The National Congenital Heart Disease Audit

Data Quality Audit for CONGENITAL HEART DISEASE Procedures April 2021 - March 2022

University Hospital Southampton NHS Foundation Trust

19 September 2022

performed by Lin Denne and Dr M Bissell

FINAL

Introduction

Prior to this validation visit, the data return to NCHDA from the Congenital Cardiac Department of University Hospital Southampton, indicates that some 787 procedures (334 surgical operations, 454 catheters, 5 Others, 4 deaths within 30 days of a Specific Procedure) have been undertaken during the data collection year of 1 April 2021 to 31 March 2022.

This validation visit has been fully funded by the Southampton University NHS Foundation NHS Trust (SGH). The visit was supported remotely by the NCHDA clinical audit nurse via an MS Teams facility and on site in person by Dr M Bissell, ST7 in Congenital Cardiology from Leeds.

Congenital Audit Data Managers Role

As previously reported 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 or surgery scheduling. From 2012 until the time of this visit there were up to four individuals covering 1.2 to currently 2.6 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. This remains unchanged in 2022.

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 may be run on a monthly basis.

FINAL

Actions Undertaken following the 2021 Validation Visit:

1. This year SGH have recruited a further staff member to the combined role of data manager and coordinator. There are now four members of the team (including a Band 4 data analyst).
2. SGH have created a Standard Operating Protocol (SOP) for the process of adding surgical and catheter data to Heartsuite information system and who is responsible for this, and there is discussion with the clinicians to increase their data entry input at the point of service at patient admission and during/following procedures.
3. There is a new staff training programme for Heartsuite and the DBMS encourage all new registrars for cardiology, ACHD and surgery to participate in an induction session where the importance of timely and accurate data input is explained.
4. SGH report that they have been unable to reverse validate data during 2021-22 due to staffing issues, but this will restart as from this visit and a SOP is being created to support this.
5. SGH report that data is being submitted in a timelier fashion and that quarterly life status checks for all NCHDA patients is planned going forwards.

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. Printed sheets from the ePR as well as some paper notes were meticulously prepared for each of the patient’s case notes to be examined. 20 patients were reviewed who had undergone a total of 30 procedures, (19 catheters and 11 operations) generating 1008 data variables. 19 data discrepancies were identified.

FINAL

The Data Quality Indicator Score (DQI)

The DQI for the Trust is calculated to be (with previous years in parentheses) **98.25%** (98.75 98.25%, 98.75) with domain scores Demographics 1.0 (1.0, .99, 1.0) Pre Procedure .96 (.99, .97, .98) Procedure 1.0 (.99, .98, .98) and Outcome .97 (.97, 99, .98). Although a small 0.5% drop these are again very good scores.

Separate DQI for Surgery and for Catheters

On further review of the overall DQI for 2021/22, when the cases were split into their surgery and catheter groups the scores are:

Year of Visit	Data Reviewed	Surgery	Catheters
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%
2022	2021-22	97.25%	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.

FINAL

Introduction

The NCHDA data return indicates that the congenital cardiac department of Southampton University Hospital Trust has undertaken 787 procedures (334 surgical operations, 454 catheters, 5 Others, 4 deaths within 30 days of a Specific Procedure) have been undertaken during the data collection year of 1 April 2021 to 31 March 2022.

The Congenital Data Auditor for the NCHDA undertook the visit remotely with an external ST7 in Congenital Cardiology 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 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. 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 very challenging to find explicit documentation on function of each individual ventricle. There are two 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.

FINAL

6. It was observed on several occasions in the hospital notes of patients who had undergone a surgical procedure that there was a discrepancy between the e-noting system, the clinician's own procedure note and the typed operation note.

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 handwriting 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 2016-21 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 four cardiac theatres at SGH. This appears to be one less than at the 2021 site validation. Congenital cardiac surgery is mainly performed in Theatre 3 and Theatre B. Sticky labels are used to identify patient episodes followed by handwritten completion of the procedures performed and operators etc.

1. 15 submitted surgical records appear to have a coding error.
2. 27 surgery procedures were identified that may have been missed from the data submission.

Cath Lab

There are four catheter laboratories at SGH. This appears to be one less than at the 2021 site visit. 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 consistently used. The log books for all cath labs were made available to the reviewers. All fields in the books seen are completed in handwritten entries.

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

FINAL

1. One submitted catheter record appears to an have errors in it.
2. Five records were identified in the log books that may be suitable for this data collection.
3. One 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.

FINAL

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.

Four patients who had died within 30 days of having a Specific Procedure were identified in the data return for 2021-22.

The Partial Risk Analysis in Surgery (PRAiS) sensitive fields were reviewed for each of the four patients identified above and the findings were:

1. All dates of death were found to be correct.
2. One record may have missing comorbidities.
3. One record for a further procedure prior to date of death appears to be absent.
4. One record may have incomplete procedure performed coding.
5. One record appears to have an incomplete field for Complications.
6. The field for Discharge Destination may be incomplete for all records.
7. Two records may have missing data in the attribution of death field.

Whilst reviewing the four 30-day post procedure deaths, it was sometimes very challenging to find specific documentation of the process undertaken to discuss each case with a Medical Examiner or Coroner or whether or not the patient had been reviewed at a Mortality meeting. Referral to Medical Examiner/Coroner and Attribution of Death are required fields in the NCHDA dataset.

FINAL

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		14	6
2	NHS Number	20	20		14	6
3	Surname	20	20		14	6
4	First Name	20	20		14	6
5	Sex	20	20		14	6
6	DOB	20	20		14	6
7	Ethnicity	19	20		14	6
8	Patient Status	20	20		14	6
9	Postcode	20	20		14	6
10	Pre Procedure Diagnosis	29	30	1 incorrect	19	10/11
11	Previous Procedures	57	60	3 incorrect	45	12/15
12	Patients Weight at Operation	30	30		19	11
13	Height	24	25	1 incorrect	15	9/10
14	Ante Natal Diagnosis	2	2		-	2
15	Pre Proc Seizures	30	30		19	11
16	Pre Proc NYHA	5	5		5	-
17	Pre Proc Smoker	4	5	1 incorrect	4/5	-
18	Pre Proc Diabetes	5	5		5	-
19	Hx Pulmonary Dis	5	5		5	-
20	Pre Proc IHD	5	5		5	-

FINAL

21	Comorbidity Present	30	30		19	11
22	Comorbid Conditions	32	38	6 incorrect	15/20	17/18
23	Pre Proc Systemic Ventricular EF	29	30	1 absent	19	10/11
24	Pre Proc Sub Pul Ventricular EF	29	30	1 absent	19	10/11
25	Pre-proc valve/septal defect/ vessel size	9	9		8	1
26	Consultant	30	30		19	11

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	30	30		19	11
28	Proc Urgency	30	30		19	11
29	Unplanned Proc	2	2		-	2
30	Single Operator	7	7		7	-
31	Operator 1	30	30		19	11
32	Operator 1 Grade	30	30		19	11
33	Operator 2	23	23		12	11
34	Operator 2 Grade	23	23		12	11
35	Procedure Type	30	30		19	11
36	Sternotomy Sequence	8	8		-	8

FINAL

37	Operation Performed	30	30		19	11
38	Sizing balloon used for septal defect	5	5		5	-
39	No of stents or coils	3	3		2	1
40	Device Manufacturer	10	10		9	-
41	Device Model	10	10		9	1
42	Device Ser No	10	10		9	1
43	Device Size	9	9		8	1
44	Total Bypass Time	8	8		-	8
45	XClamp Time,	5	5		-	5
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	19	19		19	-
48	Cath Fluro Time,	15	15		15	-
49	Cath Fluro Dose,	15	15		15	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	9	11	2 incorrect	-	9/11
51	Post Procedure Seizures	30	30		19	11
52	Post Proc Complications	4	4		1	3
53	Date of Discharge	29	30	1 incorrect	18/19	11
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	30	30		19	11
57	Discharge Destination	30	30		19	11

FINAL

Data Quality Indicator Assessment:

The Overall Trust DQI = 98.25% Cardiology DQI = 99% Surgery DQI = 97.25%

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.

<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 .96</td></tr>
<tr><td>Card
.97</td><td>Surg
.93</td></tr>
<tr><td><u>Procedure</u></td><td colspan="2">Overall 1.0</td></tr>
</table>

FINAL

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** 1.0
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** .99	 **Surg** .96

Data Quality Indicator Assessment

The Overall Trust DQI = 98.25% (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	2022	2021	2020	2019	2018
Demographic	1.0	1.0	.99	1.0	1.0
Pre Procedure	.96	.99	.97	.98	.95
Procedure	1.0	.99	.98	.99	.99
Outcome	.97	.97	.99	.98	1.0

FINAL

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%. Although a slight drop, 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's 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's 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. 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 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. 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 also 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 of this information system.

FINAL

Deceased Patients Data Validation

Case notes for all deceased patients were made available. As previously reported, there did not appear always 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 is 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.

FINAL

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 (Partial Risk Analysis in Surgery) analysis tool monthly where possible. This will inform the quarterly NHSE Dashboard reports.

FINAL

   f. Where a patient has died within 30 days of a procedure, documenting 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. Leading the local NCHDA data review (and how frequently and in which forum for both disciplines).
   i. Making timely submissions when possible (monthly is recommended).

3. 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.
4. Hybrid procedures should only be submitted once to NCHDA in the procedure type of Hybrid.
5. 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.
6. 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.
7. All senior trainees (ST6 and above) should be actively encouraged to volunteer to assist with external validation visits to other centres.

FINAL