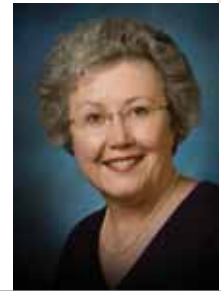


EVOLUTION OF THE SOCIETY OF THORACIC SURGEONS NATIONAL CARDIAC SURGERY DATABASE

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INTRODUCTION

The Society of Thoracic Surgeons (STS), which represents essentially all Board certified Cardiothoracic Surgeons, was the first medical or surgical specialty society to recognize that a national database of procedures would not only be a powerful tool for quality improvement and professional advancement, but would also provide abundant clinical material for outcomes research. In addition, an accurate understanding of outcomes would permit more realistic discussions of individual risk with patients.

HISTORY

The Beginning

A national database for adult cardiac surgery procedures was voluntarily initiated by the STS in 1989, and first data were accepted in 1990. The STS National Database had very strong participation from the beginning. In fact, a number of cardiac surgeons had independently begun individualized databases some years earlier, for the same reasons mentioned above related to quality, professional improvement, and accurate risk assessment. These databases used software purchased from entrepreneurial vendors who saw a growth opportunity in this niche market. When the STS Database began, it encouraged those independent databases that were using compatible software to merge into the STS Database. This policy allowed early STS reports to be based on a fairly robust data set, with dates of surgery ranging from 1980 – 1991. By January 1993, 530 hospitals belonged to the National Database, representing 40% of the cardiac surgical community.¹ By December 1992, the Database reported that it contained 216,075 procedures.² Initially, the Database only analyzed isolated coronary artery bypass or valve procedures, but by the third year, when more than 600 hospitals in almost all states were contributing, the Database included combinations of aortic and mitral valve replacements with coronary artery bypass operations. By the fourth year, hospitals in 48 states and five hospitals in Canada were represented, and in the fifth year the Database had grown to 750 hospitals.

Since each participating site had to develop its own data manager in an era when computer expertise was much less common than it is today, standardization was felt to be a crucial attribute at the beginning. It was felt that a single provider would simplify the task of standardizing datasets, data forms, and algorithms for risk analysis. The STS contracted with Summit Medical Systems in Minneapolis to be the exclusive software provider. Summit was already providing software and technical support to many of the independent databases that had been developed over the previous decade. Summit's contractual responsibilities to the STS were to include data "harvest", data analysis, and periodic reporting. Summit's software was user friendly and included many report templates, an important factor considering that most data managers had a clinical background and were not proficient in Information Technology. Importantly, from the outset Database participants could query their own data at the local level. In addition, Summit's software allowed users to customize their databases by adding extra fields of special interest to them.

Advances in Data Analysis

A risk stratification system, developed by the STS under the leadership of Dr. Fred Edwards, an academic cardiac surgeon with a Master of Science in Engineering before he went to medical school, became part of the standard software in the second year. Risk calculation could now be done at the local level. During entry of a patient's data, a specific risk percentage for that individual patient appeared automatically, based on the medical and surgical history. Software upgrades were provided subsequently whenever the outcomes data accumulating rapidly in the National Database indicated that the risk algorithms should be changed. In addition, as weaknesses in data definitions surfaced, data definitions were upgraded.

Evolution of Software

For such an ambitious project, growing pains were inevitable. In 1999 the STS leadership decided it was precarious to have only one software vendor. It would be healthier for the continued evolution of the Database,

it was felt, if the software “monopoly” were ended, and other software vendors were permitted to apply to the STS for approval as “certified vendors.”³ Although this meant that every participant in the STS National Database would be forced to choose a new software product, it meant that several vendors would compete. Now each participant could select software tailored to the specific needs of their cardiothoracic surgery program. Sixteen software vendors became certified providers and the choices varied widely. For example, one software option offered the ability to track multiple patient follow-up visits, whereas most programs were weak in tracking long-term follow-up. Another software option interfaced with hemodynamic monitoring equipment but limited the user’s ability to add fields. Yet another choice offered touch-screen capability designed for the patient to use on follow-up.

Not all certified software vendors were willing to roll forward historical data from the “Summit Years” in a live, usable format. At this juncture the National Database experienced a temporary drop in the number of data submissions, as users chose and implemented new software. The number of sites submitting data in the next Fall (2000) was only 160. However, while the number of participants who were able to submit data temporarily decreased, the total number of reported procedures passed 1.5 million.

Since there were now multiple vendors, a second major component of the 1999 reorganization was the associated decision to contract with a third party to “harvest” and analyze the national data. The Duke Clinical Research Institute was selected, and for the first time the STS issued participant-specific reports enabling participants to see how they compared to the aggregate data in the National Database without running custom reports locally. This period of transition lasted several years while the wrinkles were smoothed out, but from this point forward the Database experienced steady growth in membership and according to the most recent report (April 2009), 859 of 969 participants submitted data.

Management of Data

As mentioned earlier, each site was responsible for developing its own capability to enter and manage data. The individuals who filled these responsibilities varied widely in background and training. Evolution of the National Database accelerated in 1997 with their hiring of a nurse

manager at the national level, and the advent of national meetings for data managers. At first these meetings were attached to the Annual Meeting of the STS, but they eventually became freestanding. These meetings provide opportunities for data managers to share experiences and problems, to form networks for subsequent interactions, and to talk with the surgeons responsible for development of the Database. When e-mail became widely available, communication was further enhanced.

Other noteworthy events were the launching of the Data Managers’ Web Site and the online Risk Calculator; increased frequency of data harvests (to semi-annual in 2000 and quarterly in 2008); and the Electronic Report (a CD was first enclosed with the report in Fall 2003).

Offspring of the STS Adult National Cardiac Surgery Database

The Cardiac Surgery Database paved the way for the addition of two additional Databases: The STS Congenital Heart Surgery Database and the STS General Thoracic Surgery Database. Data forms for these other disciplines were made available as early as January 1993. The first harvest of the Congenital Database took place in 2002, at which time data collection had just begun in the General Thoracic Surgery Database.

DATA QUALITY AND AUDITS

The STS has contracted with the Iowa Foundation for Medical Care (IFMC), an independent medical audit firm, to conduct ongoing on-site audits of a random sampling of at least 10 STS Database participants per year. The audits’ goals are to evaluate the accuracy of the data and the consistency of data collection methods, as well as to provide education to (and learn from) data managers. Auditors review hospital charts and/or data collection forms and compare values for multiple data elements in the records with previously submitted data. An average score is calculated for all data elements at the site. In 2008, audited sites received overall scores ranging from 92.1%-97.8%.

In addition to the on-site audits, an intrinsic verification process which identifies data inconsistencies as well as missing data takes place automatically as quarterly data are submitted to Duke Clinical Research Institute. Data managers are encouraged to take advantage of these computer-generated reports by sending data early in the “harvest window” and as often as needed until satisfied with data quality.

ACCOMPLISHMENTS: JOURNAL PUBLICATIONS AND QUALITY INITIATIVES

There have already been more than 80 journal publications based on the aggregate data in the STS Databases,^{4,5} and the Database center at Duke University receives more requests for research data continuously. One of the earliest publications described the historical framework behind the development of the STS National Database, the initial growth of the database, and the Database experience to that point.⁶ Another of the early publications described the risk assessment methodology used to predict operative death,⁷ and another described the influence of internal mammary artery conduits on CABG operative mortality.⁸

An important STS National Quality Initiative involved use of STS Data for the first randomized study of Continuous Quality Improvement measures (CQI) in medical practice carried out on a national scale.⁹ 359 academic and non-academic hospitals were randomized to a control arm or to 1 of 2 groups that used CQI interventions designed to increase use of two process-of-care measures - preoperative beta blockade and IMA grafting in patients older than 75 years. Each intervention group received measure-specific information, including a call to action to a physician leader; educational products; and periodic longitudinal, nationally benchmarked, site-specific feedback. Use of beta blockade increased significantly at the intervention sites. IMA use increased significantly at low volume sites, but the increase was not significant at high volume sites or overall. A second project addressed secondary prevention of ischemic heart disease after coronary bypass grafting by studying the postoperative use of aspirin, beta blockers, statins, ACE inhibitors, exercise, and smoking cessation. Once again, database participants received data for these measures comparing their program to the STS average as well as to STS best practice.

THE CREDIBILITY BONUS

The Database has given the STS exceptional credibility in Congress. The afore-mentioned studies were cited by Dr. Jeffrey Rich, Chairman of the STS Taskforce on Pay for Performance, in his 2005 testimony to the House Ways and Means Health Subcommittee on Measuring Physician Quality and Efficiency of Care for Medicare Beneficiaries. The Database has been an integral part of the STS future planning process,¹⁰ and also resulted in Dr. Rich being appointed to serve for a year in CMS as Director of the Center for Medicare Management. He

also served on the National Quality Forum to develop National Voluntary Consensus Standards for Cardiac Surgery.

The credibility achieved by the STS National Adult Cardiac Surgery Database has had an impact on public reporting of cardiothoracic surgical outcomes in the lay press. New York State and Pennsylvania were the first two states to assess “quality” by publishing cardiac surgical outcomes. Their risk-adjustment models have long been criticized for their complexity, much smaller than the STS sample size, lack of transparency, and random variation.¹¹ Some models that use Medicare claims data have additional pitfalls in risk-adjustment. It seems obvious to us, and the STS leadership has also stated, that if participation in the STS Database and release of the data were simply made mandatory as a replacement for single state public reporting systems, there would be considerable cost-savings, improvements in the quality of data, and increased transparency and comprehension by the lay public.

THE DATABASE AT LANCASTER GENERAL HOSPITAL

It was the conviction of Lawrence I. Bonchek, MD, founder of the cardiac surgery program at Lancaster General Hospital, that from the start of the program documentation of every case in our own database would be essential to assure continuous improvement of the program, to benchmark ourselves against national and international standards, and to establish our reputation nationally and internationally by reporting our distinctive techniques, insights, and results. The hospital administration agreed to collaborate in supporting the project.

At that time only a limited number of hospitals nationwide maintained private databases. We elected to contract for data entry and processing services from Medical Information Systems to begin the database from the first operation in September 1983. Detailed clinical information relevant to every hospitalization for open heart surgery was entered on paper data collection forms that we developed. We entered the data manually and sent the forms off-site to Medical Information Systems for computer processing and archiving; reports were sent back at regular intervals. In 1990, with the purchase of software from Summit Medical Systems, data management was moved in-house to the office of Cardiothoracic Surgeons of Lancaster, PC (CTSL). To conform with STS stipulations, the software was purchased and owned by

the participating surgeons, but the staffing of the data management office was supported by LGH. The author, a part-time nurse with medical records experience, was recruited from within the hospital staff to manage the database, to coordinate the process of joining the STS National Cardiac Surgery Database, and to initiate long-term follow-up.

When we joined the STS National Cardiac Surgery Database in 1992 we transferred 3500 historical records from our database. Before doing so we had to clean up demographic data from previous years with the help of the hospital's Information Services Department. We also set up a regular batch download of data from the hospital mainframe so that future demographics would continue to be uniform and accurate. Because of our experience developing our own large database, the STS Database incorporated most of the data fields in our forms. We also created separate custom data fields that were of particular interest to us, even if not to the STS. (For example, for mitral valve repair, we collected more details than the STS did about valve anatomy and the corrective surgical techniques that were used.)

When the STS Database reorganized in 1999 and allowed competition among vendors, we selected the Patient Analysis and Tracking System (PATS) by Axis Clinical Software, Inc. in Portland, Oregon. They successfully rolled over our legacy data from Summit software into PATS, and electronically tied our existing annual follow-up encounters to the surgical record. PATS is a client/server application with a real-time mainframe interface for demographic information requiring ongoing sophisticated technical support. At this juncture the database software became hospital owned and supported.

Publications and Reports

With the database on site, we were able to query our own data at any time to review outcomes and to provide reports to the hospital administration, supervisory agencies, and referring physicians. Over the years, we have published more than 30 articles in peer reviewed journals, and made more than 50 presentations around the world. None would have been possible without the database. In 1987 we first published our results with our distinctive technique of intermittent ischemia rather than cardioplegic arrest for coronary bypass.¹² After accumulating a much larger cohort of patients, we presented the Lancaster experience with 3,000 patients who had

isolated CABG to the Annual Meeting of the American Association for Thoracic Surgery, and published a comprehensive report.¹³

Establishing and Maintaining A Successful Database

We have found that successful management of a participant database depends on certain factors:

1. Adequate resources.
 - a. *Collection of accurate clinical information.* The vast majority of national database participants use chart abstraction to obtain data. From the outset we stipulated that data collection is part of the clinician's job; our data collection is performed by perfusionists and nurse clinicians, thus eliminating the need for chart abstraction. Data collected by care-givers is high quality, which has been a huge factor in the success of our database. (This is not to say that chart abstraction cannot be accurate but data quality is dependent on the understanding of the abstractor.)
 - b. *System administration.* Our database coordinator assures data definitions are followed, analyzes our data, produces a quarterly report, prepares the bi-monthly presentations for the CT Surgery Care Management Team Meetings, acts as system administrator for the software, and implements STS registry upgrades. A part-time data entry clerk checks for data deficiencies as she keys in data.
2. Choice of software.

In addition to submitting data to the National Database, we have always insisted on being able to extract our data locally at any time, a capability that is not supported by all certified software. Initially our data were used for publication and to support presentations in many venues by our senior surgeon Dr. Lawrence Bonchek, but more recently they have been principally used to support clinical decision making. Our data are presented regularly at our bimonthly inter-disciplinary Cardiothoracic Surgery Care Management Team Meetings. We add and delete computer fields as needed to track our current initiatives. We regularly look at trends in volume, length of stay, initial hours of mechanical ventilation, status of surgery (elective, urgent, emergent), mortality, and individual complications. Our quarterly report includes process control charts as well as graphs showing how we compare to the aggregate STS data. Examples of some in-depth projects included looking at our data for mitral valve repair, risk of

obesity, initial ventilator hours, and peri-operative glucose management. We've also been able to see how subjects of public concern are reflected in our own experience. An example is the recent report which implicated the anti-fibrinolytic aprotinin (Trasylol®) in postoperative renal failure.¹⁴ We had tracked our use of aprotinin for a decade as a custom field, and were thus able to correlate our incidence of renal insufficiency with the use of aprotinin. By the time the FDA placed a "hold" on sales of aprotinin, we had already reduced its use by 80%.

With the success of the National Database for Cardiac Surgery, the STS eventually developed a General Thoracic Surgery Database, which we joined in 2007. However, for six prior years we had our own limited data collection for thoracic surgery in a separate PATS module of our own creation.

ADVANTAGES AND CHALLENGES OF BELONGING TO THE STS NATIONAL DATABASE

The most obvious and long-standing advantage of belonging to the National Database is the ability to benchmark our risk-adjusted outcomes against aggregate national data. Because we have the risk calculations in our local software, we can see if one surgeon's patients are sicker than another's. Not only can we calculate predicted risk of death for each isolated valve or coronary procedure, we also have risk predictions for specific morbidities in isolated CABG such as deep sternal wound infection or permanent stroke. Participation in national quality initiatives is also facilitated.

Membership in the STS Databases offers the potential for cost analysis at the local or national level. Locally, we can do our own cost analysis by procedure, complication, length of stay, or any other variable. The potential exists to do the same nationally if sites were to submit data for hospital costs or charges. The Virginia Cardiac Surgery Initiative, a consortium of cardiac surgeons, nurses, and administrators in Virginia, combined their STS data with Medicare Claims Data to demonstrate the costs of atrial fibrillation, stroke, and other complications. They demonstrated that "reducing the incidence of complications by small fractions can yield significant savings."¹⁵

There are also challenges. First, we are typically about two years ahead of the STS in adding new fields, which

must be rolled forward during software upgrades. When the STS eventually adds those fields to the National Database, they must be reconciled with ours. Second, software upgrades, registry upgrades, and data submissions can be tedious. Data definitions are changed every three years and data fields are added or deleted. Our locally created data fields are always at the end of the database, and must be renumbered during upgrades. Flexible software allows the user to recreate data entry screens in a logical order, but it takes time to remap the screens after the fields have been renumbered and the definitions changed.

THE FUTURE

Anyone who has worked on databases knows that longitudinal follow-up presents unique challenges. The STS Database is now implementing that capability, to great enthusiasm among the Database leadership. Collection of patient identifiers will allow correlation with government databases such as the Social Security Death Index for accurate survival rates. Correlation with the recently introduced American College of Cardiology National Database will provide new insights. Submission of data from the STS Database for the Medicare Physician Quality Reporting Initiative will be a milestone in the quest to have STS data rather than administrative data used for quality reporting. Use of multiple software vendors has provided choices to STS Database participants but each software provider must be recertified when new versions of the registry are released. This cumbersome recertification process is so extensive that only one of the three STS Databases can be upgraded each year and thus individual databases can only be upgraded every three years. Web-based uniform software would provide the STS the means to make changes more frequently but would the local program's ability to query their data suffer? Now that membership in the STS national databases is at an all-time high will the focus shift to meeting national goals rather than helping sites to achieve local goals?

CONCLUSION

The STS National Adult Cardiac Surgery Database has paved the way for other databases of its kind. Cardiothoracic surgeons have now been collecting uniform clinical data for more than 20 years. With over 2.7 million patient records, The National Database has been a powerful tool for quality improvement, research, and reporting of audited results.

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