The National Congenital Heart Disease Audit

Data Quality Audit for CONGENITAL HEART DISEASE Procedures April 2020 - March 2021

University Hospital Southampton NHS Foundation Trust

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performed by Lin Denne and Dr A J P Tometzki

Introduction

Prior to this validation visit, the data return to NCHDA from the Congenital Cardiac Department of University Hospital Southampton, indicates that some 674 procedures (268 surgical operations, 405 catheters, 8 deaths) have been undertaken during the data collection year of 1 April 2020 to 31 March 2021. This represents an approximate 10% drop in overall numbers of procedures undertaken when compared with 2019 – 2020 in a time of the SARS-COV-2 pandemic.

This validation visit has been fully funded by the Southampton University NHS Foundation NHS Trust. The visit was supported remotely by the NCHDA clinical audit nurse via an MS Teams facility and on site in person by Dr A J P Tometzki, Consultant Congenital Cardiologist from Bristol.

Congenital Audit Data Managers Role

As previously reported SGH have at times 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 or surgery scheduling. From 2012 until the time of this visit 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 an extra burden for the data managers at all congenital centres.

Actions Undertaken following the 2020 Validation Visit:

- Recruitment for the CNS/Database Manager permanent role is complete with two staff due to start imminently after this validation for a combined role of data manager and congenital coordinator, with consideration to recruit further data assistant (AfC Band 4).

- The reverse validation of the monthly data submitted to NCHDA will be reinstated once the new Data Managers are in post.

- Review of the patient's quarterly life status checks/deaths has taken place and it is hoped that going forward this will be done in the future by the NCHDA data managers.

- Improvement in documentation of NYHA functional class and smoking status, will now be included in ACHD clinic letters following discussion with ACHD consultants to improve these data entries.

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.

Since 2018 SGH has been mostly 'paper-lite' using a mixture of paper and digital hospital notes. Printed sheets from the ePR as well as some paper notes were meticulously prepared for each patients case note examined. 20 patients were reviewed who had undergone a total of 26 procedures, (17 catheters and 9 operations) generating 943 data variables. 12 data discrepancies were identified.

The Data Quality Indicator Score (DQI)

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

Separate DQI for Surgery and for Catheters

On further review of the overall DQI for 2020/21, when the cases were split into their surgery and catheter groups the scores are:

Year of Visit	Data Reviewed	Surgery	Catheters
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%
2021	2020-21	98.75%	99%

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 674 procedures (268 surgical operations, 405 catheters, 8 deaths) have been undertaken during the data collection year of 1 April 2020 to 31 March 2021.

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. Some of the printed electronic data was a little difficult to decipher if the electronic document was a scanned copy of a paper note.
2. Occasionally the information recorded on ePR documents appeared to be incomplete.
3. 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.
4. It was again difficult to find specific comments relating to the NCHDA adult congenital risk fields such as NYHA status, smoking, diabetes etc
5. It was also very difficult to accurately validate catheter procedure skin (sheath in) time to skin (sheath out) time for some procedures as it appears not to be routinely recorded on all catheter reports
6. It appeared at times that the HeartSuite software currently being used may not be the most current and up to date version as incomplete options are reported on the field for Discharge Destination for example.

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 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 2016-20 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 was mainly performed in Theatre B and Theatre A during 2020/21 Sticky labels are used to identify patient episodes followed by hand written completion of the procedures performed and operators etc.

1. 4 submitted surgical records appear to have a coding error
2. 1 surgery procedure was identified that may have been missed from the data submission

Cath Lab

There are 5 catheter laboratories at SGH numbered 1-5. 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. 4 submitted catheter records appear to have errors in them
2. 2 records were identified in the log books that may be suitable for this data collection
3. 2 submitted records were not validated in the log books and some of these procedures may have been performed in other areas such as PICU.

We are pleased to report that all discrepancies highlighted have been reviewed and any necessary data changes have been made since this site visit took place.

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.

8 deceased patients were identified in the data return for 2020-21. 5 of these patients had died within 30 days of a therapeutic procedure and these were prioritised for the review.

The PRAiS sensitive fields were reviewed for each of the 5 patients identified above and the findings were:

1. All dates of death were found to be correct.
2. 1 record may have missing comorbidities
3. 1 record may have incomplete procedure performed coding
4. 2 records may have missing data in the attribution of death field
5. 2 records may have an incorrect discharge destination

Casenote Audit

20 patients who underwent 26 Procedures. 9 operations and 17 therapeutic catheter procedures

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		15	5
2	NHS Number	20	20		15	5
3	Surname	20	20		15	5
4	First Name	20	20		15	5
5	Sex	20	20		15	5
6	DOB	20	20		15	5
7	Ethnicity	19	20		15	5
8	Patient Status	20	20		15	5
9	Postcode	20	20		15	5
10	Pre Procedure Diagnosis	25	26	1 incorrect	16/17	9
11	Previous Procedures	53	53		36	17
12	Patients Weight at Operation	26	26		17	9
13	Height	23	23		16	7
14	Ante Natal Diagnosis	6	6		4	2
15	Pre Proc Seizures	26	26		17	9
16	Pre Proc NYHA	2	2		2	-
17	Pre Proc Smoker	2	2		2	-
18	Pre Proc Diabetes	2	2		2	-
19	Hx Pulmonary Dis	2	2		2	-
20	Pre Proc IHD	2	2		2	-
21	Comorbidity Present	25	26	1 incorrect	16/17	9
22	Comorbid Conditions	14	15	1 absent	10/11	4
23	Pre Proc Systemic Ventricular EF	26	26		17	9
24	Pre Proc Sub Pul Ventricular EF	25	25		17	8
25	Pre-proc valve/septal defect/ vessel size	8	8		8	-
26	Consultant	26	26		17	9

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	26	26		17	9
28	Proc Urgency	26	26		17	9
29	Unplanned Proc	-	-		-	-
30	Single Operator	4	4		13	-
31	Operator 1	25	26	1 unable to validate	16/17	9
32	Operator 1 Grade	26	26		17	9
33	Operator 2	21	22	1 unable to validate	12/13	9
34	Operator 2 Grade	22	22		13	9
35	Procedure Type	26	26		17	9
36	Sternotomy Sequence	7	7		-	7
37	Operation Performed	26	26		17	9
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	5	5		-	5
40	Device Manufacturer	10	10		8	1
41	Device Model	10	10		9	1
42	Device Ser No	10	10		9	1
43	Device Size	5	5		5	-
44	Total Bypass Time	5	6	1 incorrect	-	5/6
45	XClamp Time,	6	6		-	6
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	16	17	1 incorrect	16/17	-
48	Cath Fluro Time,	14	14		15	-
49	Cath Fluro Dose,	14	14		15	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	6	9	3 incorrect	-	6/9
51	Post Procedure Seizures	26	26		17	9
52	Post Proc Complications	-	-		-	-
53	Date of Discharge	25	26	1 incorrect	16/17	9
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	26	26		17	9
57	Discharge Destination	25	26	1 incorrect	16/17	9

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.75% Cardiology DQI = 99% 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	
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	**Overall 1.0**	
	Card 1.0	**Surg** 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	**Overall .99**	
	Card .985	**Surg** 1.0
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,**	**Overall** .99	
	Card .99	**Surg** .99
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .97	
	Card .97	**Surg** .96

Data Quality Indicator Assessment

The Overall Trust DQI = 98.75% (98.75, 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	2021	2020	2019	2018	2017
Demographic	1.0	.99	1.0	1.0	1.0
Pre Procedure	.99	.97	.98	.95	.98
Procedure	.99	.98	.99	.99	.99
Outcome	.97	.99	.98	1.0	1.0

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 98.75%. This is an excellent 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 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 still stretched to capacity with one individual, at the time of visit, a secondee from a frontline clinical facing role due to return to that environment. 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 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, 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. 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.

As previously noted, 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. It was noted on several occasions that the coding used may not be the most up to date version within the HeartSuite database and this may require a review with the supplier.

Deceased Patients Data Validation

Case notes for all deceased patients were made available. As previously reported, there did not appear to be a regular cross check with NHS Strategic Tracking to identify out of hospital deaths of NCHDA patients. The Reviewers are pleased to note at this visit that this task will be planned going forward with the appointment of the new CNS/Database Managers.

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. 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 (Paediatric Risk Analysis in Surgery) analysis tool monthly. This will inform the quarterly NHSE Dashboard reports.
    f. 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
    g. Leading the local review (and how frequently and in which forum for both disciplines)
    h. Making timely submissions when possible (monthly is recommended) and
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 either face to face or virtually.
6. All senior trainees (ST6 and above) should be actively encouraged to volunteer to assist with external validation visits to other centres.