The National Congenital Heart Disease Audit Database

Data Quality Audit

for

Apr 2018 - Mar 2019

Royal Brompton & Harefield NHS Foundation Trust

21 and 22 May 2019

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Summary

Prior to this validation visit, the data return to NCHDA from Royal Brompton & Harefield NHS Foundation Trust (RBH) for the data collection year 2018/19 indicated that some 1222 procedures (634 surgery, 384 catheterisations, 204 others, 5 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.

As reported 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. The current role holder has been in post for 8 months prior to this visit. It is reported that there were found to be some difficulties with the physical process of data collection and local validation at both sites that delayed the data submission.

It is also reported that during this time there had been a number of delays from NICOR in arranging the appropriate database access for the recently appointed Senior Information Analyst or Data Manager (DM).

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 at this visit in May 2019.

The Quality and Safety Team at the Trust had printed off the relevant documents from the ePR that held the data that was to be audited and highlighted many of these data items. Therefore, it was easy to find the majority of data required. Access to the ePR was also provided in case the Reviewers wished to scrutinise any other documents.

Consent for External Validation of Notes.

As previously reported, since February 2011, this centre has started to use a modified version of their generic patient registration form to include a clause to accommodate consent for external case note validation.

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. As such, NCHDA now no longer require individual patient informed consent.

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 2018

- A full time Senior Clinical Outcomes Analyst (DM) was appointed, starting in September 2018. This was an internal promotion from within the Quality and Safety team but from a different division.
- A full time Clinical Outcomes Officer/MDT coordinator was appointed, starting mid-December 2018. This was an external appointment
- Due to the technical difficulties and constraints mentioned above, these data were not submitted until mid March 2019.

Data Quality Indicator

The DQI for the Trust is calculated to be **87.5%** (99, 99.25, 99.25,at previous visits). The Domain scores for this visit are; (with previous years in parentheses) Demographics .99 (1.0, 1.0, 1.0), Pre Procedure .90 (.99 .99 .99), Procedure .83 (.98, .98, 99) and Outcome .78 (.99, .99, .99). This represents a 11.5% drop in DQI.

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
2009	07/08	98.25%	97%
2010	08/09	98%	96%
2011	09/10	97.25%	99.5%
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	92.5%	80%

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 2018/19 indicated that some 1222 procedures (634 surgery, 384 catheterisations, 204 others, 5 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 ST6 Trainee 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 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 33 procedures (17 operations and 16 therapeutic catheters). As previously, the notes were bundles of very tidy print outs from the ePR, and meticulously prepared for the visit.

1. The NHS Number was present in all notes and is included on the patients' identity label.
2. Perfusion records were seen in all the case notes of bypass patients
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.

The fields with the most discrepancies were as follows;

- Implantable device details 20 absent
- Duration of Post Op Intubation 16 discrepancies

- Catheter Xray dose and time 18 discrepancies
- Single Operator Procedures 12 discrepancies
- Catheter Procedure Skin to Skin Time 11 discrepancies
- Previous Procedures 10 discrepancies
- Post Procedure Seizure Status 8 absent

There were 148 discrepancies raised in 1144 data variables.

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

The electronic theatre records, cath lab system records and records for implantable devices and electrophysiology were validated against the data submitted to congenital NICOR. As reported previously, it was not completely clear exactly where the records provided were sourced from or how complete they may be. It was also noted that the Data Manager (DM) at NHB has difficulty with accessing the Harefield Hospital data to ensure complete activity ascertainment.

- There were 7 queries raised from the surgery records submitted to NCHDA
- 5 surgery records were identified in the activity log that may be suitable for this Registry
- There were 175 queries raised from the cath lab records submitted to NCHDA
- 1 catheter record was identified that should be removed
- 32 records were identified that may be suitable for this Registry
- The description of procedures were sometimes rather vague and it was difficult to ascertain exactly what procedure had been performed.

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.

On the day as stated above, it was not clear exactly where the electronic activity data offered for this part of the review originated. Therefore it is possible that there is incomplete case ascertainment.

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. 14 post procedural deaths were submitted in the data from NHB for the year 2018/19. 3 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
- 1 record appears to have incomplete comorbidities recorded.

The Pre Visit Questionnaire was completed and returned prior to the validation visit and confirms that there are 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 18 catheter interventions and 5 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	17	20	3 absent	6/9	11
8	Patient Status	20	20		9	11
9	Postcode	20	20		9	11
10	Pre Procedure Diagnosis	31	33	1 incorrect, 1 absent	15/16	16/17
11	Previous Procedures	36	46	10 absent	14/24	22/23
12	Patients Weight at Operation	31	33	2 incorrect	15/16	16/17
13	Height	29	31	1 incorrect, 1 absent	15/16	14/15
14	Ante Natal Diagnosis	3	3		1	2
15	Pre Proc Seizures	31	33	2 absent	14/16	17
16	Pre Proc NYHA	1	3	1 absent, 1 unable to validate	0/1	½
17	Pre Proc Smoker	0/1	3	1 absent, 1 unable to validate	0/1	2
18	Pre Proc Diabetes	0/1	3	1 absent, 1 unable to validate	0/1	2
19	Hx Pulmonary Dis	0/1	3	1 absent, 1 unable to validate	0/1	2
20	Pre Proc IHD	0/1	3	1 absent, 1 unable to validate	0/1	2
21	Comorbidity Present	31	33	2 absent	14/16	17
22	Comorbid Conditions	17	17		10	7
23	Pre Proc Systemic Ventricular EF	31	33	2 absent	14/16	17
24	Pre Proc Sub Pul Ventricular EF	24	27	2 absent, 1 incorrect	12/13	12/14
25	Pre-proc valve/septal defect/ vessel size	0	0		0	0
26	Consultant	32	33	1 absent	15/16	17

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	33	33		16	17
28	Proc Urgency	30	33	3 incorrect	15/16	15/17
29	Unplanned Proc	29	33	1 incorrect, 3 absent	13/16	16/17
30	Single Operator	21	33	8 incorrect, 4 absent	11/16	16/17
31	Operator 1	32	33	1 absent	15/16	10/17
32	Operator 1 Grade	32	33	1 absent	15/16	17
33	Operator 2	27	29	2 absent	12/14	17
34	Operator 2 Grade	27	29	2 absent	12/14	17
35	Procedure Type	33	33		16	17
36	Sternotomy Sequence	12	12		-	12
37	Operation Performed	33	33	1 incomplete	16	17
38	Sizing balloon used for septal defect	10	10		10	-
39	No of stents or coils	2	2		2	-
40	Device Manufacturer	6	10	4 absent	6/9	0/1
41	Device Model	6	10	4 absent	6/9	0/1
42	Device Ser No	2	10	7 absent, 1 unable to validate	1/9	0/1
43	Device Size	3	7	4 absent	3/6	0/1
44	Total Bypass Time	12	12		-	12
45	XClamp Time,	12	12		-	12
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	5	16	4 incorrect, 7 unable to validate	5/16	-
48	Cath Fluro Time,	8	16	2 absent, 6 unable to validate	8/16	-
49	Cath Fluro Dose,	6	16	2 absent, 8 unable to validate	6/16	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	1	17	16 absent	-	1/17
51	Post Procedure Seizures	25	33	8 absent	8/16	17
52	Post Proc Complications	11	17	5 absent, 2 unable to validate	0/7	11
53	Date of Discharge	30	33	3 absent	13/16	17
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	30	33	3 absent	13/16	17
57	Discharge Destination	30	33	3 absent	13/16	17

Data Quality Indicator Assessment:

The Overall Trust DQI =87.5% Cardiology DQI =80% Surgery DQI = 92.75%

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 .98**	
	Card .96	**Surg** .99
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 .90**	
	Card .98	**Surg** .96
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** .83	
	Card .755	**Surg** .93
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .78	
	Card .66	**Surg** .83

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	**2019 May 18/19**	**2018 June 17/18**	**2017 May 16/17**	**2016 Oct 15/16**
Demographics	.98	1.0	1.0	1.0
Pre Procedure	.90	.99	.99	.99
Procedure	.83	.98	.98	.99
Outcome	.78	.99	.99	.99

Conclusions

The Validation Team would like to commend the Quality and Safety Team not only for the attention to detail in the preparation of the case notes, which greatly enhanced this part of the Review, but in particular the DM for attempting almost singlehandedly, to manage the data collection, quality management and then submission of these data for one of the largest Congenital Cardiac Centres in the UK when being completely new to this specialty.

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.

There were considerable technical challenges during the data collection year of 2018/19. The newly appointed Senior Clinical Outcomes Analyst (DM) did not get access to the NCHDA database until some 6 months into the data collection year. It is also recognised 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. 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. The drop in the data quality indicator (DQI) score may be indicative of this.

This is further compounded as the DM does not appear to have easy or regular access to procedural and activity data from Harefield Hospital. It is possible that there are still outstanding NCHDA procedures from this site.

On the whole the NCHDA data that were seen, were very well documented, high quality and were appropriately recorded in the electronic printouts 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 2018) 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 Childrens Cardiac Services in Bristol (June 2016 Grey, Kennedy 1.22(2) and Ch17).

Validation of Deceased Patients Diagnostic and Procedure Coding

Just 2 queries was raised with these data and all of the dates of death were found to be correct.

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.

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. Input of fetal data and at which point of service delivery when this data collection goes 'live'
   iii. 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.
   iv. Careful and consistent descriptions of ventricular function
   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 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.

4. It is recommended that the DM be given priority access to activity log books in the Harefield catheter laboratory and operating rooms with immediate effect.