Coroner and often included a copy of the Death Certificate. Both of which are extremely helpful when undertaking this part of the review.

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 13 catheter procedures and 17 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	30	30		13	17
11	Previous Procedures	85	86	1 absent	45	40/41
12	Patients Weight at Operation	30	30		13	17
13	Height	29	29		12	17
14	Ante Natal Diagnosis	2	2		-	2
15	Pre Proc Seizures	30	30		13	17
16	Pre Proc NYHA	2	2		1	1
17	Pre Proc Smoker	2	2		1	1
18	Pre Proc Diabetes	2	2		1	1
19	Hx Pulmonary Dis	2	2		1	1
20	Pre Proc IHD	2	2		1	1

21	Comorbidity Present	30	30		13	17
22	Comorbid Conditions	59	59		17	42
23	Pre Proc Systemic Ventricular EF	29	30	1 incorrect	12/13	17
24	Pre Proc Sub Pul Ventricular EF	30	30		12/13	17
25	Pre-proc valve/septal defect/ vessel size	-	-		-	-
26	Consultant	30	30		13	17

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	30	30		13	17
28	Proc Urgency	30	30		13	17
29	Unplanned Proc	2	2		-	2
30	Single Operator	0	1	1 incorrect	0/1	-
31	Operator 1	30	30		1	17
32	Operator 1 Grade	30	30		13	17
33	Operator 2	29	29		12	17
34	Operator 2 Grade	29	29		12	17
35	Procedure Type	30	30		13	17
36	Sternotomy Sequence	15	15		-	15

37	Operation Performed	29	30	1 incorrect	13	16/17
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	5	5		5	-
40	Device Manufacturer	8	8		7	1
41	Device Model	10	10		9	1
42	Device Ser No	10	10		9	1
43	Device Size	9	9		9	-
44	Total Bypass Time	14	14		-	14
45	XClamp Time,	10	10		-	10
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	13	13		13	-
48	Cath Fluro Time,	13	13		13	-
49	Cath Fluro Dose,	13	13		13	-

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	16	16		-	16
51	Post Procedure Seizures	30	30		13	17
52	Post Proc Complications	6	8	2 incorrect	0/2	6
53	Date of Discharge	30	30		13	17

54	Date of Death	1	1		-	1
55	Attribution of Death	1	1		-	1
56	Status at Discharge	30	30		13	17
57	Discharge Destination	30	30		13	17

The Overall Trust DQI = 99.25% Cardiology DQI = 98.5% 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.

<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 .99</td></tr>
<tr><td>Card
.99</td><td>Surg
.99</td></tr>
<tr><td><u>Procedure</u></td><td colspan="2">Overall .99</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** .99	**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** .96	 **Surg** 1.0

DOMAIN	2022	2021	2020	2019
Demographics,	1.0	1.0	1.0	1.0
Pre Procedure	.99	.99	.95	.97
Procedure	.99	.99	.997	.98
Outcome	.99	1.0	.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 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 99.25% for the 21/22 data. This is another very good score. There were just 7 discrepancies in 1071 variables. The Reviewers note that is now a dedicated assistant NCHDA data manager role 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 was 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).

In relation to auditing for maximum NCHDA case ascertainment, this was not possible to complete as a log book for room 4 for the year April to March 2021-22 was absent and its location unknown.

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.

The amount of the data that appear to be input by the audit team is decreasing. 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. The local audit team do not appear to have access to the database where echo reports may be stored and the reports for referred patients who had had this investigation at another hospital appeared to be either missing from the ACH notes or not sent with the transfer documents.

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 very small number of queries identified. All dates of death were correct. As stated elsewhere, there was some dated documentation of conversations with a medical examiner or coroner and copies of a death certificate, but it was not always possible to clearly identify whether or not the death was related to the procedures performed or another cause.

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 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 validate NCHDA data can be identified correctly.

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. 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 an MDT and whether or not the death was related to the procedure as these are NCHDA dataset items.
j. Leading the local review (and how frequently and in which forum for both disciplines)
k. Making timely submissions (monthly is recommended where possible) and
l. Including details of manufacturer, model and serial numbers of all implantable devices the procedure record for each patient.
m. 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.