



The National Congenital Heart Disease Audit

**Data Quality Audit for
CONGENITAL HEART DISEASE Procedures
April 2019 - March 2020**

University Hospital Southampton NHS Foundation Trust

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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 756 procedures (357 surgical operations, 399 catheters, 14 deaths) have been undertaken during the data collection year of 1 April 2019 to 31 March 2020.

This validation visit has been fully funded by the Southampton University NHS Foundation NHS Trust. This visit was supported remotely by the NCHDA clinical audit nurse via an MSTeams facility and on site in person by Dr Rodney Franklin, Consultant Congenital Cardiologist from London.

Congenital Audit Data Managers Role

As previously reported SGH have at times struggled to establish a full complement of dedicated data managers who are specialist nurses with specific protected time to manage the congenital data collection; often splitting the role with catheter lab and or surgery scheduling. From 2012 until present there were up to 3 individuals covering 1.2 to currently 1.5 WTEs of the data manager roles.

The New Congenital Heart Disease Review (NHSE June 2016) recommendation B32(L1) and B33 (L1) 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. As previously reported, NHSE 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 is run on a monthly basis.

There are now also much stricter controls on which data will be accepted by the database at the time that information is ready to be submitted and this has created a considerable burden for the data managers at all congenital centres.

Actions Undertaken following the 2019 Validation Visit:

- No changes or actions were reported.

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.



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Since 2018 SGH has been mostly 'paper-lite' using a mixture of paper and digital hospital notes. 20 Sample patients' notes that were randomly selected for validation had either a signed consent form, label in or telephone consent for examination of their hospital notes. 1 set of notes were required from the Reserve list to make the 20 casenote sample. These 20 patients had a total of 30 procedures, (15 catheters and 15 operations).

The Data Quality Indicator Score (DQI)

The Provisional DQI for the Trust is calculated to be (with previous years in parentheses) **98.25%** (98.75, 98.75, 99) with domain scores Demographics .99 (1.0, 1.0, 1.0) Pre Procedure .97 (.98, .96, 98,) Procedure .98 (.98, .99, 997) and Outcome .99 (.98, 1.0, 99). These are again very good scores.

This is based on 20 patients who had a total of 30 procedures, (15 catheters and 15 operations) generating 1069 data variables. 28 data discrepancies were identified.

Separate DQI for Surgery and for Catheters

On further review of the overall DQI for 2019/20, when the cases were split into their surgery and catheter groups the scores are:

Year of Visit	Data Reviewed	Surgery	Catheters
2012	2010-11	93.5%	95.75%
2013	2011-12	98.75%	99.75%
2013(Nov)	2012-13	95.6%	95.4%
2014	2013-14	98.25%	98.25%
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%

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 756 procedures (357 surgical operations, 399 catheters, 14 deaths) have been undertaken during the data collection year of 1 April 2019 to 31 March 2020.

The Congenital Data Auditor for the NCHDA undertook the visit remotely with an external Consultant Congenital Cardiologist on site at SGH.

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. The case notes had been meticulously printed when required from the ePR and prepared for the validation, with each relevant document carefully identified with a sticky note. The accuracy of the NCHDA data return was then checked against each set of 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 and it was noted that some, while not incorrect, were not quite complete.
2. Some of the printed electronic data was a little difficult to decipher if the electronic document was a scanned copy of a paper note.
3. Sometimes the information recorded on ePR documents appeared to be incomplete.
4. Also as previously reported, the documentation of the NYHA status was not always clear in the hospital notes of ACHD patients.
5. Perfusion records were seen in all of the surgical patients notes at this visit.
6. As previously reported, it was observed that details of implantable devices did not appear to be routinely included in the procedure performed or operation notes seen.
7. Documentation of sheath in and sheath out times for patients who underwent cath lab procedures was difficult to find in electrophysiological (EP) procedures.
8. Discharge information was variably found within ICP or within other areas of the patient notes.
9. 3 patients whose case notes were reviewed were found to have missing procedures that should be reported to NHCDA.

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 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



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and whether or not it is for congenital heart disease. As in 2016-19 it is reported at this visit that there are no plans to move to electronic operating or cath lab log books.

The CNS also reported that there has been difficulty during this data collection year with getting access to the OR log books to validate them to ensure complete case ascertainment.

Review of the Theatre Log Books

There are reported to be 5 cardiac theatres at SGH. Congenital cardiac surgery is mainly performed in Theatre 3 and Theatre B. Sticky labels are used to identify patient episodes followed by hand written completion of the procedures performed and operators etc.

1. 9 submitted surgical records appear to have a coding error
2. 5 surgery procedures were identified that may have been missed from the data submission

Cath Lab

There are 4 catheter laboratories at SGH; 1,2, 3 and 4. Cath labs 1 and 2 are biplane. The reviewers are pleased to note that the self inking stamp with the word Congenital is still used to help identify relevant procedures. 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 a problem.

1. 5 submitted catheter records appear to have errors in them
2. 18 submitted records were not validated in the log books and some of these procedures may have been performed in other areas such as PICU

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.

14 deceased patients were identified in the data return for 2019-20. 11 of these patients had died within 30 days of a therapeutic procedure and these were prioritised for the review.

The PRAiS2 sensitive fields were reviewed for each of the 11 patients identified above and the findings were:

1. All dates of death were found to be correct.
2. 6 records may have missing elements from the diagnosis coding
3. 3 records may have previous procedures missing
4. 8 records may have missing comorbidities
5. 4 records may have incomplete procedure performed coding
6. 2 records may have missing data in the attribution of death field
7. 2 records for the same patient may require recoding into one hybrid record



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Casenote Audit

20 patients who underwent 28 Procedures. 17 operations and 11 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	1 incorrect	9/10	10
8	Patient Status	20	20		10	10
9	Postcode	20	20		10	10
10	Pre Procedure Diagnosis	29	30	1 incorrect, 10 incomplete	15	14/15
11	Previous Procedures	70	73	3 absent	19	51/54
12	Patients Weight at Operation	30	30		15	15
13	Height	29	29		15	14
14	Ante Natal Diagnosis	3	3		1	2
15	Pre Proc Seizures	28	30	2 incorrect	14/15	14
16	Pre Proc NYHA	4	4		2	15
17	Pre Proc Smoker	4	4		2	2
18	Pre Proc Diabetes	4	4		2	2
19	Hx Pulmonary Dis	4	4		2	2
20	Pre Proc IHD	3	4	1 incorrect	½	2
21	Comorbidity Present	29	30	1 incorrect	14/15	15
22	Comorbid Conditions	40	43	3 absent	25/27	15/16
23	Pre Proc Systemic Ventricular EF	30	30		15	15
24	Pre Proc Sub Pul Ventricular EF	28	28		15	13
25	Pre-proc valve/septal defect/ vessel size	5	5		5	-
26	Consultant	30	30		15	15



	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	30	30		15	15
28	Proc Urgency	30	30		15	15
29	Unplanned Proc	4	4		2	2
30	Single Operator	3	4	1 incorrect	$\frac{3}{4}$	-
31	Operator 1	30	30		15	15
32	Operator 1 Grade	30	30		15	15
33	Operator 2	26	26		11	15
34	Operator 2 Grade	26	26		11	15
35	Procedure Type	30	30		15	15
36	Sternotomy Sequence	15	15		-	15
37	Operation Performed	30	30		15	15
38	Sizing balloon used for septal defect	1	1		1	-
39	No of stents or coils	4	4		4	-
40	Device Manufacturer	8	9	1 absent	4	4/5
41	Device Model	11	12	1 absent	7	4/5
42	Device Ser No	11	12	1 absent	7	4/5
43	Device Size	7	8	1 absent	4	$\frac{3}{4}$
44	Total Bypass Time	14	14		-	14
45	XClamp Time,	11	11		-	11
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	13	15	2 unable to validate	13/15	-
48	Cath Fluro Time,	13	14	1 unable to validate	13/14	-
49	Cath Fluro Dose,	13	14	1 unable to validate	13/14	-



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	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	13	15	2 incorrect	-	11/15
51	Post Procedure Seizures	30	30		15	15
52	Post Proc Complications	3	3		-	2/3
53	Date of Discharge	28	30	2 incorrect	114/15	14/15
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	30	30		15	15
57	Discharge Destination	30	30		15	14/15



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Data Quality Indicator Assessment:

The Overall Trust DQI = 98.25%

Cardiology DQI = 97.75%

Surgery DQI = 96.75%

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

DOMAIN	DOMAIN Score	
<p><u>Demographics</u></p> <p>Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,</p>	Overall .99	
	Card .99	Surg 1.0
<p><u>Pre Procedure</u></p> <p>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,</p> <p>Note, the scores for his domain are affected by the selected previous procedure and pre procedure diagnosis</p>	Overall .97	
	Card .97	Surg .97
<p><u>Procedure</u></p> <p>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,</p>	Overall .98	
	Card .97	Surg .99
<p><u>Outcome</u></p> <p>Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination.</p> <p>Post Procedure Complications.</p>	Overall .99	
	Card .98	Surg .91



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Data Quality Indicator Assessment

The Overall Trust DQI = 98.25% (98.75, 98.75, 99)

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	2020	2019	2018	2017	2016
Demographic	.99	1.0	1.0	1.0	1.0
Pre Procedure	.97	.98	.95	.98	.92
Procedure	.98	.99	.99	.99	.93
Outcome	.99	.98	1.0	1.0	.98

FEMVA



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 98.25%. This is an excellent achievement again this year. This demonstrates a continued strong commitment to good quality verified clinical data. There appears 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 and Data Analyst (DBMs) in maintaining this at time when there have been considerable challenges both technically and with staffing these roles. The Reviewers would also like to particularly thank both the CNS and Analyst for their very high standard of document preparation for this visit. This greatly assisted the process. It was noted that the DBMs roles are stretched to capacity with one individual on a short term secondment in this role from ICU. We would strongly recommend that consideration is given to creating a further 1.0WTE data quality/audit facilitator role to compliment the current team. Making a total of 3.0WTE supporting the NCHDA activity and its related tasks and responsibilities.

As previously reported, the handwritten entries in the cath lab and theatre log books while quite neat and well kept were sometimes very 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 does 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.

Care should be taken to ensure that diagnoses coding wherever possible reconciles with the procedure performed and explicit coding of balloon atrial septostomy will ensure that the Specific Procedure algorithm will count these procedures correctly. Care should also be taken with the specificity of defects such as Perimembranous or Muscular VSDs for instance.

Deceased Patients Data Validation

Case notes for all deceased patients were made available. As previously reported, there does not appear to be a regular cross check with NHS Strategic Tracking to identify out of hospital deaths of NCHDA patients.

As described above, there were a small number of errors identified and these have since been checked and rectified post visit.

Recommendations.

1. 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. Ensuring that all patients/parents and guardians are given full information of how their data are securely recorded, stored, where this information is shared and who with. And opting out is explained to patients/carers
 - b. 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.
 - c. Encouraging responsible clinician input of the procedure data for each operation, diagnostic or catheter intervention at the point of the service delivery
 - d. Recording the knife to skin time for all surgical procedures where it can be validated (ie perfusion or anaesthetic record).
 - e. 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.
 - f. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the CNSs/Data Managers at least monthly.
 - g. Running the PRAiS2 (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 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
 - i. Leading the local review (and how frequently and in which forum for both disciplines)
 - j. Making timely submissions when possible (monthly is recommended) and



- k. Including details of manufacturer, model and serial numbers of all implantable devices with each patient record for a procedure.
3. To ensure all staff collecting and submitting data have access to the correct database platform for NCHDA for the purpose of validation of data and communication from NCHDA of patient identifiable data etc. as previously recommended
4. It is recommended to identify analytical support to the DBMs to enable running of both Specific Procedures and Activity algorithms to give timely feedback to clinicians. These algorithms run in R Code Freeware and are downloadable and widely used in the NHS community. The scripts to run these algorithms is supplied by NCHDA, with support from the national UK lead DBM for NCHDA data returns.
5. 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.
6. All senior trainees (ST6 and above) should be actively encouraged to volunteer to assist with external validation visits to other centres.

FINAL