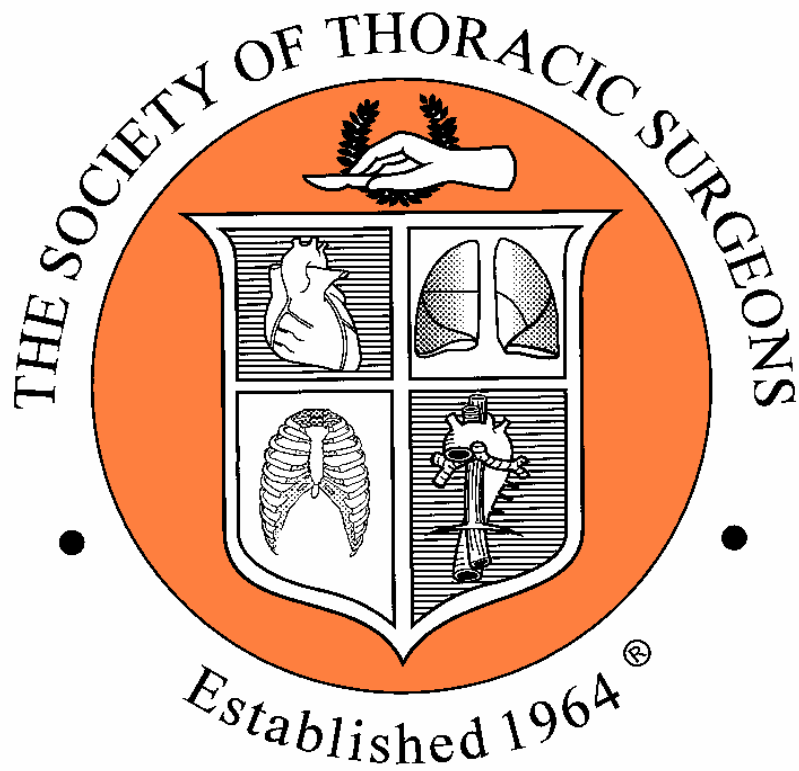


**The Society of Thoracic Surgeons
National Adult Cardiac Surgery Database and Outcomes Program
Participation Manual**



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I. INTRODUCTION:

This manual has been developed to assist you with any questions or uncertainty you may have about getting a database started in your hospital. If you're not yet participating in the National Database, we hope the support offered by this guidebook and by the references it provides, will ease your concerns and will lead to your participation. This is a practical guide that explains how to put together the key ingredients of a good program. We also suggest you read the STS Database Marketing Brochure for more detailed information about the benefits of the Database for your practice, your patients, and your specialty.

The Society of Thoracic Surgeons National Adult Cardiac Surgery Database was begun in 1990 as an initiative for quality improvement and patient safety, with the corollary potential to be a powerful tool for clinical research. More than 500 participating sites have entered over 2.2 million patients, making the STS Database the largest cardiothoracic surgery outcome and quality improvement program in the world.¹ Most members of the STS Database are hospitals, but many are surgeons' practices. Data collected by participating surgeons and institutions are transmitted to the Duke Clinical Research Institute (DCRI) without patient identifiers where they undergo data quality checks, and are warehoused, analyzed, and reported back to each institution. Data may be submitted to DCRI from a hospital or a surgical practice, and reports are provided to the entities that submit the data, for use as they wish. (This matter is discussed further in Section 6 below.)

Data are collected and analyzed for coronary bypass procedures, valve procedures, and valve/coronary procedures. Databases in Congenital Heart Surgery and General Thoracic Surgery have also been developed, and are available for dissemination. Additional information on these databases is available on the Database page of the STS Web site.¹

At this writing, Adult Cardiac Surgery risk stratification models (i.e. adjustments for differences in case mix) have been developed not only for operative mortality, but also for measures of cost effectiveness such as operative morbidity, and length of stay. Every six months, each Database participant contributing data receives an outcomes report which has been risk-adjusted. Examples of the many complications reported in the data set include perioperative myocardial infarction, atrial fibrillation, readmission within 30 days, and reoperation. Participants also receive data on several processes of care such as the frequency of use of the internal mammary artery, minimally invasive and off pump approaches, types of valves, and cardiopulmonary bypass and ischemic times. Data are presented in graphics and tables that compare the local institution to regional and to national benchmarks. These comparisons of risk adjusted operative mortality and morbidity, as well as processes of care, should help participating institutions identify medical errors and improve overall quality of care.

II. WHY YOUR HOSPITAL SHOULD SUPPORT THE DATABASE:

The STS National Adult Cardiac Database is a clinical registry initiated by surgeons, but the majority of the cost of a hospital's database should be borne by hospitals. How then does one interest a hospital in paying for most of this type of project? The following factors should be helpful:

A. Hospital CQI

Because it can be tailored to suit the hospital's individual needs, a database quickly becomes invaluable for hospital initiatives in Quality Improvement, Patient Safety, and Operations Management. *When properly used, the database reports become indispensable to the management team.* For example, if a hospital introduces a clinical pathway to decrease the average time to extubation, the Database provides a means of tracking not only the impact of the initiative on duration of intubation, but also on ICU time, LOS, and other processes of care.

With the addition of appropriate software that may be developed in house or purchased from a certified vendor, the Database can be linked with the hospital's information systems. The Database processes for retrieving and storing clinical data can then be used to cross-tabulate clinical information with DRG and cost data, so that costs can be correlated with complications and patient severity indices. At the same time, the process will minimize errors and redundant data entry.

B. Accreditation

All hospitals must submit data to accrediting agencies such as JCAHO, and in some states hospitals are also required to submit data to state agencies (sometimes for publication in consumer guides). The STS Database reports may be sufficient to meet those requirements in several states, such as California, but even where another system is mandated, such as in Pennsylvania and New York, the processes used to collect data for the STS Database provide an efficient means of cross checking the data that these agencies require for completeness and accuracy.

C. Cost, Quality and Outcomes Data

Pricing contracts for cardiac surgery (including Global Pricing) are becoming more common, and require that certain outcome standards be met. Outcomes data are already being requested by influential payers. The "Leapfrog" program of Fortune 200 companies (which is estimated to have 20,000,000 subscribers, counting patients and their families), requires that referrals for cardiac surgery be made only to institutions that meet certain benchmarks for volume/quality. In addition, Leapfrog is actively discussing the prospect of mandating systematic analysis of risk adjusted outcomes. Participation in the STS National Database will meet their requirements. The Institute of Medicine report, "Crossing the Quality Chasm, A New Health System for the 21st Century," recommended that levels of reimbursement should be tied to levels of quality; a prospect being widely discussed by government agencies and third party payers.²

The requirements for comparisons of quality cannot be met without models for risk adjustment based on severity. Although other agencies have developed their own risk adjustment models, these models are often inaccurate when applied to populations that are different from the population that was used to develop the original risk algorithm.³ The STS database is continuously updated and revalidated with contemporary patient cohorts, and is thus a strong model due to the volume of procedures used to develop the models.

D. Benchmarking

Finally, everything in life is not economics. The process of Quality Assurance must be a partnership between surgeons and hospital administrators, both of whom should be vitally interested in knowing that their cardiac and thoracic surgery programs meet (or, hopefully, surpass) national benchmarks for quality. Without the availability of risk adjusted outcomes, hospital administrators have limited ability to judge how good their programs are. The Database also provides a mechanism for assuring and improving processes that impact patient safety.

III. FINDING PERSONNEL:

A. Data Manager (DM):

It is best to begin the search in one's own institution. The best DM's have a clinical background, preferably in the critical care environment. A registered nurse, or a person with similar clinical training such as a Physician's Assistant, has the depth of clinical knowledge to interpret data definitions. Even if their clinical experience is in non-cardiac disciplines, such individuals can quickly acquire a working knowledge of cardiothoracic surgery. They must understand file management in the personal computing environment. Compulsive attention to detail, self-motivation, a readiness to work alone, and a commitment to long term objectives, are all highly advantageous personal attributes. A background in Utilization Management or Quality Assessment is also advantageous. Nurses working in care management or medical record review will have a working knowledge of chart abstraction, coding, and, hopefully, DRG payment, which can all be useful in maximizing the hospital benefit of having a database.

The DM's time in a busy institution will be spent entering data, extracting data via computer reports, analyzing reports, and sharing these analyses with hospital administrators and surgeons via computer graphics and narratives. Although a nurse may seem overqualified for the job, the activity is an excellent opportunity to perform the final data quality check, for which knowledge of clinical matters is vital.

A full-time rather than a part-time DM will be necessary if:

- The DM is personally responsible for data entry;
- The volume of surgery is high;
- The data are not only entered into the National Database for analysis at DCRI, but are also used locally for clinical studies and quality initiatives.

B. Other Personnel:

Hospital volunteers can be an important part of personnel needs. For example, they can be trained to crosscheck catheterization reports against the data forms, to be sure that all necessary information has been entered. They are particularly useful in making follow up phone calls for longitudinal studies.

IV. CHOOSING CERTIFIED SOFTWARE:

The STS website lists all the certified software vendors, including basic contact information.⁴ Vendor information is continuously updated, and is therefore not reprinted here. Costs are discussed below in Section 5.

There is no single software product that is right for every surgical program. If, for example, you are interested in long-term follow-up, your software must allow you to enter multiple follow-up encounters in the same set of computer fields, and to relate those follow-ups to the appropriate surgical record. Other options from some vendors include the ability to create a whole new database for your specific interests without incurring additional cost; touch screen technology for patient data entry; integration into the cath lab system to obtain cath lab data directly; the ability to create new fields yourself rather than to depend on the software vendor; and the ability to create an unlimited number of customized fields. Some software programs have a library of built-in reports, and others provide the ability to write customized reports.

Web-based products are now available that can provide software upgrades at minimal cost. These databases are secure, except for potential exposure to determined hackers, but transmission of data over the internet may be frowned upon by CMS, unless patient identifiers or dates are stripped. CMS has issued regulations forbidding internet transmission of unencrypted Medicare data that are not password protected.⁵ HIPAA, the Health Insurance Portability and Accountability Act, may impose additional restrictions. Please contact the HIPAA Privacy Officer at your institution for answers to any questions related to the impact of HIPAA regulations on your choice of STS certified software.

Web-based programs, with point of care data entry wherever there is a computer terminal, also enable maintenance of a real-time database within your institution. Even without a Web-based program, point of care data entry into the institution's own database can be done with a client/server setup, in which a central computer serves multiple peripheral users (clients) simultaneously. (See section V. below for a discussion of the quality and cost concerns raised by point of care data entry.) Finally, you should have broadband internet access to run a Web-based program, as dial-up connections are too slow.

Clearly, not all systems do all things, so it is important to know what you want and need, before getting a software demonstration. It may be beneficial to appoint a software selection committee to receive these presentations, as software vendors will come to your site. The committee should not only include the DM designate, but also representatives from the administration, the surgical group(s), and most importantly, a computer technician or programmer from your institution. All STS certified products are relational databases (see Definitions, below), but these products use various operating platforms (see Definitions, below) and their complexity varies considerably. Software vendors can also provide you with a list of other programs using their software that you can call for additional information. Even the most satisfied users will be able to tell you about the strengths, weaknesses, and peculiarities of each program. Finally, the Data Manager's page

on the STS website is a source of considerable help about software, and it hosts continuing discussion forums about many issues.⁷

Issues to consider when purchasing STS certified software:

- ❑ Cost
- ❑ Whether existing data can be imported
- ❑ Speed
- ❑ Flexibility
- ❑ Links with existing hospital system
- ❑ User-friendliness
- ❑ Customer support
- ❑ Other hospital-specific issues

V. COST OF STARTUP AND MAINTENANCE:

A. Personnel:

The Data Manager's salary will vary depending on the workload, which will reflect the volume of surgery in your program. The DM will, in most cases, be a hospital employee. Many hospitals have a higher pay scale for bedside nurses than for data management personnel, and despite the Data Manager's multi-faceted responsibilities, as well as vigorous discussion with your hospital's administration, it may not be possible to prevent a pay cut for a Data Manager who was a bedside nurse. Do not be defensive about this matter when interviewing Data Manager candidates. Most nurses understand and accept these pay differentials, and accept lower pay to have nights and weekends off, to work in a low stress environment, and to have a measure of autonomy.

Depending on the candidate's experience and the local cost of living (e.g. housing costs etc.), your Data Manager's annual starting salary will probably range from \$45,000 to \$50,000, plus fringe benefits (as of the beginning of 2003). If you wish to carry out any additional time consuming initiatives, such as long-term follow-up, salary costs could be higher, because extra hours of work may be needed. On the other hand, low volume hospitals may require the Data Manager to perform other duties in addition to data management, because the latter will not require full-time effort.

B. Software:

The purchase price of software packages varies from \$11,000 to \$75,000 or more, depending on the product's features, the number of users, the interfaces, and the platform. If there is no need to support extensive research studies, costs will be at the lower end of the range. The database operating platform may impose separate costs. Software maintenance costs vary widely depending on the software vendor, and average costs start at about \$2,500. As noted above, the STS website provides information about STS certified software vendors.¹

C. Participation Fees

The current participation fee for the STS National Cardiac Surgery Database is \$2,100 per year if a majority of participating physicians at your institution or practice are STS Members and \$2,400 per year if a majority of participating physicians at your institution or practice are not STS Members.

D. Hardware:

Exact costs are difficult to provide here, as hardware requirements are influenced by many factors, including the chosen software and the number of users. For instance, client/server applications, which enable multiple users to work simultaneously, usually require a separate computer to be used as a server. Your software vendor and your hospital's Information System personnel will advise you about the minimal requirements to accommodate your needs and the software programs you have chosen. We recommend that if possible, the system should also be

integrated with the hospital's Information System (e.g. to obtain data such as costs and demographics). To do so, it may be necessary to have specific software and hardware that are compatible with the hospital's system. Web-based programs have fewer and less expensive hardware requirements, but are more difficult to interface with the hospital mainframe.

Nonetheless, considering the dramatic and continuing decline in the price of hardware, and the powerful devices now available, the computer will be the least expensive component of your startup costs. Including a laser printer, monitor, and computer, the initial cost should be less than \$2500. Since the Database project should foster a spirit of partnership between the hospital and the surgeons, it is unreasonable, and often unproductive from a negotiating standpoint, to expect the hospital to bear the entire cost of the Database program. We recommend that the surgeons accept responsibility for buying the hardware. Current computers are so powerful that they should not need replacement for many years.

E. Office Space:

Space requirements are modest, and initially can be as little as 75 sq. ft. However, there must be space not only for a desk with its computer, monitor, and printer, but also ample file space for archiving the paper data forms, and for storing reports and communications from the DCRI and the STS. To maximize productivity, the DM should not be placed within the busy office environment of the surgical practice, but should have a dedicated office with a pleasant and non-distracting atmosphere. Still, the DM's office should be part of the main surgical office suite, so there will be opportunities for frequent and spontaneous discussions between the DM and the surgeons about the data and its lessons.

VI. DATA ACQUISITION, QUALITY ASSURANCE, AND SUBMISSION:

A. Acquisition and Quality Assurance:

The use of retrospective chart abstraction to gather data is time consuming and therefore costly. Chart abstraction promotes the entry of inaccurate data:⁸ first, because hindsight inevitably colors recollections of remote events by clinical personnel who are responsible for incomplete portions of the charts; second, because the abstractor may misinterpret data entered earlier by a clinician. It is preferable to use a process flow that - as much as possible - eliminates chart abstraction by entering data as they are acquired "at the bedside." The clinical staff, including residents, perfusionists, physician's assistants, and nurse clinicians, should all contribute to filling out sections of the data collection forms, based on information from their particular sphere of interaction with the patient. For example, all operative data should be completed in the operating room by the perfusionist before the patient leaves the operating room.

Either the perfusionists or the nurse clinicians should also be responsible for final review of the form before it is forwarded to the DM. This review can be completed at the time the patient is discharged, thus enabling the database to be current, while minimizing the inaccuracies of chart abstraction. This process also provides an opportunity for the DM to check the record for quality and completeness before the data are submitted to the DCRI.

"Point-of-care" data entry means the direct entry of data as they are acquired "at the bedside," either into a computer terminal connected to a server or into a laptop for subsequent transfer to the database. This process sounds efficient and economical, because it eliminates all the redundancy in the process flow outlined above, and seems the best way to obtain data that are fresh and therefore accurate. Unfortunately, it may not be feasible within certain environments.

First, regarding cost, point-of-care entry requires expensive hardware at multiple sites. It is not always feasible to have a bulky terminal at hand (e.g. during the pump run in the O.R.). Although ubiquitous laptops could theoretically overcome this problem, their expense is prohibitive for most programs. Palm Pilots are cheaper, and may eventually become feasible, but theft will always be a problem, and the expense of wireless transmission must be considered. Furthermore, even in this technological age, it generally takes longer to enter data on a computer-based form, than to make a few checkmarks on paper. Finally, personnel that provide bedside care (e.g. ICU nurses) are paid more than a data manager, so use of their time for data entry is more expensive.

Second, point-of-care entry encourages inaccuracy for two reasons. 1) When a computer is not immediately accessible, but is nearby, caregivers will be tempted to enter data later from memory. Such data cannot be as accurate as data entered immediately onto a paper form that is always available. 2) Point-of-care entry also encourages the direct submission of data that have not been repeatedly checked for inaccuracies. (If the process is designed so that data undergo

subsequent reviews *before* being submitted to DCRI, the "efficiency" of point-of-care data entry is eliminated, and the cost cannot be justified.)

Whether data are entered by the process flow or the point-of-care method, accuracy will depend on the continuity and commitment of the personnel who are entering data at the front lines. If there is high personnel turnover, and new team members are either inadequately instructed or are not committed to the project's objectives and values, the inevitable inaccuracies may negatively influence the data collection process and overburden the DM.

Thus, for reasons of cost, accuracy, and convenience, we favor the use of a paper form. This method encourages quick and immediate entry of data that are more accurate to begin with and can easily be rechecked for accuracy before submission; it also provides a hard copy for the files without any additional steps.

B. Data Submission:

Data may be submitted from a hospital or a surgical group. The DCRI report is issued according to how the data are submitted. If a surgical group works at multiple institutions, it is likely that each hospital will want a report of their activities, and will not want the other hospital to see their data. It is possible under such circumstances for a surgical group to submit data under two or more member ID's, one for each hospital. Thus, each hospital will get a site-specific report from DCRI. However, DCRI will not combine these data into a blended outcomes report, which can make it difficult for a surgical practice to compare their overall quality parameters to regional and national benchmarks. Instead, they will only be able to compare their experience at each hospital individually with the benchmarks, and at some of the hospitals there may be too few patients to allow reliable conclusions.

Of course, if a group's practice at one hospital is dominant, and is representative of their overall experience, those data can be used for comparisons. If, however, a group has relatively small programs in multiple locations, it may be better to submit one file as a surgical practice, and thus obtain DCRI reports with statistically meaningful regional and national comparison.

C. HIPAA

After a great deal of research and consultation with legal counsel, the STS has concluded that the unique needs of the National Database preclude STS from accepting Participant Sites' BA Agreements. In order to address the provisions of the HIPAA Privacy rule, the STS has developed the Standard Form Agreement, which is a special "hybrid" format, one that complies with the HIPAA Privacy Rule's provisions for both BA Contracts and Data Use Agreements. This "hybrid" structure, which is expressly permitted under the Privacy Rule, is designed to meet the current operational needs and requirements of the STS National Database and provide flexibility for expanded operations in the future.

The data that Participant Sites currently contribute to the National Database are partially de-identified and, hence, constitute Limited Data Set information. As such, these data can be used

and disclosed to the STS and its agents or subcontractors under the HIPAA Privacy Rule in accordance with the rules for Limited Data Sets and Data Use Agreements. However, by expanding its provisions to satisfy the Privacy Rule's requirements for BA Contracts, the Standard Form Agreement provides the flexibility to permit participating sites to disclose Protected Health Information beyond Limited Data Set information to the STS National Database in the future without amending the Agreement, should such a need arise.

The Privacy Rule also requires BA Contracts and Data Use Agreements to ensure that subcontractors agree to the same restrictions and conditions that apply to the Business Associate. To satisfy this requirement, the STS has negotiated a HIPAA Amendment Agreement with its subcontractor, the Duke Clinical Research Institute (DCRI). This Amendment Agreement revises the STS existing contract with Duke under which DCRI performs data aggregation and research functions in connection with the operation and maintenance of the STS National Database. At the same time, the Amendment Agreement also prohibits DCRI from collecting or handling PHI beyond Limited Data Set information, unless it specifically agrees to comply with the relevant Business Associate provisions of the Standard Form Agreement.

Please see the Department of Health and Human Services (DHHS) Web site for more information on the HIPAA privacy rule and DHHS regulations (<http://www.hhs.gov/ocr/hipaa/>).

VII. CONCLUSIONS:

You are initiating a process that may seem intimidating at first, but you are doing so at a very favorable time. The STS National Adult Cardiac Database has many certified software vendors to ensure that you are able to find a software product that exactly meets your institution's needs.⁹ Data harvest as well as semiannual and site-specific reports are now provided by the Duke Clinical Research Institute (DCRI). This highly experienced and knowledgeable center for data analysis provides another resource for support for harvesting and reports, in addition to your software and hardware vendors, and the STS website.

Hopefully, this manual will assist you to plan carefully, to avoid unforeseen expenditures and false starts, and to realize the full potential of the database. The STS National Database, when applied to your practice, will be a powerful tool that will enable you to realize many goals, the most important of which is the enhancement of the quality and efficiency of your practice.

VIII. REFERENCES:

1. <http://www.sts.org/>
Go to the Database section and click on “How to become a Participant,” click on “Adult Cardiac,” and click on “National Adult Cardiac Surgery Database and Outcomes Program Participation Manual.”
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<http://www.cardiosource.com/site.mash?left=&m1=4&m2=1&right=&action=vol&source=now&node=TOC@@JAC&jcode=JAC>)
4. <http://www.sts.org/doc/2654>
5. <http://www.hcfa.gov/security/iseclply.htm>
6. <http://aspe.hhs.gov/admsimp/Index.htm> (click on "Regulation Preamble", go to part 2 and find section 164.514. This section states which data must be stripped if patient consent is not obtained.) Or, <http://aspe.hhs.gov/admsimp/final/PvcTxt01.htm> will take you directly to this section.
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IX. DEFINITIONS:

1. Relational database: A database based on the relational model by E.F. Codd. In such a database, the data and relations between them are organized in tables, which function as modules. This type of database allows sharing of information across modules as well as more complex reporting, because tabulated information in one module (e.g. the surgical event) is "related" to information in another module (e.g. late follow up). Thus, the relationship between, for example, IMA use and late mortality, can be analyzed.
See <http://burks.brighton.ac.uk/burks/foldoc/94/95.htm>

Operating platform: This is the structure of the back-end database, which holds the data for the front-end application (which accepts data entry). Examples of operating platforms are SQL Server (Microsoft), Sybase Anywhere (Sybase, Inc.) and Cache (InterSystems, Inc.). This distinction impacts you, the user, because separate software licenses are occasionally required for the "back-end" operating platform, which can add further expense to the cost quoted by the certified software vendor. (Be sure to ask them about it.)

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