The National Congenital Heart Disease Audit Combined Reports on Procedures for

CONGENITAL HEART DISEASE

Data Quality Audit For the year 2021/22

Evelina London Children's and St Thomas' Hospitals

Guys & St Thomas NHS Foundation Trust (GUY)

29 September 2022

performed by Lin Denne, and Dr S Narayan

and

Royal Brompton & Harefield Hospitals as part of GUY

4 October 2022

performed by Lin Denne and Dr P Zemrak

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 and it is anticipated that numbers of procedures in both paediatric and ACHD patients will slowly increase as expanded facilities become available.

In future years it is expected that there will be one external NCHDA site validation visit to review the combined data from both NHS Trusts. A combined data submission from the new organisation is anticipated for the year April 2022 to March 2023. The new organisation is planning to migrate to EPIC health care record system in April 2023. EPIC is an all-encompassing health care record from tertiary centre to a community settings information system.

For this visit in 2022, there is one combined site validation report with identified reporting for GUY and for Royal Brompton & Harefield Hospitals (NHB), as the data for April 2021 – March 2022 were submitted from their respective hospital sites, using the individual data systems at those centres. The data for each site was managed during that period by the individual clinical audit teams at each centre.

The Congenital NICOR data return, prior to this validation visit, from the Congenital Cardiac Department of GUY indicated that a total of 787 cases had been undertaken and NHB a total of 1096 procedures had been undertaken during the year 2021/22.

This number of procedures are broken down further below.

Year	Total	Surgery	Catheters	Others
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
2021/22 GUY	787	331	441	15
2021/22 NHB	1096	348	742	6

This validation visit to GUY 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.

These procedures at NHB take place at both Royal Brompton and Harefield Hospitals.

The NHB validation visit was fully funded by the Royal Brompton & Harefield Hospitals as part of Guy's & St Thomas's NHS Foundation Trust.

For the Validation at GUY

The clinical audit nurses 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. This validation has been undertaken entirely remotely due to the highly advanced level of digitisation of hospital records at this NHS Trust. The external clinician was also connected remotely via MS Teams was Dr S Narayan from Bristol.

Three data managers from other NCHDA centres and one clinical researcher attended the visit virtually as observers during the day.

The congenital cardiac department at GUY has been using 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), e-noting (om the wards), eVision (PICU) and e-pr (Trust wide) are used. GUY have been compiling digital data in the manner described and using a number of systems that inter locate for the last eight years of NCHDA site visits.

The Trust is in the process of implementing a new electronic healthcare registry (EHR) system.

The NCHDA Data team at GUY 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 GUY Centre has 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.

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

For the validation at NHB

There is one single dedicated 1.0WTE Senior Clinical Outcomes Analyst (DBM) role and 1.0WTE assistant data analyst/coordinator role. The assistant data analyst/coordinator at this visit was appointed in mid 2021 and is a novice to the data collection environment. Neither poster holders for these roles, have a clinical background.

A locum DBM was in post during most of this data period with no previous NCHDA registry experience. At this visit, it appeared that the novice assistant DBM/analyst has no protected time for NCHDA.

The external clinician at NHB was Dr F Zemrak, Consultant Congenital Cardiologist from London who was physically present and the NCHDA Clinical Data Auditor who was present on MS Teams.

NHB are now mostly paper free. For this visit digital files for each patient that was to be reviewed were compiled. Each file contained a screen shot of the relevant document to validate the submitted data field from.

Access to the ePR and other digital systems was enabled and screen sharing was also provided in case the Reviewers wished to scrutinise any other documents.

As stated at all previous visits to NHB, it is reported that most data were input to the Dendrite information system by consultants and trainee medical staff. This system is 'web enabled' and is called INTELLECT. Computer terminals are available in a variety of different clinical locations including operating theatres and catheter laboratories and real time data input is expected.

Actions Taken since the previous Validation Visit to GUY in 2021:

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

1. At the time of this visit GUY were less than seven months from the planned rollout of a new combined EHR. This will significantly change practice and processes at GUY (Evelina & RBH sites) resulting in the retirement of many systems.
2. One of the major changes is that all patients will be issued with a new hospital number
3. GUY have requested some clarity from NICOR on how the NCAP system will handle this. NHS numbers will not be affected but for patients who do not have an NHS number this may pose a risk.

Feedback on Actions Implemented following the last NCHDA Validation Visit to NHB in 2021

1. No specific actions reported and no pre visit questionnaire received prior to this visit.

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.

At GUY 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 GUY

The DQI for the Trust is calculated to be (with the previous visit scores are in parentheses), **99.75%** (98.75, 97.75, 99.3). The domain scores are as follows: Demographics 1.0 (.99, .99, 1.0), Pre Procedure .99 (.98, .94, .993), Procedure 1.0 (.99, .99, .998), and Outcome 1.0 (.99, .99, .98).

This is based on 20 patients who underwent 23 procedures, 11 catheter interventions and 12 operations. Seven patients were from the ACHD cohort.

There were four discrepancies in 866 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
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%
2022	21/22	100%	99.25%

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.

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

The DQI for NHB is calculated to be **94.75%** (98, 95.75, 87.5, at previous visits). The Domain scores for this visit are: (with previous years in parentheses) Demographics .95 (1.0, 1.0, .99,), Pre Procedure .97 (.95, .95, .90), Procedure .95 (.99, .95, .83) and Outcome .92 (1.0, .93, 78). This represents a 3.25% drop in DQI but is still a good score.

There were 45 discrepancies identified in 967 variables.

The fields with the most discrepancies were:

Device fields for manufacturer, product name and size	5 discrepancies
Post procedural complications	5 discrepancies
Comorbidities	4 discrepancies
Catheter procedure times (sheath in to caths out)	3 discrepancies
Post op intubation	3 discrepancies
Discharge Destination	2 discrepancies
Date of Death	2 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 five surgical and five cardiology case notes in the randomised sample.

Year of visit	Data year validated	Surgery	Catheter Interventions
2013(ii)	12/13	97.86%	96.43%
2014	13/14	99.25%	96.25%
2015	14/15	98.75%	97.75%
2016	15/16	99.5%	98.75%
2017	16/17	99.25%	98.75%
2018	17/18	98%	99.25%
2019	18/19	92.75%	80%
2020	19/20	93%	98%
2021	20/21	99%	96%
2022	21/22	92.5%	95.75%

Introduction for GUY

The NCHDA data return, 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 787 cases had been undertaken during the year 2021/2. 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. There were 23 procedures reviewed for 20 patients - 12 operations and 11 catheter procedures.

As at previous visits, 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 GUY. 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.

Introduction for NHB

Prior to this validation visit, the data return to NCHDA from Royal Brompton & Harefield NHS Foundation Trust (NHB) for the data collection year 2021/22 indicated that some 1096 procedures had been undertaken in children and adults with congenital heart disease, of which 20 cases were randomly selected for the case note review.

For this visit digital files for each patient that was to be reviewed were compiled. Each file contained a screen shot of the relevant document to validate the submitted data field from.

Access to the ePR and other digital systems was enabled and screen sharing was also provided in case the reviewers wished to scrutinise any other documents.

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

All GUY 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. As at the previous validation visits, individual patient files were meticulously ordered and this aided the review greatly.

Review of the Theatre and Cath Lab Activity Logs at GUY

As previously reported, all cardiac surgery is performed in St Thomas's Hospital. There are four cardiac operating theatres plus a hybrid operating room. There are five cath labs at the St Thomas' site and two 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.

As previously reported, the Trust, in line with NHSE guidance has moved to e-records and has invested in NHS approved systems to record and log theatre (OR) 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.

- Zero surgery procedures were identified prior that may have been missed from the data submission.
- Two submitted records for surgery may have errors in them
- Two submitted catheter records were identified that may have an errors in them.

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

Review of hospital notes at NHB

Of the 20 patients in the sample, had undergone 26 procedures (9 operations and 17 therapeutic catheters. As previously, each of the individual files of digital notes were meticulously prepared for the visit.

1. It was again apparent that there had been small programming problem in Dendrite with the field for ethnicity particularly in the surgical data. This was first identified at the 2020 validation.
2. As previously reported, some names of operators appear to be absent and only GMC numbers present.
3. Of the surgical case notes reviewed, it was noted that all had a typed surgical summary. This is a commendable practice and tremendously aided the data review.
4. There appears to be a large number of varying adjectives used to describe ventricular function seen in the sample notes.
5. Specific documentation of the date and time of patient extubation in hospital records of surgical patients was challenging to find on occasions.
6. Sheath in and sheath out time is required for catheter patients not time in/time out of cath lab in the NCHDA registry.
7. One catheter record was identified in the case note review that was for a Specific Procedure but appeared to be incorrectly coded and would not be analysed properly.

Theatre & Catheter Lab Records and Review of the Catheter Laboratory Log Books at NHB

As at previous NCHDA validation visits it has been reported that across both sites, the radiologists use a customised electronic data collection tool (Radiology Information System or RIS) in the catheterisation laboratories. This has been adapted for the collection of all catheter intervention and diagnostic data, rather than just for radiology. Infoflex is a database that is used in the cath labs to collect information on electrophysiology activity and PACEnet is a data base used in the cath labs to collect information on all pacing procedures. COGNOS is the software used to extract data and run reports. The only congenital catheter interventions taking place at Harefield site are some closures of PFOs in adults. This activity is easily picked up from the COGNOS reports.

This local record is derived from ICIP in the operating room and RIS from the cath labs. It is reported that these electronic records are considered to be the gold standard record of all activity in the operating theatres and cath labs.

On the day it became apparent that no extract had been prepared for the surgical procedures across NHB. The external validation team are very grateful to the swift actions of the locum DBM to rectify this and provide exactly what was required within an hour.

The findings were:

- All 348 submitted surgery records have a least one error in them. As reported in 2021 there may be a formatting issue with the field for ethnicity in the surgical data
- One surgery record was identified that may have been missed from the submission
- One surgery record may have a duplicate entry submitted
- One surgery record appears to be for a non NCHDA procedure and if so should be removed
- There were 54 queries raised from the submitted catheter records. 44 of these submitted records do not appear to have a first operator for the procedure
- Two records appear to have duplicate entries.

As noted previously it is of great assistance when reviewing these documents if a single consistent approach to identifying NCHDA procedures within log books (electronic or hand written) that can be used across all hospital sites.

Validation of Deceased Patients Diagnostic and Procedure Coding GUY

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.

14 congenital patients were known to have died during the data collection period under review. Eight 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 data were confirmed as correct.

The NCHDA clinical audit team at GUY confirmed that regular life status checks are run Trust wide against NHS Spine and the local patient administration data system 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.

Validation of Deceased Patients Diagnostic and Procedure Coding NHB

Four post procedural deaths were submitted in the data from NHB for the year 2020/21. All four deaths occurred within 30 days of a therapeutic procedure and these were prioritised for the review.

One further 30 day death was identified during the case note review, as the date of death had not been submitted to NCHDA.

- All dates of death that were submitted were found to be correct.
- Each of seven procedural records had at least one discrepancy and will need to be reviewed and amended.

It was unclear at this site visit whether or not the life status of NCHDA patients from NHB was regularly undertaken or in what intervals. It was also quite difficult to find specific documentation to indicate whether or not a post procedural death has been discussed with the local Medical Examiner or Coroner.

Pre Visit Questionnaire Completion

The Congenital NICOR pre visit questionnaire was completed and returned prior to the validation visit from GUY. 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.

No completed pre-visit questionnaire was received from NHB and the external Validation Team are not able to completely confirm that there remain appropriate measures in place in respect of the above or that any actions had been taken in response to the recommendations made a the 2021 NCHDA site validation.

Casenote Audit GUY

Case note audit based on 20 patients who underwent 12 operations and 11 catheter procedures

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		10	10
2	NHS Number	20	20		10	10
3	Surname	20	20		10	10
4	First Name	20	20		10	10
5	Sex	20	20		10	10
6	DOB	20	20		10	10
7	Ethnicity	19	20		10	10
8	Patient Status	20	20		10	10
9	Postcode	20	20		10	10
10	Pre Procedure Diagnosis	23	23		11	12
11	Previous Procedures	44	44		19	25
12	Patients Weight at Operation	23	23		11	12
13	Height	23	23		11	12
14	Ante Natal Diagnosis	2	2		2	-
15	Pre Proc Seizures	23	23		11	12
16	Pre Proc NYHA	7	7		5	2
17	Pre Proc Smoker	7	7		5	2
18	Pre Proc Diabetes	7	7		5	2
19	Hx Pulmonary Dis	7	7		5	2
20	Pre Proc IHD	7	7		5	2
21	Comorbidity Present	22	23	1 incorrect	10/11	12

22	Comorbid Conditions	31	34	3 incorrect	14/17	17
23	Pre Proc Systemic Ventricular EF	23	23		11	12
24	Pre Proc Sub Pul Ventricular EF	21	21		10	11
25	Pre-proc valve/septal defect/ vessel size	4	4		4	-
26	Consultant	23	23		11	12

	Parameter GUY	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	23	23		11	12
28	Proc Urgency	23	23		11	12
29	Unplanned Proc	-	-		-	-
30	Single Operator	1	1		1	12
31	Operator 1	23	23		11	12
32	Operator 1 Grade	23	23		11	12
33	Operator 2	22	22		10	12
34	Operator 2 Grade	22	22		10	12
35	Procedure Type	23	23		10	12
36	Sternotomy Sequence	10	10		-	10

37	Operation Performed	23	23		11	12
38	Sizing balloon used for septal defect	1	1		1	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	10	10		7	3
41	Device Model	11	11		7	3
42	Device Serial No	11	11		7	3
43	Device Size	9	9		6	3
44	Total Bypass Time	10	10		-	10
45	XClamp Time,	9	9		-	9
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	11	11		11	-
48	Cath Fluro Time,	6	6		6	-
49	Cath Fluro Dose,	6	6		6	-

	Parameter GUY	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	12	12		-	12
51	Post Procedure Seizures	23	23		11	12
52	Post Proc Complications	5	5		1	4
53	Date of Discharge	23	23		11	12
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	23	23		11	12
57	Discharge Destination	23	23		11	12

Data Quality Indicator Assessment:

The Overall Trust DQI GUY = 99.75% Cardiology DQI = 99.25% Surgery DQI = 100%

Total Procedures = 23 Catheter Procs = 11 Surgery Procs = 12

DOMAIN GUY	DOMAIN Score	
Demographics	Overall, 1.0	
Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status	Card 1.0	Surg 1.0

<table>
<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 .99</td></tr>
<tr><td>Card
.97</td><td>Surg
1.0</td></tr>
<tr><td rowspan="2"><u>Procedure</u>
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</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>Outcome</u>
Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge Date of Death, Status at Discharge, Discharge Destination.
Post Procedure Complications.</td><td colspan="2">Overall 1.0</td></tr>
<tr><td>Card
1.0</td><td>Surg
1.0</td></tr>
</table>

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	2022 21/22 data	2021 20/21 data	2020 19/20 data	2019 18/19 data
Demographics	1.0	.99	.99	1.0
Pre Procedure	.99	.98	.94	99
Procedure	1.0	.99	.99	.998
Outcome	1.0	.99	.99	.98

Case Note Audit NHB:
Patient's notes were audited covering 17 catheter interventions and 9 operations.

	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	13	20	5 absent, 2 unable to validate	11/13	5/7
8	Patient Status	20	20		13	7
9	Postcode	20	20		13	7
10	Pre Procedure Diagnosis	26	26		17	9
11	Previous Procedures	36	37	1 absent	30/31	6
12	Patients Weight at Operation	26	26		17	9
13	Height	23	24	1 absent	25	8/9

14	Ante Natal Diagnosis	5	6	1 incorrect	2	¾
15	Pre Proc Seizures	26	26		17	6
16	Pre Proc NYHA	5	5		3	2
17	Pre Proc Smoker	5	5		3	2
18	Pre Proc Diabetes	5	5		3	2
19	Hx Pulmonary Dis	5	5		3	2
20	Pre Proc IHD	5	5		3	2
21	Comorbidity Present	25	26	1 incorrect	16/17	9
22	Comorbid Conditions	16	20	4 absent	11/15	5
23	Pre Proc Systemic Ventricular EF	26	26		17	9
24	Pre Proc Sub Pul Ventricular EF	26	26		17	9
25	Pre-proc valve/septal defect/ vessel size	2	2		2	-
26	Consultant	26	26	6 GMC numbers only	17	9

	Parameter NHB	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	25	26	1 incorrect	17	8/9
28	Proc Urgency	26	26		17	9
29	Unplanned Proc	1	1		-	1
30	Single Operator	5	5		5	-
31	Operator 1	26	26	2 GMC number only	17	7/9
32	Operator 1 Grade	26	26		17	7/9
33	Operator 2	20	21	10 GMC only, 1 absent	12	8/9
34	Operator 2 Grade	20	21		12	8/9
35	Procedure Type	26	26		17	9
36	Sternotomy Sequence	9	9		-	9
37	Operation Performed	25	26	1 incorrect	17	9
38	Sizing balloon used for septal defect	1	1		1	-
39	No of stents or coils	9	11	2 absent	9/11	-
40	Device Manufacturer	14	15	1 absent	13/14	1
41	Device Model	21	22	1 absent	20/21	1
42	Device Ser No	19	22	2 incorrect, 1 absent	19/21	1
43	Device Size	20	21	1 absent	19/20	1

44	Total Bypass Time	8	8		-	8
45	XClamp Time,	8	8		-	8
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	13	17	3 incorrect	14/17	-
48	Cath Fluro Time,	15	16	1 absent	15/16	-
49	Cath Fluro Dose,	16	16		16	-

	Parameter NHB	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	-	4/7	3 incorrect	-	4/7
51	Post Procedure Seizures	26	26		17	9
52	Post Proc Complications	8	13	1 incorrect, 4 absent	4/8	4/5
53	Date of Discharge	26	26		17	9
54	Date of Death	0	1	1 absent	-	0/1
55	Attribution of Death	0	1	1 absent	-	0/1
56	Status at Discharge	26	26		17	9
57	Discharge Destination	24	26	2 incorrect	17	8/9

Data Quality Indicator Assessment:

The Overall Trust DQI NHB = 94.75% Cardiology DQI = 95.75% Surgery DQI = 92.5%

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 NHB	**DOMAIN Score**	
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status	**Overall .95**	
	Card	**Surg**
	.98	.88
Pre Procedure 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	**Overall .97**	
	Card	**Surg**
	.97	.98
Procedure	**Overall .**95	

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** .95	**Surg** .94
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .92 **Card** .93	**Surg** .90

This DQI 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 NHB	**2022 21/22**	**2021 20/21**	**2020 19/20**	**2019 18/19**
Demographics	.95	1.0	1.0	.98
Pre Procedure	,97	.98	.95	.90
Procedure	.95	.99	.95	.83
Outcome	.92	1.0	.93	.78

Conclusions GUY

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 GUY. The 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 continued infrastructure and location challenges.

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

GUY 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 seven 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.

GUY have now merged congenital cardiac services with Royal Brompton and Harefield Hospitals and plan to make one combined data submission to NCHDA from 1 April 2022.

The GUY 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.

Conclusions NHB

The Validation Team would like to commend the Quality and Safety Team and the Locum DBM for the attention to detail in the preparation of the digital case notes, which greatly enhanced this part of the review.

The Validation Team would also like to thank the NCHDA Lead Clinician Dr Franklin at NHB for making the time to meet them and assist with the validation task.

The Validation Team acknowledge also that there have been some continuing difficulties with clinician engagement in some areas particularly with timely data collection and data quality checking at the point of service, but this is continuing to improve. The decrease in the data quality indicator (DQI) score and insufficient support for the Locum DBM and Assistant DBM is indicative of this also. As previously observed, it appears that there is still a lack of ownership of the data by some clinicians and reliance on one non-clinical Data Manager (DBM) to ensure accuracy and quality.

The DBM in post during 50% of this the data collection period was a non-clinical locum data manager from a non NHCDA registry. The returning DBM is also non-clinical but has been in the role for four years previously.

It is also of concern that the assistant data manager role does not have protected time to support NCHDA.

The Validation Team note that it is recommended 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).

As the cardiovascular service at this Trust is now merged with St Thomas' and Guys NHS Foundation Trust (GUY), this standard may need to be closely considered closely to ensure that the changing workload of procedures in this new combined multi sited provider is adequately reflected with a sufficient number of DBM roles at each site. 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.

On the whole the NCHDA data that were seen at NHB, were very well documented, high quality and were appropriately recorded in the electronic records seen at this validation visit. However, as mentioned in previous validation reports, the precise descriptions of the procedures performed and whether or not it was for congenital heart disease were often not recorded but this is improving slowly year on year. The overall quality of the electronic notes is to be commended. The PICU discharge summaries and the inpatient discharge letters were of great help during the review.

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. It's very important that the diagnosis for instance, reconciles with the procedure performed, this may also affect what ends up in the NCHDA database etc. 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.

The availability of electronic theatre and catheter lab registries is very useful and expedites the time needed to perform this task. The reviewers were informed that NCHDA patients are flagged within the system and would recommend that robust procedures are in place to check the reliability of this flagging system as the Trust progresses with new electronic records. However, as stated above it was often not clear to the reviewers whether or not a procedure was being performed for congenital heart disease.

Validation of Deceased Patients Diagnostic and Procedure Coding at NHB

As reported above, the data were of good quality and clearly recorded. Several discrepancies were identified as detailed above and were notified to the centre immediately post visit.

One further death within 30 days of a procedure was identified during the site visit that had not been notified to NCHDA.

Recommendations for combined GUY and NHB Service 2022

1. It is recommended that the recently combined congenital cardiac service GUY and NHB, 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. These should fulfil dedicated roles to meet the growing demands of the NCHDA data collection and NHSE with no other 'add on' parts.
2. It is recommended that all colleagues who handle/data analyse/coordinate should have defined protected time for these specific roles and access to the NCHDA database and also have a secure NHSMail email address.
3. It is recommended that any Standard Operating Protocols (SOP) that support the congenital data collection at each centre be combined and, 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) where possible.
    f. Ensuring operators names and GMC and Name are always submitted.
    g. Careful and consistent descriptions of ventricular function.

h. Careful and detailed recording of all manufacturers details and serial numbers of implanted devices.
i. Ensuring that relevant case and procedural records and logs are extracted and printed from electronic sources in advance to be easily accessible by the Auditors on the day of the external visit.
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 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.
l. Timely reverse validation together with the Clinical Lead(s) for Congenital Cardiology and the responsible clinicians.
m. Reviewing/Updating the SOP at timely intervals.

4. It is recommended that all staff connected with NCHDA audit should observe at least one other site validation per year. It is recommended that a formal follow up 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 merged NHS Trusts.
5. It is also recommended that the combined organisation continue to advise NICOR on the potential impacts that EPIC may have initially on data submission and in particular the changing of the patient hospital record (CRN) number.