

**Statement of
The Society of Thoracic Surgeons
MEDCAC Consideration of Evidentiary Characteristics for
Coverage with Evidence Development (CED)
April 16, 2012**

The Society of Thoracic Surgeons (STS), the largest organization representing cardiothoracic surgeons in the United States and the world, is pleased to submit comments for the Medicare Evidence Development & Coverage Advisory Committee's (MEDCAC) consideration of evidentiary characteristics for Coverage with Evidence Development (CED). STS is a not-for-profit organization representing more than 6,400 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. Our membership possesses extensive experience and expertise making clinical judgments on appropriate procedures for specific conditions and employing technologies to address the needs of patients.

The STS supports the development and use of data collection systems to ensure that patients, providers, and decision-makers, like CMS, can make decisions based on the best available clinical evidence. To that end, we strongly support CMS' use of CED. We believe that the collection of additional information may be useful in determining that a treatment is reasonable and necessary while also serving to ensure the safety of those receiving the treatment in question. Additionally, we believe that CED may better ensure that beneficiaries have appropriate access to new medical technologies and services at an earlier stage.

We believe that the health care community, and the physician community in particular, has the ability and the responsibility to play an active role in the CED process. The STS has a mature and extensive national registry used by over 90 percent of cardiac centers in the country. The data are formally audited by independent, on-site reviews to ensure accurate data quality.

As you are aware, STS and the American College of Cardiology (ACC) initiated a request on September 22, 2011, for a national coverage determination (NCD) on Transcatheter Aortic Valve Replacement (TAVR) that would tie coverage collection through the Transcatheter Valve Therapy (TVT) Registry. The STS/ACC TVT Registry was jointly developed to track real-world outcomes related to TAVR. We believe there are important best practices illustrated by our experience with the TVT Registry that should be explicitly encouraged within new CED policy.

We believe CMS' revised CED policy should align with a number of principles to ensure the successful development, review, and use of resulting evidence. In 2006, CMS outlined certain key principles governing the application of CED; the suggested principles below are complementary to, if not aligned with, those 2006 principles.ⁱ We believe the policy should encourage the following three principles:

1. Coordination among relevant stakeholders;

2. Early discussions among the agency and relevant stakeholders so as to allow sufficient time for ensuring appropriate application, design, and implementation of CED; and
3. Flexibility of the CED data collection mechanism to adjust the inputs and outputs based on new developments.

Key Principle 1: Coordination among relevant stakeholders

It is crucial that any CED effort permits collaboration and generates buy-in from relevant stakeholders, including professional societies, government agencies, and industry. Current activities fail to ensure complementary and collaborative activities between healthcare stakeholder segments. As such, many manufacturers of similar products in the same class are often designing their studies differently or collecting disparate evidence. Further, different government agencies often have disparate evidentiary needs, forcing stakeholders to generate significant, varied data for different stakeholders.

STS believes that CED policy can and should encourage integration and collaboration among different stakeholders. Given that many interventions are unproven from a real world perspective, CED can be used to help all stakeholders to understand how new technologies work in patients. This can be accomplished by supporting the integration of clinical and administrative data which allows for real time clinical analyses and feedback to stakeholders. Protocol should be designed to enhance the ability for partnerships among industry members to better align development and data collection efforts and to meet the needs of regulators and payors.

- STS' experience with the TVT Registry demonstrates that this model may be an effective platform to support collaboration and meet the needs of varied stakeholders. The TVT Registry relies on the integration of clinical and administrative data (e.g., it can be linked to CMS MEDPAR information) to obtain longitudinal outcomes data for a wide array of cardiothoracic surgery operations. The Registry tracks relevant outcomes, which allows stakeholders to use the information to enhance evidence-based shared decision-making with patients and caregivers. Standardized definition and data endpoints in the registry reduce redundancy, decrease unnecessary duplication, and increase important standardization in evidence development efforts. The TVT Registry model allows the varied needs of stakeholders to be addressed but does not “blend” or change different agencies' requirements (and thereby compromise the level or quality of evidence needed by one particular entity). The TVT Registry supports coordination among manufacturers on data collection efforts and has the potential to support the joint evidentiary needs of both CMS and FDA in light of the recently established parallel review initiative.

Key Principle 2: Early discussions among stakeholders

Given the limited statutory timeframes of issuing a NCD, it is important to start the CED discussion early to ensure sufficient time to setup the mechanism to capture the appropriate data elements and engage relevant stakeholders. In fact, going through a more robust and thorough process for designing CED may have addressed previous CED implementation challenges including the following:

- Since the final CED decision was published in 2005 on cochlear implantation, there have not been any clinical trials established to satisfy the terms of the coverage decision
- Due to implementation challenges, there are only two examples thus far where CED has led to instances of coverage (e.g., Lung Volume Reduction Surgery and Positron Emission Tomography)

STS and ACC initiated conversations with CMS, FDA, and other relevant stakeholders early to ensure upfront agreement on the components and structure of the TVT Registry. Lessons learned from STS/ACC's experience developing the TVT Registry suggests that CED policy decisions can be successful if CMS facilitates early discussions among CMS and relevant stakeholders so as to allow sufficient time for ensuring appropriate application, design, and implementation of CED

Key Principle 3: Flexibility of the CED data collection mechanism

The CED process must be adaptable and able to evolve in order to respond the changing evidentiary and technology landscape, which may introduce new or different indications, outcomes, and subpopulations, among others. Data collection should be useable to identify anomalies, target the causes of adverse events, or identify the reason for changes in outcomes. Once a medical specific issues/problem or population is identified, the data collection activities should be able to be adjusted to better capture specific types of information if early results suggest a need to focus on a specific outcome, population, etc.

STS' experience with the TVT Registry suggests that data collection through a registry allows for the necessary flexibility and can evolve alongside the changing environment. The TVT Registry is able to target specific areas for clinical practice improvements, reflect actual practice patterns, assess national and regional averages, and support quality improvement

Conclusion:

STS appreciates the opportunity to comment to the MEDCAC as it considers the further development of CMS' CED policy. In our experience, the TVT Registry has been a valuable data collection tool to support the introduction of TAVR to clinical practice. It has the potential to enable the execution of new payment models, real-time execution of comparative effectiveness research, and post-market surveillance. We believe that clinical registries have a significant role to play as a potential data collection tool for healthcare innovations facing similar challenges to those of TAVR. We look forward to further collaboration with CMS and other relevant stakeholders to support improved innovation for medical technologies, development of important information to improve decision making, and greater access to needed therapies for patients.

ⁱ Centers for Medicare & Medicaid Services (CMS). Guidance for the Public, Industry, and CMS Staff: National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development. *Coverage and Analysis Group*. July 12, 2006.