The National Congenital Heart Disease Audit Database

Data Quality Audit

for

Apr 2019 - Mar 2020

Royal Brompton & Harefield NHS Foundation Trust

28 and 29 September 2020

performed by Lin Denne, and Dr A Magee

Summary

Prior to this validation visit, the data return to NCHDA from Royal Brompton & Harefield NHS Foundation Trust (RBH) for the data collection year 2019/20 indicated that some 1194 procedures (354 surgery, 814 catheterisations, 25 others, 15 deaths) had been undertaken in children and adults with congenital heart disease. These procedures take place at both Royal Brompton and Harefield Hospitals.

This validation visit was fully funded by the Royal Brompton & Harefield NHS Foundation Trust.

The visit was undertaken by Dr A Magee, Consultant Congenital Cardiologist from Southampton who was physically present and the NCHDA Clinical Data Auditor who was present on MS Teams.

We also note that many extra hours have been invested by the Data Manager to enable timely data submission. This is also the first time that is has been possible to complete the whole validation in one day since 2006. 2006 was the year that NCHDA began to automatically include all ACHD procedures and the dataset went from 28 items to over 40. The dataset now has in the region of 60 data fields.

The Reviewers recognise that the Trust is well advanced in its move towards full electronic records and fully support and encourage this process, noting that systems must continue to be in place to ensure complete and accurate identification of patients for submission to NCHDA. RBH 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, it is reported that most data were input to the Dendrite information system by consultant and junior 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. There is one single dedicated 1.0WTE Senior Clinical Outcomes Analyst and 1.0WTE assistant data analyst.

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.

The Royal Brompton and Harefield NHS Foundation Trust; following a NHSE review are now in the process of developing a working partnership with Guys and St Thomas's NHS Foundation Trust to provide Level 1 services for patients with congenital heart disease on a single site in the next five to seven years (2024/5).

Feedback on Actions Implemented following the last NCHDA Validation Visits in 2019

1. No specific actions reported
2. There is now a 1.0WTE individual tasked to assist with the NCHDA data collection
3. Due to the pandemic status much of the physical work of ensuring timely and accurate data collection now occurs remotely.

Data Quality Indicator

The DQI for the Trust is calculated to be **95.75%** (87.5, 99, 99.25,,at previous visits). The Domain scores for this visit are; (with previous years in parentheses) Demographics 1.0 (.99, 1.0, 1.0,), Pre Procedure .95 (.90, .99 .99), Procedure .95 (.83, .98, .98) and Outcome .93 (78, .99, .99). This represents a 8.25% increase in DQI. An excellent improvement. Well done.

As well as the overall DQI for each centre, the DQI for surgery and catheters is being calculated. On review of the DQI when the cases were split into their surgery and catheter groups the scores are:

Year of visit	Data year being validated	Surgery	Therapeutic Catheter Interventions
2012	10/11	97.75%	98%
2013(i)	11/12	99.75%	98.25%
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%

The body of this report is drawn from answers given on the NICOR pre-visit Questionnaire (PVQ).

Introduction

Prior to this validation visit, the data return to NCHDA from Royal Brompton & Harefield NHS Foundation Trust for the data collection year 2019/20 indicated that some 1194 procedures (354 surgery, 814 catheterisations, 25 others, 15 deaths) had been undertaken in children and adults with congenital heart disease. had been undertaken in children and adults with congenital heart disease, of which 20 cases were randomly selected for the case note review.

The NICOR Data Auditor and one external Consultant in congenital heart disease undertook the site audit.

20 sets of notes were requested (the Sample). A list of 10 records (the Reserves) was also supplied in case any of the Sample were unavailable. On the day of the validation no Reserve case notes were required. The accuracy of the NCHDA data return was then checked against each set of digital notes in order to calculate the Data Quality Indicator (DQI).

Review of notes

Of the 20 patient's case notes that were reviewed, these 20 patients had undergone 24 procedures (11 operations and 13 therapeutic catheters). As previously, each of the individual files of digital notes were meticulously prepared for the visit.

1. It was apparent that there had been small programming problem in Dendrite with the field for ethnicity. This was not allowed to impinge on the DQI score.
2. Product names and serial numbers of implanted devices were challenging to find in several records.
3. Some names of operators appear to be absent and only GMC numbers present
4. 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.
5. There appears to be a large number of varying adjectives used to describe ventricular function seen in the Sample notes.

There were 37 discrepancies raised in 870 data variables.

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

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.

The electronic theatre records, cath lab system records and records for implantable devices and electrophysiology were validated against the data submitted to NCHDA. This local record is derived from ICIP in the OR and RIS from the cath labs. It is reported that these electronic records are considered to a gold standard in terms of recording activity in each clinical area.

- There were 0 queries raised from the surgery or catheter records submitted to NCHDA
- 0 surgery or catheter records were identified in the activity log that may be suitable for this Registry
- As previously reported, when reviewing the pacing activity records it was sometimes quite difficult to know whether or not a patient having a procedure had congenital heart disease or not. .

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 both hospital sites.

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 notified to them from the hospital under in the year under review. The diagnosis and procedure coding will also be validated. 15 post procedural deaths were submitted in the data from NHB for the year 2019/20. 10 deaths occurred within 30 days of a therapeutic procedure and these were prioritised for the Review.

- All dates of death were correct.
- 1 record appears to have a previous procedure absent
- 3 records appear to have incomplete comorbidities recorded.

The Pre Visit Questionnaire from 2019 was reused was completed confirms that there remain appropriate measures in place in respect of;

Security and Confidentiality (Data Management)
Coverage (Data Management)
Quality Assurance of Data (internally and externally)
Training for Data collection, handling and Information Governance
Communications
Accountability
Health Records Management
Timeliness
Completeness and Validity
Accuracy

Case Note Audit:

Patient’s notes were audited covering 13 catheter interventions and 11 operations.

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		9	11
2	NHS Number	20	20		9	11
3	Surname	20	20		9	11
4	First Name	20	20		9	11
5	Sex	20	20		9	11
6	DOB	20	20		9	11
7	Ethnicity	20	20	3 absent	9	11
8	Patient Status	20	20		9	11
9	Postcode	20	20		9	11
10	Pre Procedure Diagnosis	24	24		13	11
11	Previous Procedures	38	44	6 absent	14/18	24/26
12	Patients Weight at Operation	24	24		13	11
13	Height	24	24		13	11
14	Ante Natal Diagnosis	-	-		-	-
15	Pre Proc Seizures	24	24		13	11
16	Pre Proc NYHA	6	9	3 incorrect	5	¼
17	Pre Proc Smoker	9	9		5	4
18	Pre Proc Diabetes	9	9		5	4
19	Hx Pulmonary Dis	9	9		5	4
20	Pre Proc IHD	9	9		5	4
21	Comorbidity Present	24	24		13	11
22	Comorbid Conditions	15	21	1 incorrect, 5 absent	10/15	5/6
23	Pre Proc Systemic Ventricular EF	24	24		13	11
24	Pre Proc Sub Pul Ventricular EF	24	24		13	11
25	Pre-proc valve/septal defect/ vessel size	2	2		2	-
26	Consultant	24	24		13	11

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	24	24		13	11
28	Proc Urgency	24	24		13	11
29	Unplanned Proc	2	3	1 incorrect	2	0/1
30	Single Operator	3	3		3	-
31	Operator 1	24	24		13	11
32	Operator 1 Grade	24	24		13	11
33	Operator 2	20	21	1 incorrect	10	10/11
34	Operator 2 Grade	20	21	1 incorrect	10	10/11
35	Procedure Type	23	24	1 incorrect	13	10/11
36	Sternotomy Sequence	9	10	1 incorrect	-	10/11
37	Operation Performed	24	24		13	11
38	Sizing balloon used for septal defect	1	1		1	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	10	12	2 incorrect	6	4/6
41	Device Model	10	12	2 incorrect	6	4/6
42	Device Ser No	10	12	2 incorrect	6	4/6
43	Device Size	8	8		5	3
44	Total Bypass Time	11	11		-	11
45	XClamp Time,	11	11		-	11
46	Total Arrest	0	0		-	0
47	Cath Proc Time,	9	13	4 unable to validate	9/13	-
48	Cath Fluro Time,	13	13		13	-
49	Cath Fluro Dose,	13	13		13	-

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	2	8	6 incorrect	-	2/8
51	Post Procedure Seizures	24	24		13	11
52	Post Proc Complications	6	7	1 absent	1	4/5
53	Date of Discharge	24	24		13	11
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	24	24		13	11
57	Discharge Destination	24	24		13	11

Data Quality Indicator Assessment:

The Overall Trust DQI =95.75%   Cardiology DQI =98%   Surgery DQI = 93%

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**		
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	**Overall 1.0**	**Card** 1.0	**Surg** 1.0
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 .95**	**Card** .94	**Surg** .95
Procedure 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** .95	**Card** .98	**Surg** .92
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .93	**Card** 1.0	**Surg** .85

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	2020 19/20	2019 18/19	2018 17/18	2017 16/17
Demographics	1.0	.98	1.0	1.0
Pre Procedure	.95	.90	.99	.99
Procedure	.95	.83	.98	.98
Outcome	.93	.78	.99	.99

Conclusions

The Validation Team would like to commend the Quality and Safety Team 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 like to thank the Lead Clinician Dr Franklin and the Deputy Divisional Manager (Cardiac) at RBH for making the time to meet them and assist with the validation task.

It is recognised again that a large number of extra hours had been invested by the DM to try to ensure that the data that were submitted were as complete as possible prior to submission to NCHDA and met the prescribed deadline. The Validation Team acknowledge also that there have been particular difficulties with clinician engagement in some areas particularly with timely data collection and data quality checking at the point of service but this has greatly improved since 2019. The increase in the data quality indicator (DQI) score is indicative of this.

On the whole the NCHDA data that were seen, 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 and data submission 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. 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 as well marked up as the RBH team do as some 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 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.

High standards of data quality may be compromised without at least 2.0 WTE data managers to support not only the NCHDA, but also the various related NHSE monthly and quarterly activity analyses and 'dashboard' requests.

The Validation Team (as in 2016-19) 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. As this Trust moves further forward with it merger with St Thomas' and Guys NHS Foundation Trust (GSTT) this standard may need to be reconsidered at NHB.

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 Childrens Cardiac Services in Bristol (June 2016 Grey, Kennedy 1.22(2) and Ch17).

Validation of Deceased Patients Diagnostic and Procedure Coding
As reported above, the data were of good quality and clearly recorded.

Recommendations (as in 2018)

1. To continue to strive 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. It is acknowledged at as NBH merges further with GSTT these standards may not reflect the level of service provided at this site in the future.

2. It is recommended that the Standard Operating Protocols for this data collection are regularly reviewed and include detailed guidance on and **exactly who** is responsible (and in what timeframe) for;
    i. Input of the data for each procedure and at which point of the service delivery
    ii. 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.
    iii. Careful and consistent descriptions of ventricular function
    iv. Careful and detailed recording of all manufacturers details and serial numbers of implanted devices
    v. Leading the local review (and how frequently and in which forum for both disciplines)
    vi. Making timely submissions (monthly is recommended) where possible and
    vii. Timely reverse validation with all relevant clinical teams with their full involvement.
    viii. Monthly to quarterly PRAiS analysis as required
    ix. 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 visit.
    x. Checking for any out of hospital deaths that may have occurred in the congenital cohort.

3. It is recommended that DM run regular (ie quarterly queries of all NCHDA patients against the NSTS (NHS Spine) to confirm life status of NHB patients. This is only possible for patients with an English postal address. Liaison with equivalent DMs in NI, ROI and Scotland should be encouraged for this purpose.
4. It is recommended that all staff involved with managing and collecting NCHDA data undertake an annual visit to another congenital centre to observe the validation processes and practices and share experiences with colleagues.