Executive Summary

2019 and early 2020 have been an exciting time in the world of vascular surgery. It has been another successful year for the Society for Vascular Surgery's Vascular Quality Initiative (SVS VQI). We are pleased to report SVS VQI has added 111 centers, bringing its total membership to 676 centers and over 4,700 physicians. More than 704,000 procedures have been captured in the SVS VQI's 14 clinical registries.

The big issue in 2020 is COVID-19. All of our personal and professional lives have been disrupted by this pandemic. COVID-19 will impact SVS VQI data collection for procedure, long-term follow-up and claims validation. SVS VQI is working with centers to minimize the impact as well as accommodate the disruptions in workflow. The SVS PSO has also caused a COVID taskforce and will be implementing COVID variables in the SVS VQI registries. All the Spring 2020 regional meetings were held as remote meetings with presentations and web attendance. Decisions regarding Fall 2020 regional meetings will be made by each region.

Another significant issue in vascular surgery in 2019 was the Paclitaxel controversy. A meta-analysis by Katsanos et al reported an increase in late mortality in patients being treated with devices using Paclitaxel technology. This report initiated a flurry of investigations aimed at determining the role of Paclitaxel devices in late mortality. As it turns out, SVS VQI is the only clinical registry that records device specific identification, i.e. a Paclitaxel drug coated balloon or Paclitaxel drug eluting stent. This granular clinical detail has allowed SVS VQI to perform a detailed analysis that has contributed to the discussion on the impact of Paclitaxel. We plan to continue to use SVS VQI data to further analyze this concerning relationship.

In 2019, SVS VQI began a process to integrate Data Extraction and Longitudinal Trend Analysis (DELTA) into our database. DELTA is an open source software application that is designed to detect early signal discernment. DELTA was developed by Frederic Resnic, an interventional cardiologist at Lahey Clinic, Boston, MA, and has been used to detect failure of ventricular pacemaker leads and vascular closure devices. We have used DELTA to analyse SVS VQI Paclitaxel patients (no adverse mortality was seen at 17 months) and plan further projects with more patients and longer follow-up.

SVS VQI has recently released two new registries, Venous Stent released in October 2019 and Vascular Medicine Consult registry released in February 2020. The Venous Stent registry records patients who have undergone placement of a venous stent for venous obstructive disease in the femoral vein, iliac vein and inferior vena cava.

The Vascular Medicine Consult registry records patients with abdominal aortic aneurysms, carotid stenosis, and lower extremity occlusive disease who are being managed medically. This registry will help us learn about the natural history of these diseases as well as the outcome of medical management. Other than vascular medicine specialists, we hope to have participation from medical colleagues in cardiology, internal medicine and other primary care specialties.

In 2019/20, 74 different primary SVS VQI investigators initiated 187 new research projects, and 129 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/.

To further enhance the value of SVS VQI data to members, there are on-going quality improvement programs in several areas.

Strategic Focus

During 2019/20, the Society for Vascular Surgery Patient Safety Organization (SVS PSO) has identified areas of strategic importance, including:

- EMR integration with Cerner and EPIC
- New reporting and analytics for SVS VQI members
- Long term claims-matched reports (EVAR first pilot)
- Standard operative notes (CEA first pilot)
- Collaboration with SVS Clinical Practice Guidelines with SVS VQI data
- Source data audits

FIGURE 1

Growth in Participating Centers

SOURCE: M2S PATHWAYS
Current Registry Development/Revisions

- Hemodialysis Access Revisions: Released Q4 2019
- NEW Venous Stent Registry: Released in Q4 2019
- Varicose Vein Revisions: Released in Q1 2020
- NEW Vascular Medicine Registry: Released in Q1 2020 (collaboration with SVM and AHA)
- 2020 Planned Revisions: Open AAA
- NEW 2020 Addition of COVID variables

Launch of Venous Stent Registry
The new Venous Stent Registry, launched in Quarter 4 2019, will collect data on percutaneous and open procedures that use a stent to treat patients with venous obstruction. This registry is designed to collect data on patient undergoing stent placement in the inferior vena cava, common iliac vein, external iliac vein, common femoral vein, deep femoral vein, femoral vein, and popliteal vein for obstruction due to thrombosis or compression.

Launch of Vascular Medicine Consult Registry
The SVS PSO, in collaboration with the Society for Vascular Medicine (SVM) and the American Heart Association (AHA) introduced the Vascular Medicine Consult registry (VMC) in Quarter 1 2020.

INCLUSIONS
New Outpatient Consults who are being treated medically for peripheral arterial disease due to atherosclerosis, atherosclerotic carotid artery occlusive disease, or abdominal aortic aneurysm.

EXCLUSIONS
- Evaluation/diagnosis of pseudo or neurogenic claudication, peripheral arterial disease due to trauma, popliteal entrapment, medial adventitial cystic disease, chronic compartment syndrome
- Carotid disease due to dissection, infection, aneurysm, tumor, isolated common carotid lesion not thought to involve the bifurcation, disease of the carotid bifurcation due solely to vasculitis, Moyamoya disease, and fibromuscular dysplasia
- Isolated aortic dissection without aneurysm
- Thoracic, thoraco-abdominal, and mycotic aneurysms

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

COVID-19
The COVID-19 pandemic is having a far-reaching global impact affecting geopolitical, financial and medical institutions worldwide. To paraphrase the great physicist Richard Feynman, “we cannot understand what we cannot measure”.

The SVS PSO has begun the process of measuring COVID-19’s impact on our patients through a survey of SVS VQI physicians and data managers. Our goal is to incorporate COVID-19 variables into the registries. The following variables will be added for an undetermined amount of time. Help text will be provided when released.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>COVID status at time of procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0=Unknown, not tested; 1=Tested negative pre-op; 2=Tested positive pre-op but positive post-op</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure</th>
<th>COVID symptoms pre-procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1=Asymptomatic, 2=Symptomatic, not intubated, 3=Symptomatic, intubated</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Treatment delay by pandemic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0=None, 1= Delayed &lt; 2 weeks, 2=Delayed 2-6 weeks, 3=Delayed, &gt; 6 weeks, 4=Uncertain</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Impact of delay in treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0=None-Mild worsening, 1=Moderate worsening, 2= Severe worsening, 3=Indeterminate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>30 Day and LTFU</th>
<th>COVID status after D/C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0=Tested negative, 1=Tested positive, 2=Unknown, not tested</td>
</tr>
</tbody>
</table>
SVS PSO Quality Councils and Committees

Arterial Quality Council (AQC)
The mission of the AQC is to maximize the value of the data collected in the arterial registries. Members include a chair and vice chair, two representatives from the Society for Vascular Surgery (SVS), one representative from the Society of Interventional Radiology (SIR), two representatives from the Society for Vascular Ultrasound (SVU), two representatives from the Society for Vascular Medicine (SVM), plus representatives from each regional vascular quality group.

AQC Update
- Opioid Workgroup formed and charged with putting forth recommendations on how the SVS VQI can be used to track, monitor and benchmark opioid utilization. Pilot planned with Infra-Inguinal Bypass registry.
- Continued refinement to Global Unique Device Identification Database (GUIDID) integration in PVI
- Initiating future registry updates
  - Harmonizing common variables across all registries
  - Updating INFRA/SUPRA registries
  - Updating Open Abdominal Aortic Aneurysm (OAAA) registry
- Structured Notes: Use the structured note as a standard for all providers, hospitals, EMRs, societies, and registries to be used as a template
  - Pilot Carotid Endarterectomy (CEA) registry
  - The SVS and SVS VQI have embarked on an effort to create standardized structured notes. The idea is to use the structured note as a standard for all hospitals, EMR’s, etc. to be used as a template for the future. We hope that we can get buy in from all stakeholders.
  - CEA experts from all stakeholders including SVS, the Society for Thoracic Surgeons, Society of NeuroInterventional Surgery, and American College of Surgeons, Vascunet, SVS Document Oversight committee, SVS Clinical Practice Council, SVS PSO operations, EPIC, Cerner and MedStreaming/M2S (SVS VQI technology partner).

Venous Quality Council (VQC)
The mission of the VQC is to maximize the value of the data collected in the venous registries. Members include a chair and vice chair, two representatives from SVS, one representative from the Society of Interventional Radiology, two representatives from the Society for Vascular Medicine, two representatives from the Society for Vascular Ultrasound, plus representatives from each regional vascular quality group. Three members including the chair are appointed by the American Venous Forum.

VQC Update
- Council Transition: Dr. Marc Passman appointed as new Chair for 2020
- Continued Interest from United Healthcare on collaborating on Appropriateness for ablations.
- Formation of Venous RAC Chair: Nicholas Osborne, MD

For the full list of Council members, please see the Data Analysis section of the SVS VQI website, https://www.vqi.org/data-analysis/research-advisory-council/

- “COVER”: Consortium Of VEnous Registries
  - Stakeholders:
    - Society for Vascular Surgery Vascular Quality Initiative (SVS VQI)
    - American Venous Forum (AVF)
    - American Vein & Lymphatic Society (Patient Reported Outcome Registry (AVLS PRO))
    - Medical Device Epidemiology Network (MDepiNet)
    - Food and Drug Administration (FDA)
    - Venous industry partners
  - Objectives: To combine resources, talent and information of SVS VQI and AVLS PRO registries to promote better understanding of optimal treatment of superficial venous disease by harmonizing data elements for interoperability

New SVS PSO Executive Committee Members and Associate Medical Directors
The SVS PSO Executive Committee welcomes one new member, Dr. Yazan Duwayri from The Emory Clinic, Atlanta, GA. The SVS PSO Executive Committee has also appointed two part-time Associate Medical Directors, reporting to Dr. Jens Eldrup-Jorgensen, SVS PSO Medical Director – Dr. Leila Mureebe from Duke University and Dr. Gary Lemmon from IU Health. A full listing of Governing Council members can be found on the SVS VQI website at https://www.vqi.org/about/svs-patient-safety-organization-psosps-governing-council/.

AAA Guidelines
In January 2018, the SVS published Clinical Practice Guidelines on the management of AAA, and the SVS Document Oversight Committee has engaged the SVS PSO to help assess compliance with and impact of these measures using data from the SVS VQI Open AAA and Endovascular AAA registries. Findings were presented at the Charing Cross meeting in London, April 2019, and also at SVS Vascular Annual Meeting (VAM) in June 2019 and published in the Journal of Vascular Surgery (https://www.sciencedirect.com/science/article/abs/pii/S0741521419326540). Compliance with guidelines especially those with high levels of evidence, 1A and 1B, were found to be high and associated with improved outcomes. SVS VQI was found to be a valuable tool for assessment of compliance with guidelines. SVS VQI reports provide an objective assessment of performance and compliance with guidelines. SVS VQI provider and center reports may be used as a focus for quality improvement efforts. Pertinent findings and the implications of guideline compliance will be incorporated into regional reports and presented at Regional meetings.

Claudication Guidelines
In a similar manner, SVS VQI registries, PVI, INFRA and SUPRA, were used to measure compliance with SVS claudication guidelines. The preliminary findings were summarized in an abstract, “Lack of Adherence to SVS Grade 1A Guidelines in Patients Undergoing Peripheral Vascular Intervention”. The authors found significant lack of compliance with SVS guidelines – less than half of patients received optimal medical therapy (OMT), a 1A guideline, prior to peripheral vascular intervention for claudication. The study suggests increased awareness and compliance with SVS guidelines may benefit patient outcomes.
Quality Initiatives

The main focus for quality initiatives is to encourage centers to use their registry data. Centers are asked to review the many and varied SVS VQI reports that are released during the course of the year, and use the SVS guidelines and recommendations to compare their data to regional and national benchmarks in order to decide if they need to develop and implement a quality improvement project. The SVS PSO provides resources to assist 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. In 2019, 38 new charters were submitted for quality improvement projects.

In 2018, the SVS PSO introduced a Quality Improvement component to the SVS VQI Participation Awards. For the 2019 awards, eligible 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.

Quality Charters

In 2019, 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 SVS VQI Participation Awards. Members presented QI projects at regional meetings and at the 2019 VQI Annual Meeting (www.vqi.org/quality-improvement/qi-projects).

2019 SVS VQI Participation Awards

In an attempt to recognize centers with meritorious performance, SVS VQI has established an award system. The award combines key engagement activities, including long-term follow-up rates, regional meeting attendance, QI projects, and registry subscriptions. The 2019 Awards were released in March 2020 showed209 of 469 eligible centers received one or more stars and are listed on the SVS VQI website under Participation Awards 2019, (https://www.vqi.org/wp-content/uploads/Participating-Awards-2019-Listings.pdf). The SVS PSO staff presented certificates of achievement to sites that achieved the highest participation level of 3 Stars at the Spring and annual SVS VQI meetings in 2019.

Quality Improvement Reporting

The SVS PSO provides regular performance reports, including quarterly Center Dashboards, semiannual Regional Reports, and the introduction of quarterly status reports on our QI initiatives, discharge medications and Long-Term Follow-Up for EVAR imaging.

Congratulations to 3 Star Centers

The SVS VQI Participation Awards are a key component of the SVS PSO’s effort to improve quality, and this year, 45 centers earned the maximum 3-Star rating received special recognition. Each center will be presented with a Certificate of Achievement at its Regional meeting. a press release template will be provided so centers can make announcements in their local media.

SVS VQI Centers with 3 Stars in 2019

Baylor Jack and Jane Hamilton Heart and Vascular Hospital (TX)
Baystate Medical Center (MA)
Beth Israel Deaconess Medical Center (MA)
Borgess Hospital (MI)
Boston Medical Center (MA)
Cleveland Clinic (OH)
Froedert Health (WI)
Goshen Hospital (IN)
IU Health - Methodist (IN)
Mayo Clinic Hospital - Rochester (MN)
McLeod Regional Medical Center (SC)
Medical University of South Carolina Hospital (SC)
MercyOne Des Moines Medical Center (IA)
Mission Hospital (NC)
Nashville Vascular and Vein Institute (TN)
Northwestern Memorial Hospital (IL)
OSF Saint Francis Medical Center (IL)
OSUMC/Wexner Medical Center (OH)
Pima Vascular (AZ)
ProMedica Toledo Hospital (OH)
Providence Medford Medical Center (OR)
Roper St. Francis (SC)
Sanford Vascular Associates (SD)
Scott & White Memorial Hospital (TX)
Self Regional Health (SC)
St. Luke’s Hospital - Allentown Campus (PA)
St. Luke’s Hospital - Bethlehem Campus (PA)
St. Luke’s Regional Medical Center (ID)
St. Vincent Healthcare (MT)
Stanford Hospital & Clinics (CA)
The Emory Clinic (GA)
The Heart Hospital Baylor Denton (TX)
The Heart Hospital Baylor Plano (TX)
The University of California Irvine (CA)
Toronto General Hospital (ON, Canada)
UC Davis Health System (CA)
UCLA Ronald Reagan Medical Center (CA)
University of Florida, Gainesville (FL)
University of Michigan (MI)
University of Rochester Medical Center (NY)
University of Utah Hospital and Clinics (UT)
University of Virginia Health System (VA)
West Virginia University Hospital (WV)
Winchester Medical Center (VA)
Yale-New Haven Hospital (CT)
QI Events and Educational Outreach

Webinar Series
Quarterly webinars were presented in 2019 and 2020. 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 provides up-to-date information on QI activities, SVS VQI data analysis related to quality projects, and activities with SVS VQI industry partners. We’ve added information on new Venous RAC and submission process in the Data Analysis section. See www.vqi.org.

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. Click here to see the Member Guide in the Resource section of the SVS VQI website, https://www.vqi.org/wp-content/uploads/Member-Guide-2019-FINAL-2.12.20-for-web-1.pdf

2020 Vascular Annual Meeting (VAM) and VQI@VAM
Unfortunately, the SVS had to make the difficult decision to cancel the VAM and the VQI Annual Meeting. As an alternative, we are offering a virtual education experience in place of the VQI Annual Meeting, “VQI ONLINE”. While we will try to retain much of the format and content similar to past VQI@VAM, we want to ensure we are providing the most compelling information in an engaging online format. The education will be provided in one to two-hour sessions over the course of six weeks, beginning the week of June 22nd (https://www.vqi.org/resources/vqi-annual-meeting/).

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.

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). Project analysis can be done at either the regional or national level. For 2019/2020, 187 national projects were approved by the RAC compared to 142 projects in the prior year, submitted by 74 investigators. An additional 49 projects were approved at the regional level. A total of 129 journal articles was published over the year based on SVS VQI data.

Since 2011, 566 national research projects have been approved across all registry datasets and 288 articles have been published. For more details, visit https://www.vqi.org/data-analysis/vqi-publications/.

Due to the volume of proposals and the introduction of the Venous Stent Registry, the Executive Committee and the National RAC have created a new Venous RAC, chaired by Dr. Nicholas Osborne. We look forward to increasing the volume of venous proposals under the new Venous RAC.

The RAC continues to monitor projects related to implantable devices and pharmaceutical products. The new Product Identification Policy, https://www.vqi.org/wp-content/uploads/VQI-Device-Identification-Policy_final-1.pdf, ensures the highest quality analytics and appropriate oversight, consideration, and disclosure are applied toward these projects.

FIGURE 2

SVS VQI Physician Specialty Distribution

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular Surgery</td>
<td>47%</td>
</tr>
<tr>
<td>Radiology</td>
<td>15%</td>
</tr>
<tr>
<td>Cardiology</td>
<td>15%</td>
</tr>
<tr>
<td>General Surgery</td>
<td>7%</td>
</tr>
<tr>
<td>Other</td>
<td>6%</td>
</tr>
<tr>
<td>Cardiothoracic Surgery</td>
<td>5%</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>4%</td>
</tr>
<tr>
<td>None</td>
<td>3%</td>
</tr>
</tbody>
</table>

Physician Specialty %

47%  
15%  
15%  
7%  
6%  
5%  
4%  
3%

Total 100%

SVS VQI Year in Review Graphs

<table>
<thead>
<tr>
<th>Year</th>
<th>Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>100</td>
</tr>
<tr>
<td>2011</td>
<td>150</td>
</tr>
<tr>
<td>2012</td>
<td>200</td>
</tr>
<tr>
<td>2013</td>
<td>250</td>
</tr>
<tr>
<td>2014</td>
<td>300</td>
</tr>
<tr>
<td>2015</td>
<td>350</td>
</tr>
<tr>
<td>2016</td>
<td>400</td>
</tr>
<tr>
<td>2017</td>
<td>450</td>
</tr>
<tr>
<td>2018</td>
<td>500</td>
</tr>
<tr>
<td>2019</td>
<td>550</td>
</tr>
<tr>
<td>2020</td>
<td>600</td>
</tr>
</tbody>
</table>

VQI Projects
Outcomes Reporting and Data Audits

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 data points in the Hemodialysis, CAS, CEA and EVAR registries. SVS PSO also engaged a third-party auditor, Q-Centrix, to do source data auditing. The analysis of source data is underway, and we plan to audit one third of sites every year. To learn more about our data quality efforts see this link on our website, https://www.vqi.org/about/importance-of-data-accuracy/

Regional Reporting
In 2020, the SVS PSO will continue to expand its outcomes reporting. This year the SVS PSO has added/revised four reports to its semiannual Regional Reports:

- Transfemoral Carotid Artery Stent (CAS): Stroke or Death in Hospital
  - Rate of in-hospital stroke or death for Transfemoral CAS procedures performed on asymptomatic patients
- TransCarotid Artery Revascularization (TCAR): Stroke or Death in Hospital
  - Rate of in-hospital stroke or death for TCAR procedures performed on asymptomatic patients
- Carotid Endarterectomy (CEA): Symptomatic Stroke or Death in Hospital
  - Rate of in-hospital stroke or death for CEA procedures performed on asymptomatic patients
- Carotid Endarterectomy (CEA): Percentage of Symptomatic Patients with LOS > 1 Day
  - Percent of CEA procedures (performed on symptomatic patients) where LOS > 1 Day

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

System-Level Reporting
The SVS PSO continues development on system level reports to release to its hospital systems members.

VISION Survival, Reintervention, and Surveillance (SRS) Reports
The Vascular Implant Surveillance and Interventional Outcomes Network (VISION) is a partnership between SVS VQI and MDEpiNet. VISION provides long term follow up for SVS VQI patients via claims matching with the CMS database. This enhanced follow-up extends indefinitely beyond the one year follow-up recorded in SVS VQI. Longer follow-up provides better evaluation of patient outcomes that is critical for vascular care. VISION has produced a new report which focuses on the care provided to patients who underwent Endovascular Aortic Aneurysm Repair (EVAR). The SRS reports show a center’s five-year outcomes for EVAR in comparison to the SVS VQI overall and will be available in the Spring of 2020. VISION will also be used to evaluate Paclitaxel and other vascular devices.

Data Accuracy
The SVS PSO continues to audit entire case records at randomly selected centers to assess and improve the accuracy of SVS VQI data entry. Centers were randomly selected for audit, with every center guaranteed to be audited once every three years. Centers selected for audit are notified beforehand, told of the audit requirement, and provided support during the process.

- PATHWAYS Audit Tool: done via SVS PSO staff using the PATHWAYS platform
- Third Party Source Data Audits: Q-Centrix

SVS VQI Member Characteristics

**FIGURE 3**

SVS VQI Physician Specialty Distribution

**FIGURE 4**

Types of Affiliation, SVS VQI Centers
MEDICAL DEVICE MANUFACTURER PROJECTS

The TCAR Surveillance Project
This project is designed to compare the performance of trans-carotid artery revascularization (TCAR) with the standard of care, carotid endarterectomy. The primary comparison will be 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 into the SVS VQI CAS registry. Enrollment into the project has been strong, with 364 centers entering 12,143 of TCAR procedures as of April 30, 2020. In 2019, the SVS PSO Steering Committee provided CMS with preliminary findings and will continue to make periodic data analyses as more data are collected.

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 February, the study reached a milestone, and met enrollment of 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, completed enrollment (N= 300) in January of 2020 and is focusing on long-term follow-up of mortality. The SVS VQI is considering mechanisms to extend this follow-up out to five years.

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 ups continuing for five years, and the one-year cohort of 200 patients otherwise recorded in the TEVAR registry. Cook was added to the project in late-2019 and recruitment was commenced.

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. The study has reached the projected enrolled of 74 patients studying 76 limbs with 29 sites participating. The project will continue follow-up out to two years.

Paclitaxel (PTX) Projects
As mentioned, concerns have been raised about the long-term implications of Paclitaxel devices.
- December 2018 - Katsanos meta-analysis reported increased mortality with Paclitaxel devices at 2-5 years.
- SVS VQI used Data Extraction and Longitudinal Trend Analysis (DELTA), a risk-adjusted software application designed for signal detection in clinical registries, to evaluate mortality of Paclitaxel devices in PVI registry (see Figures below)
- Full details about the study are available at clinicaltrials.gov under the identifier NCT04110288.

No Difference Mortality in VQI– Balloon vs DCB


Full details about the study are available at clinicaltrials.gov under the identifier NCT04110288.
SVS VQI ACTIVITY WITH EXTERNAL STAKEHOLDERS (Cont.)

COLLABORATIVE PROJECTS WITH OTHER ORGANIZATIONS

Registry Assessment of Peripheral Interventional Devices (RAPID)
RAPID is a public private partnership that includes clinical registries such as the SVS VQI and ACC NCDR, federal regulators, industry and academia. RAPID has developed objective performance goals for femoral popliteal interventions based on device type (angioplasty, stenting, atherectomy and all treatment type). “RAPID Objective Performance Goals for Superficial Femoral and Popliteal Artery Peripheral Vascular Interventions” manuscript is currently undergoing peer review and is expected to inform more efficient peripheral device clinical trial designs to support regulatory and clinical 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. In 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.

Technology Improvements through M2S

Registry Updates
- New patient-level data field was introduced to capture Medicare Beneficiary Identifier (MBI)
- PATHWAYS Hospital Managers were given expanded access to account permissions providing additional controls for more efficient user access management
- Minor updates were made to the TEVAR registry, including the addition of a new data field (Relation to Prior Dissection), updated help text and field dependencies
- The Endovascular AAA Repair (EVAR) registry added fields to collect closure device details for right/left access and changed post-op complications fields to be access side specific
- The Infra-inguinal and Supra-inguinal Bypass registries added fields related to groin incision to capture more granular information
- The SVS VQI 30-day follow-up was added for the Hemodialysis Access and Venous Stent registries, providing centers with the ability to capture CMS required 30-Day re-admission data and post-discharge short-term outcomes.
- GUDID device lists were refreshed (PVI and Hemodialysis Access)
- Manual dropdown device list updates were implemented for PVI, EVAR, TEVAR, and CEA registries
- New drilldown feature for the Long-term Follow-up (LTF) Completion Rate by Procedure Report was introduced to help members better understand calculated LTF rates
- PVI registry was updated with a barcode scanner feature to capture device information by scanning the device label to import the GUDID code directly into PATHWAYS

Industry Support

Quality Champions
BD
BARD

Quality Partners
Boston Scientific
Gore

Quality Associates
Abbott Vascular
Cook Medical
Getinge
Medtronic

KCI
Existing SVS VQI Centers and Health Systems (as of 4/30/20) ctd.