National Congenital Heart Disease Audit Report

On

Data Quality of Procedures for CONGENITAL HEART DISEASE

For April 2023 – March 2024

At

University Bristol Hospitals NHS Foundation Trust (BRC)

13 June 2024

performed by Lin Denne, and Dr N Hayes

Summary

A total of 1098 procedures were included in the BRC data return to NCHDA for the year April – March 2023-24 harvested on 13 May 2024. These comprised (373 Surgery, 712 Catheters, 13 others, 7 deaths within 30 days of a procedure) for the year 2023/2024 that were undertaken. These numbers include adult congenital procedures carried out at Bristol Heart Institute (BHI).

Following review of the catheter laboratory and operating room activity log books on the day of the validation visit, 1 additional procedures was identified and subsequently submitted to the Registry.

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 this Registry and will undergo the necessary internal validations and be submitted as necessary.

This validation visit has been funded by the University Hospitals Bristol NHS Foundation Trust. Bristol Royal Children's Hospital (BRC) is part of the UHBristol NHS Foundation Trust.

BRC have had a dedicated congenital cardiac information team since 2014. There are 4 individuals who cover a total of 2.38 WTE.

- Information Analyst & Clinical Data Manager band 6 (0.68 WTE)
- Cardiac Data Manager band 5 (0.4 WTE)
- Assistant Data Manager band 4 (1.0 WTE)
- Cardiac Data Quality and Audit Nurse band 5 (0.3 WTE)

It should be noted that it is a recommended standard in the New Congenital Heart Disease Review (NHSE July 2016) Recommendations number B32(L1) that states there should be a minimum of 1.0 WTE dedicated Level 1 paediatric cardiac surgery/cardiology data collection manager and 1.0WTE assistant paediatric cardiac surgery/cardiology data collection manager; and Recommendation (B33 (L1) states that there should be 1.0WTE data manager for Level 1 ACHD services.

Real time data input by all clinicians is encouraged at BRC and is mostly undertaken.

Patient Consent for External Validation of Hospital Notes

Under the General Data Protection Regulation (GDPR) of May 2018, it is expected that patients will be made aware by all Organisations who care for them and produce data relating to their medical conditions to be open and transparent about how their data is being kept, used and who it is being shared with and how it may be disposed of. As such, NCHDA now no longer require individual patient informed consent.

Data Quality Indicator (DQI)

The DQI for the Trust is calculated to be (with the previous year in parentheses) **99.75%** (99.75, 99.75, 99.5) with domain scores Demographics 1.0 (1.0, 1.0, 1.0,) Pre Procedure .99 (1.0, .99, .98) Procedure 1.0 (.99, 1.0, 1.0) and Outcome 1.0 (1.0, 1.0, 1.0).

There were 4 discrepancies in a total of 1333 variables across 20 patients who underwent 35 therapeutic procedures (15 catheter interventions, 20 operations).

This demonstrates that there are good processes, practices and procedures in place to collect and validate accurate data at BRC.

Separate DQI for Catheters and Surgery

Since the 2009 cycle of visits commenced, as well as the overall DQI for each centre, the DQI for surgery and catheters is being calculated. It is recommended that a minimum number of 5 procedures in either group are required for the differential DQI calculation.

Year	Data Year Validated	Surgery DQI	Catheter DQI
2013	12/13	87%	96.5%
2014	13/14	98.25%	93.25%
2015	14/15	95%	94%
2016	15/16	99.25%	98.25

2017	16/17	99.25%	98%
2018	17/18	99.25%	99%
2019	18/19	98.75%	99.8%
2020	19/20	100%	99%
2021	20/21	98.75%	100%
2022	21/22	100%	99.75%
2023	22/23	99.75%	99.75%
2024	23/24	99.75%	99.75%

The body of this report is drawn from answers given on the NCHDA pre visit questionnaire and from discussions on the day of the visit.

Actions or changes undertaken since 2023 Validation Visit:

1. The data collection Standard Operating Protocols (SOPs)s are in place for both the paediatric and ACHD services. They are regularly reviewed. The Cardiac Data Team made monthly uploads to NCHDA in 23-24.
2. One of the Data Managers attended an NCHDA site validation virtually as an observer during 2023.
3. The paediatric cardiac service moved over to Mac-Lab Hemodynamic Recording System (GE software) in February 2022. Currently catheter procedure logs are generated within Mac Lab. There is an expectation to use Centricity Cardio Workflow system (CCW, also GE Software) which is currently used in BHI, for generating procedure logs going forward.

Introduction

Prior to the validation visit the combined NCHDA return from the cardiac department of Bristol Royal Hospital for Children and Bristol Royal Infirmary indicated that 1098 procedures were included in the data return to NCHDA for the year April – March 2023-24. These comprised (373 Surgery, 712 Catheters, 13 others, 7 deaths within 30 days of a procedure) for the year 2023/2024 that were undertaken. As stated above, these numbers include adult congenital procedures carried out at Bristol Heart Institute (BHI)

20 Sample sets of case notes were selected for review on each day. A Reserve list of 10 was also supplied by NCHDA in case any of the first 20 were irretrievable. On the day nil records were required from the Reserve list to replace those that were unavailable from the Sample. The accuracy of the NCHDA data return was then checked against each set of notes on each day.

One external Consultant in Paediatric Cardiology undertook the validation visit on site at Bristol Royal Children's Hospital with the NCHDA Clinical Data Auditor.

Review of the notes

BRC is still in the process of moving towards 'paper light' hospital record keeping. This involves having a paper copy of patient's notes only during an in-patient admission or an outpatient appointment. On discharge or completion of the episode the patient's notes are immediately scanned onto an electronic patient record system 'Evolve'. The process of scanning all historical patient notes is now established in the paediatric cardiac service and usually there are no significant delays reported with notes being scanned. In the Bristol Heart Institute (BHI) there are occasional delays related to the scanning of patient notes which sometimes results in delayed upload of certain records to NCHDA.

The hospital case notes seen on the day of the validation visit, were digital images compiled from the ePR into folders for each patient. On the whole, the images were very tidy, very good quality and made up of very few scans of traditional paper bound documents. The pages that were required to be seen by the Reviewers, although sometimes a little small, had been meticulously ordered.

1. The Joint Clinical Conference (JCC) discussion sheets were seen in almost all of the case notes and these were very detailed.
2. As previously reported, the cardiac catheter procedure sheet was easy to read and well laid out. Labels from implantable devices were often stuck to these sheets and this was useful for validation of these data.
3. Operation notes were likewise very clearly set out, and scans of the hand written procedure notes were seen.
4. The transfer from OR to PICU document that would confirm whether or not a patient had been extubated in theatre was useful but did not always appear to be present in the digital images that had been collected.
5. Specific documentation of the date and time of extubation did not always appear to be clearly noted.
6. As previously reported, the PICU discharge summaries were very detailed and therefore extremely helpful in validating the perioperative data fields.
7. In the discharge summaries of ACHD patients it was difficult at times to find the detail of the timeline of actions and interventions of an episode.
8. As previously reported, NYHA status did not appear to be routinely recorded in the hospital records of patients aged over 16 at admission clerking or outpatient pre admission appointments. The specific proforma created and available for the ACHD risk data appeared to be variably completed. These fields are part of specific pre procedure risk assessment used in the NCHDA ACHD dataset.

Validation of Deceased Patients Diagnostic and Procedure Coding

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 Partial Risk Adjustment in Surgery (PRAiS) fields will also be validated. 7 deaths occurred within 30 days of a therapeutic catheter or surgical procedure and these case notes were examined in closer detail. The PRAiS sensitive fields (demographics, diagnosis, previous procedures, comorbidities and procedure performed) were reviewed for each of the patients and the findings were:

- All dates of death were correct
- No discrepancies noted in any other field
- It was a little easier to find documentation or confirmation of whether or not there had been a discussion with the Medical Examiner or Coroner after a patients death.
- It is noted that BRC have recently set up a Medical Examiners office and are defining the operational terms of reference for this.

As reported in 2023, an annual query was run and in 2024 this will now be quarterly, to compare life status on NHSE Summary Care Record with known NCHDA patients as a further check for individuals who may have died post discharge.

Log Book Check for full NCHDA case ascertainment

The Bluespier theatre booking application is used across all operating rooms and cathlabs at UHBW NHS Trust. It is not clear whether or not this application is considered a 'gold standard' of activity or how the information collected is used. The output from Bluespier was audited alongside the other log books and digital data identified below.

Review of the Theatre Log Books

Log books from BRC operating theatres and one Hybrid room were made available. BRI theatres 1, 2, 9 and Hybrid were offered for review. The log books that were reviewed are bound bespoke ledgers with large wide ruled lines for entries. Each entry is hand written and as previously noted, at times this was difficult to decipher. Some entries used the patient identity labels which was helpful. The log books for operating rooms 3 and 5 (paediatric) were also offered for review.

1. nil records were identified in the log books that may be suitable for submission to NCHDA

Review of the Cath Lab Log Books at BRC/BRI

There is 1 paediatric catheter laboratory at BRC and 5 catheter laboratories at BRI. The log book for the paediatric catheter laboratory was made available. A printout from the CCW (a GE information system) was provided. This is considered to be the 'gold standard' of recording of activity in the adult congenital heart disease cath labs.

As previously reported, the CCW printout was fairly easy to use. It was not always clear whether or not the cases were for ACHD patients.

1. 2 records were identified in the log books that may be suitable for submission to NCHDA

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

Data Quality Indicator Assessment:

20 Patients who had 35 Procedures – 15 Caths and 30 operations.

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		9	11
2	NHS Number	20	20		9	11
3	Surname	20	20		9	11
4	First Name	20	20		9	11
5	Sex	20	20		9	11
6	DOB	20	20		9	11
7	Ethnicity	20	20		9	11
8	Patient Status	20	20		9	11
9	Postcode	20	20		9	11
10	Pre Procedure Diagnosis	35	35		15	20
11	Previous Procedures	113	113		15	69
12	Patients Weight at Operation	35	35		44	20
13	Height	33	33		15	18
14	Ante Natal Diagnosis	4	4		15	2
15	Pre Proc Seizures	35	35		2	20
16	Pre Proc NYHA	11	11		15	4
17	Pre Proc Smoker	11	11		7	4
18	Pre Proc Diabetes	11	11		7	4
19	Hx Pulmonary Dis	11	11		7	4
20	Pre Proc IHD	11	11		7	4

21	Comorbidity Present	33	35	2 incorrect	14/15	19/20
22	Comorbid Conditions	70	72	2 incorrect	32/33	38/39
23	Pre Proc Systemic Ventricular EF	35	35		15	20
24	Pre Proc Sub Pul Ventricular EF	30	30		14	16
25	Pre-proc valve/septal defect/ vessel size	7	7		7	-
26	Consultant	35	35		15	20

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	35	35		15	20
28	Proc Urgency	35	35		15	20
29	Unplanned Proc	8	8		2	6
30	Single Operator	6	6		9	-
31	Operator 1	35	35		15	20
32	Operator 1 Grade	35	35		15	20
33	Operator 2	29	29		9	20
34	Operator 2 Grade	29	29		9	20
35	Procedure Type	35	35		9	20
36	Sternotomy Sequence	17	17		-	17
37	Operation Performed	35	35		15	20

38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	4	4		4	-
40	Device Manufacturer	20	20		11	9
41	Device Model	20	20		11	9
42	Device Ser No	20	20		11	9
43	Device Size	16	16		9	7
44	Total Bypass Time	15	15		-	15
45	XClamp Time,	14	14		-	14
46	Total Arrest	4	4		-	4
47	Cath Proc Time,	15	15		15	-
48	Cath Fluro Time,	12	12		12	-
49	Cath Fluro Dose,	12	12		12	-

	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	35	35		15	20
52	Post Proc Complications	21	21		-	21
53	Date of Discharge	35	35		15	20

54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	35	35		15	20
57	Discharge Destination	35	35		15	20

The Overall Trust DQI = 99.75% Cardiology DQI = 99.75% Surgery DQI = 99.75%
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.

<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 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** 1.0 **Card** 1.0	 **Surg** 1.0

Data Quality Indicator Assessment

The Trust DQI = 99.75%

This DQI is based upon the domain scoring below. The methodology for this DQI is provided in the paper The NCHDA CCAD Audit – An Introduction to the Process.

DOMAINS	2021 20/21	2022 21/22	2023 22/23	2024 23/24
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.98	.99	1.0	.99
Procedure	1.0	1.0	.99	1.0
Outcome	1.0	1.0	1.0	1.0

Conclusions

On the whole the NCHDA data are accurate, well documented, good quality and were appropriately recorded in the Theatre and Cath Lab logs books that were seen for BRC. The digital case note files for each patient were well put together and easy to follow.

The Data Quality Indicator Score for this validation visit has remained excellent at 99%+. Well done. The DQI score is also now included in the NHSE CQINs quarterly dashboards for congenital heart disease.

The Trust allowed a decrease the 0.2WTE in the congenital cardiac team information team in 2022 and this remains unaddressed. The Centre appears to have more or less returned to full pre pandemic NCHDA activity levels within the congenital cardiac service and further demonstrates that the full complement of 3.0WTEs (2.0WTE for paediatric and 1.0WTE for ACHD) to manage these data are required as specified in: Standard B32(L1) in NHSE Paediatric Congenital Heart Disease Standards – Specialist Children's Surgical Centres, 2016 and Standard B33 (L1) NHSE Congenital Heart Disease Standards for ACHD Surgical Centres 2016.

As previously reported while the Reviewers note that there are 4 individuals in post covering 2.38WTEs to support all of congenital heart disease data collection, just one of these individuals (0.3WTE) has a clinical background.

Review of Deceased Patients case notes.

As stated above, all data were found to be correct. The death summaries for paediatric patients were very informative. There are processes in place to capture out of hospital deaths for this patient cohort.

Recommendations

1. Active consideration of appointing a further 1.0WTE dedicated data manager for the NCHDA adult congenital (ACHD) data.
2. It is recommended that the Standard Operating Protocols (SOPs) for the congenital data collection, (paediatrics and ACHD), continue to be reviewed to ensure that they include detailed guidance on and **exactly who** is responsible (and in what timeframe) for;
   i. Input of the data for each procedure and at which point of the service delivery
   ii. 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
   iii. Leading the local review (and how frequently and in which forum for both disciplines)
   iv. Making timely submissions (monthly is required) as NICOR are now commissioned by NHSE to report each month all activity within 2 weeks of a procedure occurring.
   v. Timely reverse validation with all relevant clinicians
   vi. Monthly to quarterly PRAiS analysis as required as this analysis co-informs the NHSE quarterly dashboard activity data.
   vii. Ensuring that relevant case and procedural records and logs are extracted and printed from electronic sources (HeartSuite, Bluespier, CCW, etc) in advance to be easily accessible by the Auditors on the day of the visit.
   viii. Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.
   ix. Checking for any out of hospital deaths that may have occurred in the congenital cohort.
3. As recommended in 2011-23, it is suggested that consideration be given to identifying congenital procedures in the BRI electronic theatre log books as the entries are made. Precise, specific congenital diagnosis descriptions would be very helpful in this application.
4. It is recommended that care should be taken when hand writing entries of each procedure performed in any bound log books to ensure clarity and specificity.

5. Entries to the cath lab information system CCW should continue to be reviewed monthly and if necessary staff given extra training to more specifically describe procedures performed and how to identify patients with adult congenital heart disease rather than inherited heart disease. Shortening of names of procedures should be avoided as this may lead to mis interpretation. The use of recognised clinical coding such as OPCS, ICD10/11 and IPCC should be encouraged when it becomes available.
6. To establish if Bluespier operating theatre management system is a 'gold standard reference' for all catheter lab and operating room activity. If so, does it link to OPCS, ICD10 coding and used for Health Resource Groups (HRGs)?
7. It is also recommended that the DBMs should visit with other centres that send congenital cardiac data to NCHDA.
8. It is recommended that regular, training sessions and updates for all staff who may be involved with data input and should continue to be part of the induction process for new staff. This should include adult congenital staff members, who may be working solely within the BRI.
9. It is recommended that ST6's and above are encouraged to volunteer to assist with a NCHDA site validation visit.