SVS | PSO
PATIENT SAFETY ORGANIZATION

Answers to questions about the Trans-Carotid Artery Revascularization (TCAR) Surveillance Project (TSP)

How does the TSP work?

Like the other surgical and endovascular procedures tracked by the Society for Vascular Surgery Vascular Quality Initiative (VQI), procedural and outcomes data from TCAR procedures will be input via a web-based electronic data capture system that is provided by Fivos. TCAR data will be entered into the Carotid Artery Stenting Registry of the VQI. Carotid endarterectomy (CEA) procedures entered into the VQI CEA Registry will be compared with TCAR procedure outcomes.

What patients are included in the TSP?

As of May 31, 2022, the TSP is now also accepting Standard Risk patients to be included as part of the TSP. Stroke and death outcomes data in TCAR and CEA patients deemed to be at standard or high risk for complications from CEA will be collected and analyzed using the SVS PSO CAS and CEA Registries.

What is the definition of High Risk and Standard Risk patients?

High surgical risk is defined according to the CMS criteria published in the National Coverage Determination for Percutaneous Transluminal Angioplasty (20.7) and listed in the inclusion criteria. Standard risk patients are all other patients not defined as high risk.

Are TCAR procedures reimbursed by Medicare?

TCAR procedures entered into the SVS PSO CAS registry for the TSP are eligible for reimbursement by Medicare under NCD 20.7 if the patients and facilities meet the requirements set forth in the NCD. The TCAR Registry is listed as an approved registry on the Medicare website (here).

How will follow-up be monitored in the TSP?

The SVS PSO requires one-year follow-up for all CAS and CEA procedures entered into VQI. The TSP Steering Committee will audit the completeness of follow-up data entered into the TSP.

What will be done with TCAR data that is entered into the TSP?

All standard and high surgical risk patients treated with TCAR and CEA in the SVS PSO CAS and CEA Registries will be included and separately analyzed as symptomatic and asymptomatic, with symptomatic defined as a history of ipsilateral stroke, TIA and/or amaurosis fugax within 180 days of the procedure. 30-day and one-year outcomes will be analyzed in propensity matched, risk adjusted cohorts. The TSP steering committee will analyze data with the assistance of SVS PSO statisticians, and will publish and present scientific papers derived from these analyses. De-identified data from VQI registries is also provided to participating hospitals so that they can benchmark their results with other participants.

What technologies/devices can be used in the TSP?

All FDA-cleared proximal embolic protection device and FDA-approved carotid artery stent system indicated for the transcarotid approach will be eligible for use in the TSP.

Who do I contact if I am interested in participating?

To sign up for the VQI or for the TSP, contact vqi@fivos.com or call (603) 298-5509.

Is the TSP limited to vascular surgeons?

No, any specialty is eligible to enter TCAR procedure data into the TSP if the hospital is a participating member of the VQI and has subscribed to the CAS Registry. This also applies to the CEA Registry.

Are there any costs for a hospital to submit TCAR data to CAS Registry?

The SVS PSO charges hospitals for subscription to the CAS and CEA Registries. There is no incremental cost for the hospital to submit data that will be used in the TSP. Hospitals pay an annual fee for access to each registry. Hospitals that are new to the VQI also pay a one-time set up fee.

What are the VQI participation requirements?

There are two contracts plus appropriate Business Associate Agreements (BAAs), one with the SVS PSO and one with Fivos for the Fivos PATHWAYS database management services. All contracting is facilitated through Fivos, and both agreements are required in order to participate in the VQI Registries.

For the VQI CAS and CEA registries, a participating physician must enter all of their TCAR, CAS and CEA Cases. The VQI requires participating sites to submit claims data verifying that all cases have been submitted to the VQI. Centers and physicians may choose to participate in the TCAR/CAS, CEA or both registries.

For each case, participating physicians are also required to document one-year follow-up (any follow-up with the patient at least 9 months after treatment qualifies)

What is an annual claims validation?

On an annual basis, participating sites submit claims data associated with the registries to which they are subscribed a. Claims data are matched with cases that have been entered by the site into the SVS PSO, and any missing cases must be entered by the site. This ensures that all cases have been entered and is a useful confirmation for sites that all cases in the VQI have been billed correctly.