

ECHSA
CONGENITAL DATABASE



No. 2 - January 2020

The ECHSA CHSD wishes a

Successful Year 2020

to all Database Users, Members,
Collaborators and Friends!

Celebrate this year the 25th anniversary of the ECHSA CHSD with us!

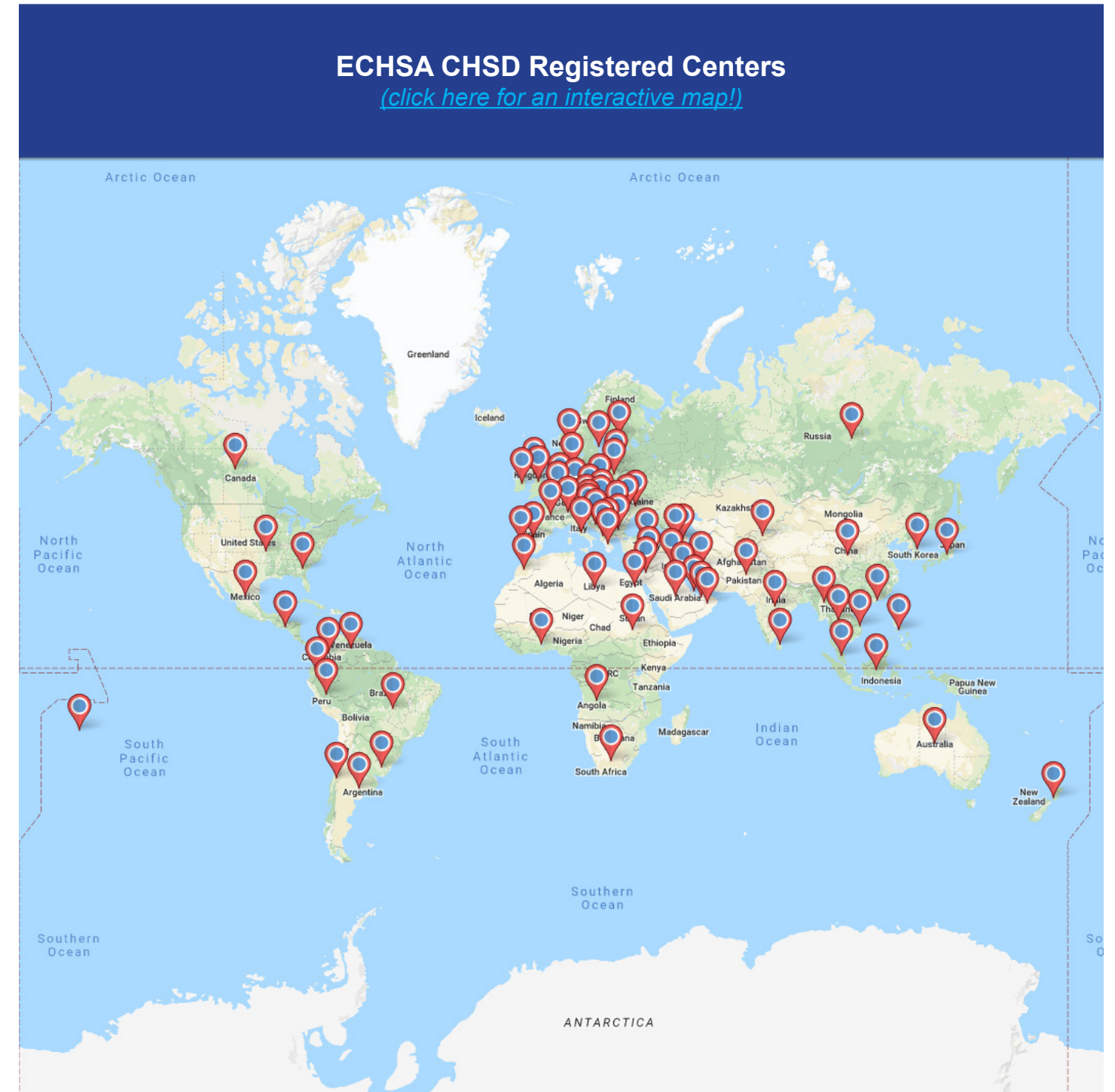
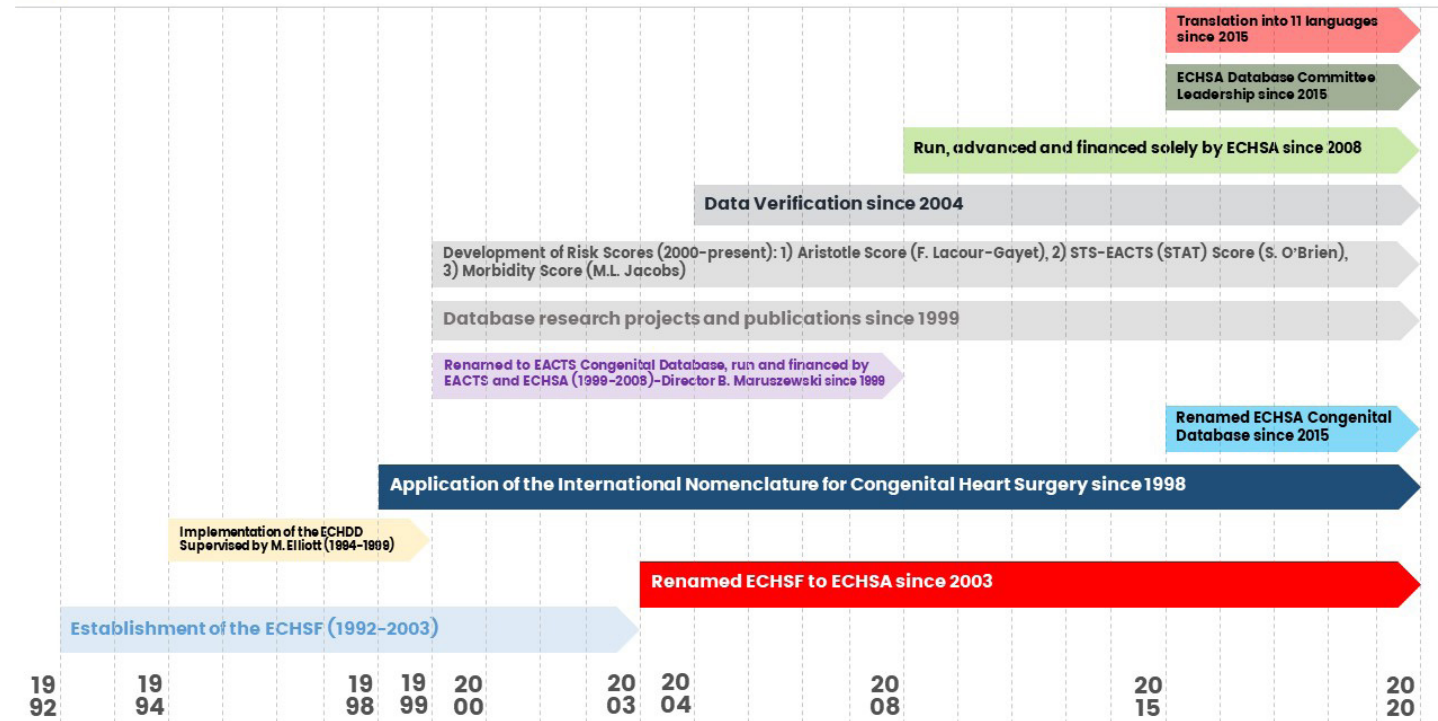
ECHSA CHSD HISTORY: INTRODUCTION

Bohdan Maruszewski MD, PhD, and George Sarris, MD

The ECHSA-CHSD can look back on a 25year history of support, development and research in congenital heart surgery. The initial aim of collecting data on the outcomes of congenital heart surgery procedures across Europe was to make possible comparison of results and definition of mortality and morbidity, risk factors as well as targeting research activities. This requires good quality data obtained on a large scale from numerous congenital surgical cardiothoracic units primarily from Europe (but also from other parts of the world) as well as data validation and verification.

See below the timeline of the establishment and development of the ECHSA CHSD.

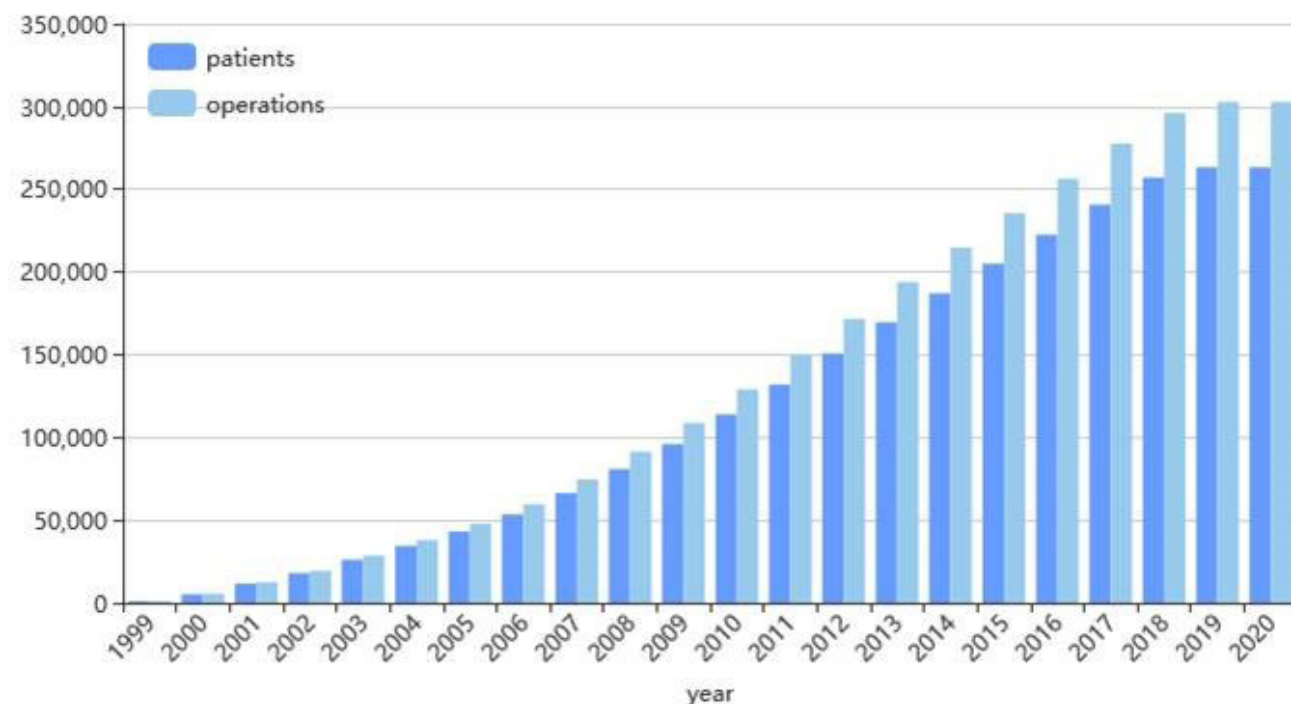
ECHSA CHSD HISTORY



By January 2020:

- 398 centers from 85 countries are registered to the ECHSA CHSD
- >300,000 procedures from >260,000 patients are recorded in the ECHSA CHSD: that makes the 2nd biggest Congenital Heart Surgery Database in the world
- 70% of the data comes from Europe
- The ECHSA CHSD is based in Europe as a worldwide database, open for everyone

ECHSA Database Growth



HISTORICAL TEXT: TREATMENT OF CONGENITAL HEART DISEASE IN 1911

Excerpt, translated from German. Found in: O. Heubner, Lehrbuch der Kinderheilkunde, II. Band, Verlag von Johann Ambrosius Barth, 1911, 3. Auflage, Elfter Abschnitt. Die Herzkrankheiten des Kindesalters, S. 360 f

[Textbook of Pediatrics, 2nd Volume, Verlag von Johann Ambrosius Barth, 1911, 3rd edition, Chapter 11: Cardiac Diseases in Childhood, pg. 360-]

The treatment should not be directed by the physical findings, but by the state of the heart's power and its performance reserve. If one finds a cardiac anomaly in a child that is in excellent shape, one should not frighten the parents and the child by emphasizing the problem and immediately alter the way of living by dissuading anything possible, etc. One informs the parents about the findings and advises them next to a careful observation of any possible disturbance of the cardiac function at stronger exercise such as running, go-

ing up stairs, jumping, dancing, etc., and observe also, when possible, the child itself. When no disturbances from normal are observed, one should not compel the child to avoid vigorous movements, because a certain exercise keeps the muscles in better shape, instead of forced inactivity. One should take care that overly strenuous exercise should be avoided and various exercises such as swimming, fencing, gymnastics, crewing and biking should not be undertaken until the muscle system is fully developed, that is, after the onset of puberty, and even then, with moderation as to duration and level of exercise. In the meantime, simple strolling, ice skating and riding can well be undertaken and from a teacher educated in orthopaedics one could learn if free exercise in school gymnastics is allowed. In the diet, all excitement should be avoided, such as tea, coffee, natural alcohol in any form, and one should be mostly vegetarian nature, with a single serving of meat and a moderate amount of milk (about half a litre).

When subjective signs of failure of the compensation mechanisms develop at strong demand on the heart, or even without such signs in children

with a cardiac anomaly, the rules should be more restrictive and all forms of exercise and games requiring more-or-less strong or sudden muscle movement (ball games, lawn-tennis, the exercises mentioned above, including dancing and biking) should be withheld. For exercising the heart, then, it is enough to just engage in simple strolling on flat or moderately sloping terrain and passive and Swedish gymnastics, in any case horseback riding under the guidance of a good teacher, by work in the garden or playing in the sand, free exercise in fresh air, a visit to a rehabilitation facility in the woods, the middle mountains, on the beach. In such cases, it is often advisable to let the children rest totally for a few weeks, either in bed (possibly with an open window) or also in an open-air sanatorium or similar. During these rest periods, one has to take care of the regulation of the cardiac function with medication such as digitalis, strophanthus, caffeine, etc. When the children get up again, one should continue the medication for a few days or weeks.

Finally, the bath cures prove to be beneficial in Nauheim and other carbon dioxide-rich sources (Cudowa, Pyrmont, Elster) and have earned the same respect for children as for adults. The proof by M. Winternitz that the carbon dioxide bath causes a higher impulse for deep inhalations, that the pulmonary gas exchange remarkably rises,

that also the inflow of blood into the left heart increases, that the diastole becomes larger, lets the positive effect of these cures become understandable for the recovery of the normal compensation.

When finally, serious compensation failure is present, then first of all strict bed rest is necessary. Secondly, a methodical cure with cardiac medication is indicated, in particular digitalis infusion, or Digipurat, alternating with strophanthus tincture, diuretin and other medications that positively influence the cardiac muscle and nerve regulating substances. A combination with Camphor is usually very recommendable in such cases. Often, by prescribing an absolute milk diet, one can establish a good diuresis. But one should not continue with children in a poor situation. One should not hesitate in cases with generalised effusions with their evacuation from the abdomen and pleural spaces, because recuperation of the heart by free unfolding of the lungs through the other measures then is easier to establish. Also, an early, not too limited venesection can often, in desperate cases, still bring about a turn for the better.

¹Synonym: ouabain (arrow poison)

²Digipurat: specific digitalis preparation

³Diuretin: theobromine-sodium salicylate, a diuretic related to caffeine

CURRENT CONGENITAL HEART SURGERY DATABASES

Claudia Herbst, MD, with the contribution of Jeffrey P. Jacobs, MD and James St. Louis, MD

Quality assurance and quality management are essential tools in congenital heart surgery. In some countries an implementation of a quality control tool is regulated by law. Even if it's not an obligation, the responsibility as a physician caring for patients with congenital heart disease is to know the results of the treatment that he recommends as is stated by W.G. Williams.

For quality control, databases are helpful tools. To make a decision for a certain database there are a few main points to consider:



- What do I get for my data?
- What should the data entry set cover?
- What is the type of analysis, graphs and tables I need?

- With which area will I perform benchmarking?

Below, you can find an overview of current congenital databases including the STS, ECHSA and World Database.

	<i>STS congenital heart surgery database</i>	<i>ECHSA CHSD</i>	<i>World database for pediatric and congenital heart surgery</i>	<i>National databases</i>
<i>Founded</i>	<i>1984</i>	<i>1999</i>	<i>2017</i>	
<i>Located</i>	<i>United States of America</i>	<i>Europe, Poland</i>	<i>University of Alabama: Birmingham</i>	<i>National</i>
<i>Number of registered centers</i>	<i>113</i>	<i>398</i>	<i>65</i>	<i>Different types of databases In regard to dataset and outcome analysis Data not comparable with another database or country</i>
<i>Number of registered countries</i>	<i>5</i>	<i>85</i>	<i>21</i>	
<i>Area</i>	<i>Predominantly North America</i>	<i>worldwide</i>	<i>worldwide</i>	
<i>Data entry</i>	<i>Data is entered at the individual hospital and sent to STS</i>	<i>local</i>	<i>webbased</i>	
<i>Reports</i>	<i>Feedback Reports sent to each Hospital every 6 months benchmarking individual programmatic data to national aggregate data</i>	<i>Unlimited 365 days 24hours customized reports available *Online access to outcome reports *17 different report forms * National reports</i>	<i>Bi-Annual</i>	
<i>Dataset</i>	<i>Patient information Preoperative Data Operative Data Postoperative Data</i>	<i>Full dataset for every patient and every procedure</i>	<i>Tier 1 surgery details, discharge, one year follow up, patient death Tier 2 minimal dataset</i>	

<i>Number of Procedures</i>	<i>328</i>	<i>279</i>	<i>Tier 1: 10 Tier 2: all other congenital heart surgeries</i>
<i>Number of Diagnosis</i>	<i>221</i>	<i>196 (IPCCC diagnosis) plus 89 non cardiac abnormalities</i>	<i>All IPCCC diagnosis</i>
<i>Mortality categories used</i>	<i>Primarily STAT Mortality Score and STAT Mortality Categories (STS-EACTS Mortality Score and STS-EACTS Mortality Categories)</i>	<i>STS-EACTS (STAT) mortality score and category and STS-EACTS morbidity score Aristotle Score</i>	<i>STAT RACHS</i>
<i>Costs</i>	<i>5 250 US Dollar per year and</i>	<i>750 € per year</i>	<i>none</i>
<i>Additional Costs</i>	<i>5 US Dollar per record</i>	<i>none</i>	<i>desired to be a member of the WSPCHS</i>
<i>Languages</i>	<i>English</i>	<i>11 English Mandarin Dutch French German Italian Polish Portuguese Russian Spanish Turkish</i>	<i>5 English Mandarin Spanish Portuguese Vietnamese</i>




HOW TO CODE - PATIENT'S HISTORY OF OPERATIONS

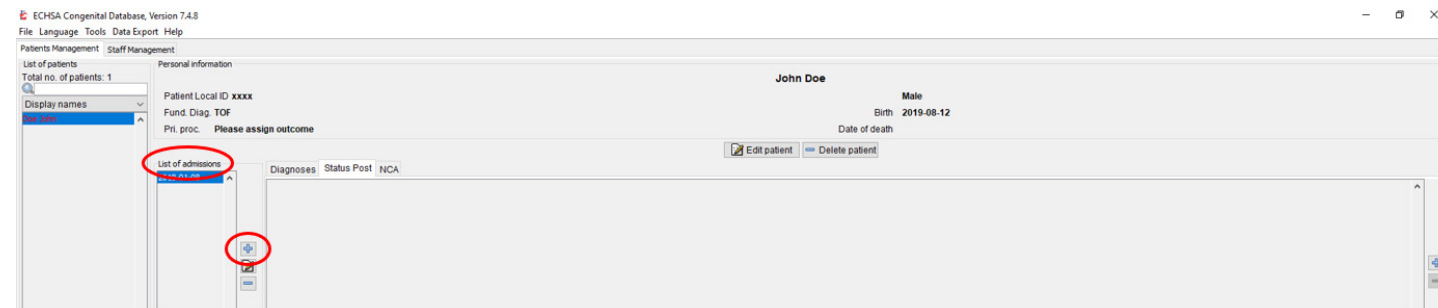
Claudia Herbst, MD

If you have a patient undergoing their second or even more reoperation, you may want to add their former operations in the database too. In that case, you have two possibilities:

1. Option: The former operation was performed in your center and you have all data needed for a dataset available. Open the patients file in the database.

Click on the  button at the **List of admissions** section.

Enter the former date of admission and discharge. Select this date and enter the patient's data in a regular way.



2. Option: The former operation was performed in another center, or the former operation was at your center, but you don't have all data available and/or you want to go the short way.



Open the patient's file in the Database and click on the **Status Post** button.

Click on the  on the right side and select the former procedure from the list. Done.

Do you have a question, comment or input about coding?

Contact us at dbnewsletter@echsa.org

We would be very pleased to hear from you!

DATABASE REPORTS: PERIODICAL RESULTS

Claudia Herbst, MD

The ECHSA CHSD offers several report forms to show periodical results.

As an example, three different report forms are shown and explained in this issue:

- Trends
- Quality of Care Charts
- Outcome prognosis

By logging in to the ECHSA congenital database website (www.echsacongenitaldb.org), every user could create his customized report of interest (**Fig. 1**).



Fig. 1. Menu for Online Reports on the website

Trend graphs display a trend over time. **Fig. 2** shows the decline of 30 days mortality, of all patients with congenital heart disease entered in the ECHSA CHSD, over a time period of 20 years. **Fig. 3** is more specific and shows 30 days mortality (%) of neonates in the ECHSA CHSD.



Fig. 2. 30 days mortality of all patients ECHSA CHSD.

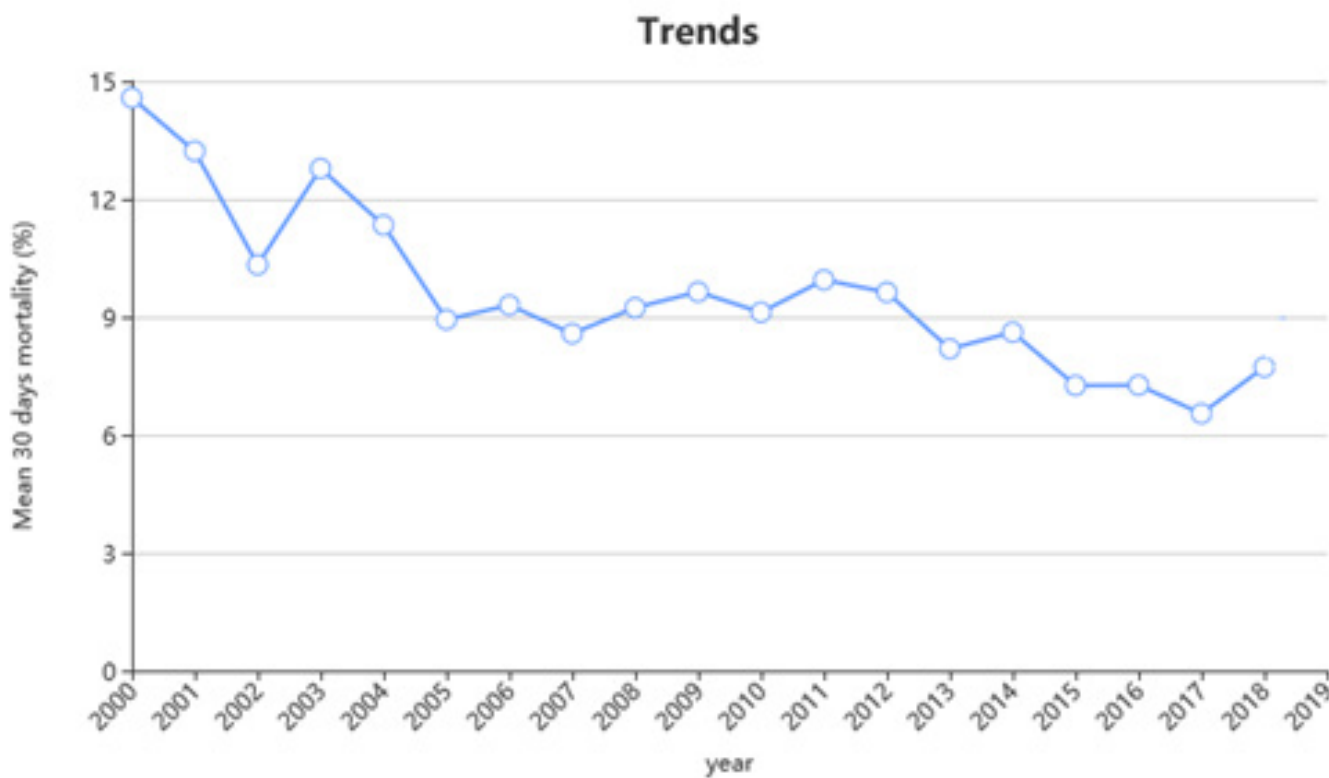


Fig. 3. 30 days mortality of neonates in the ECHSA CHSD

Trends can be shown for 10 different variables (see Fig. 4). According to the filters set, there are numerous ways of output. Very useful are center related, disease or procedure related or age-group related graphs.

- Number of procedures
- Mean age at procedure (months)
- Mean hospital mortality (%)
- Mean 30 days mortality (%)
- Mean LOS (days)
- Mean IPPV (hours)
- Mean weight (kg)
- Mean Basic Score
- Mean Mortality Score
- Mean Performance

Fig. 4. Types of Trend Reports.

Quality of Care Charts (also known as Bubble Charts) are the most popular graphs of the ECHSA CHSD. They can show a single year of interest or some years combined in one graph. The graph is created by choosing the time split option from the report select option menu. (Fig. 5). Figure 6 shows a Quality of Care Chart for a 5-year time period (2014-2018). On the x-axis a score is shown versus 30-days mortality on the y-axis. In this example, by using the STS-EACTS (STAT) mortality score like in Figure 6a the bubbles are overlapping. You can see that there's no difference between those years. By using the Ar-

istotle Basic Score separated bubbles are shown (Fig. 6b). 30-days mortality indicates to the primary procedure. These values could be easily changed to other topics of interest (e.g. number of operations or hospital survival). Horizontal and vertical lines indicate mean values. Each bubble stands for a specific center, their size is in relation to the case load of the indicated center. Own center is shown as a red bubble (see example center in this figure in red). According to the axis values there is always a field where it is best to be. In our example this would be the right bottom field, which indicates high STAT score and low mortality rate. The left bottom field which is low mortality rate with lower STAT categories is desirable for centers with low complex cases.

QUALITY OF CARE CHARTS

SELECT REPORT OPTIONS

X Axis:	STS-EACTS Mortality Score
Y Axis:	30-days Mortality (%)
Unit Split:	Split by Hospital
Time Split:	Split by Year
Procedure Split:	No Procedure Split
Exclude Minor Procedures:	<input type="checkbox"/>

Generate report

Figure 5. Quality of Care Charts report.

Outcome prognosis

Outcome prognoses are calculated with the data of past years. For the outcome prognosis report data filters are inactive. Filters are set direct in the report options menu. Choose a primary diagnosis, optional secondary diagnosis, age, patient weight plus weight range. (Fig. 7) A report of the whole database (all centers), national report (if at least 3 centers of your country submit data to the ECHSA CHSD) and a center report are available (Fig. 8).

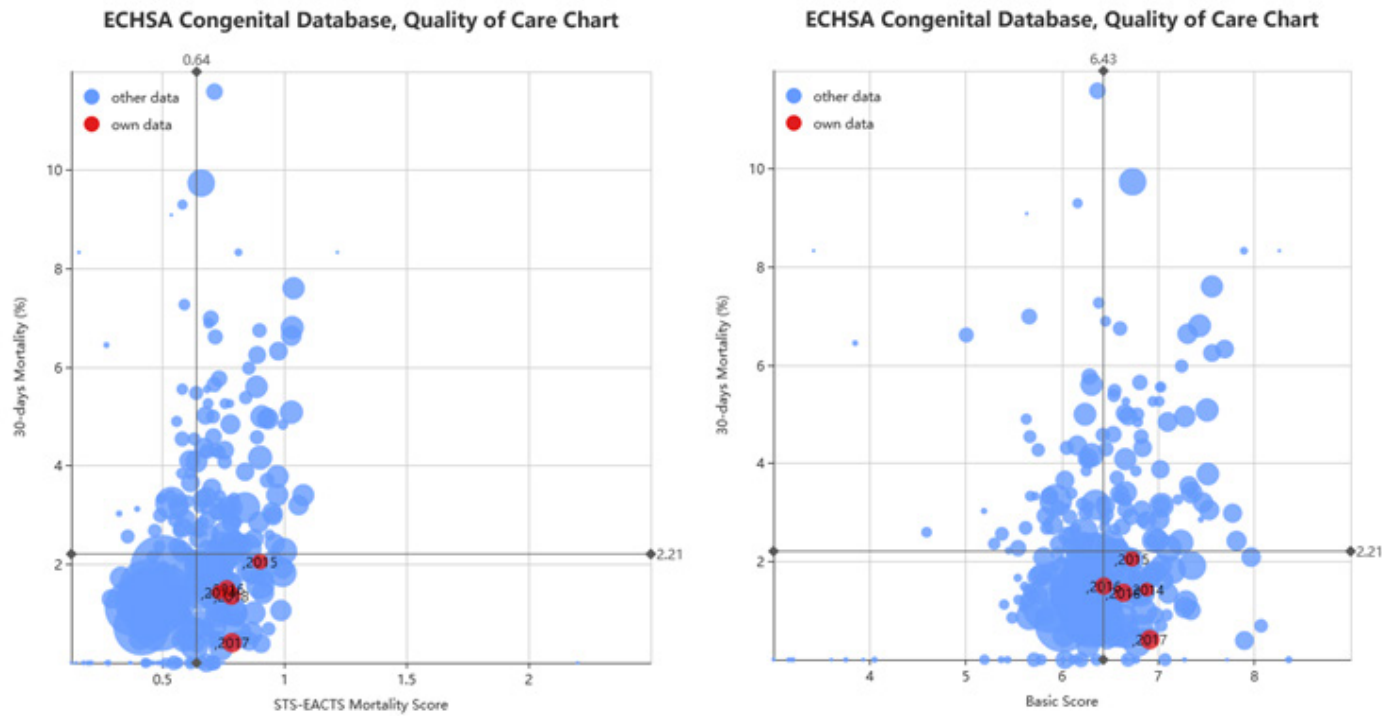


Figure 6. ECHSA CHSD Quality of Care Chart. a) STAT Mortality Score vs. 30 days mortality; b) Aristotle Basic Score vs. 30day mortality.

OUTCOME PROGNOSIS REPORT

SELECT REPORT OPTIONS

Please notice that data filter is inactive in Outcome Prognosis report.

Primary diagnosis:

Secondary diagnosis:

Age groups: Neonates Infants Children Adults

Patient weight:

Weight range:

Data set:

Generate report

Figure 7. Outcome prognosis report – report options menu.

Data set:

Generate report

Figure 8. Data set for Outcome Prognosis Report.

As an example, TGA, IVS is shown in **Fig. 9** and **Table 1**. First an overview of the results is given with number of distinct procedures, total number of operations and total number of patients. Then for every procedure count, 30-day mortality, hospital mortality, mean IPPV (intermittent positive pressure ventilation) time and mean LOS (length of stay) is shown. This is followed by a table of additional diagnosis and complications, where for each a patient count is mentioned.

OUTCOME PROGNOSIS REPORT

REPORT OPTIONS

Primary diagnosis: (10,05) TGA, IVS

Age groups: Neonates

Patient weight: 3.5 kg (±20%)

Data set: All centers

RESULTS

Number of distinct procedures: 128

Total number of operations: 7079

Total number of patients: 5463

Figure 9. Outcome prognosis report for TGA, IVS.

Complications

- Sternum left opened (505 patients)
- Sternum left open, Planned (320 patients)
- Postoperative/Postprocedural respiratory insufficiency requiring mechanical ventilatory support > 7 days (254 patients)
- Cardiac dysfunction resulting in low cardiac output (219 patients)
- Arrhythmia (203 patients)
- Renal failure - acute renal failure, Acute renal failure requiring temporary dialysis with the need for dialysis not present at hospital discharge (173 patients)
- Other postoperative complication (141 patients)
- Bleeding, Requiring reoperation (123 patients)
- Sepsis (115 patients)
- Pleural effusion, Requiring drainage (102 patients)
- Postoperative/Postprocedural mechanical circulatory support (IABP, VAD, ECMO, or CPS) (102 patients)
- Paralyzed diaphragm (possible phrenic nerve injury) (94 patients)
- Pneumonia (94 patients)
- Sternum left open, Unplanned (91 patients)
- Arrhythmia requiring drug therapy (90 patients)
- Chylothorax (83 patients)
- Wound infection (80 patients)
- Other complication (65 patients)
- Arrhythmia necessitating pacemaker, Temporary pacemaker (64 patients)
- Wound infection Superficial wound infection (56 patients)
- Pericardial effusion, Requiring drainage (51 patients)
- Cardiac arrest, Timing = Cardiac arrest (M) during or following procedure (Perioperative/Periprocedural = Intraoperative/Intraprocedural and/or Postoperative/Postprocedural) (48 patients)
- Pneumothorax, Requiring intervention (47 patients)
- Wound dehiscence (42 patients)
- Postoperative acidosis (34 patients)
- Reoperation during this admission (unplanned reoperation) (34 patients)
- Cardiac failure (severe cardiac dysfunction) (30 patients)
- Pulmonary hypertensive crisis (PA pressure > systemic pressure) (27 patients)
- Seizure (26 patients)
- Systemic vein obstruction (25 patients)

- Postoperative/Postprocedural respiratory insufficiency requiring reintubation (21 patients)
- Unplanned cardiac reoperation during the postoperative or postprocedural time period, exclusive of reoperation for bleeding (21 patients)
- Wound infection Mediastinitis (20 patients)
- Vocal cord dysfunction (possible recurrent laryngeal nerve injury) (19 patients)
- Neurological deficit, Neurological deficit persisting at discharge (19 patients)
- Pulmonary hypertension (15 patients)
- Unplanned interventional cardiovascular catheterization procedure during the postoperative or postprocedural time period (14 patients)
- Wound dehiscence (sterile), Median sternotomy (13 patients)
- Multi-System Organ Failure (MSOF) = Multi-Organ Dysfunction Syndrome (MODS) (12 patients)
- Renal failure - acute renal failure, Acute renal failure requiring dialysis at the time of hospital discharge (11 patients)
- Renal failure - acute renal failure, Acute renal failure requiring temporary hemofiltration with the need for dialysis not present at hospital discharge (10 patients)
- Wound dehiscence (sterile) (10 patients)
- Other operative/procedural complication (10 patients)
- Arrhythmia requiring electrical cardioversion or defibrillation (9 patients)
- Unplanned non-cardiac reoperation during the postoperative or postprocedural time period (8 patients)
- Unplanned readmission to the hospital within 30 days of surgery or intervention (7 patients)
- Wound infection Deep wound infection (7 patients)
- Neurological deficit, Transient neurological deficit not present at discharge (6 patients)
- Respiratory failure, Requiring tracheostomy (6 patients)
- Intraoperative death or intraoperative death (5 patients)
- Stroke (4 patients)
- Arrhythmia necessitating pacemaker, Permanent pacemaker (3 patients)
- Endocarditis postprocedural infective endocarditis (2 patients)
- Intraoperative death (1 patients)

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Do you have a question on database reports?

Are you interested in a specific report?

Contact us at dbnewsletter@echsa.org

We would be very pleased to hear from you!

THE ECHSA CHSD IN CHINA

The ECHSA CHSD is based in Europe as a worldwide Database, open for every country. Since 2006, Chinese centers have been taking part in the ECHSA CHSD. Currently, 13 centers from China are registered. Hence, the dataset includes a large amount of data from both Europe and China. This was a good reason to start the European-China project and compare patterns of practice and outcomes in Europe and China.

In regard to the European-China project, Prof. Bohdan Maruszewski (ECHSA CHSD Director and Chair) and Dr. Claudia Herbst (ECHSA CHSD Committee member and European-China Project leader) travelled to China to meet the cooperation partners in Shanghai and attend the 19th Annual Scientific Meeting of the Chinese Society for Thoracic and Cardiovascular Surgery in Wuhan.



In comparison, Europe has an area of about 10.2 Mio km² and China has about 9.6 Mio km². There are about 743 Mio people living in Europe, and about 1.4 Billion people living in China. Thus, in China, twice as many people live in almost the same area. In 2013, China announced the decision to relax the one-child policy. Under the new policy, families could have two children if one parent, rather than both parents, was an only child. The average fertility rate - the number of children a woman is expected to have in her reproductive age - is now 1.6 in China. In Europe this, number varies in different countries; from 2.08 in Turkey, to 1.34 in Spain, as an example. There is a total number of around 5 Mio live births per year in Europe and 15 Mio live births per year in China. Consequently, the number of children born with a Congenital Heart Defect is 40.000 per year in Europe versus 120.000 per year in China. (See an overview in Table 1)



	Europe	China
Area	10 180 000 km ²	9 597 000 km ²
Population	742 913 210	1 386 000 000
Live births/year	5 000 000	15 000 000
CHD/year	40 000	120 000

Table 1. Comparison of Europe and China



The Shanghai Children's Heart Center is part of the Shanghai Children's Medical Center. It is on top of the biggest congenital heart centers in China with a performance of more than 3500 operations per year. It is the only National Post-course Training Center for Pediatric CHD in China.

Overview of the Shanghai Children's Heart Center

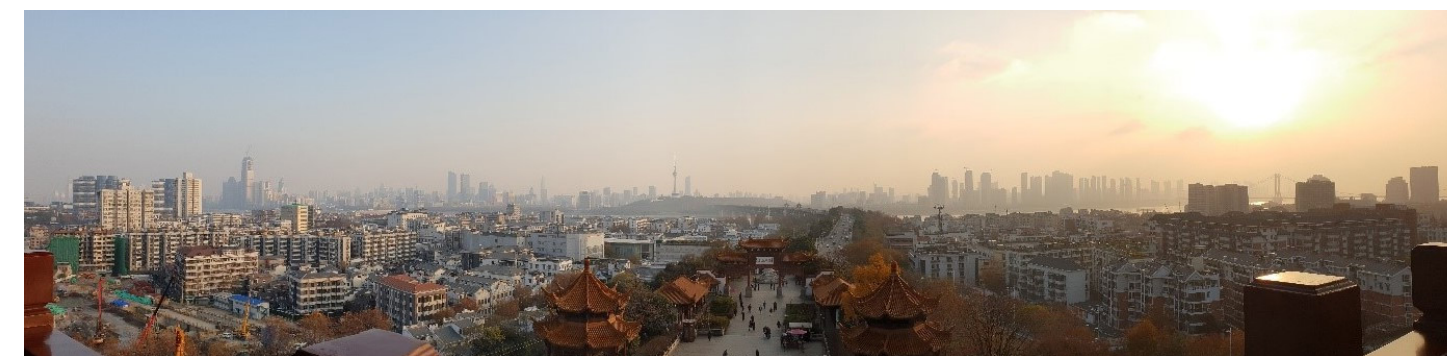
- 105 beds (general ward)
- 50 beds (CICU)
- 6 Operation Suits
- 6 Surgeon Teams
- 7 Perfusionists/3 Technicians
- CICU 11 Doctors/100 Nurses



Prof. Maruszewski and Dr. Herbst in front of the Outpatients Clinic Board



Shanghai Skyline



Wuhan Skyline



19th Annual Scientific Meeting Of The Chinese Society For Thoracic And Cardiovascular Surgery In Wuhan

The 19th Annual Scientific Meeting of the Chinese Society for Thoracic and Cardiovascular Surgery in Wuhan was an exchange of professional knowledge.

Three talks about the usage of the ECHSA CHSD were held:



December 20th, 2019
 Bohdan Maruszewski, ECHSA CHSD Director
 Modern outcome analysis in congenital heart surgery. The ECHSA congenital database



December 20th, 2019
 Jimei Chen, Guangdong Provincial People's Hospital
 Quality of care for adult congenital heart surgery operations: ten years of experience from a single center in China



December 21st 2019
 Haibo Zhang, Shanghai's Children's Medical Center
 The comparison of ten benchmark procedures between European and Chinese centers from the ECHSA Database

DATABASE STUDIES - EARLY DATABASE PUBLICATIONS

Claudia Herbst, MD

25 years after the initiation of congenital databases the idea of the congenital database is still the same. As written in "Virtues of a world-wide congenital heart surgery database" by Mavroudis et al. in 2002¹, it is a tool for a congenital heart center to:

- accomplish programmatic evaluation
- monitor clinical outcomes
- comply with governmental requirements
- perform retrospective and prospective clinical studies
- participate in local, national, and global improvement strategies
- assess residency/fellowship programs
- use for resource allocation
- show major therapeutic trends
- show manpower issues
- deliver accurate information



Databases are meant to be a tool for self-control of a congenital heart center.

¹Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu. 2002;5:126-31. Virtues of a worldwide congenital heart surgery database. Mavroudis C, Gevitz M, Elliott MJ, Jacobs JP, Gold JP.

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, con-



sistency, 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 Database 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.

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 ✓ <i>u 27</i>
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
Diagnosis 1. TOF (prio. 1) 2. Pulmonary insufficiency (prio. 2) ✓	Diagnosis 1. VSD, Multiple (prio. 1) 2. PFO (prio. 2) 3. Patent ductus arteriosus (prio. 3) 4. Miscellaneous, Other (prio. 4) ✓	Diagnosis 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 (x)	Is correct (✓) / Is not correct (x)	Is correct (✓) / Is not correct (x)
	<i>AV-PA Conduit</i>	

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



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

www.echsacongenitaldb.org

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:



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%	1,10%
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%

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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		p-value
	Before verification		After verification		
	Mean	Std Dev	Mean	Std Dev	
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		p-value
	Before verification		After verification		
	No of deaths	Mortality (%)	No of deaths	Mortality (%)	
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.

ANNOUNCEMENT

ECHSA Symposium, Warsaw, Poland, June 17-20, 2020

The highlights of the meeting will be as follows:

- The Critical Aortic Stenosis from the foetus until childhood
- Postgraduate training in Congenital Heart Surgery
- The Quality Assurance in Congenital Heart Surgery - 25th Anniversary of ECHSA-CHSD



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

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