The World Database for Pediatric and Congenital Heart Surgery *"A Call to Service for North American Congenital Heart Surgery Programs"*

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The World Society for Pediatric and Congenital Heart Surgery has endorsed the establishment of an international platform for the exchange of knowledge and experience for those that treat patients with a congenital heart defect. On January 1, 2017, the release of the World Database for Pediatric and Congenital Heart Surgery opened a new era in evaluation of treatment with congenital heart defects. The contribution of data from countries with established congenital surgical databases will greatly enhance the efforts to provide the most accurate measure of overall surgical outcomes across the globe.

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Central Message

North American congenital heart surgical programs need to provide their outcomes data as acquired by a national congenital heart surgery database to assist in establishing benchmarking of outcomes across the globe.

INTRODUCTION

More than a decade has elapsed since the inaugural meeting of the World Society for Pediatric and Congenital Heart Surgery (WSPCHS) was held in Washington, DC in May 2007. During this event, the organizers and participants were motivated and inspired by the prospect of a new era of global communication in the field of congenital heart disease.[1] A dominating theme was the desire to create a mechanism by which developed countries could share their outcomes and experiences managing congenital heart disease patients with countries whose ability to treat this fragile population was still evolving. The Constitution created and approved by this new society specifically included "To establish a World Database for Pediatric and Congenital Heart Surgery." To satisfy this tenet, the WSPCHS retained the services of the James and John Kirklin Institute for Research in Surgical Outcomes at the University of Alabama at Birmingham. Under the leadership of James K. Kirklin MD, this institute and its precursor organization have been and continue to be responsible for several nationally and internationally acclaimed clinical databases.[2] With the experience of this institute and invaluable

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input from multiple international experts in the fields of both congenital heart disease and database development, a process was initiated to create a global platform of information exchange across all social and economic barriers.

After nearly 5 years of planning, this dream was realized with the establishment of the World Database for Pediatric and Congenital Heart Surgery (WDPCHS), which began collecting data from around the world on January 1, 2017.[3] The function of the database is multifaceted and includes creation of an international registry of active congenital heart surgeons and centers, provision of an accurate and efficient quality improvement tool for active congenital heart programs and harvesting the immense experience and data from established congenital heart databases to provide benchmark outcomes to centers across the globe. The objectives of this review are to provide North American congenital heart surgery programs, both in the United States and Canada, with an update on the progress of the WDPCHS and to request their support for the benchmarking of surgical outcomes.

THE WORLD DATABASE FOR PEDIATRIC AND CONGENITAL HEART SURGERY

The creation of a global database for pediatric cardiac surgery has been a desirable goal for many years.[4,5] The concept of a global database was first formally discussed in July 2014 at the Fourth Scientific Meeting of WSPCHS in Sao Paulo, Brazil. Over the next several years, a database committee was established (Table 1), a data center and warehouse site was selected (University of Alabama at Birmingham), and the database design and content were created. All participants of this database committee agreed that the fundamental priority of this endeavor should be the "improvement of global outcomes in surgery for congenital heart disease."

In developing the database, several tenets were followed: the importance of longer term survival data beyond the index hospitalization (1-year follow-up); collection of data for all cardiac surgical cases implemented in a way that would be feasible for most centers; the provision of feedback reports to all centers that showcase annual risk-adjusted outcomes, with confidential comparison of local outcomes to global aggregates; and development of flexible data downloads and customized queries.

Table 1. World Database for Pediatric and Congenital Heart Surgery Database Working Group

Member Name	Country Represented
James K. Kirklin	United States
Jorge Cervantes	Mexico
Sertaç Çiçek	Turkey
Frank Edwin	Ghana
Kirsten Finucane	New Zealand
Jose Fragata	Portugal
Jeff Jacobs	United States
Hani Hajm	Saudi Arabia
Kisaburo Sakamoto	Japan
Christo Tchervenkov	Canada
Rodney Franklin	United Kingdom
Marshall Jacobs	United States
Krishna Iyer	India
James St. Louis	United States

Centers submit their case data via a password-protected website maintained at the University of Alabama at Birmingham. The online data input process was constructed to include 7 collection forms, which the user is automatically prompted to complete depending on the category of the procedure. Table 2 illustrates the organization and types of information that are currently collected by the database. Surgical procedures are assigned to 1 of 2 categories within the database. This 2-tiered system was created to allow for both the input of detailed data for a preselected group of surgical procedures, as well as the collection of a limited number of variables for all other congenital cardiac procedures conducted. Table 3 lists the current Tier I procedures. All additional congenital heart cases are submitted as a Tier II procedure. The WDPCHS was developed utilizing the standardized terms and definitions of the International Paediatric and Congenital Cardiac Code, developed by the International Society for Nomenclature of Paediatric and Congenital Heart Disease in collaboration with several national and international organizations.[6] Variables in WDPCHS were selected that were believed to provide the greatest opportunity to evaluate programmatic deficiencies and to effect necessary changes in preoperative selection, intraoperative performance, and postoperative management.[7]

Between January 2017 and November 2018, 12,183 operations (6848 Tier 1 and 5335 Tier 2) from 51 hospitals representing 19 countries were entered into the database. This initial cohort of hospitals provides wide geographic representation, including Africa, Asia, Australia, Europe, North America, and

Table 2. Data Collection Forms

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

Table 3. Tier I Procedures

Procedure Name
Ventricular septal defect 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

South America. To advance this mission of the WSPCHS, access to the database is free to all members. For members who lack sufficient resources and facilities to undertake sophisticated outcomes analyses or who resides in a country that lacks the infrastructure to support a national congenital surgical database, having this resource will certainly improve the overall outcomes. For WSPCHS members that are fortunate to participate in a mature national congenital heart surgery database, participation in the World Database will enhance the overall power of these analyses and enhance both national and international aggregate data. This collection of data will provide all centers, regardless of their economic or political status, with the ability to benchmark their outcomes to these aggregate data and therefore improve the overall quality of the surgery provided to children with a congenital heart defects across the world.[4,5,8,9]

CALL TO SERVICE FOR US AND CANADIAN CONGENITAL HEART SURGERY PROGRAMS

The Society of Thoracic Surgery (STS) has been instrumental in the creation and maintenance of clinical databases that capture the practice of cardiothoracic surgery in the United States and Canada; including adult cardiac surgery, general thoracic surgery, and congenital surgical subspecialties. The STS Congenital Heart Surgery Database (CHSD) has successfully accumulated over 400,000 operations over the last 15 years. STS CHSD provides a quality improvement tool to US and Canadian centers by which mortality and morbidity in children with congenital heart disease have been measured.[10] These efforts have resulted in the improvement of outcomes across all complexities of surgical interventions.[11] Information harvested from this database has produced extremely detailed and accurate quality reports which are provided to the 119 participating centers on a biannual basis. In just 25 years,[12] STS CHSD has evolved to provide not only a powerful quality improvement tool but also a research tool from which hundreds of articles have made significant contribution to the practice of congenital heart surgery. It is therefore essential that US and Canadian centers share this fortune with other centers across the globe. Centers outside the United States and Canada that do not possess the ability or resources to critically evaluate outcomes of children undergoing surgery for a congenital heart defect will benefit immensely from these types of data for comparison. With the development of such a platform by which US and Canadian centers can provide benchmark data, the WSPCHS can provide all centers across the globe an unbiased tool by which quality improvement efforts can be successful.

THE PROCESS FOR US AND CANADIAN SUBMISSION TO THE WDPCHS

To best facilitate the submission of congenital cardiac procedural data to the WDPCHS, a mechanism was conceived and implemented by which adjudicated “in-house registry (or national registry) software” are uploaded via a password-protected online process from individual US and Canadian centers. Submission to the WDPCHS simply requires the ability to generate these files from the in-house data entry software currently utilized by each center for participation in exciting registries. The software must be able to designate a date range of data for the files generation. For example, centers that submitted data during the most recent harvest were asked to generate a Harvest file from January 1, 2017 to June 31, 2018. The files requirements stipulate that the submission must be a text file, and there must be a defined “table” structure within the files (eg, demographics, operations, diagnosis, etc.).

The process of submission is straightforward and can be found in detail on the WDPCHS website. Briefly, once the legal agreements have been reviewed and signed, the center will receive authorization from the WDPCHS Data Center to submit data and will be given a username and password to access the upload site. With the confirmed final version of the Harvest file to be transmitted, including the defined date range, the file will upload and the submitting center will receive confirmation that the data have been accepted. The UAB Data Center will then cross link the submitted data fields with those of the World Database, allowing this information to be analyzed as procedure-specific aggregate data and utilized for comparison reporting. In addition to these comparisons, after accumulating data for large numbers of procedures, the WDPCHS Data Center will be able to construct country-specific risk models accounting for defined differences in risk factors for congenital heart defects.

US CONGENITAL HEART SURGICAL PROGRAMS

As of June 2018, 119 congenital heart surgical programs submit data to the STS CHSD; this is inclusive of 375 active surgeons. Over the last decade, members have enrolled on average a total of 40,000 new operations annually. Currently, data on over 474,000 operations are held within this database.[13] Beginning mid-2018, an effort was initiated to recruit US centers to actively their “in-house registry (or national registry) software” files to the WDPCHS database via the process described above. By the end of September 2018, 7 centers had completed the enrollment process (Table 4). These centers were asked to submit the adjudicated files for the period from

Table 4. Participating US Institutions

Institution	Principal Investigator
Nicklaus Children's Hospital	Kristine Guleserian
Penn State Children's Hospital	John Myers
University of Louisville, Norton Children's Hospital	Erle Austin
Children's Hospital of Illinois	Mark Plunkett
Herma Heart Institute, Medical College of Wisconsin	Viktor Hraska
Children's National Medical Center	Pranava Sinha
Children's Mercy Kansas City	James O'Brien Jr.

January 1, 2017 to June 30, 2018, resulting in the submission of data for 3923 operations for this timeframe. The submission process occurred without any significant problems, and all participants commented on the ease of the process. This data is currently being linked and integrated into the overall aggregate of the database and included in the initial analysis of the outcomes. All centers will receive a detailed report comparing their outcomes to a global aggregate for the all Tier I cases.

CONCLUSION

By establishing the WDPCHS, the WSPCHS is taking an essential step in the process of global improvement of care for children with congenital heart disease. In the longer term, we anticipate that the greater numbers in a global database will allow for more accurate risk adjustment than is possible in national registries. The WSPCHS has developed a simple, yet efficient pathway for US and Canadian congenital heart surgical programs to share their experience and outcomes with others across the world. US centers should feel compelled to share these experiences for the betterment of all children afflicted with a congenital heart defect (http://www.uab.edu/medicine/wdpchs/).

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