



## Why national databases are necessary for pediatric and congenital heart surgery practice?

*Pediyatrik ve konjenital kalp cerrahisinde ulusal veri tabanları neden gereklidir?*

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### ABSTRACT

In international experience, performance improvement, patient safety, and quality assurance are mainly based on database studies in the field of pediatric and congenital cardiac surgery. Data collection and analysis of the databases allow the clinician to identify the complexity, to predict possible risks and complications, and to appropriately evaluate the outcomes and performances. Recently, the Children's Heart Foundation Working Group has developed a database project in Turkey based on the parameters and methodologies of the international databases, namely the Pediatric Heart Surgery National Database. Currently, it is a must for us to put this project into practice to reach the global standards in the pediatric and congenital heart surgery in our country. We believe that all children with congenital heart disease should have an opportunity to benefit from the most recent medical and surgical treatment modalities with the most favorable results.

**Keywords:** Outcome analysis, patient safety, pediatric and congenital heart surgery, quality improvement.

Over the past three decades, the concept of quality has evolved in every aspect of daily life. From the philosophical and overall perspective, quality can be defined as an attempt to reach perfection. In other words, it is the degree of excellence with commitment and aim to do best in any work, production, or service industry. However, this aim is not an abstract desire or

### ÖZ

Uluslararası deneyimlerde, pediyatrik ve konjenital kalp cerrahisi alanında, performansın iyileştirilmesi, hasta güvenliği ve kalitenin güvence altına alınması esas olarak veri tabanı çalışmalarına dayandırılmaktadır. Veri tabanlarından verilerin toplanması ve analizi; klinisyenin kompleksiteyi belirlemesine, muhtemel riskleri ve komplikasyonları öngörmesine ve sonuçları ve performansını uygun bir şekilde değerlendirilmesine olanak sağlayacaktır. Son yıllarda Çocuk Kalp Vakfı Çalışma Grubu tarafından, uluslararası veri tabanlarının parametreleri ve metodolojisi dikkate alınarak, ülkemizde bir Ulusal Çocuk Kalp Cerrahisi Veri Tabanı projesi geliştirilmiştir. Bu projenin hayata geçirilmesinin, ülkemizdeki Çocuk Kalp Sağlığı ve pediyatrik ve konjenital kalp cerrahisi uygulamalarının dünya standartlarına yükseltilebilmesi bakımından zorunlu olduğunu düşünmekteyiz. İnanıyoruz ki; konjenital kalp hastalığı ile doğan her çocuk, mümkün olan en iyi sonuçlarla tıbbi ve cerrahi tedavi imkanlarına kavuşma şansına sahip olmalıdır.

**Anahtar sözcükler:** Sonuç analizi, hasta güvenliği, pediyatrik ve konjenital kalp cerrahisi, kalite iyileştirme.

demand. For the quality improvement and assurance, a methodological system based on the accurate assessment and evaluation process, identification of problems, and solution and improvement must be functioned.<sup>[1]</sup>

Considerable improvements and advancements have been made in pediatric and congenital heart surgery

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over the past six decades. The increased success rates in complex congenital heart malformations in neonates and infants have promoted further expectations and efforts to be undertaken to predict perioperative risks and early and late complications and to improve the patient outcomes. In recent years, several studies carried out in developed countries to improve quality and patient safety using data collection and outcome analysis have led to improved quality and patient safety. From this point of view, we hold the responsibility for delivering all treatment opportunities with best possible outcomes for each child with congenital heart disease in Turkey. The liability is primarily held by pediatric cardiac surgeons and cardiologists, medical societies, health policymakers and health management authorities. In this context, the Pediatric Cardiac Surgery National Database Project of the Children's Heart Foundation (CHF) is one of the mainstays to fulfill this responsibility.

Improvement of the performance and quality assurance in pediatric cardiology and cardiac surgery are mainly based on database projects.<sup>[2-4]</sup> Data collection and analysis of the databases allow the clinician to identify the complexity, to predict possible risks and complications, and to accurately evaluate the outcomes and performances. We believe that our national database project would pave the way for reaching the global standards in the pediatric and congenital heart surgery practice.

The national database project of the CHF has been designed as a national data collection and analysis system. It offers to maintain quality and performance assurance and to optimally coordinate the pediatric heart health and congenital heart surgery procedures in Turkey. It is also a guide to identify national socioeconomic policies on pediatric heart health, to ascertain necessities and priorities, to provide budget and financial support, to utilize sources appropriately, and to evaluate productivity. It is also helpful to shed light into several issues including the number of pediatric heart centers, geographical distribution, architectural and technological infrastructure, human resources, and administrative organization and to provide basis for scientific studies and publications in accordance with the international standards.

International systematic studies on the quality improvement and patient safety in the pediatric and congenital heart surgery practice date back to 1990s.<sup>[2-4]</sup> Extensive studies conducted by the Society of Thoracic Surgery (STS), the European Association for Cardiothoracic Surgery (EACTS), and the European Congenital Heart Surgeons Association

(ECHSA) are ongoing. Initially, the STS and EACTS jointly adopted the uniform diagnostic, procedural, and complication codes (Nomenclature and Coding System) and, later on, the STS and ECHSA database projects were developed to collect data from national and international sources.<sup>[2-6]</sup> According to each procedure, risk factors, difficulty level, complication rates, length of hospital stay, and in-hospital mortality were classified. In this context, at the beginning, the STS-Risk Adjustment Congenital Heart Surgery (RACHS-I) method was used. Currently, however, the Aristotle Complexity Score developed by the EACTS (ECHSA) Congenital Heart Surgery Database and STAT Mortality Scores and Categories developed by the Joint STS-EACTS Congenital Database Committee have been used.<sup>[5,6]</sup> Databases compare and classify the outcomes according to these results and performances.<sup>[7,8]</sup> The STS National Database Initiatives, on a regular basis, announce data regarding operative mortality and length of hospital stay related to the common index procedures.<sup>[9-11]</sup> In addition to STS and ECHSA databases, national database projects are being conducted in Japan, United Kingdom, Germany, and Australia recently. In January 2017, the World Society for Pediatric and Congenital Heart Surgery (WSPCHS) attempted to develop a global database (World Database). This project, which particularly encourages the participation of the developing countries, has been carried out by the Alabama University, United States, World Database Team under the supervision of James K. Kirklin.<sup>[12,13]</sup>

In recent years, many attempts have been made to develop a national database in Turkey.<sup>[1,14,15]</sup> The meetings of the Turkish Children's Heart Health Platform organized by the CHF, Turkish Society of Cardiovascular Surgery (TSCVS) and the Turkish Pediatric Cardiology and Heart Surgery Association (TPCHSA) with the participation of the Turkish Ministry of Health and Social Security Institution (December 2012 and 2013, Istanbul), the Children Heart Centers workshops jointly held by the TSCVS and Turkish Ministry of Health (September 2016, Istanbul), the Joint Database Workshop by the TSCVS, Turkish Society of Cardiology (TSC), and TPCHSA (February 2017, Izmir) have highlighted the importance of national databases and the basic principles have been discussed.

In practice, international databases may be restricted by several limitations to analyze data and may be unable to meet the all expectations of the data registry centers and national requirements. The transferred data are at the risk of becoming almost

disappeared or lost in the data pool. The annual fee of data transfer is also not affordable for many centers, and the registry does not allow the user to analyze their own data. To illustrate, the basic inquiry is unable to be performed including the number of neonates operated and the outcomes of a procedure. As a data input center to the EACTS Congenital Database for many years, we have only a simple volume-complexity-outcome bubble graphic.<sup>[14]</sup> In addition, with the introduction of annual fee, we are unable to reach our own data. Also, the systems configured by the foreign companies pose several challenges in the maintenance with expensive installation and maintenance fees. In 2000s, the TSCVS settled an agreement with the Dendrite Database; however, this attempt failed due to sluggish processes and non-affordable costs. Considering all these facts, it is, currently, a must for us to establish a national database on pediatric heart surgery using national resources and facilities.

Recently, the CHF has obtained the results of its long-term efforts in which we developed the national Pediatric Heart Surgery Database. This program has been designed as a web-based online national system. It allows data input from all centers in Turkey. It is configured as a rapid, simple, and user-friendly software. It is open to have further requirements and expectations. A professional software company is responsible for the technical support, maintenance, and follow-up.<sup>[16]</sup>

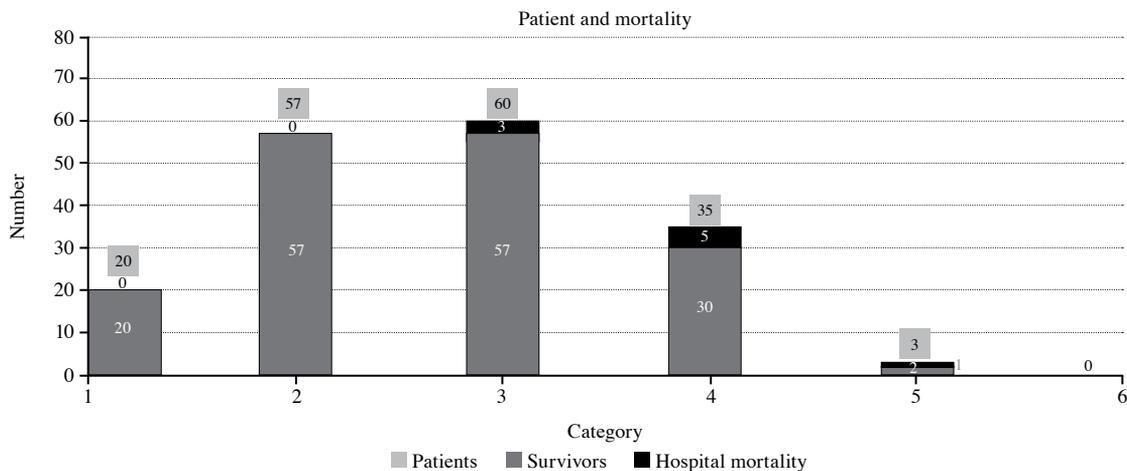
The database has been developed in accordance with the variables and methodologies of the international databases including STS-EACTS Nomenclature and Coding System for diagnostic, procedural, and complication codes. The complexity, risk factors, and difficulty level of an individual procedure are evaluated using the Aristotle Complexity Scoring and

STAT Mortality Scores and Categories with certain adaptations. Through this attempt, it would be possible to compare our experiences and knowledge with global data.

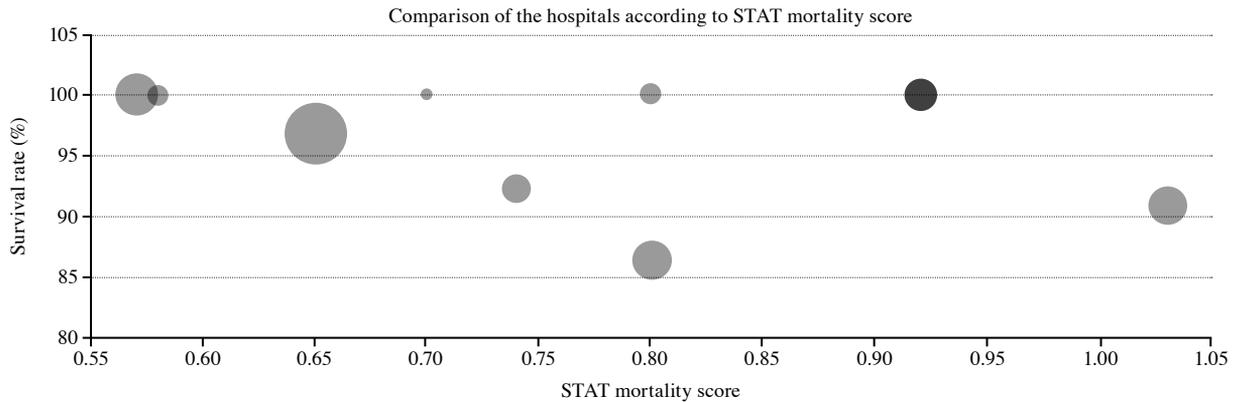
The main advantage of the national Pediatric Heart Surgery Database is that it allows the user detailed data analysis. Currently, the global databases lack of an extensive preliminary analysis reporting system. Our national database offers 10 online analysis reporting forms for data analysis (examples: Figure 1 and 2), as follows:

1. The number of centers and patients
2. Procedures and results
3. The number of procedures, mortality rate, and mean Aristotle scores
4. The number of extracorporeal membrane oxygenation (ECMO)/ventricular assist devices (VADs) and results
5. Complications
6. Age group statistics
7. Simplified Aristotle Complexity Category statistics and STAT mortality categories
8. Comparison of hospital scores
9. The number of procedures and results according to the priority status of the operations
10. The length of hospital and intensive care unit stay according to the procedure

This database offers instant access to the data analysis in active graphics. It also allows all participating centers to access their own statistics and results and to compare their results with other results in the online setting. The users are also able to reach the number of



**Figure 1.** The simplified Aristotle complexity category statistics in the national pediatric heart surgery database.



**Figure 2.** Comparison of centers according to the STAT mortality scoring system in the National Pediatric Heart Surgery Database.

participating centers and the total number of patients and the overall results. On a regular basis, the database offers data analysis reports of selected most common index procedures.

It has been anticipated that the execution and management of the national database project by the TSCVS in accordance with the local regulations. The verification audits can be carried out by an empowered commission of the society. Of note, the identities of the participating centers are kept confidential and no comment or status for a specific center are permitted. In addition, necessary precautions have been taken to keep personal health data confidential. The participation is on a voluntary basis. The database also enables another version for the users to solely registry and analyze their own data. Undoubtedly, as in all data registry and analysis system, accurate and complete data registry is of utmost importance for the national database to obtain successful and beneficial results.

It is obvious that the quality is a more important measure in healthcare systems than other work, production, and service industry. As the CHF, our first work on quality concept dates back to nearly 20 years ago. In March 2002, for the first time in Turkey in a hospital in which we, as the CHF, were the founding managers and administrators, we were awarded with the accreditation certificate of the Joint Commission International (JCI)<sup>[17]</sup> which was established to accredit healthcare organizations around the world and developed measures in quality and patient safety. With this occasion, international healthcare standards and quality concepts were introduced to the Turkish healthcare sector. Later on, the Turkish Ministry of Health, Directorate of Healthcare Services, Office of

Quality and Accreditation was established, bringing the patient safety and quality control in healthcare centers to the forefront. In this context, we believe that the national Pediatric Heart Database project of the CHF will be a remarkable progress to reach the global standards in the pediatric and congenital heart surgery practice. All children with congenital heart disease should have an opportunity to benefit from the most recent medical and surgical treatment modalities with the most favorable results. Being committed to this effort, it is our mission to put the project of the CHF into practice.

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