International Participation in The Society of Thoracic Surgeons Adult Cardiac Surgery Database: From Institutional to National

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Background

The Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database (ACSD) was established in 1989. This pioneering initiative reflected the vision of our specialty leaders who understood the enormous value of a voluntary, robust data repository to facilitate accurate and fair assessment clinical performance [1]. They realized that surgeons have the most in-depth knowledge and understanding of our specialty. Having them take the initiative to create a clinical database is a far better option compared with other options, such as those designed for billing, administrative, or regulatory purposes.

More than 25 years later, the STS ACSD contains data on close to 6 million cardiac surgical procedures [1, 2]. The STS ACSD data collection methodology, sophisticated risk-prediction models, quality metrics, and public reporting options have become the "gold standard" among registries, being endorsed rapidly and enthusiastically by the major stakeholders involved in health care, including the U.S. governmental bodies, quality research institutions, insurance companies, health care providers, professional societies, and patient organizations [1, 2].

In recent years, it has become clear that value (defined as positive health outcomes achieved per dollar spent) must become the ultimate goal of health care delivery [3]. Improvements in value benefit the patients, providers, payers, and suppliers and are essential for economic sustainability. The vast amount of data in the STS ACSD together with sophisticated analytics afford the opportunity to assess the value of a specific cardiac surgical procedure for a specific disease and patient performed by a specific institution and an individual caregiver.

In 2011, the STS leadership expanded participation in the STS ACSD internationally to facilitate a worldwide quality collaborative in cardiac surgery [4]. The Department of Cardiothoracic Surgery at Hadassah, The Hebrew University Medical Center (Jerusalem, Israel), was among the first international sites to join this collaborative. However, the fundamental social, economic, and cultural differences between the United States and Israel, coupled with marked differences in health care systems, infrastructure, patient profiles, referral and practice patterns have all raised concerns regarding applicability and validity of STS ACSD risk-prediction models and quality assessment tools in Israeli patients. Development of an Israeli National Database linked to the STS ACSD was needed to address these concerns and to provide a local benchmark.

The Process

Establishing a de novo national database is a challenging process. There were five steps (with a time overlap) in this complex process: decision; funding; contractual relationships among the ICDC, participating centers and the STS; design and construction of infrastructure; and implementation.

Decision

The first and most difficult step was convincing the leadership of the Israel Society of Cardiothoracic Surgery (ISCTS) that a carefully designed national registry, run by an external nonbiased entity is the best approach for our specialty. It took years of intense discussions among department heads before the majority would agree to creation of a voluntary national database. Valid concerns that were raised included data completion and accuracy, gaming of data, validity of risk-prediction models, fair reporting, risk aversion, teaching aversion, and funding. Another major debate focused on the value of a procedure-specific versus disease-specific database. There was a consensus that a national disease-specific database consisting of three arms—cardiac surgery, interventional cardiology and optimal medical therapy for the major cardiovascular disorders—would be optimal. However, the complexity, infrastructure and resources required for such an endeavor made it impractical. We eventually opted to start with the cardiac surgery database initiative, hoping that cardiology will follow as in the United States and other countries.

Funding

The second major step was to secure funding. After reaching a decision to move forward with the database

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initiative, representatives of the ISCTS approached the Director General of the Israeli Ministry of Health for national funding. Impressed by the unprecedented voluntary initiative of the ISCTS as a prime example of a professional society willing to lead the way in the spirit of transparency, quality improvement, and cost-effective analyses on a national level, the director general elected not only to fund the project, but also to host the registry within the Israeli Centers of Disease Control (ICDC) of the Ministry of Health (MOH) and provide all the necessary infrastructure. Together with the Ministry of Finance, the project received an operational 5-year budget of close to 5.5 million NIS (1.4 million USD). The agreement between the MOH and the ISCTS was that the MOH will fund the infrastructure and software (42% of the budget, or 2.3 million NIS [610,000 USD]), MOH personnel and operating budget (40% of the budget, or 2.2 million NIS [571,000 USD]), and the annual STS ACSD annual fee for all the participating centers (18% of the budget, or 1 million NIS [273,000 USD]). In turn, each participating center will cover the salary of a database manager at a level proportional to the institution case volume. The Director General of the MOH and each participating center Director General and Cardiac Surgery Department Head signed a contract covering the entire spectrum of the administrative, operational, financial, and legal aspects of the database.

Relationships

The third step involved establishing a relationship with the STS ACSD. Because of the relatively low national case volume (approximately 4000 annually), it was deemed that linking to a well-established, organized, and validated database that will serve as a benchmark is mandatory. We evaluated several large-scale registries, including the STS ACSD and the European database. We eventually selected the STS ACSD because it is the largest clinical cardiac surgery database using a comprehensive and periodically updated data collection tool, it provides risk-prediction models for mortality and major complications for the most commonly performed operations, and it provides additional composite metrics allowing in-depth quality assessment.

Once a decision to link to STS ACSD was made, the ICDC initiated a dialogue with STS leaderships and STS ACSD administration to formalize the relationship. After a careful review of a wide range of administrative, technical, and legal aspects, each participating center and individual surgeon signed the standard contract with the STS ACSD. Special consideration was given to secure patient confidentiality.

Three features in this unique setting deserve special mention. First, the annual participation fee of all participating centers will be covered by the ICDC. Second, each center gave the STS ACSD permission to share its performance report with the ICDC. Finally, the STS ACSD agreed to add an important benchmark to its periodical reports—the Israel national results. Thus, each participating center performance report will consist of the center's outcomes compared with three benchmarks, such as

hospitals in the United States, the entire STS ACSD, and the Israel national outcomes.

Infrastructure Design and Construction

The fourth step was to construct a multidisciplinary database taskforce to lay the foundation for the database. Included in this taskforce were representatives of the ICDC, the Ministry of Health Information Technology department, the MOH Quality Assurance department, and the ISCTS. The mandate of this taskforce was to design the electronic infrastructure of the database, select an STS-approved software vendor, customize the STS ACSD collection tool to the special needs of Israel, and carefully plan the implementation of the entire project in a reasonable period and within the allocated budget. The structure of the database is illustrated in Figure 1. Data collection will be performed using the most updated version of the STS ACSD collection tool, following the STS ACSD definitions. Harvesting of data to the STS ACSD will be performed separately by each institution according to the STS ACSD guidelines on a quarterly basis.

Electronically, we created a network consisting of a central repository and multiple working stations. The core of the database resides on a central server within the MOH. Each participant enters the data online using an institutional working station backed up within the institution. Particular attention was made to ensure data safety and patient confidentiality. Access to institutional data will be regulated by predefined levels of permissions for data entry and analysis. Importantly, each participating center has access to its own identifiable data only, but is blinded to other centers' data. The ICDC has access to the entire set of data. Using the MOH unique coding system, the ICDC will be able to link the Israeli Cardiac Surgery Database to other governmental databases. According to the MOH regulations, a formal open tender was required for software vendor selection. Specific information technology requirements included modern and user-friendly platform; ability to customize fields; ability to add modules including thoracic surgery, pediatric cardiac surgery, and a variety of cardiology modules for future expansion of the national database to these specialties; the ability to import and export data to and from a wide range of hospital information systems; and the ability to import data from existing departmental databases, such as that at Hadassah. The selected software includes a dashboard that is available to each participant, allowing on-line, real-time reporting and sophisticated analytics. The tender included specifics regarding software installation, training of the team members, and technical support. These issues are particularly important given the language barrier and the 7–10-hour time zone difference between Israel and the United States. To overcome these issues, the American software company elected to team up with a local partner.

Implementation

The fifth and final step of this complex process was implementation. The structure and workflow of the database and the role and responsibilities of the involved parties were summarized in an official MOH Health