The National Congenital Heart Disease Audit Database

Data Quality Audit for CONGENITAL HEART DISEASE

For the data period **Apr 2020 - Mar 2021**

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

6 October 2021 *performed by M C Austin and Lin Denne*

Summary

This congenital validation visit by NCHDA is funded by the Republic of Ireland, Health Service Executive. The year reviewed is April to March 2020 - 2021. This is the ninth visit to Children's Health Ireland Crumlin. (OLS) 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 NICOR national audit website https://nicor5.nicor.org.uk/

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

This visit has been substantially delayed as all information systems at OLS were significantly disabled by a malware ransom attack in May 2021. Some databases were still not functioning at the time of this visit. It had not been possible to access local databases or retrieve or submit data to the NCHDA database at NICOR in that time. Much of the data collection from May 2021 onwards was being done in paper form while the technical work to safely access local data systems was being done.

This visit was conducted via the local WebEx application with the external consultant colleague on site and the NCHDA Audit Nurse connecting remotely.

The case notes had been prepared with digital or photocopies of relevant documents in a patient specific folder that the DBMs displayed on a large screen in the room being used and could be shared with the external reviewers via WebEx.

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 (OLS) indicates that some 1093 therapeutic cardiac procedures had been undertaken during the 2020/2021 data collection year (surgery 392, catheters 623, others 76, Deaths 23), in in predominantly paediatric patients with congenital heart disease. This represents a drop in procedural activity of approximately 7% during the ongoing SARS-COV-2 pandemic. 51 of these patients were found to be in 16-20 years age group.

There are 3 DBMS providing 2.75WTEs to cover NCHDA congenital registry at OLS.

During the preparation for this visit the DBMs reported that 3 further records had been identified for this cohort that had been accidentally missed from the submission.

The DBMs regular protocol is, after local validation with responsible clinicians, to submit the data directly from the recently commissioned cardiac services database Health Insights to the live NCHDA Congenital Database (Qreg5) via a CSV file.

As previously reported when all local IT infrastructure is fully functioning, there is real time data entry to a number of different access points 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 these points.

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

Actions Implemented since the last Validation Visit in 2020:

- No new actions reported
- Due to the current pandemic status the DBMs have successfully pivoted from office based to predominately remote working
- Agreement was reached with the Information Governance Lead at OLS to supply patient identifiers for the immediate preparation and duration of the site visit with removal immediately on completion of site visit written Data Quality Indicator feedback. This has considerably enhanced the site visit experience for the both the hosts and the external reviewers in 2021.

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. Although UK is now no longer part of the EU, the spirit, beliefs and values of the GDPR are still firmly upheld within Great Britain and Northern Ireland.

Initially in 2012, the ROI Information Commissioner did not allow any patient identifiers to be submitted to NCHDA other than date of birth (DOB) and gender. A method of pseudo identifiers was 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. In 2019 OLHSC were directed by the local Information Governance manager to no longer submit patient names. No patient identifiers were included in the 2019-2020 data submission on the pseudonymised identities. Therefore, at the 2020 visit the time needed to examine the hospital records and log books was considerably extended to 1.5 days and was a physically and mentally exhausting process for all concerned.

Also as previously reported in 2012-20, in ROI there is as yet no individual lifetime 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.

Mr Conal Austin, Consultant Cardiac Surgeon from London undertook the validation visit on site and the NCHDA Clinical Data Auditor remotely accessing and supporting the review via the WebEx link.

Data Quality Indicator Scores (DQI)

The DQI score for OLS is (with previous years in parentheses); **98.5%** (.99, .99, 98.25), with domain scores Demographics 1.0 (1.0, .99, .99,), Pre Procedure .97 (99, .98, .98,), Procedure .99 (.975, .99, 97, .97), and Outcome .98 (.98, .985, .99). This is another excellent score.

This is based on 20 randomly selected patients who had 24 procedures (10 catheters, 14 operations). There were 12 discrepancies in 779 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%
2020	2019-20	97.75%	99.25%
2021	2020-21	98%	98.5%

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 1093 therapeutic cardiac procedures had been undertaken during the 2020/2021 data collection year (surgery 392, catheters 623, others 76, Deaths 23), in patients with congenital heart disease aged up to 16 years of which 20 cases were randomly selected for review.

On the day, 5 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 creating digital files of each patients' case notes and marking many of the relevant documents in each digital case note that needed to be seen. This greatly aided the validation process.

The notes were almost all in chronological order and excellently presented.

1. It was noted on several occasions that the diagnosis did not always reconcile with the procedure performed.
2. As previously reported in 2012-20, the actual catheter procedure report does not always include xray time and dose data, the sheath in to catheters out times or the names of both of the operators
3. 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.
4. The typed operation notes were easy to find and the green edged anaesthetic sheets, when seen, were easy to locate.
5. The perfusion record was present in all sets of surgical notes seen.

Review of the Cath Lab log books

There is 1 cath lab at OLS. 1 log book was made available to reviewers, 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 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. Reveal device (IRL) implant/explant are no longer required to be submitted to NCHDA
3. 3 catheter procedures were identified by the DBMs prior to the visit were missed from the data submission
4. 2 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. Delayed closure of sternum, ECMO decannulation, sternal wire removal, mediastinal exploration and are not required to be submitted to NCHDA at this time
2. Pectus Repairs should be submitted in the category Thoracic
3. 0 records were identified that may have been missed from the submission.
4. 1 record was identified that does not appear to be suitable for the NCHDA data collection and if so, should be removed.

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. Under GDPR 2018 the requirement for patient/parent/guardian consent to review the case notes is no longer required.

Review of Deceased Patients Case notes

23 deceased patients were identified in the data return for 2020-21. 13 of these patients had died within 30 days of a therapeutic catheter intervention or surgical operation. 2 of these case notes were reviewed at the last visit as they were for March 2020 procedures and had died early in April 2020. The PRAiS sensitive fields were reviewed for each of the remaining 11 records and the findings were:

1. 1 date of death appears to be incorrect
2. 1 record may have an incorrect NI post code
3. 1 record appears to have incomplete comorbidities listed
4. 1 record may have incomplete complications listed
5. Attribution of Death field appears to be incorrect or absent in 3 records

It is noted that it was not always possible to discern from the case notes seen, if patients who had died within 30 days were discussed with the coroner (when required), were discussed at an MDT and whether or not the death was related to the procedure.

Case Note Audit

20 patients underwent 24 procedures. 14 operations and 10 therapeutic catheter procedures

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		9	11
2	NHS Number	-	-		-	-
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		9	11
8	Patient Status	20	20		9	11
9	Postcode	20	20		9	11
10	Pre Procedure Diagnosis	24	24		10	14
11	Previous Procedures	16	17	1 incorrect	½	15
12	Patients Weight at Operation	24	24		10	14
13	Height	23	24	1 unable to validate	9/10	14
14	Ante Natal Diagnosis	3	3		1	2
15	Pre Proc Seizures	24	24		10	14
16	Pre Proc NYHA	-	-		-	-
17	Pre Proc Smoker	-	-		-	-
18	Pre Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre Proc IHD	-	-		-	-
21	Comorbidity Present	24	24		10	14
22	Comorbid Conditions	14	16	1 incorrect, 1 absent	¾	10/11
23	Pre Proc Systemic Ventricular EF	23	24	1 incorrect	10	13
24	Pre Proc Sub Pul Ventricular EF	18	18		8	14
25	Pre-proc valve/septal defect/ vessel size	0	1	1 incorrect	0/1	-
26	Consultant	24	24		10	14

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	24	24		10	14
28	Proc Urgency	22	24	2 incorrect	10	12/14
29	Unplanned Proc	2	2		1	1
30	Single Operator	-	-		-	-
31	Operator 1	24	24		10	14
32	Operator 1 Grade	24	24		10	14
33	Operator 2	24	24		10	14
34	Operator 2 Grade	24	24		10	14
35	Procedure Type	24	24		10	14
36	Sternotomy Sequence	13	13		-	13
37	Operation Performed	24	24		10	14
38	Sizing balloon used for septal defect	3	3		3	-
39	No of stents or coils	9	9		9	-
40	Device Manufacturer	9	9		9	-
41	Device Model	9	9		9	-
42	Device Ser No	9	9		9	-
43	Device Size	8	9	1 incorrect	8/9	-
44	Total Bypass Time	13	13		-	13
45	XClamp Time,	12	12		-	12
46	Total Arrest	0	1	1 incorrect	-	0/1
47	Cath Proc Time,	9	10	1 absent	9/10	-
48	Cath Fluro Time,	10	10		10	-
49	Cath Fluro Dose,	10	10		10	-

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	9	11	2 incorrect	-	9/11
51	Post Procedure Seizures	24	24		10	14
52	Post Proc Complications	4	4		1	3
53	Date of Discharge	24	24		10	14
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	24	24		10	14
57	Discharge Destination	24	24		10	14

Casenote Audit
Data Quality Indicator Assessment:

The Overall Trust DQI = 98.5% Cardiology DQI = 98.5% Surgery DQI = 98%

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 .97**	
	Card .95	**Surg** .985
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 .99	**Surg** .99
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .98	
	Card 1.0	**Surg** .96

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	2021 20-21	2020 19-20	2019 18-19	2018 17-18
Demographics	1.0	1.0	.99	.99
Pre Procedure	.97	.99	.98	.98
Procedure	.99	.975	.99	.97
Outcome	.98	.98	.985	.99

Conclusions

The Reviewers acknowledge that there have been long and protracted difficulties with IT infrastructure at OLS following the malware attack earlier this year in May. We also acknowledge that this year has been challenging due to the ongoing pandemic situation as well.

In spite of the multiple challenges described above, the DBMs had again demonstrated excellent case note preparation and facilitated the day very smoothly and efficiently. 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.

As previously reported, on the whole the Theatre log books/printouts appear to be of a good standard, accurate and precise. The most profound difference was having the patient names for each record and this enabled all parts of review to run in a much more timely and efficient manner.

There were 779 data variables reviewed and 12 discrepancies identified.

Diagnoses coding must, wherever possible reconcile with the procedure performed and this was sometimes observed to be incorrect at this visit.

Recording of procedures performed should be described as accurately as possible in cath lab and theatre log books to ensure correct interpretation when auditing. Over coding of procedures should be avoided as this may lead to procedures not being allocated to the correct grouping during analyses. For example it is not necessary to code individual components of a Fallot Repair. One main code is all that is required whichever is most suitable.

As mentioned elsewhere we note that some local colleagues did pop in to the validation room and 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 digitally collated and marked up by the DBMs.

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 and it is acknowledged that the current pandemic status and the malware attack has considerably slowed the process during this data collection year.

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 QReg5 for patients who have died following surgical or interventional catheter procedures.

Deceased Case Notes Review

As reported elsewhere there were a very small number of errors identified. It was noted however that there did not always appear to be a detailed death or discharge summary for patients who had died in hospital and no Coroners Reports were seen. As stated above, it was not always possible to tell if patients who had died within 30 days were discussed with the coroner (when required), were discussed at an MDT and whether or not the death was related to the procedure

Recommendations

1. To submit patient identifiable data whenever possible and where full consent has been gained as set out below and avoid submitting anonymised data.
2. 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. 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.
    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. 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
    c. Leading the local review (and how frequently and in which forum),
    d. Running the monthly PRAiS analysis
    e. Identifying analytical support to the DBMs to enable running of both Specific Procedures and Activity algorithms to give immediate feedback to clinicians. These algorithms run in R Code Freeware and are downloadable and widely used in the UK NHS community. The scripts to run these algorithms can be supplied by NCHDA.
    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. 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.
    i. Updating life status as any dates of death become known

3. 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
4. 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. During the pandemic this is occurring virtually using MS Teams or similar service.
5. 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.