# The National Congenital Heart Disease Audit

# Procedures for CONGENITAL HEART DISEASE

## Data Quality Audit for April 2023 – March 2024
## University Hospitals Birmingham NHS Foundation Trust



**19 September 2024**

*Performed by Lin Denne*

## 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 26 July 2024, indicated that some 262 (surgery 70, catheter 184, others 8, Deaths 0 within 30 days of a therapeutic procedure) procedures had been undertaken during the data collection year of 2023/2024.

Following review of the catheter laboratory and operating room activity log books on the day of the validation visit, 4 additional procedures were identified and where found suitable were subsequently submitted to the Registry.

This validation visit has been fully funded by UHB NHS Foundation Trust. The external assisting clinician was unable to attend at the last minute and after consultation and with the agreement of the local ACHD Lead Clinician at QEB, the visit went ahead with the NCHDA Clinical Audit Nurse only.

At the time of this visit the Data Manager at QEB had been in post for 8 months. The post had been unfilled for the previous 18 months and the data collection and submission was entirely dependent on one consultant clinician investing may unpaid hours.

As previously reported, it is noted from the NCHDA Pre Visit Questionnaire that there does not appear to be any audit of data collection routines or activities, such as checking completeness or quality, or any Standard Operating Protocols for these processes. There does not appear to be any internal targets for completion of and timeliness of data collection and submission. It also appears that there is no reverse validation of the data once submitted to the NCHDA database either or a designated person responsible for data quality and standards conformance.

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

This is the 20th 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. This is an internally developed and fully unified electronic medical record system that is used throughout this NHS Foundation Trust.

Of the 5 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.

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 2023 Validation Visit:**

1. A new Database manager was appointed in January 2024.
2. QEB report that the Congenital Cardiac Team will be looking to develop a more robust internal audit of data collection now that there is a DBM in post.

**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; **97.75%** (97, 97, 95.25). The Domain scores are; Demographics 1.0 (1.0, 1.0, .99), Pre Procedure .98 (.985, .95, .95), Procedure .9,9 (.98, .98, .94,.91), Outcome .94 (.93, .92, 1.0, .98).

This is another very good score and an increase of 0.75%.

This DQI is based on the case notes of 20 patients who underwent 21 procedures (14 interventional catheters and 7 operations) that had been submitted during the year April – March 2023/24.

926 variables were reviewed, and 13 discrepancies were identified. The fields with the most errors were;

| | |
|---|---|
| Comorbidities | 3 discrepancies |
| Post op Intubation | 2 discrepancies |
| Discharge Date | 2 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 |
|---|---|---|---|
| **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% |
| **2023** | 2022/23 | 97% | 99% |
| **2024** | 2023/24 | 97% | 97.75% |

There are no identified accountable persons/people for NCHDA data collection or for quality and information validity. Data Submissions were not always timely or met deadlines during the 2023/4 data collection year.

**Introduction**

Queen Elizabeth Medical Centre (UHB NHS FT) indicated that some 262 (surgery 70, catheter 184, others 8, Deaths 0 within 30 days of a therapeutic procedure) procedures had been undertaken during the data collection year of 2023/2024.

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 has moved to an almost completely electronic patient record (ePR) and information was displayed directly from the ePR onto a large screen. The transition from screen to screen was very quick.

1. As previously noted, a few patients whose date of birth was after 1988 had their field for ante natal diagnosis listed as unknown but on further investigation on the day the information was obtained.
2. Echo reports to assess ventricular function were available in the patients ePR and easily laid out and to follow.
3. Reports of cath lab procedures and fluoroscopy used, appeared to record radiation in milligray (mGY) on occasions rather than centigray (cGy). Centigray is the measurement required by NCHDA.
4. The ACHD DBM does not appear to have access to RIS to cross validate the radiation exposure time and dose if required. It would be helpful if this was available to the DBM.

**Review of the Cath Lab Log Books at UHB**

At QEB/UHB, there are congenital catheter books that are bespoke printed and spiral bound A4 books. These are in addition to the large double A3 size printed and bound ledgers that are used in each cath lab to record every procedure. The bound ledgers for cath labs 1-4 were presented.

There is no electronic log of catheter laboratory activity at this centre.

1. 4 catheter records were identified that may be suitable for inclusion in NCHDA. These are mainly procedures for EP and Pacing
2. 4 submitted catheter records appear to have discrepancies in them

**Review of the Operating Theatre Log Books at UHB**

There are some 15 operating rooms at UHB. 3 of these are cardiac operating theatres. Operating Rooms 6 + 7 + 9 are primarily used for ACHD procedures. The Reviewer is extremely grateful to Viv Barnett, the Adult Cardiac Surgery Data Analyst who

was again able to provide a spreadsheet from iSoft Galaxy electronic information system of much of the congenital cardiac theatre activity.

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

1. 0 surgical cases were identified that may be suitable for inclusion in NCHDA.
2. 5 submitted records appear to be for minor and non countable procedures in NCHDA. These cases such as removal of sternal wires are not required for NCHDA

# 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 also. This information can be obtained on a regular reporting cycle that could be run by the local cardiac information team from the NHS Spine, for instance monthly or quarterly.

There were no deaths within 30 days of a Specific Procedure at QEB during 2023-24 data collection year.

**Casenote Audit**

| | Parameter | Total Score | Total No | Comments | Scores for Cardiology & Surgery | |
|---|---|---|---|---|---|---|
| | | | | | C | S |
| 1 | Hospital Number | 20 | 20 | | 13 | 7 |
| 2 | NHS Number | 20 | 20 | | 13 | 7 |
| 3 | Surname | 20 | 20 | | 13 | 7 |
| 4 | First Name | 20 | 20 | | 13 | 7 |
| 5 | Sex | 20 | 20 | | 13 | 7 |
| 6 | DOB | 20 | 20 | | 13 | 7 |
| 7 | Ethnicity | 20 | 20 | | 13 | 7 |
| 8 | Patient Status | 20 | 20 | | 13 | 7 |
| 9 | Postcode | 20 | 20 | | 13 | 7 |
| 10 | Pre Procedure Diagnosis | | 21 | | 14 | 7 |
| 11 | Previous Procedures | 81 | 81 | | 53 | 28 |
| 12 | Patients Weight at Operation | 21 | 21 | | 14 | 7 |
| 13 | Height | 21 | 21 | | 14 | 7 |
| 14 | Ante Natal Diagnosis | 21 | 21 | | - | - |
| 15 | Pre Proc Seizures | 21 | 21 | | 14 | 7 |
| 16 | Pre Proc NYHA | 21 | 21 | | 14 | 7 |
| 17 | Pre Proc Smoker | 20 | 21 | 1 incorrect | 14 | 6/7 |
| 18 | Pre Proc Diabetes | 20 | 21 | 1 incorrect | 14 | 6/7 |
| 19 | Hx Pulmonary Dis | 21 | 21 | | 14 | 7 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 20 | Pre Proc IHD | 21 | 21 | | 14 | 7 |
| 21 | Comorbidity Present | 21 | 21 | | 14 | 7 |
| 22 | Comorbid Conditions | 26 | 26 | | 16/18 | 7/8 |
| 23 | Pre Proc Systemic Ventricular EF | 21 | 21 | | 14 | 7 |
| 24 | Pre Proc Sub Pul Ventricular EF | 19 | 19 | | 14 | 5 |
| 25 | Pre-proc valve/septal defect/ vessel size | 5 | 5 | | 5 | - |
| 26 | Consultant | 21 | 21 | | 14 | 7 |

| | **Parameter** | **Total Score** | **Total No** | **Comments** | **Scores for Cardiology & Surgery** | |
|---|---|---|---|---|---|---|
| | | | | | **C** | **S** |
| 27 | Date of Procedure + Time Start | 21 | 21 | | 14 | 7 |
| | Proc Urgency | 21 | 21 | | 14 | 7 |
| 29 | Unplanned Proc | - | - | | - | - |
| 30 | Single Operator | 9 | 10 | 1 incorrect | 9 | 0/1 |
| 31 | Operator 1 | 21 | 21 | | 14 | 7 |
| 32 | Operator 1 Grade | 21 | 21 | | 14 | 7 |
| 33 | Operator 2 | 11 | 12 | 1 absent | 11 | 0/1 |
| 34 | Operator 2 Grade | 11 | 12 | 1 absent | 11 | 0/1 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 35 | Procedure Type | 21 | 21 | | 14 | 7 |
| 36 | Sternotomy Sequence | 5 | 5 | | - | 5 |
| 37 | Operation Performed | 21 | 21 | | 14 | 7 |
| 38 | Sizing balloon used for septal defect | 3 | 3 | | 3 | - |
| 39 | No of stents or coils | - | - | | - | - |
| 40 | Device Manufacturer | 15 | 15 | | 10 | 5 |
| 41 | Device Model | 15 | 15 | | 10 | 5 |
| 42 | Device Ser No | 15 | 15 | | 10 | 5 |
| 43 | Device Size | 10 | 10 | | 7 | 3 |
| 44 | Total Bypass Time | 5 | 5 | | - | 5 |
| 45 | XClamp Time, | 5 | 5 | | - | 5 |
| 46 | Total Arrest | 0 | 0 | | - | 0 |
| 47 | Cath Proc Time, | 14 | 14 | | 14 | - |
| 48 | Cath Fluro Time, | 13 | 13 | | 13 | - |
| 49 | Cath Fluro Dose, | 13 | 13 | | 13 | - |

| | Parameter | Total Score | Total No | Comments | Scores for Cardiology & Surgery | |
|---|---|---|---|---|---|---|
| | | | | | C | S |
| 50 | Duration of Post Op Intubation | 3 | 5 | 2 incorrect | - | 3/5 |
| 51 | Post Procedure Seizures | 21 | 21 | | 14 | 7 |
| 52 | Post Proc Complications | 1 | 1 | | - | 1 |
| 54 | Date of Discharge | 19 | 21 | 1 absent, 1 incorrect | 12/14 | 7 |
| 55 | Date of Death | - | - | | - | - |
| 56 | Attribution of Death | - | - | | - | - |
| 57 | Status at Discharge | 21 | 21 | | 14 | 7 |
| 58 | Discharge Destination | 20 | 21 | 1 absent | 13/14 | 7 |

Data Quality Indicator Assessment:

The Overall Trust DQI = 97.75% Cardiology DQI = 98.25% Surgery DQI = 97%

<table>
<tr><th>DOMAIN</th><th colspan="2">DOMAIN Score</th></tr>
<tr><td rowspan="2"><u>Demographics</u><br><br>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<br>1.0</td><td>Surg<br>1.0</td></tr>
<tr><td rowspan="2"><u>Pre Procedure</u><br><br>Pre procedure Diagnosis, Selected Previous Procedures, Patient Weight at Operation, Consultant, Antenatal Diagnosis, Pre Procedure Seizures, Comorbid Conditions,<br>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,<br><br>Note, the scores for his domain are affected by the selected previous procedure and pre procedure diagnosis</td><td colspan="2">Overall .98</td></tr>
<tr><td>Card<br>.98</td><td>Surg<br>.976</td></tr>
<tr><td><u>Procedure</u></td><td colspan="2">Overall .99</td></tr>
</table>

| | | |
|---|---|---|
| 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,<br>**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**<br>1.0 | **Surg**<br>.96 |
| **Outcome**<br>Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination.<br>**Post Procedure Complications.** | **Overall** .94<br>**Card**<br>.95 | **Surg**<br>.94 |

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 2024 | Score 2023 | Score 2022 | Score 2021 |
|---|---|---|---|---|
| **Demographics** | 1.0 | 1.0 | 1.0 | .99 |
| **Pre Procedure** | .98 | .985 | .95 | .95 |
| **Procedure** | .99 | .98 | .98 | .94 |
| **Outcome** | .94 | .93 | .92 | 1.0 |

## 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 is 97.75% t. This is a very good score, increased 0.75% from 2023 and further demonstrates how critical the role of a clinical ACHD data manager is within congenital heart disease.

We would also like to commend the new ACHD Data Manager, for sterling efforts in identifying, collecting and submitting the NHCDA data for 2023/24 year. There had been no clinical data manager in post for NCHDA for over a year. It is reported that that is no reverse validation of the data and no established data quality audit programme running for this registry. It is hoped that now that there is dedicated DBM in post these activities will be developed into practice over the coming months.

It should also be noted that NHSE has commissioned NICOR to publish data from all cardiac registries on a quarterly basis and these data should be submitted within 2 weeks of each quarter end. NHSE has also commissioned NICOR to collect procedural data within 2 weeks of the date of a catheter or surgery intervention.

As noted elsewhere, the NHSE ACHD Specialist Surgical Standards (NHSE May 2016) recommendations state (B33L1) that each Level 1 centre must have a dedicated congenital cardiac surgery/cardiology data collection manager, responsible for audit and database submissions in accordance with necessary timescales. As documented in previous NCHDA Reports, the location of an experienced 1.0WTE NCHDA DBM to the same operational hub as the ACHD nurses will provide much greater support to the role and the wider ACHD practice at this Centre..

The Validation Team would also like to thank the Cardiac Operations Managers for supporting ensuring the site visit was well run and well organised.

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.

## Validation of Case Notes of Deceased Patients.

There were no deaths within 30 days of a Specific Procedure at QEB during the 2023/24 data collection year.

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. There does not appear to be any regular reporting to identify these deaths.

## Recommendations

1. It is recommended that in order to retain staff in the DBM role for NCHDA, that the NCHDA recommendations on Agenda for Change Banding of this role that is contained in the NCHDA Annual Report published in 2016. (Ref; p25, Section III, Congenital Cardiac Audit Teams, point 1) is adhered to.

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) Recording radiation exposure in centigrays (cGy) for catheter procedures
   g) 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
   h) 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 and this is an essential practice to ensure data accuracy and correct analysis by the Specific Procedures Algorithm and Activity Algorithms.
   i) 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.
- Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.

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

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

l) Making timely submissions (monthly is recommended where possible) and

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

n) 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 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 updated promptly.