Year in Review

Since May 1, 2018, the Society for Vascular Surgery’s Vascular Quality Initiative (SVS VQI) has added 95 centers, bringing its total membership to 565 centers and over 4,100 physicians (Figure 1). More than 585,000 procedures have been captured in the SVS VQI’s 12 clinical registries, with work in progress on several others. Participants included a wide variety of physician specialties as well as practice types (see Figures 3 and 4). To enhance the value of VQI data to members, there are on-going quality improvement programs in several areas:

Strategic Focus
During 2018/19, the Society for Vascular Surgery Patient Safety Organization (SVS PSO) has identified areas of strategic importance, including the addition of a quality improvement component to the Participation Awards, launch of the Vascular Medicine and Venous Stent registries, introduction of a basic data-entry form for peripheral vascular intervention (PVI) to decrease abstraction by 40%, simplification of the Varicose Vein registry to focus only on the treated leg, and the enhancement of statistical and source data audits.

Quality Charters
In 2018, SVS VQI centers submitted charters across a range of clinical topics, including discharge medications and long-term follow-up. The submission of charters is linked to the Participation Awards. Members presented PI projects at regional meetings and at the VQI Annual Meeting (VQI@VAM, www.vqi.org/quality-improvement/qi-projects).

2019 SVS VQI Participation Awards
This year’s award combines key engagement activities, including long-term follow-up rates, regional meeting attendance, PI projects and registry subscriptions. For the 2019 Awards, which were based on 2018 performance, 197 of 383 eligible centers received one or more stars and are listed on the SVS VQI website under Participation Awards 2019, https://www.vqi.org/about/long-term-follow-up/. At regional meetings, SVS PSO staff presented certificates of achievement to sites that achieved the highest participation level of 3 Stars.

Data Analysis
SVS VQI members can access registry datasets for quality analysis and other projects by submitting an application to the Research Advisory Council (RAC). For 2018/19, 142 national projects were approved by the RAC compared to 89 projects in the prior year, submitted by 81 investigators. An additional 48 projects were approved at the regional level. A total of 76 journal articles were published based on SVS VQI data. Since 2011, 376 national research projects have been approved across all registry datasets and 186 articles have been published (Figure 2). For more details, visit https://www.vqi.org/data-analysis/vqi-publications/.

This year, Dr. Grace Wang was elected vice chair of the RAC. Dr. Wang is a nationally recognized vascular surgeon from the Hospital of the University of Pennsylvania, and is a leader in SVS VQI projects, especially those related to the role of the registry in thoracic aortic device regulatory approval, utilization, and outcomes.

The RAC also began to consider challenging issues regarding analyses related to implantable devices. The new Device Identification Policy, https://www.vqi.org/data-analysis/svs-psos-data-analysis-guidelines-use/, will help ensure the highest quality analytics and appropriate oversight, consideration, and disclosure are applied toward these projects.

Quality Improvement Reporting
The SVS PSO provided several reports, including quarterly Center Dashboards, biannual Regional Reports, Center Opportunity Profile for Improvement (COPI) reports, and the introduction of quarterly status reports on our PI initiatives, discharge medications and EVAR imaging.

National Research Projects
In 2018/19, 81 different investigators initiated 142 research projects (Figure 2), and 76 publications based on SVS VQI data appeared in peer-reviewed journals. A selection of the best SVS VQI papers can be found on the SVS VQI website, https://www.vqi.org/data-analysis/.

Data Quality
To improve the quality of SVS VQI data, the SVS PSO began using a new web-based platform to query centers about possibly inaccurate data values. This effort has so far resulted in the correction or verification of thousands of data points in the Hemodialysis, CAS, CEA and EVAR registries.

FIGURE 1

![Growth in Participating Centers](image1)

FIGURE 2

![VQI Projects](image2)
Launch of Venous Stent Registry
The new Venous Stent registry, scheduled for delivery in the fall of 2019, will collect data on percutaneous and open procedures that use a stent to treat patients with venous obstruction.

INCLUSION CRITERIA
Percutaneous (closed) and/or cut-down (open) procedures to treat patients with symptomatic venous obstructions due to chronic thrombosis and/or venous compression disorders. Vessels included: inferior vena cava, common iliac vein, external iliac vein, common femoral vein, deep femoral vein, femoral vein, and popliteal vein.

- Reflux-Duplex >1.0 for femoral; popliteal and reflux > 0.5 sec. for all other veins
- Acute obstruction of the vein
- Chronic thrombotic obstruction= Chronic stenosis/obstruction of the vein
- Non-thrombotic stenosis/compression such as May Thurner (iliac vein compression syndrome)

EXCLUSION CRITERIA
- Venous Stent of the Internal Iliac (hypogastric), great saphenous vein, superior vena cava, renal veins, Subclavian vein, Jugular vein, Innominate vein and any upper extremity veins
- Vein diameters that are not treatable per stent sizing recommendations
- Veins for which there is not adequate inflow or outflow

The Venous Stent Registry will allow members to:
- Better understand the performance of venous stents
- Analyze procedural and follow-up data
- Benchmark outcomes regionally and nationally
- Participate in regional quality improvement groups
- Reduce costs and improve outcomes by developing best practices
- Help meet board certification for physicians

Launch of Vascular Medicine Registry
The SVS PSO, in collaboration with the Society for Vascular Medicine (SVM), is excited to introduce the Vascular Medicine registry (VascMed) in Quarter 3 2019. This registry will target the management of new outpatient consults who are being treated medically for:

- Atherosclerotic carotid artery occlusive disease
- Abdominal aortic aneurysm
- Lower-extremity arterial disease due to atherosclerotic stenosis or true aneurysm

EXCLUSION CRITERIA
Detailed Exclusion criteria are covered in the new VQI Vascular Medicine Registry flyer, available from M2S at vqi@m2s.com.

The registry will collect data on medication details and dosages, risk factors and lifestyle modifications, non-operative treatments and counseling to help define the natural history of disease processes and the impact of medical management.

Vascular Ultrasound Registry Update
The Vascular Ultrasound registry initial efforts will focus on establishing the technical means to collect and analyze vascular laboratory data associated with the diagnosis and treatment of carotid artery disease. Seven sites have accepted invitation to participate in the pilot and an update will be provided by Medstreaming at 2019 Vascular Annual Meeting (VAM). M2S/Medstream are working with the pilot sites to update software to enable images to be transmitted to the registry.

Changes to forms for PVI and Varicose Vein Registries
In response to customer feedback about the burden of data entry, especially in the outpatient setting, simplified data-entry forms have been developed to minimize data-entry requirements. The Varicose Veins form has been shortened to focus on the treated leg only, and PVI now has two forms, Basic and Comprehensive. The Basic form includes only essential data elements, decreasing data abstraction by 40%, while the Comprehensive form includes device-level details.
New SVS PSO Executive Committee Members
The Executive Committee welcomes two new members following their election – Randall DeMartino from the Mayo Clinic, Rochester, MN, and Leila Murukee from Duke University, Chapel Hill, NC. A full listing of Executive Committee and Governing Council members can be found on the SVS VQI website at https://www.vqi.org/about/svs-patient-safety-organization-pso/svs-pso-governing-council/.

Improving Appropriateness of Care
Appropriateness of care is critically important for both venous and arterial disease. The SVS VQI committee has been working on multiple different approaches including 1) feedback and benchmark reports – Clinical Appropriateness Performance Indicators (CAPI), 2) using RAND Appropriateness Method, and 3) reviewing other society efforts (ACC and ACR). The committee work has been recognized by the SVS which has made the Appropriateness Committee a standing committee within the SVS Quality Council. Most of the SVS PSO committee members were incorporated into this new SVS effort.

Quality Initiatives
In 2018, the SVS PSO introduced a Quality Improvement component to the Participation Awards. For the 2019 awards, centers received points toward their overall star rating for initiating and executing QI projects, and for improving or maintaining high performance on the SVS PSO’s two national QI initiatives, Discharge Medications and Long-Term Follow-Up Imaging after EVAR.

The SVS PSO provided resources to assist the participants in developing a successful project, including group phone calls to allow participants to share experiences and strategies, webinars, one-on-one calls, and sample charters posted on the SVS VQI website. Charters for the 2020 awards will be accepted throughout 2019.

Congratulations to 3 Star Centers
The Participation Awards are a key component of the SVS PSO’s effort to improve quality, and this year, centers that earned the maximum 3 Star rating received special recognition. Each center will be presented with a Certificate of Achievement at its regional meeting and at VQI@VAM, a press release template will be provided so centers can make announcements in their local media.

SVS VQI Centers with 3 Stars in 2018

| Aurora Medical Center, Grafton | McLeod Regional Medical Center | St. Luke’s Regional Medical Center |
| Aurora St. Luke’s Medical Center, Milwaukee | Medical University of South Carolina Hospital | Stony Brook University Medical Center |
| Baylor Jack and Jane Hamilton Heart and Vascular Hospital | Michigan Vascular Center | The Emory Clinic |
| Beth Israel Deaconess Medical Center | Nashville Vascular and Vein Institute | The Heart Hospital Baylor Plano |
| Boston Medical Center | Novant Health Forsyth Medical Center | Thunder Bay Regional Health Science Center (CAN) |
| Charleston Area Medical Center | NYU Langone Medical Center | Toronto General Hospital (CAN) |
| Cleveland Clinic | OSF Saint Francis Medical Center | U Mass Memorial |
| Froedtert Health | ProMedica Toledo Hospital | University of Florida, Gainesville |
| Geisinger Medical Center | Providence Sacred Heart Medical Center | University of Michigan |
| Goshen Hospital | Saint Francis Hospital | University of Minnesota Medical Center Fairview |
| Henry Ford Hospital, Detroit MI | Scott & White Memorial Hospital | University of Rochester Medical Center |
| Iowa Heart Center at Mercy Medical Center | Self Regional Health | University of Utah Hospital and Clinics |
| IU Health - Arnett Hospital | Sentara Careplex Hospital | University of Virginia Health System |
| IU Health - Methodist | Sentara Princess Anne Hospital | West Virginia University Hospital |
| IU Health - Saxony Hospital | Sentara Williamsburg Regional Medical Center | Wexner Medical Center/OSUMC |
| Keck Medical Center of USC | St. Luke’s Allentown Hospital | Winchester Medical Center |
| Maine Medical Center | St. Luke’s Anderson Hospital | Yale-New Haven Hospital |
| Mayo Clinic Hospital - Rochester | St. Luke’s Bethlehem Hospital | |
QI Events and Educational Outreach

Webinar Series
Quarterly webinars were presented in 2018 and 2019. The webinars gave tutorials on QI tools and methodologies, presented case studies by members, and tips on refining project charters.

SVS VQI Website Update
The website has been restructured to provide more up-to-date information on QI activities, SVS VQI data analysis related to quality projects, and activities with SVS VQI industry partners. In addition to a new Home page, there are new dedicated sections for these areas, as well as a Contact page so members can find the right SVS VQI contact.

Member Guide Update
This Guide has been updated with more detail on the Participation Awards and changes to Data Analysis guidelines for use of SVS VQI datasets, including guidelines related to use of device-related data and access to industry project data.

Regional Bi-Annual Meetings
There are 18 Regional Study groups that host bi-annual meetings. The meetings provide an excellent opportunity to review outcomes, share best practices and work on quality improvement projects. Each Regional Group runs both a Spring and Fall Meeting, organized by the Regional Leader and the SVS PSO.

SVS VQI Annual Meeting
The VQI@VAM meeting, co-located with the Vascular Annual Meeting, is geared toward data managers and abstractors and provides continuing education on vascular and quality improvement topics as well as SVS VQI updates. Members have provided positive feedback for both the in-depth registry sessions, the introduction of the Poster Networking Session and case study presentations.

SVS VQI News (e-newsletter)
This e-newsletter, written by SVS PSO Quality Director Cheryl Jackson (cjackson@svspso.org), is distributed every other month and provides information on regulatory issues and technical updates.

SVS VQI Quality Improvement (e-newsletter)
This bimonthly e-newsletter, also written by Cheryl Jackson, focuses on advice for centers on how to start and maintain quality improvement activities using SVS VQI data.

Technology Improvements Through M2S

Registry Revisions
- In September, a core set of variables were made mandatory on long-term follow-up forms. Compliance with the mandatory fields is now part of the LTFU calculation for each registry.
- A new 30-Day Follow-Up form was added for the CEA, EVAR, INFRA, TEVAR, LE AMP, PVI, CAS, OPEN and SUPRA registries.
- Revisions to the PVI registry were completed. The registry now includes two options for capturing PVI procedures, a basic and a comprehensive version. The current PVI registry, or Comprehensive PVI, remains relatively unchanged, and the new Basic PVI is an abbreviated version to expedite data entry. Comprehensive PVI remains the most appropriate option for most SVS VQI centers, as it provides the most meaningful data collection.
- Minor updates were made to several registries to capture the latest medical devices that are commercially available.

Two-factor authentication for PATHWAYS
An extra layer of security is now available to SVS VQI participants when logging in to PATHWAYS. Once enabled, users can access a smart phone app to receive a second-factor security code before logging in. Alternatively, users can opt-out of using the multi-factor security feature of each session and set the verification requirements for every 30-days.

PATHWAYS Customer Support Ticketing System
This year, M2S introduced a new ticketing system to improve service to SVS VQI members. The new system provides an automated response to confirm that an email was received and allows the PATHWAYS Support Team to triage and prioritize requests, and more efficiently route inquiries.
Outcomes Reporting and Data Audits

Regional Reporting
In 2019, the SVS PSO will continue to expand its outcomes reporting via Share-A-File. This year the SVS PSO has added three reports to its biannual Regional Reports that are based on SVS guidelines for EVAR and OAAA. These reports look at the rate of elective EVAR cases performed on men and women with AAA diameters >=5.5 cm and >=5.0cm, respectively; the rate of OAAA cases in which flow to the internal iliac artery is maintained; and the rate of OAAA cases in which cell salvage or an ultrafiltration device was used.

Quarterly Dashboards
The SVS PSO also will deliver quarterly Dashboard reports to all member centers. These reports will include approximately 20 outcomes per registry and allow centers to compare their performance to regional and national benchmarks.

System-Level Reporting
The SVS PSO has developed system-level reports it will begin to release to its hospital systems members, and will continue to provide centers with updates each quarter on their performance on the SVS PSO’s two quality initiatives — Discharge Medications and Long-term Follow-up Imaging after EVAR.

AAA Guidelines Reporting
New reports, demonstrating center compliance with SVS AAA guidelines, were developed and included in the SVS PSO’s Regional semi-annual benchmarking reports. The impact of compliance on outcomes will be used as a reference emphasizing the importance of adherence to specific guidelines.

Data Audits
This year, the SVS PSO will begin auditing entire case records at selected centers to assess and improve the accuracy of SVS VQI data entry. Centers will be randomly selected for audit, with every center guaranteed to be audited once every three years. Centers selected for audit in 2019 will be notified beforehand, told of the audit requirements and provided support during the process.

SVS VQI Member Characteristics

FIGURE 3

VQI Physician Specialty Distribution

FIGURE 4

Types of Affiliation, VQI Centers
SVS VQI ACTIVITY WITH EXTERNAL STAKEHOLDERS

MEDICAL DEVICE MANUFACTURER PROJECTS

SVS VQI TransCarotid Revascularization Surveillance Project (TSP)
This project is designed to compare the performance of trans-carotid artery revascularization (TCAR) with the standard of care, carotid endarterectomy. The comparison will be based primarily on stroke and death in-hospital and at one year. In September 2016, CMS approved reimbursement for physicians and centers that perform TCAR procedures on both symptomatic and asymptomatic medical high-risk patients, provided that those procedures and follow-up are entered the SVS VQI CAS registry. Enrollment into the project has been strong, with 250 centers entering 6,307 of TCAR procedures as of April 30, 2019. In 2018, the SVS PSO Steering Committee provided CMS with preliminary findings and will continue to make periodic data analyses as more data are collected.

TEVAR Dissection Project
The purpose of the thoracic endovascular aortic repair (TEVAR) for dissection project is to assess the effectiveness of TEVAR for type B dissection by evaluation in a prospective quality improvement registry. This project, initiated in 2014, has demonstrated the value of expanding surveillance to real-world device performance while meeting FDA requirements, with faster patient enrollment compared to traditional study methodology. In partnership with Gore and Medtronic, the SVS PSO and M2S completed enrollment of the five-year cohort with annual follow up continuing for five years, and the one-year cohort of 200 patients otherwise recorded in the TEVAR registry. Discussions are underway to incorporate the Cook TEVAR device into this project.

Bard LifeStent® Popliteal Artery Stent Project
This post-approval surveillance project is designed to further evaluate the Bard LifeStent® for treatment of popliteal artery atherosclerosis. It will enroll 74 patients with two-year follow-up and remains open for patient recruitment. The study has enrolled 51 of the planned 74 patients with 28 sites participating.

Medtronic IN.PACT Admiral DCB ISR Project
This post-approval surveillance project is designed to confirm that IN. PACT Admiral drug-coated balloons are safe and effective for treatment of in-stent restenosis lesions in the superficial femoral and popliteal arteries. In April, the study reached a milestone, enrolling 200 of the planned 300 patients and will continue follow-up out to three years. The study, which is a collaboration between the SVS VQI, industry and the FDA, includes 50 SVS VQI centers so far and remains open for further member participation.

COLLABORATIVE PROJECTS WITH OTHER ORGANIZATIONS

Registry Assessment of Peripheral Intervenational Devices (RAPID)
RAPID is a public-private partnership between the FDA, professional societies (SVS, ACC, SIR), academia, industry, payers, and others to support a national medical-device evaluation system. Phase 1 developed a minimum core dataset (100 common data elements (CDE) - with agreed upon definitions). Phase 1 also recommended incorporation of GUDID into the registries. In Phase 2 in September 2017, the CDE's were incorporated into SVS VQI. SVS VQI data was used to develop objective performance goals (OPG) for contemporary interventional treatment of SFA-popliteal arteries. A manuscript on the superficial popliteal evidence development is in preparation with the goal of providing historical controls and OPG’s for the treatment of occlusive disease of the superficial femoral and popliteal artery using balloon angioplasty, stents, and atherectomy. In Phase 3, RAPID plans a device-evaluation project, such as a registry-based observational project, safety surveillance project, or a registry-based randomized clinical trial. These projects could demonstrate the value of a registry for regulatory decision making.

International Consortium of Vascular Registries (ICVR)
SVS VQI and 11 other national vascular registries from Europe and Australasia combine data to analyze variation in treatment of peripheral vascular disease across countries. Current projects are analyzing volume-outcome relationships and variations between countries for carotid and AAA treatment, as well as developing a core dataset for future PAD projects. A project to evaluate EVAR devices used to treat ruptured AAA is underway. The fall ICVR meeting was used for an in depth discussion of the new EU data privacy rules and medical device reporting, which may have international implications for industry and regulatory agencies.

CREST-2 Registry
This randomized controlled clinical trial compares CEA and CAS to best medical therapy. Investigators use SVS VQI to report CAS procedures to become qualified for this trial and then report non-randomized procedures during the trial. This year more than 90 interventionists used SVS VQI to report more than 800 CAS procedures for the CREST-2 Registry project.
Ongoing Registry the Society for Vascular Ultrasound, two representatives from Society for Vascular Surgery, one representative in the arterial registries. Members include a chair and vice chair, two serves as a reference catalog for every device with a unique device Database (GUDID), a database administered by the FDA that (PVI) and Hemodialysis Access registries.

focus on vascular patients. The group's mission is to develop recom-

University of Michigan to address the national opioid epidemic with a • The AQC has formed a new work group led by Dr. Peter Henke of the • Veins for which there is not adequate inflow or outflow • Vein diameters that are not treatable per stent sizing recommend-

nate vein and any upper extremity veins • Chronic thrombotic obstruction= Chronic stenosis/obstruction of the • Acute obstruction of the vein • other veins • Reflux=Duplex >1.0 for femoral; popliteal and reflux > 0.5 sec. for all deep femoral vein, femoral vein, and popliteal vein.

INCLUSION CRITERIA to treat patients with venous obstruction.

will collect data on percutaneous and open procedures that use a stent temporary filters • Finalized specifications for revisions to the Varicose Vein registry, which • Development of venous data for appropriateness • Members

VQC Update

Forum.

Three members including the chair are appointed by the American Venous Ultrasound, plus representatives from each regional vascular quality group.

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Existing SVS VQI Centers and Health Systems (as of 4/30/19)
YEAR IN REVIEW 2018/2019

Memorial Hermann South Texas (TX)
Memorial Hermann Sugar Land (TX)
Memorial Hermann The Woodlands (TX)
Memorial Hospital of South Bend (IN)
Memorial Hospital of Peoria (IL)
Memorial Hospital West (FL)
Memorial Hospital West Palm Beach (FL)
Memorial University Health Center - South Carolina (SC)
Memorial University Health Center - South Carolina (SC)
Memorial University Health Center - South Carolina (SC)
Memorial University Medical Center - Savannah (GA)
Memorial Hermann Memorial Hermann Surgical Center (TX)
Memorial Hermann Katy (TX)
Memorial Hermann Memorial City Medical Center (TX)
Memorial Hermann Northeast Hospital (TX)
Memorial Hermann Southeast Houston (TX)

Existing SVS VQI Centers and Health Systems (as of 4/30/19) cttd.

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