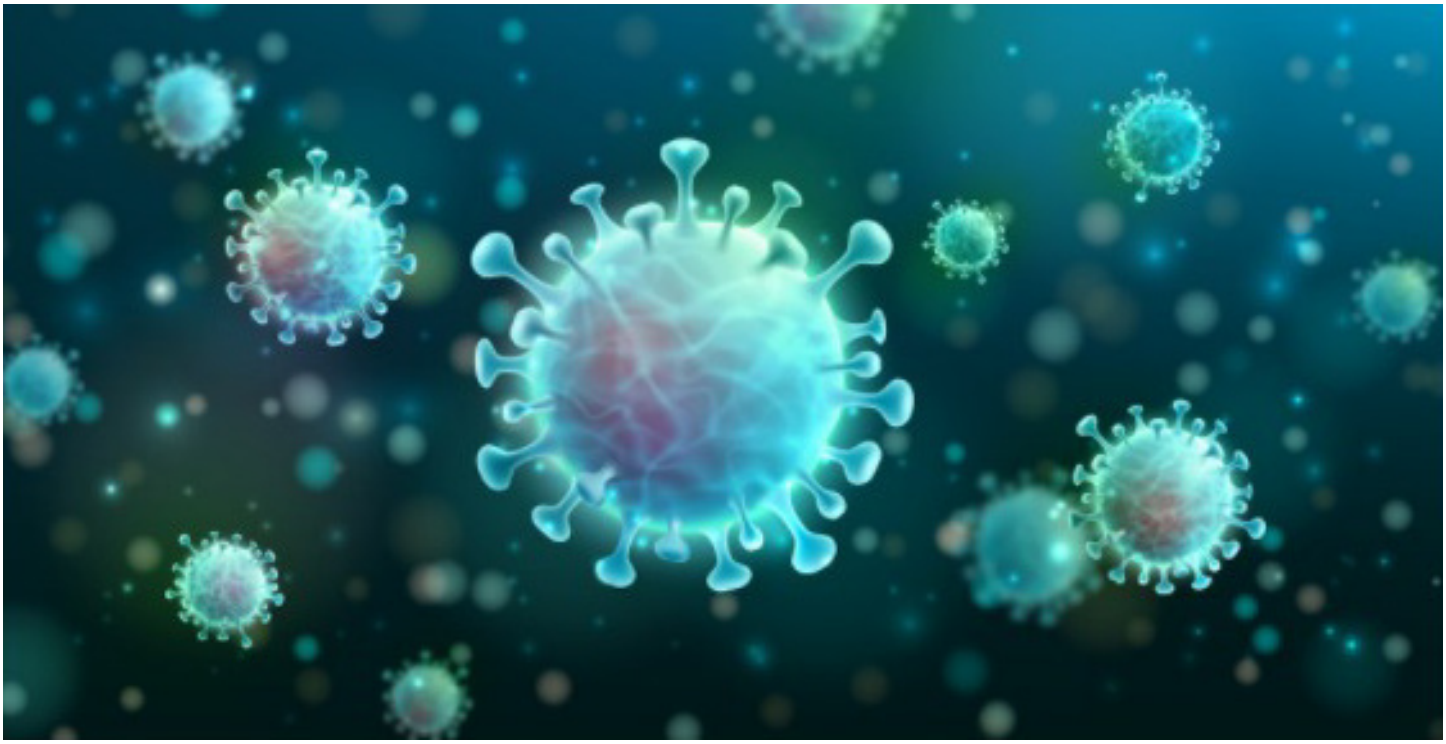
ECHSA
CONGENITAL DATABASE

No. 3 - December 2020

# 2020 - What a crazy year



Dear Database Users, Members, Collaborators and Friends,

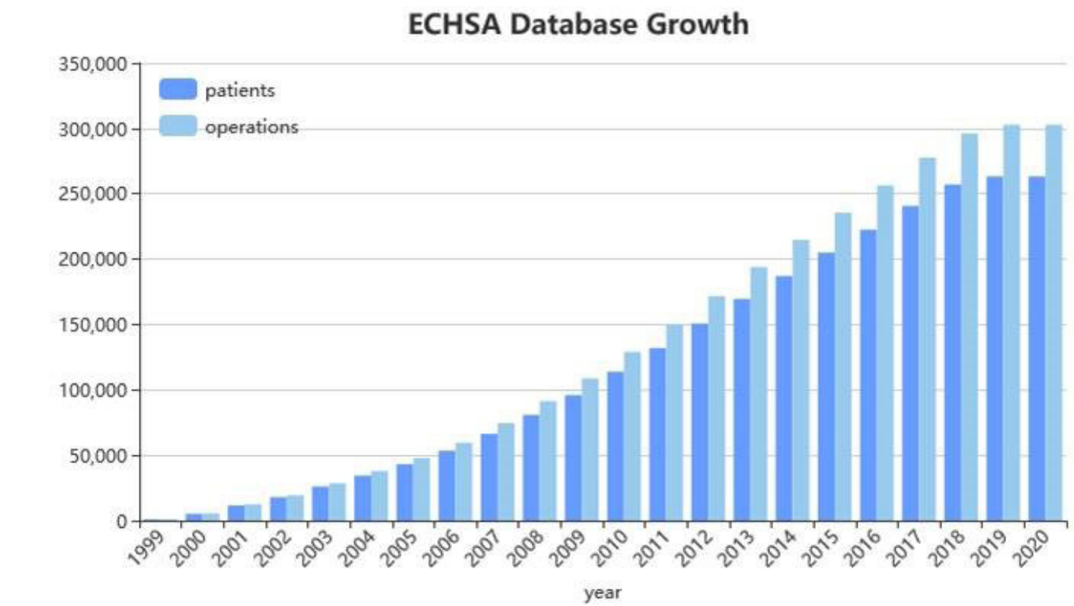
The COVID-19 pandemic in year 2020 kept the world in suspense. We hope that all of you and your beloved ones are healthy and safe. Everybody is needed to bring a contribution in containing the infection and protecting patients, colleagues, families and ourselves. This global health care problem, affects all aspects of health care, social and economic life. Even if not directly involved in the care of patients with COVID-19, every health care worker may be involved due to resource restrictions and the challenge of keeping the care of other patients, like ours with congenital heart defects, ongoing and on a high-quality level.

Nevertheless, the challenges of the pandemic strengthened human bonds in various ways and the world was growing even closer together. Technologies made things possible we never thought of before. Science developed in a rapid way.

For sure at the turn of the year, COVID-19 may not disappear suddenly, but we can go on with strength and empowered by new developments into a hopefully brighter 2021.

We wish you and your families a Happy Holiday Season and all the best for the New Year.

Your ECHSA CHSD Team




The ECHSA CHSD committee meet twice in the year 2020 via teleconference and continued to work on the improvement of the ECHSA CHSD.

## NEW DEVELOPMENTS AND UPCOMING NEWSLETTER TOPICS

### SCORES IN CONGENITAL HEART SURGERY

We have prepared a special issue of this newsletter about scores in congenital heart surgery. Read all about scores, their development and usage written by the experts of this field. Further, information on how to code and use them should support you in your daily practice.

### ARTIFICIAL INTELLIGENCE AND CONGENITAL HEART SURGERY

In close collaboration with one of the world's most prominent academic institution, the Department of Operations Research at the MIT, a risk calculator was developed by using a non-linear methodology based on machine learning and artificial intelligence, to develop new objective risk models for congenital heart surgery. This will lead to valuable information for centers regarding their areas of strength and opportunities and further, will be of major impact in quality improvement. We will provide you with more detailed information on artificial intelligence and congenital heart surgery.

### DEVELOPMENT OF AN INTERVENTIONAL CARDIOLOGY MODULE

In close collaboration with the AEPC the development of an interventional cardiology module is progressing very well. It will facilitate to enter interventional cardiology data into our database. This will allow a holistic picture of our patients with congenital heart disease. In addition, it could improve the collaboration between medical disciplines, like cardiology and cardiac surgery. Furthermore, it will help in follow-up our patients. This effort will lead to our database being the only congenital database in the world, which includes both surgical and cardiological data. We will keep you updated.

### CONGENITAL HEART SURGERY IN EUROPE

The aim of the ECHSA, as a scientific society representing the congenital heart surgeons of Europe, is to improve the surgical treatment of patients with congenital heart disease. One of our goals is to achieve a maximum of information and insight on the education, the health care provision and the quality of congenital heart surgery in Europe. The ECHSA CHSD is an analytical and quality improvement tool empowering centers with sophisticated risk stratification, benchmarking and quality improvement initiatives. We will support you with an overview of the current situation of congenital heart surgery in Europe.



## SOURCE DATA VERIFICATION

*Zdzislaw Tobota, MD and Bohdan Maruszewski, MD, PhD*

**Introduction**

The purpose of the source data verification (SDV) is to ensure that reported data are accurate, complete, and verifiable from source documents and the conduct of the data collection (e.g. the coding of diagnoses, procedures and complication) is in compliance with the recommendations.

According to Good Clinical Practice recommendations:

"Centralized monitoring processes provide additional monitoring capabilities that can complement and reduce the extent and/or frequency of on-site monitoring and help distinguish between reliable data and potentially unreliable data. Review, that may include statistical analyses, of accumulating data from centralized monitoring can be used to:

a) identify missing data, inconsistent data, data outliers, unexpected lack of variability and protocol deviations.

b) examine data trends such as the range, consistency, and variability of data within and across sites.

c) evaluate for systematic or significant errors in data collection and reporting at a site or across sites; or potential data manipulation or data integrity problems.

d) analyze site characteristics and performance metrics.

e) select sites and/or processes for targeted on-site monitoring."

**Source Data Verification Program in ECHSA Congenital Database**

Following the EACTS Council directives and internationally admitted rules of data verification the EACTS Congenital Database management has created and applied in 2004 the step-wise protocol for control of the data completeness and accuracy. At that time the database has been co-managed by ECHSA and EACTS and had the name of the EACTS Congenital Database.

Each year since 2005 we verify the data in 4 (first year of the program activity) to 9 centers (mean 7,6). During the verification visit, which consist usually of 2 working days, the data of previous year(s) are being verified. In two days ca. 400 procedures can be verified. The possible number of verified procedures is mostly determined by the type of the source documents; paper documents, computerized hospital system, the data exported from hospital system etc. In the centers with small annual volume of procedures 2 or 3 years is verified during one visit. All together during 16 years the data of 122 annual volumes of procedures in 23 different centers has been verified, in many of them several times.

**How to apply for data verification**

The Congenital Heart Surgery Centre that wants to participate in the SDV program should collect and upload to the ECHSA Congenital Da-

tabase website the complete set of the data of all operations done in the previous year.

Nowadays, because of the personal data protection law, patients have a right to deny consent for their data collection. The patient should be informed that the data sent to the international database are anonymized. If the patient does not agree anyway, these very few operations can be skipped. Experience has shown that this applies to exceptional cases.

If the annual volume of the procedures is small it is recommended to collect the data of 2 or 3 years, at least 200 – 250 procedures for a verification visit to be efficient.

In matters of including the center in the SDV Program and arranging an appointment, please contact the technical director of the database, Dr. Zdzislaw Tobota - ztobota@ecdb.pl.pl.

**The verification process**

*Source data:* Source data are contained in source documents (original records or certified copies) and can be said to be the first place where information is recorded/captured. In practice it can be the paper documents (perfusionist charts, descriptions of operations), access to the Hospital Information System (HIS), or the data exported from HIS e.g. in excel format.

*Legal issues:* the person who visits the center for data verification has no the rights to access the patients' data. There are at least two solutions of this problem; back to back method. The visitor works with the verification forms and says the patient id number and only the person from local staff access the source data. This method solves also the language problems, if they occur. Alternatively, the hospital's legal department may prepare a document authorizing temporary access to patient data and requiring the auditor to maintain professional secrecy.

*The process:* The auditor comes to the center with printed Verification Forms for all operations transferred to the database from agreed years. Then the auditor himself or with the help of a person from the hospital team checks each of the fields subject to verification with the source documents.

The 13 verified fields are as follows:

| |
|---|
| *Patient local ID* |
| *Date of birth* |
| *Date of admission* |
| *Date of operation* |
| *Date of discharge* |
| *Weight at operation* |
| *Case category* |
| *CPB Time* |
| *AoX clamp time* |
| *Date of death* |
| *IPPV (if available)* |
| *Diagnosis* |
| *Procedures* |

Each item can be marked as correct, is not correct, or data unavailable for verification.



Please see the example of the Verification form, after verification:

| Patient local ID | Patient local ID | Patient local ID |
|---|---|---|
| Operation ID .1980 | Operation ID .1994 | Operation ID .1981 |
| Date of birth 1994-01-05 ✓ | Date of birth 2014-08-05 ✓ | Date of birth 2000-05-13 ✓ |
| Date of admission 2014-12-02 ✓ | Date of admission 2014-12-03 ✓ | Date of admission 2014-09-04 ✓ |
| Date of surgery **2014-12-03** ✓ | Date of surgery **2014-12-04** ✓ | Date of surgery **2014-12-05** ✓ |
| Date of discharge 2014-12-08 ✓ | Date of discharge 2014-12-09 ✓ | Date of discharge 2014-12-10 ✓ |
| Weight 71 kg ✓ | Weight 5 kg ✓ | Weight 51 kg ✓ |
| Case category CPB ✓ | Case category CPB ✓ | Case category CPB ✓ |
| CPB Time 68.0 ✓ | CPB Time 241.0 ✓ | CPB Time 132.0 ✓ |
| AoX Time | AoX Time 150.0 ✓ | AoX Time |
| Date of death | Date of death | Date of death |
| IPPV 11:00:00 ✓ | IPPV 29:00:00 ✓ | IPPV 11:00:00 ✓ |
| Validation Rules OK | Validation Rules OK | Validation Rules OK |
| Is valid? OK | Is valid? OK | Is valid? OK |
| Diagnoses **1.** TOF (prio. 1) **2.** Pulmonary insufficiency (prio. 2) ✓ | Diagnoses **1.** VSD, Multiple (prio. **1**) **2.** PFO (prio. 2) **3.** Patent ductus arteriosus (prio. 3) **4.** Miscellaneous, Other (prio. 4) ✓ | Diagnoses **1.** TGA, VSD (prio. 1) **2.** Pulmonary artery stenosis (hypoplasia), Main (trunk) (prio. **2**) **3.** Pulmonary stenosis, Valvar (prio. 3) **4.** ASD, Secundum (prio. 4) **5.** Patent ductus arteriosus (prio. 5) ✓ |
| Procedures **1.** Valve surgery, Other, Pulmonic (prio. 1) ✓ | Procedures **1.** VSD, Multiple, Repair (prio. 1) **2.** ASD repair, Patch (prio. 2) ✓ | Procedures **1.** PA, reconstruction (plasty), Main (trunk) (prio. 1) ✓ |
| Is correct (√) / Is not correct (×) ✓ | Is correct (√) ✓ / Is not correct (×) | Is correct (√) / Is not correct (×) ✓ |

RV-PA Conduit

The verified Center receives the data verification certificate (in an electronic and printed in a frame version).

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# Data Verification Certificate

This is to certify that:

*Cardiac Surgery - Pediatric Heart Center*

Successfully underwent verification of the data of operations performed in year **2018** according to the Source Data Verification Protocol of the ECHSA Congenital Database on August 1st – 2nd, 2019

Database Technical Director
**Zdzislaw Tobota, MD**

Database Committee Chair
Database Director
**Bohdan Maruszewski MD, PhD**
Prof. of Cardiothoracic Surgery

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At the end of the year after finishing the data verification in the current year, the center receives the data verification summary showing the percentage of own mistakes and comparison to the other verified centers:

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## Data verification summary
## Dept. of Congenital Heart Surgery / Pediatric Heart Surgery, 2017

| | | % | % of all verified data of 2017 | % of all verified data 2003-2017 |
|---|---|---|---|---|
| The number of all operations before verification: | 849 | | | |
| The number of deleted operations: | 0 | 0,00% | 0,03% | 0,38% |
| The number of added operations: | 3 | 0,35% | 1,03% | 1,14% |
| The number of all operations after verification: | 852 | | | |
| The number of not verified operations: | 3 | 0,35% | 2,62% | 1,41% |
| The number of not verified data in the field "Date of discharge": | 31 | 3,65% | 1,14% | 0,63% |
| The number of changes in the field "Weight": | 20 | 2,36% | 2,34% | 1,81% |
| The number of not verified data in the field "Weight": | 37 | 4,36% | 4,07% | 2,72% |
| The number of changes in the field "Case category name": | 58 | 6,83% | 2,41% | 1,19% |
| The number of changes in the field "CPB time": | 6 | 0,71% | 1,27% | 1,52% |
| The number of not verified data in the field "CPB time": | 6 | 0,71% | 1,10% | 0,31% |
| The number of changes in the field "AOX time": | 5 | 0,59% | 1,34% | 1,32% |
| The number of not verified data in the field "AOX time": | 5 | 0,59% | 1,48% | 0,41% |
| The number of changes in the field "Diagnoses": | 13 | 1,53% | 3,03% | 1,73% |
| The number of priority changes in the field "Diagnoses": | 15 | 1,77% | 1,38% | 0,88% |
| The number of changes in the field "Procedures": | 10 | 1,18% | 2,24% | 1,64% |
| The number of priority changes in the field "Procedures": | 7 | 0,82% | 0,45% | 0,28% |

Database Technical Director
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The comparative statistics of the data verification results is published on database web site and is updated every year with the new data verification data:

## Data Verification Results

**Data Of 2003 - 2017**

### All Patients

- No of all collected procedures for 2003 - 2017: 257,939
- No of verified procedures: 37,699 (14.62%)
- No of procedures in whole database: 301,074
- No of verified procedures: 37,699 (12.52%)

**Verification Results**

| Procedures | 37,105 | | 37,699 | | |
|---|---|---|---|---|---|
| | Before verification | | After verification | | |
| | Mean | Std Dev | Mean | Std Dev | p-value |
| Age (days) | 2316.26 | 4367.37 | 2303.38 | 4308.61 | 0.68 |
| AOX time (min) | 63.57 | 46.47 | 63.61 | 46.63 | 0.93 |
| CPB time (min) | 111.39 | 81.87 | 111.42 | 80.37 | 0.97 |
| IPPV (min) | 88.15 | 282.37 | 89.59 | 287.21 | 0.60 |
| LOS (days) | 23.14 | 418.89 | 19.26 | 171.98 | 0.10 |
| Weight (kg) | 19.07 | 29.43 | 18.80 | 23.58 | 0.18 |

**Verification Results - Mortality**

| Patients | 29,593 | | 29,894 | | |
|---|---|---|---|---|---|
| | Before verification | | After verification | | |
| | No of deaths | Mortality (%) | No of deaths | Mortality (%) | p-value |
| 30 days mortality | 988 | 3.34 | 1032 | 3.45 | 0.44 |
| hospital mortality | 1087 | 3.67 | 1141 | 3.82 | 0.36 |

**Costs of data verification**
The work of the Auditor is covered by the Database annual budget.
The verified center covers the travel and accommodation (flight ticket and hotel bill) costs of the auditor.

## GENERAL INFORMATION

**Editor-in-Chief: Claudia Herbst, MD**

Questions or Requests regarding the newsletter or the ECHSA-CHSD itself?
Want to enroll your center to the ECHSA-CHSD?
Contact us: dbnewsletter@echsa.org