# The National Congenital Heart Disease Audit

# Procedures for CONGENITAL HEART DISEASE

## Data Quality Audit For the year 2020/21

## Evelina London Children's and St Thomas' Hospitals

## Guys & St Thomas NHS Foundation Trust (GSTT)

## 27 July 2021

*performed by Lin Denne, and Dr G Skinner*

## Summary and Overview

The Congenital NICOR data return, prior to this validation visit, from the combined Congenital Cardiac Department of Guy's and St Thomas' NHS Foundation Trust (GSTT) indicated that a total of 852 cases had been undertaken during the year 2020/21. This represents an approximate 9% drop in procedural activity during the SARS-COV-2 pandemic.

This number of procedures are broken down further below.

| Year | Total | Surgery | Catheters | Others |
|---|---|---|---|---|
| 2011/12 | 777 | 442 | 319 | 16 |
| 2012/13 | 830 | 488 | 327 | 15 |
| 2013/14 | 879 | 504 | 348 | 27 |
| 2014/15 | 980 | 491 | 422 | 67 |
| 2015/16 | 976 | 497 | 357 | 122 |
| 2016/17 | 998 | 494 | 390 | 114 |
| 2017/18 | 1006 | 620 | 290 | 96 |
| 2018/19 | 988 | 467 | 436 | 95 |
| 2019/20 | 934 | 418 | 472 | 43 |
| 2020/21 | 852 | 409 | 433 | 11 |

This validation visit has been fully funded by the Guys and St Thomas' NHS Foundation Trust. This visit was supported remotely by a Consultant Congenital Cardiologist and the NCHDA Clinical Audit Nurse via the video conference facility MS Teams.

Due to the pandemic status a pilot study to assess the feasibility and practicability of a totally remote method of NCHDA data validation was undertaken in 2020. The clinical audit nurses and analytic team at GSTT were all remotely interacting and facilitating all parts of this validation. All team members continue to have equal remote access to required data systems and data bases. This validation has again been undertaken entirely remotely due to the advanced level of digitisation of hospital records at this NHS Trust and COVID restrictions upheld by GSTT at the time of this visit.

2 data managers from other NCHDA centres joined the MS Teams video conference to observe this visit.

The GSTT NHS Trust merged cardiovascular services with an adjacent NHS Trust in February 2021 and it is anticipated that numbers of procedures in both paediatric and ACHD patients will slowly increase as expanded facilities become available.

The GSTT has HeartSuite for congenital cardiac data collection since January 2004. There is real time data entry by most clinicians and there is access to HeartSuite in all clinical areas. The Trust is now very 'paper lite' and uses a combination of electronic systems through clinical areas including Badger (NNU), enoting (ward), eVision (PICU) and e-pr (Trust wide) are used. The trust is in the process of implementing a new EHR system.

## Actions Taken since the previous Validation Visit in 2020.

The NCHDA Review Team are also pleased to acknowledge the following actions continuing or implemented since the last visit.

1. Staff continue to work remotely where face to face patient contact is not required.
2. GSTT commenced provision of clinical inpatient services for patients who would normally have been treated at the adjacent NHS Trust from April 2020 due to COVID-SARS-2 pandemic.
3. The full merger of cardiovascular services of the two NHS Trusts took place in February 2021 and both Trusts are exploring processes to make a combined data submission to NCHDA in the future.

The Data team comprises of 2.0 WTEs Clinical Nurse Specialists in Audit and Research Data Management (CNSs) and a 1.0WTE ACHD data analyst The team works collaboratively to meet the needs of the Department

Data are primarily input to all systems by clinical colleagues with Consultants and Senior Trainees completing the HeartSuite data at the point of service.

The Centre have a well-established embedded culture in clinical audit and all colleagues are encouraged to own their data. Almost all data are collected contemporaneously and reviewed within a described timeframe by the data team. Discrepancies are immediately referred back to the responsible colleague(s) for urgent review and amendment.

The data, once validated locally, are submitted electronically to National Congenital Heart Disease Audit (NCHDA) managed by NICOR.

GSTT have been compiling digital data in the manner described and using a number of systems that inter locate for the last 6 years of NCHDA site visits.

Since 2016 the log books for cardiac operating theatres and catheter laboratories have been fully electronic (Galaxy/Labyrinth).

## Consent for External Validation of Notes.

In May 2018 the General Data Protection Regulation became law in the UK.

At GSTT Foundation Trust there is now displayed and available in all places of patient activity, a leaflet that describes how the Organisation use and share patients personal information to deliver and improve healthcare.

There is information in the leaflet that describes what information is kept, how safe it is and whom it may be shared with and whether it is anonymised or not. There is also information for patients who may wish to object to their data being shared and how to do this. The document also contains information on patients' rights to access their medical data.

## The overall Data Quality Indicator (DQI) for the combined data and separate DQI for Surgery and for Catheters at GSTT

The DQI for the Trust is calculated to be (with the previous visit scores are in parentheses), **98.75%** (97.75, 99.3, 99**)** The domain scores are as follows: Demographics .99 (.99, 1.0, 1.0), Pre Procedure .98 (.94, .993, .96), Procedure .99 (.99, .998, 1.0), and Outcome .99 (.99, .98, 1.0).

This is based on 20 patients who underwent 25 procedures, 7 catheter interventions and 17 operations. 6 patients were from the ACHD cohort.

There were 9 discrepancies in 865 variables.

On further review of the overall, when the cases were split into their surgery and catheter groups was;

| Year of visit | Data Year Validated | Surgery | Catheters |
|---|---|---|---|
| **2012** | 11/12 | 97% | 98.75% |
| **2013** | 12/13 | 97.5% | 96.% |
| **2014** | 13/14 | 98% | 94.25% |
| **2015** | 14/15 | 98.5% | 98% |
| **2016** | 15/16 | 99.25% | 99.5% |
| **2017** | 16/17 | 94.75% | 97% |
| **2018** | 17/18 | 98.75% | 99.5% |
| **2019** | 18/19 | 99.5% | 98.75% |
| **2020** | 19/20 | 99% | 97% |
| **2021** | 20/21 | 99% | 98.5% |

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.

## Introduction

The NCHDA data return, prior to this validation visit, from the combined Congenital Cardiac Department of Guy's and St Thomas' NHS Foundation Trust indicated that a total of 852 cases had been undertaken during the year 2020/2. 20 cases were randomly selected for the case note review.

20 sets of notes (the Sample) were requested and a Reserve list of 10 other cases was supplied approximately one month prior to this validation visit. On the day of the visit, no sets of notes were required from the Reserve list.

Prior to the visit the data team had compiled a digital file of each page from the relevant information system for each patient record. Each patient had their own folder of documents. The appropriate electronic platform was only used and shared on screen where the data were not already in the patient folder and were not recorded on any other digital system at GSTT. This was only in exceptional circumstances such as an echo report not detailing ventricular function for both chambers.

The accuracy of the NCHDA data return was then checked against each set of patient notes to enable the (DQI) to be calculated.

## Review of the digital patient notes on the shared screens.

All GSTT hosts were very responsive to requests from the Reviewers to check other digital case note documentation when requested. Where print was small, this was magnified for the Reviewers to see.

1. All individual patient files were meticulously ordered and this aided the review greatly.

## Review of the Theatre and Cath Lab Activity Logs

As previously reported, all cardiac surgery is performed in St Thomas's Hospital. There are 4 cardiac operating theatres plus a hybrid operating room. All cath lab activity at Evelina London along with all cardiac surgery is recorded in a digital information system – Galaxy (iSoft). Catheter lab activity in St Thomas' is recorded on Labyrinth. There are 5 cath labs at the St Thomas' site and 2 at Evelina London. One of these rooms is a dedicated MRI cath lab. Since mid-2018 a dedicated procedure room opened for use within the NICU, it has been used to facilitate PDA ligation surgery.During the reported financial year this room was not used as; part of the trusts Covid response.

The Trust, in line with NHSE & DH guidance has moved to E-records and has invested in NHS approved systems to record and log theatre activity – Galaxy It is an approved audit tool for theatre activity and reflects the planned procedure using OPCS 4.9 coding which in majority of cases will not cross reference accurately to EPCC coding used for the NCHDA national congenital cardiac audit. This is not something which is within

the congenital cardiac service's control. Digital surgical notes (handwritten and typed) act as the gold standard of actual surgical procedure performed.

The electronic operating theatre and cath lab records from the Galaxy (OR) and Labyrinth (Cath Labs) were made available for the time period under review. These documents in the form of excel spreadsheets, were shared on screen and each record was checked.

- 3 surgery procedures were identified prior to the site visit that may have been missed from the data submission. These are procedures that had been undertaken on patients from GSTT at another hospital by GUY surgeons
- 3 submitted records for surgery were not validated in Galaxy
- 1 submitted catheter record was identified that may have an error in it
- 12 submitted catheter procedures were not validated in the shared log books that were screened and these may have been performed in other locations such at NICU or PICU

The Trust have reviewed the cases identified above and have made new submissions or amendments where appropriate.

# Validation of Deceased Patients Diagnostic and Procedure Coding

This commenced with the validation of the 2013/14 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.

24 congenital patients were known to have died during the data collection period under review. 13 deaths occurred within 30 days of a therapeutic specific procedure and these were reviewed. The data team had prepared digital files for each patient record.

Of the data reviewed the findings are;-

- All dates of death were confirmed as correct
- 5 records may have single discrepancies in them

The 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

## Casenote Audit

Case note audit based on 20 patients who underwent 12 operations and 9 catheter procedures

| | Parameter | Total Score | Total No | Comments | Scores for Cardiology & Surgery | |
|---|---|---|---|---|---|---|
| | | | | | C | S |
| 1 | Hospital Number | 20 | 20 | | 7 | 13 |
| 2 | NHS Number | 20 | 20 | | 7 | 13 |
| 3 | Surname | 20 | 20 | | 7 | 13 |
| 4 | First Name | 20 | 20 | | 7 | 13 |
| 5 | Sex | 20 | 20 | | 7 | 13 |
| 6 | DOB | 20 | 20 | | 7 | 13 |
| 7 | Ethnicity | 19 | 20 | 1 incorrect | 6/7 | 13 |
| 8 | Patient Status | 20 | 20 | | 7 | 13 |
| 9 | Postcode | 19 | 20 | | 7 | 13 |
| 10 | Pre Procedure Diagnosis | 24 | 24 | | 7 | 17 |
| 11 | Previous Procedures | 21 | 21 | | - | 21 |
| 12 | Patients Weight at Operation | | 24 | | 7 | 17 |
| 13 | Height | 23 | 24 | 1 absent | 7 | 17 |
| 14 | Ante Natal Diagnosis | 4 | 4 | | - | 4 |
| 15 | Pre Proc Seizures | 24 | 24 | | 7 | 17 |
| 16 | Pre Proc NYHA | 6 | 6 | | 4 | 2 |
| 17 | Pre Proc Smoker | 6 | 6 | | 4 | 2 |
| 18 | Pre Proc Diabetes | 6 | 6 | | 4 | 2 |
| 19 | Hx Pulmonary Dis | 6 | 6 | | 4 | 2 |
| 20 | Pre Proc IHD | 6 | 6 | | 4 | 2 |
| 21 | Comorbidity Present | 24 | 24 | | 7 | 17 |
| 22 | Comorbid Conditions | 27 | 29 | 2 absent | 4 | 23/25 |
| 23 | Pre Proc Systemic Ventricular EF | 23 | 24 | 1 incorrect | 6/7 | 17 |
| 24 | Pre Proc Sub Pul Ventricular EF | 23 | 23 | | 7 | 16 |
| 25 | Pre-proc valve/septal defect/ vessel size | 3 | 4 | 1 incorrect | 4 | - |
| 26 | Consultant | 24 | 24 | | 7 | 17 |

| | Parameter | Total Score | Total No | Comments | Scores for Cardiology & Surgery | |
|---|---|---|---|---|---|---|
| | | | | | C | S |
| 27 | Date of Procedure + Time Start | 24 | 24 | | 7 | 17 |
| 28 | Proc Urgency | 24 | 24 | | 7 | 17 |
| 29 | Unplanned Proc | - | - | | - | - |
| 30 | Single Operator | 23 | 24 | 1 incorrect | 6/7 | 17 |
| 31 | Operator 1 | 24 | 24 | | 7 | 17 |
| 32 | Operator 1 Grade | 24 | 24 | | 7 | 17 |
| 33 | Operator 2 | 24 | 24 | | 7 | 17 |
| 34 | Operator 2 Grade | 24 | 24 | | 7 | 17 |
| 35 | Procedure Type | 24 | 24 | | 7 | 17 |
| 36 | Sternotomy Sequence | 15 | 15 | | - | 15 |
| 37 | Operation Performed | 24 | 24 | | 7 | 17 |
| 38 | Sizing balloon used for septal defect | - | - | | - | - |
| 39 | No of stents or coils | 1 | 1 | | 1 | - |
| 40 | Device Manufacturer | 8 | 8 | | 4 | 4 |
| 41 | Device Model | 8 | 8 | | 4 | 4 |
| 42 | Device Serial No | 8 | 8 | | 4 | 4 |
| 43 | Device Size | 7 | 7 | | 4 | 3 |
| 44 | Total Bypass Time | 15 | 15 | | - | 15 |
| 45 | XClamp Time, | 15 | 15 | | - | 15 |
| 46 | Total Arrest | 1 | 2 | 1 incorrect | - | ½ |
| 47 | Cath Proc Time, | 7 | 7 | | 7 | - |
| 48 | Cath Fluro Time, | 5 | 5 | | 5 | - |
| 49 | Cath Fluro Dose, | 5 | 5 | | 5 | - |

| | Parameter | Total Score | Total No | Comments | Scores for Cardiology & Surgery | |
|---|---|---|---|---|---|---|
| | | | | | C | S |
| 50 | Duration of Post Op Intubation | 14 | 15 | 1 incorrect | - | 15/16 |
| 51 | Post Procedure Seizures | 24 | 24 | | 7 | 17 |
| 52 | Post Proc Complications | 6 | 6 | | - | 6 |
| 53 | Date of Discharge | 24 | 24 | | 7 | 17 |
| 54 | Date of Death | 1 | 1 | | - | 1 |
| 55 | Attribution of Death | - | - | | - | - |
| 56 | Status at Discharge | 24 | 24 | | 7 | 17 |
| 57 | Discharge Destination | 24 | 24 | | 7 | 17 |

Data Quality Indicator Assessment:
The Overall Trust DQI = 98.75% Cardiology DQI = 98.5% Surgery DQI = 99%

. Total Procedures = 24 Catheter Procs = 7 Surgery Procs = 17

| DOMAIN | DOMAIN Score | |
|---|---|---|
| **Demographics**<br>Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status, | **Overall .99** | |
| | **Card**<br>.98 | **Surg**<br>1.0 |
| **Pre Procedure**<br>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,**<br>Note, the scores for his domain are affected by the selected previous procedure and pre procedure diagnosis | **Overall .98** | |
| | **Card**<br>.97 | **Surg**<br>.98 |
| **Procedure**<br>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,** | **Overall** .99 | |
| | **Card**<br>.99 | **Surg**<br>.99 |
| **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** .99 | |
| | **Card**<br>1.0 | **Surg**<br>.99 |

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**. | **2021 20/21 data** | **2020 19/20 data** | **2019 18/19 data** | **2018 17/18 data** |
|---|---|---|---|---|
| **Demographics** | .99 | .99 | 1.0 | 1.0 |
| **Pre Procedure** | .98 | .94 | 99 | .97 |
| **Procedure** | .99 | .99 | .998 | 1.0 |
| **Outcome** | .99 | .99 | .98 | 1.0 |

**Conclusions**

On the whole the NCHDA data for congenital procedures was accurate, well-documented, good quality and was appropriately recorded in the Theatre and Cath Lab Management systems (Galaxy and Labyrinth) at GSTT. A high Data Quality Indicator Score has been maintained above 97% which is excellent and demonstrates a continuing strong commitment to good quality verified clinical data. There appears to be a very robust culture of clinical audit embedded within the Trust. The Validation Team would like again, to commend the efforts of both of the CNSs and Analyst, and the ACHD Team in maintaining this at a time when there have been considerable infrastructure and location challenges.

The Trust has developed and regularly reviews SOPs to inform the congenital data collection which further underpins this registry.

GSTT have clearly made a strong and early commitment to move to entirely electronic record keeping. The electronic log books were first trialled alongside bound logs at the 2014 site visit. For the last 5 years of site validation visits data have been presented digitally for the patient records and in A3 size print outs from the cath labs (Labyrinth) and operating log books (Galaxy).

The digital presentation of documentation via MS Teams with the external clinician and NCHDA Clinical Auditor remotely connected worked very well for this annual NCHDA validation. This level of connectivity was maintained throughout the day.

GSTT are actively moving forward with merging congenital cardiac services following the merger with Royal Brompton & Harefield Hospitals particular with making one combined data submission to NCHDA from 1 April 2022 if possible.

The Trust would like to note that they have raised concerns regarding data produced by NICOR that remain unresolved for instance using out of date postcode data that results in extra work at unit level.

The Trust would also like to state that they do not believe that it is good practice for NICOR to ask for unvalidated data to be issued to them for use in analysis. The Trust confirms that at no point will the Organisation support the use of unvalidated data for the production of any reports.

**Recommendations**

1. It is recommended that any Standard Operating Protocols (SOP) that support the congenital data collection, should continue to be regularly reviewed to ensure that details are current and clear as to **exactly who** is responsible for;

    a. Input of the data for each procedure and at which point of the service delivery
    b. 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
    c. Reverse validation of the data submitted to NCHDA against locally held 'gold standard' clinical information systems in conjunction with clinician colleagues.
    d. Leading the local review (and how frequently and in which forum for both disciplines)
    e. Making timely submissions (monthly is recommended) where possible.
    f. It is recommended that all staff connected with NCHDA audit should observe at least one other site validation per year.

2. It is recommended that a formal request is made to NICOR to explore and agree the process for combining future NCHDA data and other cardiac registry submissions if applicable, from the two recently merged NHS Trusts.