The Society of Thoracic Surgeons Congenital Heart Surgery Database: 2017 Update on Research

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The Society of Thoracic Surgeons Congenital Heart Surgery Database (STS CHSD) is the largest congenital and pediatric cardiac surgical clinical data registry in the world. It contains data pertaining to more than 435,000 total operations. The most recent biannual feedback report to participants (Spring 2017, Report of the Twenty-Sixth Harvest) included analysis of data submitted from 127 hospitals in North America. That represents nearly all centers performing pediatric and congenital heart operations in the United States and Canada. As an unparalleled platform for assessment of outcomes and for quality improvement activities in the subspecialty of surgery for pediatric and congenital heart disease, the STS CHSD continues to be a primary data source for clinical investigations and for research and innovations related to quality measurement. In 2016, several major original publications reported analyses of data in the CHSD pertaining to various processes of care, including assessment of variation across centers and associations between specific practices, patient characteristics, and outcomes. Additional publications reported the most recent development, evaluation, and application of metrics for quality measurement and reporting of pediatric and congenital heart operation outcomes and center level performance. Use of the STS CHSD for outcomes research and for quality measurement continues to expand as database participation has grown to include nearly all centers in North America, and the available wealth of data in the database continues to grow. This article reviews outcomes research and quality improvement articles published in 2016 that are based on STS CHSD data.

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Over the 23 years of its existence, The Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database (CHSD) has grown steadily to become the largest congenital and pediatric cardiac surgical clinical data registry in the world. More than 95% of centers in North America with programs for surgical management of pediatric and congenital heart disease (CHD) participate in the STS CHSD. The database contains data pertaining to a total of 435,373 operations entered between 2002 and 2016, with approximately 40,000 operations added each year [1]. Since 2010, the STS CHSD has included an anesthesia module in conjunction with the Congenital Cardiac Anesthesia Society.

The importance of the STS CHSD as a platform for quality assessment and quality improvement is related to much more than the quantity of data accumulated in the database. The STS CHSD data collection platform is thoroughly reviewed, assessed, and updated roughly every 3 years to ensure that data collection is optimally relevant and up to date with respect to innovations in the practice of surgery for CHD and current with respect to progress and new perspectives in the broader context of outcomes reporting and quality measurement. Updates are carefully engineered to maintain the utility of the "legacy" data that have previously been entered into the database using earlier versions. That is essential in terms of the opportunity for investigators to be able to carry out research that is relevant with respect to the most contemporary challenges and trends in patient management, at the same time being informative with respect to

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Abbreviations and Acronyms

CCAS	=	Congenital Cardiac Anesthesia Society
CHD	=	congenital heart disease
CHSD	=	Congenital Heart Surgery Database
CI	=	confidence interval
DCRI	=	Duke Clinical Research Institute
DHCA	=	deep hypothermic circulatory arrest
dSLO	=	duration of sternum left open
IQR	=	interquartile range
LFLR	=	Longitudinal Follow-Up and Linked Registries
NC/GA/S	=	noncardiac congenital anatomic abnormalities, genetic abnormalities, and syndromes
OR	=	odds ratio
PHN	=	Pediatric Heart Network
PUF	=	Participant User File
RCP	=	regional cerebral perfusion
SLO	=	sternum left open
STAT	=	The Society of Thoracic Surgeons–European Association for Cardio-Thoracic Surgery
STS	=	The Society of Thoracic Surgeons
TOF	=	tetralogy of Fallot
VSD	=	ventricular septal defect

the evolution of practice and trends in outcomes across eras. The last such updated version of the data collection form has been in use since January 2016, at which time implementation of Version 3.3 of the STS CHSD took place [2]. The STS CHSD Task Force has already begun work on the next update.

The Duke Clinical Research Institute (DCRI) serves as the data warehouse for the STS CHSD and performs the biannual data harvests and analysis of all STS CHSD data collected over a 4-year period. The DCRI also collaborates with the STS Workforce for National Databases and the STS Quality Measurement Task Force to provide the state-of-the-art statistical and analytic expertise essential to developing robust tools for reporting of risk-adjusted outcomes. These tools, or risk models, are key to the understanding and equitable reporting of outcomes and to facilitating quality improvement. Collaboration between the STS CHSD Task Force, the Congenital Subcommittee of the STS Access and Publications Task Force, and DCRI's STS Programming Task Force and team of dedicated clinical investigators and biostatisticians is the basis for an essential framework that makes database-related research possible.

The STS CHSD has been, and continues increasingly to be, a platform for clinical investigation broadly divided into two major categories: outcomes research, and quality measurement. Despite some overlap, these two domains have fundamental differences with respect to the major objectives as well as the types of analyses, funding sources, and the nature of the investigative teams.

Outcomes Research

Outcomes research based on the STS CHSD mainly involves the investigation of associations between patient factors, procedural factors, processes of care, and outcomes from surgical management. Individual investigations may focus on specific diagnostic and procedural groups, age-defined cohorts, or the entire population of patients undergoing pediatric and congenital heart operations at participating centers. Most often, such studies are hypothesis driven and help to advance the understanding of factors that affect surgical outcomes. Sometimes they are merely descriptive of patterns of practice and shed light on the patterns of dissemination and adoption of new therapeutic modalities or on variation in care. The latter, when significant, may point to target areas for quality improvement initiatives.

Access and Publications Pathway

Most STS CHSD-related outcome studies are initiated by database participants and their colleagues through submission of a proposal to the Congenital Subcommittee of the STS Access and Publications Task Force using submission forms that are available at the STS website [3]. The proposals are evaluated by a panel of clinicians, outcomes research specialists, and statisticians and are scored competitively. Scoring is based on categories of scientific merit, feasibility, potential impact of the proposal, appropriate use of the database, and the nature of the investigative team. Based on this system of evaluation, the highest-ranking proposals are approved, to be carried out with analytics performed by DCRI as well as with the support and guidance from members of the STS CHSD Task Force and Congenital Subcommittee of the Access and Publications Task Force. Given the limits on available funding, some projects proposed to the Access and Publications Task Force that are found to have scientific merit are approved for self-funding, namely, with the financial support originating from the proposing institution. Submission and evaluation of proposals takes place twice a year, in the spring and the fall.

Alternative Pathways

The STS CHSD-based outcomes research can also be proposed through the STS Task Force on Longitudinal Follow-Up and Linked Registries (LFLR) or the STS Participant User File (PUF) Research Program. The LFLR is the appropriate pathway for evaluation of proposals that involve linkage of STS CHSD and other registries or sources of administrative data. These studies are usually funded by investigator institutions or other external funding sources. At the present time, several projects involving linkage of STS CHSD data to other registries or external datasets are underway, under the auspices of the Task Force on LFLR. The STS PUF program was recently launched to allow analysis at investigators' institutions of national-scale deidentified data from the database. The PUF program was designed primarily as an option for investigators to pose research questions, quickly obtain