



NCHDA Report 2022 OLS

# The National Congenital Heart Disease Audit Database

## Data Quality Audit for CONGENITAL HEART DISEASE

For the data period **Apr 2021 - Mar 2022**

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

**22 June 2022** *performed by Dr M Chaudhary and Lin Denne*

NCHDA Report – OLS - 2022



## Summary

This congenital validation visit by NCHDA is funded by the Republic of Ireland, Health Service Executive. The year reviewed is April to March 2021 - 2022. This is the tenth 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://www.nicor.org.uk/>.

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

As previously reported, OLS were significantly disabled by a malware ransom attack in May 2021. Some databases were still not functioning at the time of this visit.

This visit was conducted via the local WebEx application with the external consultant colleague on site and the NCHDA Audit Nurse connecting remotely. Another external NCHDA data manager observed the site visit as a peer support and learning exercise.

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 but it was, as at the 2021 visit, not possible to share these data 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 1027 therapeutic cardiac procedures had been undertaken during the 2021/2022 data collection year (surgery 335, catheters 613, others 79, deaths 23), in patients with congenital heart disease. 46 of these patients were found to be in 16-20 years age group.

At the time of this visit there are three DBMS providing 2.75WTEs to cover NCHDA congenital registry at OLS.

The DBMs regular protocol is, 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.



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 2021:**

- No new actions reported
- Due to the pandemic the DBMs have successfully pivoted from office based to predominately remote/hybrid working and continue to do so.
- 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 since 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 the 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.

Historically, 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

NCHDA Report – OLS - 2022



NCHDA Report 2022 OLS

analysed by NCHDA and published on the NCHDA Public Portal it considerably hindered the physical process of external validation as each pseudo-ID must 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 widely used individual lifetime identifier issued to every individual similar to the NHS, CHI or HNC Number that is used in other UK countries. This is being slowly introduced. Therefore, there was no independent source of death date for NCHDA to effectively track one year mortality in these patients.

Dr Milind Chaudhary, Consultant Congenital Cardiologist from Birmingham 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); **99.25%** (.985, .99, .99), with domain scores Demographics 1.0 (1.0, 1.0, .99), Pre Procedure .99 (.97, .99, .98), Procedure .99 (.99, .975, .99), and Outcome .99 (.98, .98, .985, .99). This is another excellent score.

This is based on 20 patients who had 23 procedures (10 catheters, 13 operations). There were four discrepancies in 812 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 five procedures in either group are required for the differential DQI calculation.

<b>Year of Visit</b>	<b>Data Years reviewed</b>	<b>Surgery DQI</b>	<b>Catheters DQI</b>
<b>2013</b>	2012-13	98%	96%
<b>2014</b>	2013-14	96.25%	96.5%
<b>2015</b>	2014-15	97.25%	96%
<b>2016</b>	2015-16	94.25%	95%
<b>2017</b>	2016-17	96.75%	97.5%
<b>2018</b>	2017-18	99%	98%
<b>2019</b>	2018-19	99.75%	98.25%
<b>2020</b>	2019-20	97.75%	99.25%
<b>2021</b>	2020-21	98%	98.5%
<b>2022</b>	2021-22	99%	99.75%

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 1027 therapeutic cardiac procedures had been undertaken during the April 2021 - March 2022 data collection year (surgery 335, catheters 613, others 79, Deaths 23), in patients with congenital heart disease. 20 cases were randomly selected for review.

On the day, two 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. As noted previously, on several occasions the diagnosis did not always reconcile with the procedure performed.
2. As previously reported in 2012-21, the actual catheter procedure report does not always include x-ray 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. As previously, 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 one cath lab at OLS. One log book was made available to reviewers, the nurses log.



NCHDA Report 2022 OLS

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. One catheter procedure was identified by the DBMs prior to the visit that appeared to be missed from the data submission.
4. Two 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 one dedicated congenital cardiac operating theatre at OLCHC.

1. Delayed closure of sternum, ECMO decannulation, sternal wire removal, and mediastinal exploration are not required to be submitted to NCHDA at this time.
2. Pectus Repairs should be submitted in the category Thoracic.
3. Three records were identified that may have been missed from the submission.



### **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**

21 deceased patients were identified in the data return for 2021-22. 10 of these patients had died within 30 days of a therapeutic catheter intervention or surgical operation. The Partial Risk Adjustment in Surgery (PRAiS) analysis sensitive fields were reviewed for each of the remaining 10 records and the findings were:

1. All data were found to be correct.

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 local Medical Examiner or Coroner (when required), at an MDT and whether or not the death was related to the procedure.



NCHDA Report 2022 OLS

**Case Note Audit**

20 patients underwent 23 procedures. 13 operations and 10 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	23	23		10	13
11	Previous Procedures	38	38		11	27
12	Patients Weight at Operation	23	23		10	13
13	Height	23	23		10	13
14	Ante Natal Diagnosis	4	4		1	3
15	Pre Proc Seizures	23	23		10	13
16	Pre Proc NYHA	1	1		1	-
17	Pre Proc Smoker	1	1		1	-
18	Pre Proc Diabetes	1	1		1	-
19	Hx Pulmonary Dis	1	1		1	-
20	Pre Proc IHD	1	1		1	-



NCHDA Report 2022 OLS

21	Comorbidity Present	23	23		10	13
22	Comorbid Conditions	30	30		7	23
23	Pre Proc Systemic Ventricular EF	22	23	1 incorrect	10	12/13
24	Pre Proc Sub Pul Ventricular EF	22	23	1 incorrect	10	12/13
25	Pre-proc valve/septal defect/ vessel size	-	-		-	-
26	Consultant	23	23		10	

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	23	23		10	13
28	Proc Urgency	23	23		10	13
29	Unplanned Proc	2	2		-	2
30	Single Operator	-	-		-	-
31	Operator 1	23	23		10	13
32	Operator 1 Grade	23	23		10	13
33	Operator 2	23	23		10	13
34	Operator 2 Grade	23	23		10	13
35	Procedure Type	23	23		10	13



NCHDA Report 2022 OLS

36	Sternotomy Sequence	12	12		-	12
37	Operation Performed	23	23		0	13
38	Sizing balloon used for septal defect	-	-		-	-
39	No of stents or coils	7	7		7	-
40	Device Manufacturer	7	7		7	-
41	Device Model	7	7		7	-
42	Device Ser No	7	7		7	-
43	Device Size	7	7		7	-
44	Total Bypass Time	10	10		-	10
45	XClamp Time,	9	9		-	9
46	Total Arrest	1	1		-	1
47	Cath Proc Time,	12	13	1 absent	12/1 3	-
48	Cath Fluro Time,	13	13		13	-
49	Cath Fluro Dose,	13	13		13	-



NCHDA Report 2022 OLS

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	8	9	1 incorrect	-	8/9
51	Post Procedure Seizures	23	23		10	13
52	Post Proc Complications	4	4		1	3
53	Date of Discharge	23	23		10	13
54	Date of Death	2	2		-	2
55	Attribution of Death	2	2		-	2
56	Status at Discharge	23	23		10	13
57	Discharge Destination	23	23		10	13



NCHDA Report 2022 OLS

**Casenote Audit**

Data Quality Indicator Assessment:

The Overall Trust DQI = 99.25%    Cardiology DQI = 99.75%    Surgery DQI = 99%

DOMAIN	DOMAIN Score					
<p><b><u>Demographics</u></b></p> <p>Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status</p>	<p><b>Overall 1.0</b></p> <table border="1" data-bbox="1126 786 1370 918"> <thead> <tr> <th data-bbox="1126 786 1251 831">Card</th> <th data-bbox="1251 786 1370 831">Surg</th> </tr> </thead> <tbody> <tr> <td data-bbox="1126 831 1251 918">1.0</td> <td data-bbox="1251 831 1370 918">1.0</td> </tr> </tbody> </table>		Card	Surg	1.0	1.0
Card	Surg					
1.0	1.0					
<p><b><u>Pre Procedure</u></b></p> <p>Pre procedure Diagnosis, Selected Previous Procedures, Patient Weight at Operation, Consultant, Antenatal Diagnosis, Pre Procedure Seizures, Comorbid Conditions</p> <p><b>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</b></p> <p>Note, the scores for his domain are affected by the selected previous procedure and pre procedure diagnosis</p>	<p><b>Overall .99</b></p> <table border="1" data-bbox="1126 1126 1370 1641"> <thead> <tr> <th data-bbox="1126 1126 1251 1171">Card</th> <th data-bbox="1251 1126 1370 1171">Surg</th> </tr> </thead> <tbody> <tr> <td data-bbox="1126 1171 1251 1641">1.0</td> <td data-bbox="1251 1171 1370 1641">.99</td> </tr> </tbody> </table>		Card	Surg	1.0	.99
Card	Surg					
1.0	.99					
<p><b><u>Procedure</u></b></p>	<p><b>Overall .99</b></p>					



NCHDA Report 2022 OLS

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 <b>Time Start, Procedure Urgency, Unplanned Procedure, Single Operator,          Sizing Balloon Used, No of Stents/Coils, Device Mfr, Device Model,          Device Ser No, Device Size</b>	<b>Card</b>  .99	<b>Surg</b>  1.0
<b><u>Outcome</u></b>	<b>Overall .99</b>	
Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. <b>Post Procedure Complications.</b>	<b>Card</b>  1.0	<b>Surg</b>  .985

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.

<b>DOMAIN</b>	<b>2022 21-22</b>	<b>2021 20-21</b>	<b>2020 19-20</b>	<b>2019 18-19</b>
<b>Demographics</b>	1.0	1.0	1.0	.99
<b>Pre Procedure</b>	1.0	.97	.99	.98
<b>Procedure</b>	.99	.99	.975	.99
<b>Outcome</b>	1.0	.98	.98	.985



## **Conclusions**

The reviewers acknowledge that there have been long and protracted difficulties with IT infrastructure at OLS following the malware attack earlier in May 2021.

In spite of the multiple challenges, the DBMs had again demonstrated excellent case note preparation and facilitated the day very smoothly and efficiently. This 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. It is clear that many extra hours have been invested by the DBMs to maintain a demonstrably high DQI.

This visit was conducted via the local WebEx application with the external consultant colleague on site and the NCHDA Audit Nurse connecting remotely. There was also another NCHDA data manager observing the validation remotely. The reviewers were very pleased that the WebEx application had a webcam provided again at this visit and that file sharing was fully enabled this year. However, it was not possible for the external reviewers to actually view any of the data.

As previously reported on the whole the TMS Theatre log books/printouts appear to be of a 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 822 data variables reviewed and four discrepancies identified.

Diagnoses coding must, wherever possible reconcile with the procedure performed and this was sometimes found 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 Falot Repair. One main code is all that is required whichever is most suitable.



NCHDA Report 2022 OLS

As mentioned elsewhere we note that some local colleagues did pop into 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 catheters it was quite easy to find the product codes for implants as they are on the cath form but for hybrid procedures this was extremely difficult. So particularly for the people doing procedures and entering the data it's 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 previously reported, in the coding of deceased patients, the attribution of death field may need a little attention. As was noted in 2021, there did not always appear to be a detailed death or discharge summary for patients who had died in hospital and no Coroners or Medical Examiners Reports were seen and it was not always possible to tell if patients who had died within 30 days 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 where possible.
  - 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).
  - 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 medical examiner or 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.



NCHDA Report 2022 OLS

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.

FINAL