ECHSA
CONGENITAL DATABASE

NEWSLETTER

No.1 – September 2019

## The ECHSA-Congenital Heart Surgery Database is launching a Newsletter FOR YOU

Quarterly, we will provide you with news, facts and information from the ECHSA-CHSD.

*In this issue, read about:*

- *Background information*
- *Hot topics*
- *Reports on Congenital Heart Surgery*
- *Interesting Database studies*
- *Quality assurance in Congenital Heart Surgery*
- *Quality management in Congenital Heart Surgery*
- *Pediatric and Congenital Cardiac Care*
- *Diamonds for Database users*

## ECHSA CONGENITAL DATABASE HISTORY

*Bohdan Maruszewski, MD, PhD, and George Sarris, MD*


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.

Such data collection should allow risk stratification and help define optimal surgical treatment strategies for certain subsets of patients exposed to incremental mortality and morbidity risk factors. We are convinced that study of the wealth of information collected in the Database will also contribute towards improved early and late survival as well as in enhanced quality of life of surgically treated patients with Congenital Heart Disease across Europe and the world.

A further goal of data collection is to enable predictive statistical analysis and comparison of results according to pathologies and procedures from various centers and countries, helping to define official European standards available for the scientific community, health care organizations, legal assistance, and public information.

The *European Congenital Heart Surgeons Foundation (ECHSF)*, which was established in 1992 and renamed as the ***European Congenital Heart Surgeons Association (ECHSA)*** in 2003, created the *European Congenital Heart Defects Database (ECHDD)* in ***1994***, the precursor of today's ***ECHSA Congenital Database***.

The ECHDD was supervised by Martin Elliott, based at the Great Ormond Street Hospital For Sick Children, London, UK. In the year 2000, for legal and logistical reasons, the ECHDD was moved to the Department of Pediatric Cardiothoracic Surgery, Children's Memorial Health Institute, in Warsaw, Poland, under the responsibility of Bohdan Maruszewski.

**In September 1999**, during the EACTS Annual Meeting in Glasgow, a decision was made that the ECHDD, which, as noted above, had been created, owned and run by ECHSF, ECHSA's precursor, would be supported partially by EACTS, and that the ECHDD would be renamed as the EACTS Congenital Database. During its subsequent development under the leadership of Bohdan Maruszewski, the Database was co-financed by the EACTS and ECHSA until the year 2008. Since then, the database has been developed and financed solely by ECHSA.

Concurrently, an *International Nomenclature for Congenital Heart Surgery* was officially adopted; this was the outcome of one year's work of the International Nomenclature and Database Committees for Congenital Heart Disease of both EACTS and the Society of Thoracic Surgeons (STS) in the USA, led by B. Maruszewski representing ECHSA and the EACTS, and C. Mavroudis representing the STS. Over the course of eight meetings at several venues on both sides of the Atlantic, in 1998 and 1999, the International Nomenclature and Database Committee met with 36 experts from the memberships of the EACTS, ECHSA, STS, AATS, AHA and associated surgeons, cardiologists and cardiac pathologists from the United States, Canada, Australia and Europe. These efforts resulted in the creation of the *International Nomenclature for Congenital Heart Surgery*, including the Minimum Data Set and the lists of Diagnoses, Procedures, Complications, as well as extra cardiac anomalies and preoperative risk factors encoded in the Database.

The risk stratification project, which has always been one of the major goals of collecting congenital heart surgery (CHS) outcomes data, was initiated in 2000 by Francois Lacour-Gayet and resulted in establishing the Aristotle Basic and Comprehensive Scores. Both risk scales were used by many surgeons and centers across the world to predict the risk of surgical operations and to evaluate their outcomes, compared to the others. The Aristotle Score and categories have been on the subjective opinions of experts. Further research efforts concentrated on developing an objective, empirically based index that can be used to identify the statistically estimated risk of in-hospital mortality by procedure, and to group procedures into risk categories. These efforts resulted in creation of the STAT risk score, which was based on empirically delivered outcomes from both the STS and the ECHSA Databases. Additionally, the Morbidity score has been developed by Marshall L. Jacobs, based on STS Congenital Heart Surgery data. All three risk adjustment scales are used in the ECHSA Congenital Database for comparing mortality and morbidity outcomes across institutions and surgeons having different case mixes.

In 2015, for legal and financial reasons, the Database, which has always been owned by ECHSA and seated in Warsaw since 2000, reverted back to exclusive management by ECHSA under the name ***ECHSA Congenital Database*** (*https://www.echsacongenitaldb.org/*), under the responsibility of the *ECHSA Database Committee*.

The ECHSA Database Committee's leadership includes the Chair, the Director, and the Technical Director, as well as other ECHSA Members and representatives of the STS National Database and other Scientific Associations. During the recently completed very successful tenure of the Committee's first Chair, Professor Tjark Ebels, the Database has been translated to many languages and has achieved a truly global outlook. Professor Bohdan Maruszewski, who has served as the Database Director from the beginning, has now also assumed the Chairmanship of the Committee, continuing the remarkable efforts of Database development with new, user – friendly and extremely powerful online tools, international cooperation initiatives, and production of major scientific publications, all supported at the Database's seat in Warsaw, under the continued information technology support of Dr. Zdzislaw Tobota, the Database Technical director. The Database Committee also includes selected ECHSA Members as well as representatives of other Scientific Societies, notably the STS, represented by Dr. Jeff Jacobs. In fact, in cooperation with the STS Congenital Database, many landmark publications have been produced, and more are underway.



It should be emphasized that the Database is supported by ECHSA to serve its Members and its Data Contributors, to which ECHSA is more than grateful. The Data, resources, and facilities of the Database are available for use to achieve worthy clinical research projects, which may be proposed by any Member, an activity which is highly recommended and encouraged by the ECHSA Leadership!

Currently, two very important international scientific projects have been initiated, with the aim of comparison of the patterns of practices and outcomes in Congenital Heart Surgery between China versus Europe and Japan versus Europe. The data used for these purposes are those submitted by major Chinese centers to the ECHSA Congenital Database. The "Japanese" project uses data from the Japanese Congenital Heart Surgery Database, which has been very successfully established by Japanese colleagues using the same international nomenclature for CHS as the STS and ECHSA registries.

Until September 2019, data on almost 300,000 procedures have been collected from 194 centers and 52 countries around the globe, including data on over 51,000 neonatal and 100,000 infant CHS surgical procedures.

The database functions allow users to create of on-line reports on subgroups of patients and procedures selected according to various user-defined criteria!

The ECHSA Database Verification project was initiated in the year 2004. All-together, 118 site visits have been performed which resulted in having verified approximately 15% (37,699) of collected data. Importantly, this experience has proven that no statistically significant difference exists between verified versus non-verified data, a testament to the quality of the overall data.

Numerous database research projects have resulted in over 50 scientific publications based on the ECHSA Congenital Database data.

Next year, we will celebrate ***25 years or a quarter of the century*** of huge efforts by the community of European Congenital Heart Surgeons, led by ECHSA, that have resulted in the creation of the most modern and comprehensive tool for evaluation and improvement of the outcomes of surgical treatment of children with Congenital Heart Defects, the **ECHSA Congenital Database**. These pioneering contributors, and, most importantly, the children and adult patients with congenital heart disease around the world, surely deserve that these efforts are to be vigorously and devotedly continued!

## CORE REQUIREMENTS OF A DATABASE

*by Claudia Herbst, MD*

*"...One of our responsibilities as physicians caring for patients with Congenital Heart Disease is to know the results of the treatment that we recommend..." W.G.Williams*


If we want to know the results of a treatment, a benchmark system may be the best to do so. Databases have been developed for quality assurance and to benchmark procedures and centers. The ECHSA Congenital Heart Surgery Database was established in 1999. Since then, constant improvement in hardware, software and the dataset is realized. Barach et al. describes seven essential elements that a database should incorporate for a meaningful analysis of outcomes.[1] In the following, these elements will be discussed in regard to the ECHSA-CHSD.

**1) Common Language And Nomenclature**

The ECHSA-CHSD uses the common medical language English. Hence, it is feasible to manage the data entry for every academic English-speaking person. Furthermore, a translation of the data collection software and the website, for analysis and creating reports, was done into ten languages (*Tab. 1, Fig. 1a and Fig. 1b*). This as well, helps for scientific writing to use or check for correct terms.

**2) Uniform Core Dataset**

The main objective in the ECHSA-CHSD core dataset is the patient with personal data and diagnosis (*Fig. 2*). Each admission follows a structure guiding through the patient's hospital stay. This includes procedures (with extended dataset for operative variables) and complications. As well as general preoperative risk factors (GPRF) and anesthesia adverse events (AAE) may be added.

**3) Mechanism For Evaluating Case Complexity**

In 2002, the Aristotle Score[2] was developed based on the consensus of a panel of experts and implemented as complexity score in the ECHSA-CHSD. In 2010, the STAT Score3 was developed by complexity stratification and added to evaluate complexity of procedures, as well to the STS Congenital Database and the ECHSA-CHSD. Both scores can be calculated optionally by the user.

**4) Assure And Verify The Completeness And Accuracy Of The Data Collected**

Two systems for the proof of accuracy of the data exist in the ECHSA-CHSD. The validation ensures internal integrity by finding inconsistencies, according to predefined validation rules which are logical constructions of the modeled reality (*Fig. 3*). The verification is an external audit where the collected data in the database is compared with another source of information for correctness and completeness.


*Figure 1a. How to choose a language on the website*

| ECHSA-CHDB languages |
|---|
| Chinese |
| Dutch |
| English |
| French |
| German |
| Italian |
| Polish |
| Portuguese |
| Russian |
| Spanish |
| Turkish |

*Table 1. ECHSA-CHDB languages*

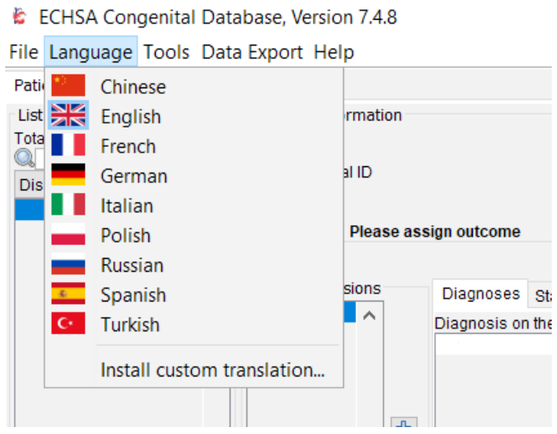


*Figure 1b. How to choose a language in the database software*



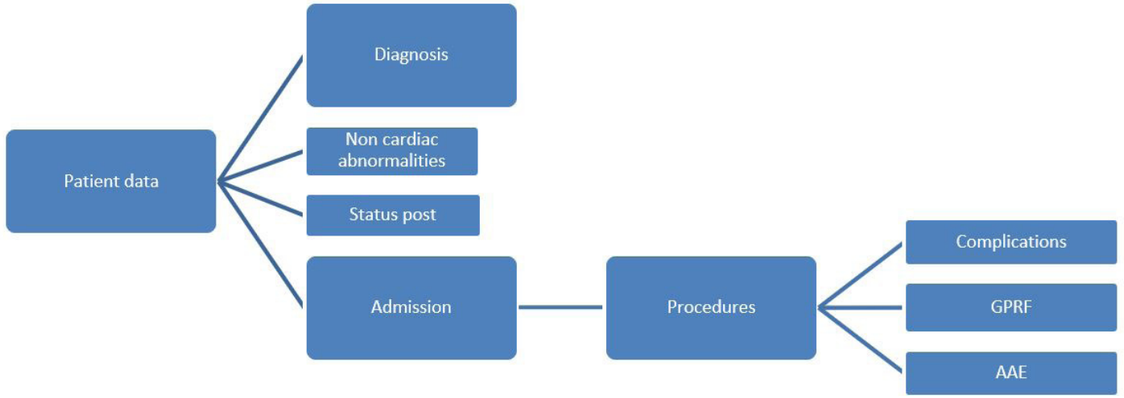


*Figure 2. ECHSA-CHSD core dataset*


*Figure 3. ECHSA-CHSD validation process*

**5) Collaboration Between Medical, Surgical And Research Subspecialties**

Congenital Heart Surgery is a field of collaboration. Hence, in regard of the database it is something natural. For entering data to a respective dataset, variables from all involved entities (e.g., cardiology, surgery, ICU, anesthesia) are needed. The ECHSA-CHSD plans to incorporate a cardiology interventional tool to the existing dataset in near future. Thus, the collaboration between cardiology and surgery will be further encouraged. Beside surgeons, cardiologists are Associate Members of the Database Board. Researchers and statisticians are included, and their projects supported. This collaboration leads to benefit for the patient (***Fig. 4***).

**6) Standardization Of Data Collection Protocol**

The data collection is entrusted to the database users. Though, support from the ECHSA-CHSD is provided. As well as a data collection protocol is available on request.

**7) Strategies For Quality Assessment And Quality Improvement**

The ECHSA-CHSD offers support for database users on request for collaboration between centers and quality improvement. Further, benchmark database studies are conducted for optimization of congenital cardiac care.

In summary, the ECHSA-CHSD incorporates all core requirements of a database. Equipped with the newest technology in hardware and software and a top up-to-date security system, it offers the highest standard available today. A new way of loading reports with an asynchronous request saves time when showing the results of the reports in a user-friendly way.

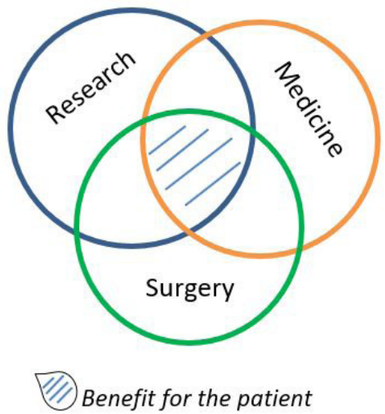


*Figure 4. Benefit of collaboration for the patient*

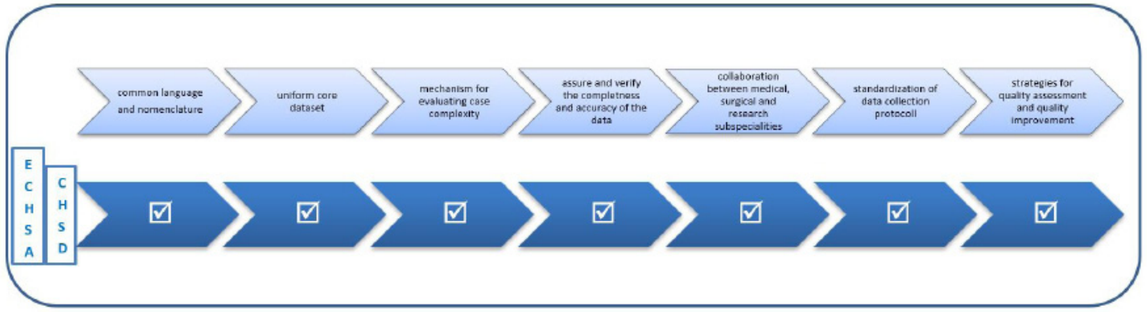


*Figure 1. Core requirements of a database[1] fulfilled by the ECHSA-CHSD*

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## COLLABORATION BETWEEN THE SOCIETY OF THORACIC SURGEONS CONGENITAL HEART SURGERY DATABASE (STS-CHSD) AND THE EUROPEAN CONGENITAL HEART SURGEONS ASSOCIATION CONGENITAL HEART SURGERY DATABASE (ECHSA-CHSD)

*by Jeffrey P. Jacobs, MD and Bohdan Maruszewski, MD, PhD*

Collaboration efforts between The Society of Thoracic Surgeons Congenital Heart Surgery Database (STS-CHSD) and The European Congenital Heart Surgeons Association Congenital Heart Surgery Database (ECHSA-CHSD) have spanned the past 2 decades and resulted in multiple scientific publications.[1-141]

These collaborative initiatives have advanced the art and science of pediatric and congenital cardiac surgical outcomes analysis in multiple domains:

- Nomenclature [1-35,43-47,50,62,64,65,70,111,116-119,122,124,126,138,140]
- Databases [3,35-38,40-42,48,52,53,59,60,63,67,68,71,72,108-110,112,113,123,127,129-132,134,135,137,139]
- Risk Stratification [39,49,51,54-56,61,66,69,73,74,106,107,120,121,125,128,133,136]
- Data Verification[57,58,141]
- Subspecialty Collaboration[75-105,114,115]

Perhaps the earliest collaborative initiative between ECHSA and STS was The International Congenital Heart Surgery Nomenclature and Database Project, which began in 1998 and was published in April 2000 as a Supplement to The Annals of Thoracic Surgery.1-34 This 372-page freestanding supplement to The Annals of Thoracic Surgery was a joint collaborative effort of members of multiple societies including STS and ECHSA. The nomenclature described by The International Congenital Heart Surgery Nomenclature and Database Project was then combined with the European Paediatric Cardiac Code and resulted in the creation of The International Pediatric and Congenital Cardiac Code (IPCCC).[43-47,50] The IPCCC is a system of nomenclature that is now used by all major database in the world devoted to pediatric and congenital cardiac care. The IPCCC was developed and is maintained by The International Society for Nomenclature of Paediatric and Congenital Heart Disease (ISNPCHD).[43-47,50,62,64,65,70,111,116-119,122,124,126,138,140] Members of STS and ECHSA are very active in the leadership of ISNPCHD. Several manuscripts have been published by ISNPCHD to clarify the nomenclature of challenging congenital cardiac malformations, including functionally univentricular heart,[62] hypoplastic left heart syndrome,[64] discordant atrioventricular connections and congenitally corrected transposition,[65] and heterotaxy.[70] Under the leadership of ISNPCHD and in collaboration with The World Health Organization (WHO), IPCCC will be the congenital and pediatric cardiac nomenclature of the eleventh version of the International Classification of Diseases (ICD-11); this accomplishment is significant because for the first time, the clinical and administrative nomenclature of pediatric and congenital cardiac care will be harmonized.[138,140]

ECHSA and STS have also collaborated to create the standards and definitions for databases for pediatric and congenital cardiac surgery. Collaborative initiatives involving STS and ECHSA have standardized definitions for mortality[63,123] and morbidity.[68,72] Indeed, the nomenclature and database standards in STS CHSD and ECHSA CHSD are identical and have been identical since 2000.

ECHSA and STS have also collaborated to develop tools for risk stratification of patients undergoing pediatric and congenital cardiac surgery.[39,49,51,54-56,61,66,69,73,74,106,107,120,125] These collaborations started with the development of the Aristotle Complexity Score[39,49,51,54-56,61,66,69,73,74,106,125] and matured with the development of the STAT Mortality Score and STAT Mortality Categories.[107,120,125] The Aristotle Complexity Score was developed by multiple leaders in ECHSA and STS and was were introduced into STS CHSD and ECHSA CHSD in 2002. The Aristotle Complexity Score is a measure of procedural complexity based on the potential for mortality, the potential for potential, and the technical difficulty of an operation. In 2010, the STAT Mortality Score and STAT Mortality Categories were introduced into STS CHSD and ECHSA CHSD. The STAT Mortality Categories are an empirically derived methodology of risk stratification based on statistical estimation of the risk of mortality from an analysis of objective data from STS CHSD and ECHSA CHSD. The STAT Mortality Score and STAT Mortality Categories were developed based on analysis of 77,294 operations entered in the STS CHSD and ECHSA CHSD (ECHSA CHSD provided 33,360 operations and STS CHSD provided 43,934 operations).[107] Procedure-specific mortality rate estimates were calculated using a Bayesian model that adjusted for small denominators.[107] Operations were sorted by increasing risk and grouped into 5 categories that were designed to minimize within-category variation and maximize between-category variation.[107] Both the Aristotle Complexity Score and the STAT Mortality Score and STAT Mortality Categories represent important collaborative initiatives of ECHSA and STS.

ECHSA and STS have also collaborated to develop tools for verification of the completeness and accuracy of data in their databases.[57,58,141] STS CHSD[141] and ECHSA CHSD[57,58] both utilize intrinsic data verification (designed to identify and correct missing and out of range values and inconsistencies across fields). STS CHSD and ECHSA CHSD also both utilize sophisticated audit programs designed to verify the completeness and accuracy of data through source data verification using hospital medical records. Both ECHSA CHSD[57,58] and STS CHSD[141] have published the results of these audits and documented that the data quality is quite good in both ECHSA CHSD and STS CHSD.

Finally, leaders from ECHSA and STS have actively participated in efforts to foster subspecialty collaboration involving all professionals providing pediatric and congenital cardiac care in multiple domains including surgery, cardiology, anesthesia, critical care, nursing, perfusion, respiratory therapy, patient and family advocacy groups, and all others involved in pediatric and congenital cardiac care. The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease exemplifies this collaboration. Multiple members of ECHSA and STS have been actively involved in The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, which has held twelve annual retreats, each lasting one or two days, in 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, and 2018. Leaders from ECHSA and STS have made important contributions to this initiative and have participated in the generation of multiple publica-

tions designed to facilitate subspecialty collaboration involving all professionals providing pediatric and congenital cardiac care.[75-105] In December 2008, The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease published a 530-page freestanding supplement to Cardiology in the Young entitled: "Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease". This supplement to Cardiology in the Young provided a framework for collaboration amongst the various subspecialties providing pediatric and congenital cardiac care.

In the final analysis, collaboration between ECHSA CHSD and STS CHSD has advanced the art and science of nomenclature, databases, risk stratification, data verification, and subspecialty collaboration. It is a fact that collaboration between STS and ECHSA has spanned 2 decades and had certainly improved pediatric and congenital cardiac care.

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## HOW TO CODE

*by Claudia Herbst, MD*

In this section, we would like to picture a specific diagnosis group or procedure group to make coding more transparent for you.

***In this issue:***
***Tetralogy Of Fallot***

**Diagnostic Codes**

Hearts with Tetralogy of Fallot will always have a ventricular septal defect with an aortic override, a narrowing or atresia of the pulmonary outflow, and most often right ventricular hypertrophy.

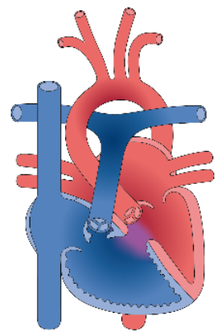


**Illustration taken from http://www.chd-diagrams.com*

In a more precise anatomic description, Tetralogy of Fallot is defined as a group of malformations with biventricular atrioventricular alignments or connections characterized by anterosuperior deviation of the conal or outlet septum or its fibrous remnant, narrowing or atresia of the pulmonary outflow, a ventricular septal defect of the malalignment type, and biventricular origin of the aorta.

The code for Tetralogy of Fallot is:

- TOF and found under right heart lesions (***Fig. 1***)

There are three more codes for TOF with associated lesions:

- TOF, AVC (AVSD)

Use this diagnosis if the patient has TOF with complete common atrioventricular canal defect. It is a rare variant of common atrioventricular canal defect with the associated conotruncal abnormality of TOF. The anatomy of the endocardial cushion defect is that of Rastelli type C in almost all cases.

- TOF, Absent pulmonary valve

All the morphologic characteristics of Tetralogy of Fallot with the main pulmonary artery feature an atypical valve with rudimentary cusps that lack the anatomical semi-lunar features of normal valve cusps and which functionally do not achieve central coaptation. The physiologic consequence is usually a combination of variable degrees of both stenosis and regurgitation of the pulmonary valve. A developmental accompaniment of this anatomy and physiology is dilatation of the main pulmonary artery and central right and left pulmonary arteries, which, when extreme, is associated with abnormal arborization of lobar and segmental pulmonary artery branches and with compression of the trachea and mainstem bron-

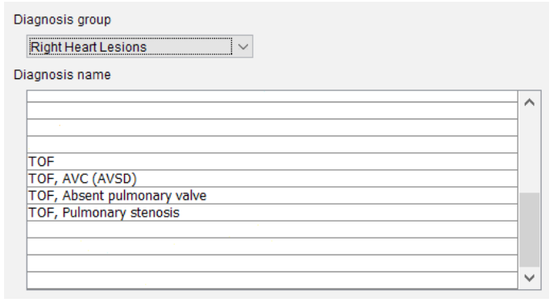



*Figure 1. Coding of Tetralogy of Fallot*

chi. One theory holds that absence of the arterial duct or ductal ligament (which is a nearly constant finding in cases of tetralogy of Fallot with absent pulmonary valve) in combination with pulmonary valve stenosis and regurgitation, comprise the physiologic conditions which predispose to central pulmonary artery dilatation during fetal development. Tetralogy of Fallot with Absent Pulmonary Valve Syndrome is a term frequently used to describe the clinical presentation when it features both circulatory alterations and respiratory distress secondary to airway compression.

- TOF, pulmonary stenosis

Use this diagnosis if the patient has Tetralogy of Fallot combined with pulmonary stenosis.Additional coding for additional lesions:An additional lesion like an atrial septal defect, additional VSD (often muscular), absent or diminutive pulmonary arteries, right aortic arch, left superior vena cava, and coronary artery anomalies must be subspecified as an additional or secondary diagnosis under the primary TOF diagnosis.

Differentiation to

- **Double Outlet Right Ventricle** (DORV) (*Fig. 2*)

DORV which is defined as a type of ventriculoarterial connection in which both great vessels arise predominantly from the right ventricle.

- code: DORV, TOF type

Double outlet right ventricle with an associated subaortic or doubly-committed VSD and pulmonary outflow tract obstruction. Subaortic VSD's are located beneath the aortic valve. Doubly-committed VSDs lie beneath the leaflets of the aortic and pulmonary valves (juxtaarterial). DORV can occur in association with pulmonary atresia, keeping in mind in coding that in the nomenclature developed for DORV, there must be usual atrial arrangements and concordant atrioventricular connections, and normal or near-normal sized ventricles. Discordant atrioventricular connection with DORV is to be coded under congenitally corrected TGA. DORV associated with univentricular atrioventricular connections, atrioventricular valve atresia, or atrial isomerism is to be coded under the appropriate Single ventricle listing.



- **Pulmonary atresia**, which is coded as

- Pulmonary atresia- VSD (Including TOF, PA) (*Fig. 3*)

Pulmonary atresia (PA) and ventricular septal defect (VSD) is a heterogeneous group of congenital cardiac malformations in which there is lack of luminal continuity and absence of blood flow from either ventricle and the pulmonary artery, in a biventricular heart that has an opening or a hole in the interventricular septum (VSD). The malformation forms a spectrum of lesions including Tetralogy of Fallot with pulmonary atresia. Tetralogy of Fallot with PA is a specific type of PAVSD where the intracardiac malformation is more accurately defined (extreme underdevelopment of the RV infundibulum with marked anterior and leftward displacement of the infundibular septum often fused with the anterior wall of the RV resulting in complete obstruction of blood flow into the pulmonary artery and associated with a large outlet, subaortic ventricular septal defect). In the vast majority of cases of PA-VSD the intracardiac anatomy is that of TOF. The pulmonary circulation in PA-VSD is variable in terms of origin of blood flow, presence or absence of native pulmonary arteries, presence or absence of major aortopulmonary collateral arteries (MAPCA(s)), and distal distribution (pulmonary parenchymal segment arborization) abnormalities. Native pulmonary arteries may be present or absent. If MAPCAs are present this code should not be used; instead, Pulmonary atresia, VSD- MAPCA (pseudotruncus) should be used.

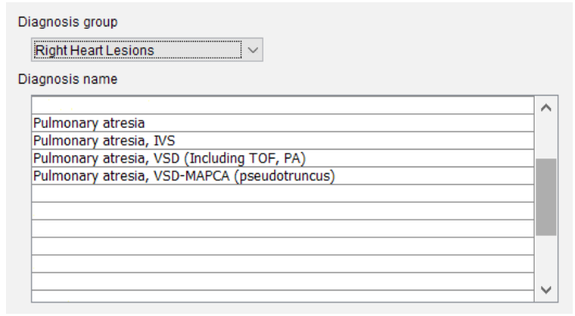



*Figure 3. Coding of Pulmonary Atresia*

**Procedure Codes**

Every diagnosis code has a suitable procedure code with regard to specific surgical techniques (*Fig. 4*).

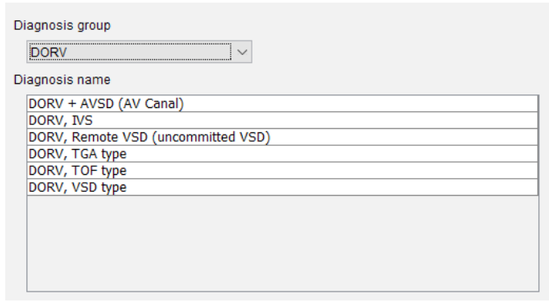



*Figure 2. Coding of Double Outlet Right Ventricle*

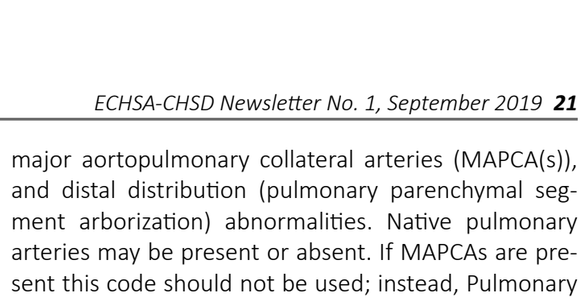



*Figure 4. Coding of TOF Procedures*

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

*by C. Herbst*

Database reports are the main output of a database. The ECHSA-CHSD offers 17 different report forms on a 24-hour online availability. Main features of a graphical or tabular report are structure, presentation and simplicity, to be easily understood at first sight. Tables should be ordered and with a clear layout.

In this issue, some most used reports for the diagnose of Tetralogy of Fallot are shown as an example.

By logging in to the ECHSA Congenital Database website (www.echsacongenitaldb.org), every user can create their customized report of interest (*Fig. 1*). The 17 report forms could be varied by setting filters to the data (***Appendix A***). Hence, the amount of different reports becomes almost uncountable. The available database reports and their frequently usage are shown in *Table 1*.

**Quality of Care Charts** (also known as Bubble Charts) are the most popular graphs. Due to their clear structure and statement, they are frequently used for stakeholder presentations. *Fig. 2* shows a Quality of Care Chart for TOF. On the x-axis, the STS-EACTS (STAT) mortality score is shown versus 30-days mortality on the y-axis. 30-days mortality indicates to the primary procedure. These values could be easily changed to other topics of interest (e.g., number of operations, hospital survival). Horizontal and vertical lines indicate mean values. Each bubble stands for a specific center, and 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.

**Gold Standard Reports** give information about the values (min, max, mean and stddev) in the basic dataset. *Fig. 3* shows a Gold Standard Report for the repair of TOF. These tables are clearly shown and self-explanatory. 30-days mortality indicates to any procedure in this time period. An additional selection allows to analyze the mean values of the "Top Three Centers" for direct benchmarking (*Fig. 4*).

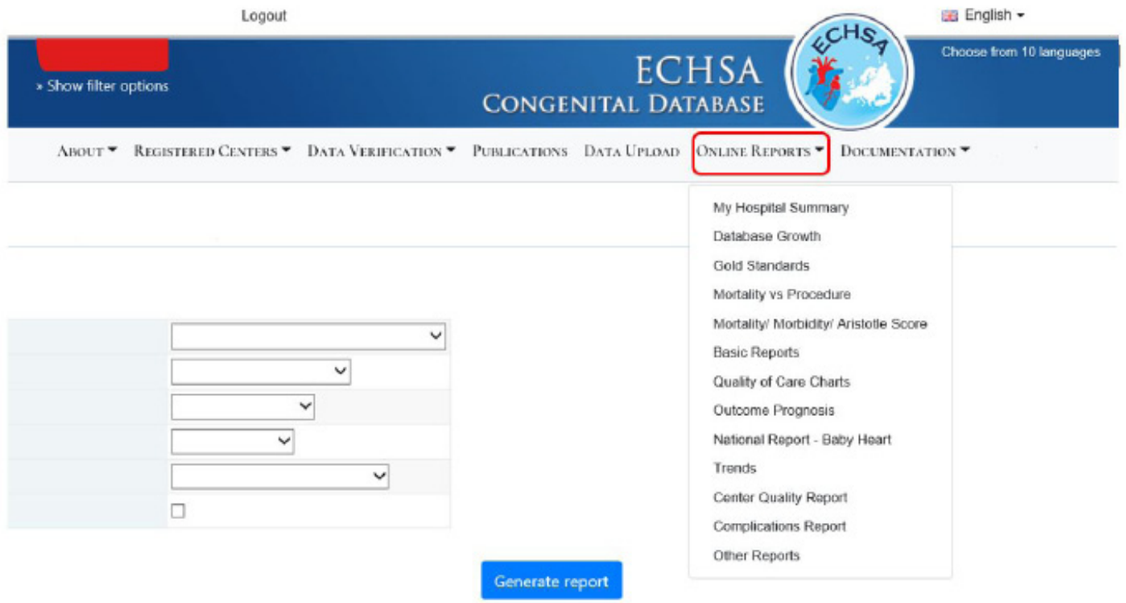



*Figure 1. Menu for Online Reports on the website*



| | Report | Usages | Distict Users |
|---|---|---|---|
| 1 | Quality of Care Chart | 3545 | 78 |
| 2 | Gold Standards | 2165 | 76 |
| 3 | Mortality vs. Procedure | 2012 | 95 |
| 4 | Trends | 1764 | 67 |
| 5 | Primary Report: Number of Procedures by Hospital | 1583 | 91 |
| 6 | Mortality/ Morbidity/ Aristotle Score | 1373 | 80 |
| 7 | Center Quality | 860 | 82 |
| 8 | Primary Report: Mortality by Primary Procedure | 689 | 61 |
| 9 | Primary Report: Number of Patients by Age Group | 632 | 61 |
| 10 | Primary Report: Mortality by Hospital | 620 | 72 |
| 11 | Database Growth | 601 | 90 |
| 12 | Primary Report: Mortality by Case Category | 475 | 54 |
| 13 | Baby Heart | 475 | 65 |
| 14 | Outcome Prognosis | 454 | 49 |
| 15 | Primary Report: Mortality by Primary Diagnosis | 407 | 51 |
| 16 | Complications | 244 | 34 |
| 17 | Primary Report: Patients and Procedures by Continent | 122 | 28 |

*Table 1. Available database reports and their usage*

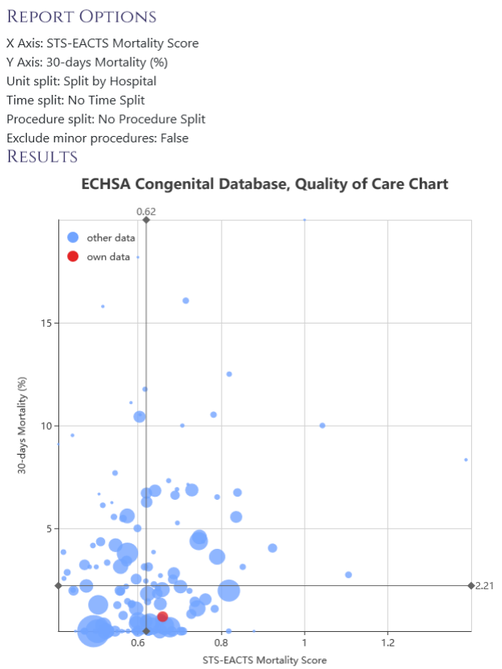



*Figure 2. Quality of Care Chart for TOF*

**Trend Tables** display a trend over time. *Fig. 5* pictures the trend of mean 30-days mortality for TOF repair (any procedure type). When comparing the three main types of TOF-repair, transanular patch, nontransanular patch and RV-PA conduit similarities and dissimilarities become visible. The most frequent used procedure for the repair of a TOF is a ventriculotomy with a transanular patch, but the performing of a nontransanular patch increased over time, while implantation of a RV-PA conduit was stable (*Fig. 6*). Whereas the age of the patients with repair with patch (nontransanular and transanular) was solid, the graph shows a variety of implantation ages for the RV-PA conduit (*Fig. 7*). Since 2012, 30-days mortality for TOF repair with patch (nontransanular or transanular) is below 2%. A varying 30-days mortality rate with spikes for TOF-repair with RV-PA may arouse interest to take a look at the different conduits used over time.

## GOLD STANDARDS REPORT

### DATA FILTER OPTIONS

**Fundamental Diagnoses Only:**

- True

**Diagnoses:**

- (10,05) TOF
- (10,05) TOF, Absent pulmonary valve
- (10,05) TOF, AVC (AVSD)
- (10) TOF, Pulmonary stenosis

**Patients: 20033**
**Operations: 24545**

### RESULTS FOR ALL SELECTED DATA

| | |
|---|---|
| Number of patients | 20033 |
| Number of procedures | 24545 |
| Number of deaths (30 day) | 563 |
| Mortality (30 day) | 2.81% |
| Number of deaths (hospital) | 600 |
| Mortality (hospital) | 3.00% |

| | No of cases | % of all | Min | Mean | Stddev | Max |
|---|---|---|---|---|---|---|
| IPPV (hour) | 16118 | 65.67 | 1 | 64.36 | 165.85 | 6400 |
| CPB time (min) | 20573 | 83.82 | 2 | 117.72 | 56.37 | 749 |
| Aortic X time (min) | 17998 | 73.33 | 1 | 73.02 | 35.71 | 541 |
| Circulatory arrest (min) | 719 | 2.93 | 1 | 32.56 | 20.45 | 100 |
| Weight (kg) | 24335 | 99.14 | 1 | 14.81 | 18.49 | 170 |
| Age at operation (month) | 24545 | 100 | 0 | 54.21 | 113.24 | 903 |
| LOS (day) | 24545 | 100 | 0 | 13.92 | 17.43 | 470 |

*Figure 3. Gold Standard Report for TOF repair*

### SELECT REPORT OPTIONS

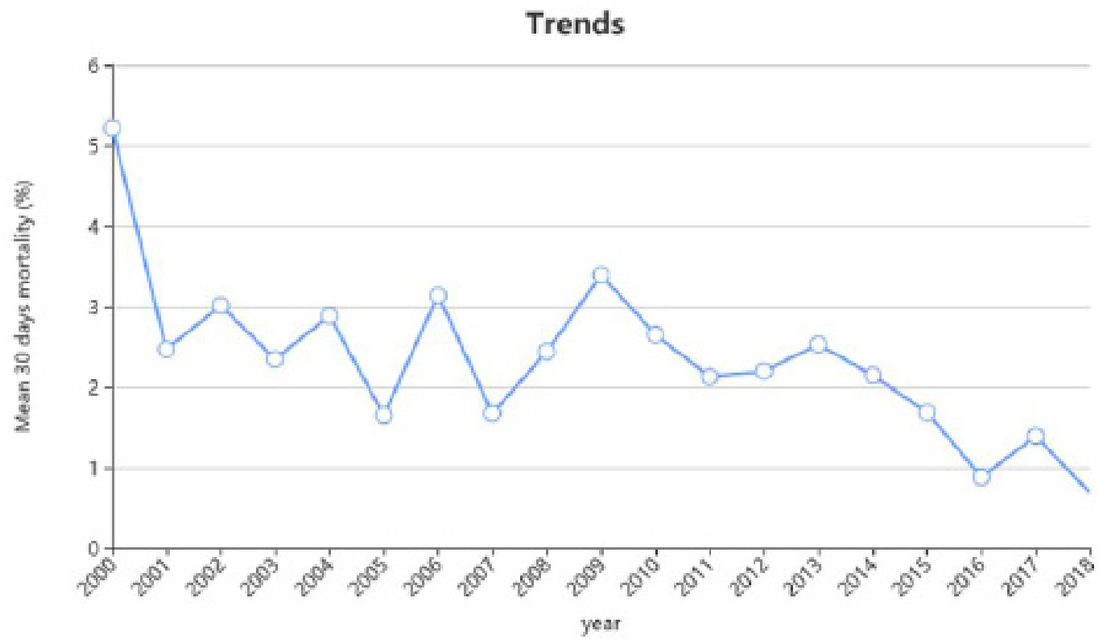
**The Gold Standard Report Can Present The Mean Values For The Top Three Centers According To The Criterion You Choose.**

Please select the criterion for the best hospitals: lowest mortality, shortest LOS or IPPV time, or biggest number of records submitted to the database.

| | |
|---|---|
| Criterion for three best hospitals: | Mortality (hospital) |
| Minimal number of records for three best hospitals: | Mortality (30 day)<br>LOS (day)<br>IPPV (hour)<br>No of cases |

Generate report

*Figure 4. Selection Option for the Top Three Centers*




**Procedures:**

- (10,05) Pulmonary atresia - VSD (including TOF, PA) repair
- (10,05) TOF - Absent pulmonary valve repair
- (10,05) TOF - AVC (AVSD) repair
- (00) TOF repair, NOS
- (10,05) TOF repair, No ventriculotomy
- (10,05) TOF repair, RV-PA conduit
- (10,05) TOF repair, Ventriculotomy, Nontransanular patch
- (10,05) TOF repair, Ventriculotomy, Transanular patch

*Figure 5. Trends in mean 30-days mortality for TOF repair (all procedures)*

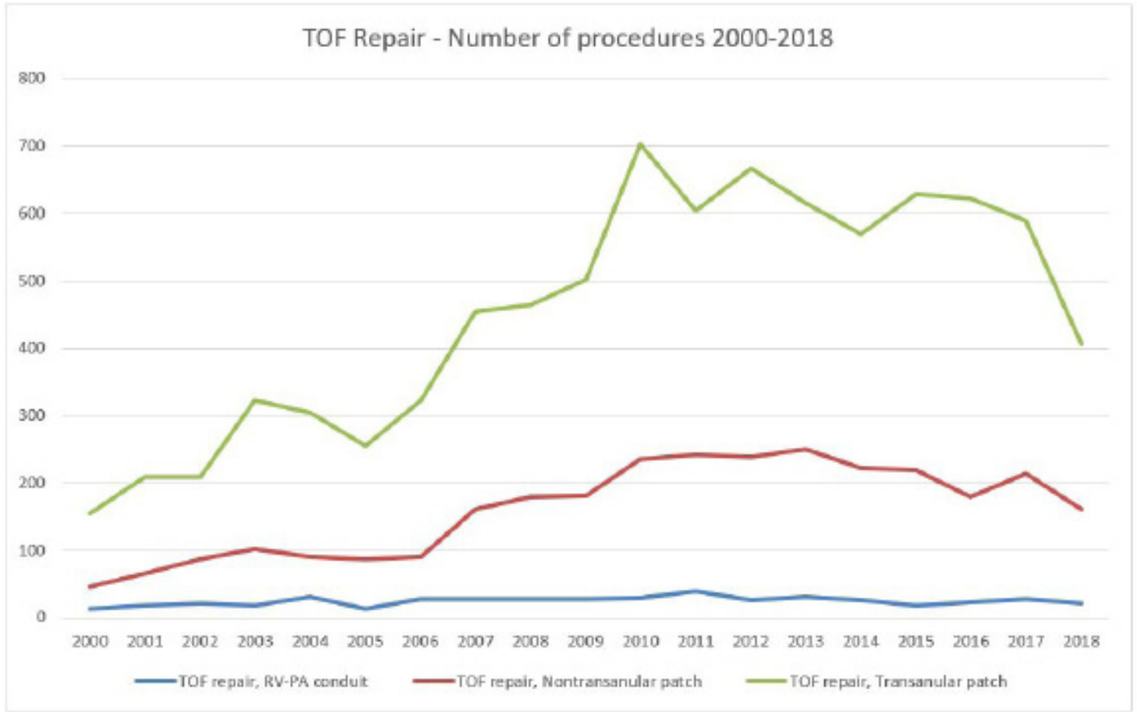



*Figure 6. Trend in TOF repair - number of procedures for the three main types of repair*

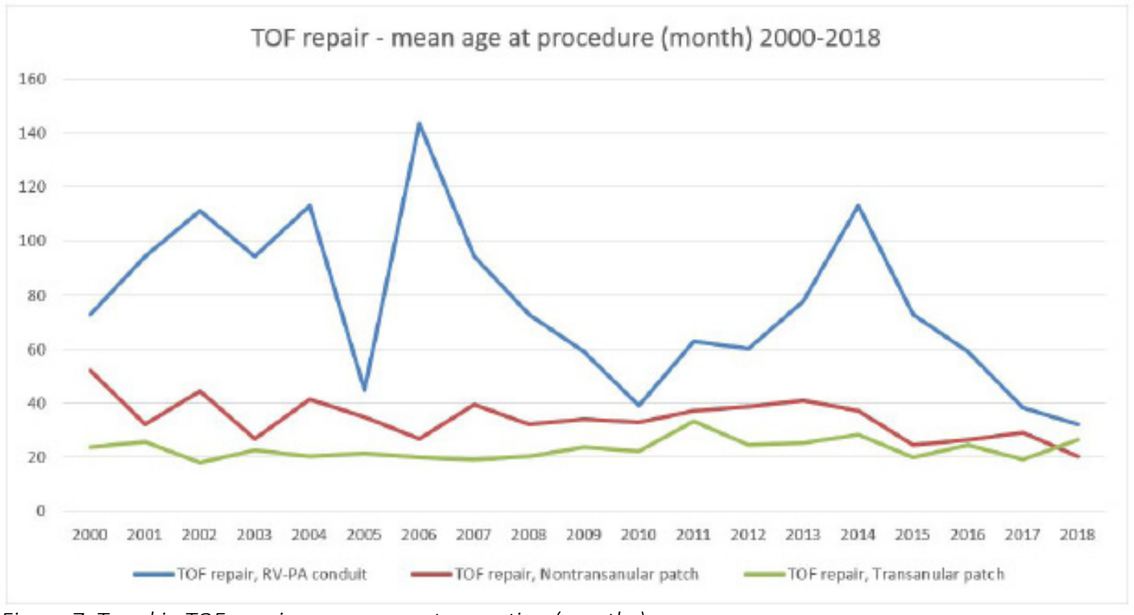



*Figure 7. Trend in TOF repair - mean age at operation (months)*



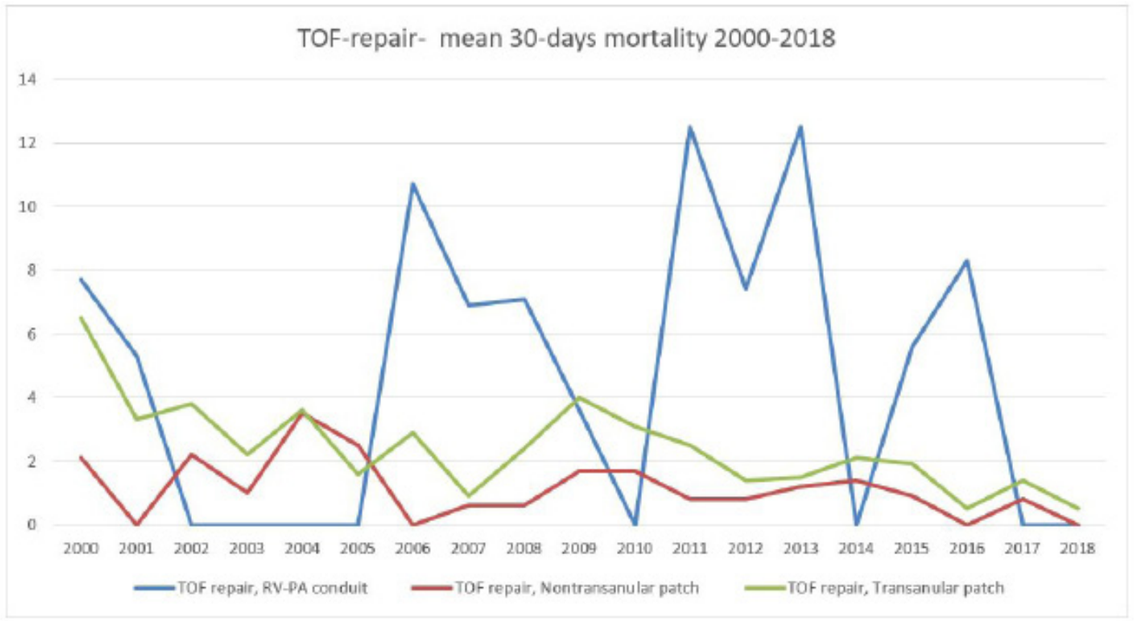
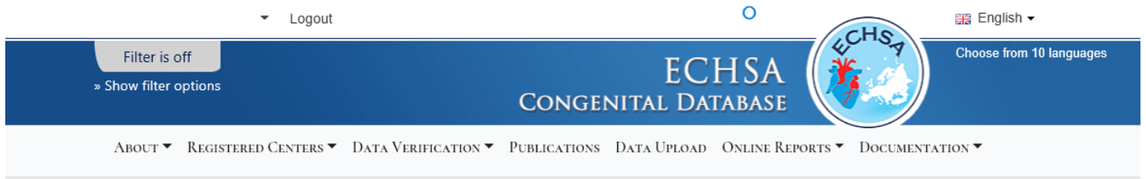



*Figure 8. Trend in TOF repair - mean 30-days mortality*

In conclusion, the pictured graphs and reports give a bit of insight on the possibilities of Database reports. They can be made for every diagnosis, diagnosis group or procedure as required by the Database user.

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!




# Data Selection

## Selection Criteria

**General notice:** Selecting criteria for your query, you may use any combination of the fields available below.

Cancel Apply

**Verified Data Only:**

☐

Mark this option, if you want to use the verified data only.

**Own Data Only:**

☐

Mark this option, if you want to use the data from your unit only.

**National Report:**

☐

Mark this option, if you want to use the data from your country only.

**Select Years:**

☐

Mark this option, if you want to use the data from one or more years.
Unmarked - all years.

**Years:**

2019
2018
2017
2016
2015
2014

**Select Continents:**

☐

Mark this option, if you want to use the data from one or more continents.
Unmarked - all continents.

**Continents:**

Europe
North America
South America
Asia
Africa
Australia and Oceania

**Select Age Groups:**

☐

Mark this option, if you want to use the data of one or more age groups.
Unmarked - all patients.

**Age Groups:**

Neonates
Infants
Children
Adults

**Select Diagnoses:**

☐

Mark this option, if you want to search for the patients with one or more specific diagnoses.
Unmarked - all diagnoses.

**Fundamental Diagnoses Only:**

☐

Mark this option, if you to want to search for diagnoses with priority=1 only.
Unmarked - system will search for diagnoses with all priorities.

**Diagnoses:**

(10,05) Aortic stenosis, Valvar
(10,05) Aortic valve atresia
(10,05) Aortic valve, Other
(10,05) Hypoplastic left heart syndrome (HLHS)
(10,05) LV to aorta tunnel
(10,05) Mitral regurgitation
(10,05) Mitral regurgitation and mitral stenosis
(10,05) Mitral stenosis
(00) Mitral stenosis, NOS
(10,05) Mitral stenosis, Subvalvar

Hold down "Control", or "Command" on a Mac, to select more than one.

**Select Noncardiac Abnormalities:**

☐

Mark this option, if you want to search for the patients with one or more specific NCA.Unmarked - all patients.
Important notice! If you mark this option and do not select any NCA from the list, the system will show the patients without NCA.

**Noncardiac Abnormalities:**

**Anatomic Abnormality**
(10) Anal Atresia (imperforate anus)
(10) Congenital diaphragmatic hernia (CDH)
(10) Gastroschisis
(10) Hirschsprung's disease (Congenital aganglionic megacolon)
(10) Intestinal malrotation
(10) Omphalocele
(10) Tracheoesophageal fistula (TEF)
**Chromosomal Abnormality**
(10) 11p15.5

Hold down "Control", or "Command" on a Mac, to select more than one.

**Select Procedures:**

☐

Mark this option, if you want to search for the patients with one or more specific procedures.
Unmarked - all procedures.

**Primary Procedures Only:**

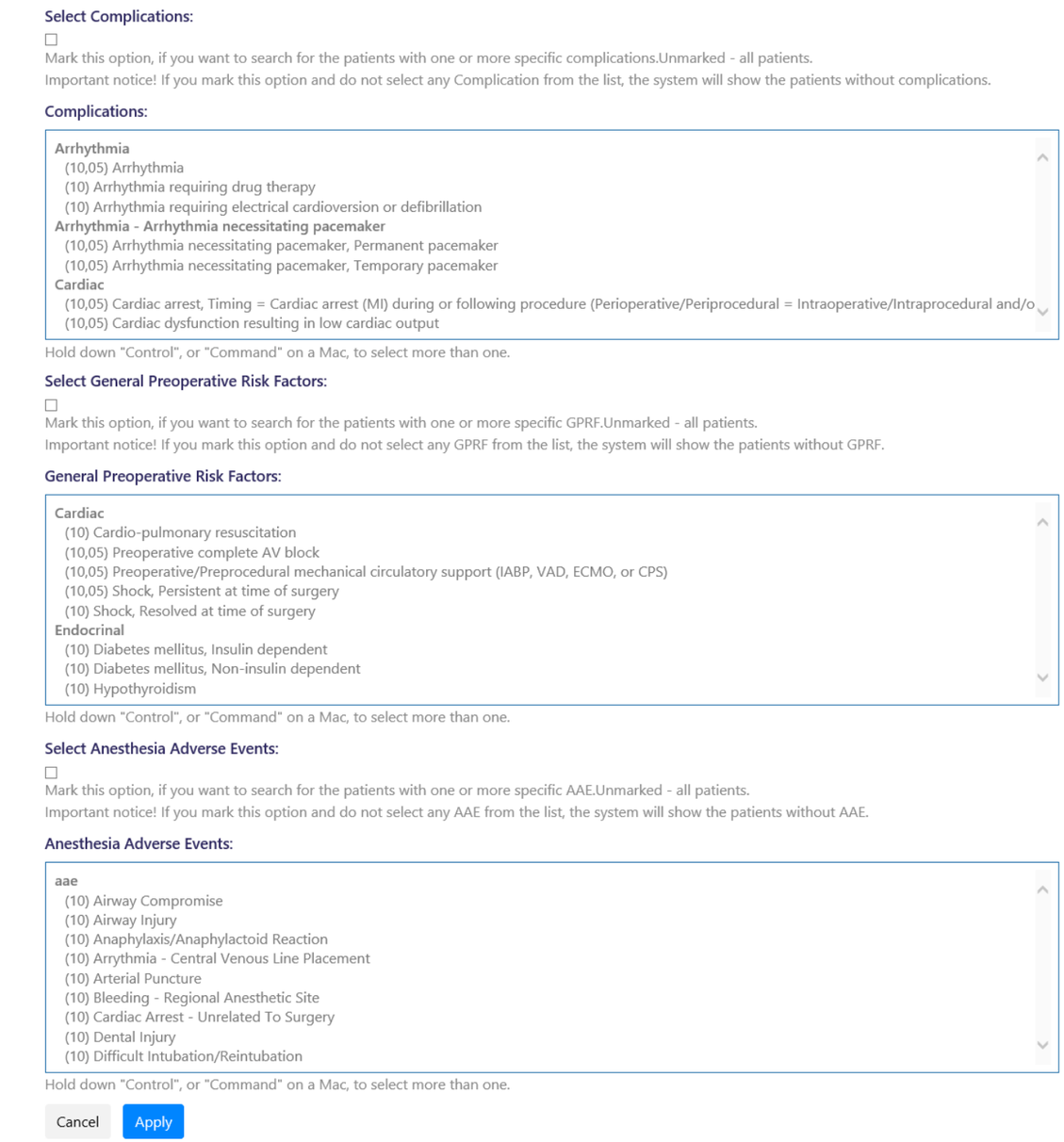
☐

Mark this option, if you want to search for procedures with priority=1 only.
Unmarked - system will search for procedures with all priorities.

**Procedures:**

**Anesthetic procedures**
(10) Echocardiography procedure, Sedated transesophageal echocardiogram
(10) Echocardiography procedure, Sedated transthoracic echocardiogram
(10) Non-cardiovascular, Non-thoracic procedure on cardiac patient with cardiac anesthesia
(10) Radiology procedure on cardiac patient, Cardiac Computerized Axial Tomography (CT Scan)
(10) Radiology procedure on cardiac patient, Cardiac Magnetic Resonance Imaging (MRI)
(10) Radiology procedure on cardiac patient, Diagnostic radiology
(10) Radiology procedure on cardiac patient, Non-Cardiac Computerized Tomography (CT) on cardiac patient
(10) Radiology procedure on cardiac patient, Non-cardiac Magnetic Resonance Imaging (MRI) on cardiac patient
(10) Radiology procedure on cardiac patient, Therapeutic radiology

Hold down "Control", or "Command" on a Mac, to select more than one.




*Appendix A: Selection criteria to set a data filter*



## DATABASE STUDIES

*by Vladimiro Vida, MD, and Claudia Herbst, MD*


Database studies are a fundamental outcome of databases on equal terms to single center and benchmark reports. They are an essential part to improve outcome in congenital cardiac care. For two decades the European Congenital Heart Surgeons Association is very active in collecting data from affiliated centers about their surgical activities. Currently, the ECHSA-CHSD represents one of the two largest datasets, of patients requiring cardiac surgery for their congenital heart disease, worldwide with current about 300,000 procedures available. ECHSA-CHSD studies include the use of anonymized data coming from the ECHSA database. The possibility of extracting data from the ECHSA-CHSD enables the comparison of outcomes on every procedure. For better analysis specific benchmark procedures have been set to get a more precise conclusion. Hence, a comparison between different countries or different continents is possible with the aim of analyzing the quality of care, comparing patterns of practice and globalizing current best standards of care in congenital heart surgery.

**Recent database studies:**

The current dataset includes large amounts of data from both Europe and Asia. Thus, three studies are conducted by the ECHSA-CHSD to compare patterns of practice and outcomes:

- Pediatric Cardiac Surgical Patterns of Practice and Outcomes in Europe and China
- Pediatric Cardiac Surgical Patterns of Practice and Outcomes in Europe and Japan
- ALCAPA Study- an ECHSA/Japanese collaboration
-

Other studies which are very encouraged by the ECHSA are ***Multi-Institutional Studies***.

The goal is to analyze and evaluate the outcome of congenital heart surgery in selected populations of patients and especially in patients requiring surgical treatment of rare congenital heart malformations. Multicenter clinical studies are important research tools. Conducting a multicenter study helps to include a sufficient number of patients who underwent a peculiar type of surgical intervention over a short period of time. The objective is to analyze short and long-term outcomes and compare results among centers. Planning a multicenter clinical study may represents a long and arduous task. Each ECHSA member, who is going to propose a multicenter clinical study, will find the assistance of the ECHSA Research Committee which will discuss the steps to plan the study, will help refine the protocol of the study and the dataset which will be used later on for data collection. Each study needs the approval of the Research committee for scientific accuracy and respect of patient's confidentiality before being distributed between members. The philosophy among collaborators should be consensus and commitment in the team effort to achieve goals that cannot be reached by a single-center effort.

Recent Multi-Institutional Studies can be found under this link: http://www.echsa.org/multi-institutional-studies

Do you have a question about Database studies?
Do you have an idea for a study?
Contact us at dbnewsletter@echsa.org
We would be very pleased to hear from you!

# DATA VERIFICATION IN THE CONTEXT OF THE ECHSA CONGENITAL DATABASE

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

One of the major challenges facing any data collection endeavor is data verification. It is essential to assure the quality of data analysis and the reliability of results which is two-pronged: data completeness and data accuracy. Source Data Verification (SDV) is an evaluation of the conformity of the data submitted to the database with source data.

**Introduction**

Good Clinical Practice (GCP) guidelines provide international ethical and scientific quality standards for the design, conduct, monitoring, auditing, analysis and reporting of clinical research that assure that the data and reported outcomes are credible and accurate. GCP guidelines for performance of high-quality clinical research have been developed nationally and internationally. GCP requires Source Data Verification (SDV) to be undertaken for all studies.

**Source Data Verification (SDV)**

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. Source Data Verification (SDV) is an evaluation of the conformity of the data submitted to the database with source data. In this process, information reported by an investigator is compared with the original records to ensure that it is complete, accurate and valid. The aim of SDV is to ensure that the data collected are reliable, complete and true.
Following internationally accepted rules of data verification the ECHSA Congenital Database (ECHSA-CHSD) management has created and applied the stepwise protocol for control of the data completeness and accuracy.

**Data Validation**

The initial approach to this issue was to create and inbuilt the internal data validation software that has been working quite effectively using predefined data accuracy criteria. Currently four kinds of rules are implemented:

- Mandatory rules: this rule has to be matched for the operation to be valid.
- Helper rules: First, the operation is rejected, but if the center says that this information is correct, operation gets validated. It's used for example to check the extremely overweight or underweight patients.
- Info rules: User is notified about the violated rule, but operation gets validated.
- Silent rules: User doesn't see any information about the problem, but the operation doesn't get validated.

This tool regularly excludes the data lacking internal consistency and/or completeness. For the time period 2004-2009, out of 308,947 collected procedures, 13,328 had been excluded, amounting to 4.31%.

**Organizational rules and time frame of the SDV**

The SDV program in the ECHSA-CHSD was started in 2004 and continues to the present. In the first year, the data of 4 centers were verified, and in the following years, their number fluctuated from 7 to 10 each year.

Every time, 100% of operations from the last year are subject to verification. Depending on the annual number of operations performed in the center, sometimes it is possible to verify operations from the last 2-3 years. For each operation, 12 fields (***Tab. 1***) are verified, starting with local patient identification: date of birth, admission, surgery and discharge, weight, case category (CPB, non-CPB, Thoracic etc.), CPB time, AoX clamp time, IPPV, date of death, Diagnoses, Procedures. With 15 years' experience, we can state that 300-350 operations per one verification working day can be verified. The verification visit usually lasts 2 days. In the year 2010, we stopped verifying IPPV, because this data was not available in over 60% of the centers.



| | |
|---|---|
| 1 | Patient ID |
| 2 | Date of Birth |
| 3 | Date of Admission |
| 4 | Date of Surgery |
| 5 | Date of Discharge |
| 6 | Weight |
| 7 | Case category |
| 8 | CPB time |
| 9 | AoX time |
| 19 | Date of Death |
| 11 | Diagnoses |
| 12 | Procedures |

*Table 1. Fields undergoing verification*

The end point of the verification process is to correct in the database any wrong data that have been found.

Since 2004, 118 site visits have been performed, which resulted in having verified ca. 15% (n=37,699) of the data collected during the time the verification program was running.

The centers are included to data verification on a voluntary basis: some of them are verified every year, the others every two or three years.

The verified center covers the travel and accommodation costs of the auditor.

**Personal data protection**

The data submitted to the ECHSA Congenital Database are anonymous. To fulfill the personal data protection requirements, two basic methods of SDV are being used: back-to-back and direct inspection. In the back-to-back method, the person from hospital staff (doctor, secretary, nurse, student) holds all the source documents and answers specific questions asked by the auditor regarding the data, without giving the auditor access to the documents. In the direct method, the auditor has direct access to the source documents. To make it legal, the hospital administration prepares a document for the auditor entitling him to temporary access to the data. Access to hospital data is possible after the auditor has signed such a document.

**The results of the SDV**

Each year, after the data verification is finished, the results of comparative statistics are published on the Database's website. It has been proved that there has never been found any statistically significant differences in mean values of the verified parameters. *Table 2* shows the results of the SDV statistics.

Similar tables are available for each age group (neonates, infants, children, adults) and can be retrieved at the following address: https://echsacongenitaldb.org/data_verification_results/

The verified center receives the SDV Certificate, which is in a frame, ready to hang on the wall, as well as in its electronic version (*Fig. 2*).

The verified center receives also the SDV summary (*Fig. 3*) indicating how many changes have been made for each verified parameter in their own data in comparison with all verified centers in the current year and in all years.

**Summary**

The data verification is an extremely important tool in the process of obtaining complete and true data. This process provides "clean data" that can be used for the research purposes.

In addition, many inaccuracies in the coding of diagnoses and procedures and complications are cleared up during the verification.

The Source Data Verification program needs to be continued, and the level ca. 15% of verified data should be maintained.

## *Data Verification Results*

Data Of 2003 - 2017

### All Patients

- No of all collected procedures for 2003 - 2017: 257,252
- No of verified procedures: 37,699 (14.65%)
- No of procedures in whole database: 295,619
- No of verified procedures: 37,699 (12.75%)

**Verification Results**

| Procedures | 37,105 Before verification | | 37,699 After verification | | |
|---|---|---|---|---|---|
| | Mean | Std Dev | Mean | Std Dev | p-value |
| Age (days) | 2316.26 | 4367.37 | 2303.36 | 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 Before verification | | 29,894 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 |

*Table 2. Data Verification results 2003-2017*


ECHSA
CONGENITAL DATABASE

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
Zdzisław Tobota, MD

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

www.echsacongenitaldb.org

*Figure 1. Data Verification Certificate (example)*



ECHSA
CONGENITAL DATABASE

**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% | 0,09% | 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% | 1,49% | 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% | 0,46% | 0,29% |

Database Technical Director
Zdzisław Tobota, MD

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

www.echsacongenitaldb.org

*Figure 2. Data Verification Summary (example)*

Do you have a question about Data Verification?
Do you want your center verified ?- Register today!
Contact us at dbnewsletter@echsa.org
We would be very pleased to hear from you!


## UPCOMING NEWSLETTER

25th Anniversary of the ECHSA Congenital Database: A retrospective view, as well as an outlook to the future.
Stay curious!

*Release date: January 2020*

## 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

## THE ECHSA-CHSD COMMITTEE