The National Congenital Heart Disease Audit

Data Quality Audit for CONGENITAL HEART DISEASE Procedures April 2018 - March 2019

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 812 procedures (502 surgical operations, 197 catheters, 113 others, 11 deaths) have been undertaken during the data collection year of 1 April 2018 to 31 March 2019.

Following the log book audit of cardiac theatres and cath labs 4 procedures were identified that may be suitable for inclusion in NCHDA. These cases were very promptly reviewed after the validation visit and any changes made.

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 a teleconference facility and on site in person by Dr K VonKlemperer, 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 WTEs of the data manager roles.

As previously stated, many units have recognised the value and importance of these data and have a totally dedicated 2.0 WTEs or greater to provide congenital cardiac data management for the NCHDA and NHS England requests. 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 PRAiS (Paediatric Risk Analysis in Surgery) software reports on a quarterly basis. In busy centres with high numbers of procedures, PRAiS is run on a monthly basis.

We also acknowledge that there have been long and protracted difficulties with data submission to a NCHDA database at NICOR. This has affected all centres.

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 2018 Validation Visit

- In September 2018 SGH became paper light. Whilst this is beneficial in many ways, it has proved challenging whilst preparing for this external review. Some of the documents SGH

would regularly use for validation cannot be found and there does not appear to be the back up of paper notes to check.

- Due to the above challenges, SGH intend to spend 2019/20 ironing out the paper light issues, working with the Electronic Documentation Management Team
- 2018/19 audit year has very much been a time of challenge based on the previously stated sickness. The Trust have employed a data analyst at band 4, 15 hours a week on a six month trial. This individual is due to start in January/February 2020. This role was converted from a 7.5 hours a week, band 5 clinical post.

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.

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. No sets of notes were required from the Reserve list to make the 20 casenote sample. These 20 patients had a total of 28 procedures, (11 catheters and 17 operations).

The Data Quality Indicator Score (DQI)

The Provisional DQI for the Trust is calculated to be (with previous years in parentheses) **98.75%** (98.75, 99, 95.75,) with domain scores Demographics 1.0 (1.0, 1.0, 1.0) Pre Procedure .98 (.96, 98, .92) Procedure .99 (.99, 997, .93) and Outcome .98 (1.0, 99, .98). These are again very good scores.

Separate DQI for Surgery and for Catheters

On further review of the overall DQI for 2018/19, when the cases were split into their surgery and catheter groups the scores are:

Year of Visit	Data Reviewed	Surgery	Catheters
2009	2007-08	96.5%	93.7%
2010	2008-09	97.25%	98.25%
2011	2009-10	97.75%	96.25%
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%

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 812 procedures (502 surgical operations, 197 catheters, 113 others, 11 deaths) have been undertaken during the data collection year of 1 April 2018 to 31 March 2019.

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 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 accuracy was then recorded to enable the Data Quality Indicator (DQI) to be scored.

1. As previously, the notes on the whole were tidy, but on occasions were not in chronological order.
2. The Trust is currently 'paper lite' with a mix of paper and electronic medical records. Some of the electronic data had been printed but at times it 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. As at the previous visits, the physical PICU and medical notes were colour edged green and blue respectively making them easy to locate.
6. The operation notes were also easy to locate as these are coloured pink.
7. Perfusion records were seen in all of the surgical patients notes at this visit.
8. It was observed that details of implantable devices did not appear to be routinely included in the procedure performed or operation notes seen.
9. Documentation of sheath in and sheath out times for patients who underwent cath lab procedures was difficult to find in electrophysiological (EP) procedures.
10. Discharge information was variably found within ICP or within other areas of the patient notes.

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 2016-18 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 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. There is also an additional column to identify the surgical specialty (ie congenital cardiac) from which the patient comes from.

1. 2 submitted surgical records appear to have a coding error

2. 6 surgery procedures were identified that may have been missed from the data submission but these patient may still be current inpatients
3. 1 submitted record was not validated in the log books seen

Cath Lab

There are 4 catheter laboratories at SGH; 1,2,3, 4 and a hybrid room. Cath labs 1 and 2 are biplane. The reviewers are pleased to note that there is now a self inking stamp with the word Congenital in use to help identify relevant procedures. The log books for all cath labs except lab 3 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. 2 submitted catheter records appear to have errors in them
2. 60 submitted records were not validated in the log books and some of these procedures may have been performed in other areas such as PICU or cath lab 3.

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 now longer needed.

11 deceased patients were identified in the data return for 2018-19 who had died. 10 of these patients within 30 days of an operation or therapeutic catheter procedure.

The PRAiS sensitive fields were reviewed for each of the 10 patients identified above and the findings were:

1. All dates of death were found to be correct.
2. 2 records may have missing data in the attribution of death field
3. 2 records for the same patient may require recoding into one hybrid record

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		9	11
2	NHS Number	20	20		9	11
3	Surname	20	20		9	11
4	First Name	20	20		9	11
5	Sex	20	20		9	11
6	DOB	20	20		9	11
7	Ethnicity	20	20		9	11
8	Patient Status	20	20		9	11
9	Postcode	20	20		9	11
10	Pre Procedure Diagnosis	28	28		11	17
11	Previous Procedures	54	55	1 absent	41/42	13
12	Patients Weight at Operation	28	28		11	17
13	Height	27	27		10	17
14	Ante Natal Diagnosis	4	4		2	2
15	Pre Proc Seizures	28	28		11	17
16	Pre Proc NYHA	7	8	1 unable to validate	5/6	2
17	Pre Proc Smoker	7	8	1 unable to validate	5/6	2
18	Pre Proc Diabetes	7	8	1 unable to validate	5/6	2
19	Hx Pulmonary Dis	8	8		6	2
20	Pre Proc IHD	8	8		6	2
21	Comorbidity Present	28	28		11	27
22	Comorbid Conditions	29	30	1absent	8/9	21
23	Pre Proc Systemic Ventricular EF	27	27		11	17
24	Pre Proc Sub Pul Ventricular EF	22	23	1 incorrect	7/8	17
25	Pre-proc valve/septal defect/ vessel size	3	4	1 unable to validate	¾	-
26	Consultant	28	28		11	17

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	28	28		11	17
28	Proc Urgency	24	28		11	16/17
29	Unplanned Proc	28	28		11	17
30	Single Operator	28	28		11	17
31	Operator 1	28	28		11	17
32	Operator 1 Grade	28	28		11	17
33	Operator 2	26	26		9	17
34	Operator 2 Grade	26	26		9	17
35	Procedure Type	28	28		11	17
36	Sternotomy Sequence	15	15		-	15
37	Operation Performed	28	28		11	17
38	Sizing balloon used for septal defect	1	1		1	-
39	No of stents or coils	1	1		1	-
40	Device Manufacturer	7	8		5/6	2
41	Device Model	6	8		5/6	½
42	Device Ser No	6	8		5/6	½
43	Device Size	4	4		3	1
44	Total Bypass Time	13	13		-	13
45	XClamp Time,	13	13		-	13
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	7	11		7/11	-
48	Cath Fluro Time,	11	11		11	-
49	Cath Fluro Dose,	9	11		9/11	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	15	15		-	15
51	Post Procedure Seizures	27	28	1 absent	10/11	17
52	Post Proc Complications	3	3		2	1
53	Date of Discharge	27	28	1 unable to validate	11	16/17
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	28	28		11	17
57	Discharge Destination	28	28		11	17

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.75% Cardiology DQI = 97% Surgery DQI = 99.25%

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 .98**	
	Card .96	**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 .94	**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** .98	
	Card .98	**Surg** .99

Data Quality Indicator Assessment

The Overall Trust DQI = 98.75% (98.75, 99, 97.5,)

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	2019	2018	2017	2016	2015
Demographic	1.0	1.0	1.0	1.0	.99
Pre Procedure	.98	.95	.98	.92	.95
Procedure	.99	.99	.99	.93	.97
Outcome	.98	1.0	1.0	.98	.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 98.75%. 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 CNSs (Data Managers) in maintaining this at time when there have been considerable technical challenges. The Reviewers would also like to particularly thank the CNSs 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 and on this occasion one was off sick and the other post is vacant. We would strongly recommend that consideration is given to creating a further 1.0WTE data quality/audit facilitator role to compliment the current team.

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. 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 continue to strive 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;
    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 service delivery, particularly data that cannot be entered at the time of the procedure 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 checking and completeness and the time intervals for feedback to responsible clinicians on this with a clear time scale and line of responsibility for rectifying any omissions or errors in both surgery and cardiology disciplines
    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 PRAiS (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 that all staff who are involved with collecting, reviewing and managing the NCHDA data should attend at least one external validation visit per year.
5. All senior trainees (ST6 and above) should be actively encouraged to volunteer to assist with external validation visits to other centres.