

The world database for pediatric and congenital heart surgery: A collaboration with the Registro Nacional de Cirugía Cardíaca Pediátrica

La base de datos mundial de cirugía cardíaca pediátrica y congénita: una colaboración con el Registro Nacional de Cirugía Cardíaca Pediátrica (RENACCAPE)

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Abstract

Objective: Following the notable work accomplished by the Mexican Association of Specialists in Congenital Heart Disease (Asociación Mexicana de Especialistas en Cardiopatías Congénitas) with the development of a national registry for congenital cardiac surgery, the World Society for Pediatric and Congenital Heart Surgery has implemented an international platform to collect data and analyze outcomes of children with congenital heart disease. **Methodology:** This manuscript proposes a possible collaboration between Mexico's national congenital cardiac database (Registro Nacional de Cirugía Cardíaca Pediátrica) and the World Database for Pediatric and Congenital Heart Surgery. **Conclusion:** Such a partnership would advance the countries' desire for the ongoing development of quality improvement processes and improve the overall treatment of children with congenital heart disease.

Key words: Congenital heart disease. Database. Cardiac surgery. Quality improvement. Outcomes. United States of America.

Resumen

Objetivo: Siguiendo el notable trabajo realizado por la Asociación Mexicana de Especialistas en Cardiopatías Congénitas (Asociación Mexicana de Especialistas en Cardiopatías Congénitas: AMECC) con el desarrollo de un registro nacional para la cirugía cardíaca congénita, la Sociedad Mundial de Pediatría y Cirugía Cardíaca Congénita ha implementado una

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plataforma internacional para recopilar datos y analizar los resultados de los niños con cardiopatía congénita. **Metodología:** Este manuscrito propone una posible colaboración entre la base nacional de datos cardíacos congénitos de México (RENAC-CAPE) y la Base de Datos Mundial para la Cirugía Cardíaca Pediátrica y Congénita (WDPCHS). **Conclusión:** Esta asociación promovería el deseo de los países de seguir desarrollando procesos de mejora de la calidad y mejorar el tratamiento general de los niños con cardiopatía congénita.

Palabras clave: Cardiopatía congénita. Base de datos. Cirugía cardíaca. Mejora de calidad. Resultados. Estados Unidos de América.

In 2007, the historic inaugural meeting of the World Society for Pediatric and Congenital Heart Surgery (WSPCHS) was convened in Washington D.C. The organizers and participants of this event were motivated and inspired by the prospect of a new era of global communication in the field of congenital heart disease. Their mission, galvanized with ratification of the society's constitution, directed members to promulgate efforts to *"to promote the highest quality of comprehensive cardiac care to all patients with congenital heart disease, from the fetus to the adult, regardless of the patient's economic means, with an emphasis on excellence in education, research, and community"*^{1,2}. Shortly following this meeting, the Mexican Association of Specialists in Congenital Heart Disease (Asociación Mexicana de Especialistas en Cardiopatías Congénitas [AMECC]) was created to partner with the WSPCHS for the purpose of fulfilling this mission in Mexico. This group of prestigious pediatric cardiologists and cardiac surgeons, with governmental support, began to work on several initiatives, including the initiation of a national registry, a plan for regionalization of congenital cardiac care, and an evaluation of current resources dedicated to the treatment of congenital heart disease within the country. The Pediatric Cardiovascular Surgical Database Registry/Registro Nacional de Cirugía Cardíaca Pediátrica (RENACCAPE), which would collect information about the practice of congenital heart surgery within the country, was launched as a national effort³. In 2012, RENACCAPE was able to recruit 11 congenital cardiac surgical programs, with annual case volumes ranging from 70 to 690⁴. **Table 1** provides a representation of the case complexity over a 1-year period for centers submitting to this national registry (**Table 1**). However, due to both financial limitations and the hesitation of many centers to publically report their surgical outcomes, participation in the database slowed, resulting in the temporary suspension of its activity.

Nevertheless, following the initial excellent work achieved by AMECC, the WSPCHS has worked to implement a process by which information concerning the practice of congenital cardiac surgery will be

Table 1. Surgical procedures performed from August 1, 2011, to July 31, 2012^a

Surgical procedures	Cases (%)
Septal defect repair	109 (12)
Closure of patent ductus arteriosus	97 (10)
Repair of systemic to pulmonary fistula	85 (9)
Correction of TAPVC	67 (7)
Repair of atrial septal defect	64 (7)
Aortic coarctation repair	55 (6)
Tetralogy of Fallot repair	57 (6)
Atrioventricular canal correction	33 (3)
Pulmonary artery cerclage	23 (2)
Bidirectional cavopulmonary derivation	28 (3)
Total cavopulmonary connection (fontan)	21 (2)
Mitral valve surgery	21 (2)
Jatene surgery	14 (1)
Jatene surgery + VSD closure	13 (1)
Subvalvular aortic stenosis repair	11 (1)
Arterial trunk total correction	11 (1)
Correction of PAPVC	11 (1)
Double outlet right ventricle repair	10 (1)
Aortic arch repair	7 (1)
Other procedures	206 (22)

^aAdapted from Cervantes-Salazar J, Calderon-Colmenero J, Ramirez-Marroquin S, et al. Pediatric cardiovascular surgical database registry in Mexico: First report. Rev Invest Clin. 2013. PAPVC: partial anomalous pulmonary venous connection; TAPVC: total anomalous pulmonary venous connection; VSD: ventricular septal defect

recorded and analyzed on a global scale⁵. During the 4th Scientific Meeting of the WSPCHS held in Sao Paulo, Brazil, a Town Hall meeting entitled "A World Database for Pediatric and Congenital Heart Surgery (WDPCHS)" was convened to explore the possibility of establishing a global database that would be available to all members of the World Society. After much

Table 2. Data collection forms

Form name	Data to be entered
Institutional practice details	Information detailing institution's congenital cardiac surgical practice (e.g., annual case volume, population and region served, number of congenital heart surgeons)
Demographics	Patient information (e.g., patient name, gender, DOB)
Preoperative	Pre-operative details of patient history (e.g., prior cardiac operations, chromosomal or syndromic abnormalities, and pre-operative risk factors)
Surgery	Surgical data (e.g., height and weight at surgery, bypass time, and cross-clamp time)
Discharge	Complication and discharge information (e.g., reoperations required, nature of post-operative complications)
Follow-up	Data from 1-year post-index operation (e.g., readmission required, reoperation required, and patient status)
Death	Details of death (e.g., date of death, cause of death, and autopsy findings)

debate and consideration, the Database Committee received the mandate to establish a database which would collect vital information, allowing all centers to benchmark their outcomes and progress in providing surgical care to children with congenital heart disease. The effort to establish a global database continued at the Joint Scientific Meeting of the World Society with Sociedad Latina de Cardiología y Cirugía Cardiovascular Pediátrica held in Cartagena, Colombia, in February of 2015.

The WSPCHS was fortunate to retain the services of the James and John Kirklin Institute for Research in Surgical Outcomes (KIRSO) at the University of Alabama at Birmingham. Under the leadership of James K. Kirklin, KIRSO has been responsible for the creation and current maintenance of both nationally and internationally acclaimed clinical databases. With the experience of this institute and invaluable input from multiple international experts in the fields of both congenital heart disease and database development, a global platform for information exchange was created and adjudicated by members of the society. The WDPCHS went live on January 1, 2017, following an extensive period of planning focused on determining the appropriate variables to collect, creating a design that can be applied on a global scale regardless of socioeconomic status, and engaging in strategies to encourage international participation.

The WDPCHS is designed to produce meaningful performance and quality analyses of surgical outcomes that extend beyond immediate hospital survival, capturing important morbidities and mortalities for up to 1 year

postoperatively. By utilizing standardized terms and definitions developed and adjudicated by several national and international expert organizations^{6,7}, the World Database has embraced a common language, communication, and assessment of congenital cardiac practices across the globe. To provide individual centers adequately detailed outcomes analyses while remaining cognizant of limited financial and personnel resources, variables were selected to provide the greatest opportunity to evaluate programmatic deficiencies and to effect necessary improvements in pre-operative selection, intraoperative performance, and post-operative management. Institutions will be able to confidentially compare their center-specific data to regional, national, and international aggregate data, allowing for the identification and implementation of quality improvement strategies.

Table 2 illustrates the organization of the World Database and the types of information that are being collected (Table 2). Institutional practice data are collected in sufficient detail to facilitate the creation of an international registry of congenital cardiac centers. Such information collected includes annual center case volumes, the number of congenital cardiac surgeons actively practicing in the center, geographic region served, population served, the number of other institutions within the geographic region, and a description of the services provided. The surgery form requires the input of only 17 variables. Several of these variables, such as primary cardiac procedure and cardiac diagnosis, are organized into easy-to-navigate drop-down menus categorized for routine clinical practice. These variables, including prior

cardiac operations, pre-operative risk factors, weight, cardiopulmonary bypass times, and intraoperative complications, were chosen by international experts in the field of congenital cardiac surgery to reliably represent the operative components of a surgical program. The collection of follow-up information on readmission, morbidities, and mortalities for up to 1 year after surgery is a distinguishing feature that separates this database from others. This longitudinal follow-up will for the 1st time provide a global picture of longitudinal care beyond the immediate post-operative period.

Data quality is critical, and collection of too much data may lead to the dilution of efficient and effective analysis, increased expenditure of valuable resources, and loss of enthusiasm from participating members. For these reasons, surgical procedures are assigned to one of two categories within the database. This two-tiered system was created to allow for both the input of detailed data for a pre-selected group of surgical procedures and collection of a limited number of variables for all cardiac operations performed (Table 3). Additional follow-up data cover important morbidities, readmission for intervention related to the index surgical procedure, and mortality for up to 1 year postoperatively. Importantly, the database will maintain the flexibility to incorporate additional procedures in the Tier I category as centers gain experience with the database and understand its value, both for quality assurance and research.

To advance its mission, the WSPCHS has made this global quality improvement program available to its individual members free of charge. On a national level, congenital cardiac programs in Mexico that lack sufficient resources and facilities to undertake sophisticated outcomes analyses will be able to utilize this service with limited dedication of resources. Centers are assured that their data are only identified to their institution. Centers will also have the ability to draw comparisons to deidentified regional and national aggregate outcomes. With this in mind, there exist two possible avenues by which the WDPCHS could be implemented within Mexico. First, recent efforts by many leaders in congenital cardiac surgery and pediatric cardiology have reengaged the RENACAPPE registry and will begin recruiting patients in the very near future. If this successful, it would be possible to establish a cross-map with WDPCHS, allowing centers to submit their RENACAPPE data to WDPCHS with little additional expenditure of valuable resources. The center-specific data could then be benchmarked against international aggregate data, allowing for the

Table 3. Tier I procedures

Procedure name
VSD repair
Atrioventricular septal defect repair
Coarctation repair
PAPVC repair
TAPVC repair
Glenn/hemi-Fontan procedure
Fontan procedure
Tetralogy of Fallot repair
Arterial switch operation
Ebstein's anomaly repair
Truncus arteriosus repair
Modified Norwood procedure
HLHS biventricular repair

VSD: ventricular septal defect; HLHS: hypoplastic left heart syndrome; PAPVC: partial anomalous pulmonary venous connection; TAPVC: total anomalous pulmonary venous connection

development of quality improvement projects and processes to improve overall outcomes. Alternatively, if this national database lacks the resources and supports necessary to maintain such a costly endeavor, and then, the WDPCHS could be modified to serve as a primary national resource for the collection and evaluation of information that would contribute to the improvement of overall care of children with congenital heart disease within Mexico. In any case, finally, being able to create a national database within Mexico is of utmost importance to AMECC and the WSPCHS. It is the responsibility of both of these organizations to make the government aware of the need for a reliable source of information to improve the quality of care for congenital heart disease throughout Mexico and to assist in defining its health-care policies for decades to come.

With the creation of the WDPCHS, the WSPCHS is taking an essential step in the process of global improvement of care for children with pediatric and congenital heart disease. Regardless of the specific path chosen by the governing organizations within Mexico, the World Society invites all its members and partners to fully participate in this important initiative. More detailed information concerning the WDPCHS can be found at <http://www.uab.edu/medicine/wdpchs/>.

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Ethical disclosures

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