



The STS National Database™ News

The Society of
Thoracic Surgeons

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2003 STS National Database Managers Meeting

What better way to start off the New Year than in San Diego? The 7th Annual Society of Thoracic Surgeons (STS) National Database Managers Meeting will be held in conjunction with the STS Annual Meeting on February 1st and 2nd, 2003. This year's meeting includes several new sessions focused on outcomes and on the ongoing clinical education of STS Data Managers.

New this year, on Saturday evening, February 1st, we will be hosting a cocktail reception which will include a poster session. These posters will focus on how use of the STS National Database has resulted in significant improvement in cardiothoracic practice and outcomes at the local or regional level. A call for posters was sent to all primary contacts in our Participant Information Database. If you are

interested in presenting a poster please use the form on our web page <http://www.sts.org> (Database-2003 DM Mtg-Call for Posters).

The formal program will begin on Sunday, February 2nd, with a welcome from STS President, William A. Baumgartner, MD. This year marks the introduction of the Database Managers Training and Education Manual. The program will also include a technical session on collecting operative data, updates on the General Thoracic and Congenital Heart Surgery Databases, and a clinical session featuring a presentation of surgical procedures captured by the STS National Database.

Advance Registration is required to attend this highly informative program. A direct link to the registration form is



provided here: <http://www.ctsnet.org/file/2003RegForm.pdf>. A registration form has also been included with this newsletter. If you need assistance, please contact Lauracyn Mayfield at STS Headquarters at (312) 202-5832.

Recognizing that each Data Manager brings his or her own unique experiences and interests to the program of our annual Database Managers Meeting, we look forward to seeing all of our participants there!

Regional Update: Iowa Completes Regional Data Audits

The Iowa Society of Thoracic Surgeons (IASTS) is a voluntary, not-for-profit organization whose purpose is to bring together the thoracic surgeons of Iowa to engage in activities of mutual benefit including continuous quality improvement activities aimed at improving outcomes for open-heart surgery patients. Currently all sites performing cardiothoracic surgery in Iowa submit data to the Society of Thoracic Surgeons National Adult Cardiac Database (STSNDB).

The Iowa Foundation for Medical Care (IFMC) has been the Quality Improvement Organization

(QIO) for Iowa since the inception of the QIO program in 1984. The Iowa Foundation for Medical Care (IFMC) is a private, non-profit organization composed of health care professionals dedicated to improving health care quality.

In March of 2000, the IASTS and the IFMC entered into an agreement to work together in support of the Society's quality improvement goals. IFMC's extensive experience in quality improvement activities, including developing collection tools and data element definitions, collecting data, performing inter-rater reliability (agreement) rates and

experience in collaborating with health care providers presented an unique opportunity for a partnership between the IASTS and the IFMC.

The IFMC and IASTS members recognize that data managers play an important role in serving as a conduit for information relating to quality improvement, and are the driving force in collection of quality data. In July 2000, Iowa data managers began meeting with a primary goal of building consensus on clarifying data element definitions to ensure that data are collected consistently across the state. (continued on page 4)

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Did you know:

Each STS National Adult Cardiac Database harvest accepts data on a rolling two-year basis. This means you can submit up to two years of historical data each time you harvest!



HIPAA: The STS Response

HIPAA, the Health Insurance Portability and Accountability Act of 1996, is an acronym that many, if not all of us are familiar with. HIPAA recognized the need for national patient record privacy standards. The law gave Congress until August 21, 1999 to pass comprehensive health privacy legislation. When Congress did not enact such legislation after three years, the law required the Department of Health and Human Services (HHS) to craft such protections by regulation. This rule will be enforced by the HHS Office for Civil Rights.

In response to the HIPAA regulations, The Society of Thoracic Surgeons (STS) National Databases have elected to pursue Business Associate agreements with all STS National Database participating hospitals and physician groups. The Business Associate (BA) Agreements are necessary to assist participants in complying with their obligations as "covered entities" under the HIPAA Final Privacy Rule. The BA Agreement amends the existing written agreements between STS and the Participants (the "Participation Agreements"), which permit STS, and its subcontractor Duke University, to use and disclose protected health

information for the purposes of collecting, analyzing and reporting data.

The STS will enter into a separate BA Agreement for each of the Databases: Adult Cardiac, Congenital, and General Thoracic. Completion of a BA Agreement will be required from all STS National Database participants to ensure that all participants are compliant with the HIPAA regulations for the purposes of participation in the STS National Database(s).

Compliance Deadline

Under the Final Privacy Rule's transition provision, Participants will have from August 9, 2002 until April 14, 2004, to execute a HIPAA-compliant BA Agreement with STS, provided they have a Participation Agreement in place with STS before October 15, 2002. However, under the Final Rule, covered entities are not relieved of their obligations to monitor the activities of their business associates during the transition period. In particular, covered entities remain obligated to make information available to the Secretary of Health and Human Services, fulfill an individual's rights with respect to the access, amendment, or accounting of protected health information, and miti-

gate the harmful effects of any improper use or disclosure of protected health information during the transition period. These obligations apply regardless of whether the protected health information in question is held by a business associate.

The STS is currently developing the BA Agreements for review and comment by both Duke University and STS National Database participants. The STS recognizes the importance of participant comment in the development of a standard BA Agreement for all participating sites. The STS expects that at least some participants will be anxious to enter into a HIPAA-compliant BA Agreement with STS by the April 14, 2003 compliance date, regardless of the Final Rule's transition provision. Therefore, the schedule proposed below is designed to meet this deadline.

The proposed timeline would give participants with early internal deadlines eight weeks between receipt of the new STS National Database BA Agreements and the HIPAA compliance date of April 14, 2003. The STS has invested a great deal of time and thought in establishing this timeline, and is confident that the process outlined below will result in the development of BA Agreements that meet the HIPAA compliance require-

ments of all of our participating physicians and institutions. Please continue to check the National Database section of www.sts.org for more information.

Proposed Timetable

- Preliminary Agreements Submitted to Duke: Mid October, 2002
- Comments Received from Duke: Mid November, 2002
- Initiation of Notice & Comment Process with Participants: Early December, 2002
- Comments Received from Participants: Early January, 2003
- Final Approval of BA Agreement by Duke: Mid January, 2003
- Agreements Approved by STS Board: Late January, 2003
- Final Agreements Released to Participants: Mid-February, 2003



Data Quality Tip of the Quarter: Clean up those Hospital Names!

Much of the research being done on the STS database requires DCRI to group the data by hospital. In order for analysis to be accurate, special care must be taken to ensure that each facility is clearly and consistently identified. Keep in mind that multiple STS participants may submit records for procedures performed at a single hospital. The only way the records from a single hospital can be grouped together correctly is if the hospital names are always entered the same way.

For example, suppose you use the common name for your hospital "General Hospital", but another participant uses the official name of "General Hospital of Pleasantville". When the data are analyzed, these two names will look like two different hospitals and the analysis will not accurately reflect the procedures done at your facility.

To avoid this issue, please follow these guidelines:

- Edit the drop-down list of hospital name choices available to you for data entry to include only the full, "official" hospital names. Use the names as they appear on letterhead or billing statements.
- If the drop-down list contains multiple name variations for the same facility, choose one and remove the others.
- Do not abbreviate any part of your hospital names.
- Clean up your existing data to change the names to the official version. This does not have to be done one record at a time, but can be done with a quick update query. You might need the help of your vendor to accomplish this.

Making sure your data contain the appropriate hospital names will go a long way to ensure the data for your facility is analyzed correctly. It will also make filling out your Hospital Name Clarification Form much easier!



The STS Launches Clinical Trials

In anticipation of increased activity in the area of clinical trials, the Society of Thoracic Surgeons (STS) recently established a Workforce on Clinical Trials under the Council on Quality Assurance and Patient Advocacy for physician oversight of research and trials activity. Workforce members include Chair, Joe B. Putnam, Jr., MD, Alfred Casale MD, T. Bruce Ferguson Jr. MD, David Fullerton MD, Henning Gaissert MD and W. Steves Ring MD. The creation of this workforce recognizes the Society as a surgical specialty society uniquely positioned to facilitate participation in clinical trials through the STS NCD participating sites and Society membership.

In November 2000, a survey was sent to STS National Database participating sites soliciting interest in participating in clinical trials. The response to this survey was extremely favorable with 94% of members indicating interest in performing clinical trials. The Workforce on Clinical Trials has recently started their clinical trials activity by working with the DCRI Clinical Trials and STS National Database sites on the Prevent IV trial. This exciting activity is another potential benefit for STS National Database participants and Society members, and will allow the Society to grow in new directions.

In addition to a base of interested and committed sites for trials, the Society has established a solid administrative structure for the STS National Database that is currently being extended to facilitating the development and conduct of clinical trials. To date, 460 STS National Database

sites have a data collection infrastructure in place. Through the current activity taking place within the STS National Database and Office of Research, the Society has established a proven track record in developing educational materials for site personnel, organizing, tracking and communicating information to participating sites, and maintaining regular contact with physicians and staff at participating sites.

"...the Society as a surgical specialty society [is] uniquely positioned to facilitate participation in clinical trials through the STS NCD participating sites and Society membership."

Working from the established infrastructure of the STS National Database and STS Office of Research, the research activity currently taking place is being translated into a site management program for facilitation (not conduct) of clinical trials, with the Society providing experienced project management in the following areas:

Investigator & site recruitment, evaluation and regulatory start-up:

Beginning with the pool of clinical centers currently involved with the STS National Databases and the Society membership, the

Society is able to ensure a qualified investigator base to meet the needs of other/outside clinical trials organizations. Through the development of a comprehensive investigator database, the Society will collect and maintain core investigator data, capture trial participation and performance data and develop tools to adequately profile the investigator pool in order to respond to investigator inquiries in a timely manner. In addition, the Society will be able to capture and analyze site performance metrics, such as how well a site performs in a trial with regard to enrollment and submission of required documents, in support of site selection. This database will also allow the Society to refer sites to trials that are actively recruiting.

Enhancement of clinical trial enrollment:

By establishing an interface between a comprehensive clinical trials contact database and STS National Database participants, the Society will be able to provide site information to clinical trials' sponsors, including potential investigator lists based on trial-specific criteria agreed upon by trial leadership and sponsors. Such criteria might include volume, percentage of patients in a minority or demographic group, or percent of patients with EF > 20%. As the Society continues to gather information about participating sites, the contact database will include information on investigator participation and performance metrics in previous trials to aid in site selection.

Support of site development and education:

In addition to providing clinical trials with potential sites and

investigators in the initial phase of the trial, the Society will be able to provide site development and support on an ongoing basis during the course of the trial. The Society will also be in an excellent position to review potential investigators provided by external groups who may be Society members and add to the database those investigators that are not already present to make the available for review. As a membership organization, the Society is also uniquely positioned to provide investigator networking opportunities at current Society meetings and educational events. The Society is keenly aware of the need to support education for surgeons and staff to facilitate their participation in clinical trials.

Through the establishment of a Workforce on Clinical Trials, the Society is taking the initial step in developing and implementing innovative methods to facilitate clinical trial management and ensure consistent access to quality investigative sites for clinical trials through the infrastructure of the STS National Cardiac Database. In the next month, Society members will receive an investigator profile form to complete and return to the STS. The information collected will enable the Society to build our clinical trials database of interested investigators and take the exciting next step of facilitating clinical trials participation for our membership.

The STS National Database™ Newsletter is published periodically throughout the year for participants in the STS National Databases. Comments concerning content may be referred to STS Headquarters, 633 N. Saint Clair St., Suite 2320, Chicago, IL 60611-3658; Phone: 312.202.5800; Fax: 312.202.5801;

E-mail: sts@sts.org, Web: www.sts.org

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Iowa Completes Regional Data Audits (continued)

After data managers achieved consensus on data element definitions, and at the request of the IASTS members, IFMC initiated onsite data quality audits. The primary objectives of data audits include:

- Ensuring IASTS members that data is reliable
- Identifying varying interpretations of data element definitions
- Identifying definitional issues requiring clarification from National STS and the IASTS surgeon group
- Determining statewide inter-rater reliability rates
- Providing educational feedback to data managers

In the spring of 2001, IFMC performed data quality audits on five randomly selected isolated CABG records at each of the twelve sites in the state. The audits did not include the entire data collection tool, but focused on CABG operative risk of mortality data elements. Following a blinded review, a comparison was made between data collected by the IFMC staff and data submitted by the hospital staff. Each identified discrepancy was discussed with the data manager.

A statewide inter-rater reliability rate was calculated identifying the frequency and reason for each discrepancy noted during the audit. The overall inter-rater reliability rate for the audited data variables was 95.8 percent. The agreement rate for the audited variables ranged from 80 to 100 percent. Results were reviewed and discussed by the IASTS members and the Iowa data manager group.

The audit process was repeated by the IFMC in the spring of 2002 adding postoperative atrial fibrillation to the audited data elements at the request of the surgeons due to the wide range of occurrence noted in the state. Ten randomly selected records were reviewed at all sites. The overall inter-rater reliability rate for the audited data variables was 96.2 percent with postoperative atrial fibrillation at 96.4 percent. The agreement rate for the remaining audited variables ranged from 85 to 100 percent.

This type of audit activity represents the first external review of voluntarily submitted data by an experienced, objective third party. The Iowa data manager group recognizes the importance of data auditing, is committed to submitting quality data to the STSNDB and appreciates the opportunity for networking with all sites in the state.

Fall Publications and Presentations from the STS National Database

Diabetes Mellitus Increases Short-Term Mortality and Morbidity in Patients Undergoing Coronary Artery Bypass Graft Surgery. Jeffrey L. Carson, MD, Peter M Scholz, MD, Anita Y. Chen, MS, Eric D. Peterson, MD, MPH, FACC, Jeffrey Gold, MD, FACC, Stephen H. Schneider, MD. J Am Coll Cardiol 2002;40:418-23.

Cardiac Surgery in Nonagenarians and Centenarians. Charles R. Bridges MD, ScD, FACS, Eric D. Peterson MD, MPH, Fred H. Edwards MD, Laura P. Coombs PhD, T. Bruce Ferguson, Jr. MD. 88th Annual Clinical Congress of the American College of Surgeons, San Francisco, CA. Tuesday, October 8, 2002.

Comparative Risk-Adjusted Outcomes Between Genders Among Elderly Coronary Bypass Patients. Jun R Chiong, MD, Stephen A Geraci, MD, Fred H Edwards, MD and Constance K Haan, MD. CHEST 2002. November 2-7, 2002.

CQI in CABG: A National Randomized Trial in Quality Improvement. T. Bruce Ferguson, Jr. MD. American Heart Association Late-Breaking Clinical Trials 2002. Tuesday, November 19, 2002.

From Controlled Trials to Clinical Practice: Monitoring Transmyocardial Revascularization Use and Outcomes. Padma Kaul MD, Bradley G Hammill MS, T. Bruce Ferguson, Jr. MD, Eric D Peterson MD, MPH. American Heart Association Scientific Sessions 2002. Tuesday, November 19, 2002.

Use of Procedural Volume as a Marker of Bypass Surgery Quality: Results from the Society of Thoracic Surgery (STS) National Cardiac Database. Eric D Peterson, Laura P Coombs, Constance K Haan, Elizabeth R DeLong, T. Bruce Ferguson. American Heart Association Scientific Sessions 2002. Tuesday, November 19, 2002.

Guidelines in Selecting Patients Most Likely to Benefit from Off-Pump Coronary Artery Bypass Surgery. Mitchell J Magee MD, Laura P Coombs PhD, Michael J Mack MD. American Heart Association Scientific Sessions 2002. Wednesday, November 20, 2002, 8:30 AM.

Use of Mitral Valve Repair: Analysis of Contemporary US Experience Reported to the STS National Cardiac Database. Edward B. Savage M.D., T. Bruce Ferguson Jr. M.D., Verdi J. DiSesa M.D. Accepted for publication in the Annals of Thoracic Surgery.

THE SOCIETY OF THORACIC SURGEONS PRESENTS
The 2003 National Adult Cardiac Database Managers Meeting

SUNDAY, FEBRUARY 2, 2003 (8:00 AM - 3:30 PM)
THE MANCHESTER GRAND HYATT SAN DIEGO HOTEL
SAN DIEGO, CA

Registrant Information:

(Please print)

| | | |
|-----------------------|-------------------------|-----------------------------|
| First Name | Last Name | Degree |
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| City | State/Province | Zip/Postal Code |
| E-mail address | Telephone Number | Fax Number |

Registration Fee: \$175.00 per person

Amount Enclosed: Check Visa MasterCard American Express \$ _____

Credit Card #: _____ Expiration Date: ____/____/____
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Card Holder Name: _____

Signature: _____

Please check here if you cannot attend the meeting but wish to receive the meeting materials via mail. (There is a \$75.00 charge. List payment information above)

Registration, Hotel and Poster Presentation Session Information:

Mail this registration form and payment to: The Society of Thoracic Surgeons, Attn: Lauracyn Mayfield, 633 St. Clair Street, Suite 2320, Chicago, IL 60611. Also, make your check payable to: The Society of Thoracic Surgeons, or fax this form with your credit card information to 312-202-5801. **The deadline for submitting this form is January 3, 2003. All requests for cancellations must be submitted in writing to The Society of Thoracic Surgeons by Friday, January 3, 2003. Requests for refunds will not be honored after that date. Please note: A processing fee of \$50.00 will be charged for all cancellations.**

All data managers are encouraged to use the STS housing bureau for hotel accommodations. A direct link to the web address is provided for your convenience. <http://www.houseol.com/conventions/sts/> OR call (800) 282-3204.

Be sure to pick up your registration materials early when you attend the Poster Presentation Session on Saturday evening, February 1st beginning at 5:00 PM. Each poster presented will outline how use of the STS National Database has resulted in significant improvement in cardiothoracic practice and outcomes at the local or regional level. A reception for all attendees will immediately follow the poster presentation session.