The National Congenital Heart Disease Audit

Data Quality Audit for CONGENITAL HEART DISEASE Procedures April 2023 - March 2024

University Hospital Southampton NHS Foundation Trust

6 August 2024

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Introduction

Prior to this validation visit, the data return to NCHDA from the Congenital Cardiac Department of University Hospital Southampton, indicates that some 865 procedures (390 surgical operations, 464 catheters, 11 Others, 7 deaths within 30 days of a Specific Procedure) have been undertaken during the data collection year of 1 April 2023 to 31 March 2024.

The visit was undertaken by the NCHDA Clinical Audit Nurse and Dr T Prendiville, Consultant in Congenital Cardiology from Dublin on site in person.

Following review of the catheter laboratory and operating room activity log books on the day of the validation visit, 13 additional procedures were identified and where found suitable were subsequently submitted to the Registry.

This site validation visit has been fully funded by University of Southampton NHS Foundation Hospital Trust.

Congenital Audit Data Managers Role

As previously reported over the last decade, SGH have struggled to establish a full complement of dedicated clinical data managers who are specialist nurses (CNS) with specific protected time to manage the congenital data collection; often splitting the role with catheter lab and surgery admission scheduling. At this visit, there are 3 individuals that provide 1.3WTE to the data manager roles and this is 1.7 WTE less than the recommended minimum standard for a mixed practice Level 1 service provider for congenital heart disease (NHSE 2016).

The recommended minimum standard for NCHDA data managers is set out in the document The New Congenital Heart Disease Review (NHSE June 2016). That documents recommendations B32(L1) and B33 (L1) and state 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 assistant, and 1.0WTE for ACHD responsible for audit and database submissions in accordance with necessary timescales. NHSE may use NCHDA

data to underpin CQUINs (Commissioning for Quality and Innovation) quarterly dashboards. This remains unchanged in 2024.

In addition, NHSE have commissioned NICOR in 2024 to receive data from all centres within 2 weeks of a cardiac catheter or surgery procedure occurring and to provide quarterly reports on all procedural activity within 2 weeks of the end of each 3 month (quarterly) period on its website. This has a direct demand on DBMs work load.

As previously reported, NHSE also require dashboards to be underpinned by PRAiS2 (Paediatric Risk Analysis in Surgery version 2) software reports on a quarterly basis. In busy centres with high numbers of procedures, PRAiS2 may be run on a monthly basis.

Actions Undertaken or Challenges following the 2023 Validation Visit:

1. It is reported that there are now insufficient staff trying to adequately support and manage the NCHDA data collection, quality assure the data and submission of NCHDA data at SGH in the timescales required by NHSE.
2. It is reported that reverse validation of submitted data has not been done due to lack of staff available to do this task.
3. SGH report that they have severe time related challenges to enable running PRAiS 2 analysis quarterly to be able to present this to the joint cardiac and ICU meeting.
4. None of the current post holders have been able to attend an external validation visit this year due to the lack of staff supporting the NCHDA data collection and quality management.
5. It is reported that there are an increasing number of clinicians entering data following patient procedures and all are actively encouraged to do so. However these data require quality checks prior to submission.
6. All new registrars and consultants are required to attend training on data entry and understand its importance,

Consent for External Validation of Hospital Notes

Since May 2018, the General Data Protection Regulation requires that patients are made aware of how their data collected and used. As such, NCHDA now no longer requires a specific consent to examine hospital case notes. 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 be respected.

SGH has been mostly 'paper-lite' since 2018 using a mixture of paper and digital hospital notes. The electronic information system used is Enterprise CaMis. https://www.emishealth.com/products/camis-pas. Printed sheets from the ePR were meticulously prepared for each of the patients case notes to be examined. There is not yet one unified database for information, but a number of different ones holding different data on the inpatient episode.

20 patients were randomly selected who had had 26 procedures, (12 catheters and 14 operations) generating 982 data variables. 18 data discrepancies were identified.

The Data Quality Indicator Score (DQI)

The DQI for the Trust is calculated to be (with previous years in parentheses) **97.5%** (97.75, 98.25, 98.75) with domain scores Demographics 1.0 (1.0, 1.0, 1.0) Pre Procedure .99 (.97, .96, .99) Procedure .98 (.97, 1.0, .99) and Outcome .93 (.97, .97, .97 Although a small drop these are again good scores.

Field(s) with most discrepancies:

ACHD Risk fields 3
Post op Intubation 4
Details of implanted devices 4

Separate DQI for Surgery and for Catheters

On further review of the overall DQI for 2023/2024, when the cases were split into their surgery and catheter groups the scores are:

Year of Visit	Data Reviewed	Surgery	Catheters
2015	2014-15	98%	97.5%
2016	2015-16	98%	93%

2017	2016-17	99.25%	99%
2018	2017-18	98.25%	99%
2019	2018-19	99.25%	97%
2020	2019-20	96.75%	97.75%
2021	2020-21	98.75%	99%
2022	2021-22	97.25%	99%
2023	2022-23	98.25%	98%
2024	2023-24	96%	99.5%

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.

Introduction

The NCHDA data return indicates that the congenital cardiac department of Southampton University Hospital Trust has undertaken 865 procedures (390 surgical operations, 464 catheters, 11 Others, 7 deaths within 30 days of a Specific Procedure) have been undertaken during the data collection year of 1 April 2023 to 31 March 2024.

Review of notes

As stated above, 20 Sample sets of patient notes were requested for review, a further 10 sets were selected as Reserves in case any of the first 20 were unavailable. As reported elsewhere, for each patient record to be reviewed, the case notes had been meticulously printed when required from the ePR and prepared for the validation, with each document carefully identified and highlighted at the important segment. The accuracy of the NCHDA data return was then checked against each set of patients notes. The ePR was available if the Reviewers required to view any other documents or patient information. The accuracy was then recorded to enable the Data Quality Indicator (DQI) to be scored.

1. As previously noted, diagnoses coding should wherever possible reconcile with the procedure performed.
2. It was again difficult to find specific comments relating to the NCHDA adult congenital risk fields such as NYHA status, smoking, diabetes etc recorded in a specific place or on a regular proforma.
3. It was noted in younger ACHD or recently transitioned patients there was little or no documentation of whether or not they had been antenatally diagnosed.
4. As previously reported, it was sometimes challenging to find explicit documentation on function of each individual ventricle. There are 2 fields in the NCHDA dataset, one for systemic ventricular function and one for sub pulmonary ventricular function. For patients on a single ventricle pathway it is only necessary to complete one of these fields.

Review of the Log Books

As in the previous visits, the Reviewers make the observation that the both the theatre and cath lab log books are bespoke bound volumes with ruled lines and columns for certain items of information. The entries are made in hand writing and at times it was difficult to identify exactly what procedure had taken place and whether or not it is for congenital heart disease. As in 2016-23 it is reported at this visit that there are no plans to move to electronic operating or cath lab log books.

Review of the Theatre Log Books

There are reported to be 5 functional cardiac theatres at SGH during 2023/4. Congenital cardiac surgery is mainly performed in Theatre A and Theatre B. Sticky labels are used to identify patient episodes followed by hand written completion of the procedures performed and operators etc.

1. 6 submitted surgical records appear to have a coding error
2. 2 surgery procedures were identified that may have been missed from the data submission
3. 3 submitted records were identified to be in the incorrect procedure type

Cath Lab

There are 4 catheter laboratories at SGH; 1,2, 3 and 4. Cath labs 1 and 2 are reported to be biplane. The reviewers are pleased to note that the self inking stamp with the word 'Congenital' is still used to help identify relevant procedures. However this wasn't always consistently used. The log books for all cath labs were made available to the Reviewers. All fields in the books seen are completed in hand written entries.

As noted in other mixed practice centres identifying adult congenital cases undergoing ablations and pacemakers can be challenging when trying to decipher unclear hand writing.

1. 1 submitted catheter record appears to an have error.
2. 11 records were identified in the log books that may be suitable for this data collection

Validation of Deceased Patients Diagnostic and Procedure Coding

Commencing with the validation of the 2013/14 data, the National Congenital Heart Disease Audit wish to verify any dates of death of deceased patients in the year under review. The diagnosis and procedure coding will also be validated. Under the GDPR regulation, consent to view these hospital records is no longer needed.

7 patients who had died within 30 days of having a Specific Procedure were identified in the data return for 2023-24.

The PRAiS sensitive fields were reviewed for each of the 6 patients identified above and the findings were:

1. All dates of death were found to be correct.
2. 2 records may have incorrect comorbidities
3. 2 records appear to have discrepancies in the fields for procedure type and/or sternotomy sequence
4. 2 records appear to have discrepancies in fields for Attribution of Death and/or discharge destination. It is reported that the completion of this data for NCHDA is not discussed at the mortality meeting or similar clinical interface
5. It maybe helpful to have a standard proforma to record such items as date of discussion with Medical Examiner/Coroner and mortality review etc.

Casenote Audit

20 patients who underwent 26 Procedures. 14 operations and 12 therapeutic catheter procedures

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		10	10
2	NHS Number	20	20		10	10
3	Surname	20	20		10	10
4	First Name	20	20		10	10
5	Sex	20	20		10	10
6	DOB	20	20		10	10
7	Ethnicity	19	20		10	10
8	Patient Status	20	20		10	10
9	Postcode	20	20		10	10
10	Pre Procedure Diagnosis	25	25	1 missing component	12	14
13	Previous Procedures	26	26		44	45
12	Patients Weight at Operation	89	89		12	14
13	Height	26	26		12	12
14	Ante Natal Diagnosis	24	24		2	1
15	Pre Proc Seizures	3	3		12	14
16	Pre Proc NYHA	26	26		3	4
17	Pre Proc Smoker	7	7		3	4
18	Pre Proc Diabetes	7	7		3	4
19	Hx Pulmonary Dis	6	7	1 incorrect	2/3	4
20	Pre Proc IHD	5	7	2 incorrect	2/3	¾

21	Comorbidity Present	26	26		12	14
22	Comorbid Conditions	26	27	1 absent	15	11/12
23	Pre Proc Systemic Ventricular EF	27	27		12	14
24	Pre Proc Sub Pul Ventricular EF	26	26		12	14
25	Pre-proc valve/septal defect/ vessel size	26	26		8	-
26	Consultant	26	26		12	14

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	26	26		12	14
28	Proc Urgency	26	26		12	14
29	Unplanned Proc	0	1	1 incorrect	-	0/1
30	Single Operator	7	7		7	-
31	Operator 1	26	26		12	114
32	Operator 1 Grade	26	26		12	14
33	Operator 2	19	19		5	14
34	Operator 2 Grade	19	19		5	14
35	Procedure Type	26	26		12	14

36	Sternotomy Sequence	10	10		-	10
37	Operation Performed	26	26		12	14
38	Sizing balloon used for septal defect	2	2		2	-
39	No of stents or coils	3	3		3	-
40	Device Manufacturer	13	14	1 absent	9	4/5
41	Device Model	13	14	1 absent	9	4/5
42	Device Ser No	13	14	1 absent	9	4/5
43	Device Size	12	13	1 absent	9	3/4
44	Total Bypass Time	9	9		-	9
45	XClamp Time,	8	8		-	8
46	Total Arrest	0	1	1 incorrect	-	0/1
47	Cath Proc Time,	12	12		12	-
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	10	14	4 incorrect	-	10/14
51	Post Procedure Seizures	26	26		12	14
52	Post Proc Complications	2	3	1 incorrect	-	2/4
53	Date of Discharge	26	26		12	14
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	26	26		12	14
57	Discharge Destination	26	26		12	14

Data Quality Indicator Assessment:

The Overall Trust DQI = **97.5%** Cardiology DQI = 99.5% Surgery DQI = 96%

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
.98</td><td>Surg
.99</td></tr>
<tr><td><u>Procedure</u></td><td colspan="2">Overall .98</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** .96
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .93 **Card** 1.0	 **Surg** .89

Data Quality Indicator Assessment

The Overall Trust DQI = 97.5% (97.75, 98.75, 98.75)

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

DOMAIN	2024	2023	2022	2021	2020
Demographic	1.0	1.0	1.0	1.0	.99
Pre Procedure	.99	.97	.96	.99	.97
Procedure	.98	.97	1.0	.99	.98
Outcome	.93	.97	.97	.97	.99

Conclusions

On the whole the NCHDA data were accurate, well documented, and were appropriately recorded in the Theatre and Cath Lab log books that were seen

The Data Quality Indicator (DQI) is 97.5%. Although another slight drop, this is a very good achievement again this year and demonstrates a continued strong commitment to good quality verified clinical data. There appears to continue to be a very robust culture of clinical audit embedded within the Trust. The Validation Team would like again, to commend the efforts of the CNS's and Data Analyst (DBMs) in maintaining this in circumstances when there have been considerable challenges with staffing these roles and now appear to be extremely stretched in their capacity to scrutinise for accuracy, quality assure, analyse and submit to NCHDA in a timely manner. NHSE now require data submissions within 2 weeks of a catheter or surgery procedure where possible. We would strongly recommend that consideration is given to creating a total of 3.0WTEs supporting the NCHDA activity and its related tasks and responsibilities to meet the NHSE 2016 guidelines as soon as possible.

The Reviewers would also like to particularly thank both the CNS's and Analyst for their very high standard of document preparation for this visit. This greatly assisted the process.

As previously reported, the handwritten entries in the cath lab and theatre log books while quite neat and well kept were sometimes extremely difficult to transcribe and it was impossible without further research to determine if some patients had congenital or acquired heart disease. The use of the Congenital stamp in the cath lab log book, when used, continues to help identify cases. The column in the theatre log books used to indicate the clinical specialty from which each patient comes from that was also very useful. However, 13 cases were raised as queries as it was unclear in the log books if these patients had a diagnoses for congenital heart disease or not. It is not known if this NHS Trust has any plans to move to an electronic record of cath lab and operating room activity logs yet.

As previously noted, care should be taken to ensure that diagnoses coding wherever possible reconciles with the procedure performed.

Deceased Patients Data Validation

Case notes for all deceased patients were made available. The Reviewers are pleased to note that quarterly cross checks with NHS Strategic Tracking is now undertaken to identify out of hospital deaths of NCHDA patients.

As described above, there were a small number of discrepancies identified. It is reported that the completion of the field Attribution of Death for NCHDA is not discussed at the mortality meeting or similar clinical interface. It was also noted that there does not appear to be a standard proforma to record such items as date of discussion with Medical Examiner/Coroner and mortality review etc. Or copies of the death certificate where one has been issued.

Recommendations

1. As previously and recommended as essential, to meet the New Congenital Heart Disease Review (NHSE June 2016) recommendation B32(L1) and B33 (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 assistant, and 1.0WTE for ACHD responsible for audit and database submissions in accordance with necessary timescales. These should fulfil dedicated roles to meet the growing demands of the NCHDA data collection and NHSE with no other 'add on' parts.

2. It is recommended that in liaison with the Lead Clinicians for cardiology and cardiac surgery, the CNSs/Congenital Data Manager(s), regularly review a standard operating procedure (SOP) to capture all data on congenital patients in a timely manner. The SOP should clearly set out exactly **who** is responsible for, and in what time frame the following should occur:
    a. Input of congenital patients' NCHDA required dataset items and at which point of the treatment delivery pathway, particularly data that cannot be entered at the time of the procedure is to be added, such as intubation time and complications.
    b. Encouraging responsible clinician input of the procedure data for each operation, diagnostic or catheter intervention at the point of the service delivery
    c. Validity (sense) checking and data completeness assessment with time intervals for feedback to responsible clinicians is documented, along with a clear time scale and line of responsibility for rectifying any omissions or errors in both surgery and cardiology disciplines. It is recommended that this is done soon after each patient treatment episode and again as soon after discharge from hospital as possible. Each clinician should be encouraged to 'own' their data.
    d. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the CNSs/Data Managers at least monthly.
    e. Running the PRAiS2 (Partial Risk Analysis in Surgery) analysis tool monthly where possible. This will inform the quarterly NHSE Dashboard reports.

f. Where a patient has died within 30 days of a procedure, clear specific documentation of 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.
g. Ensuring that dates of death are reported for any patient who has previously had a record submitted to the NCHDA by requesting and/or carrying out quarterly life status checks with NHS Strategic Tracking for SGH NCHDA patients
h. Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.
i. Leading the local NCHDA data review (and how frequently and in which forum for both disciplines)
j. Making timely submissions when possible (monthly is recommended).

3. It is recommended that for ACHD patients (ages 16 years and above) who attend a pre operative assessment appointment that the specific fields for NYHA, Smoking, Diabetes, Ischaemic Heart Disease, and Pulmonary Disease are clearly and concisely documented at that time.
4. It is also recommended that where a patient transitions into ACHD from another place it is documented whether or not their congenital cardiac defect was detected antenatally.
5. It is recommended that only clear succinct and specific descriptions or names of procedures are used in the log books of procedures in the operating rooms and catheter labs.
6. It should be noted that PRAiS 4 will be used as from April 2025 and will include all congenital surgical patients aged up to 18 years at the time of their procedure.
7. It is recommended that all staff who are involved with collecting, reviewing and managing the NCHDA data should attend at least one external validation visit per year either face to face or virtually.
8. All senior trainees (ST6 and above) should be actively encouraged to volunteer to assist with external validation visits to other centres.