



The National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit for April 2020 – March 2021

University Hospitals Birmingham NHS Foundation Trust

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Summary

Prior to this validation visit the combined Congenital NICOR data return from the Queen Elizabeth Medical Centre (QEB, UHB FT) indicated that some 139 (surgery 22, catheter 117, others 0, Deaths 1) procedures had been undertaken during the data collection year of 2020/2021 on adults with congenital heart disease. This represents an approximate 20% drop in procedural activity during the SARS-COV-2 pandemic.

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

There is a 1.0WTE NCHDA Data Manager at QEB who has been in post for approximately three years.

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

This is the 17th successive external validation visit to QEB. As previously reported, the HeartSuite cardiac information is fully available at UHB but only appeared to be used to review congenital cardiac surgical data. No congenital data have been input to HeartSuite on the QEB site historically. The data for therapeutic interventional cardiology and congenital surgical procedures are input directly to the NCHDA web application (Qreg5) at QEB. 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.

It was reported that immediately prior to the 2019 NCHDA visit that QEB had agreed to fully commission HeartSuite in all locations where ACHD patients are seen to allow the contemporaneous capture all data points within the NCHDA dataset. In 2020 this was not operational and had been paused during the initial SARS-COV-2 pandemic months. In 2021 HeartSuite was not being used and direct data entry to Qreg5 by the DBM was continuing.

Of the 4 consultant cardiologists for adults with congenital heart disease at UHB, 2 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.



Actions taken in response to the Recommendations at the 2020 Validation Visit:

1. The DBM is now co-located with the ACHD Nurses to enable greater support with the clinical aspects of this data collection

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 **97%** (95.25, 87.25, 94.5). The Domain scores are; Demographics .99 (1.0, .96, 1.0), Pre Procedure .95 (.92, .85, .90), Procedure .94 (.91, .84, .96), Outcome 1.0 (.98, .84, .92). This is another increase of 2.25%.

This DQI is based on the case notes of 20 patients who underwent 21 procedures (15 interventional catheters and 6 operations) that had been submitted during the year April – March 2020/21.

879 variables were reviewed and 32 discrepancies were identified. The fields with the most errors were;

Previous procedures –	9 discrepancies
Implanted devices –	11 discrepancies
Pre procedure ventricular function –	4 discrepancies
Procedure Type –	3 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%

The body of this report is drawn from answers given on the NCHDA pre visit Questionnaire and from discussions on the day of the visit. This 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 FT) indicated that some 139 (surgery 22, catheter 117, others 0, Deaths 1) procedures had been undertaken during the data collection year of 2020/2021 on adults with congenital heart disease.

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 are moving increasingly to an electronic patient record (ePR) or 'paper-lite' and where paper records were not available, some were reproduced on the request of the Validation Team from the EPR

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or made available on a computer screen. There were some files of paper hospital case notes but these were often incomplete as more 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. 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.
3. 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.
4. The details of devices such as stents, pacemakers and valves implanted in the hospital notes seen were sometimes challenging to locate and these are part of the NCHDA dataset.
5. Echo reports to assess ventricular function while available digitally were not always easy to locate.
6. 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.

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. 10 catheter records were identified that may be suitable for inclusion in NCHDA.
2. 18 submitted catheter records appear to be in the in an incorrect procedure type category
3. 5 submitted catheter records for device implants appear to have no device details
4. 1 submitted record may not be for congenital heart disease and if so, this should be deleted from the NCHDA database.

Review of the Theatre Log Books at UHB

There are some 15 operating rooms at UHB. 3 of these are cardiac operating theatres. The Cardiac Operations Manager made available an internally validated spreadsheet from the Galaxy Surgery electronic information system of all theatre activity for theatres 6,7 and 9.

If ICD 10 or 11 and OPCS codes are activated in this application, reports can be generated to identify all congenital cardiac procedures.

1. 8 submitted records appear to have errors in them
2. 6 submitted surgery records appear to be in the in an incorrect procedure type category
3. There were no heart transplant procedures submitted for ACHD patients and these should be submitted to NCHDA if they occur.
4. 2 surgical cases were identified in the log books that may be suitable for inclusion in NCHDA.

FENVA

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.

1 congenital patient was noted on the data harvested for this visit to have died following a non specific procedure and outside the 30 day survival benchmark. This record was not examined.

Casenote Audit

	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	20	20		14	6
8	Patient Status	20	20		14	6
9	Postcode	19	20	1 incorrect	13/14	6
10	Pre Procedure Diagnosis	21	21	6 incomplete	10/15	6
11	Previous Procedures	40	40	9 absent	24/28	6
12	Patients Weight at Operation	21	21		15	6
13	Height	21	21		15	6
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	21	21		15	6
16	Pre Proc NYHA	21	21		15	6
17	Pre Proc Smoker	20	21	1 absent	15	5/6
18	Pre Proc Diabetes	21	21		15	6
19	Hx Pulmonary Dis	21	21		15	6
20	Pre Proc IHD	21	21		15	6
21	Comorbidity Present	20	21	1 incorrect	14/15	6
22	Comorbid Conditions	9	10	1 absent	8/9	1
23	Pre Proc Systemic Ventricular EF	18	19	1 incorrect	12/13	6
24	Pre Proc Sub Pul Ventricular EF	16	19	3 incorrect	10/13	6
25	Pre-proc valve/septal defect/ vessel size	-	-		-	-
26	Consultant	21	21		15	6



	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	21	21		15	6
	Proc Urgency	21	21		15	6
29	Unplanned Proc	-	-		-	-
30	Single Operator	7	7		8	6
31	Operator 1	21	21		15	6
32	Operator 1 Grade	21	21		15	6
33	Operator 2	14	14		8	6
34	Operator 2 Grade	14	14		8	6
35	Procedure Type	18	21	3 incorrect	12/15	6
36	Sternotomy Sequence	5	5		-	5
37	Operation Performed	21	21		15	6
38	Sizing balloon used for septal defect	1	1		1	-
39	No of stents or coils	0	2	2 absent	0/2	-
40	Device Manufacturer	16	18	2 absent	11/13	5
41	Device Model	16	18	2 absent	11/13	5
42	Device Ser No	16	18	2 absent	11/13	5
43	Device Size	10	13	3 absent	5/8	5
44	Total Bypass Time	6	6		-	6
45	XClamp Time,	6	6		-	6
46	Total Arrest	-	-		-	-
47	Cath Proc Time,	15	15		15	-
48	Cath Fluro Time,	14	15	1 absent	14/15	-
49	Cath Fluro Dose,	14	15	1 absent	14/15	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	6	6		-	6
51	Post Procedure Seizures	21	21		15	6
52	Post Proc Complications	-	-		-	-
54	Date of Discharge	21	21		15	6
55	Date of Death	-	-		-	-
56	Attribution of Death	-	-		-	-
57	Status at Discharge	21	21		15	6
58	Discharge Destination	21	21		15	6

Data Quality Indicator Assessment:

The Overall Trust DQI = 97% Cardiology DQI = 96.75% Surgery DQI = 98.7%

DOMAIN	DOMAIN Score					
<p><u>Demographics</u></p> <p>Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,</p>	<p>Overall .99</p> <table border="1" data-bbox="1157 593 1396 705"> <thead> <tr> <th>Card</th> <th>Surg</th> </tr> </thead> <tbody> <tr> <td>.99</td> <td>1.0</td> </tr> </tbody> </table>		Card	Surg	.99	1.0
Card	Surg					
.99	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>	<p>Overall .95</p> <table border="1" data-bbox="1157 907 1396 1160"> <thead> <tr> <th>Card</th> <th>Surg</th> </tr> </thead> <tbody> <tr> <td>.96</td> <td>.945</td> </tr> </tbody> </table>		Card	Surg	.96	.945
Card	Surg					
.96	.945					
<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>	<p>Overall .94</p> <table border="1" data-bbox="1157 1321 1396 1541"> <thead> <tr> <th>Card</th> <th>Surg</th> </tr> </thead> <tbody> <tr> <td>.92</td> <td>1.0</td> </tr> </tbody> </table>		Card	Surg	.92	1.0
Card	Surg					
.92	1.0					
<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>	<p>Overall 1.0</p> <table border="1" data-bbox="1157 1668 1396 1818"> <thead> <tr> <th>Card</th> <th>Surg</th> </tr> </thead> <tbody> <tr> <td>1.0</td> <td>.1.0</td> </tr> </tbody> </table>		Card	Surg	1.0	.1.0
Card	Surg					
1.0	.1.0					



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 2021	Score 2020	Score 2019	Score 2018
<u>Demographics</u>	.99	1.0	.96	1.0
<u>Pre Procedure</u>	.95	.92	.85	.90
<u>Procedure</u>	.94	.91	.84	.84
<u>Outcome</u>	1.0	.98	.84	.84

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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 risen by a further 2.25% since the 2020 NCHDA Validation visit. This is another excellent improvement. This demonstrates how critical this role is within congenital heart disease.

We would also like to commend the ACHD Lead Clinician, the Cardiac Operations Manager and the NCHDA database manager for their sterling efforts in identifying, collecting and submitting the NCHDA data for 2020/21 year. As documented elsewhere the re location of the NCHDA DBM to the same office 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 no 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. 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 Childrens Hospital. However, while the work to unify the paediatric records, and making this system fully functional at UHB to accept ACHD updates has been started, it has unfortunately remained paused.

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 any year.

Validation of Case Notes of Deceased Patients.

No relevant case notes to be seen at this validation.

Recommendations

1. It is recommended as an immediate priority consideration, a cardiac information system that can accommodate all of the NCHDA dataset items should be identified and used to collect, validate and submit these data.
2. It is recommended that Standard Operating Protocols are devised for the congenital data collection, to include detailed guidance on and exactly **who is responsible** 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 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.
 - 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) and
 - 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
3. 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 reviewers perspective, network with a colleague(s), trouble shoot and problem share.

4. Involve all clinically relevant staff in a review of audit data collection, review and quality initiatives
5. It is suggested that it may be helpful for the NCHDA data manager 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.

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