The National Congenital Heart Disease Audit

Data Quality Audit for
CONGENITAL HEART DISEASE Procedures
April 2024 - March 2025

University Hospital Southampton NHS Foundation Trust

23 October 2025

performed by Lin Denne and Dr Ronel Talker

Introduction

Prior to this validation visit, the data return to NCHDA from the Congenital Cardiac Department of University Hospital Southampton, indicates that some 830 procedures (379 surgical operations, 444 catheters, 7 Others, 9 deaths within 30 days of a Specific Procedure) have been undertaken during the data collection year of 1 April 2024 to 31 March 2025.

The visit was undertaken by the NCHDA Clinical Audit Nurse and Dr R Talker, Specialty Trainee in Paediatric Cardiology from London on site in person.

Following review of the catheter laboratory and operating room activity log books on the day of the validation visit, 12 additional procedures were identified and where found suitable were subsequently be 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 meet the recommended number of dedicated clinical data managers with specific protected time to manage the NCHDA data collection; the role has been combined with surgery admission scheduling which is an admin role. At this visit, there are 3 individuals that provide 1.3 WTE to the data manager roles and this is over 50% WTE less than the recommended minimum standard for a mixed practice Level 1 service provider for congenital heart disease (NHSE 2016). It was also reported at this visit that one of the individuals will be further reducing their hours by approximately 0.3 WTE so this will leave the data collection and management at great risk of being unable to meet any required national standards in a timely manner and may in turn lead to the Trust being subject to contractual performance measures. The NCHDA Data collection are further challenged as only 1 of the 3 current individuals manages the catheter data. It is reported and was clearly apparent at this visit that there is minimal cross over between surgery and catheter data management and quality assurance.

The recommended minimum standard for NCHDA data managers is set out in the document mentioned above; 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 1.0 WTE 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 2025.

As previously reported, NHSE require dashboards to be underpinned by PRAiS 4.2 (Paediatric Risk Analysis in Surgery version 4.2) software reports on a quarterly basis. In busy centres with high numbers of procedures, PRAiS 4.2 may be run on a monthly basis.

Actions Undertaken or Challenges following the 2024 Validation Visit:

1. It is again reported that there are now insufficient staff trying to support and manage the NCHDA data collection, quality assure the data and submit NCHDA data at SGH in the timescales required by NHSE.
2. It is reported that reverse validation of submitted data has not been done for the 2nd year running due to lack of staff available to do this task.
3. SGH again report that they have severe time-related challenges to enable running PRAiS 4.2 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 and reverse validation after submission and this is not being done.
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 patient record 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 patient’s case notes to be examined. As stated elsewhere, there is not yet one unified database for information, but a number of different ones holding different data on the inpatient episode, each requiring a separate user ID and password.

Data Quality Indicator Score

The DQI for the Trust is calculated to be (with previous years in parentheses) **97%** (97.5, 97.75, 98.25) with domain scores: Demographics 1.0. (1.0, 1.0, 1.0), Pre Procedure .97 (.99, .97, .96), Procedure .95 (.98, .97, 1.0) and Outcome .98 (.93, .97, .97). This is a further small drop in the DQI score.

20 patients were randomly selected who had a total of 26 procedures, (15 catheters and 11 operations) generating 1085 data variables. 31 data discrepancies were identified.

Field(s) with most discrepancies:

Previous Procedures	7
Operator Name and Grade	4
Number of Stents or Coils	5

Separate DQI for Surgery and for Catheters

On further review of the overall DQI for 2024/2025, when the cases were split into their surgery and catheter groups the scores are:

Year of Visit	Data Reviewed	Surgery	Catheters
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%
2025	2024-25	98.5%	97%

Congenital NICOR pre-visit Questionnaire was completed and returned prior to the validation visit. This confirmed that there are processes and procedures in place in regard to:

Data Security and Management
Validation and Quality Assurance – reverse validation is not being carried out.
Training in Data Management
Information Governance Training
There is or are identified accountable person/people for NCHDA data quality and information validity
Data Submissions struggle to be timely and are not reverse validated.

Digital Maturity in 2025

As documented above, SGH does not yet have a fully digital electronic patient health record system that requires a single user ID and sign in process to access all electronic patient health records to view the NCHDA applicable data.

The NCHDA data collection tool is HeartSuite, a standalone system. Individual user id and passwords are required by each CNS/DBM to access the various data that their role requires. The CNS/DBM user may need to log in to different domains within the electronic health record with different passwords to access some parts of the information system.

On average, each DBM user may need to log in and out to between 5 and 7 different parts of the electronic health records system at SGH to record, view or edit NCHDA data depending on level of access.

There are still some paper based systems such as operating room and Cath Lab activity logbooks used. It is reported that there are no plans to digitise the current data that are collected on paper.

Introduction

The NCHDA data return indicates that the congenital cardiac department of Southampton University Hospital Trust has undertaken some 830 procedures (379 surgical operations, 444 catheters, 7 Others, 9 deaths within 30 days of a Specific Procedure) during the data collection year of 1 April 2024 to 31 March 2025.

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 consistently in a specific place or on a regular proforma in the patient record.
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 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 written by hand 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 2016-24 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 2024/5. Operating Rooms A, B, C, 3 and 4. Sticky labels are used to identify patient episodes followed by handwritten completion of the procedures performed and operators etc. The full year from April 2024 – March 2025 was reviewed in the books made available.

1. 1 submitted surgical record appears to have a coding error
2. 11 surgery procedures were identified that may have been missed from the data submission
3. 1 submitted record was identified to be in the incorrect procedure type
4. 4 submitted records were not validated

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 logbooks for all cath labs were made available to the Reviewers. All fields in the books seen are completed in handwritten entries.

There is clearly a locally curated number of short hand acronyms for some procedure descriptions but no translation reference was included in the logbooks.

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

Due to time pressures, it was only possible to validate April to June 2024. Therefore we are not able to state whether or not the catheter procedure data submission is a complete record of activity at this Centre.

1. 1 record was 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.

9 patients who had died within 30 days of having a Specific Procedure were identified in the data return for 2024-25.

The PRAiS sensitive fields were reviewed for each of the 9 patients identified above and the findings were:

1. All dates of death were found to be correct.
2. 1 record may have incorrect comorbidities
3. 1 record appears to have absent complications
4. 2 records appear to have discrepancies in the field 4.04 Discharge Destination
5. 4 records appear to have discrepancies in fields for Attribution of Death and/or discharge destination. It is again reported that the completion of this data for NCHDA is not discussed at the mortality meeting or similar clinical interface
6. There does not appear to be a standard proforma on the e-PR to record such items as date of discussion with Medical Examiner/Coroner and mortality review etc. Guidance on how and when steps should be taken are set out in the Child Death Review Statutory and Operational Guidance England (2018)
7. Coroners Reports and MCCDs were not seen but would be very helpful for this review and in other centres are included in the patient notes.

Casenote Audit

20 patients who underwent 26 Procedures. 11 operations and 15 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	26	26		15	11
13	Previous Procedures	117	124	7 incorrect	81/87	36/37
12	Patients Weight at Operation	25	26	1 incorrect	15	10/11
13	Height	25	25		15	10
14	Ante Natal Diagnosis	1	1		1	-
15	Pre Proc Seizures	26	26		15	11
16	Pre Proc NYHA	4	6	2 incorrect	2/4	2
17	Pre Proc Smoker	6	6		4	2
18	Pre Proc Diabetes	6	6		4	2
19	Hx Pulmonary Dis	6	6		4	2
20	Pre Proc IHD	6	6		4	2
21	Comorbidity Present	26	26		15	11
22	Comorbid Conditions	74	75	1 incorrect	40	34/35
23	Pre Proc Systemic Ventricular EF	25	26	1 incorrect	14/15	11
24	Pre Proc Sub Pul Ventricular EF	20	20		10	10
25	Pre-proc valve/septal defect/ vessel size	3	3		3	-
26	Consultant	26	26		15	11

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	26	26		15	11
28	Proc Urgency	26	26		15	11
29	Unplanned Proc	-	-		-	-
30	Single Operator	8	8		8	-
31	Operator 1	25	26	1 incorrect	15	10/11
32	Operator 1 Grade	25	26	1 incorrect	15	10/11
33	Operator 2	17	18	1 incorrect	7	10/11
34	Operator 2 Grade	17	18	1 incorrect	7	10/11
35	Procedure Type	26	26		15	11
36	Sternotomy Sequence	8	9	1 incorrect	-	8/9
37	Operation Performed	26	26		15	11
38	Sizing balloon used for septal defect	1	1		1	-
39	No of stents or coils	16	21	5 absent	16/21	-
40	Device Manufacturer	18	18		16	2
41	Device Model	32	32		30	2
42	Device Ser No	32	32		30	2
43	Device Size	31	31		29	2
44	Total Bypass Time	9	9		-	9
45	XClamp Time,	7	7		-	7
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	15	15		15	-
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	10	10		-	10
51	Post Procedure Seizures	26	26		15	11
52	Post Proc Complications	0	2	2 incorrect	0/2	-
53	Date of Discharge	26	26		15	11
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	26	26		15	11
57	Discharge Destination	26	26		15	11

Data Quality Indicator Assessment:

The Overall Trust DQI = **97%** Cardiology DQI = 97% Surgery DQI = 98.5%

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.

DOMAIN	**DOMAIN Score**		
	Overall	**Card**	**Surg**
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	**1.0**	1.0	1.0
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	**.97**	.96	.98
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,**	**.95**	.98	.96
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	.98	.94	1.0

Data Quality Indicator Assessment

The Overall Trust DQI = 97% (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	2025	2024	2023	2022	2021
Demographic	1.0	1.0	1.0	1.0	1.0
Pre Procedure	97	.99	.97	.96	.99
Procedure	95	.98	.97	1.0	.99
Outcome	.98	.93	.97	.97	.97

Conclusions

On the whole the NCHDA data that were reviewed 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% for this visit. This is the third successive albeit small drop, but nevertheless is concerning, particularly in light of the mixed roles the NCHDA Data Managers are expected to fulfil between surgery scheduling and data management. The lack of resources allocated to supporting the NCHDA data collection and management is severely impacting not just the quality of the data but the basic management of the completeness of the information submitted and the timeliness of this. The clinical congenital community at SGH remain very committed to NCHDA but appear to lack support from the senior management of this NHS Trust. The Validation Team would like again, to commend the efforts of the CNS's and Data Analyst (DBMs) in trying to maintain this dataset in incredibly difficult circumstances when there have been considerable challenges and they now appear to be unable to scrutinise for accuracy, quality assure, analyse and submit to NCHDA in a timely manner. NHSE require data submissions (at a minimum) to be within 2 weeks of the end of each quarter. We would strongly recommend that consideration is given to creating a total of 3.0 WTEs supporting the NCHDA activity and its related tasks and responsibilities to meet the NHSE 2016 guidelines as soon as possible.

Congenital surgery scheduling at all other NCHDA Level 1 providers is an administrative role, part of patient service provision and performed in conjunction with the consultant surgeons, their secretaries, the Network CNS's/Liaison Nurses, and the relevant business manager(s).

The Reviewers would also like to particularly thank both the CNS's/DBMs and Analyst for their very high standard of document preparation for this visit. This greatly assisted the process and it is recognised that the Trust had to pay overtime to enable this due to previously documented lack of investment and support for these roles.

As previously reported, the handwritten entries in the Cath Lab and theatre logbooks 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 logbook, when used, continues to help identify cases. As noted above, there appears to be a locally curated list of acronyms for some Cath Lab procedures but there is no library list of what these acronyms mean.

The column in the theatre logbooks used to indicate the clinical specialty from which each patient comes from was also very useful. However, a total of 12 cases were raised as queries as it was unclear in the logbooks if these patients had a diagnosis of congenital heart disease or not. The Cath Lab logbook procedures ascertainment checks were not completed due to time pressures and it is not possible to say if this submission for 2024-25 therapeutic interventions is complete 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 are reported to be 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 and there is not a nominated consultant clinician to do this. There does not appear to be a standard proforma on the e-PR to record such items as date of discussion with Medical Examiner/Coroner and mortality review etc. Guidance on how and when steps should be taken are set out in the Child Death Review Statutory and Operational Guidance England (2018).

Coroners Reports and MCCDs were not seen but would be very helpful for this review and in other centres are included in the patient notes.

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 1.0 WTE 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 such as cardiac surgery scheduling.

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 PRAiS 4.2 (Partial Risk Analysis in Surgery) analysis tool monthly where possible. This will inform the quarterly NHSE Specialised Commissioning 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 18 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 and should also be included in the MDT template.
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. GMC numbers with clinicians names should be included in the required format as of April 2025 in every submission
6. It is recommended that all of those in the role of NCHDA data manager should be trained to collect, quality assure and analyse data from congenital surgery and also diagnostic and therapeutic catheter procedures.
7. PFOs are no longer required by NCHDA from April 2025 and should be submitted to the PFOC Database hosted by NICOR.
8. It is recommended that only clear succinct and specific descriptions or names of procedures are used in the logbooks of procedures in the operating rooms and catheter labs.
9. 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.
10. All senior trainees (ST6 and above) should be actively encouraged to volunteer to assist with external validation visits to other centres.