The National Congenital Heart Disease Audit

Procedures for
CONGENITAL HEART DISEASE

Data Quality Audit for April 2021 – March 2022
University Hospitals Birmingham NHS Foundation Trust

14 September 2022

Performed by Lin Denne and Dr T Mukasa

Summary

Prior to this validation visit, the combined Congenital NICOR data return from the Queen Elizabeth Medical Centre (QEB, UHB FT) when exported from the NCHDA database on 3 August 2022, indicated that some 196 (surgery 27, catheter 169, others 0, Deaths 0) procedures had been undertaken during the data collection year of 2021/2022.

This validation visit has been fully funded by UHB NHS Foundation Trust. The external clinician assisting was a Consultant Congenital Cardiologist from Leicester. The NHCDA Clinical Auditor participated via MS Teams.

At the time of this visit the post of Data Manager at QEB was vacant.

The external validation team would like to commend the ACHD Lead Clinician, the Cardiac Operations Manager and the ACHD CNS for their combined sterling efforts and many extra hours in identifying, collecting and submitting the NHCDA data for 2021/22 year.

20 sets of case notes are randomly selected from the submission from QEB.

This is the eighteenth successive external validation visit to QEB. The data for therapeutic interventional cardiology and congenital surgical procedures are input directly to the NCHDA web application (Qreg5) at QEB using a secure login. As previously reported, the Queen Elizabeth Hospital Birmingham (UHB/QEB) are a designated NHS England NHS Global Digital Exemplar. In August 2017 the electronic patient record system Oceano was launched.

Of the four consultant cardiologists for adults with congenital heart disease at UHB, two undertake interventional procedures.

There is very clear guidance on standards for data management in both paediatric and adult congenital surgical centres. Each Specialist ACHD Surgical Centre must have a dedicated congenital cardiac surgery/cardiology data collection manager, responsible for audit and database submissions in accordance with necessary timescales (B33 L1 NHSE July 2015). QEB was peer reviewed against these standards in June 2019.

The NCHDA recommendations on Agenda for Change Banding of this role is contained in the NCHDA Annual Report published in 2016 (Ref; p25, Section III, Congenital Cardiac Audit Teams, point 1).

Actions taken in response to the Recommendations at the 2021 Validation Visit:

1. None reported.
2. The DBM post is vacant.

Consent for External Validation of Notes.

Since May 2018, the General Data Protection Regulation required 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 or patient data to be examined by others not connected to their care, these wishes will be respected.

Data Quality Indicator

The provisional DQI for QEB is **96.25%** (97, 95.25, 87,25,). The Domain scores are Demographics 1.0 (.99, 1.0, .96), Pre Procedure .95 (.95, .92, .85), Procedure .98 (.94,.91, .84, .96), Outcome .92 (1.0, .98, .84, .92).

This DQI is based on the case notes of 20 patients who underwent 20 procedures (15 interventional catheters and 5 operations) that had been submitted during the year April 2021 – March 2022.

879 variables were reviewed, and 29 discrepancies were identified. The fields with the most errors were:

Previous procedures	5 discrepancies
Post Procedure Complication	5 discrepancies
Comorbid conditions	4 discrepancies

Differential DQI for Surgery and Catheters

As well as the overall DQI for each centre, DQI scores for surgery and catheters are being calculated. The scores are:

	Data Year Reviewed	Surgery	Catheters
2013	2011/12	Insufficient sample	Insufficient sample
2014(i)	2012/13	90%	89%
2014(ii)	2013/14	82.25%	79.95%
2015	2014/15	77%	87.5%
2016	2015/16	66.75%	89.75%
2017	2016/17	89.75%	95.5%
2018	2017/18	94.5%	79.5% (4 records)
2019	2018/19	87%	89.25%
2020	2019/20	94.5%	95.3%
2021	2020/21	98.7%	96.75%
2022	2021/22	92.25%	98.25%

The NCHDA pre visit questionnaire was not returned from QEB prior to this visit. However, prior to the previous visit in 2021, it confirmed that there are some good processes and procedures in place in regard to Data Security and Management, but further consideration is required to confer validity and quality assurance of data and training in Data Management. The NHS Information Governance Training programme is used in the Trust.

There is or are identified accountable person/people for NCHDA data quality and information validity. Data Submissions are not always accurate.

Introduction

Queen Elizabeth Medical Centre (UHB NHS FT) indicated that some 196 (surgery 27, catheter 169, others 0, Deaths 0) procedures had been undertaken during the data collection year of 2021/2022.

The accuracy of the NCHDA data return was then checked against each set of case notes to enable the Data Quality Indicator (DQI) to be scored.

Review of the case notes at UHB

This centre is moving increasingly to an electronic patient record (ePR) or 'paper-lite' and where paper records were no longer available, they were reproduced on the request of the Validation Team from the ePR or made available on a computer screen. There were some files of paper hospital case notes, but these were often incomplete as most information is now stored digitally.

1. As previously reported, operation notes did not always appear to include the name and grade of the second operator .
2. It was often very difficult to find details of a patients' tobacco use (or not) noted.
3. Where possible, all previous procedures for congenital heart disease should be included in the data submission regardless of which country or geographic location the operation or intervention has occurred.
4. It was not always clear in the hospital notes what the NYHA status was of every patient, and this is a required field for NCHDA.
5. The names and status of the second operator did not always appear to be present in the hospital procedure notes.
6. The details of devices such as stents, pacemakers and valves implanted in the hospital e-notes seen were sometimes challenging to locate and these are part of the NCHDA dataset.
7. Echo reports to assess ventricular function while available digitally were not always easy to locate.
8. It was also noted that on several occasions' pacemaker procedures had been submitted as Support or Other procedures and they should be either electrophysiology surgery or

electrophysiology catheter to be correctly analysed but the Specific Procedures and Activity algorithm.

9. It was clear from the patient notes that were examined, that post procedure complications had been omitted from the submission in five records.

Review of the Cath Lab Log Books at UHB

At QEB, the separately kept congenital catheter log books that are kept in addition to a bound ledger were made available. The congenital catheter books are bespoke printed and spiral bound A4 books that are neatly kept.

There does not appear to be electronic log of catheter laboratory activity at this centre.

1. 27 catheter records were identified that may be suitable for inclusion in NCHDA.
2. Two submitted catheter records appear to have errors in them.
3. Two submitted catheter records were not validated in the log books seen.

Review of the Theatre Log Books at UHB

As previously reported, there are some 15 operating rooms at UHB. At least three of these are cardiac operating theatres. Operating Rooms 6 and 7 are primarily used for ACHD procedures. The complete log books of one operating room were made available and a part of a log book for the other. The reviewers are extremely grateful to the Adult Cardiac Surgery Data Analyst who was able to provide a spreadsheet from Galaxy electronic operating room information system of all theatre activity for cardiac theatres 6 and 7.

If ICD 11 and OPCS 4.8 codes are activated in this application, reports can be generated to identify all congenital cardiac procedures.

1. One submitted record appears to be a duplicate.
2. There were no heart transplant procedures submitted for ACHD patients and these should be submitted to NCHDA if they occur.
3. Two surgical cases were identified that may be suitable for inclusion in NCHDA.
4. One incidental record was identified that was for a complication of a previous procedure for congenital heart disease.

Validation of Deceased Patients Diagnostic and Procedure Coding

This commenced with the validation of the 2014/15 data. The NCHDA wish to verify any dates of death of deceased patients included in the year under review. The diagnosis and procedure coding will also be validated. The requirement for patient/parent/guardian consent to review the case notes is the same as for the congenital procedures review.

It is strongly recommended that if information regarding a date of death for a pre-existing congenital patient on the NCHDA database post discharge is or becomes available this should be submitted to that individual's record in the NCHDA registry. However, this piece of information, once submitted to the NCHDA database is not always easily visible when the data are exported back to the centre.

No post procedural deaths in congenital patients were noted on the data harvested for this visit. However, during the visit it was reported that there had been 1 post procedural death and this was reviewed. The findings were:

- The diagnoses coding appeared to have a discrepancy
- The pre procedure coding appeared to have a discrepancy
- The field for complications appeared to have a discrepancy
- The date of death was not present in the correct field
- The field for attribution of death field was not completed.

Casenote Audit

	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	20	20		15	5
8	Patient Status	20	20		15	5
9	Postcode	20	20		15	5
10	Pre Procedure Diagnosis	18	20	2 incorrect	13/15	5
11	Previous Procedures	47	52	5 absent	31/33	16/19
12	Patients Weight at Operation	20	20		15	5
13	Height	20	20		15	5
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	20	20		15	5
16	Pre Proc NYHA	20	20		15	5
17	Pre Proc Smoker	17	20	3 incorrect	12/15	5
18	Pre Proc Diabetes	20	20		15	5
19	Hx Pulmonary Dis	20	20		15	5
20	Pre Proc IHD	20	20		15	5

21	Comorbidity Present	19	20	1 incorrect	15	5
22	Comorbid Conditions	6	10	4 absent	6/10	-
23	Pre Proc Systemic Ventricular EF	17	18	1 incorrect	13/14	4
24	Pre Proc Sub Pul Ventricular EF	18	20	2 incorrect	13/15	5
25	Pre-proc valve/septal defect/ vessel size	2	2		2	-
26	Consultant	20	20		15	5

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	20	20		15	5
	Proc Urgency	20	20		15	5
29	Unplanned Proc	-	-		-	-
30	Single Operator	2	2		2	-
31	Operator 1	20	20		15	5
32	Operator 1 Grade	20	20		15	5
33	Operator 2	18	18		13	5
34	Operator 2 Grade	18	18		13	5

35	Procedure Type	19	20	1 incorrect	14/15	5
36	Sternotomy Sequence	4	5	1 incorrect	-	4/5
37	Operation Performed	19	20	1 incorrect	15	4/5
38	Sizing balloon used for septal defect	2	2		2	-
39	No of stents or coils	0	1	1 absent	0/1	-
40	Device Manufacturer	19	19		15	4
41	Device Model	19	19		15	4
42	Device Ser No	18	19	1 incorrect	14/15	4
43	Device Size	14	14		10	4
44	Total Bypass Time	4	4		-	4
45	XClamp Time,	2	2		-	2
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	15	15		15	-
48	Cath Fluro Time,	15	15		15	-
49	Cath Fluro Dose,	14	15	1 incorrect	14/15	-

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	3	4	1 incorrect	-	¾
51	Post Procedure Seizures	20	20		15	5
52	Post Proc Complications	0	5	5 absent	-	0/5
54	Date of Discharge	19	20	1 incorrect	15	4/5
55	Date of Death	-	-		-	-
56	Attribution of Death	-	-		-	-
57	Status at Discharge	20	20		15	5
58	Discharge Destination	20	20		15	5

Data Quality Indicator Assessment:

The Overall Trust DQI = 96.25% Cardiology DQI = 98.25% Surgery DQI = 92.25%

DOMAIN	**DOMAIN Score**	
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status	**Overall 1.0**	
	Card	**Surg**
	1.0	1.0

<table>
<tr><td rowspan="3">**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.</td><td colspan="2">**Overall .95**</td></tr>
<tr><td>**Card**</td><td>**Surg**</td></tr>
<tr><td>.95</td><td>.96</td></tr>
<tr><td rowspan="3">**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.</td><td colspan="2">**Overall .**98</td></tr>
<tr><td>**Card**</td><td>**Surg**</td></tr>
<tr><td>.98</td><td>.97</td></tr>
<tr><td>**Outcome**</td><td colspan="2">**Overall** .92</td></tr>
</table>

Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Card** 1.0	**Surg** .76

The DQI for UHB Foundation Trust congenital cardiology is based upon the domain scoring below. The methodology for this DQI is provided in the paper The NICOR Audit – An Introduction to the Process.

DOMAIN.	**Score 2022**	**Score 2021**	**Score 2020**	**Score 2019**
Demographics	1.0	.99	1.0	.96
Pre Procedure	.95	.95	.92	.85
Procedure	.98	.94	.91	.84
Outcome	.92	1.0	.98	.84

Conclusions

On the whole the submitted NCHDA data were accurate, well documented, good quality and were appropriately recorded in the Theatre and Cath Lab log books that were seen. The DQI has dropped very slightly to 96.25% since the 2021 NCHDA Validation visit. This is still a good score and further demonstrates how critical the role of ACHD data manager is within congenital heart disease.

We would also like to commend the ACHD Lead Clinician, the Cardiac Operations Manager and the previous NCHDA database manager for their sterling efforts in identifying, collecting and submitting the NHCDA data for 2020/21 year. As documented elsewhere in previous NCHDA Reports, the location of an experienced 1.0WTE NCHDA DBM to the same location as the ACHD nurses will provide much greater support to the role.

The reviewers would also like to thank the Director of Operations for making the time to meet with them during the validation visit.

There are still a few concerns. It appears that there is still no defined regular reverse validation of the congenital data with the responsible clinicians. Details on all implanted devices and valves are required, as well as more data on ACHD comorbidities and post procedure complications. Care should also be taken to ensure that the preprocedural diagnosis coding reconciles with the procedure performed.

Many of the NCHDA data fields are now included in the congenital cardiac NHS Commissioning for Quality and Innovation (CQINs) dashboard. Each congenital centres' Data Quality Indicator Score (DQI) is also included in the quarterly dashboard. The reviewers have always been aware that the HeartSuite cardiac information is available at UHB and many of the ACHD patients transition from the adjacent paediatric service at Birmingham Children's Hospital (BCH). It should be relatively easy to identify the previous procedures for those patients from BCH who undergo further operations or catheter interventions at QEB.

The reviewers note that on occasions documentation on paper notes/ePR did not always appear to be completed with dates of entries apparently absent. Also, the names and status of second operators appeared to be absent at times.

There appeared to be no heart transplant procedures in patients with congenital heart disease reported from this centre for the year 2021/22.

Validation of Case Notes of Deceased Patients

As noted elsewhere, it was brought to the reviewers' attention that there had been one death within 30 days of a procedure but it had not been submitted to the NCHDA registry and this is of concern.

NHCDA has always strongly recommended that if information regarding a date of death for a pre-existing congenital patient on the NCHDA database post discharge is or becomes available this should be submitted to that individual's record in the NCHDA registry also.

Recommendations

1. As a matter of urgency and following the very clear guidance on standards for data management in both paediatric and adult congenital surgical centres. Each Specialist ACHD Surgical Centre must have a dedicated congenital cardiac surgery/cardiology data collection manager, responsible for audit and database submissions in accordance with necessary timescales. (B33 L1 NHSE July 2015). QEB was peer reviewed against these standards in June 2019.

   The NCHDA recommendations on Agenda for Change Banding of this role is contained in the NCHDA Annual Report published in 2016. (Ref; p25, Section III, Congenital Cardiac Audit Teams, point 1).
2. It is recommended as an immediate priority consideration, a cardiac information system that can accommodate all the NCHDA dataset items should be identified and used to collect, validate and submit these data.
3. It is recommended that Standard Operating Protocols are devised for the congenital data collection, to include detailed guidance on and exactly **<u>who is responsible</u>** for:
   a) Ensuring each patient/parent/guardian is given appropriate information in relation to how their data are recorded, stored and who it is shared with in line with GDPR 2018.
   b) Input of congenital patients NCHDA required dataset items, and at which point of service delivery.
   c) Encouraging every responsible clinician or allied professional to input complete data for each operation, diagnostic or catheter intervention at the point of the service delivery from admission to discharge and to own their data.
   d) Ensuring the diagnosis reconciles with the procedure performed.
   e) Recording the knife to skin time for all surgical procedures where it can be validated (ie perfusion or anaesthetic record).
   f) 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.
   g) Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data/Audit Managers at least monthly. This will assist in informing the quarterly NHSE Dashboard reports.

h) Where a patient has died within 30 days of a procedure, documenting:
    - whether or not there was a discussion with the Medical Examiner/Coroner
    - and/or was discussed at an MDT and
    - whether or not the death was related to the procedure as these are NCHDA dataset items.

i) Ensuring that dates of death are reported for any QEB patient who has previously had a record submitted to the NCHDA.

j) Leading the local review (and how frequently and in which forum for both disciplines).

k) Making timely submissions (monthly is recommended where possible).

l) Including details of manufacturer, model and serial numbers of all implantable devices the procedure record for each patient.

m) Reviewing/Updating the SOP at timely intervals.

4. It is recommended that all Congenital Audit or Data Managers visit other congenital centres at least once annually to experience a validation from the external reviewer's perspective, network with a colleague(s), trouble shoot and problem share.
5. Involve all clinically relevant staff in a review of audit data collection, review and quality initiatives.
6. It is suggested that it may be helpful for the next NCHDA data manager in this post to attend MDT meetings to gain knowledge on cardiac diagnoses and procedures and to receive quarterly life status reports on all ACHD patients to enable dates of death to be updated promptly.