



FRE NCHDA Report 2022

The National Congenital Heart Disease Audit

**Procedures for
CONGENITAL HEART DISEASE,
April 2021 – March 2022**

Data Quality Audit

**The Newcastle Upon Tyne Teaching Hospitals NHS
Foundation Trust.**

8 September 2022

performed by Lin Denne and Dr S Durairaj



Summary

The NCHDA data return from the cardiac department of the Freeman Hospital for the data collection year 2021/22 indicated that 764 procedures (278 surgery, 443 catheters, 45 others, 7 deaths [within 30 days of a procedure]) had been undertaken in patients with congenital heart disease.

This validation visit has been fully funded by Newcastle upon Tyne University Hospitals NHS Foundation Trust.

As previously reported, there is a Cardiothoracic Services Information Manager post at this Trust whose remit covers all 6 of the NICOR data collections. There have been several post holders of this role since 2018 and there was a further recruitment drive during mid 2022. There are 6 other members of the Cardiac Information Team at FRE covering 6.0WTEs. There is a 1.0WTE individual Data Manager (DM) dedicated to the NCHDA collection and in February 2020 an assistant data manager post was created and appointed.

Data are entered into a Dendrite Intellect system at various points of service throughout the hospital, ie operating theatres, cath labs etc. When checked for accuracy, completeness and validity these data are submitted to the NCHDA database.

Actions Reported since previous validation visit in 2021:

1. It is reported that the FRE NCHDA data team have implemented a new process to check the life status of congenital patients on a quarterly basis.

Data Quality Indicator (DQI)

The DQI for the Trust is calculated to be (with previous years in parentheses) **99.5%** (99.8, 99.75, 99, 98.75) with domain scores Demographics .99 (1.0, 1.0 1.0) Pre Procedure .997 (.99, .985, .96,) Procedure 1.0 (1.0, 1.0, .99,) and Outcome .99 (1.0, 1.0, .99).

There were 3 discrepancies in 1008 data variables.

The calculation is based on the validation of 20 patients' hospital notes who underwent 24 procedures (10 therapeutic catheter procedures and 14 surgical operations).



FRE NCHDA Report 2022

Separate DQI for Surgery and for Catheters

On further review of the DQI when the cases were split into their surgery and catheter groups and the scores were:

| Year | Data Year Validated | Surgery | Caths |
|------|---------------------|---------|--------|
| 2013 | 11/12 | 97% | 99% |
| 2014 | 13/14 | 97.25% | 95.50% |
| 2015 | 14/15 | 97.25% | 97% |
| 2016 | 15/16 | 98.5% | 97% |
| 2017 | 16/17 | 98.25% | 99% |
| 2018 | 17/18 | 98.25% | 99.5% |
| 2019 | 18/19 | 99% | 99% |
| 2020 | 19/20 | 100% | 99.5% |
| 2021 | 20/21 | 100% | 99.6% |
| 2022 | 21/22 | 100% | 99% |

The NCHDA 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.

Consent for External Validation of Notes.

Since May 2018, the General Data Protection Regulation (GDPR) 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



FRE NCHDA Report 2022

allow their case notes to be examined by others not connected to their care, these wishes will be respected.

Prior to the visit a file with 20 case notes (the Sample) and 10 Reserves was sent to the cardiothoracic information manager. 20 sets of notes (13 Samples, 7 Reserves) were available on the day. The Trust are currently using mixed paper and electronic patient hospital notes.

FENVAL



Introduction

As stated above, the NCHDA data return from the cardiac department of the Freeman Hospital for the year 2021/22 and harvested for this visit, indicated that 764 procedures (278 surgery, 443 catheters, 45 others, 7 deaths [within 30 days of a procedure]) had been performed in patients with congenital heart disease.

The Congenital Data Auditor for the NCHDA undertook the visit remotely via a MS Teams connection with an external Consultant Congenital Cardiologist on site in person.

As stated above, 20 sets of notes were requested. The accuracy of the NCHDA data return was then checked against each set of notes. The Specific Procedures algorithm grouping is also validated for the case notes seen.

FRE are still in the process of going paper lite. Some documents were viewed on the electronic patient record or had been printed and added to the hospital paper bound notes. The paper case notes when present, were often large and bulky. The DBM reported that there had been a number of Trust wide technical errors with the ePR in the months preceding this site visit and this has slowed the further digitisation of medical information recording considerably.

Review of case notes

1. The case note bundles that had been printed from the ePR, had been meticulously prepared with sticky notes or highlighted text to identify many of the particular pages that the Reviewers needed to validate data.
2. As previously reported, the case notes were mostly in chronological order. The assistance of the local NCHDA Data Managers on the day was invaluable.
3. As previously reported, echocardiography reports were seen in the case notes but did not always describe the percentage of function for each ventricle.
4. It became apparent that the software used to record congenital cardiac information for the NCHDA dataset was not able to reliably record repeat procedures ie balloon dilation of a right pulmonary artery or redo permanent pacemaker implant/replacement.
5. On occasions it was sometimes challenging to find documentation for complex patients who had undergone many previous procedures, listed chronologically.



Review of Log Books for Operating Rooms and Cardiac Catheter Laboratories

Log books from Cath Labs 1-6 and the screening room were offered for review.

The cath lab log books are bespoke bound volumes with ruled columns for various pieces of information which are completed by hand. As previously reported, product identifying labels are also adhered to the relevant entry. Sometimes the labels overlay the procedure descriptions. This made it difficult on occasions to identify if a procedure was for congenital heart disease or not or exactly what procedure had actually been performed. It was not known if there were any confirmed plans as yet to move to using an electronic record of cath lab activity at this visit.

1. Approximately 64 catheter procedures were not validated in the log book. This may be because it is unclear in the actual log book entry whether or not procedures are for patients with congenital heart disease.

Registers Operating Theatres 1, 2, 3 4 and 19 were offered for review.

The log books are bespoke bound volumes with ruled columns for various pieces of information which are completed by hand. As reported previously, the legibility of the handwriting for some entries was quite poor. It was extremely challenging at times to identify whether younger adult patients were having operations for congenital heart disease or acquired or inherited heart disease.

It was not known if there were any confirmed plans as yet to move to using an electronic record of operating room activity at this visit.

1. Zero records were identified that may have been missed from the submission

It has been reported in previous years that Cerner SurgiNet is used in the operating rooms at FRE to record procedural activity. Cerner SurgiNet information system encapsulates preoperative, intraoperative and perioperative information. This resource may be a useful to accurately identify cases that occur in other operating rooms in future years, but the entries do not appear to include details of the patient diagnosis.

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 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 as stated above. Seven deaths within 30 days of a specific procedure for congenital heart disease were identified from the submitted data. for 2021-22. The Partial Risk Analysis in Surgery (PRAiS) sensitive fields were reviewed for each of the patients and the findings were:

1. All dates of death were found to be correct

It was noted that for one overseas patients' record for a post procedural death the incorrect post code for that country had been used.

It was enormously helpful to have both the copies of detailed discharge summaries, including hospital death certificates and the detail of whether or not there had been a discussion with the Medical Examiner/Coroner and, where completed, the Coroners Reports in each pack. This really does make this part of the review much more timely.

It is reported that the DBM now requests a quarterly report on patient's life status to ensure any all deaths are captured promptly.



Casenote Audit – 20 patients who underwent 10 catheter and 14 surgical procedures

| | Parameter | Total Score | Total No | Comments | Scores for Cardiology & Surgery | |
|----|------------------------------|-------------|----------|----------|---------------------------------|----|
| | | | | | C | S |
| 1 | Hospital Number | 20 | 20 | | 8 | 12 |
| 2 | NHS Number | 19 | 20 | 1 absent | 7/8 | 12 |
| 3 | Surname | 20 | 20 | | 8 | 12 |
| 4 | First Name | 20 | 20 | | 8 | 12 |
| 5 | Sex | 20 | 20 | | 8 | 12 |
| 6 | DOB | 20 | 20 | | 8 | 12 |
| 7 | Ethnicity | 20 | 20 | | 8 | 12 |
| 8 | Patient Status | 20 | 20 | | 8 | 12 |
| 9 | Postcode | 20 | 20 | | 8 | 12 |
| 10 | Pre Procedure Diagnosis | 24 | 24 | | 10 | 14 |
| 11 | Previous Procedures | 60 | 61 | 1 absent | 22/23 | 38 |
| 12 | Patients Weight at Operation | 24 | 24 | | 10 | 14 |
| 13 | Height | 22 | 22 | | 8 | 14 |
| 14 | Ante Natal Diagnosis | 1 | 1 | | 1 | - |
| 15 | Pre Proc Seizures | 24 | 24 | | 10 | 14 |
| 16 | Pre Proc NYHA | 12 | 12 | | 4 | 8 |
| 17 | Pre Proc Smoker | 12 | 12 | | 4 | 8 |
| 18 | Pre Proc Diabetes | 12 | 12 | | 4 | 8 |
| 19 | Hx Pulmonary Dis | 12 | 12 | | 4 | 8 |
| 20 | Pre Proc IHD | 12 | 12 | | 4 | 8 |



FRE NCHDA Report 2022

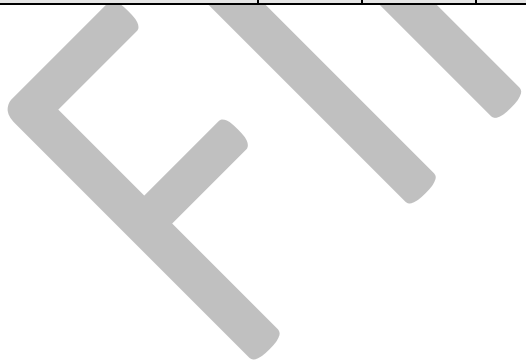
| | | | | | | |
|----|---|----|----|--|----|----|
| 21 | Comorbidity Present | 24 | 24 | | 10 | 14 |
| 22 | Comorbid Conditions | 58 | 58 | | 20 | 38 |
| 23 | Pre Proc Systemic Ventricular EF | 24 | 24 | | 10 | 14 |
| 24 | Pre Proc Sub Pul Ventricular EF | 22 | 22 | | 9 | 13 |
| 25 | Pre-proc valve/septal defect/ vessel size | 3 | 3 | | 3 | - |
| 26 | Consultant | 24 | 24 | | 10 | 14 |

| | Parameter | Total Score | Total No | Comments | Scores for Cardiology & Surgery | |
|----|--------------------------------|-------------|----------|----------|---------------------------------|----|
| | | | | | C | S |
| 27 | Date of Procedure + Time Start | 24 | 24 | | 10 | 14 |
| 28 | Proc Urgency | 24 | 24 | | 10 | 14 |
| 29 | Unplanned Proc | 9 | 9 | | 4 | 5 |
| 30 | Single Operator | 2 | 2 | | 2 | - |
| 31 | Operator 1 | 24 | 24 | | 10 | 14 |
| 32 | Operator 1 Grade | 24 | 24 | | 10 | 14 |
| 33 | Operator 2 | 22 | 22 | | 8 | 14 |
| 34 | Operator 2 Grade | 22 | 22 | | 8 | 14 |
| 35 | Procedure Type | 24 | 24 | | 10 | 14 |
| 36 | Sternotomy Sequence | 11 | 11 | | - | 11 |



FRE NCHDA Report 2022

| | | | | | | |
|----|---------------------------------------|----|----|--|----|----|
| 37 | Operation Performed | 24 | 24 | | 10 | 14 |
| 38 | Sizing balloon used for septal defect | 4 | 4 | | 4 | - |
| 39 | No of stents or coils | 3 | 3 | | 2 | 1 |
| 40 | Device Manufacturer | 15 | 15 | | 6 | 9 |
| 41 | Device Model | 15 | 15 | | 6 | 9 |
| 42 | Device Ser No | 15 | 15 | | 6 | 9 |
| 43 | Device Size | 13 | 13 | | 5 | 8 |
| 44 | Total Bypass Time | 12 | 12 | | - | 12 |
| 45 | XClamp Time, | 12 | 12 | | - | 12 |
| 46 | Total Arrest | - | - | | - | - |
| 47 | Cath Proc Time, | 10 | 10 | | 10 | - |
| 48 | Cath Fluro Time, | 10 | 10 | | 10 | - |
| 49 | Cath Fluro Dose, | 10 | 10 | | 10 | - |





FRE NCHDA Report 2022

| | Parameter | Total Score | Total No | Comments | Scores for Cardiology & Surgery | |
|----|--------------------------------|-------------|----------|-------------|---------------------------------|----|
| | | | | | C | S |
| 50 | Duration of Post Op Intubation | 12 | 12 | | - | 12 |
| 51 | Post Procedure Seizures | 24 | 24 | | 10 | 14 |
| 52 | Post Proc Complications | 9 | 10 | 1 incorrect | 0/1 | 9 |
| 53 | Date of Discharge | 24 | 24 | | 10 | 14 |
| 54 | Date of Death | 2 | 2 | | - | 2 |
| 55 | Attribution of Death | 2 | 2 | | - | 2 |
| 56 | Status at Discharge | 24 | 24 | | 10 | 14 |
| 57 | Discharge Destination | 24 | 24 | | 10 | 14 |



FRE NCHDA Report 2022

Data Quality Indicator Assessment:

The Overall Trust DQI = 99.5% Cardiology DQI = 99% Surgery DQI = 100%

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 | | | | | |
|--|--|--|------|------|-----|-----|
| <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="1155 779 1398 904"> <thead> <tr> <th data-bbox="1155 779 1278 813">Card</th> <th data-bbox="1278 779 1398 813">Surg</th> </tr> </thead> <tbody> <tr> <td data-bbox="1155 813 1278 904">.99</td> <td data-bbox="1278 813 1398 904">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,</p> <p>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 .997</p> <table border="1" data-bbox="1155 1115 1398 1630"> <thead> <tr> <th data-bbox="1155 1115 1278 1149">Card</th> <th data-bbox="1278 1115 1398 1149">Surg</th> </tr> </thead> <tbody> <tr> <td data-bbox="1155 1149 1278 1630">.99</td> <td data-bbox="1278 1149 1398 1630">1.0</td> </tr> </tbody> </table> | | Card | Surg | .99 | 1.0 |
| Card | Surg | | | | | |
| .99 | 1.0 | | | | | |
| <p><u>Procedure</u></p> | <p>Overall 1.0</p> | | | | | |



FRE NCHDA Report 2022

| | | | | |
|---|---|------------------------|---------------------|--------------------|
| 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 | | |
| <u>Outcome</u> Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. Post Procedure Complications. | Overall .99 <table border="1"> <tr> <td data-bbox="1155 925 1278 1102"> Card .975 </td> <td data-bbox="1278 925 1398 1102"> Surg 1.0 </td> </tr> </table> | | Card .975 | Surg 1.0 |
| Card .975 | Surg 1.0 | | | |

Data Quality Indicator Assessment by domain:

| DOMAIN | 202 | 202 | 202 | 201 | 201 |
|----------------------|------|------|-----|------|-----|
| | 2 | 1 | 0 | 9 | 8 |
| Demographics | .99 | 1.0 | 1.0 | 1.0 | 1.0 |
| Pre Procedure | .997 | .995 | .99 | .985 | .97 |
| Procedure | 1.0 | .997 | 1.0 | .99 | .99 |
| Outcome | .99 | 1.0 | 1.0 | .99 | 1.0 |



Conclusions

On the whole the NCHDA data was accurate, well documented, good quality and were appropriately recorded in the Cath Lab and Theatre log books. The hospital case note bundles for each of the patients included in the Data Quality Indicator (DQI) analysis had been meticulously prepared by the Congenital Data Managers.

Electronic log books are not yet in use at this centre. The DQI continues to be of an excellent standard and demonstrates that the NCHDA data collection and audit processes in place to support it at this centre are working well. It is clear that the Data Manager has invested many extra hours some of which were outside those contracted, to ensure this.

The Reviewers are pleased to report that FRE now has 2.0WTE dedicated individuals who look after the NCHDA data. However, it should be noted that it is a recommended standard of the New Congenital Heart Disease Review (NHSE May 2016 for Level 1 ACHD services (B33L1) that each centre providing these services must also have a dedicated congenital cardiac surgery/cardiology data collection manager, responsible for ACHD data and data submissions in accordance with necessary timescales.

As previously reported, data entry is now possible at a wider range of locations as each user has their own user ID and password to the information collection system Intellect.

It was also noted that on some occasions that the diagnoses coding used did not always completely reconcile with the procedure performed.

As previously reported, there was also some difficulty in accurately identifying procedures for congenital heart disease in all of the log books seen. Some operating theatre and cathlab log book entries did not record what procedure was performed at all and in other records for young adult patients it was not clear whether or not the procedure being performed was for congenital, acquired or inherited heart disease.

Validation of Deceased Patients Case Notes

All data were found to be accurate and complete. As noted above, it was enormously helpful to have both the copies of detailed discharge summaries, including hospital death certificates and the detail of whether or not there had been a discussion with the Medical



Examiner/Coroner and where completed, the Coroners Reports in each pack. This really does make this part of the review much less time consuming.

Recommendations (unchanged since 2021)

1. It is suggested that in line with the ACHD Specialist Surgical Standards (NHSE May 2016, B33L1) a dedicated data collection manager is recruited, to be responsible for ACHD audit and database submissions in accordance with necessary timescales
2. The standard operating procedures (SOP) for the NCHDA data collection should be reviewed to ensure that clear guidance is given on exactly how to capture all data on both paediatric and adult congenital cardiac patients in a timely manner. The SOP should clearly set out exactly who is responsible for:
 - a. Input of congenital patients NCHDA required dataset items and at which point of service delivery
 - b. Encouraging responsible clinician input of the procedure data for each operation, diagnostic or catheter intervention at the point of the service delivery and particularly data that cannot be entered at the time of the procedure, such as intubation time and complications prior to discharge.
 - c. 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
 - d. Ensuring diagnosis coding reconciles with the procedure performed
 - e. 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.
 - f. Reverse validation of the data submitted to NCHDA by responsible clinicians in conjunction with the Data Managers at least monthly.
 - g. Running the PRAiS (Paediatric Risk Analysis in Surgery) analysis tool monthly when software is available. This will inform the quarterly NHSE Dashboard reports.
 - h. Leading the local review (and how frequently and in which forum for both disciplines)
 - i. Making timely submissions (monthly is recommended)



FRE NCHDA Report 2022

3. It is recommended to clearly identify in log books for both cath lab and operating room congenital patients who undergo therapeutic cardiac procedures by non-congenital colleagues.
4. It is recommended that the use of Cerner SurgiNet be further explored as means of accurate and complete electronic data capture for NCHDA surgery procedures
5. It is recommended that all NCHDA Data Managers visit another congenital centre on an annual basis to observe processes and practices, share experiences and network.
6. Attendance at the next NCHDA Stakeholders (venue and date tbc) by DBM and lead clinician for congenital heart disease

DRAFT