The National Congenital Heart Disease Audit

Database

Data Quality Audit for
CONGENITAL HEART DISEASE

For the data period **Apr 2023 - Mar 2024**

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

4 September 2024

performed by Dr A Magee 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 2023 - 2024. This is the thirteenth visit to Children's Health Ireland Crumlin (OLS). All congenital cardiac centres in England Wales and N Ireland 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/ NCHDA is fully supported by the Society of Cardiothoracic Surgeons Of the United Kingdom and Ireland and the British Congenital Cardiac Association of UK and 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 (OLS) indicates that some 1018 therapeutic cardiac procedures had been undertaken during the 2023/2024 data collection year (surgery 357, catheters 555, others 106, Deaths 2 within 30 days of a Specific Procedure), in patients with congenital heart disease. 33 of these patients were found to be aged over 16 years. It was reported at this visit, that it is now no longer the policy for patients who will be aged 16 years at the time of their procedure to have these done at OLS. These patients will be treated in an adult hospital elsewhere in ROI.

Following review of the catheter laboratory and operating room activity log books on the day of the validation visit, 6 additional procedures were identified and where found suitable, were subsequently submitted to the Registry.

At the time of this visit there are 3 DBMS in post providing 2.5WTEs to cover NCHDA congenital registry at OLS and 1.0WTE Consultant Data Manager. This consisted of the external 1.0WTE Senior Data Manager on an advisory, training and consultancy role. 1.0WTE brand new appointee Data Manager and 0.5WTE Data Analyst. During the preceding 4 months prior to this site validation the number of WTEs had dropped to 1.25WTE and then immediately prior to the visit just 0.5WTE. On the day of the NCHDA validation 1.0WTE newly appointed Data Manager was introduced along with a further 1.0WTE Data Manager who will

take up their roles in mid September 2024. Following an initial period of training OLS expects to have a minimum of 2.5WTE Data Managers in post for NCHDA.

The DBMs regular protocol previously for this data submission was, after local validation with responsible clinicians, to submit the data directly from a local database to the live NCHDA Congenital Database (Qreg5) via a CSV file.

In 2022 Children's Health Ireland commissioned the all-encompassing digital information and patient record system EPIC. An anticipated 'go live' date' has not yet been agreed but is expected to be during mid to late 2025. Discussions continue regarding integration of the NCHDA Dataset and its planned inclusion when EPIC is launched. It may also be wise to incorporate in these discussions, a method of archiving the historic congenital data gathered over the last 40-50 years to make it accessible to EPIC.

An external NCHDA data manager observed the site visit in person as part of peer support and a learning experience.

The case notes had been prepared with digital or screen shots of relevant documents in an individual patient specific folder that the DBMs displayed on a large screen in the room being used.

As previously reported when all local IT infrastructure is fully functioning, there is real time data entry to a number of different entry points by clinical staff with access in the DBMs office and conference room area, operating theatre and the catheter lab in the Children's Hospital. However, there is just one computer in the operating theatre and one in the cath lab to serve these two areas currently.

There is an in formal audit programme for congenital procedures and the predominately digital or electronic notes are used to check the data in the majority of the cases and clinicians are involved. Following local validity checking, the data will be submitted electronically to NCHDA on an ongoing basis.

Actions Implemented since the last Validation Visit in 2023:

- No new actions reported although as was reported at the last site validation visit, clinicians are more invested in ensuring the clinical coding is accurate at internal data quality and completeness reviews.
- Immediately prior to this site validation two 1.0WTE Data Managers had been appointed and were present as observers

Patient Consent for External Validation of Case Notes

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 explaining data submission to NCHDA. 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 and pseudonymised identities were used. 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.

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 by 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.

Also as previously reported in 2012-20, in ROI there is as yet no widely used individual lifetime identifier issued to every individual that is similar to the NHS Number in England and Wales, CHI or HNC Number that is used in Scotland or Northern Ireland. This identifier is being slowly introduced in ROI. Therefore, there was no independent source of death date for NCHDA to effectively track 1 year mortality in these patients.

Dr Alan Magee, Consultant Congenital Cardiologist from Cardiff undertook the validation visit with the NCHDA Clinical Audit Nurse. Both were on site face to face with OLS colleagues at this visit.

Data Quality Indicator Scores (DQI)

The DQI score for OLS is (with previous years in parentheses); **99%** (99.5, 99.25, .985), with domain scores Demographics 1.0 (1.0, 1.0, 1.0), Pre Procedure .975 (.99, .97, 99), Procedure .99 (.99, .99, .99), and Outcome .99 (1.0, .99.98, .98,). This is another excellent score and demonstrates that there are robust policies procedures and practices in place to support the timely collection of good quality complete data.

This is based on 20 patients who had 31 procedures (18 catheters, 13 operations). There were 12 discrepancies in 1017 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%
2022	2021-22	99%	99.75%
2023	2022-23	99.75%	99%
2024	2023-24	98.8%	99.3%

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

As stated in the Summary above, 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 (surgery 300, catheters 634, others 121, Deaths 18), in patients with congenital heart disease during the April – March 2023/2024 data collection year. 20 cases were randomly selected for review.

On the day, 1 set of case notes from the Reserves was 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 Reviewers are also grateful to one of the cardiac surgeons who took time to spend with them during this case note review.

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

1. As noted previously, on occasions the diagnosis did not always completely reconcile with the procedure performed and 3 records appeared to have absent but very important components of the diagnoses.
2. The documentation of ante natal diagnosis appeared to be contradictory in 2 patient records
3. As previously reported in 2012-22, the actual catheter procedure report does not always include the following NCHDA dataset items: xray time and dose data, the sheath in/catheters out times or the names of both of the operators. These data were often validated against the nurses log from the cath lab.

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. The book is generally very neat and well kept.

1. 4 records were identified in the log book that may have been missed from the submission
2. 4 records were identified that may have errors in their coding

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Theatre Log Books

An electronic theatre management system (TMS Sapphire) is kept at OLS. An electronic print out of this was provided on the large screens for the reviews. There is 1 dedicated congenital cardiac operating theatre at OLS.

1. Delayed closure of sternum, ECMO decannulation, sternal wire removal, mediastinal exploration are not required to be submitted to NCHDA at this time
2. Pectus Repairs should be submitted in the category Thoracic
3. 1 record was identified that may have been missed from the submission.
4. 5 submitted records were identified that may have coding discrepancies
5. 2 countable surgical records were found to be submitted as ‘Thoracic’ rather than ‘Non-Bypass’

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

20 deceased patients were identified in the data return for 2023-24. 2 of these patients had died within 30 days of a therapeutic catheter intervention or surgical operation. The PRAiS sensitive fields were reviewed for each of the 2 records and the findings were:

1. All dates of death were found to be correct.
2. Death Certificates were not seen
3. No Coroners reports were seen, although documentation and noting of a discussion with the Coroner was seen in some hospital notes.
4. It was reported at this visit that all deaths are reviewed thoroughly in morbidity and mortality meetings and the Attribution of Death field completed by the clinicians.

Case Note Audit

20 patients underwent 31 procedures. 13 operations and 18 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	20	20		11	9
9	Postcode	20	20		11	9
10	Pre Procedure Diagnosis	31	31	3 missing components	18	13
11	Previous Procedures	39	39		19	20
12	Patients Weight at Operation	31	31		18	13
13	Height	30	31	1 absent	18	12/13
14	Ante Natal Diagnosis	5	6	1 absent	2	¾
15	Pre Proc Seizures	31	31		18	13
16	Pre Proc NYHA	-	-		-	-
17	Pre Proc Smoker	-	-		-	-
18	Pre Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre Proc IHD	-	-		-	-
21	Comorbidity Present	30	31	1 incorrect	18	13
22	Comorbid Conditions	32	32	6 incorrect	10/14	26/28

23	Pre Proc Systemic Ventricular EF	31	31		18	13
24	Pre Proc Sub Pul Ventricular EF	26	26		16	10
25	Pre-proc valve/septal defect/ vessel size	-	-		-	-
26	Consultant	31	31		18	13

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
27	Date of Procedure + Time Start	31	31		18	13
28	Proc Urgency	31	31		18	13
29	Unplanned Proc	0	1	1 incorrect	0/1	-
30	Single Operator	0	0		-	-
31	Operator 1	31	31		18	13
32	Operator 1 Grade	31	31		18	13
33	Operator 2	31	31		18	13
34	Operator 2 Grade	31	31		18	13
35	Procedure Type	31	31		18	13
36	Sternotomy Sequence	11	11		-	11
37	Operation Performed	31	31		18	13
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	10	10		9	1
40	Device Manufacturer	11	11		9	2
41	Device Model	11	11		9	2

42	Device Ser No	11	11		9	2-
43	Device Size	9	9		9	11
44	Total Bypass Time	11	11		-	11
45	XClamp Time,	11	11		-	1
46	Total Arrest	1	1		-	-
47	Cath Proc Time,	18	18		18	-
48	Cath Fluro Time,	18	18		18	-
49	Cath Fluro Dose,	18	18		18	-

	Parameter	**Total Score**	**Total No**	**Comments**	**Scores for Cardiology & Surgery**	
					C	**S**
50	Duration of Post Op Intubation	13	14	1 incorrect	-	12/13
51	Post Procedure Seizures	31	31		18	13
52	Post Proc Complications	1	1		-	1
53	Date of Discharge	30	31	1 incorrect	18	12
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	31	31		18	13
57	Discharge Destination	31	31		18	13

Casenote Audit

Data Quality Indicator Assessment:

The Overall Trust DQI = 99% Cardiology DQI = 99.3% Surgery DQI = 98.8%

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 .975**	
	Card .98	**Surg** .973
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**	**Overall** .997	
	Card .995	**Surg** 1.0

Used, No of Stents/Coils, Device Mfr, Device Model, Device Ser No, Device Size,		
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .99 **Card** 1.0	**Surg** .98

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	2024 23-24	2023 22-23	2022 21-22	2021 20-21
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.975	.99	1.0	.97
Procedure	.997	.99	.99	.99
Outcome	.99	1.0	1.0	.98

Conclusions

On the whole the NCHDA data was accurate, well documented, good quality and was appropriately recorded in the relevant health records and log books.

The DBMs had again demonstrated excellent case note preparation and facilitated the day very smoothly and efficiently. The is an excellent DQI and represents another 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

Loosing 2 very experienced data managers in close succession is very challenging in a highly complex data registry in a very large congenital cardiac Centre. The two newly appointed DBMs will need a fully clinically supported and carefully constructed training programme to maintain the previously high standard of data quality. This is likely to take many months to reach a novice level.

As previously reported, on the whole the TMS Theatre log books/printouts appear to be of a very good standard, accurate and precise. The most profound difference is 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 1017 data variables reviewed and 12 discrepancies identified.

Diagnoses coding must, wherever possible reconcile with the procedure performed and this was sometimes found to be incomplete at this visit

It should be noted that PRAiS4 is about to be launched. This latest iteration will include patients up to the age of 18 who undergo surgical procedures. It is expected to be used for analysis of the surgical data for the year April to March 2022-2025.

As mentioned elsewhere, some local colleagues did make time to come to the validation room and it is helpful to both understand the process of the case note review in general and also to appreciate the accessibility in reverse of their own data systems. 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. Once EPIC is launched this will aid data timely collection and quality control.

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, all data were found to be correct and without discrepancy.

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. NHSE who commission NICOR to collect the NCHDA Data request that procedures are submitted within 2 weeks of operation or intervention where 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 where possible
    e. For patients aged 16 years or more, collecting and input of the data for the ACHD fields for NYHA, Smoking, Diabetes, Respiratory Disease and Ischaemic Heart Disease.
    f. 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.
    g. Making timely submissions where possible. 2 weeks after a procedure is requested where possible and completion of record within 1 month is required.
    h. Timely reverse validation at OLS with involvement from the responsible clinicians.
    i. 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. Inclusion of a copy of the Death Certificate would also be helpful.

j. Identifying the responsible clinician for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility.

k. 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. It is recommended that the two newly appointed DBMs will need a fully clinically supported and carefully constructed training programme to maintain the previously high standard of data quality. This is likely to take many months to reach a novice level competency.
5. 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.
6. Also to have a clearly documented training programme for new Data Managers listing competencies to be achieved for each part of the role.
7. 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.