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Linking the Congenital Heart Surgery Databases of the Society of Thoracic Surgeons and the Congenital Heart Surgeons' Society: Part 1—Rationale and Methodology

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Abstract

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Purpose—The Society of Thoracic Surgeons Congenital Heart Surgery Database (STS-CHSD) is the largest Registry in the world of patients who have undergone congenital and pediatric cardiac surgical operations. The Congenital Heart Surgeons' Society Database (CHSS-D) is an Academic Database designed for specialized detailed analyses of specific congenital cardiac malformations and related treatment strategies. The goal of this project was to create a link between the STS-CHSD and the CHSS-D in order to facilitate studies not possible using either individual database alone and to help identify patients who are potentially eligible for enrollment in CHSS studies.

Methods—Centers were classified on the basis of participation in the STS-CHSD, the CHSS-D, or both. Five matrices, based on CHSS inclusionary criteria and STS-CHSD codes, were created to facilitate the automated identification of patients in the STS-CHSD who meet eligibility criteria for the five active CHSS studies. The matrices were evaluated with a manual adjudication process and were iteratively refined. The sensitivity and specificity of the original matrices and the refined matrices were assessed.

Results—In January 2012, a total of 100 centers participated in the STS-CHSD and 74 centers participated in the CHSS. A total of 70 centers participate in both and 40 of these 70 agreed to participate in this linkage project. The manual adjudication process and the refinement of the matrices resulted in an increase in the sensitivity of the matrices from 93% to 100% and an increase in the specificity of the matrices from 94% to 98%.

Conclusion—Matrices were created to facilitate the automated identification of patients potentially eligible for the five active CHSS studies using the STS-CHSD. These matrices have a sensitivity of 100% and a specificity of 98%. In addition to facilitating identification of patients potentially eligible for enrollment in CHSS studies, these matrices will allow (1) estimation of the denominator of patients potentially eligible for CHSS studies and (2) comparison of eligible and enrolled patients to potentially eligible and not enrolled patients to assess the generalizability of CHSS studies.

Keywords

database (all types); outcomes (includes mortality, morbidity); congenital heart disease (CHD); congenital heart surgery

Background

The Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database (CHSD) is the largest database in the world of patients who have undergone congenital and pediatric cardiac surgical operations. The Congenital Heart Surgeons' Society Database (CHSS-D) is one of the most respected and accomplished databases in the world that performs specialized detailed analyses related to specific congenital cardiac malformations. Each database has unique strengths and weaknesses. The STS-CHSD tracks short-term outcomes on all patients undergoing pediatric and congenital cardiac surgery at participating institutions but lacks data about long-term outcomes. The CHSS-D tracks detailed long-term outcomes on very specific cohorts of enrolled patients but lack data about the overall denominator of patients eligible for CHSS protocols.

The overall goal of this project was to create a link between the STS-CHSD and the CHSS-D in order to facilitate studies not possible using either individual database alone. Our overall hypothesis was that the automated identification and reporting of CHSS-eligible patients at the time of STS data entry will increase enrollment in CHSS cohorts and facilitate the comparison of outcomes between enrolled and not enrolled patients. Specific tenets of the overall hypothesis include the following:

- Linking together the STS-CHSD and the CHSS-D will address many of the current limitations and knowledge gaps in the domain of congenital and pediatric cardiac surgery by expanding the pool of data available for analysis.
- Linking these data sets can facilitate studies not possible using individual databases alone.
- Linking these data sets will increase participation and enrollment in both databases.
- Linking these databases will provide evidence that the outcome of patients enrolled in CHSS studies is comparable to outcomes of eligible patients at CHSS member institutions who are not enrolled.

To evaluate our overall hypothesis we pursued three specific objectives:

- To develop and operationalize an automated process where all patients at CHSS member institutions who are enrolled in the STS-CHSD are screened for eligibility for CHSS protocols and centers participating in the STS-CHSD are notified of the registry record numbers of potentially eligible patients.
- To develop and operationalize an automated process where CHSS-D participants are given an annual report documenting the volume and outcome of all patients enrolled in CHSS studies and the volume and outcome of potentially eligible patients at CHSS member institutions who are not enrolled.
- To compare outcomes of patients enrolled in CHSS studies to those potentially eligible patients at CHSS member institutions who are not enrolled; and therefore, address the gap in knowledge concerning the generalizability of findings in CHSS studies.

The purpose of this article is to describe the rationale for the creation of the STS-CHSS Link and the methodology used in the STS-CHSS Link; a second article will describe the lessons learned and implications.

Materials and Methods

Databases

One of the authors of this article previously offered the following definitions:

> “A database is simply a structured collection of information. A clinical database may be a Registry (a limited amount of data for every patient undergoing heart surgery) or Academic (an organized and extensive dataset of an inception cohort of carefully selected subset of patients). A registry and an academic database have different purposes and cost.”[1]

Based on these definitions, the STS-CHSD is a Registry that collects "some of the data about all of the patients" undergoing pediatric and congenital cardiac surgery, while the CHSS-D is an Academic Database that collects "all of the data about some of the patients" undergoing pediatric and congenital cardiac surgery. Details of the STS-CHSD and the CHSS-D are provided below.

Society of Thoracic Surgeons Congenital Heart Surgery Database—The STS-CHSD is the largest database in the world that tracks the outcomes of patients with pediatric and congenital cardiac disease.[2–4] In 2013, STS-CHSD contains data from 117 of the 125 hospitals (93.6% penetrance by hospital) in the United States and 3 of the 8 centers in Canada.[5–7] Over the past 15 years, important advances have been made by STS-CHSD in the following domains[2–28]:

- use of a common language and nomenclature (The International Pediatric and Congenital Cardiac Code [IPCCC]; http://www.ipccc.net/)[2–4];
- use of an established uniform core dataset for collection of information[2–4,7];
- incorporation of a mechanism of evaluating case complexity[8–18];
- implementation of a mechanism to assure and verify the completeness and accuracy of the data collected[19];
- collaboration between medical and surgical subspecialties[4];
- development of strategies for linking registries and life-long longitudinal follow-up[20–27];
- availability of standardized tools for quality assessment and quality improvement.[28]

The STS-CHSD has the following strengths:

- The STS-CHSD currently receives data from 93.6% of pediatric and congenital cardiac surgical programs in the United States.
- At participating institutions, nearly 100% of operations are captured in the STS-CHSD.
- The Duke Clinical Research Institute (DCRI) serves as the data warehouse and analytic center for the STS-CHSD, allowing for reputable, independent, and sophisticated statistical analyses.

  The STS-CHSD uses a standardized nomenclature, the IPCCC.
- In the STS-CHSD, data are reported using validated complexity stratification tools.
- In the STS-CHSD, data quality and reliability are assured through intrinsic verification of data as well as a formal process of site visits with onsite data audits.

The major weakness of the STS-CHSD is its lack of information about longitudinal follow-up and long-term outcomes. Follow-up information in the STS National Database is currently collected for two short-term end points: (1) status at discharge from the hospital after surgery and (2) status 30 days after surgery.

Congenital Heart Surgeons' Society Database—The CHSS is a group of 140 pediatric heart surgeons representing 74 North American institutions that specialize in the treatment of patients with congenital heart defects. The CHSS was formed in 1972 on the suggestion of Eoin Aberdeen, then at Children's Hospital of Philadelphia, to include surgeons of compatible character with a special interest in pediatric cardiac surgery.[29] From the time of its establishment nearly three decades ago, a basic premise motivating the establishment of the CHSS Data Center and research cohorts has been the idea that in order to answer fundamental questions about the management of complex and relatively uncommon forms of congenital heart disease, it is necessary to pool information from the experiences of multiple centers and systematically collect patient information over a period of decades.

In 1984, Drs John Kirklin and Eugene Blackstone proposed that the CHSS surgeons pool their experience in managing infants with rare congenital anomalies of the heart, a concept that led to the establishment of the CHSS Data Center. Drs Kirklin and Blackstone recognized that the occurrence of congenital heart disease is low (ie, 8/1,000 live births) and that any single institution requires a great deal of time to learn from their experience and improve the management of patients with congenital heart disease. By pooling the experience of all the CHSS members, Drs Kirklin and Blackstone proposed that the CHSS surgeons could improve their ability to determine the best methods of treating patients with pediatric and congenital heart disease.[30–32]

The first group of patients studied included all babies born with complete transposition of the great arteries (TGAs) who were admitted to any of the CHSS institutions within the first 2 weeks of life. During the four years of data collection (1985–1989), information on more than 900 babies with transposition was collected. An important component of the research protocol is cross-sectional follow-up of the entire cohort during a three-month interval each year. The data analyses on these patients have resulted in a wealth of information that is contained in nine publications to date.[33–41]

The success of data collection in the transposition babies led to 11 subsequent prospective observational studies of neonates, infants, children, and adults with congenital heart disease, which have generated multiple peer-reviewed publications.[30–66] The 12 CHSS Study Cohorts are displayed in Table 1. Seven of these studies are no longer actively enrolling patients and five of these studies are still actively enrolling patients.

Data collection required the establishment of a Data Center, initially in Birmingham, Alabama. In 1997, the Data Center moved from Birmingham, Alabama to the Hospital for Sick Children in Toronto, Canada. The Data Center employs six full-time people, and, in addition to this full-time staff of six, has four physicians/surgeon-consultants and a Clinical Research Fellow (the Kirklin/Ashburn Fellow). Patients in the earliest established CHSS cohorts (eg, TGAs) continue to be contacted annually, more than two decades after enrollment. Data related to functional status and health-related quality of life are collected, in addition to clinical data pertaining to interventions, medical management, and vital status.

The CHSS-D has the following strengths:

- The CHSS-D has the ability to maintain lifetime follow-up of enrolled patients and the infrastructure to maintain this follow-up. A fundamental role of CHSS full-time staff is to maintain contact with patients enrolled in CHSS studies and their health care providers in order to achieve lifetime follow-up. This ability to perform lifetime follow-up makes these studies ideal for establishing temporal relationships for multiple outcomes of interest in these rare diseases. This strength distinguishes the CHSS-D from the STS Database.
- The CHSS-D and Data Center have state-of-the-art statistical capability.
- The CHSS-D has a track record of representative analysis across our field.
- The CHSS-D contains specific diagnostic cohorts that represent small “slices” of the population of patients with congenital heart disease but were specifically created to discern best management strategies to improve outcomes in high-risk patients.

The longitudinal prospective and systematic collection of data with protocols for standardized annual cross-sectional follow-up facilitates the generation of secondary hypotheses that can answer new research questions, which emerge over the lifespan of these patients.

The major weakness of the CHSS-D is its voluntary enrollment and the probability that this method will not capture ALL eligible patients. Furthermore, although the CHSS has 74 North American member institutions, participation in CHSS research studies is voluntary and not all member institutions participate in CHSS studies. Therefore, the potential denominator of eligible patients for any given CHSS protocol is not known. Furthermore, it has never been demonstrated that the enrolled patients are truly representative of the entire population of patients potentially eligible for CHSS studies.

Participation in the STS database and CHSS-D—The first step of this project was to identify all centers participating in the STS-CHSD, the CHSS-D, or both. These centers were then classified into one of the following three categories:

- centers that participate in the STS-CHSD and the CHSS-D;
- centers that participate in the STS-CHSD only;
- centers that participate in the CHSS-D only.
- Next, centers that participate in both the STS-CHSD and the CHSS-D were contacted to invite them to participate in this project. These centers that participate in both the STS-CHSD and the CHSS-D were then classified into three categories:
- centers that participate in the STS-CHSD and the CHSS-D and consented to participate in this project;
- centers that participate in the STS-CHSD and the CHSS-D who responded to the invitation to participate in this study and declined to participate;
- centers that participate in the STS-CHSD and the CHSS-D who never responded to the invitation to participate in this study.

Matrices

Using the inclusion and exclusion criteria of the five active CHSS cohorts, five matrices were created by members of the investigative team. The purpose of these matrices was to facilitate identification (at the time of data entry into the STS-CHSD) of all patients who are potentially eligible for these CHSS studies. The objective of creating these matrices was to facilitate easy identification of these eligible cases without duplication of labor and resources at the member institution level and to eventually determine an approximate denominator of eligible cases—a feature that has previously been elusive with respect to CHSS enrollment. Furthermore, these matrices provide the foundation for formalizing the STS-CHSS Link, by creating an automated process for identification of eligible patients.

The five matrices were created by members of the investigative team. This concept was introduced to STS Database Managers at the annual STS “Advances in Quality and Outcomes” Program in November 2010 and to the CHSS members and Data Center staff during the January 2011 CHSS Work Weekend in Toronto. Acting on Dr Eugene Blackstone’s suggestion, the CHSS-STS matrix for each cohort was reviewed by all in attendance at the CHSS Work Weekend, and refinements were made based on the suggestions of CHSS members.

Manual Adjudication of Matches

The five matrices that were created by members of the investigative team and then revised based on the input from STS Database Managers and CHSS members were then evaluated in a pilot project involving four centers that participate in the STS-CHSD and the CHSS-D and consented to participate in this project. Four “alpha test centers” were selected to participate in the testing of these matrices, and the manual adjudication of patients identified as potentially eligible for CHSS studies by the matrices. The following four centers were selected as “alpha test centers” in order to assure a range of center surgical case volume and geography:

- Children’s Hospital of Philadelphia, Philadelphia, Pennsylvania
- Kosair Children’s Hospital, University of Louisville, Louisville, Kentucky
- Northwestern University Feinberg School of Medicine, Ann & Robert H. Lurie Children’s Hospital of Chicago, Chicago, Illinois
- University of Michigan, Ann Arbor, Michigan

These four alpha test centers were given five lists generated at DCRI using the specific study matrices and containing indirect identifiers of potentially eligible cases entered in the STS-CHSD. These five lists per center contained the date of birth, date of surgery, and primary procedure of all patients identified as being potentially eligible for each active CHSS study. The alpha test centers were asked to manually adjudicate each patient that was identified by the matrices as being potentially eligible for a CHSS study. This manual adjudication process involved classifying each patient that was identified by the matrices as being potentially eligible for a CHSS study into one of the following four categories:

- identified as potentially CHSS eligible and incompletely or incorrectly coded by the participant site during entry into the STS-CHSD;
- identified as potentially CHSS eligible and coded properly—eligible and enrolled;
- identified as potentially CHSS eligible and coded properly—eligible and not enrolled;
- identified as potentially CHSS eligible and coded properly—judged to be not eligible (on the basis of additional variables not accounted for in the initial versions of the matrices).

The alpha test centers were also asked to create a list of any patients within their individual institutional STS-CHSD that they identified as being eligible for CHSS study cohorts who had not been identified by DCRI using the matrices. This manual adjudication process allowed calculation of the sensitivity and specificity of the initial versions of the matrices.

Based on the initial manual adjudication process, the five matrices were revised by the members of the investigative team. The revised matrices are presented in Appendix A. The sensitivity and specificity of these revised matrices were also calculated.

Institutional Review Board Approval

The Duke University Health System Institutional Review Board approved the study and provided a waiver of informed consent. Although the STS data used in the analysis contain patient identifiers, they were originally collected for nonresearch purposes and the risk to patients was deemed to be minimal.[67]

This article was reviewed and approved by the STS-CHSD Access and Publications Committee. This article was also reviewed and approved by the CHSS Committee on Quality Improvement and Outcomes.

Results

Participation in the STS Database and CHSS-D

At the time that this project began (January 2012), 100 centers participated in the STS-CHSD and 74 North American centers participated in the CHSS. Table 2 classifies these centers. Table 3 lists the 40 centers that participate in both the STS-CHSD and the CHSS and consented to participate in this project.

Manual Adjudication of Matches

The initial manual adjudication process was based on 247 patients who underwent cardiac surgery in 2010 and 2011 at the four “alpha test centers” who were identified as potentially eligible for a CHSS study. Table 4 documents the results of the manual adjudication. Based on this manual adjudication process the matrices were revised. Appendix A shows the final version of the matrices after revision.

The subsequent manual adjudication process with the revised matrices was based on 239 patients who underwent cardiac surgery in 2010 and 2011 who were identified as potentially

eligible for a CHSS study. The manual adjudication process with the revised matrices did not include any patients that were incompletely or incorrectly coded by the participating site during entry into the STS-CHSD because all of these coding errors were corrected prior to the second round of manual adjudication. (During the initial round of manual adjudication, 14 [5.7%] of the 247 records were identified as being incompletely or incorrectly coded by the participant site; these 14 records were excluded from the manual adjudication process with the revised matrices.) It is notable that 16 patients who were potentially CHSS eligible were not identified by the original matrices; however, the revised matrices successfully identified all these patients. Similarly, the original matrices identified 15 patients as potentially CHSS eligible who were eventually judged to be not eligible, while the revised matrices identified only 5 patients as potentially CHSS eligible who were eventually judged to be not eligible.

Examples of revisions made to the matrices as a result of the manual adjudication process are listed below:

- In the CHSS Pulmonary Conduit (PC) Study, “Mortality Status at Hospital Discharge = Alive” was added as an inclusionary requirement; the following STS procedure was added as an exclusionary procedure: STS Procedural Code 150 = Ventricular septal fenestration; and the following STS diagnoses were added as exclusionary diagnoses: STS Diagnostic Code 520 = Conduit failure, 4380 = Status post - TOF repair, RV-PA conduit, 4610 = Status post - Conduit placement, RV to PA, 4620 = Status post - Conduit placement, LV to PA, 5060 = Status post - Congenitally corrected TGA repair, Atrial switch and Rastelli, 5080 = Status post - Congenitally corrected TGA repair, VSD closure and LV to PA conduit, 5150 = Status post Rastelli. (All of the refinements with respect to eligibility and ineligibility related to the codes used in the STS-CHSD codes are consistent with the eligibility requirement of the CHSS Pulmonary Conduit (PC) Study of first time conduit placement between the sub-pulmonary ventricle and the pulmonary arteries). Please note: TOF = tetralogy of Fallot, RV = right ventricle, PA = pulmonary artery, LV = left ventricle.
- In the CHSS Critical Left Ventricular Outflow Tract (LVOTO) Study, the following STS diagnosis was added as an exclusionary diagnosis: STS Diagnostic Code 790 = Single ventricle, DILV.

Table 5 documents the sensitivity and specificity of the initial matrices and the revised matrices. The sensitivity increased from 93% to 100% as a result of the manual adjudication process and the revision of the matrices. The specificity increased from 94% to 98% as a result of the manual adjudication process and the revision of the matrices.

Discussion

This article describes the rationale and methodology of the creation of the STS-CHSS Link. This methodology has allowed the creation of five matrices that will facilitate automated identification of patients who are potentially eligible for the five active CHSS studies using the STS-CHSD. The objective of creating these matrices is to facilitate identification of

these eligible cases without duplication of labor and resources at the member institution as well as to determine an approximate denominator of eligible cases—a feature that has been previously elusive with respect to CHSS enrollment.

When tested at four participating centers representing a range of surgical case volume and geography, the five final matrices were shown to have a sensitivity of 100% and a specificity of 98%. These findings are certainly an encouraging approximation of the performance of these matrices when eventually applied across all participating centers. A feature of the design of the matrices is the recognition that they are intended to identify all patients in the STS-CHSD who are potentially eligible for enrollment in CHSS studies. Because of the nature of the data fields in the STS-CHSD and the nature of the temporal, diagnostic, and procedural fields that are specified in the inclusionary and exclusionary criteria of each of the CHSS study protocols, it is anticipated that the matrices will occasionally identify a patient as potentially eligible for enrollment in one of the CHSS studies, when ultimately this patient is found to be ineligible for enrollment. These instances do not represent a failure of the matrices or the process but rather are indicative of the different nature of the fields specified in the STS-CHSD and the CHSS-D. Designing the matrices in a way that would underestimate (rather than overestimate) the number of potentially eligible patients would be a less productive and less informative strategy. In our current analysis, over estimation of potentially eligible patients is represented by only 5 records of nearly 250 (5 out of 239 [2.1%]).

Beginning with the Fall 2013 STS-CHSD Feedback Report, every 6 months, all STS-CHSD participants will receive a list of the registry record numbers of all patients identified as potentially eligible for CHSS studies over the previous four years, using a rolling four-year time window. Table 6 displays the appearance of this report. This process will alert centers as to the potential eligibility of patients for CHSS study cohort enrollment. Ultimately, this initiative will make it possible to compare characteristics and outcomes of patients enrolled in CHSS studies to those eligible patients who are not enrolled and therefore address the gap in knowledge concerning the generalizability of findings in CHSS studies. Furthermore, in the future, the methodology of the STS-CHSS Link can be applied to new CHSS Studies; the application of this methodology to new CHSS Studies will be facilitated and enhanced using the international nomenclature used in the STS-CHSD (the IPCCC) at the time of inception of new CHSS cohorts when developing inclusionary and exclusionary criteria.

This article is the first in a series of two articles that will report the results of the STS-CHSS Link. This article describes the rationale and methodology of the STS-CHSS Link. The second article will describe the lessons learned to date from the STS-CHSS Link and the implications of this analysis.

Limitations

The STS-CHSS Link is designed to use the STS-CHSD to identify patients who are potentially eligible for CHSS studies. Our analysis found 5.7% of potentially eligible patients were found to be incompletely or incorrectly coded by the participant site. These

patients would be identified as potentially eligible by the matrices and then their records could be updated at the time of actual evaluation for enrollment in a CHSS study.

The CHSS-D includes some patients with congenital heart disease who have not had surgery. The STS-CHSD is procedure-based and therefore cannot be used as a tool to identify these patients who have not had surgery. This limitation can be overcome in the future with additional links to other databases of patients with congenital heart disease that capture patients who have not had surgery such as:

- the IMPACT Registry (IMproving Pediatric and Adult Congenital Treatment) of the National Cardiovascular Data Registry of The American College of Cardiology;
- the Congenital Cardiac Anesthesia Society Database;
- the Pediatric Cardiac Critical Care Consortium (PC4);
- the Cardiac Module of the Virtual Pediatric Intensive Care Unit System (VPS) Database; and
- the Children's Hospital Association Pediatric Health Information System (PHIS) Database.

We hope and expect, nonetheless, that operationalizing this linkage will facilitate identification of all surgical patients who are eligible for enrollment in CHSS study cohorts. For most CHSS cohorts, the surgical patients constitute a significant majority of enrolled patients, and for some CHSS cohorts, surgical patients represent the entirety of the eligible population.

Additional Planned Analyses

This analysis involves patients who have surgery at institutions that participate in both the STS-CHSD and the CHSS-D. This analysis will answer the question of whether or not patients who are enrolled in CHSS studies are representative of those patients at CHSS institutions who are eligible but not enrolled. This analysis will not answer the question of whether or not patients who are enrolled in CHSS studies are representative of those patients who have surgery at institutions who are not CHSS members. In the future, we can perform additional analyses that will address this question of whether or not the results of patients in CHSS studies are generalizable to the population of institutions who are not CHSS members. This future analysis would focus on outcomes at institutions that participate in the STS-CHSD and would compare outcome of patients enrolled in CHSS studies to similar patients at non-CHSS institutions who would have been eligible for enrollment in CHSS studies.

Conclusion

Linkage of the CHSD of the STS and the CHSS has been achieved through the creation of five matrices that will facilitate the automated identification of patients who are potentially eligible for the five active CHSS studies using the STS-CHSD. Very high rates of sensitivity and specificity of these matrices have been demonstrated. These matrices will allow (1) estimation of the denominator of patients eligible for CHSS studies and (2) comparison of

eligible and enrolled patients to eligible and not enrolled patients to assess the generalizability of CHSS studies.

Acknowledgment

This article is the first in a series of 2 articles that will report the findings of a research project generously funded by the Children's Heart Foundation (http://www.childrensheartfoundation.org/) titled: "Linking the Congenital Heart Surgery Database of the Society of Thoracic Surgeons (STS) with the Congenital Heart Surgeons' Society (CHSS) Database." This article will describe the rationale and methodology of the STS-CHSS Link. The second article will describe the lessons learned to date from the STS-CHSS Link and the implications of this analysis.

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Appendix A

Inclusionary and Exclusionary Criteria for Currently Enrolling CHSS Studies Based on the STS Congenital Heart Surgery Database

I. Tricuspid atresia (TA)

A. STS codes (inclusion; all of these criteria are required for inclusion):

1. Date of Birth after September 30, 1998
2. Date of Admission after Dec 31, 1998
3. Fundamental Diagnosis or Primary Diagnosis = 820 = Single ventricle, Tricuspid atresia
4. ZERO Prior Cardiothoracic Operations and ZERO Prior CPB Cardiothoracic Operations:
5. Procedure: any procedure

B. STS codes (exclusion; any of these criteria result in exclusion):

1. Any transposition

Transposition of the great arteries

Transposition of the great arteries

880 = TGA, IVS

890 = TGA, IVS-LVOTO

900 = TGA, VSD

910 = TGA, VSD-LVOTO

TGA, NOS

Congenitally corrected TGA

870 = Congenitally corrected TGA

872 = Congenitally corrected TGA, IVS

874 = Congenitally corrected TGA, IVS-LVOTO

876 = Congenitally corrected TGA, VSD

878 = Congenitally corrected TGA, VSD-LVOTO

2. Any double outlet

DORV

930 = DORV, VSD type

940 = DORV, TOF type

950 = DORV, TGA type

960 = DORV, Remote VSD (uncommitted VSD)

2030 = DORV + AVSD (AV canal)

975 = DORV, IVS

DORV, NOS

DOLV

980 = DOLV

II. Pulmonary conduit (PC)

A. STS inclusion criteria (all of these criteria are required for inclusion):

1. Date of surgery after December 31, 2001

2. Age at surgery < 2 years

3. Mortality Status at Hospital Discharge = Alive

4. Any diagnosis except any of the following:

520 = Conduit failure

790 = Single ventricle, DILV

800 = Single ventricle, DIRV

810 = Single ventricle, Mitral atresia

820 = Single ventricle, Tricuspid atresia

830 = Single ventricle, Unbalanced AV canal

840 = Single ventricle, Heterotaxia syndrome

850 = Single ventricle, Other

851 = Single ventricle + Total anomalous pulmonary venous connection (TAPVC)

730 = Hypoplastic left heart syndrome (HLHS)

4380 = Status post − TOF repair, RV-PA conduit

4610 = Status post − Conduit placement, RV to PA

4620 = Status post − Conduit placement, LV to PA

5060 = Status post − Congenitally corrected TGA repair, Atrial switch, and Rastelli

5080 = Status post − Congenitally corrected TGA repair, VSD closure and LV to PA conduit

5150 = Status post − Rastelli

5. STS procedures eligible (the operation must include one of the following procedures)
    a. 230 = Truncus arteriosus repair
    b. 2220 = Truncus + Interrupted aortic arch repair (IAA) repair
    c. 380 = TOF repair, RV-PA conduit
    d. 420 = Pulmonary atresia − VSD (including TOF, PA) repair
    e. 430 = Pulmonary atresia − VSD − MAPCA (pseudotruncus) repair
    f. 610 = Conduit placement, RV to PA
    g. 620 = Conduit placement, LV to PA
    h. 740 = Ross procedure
    i. 760 = Ross-Konno procedure
    j. 1060 = Congenitally corrected TGA repair, Atrial switch and Rastelli
    k. 1080 = Congenitally corrected TGA repair, VSD closure and LV to PA conduit
    l. 1150 = Rastelli
    m. 2190 = Aortic root translocation over left ventricle (including Nikaidoh procedure)
6. Exclude the following procedure: 150 = Ventricular septal fenestration

III. Anomalous aortic origin of a coronary artery

A. STS inclusion criteria (all of these criteria are required for inclusion):
    a. Date of admission after December 31, 1997
    b. Age ≤ 30 years at time of surgery
    c. Fundamental diagnosis or primary diagnosis = 1010 = Coronary artery anomaly, Anomalous aortic origin of coronary artery (AAOCA)
    d. No other STS diagnosis except:
        1. 10 = PFO

2. 20 = ASD, Secundum
3. 30 = ASD, Sinus venosus
4. 40 = ASD, Coronary sinus
5. 50 = ASD, Common atrium (single atrium)
6. 71 = VSD, Type 1 (Subarterial) (Supracristal) (Conal septal defect) (Infundibular)
7. 73 = VSD, Type 2 (Perimembranous) (Paramembranous) (Conoventricular)
8. 75 = VSD, Type 3 (Inlet) (AV canal type)
9. 77 = VSD, Type 4 (Muscular)
10. 79 = VSD, Type: Gerbode type (LV-RA communication)
11. 80 = VSD, Multiple
12. 1080 = Patent ductus arteriosus
13. 420 = Pulmonary stenosis, Valvar
14. 740 = Cardiomyopathy (including dilated, restrictive, and hypertrophic)
15. 750 = Cardiomyopathy, end-stage congenital heart disease
16. 760 = Pericardial effusion
17. 770 = Pericarditis
18. 780 = Pericardial disease, other
19. 1180 = Arrhythmia
20. 2040 = Arrhythmia, Atrial
21. 2050 = Arrhythmia, Junctional
22. 2060 = Arrhythmia, Ventricular
23. 1185 = Arrhythmia, Heart block
24. 1190 = Arrhythmia, Heart block, Acquired
25. 1200 = Arrhythmia, Heart block, Congenital
26. 1220 = Arrhythmia, Pacemaker, Indication for replacement

B. STS diagnosis codes (exclude):

1. 1020 = Coronary artery anomaly, Anomalous pulmonary origin (includes ALCAPA)
2. 1030 = Coronary artery anomaly, Fistula
3. 1040 = Coronary artery anomaly, Aneurysm

4. 1050 = Coronary artery anomaly, Other
5. Any transposition

Transposition of the great arteries

Transposition of the great arteries

880 = TGA, IVS

890 = TGA, IVS-LVOTO

900 = TGA, VSD

910 = TGA, VSD-LVOTO

TGA, NOS

Congenitally corrected TGA

870 = Congenitally corrected TGA

872 = Congenitally corrected TGA, IVS

874 = Congenitally corrected TGA, IVS-LVOTO

876 = Congenitally corrected TGA, VSD

878 = Congenitally corrected TGA, VSD-LVOTO

C. Any double outlet

DORV

930 = DORV, VSD type

940 = DORV, TOF type

950 = DORV, TGA type

960 = DORV, Remote VSD (uncommitted VSD)

2030 = DORV + AVSD (AV canal)

975 = DORV, IVS

DORV, NOS

DOLV

980 = DOLV

D. STS procedures (exclude):

1. 1290 = Coronary artery fistula ligation
2. 1291 = Anomalous origin of Coronary artery from pulmonary artery repair

Note that the CHSS protocol for the Anomalous Aortic Origin of a Coronary Artery Study lists as an inclusionary criteria: “Structurally normal heart or with small, hemodynamically insignificant lesions (eg, patent ductus arteriosus, atrial septal defect, ventricular septal defect, mild pulmonic valvar stenosis, or bicuspid aortic valve without aortic stenosis).” The

investigative team that created this matrix translated this concept of a “structurally normal heart” into a matrix that allows for the 26 concomitant diagnoses listed in Section III.A.d. The STS-CHSS Link is designed to use the STS-CHSD to identify patients who are potentially eligible for CHSS studies. If a patient with one of the above 26 acceptable concomitant diagnoses is felt to not have a structurally normal heart at the time of evaluation for enrollment in a CHSS study, this patient should not be enrolled.

IV. Critical left ventricular outflow obstruction

A. STS codes:

1. Age: ≤30 days at admission AND 2.1. Date of Admission AFTER December 31, 2004.

2. Any of the following STS diagnoses:

a. 730 = Hypoplastic left heart syndrome (HLHS)

b. 550 = Aortic stenosis, Subvalvar

c. 560 = Aortic stenosis, Valvar

d. 570 = Aortic stenosis, Supravalvar

e. 590 = Aortic valve atresia

3. OR any of the following STS procedures:

a. 660 = Valvuloplasty, Aortic

b. 760 = Ross-Konno procedure

c. 870 = Norwood procedure

d. 880 = HLHS biventricular repair

e. 2160 = Hybrid approach “stage 1”, Application of RPA & LPA bands

f. 2170 = Hybrid approach “stage 1”, Stent placement in arterial duct (PDA)

g. 2180 = Hybrid approach “stage 1”, Stent placement in arterial duct (PDA) + application of RPA and LPA bands

h. 1660 = Damus-Kaye-Stansel procedure (DKS) (creation of AP anastomosis without arch reconstruction)

i. 890 = Transplant, Heart (note that this procedure requires one of the above STS diagnoses while the other procedure do not.)

4. EXCLUDE the following STS diagnoses:

a. Any transposition

Transposition of the great arteries

Transposition of the great arteries

880 = TGA, IVS

890 = TGA, IVS-LVOTO

900 = TGA, VSD

910 = TGA, VSD-LVOTO

TGA, NOS

Congenitally corrected TGA

870 = Congenitally corrected TGA

872 = Congenitally corrected TGA, IVS

874 = Congenitally corrected TGA, IVS-LVOTO

876 = Congenitally corrected TGA, VSD

878 = Congenitally corrected TGA, VSD-LVOTO

b. Any double outlet

DORV

930 = DORV, VSD type

940 = DORV, TOF type

950 = DORV, TGA type

960 = DORV, Remote VSD (uncommitted VSD)

2030 = DORV + AVSD (AV canal)

975 = DORV, IVS

DORV, NOS

DOLV

980 = DOLV

c. Any AV canal

100 = AVC (AVSD), Complete (CAVSD)

110 = AVC (AVSD), Intermediate (transitional)

120 = AVC (AVSD), Partial (incomplete) (PAVSD) (ASD, primum)

300 = TOF, AVC (AVSD)

2030 = DORV + AVSD (AV canal)

830 = Single ventricle, Unbalanced AV canal

d. Any double inlet left ventricle

790 = Single ventricle, DILV

e. Any cardiomyopathy

740 = Cardiomyopathy (including dilated, restrictive, and hypertrophic)

V. Unbalanced AVSD study

A. STS inclusion codes (all of these criteria are required for inclusion):

1. Date of admission after December 31, 2011

2. Age 0 to 365 days at time of admission

3. Any of the following diagnoses:

100 = AVC (AVSD), Complete (CAVSD)

300 = TOF, AVC (AVSD)

2030 = DORV + AVSD (AV canal)

830 = Single ventricle, Unbalanced AV canal

4. STS Procedures ELIGIBLE:

Any

B. STS exclusion codes:

1. 110 = AVC (AVSD), Intermediate (transitional)

2. 120 = AVC (AVSD), Partial (incomplete) (PAVSD) (ASD, primum)

3. 590 = Aortic valve atresia

4. Any one or more of the following diagnoses:

870 = Congenitally corrected TGA

872 = Congenitally corrected TGA, IVS

874 = Congenitally corrected TGA, IVS-LVOTO

876 = Congenitally corrected TGA, VSD

878 = Congenitally corrected TGA, VSD-LVOTO

880 = TGA, IVS

890 = TGA, IVS-LVOTO

900 = TGA, VSD

910 = TGA, VSD-LVOTO

TGA, NOS

180 = Partial anomalous pulmonary venous connection (PAPVC)

190 = Partial anomalous pulmonary venous connection (PAPVC), Scimitar

200 = Total anomalous pulmonary venous connection (TAPVC), Type 1 (supracardiac)

210 = Total anomalous pulmonary venous connection (TAPVC), Type 2 (cardiac)

220 = Total anomalous pulmonary venous connection (TAPVC), Type 3 (infracardiac)

230 = Total anomalous pulmonary venous connection (TAPVC), Type 4 (mixed)

840 = Single ventricle, Heterotaxia syndrome

851 = Single ventricle + Total anomalous pulmonary venous connection (TAPVC)

4280 = Status post − TAPVC repair

6200 = Status post − TAPVC repair + Shunt − systemic-to-pulmonary

1230 = Atrial isomerism, Left

1240 = Atrial isomerism, Right

5. Any one or more of the following syndromes:

180 = Heterotaxy syndrome

190 = Heterotaxy syndrome, Asplenia syndrome

200 = Heterotaxy syndrome, Polysplenia syndrome

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Table 1

Twelve CHSS Diagnostic Cohorts.

Diagnostic Cohort	Enrollment	Number of Patients Enrolled	References
Transposition of the Great Arteries (TGA) Study[a]	1985–1989	891	33–41
Interrupted Aortic Arch (IAA) Study[a]	1987–1997	470	42–47
Coarctation Study[a]	1990–1993	883	48
Pulmonary Atresia Intact Ventricular Septum (PAIVS) Study[a]	1987–1997	444	49–52
Pulmonary Stenosis with Intact Ventricular Septum (PSIVS) Study[a]	1987–1997	187	
Critical Aortic Stenosis Study[a]	1987–1997	422	53–55
Aortic Valve Atresia Study[a]	1987–1997	563	56,57
Tricuspid Atresia (TA) Study[b]	1999–	307	58
Pulmonary Conduit (PC) Study[b]	2002–	591	59–61
Critical Left Ventricular Outflow Tract (LVOTO) Study[b]	2005–	674	62,63
Anomalous Aortic Origin of a Coronary Artery (AAOCA) Study[b]	1998–	284	64
Unbalanced Atrioventricular Septal Defect (uAVSD) Study[b]	2012–	84	65,66

Abbreviation: CHSS, Congenital Heart Surgeons' Society.

[a]This study is no longer enrolling patients.

[b]This study is still actively enrolling patients.

Table 2

Classification of All Participating Centers in the STS-CHSD and the CHSS.

Number	Category
100	Centers that participate in STS-CHSD in January 2012
74	Centers that participate in the CHSS in January 2012
70	Centers that participate in the STS-CHSD and the CHSS
30	Centers that participate in the STS-CHSD only
4	Centers that participate in the CHSS only
Of the 70 centers that participate in the STS-CHSD and the CHSS	
40	Centers that participate in the STS-CHSD and the CHSS and consented to participate in this project
8	Centers that participate in the STS-CHSD and the CHSS who responded to the invitation to participate in this study and declined to participate
22	Centers that participate in the STS-CHSD and the CHSS who never responded to the invitation to participate in this study

Abbreviations: CHSS, Congenital Heart Surgeons' Society; STS-CHSD, Society of Thoracic Surgeons Congenital Heart Surgery Database.

Table 3

Forty Centers That Participate in the STS-CHSD and the CHSS-D and Consented to Participate in This Project.

	Name
1	Advocate Hope Children's Hospital, Illinois
2	All Children's Hospital Johns Hopkins University, Florida
3*	Ann & Robert H. Lurie Children's Hospital, Illinois
4	Arnold Palmer Medical Center, Orlando
5	British Columbia Children's Hospital, Vancouver
6	Cardinal Glennon/St Louis University
7	Children's Hospital and Medical Center, Omaha
8	Children's Hospital Colorado
9	Children's Hospital of Los Angeles
10*	Children's Hospital of Michigan
11	Children's Hospital of Orange County (CHOC)
12	Children's Hospital of Pittsburgh
13	Children's Hospital of Wisconsin
14	Children's Hospitals and Clinics of MN
15	Children's National Medical Center, District Colombia
16	Duke University Hospital
17	Joe DiMaggio Children's Hospital, Florida
18*	Kosair Children's Hospital/Norton
19	Loma Linda
20	Mattel Children's Hospital at UCLA
21	Miami Children's Hospital, Florida
22	Montefiore Medical Center, New York
23	MUSC Children's Hospital, Charleston
24	Pennsylvania State University, Hershey
25	Rady Children's Hospital, San Diego, California
26	Saint Joseph's Children's Hospital of Tampa
27	Strong Memorial Hospital at U of Rochester
28	The Alfred I DuPont Hospital for Children
29*	The Children's Hospital of Philadelphia
30	The Children's Mercy Hospital, Kansas City
31	The Johns Hopkins Hospital, Baltimore
32	The University of Michigan
33	University of Alabama Birmingham
34	University of Kentucky Medical Center
35	University of Maryland Children's Hospital
36	University of Minnesota Amplatz Children's Hospital
37	University of Texas Health Science Center, San Antonio

	Name
38	Washington University School of Medicine, St Louis
39	WV University Hospitals
40	Yale New Haven Hospital, Connecticut

Abbreviations: CHSS-D, Congenital Heart Surgeons' Society Database; STS-CHSD, Society of Thoracic Surgeons Congenital Heart Surgery Database;

* = Four "alpha test centers".

Table 4

The Results of the Manual Adjudication.

Initial matrices	
247	Patients identified as potentially CHSS eligible
14	Identified during manual adjudication as being incompletely or incorrectly coded by site
233	Potentially CHSS eligible and coded properly
30	Eligible and enrolled
188	Potentially eligible and not enrolled
15	Identified as potentially CHSS eligible but judged to be not eligible
16	CHSS eligible patients not identified by matrices
Revised matrices after manual adjudication	
239	Potentially CHSS eligible and coded properly
30	Eligible and enrolled
204	Potentially eligible and not enrolled
5	Identified as potentially CHSS eligible but judged to be not eligible
0	CHSS eligible patients not identified by Matrices
12.8%[a]	Percentage of potentially eligible patients who were enrolled = 30/234 = 12.8%

Abbreviation: CHSS, Congenital Heart Surgeons' Society.

[a]Note that not all alpha sites participated in all five CHSS cohort studies; and therefore, some alpha sites did not actually enroll any patients in some of the CHSS cohorts. The second article in our series of two articles about the STS-CHSS Link provides a detailed analysis of the completeness of enrollment in CHSS studies across the entire CHSS and documents that completeness of enrollment in CHSS studies at centers actively participating in these studies ranged from 29% to 40% across CHSS studies.

Table 5

Four by Four Tables Documenting the Sensitivity and Specificity of the Initial Matrices and the Revised Matrices after Manual Adjudication.

	Initial Matrices		
	Matrix Says CHSS Eligible	Matrix Says CHSS Not Eligible	Total
True CHSS eligible	218	16	234
True CHSS not eligible	15		
Total	233		
Sensitivity = 218/234 = 93.2%			
Specificity = 218/233 = 93.6%			

	Revised Matrices After Manual Adjudication		
	Matrix Says CHSS Eligible	Matrix Says CHSS Not Eligible	Total
True CHSS eligible	234	0	234
True CHSS not eligible	5		
Total	239		
Sensitivity = 234/234 = 100%			
Specificity = 234/239 = 97.9%			

Abbreviation: CHSS, Congenital Heart Surgeons' Society.

Table 6

Congenital Heart Surgeon's Society (CHSS) Enrollment—Report of Potentially Eligible Surgical Patients.[a]

Operation ID	Date of Birth	Date of Surgery	Primary Diagnosis	Primary Procedure	CHSS Study	Enrolled in CHSS-Yes/No[b]
1157234	July 7, 2011	August 8, 2011	160	230	Left ventricular outflow obstruction	
1115822	May 4, 2010	April 4, 2011	940	1,150	Pulmonary conduit	
1146321	February 4, 2011	February 8, 2011	820	1,590	Tricuspid atresia	
1146885	March 16, 2011	November 17, 2011	290	540	Pulmonary conduit	
1163867	June 17, 2011	June 24, 2011	1,000	1,280	Left ventricular outflow obstruction	
1143123	April 7, 1995	March 11, 2011	1,010	1,310	Anomalous aortic origin of a coronary artery	

[a] Participant ID: 99999. This table lists the operations associated with your participant ID, from the data files that have been submitted, which are potentially eligible for enrollment in the indicated CHSS Study.

[b] CHSS enrollment data are being collected for the first time in version 3.2, starting January 1, 2014. This field will be populated beginning with Fall 2014 Harvest.