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

quality data, analyze these data themselves, receive feedback, and develop their efforts into abstracts and manuscripts [4]. The first few proposals submitted for consideration as CHSD PUF projects are in various stages of proposal review, delivery of data, or actual analysis. The PUF research proposals are received and reviewed on a continuous basis.

Outcomes Research Publications 2016

The following is a summary of CHSD-based outcomes research articles published in peer-reviewed journals during calendar year 2016. These represent the work product of STS member investigators with support from the STS CHSD Task Force, the Congenital Subcommittee of the Access and Publications Task Force and the analytics team at DCRI. Below are brief synopses of these articles.

Tracheostomy After Surgery for Congenital Heart Disease

Among patients who have a prolonged postoperative course after surgery for pediatric and CHD, the need for extended periods of mechanical ventilatory support represents one of the important morbidities. When liberation from mechanical ventilation is not possible, tracheostomy is considered. Until recently, information regarding the use of tracheostomy after pediatric cardiac surgery came primarily from a handful of single-center reports. These, of course, are potentially prone to varying degrees of bias owing to practice pattern variation.

Mastropietro and associates [5] undertook the first large, multicenter study of postoperative tracheostomy for pediatric cardiac patients using clinical registry data. Based on their analysis of data collected from 2000 to 2014, they reported that the incidence of tracheostomy after operations for CHD increased from 0.11% in 2000 to a high of 0.76% in 2012 ($p < 0.0001$). Postoperative tracheostomy was performed on 648 patients. Median age at the time of the index cardiovascular operation was 2.5 months (25th, 75th percentile: 0.4, 7). Common features among patients who eventually underwent tracheostomy were prematurity (n = 165, 26%), genetic abnormalities (n = 298, 46%), and preoperative mechanical ventilation (n = 275, 43%). Postoperative adverse events were common (Fig 1) and included cardiac arrest (n = 131, 20%), mechanical circulatory support (n = 87, 13%), phrenic or laryngeal nerve injury (n = 114, 18%), and neurologic deficit (n = 51, 8%). After tracheostomy, the aggregate rate of mortality before discharge, after discharge but within 30 days of the index cardiac operation, or within 180 days of transfer to a secondary acute care or rehabilitation facility was 25% (n = 153; Table 1). Having observed that the incidence of tracheostomy after operations for CHD has consistently increased since 2000, the researchers suggested that use of tracheostomy may not be of equivalent benefit for all types of patients. They recommended that identification of patient groups most likely to derive maximal benefit (those likely to recover respiratory function and achieve liberation from mechanical ventilatory support) should be the subject of further investigation, with evaluation of long-term follow-up data in a large cohort of these patients.

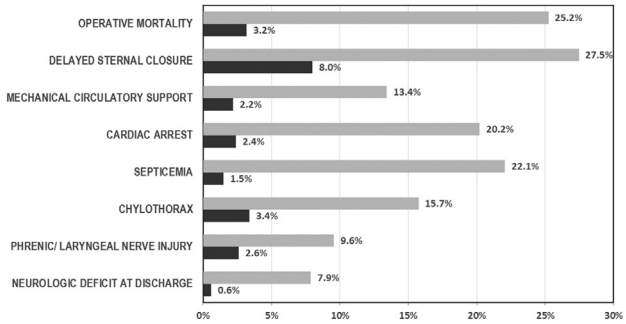


Fig 1. Operative mortality and adverse events in patients who required tracheostomy after cardiac operation (gray bars) and patients who did not (black bars), 2010 to 2014. (Republished from [5] with permission of The Society of Thoracic Surgeons.)

Early Extubation After Surgery for Congenital Heart Disease

In the context of increasing interest in the potential benefits and the limits of reducing the duration of mechanical ventilation after pediatric cardiac operations, Mahle and associates [6] used the STS CHSD as a platform to examine trends and associations with respect to early extubation of the trachea after repair of tetralogy of Fallot (TOF) and after the Fontan procedure. Historically, postoperative mechanical ventilatory support has been considered an important component of patient stabilization. It is recognized, however, that mechanical ventilation may impart some risk in the postoperative period, and that positive pressure ventilation may present particular disadvantages in the setting of certain types of circulatory physiology.

Several centers have advocated for early extubation after many pediatric cardiac operations. Investigators chose to focus their study on patients undergoing either reparative surgery for TOF (aged more than 45 days at time of operation) or the Fontan operation. The choice of these two procedural groups was predicated on the idea that both operations could lend themselves to an early extubation strategy, and the fact that some investigators have proposed potential physiologic benefits of early extubation in these settings. Early extubation was defined as extubation in the operating room at completion of the surgical procedure or less than 6 hours after leaving the operating room. Analysis was limited to patients who achieved extubation within 48 hours after leaving the operating room. Patients requiring longer ventilatory support were excluded from comparative analysis. Among eligible patients at 92 centers, early extubation was performed in 31.5% of children (478 of 1,519) undergoing TOF repair and in 69.8% (1,153 of 1,653) of children undergoing the Fontan operation (Fig 2).

Table 1. Comparison of Preoperative Characteristics Between Patients Who Died and Patients Who Survived Tracheostomy After Surgery for Congenital Heart Disease[a]

Preoperative Characteristics	Survived (n = 453)	Died (n = 153)	*p* Value
Age at surgery, months	2.6 (0.5, 7.0)	2.0 (0.3, 7.4)	0.2370
Sex			
Male	242 (53.4)	85 (55.6)	0.2006
Female	210 (46.4)	67 (43.8)	
Ambiguous	0 (0)	1 (0.7)	
Weight at surgery, kg	4.0 (3.1, 6.8)	3.9 (3.0, 6.1)	0.3426
Prematurity, <37 weeks completed gestation	120 (26.5)	33 (21.6)	0.3013
Mechanical ventilator support[b]	183 (40.4)	76 (49.7)	0.0247
Neurologic deficit	40 (8.8)	11 (7.2)	0.5730
Down syndrome (Trisomy 21)	41 (9.1)	11 (7.2)	0.4669
DiGeorge syndrome (22q11 deletion)	36 (7.9)	8 (5.2)	0.2563
Any other genetic/chromosomal abnormality	140 (30.9)	50 (32.7)	0.7077
STAT Mortality Category			
1	53 (11.7)	9 (5.9)	0.1314
2	81 (17.9)	29 (19)	
3	68 (15)	20 (13.1)	
4	188 (41.5)	60 (39.2)	
5	54 (11.9)	27 (17.6)	
Unclassified	9 (2.0)	8 (5.2)	

[a] Republished from [5] with permission of The Society of Thoracic Surgeons. [b] Mechanical ventilator support is coded as a preoperative factor when a patient is "supported with mechanical ventilation to treat cardiorespiratory failure during the hospitalization of his or her operation and before operating room entry date and time."

Values are median (25th percentile, 75th percentile) or n (%).

STAT = The Society of Thoracic Surgeons–European Association for Cardio-Thoracic Surgery Congenital Heart Surgery.

For each procedural cohort, centers were stratified on the basis of their tendency to undertake early extubation. Early extubation after TOF repair was associated with heavier weight at operation ($p < 0.001$) and fewer preoperative risk factors ($p = 0.016$). Most patients who were extubated early after TOF repair were extubated in the operating room. The median duration of ventilation was 0 hours (interquartile range [IQR]: 0.0 to 3.1). For TOF repair patients who did not undergo early extubation but were still extubated before 48 hours, the median duration of postoperative ventilation was 20.9 hours (IQR: 15.0 to 26.2). After adjustment for covariates, average postoperative length of stay after TOF repair was approximately 10% shorter for centers in the highest tertile of

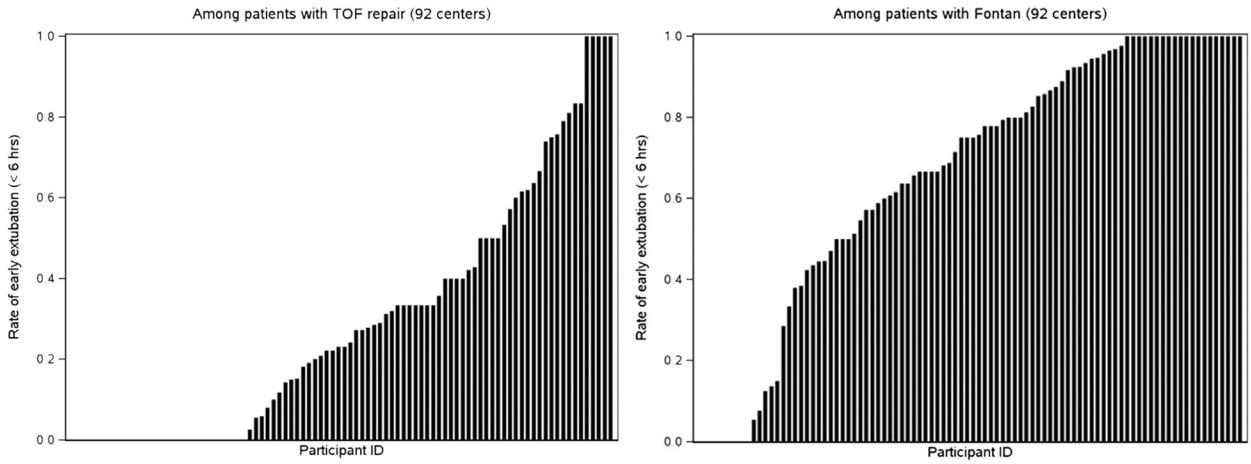


Fig 2. Frequency of early extubation by center for tetralogy of Fallot (TOF) repair (left panel) and for Fontan operation (right panel). Individual centers are plotted along the x-axis from left to right in order of increasing rates of early extubation. (ID = identification.) (Republished from [6] with permission of The Society of Thoracic Surgeons.)

early extubation rate than for the lowest tertile centers ($p = 0.04$). Most of the early extubation Fontan patients likewise were extubated in the operating room, with a median duration of postoperative ventilation of 0.0 hours (IQR: 0.0 to 2.6). For Fontan patients not undergoing early extubation but still extubated before 48 hours, the median duration of postoperative ventilation was 16.0 hours (IQR: 9.3 to 21.8). No association was found between a center's early extubation rate and postoperative length of stay for Fontan procedures ($p = 0.08$). In summary, a relatively high proportion of pediatric patients undergoing repair of TOF or the Fontan procedure are extubated early after the operation. Having observed that some institutions have embraced this strategy more than others, and that a center's rate of early extubation after TOF repair appears to be associated with postoperative length of stay, Mahle and associates [6] suggested that further investigation of this strategy may lead to more predictable and effective utilization of early extubation as a possible outcome improvement intervention.

Perfusion Strategies for Neonatal and Infant Aortic Arch Repair

Neonates and infants who require aortic arch reconstruction as part of the surgical management of various complex forms of CHD constitute a group for whom reliance on the use of deep hypothermic circulatory arrest (DHCA) became customary over the decades of the 1980s and 1990s. More recently, techniques involving use of selective antegrade regional cerebral perfusion (RCP) as a means of support that allows avoidance or reduction of the duration of DHCA have emerged as adjuncts or alternatives to DHCA and have been adopted by many practitioners, despite a paucity of data clearly supporting the superiority of either DHCA or RCP [7, 8].

Meyer and associates [9] analyzed data in the STS CHSD to provide a descriptive analysis of current practice patterns with respect to perfusion techniques during aortic arch repair in children to 1 year of age. The study population, consisting of 4,523 patients undergoing aortic arch repair as part of the index operation at 106 centers during 2010 through 2013 was divided into procedural groups: (1) Norwood stage I (n = 2,437); (2) repair of interrupted aortic arch with or without ventricular septal defect (VSD [n = 459]); (3) aortic arch repair with VSD repair (n = 614); and (4) aortic arch repair but no VSD repair (n = 1,013). Procedures that were not the index operation and procedures that included repair of truncus arteriosus, repair of atrioventricular canal defect, or arterial switch operation were excluded. Median age at surgery was 7 days (IQR: 5 to 13). Regional cerebral perfusion was the most prevalent perfusion strategy, being utilized in 59% of operations, including isolated RCP (RCP with 10 minutes or less DHCA) in 43% and RCP in combination with DHCA (mixed; RCP with more than 10 minutes of DHCA) in 16%. Some period of DHCA was used in 48% of operations, including 32% of operations in which there was no period of RCP (isolated DHCA). Relative prevalence of use of RCP versus DHCA versus mixed or other strategies was relatively consistent across procedural subgroups (RCP 42% to 45% across procedural groups; isolated DHCA 30% to 36% across procedural groups).

Despite the prevalence of RCP, some period of DHCA was still included as a component of the strategy in a significant percentage of cases in each of the procedural subgroups (43% to 50%). Curiously, in each of the four procedural subgroups, operations in the mixed category (RCP plus more than 10 minutes of DHCA) had significantly longer combined DHCA plus RCP time than RCP and DHCA times for operations using RCP or DHCA as an isolated strategy. Deep hypothermic circulatory arrest was the most prevalent perfusion strategy for aortic arch operations performed on patients who had undergone previous cardiac operations. Finally, there was no significant correlation between center volume and proportion of DHCA or RCP use in the overall cohort. Meyer and associates [9] concluded that in North American practices, there is currently no clearly dominant perfusion strategy for aortic arch repair involving cardiopulmonary bypass in infants and neonates. Use of antegrade RCP is more prevalent than isolated DHCA in this cohort of patients, but there is substantial variability across centers and DHCA remains in wide use. That is likely a reflection that, at the present time, there has not been enough rigorously derived data relating outcomes to perfusion strategy or demonstrating an advantage of one or another bypass technique to sway the field in a particular direction [8].

Impact of Critical Care Nursing on Pediatric Cardiac Surgery Outcomes

Previous studies have demonstrated the effects of nursing skill mix, staffing ratios, and level of nurse education on mortality and complication rates and failure to rescue among adult cardiac surgical patients. The area had, until recently, been largely unexplored with respect to pediatric and congenital heart surgery outcomes. Hickey and associates [10] undertook an analysis based on linkage of data from a nursing survey to clinical data collected in the STS CHSD. The objective was to address the question whether center-level characteristics, in terms of levels of nursing education and experience, are associated with outcomes after pediatric cardiac operations. Among 15,463 patients (29 hospitals), the inhospital mortality rate was 2.8%, postoperative complications occurred in 42.4%, and the failure to rescue rate was 6.4%. After covariate adjustment, pediatric critical care units with a higher proportion of nurses with a Bachelor of Science degree or higher had lower odds of complication (odds ratio for 10% increase in proportion of nurses, 0.85; 95% confidence interval: 0.76 to 0.96; $p = 0.009$). Units with a higher proportion of nurses with more than 2 years of experience had lower mortality rates (odds ratio for 10% increase, 0.92; 95% confidence interval: 0.85 to 0.99; $p = 0.025$). This analysis linking detailed clinical data with nursing and unit characteristics data may help inform a developing model of cardiovascular care. These data should be useful to administrative and clinical leaders in the formulation of policies and programmatic objectives designed to

optimize care and outcomes for this complex patient population whose care consumes a large share of hospital resources.

Prevalence of Noncardiac and Genetic Abnormalities in Neonates Undergoing Cardiac Operations

Among patients with CHD, the coexistence of noncardiac congenital anatomic abnormalities (NC), genetic abnormalities (GA), and syndromes (S) may influence therapeutic strategies and outcomes. Patel and associates [11] examined the contemporary prevalence and distribution of NC/GA/S across diagnostic groups among neonates undergoing cardiac operations using the STS CHSD [11]. Of 15,376 index neonatal operations at 112 centers (2010 to 2013), 18.8% of operations (2,894 of 15,376) were performed on neonates with NC/GA/S. Patients were divided into 10 groups based on the fundamental cardiac diagnosis. Rates of NC/GA/S varied substantially across groups. The highest prevalence of NC/GA/S abnormalities was among patients with atrioventricular septal defect (212 of 357 [59.4%]), interrupted aortic arch (248 of 567 [43.7%]), truncus arteriosus (204 of 554 [36.8%]), and TOF (417 of 1,383 [30.2%]), whereas patients with transposition of the great arteries (111 of 2,778 [4.0%]) had the lowest prevalence. The most commonly identified NC/GA/S included heterotaxy (597 of 15,376 [3.9%]), DiGeorge syndrome or 22q11 deletion (550 of 15,376 [3.6%]), Down syndrome or trisomy 21 (318 of 15, 376 [2.1%]), intestinal malrotation (220 of 15,376 [1.4%]), and Turner syndrome or 45XO (189 of 15,376 [1.2%]). The prevalence of NC/GA/S varies widely across groups with different CHD fundamental diagnoses. These findings have important implications for patient counseling and screening recommendations and suggest a heightened focus on some diagnostic groups for genetic screening. They also support a more comprehensive approach to consideration of noncardiac congenital anatomic abnormalities, genetic abnormalities, and syndromes in future versions of STS CHSD risk models.

Delayed Sternal Closure in Infant Heart Surgery

Delaying closure of the sternum and the median sternotomy incision is a tactic that is commonly used to optimize hemodynamic stability after neonatal and infant heart surgery. Nelson-McMillan and associates [12] explored potential associations between the duration of sternum left open (SLO) and the rate of occurrence of infection complications [12]. The primary outcome of interest was occurrence of an infection complication, defined as one or more of the following: endocarditis, pneumonia, wound infection, wound dehiscence, sepsis, or mediastinitis. Multivariable regression models were fit to assess association of infection complication with duration of SLO (days), location of delayed sternal closure procedure (operating room versus elsewhere), and patient and procedural factors. A total of 6,127 patients with SLO at 100 centers were included in analysis. Median age and weight at index operation were 8 days (IQR: 5 to 24) and 3.3 kg (IQR: 2.9 to 3.8 kg). The strategy tended to be used most commonly for patients undergoing operations in the higher-level STS morbidity categories [13], with 66% of cases being in STS morbidity categories 4 or 5. The final delayed sternal closure procedure was most often carried out in an intensive care unit setting, with only 16% being performed in the operating room (Fig 3).

At least one infection complication occurred in 18.7% of patients (1,144 of 6,127) with SLO. This compares with rate of infection complication of 6.6% among potentially eligible neonates and infants without SLO. For the SLO cohort, of the six infection complications, sepsis was most common at 8.2% (505 of 6,127), with wound infection second most common at 6.3% (384 of 6,127). Mediastinitis occurred in 1.8% of cases (107 of 6,127) with SLO. Increased duration of sternum left open (dSLO) was associated with an increased rate of all infectious complications evaluated. When dSLO was coded as a continuous variable, a statistically significant association between dSLO and infection rate was observed ($p < 0.001$). After fitting restricted cubic splines, the rate of occurrence of infection was seen to increase progressively with increasing dSLO (14% with dSLO 0 to 1 day, 15% with dSLO 2 days, 17% with dSLO 3 days, 16% with dSLO 4 to 6 days, and 35% with dSLO 7 days). Rate of mediastinitis increased from 0.5% for dSLO 0 of 1 days versus 4.9% for dSLO for 7 or more days.

By multivariable analysis, independent risk factors for infection were dSLO (adjusted odds ratio [OR] 3.87, 95% confidence interval [CI]: 3.00 to 4.99, $p < 0.0001$ for SLO 7 days versus 0 to 1 days), preoperative renal dysfunction or renal failure requiring dialysis (OR 1.71, 95% CI: 1.09 to 2.67, $p = 0.02$), preoperative mechanical ventilation (OR

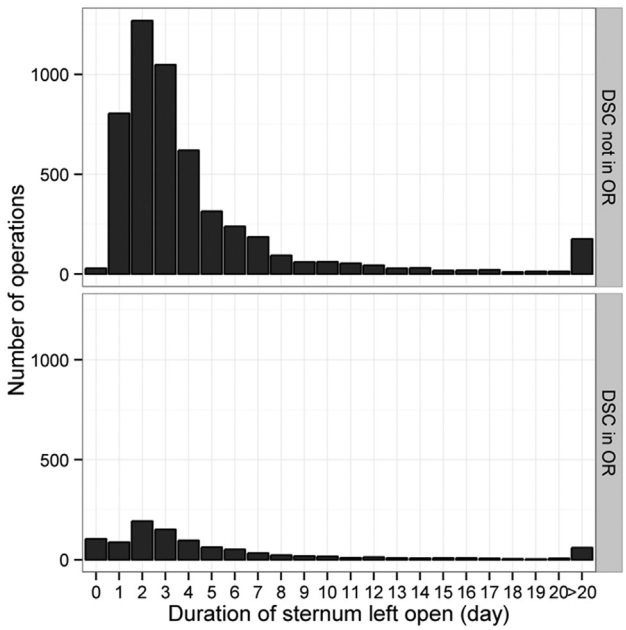


Fig 3. Number of operations (count) by duration of sternum left open (days) and by location of last delayed sternal closure (DSC) procedure: (upper panel) not in operating room (OR), or (bottom panel) in operating room. (Republished from [12] with permission of The Society of Thoracic Surgeons.)

1.21, 95% CI: 1.03 to 1.42, $p = 0.02$), any other STS CHSD preoperative factor (OR 1.30, 95% CI: 1.07 to 1.57, $p = 0.007$), Z-score for weight in neonates (OR 1.11, 95% CI: 1.02 to 1.20, $p = 0.013$), and the Norwood procedure when compared with any other index operation with SLO (OR 1.69, 95% CI: 1.08 to 2.65, $p = 0.02$). Location where the final delayed sternal closure was performed was not associated with risk of infection complication. Nelson-McMillan and associates [12] inferred from these data that delayed sternal closure should be used judiciously, with the goal of achieving definitive closure within the first few days after surgery, and certainly as soon as cardiovascular stability permits. Maintaining an open sternum for a few days is associated with considerable risk of infection, with only small day-to-day increments in risk over the first several days. Closure of an open sternum should be considered as soon as it is considered feasible. Location of delayed sternal closure in an intensive care unit setting was not associated with increased risk of infection.

Perioperative Use of Dexmedetomidine in Pediatric Patients With Congenital Heart Disease

The Congenital Cardiac Anesthesia Section of the STS CHSD serves as the official database of the Congenital Cardiac Anesthesia Society (CCAS). This database continues to grow, with more than 110,546 anesthetic records included in the Spring 2017 Harvest and Feedback Report (of which 75,582 records pertained to the 4-year analytic window of January 1, 2013, to December 31, 2016, inclusive). The CCAS module now includes data from 58 participants in North America, representing a wide spectrum of programmatic size.

Schwartz and associates [14] undertook an analysis of multicenter data with the objectives of characterizing and better understanding contemporary practices with respect to the use of dexmedetomidine in the perioperative setting in children with heart disease [14]. Dexmedetomidine is a selective α-2 receptor agonist with a sedative and cardiopulmonary profile that makes it an attractive anesthetic for pediatric patients with CHD. The analysis included all index cardiopulmonary bypass operations entered in the CCAS-STS database from 2010 to 2013. Of the 12,142 eligible operations, 3,600 (29.6%) were performed with an overall anesthesia management strategy that included perioperative administration of dexmedetomidine, and 8,542 did not receive the drug. Patient characteristics were different between the two groups, with the dexmedetomidine group generally exhibiting both lower patient and procedural risk factors. Operations for which patients received dexmedetomidine were more likely to be in lower Society of Thoracic Surgeons–European Association for Cardio-Thoracic Surgery (STAT) Mortality Categories [15] than operations on patients who did not receive it. Consistent with their overall lower risk profile, children in the dexmedetomidine group also demonstrated better outcomes compared with patients who did not receive dexmedetomidine. This first analysis of the anesthesia data in the CCAS-STS Congenital Heart Disease Database provides insights into the growing use of dexmedetomidine among children anesthetized for surgical repair of CHD. Dexmedetomidine appears to be preferentially given to older and larger children who are undergoing less complex surgical procedures.

Research Related to Quality Measurement

Importance of Case Mix in Analysis of Outcomes and Performance in Congenital Heart Surgery

Assessment of performance in congenital heart surgery is challenging owing to the wide heterogeneity of disease and the very large number of distinct procedure types that are performed. In addition, there is variation across centers in terms of case mix and the number and type of patients treated. The STS-CHSD feedback reports to participants currently describe center level outcomes stratified by STAT Mortality Category [15] as well as outcomes related to a selected group of representative and somewhat commonly performed procedures (benchmark operations). At present, the recently developed STS CHSD Mortality Risk Model [16, 17] is applied at center level to the aggregate of all cardiovascular surgical operations. Risk-adjusted mortality rates are reported for this universe of all cases as well as for subsets of patients stratified by age group and STAT Mortality Categories.

Pasquali and associates [18] undertook a study to describe current case mix across centers, and to evaluate methodology inclusive of all cardiac operations versus a more homogeneous subset defined by STS benchmark operations (Table 2) [19], with an objective of describing implications of these two alternative methodologies when used for performance assessment. Centers (n = 119) participating in the STS CHSD (2010 through 2014) were included. Index cardiovascular operation type (based on primary procedure) and frequency across centers were described. Center performance (risk-adjusted operative mortality) was evaluated and classified when the analysis was based only on the benchmark operations, and also when based on all cardiovascular operations. The analytic cohort comprised 112,140 cases during the 5-year study period. Overall, 207 different types of operations were performed across the 119 centers. Many operations were performed infrequently, with 92 of 207 (44%) performed fewer than 100 times in the 5-year study period. Overall, 19 of the 207 operation types (9.2%) captured at least 50% of the total cases; 42 operations (20.3%) captured at least 75% of the total cases, and 74 operations (35.7%) captured at least 90% of the total cases. On a center level, 95 (45.9%) of the 207 total operation types were performed at least once during the 5-year study period by 50% or more of the centers, 52 operations (25.1%) were performed at least once by 75% or more of the centers, and 22 operations (10.6%) were performed at least once by 90% or more of the centers. In other words, relatively few of the 207 different types of operations were performed across all centers, and many operations were only performed at certain subsets of centers.

Table 2. Ten Benchmark Operations[a]

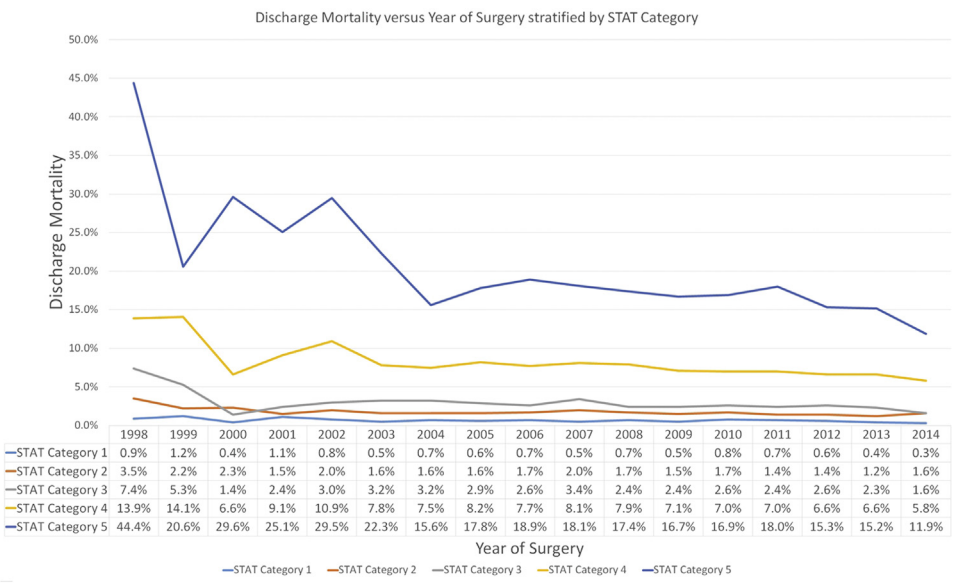
Procedure Type	Abbreviation	STS-CHSDB Primary Procedure Codes
1. Ventricular septal defect repair	VSD	110 = VSD repair, patch
2. Tetralogy of Fallot repair	TOF	350 = TOF repair, no ventriculotomy
		360 = TOF repair, ventriculotomy, nontransanular patch
		370 = TOF repair, ventriculotomy, transanular patch
3. Complete atrioventricular canal repair	AVC	170 = AVC (AVSD) repair, complete (CAVSD)
4. Arterial switch operation	ASO	1110 = Arterial switch operation
5. Arterial switch + VSD repair	ASO + VSD	1120 = Arterial switch operation and VSD repair
6. Glenn/hemiFontan	Glenn/ hemiFontan	1670 = Bidirectional cavopulmonary anastomosis (BDCPA [bidirectional Glenn])
		1680 = Glenn (unidirectional cavopulmonary anastomosis [unidirectional Glenn])
		1690 = Bilateral bidirectional cavopulmonary anastomosis (BBDCPA [bilateral bidirectional Glenn])
		1700 = HemiFontan
		2130 = Superior cavopulmonary anastomosis(es) + pulmonary artery reconstruction
7. Fontan operation	Fontan	970 = Fontan, TCPC, lateral tunnel, fenestrated
		980 = Fontan, TCPC, lateral tunnel, nonfenestrated
		1000 = Fontan, TCPC, external conduit, fenestrated
		1010 = Fontan, TCPC, external conduit, nonfenestrated
		2780 = Fontan, TCPC, intra/extracardiac conduit, fenestrated[c]
		2790 = Fontan, TCPC, intra/extracardiac conduit, nonfenestrated[c]
		3310 = Fontan, TCPC, external conduit, hepatic veins to PA, fenestrated[d]
		3320 = Fontan, TCPC, external conduit, hepatic veins to PA, nonfenestrated[d]
8. Truncus arteriosus repair	Truncus	230 = Truncus arteriosus repair
9. Norwood procedure	Norwood	870 = Norwood procedure
10. Off-bypass coarctation[b]	Coarctation	1210 = Coarctation repair, end to end
		1220 = Coarctation repair, end to end, extended
		1230 = Coarctation repair, subclavian flap
		1240 = Coarctation repair, patch aortoplasty
		1250 = Coarctation repair, interposition graft
		1280 = Aortic arch repair

[a] Republished from [19] with permission of The Society of Thoracic Surgeons. [b] Include only cases with operation type (no cardiopulmonary bypass cardiovascular). [c] Available only in data version 3.22 and 3.3. [d] Available only in data version 3.3.

The 10 current benchmark operations, together with The Society of Thoracic Surgeons Congenital Heart Surgery Database (STS CHSD) procedural codes (version 3.0, version 3.22, and version 3.3) that qualify for inclusion in each of the benchmark operation groups. (Note that benchmark operations 6 and 10 are not included in the initial publication of these benchmark operations [27] and were added to the list after the publication of the initial list of benchmark operations. Also, note that operations are classified into the various benchmark procedure groups according to the assigned primary procedure for that operation.)

AVC = atrioventricular canal; AVSD = atrioventricular septal defect; CAVSD = complete atrioventricular septal defect; PA = pulmonary artery; TCPC = total cavopulmonary connection.

The benchmark operations, 10 groups of related procedures (Table 2), accounted for 36% of the total cases (40,545 of 112,140) and accounted for 33.5% of the mortalities during the study period. Most of the benchmark operations were performed by at least 90% of centers during the 5-year study period, with the exception of arterial switch operation with ventricular septal defect repair (89% of centers), and truncus arteriosus repair (82% of centers). Although most centers performed most of these types of these operations, the number of cases performed varied widely across centers. The median risk-adjusted operative mortality rate for all index cardiovascular operations was 3.5% (range, 0% to 13.4% across centers). For benchmark operations, the median risk-adjusted operative mortality rate was 3.1% (range, 0% to 20.4% across centers). When centers were classified into performance categories (lower, higher, or same-as-expected risk-adjusted mortality) based on models that included the benchmark operations only versus all operations, 81 of 95 centers (85%) did not change performance classification. The other 14 centers (15%) changed by one category; no center changed by two categories. Methodology based on analysis of the benchmark operations only versus all operations was associated with lower power: 35% versus 78% of centers, respectively, met the volume threshold during a 4-year period needed to



	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
STAT Category 1	0.9%	1.2%	0.4%	1.1%	0.8%	0.5%	0.7%	0.6%	0.7%	0.5%	0.7%	0.5%	0.8%	0.7%	0.6%	0.4%	0.3%
STAT Category 2	3.5%	2.2%	2.3%	1.5%	2.0%	1.6%	1.6%	1.6%	1.7%	2.0%	1.7%	1.5%	1.7%	1.4%	1.4%	1.2%	1.6%
STAT Category 3	7.4%	5.3%	1.4%	2.4%	3.0%	3.2%	3.2%	2.9%	2.6%	3.4%	2.4%	2.4%	2.6%	2.4%	2.6%	2.3%	1.6%
STAT Category 4	13.9%	14.1%	6.6%	9.1%	10.9%	7.8%	7.5%	8.2%	7.7%	8.1%	7.9%	7.1%	7.0%	7.0%	6.6%	6.6%	5.8%
STAT Category 5	44.4%	20.6%	29.6%	25.1%	29.5%	22.3%	15.6%	17.8%	18.9%	18.1%	17.4%	16.7%	16.9%	18.0%	15.3%	15.2%	11.9%

Fig 4. Discharge mortality versus year of operation stratified by The Society of Thoracic Surgeons–European Association for Cardio-Thoracic Surgery Congenital Heart Surgery (STAT) Mortality Category—1 (light blue), 2 (orange), 3 (gray), 4 (yellow), and 5 (dark blue)—for the years 1998 to 2014, including all 118 programs. (Republished from [20] with permission of The Society of Thoracic Surgeons.)

detect a doubling of mortality. Despite this, the overall proportion of centers classified as a statistical outlier (either higher or lower than expected mortality) was similar regardless of the methodology.

Pasquali and associates [18] concluded that there is wide variation in case mix across centers performing surgery for pediatric and CHD. This, of course, must be accounted for in the analysis of outcomes and the development of performance metrics. Choice of the target population for analysis and reporting is likewise important. This analysis showed that there are strengths and limitations to both the approach of including all operations and the approach of focusing on a more homogeneous subset (eg, benchmark operations). These approaches may be viewed as complementary, and may be reported together providing different windows into performance, or used preferentially depending on the goals of various initiatives, with limitations acknowledged. This information can help to further refine the assessment of performance based on existing risk models, and can also inform the development of new performance metrics that extend beyond the perioperative period and that consider additional outcome domains, such as morbidity.

Mortality Trends in Pediatric and Congenital Heart Surgery

Jacobs and associates [20] undertook an analysis of multiinstitutional data in the STS CHSD to assess and describe trends over time with respect to outcome metrics of discharge mortality and postoperative length of stay. Index cardiovascular surgical operations from 1998 to 2014, inclusive, were grouped by STAT Mortality Category. Inclusion criteria were identical to those used in the analysis and reporting of mortality outcomes in the biannual STS CHSD feedback reports to participants. Endpoints were discharge mortality and postoperative length of stay in survivors for the entire period and for 4-year epochs. The Cochran-Armitage trend test was used to test the null hypothesis that the mortality was the same across epochs, by STAT Mortality Category. The analysis encompassed 202,895 index operations at 118 centers. The number of centers participating in STS CHSD increased in each epoch. Overall discharge mortality was 3.4% (6,959 of 202,895) for 1998 to 2014 and 3.1% (2,308 of 75,337) for 2011 to 2014. Statistically significant improvement in discharge mortality was seen in STAT Mortality Categories 2, 3, 4, and 5 (p values for STAT Mortality Categories 1 through 5 are 0.060, <0.001, 0.015, <0.001, and <0.001, respectively; Fig 4). Postoperative length of stay among survivors was relatively unchanged over the same intervals. A sensitivity analyses was performed for the year-by-year analysis, involving the entire period but limited to data from the 30 programs that participated since 2003. That confirmed that the finding of declining risk-stratified rates of discharge mortality over time is not simply attributable to the addition of more centers to the cohort over time.

Completeness and Accuracy of Clinical Registry Data

The Pediatric Heart Network (PHN), funded by the National Heart, Lung, and Blood Institute, conducts clinical trials and other prospective investigations related to pediatric cardiovascular disease. Although the PHN has traditionally created customized study-specific platforms for prospective data collection and relied upon specially trained research coordinators, many of the surgical variables of interest for prospective investigations are now routinely captured within participating sites' local registry software, for which the primary use has been submission to the STS CHSD. These data are generally collected by a combination of clinicians and trained data managers. Nathan and associates [21] undertook a study to evaluate the completeness and accuracy of

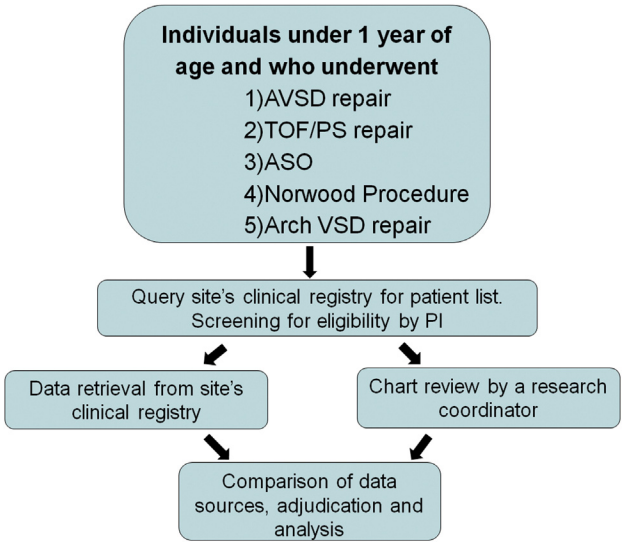


Fig 5. Schematic diagram of registry data quality study by Nathan et al. (ASO = arterial switch operation; AVSD = atrioventricular septal defect; PI = principal investigator; TOF/PS = tetralogy of Fallot/pulmonary stenosis; VSD = ventricular septal defect.) (Republished from [21] with permission of The Society of Thoracic Surgeons.)

perioperative data available in PHN sites' local surgical registries compared with data collected by trained PHN coordinators. The fundamental research question was whether these existing registry data may serve as a high-quality data source for more efficient conduct of prospective trials and other studies in the congenital heart surgery population. At 12 PHN sites, data pertaining to 31 perioperative variables (and their subcategories, totaling 113 unique fields) that were collected using sites' local clinical registry software (which the sites use for submission to the STS Database) were compared with data abstracted in the course of study-specific chart review by PHN research coordinators. Both used standard STS definitions. Data were collected on 10 subjects for 2 to 5 procedures per site and were adjudicated by the study team. Completeness and accuracy (agreement of registry data with medical record review by PHN coordinator, adjudicated by the study team) were evaluated (Fig 5).

A total of 56,500 data elements were collected on 500 subjects. Data completeness was assessed: 3.1% of data elements were missing from the registry, 0.6% from coordinator-collected data, and 0.4% from both. Overall, registry data accuracy was 98%. In total, 94.7% of data elements were both complete and accurate within the registry, with some variation across data fields and sites. Mean total time for coordinator chart review per site was 49.1 hours versus 7.0 hours for registry query. This important preliminary study suggests that existing surgical registry data constitute a complete, accurate, and efficient information source for prospective research. Variability across data fields and sites also suggest areas for improvement in some areas of data quality.

Conclusion

As the largest congenital and pediatric cardiac surgical clinical data registry in the world, the STS CHSD contains data pertaining to nearly all pediatric cardiovascular surgical operations performed in the United States. This inclusive and representative dataset has now been collected for more than 2 decades for the primary purposes of outcomes assessment and quality improvement. It also represents a unique resource for research designed to further our understanding of associations between diagnoses, patient factors, treatment strategies, procedural factors, and outcomes. Summarized herein are reports published during 2016 in the peer-reviewed literature. All are based on STS CHSD-related research. Most of these undertakings were investigator-proposed projects that were ultimately performed under the auspices of the STS Access and Publications Task Force, with support from STS, from the STS CHSD Task Force, and with the analytic support and expertise of DCRI. Others were organized and supported by the National Heart, Lung, and Blood Institute through the PHN [21] or through direct grant support to the principle investigator and investigative team [18]. In addition to these avenues for data access and support for research, the STS continues to provide access to registry data by investigators through the STS Task Force on LFLR, and most recently, through the STS PUF Research Program.

The STS CHSD is a unique and rich data source that provides a reliable bedrock of information that supports improvement in care. Although unproven, it seems reasonable to speculate that many of the improvements in care and outcomes cited in this update were related to the fund of data and the research infrastructure associated with this registry. Continuing growth of the registry, together with numerous pathways for data access by qualified investigators, virtually insures that the STS CHSD will continually, and increasingly, be a resource for research that has the potential to benefit patients by providing evidence and insights that support meaningful progress in patient care.

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