

# Vascular Quality Initiative®

vascularqualityinitiative.org

## TRANS-CAROTID ARTERY REVASCULARIZATION (TCAR) SURVEILLANCE PROJECT

The TCAR Surveillance Project (TSP) is an initiative of the Society for Vascular Surgery Patient Safety Organization (SVS PSO). The TSP is a surveillance registry designed to monitor the safety and effectiveness of transcatheter stents placed directly into the carotid artery while reversing blood flow within the carotid artery to reduce stroke risk. It will compare this less-invasive surgical procedure with standard carotid endarterectomy in centers that participate in the Vascular Quality Initiative (VQI).

### OBJECTIVES OF THE TSP

- Obtain more data about real-world outcomes of TCAR in comparison with CEA as performed by centers participating in the VQI.
- Serve as a repository for TCAR procedures and outcomes data to broaden the evidence base for TCAR.
- Benchmark outcomes against other participants

### PARTICIPATE IN TSP

#### STEP 1

Subscribe to the VQI CAS Registry. Hospitals and physicians participating in the TSP must enter their cases in the VQI CAS Registry. Specific data fields in the web-based electronic data capture system are used to identify TCAR procedures. Contact [vqi@m2s.com](mailto:vqi@m2s.com) for information about how to participate in the VQI.

#### STEP 2

A participating physician must enter all TCAR and CAS data into the VQI CAS registry. The VQI requires participating sites to submit claims data verifying that all cases have been submitted to the VQI. The SVS PSO will audit the completeness of the data entered into the TSP and the follow-up will be monitored by the TSP steering committee.

#### VQI®

The Vascular Quality Initiative is a distributed network of regional groups that use a Patient Safety Organization and the M2S PATHWAYS cloud based system to collect and analyze data to improve the quality of vascular health care.

#### REGIONAL QUALITY GROUPS

Through regional quality group meetings, VQI participants share data to develop quality improvement projects designed to standardize processes, improve outcomes, and reduce complications and costs.

#### SVS PSO

The Society for Vascular Surgery Patient Safety Organizations houses the data registries used by VQI and collaborates with the FDA and medical device companies to evaluate the safety and effectiveness of vascular devices.

#### M2S, INC.

M2S is the technology partner for the SVS PSO, providing the M2S PATHWAYS cloud-based platform for the collection and analysis of clinical quality improvement data.

#### CONTACT US

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### FREQUENTLY ASKED QUESTIONS

#### When does the TSP start?

The current SVS PSO CAS Registry must be revised to capture appropriate data for the TSP, and was planned for revision to better assist the CREST 2 Registry, and to align with the more recently revised CEA Registry. This revision is expected to be completed by late November. TCAR cases that fall within the inclusion criteria to be reimbursed by CMS, under the TCAR Surveillance Project # NCT02850588, must be entered into the new CAS data form to be eligible for reimbursement. If a surgeon performs a TCAR procedure before the new CAS Registry is available, he/she could wait to submit the Medicare claim until after the TCAR procedure is entered into the new CAS Registry. Most payers allow claims to be submitted 3-6 months after a procedure.

#### Are there any costs for a hospital to submit data to the TSP?

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 if they already subscribe to these registries. Hospitals pay an annual fee for access to each registry (currently \$2,300 per year). Hospitals that are new to the SVS VQI also pay a one-time set up fee and then for the modules that they select.

#### What technologies/devices can be used in the TSP?

All FDA-cleared transcarotid proximal embolic protection devices and FDA-approved transcarotid stent systems intended for transcarotid delivery are eligible for use in the TSP.

#### What is the primary outcome measure of the TSP?

The primary outcome measure is one year ipsilateral stroke or death defined as any death or stroke in the territory of the treated carotid artery within one year of the carotid artery treatment.

#### Are there any other outcomes tracked by the TSP?

Yes, the TSP will also track 30-day stroke and death as well as 30-day stroke, death or myocardial infarction. Other outcomes, such as cranial nerve injury and re-intervention will also be reported. These are considered secondary outcome measures.

### VQI REGISTRIES

- Carotid Endarterectomy
- Carotid Artery Stenting
- Open AAA Repair
- Endovascular AAA Repair
- TEVAR and Complex EVAR
- Infra-Inguinal Bypass
- Supra-Inguinal Bypass
- Lower Extremity Amputation
- Peripheral Vascular Intervention
- Hemodialysis Access
- Inferior Vena Cava Filter
- Varicose Vein
- Vascular Medicine Registry\*

\*Soon to be released

### EMR INTEGRATION

The SVS PSO and M2S continue to work with EMR vendors to automatically populate the Registry and streamline the data collection process. We currently have relationships with:

- Medstreaming
- SonoSoft
- mTuitive

We will provide the specifications to any interested EMR vendors.

Ask your EMR vendor if they support the Vascular Medicine Registry.

For more information, or to arrange a one-to-one interactive demonstration, please email [vqi@m2s.com](mailto:vqi@m2s.com) or call the VQI Account Team on (603) 298-5509.