The National Congenital Heart Disease Audit Database

Data Quality Audit for CONGENITAL HEART DISEASE

Apr 2018 - Mar 2019

Childrens Health Ireland (CHI), Crumlin, Dublin
(formerly known as Our Ladies' Children's Hospital)

19 June 2019

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Summary

This congenital validation visit by NCHDA is funded by the Republic of Ireland, Health Service Executive. The year reviewed is April to March 2018 - 2019. This is the eighth visit to Our Lady's Children's Hospital Crumlin. (OLCHC) All congenital cardiac centres in the UK participate in annual reviews of therapeutic procedures undertaken and further information on all of those centres can be found at the national audit website https://nicor5.nicor.org.uk/

This validation visit has been fully funded by the Health Department of the Republic of Ireland.

Prior to the review of the hospital log books, the data return to NCHDA from the cardiac department of the Our Ladies' Children's Hospital (OLCHC) indicates that some 1047 procedures have been undertaken during the data collection year of April 2018 to March 2019 in patients with congenital heart disease aged up to 16 years.

As previously reported an access database of congenital procedures is maintained by the Cardiac Services Data Manager (DBM). Since February 2017 a further DBM post was recruited and there are now 2 DBMS providing 1.75WTEs to cover this congenital registry at OLCHC. The DBMs submitted the data directly from the Access database to the live NCHDA Congenital Database via a CSV file. An additional 1.0WTE DBM was recruited in July 2019 making a total of 2.75WTE During the summer of 2019 a new cardiac services database was commissioned, Health Insights. Submissions for April 2019 onwards will be made from this database via .csv file.

As previously reported there is real time data entry to a number of different data bases by clinical staff with access in the operating theatre and the catheter lab as well as the ward areas in the Children's Hospital. There is just one computer in the operating theatre and one in the cath lab to serve all the various databases.

There is no formal audit programme for congenital procedures and the case notes are used to check the data in the majority of the cases. Following local validity checking of the data will be submitted electronically to NCHDA on an ongoing basis when the NCHDA Qreg5 database is able to accept submissions.

Actions Implemented since the last Validation Visit in 2018:

1. The consent for external validation of case notes is now part of a new hospital consent for operation form signed by parents and guardians.
2. One of the DBMs and the Business Manager for Paediatric Cardiac Services at OLS attended the NCHDA Contributors meeting in London in March 2019

Patient Consent for External Validation of Case Notes

Since May 2018, the EU General Data Protection Regulation required that patients are made aware of how their data collected and used. As such, NCHDA now no longer requires a specific consent to examine hospital case notes. If a patient has expressed a wish not to allow their case notes to be examined but others not connected to their care, these wishes will be respected.

As previously reported, restrictions imposed by the ROI Information Commissioner did not allow any patient identifiers to be submitted to NCHDA other than date of birth (DOB) and gender. There had been an established method of pseudo identifiers created to enable data submission. However whilst that allowed for specific procedures to be analysed by NCHDA and published on the NCHDA Public Portal it considerably hindered the physical process of external validation as each pseudo id has to be cross checked twice to ensure the correct patient and procedure had been identified. Theoretically it could be possible to confuse two records that have the same DOB and gender that have similar or the same procedures performed on the same day.

In March 2015 it was agreed that an appropriately worded clause would be included in the generic consent for operation form used at this Centre. This became standard practice from April 2016 and become further embedded during 2017-18. OLHSC has chosen to continue with this.

Also as previously reported in 2012-16, in ROI there was no individual life time identifier issued to every individual similar to the NHS, CHI or HNC Number that is used in other UK countries. Therefore there was no independent source of death date for NCHDA to effectively track 1 year mortality in these patients. However since 2016, a unique identifier similar to the UK NHS Number is being gradually introduced throughout ROI.

NICOR also acknowledge that there have been long and protracted difficulties with data submission to the web facing NCHDA database at NICOR. This has affected all centres.

Professor Dr F Bu'Lock from Leicester undertook the validation visit on site and the NCHDA Clinical Data Auditor remotely accessing and supporting the review via Skype and Zoom.

Data Quality Indicator Scores (DQI)

The overall DQI score is (with previous years in parentheses); **99%** (98.25, 97, 94.5), with domain scores Demographics .99 (.99, 1.0, 1.0), Pre Procedure .98 (.98, .92 .85,), Procedure .99 (.97, .97, .96), and Outcome .985 (.99, .99, .97). This is another excellent score. Well done!

This is based on 20 patients who had 33 procedures (22 catheters, 11 operations). There were 14 errors or omissions in 1106 variables.

Separate DQI for Catheters and Surgery

Since the 2009 cycle of visits commenced, as well as the overall DQI for each centre, the DQI for surgery and catheters is being calculated. It is recommended that a minimum number of 5 procedures in either group are required for the differential DQI calculation.

Year of Visit	Data Years reviewed	Surgery DQI	Catheters DQI
2012	2011-12	92.5%	92.75%
2013	2012-13	98%	96%
2014	2013-14	96.25%	96.5%
2015	2014-15	97.25%	96%
2016	2015-16	94.25%	95%
2017	2016-17	96.75%	97.5%
2018	2017-18	99%	98%
2019	2018-19	99.75%	98.25%

Staff and Colleagues have completed the NCHDA pre visit questionnaire and 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

Introduction

Prior to the log book review by the NCHDA audit team, the data returned to NCHDA and used to provide the records for this validation visit, indicated that the cardiac department of the Our Ladies' Hospital for Children had undertaken 1047 procedures (8 deaths within 30 days of procedure) in the data collection year 2018/2019 of which 20 cases were randomly selected for review.

20 sets of notes were requested (the Sample) and a reserve list of 10 further records (the Reserves) were also supplied in case any of the first 20 were irretrievable. On the day, 6 sets of case notes from the Reserves were required. The accuracy of the NCHDA data return was then checked against each set of notes and then recorded on a database to enable the Data Quality Indicator (DQI) to be scored.

Review of notes

The Reviewers are extremely grateful to the DBMs who had clearly spent some considerable time marking many of the relevant documents in each case note that needed to be seen. This greatly aided the speed of the validation process.

The notes were mostly tidy and in chronological order.

1. As previously reported, some of the case notes seen were bulky, of several volumes and sometimes not in chronological order.
2. Ventricular function documentation was occasionally difficult to find in the hospital notes of surgical patients.
3. In the case notes seen, there are care pathway documents for catheter admissions and this greatly aided the review. These notes generally appeared to be well organised and the data easy to retrieve and validate. However, as previously reported in 2012-18, the actual catheter procedure report does not always include fluroscopy data, the sheath in to catheters out times or the names of both of the operators
4. There did not appear to be a consistent method used to record the labels with the details of implanted devices across all types of procedures.
5. The typed operation notes were easy to find and the green edged anaesthetic sheets were fairly easy to locate.
6. The perfusion record was present in all sets of surgical notes seen.

It is helpful for local colleagues both to understand the process of the case note review in general and also to appreciate the accessibility in reverse of their own data systems. For regular interventional caths it was quite easy to find the product codes for implants as they are on the cath form but that for hybrid procedures this was extremely difficult. So particularly for the people doing procedures and entering the data its quite informative

for them to be present for some part of this external review. It also very much helps the Reviewers to have some local colleagues around when looking through the notes even when they have been well marked up by the DBMs.

It can take about half an hour to work out what is actually happening from a complex hospital case note sometimes and to have a local clinician to contribute can be very useful and speed up the process. Its probably more helpful for a smaller number of people to be involved each visit and to ensure that over a period of time everyone has an opportunity to participate in this part of the review.

Review of the Cath Lab log books

There is 1 cath lab at OLCHC. 2 log books were made available to reviewers, the radiographers log and the nurses log.

The nurses log book showed that patient identity labels were used mostly to indicate each patients case.

As previously reported septostomies are often performed in other areas outside the cath lab ie NICU and there is not a log of these cases. However some septostomies have been included in the submission to NCHDA but it is not clear if it is all of these procedures.

1. As previously stated, TOE, Provocation Testing and DC conversion procedures are not required to be submitted to NCHDA at this time
2. 0 catheter procedures were identified that may have been missed from the data submission
3. 5 records were identified that may have errors in their coding

Theatre Log Books

An electronic theatre management system (TMS Sapphire) is kept at OLCHC and print out of this was provided for the review. There is 1 dedicated congenital cardiac operating theatre at OLCHC.

1. 3 submitted records were identified that may have errors in them
2. Delayed closure of sternum is not required to be submitted to NCHDA at this time
3. Pectus Repairs should be submitted in the category Thoracic
4. 4 records were identified that may have been missed from the submission. 3 of which has been identified by the DBMs immediately prior to the validation visit

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 included in the year under review. The diagnosis and procedure coding will also be validated. The requirement for patient/parent/guardian consent to review the case notes is the same as for the congenital procedures review. In cases where it is unclear if this consent has been obtained during life, the Medical Director or CEO is asked for permission to undertake this review. The Validation Team are grateful to the CEO of OLHSC for giving this permission.

Review of Deceased Patients Case notes

12 deceased patients were identified in the data return for 2018-19. 8 of these patients had died within 30 days of a therapeutic catheter intervention or surgical operations. The PRAiS sensitive fields were reviewed for each record and the findings were:

- 1 records appears to have incomplete comorbidities listed
- 1 record has an incorrect diagnosis coded
- 2 records appear to have incomplete diagnoses strings
- 2 records appear to have previous procedures missing
- 2 records appear to have incorrect pre operative weights entered
- 2 records may have incomplete procedure performed coding
- 2 records may have incomplete complications listed
- Mode of discharge appears to be incorrect in 1 record
- The Attribution of Death field appears to be incorrect or absent in 5

Case Note Audit

20 patients underwent 33 procedures. 11 operations and 22 therapeutic catheter procedures

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		11	9
2	NHS Number	-	-		-	
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	20	20		11	9
8	Patient Status	19	20	1 absent	10/11	9
9	Postcode	20	20		11	9
10	Pre Procedure Diagnosis	33	33		22	11
11	Previous Procedures	61	61		40	21
12	Patients Weight at Operation	33	33		22	11
13	Height	33	33		22	11
14	Ante Natal Diagnosis	5	5		3	2
15	Pre Proc Seizures	33	33		22	11
16	Pre Proc NYHA	-	-		-	-
17	Pre Proc Smoker	-	-		-	-
18	Pre Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre Proc IHD	-	-		-	-
21	Comorbidity Present	11	11		2	7
22	Comorbid Conditions	16	16		7	9
23	Pre Proc Systemic Ventricular EF	25	25		15/16	9
24	Pre Proc Sub Pul Ventricular EF	33	33		19/22	10/11
25	Pre-proc valve/septal defect/ vessel size	3	3		3	-
26	Consultant	33	33		22	11

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	33	33		22	11
28	Proc Urgency	33	33		22	11
29	Unplanned Proc	32	33	1 incorrect	21/22	11
30	Single Operator	1	1		1	-
31	Operator 1	33	33		22	11
32	Operator 1 Grade	33	33		22	11
33	Operator 2	31	32	1 incorrect	20/21	11
34	Operator 2 Grade	31	32	1 incorrect	20/21	11
35	Procedure Type	33	33		22	11
36	Sternotomy Sequence	11	11		-	11
37	Operation Performed	33	33		22	11
38	Sizing balloon used for septal defect	1	1		1	-
39	No of stents or coils	8	8		7	1
40	Device Manufacturer	24	24		20	4
41	Device Model	23	23		20	3
42	Device Ser No	30	30		26	4
43	Device Size	20	21	1 absent	19/20	1
44	Total Bypass Time	9	9		-	9
45	XClamp Time,	7	7		-	7
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	21	22	1 unable to validate	21/22	-
48	Cath Fluro Time,	21	21		21	-
49	Cath Fluro Dose,	21	21		21	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	10	10		-	10
51	Post Procedure Seizures	33	33		22	11
52	Post Proc Complications	3	3		-	3
53	Date of Discharge	32	33	1 incorrect	21/22	11
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	33	33		22	11
57	Discharge Destination	32	32		21/22	11

Casenote Audit
Data Quality Indicator Assessment:

The Overall Trust DQI = 99% Cardiology DQI = 98.25% Surgery DQI = 99.75%

DOMAIN	DOMAIN Score	
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	**Overall .99**	
	Card .99	**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 .98**	
	Card .98	**Surg** .99
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** .99	
	Card .98	**Surg** 1.0
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .985	
	Card .98	**Surg** 1.0

This DQI is based upon the domain scoring below. The methodology for this DQI is provided in the paper The NCHDA Audit – An Introduction to the Process.

DOMAIN	2019 18-19	2018 17-18	2017 16-17	2016 15-16
Demographics	.99	.99	1.0	1.0
Pre Procedure	.98	.98	.92	.85
Procedure	.99	.97	.97	.96
Outcome	.985	.99	.99	.97

Conclusions

As previously reported, on the whole the Theatre log books/printouts appear to be of a good standard, accurate and precise. The is an excellent DQI and represents a very good validation result. The NCHDA Review Team would like to commend the DBMs for exceptional and conscientious efforts to ensure all the appropriate data were submitted. It is clear that many extra hours have been invested by the DBMs to maintain a demonstrably high DQI.

There were 1106 variables reviewed and 14 discrepancies identified.

The Reviewers are very pleased to report that there is a process to obtain prospective consent for external validation of case implemented. However in light of the GDPR regulation this may now not be needed.

As mentioned elsewhere, it is helpful for local colleagues both to understand the process of the case note review in general and also to appreciate the accessibility in reverse of their own data systems. For regular interventional caths it was quite easy to find the product codes for implants as they are on the cath form but that for hybrid procedures this was extremely difficult. So particularly for the people doing procedures and entering the data its quite informative for them to be present for some part of this external review. It also very much helps the Reviewers to have some local colleagues around when looking through the notes even when they have been well marked up by the DBMs.

It can take about half an hour to work out what is actually happening from a complex hospital case note sometimes and to have a local clinician to contribute can be very useful and speed up the process. Its probably more helpful for a smaller number of people to be involved each visit and to ensure that over a period of time everyone has an opportunity to participate in this part of the review.

A more formal process of data collection and review is slowly developing with steps set out to maintain a robust audit cycle. However it appears, as previously reported that some areas are still more proactive than others in supporting timely data review prior to submission to NCHDA.

It is recognised that there is now an individual identifier issued at birth in ROI and a developing national independent system of mortality tracking available in the ROI. It is reported to the NCHDA Validation Team that the DBMs continue to submit life status reports directly on to Lotus Notes and NCHDA Web for patients who have died following surgical or interventional catheter procedures.

Deceased Case Notes Review

As reported elsewhere there were a small number of errors identified.

Recommendations

1. It is recommended that in liaison with the Lead Clinicians for cardiology and cardiac surgery, the congenital Database Managers should continue to regularly review the standard operating procedures (SOPs) to for this registry. Each SOP should clearly set out exactly **who** is responsible for and in what time frame the following should occur;

    a. Ensuring information is given to each patient and consent for external validation of hospital notes is obtained from the patient/parent/guardian at first hospital attendance. That this consent is in line with the GDPR, and all patients/parents and guardians are given full information of how their data are securely recorded, stored, where this information is shared and who with. And op out explained to patients/carers.
    b. Input of the data for each episode and at which point of the treatment delivery particularly data that cannot be entered at the time of procedure such as intubation time and complications.
    c. 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. It is recommended that this is done as soon after each patient treatment episode and again as soon after discharge from hospital as possible. Each clinician should be encouraged to 'own' their data
    d. Leading the local review (and how frequently and in which forum),
    e. Running the monthly PRAiS analysis
    f. Making timely submissions where possible (monthly is recommended, quarterly is mandatory) and
    g. Timely reverse validation at OLHSC with involvement from the responsible clinicians.
    h. Updating life status as any dates of death become known

2. As previously, ensure that the primary diagnosis reconciles with the primary procedure performed and that this is consistently applied across each of the patients procedures
3. As part of the DBMs ongoing training and development, it is suggested that visits to other centres to view their procedures and practices is a valued and important exercise in maintaining good standards.
4. It is recommended that consideration by the ROI Health Service Executive for the future funding to facilitate the annual validation process by NCHDA be given for each UK fiscal year.