The STS National Database

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The initial stimulus for developing The Society of Thoracic Surgeons (STS) National Database came in 1986 when the Health Care Financing Administration (HCFA) publicly reported hospital mortality using minimally adjusted, non-clinical data. Because of the lack of adequate risk adjustment and questions regarding the accuracy of diagnoses and procedures, cardiothoracic surgeons became very concerned that such data could be misleading.

The STS Standards and Ethics Committee released a “Statement of Concern” in 1986, followed by the Society appointing an Ad Hoc Committee on Risk Factors for Coronary Bypass Surgery, which issued a report in 1988 stating:

“The Society is committed to the principle of providing the public with accurate information regarding the conduct of coronary artery surgery. However, it believes that the data provided by HCFA do not provide this information and should not be used as the sole index of quality of care following coronary artery bypass surgery.” [1]

Shortly after that report, Richard E. Clark, MD (Fig 1), was appointed Chair of a newly formed Ad Hoc Committee to Develop a National Database for Thoracic Surgery [2].

The new committee acted as a consensus panel, identifying comorbidities and perioperative and procedure-specific characteristics that were likely to impact the risk of a given procedure in the three specialty areas of cardiothoracic surgery. Definitions were also developed for each of the data elements. Initially, the major outcomes to be measured were operative mortality, morbidity, and length of stay, with the intent to develop risk models when data from an adequate number of procedures were entered.

Although the STS National Database began with the infrastructure for three components—the Adult Cardiac Surgery Database (ACSD), the Congenital Heart Surgery Database (CHSD), and the General Thoracic Surgery Database (GTSD)—it took a little longer for the CHSD and the GTSD to become the robust registries they are today.

Adult Cardiac Surgery Database

In September 1989, the STS Council approved the terms of a proposed contract between the Society and Summit Medical Systems, a for-profit company based in Minneapolis, Minnesota, whereby Summit would develop software for data entry at local sites that would be transmitted to Summit for warehousing, analysis, and reporting. The first mailing announcing the STS National Database was sent in June 1990 [3]. By mid-February 1991, 330 STS members from 81 centers were subscribed and had submitted data from almost 70,000 cardiac surgical patient records. In 1995, Dr Clark reported that 1,500 surgeons working at 706 hospitals in 49 states had entered data from more than 500,000 patient records [4]. He also noted a significant shortening of the length of postoperative stay for adult cardiac surgery and a modest decrease in operative mortality, in spite of an increased incidence of high-risk cases.

When Fred H. Edwards, MD (Fig 2), joined the Committee in 1992, he was asked to direct the statistical risk-adjustment methodology for the Database. He introduced a Bayesian risk-adjustment model [5], which has particular advantages in databases where data are missing, which was the case in the early years of the STS National Database.

In 1991 STS created an Ad Hoc Database Liaison Committee, chaired by Richard P. Anderson, MD (Fig 3A). It was charged with overseeing the business activities and finances of the Database, and with making associated policy recommendations to the Council. A primary Database goal was providing surgeons access to their own data with comparison of risk-adjusted results to those of regional and national peers. Another goal was to increase access to data for research, quality improvement, and the generation of reports that could affect health care policy.

Dr Clark continued to Chair the National Database for Thoracic Surgery Committee until 1997, when Frederick L. Grover, MD (Fig 4), was appointed as his successor and began an effort to improve data quality and auditing. Dr Grover accepted the appointment with the understanding that STS would hire its first full-time database manager, Mary Eiken, RN, MS, and also A. Laurie W. Shroyer, PhD, MSHA, a researcher and statistician, to consult and advise the Committee on a part-time basis.

A subcommittee critically examined all of the 512 data elements in the ACSD, eliminating elements that were found to be irrelevant. In addition, STS Database leaders met with leaders of the American College of Cardiology National Cardiac Data Registry to create common data points and definitions, where appropriate.
A number of operational enhancements were also implemented, including modernization of the national reports and increasing the sophistication and flexibility of the data entry software. The Committee saw a need for a formal annual training program for database managers, and it convened the first such meeting at the 1997 STS Annual Meeting in San Diego. Data managers were instrumental in advising the Database Committee and STS leadership on definitions that needed to be revised and data elements that were very difficult to obtain and that should be eliminated. This annual training program later became the standalone conference, Advances in Quality & Outcomes: A Data Managers Meeting (commonly referred to simply as AQO).

The Database Committee was subsequently enlarged to 21 members and 4 International Members were added in an effort to create common data elements and definitions that could be used by other large international databases. The Society owes a great debt of gratitude to T. Bruce Ferguson, Jr, MD, and Stanley W. Dziuban, Jr, MD, who worked tirelessly to redefine the datasets. Dr Dziuban developed a data dictionary and rewrote software specifications for the entire database. This allowed internal quality checking to be implemented electronically.

In 1998, members of the National Database for Thoracic Surgery and Database Liaison Committees, led by Dr Grover and Peter C. Pairolero, MD (Fig 3B), respectively, decided that data collection and data warehousing/analysis functions should be handled by separate entities. They requested proposals for multiple data entry software companies to give cardiothoracic surgery groups a range of choices. Eleven vendors responded and 8 underwent certification. Proposals for warehousing and analysis services were also requested and resulted in the Duke Clinical Research Institute (DCRI) being selected. Although the transition from Summit to DCRI and the corresponding shift in participant software licensing was lengthy, complex, and costly for the Society, the relationship with DCRI and Database operations overall have proven to be very successful for more than 15 years.

Several very significant annual financial deficits occurred during the transition period. Much credit needs to be given to then STS Treasurer Robert A. Guyton, MD, and other STS leaders for their continued faith in the project and their vision for seeing the long-term strategic value of the database.

In 1999, the National Database for Thoracic Surgery Committee established database goals, many of which have been achieved [6, 7]. The goals included the following: (1) not only measurement of risk-adjusted mortality and morbidity, but also functional health status, re-interventions, quality of life, patient satisfaction, and cost; (2) development of a protocol to review and capture the outcomes of coronary bypass, angioplasty, and stenting; (3) achievement of a stature and quality of data that other stakeholders would respect and therefore use, rather than trying to collect data on their own; (4) making the STS Database relevant to members’ clinical decision making; (5) increasing research productivity based on the database; (6) using the database to establish the value of cardiothoracic surgery in negotiations with the government, third party carriers, other health care organizations and the public; and (7) capturing long-term data, particularly focusing on the relative efficacy of cardiothoracic procedures compared to other procedures and treatments such as stent placement for coronary artery disease.
In 2000, annual Database reports increased to twice a year and were presented in a format that allowed members to compare their data with local/regional and national cohorts. The adult cardiac risk model's statistical methodology was changed from a Bayesian approach to logistic regression analysis. Under the leadership of Drs Edwards and Shroyer, new risk models, in addition to coronary artery bypass grafting (CABG) surgery, were developed for adult valve surgery, including aortic valve replacement and mitral valve replacements, with and without CABG [8–12].

International initiatives, particularly the European Cardiac Surgical Registry which was being developed by Kenneth M. Taylor, MD, and Richard K.H. Wyse, PhD, incorporated the STS risk variables into their datasets. Working with Bruce Keogh, FRCS, from Great Britain and Paul T. Sergeant, MD, PhD, from Belgium, these collaborations helped develop the European Association for Cardio-Thoracic Surgery (EACTS) Adult Cardiac Surgery Database.

At the beginning of the 21st century, there was an emphasis on making the STS National Database better known among health policy experts, government agencies, insurance companies, and the public, and to seek their approval of its scientific validity. Prominent among these groups were the National Quality Forum (NQF), established in 1999, and the AMA Physician Consortium for Performance Improvement, established in 2001. Other important stakeholder groups were the Ambulatory Care Quality Alliance, which later became known as the AQA, the Hospital Quality Alliance, and the Quality Assurance Steering Committee. STS National Database leaders became members and leaders in a majority of these organizations. In 2004, the NQF Steering Committee for Adult Cardiac Surgery approved ACSD data elements. This was critical for STS, because approval by this highly respected independent and multidisciplinary group gave the Database credibility outside of the cardiothoracic surgery community.

In 2002, STS appointed Robert A. Wynbrandt, JD, who as outside legal counsel had worked extensively with the surgeon leadership since 1989 to devise and execute a series of business models for the National Database, as STS Executive Director & General Counsel (see Chapter 2). Under the new STS governance structure, the National Database for Thoracic Surgery Committee and the Database Liaison Committee merged to become the Workforce on National Databases under the Council on Quality Assurance and Patient Advocacy (now the Council on Quality, Research and Patient Safety). The governance structure also allowed for the creation of distinct task forces for the ACSD, CHSD, and GTSD, of which the latter two were blossoming into robust databases.

In 2004, Eiken left STS and, after a national search, she was succeeded by Cynthia M. Shewan, PhD, as STS Director of Quality, Research and Patient Advocacy. Also in 2004, Dr Edwards became Chair of the Workforce on National Databases when Dr Grover was elected to STS leadership positions that led to his Presidency in 2006. David M. Shahian, MD (Fig 5), succeeded Dr Edwards as Workforce Chair in 2010.

The Adult Cardiac Surgery Database Task Force is currently chaired by Richard L. Prager, MD. As of late August 2013, the ACSD had 1,078 participants, including five international participants, representing more than 3,000 surgeons. More than 5.1 million surgical procedure records have been entered into the ACSD, including 2 million isolated CABG records from 2000 to 2009. These data helped show significant improvements in reoperative CABG and risk-adjusted mortality. Ravi K. Ghanta, MD and colleagues found that reoperative CABG declined from 6.0% in 2000 to 3.4% in 2009, and risk-adjusted mortality decreased from 6.0% to 4.6%—a relative risk reduction of 23.7% [13].

Fig 3. (A) Richard P. Anderson, MD; and (B) Peter C. Pairolero, MD.
In 2007, Dr Shahian and his colleagues published two landmark papers [14, 15] describing a composite score initially developed for CABG surgery, which included perioperative drugs, the use of at least one internal mammary artery, risk-adjusted operative mortality, and the absence of any serious postoperative morbidity. The STS CABG Composite Score was endorsed by the NQF in 2010. A similar STS composite score for isolated aortic valve replacement was developed in 2012 [16].

The most recent short-term risk models for CABG, valve, and CABG/valve procedures were developed in 2008 [17–19]. A long-term survival model for CABG was developed in 2012 [20] along with a risk model for multiple valve replacement. An atrial fibrillation module has been completed and modules for valvular heart disease and thoracic aortic disease are being developed.

In January 2013, an agreement was reached between STS and the Society of Cardiovascular Anesthesiologists for DCRI to build an Adult Cardiac Anesthesia Module linked to the ACSD with approximately 70 elements. The module launched in July 2013.

Congenital Heart Surgery Database
The first harvest from the CHSD consisted of 8,149 patient records from 1994 to 1997 from 24 participant sites [21]. As of August 2013, the CHSD had more than 218,000 patient records from 109 participant sites, including one international site, representing more than 350 surgeons and more than 300 anesthesiologists.

The CHSD owes much of its success to the persistence of its first Chair, Constantine (Gus) Mavroudis, MD, who made an enormous effort in the 1990s and early 2000s to establish the Database. Thanks to Dr Mavroudis’ leadership, the Congenital Heart Nomenclature and Database Project was initiated and published as a supplement to The Annals of Thoracic Surgery in 2000. The goals of the project were to begin standardization of nomenclature and reporting strategies and establish the foundation for an international congenital heart surgery database. This was a necessary undertaking because of the tremendous variations and complexity of congenital heart defects. The effort resulted in an International Summit on Nomenclature for Congenital Heart Disease in Toronto in 2001.

In 2005, Jeffrey P. Jacobs, MD, and colleagues reported on the addition to the CHSD of the Basic Complexity Score, which rates each operation for various defects by complexity (1.5–15) and level (1–4) based on the EACTS/STS Aristotle Committee recommendations [22]. This was a precursor for a study incorporating the comprehensive Aristotle score and patient risk modifiers to increase the preciseness of the estimated risk. Much of the credit for development of risk stratification using the Aristotle score goes to François G. Lacour-Gayet, MD.

Dr Jacobs became Chair of the Congenital Heart Surgery Database Task Force in 2007, succeeding Dr Mavroudis. In 2008, an agreement was completed which added the Congenital Cardiac Anesthesia Society component to the CHSD. The NQF approved several congenital database elements in 2012, and the database has generated numerous publications.

General Thoracic Surgery Database
The GTSD was somewhat slow to develop in the early years; however, in the mid-late 1990s, David H. Harpole, Jr, MD, was appointed Chair for this effort. He invested considerable time into demonstrating the utility of the GTSD for quality assessment and practice improvement. He was followed as Chair by Joe B. (Bill) Putnam, Jr, MD,
and Mark S. Allen, MD, both of whom continued to build the Database and establish its utility.

Cameron D. Wright, MD, was appointed Chair of the GTSD Task Force in 2005, and over the past several years there has been a significant growth in Database participation and patient records. In 2006, only 51 participants were enrolled in the GTSD. As of August 2013, the Database had 244 participants representing 813 surgeons, a growth rate of nearly 500%.

The NQF endorsed seven GTSD measures in 2008 and several important papers have emanated from data in the GTSD. One very important publication was by Daniel J. Boffa, MD, and colleagues in 2008, in which they reported GTSD. As of August 2013, the Database had 244 participants representing 813 surgeons, a growth rate of nearly 500%.

The NQF endorsed seven GTSD measures in 2008 and several important papers have emanated from data in the GTSD. One very important publication was by Daniel J. Boffa, MD, and colleagues in 2008, in which they reported on all pulmonary resections recorded in the database between 1999 and 2006 [23]. More than 49,000 records were entered, including more than 9,000 pulmonary resections for lung cancer. This study reviewed the number of lung cancers that were removed by wedge resection, segmentectomy, and lobectomy, as well as evaluation of mediastinal lymph node involvement and outcomes. This was an important paper because it demonstrated to the general thoracic community the type of analysis that could be done and the value of this Database.

In 2010, Mark Shapiro, MD, and colleagues, reported on the predictors of major morbidity and mortality after pneumonectomy [24], utilizing the GTSD and subsequently creating a risk model. The GTSD Task Force also developed risk models, one for esophagectomy for esophageal cancer and one for pulmonary lobectomy for lung cancer. Also in 2010, Matthew G. Hartwig, MD, and Thomas A. D’Amico, MD, used a propensity matching analysis from the GTSD to demonstrate the relative safety and potential advantages of thoracoscopic lobectomy of traditional thoracotomy for the treatment of early stage lung cancer [25].

**Current STS National Database Initiatives**

All three components of the STS National Database are currently growing and continue to benefit from excellent leadership and the participation of many STS members on various task forces, a superb STS staff, and participants who enter data from their institutions. Because of growth of the STS Research Center (see Chapter 12) and the involvement of Dr Shewan in the Research Center, DeLaine Schmitz, MSHL, RN, was hired in 2012 as STS Director of Quality.

**Data Quality**

A high priority is placed on data quality. Data managers periodically receive coordinated updates and instructional materials to help ensure uniform, high-fidelity data entry. Well-attended annual data manager meetings are held to an intense program of instruction and bidirectional feedback. In order to monitor the effectiveness of the data quality program, independent data audits are performed. In recent years, Database participant annual audits increased from 5% to 8%, and data accuracy has been found to be very high.

**Regional Collaborative**

Regional activity, specifically in the ACSD, has been growing steadily since 1993. Kit V. Arom, MD, PhD, and his colleagues in Minnesota organized the Minnesota Regional Group in response to third-party payer demands for data about practice protocols and patient outcomes. Rather than have numerous databases specific for each payer, a group was established that included 46 surgeons, 14 institutions, and more than 7,000 patients who had undergone CABG surgery. The STS generated a special Minnesota report, and the group established quarterly meetings and exchanged site visits for continuous quality improvement activities.

In 2009, Alan M. Speir, MD, Jeffrey B. Rich, MD, and colleagues reported on the Virginia Cardiac Surgery Quality Initiative, which involved cardiac surgeons and other hospital providers [26–28]. This group examined not only outcomes, but also attempted to identify ways of improving these outcomes, while at the same time containing costs.

One of the most successful regional programs has been the Michigan Society of Cardiovascular and Thoracic Surgeons Voluntary Quality Collaborative, which includes all Michigan cardiac surgeons and all Michigan hospitals where adult cardiac surgery is performed [29, 30]. This unique collaboration began in 1996 with the Blue Cross-Blue Shield Michigan Centers of Excellence Project. Blue Cross-Blue Shield partially funded the cardiac surgery portion of the collaborative program, which focused on internal mammary artery usage, preoperative intraaortic balloon pump usage, prolonged lung ventilation, postoperative atrial fibrillation, and coronary artery bypass unadjusted and risk-adjusted mortality.

Currently, the ACSD has 18 regional groups with varying degrees of involvement.

**Appropriate Care**

An Appropriateness Task Force was recently established, with Joseph C. Cleveland, Jr, MD, as its first Chair, to develop measures of appropriate care based on evidence-based guidelines beginning with CABG procedures. The Task Force formation was very timely because the federal government and commercial payers are interested in overuse of surgical procedures and appropriateness of care.

**International Initiatives**

An International Database Task Force was recently established to build upon and expand database relationships developed in the 1990s with EACTS, the European Society of Thoracic Surgeons, the Japanese Association for Thoracic Surgery, and the Asian Society for Cardiovascular and Thoracic Surgery. Chaired by John D. Puskas, MD, the Task Force offers information on Database access to the international community and demonstrates how the STS National Database complements, rather than competes with, other databases utilized by the specialty outside North America.
Reimbursement Initiatives

Peter K. Smith, MD, Chair of the Workforce on Coding and Reimbursement, has successfully used the STS National Database data for the Relative Value Scale Update Committee process. On behalf of STS, Dr Smith was particularly successful in 2005 when information from the Database was used to determine work effort for cardiothoracic surgical procedures (see Chapter 8). These initiatives resulted in an increase on total code value of 12.3% and an increased Medicare payment of 4.8% after adjustments [31].

STS also has collaborated with a number of other payers, including WellPoint, Blue Cross-Blue Shield, and United Healthcare to promote the STS National Database as the measure of cardiothoracic surgical performance, as distinct from those registries utilizing administrative data.

Quality Assessment Program

In 2008, Dr Grover and John E. Mayer, Jr, MD, were invited to be part of the Physician Advisory Group to the US Senate Committee on Health, Education, Labor & Pensions during the height of the health care reform debate. The group was involved in weekly calls and face-to-face meetings from November 2008 through September 2009.

Richard L. Prager, MD currently chairs the Quality Initiative Task Force, which monitors and facilitates STS involvement with external entities such as the NQF and Centers for Medicare & Medicaid Services (CMS). STS adult cardiac and general thoracic quality measures have been accepted by CMS for Database participants to use in PQRS, and the STS National Database is a “qualified” registry for PQRS measure submission directly to CMS.

Public Reporting

In a first for any major medical specialty society, STS launched a voluntary public reporting initiative in fall 2010, based upon a belief among the STS leadership that patients have an ethical right to know the performance of their providers. This initiative was in conjunction with the Consumers Union Health website; 221 surgical groups agreed initially to publicly report their CABG results. An accompanying article was published in the September 2010 issue of Consumer Reports magazine. A composite star rating system was used along with scores from each of four individual quality domains. Data from consenting participants were also posted on the STS website in November 2010. A Perspective article by Timothy G. Ferris, MD, MPH, and David F. Torchiana, MD, in The New England Journal of Medicine called the initiative “a watershed event in health care accountability.” [32]

The STS and Consumer Reports continue to periodically offer updated public reporting results. A composite score has also been developed for aortic valve replacement (AVR) procedures. As of July 2013, 481 (45%) ACSD participants were publicly reporting via STS Public Reporting Online and/or the Consumer Reports website. Plans are under way to also publicly report congenital heart surgery and general thoracic surgery outcomes.

The Impact of the STS National Database

In summary, the STS National Database is integral to the cardiothoracic surgical specialty. The ACSD, GTSD, and CHSD, along with other surgical databases, have set an example for other specialties to fulfill their professional obligations to their patients and society. Most important, monitoring of risk-adjusted outcomes by STS members has led to documented improvement in quality of care. The STS National Database has credibility with Congress, the White House, CMS, the Food and Drug Administration, payers, purchasers, and the major quality improvement organizations. In addition, the Database has given STS a great opportunity for real-world clinical research, comparative-effectiveness research, and the prospect of generating long-term data that are essential for measuring the efficacy of what the specialty does moving forward. The data allow cardiothoracic surgeons to be leaders in public reporting; they also are very useful in reimbursement negotiations and for maintenance of certification.

The STS National Database also offers an opportunity for new device monitoring and rational dispersion of new technology. Now, more than 24 years after its launch, the Database has achieved many of the goals established in the early years. Furthermore, STS continues to find more valid uses for the Database, meaning its value will continue to increase over time.

References


