

Frequently Asked Questions about the STS/ACC TVT Registry™

Why do we need a TVT Registry?

We need objective clinical data to assess the safety and efficacy of new devices. In addition to the short and long-term mortality and morbidity information, the registry will gather information on long-term quality of life.

This information can be used by participants to compare the results of their local practice against risk-adjusted results from the rest of the country.

The registry will also provide data to develop new statistical risk models of both risk and benefit, so that we can reliably predict which patients will benefit from the procedure. Having an objective index of risk / benefit will provide a yardstick that can be used to accurately assess appropriate indications for the procedure.

The TVT Registry will serve as a resource to assess procedural results, to monitor device safety, to protect our patients from inappropriate treatment, and to ensure that our patients have access to the most appropriate treatment. Participation in the TVT Registry demonstrates the highest degree of accountability to our patients.

Participants are encouraged to regard the registry as an unprecedented professional collaboration focused on the responsible application of data to optimize patient care.

What is the TVT Registry™?

The TVT Registry is a new benchmarking tool developed to track patient safety and outcomes information related to the newly introduced transcatheter aortic valve replacement (TAVR) procedure. Created by The Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC), the TVT Registry is designed to monitor the safety and efficacy of this new procedure as well as subsequent devices and procedures for the treatment of aortic stenosis in patients who undergo the procedure.

Through the capture and reporting of patient demographics, procedure details, and facility and physician information, the TVT Registry provides a data repository capable of delivering insight into clinical practice patterns and patient outcomes.

Will participating in the TVT Registry meet the registry requirement for Medicare coverage?

Yes. The TVT Registry has been designed with CMS's needs in mind and the data elements include all variables addressed in the National Coverage Determination (NCD). On May 1, 2012 the Centers for Medicare and Medicaid Services (CMS) released an NCD for TAVR, which allows Medicare coverage of TAVR under Coverage with Evidence Development (CED) with certain conditions. As part of CED, CMS has approved the TVT Registry and determined that it meets one of the major requirements of coverage.

Click here to read the NCD:

[http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+\(TAVR\)&bc=ACAAAAAIAAA&](http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+(TAVR)&bc=ACAAAAAIAAA&)

Are hospitals that perform TAVR mandated to participate in the TVT Registry?

All hospitals performing TAVR procedures on Medicare patients must participate in a CMS approved prospective, national, audited registry. The STS/ACC TVT Registry has been approved by CMS and meets this requirement of coverage. The Participation Agreement between the hospital and the STS/ACC TVT Registry requires that all patients meeting the inclusion criteria must be entered into the registry.

What structural heart disease procedures count as professional experience?

The criteria for establishing a transcatheter valve program and maintenance of competence are outlined in the SCAI/AATS/ACCF/STS Multisociety Expert Consensus Statement: Operator & Institutional Requirements for Transcatheter Valve Repair and Replacement; Part 1 TAVR (see page 23-24). This consensus statement served as the source document for the CMS NCD.

The consensus statement can be found at:

<http://content.onlinejacc.org/cgi/reprint/j.jacc.2012.02.016v1.pdf>

What data will the TVT Registry provide to CMS?

Upon written hospital consent, registry case files will be sent to CMS for the purpose of linking TVT Registry data with CMS claims data to create an analytic data file containing the index hospitalization registry data, 30-day and 1 year follow-up data, and Medicare claims data.

What if we have already done a TAVR case or cases; do those patients still need to be entered into the TVT Registry to be covered by the CMS directive?

Yes, all TAVR cases done since May 1st that fall under the registry requirement of the National Coverage Determination (NCD) need to be retroactively submitted to the TVT Registry. We strongly urge that all cases done since November 1, 2011 (the day of FDA approval of the first TAVR device) be entered into the database. The TVT Registry allows for patients to be entered into the database from November 1, 2011 forward.

Is there a deadline to submit the retroactive data to the TVT Registry for the CMS NCD?

A specific deadline for submitting retroactive cases has not been published at this time. However, the registry expects that the hospital site will join the TVT Registry and will enter all retroactive procedures into the registry within the first 3 months of enrolling into the TVT Registry.

What are the data submission deadlines for the TVT Registry?

The patient data included in the quarterly outcome report are based on the patient discharge date; for example, patients discharged between January 1 and March 31 will be included in the Quarter 1 outcome report. A Data Submission Deadline for each quarter report will be posted on the TVT Registry website.

What will I receive in return for joining the TVT Registry?

Participants will be provided with periodic reports of:

- National results with statistical analysis
- Local operative results
- Local risk-adjusted outcomes compared to national benchmarks

Participants will also have access to a repository of their own data. As with the current vendor protocols, participants will have the tools to evaluate their local practice and conduct user-specified queries of local data.

Once adequate data have been gathered, there will be opportunities to use TVT Registry information to conduct formal research projects. A protocol will be available so that interested centers can present research proposals to a joint STS-ACC committee for consideration.

How can I find more information about the TVT Registry?

Information about the TVT Registry can be found at www.tvtregistry.org. There are several public pages that provide information about the registry, data collection, and resources for background on TAVR and how to join the registry. There are additional private web pages that can be accessed once you become a participant in the TVT Registry.

How do I join the TVT Registry?

Visit www.tvtregistry.org; complete the form on the "Information and Enrollment" page to access the enrollment packet. The enrollment packet includes all of the materials and instructions needed for enrollment in the registry.

Is my hospital eligible to be a TVT Registry participant?

Hospitals performing TAVR procedures, or who are scheduled to attend clinical training programs offered by Edwards Lifesciences, are eligible to enroll in the registry. This Edwards Lifesciences clinical training is separate from the TVT Registry training on data collection and submission. A site may join the Registry at any time by completing and returning the contract and submitting payment.

Does my site need proof of Edwards Lifesciences clinical training prior to joining the TVT Registry?

We do not require proof of clinical training by Edwards Lifesciences prior to joining the TVT Registry. A site may join at any time by completing and returning the contract and submitting payment for the registry.

How much does it cost to join the TVT Registry?

The initial fee to participate in the TVT Registry is \$25,000 and the annual renewal fee is \$10,000 per year. These fees are based on expenses to develop and operate the TVT Registry.

Why should I pay to join the TVT Registry?

Considerable time, effort, and expense have been invested by the professional societies to create the registry. Funding at this point has come entirely from STS and ACC. Experience with the national databases of each professional organization has shown us that maintaining this TVT Registry will continue to require significant resources in future years.

Will a participant be able to query their own data?

In 2012 the TVT Registry will offer a feature to download a copy of your data entered into the registry.

We are collecting data but do not have a signed contract yet, how do we access the KCCQ-12 for our patient data collection?

The KCCQ -12 is available online within the password protected pages of the STS/ACC TVT Registry. This is a licensed product. As such, the registry can only release the form to contracted participants. The patients who had their TAVR performed prior to your participant agreement becoming finalized, will not be required or expected to have the KCCQ-12 completed. Your data will be accepted without the KCCQ-12 for the time frame when you were not an active participant.

We cannot require that you have data completed when you cannot access the data elements involved.

Why are there so many data elements and do all of them need to be answered?

All of the data elements are very important for the TVT Registry. Participants should provide responses for all of the data elements.

These data elements were vetted with input from a panel of expert physician cardiologists and cardiac surgeons as well as representatives from industry, the FDA (Food and Drug Administration), CMS (Centers for Medicare and Medicaid Services), VARC (Valve Academic Research Council) and other research-related groups. Based on the input from these various sources, the current list of data elements was reviewed and approved.

What is required of participants once they join the TVT Registry?

A TVT Registry Site Manager needs to be identified to ensure the facility is prepared to capture quality data and review outcome reports for quality improvement successes and opportunities for quality improvement.

Staff resources will be required to collect, enter, and submit data. Hospitals approach this in a variety of ways. Often, information technology skills as well as clinical expertise are desired qualifications for Registry Site Managers. To view a sample Registry Site Manager Job Description click [here](#) (link to updated job description).

Participants will be required to submit all data on all consecutive patients, 18 years or older at time of admission, who have undergone a TAVR procedure using approved transcatheter valve devices. Complete data will be required to pass Data Quality Checks built within the software.

Are TVT Registry patients also entered in the STS Adult Cardiac Surgery Database or ACC NCDR Registries? Will there be an expectation that cases must be entered in both registries?

The TVT Registry is a standalone registry that does not currently link to either the STS Adult Cardiac Surgery Database or any ACC NCDR Registry at this time. The STS Participation Agreement requires all consecutive cases done by surgeons listed on Schedule A of the Participation Agreement to be entered into the Adult Cardiac Surgery Database. Therefore, patients who receive a transcatheter valve intervention are entered in both the TVT Registry and STS Adult Cardiac Surgery Database. The ACC NCDR only requires patients to be entered into the TVT Registry. Future plans include linkage of the TVT Registry to both NCDR and STS Adult Cardiac Surgery Databases.

Who will own the TVT Registry data?

The TVT Registry, including all aggregated data obtained from hospitals, health care providers and others and residing in the TVT Registry is the joint property of STS and ACCF. STS and ACCF recognize and understand that all data submitted to the TVT Registry by hospitals, physicians, or others, including protected health information ("PHI"), are owned by the individual and/or the entity providing the data.

Who will have access to the TVT Registry data for research and other purposes?

STS and ACCF will have access to and can use data in the TVT Registry for research and publication purposes contingent on consent of the Research and Publications Subcommittee. Other parties may submit proposals for research based upon and using data from the TVT

Registry subject to approval by the Research and Publication Subcommittee and an IRB, if applicable.

Are there plans to certify software vendors to capture TVT Registry data?

At present the TVT Registry online data collection tool is the sole source for data capture. However, in 2012 we will examine the potential to work with software vendors to embed these data elements within their programs. More information on future integration with software vendors will be forthcoming.