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The National Congenital Heart Disease Audit

Database

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Data Quality Audit for CONGENITAL HEART DISEASE

For the data period **Apr 2024 - Mar 2025**

Children's' Health Ireland (CHI), Crumlin, Dublin

(formerly known as Our Ladies' Children's Hospital)

18 June 2025

performed by Dr G Nepali 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 2024 - 2025. This is the fourteenth visit to Children's Health Ireland Crumlin (OLS). All congenital cardiac centres in England 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://www.nicor.org.uk/national-cardiac-audit-programme/congenital-audit-nchda NCHDA is fully supported by the Society of Cardiothoracic Surgeons Of the United Kingdom (UK) 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 957 therapeutic cardiac procedures had been undertaken during the 2024/2025 data collection year (surgery 342, catheters 549, others 66, Deaths 9/17 within 30 days of a Specific Procedure), in patients with congenital heart disease. 2 of these patients were found to be aged over 16 years. It was reported at the 2024 visit, that it is was 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.

At the time of this visit there are 3 DBMS in post providing 2.5WTEs to cover NCHDA congenital registry at OLS. 2.0WTEs have been in post since September 2024 and the 0.5WTE is a maternity cover since April 2025 for permanent post holder.

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 is expected to be during September 2026. As in 2024, discussions continue regarding integration of the NCHDA Dataset and its planned inclusion when EPIC is launched. It will be pertinent to include in these discussions, a method of archiving the historic congenital data gathered over the last 40-50 years to make it accessible to EPIC.

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

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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 2024:

- No new actions reported
- 3 new data managers have been appointed, the third one as for locum maternity cover
- CHI are in the process of preparing to transition to EPIC Health Care System in 2026 on a new hospital site within Dublin city.

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.

As previously reported, 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.

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Dr Gauri Nepali, a post CCT Fellow in Congenital Cardiology from Birmingham 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); **98%** (99, 99.5, 99.25,), with domain scores Demographics 1.0 (1.0, 1.0, 1.0), Pre Procedure .97 (.975, .99, .97), Procedure .95 (.99, .99, .99), and Outcome 1.0 (.99, 1.0, .99, .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 (15 catheters, 16 operations). There were 29 discrepancies in 1038 variables.

Problem Fields:

Implanted Devices	13 discrepancies
No of stents or coils	5 discrepancies
Pre Procedure Ventricular Function	4 discrepancies

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
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%
2025	2024-25	99.25%	97%

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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

Digital Maturity.

CHI do not yet have a fully electronic health record (eHR) that requires one single sign in/log in to access all the data for each patient. There are mixed paper and digital records for vital signs observations, echocardiology reports, operating room and cathlab log books and perfusion charts that each require a separate username and password log in.

It is reported that paper documents get scanned after the clinic /admission into the electronic patient record system known as Evolve. Evolve is a Medical Record platform supporting digital maturity programmes through removal of paper from the care process. Provided as a fully managed service, delivered securely using Microsoft Azure's cloud. PedCath is used in the cath labs alongside paper log books and Sapphire Theatre Booking Management System in the operating rooms.

To collect the full NCHDA dataset at CHI (OLS), 8 different applications need to be accessed all requiring separate usernames and passwords.

CHI are planning to move from multiple digital systems to EPIC in 2026. EPIC, as stated elsewhere, is an overarching patient information system that encapsulates all hospital and community care.

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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 342, catheters 549, others 66, Deaths 9 within 30 days of a Specific Procedure), in patients with congenital heart disease during the 2024-25 data collection year.

On the day, 3 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 new 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 coordinated and presented.

1. As noted previously, on occasions the diagnosis did not always completely reconcile with the procedure performed and 2 records appeared to have missing (but very important) components of the diagnoses.
2. The clinical progress notes from transfer to the ward from PICU up and until discharge were often not seen and the DBMs reported difficulties sometimes with accessing the nurses notes.
3. It was difficult to discern from the clinical noting as this was not seen, exactly where a patient was discharged to ie home, another hospital etc.
4. As previously reported in 2012-24, 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 all in the same report. These data were often validated against the nurses log from the cath lab.

It also very much helps the Reviewers to have some local colleagues around when looking through the hospital notes even when they have been digitally collated and marked up by the DBMs. It is helpful for the local colleagues 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.

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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. Due to time constraints the months April 2024 to September inclusive only were validated.

1. 13 records were identified in the log book that may have been missed from the submission for the time period April – September 2024.
2. 268 records were not validated. These procedures occurred between 01 October 2024 to 31 March 2025.
3. It was also reported that there is reluctance from 2 clinicians to complete the procedure entries on the PedCath information system used in the cath lab.

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. For the purposes of this review, procedures classified as Hybrid type are included in Surgery.

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. 6 records were identified that may have been missed from the submission.
4. 1 submitted record was identified that may have coding discrepancies
5. 2 countable surgical records were found to be submitted as ‘Thoracic’ rather than ‘Non-Bypass’

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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

17 deceased patients were identified in the data return for 2024-25. 9 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 9 records and the findings were:

1. All dates of death were found to be correct.
2. 2 MCCD's (death) Certificates were seen
3. 8 records may have coding discrepancies in them
4. No formal discharge/death summaries were seen that documented the hospital episode
5. No Coroners reports were seen, although documentation and noting of a discussion with the Coroner was seen in some hospital notes.
6. 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.

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Case Note Audit

20 patients underwent 31 procedures. 16 operations and 15 therapeutic catheter procedures

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		10	10
2	NHS Number	-	-		-	-
3	Surname	20	20		10	10
4	First Name	20	20		10	10
5	Sex	20	20		10	10
6	DOB	20	20		10	10
7	Ethnicity	20	20		10	10
8	Patient Status	20	20		10	10
9	Postcode	20	20		10	10
10	Pre Procedure Diagnosis	29	31	2 important elements absent	13/15	16
11	Previous Procedures	62	63	1 absent	33/34	29
12	Patients Weight at Operation	31	31		15	16
13	Height	31	31		15	16
14	Ante Natal Diagnosis	6	6		2	4
15	Pre Proc Seizures	31	31		15	16
16	Pre Proc NYHA	-	-		-	-
17	Pre Proc Smoker	-	-		-	-
18	Pre Proc Diabetes	-	-		-	-
19	Hx Pulmonary Dis	-	-		-	-
20	Pre Proc IHD	-	-		-	-
21	Comorbidity Present	31	31		15	16
22	Comorbid Conditions	31	31		17	13/14
23	Pre Proc Systemic Ventricular EF	30	31	1 absent	13/15	16
24	Pre Proc Sub Pul Ventricular EF	24	26	2 absent	10/12	14
25	Pre-proc valve/septal defect/ vessel size	No data	No data		-	-
26	Consultant	31	31		15	16

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

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	14	14		-	14
51	Post Procedure Seizures	31	31		15	16
52	Post Proc Complications	-	-		-	-
53	Date of Discharge	31	31		15	16
54	Date of Death	-	-		-	-
55	Attribution of Death	-	-		-	-
56	Status at Discharge	31	31		15	16
57	Discharge Destination	31	31		15	16

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Casenote Audit

Data Quality Indicator Assessment:

The Overall Trust DQI = 98%　　Cardiology DQI = 97%　　Surgery DQI = 99.25%

DOMAIN	DOMAIN Score		
	Overall	**Card**	**Surg**
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	**1.0**	1.0	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	**.97**	.945	1.0
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,**	.95	.93	.97
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	1.0	1.0	1.0

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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	2025 24-25	2024 23-24	2023 22-23	2022 21-22
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.97	.975	.99	1.0
Procedure	.95	.997	.99	.99
Outcome	1.0	.99	1.0	1.0

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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 although very new to this role had demonstrated very good case note preparation and facilitated the day very smoothly and efficiently. There were other clinical documents that would have been useful for the reviewers to see, but for a first experience of hosting an external review, this was excellently managed. The is also good DQI result. The NCHDA Review Team would like to commend the non clinical and beginner DBMs for exceptional and conscientious efforts to ensure almost all the appropriate data were submitted and available to view.

Loosing 2 very experienced data managers in close succession in 2024 is very challenging in a very busy and highly complex data registry in a large congenital cardiac Centre. The three recently appointed beginner DBMs will continue to need a full 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. (ref; From Novice to Expert. Benner P 1982)

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.

Diagnoses coding must, wherever possible reconcile with the procedure performed and this was sometimes found to be incomplete at this visit. This in particular is where a basic clinical instruction and teaching programme for the new DBMs would be beneficial.

It should be noted that PRAiS4.2 is now 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, 2 trainee local colleagues and 1 consultant 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 digitally collated 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.

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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 dates of death were found to be correct but 8 records appear to have discrepancies in them. We also discussed the potential benefit of having data managers attend the M&M meetings to better understand the decision-making processes. Their presence could also serve as a helpful reminder for physicians to complete the "attribution to death" fields.

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Recommendations

1. It is recommended that the two newly appointed beginner and 1 locum DBMs will need a fully on going 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 from beginner, then advanced novice and then competency level and should ensure that all data managers are familiar with both surgery and catheter data.
2. It is recommended that consideration be given to engaging a highly experienced congenital data manager on a periodic consultancy basis over an elongated time span to support the new DBMs in their learning and experience with this complex dataset and its demands.
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 also recommended to have a clearly documented training programme for new Data Managers listing competencies to be achieved for each part of the role from beginner to expert. (Benner, P. From Novice to Expert. 1982). This may include for instance, attendance at MDTs and Mortality Meetings and how to apply that knowledge to understanding the data and data validation.
5. To submit patient identifiable data whenever possible and where full consent has been gained as set out below and avoid submitting anonymised data.
6. 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, (clinician ownership) 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. Each clinician should be encouraged to ‘own’ their data in the local reviews.
    c. Leading the local review, encouraging clinician ownership (and how frequently and in which forum),
    d. Running the monthly PRAiS analysis where possible
    e. For any patients aged 18 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

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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 of discharge is required.

h. Timely reverse validation at OLS with involvement from the responsible clinicians (clinician ownership).

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 (MCCD) would also be helpful.

j. It is recommended that the data managers attend the M&M meetings to better understand the decision-making processes. Their presence could also serve as a helpful reminder for clinicians to complete the “attribution to death” fields.

k. Identifying the responsible clinicians for completing the field for Attribution of Death as this should not be a non clinical DBMs responsibility. Some centres chose to do this task at the monthly mortality and morbidity meetings.

l. Updating life status as any dates of death become known

7. 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
8. 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.

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