



STS The Society of
Thoracic Surgeons

Comments to the Medicare Evidence Development & Coverage Advisory Committee

Evidentiary Characteristics for Coverage with
Evidence Development (CED)

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*The mission of the Society is to enhance the ability of cardiothoracic surgeons
to provide the highest quality patient care through education, research, and advocacy.*



The STS/ACC TVT Registry

- **Sept. 22** - STS/ACC Request for Transcatheter Aortic Valve Replacement (TAVR) NCD.
- **Nov. 2** - Food and Drug Administration (FDA) approved Edwards Life Sciences Sapien device.
 - Directs Edwards to “continue to evaluate the outcomes with the Sapien THV through a national Transcatheter Valve Therapy (TVT) registry.”
- **Dec. 1** - STS and ACC launched National TVT Registry in collaboration with CMS and FDA
 - TVT Registry will serve as a platform for continued evaluation of post market experience with this and future transcatheter devices and procedures for the treatment of aortic stenosis.



Key Characteristics for Successful CED Policy

- Coordination among relevant stakeholders
- Early discussions among stakeholders
- Flexibility of the CED data collection mechanism



Coordination Among Relevant Stakeholders

- CED should permit collaboration and generate buy-in from relevant stakeholders:
 - Professional societies, government agencies, and industry.
 - Frequently manufacturers of similar products in the same class design their studies differently or collect disparate evidence.
 - Different government agencies often have dissimilar evidentiary needs, forcing stakeholders to generate significant, varied data for different stakeholders.



Coordination Among Relevant Stakeholders

- The TVT Registry
 - Relies on the integration of clinical and administrative data to obtain longitudinal outcomes data
 - Standardized definition and data endpoints in the registry reduce redundancy, decrease unnecessary duplication, and increase important standardization in evidence development efforts.

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.



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,
- Data collection should be useable to
 - Identify anomalies,
 - Target the causes of adverse events, and
 - Identify the reason for changes in outcomes.



Flexibility of the CED Data Collection Mechanism

- TVT Registry
 - 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.



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