International Participation in The Society of Thoracic Surgeons National Database

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In 2011 The Society of Thoracic Surgeons (STS) Workforce on National Databases established the International Database Task Force devoted to expanding participation in the STS National Database internationally. The vision for this initiative was to assist in the globalization of outcomes data and share knowledge, facilitating a worldwide quality collaborative in cardiac surgery. The Department of Cardiothoracic Surgery at Hadassah Medical Center, Jerusalem, Israel, was among the first of several international sites to join the collaborative. This report outlines the rationale behind clinical databases outside of North America submitting data to the STS National Database and reviews the unique challenges and practical steps of integration through experiences by Hadassah Medical Center. Our hope is that this procedural learning will serve as a template to assist future international program integration.


Background

In 1913 soon-to-be United States Supreme Court Justice Louis Brandeis criticized the ailing banking system for failing to publicly disclose important information regarding modes of operation, decision making, and financial results. To “cure” the system, Brandeis called for a radical cultural change in these financial institutions and full public disclosure [1]. His famous quote demanding complete transparency, “Sunlight is said to be the best of disinfectants,” is as relevant today as it was then for all public services, particularly health care. The public should have full access to the range of available treatment options for a specific disease state, the algorithms behind the decision making, and the quality of care provided by a specific medical institution, department, or individual practitioner. This knowledge is a fundamental requirement to truly comply with the ethical principle of patient autonomy [2].

The best and most accurate metrics to define and quantify quality of care in cardiothoracic surgery globally are still a matter of controversy. The two most commonly used methods are measuring the rates of adherence to “best practice guidelines” authored by major professional societies and risk-adjusted rates of well-defined complications and mortality. Measuring quality of care is as important and valuable for the caregiver as it is for the patient. Having in-depth understanding of factors that determine compliance with established practice guidelines and studying the independent determinants of major outcomes provide an opportunity to improve clinical outcomes.

To promote these goals, The Society of Thoracic Surgeons (STS) established the Adult Cardiac Surgery Database (ACSD) in 1989 [3]. The ACSD was the first component of the STS National Database, which now also includes two separate and robust registries—the Congenital Heart Surgery Database and the General Thoracic Surgery Database. Participation in the ACSD grew from a few enthusiastic centers in 1989 to now well over 90% of all cardiac surgery programs in the United States. With data from more than 5 million operations, the ACSD provides an unparalleled scientific tool for risk-adjusted outcome analysis [4].

To facilitate the global expansion of a quality collaborative in cardiothoracic surgery, we have outlined the procedural learning experienced by Hadassah Medical Center in Jerusalem, Israel, one of many enthusiastic centers currently engaged in international integration with the STS National Database. Expanding the STS National Database to include international participants affords centers around the world with the opportunity to measure outcomes in a precise manner and embark on quality-improvement projects, substantially enhancing patient care along benchmarks. This is one of the prime reasons attracting international surgeons and their facilities to join the STS Database. A growing number of international sites...
and the accumulation of a critical number of procedural volumes affords the opportunity to compare practice patterns between the United States and international centers, fueling comparative effectiveness studies and possibly refining existing risk-assessment models, hence—improving patient care also in the United States.

Premise
The surgical leadership at Hadassah has enjoyed a close collaborative relationship with the Department of Cardiothoracic Surgery at Boston Medical Center, Boston, Massachusetts, which was among the first STS National Database participating sites. This relationship provided Hadassah’s leadership with a unique opportunity to witness the growth and development of the STS Database and realize the enormous value of this tool on the national, institutional, departmental, and individual caregiver levels. Thus, when the opportunity for international participation in the STS National Database was introduced in early 2012, it became clear to the surgical leadership at Hadassah (a tertiary academic center performing around 500 cases yearly), along with many international cardiac surgery program directors, that a departmental database must be an essential component of a data-driven cardiothoracic surgery department. The STS National Database was felt to be the best global tool for measuring and improving quality outcomes, examining procedural risk assessment, and providing a valuable aid in administrative, business, and marketing decisions. After receiving internal institutional support, Hadassah Medical Center was among the first international participant sites that collaborated with the STS International Database Task Force to begin integration with the STS National Database.

The Rationale for Choosing the STS National Database
From the beginning it was clear that achieving Hadassah’s above-mentioned goals by establishing an isolated departmental database would be very difficult, if not impossible, mostly because of low case volume. Therefore, the desire to join a well-established, validated, large database was the natural next step. We had two alternatives—The STS National Database and the European System for Cardiac Operative Risk Evaluation (EuroSCORE II). The EuroSCORE II provides a risk-assessment model for death as a single outcome measure [5]. Hadassah independently decided to use the not-for-profit STS National Database because it is a well-established, robust, and comprehensive registry, recognized nationally and internationally for its high quality. The ACSD’s risk-assessment models are well-calibrated and validated, encompassing a wide variety of procedural-specific models for death and selected complications, such as reoperation for bleeding, stroke, myocardial infarction, renal failure, and deep sternal wound infection, as well as hospital length of stay. These variables are extremely valuable quality benchmarks against which global institutional results could be best evaluated; they are also major determinants of procedural cost and are very useful for administrative and business planning.

Key Steps Towards Implementation
In this current era of health care reform and transparency, participating in a clinical database or registry is an essential and natural component of all cardiac surgery programs in the United States. In contrast, as an international site, realizing the dream of having an ongoing, active, comprehensive, accurate, and credible departmental clinical database linked to a major professional society requires leadership, vision, determination, and substantial commitment on three levels.

Professional Society Level
Communication of Hadassah’s strong desire to participate in the STS National Database as an international site began with contacting STS leadership and members of the STS International Database Task Force. Although the objective was mutually embraced with enthusiasm, significant legal, ethical, and contractual issues needed to be resolved through in-depth communications between Hadassah Medical Center and STS. Upfront, the whole initiative was calculated to be cost-neutral to the STS by charging a higher annual fee for international participants. Although this barrier-breaking experience took time, the end result benefited future sites through the development of a more streamlined process that is culturally and institutionally sensitive. Any program may now participate as long as it is willing to comply with STS National Database requirements established for data completeness, quality, and reliability.

Institutional Level
Given the health care system structure in Israel, the resources required for establishing a departmental database must be provided by the institution. This is the situation in most cardiac surgery programs in countries outside North America. It is, therefore, extremely important that the institution’s senior management share a vision with the department chairman and its members, acknowledging the enormous value that such a database would add to the institution and that the long-term return on investment would be positive by process improvement and reduction of major complication rates. Developing a shared vision requires tremendous cooperation due to cultural and financial challenges. Protection of patient information is paramount and is among the highest of all priorities for STS. Understanding how the STS National Database uses extremely rigorous checks and balances for protection and deidentification of patient information was a key step in providing Hadassah’s legal department with the confidence to proceed.

Departmental Level
A fundamental requirement is the support of senior surgeons within the department. As part of STS data
standards, each Hadassah faculty member signed an individual participation agreement. To produce maximal value, the department database must be comprehensive, complete, accurate, and reliable. To achieve these goals Hadassah purchased the required STS Certified Software from one of several STS-approved vendors and then established a departmental database team.

1. Software: In line with the goal to fully participate in the STS National Database and use its up-to-date collection tool and strict definitions, from inception Hadassah purchased software for all three components—Adult Cardiac Surgery, Congenital Heart Surgery, and General Thoracic Surgery Databases. The contract with the vendor was multiyear and included initial training and periodic software updates. The software purchased permitted the addition of custom fields that the STS does not require but would be of interest to Hadassah locally.

2. Team: The institutional team formed included a team leader, an outcomes collector, a database manager, and a database specialist.
   a. The team leader was a senior surgeon who oversaw the entire team and performed periodic internal auditing.
   b. The outcomes collector was a fully trained cardiac surgeon who functioned only as a first assistant. Thus, the outcomes collector had an in-depth understanding of the field but was not affected by the outcomes, thus minimizing the potential for “gaming” results.
   c. The database manager/abstractor was a full-time employee who collected and entered the required 30-day data as well as the annual follow-up data obtained by direct patient, family, or primary care physician contact.
   d. The database analyst/consultant was a unique and optional position that Hadassah added. The individual who filled this position had worked with institutional leadership in the past and had a detailed working knowledge of the STS National Database. His knowledge, experience, and expertise was used to train the Hadassah database team, update software versions, ensure the quality of data entry, resolve technical difficulties inherent to international participating sites (ie, different date format, zip codes, and provider ID numbers), add new fields and reports, and assist with data harvesting for electronic submission.

Ongoing Challenges and Future Plans

Funding
In an era of reduced health care resources and budget cuts, convincing the hospital administration to provide continuous salary support for the required personnel was a challenge. It required serious commitment from hospital senior management and the department chairman, particularly given that in many countries (Israel among them), data accumulation and public reporting are not yet required by local professional societies or the government. STS and software vendors must be sensitive to these cost issues, particularly for international sites.

Data Completeness and Accuracy
Another challenge is keeping the data entry process complete and accurate. The optimal use of STS database participation mandates submission of the full STS data set to maintain the accuracy of the STS predictive models and analytics for local reporting. This is tedious work that requires periodic auditing. Although Hadassah established a mechanism for internal auditing performed by the database team leader, international sites should have access to independent remote external STS auditing based on electronic medical records to ensure completeness and accuracy of data.

Risk Models
The STS National Database risk-prediction models are derived from a very large and continuously updated cohort of patients collected from all participating sites in North America. Application of these well-developed and detailed risk models to data from international institutions is a clear benefit of participation. Unique reports comparing international sites with the entire North American cohort will be customized and communicated regularly.

Establishing National Databases
With multisite participation of an entire country or region, customized reports comparing each site with others within the same country (eg, “STS ACSD–Israel”) or the North American cohort would be possible. The challenges involved include having a number of independent institutions and department heads endorse the concept, securing a stable funding source (possibly governmental), and agreeing on data audits to ensure optimal quality. Participating sites should be deidentified in the reports, just as the patient-specific data are currently deidentified in harvest reports. Decisions regarding whether the results would be identifiable by institution within their region or country would be an option for participants.

A fundamental question that remains involves the minimum number (or percentage) of programs within a country required to participate in the database for qualification as a national entity. The value of such a database, however, would be enormous. From a local participant point of view, it will afford the opportunity to benchmark results of a specific institution against local “like” institutions and initiate quality-improvement projects. From an STS perspective, this would be a huge step toward achieving the ultimate goal of STS National Database globalization to promote data-driven quality improvements in cardiac and thoracic surgery.

Summary
Measuring the performance of a cardiac surgery unit helps identify potential problem areas and opportunities for improvement. This transparency is a fundamental ethical obligation to our patients and society. Establishing
a departmental database with participation in an established and robust database, such as the STS National Database, is the most effective way to fulfill this obligation. The journey is long and requires considerable leadership, determination, resources, and endurance; however, we have no doubt that it is certainly possible and definitely worthwhile as we progress toward a global quality collaborative in cardiac surgery.

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References