The Society of Thoracic Surgeons (STS) is a not-for-profit organization representing more than 5,800 cardiothoracic surgeons, researchers, and allied health professionals worldwide who are dedicated to ensuring optimal surgical care for patients with diseases of the heart, lung, esophagus, and other organs in the chest. Founded in 1964, the mission of STS is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research and advocacy. STS supports data-driven approaches to quality measurement, quality improvement, and quality reporting because we recognize that collection and feedback of clinical data to our surgeons will improve patient outcomes.

STS believes that building true continuous quality improvement systems is dependent upon the collection of risk-adjusted clinical outcomes data and clinical process measures related to quality rather than simply relying on administrative claims data. Such clinical data can then be linked with administrative data to track clinical outcomes long-term and provide an assessment of appropriateness of care for specific patients, and an assessment of cost effectiveness, including the cost effectiveness of reduction in complications and potentially the use of new technologies and devices.

Since 1989, STS has fostered data-driven approaches to quality measurement and quality improvement. The STS National Database is the premier clinical data registry for cardiothoracic surgery. It includes three component parts: the Adult Cardiac Surgery Database, the General Thoracic Surgery Database, and the Congenital Heart Surgery Database. More than 90 percent of all adult cardiac surgery centers nationwide participate in the Adult Cardiac Database and 70% of the congenital heart surgery programs participate in the STS Congenital Database. Surgeons add new patient data on a continuous basis which is analyzed quarterly, thereby providing a highly dynamic, up-to-date picture of cardiothoracic surgical practice.
STS appreciates the opportunity to provide comments as part of a panel focusing on registries and quality measures and to respond to the specific questions presented by the HIT Policy Committee. Our comments today will focus on the Adult Cardiac Surgery Database (Database), which is the largest and most mature of the STS Databases. Information in this Database, collected over a 20-year period, has been used to improve the quality of care for patients undergoing cardiac surgical procedures. This Database captures data on all adult patients undergoing cardiac surgical procedures performed by Database participants throughout the United States. There are currently 1,000 participants, representing more than 2,800 individual surgeons. Currently, the Database contains more than 3.9 million surgical records and is the largest clinical cardiac surgery database in the world. Through this Database, STS has demonstrated that the systematic collection of risk-adjusted clinical data and the feedback of those data to physicians do improve outcomes. (e.g., reduction in risk adjusted mortality)

The information in this registry supports clinical performance assessment as well as the assessment of new procedures as they are introduced into routine clinical practice (e.g., the use of the internal mammary artery in Coronary Artery Bypass Graft procedures.) The Database contains detailed information, including demographics, cardiovascular history, patient risk factors, interventions, and outcomes associated with specific clinical surgical procedures. The Database has provided clinicians with important feedback on their practice patterns and performance, and is an invaluable tool for use in real world medical practice and health services research. The information from this Database also supports comparative effectiveness studies, as well as those on the integration of new treatments into routine clinical practice.

Data definitions are standardized by an experienced STS Task Force and updated at 3-year intervals. These definitions are harmonized with those of the American College of Cardiology (ACC) to ensure consistency between the STS Database and the ACC National Cardiovascular Data Registry (NCDR). A three-day conference of database managers, who code and enter the data, is held each year in order to provide uniform training for them as well as a forum for the exchange of ideas.

At three month intervals, data from all participants are harvested and transmitted to the Duke Clinical Research Institute (DCRI) where the aggregate data are internally audited and analyzed. In addition to the internal audit, on-site audits of participant programs are conducted by an independent auditing firm. All Database information is collected in a manner compliant with HIPAA regulations. IRB approval for the data collection is covered by DCRI through Duke University.

The general business plan of the STS Database is based on the concept of voluntary participation. Participants sign Participation Agreements and Business Associate/Data Use Agreements with STS and they agree to pay an annual “participation fee.” Participants also contract with commercial software vendors to use STS-certified software products, which enable participants to reliably send their data to DCRI. Participants incur both start-up fees as well as annual fees and, in addition, virtually all participants find it necessary to employ a database manager.
Quality measurement is largely based on a set of 21 STS performance measures endorsed by the National Quality Forum (NQF). In addition, a composite quality score made up of individual NQF-endorsed measures has been developed. This composite score is used to determine the net impact of its individual component measures. Detailed clinical reports, including national benchmarks and trends, are provided back to the participants in a feedback loop, which has been shown to improve quality of care. These feedback reports allow participants to pinpoint areas for quality improvement. Individual performance measures, including risk-adjusted outcomes, are analyzed for a variety of clinical entities to Database participants.

STS developed these measures and reports to serve as the standard for measuring quality in cardiac surgery. Insurers, governmental entities, and other third parties are encouraged by STS to use its quality protocols rather than systems developed by the individual organizations in an attempt to minimize the potential emergence of a “Tower of Babel” in quality measurement.

Data are analyzed using a nationally aggregated population. STS does offer the option for analyzing data on a regional/state basis in which data specific to a region are examined in addition to the national analyses. A strict scientific study of regional differences has not been carried out, but in general there are no known glaring differences among regions.

This STS Database has been approved by the Centers for Medicare and Medicaid Services (CMS) as a clinical registry to report data to the Physician Quality Reporting Initiative (PQRI). The ability to report data from surgeons directly to CMS avoids duplication of data entry and submission, thereby reducing the burden on participants. In addition, CMS recently announced its intention to consider registries, including the STS Database, as an alternative way to collect quality data from hospitals. Instead of requiring hospitals to submit the same data to CMS that they are already submitting to registries, CMS believes that it could collect the data directly from the registries, thereby enabling CMS to expand the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program measure set without increasing the burden of data collection for those hospitals participating in the registries.

A direct link between EHR systems and the Database has not been established. With the advent of EHR systems, it is critical for such links to be facilitated with new technological advances. EHR systems provide administrative data and may include some clinical information; however, not in the depth as provided by clinical registries. Interoperability between EHR systems and clinical registries is crucial in the future as both are necessary to capture all relevant data related to patient care. Interoperability of clinical registries with other databases is being established through a data-linking process using probabilistic matching methodology. To date, the clinical data in the STS Database have been linked to a CMS Medicare Provider Analysis and Review (MEDPAR) dataset. STS recently received a National Institutes of Health (NIH) Grand Opportunity (GO) grant to link the STS Database patient records to their counterparts in the ACC NCDR to conduct comparative effectiveness studies. STS also plans to obtain long-term outcomes through linking its Database with the Social Security Death Master File, thereby providing additional valuable outcomes data.
The barriers to participation in a clinical registry are primarily the cost and the administrative burden to its participants. In the STS case, it should be emphasized that the cost of this complex enterprise is borne by the individual participating surgeons. While there are many advantages to participation in a clinical registry, some of the most important include:

1. Improved patient care,
2. Comparison of operative results against national benchmarks,
3. Simplified quality reporting to numerous third party payers,
4. Automatic transmission of PQRI data to CMS (projected CMS RHQDAPU hospital reporting),
5. Research, and

Thank you again for the opportunity to participate as part of the Registries and Quality Measures Panel and providing comments to the HIT Policy Committee Hearing on Meaningful Use Measures to Specialists, Smaller Practices and Hospitals, and Providers of Underserved Areas. If you have any questions, please contact Phil Bongiorno, STS Director of Government Relations, at (202) 481-1026 or pbongiorno@sts.org.