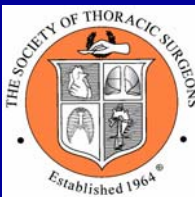


Atrial Fibrillation Ablation Thinktank

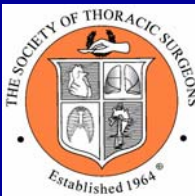
**Mitchell J. Magee, M.D.
STS National Database Taskforce
CRSTI
Dallas, TX**

**FDA, Silver Spring, MD
April 27, 2009**



STS National Database

Current Status Update



Adult Cardiac Surgery Database

Current Status Update

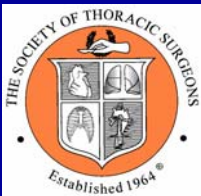
- Inception 1989
- 970 active participants; 49 states
- 3.6+ Million surgical procedures
- 4 data harvests/yr.
- 286 harvested data fields
 - Focused on CABG and Valve Replacement/Repair

Adult Cardiac Surgery Database

Current Status Update

- Conceived as quality improvement tool
- Standardized data collection of clinical data
- On-site audit program for accuracy, completeness, and comprehensiveness of data
- Resource for research (~70 publications)

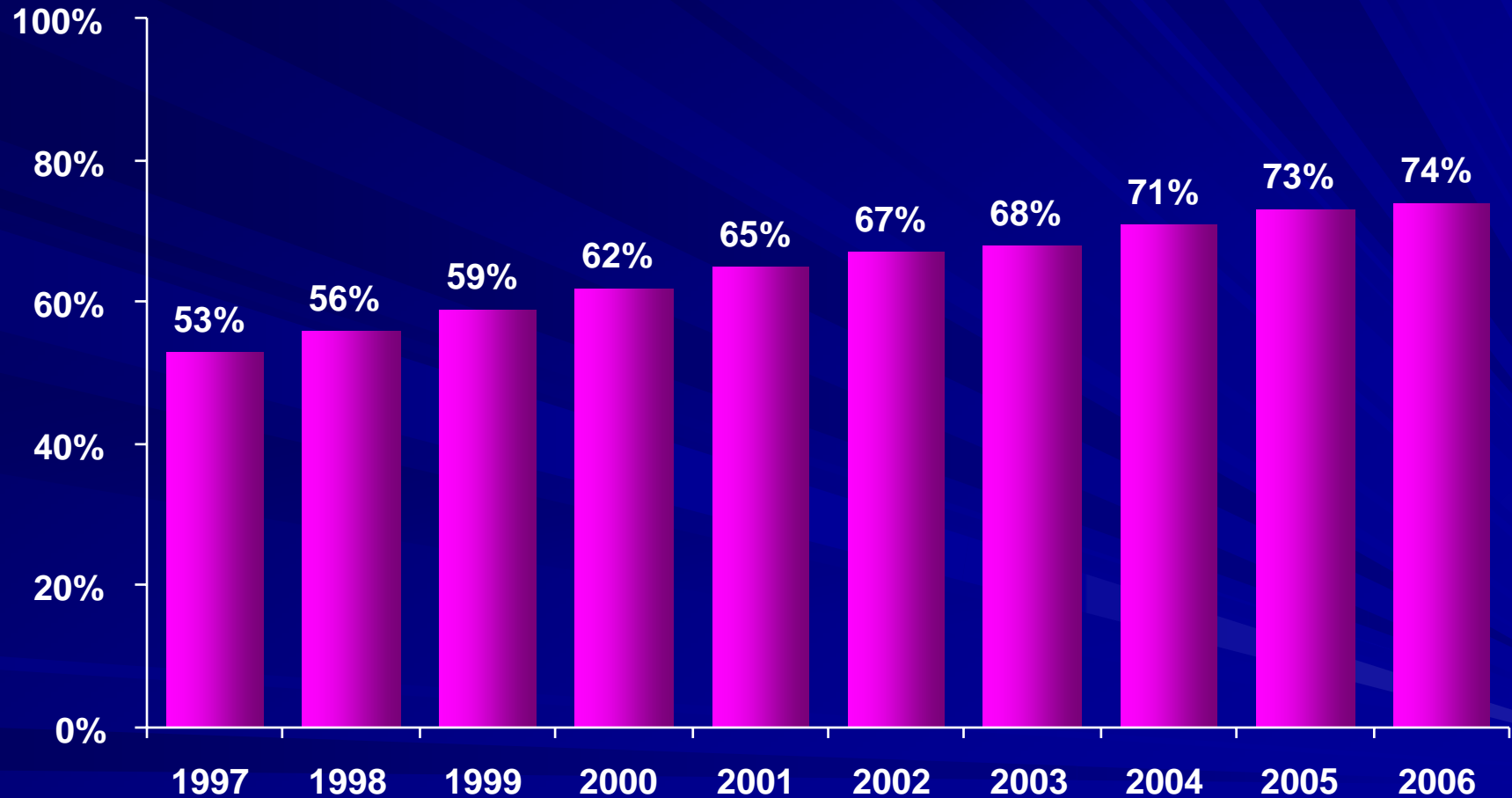
STS National Database Adult Cardiac Surgery Uses/Purposes



STS National Database Adult Cardiac Surgery Uses/Purposes

- **Quality measurement, improvement, and reporting**
 - Development of quality performance measures (21 NQF-endorsed cardiac measures)
 - Scientific literature reports improvements in mortality and morbidity

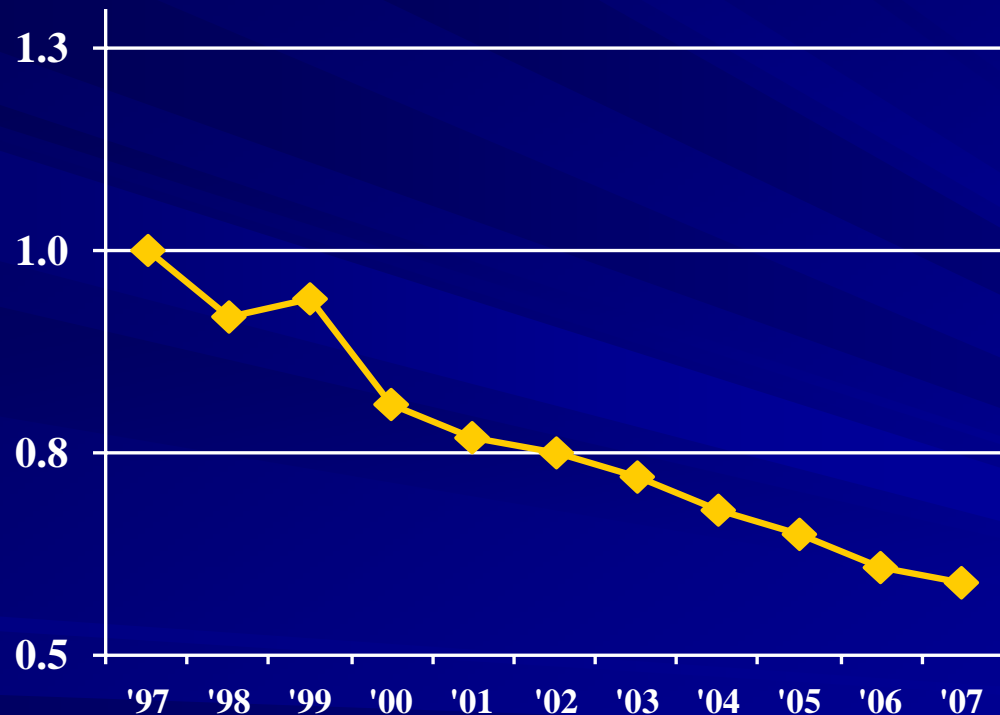
Pre-Operative Use of Beta-Blockers for CABG 1997-2006



STS National Database Adult Cardiac Surgery Uses/Purposes

- Improve patient safety

Observed-to-Expected Ratio Mortality: Isolated CABG, 1997-2007



■ Results of logistic modeling, adjusting for patient risk

STS National Database Adult Cardiac Surgery Uses/Purposes

■ Increase research

- Serves as a data source for STS member research
 - Approximately 70 peer-reviewed publications
- Used in research grants
 - Data resource for 3 NIH Challenge Grants
 - Data resource for current FDA contract
- Provides data source for industry research

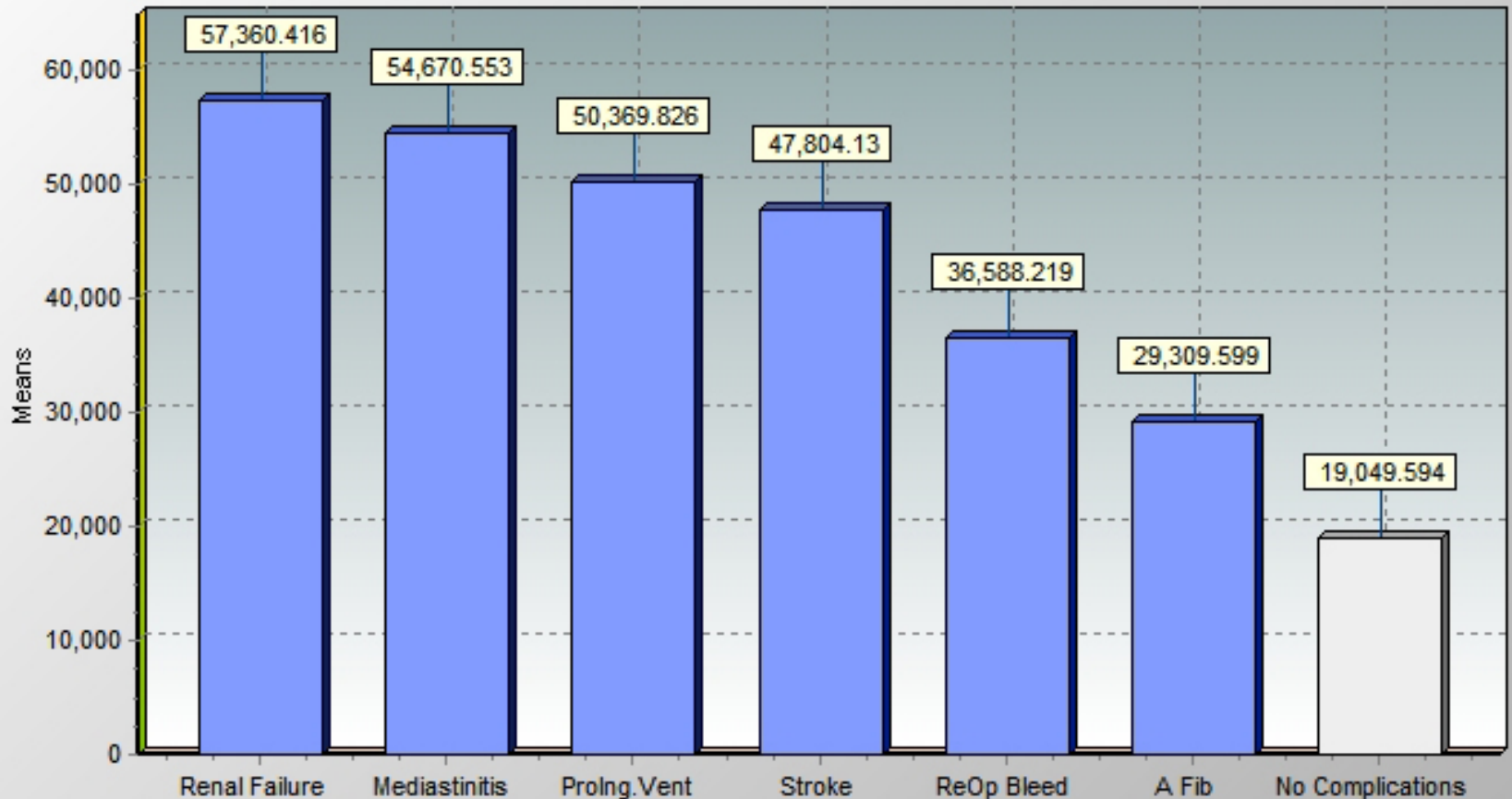
STS National Database Adult Cardiac Surgery Uses/Purposes

- **Demonstrate cost savings**
 - Reduction of complications saves money
 - Virginia experience

Cost savings are possible from Improvements

TOTAL COST - MULTIPLE COMPLICATIONS

CABG Only



STS National Database Adult Cardiac Surgery Uses/Purposes

- **Data can be used in public reporting**
 - STS participation in CMS's PQRI program
 - STS is an approved registry by CMS for PQRI reporting

STS National Database Adult Cardiac Surgery Uses/Purposes

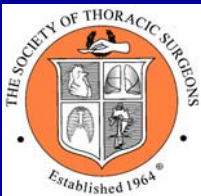
- **Reimbursement Negotiations**
 - Database information used in 5-year RUC review

STS National Database Adult Cardiac Surgery Uses/Purposes

- **Data used in developing Healthcare Policy**
 - Database used in CMS-1403-P-Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009
 - Database used in testimony before Congress
 - Database used in testimony to Institute of Medicine (IOM)

STS National Database

Successes of Registry



STS National Database

Successes of Registry

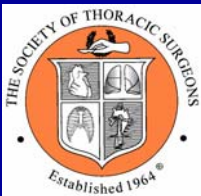
- **Tremendous Growth**
 - No. sites/centers
 - No. Participants
 - No. surgical records
- **Established credibility**
 - Internal and external audits attest to credibility
- **Data source for research**
 - More than 3.6 Million surgical procedures

STS National Database Successes of Registry

- Used as a model for other clinical registries
- Risk-adjusted clinical outcomes
- Establish national benchmarks for performance
- Provided quality measures that some insurers have adopted in their quality recognition programs

STS National Database

Lessons Learned



STS National Database

Lessons Learned

- **Requires dedication and perseverance**
 - Need local champions to promote the registry and the changes it requires
- **Costly**
 - Need to fund adequately
- **Time consuming to enter data**
 - Need adequate resources
- **Need to balance burden of collection with benefit of information**

STS National Database

Lessons Learned

- **Need a format that can be modified easily, such as web-based**
 - Multiple vendors with certified software don't want to change frequently
- **Constant maintenance and upgrading**
 - Need adequate resources
- **Requires training of personnel entering data to ensure accuracy of data**
 - High turnover of data managers

STS National Database

Lessons Learned

- **Collaboration between groups can achieve economies of scale**
 - STS added anesthesiologists to Congenital Heart Surgery Database
- **Adoption of a common nomenclature enhances communication among databases**
 - U.S. congenital heart surgeons collaborated with Europeans and adopted same registry terms and definitions

STS National Database

Lessons Learned

- STS and ACC have harmonized data elements in their respective adult databases
 - Common data fields
 - Common definitions

STS National Database Module Selection

- **STS Workforce on National Databases**
 - **Modernization of Databases Task Force has responsibility for Database Module selection and prioritization**
 - **Composed of volunteer surgeon leaders representing all 3 databases (Adult Cardiac Surgery, Congenital Heart Surgery, and General Thoracic Surgery), Duke Clinical Research Institute (DCRI), and STS staff**

STS National Database Module Selection

- **Developed specific criteria for selecting and prioritizing module development**

STS National Database Module Selection

- **Selection Criteria include:**
 - Large potential participation/broad applicability
 - FDA or other monitoring agency needs (e.g., post-market surveillance)
 - Area in evolution within CT surgery (important and novel/innovative procedures or procedure indication changes)

STS National Database Module Selection

- **Selection Criteria include (continued):**
 - Evolving care processes – operative and critical care
 - Need for longitudinal follow-up for stable and evolving areas
 - Coding and quality measures
 - Possible link for reimbursement for surgeons (PQRI, Pay for Performance)
 - Minimization of participation fees

STS National Database Module Development

- **Key components of development and roll-out include:**
 - **Data Definitions**
 - **Data Specifications**
 - **Web site programming**
 - **Reports development**
 - **Web site testing**

STS National Database Module Development

- **Key components (continued):**
 - Administrative/Operational decisions
 - Financial aspects
 - Marketing
 - Education
 - Web site launch
 - Participant management

Atrial Fibrillation Module

- **Core data elements include:**
 - **Description of the type of primary preoperative atrial fibrillation**
 - **Duration of the preoperative arrhythmia**
 - **Current antiarrhythmia drug therapy (Class I-IV)**
 - **Previous electrical cardioversions**

Atrial Fibrillation Module

- **Core data elements include (continued):**
 - Previous catheter ablation data
 - Anticoagulation with warfarin
 - Primary indication for procedure
 - Previous surgical procedures performed to control atrial fibrillation
 - Left atrial size and volume

Atrial Fibrillation Module

- **Core data elements include (continued):**
 - **Presence of left atrial thrombus per TTE or TEE**
 - **Surgical arrhythmia procedure**
 - **Procedure lesion set performed**
 - **Pulmonary vein electrical isolation confirmed**

Atrial Fibrillation Module

- **Core data elements include (continued):**
 - Left atrial appendage obliteration
 - Autonomic ganglia ablation performed
 - Predominant technique used to create the lesion set
 - Energy sources used

Atrial Fibrillation Module

Data Collection Form

STS Atrial Fibrillation Module

Data Collection



- 1. Description of the type of primary preoperative atrial fibrillation**
 - a. Paroxysmal atrial fibrillation**
 - b. Persistent (does not terminate spontaneously)**
 - c. Typical atrial flutter**
 - d. Atypical atrial flutter**
 - e. Other**

STS Atrial Fibrillation Module

Data Collection



2. Duration of the preoperative arrhythmia

Date first recognized _____
(mm/yyyy)

STS Atrial Fibrillation Module

Data Collection



3. On current antiarrhythmic drug therapy

a. No

b. Yes

If Yes, select drug Class (See reference list below)

Class I (Sodium Channel Blockers)

Class II (Beta Blockers)

**Class III (Potassium Channel
Blockers)**

Class IV (Calcium Channel Blockers)

Other

STS Atrial Fibrillation Module

Data Collection



4. Previous electrical cardioversions:

a. No

b. Yes

If Yes, no. cardioversions _____

STS Atrial Fibrillation Module

Data Collection



5. Previous catheter ablation data:

a. No

b. Yes

If Yes,

a. Total no. catheter ablation
procedures _____

b. Date of last catheter ablation _____

STS Atrial Fibrillation Module

Data Collection



6. Anticoagulated with Warfarin (Coumadin)
 - a. No
 - b. Yes

STS Atrial Fibrillation Module

Data Collection



- 7. Primary Indication for procedure: (Check one)**
- a. Antiarrhythmic drug failure**
 - b. Catheter ablation failure**
 - c. History of thromboembolic event**
 - d. Concomitant valve disease requiring surgery**
 - e. Concomitant coronary artery disease requiring surgery**
 - f. Concomitant valvular and coronary artery disease requiring surgery**
 - g. Concomitant other cardiac diseases requiring surgery**

STS Atrial Fibrillation Module

Data Collection



- 8. Previous surgical procedures performed to control atrial fibrillation**
 - a. No**
 - b. Yes**

STS Atrial Fibrillation Module

Data Collection



9. Left atrial size (diameter in cm) _____ cm
(Normal range is 1.9 -4.0 cm; report in
2.0 format)

volume _____ ml/m²
(Indexed range is 21-24 ml/m²; report
in 2.0 format)

STS Atrial Fibrillation Module

Data Collection



- 10. Presence of a LA thrombus per TTE
or TEE**
- a. No**
 - b. Yes**

STS Atrial Fibrillation Module

Data Collection



11. Surgical Arrhythmia Procedure (Check all that apply.)

a. Pulmonary Vein Isolation

b. Pulmonary Vein Isolation with Connecting Lesions

c. Right Atrial Lesion Set (“non- Maze”/”modified Maze”)

d. Right Atrial Full Maze Lesion Set

e. Left Atrial Lesion Set (“non- Maze”/”modified Maze”)

f. Left Atrial Full Maze Lesion Set

STS Atrial Fibrillation Module

Data Collection



- 12. Pulmonary vein electrical isolation was confirmed**
- a. No**
 - b. Yes**

STS Atrial Fibrillation Module

Data Collection



13. Left Atrial Appendage Obliteration

- a. No**
- b. Yes**

If Yes, choose one:

- i. Excision**
- ii. Exclusion**

STS Atrial Fibrillation Module

Data Collection



14. Autonomic ganglia ablation performed
- a. No
 - b. Yes

STS Atrial Fibrillation Module

Data Collection



15. Predominant technique used to create the lesion set (*choose one*)
- Epicardial Application of Energy
Source
 - Endocardial Application of Energy
Source
 - Incisions (surgical) “cut & sew”

STS Atrial Fibrillation Module

Data Collection



- 16. Energy sources used**
 - a. Radiofrequency**
 - b. High Intensity Focused Ultrasound**
 - c. Cryoablation**
 - d. Microwave**
 - e. Laser**
 - f. “Cut and Sew”**

STS Atrial Fibrillation Module Data Collection



Follow-up Encounter Form

Completed at: Discharge

1 month

3 months

6 months

12 months

Annually

STS National Database

CRSTI Experience

- **CRSTI: Contracts with multiple institutions to collect adult cardiac surgery data**
 - Began in 1985
 - Over 45,000 cases to date
 - >20 hospitals
 - >25 CTV surgeons

STS National Database

CRSTI Experience

- Began customized AF data collection in January 2004
- Modular Component to STS Database
 - Approximately 600 cases to date
 - Stand Alone
 - Concomitant
 - Pre-op, Intra-op, Post-op and long term follow-up data variables
 - 1 and 3 month follow-up with patient questionnaire and EKG
 - 6, 12, 18, and 24 month follow-up with patient questionnaire and LTM
 - 24 hour holter
 - 2 - 3 week event monitor
 - PPM
 - Compliant with HRS Consensus guidelines (April 07)