The National Congenital Heart Disease Audit Combined Reports on Procedures for

CONGENITAL HEART DISEASE

Data Quality Audit For the year 1 April 2023 to 31 March 2024

For the combined

Evelina London Children's Hospital, Guys and St Thomas's, Royal Brompton and Harefield NHS Foundation Trust

15th + 17th October 2024

performed by Lin Denne, and Dr T Ramcharan

Summary and Background Overview

The Guys and St Thomas' NHS Foundation Trust (GUY) merged cardiovascular services with the adjacent Royal Brompton NHS Foundation Trust (NHB) in February 2021. This is the second NCHDA validation of the combined data submission of the new NHS Trust. All NCHDA data from the now fully combined Trusts have been submitted under the GUY identifier since 1 April 2022.

The new Organisation migrated to EPIC health care record system on 4 October 2023. All legacy systems such as HeartSuite or Labyrinth ceased to be used from that date. All legacy data has been imported into EPIC. EPIC is an all encompassing health care record from tertiary centre to a community settings information system. All the NCHDA data submitted for the 2023-24 year were submitted via EPIC.

The combined Congenital NICOR data return, prior to this validation visit, from the Congenital Cardiac Department of the two combined NHS Foundation Trusts (GUY) indicated that a combined total of 1984 cases had been undertaken during the year 2023/24.

This number of procedures are broken down further below.

Year	Total	Surgery	Catheters	Others
2021/22 GUY	787	331	441	15
2021/22 NHB	1096	348	742	6
2022-23	1888	696	1175	17
2023-24	1984	692	1275	17

Following review of the catheter laboratory and operating room activity log books (worklists) at this validation visit, 62 additional procedures were identified and where appropriate, were

subsequently submitted to the Registry. 5 further deaths were identified from this group, that had occurred within 30 days of a Specific Procedure.

This validation visit to GUY has been fully funded by the combined NHS Foundation Trust. Day 1 of this visit took place face to face with the external clinician, and NCHDA Clinical Audit Nurse. 3 external Data Managers from Children's Health Ireland (CHI) in Dublin observed the validation in person as their Organisation has also commissioned EPIC. Day 2 of this visit was undertaken virtually using MS Teams.

The procedures being validated at this visit are for patients with congenital heart disease that take place at Royal Brompton, Harefield, London Evelina, Guys' and St Thomas' Hospitals.

The Validation Team are pleased to note that prior to site visit, the local congenital cardiac clinical audit team had performed a further internal data audit and identified one patient death that had been omitted from the data submission.

For the Validation Day 1

The lead clinical audit nurse and analytic team at GUY were all either remotely interacting using MS Teams and facilitating parts of this validation or were on site. All team members continue to have equal remote access to required data systems and data bases. The external clinician on site on Day 1 of the visit was Dr T Ramcharan, Consultant Paediatric Cardiologist from Birmingham.

Until October 2023, the congenital cardiac department at GUY and NHB had been using many different information systems in all clinical areas. GUY and NHB, as separate NHS Trusts and prior to the recent amalgamation in 2022 into one Organisation, had been compiling digital data that inter located for the previous 10-15 years or more of NCHDA site visits.

As noted above, the combined Trust implemented the new electronic healthcare registry (eHR) system in all areas across all sites as part of the EPIC roll out on 4 October 2023.

The NCHDA Data team at GUY comprises of 2.0 WTEs Clinical Nurse Specialists in Audit and Research Data Management (CNSs) and a 3.0WTE data analysts. The team works

collaboratively to meet the needs of the now combined Department. At the time of this validation visit there are 2.0WTEs on maternity leave and these posts have not been locum covered.

Data are input to EPIC by clinical colleagues. Each user has a specific job role identity in EPIC that provides the level and range of access related to their role.

The GUY 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 prescribed timeframe by the data team. Discrepancies are immediately referred back to the responsible colleague(s) for urgent review and amendment.

The Congenital Data Team at the combined Organisation receive every patient booking to a cardiothoracic operating room or cath lab within the cardiac domain across the whole of the Trust into a worklist generated by EPIC. Each entry is reviewed by the congenital data team and any procedures that are not for patients with confirmed congenital heart disease are voided from the work list. The data, once completed and validated locally, are submitted electronically to National Congenital Heart Disease Audit (NCHDA) database managed by NICOR.

Actions Taken since the previously separate Validation Visits to GUY and to NHB in 2023:

- Roll out of new eHR system (EPIC) in October 2023 across all GSTT Trust sites
- All data for the last financial year (April – March 2023-24) were collated and reported via EPIC
- From February 2024 the two CHD data teams across Evelina London and Royal Brompton became a single team under the management of the Cardio Respiratory and Paediatric Intensive Care (CRIC) directorate
- GSTT Trust have indicated that they wish to submit PFO data to new NICOR PFOC registry only.

- GUY have identified 1 infant death which was missed from submission – this was reported to NICOR on 01/10/24 and will be added to the review of deceased cases in the list supplied

Consent for External Validation of Notes.

Under the General Data Protection Regulation (GDPR) of May 2018, it is expected that patients will be made aware by all Organisations who care for them and produce data relating to their medical conditions to be open and transparent about how their data is being kept, used and who it is being shared with and how it may be disposed of.

Across the Guys and St Thomas' and Royal Brompton NHS hospital sites, there are 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 GUY

The DQI for the Trust is calculated to be (with the previous visit scores are in parentheses), is **97.5%** for the 23/24 data (98.5% at GUY). This is a very good score and demonstrates a consistently high regard for data accuracy and completeness within your recently formed Organisation.

This is based on 20 patients who had undergone In the random sample of combined case notes that were reviewed, we audited 20 patients records. These 20 patients had undergone 25 procedures (14 catheter interventions and 11 operations). 11 patients were from the ACHD cohort.

There were 29 discrepancies in 963 variables. The individual fields where the main discrepancies are seen are:

Operator 1 + 2 names and grades	8 discrepancies
Implanted Devices size	5 discrepancies
Previous Procedures	4 discrepancies
Comorbidities	3 discrepancies

DQI for Surgery and for Catheters

As at the previous visits, a separate DQI is being calculated for both surgery and catheters where there are at least 5 surgical and 5 cardiology case notes in the randomised sample.

Year of visit	Data Year Validated	Surgery	Catheters
2022 GUY	21/22	100%	99.25%
2022 NHB	21/22	92.5%	95.75%
2023	22/23	98.5%	98.5%
2024	23/24	97.75%	97.0%

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, extracted on 14 September 2024, prior to this validation visit, from the combined Congenital Cardiac Department of Guy's and St Thomas' NHS Foundation Trust (GUY) indicated that a total of 1984 cases had been undertaken during the year 2023/4. As stated elsewhere, 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.

The Reviewers scrutinised the pages of the Trust EPIC eHR for each patient to validate each data item as required on a large screen.

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

Review of the digital patient notes on the shared screen at GUY.

All GUY hosts were very responsive to requests from the Reviewers to check other pages or tabs of the digital eHR documentation when requested. Where print was small and difficult to read, this was magnified for the Reviewers to see.

1. As at the previous validation visits, individual patient data were meticulously organised and this aided the review greatly.
2. The sheath in/sheath out time appears to be labelled as procedure duration but on some occasions it was possible to see the time line of actions in the cath lab to cross validated this data item and all correlated similarly
3. It was noted that that while the implanted device labels were seen in the eHR the sizes of the devices did not appear to be entered into the correct field in the NCHDA data.
4. Some of the notes for ACHD patients who had undergone their procedure at Royal Brompton cath labs appeared to be a little sparse on documenting exactly what the course of action had been.

Review of the Operating Theatre and Cath Lab Activity Logs at Guys and St Thomas's

As the switch to EPIC took place in the middle of the audit year, the CNS's and Data Analysts combined all the activity data into one Excel spreadsheet, taking information from legacy systems until 3 October 2023 and then from EPIC work lists from 4 October until 31 March 2024.

As of 4 October 2023 and documented elsewhere, the congenital CNS's and Data Analysts receive all booked cardiology and cardiac surgery episodes on one WorkList generated by EPIC and shared between them whenever a patient is allocated to a cath lab or operating room. The congenital cardiac clinical audit team then investigate each patient on the list and void (remove) the cases that are not for patients with congenital heart disease. The remaining procedures are then systematically followed up in the patients electronic hospital record (eHR) that is part of EPIC to ensure all data are collected in a timely manner by all relevant clinician colleagues.

Following validation of the Excel spreadsheet that contained the combined legacy systems and WorkList data for congenital catheter and surgery procedures the findings were:

- 33 surgery procedures were identified that may have been missed from the data submission.
- 2 submitted records for surgery may have errors in them
- 1 submitted surgery record may need to be removed if not for congenital heart disease
- 29 catheter procedures were identified that may have been missed from the data submission
- 3 submitted catheter records was identified that may have an errors in them
- 1 submitted catheter record may need to be removed if not for congenital heart disease

All of the data findings identified above have been reviewed and/or amended as necessary. Where procedures were found to have been omitted from the 2023/4 data submission these have been input to the NCHDA registry.

A total of 5 further deaths within 30 days of a procedure performed were identified from the 62 cases that had been missed from the data submission for 2023/4.

Validation of Deceased Patients Diagnostic and Procedure Coding GUY

Since 2013 all case notes for patients who have died following a procedure for congenital heart disease have their case notes examined and validated against the PRAiS sensitive data fields.

At the time of the data extraction for this site visit there appeared to 6 deaths within 30 days of a Specific Procedure. 1 further death within 30 days was identified in this cohort during pre site validation checks by GUY, and was submitted to the NCHDA Registry.

It was therefore confirmed that at the time of this validation visit, 22 congenital patients were known to have died during the data collection period under review. 6+1 deaths were within 30 days of a Specific Procedure.

Of the data relating to the deceased patients reviewed the findings are;-

- 1 record appears to have a discrepancy in the field for previous procedures
- 2 records may have discrepancies in the comorbidities field
- 2 records may have an incomplete procedures submitted
- All other data were confirmed as correct

The NCHDA clinical audit team at the Organisation confirmed that regular life status checks are run Trustwide against NHS Spine and EPIC is automatically updated from this when a death has occurred.

The reviewers were also pleased to see that where a paediatric death had occurred in hospital within 30 days of a procedure, that any discussion with a Medical Examiner/Coroner was noted and where appropriate a copy of the hospital death certificate was also available.

Post Site Validation Visit

As mentioned elsewhere, during the checks for full case ascertainment for the procedures, a further 62 possible missed cases were identified. On further investigation by the GUY congenital cardiac audit team, 5 further deaths were identified that occurred within 30 days of a Specific Procedure.

We can now confirm that in the GUY NCHDA procedures cohort for 2023-2024 there was a total of 12 patients who had died within 30 days of a Specific Procedure.

Pre Visit Questionnaire Completion

The Congenital NICOR pre visit Questionnaire was completed and returned prior to the validation visit from the combined NHB and GUY. This confirmed that there are established 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 GUY

Case note audit based on 20 patients who underwent 11 operations and 14 catheter procedures

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		11	9
2	NHS Number	18	18		11	9
3	Surname	20	20		11	9
4	First Name	20	20		11	9
5	Sex	20	20		11	9
6	DOB	20	20		11	9
7	Ethnicity	19	20		11	9
8	Patient Status	20	20		11	9
9	Postcode	20	20		11	9
10	Pre Procedure Diagnosis	25	25		14	11
11	Previous Procedures	22	26	4 absent	10/11	11/14
12	Patients Weight at Operation	24	25	1 unable to validate	13/14	11
13	Height	24	25	1 incorrect	13/14	11
14	Ante Natal Diagnosis	3	3		2	1
15	Pre Proc Seizures	25	25		14	11
16	Pre Proc NYHA	14	14		9	5
17	Pre Proc Smoker	14	14		9	5
18	Pre Proc Diabetes	14	14		9	5
19	Hx Pulmonary Dis	13	14	1 incorrect	8/9	5

20	Pre Proc IHD	14	14		9	5
21	Comorbidity Present	25	25		14	11
22	Comorbid Conditions	45	48	3 incorrect	21/22	24/26
23	Pre Proc Systemic Ventricular EF	24	25	1 incorrect	13/14	11
24	Pre Proc Sub Pul Ventricular EF	24	25	1 incorrect	13/14	11
25	Pre-proc valve/septal defect/ vessel size	5	5		5	-
26	Consultant	25	25		14	11

	Parameter GUY	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	25	25		14	11
28	Proc Urgency	25	25		14	11
29	Unplanned Proc	2	4	2 absent	½	½
30	Single Operator	4	4		4	-
31	Operator 1	24	25	1 incorrect	14	10/11
32	Operator 1 Grade	24	25	1 incorrect	8/10	10/11

33	Operator 2	18	21	1 incorrect, 2 absent	8/10	10/11
34	Operator 2 Grade	18	21	1 incorrect, 2 absent	14	10/11
35	Procedure Type	25	25		14	11
36	Sternotomy Sequence	10	10		-	10
37	Operation Performed	24	25	1 incorrect	14	10/11
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	-	-		-	-
40	Device Manufacturer	11	11		9	2
41	Device Model	11	11		9	2
42	Device Serial No	11	11		9	2
43	Device Size	5	10	5 absent	3/8	2
44	Total Bypass Time	10	10		-	10
45	XClamp Time,	10	10		-	10
46	Total Arrest	1	2	1 incorrect	-	½
47	Cath Proc Time,	14	14		14	-
48	Cath Fluro Time,	13	13		13	-
49	Cath Fluro Dose,	13	13		13	-

	Parameter GUY	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	8	9	1 absent	-	8/9
51	Post Procedure Seizures	25	25		14	11
52	Post Proc Complications	8	8		-	8
53	Date of Discharge	25	25		14	11
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	25	25		14	11
57	Discharge Destination	24	25	1 incorrect	13/14	11

Data Quality Indicator Assessment:
The Overall Trust DQI GUY = 97.5% Cardiology DQI = 97% Surgery DQI = 97.75%

<table>
<tr><th>DOMAIN GUY</th><th colspan="2">DOMAIN Score</th></tr>
<tr><td rowspan="2"><u>Demographics</u>

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
1.0</td><td>Surg
1.0</td></tr>
<tr><td rowspan="2"><u>Pre Procedure</u>
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 .97</td></tr>
<tr><td>Card
.96</td><td>Surg
.98</td></tr>
<tr><td><u>Procedure</u></td><td colspan="2">Overall .95</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, **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** .94	**Surg** .95
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .98	
	Card .98	**Surg** .98

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. GUY	**2024 23/24 data**	**2023 22/23 combined data**	**2022 21/22 data NHB Score in ( )**	**2021 20/21 data**
Demographics	1.0	1.0	1.0 (95)	.99
Pre Procedure	.97	.97	.99 (97)	.98
Procedure	.95	.99	1.0 (95)	.99
Outcome	.98	.99	1.0 (92)	.99

Conclusions

On the whole the NCHDA data for congenital procedures was accurate, well-documented, good quality and was appropriately recorded across the Trust. The Data Quality Indicator Score is 97.5% 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 Analysts, in maintaining this at a time when there have been continued infrastructure and location challenges as two large NHS Trusts have come together to form one new Organisation and the launch of brand new fully inclusive electronic health record (eHR).

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

The new Organisation has clearly made a strong and early commitment to move to entirely electronic record keeping with EPIC. For the Congenital Cardiac Audit Team to receive all booked cardiac operating room and catheter lab episodes is clearly a huge advantage in ensuring that almost full case ascertainment for NCHDA is achieved whenever possible.

The NHCDA Validation Team who carried out this review note that this is the rollout/ stabilisation phase of EPIC eHR and GSTT are finding some minor issues with data points and these are addressed promptly when identified.

It was also reported to the external Validation Team that engagement of the ACHD clinicians with filling out their NCHDA Smartforms that are part of the EPIC build that generates the eventual data submission to the Registry is quite poor on occasions with the congenital data management team having to populate the vast majority of the data than cannot be collected automatically within the eHR – (EPCC codes and complications etc).

The digital presentation of documentation via MS Teams on Day 2 of the Validation with the NCHDA Clinical Auditor remotely connected worked very well. This level of connectivity was maintained throughout the day.

The Validation Team note that GUY meet the 2016 NHSE recommendation that in line with the New Congenital Heart Disease Review (NHSE May 2016) recommendation B32(L1); that each Level 1 Paediatric Specialist Congenital Cardiac Surgery Centre must have a minimum of 1.0 WTE dedicated paediatric cardiac surgery/cardiology data collection manager, with at least 1.0 WTE assistant, responsible for audit and database submissions in accordance with necessary timescales.

The 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.

This is further underpinned by The Report of the Independent Review of Children's Cardiac Services in Bristol (June 2016 Grey, Kennedy 1.22(2) and Ch17).

However, as the cardiovascular service at this Organisation is now a merger of two very large NHS Trusts, these standards may need to be considered closely to ensure that the changing workload and distribution of procedures in this new multi sited provider is adequately reflected and protected with a sufficient number of DBM roles to enable cross site data collection and to quality control the very large amount of NCHDA data that is now generated. High standards of data quality may be compromised without sufficient, well trained and well supported clinical data managers to support not only the NCHDA, but also the various related NHSE monthly and quarterly activity analyses and 'dashboard' requests.

It's always helpful for local host colleagues both to understand the site validation process in general and also to appreciate the accessibility in reverse of their own data systems. Its very important that the diagnosis for instance, reconciles with the procedure performed, this may also affect what ends up in the NCHDA database etc. So particularly for the people doing procedures and entering the data its quite informative. It also very much helps to have some local clinicians around when looking through the notes even when they have been very well collated together as of the very complex episodes can be quite hard to follow.

Recommendations for combined GUY and Royal Brompton (GSTT) Service 2024

1. It is recommended that the recently combined congenital cardiac service between Guy's St Thomas's and Royal Brompton Hospital Trusts, consider how to best to meet the New Congenital Heart Disease Review (NHSE June 2016) recommendation B32(L1) and B33 (L1) that each Specialist Surgical Centre must have a minimum of 1.0 WTE dedicated paediatric cardiac surgery/cardiology data collection manager, with at least 1.0 WTE assistant, and 1.0WTE for ACHD responsible for audit and database submissions in accordance with necessary timescales; or whether this needs to be expanded given the extremely large size of the Organisation and number of congenital cardiac procedures now being undertaken. The individuals currently in post should fulfil dedicated roles to meet the growing demands of the now enlarged, NCHDA data collection and NHSE with no other 'add on' parts.
2. It is recommended that all colleagues who handle/analyse/coordinate data should have defined protected time for these specific roles and access to the NCHDA database and also have either a secure NHSMail email address or a DCB 1586 compliant email address. https://digital.nhs.uk/services/nhsmail/the-secure-email-standard
3. 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 at each of the sites where procedures are performed.
    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) and where possible within 2 weeks of a procedure.
f. Ensuring operators names and GMC and Name are always submitted.
g. Careful and consistent descriptions of ventricular function for all procedures in patients with congenital heart disease.
h. Ensuring the correct units of measurement of radiation are recorded for each procedure. cGy/cm^2 is the measurement required.
i. Careful and detailed recording of all manufacturers details and serial numbers of implanted devices in the correct NCHDA data fields.
j. Checking for any out of hospital deaths that may have occurred in the congenital cohort.
k. Where a patient has died within 30 days of a procedure, documenting whether or not there was a discussion with the Medical Examiner or Coroner (when required), or was discussed at a Mortality and Morbidity review and whether or not the death was related to the procedure as these are NCHDA dataset items.
l. Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.
m. Timely reverse validation together with the Clinical Lead(s) for Congenital Cardiology and the responsible clinicians
n. It is recommended that all staff connected with NCHDA audit should observe at least one other site validation per year.

4. ACHD colleagues should be encouraged to take ownership of their data, to be pro active and responsive and complete the NCHDA documentation either at the point of service or as soon as possible after the patient contact.