The Society of Thoracic Surgeons Congenital Heart Surgery Database: 2019 Update on Outcomes and Quality

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The Society of Thoracic Surgeons Congenital Heart Surgery Database is a comprehensive clinical outcomes registry that captures almost all pediatric cardiac surgical operations in the United States. It is the platform for all activities of The Society of Thoracic Surgeons related to the analysis of outcomes and the improvement of quality in this subspecialty. This report summarizes current aggregate national outcomes in congenital and pediatric cardiac surgery and reviews related activities in the areas of quality measurement, performance improvement, and transparency. The reported data about aggregate national outcomes are exemplified by an analysis of 10 benchmark operation groups performed from January 2014 to December 2017. This analysis documents the overall aggregate Operative Mortality for operations performed at North American participants in The Society of Thoracic Surgeons Congenital Heart Surgery Database and the interquartile range (IQR) for participant-specific rates of Operative Mortality for the following procedural groups: off-bypass coarctation repair, 1.5% (IQR, 0.0% to 1.4%); ventricular septal defect repair, 0.5% (IQR, 0.0% to 0.5%); tetralogy of Fallot repair, 1.3% (IQR, 0.0% to 2.0%); complete atrioventricular canal repair, 2.5% (IQR, 0.0% to 4.1%); arterial switch operation, 2.2% (IQR, 0.0% to 3.0%); arterial switch operation and ventricular septal defect repair, 4.6% (IQR, 0.0% to 7.1%); Glenn/hemiFontan, 1.8% (IQR, 0.0% to 2.7%); Fontan operation, 1.0% (IQR, 0.0% to 0.4%); truncus arteriosus repair, 9.5% (IQR, 0.0% to 15.4%); and Norwood (stage 1) operation, 15.0% (IQR, 8.3% to 25.0%).

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The Society of Thoracic Surgeons Congenital Heart Surgery Database (STS CHSD) was founded in 1994 to provide assessment of programmatic and aggregate outcomes to participants and to support quality improvement and patient safety in pediatric and congenital cardiothoracic surgery [1–3]. STS CHSD is now the largest congenital and pediatric cardiac surgical clinical data registry in the world, containing data from 494,099 operations as of November 15, 2018. These data are the foundation for assessment of performance (by benchmarking and evaluation of individual programmatic outcomes within the context of national aggregate data), development and subsequent application of sophisticated risk adjustment models [4–7], quality improvement initiatives, research, voluntary public reporting [8–13], development of reimbursement strategies, and governmental and regulatory collaborations. This report is the fourth in a series of annual reports summarizing current national aggregate congenital and pediatric cardiac surgical outcomes [14–17].

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Overview of STS CHSD

Collection of detailed clinical data and feedback of risk-adjusted nationally benchmarked results to participating cardiac surgical programs are the primary functions of STS CHSD [18]. A STS CHSD participant is typically a hospital cardiac surgery program, a practice group of cardiothoracic surgeons, or uncommonly, an individual surgeon. Data are submitted to the STS data warehouse and analytical center at the Duke Clinical Research Institute (DCRI). DCRI develops Feedback Reports two times each year based on the most recently completed 48-month period of data collection and distributes these Feedback Reports every 6 months to each STS CHSD participant. These Feedback Reports facilitate internal quality assessment and serve as a platform for quality improvement. In these Feedback Reports, data about risk-stratified and risk-adjusted outcomes of the individual participant are presented within the context of multi-institutional aggregate benchmarks obtained by pooling data from all participants located in the United States or Canada.

The spectrum of individual congenital cardiac malformations is broad, and the variety of types of cardiac disease affecting individuals early in life is large. Consequently, to collect relevant data, STS CHSD must account for nearly 200 individual diagnoses and a roughly comparable number of distinct types of therapeutic interventions, which are not infrequently performed in various combinations as elements of a multiple-component operation. To maintain clinical relevance with evolving surgical practice, data elements undergo periodic revision to clarify existing variables, harmonize definitions with related national and international databases, add new variables of interest, and remove irrelevant or rarely used data elements. These updates of STS CHSD are performed on a 3-year cycle.

As of September 24, 2018, STS CHSD included 123 participants comprising 436 surgeons from 40 states (and Washington, DC) in the United States (Fig 1) and from Canada (3 Canadian Provinces), India, Israel, and Singapore [19]. The aggregate data reported in Tables 1 and 2 are derived from the Spring 2018 Harvest STS CHSD Feedback Report (STS CHSD Twenty-eighth Harvest), which includes the 4-year analytic window of January 1, 2014, through December 31, 2017, inclusive (Figs 2, 3, and 4) [18]. When reporting multi-institutional aggregate data, STS CHSD includes only data from participants located in the United States and Canada. Thus, the aggregate data in this report are from operations performed at 119 participants, 116 in the United States and 3 in Canada [18].

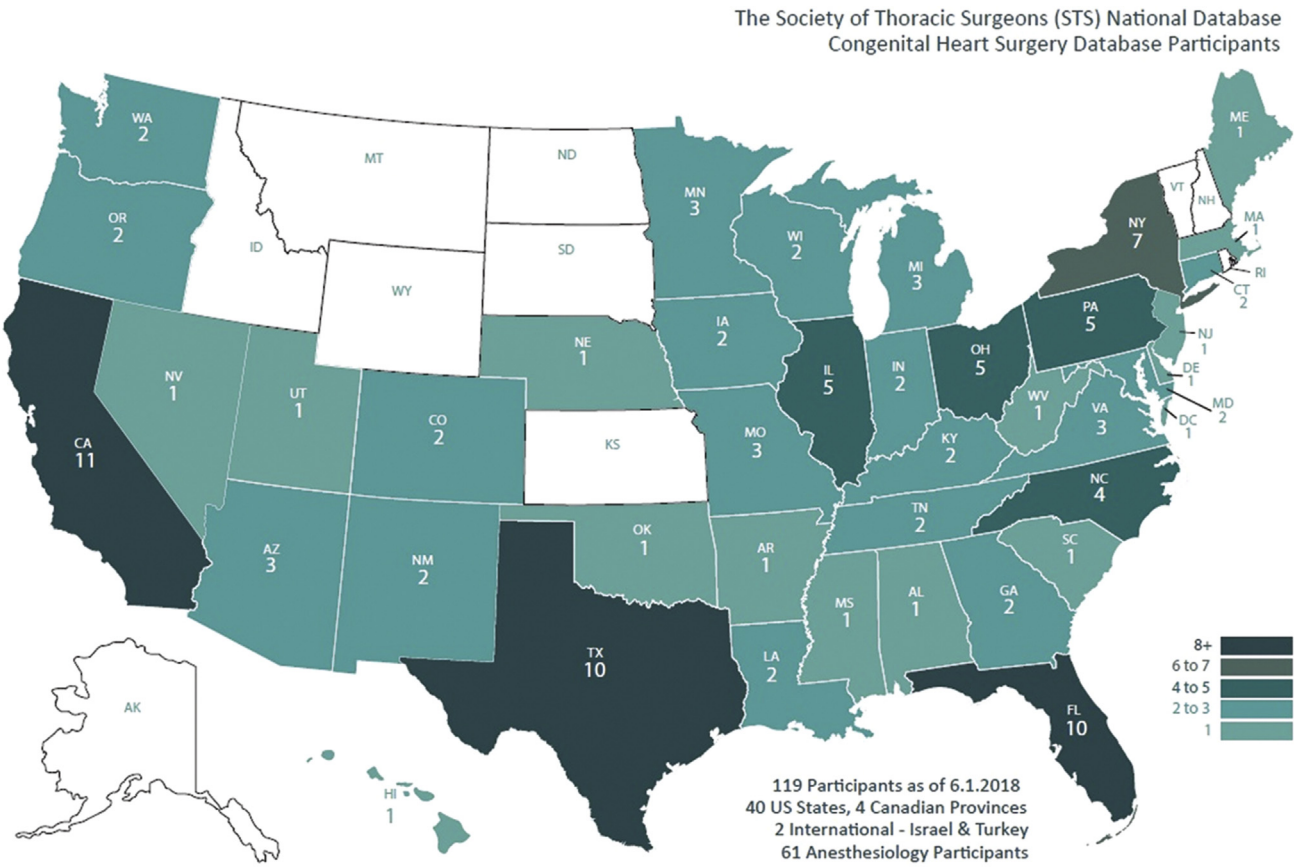

Fig 1. The map documents the number of programs located in each state in the United States that participate in The Society of Thoracic Surgeons Congenital Heart Surgery Database, as of June 1, 2018.

Table 1. The Society of Thoracic Surgeons Congenital Heart Surgery Database Aggregate Outcomes of Risk-Stratified Operations: Operative Mortality and Postoperative Length of Stay, Last 4 Years (January 2014 Through December 2017)[a]

Variable	STAT Category 1	STAT Category 2	STAT Category 3	STAT Category 4	STAT Category 5
STS overall (all participants)					
Sample size, number					
Participants	117	119	117	118	112
Operations	29,188	35,783	11,271	20,978	3,975
Participant-specific sample size					
Average	249.5	300.7	96.3	177.8	35.5
Range	6.0–1,125.0	5.0–1,327.0	2.0–471.0	2.0–855.0	1.0–183.0
Operative Mortality, %[a]					
Aggregate mortality rate	0.4	1.6	2.3	6.4	14.6
Participant-specific mortality rate					
Median	0.0	1.4	2.0	6.4	14.5
Range	0.0–2.3	0.0–14.3	0.0–12.0	0.0–25.0	0.0–100.0
Interquartile range	0.0–0.6	0.9–2.2	0.0–3.8	4.6–8.4	9.1–22.9
PLOS, days					
Aggregate average per patient	7.3	21.4	15.7	27.5	45.8
Participant-specific PLOS					
Average	7.0	20.5	15.5	26.7	42.6
Range	3.1–14.4	8.0–62.4	4.3–34.7	6.5–82.6	0.0–140.5
Interquartile range	5.8–8.2	16.5–28.6	11.8–18.3	22.9–31.4	33.7–53.8
Among sites with N $\geq$10[b]					
Sample size, number					
Participants	116	118	109	115	80
Operations	29,182	35,778	11,230	20,966	3,824
Participant-specific sample size					
Average	251.6	303.2	103.0	182.3	47.8
Range	15.0–1,125.0	10.0–1,327.0	11.0–471.0	13.0–855.0	10.0–183.0
Operative Mortality, %[a]					
Aggregate mortality rate	0.4	1.6	2.3	6.4	14.3
Participant-specific mortality rate					
Median	0.0	1.4	2.2	6.4	14.3
Range	0.0–2.3	0.0–14.3	0.0–12.0	0.0–25.0	0.0–53.8
Interquartile range	0.0–0.6	0.9–2.2	0.7–3.8	4.6–8.3	9.8–20.0
PLOS, days					
Aggregate average per patient	7.3	21.4	15.7	27.6	45.8
Participant-specific average PLOS					
Median	7.0	20.5	15.7	27.1	44.5
Range	3.1–14.4	8.0–62.4	6.0–34.7	12.1–82.6	19.8–114.4
Interquartile range	5.8–8.3	16.5–28.5	12.3–18.5	22.9–31.7	35.3–52.1

[a] The mortality rates reported here are observed (unadjusted mortality rates). Although the aggregate data in Table 1 are not risk-adjusted, these unadjusted outcomes data are risk-stratified by the The Society of Thoracic Surgeons—European Association for Cardio-Thoracic Surgery (STAT) Mortality Categories [20, 21]. [b] More than nine operations in a given category in the analytic window of time.

PLOS = Postoperative Length of Stay; STS = The Society of Thoracic Surgeons.

Of the 475,393 cumulative worldwide operations included in STS CHSD as of September 24, 2018, 461,758 were submitted by participants located in the United States [19]. On September 24, 2018, the 115 participants located in the United States represented 135 hospitals [19]. (An STS database participant is a "practice group of cardiothoracic surgeons" or, uncommonly, an individual cardiothoracic surgeon. In most instances, an STS database participant is a hospital cardiac or thoracic surgery program. In most situations, 1 STS database participant is linked to 1 hospital; however, in some instances, 1 STS database participant is linked to more than 1 hospital or 1 hospital is linked to more than 1 STS database participant. Therefore, minor differences exist between the number of STS database participants and the number of hospitals submitting data to the STS databases.)

The 2015 STS Congenital Heart Surgery Practice Survey Report, undertaken by the STS Workforce on

Table 2. The Society of Thoracic Surgeons Congenital Heart Surgery Database Aggregate Outcomes of Benchmark Operation Groups: Operative Mortality and Postoperative Length of Stay, Last 4 Years (January 2014 Through December 2017)[a]

Variable	Off Bypass Coarctation	VSD	TOF	AVC	ASO	ASO+VSD	Glenn/HemiFontan	Fontan	Truncus	Norwood
STS overall (all participants)										
Sample size, number										
Participants	116	117	117	115	108	99	115	113	101	105
Operations	3,920	7,412	4,869	3,270	1,885	810	4,387	4,157	602	2,737
Participant-specific sample size										
Average	33.8	63.4	41.6	28.4	17.5	8.2	38.1	36.8	6.0	26.1
Range	1.0–141.0	1.0–230.0	2.0–166.0	1.0–134.0	1.0–76.0	1.0–41.0	1.0–160.0	1.0–197.0	1.0–24.0	1.0–117.0
Operative Mortality, %[b]										
Aggregate mortality rate	1.5	0.5	1.3	2.5	2.2	4.6	1.8	1.0	9.5	15.0
Participant-specific mortality rate										
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	14.3
Range	0.0–20.0	0.0–6.7	0.0–16.7	0.0–18.2	0.0–100.0	0.0–100.0	0.0–20.0	0.0–16.7	0.0–100.0	0.0–100.0
Interquartile range	0.0–1.4	0.0–0.5	0.0–2.0	0.0–4.1	0.0–3.0	0.0–7.1	0.0–2.7	0.0–0.4	0.0–15.4	8.3–25.0
PLOS, days										
Aggregate average PLOS per patient	13.7	9.4	12.4	17.9	17.9	20.5	15.0	14.2	34.7	49.3
Participant-specific average PLOS										
Median	12.4	8.7	11.8	17.3	17.3	18.2	14.5	13.9	28.0	45.5
Range	3.0–40.3	3.8–23.9	3.3–40.6	4.0–58.2	5.5–77.0	5.5–126.0	4.0–42.8	5.1–40.0	7.0–183.0	1.0–140.5
Interquartile range	8.3–16.2	7.0–10.6	9.2–14.1	12.6–22.4	13.0–21.7	13.9–26.8	9.9–16.7	11.8–16.4	19.6–48.0	33.1–60.0
Among sites with N ≥10[b]										
Sample size, number										
Participants	92	113	104	90	73	31	98	91	18	72
Operations	3,807	7,400	4,800	3,118	1,701	516	4,323	4,054	252	2,598
Participant-specific sample size										
Average	41.4	65.5	46.2	34.6	23.3	16.6	44.1	44.5	14.0	36.1
Range	10.0–141.0	10.0–230.0	12.0–166.0	11.0–134.0	10.0–76.0	10.0–41.0	10.0–160.0	10.0–197.0	10.0–24.0	10.0–117.0
Operative Mortality, %[a]										
Aggregate mortality rate	1.5	0.5	1.3	2.5	2.1	3.5	1.8	1.0	9.6	14.5
Participant-specific mortality rate										
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	8.7	14.3
Range	0.0–14.3	0.0–6.7	0.0–16.7	0.0–18.2	0.0–11.8	0.0–23.1	0.0–15.0	0.0–16.7	0.0–25.0	0.0–42.9
Interquartile range	0.0–1.9	0.0–0.7	0.0–2.1	0.0–4.3	0.0–3.8	0.0–7.1	0.0–2.9	0.0–1.4	4.2–14.3	9.3–20.0
PLOS, days										
Aggregate average PLOS per patient	13.7	9.4	12.3	17.6	17.8	19.8	15.0	14.1	31.4	49.4
Participant-specific average PLOS										
Median	13.3	8.7	11.8	17.0	17.3	17.8	14.8	13.7	25.5	45.9
Range	3.8–26.7	3.8–23.9	6.0–26.6	5.2–58.2	5.8–36.8	9.8–44.1	4.4–42.8	5.1–27.7	18.6–62.1	21.7–122.5
Interquartile range	10.0–17.2	7.2–10.6	9.6–14.1	12.9–20.7	13.9–21.4	14.5–23.0	11.3–17.3	11.8–15.9	20.7–39.6	35.5–58.1

[a] Mortality rates reported in this table are observed (unadjusted) mortality rates. [b] More than nine operations in a given category in the analytic window of time.

ASO = atrial switch operation; AVC = atrioventricular canal; PLOS = Postoperative Length of Stay; STS = The Society of Thoracic Sureons; TOF = tetrology of Fallot; VSD = ventricular septal defect.

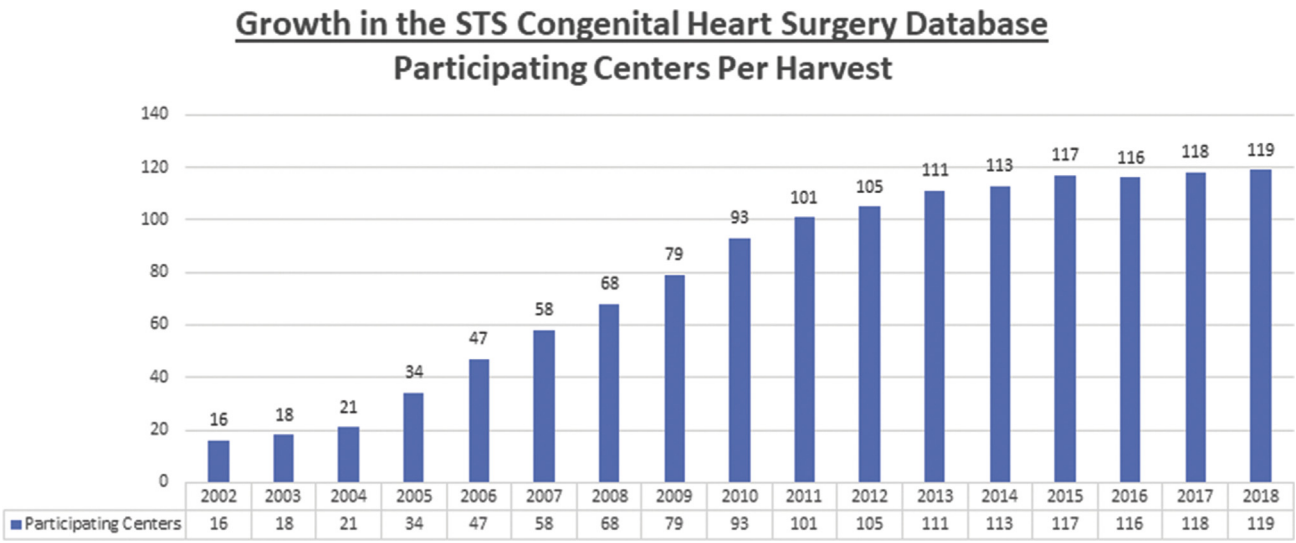

Fig 2. The graph documents the annual growth of The Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database by number of participating centers submitting data. This aggregate report from the Spring 2018 Harvest of the STS Congenital Heart Surgery Database includes data from 119 North American Congenital Database participants representing 129 congenital heart surgery hospitals in North America (126 in the United States and 3 in Canada).

Congenital Heart Surgery, estimated that 125 hospitals in the United States and 8 hospitals in Canada have pediatric cardiac surgical programs [22]. Therefore, more than 95% of hospitals that have pediatric cardiac surgical programs in the United States participate in STS CHSD; and, it is estimated that the patient-level penetration is an even higher percentage, because virtually all high-volume pediatric cardiac surgical programs in the United States participate in STS CHSD. These data suggest that nearly all pediatric cardiac operations performed in the United States are captured in STS CHSD.

STS CHSD: Aggregate Outcomes

The aggregate outcomes summarized in this section are based on data collected in STS CHSD for all operations performed from January 1, 2014, to December 31, 2017, inclusive, and presented in the 2018 Spring Harvest Feedback Report [18]. The outcomes in this report are based on the data elements specified in the current versions of the data collection instrument (version 3.22 and version 3.3, which went live on January 1, 2014, and January 1, 2016, respectively) and are presented using only data from centers located in the United States or Canada.

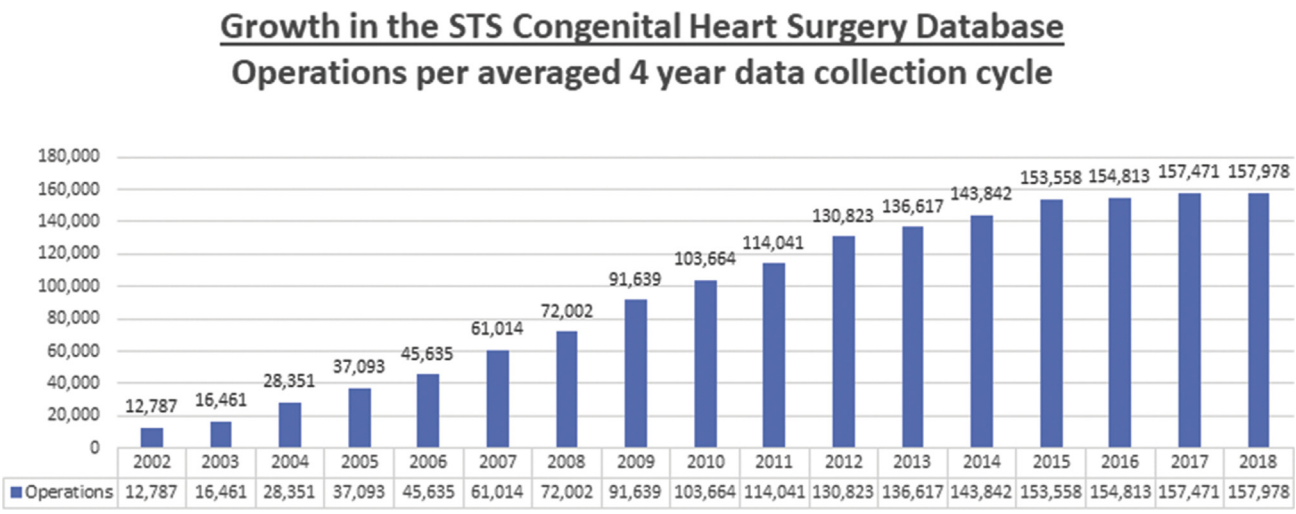

Fig 3. The graph documents the annual growth of The Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database by the number of operations per averaged 4-year data collection cycle. This aggregate report from the Spring 2018 Harvest of the STS Congenital Heart Surgery Database includes 157,978 operations performed in the 4-year period of January 1, 2014, through December 31, 2017, inclusive, submitted from 129 hospitals in North America (126 in the United States and 3 in Canada).

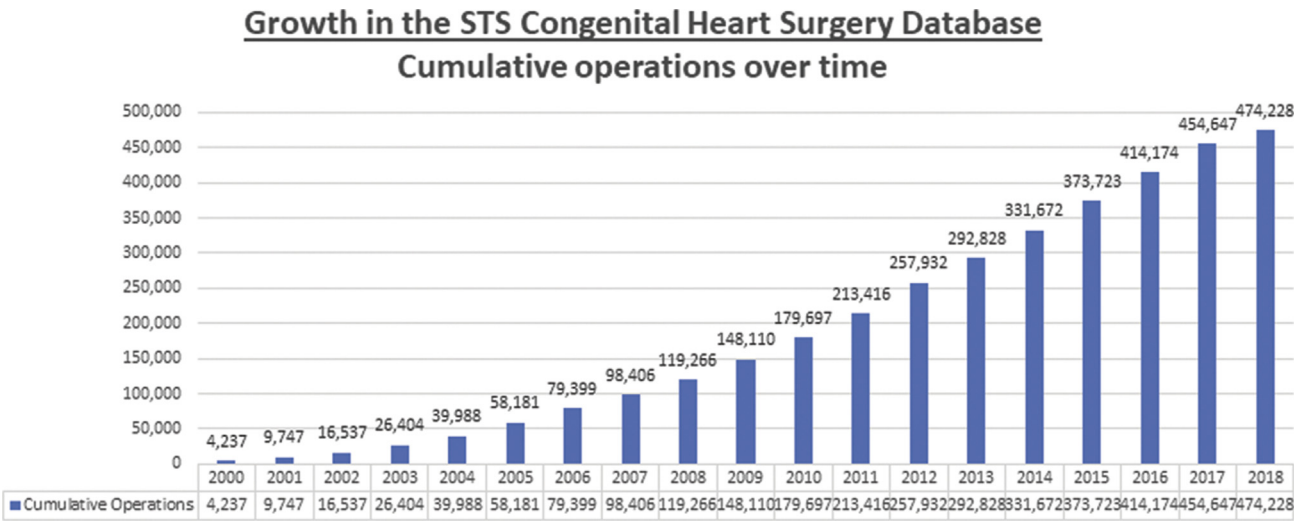

Fig 4. The graph documents the annual growth of The Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database by the cumulative number of operations over time, totaling 474,228 operations. This aggregate report from the Spring 2018 Harvest of the STS Congenital Heart Surgery Database includes 157,978 operations performed in the 4-year period of January 1, 2014, through December 31, 2017, inclusive, submitted from 129 hospitals in North America (126 in the United States and 3 in Canada).

Table 1 reports aggregate outcomes of risk-stratified operations in STS CHSD during the last 4 years (January 2014 through December 2017), with the end points of Operative Mortality and Postoperative Length of Stay (PLOS) [23]. Although the aggregate data in Table 1 are not risk adjusted, these unadjusted outcomes data are risk stratified by The Society of Thoracic Surgeons—European Association for Cardio-Thoracic Surgery (STAT) Congenital Heart Surgery Mortality Categories [20, 21]. The Appendix provides the latest version of the STAT Mortality Categories that was used to create Table 1. An interesting detail in Table 1 is that the PLOS for STAT Mortality Category 2 is longer than the PLOS for STAT Mortality Category 3, whereas the mortality for STAT Mortality Category 3 is higher than for STAT Mortality 2. The explanation for this observation is uncertain, although the STS CHSD 2016, 2017, and 2018 Updates on Outcomes and Quality [15–17] also reported this same observation. In the future, we may choose to stratify mortality outcomes by the STAT Mortality Categories [20, 21] and PLOS outcomes by the STAT Morbidity Categories [24].

Table 2 reports unadjusted aggregate outcomes for current benchmark operation groups in STS CHSD, also during the last 4 years (January 1, 2014, through December 31, 2017), and also with the end points of Operative Mortality and PLOS [25]. Data for the following 10 benchmark operation groups are included in Table 2:

1. Ventricular Septal Defect (VSD) repair
2. Tetralogy of Fallot (TOF) repair
3. Complete atrioventricular canal (AVC) repair (Complete atrioventricular septal defect repair [CAVSD repair])
4. Arterial switch
5. Arterial switch + VSD repair
6. Glenn/HemiFontan
7. Fontan operation
8. Truncus arteriosus repair
9. Norwood procedure
10. Off-Bypass Coarctation repair (only includes cases with Op Type = "No CPB Cardiovascular")

For Table 2 of this report, the relevant inclusion factors are the procedure codes listed in Table 3. Inclusion in these benchmark operation groups is not based on the intersection of diagnostic and procedural codes, as was the case in an earlier report on "Benchmark Operations" [25].

Operative Mortality is defined in all STS databases as (1) all deaths, regardless of cause, occurring during the hospitalization in which the operation was performed, even if after 30 days, including patients transferred to other acute care facilities; and (2) all deaths, regardless of cause, occurring after discharge from the hospital, but before the end of the 30th postoperative day [26, 27].

Beginning with the Spring 2014 STS CHSD Feedback Report, the STS CHSD Task Force has used the field "Mortality Status at Database Discharge" rather than the field "Mortality Status at Hospital Discharge" when calculating Operative Mortality. (In the definition of Operative Mortality above, the phrase "the hospitalization in which the operation was performed," is deemed to end at the time of database discharge, in accordance with the established definition of that term [26, 28]). This "Mortality Status at Database Discharge" field is now used in combination with the field "Status at 30 Days After Surgery" to arrive at a determination of Operative Mortality.

Similarly, beginning with the Spring 2014 STS CHSD Feedback Report, the STS CHSD Task Force has used the field "Date of Database Discharge" rather than the field "Date of Hospital Discharge" when calculating length of stay. These changes in reporting were implemented to ensure accurate

Table 3. Ten Benchmark Operation Groups[a]

Procedure Type	Abbreviation	STS CHSD 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 (ASO)
5. Arterial switch + VSD repair	ASO + VSD	1120 = Arterial switch operation (ASO) 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) + PA 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[b]
		2790 = Fontan, TCPC, Intra/extracardiac conduit, Nonfenestrated[b]
		3310 = Fontan, TCPC, External conduit, hepatic veins to pulmonary artery, Fenestrated[c]
		3320 = Fontan, TCPC, External conduit, hepatic veins to pulmonary artery, Nonfenestrated[c]
8. Truncus arteriosus repair	Truncus	230 = Truncus arteriosus repair
9. Norwood procedure	Norwood	870 = Norwood procedure
10. Off-bypass coarctation—only include cases with Op Type = No CPB Cardiovascular		
	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] Table 3 lists the 10 current benchmark operation groups, 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. (Please note that Benchmark Operation Groups 6 and 10 are not included in the initial publication of these benchmark operation [25] and are new. Also, please note that operations are classified into the various benchmark operation groups according to the assigned primary procedure for that operation.) [b] Only available in data version 3.22 and 3.3. [c] Only available in data version 3.3.

AVC = atrioventricular canal; CPB = cardiopulmonary bypass; Op Type = operation type; PA = pulmonary artery; TCPC = total cavopulmonary connection.

reporting of outcomes for all patients, including those who are transferred to another acute care facility or a chronic care facility after undergoing an operation at a participating center. The definitions of the fields "Mortality Status at Database Discharge" and "Date of Database Discharge" have been previously published [26, 28] and are summarized in Table 4 of the previously published STS CHSD 2016 Update on Outcomes and Quality [15].

Beginning with the Fall 2017 STS CHSD Feedback Report, reporting of Operative Mortality has been based on the "episode of care" and uses an episode of care–based mortality calculation. In most instances, an episode of care encompasses a single hospital admission. Less commonly, an episode of care may encompass a series of two or more consecutive hospital admissions, when a given patient is readmitted to the same database participant center after discharge to another acute care facility or to a chronic care facility, but without having been discharged to home (or residing in the chronic care facility for 183 consecutive postoperative days). An episode of care can have only one Index Operation and only one Date of Database Discharge, even though it may

Table 4. The Distribution of Star Ratings in The Society of Thoracic Surgeons Congenital Heart Surgery Database Feedback Reports[a]

STS CHSD Feedback Report	Number of Participants	Percentage of All Programs	Percentage of Programs With Star Rating
Fall 2014			
No star rating assigned	24	21.2	…
1 star	11	9.7	12.4
2 stars	72	63.7	80.9
3 stars	6	5.3	6.7
Total	113	100	100
Spring 2015			
No star rating assigned	20	17.2	…
1 star	11	9.5	11.4
2 stars	79	68.1	82.3
3 stars	6	5.2	6.3
Total	116	100	100
Fall 2015			
No star rating assigned	19	16.2	…
1 star	12	10.3	12.2
2 stars	76	65.0	77.6
3 stars	10	8.6	10.2
Total	117	100	100
Spring 2016			
No star rating assigned	12	10.3	…
1 star	14	12.0	13.3
2 stars	83	70.9	79.1
3 stars	8	6.8	7.6
Total	117	100	100
Fall 2016			
No star rating assigned	13	11.21	…
1 star	18	15.52	17.48
2 stars	74	63.79	71.84
3 stars	11	9.48	10.68
Total	116	100	100
Spring 2017			
No star rating assigned	13	11.21	…
1 star	18	15.52	17.48
2 stars	74	63.79	71.84
3 stars	11	9.48	10.68
Total	116	100	100
Fall 2017			
No star rating assigned	15	12.71	XX
1 star	17	14.41	16.50
2 stars	75	63.56	72.82
3 stars	11	9.32	10.68
Total	118	100	100
Spring 2018			
No star rating assigned	9	7.56	XX
1 star	13	10.92	11.82
2 stars	85	71.43	77.27
3 stars	12	10.08	10.91
Total	119	100	100
Fall 2018			
No star rating assigned	13	11.02	…
1 star	12	10.17	11.43
2 stars	83	70.34	79.05
3 stars	10	8.47	9.52
Total	118	100	100

[a] The distribution of star ratings is documented for the Fall 2014, Spring 2015, Fall 2015, Spring 2016, Fall 2016, Spring 2017, Fall 2017, Spring 2018, and Fall 2018 Society of Thoracic Surgeons Congenital Heart Surgery Database (STS CHSD) Feedback Reports. The star ratings were first publicly reported in August 2015 based on the Spring 2015 STS CHSD Feedback Report. The next update to the publicly reported star ratings will be in August 2019 based on the Spring 2019 STS CHSD Feedback Report. (In the Fall 2014, Spring 2015, Fall 2015, Spring 2016, and Fall 2016 STS CHSD Feedback Reports, 1, 3, 2, 2, and 1 participant(s), respectively, appear twice in this table because they are associated with more than 1 participant identification number.)

Table 5. Public Reporting With The Society of Thoracic Surgeons Congenital Heart Surgery Database

STS CHSD Public Reporting Cycle and Date the Data Were Publicly Reported on STS.org	Feedback Report and 4-Year Analytic Window	Participants in STS CHSD Who Consented to Participate and Were Enrolled in Public Reporting	Percentage of Participating Programs in the United States Enrolled in Public Reporting	Participants in STS CHSD With Data on STS Public Reporting Website	Star Rating			
		No.	% (n/N)	No.	1 Star	2 Star	3 Star	No Star Rating
Round 1	STS CHSD 2014 Fall Harvest and Feedback Report	25	23 (25/109)	19				
January 2015	July 1, 2010, to June 30, 2014							
Entire STS CHSD					11	72	6	24
Publicly reporting sites					[a]	[a]	[a]	[a]
Round 2[b]	STS CHSD 2015 Spring Harvest and Feedback Report	38	35 (38/110)	33				
August 2015	January 1, 2011 to December 31, 2014							
Entire STS CHSD					11	79	6	20
Publicly reporting sites					0	27	5	N/A
Round 3[c]	STS CHSD 2016 Spring Harvest and Feedback Report	70	61 (70/115)	61				
August 2016	January 1, 2012 to December 31, 2015							
Entire STS CHSD					14	84	8	12
Publicly Reporting Sites					3	49	8	N/A
Round 4[c]	STS CHSD 2017 Spring Harvest and Feedback Report	78	69 (78/113)	70				
August 2017	January 1, 2013 to December 31, 2016							
Entire STS CHSD					18	74	11	13
Publicly reporting sites					6	54	10	N/A
Round 5[c]	STS CHSD 2018 Spring Harvest and Feedback Report	87	76 (87/115)	85				
August 2018	January 1, 2014 to December 31, 2017							
Entire STS CHSD					13	85	12	9
Publicly reporting sites					10	63	12	N/A

[a] Round 1 publicly reported only point estimates with confidence intervals and did not publicly report star ratings. Round 2 was the first time that The Society of Thoracic Surgeons Congenital Heart Surgery Database (STS CHSD) publicly reported star ratings along with the previously reported point estimates with confidence intervals. Rounds 3, 4, and 5 again included publicly reported star ratings along with the previously reported point estimates with confidence intervals. [b] Three participants appear twice in the Spring 2015 Harvest because they are associated with more than one participant identification number. Also, in the Spring 2015 Harvest, three Canadian participants were included in the overall aggregate data but did not publicly report. [c] Two participants appear twice in the Spring 2016 Harvest because they are associated with more than one participant identification number. Also, in the Spring 2016 Harvest, the Spring 2017 Harvest, and Spring 2018 Harvest, three Canadian participants were included in the overall aggregate data but did not publicly report.

N/A = not applicable because sites with no star rating cannot publicly report; No. = number; STS = The Society of Thoracic Surgeons.

include multiple dates of admission, multiple operations, and multiple dates of hospital discharge. Although an episode of care may include multiple dates of hospital discharge, only one of those dates of hospital discharge can be a discharge to home. Determination of episode of care–based Operative Mortality is based on (1) status (alive/dead) at Date of Database Discharge, and (2) Status (alive/dead) at 30 days after the last cardiovascular surgical operation of the episode of care.

STS CHSD: Data Quality and Audit for Completeness and Accuracy

Data quality in STS CHSD is evaluated through intrinsic data verification by DCRI, including identification and correction of missing or out-of-range values and inconsistencies across fields [29]. In addition, approximately 10% of participants are randomly selected each year for center audits, in accordance with the STS CHSD Participation Agreement [29]. The audit is designed to complement the internal quality controls, with an overall objective of maximizing the integrity of the data in STS CHSD by examining the completeness and accuracy of the data. Through 2016, STS contracted with Telligen (West Des Moines, IA) to perform an independent, external audit of the STS CHSD. As the state of Iowa's Medicare Quality Improvement Organization, Telligen partners with health care professionals to ensure high-quality, cost-effective health care. As a Quality Improvement Organization, Telligen is Health Insurance Portability and Accountability Act compliant and performs audits adhering to strict security policies. In addition, an STS congenital heart surgeon volunteer leader participates in the audit. In 2017, a new organization, Cardiac Registry Support (St. Cloud, MN), began to serve as the vendor for the audits of STS CHSD. Each audit continues to include one congenital heart surgeon member of the STS CHSD Task Force.

The audit process includes:

- Completion of the STS Data Collection Questionnaire and review of responses with the primary data contact, data manager, or other relevant personnel
- Review of the data collection process and documentation to determine case eligibility for submittal to STS CHSD
- Comparison of facility operative case logs with cases submitted to STS CHSD
- Data abstraction (from original source documents) of congenital heart surgery records randomly selected by DCRI and all Operative Mortality cases for the preceding calendar year
- A summary conference with the surgeon representative, primary data contact, data manager, or other relevant personnel to discuss general trends in data collection and submission processes

In 2017, 11 participants in the STS Congenital Heart Surgery Database were selected for audit [29], and 10 sites completed the audit in 2017. The site that did not complete its audit in 2017 had issues with its Business Associate and Data Use agreement. This site was audited in 2018. During the 2017 audit, 5,769 variables were adjudicated at 10 sites.

During the 2017 audit, the rates of completeness and agreement for the variables related to Operative Mortality were as follows [29]:

- Mortality Status at Hospital Discharge: 100% completeness, 100% agreement
- Mortality Status at Database Discharge: 100% completeness, 100% agreement
- Mortality 30-Day Status: 100% completeness, 100% agreement

During the 2017 audit, rates of completeness and agreement for the following key variables were as follows [29]:

- Preoperative Factors: 100% completeness, 90.5% agreement
- Primary Diagnosis: 100% completeness, 96% agreement
- Primary Procedure: 100% completeness, 96% agreement
- Major Complications: 100% completeness, 99% agreement

STS CHSD: Transparency and Public Reporting of National Outcomes in Congenital and Pediatric Cardiac Surgery

In January 2015, STS began to publicly report outcomes of pediatric and congenital cardiac surgery [12, 13] [http://publicreporting.sts.org/] using the STS CHSD Mortality Risk Model [4–7], which calculates rates of risk-adjusted Operative Mortality for pediatric and congenital heart surgery and includes adjustment for procedural factors and patient-level factors. The STS CHSD Mortality Risk Model adjusts for the variables listed in Table 4 of the previously published STS CHSD 2017 Update on Outcomes and Quality [16]; these variables include procedural factors and individual patient factors [6]. Assessment of model fit and discrimination in the development sample and the validation sample revealed overall C statistics of 0.875 and 0.858, respectively. Importantly, coefficients for variables in the model are estimated again every 6 months to ensure that the model remains well calibrated for its intended use in STS CHSD Feedback Reports. Data in the STS CHSD includes the observed Operative Mortality of all participants. The *STS CHSD Mortality Risk Model* estimates the expected Operative Mortality of all participants. Then, the observed-to-expected (O/E) Operative Mortality ratio and associated 95% confidence intervals can be calculated for each STS CHSD participant, along with the rates of risk-adjusted Operative Mortality and associated 95% confidence intervals for each program.

For all STS CHSD participants who consent to participate in voluntary Public Reporting, STS Public Reporting Online reports the following:

- the *overall number of index cardiac operations* eligible for inclusion in the analysis of mortality, for each

STS CHSD participant over a 4-year period, for patients of all ages;
- the *number of index cardiac operations* eligible for inclusion in the analysis of mortality, for each STS CHSD participant over a 4-year period, for patients of all ages, reported separately for *each of the five STAT Mortality Categories;*
- the *number of index cardiac operations associated with Operative Mortality* (These data are reported within the overall cohort of index cardiac operations eligible for inclusion in the analysis of mortality and within each of the five STAT Mortality Categories);
- the *Observed and Expected Operative Mortality rates* for the overall cohort of index cardiac operations eligible for inclusion in the analysis of mortality and for each of the five STAT Mortality Categories;
- the *O/E Operative Mortality ratio* and associated 95% confidence intervals for the overall cohort of index cardiac operations eligible for inclusion in the analysis of mortality and for each of the five STAT Mortality Categories; and
- the *adjusted mortality rate (AMR)* and associated 95% confidence intervals for the overall cohort of index cardiac operations eligible for inclusion in the analysis of mortality and for each of the five STAT Mortality Categories.

Detailed descriptions of the multiple outcomes publicly reported by STS CHSD have been previously published [11–13, 15]. When publicly reporting outcomes for centers participating in STS CHSD voluntary Public Reporting, STS reports the data with varying degrees of granularity, ranging from point estimates with confidence intervals for more statistically sophisticated users to star ratings that may help patients and families correctly interpret complex data [15]. The Overall Star Rating of a given STS CHSD participant is based on their overall risk-adjusted O/E Operative Mortality ratio for all index cardiac operations eligible for inclusion in the analysis of mortality, as follows:

- *One Star:* higher than expected Operative Mortality (the 95% confidence interval for their risk-adjusted O/E mortality ratio was entirely above the number 1)
- *Two Stars:* same as expected Operative Mortality (the 95% confidence interval for their risk-adjusted O/E mortality ratio overlapped with the number 1)
- *Three Stars:* lower than expected Operative Mortality (the 95% confidence interval for their risk-adjusted O/E mortality ratio was entirely below the number 1)

The star rating designations are determined using the 95% confidence intervals of a center's overall risk-adjusted O/E Operative Mortality ratio for all index cardiac operations eligible for inclusion in the analysis of mortality. Table 4 documents the distribution of star ratings for the Fall 2014, Spring 2015, Fall 2015, Spring 2016, Fall 2016, Spring 2016, Fall 2017, Spring 2018, and Fall 2018 STS CHSD Feedback Reports.

Table 5 documents the history of voluntary participation in Public Reporting with STS CHSD, which began in January 2015, with the public reporting of point estimates with confidence intervals, but without publicly reporting star ratings. In January 2015, 23% (25 of 109) of participants in STS CHSD located in the United States consented to publicly report. The star ratings were first publicly reported in August 2015 based on the Spring 2015 STS CHSD Feedback Report. These publicly reported star ratings were updated in August 2016 based on the Spring 2016 STS CHSD Feedback Report. These publicly reported star ratings were again updated in August 2017 based on the Spring 2017 STS CHSD Feedback Report, and most recently in August 2018 based on the Spring 2018 STS CHSD Feedback Report. In each instance, star ratings are based on the latest version of the STS CHSD Mortality Risk Model, which is updated every 6 months. As of October 1, 2018, 77.6% (90 of 116) of participants in STS CHSD located in the United States had consented to publicly report. The most contemporary publicly reported data can be viewed at [http://publicreporting.sts.org/chsd].

STS CHSD reports the O/E Operative Mortality ratio using indirect standardization, which allows assessment of a center's observed outcomes in relation to what would be expected for their specific case-mix. Because the calculations of expected outcomes using indirect standardization are estimated only for the patients that a center actually treated, results only apply to their particular case-mix. The results derived using indirect standardization cannot be used to directly compare 2 hospitals unless their case-mix has been demonstrated to be similar, and it cannot be assumed that a center achieving better than expected results in a generally low-risk population would do the same in a population of higher-risk patients.

From the data that are publicly reported or provided in STS CHSD Feedback Reports (ie, point estimates with confidence intervals), *it is possible to determine, independently, the star rating of an individual program* simply by examining the 95% confidence interval of a center's overall risk-adjusted O/E Operative Mortality ratio for all cardiovascular surgical patients and comparing this 95% confidence interval to unity (the number 1). The star rating is provided by STS with the intent of making this statistical analysis more understandable to many patients and families [15].

STS CHSD: Ongoing and Future Quality Initiatives

In 2018, STS published the STS Pediatric and Congenital Heart Surgery Composite Quality Measure, which includes two domains: risk-adjusted mortality and risk-adjusted morbidity [30, 31]. This metric is the first composite quality measure for pediatric and congenital cardiac surgery and provides a more comprehensive view of quality than mortality alone. Because of the larger number of end points, this measure has greater ability to discriminate programmatic performance.

The STS CHSD Task Force currently has multiple ongoing quality initiatives that can be divided into short-term goals, intermediate-term goals, and long-term goals.

The short-term goals relate to refining the STS CHSD Pediatric and Congenital Heart Surgery Mortality Risk Model with more granular risk adjustment for chromosomal abnormalities, syndromes, and noncardiac congenital anatomic abnormalities [32]. This augmented STS Pediatric and Congenital Heart Surgery Database Mortality Risk Model will be incorporated into STS Congenital Heart Surgery Database Feedback Reports and Public Reporting initiatives [12, 13]. The enhanced adjustment for chromosomal abnormalities, syndromes, and noncardiac congenital anatomic abnormalities will also be applied to the STS Pediatric and Congenital Heart Surgery Composite Quality Measure [30, 31]. In the future, this augmented STS Pediatric and Congenital Heart Surgery Composite Quality Measure and its individual components will be included in STS CHSD Feedback Reports to participating centers and will likely be reported publicly by those hospitals that volunteer to participate in STS Public Reporting Online [12, 13] (https://publicreporting.sts.org/).

Intermediate-term goals relate to upgrading the existing STAT Mortality Categories and the existing STAT Mortality Score [20, 21]. (The original STAT Mortality Scores and STAT Mortality Categories were published in 2009 [20]. Risk of in-hospital mortality was estimated for 148 types of operative procedures using data from 77,294 operations. This original study population consisted of patients who underwent a congenital cardiovascular operation between 2002 and 2007 that was entered into the European Association for Cardiothoracic Surgery Congenital Heart Surgery Database [33,360 operations] and STS CHSD [43,934 patients]. Procedure-specific mortality rate estimates were calculated using a Bayesian model that adjusted for small denominators. Each procedure was assigned a numeric score [the STAT Congenital Heart Surgery Mortality Score—2009] ranging from 0.1 to 5.0 based on the estimated rate of in-hospital mortality. Procedures were also sorted by increasing risk and grouped into five categories [the STAT Congenital Heart Surgery Mortality Categories—2009] that were chosen to be optimal for minimizing within-category variation and maximizing between-category variation.)

Under the leadership of Marshall L. Jacobs, MD, this update of the existing STAT Mortality Scores and STAT Mortality Categories began in 2018 and will continue into 2019. The updated STAT Mortality Scores and STAT Mortality Categories will use Operative Mortality [26, 27] as an end point (rather than only in-hospital mortality) and will also improve the assignment of STAT Mortality Scores and STAT Mortality Categories for multiprocedural operations, with a particular focus on procedure combinations for which the estimated risk of mortality is substantially different from that of the individual component procedure with the highest risk.

This upgrade of the STAT Mortality Scores and STAT Mortality Categories will also update the original STAT Mortality Scores and STAT Mortality Categories based on the current data. (The original STAT Mortality Scores and STAT Mortality Categories were published in 2009 based on data from operations performed in 2002 and 2007.) Empirically derived STAT Mortality Scores and STAT Mortality Categories will also be developed for procedure codes that have been added to STS CHSD and the European Congenital Heart Surgeons Association CHSD since the original derivation of the STAT Mortality Scores and STAT Mortality Categories. The addition of these new codes ensures that the STAT metrics are inclusive with respect to contemporary practice. The updated STAT Mortality Scores and STAT Mortality Categories will then replace the current STAT Mortality Scores and STAT Mortality Categories in all STS and European Congenital Heart Surgeons Association quality and research initiatives and will be used to facilitate an updated analysis of the relationship of center-level volume and surgeon-level volume to congenital and pediatric cardiac surgical outcomes.

Long-term goals relate to a project under the leadership of John E. Mayer, Jr, MD, that is exploring alternative strategies for pediatric and congenital cardiac surgical outcomes analysis. In the current STS CHSD Feedback Report, most of the pediatric and congenital cardiac surgical outcomes analysis is based on procedural cohorts. This new analysis will explore alternative mechanisms of defining cohorts of patients that will incorporate cardiac diagnosis, as well as noncardiac diagnoses, preoperative condition, and procedure type, as the basis for pediatric and congenital cardiac surgical outcomes analysis. (The Lesion Specific Section of the current STS CHSD Feedback Reports contains some analyses based on diagnostic cohorts.) It may be possible to develop more advanced strategies for the analysis of outcomes based on these new techniques of creation of cohorts using machine learning and newer statistical techniques. Such new strategies for analysis of outcomes based on diagnostic cohorts may be complementary to our current strategies for analysis of outcomes based on procedural cohorts.

Summary

In the monthly STS National Database series on outcomes analysis, quality improvement, and patient safety, this report is the fourth annual article that focuses specifically on outcomes and quality in STS CHSD [15–17]. This report, the STS CHSD 2019 Update on Outcomes and Quality, provides a summary of current national aggregate outcomes of congenital and pediatric cardiac surgery as well as related quality initiatives. Six months after the publication of this article, as part of this monthly series, *The Annals of Thoracic Surgery* will publish another article derived from STS CHSD, with this additional article summarizing all research-related reports published from STS CHSD over the past 12 months, along with an update on funded research grants and grant proposals from STS CHSD [33–35]. All participants in STS CHSD can access data from STS CHSD for research or

quality improvement initiatives. A detailed description of how to access data from STS National Database is available at https://www.sts.org/registries-research-center/sts-research-center.

With information about nearly all pediatric cardiac operations performed in the United States, STS CHSD contains a highly representative sample of national aggregate data that is useful for multiple purposes. The data that are collected by STS CHSD and the analytical methods used by STS CHSD, including risk adjustment, are constantly reevaluated to ensure that they are statistically accurate and clinically meaningful. The current national aggregate congenital and pediatric cardiac surgical outcomes from STS CHSD described in this report can serve as a platform for benchmarking performance and improving quality. These activities of outcomes analysis and quality improvement will ultimately allow congenital and pediatric cardiac surgeons to provide better care for our patients [36].

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