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The mission of VQI is to improve the quality of vascular care using a data driven approach but sometimes things happen. In 2020, COVID-19 got in the way and then didn’t go away. VQI had to learn how to continue operations in the face of multiple obstacles and we had to learn about the impact of COVID-19 on vascular patients. As has been said, in adversity there is opportunity. Many VQI centers learned that important follow up could be done by telemedicine accurately and efficiently. COVID-19 variables were added to the registries so that we could see the influence on vascular procedures and determine the incidence of conversion while hospitalized. VQI also learned that virtual or remote regional meetings had many advantages. Attendance was markedly increased due to the lack of necessity for travel – reducing the time commitment and expense. Regional medical directors adapted to the virtual format encouraging participation and interaction with online attendees. The virtual meetings were considered to be an unqualified success. VQI plans to continue to offer remote attendance as we (hopefully) return to in-person meetings in the future. One downside was the inopportune time to offer new registries. In 2020, the Medical Consult Registry and the Venous Stent registry were released. Due to the pandemic, hospital resources and attention has been directed elsewhere and uptake in the new registries has been disappointing.

January 2021 marked the official start of the American College of Cardiology (ACC) National Cardiovascular Data Registry (NCDR) Peripheral Vascular Intervention (PVI) registry merger with the SVS VQI. The collaboration of the two premier vascular registries joins the forces and expertise of both. Many of the NCDR PVI sites have already joined VQI and more are in the process. We welcome our NCDR PVI colleagues and look forward to working with them.

The VQI registries continue to have strong growth in participation by new centers and providers. SVS VQI’s 14 registries contain demographic, clinical, procedural and outcomes data from more than 800,000 vascular procedures performed nationwide and in Canada, Puerto Rico and Singapore. Each record includes information from the patient’s initial treatment and one-year follow-up. Over 10,000 new procedures are added monthly. The wealth of data in the registry allows centers and providers to be aware of their performance and comparison to regional and national benchmarks.

Each center receives quarterly dashboards and regular performance reports to allow them to do meaningful quality assurance and focus their quality improvement initiatives. Biannual regional meetings allow physicians, nurses, data managers, quality officers, and others to meet, share information and ideas, and learn from each other in a positive and supportive environment. Members have used SVS VQI data to significantly improve the delivery of vascular care at a local and national level thereby reducing complications and expenses.

Investigators have used SVS VQI data for risk stratification, outcomes analysis, quality improvement, defining best clinical practices, comparative effectiveness research and reducing resource utilization. This work has resulted in more than 429 scientific publications in peer-reviewed journals since 2011. SVS VQI membership also facilitates participation in clinical trials and other medical device evaluation projects.

The SVS VQI collaborates with multiple other organizations, including the American Venous Forum (AVF), American Heart Association (AHA), Society for Vascular Medicine (SVM), Vascular Access Society of the Americas (VASA), Society for Vascular Ultrasound (SVU), governmental regulatory agencies, device manufacturers, and payers. The Registry Assessment of Peripheral Interventional Devices (RAPID) is a public/private partnership which uses the strength of different societies (SVS, ACC, and SIR) and their registries to enhance device evaluation and to develop objective performance criteria for the endovascular treatment of lower-extremity arterial occlusive disease. SVS VQI also works with industry to provide clinically detailed data for device performance, post-market surveillance, and label expansion. SVS VQI has partnered with vascular registries from Europe and Asia to form the International Consortium of Vascular Registries (ICVR) to bring a global perspective to improving vascular care and device evaluation.

We feel strongly that the best is yet to come.

Dr. Jens Jorgensen
SVS PSO Medical Director
2. 10TH ANNIVERSARY TIMELINE

- **2011**
  - Establishment of SVS Patient Safety Organization, LLC

- **2012**
  - Collaboration with American Venous Forum (AVF)
  - Launch IVC Filter Registry
  - Launch of Lower Extremity Amputation Registry

- **2013**
  - Collaboration with Registry Assessment of Peripheral Vascular Devices (RAPID)
  - Launch of Vascular Implant Surveillance and Interventional Outcomes Network (VISION) in collaboration with Medical Device Epidemiology Network (MDEpiNet) Epidemiology Network

- **2014**
  - Inaugural VQI@VAM meeting
  - Participation Awards and Star Recognition
  - 8 Regional Groups formed, including Canada

- **2015**
  - Collaboration with SVS Clinical Practice Guidelines and VQI data

- **2016**
  - Merger of ACC NCDR with VQI
  - Launch of Patient Report Outcomes (MyPAD) in PVI Registry
  - Publication VQI COVID Data
  - Publication Objective Performance Goals (OPG) Superficial Femoral-Popliteal Evidence Development (SPEED)
  - Development of Trainee Program

- **2017**
  - Data Extraction and Longitudinal Trend Analysis (DELTA)
  - Paclitaxel Analysis
  - Publication of VQI Paclitaxel Data
  - Launch of Vascular Medicine Consult Registry
  - Launch of Venous Stent Registry
  - Integration of COVID variables into the registries

- **2018**
  - 500 Participating Sites, 500,000 Procedures and 3000 Participating

- **2019**
  - First Post-Approval Study TEVAR Dissection Project
  - Inaugural meeting ICVR (International Consortium of Vascular Registries)

- **2020**
  - Initiated TransCarotid Arterial Revascularization Surveillance Project (TSP) in collaboration with CMS
  - Implementation of Source Data Audits
  - Implementation of Quality Improvement Project Charters

- **2021**
  - Expansion to 8 VQI Regional Vascular Study Group
  - Analytics and Reporting Platform for regional/national benchmarking
  - Integration of Global Unique Device Identification Database (GUDID) in PVI Registry
  - Initiated TransCarotid Arterial Revascularization Surveillance Project (TSP) in collaboration with CMS
  - Analytics and Reporting Platform for regional/national benchmarking

---

SVS VQI 2021 Annual Report
3. INTRODUCTION TO THE SVS VASCULAR QUALITY INITIATIVE

The SVS VQI is a collaboration of the SVS Patient Safety Organization (PSO), 18 regional quality improvement groups, and Fivos (Formerly Medstreaming/M2S), its commercial technology partner. The mission of SVS VQI is to improve the quality, safety, effectiveness, and cost of vascular healthcare.

The SVS PSO is a wholly owned subsidiary of the Society for Vascular Surgery, with headquarters in Chicago. The SVS PSO governs all functions of SVS VQI, including the specification of data elements captured in each registry, the standard reports made available to regional groups, member hospitals and physicians, and SVS VQI national quality improvement projects.

The SVS PSO is supported by over 250 physician volunteers who dedicate their time and effort in support of SVS VQI mission. These physicians provide content expertise, advice, clinical support to all the registries and data analyses and ad-hoc support in areas such as industry partnerships and communications. In addition, each center and region have lead physicians and regional medical directors to provide guidance, identify best practices and develop regional initiatives.

The SVS PSO operations are funded by annual registry subscription fees from participating hospitals or physician groups. Enhancements, upgrades and new projects are funded by contributions from corporate supporters.

POTENTIAL BENEFITS OF VQI FOR KEY STAKEHOLDERS

For Patients
• Improve care based on SVS VQI data and quality initiatives
• Use best practices to reduce length of stay
• Improve long-term outcomes through emphasis on follow-up and secondary prevention

For Physicians/Providers
• Adopt best practices through SVS VQI data analysis
• Improve care through quality initiatives and charters
• Monitor performance by comparison with regional and national benchmarks
• Improve patient selection using SVS VQI risk assessment calculators

For Hospitals and Quality Officers
• Improve care by quality initiatives and projects
• Regional and national benchmarks for QA and QI efforts
• Reduce expenses by addressing resource utilization and length of stay

For Policymakers
• Better data to inform decision making on policy development
• Monitor safety and efficacy using real world evidence
• Work collaboratively with the SVS to develop quality measures

For Payers
• Adopt best practices to provide better care and reduce complications and expenses
• Inform population health approaches through use of comparative data
• Reduce expenses due to decreased length of stay and resource utilization

For Industry
Enhance efficiency for label expansion using registry data
• Utilize registry-based trials for pre-market approval and post-market surveillance
• High quality, large scale, real world data for evaluation of device performance
4. IMPACT OF COVID-19

There was an abrupt shutdown nationally of routine elective vascular surgery procedures by March 15, 2020, following a plea from the US Surgeon General to help ‘Flatten the Curve’. As a result, volume in the SVS VQI dropped 7-fold for arterial procedures and 5-fold for venous procedures during mid-March to end of May in 2020 when compared to the same period in 2019.

To monitor COVID-19 impact on vascular procedures, the SVS PSO incorporated new variables in all of the procedural registries as of September 2020:

- COVID-19 testing availability at time of procedure
- COVID-19 symptoms at time of procedure
- Determination if COVID-19 delayed procedure or evaluation prior to procedure
- Judgement by clinician if delay affected patient care adversely
- For LTFU: If patient has experienced COVID-19 infection since the time of the procedure and symptom status

Collaborations/Publications/Presentations this past year:

- Seminars in Vascular Surgery publication: The Impact of COVID-19 Pandemic on Registries and Clinical Trials
- Two JVS Publications (JVS & JVSVL) on registry volumes
- AHRQ PSO Presentation on VQI Response
- Collaboration with Vascular Surgery COVID-19 Collaborative (VASC"

Review of primary outcomes in VQI Registry Data since insertion of COVID variables (Sept 2020 through Feb 21) yielded the following results:

- Overall, > 97% of variable inclusion rate for COVID status in all registries
- Only 1.2% of patients tested positive for COVID-19 restrictive practices in place and/or patient hesitation/reluctance to seek treatment during pandemic
- Baseline overall mortality across registries of 1.4% rose to 1.6% during time interval while baseline mortality for elective patients who were asymptomatic and COVID (Test negative) remained unchanged
- Patients having a COVID (Test positive) yet Asymptomatic had mortality > twice that of negative COVID test patients (odds ratio 2.4)
- Presence of any COVID symptom (aggregate) had mortality of ~4.6 times that of an Asymptomatic and (Test negative) patient (odd ratio 5)
- Mortality of Symptomatic and Intubated patient exceeded 33% across registries
- There was minimal difference in mortality across geographic regions
- Further evaluation will be done on secondary procedure outcomes such as MI, CHF, respiratory failure, graft failure etc.
- LTFU analysis of COVID variable data will require waiting until Sept 2023 for completeness

---

THE SVS VQI REGISTRIES

As of June 1, 2021, there are 14 SVS VQI registries that contain 831,524 vascular procedures. From June 1, 2020 through June 1, 2021, there were over 119,000 procedures added to the registries.

### Total Procedures Captured as of 6/1/2021

831,524

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>Count</th>
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<tbody>
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<td>Peripheral Vascular Intervention</td>
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<tr>
<td>Carotid Endarterectomy</td>
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<td>Infra-Inguinal Bypass</td>
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<tr>
<td>Endovascular AAA Repair</td>
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<tr>
<td>Hemodialysis Access</td>
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<tr>
<td>Carotid Artery Stent</td>
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<td>Varicose Vein</td>
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<tr>
<td>Supra-Inguinal Bypass</td>
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<tr>
<td>Thoracic &amp; Complex EVAR</td>
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<tr>
<td>Lower Extremity Amputations</td>
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<td>IVC Filter</td>
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<td>Open AAA Repair</td>
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<tr>
<td>Vascular Medicine Consult</td>
<td>118</td>
</tr>
<tr>
<td>Venous Stent</td>
<td>43</td>
</tr>
</tbody>
</table>

---

SVS VQI 2021 Annual Report
5. SVS VQI MEMBERS PROFILE

Participation in SVS VQI continues with steady growth reaching over 800 centers including office-based laboratories by the end of May 2021 (Figure 5.1). There is a broad distribution of different practice types – 29% academic institutions, 29% teaching hospitals and 42% community hospitals (Figure 5.2). There is also broad distribution of physician specialties – less than half vascular surgeons, 15% interventional cardiology, 14% interventional radiology, 6% general surgery, 4% cardiothoracic surgery and 4% neurosurgery (Figure 5.3).

Source: M2S PATHWAYS Data, June 2021

Figure 5.1: Growth of SVS VQI Centers (as of June, 1, 2021)

Figure 5.2: SVS VQI Participating Hospital Types

Source: PATHWAYS data, June 2021

Figure 5.3: Distribution of SVS VQI Physician Specialties

Source: PATHWAYS Data, June 2021

www.VQI.org
6. LAUNCH OF VQI TRAINEE PROGRAM

VQI wants to help medical students, residents and fellows learn about quality improvement!

Purpose:
To foster understanding of quality process and metrics among Vascular Surgery Residents, Fellow and Medical Students (‘trainees’) through mentorship in the Vascular Quality Initiative (VQI) in collaboration with the Association of Program Directors in Vascular Surgery (APDVS).

Proposal:
The SVS/PSO proposes a mentorship program for trainees to learn about surgical quality improvement and research with a focus on vascular disease. Selection of FITs would come from application to the Society for Vascular Surgery (SVS) Patient Safety Organization (PSO) VQI. FITs will be assigned a mentor(s) within one of eighteen VQI Regional Quality Groups as directed by the SVS PSO Governing Council and staff. Any active VQI member meeting requirements can volunteer to serve as a mentor in the program. Regional or Associate Medical Directors are strongly encouraged to take a leadership role in this initiative.

Vascular Trainee Work Group established in July 2021 to formalize program:
- Governing Council directed and monitored program for matching resident or fellow in training (FIT) with approved VQI mentor to increase knowledge and familiarity with VQI and the PSO
- FIT Application and selection process for residents and fellows in vascular surgery/cardiology/vascular medicine programs; listed as Tier 1 applicant
- Mentor directed FIT involvement of Regional Study groups with both passive and active participation within meeting structure (prep calls, present comparative data, new QA/QI projects, local quality charters, etc)
- Minimum program duration of one year with goal of generating work product focused on quality improvement at local/regional/national level
- Potential selection of FIT work product (after GC review) for presentation at VQI@VAM
- Scholarship awarded to those Tier 1 Applicants (limited number) to advance to Tier 2 level which increases engagement with PSO staff and committee meetings
- Communication back to FIT program of their involvement/participation in VQI and PSO to help fulfill educational requirements of training

Introducing Audible Bleeding

Another great resource for trainees and practicing vascular surgeons (especially those who are early in their careers) is Audible Bleeding - a vascular surgery focused podcast that is now an official publication of SVS!

In July 2021, the Getting Started Using the VQI for Research episode featured a panel discussion with Drs. Leila Mureebe, Jeff Siracuse, and Philip Goodney. Click here to listen to the podcast: https://www.audiblebleeding.com/vqi-research-intro/

In April 2021, Dr. Jack Cronenwett participated in a podcast titled History of the APDVS, the vascular integrated residency, and the VQI. Click here to listen to this podcast: https://www.audiblebleeding.com/2021/04/12/apdvs-lifetime-achievement-in-education-award-winner-dr-jack-cronenwett-history-of-the-apdvs-the-vascular-integrated-residency-and-the-VQI/

For a complete list of Audible Bleeding podcasts, click here: https://www.audiblebleeding.com/episodes-1/
7. **DATA QUALITY DASHBOARDS & REGIONAL REPORTS**

The SVS PSO Best Practice Dashboards allow centers to review their performance and compare to regional and national benchmarks. The SVS PSO registry committees select outcome measures to be reported in the dashboards, which are distributed quarterly to SVS VQI members. The dashboards provide each center their individual results, along with results for their region and SVS VQI overall. Results that are in the “top” 25th percentile are highlighted blue and those in the “bottom” 25th percentile are highlighted coral.

**PVI CLAUDICATION**

<table>
<thead>
<tr>
<th>Procedure Timeframe: April 1, 2020 - March 31, 2021</th>
</tr>
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<tbody>
<tr>
<td>Includes Peripheral Vascular Intervention (PVI) procedures for mild, moderate, or severe claudication.</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Category</th>
<th>Outcome/Complication</th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
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<td></td>
<td></td>
<td></td>
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<td>1935</td>
<td>12419</td>
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<td>Median Postop LOS (days)</td>
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<td>0</td>
<td>[0][0][0][0][1]</td>
</tr>
<tr>
<td>Median Total LOS (days)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>[0][0][0][0][1]</td>
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<tr>
<td><strong>Smoking</strong></td>
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<td></td>
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<tr>
<td>Never</td>
<td>10.3%</td>
<td>20.4%</td>
<td>14.8% [0][4][9][2][15][1][25][9]</td>
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</tr>
<tr>
<td>Prior</td>
<td>62.4%</td>
<td>49%</td>
<td>48.6% [3][1][4][0][8][5][0][6][4][7][1][4]</td>
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<tr>
<td>Current</td>
<td>27.4%</td>
<td>30.6%</td>
<td>36.6% [1][4][4][2][5][3][6][3][4][8][1][5][7][8]</td>
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<td><strong>Preop ABI</strong></td>
<td></td>
<td></td>
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<tr>
<td>Preop ABI/Toe Pressure Reported</td>
<td>81.2%</td>
<td>64%</td>
<td>75% [3][1][9][6][3][9][8][1][8][9][3][8][1][0][0]</td>
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<td><strong>Postop Events</strong></td>
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<tr>
<td>MI</td>
<td>2.6%</td>
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<td>0.2% [0][0][0][0][0]</td>
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</tr>
<tr>
<td>Change in Renal Status</td>
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<td>0%</td>
<td>0.3% [0][0][0][0][0][6]</td>
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</tr>
<tr>
<td>Thrombosis</td>
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<td>0.4%</td>
<td>0.5% [0][0][0][0][2]</td>
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<tr>
<td>Embolization</td>
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<td>0.4% [0][0][0][1][4]</td>
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<tr>
<td>Target Lesion Dissection</td>
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<td>1.7%</td>
<td>3.3% [0][0][3][8][10][2]</td>
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<tr>
<td>Artery Perforation</td>
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<td>Access Site Hematoma</td>
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<td>1.6% [0][0][0][6][5]</td>
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<tr>
<td>Access Site Infection</td>
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<td>0.1%</td>
<td>0% [0][0][0][0]</td>
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<tr>
<td>Unplanned Amputation</td>
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<td>0.3%</td>
<td>0.3% [0][0][0][0]</td>
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<tr>
<td><strong>Discharge Medications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antiplatelet+Statin</td>
<td>92.9%</td>
<td>92.9%</td>
<td>85.8% [66.8][8][1][8][9.9][97][100]</td>
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<td><strong>Discharge Destination</strong></td>
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<tr>
<td>Home</td>
<td>96.6%</td>
<td>96.6%</td>
<td>97.8% [93.8][9][7][1][100][100][100]</td>
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<tr>
<td>Rehab Unit</td>
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<td>Nursing Home</td>
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<tr>
<td>Dead</td>
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<td>1%</td>
<td>0.4% [0][0][0][0][5]</td>
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</tr>
</tbody>
</table>
### PVI CHRONIC LIMB THREATENING ISCHEMIA

**Procedure Timeframe: April 1, 2020 - March 31, 2021**

Includes Peripheral Vascular Intervention (PVI) procedures for ischemic rest pain, ulcer/necrosis, non-healing amputation, both ulcer + non-healing amputation, or acute ischemia.

<table>
<thead>
<tr>
<th>Legend: Blue = &quot;Top&quot; 25th percentile</th>
<th>Coral = &quot;Bottom&quot; 25th percentile</th>
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<tbody>
<tr>
<td>Category</td>
<td>Outcome/Complication</td>
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<td>Your Center</td>
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<td>Your Region</td>
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<td>VQI Overall</td>
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<td><strong>Case Data</strong></td>
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<td>65.9% [27.9, 48.1, 70.6, 84.1]</td>
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<td>87.2%</td>
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<td></td>
<td>81.8% [62.5, 71.9, 83.3, 89.1]</td>
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<tr>
<td><strong>Discharge Destination</strong></td>
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<tr>
<td>Home</td>
<td>81.1%</td>
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<tr>
<td>Rehab Unit</td>
<td>13.2%</td>
</tr>
<tr>
<td>Nursing Home</td>
<td>4.2%</td>
</tr>
<tr>
<td>Other Hospital</td>
<td>0.6%</td>
</tr>
<tr>
<td>Homeless</td>
<td>0%</td>
</tr>
<tr>
<td>Dead</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

SVS VQI 2021 Annual Report

8
8. REGIONAL QUALITY GROUPS

SVS VQI has 18 regional quality groups based on geographic proximity (Figure 8.1). Regional quality group meetings are an important aspect of SVS VQI and a key component to successful quality improvement. Regional groups distinguish SVS VQI from almost all other registries. Each of the 18 groups hold biannual meetings that provide a forum for discussion on outcomes analysis and work on quality improvement.

During each region’s bi-annual meeting, data are reviewed and discussed by the members present. Many groups identify an area for improvement and launch region-wide efforts to improve care. Topics that have been addressed include:

- Recording of hemodynamic data (ABI/Toe Pressure) prior to peripheral intervention
- Measuring aneurysm sac diameter one year following EVAR and TEVAR
- Increasing rates of IVC filter retrieval
- Reducing LOS for CEA and EVAR
- Increasing LTFU rates
- Increasing statins and antiplatelet prescriptions at discharge
- In hospital Stroke/Death for CEA, TFEM CAS, and TCAR
- Compliance with SVS EVAR sac size guidelines
- Compliance with SVS Cell-saver guidelines

Some regions have also used “hashtags” to collect unique data for quality improvement:

- Factors contributing to renal failure
- Frailty of Vascular Patients
- Patient Reported Outcomes
- Smoking Cessation
- Causes of Delirium with Vascular Patients
- EVAR SAC diameter size compliance with SVS Guidelines

Figure 8.1: SVS VQI Regional Group Map
9. QUALITY IMPROVEMENT PROJECTS: LEARNING FROM THE DATA

The SVS PSO offers a variety of resources for participating centers to improve care utilizing SVS VQI data. The SVS PSO encourages participating centers to submit quality improvement (QI) charters on projects using their own center data. This process has helped the SVS PSO identify groups working on similar initiatives and facilitate collaboration and networking opportunities.

Quality Improvement Projects
SVS VQI centers work on quality improvement projects which may be selected for presentation at the VQI Annual Meeting in June. These projects are often related to the National QI Initiatives on Discharge Medications or Endovascular AAA Long Term Follow-Up Imaging but can address any vascular topic supported by VQI data. The SVS PSO provides resources to assist SVS VQI centers with their QI projects.

Quality Improvement Tools
The SVS PSO, together with M2S, develops quality improvement tools to assist VQI members, vascular nurses, quality improvement staff and hospital administrators with their own vascular quality programs.

These tools include:
• Presentations
• Webinars/Events
• VQI Annual Meeting (presentations and videos available for attendees only)
• QI Project Guide (for VQI members only)
• Video/audio
• Case studies

Participation Awards
The SVS PSO encourages provider and center engagement through a program of annual Participation Awards. Participation Awards are given on the basis of long-term follow-up rates, regional meeting participation, quality improvement initiatives and registry participation. The Participation Awards program encourages active involvement in the registries and QI activities. Certificates are distributed to centers receiving the maximum award level at the regional and national meetings.

Participating centers can earn up to three stars based on the following criteria:
• The completeness of long-term, follow-up reporting (LTFU) based on the percentage of patients for whom they have at least nine months of follow-up data
• Attendance at semi-annual meetings of a regional quality group and VQI@VAM
• Initiation of quality improvement activities based on VQI data
• The number of vascular registries in which the center participates

SVS VQI centers work on quality improvement charter projects throughout the year. These projects are often related to the National QI Initiatives of Discharge Medications or Endovascular AAA Long Term Follow-Up Imaging, but can address any vascular topic supported by VQI data.

### Table 9.1 – Quality Improvement Projects to Date

<table>
<thead>
<tr>
<th>TOPICS</th>
<th>PARTICIPATING CENTERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge Medications</td>
<td>5</td>
</tr>
<tr>
<td>(National Initiative)</td>
<td></td>
</tr>
<tr>
<td>LTFU (including EVAR Imaging, a</td>
<td>13</td>
</tr>
<tr>
<td>National Initiative), IVCF Retrieval</td>
<td></td>
</tr>
<tr>
<td>Clinical</td>
<td>1</td>
</tr>
<tr>
<td>Documentation</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>18</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>38</strong></td>
</tr>
</tbody>
</table>

SVS VQI 2021 Annual Report
10. NATIONAL QUALITY IMPROVEMENT INITIATIVES—OPTIMAL DISCHARGE MEDICATIONS AND EVAR LONG-TERM FOLLOW-UP IMAGING

Experienced SVS VQI centers have applied registry data and implemented innovative approaches to improve success rates for the current national quality initiatives on Endovascular AAA Long-term Follow-Up Imaging and Discharge Medications.

**EVAR Long Term Follow-Up (LTFU) Imaging**

Endovascular Aortic Aneurysm Repair (EVAR) requires long-term monitoring to ensure the durability of repair. EVAR patients are susceptible to the late development of endoleaks, which can occur in up to 20% of patients and may result in rupture. Recent studies have demonstrated low compliance rates with long-term follow-up imaging after EVAR. To ensure that patients achieve successful outcomes after EVAR, long-term follow-up imaging is essential.

Our regional meetings have focused on “moving the needle” - meaning to improve reporting of EVAR sac diameter. There has been a wide variation in compliance with a VQI mean of 58.6% (22-89%) with little improvement since the inception of the national quality initiative in 2016. Barriers identified include patient factors, patient lost to follow up, imaging unavailable, and generic dictation such as “sac size unchanged.”

A 2021 Quality Charter on LTFU care shared the challenges on scheduling patients requiring 9 to 21 month follow up post EVAR procedure. Using VQI data, this site was able to “move the needle” by increasing their follow up rate from 69% in 2013 to 92% in 2017. They developed a patient-centered scheduling system, utilized telehealth follow up, sent patient reminder correspondence, obtained appropriate EVAR imaging, and developed educational tutorials for staff. They continue to increase their LTFU compliance rate today. This is an exemplary demonstration of using VQI data to improve care.

**Optimal Discharge Medications for Vascular Patients**

The SVS VQI’s first national QI initiative is the prescribing of an antiplatelet agent and statin at discharge to improve patients’ long-term health. Discharge medications was selected because there is strong evidence that antiplatelet agents and statins increase patient survival following a vascular procedure. SVS VQI data have shown that patients undergoing arterial procedures who received a discharge prescription of antiplatelet medications and a statin have significantly better 5-year survival. It is a process measure that affects most vascular surgery patients and is readily actionable.

A 2020 Quality Charter on DC medications reviewed why a facility was below the VQI 25th percentile for antiplatelet and statin medications prescribed at discharge. The facility goal was to become 100% compliant. Using VQI data, the facility was able to develop improvement strategies including education, workflow processes, electronic medical record templates, multidisciplinary collaborations, and monthly data review with communication to stakeholders. In the fall of 2018, DC medication compliance was 72.9%. The current facility compliance moved to 97.23% in 2020 and is now 100% in 2021.

https://www.vqi.org/about/quality-improvement/national-qi-initiatives/

> “It is the obligation of the operating surgeon to stress the need for lifelong surveillance and integrate discussions about LTFU into all stages of AAA EVAR care to ensure that their patients achieve optimal outcomes.” – Salvatore Scali, MD, Professor of Surgery, University of Florida.

Figure 10.1: Discharge Medications and Statin Rate for 119 SVS VQI Hospitals (2012 to Date)

SOURCE: SVSVQI
11. SVS VQI DATA ANALYSIS

SVS VQI physicians may request de-identified datasets from each registry for analysis. The SVS PSO Research Advisory Council reviews and evaluates requests for datasets by investigators, who provide the RAC a description of their proposed project. As of the end of May 2021, the RAC has approved 810 projects, and of those, 439 have been published in peer-reviewed journals. This year, the SVS PSO Executive Committee, the RAC and the Venous Quality Council agreed to create a new SVS PSO Venous RAC to facilitate the growth of venous data analyses and research, particularly in light of the new Venous Stent Registry.

The SVS VQI Vascular Implant Surveillance and Interventional Outcomes Network (VISION) is a partnership between the SVS VQI and the Medical Device Epidemiology Network (MDEpiNet) that directly supports the mission of the SVS VQI. VISION links SVS VQI registry data to Medicare claims to generate novel registry-claims linked datasets. The datasets combine the granular clinical detail from the SVS VQI with discrete long-term outcomes derived from Medicare claims. VISION data is used to generate center-specific feedback reports called, Survival, Reintervention and Surveillance (SRS). Each report shows each center’s long-term performance when compared to the VQI for Medicare patients undergoing the following procedures:

- Endovascular abdominal aortic aneurysm repairs (EVAR)
- Elective abdominal aortic aneurysm repair (EVAR + Open AAA)
- Carotid endarterectomy for asymptomatic stenosis
- Carotid artery stent procedures (TCAR and transfemoral procedures) for asymptomatic stenosis

Use of the data is governed by a Data Use Agreement (DUA) between Weill Cornell Medical College and the Center for Medicaid and Medicare Services (CMS). VISION replaces the previous Medicare-Match data process.

Visit https://www.vqi.org/data-analysis/ for everything you need to learn about blinded dataset request policies and procedures, view already approved projects for possible collaboration, and more.

12. SVS GUIDELINES AND THE SVS VQI

The SVS Document Oversight Committee approached the SVS VQI to see if the registries could be used to document compliance with SVS AAA guidelines and monitor adoption over time. In addition, we looked to define the impact of guideline compliance on outcomes. Compliance with recommendations was associated with improved outcomes and should be encouraged for providers. Participation in the SVS VQI registry provides an objective assessment of performance and compliance with the SVS guidelines. SVS VQI provider and center reports may be used as a focus for quality improvement efforts. Vascular Quality Initiative assessment of compliance with Society for Vascular Surgery clinical practice guidelines on the care of patients with abdominal aortic aneurysm was published in the September 2020 issue of the JVS. https://pubmed.ncbi.nlm.nih.gov/31973949/

A similar project is underway looking at the SVS clinical practice guidelines on the treatment of claudication. 1A Guidelines state that a patient should be on an Antiplatelet, Statin, and NOT smoking (Optimal Medical Therapy) while undergoing PVI for claudication due to lower extremity arterial occlusive disease. Initial analysis shows that less than half of the patients undergoing endovascular treatment for claudication are compliant with “optimal medical therapy” (Figure 12.1).

![Figure 12.1 Optimal Medical Rx Compliance](image)
13. COLLABORATION WITH SOCIETIES

Although VQI was begun by vascular surgeons, less than 50% of the current membership in SVS VQI are vascular surgeons. There is a broad multi-disciplinary participation in the SVS VQI, which includes physicians from Cardiology, Radiology, General Surgery, Cardiothoracic Surgery, Neurology, Neurosurgery and other specialties. Recognizing this fact, the SVS VQI has fostered working relationships with many of the societies that represent these various specialties to help inform and promote the registries. The SVS VQI’s governing council and registry committees also include volunteers from these different disciplines. The SVS VQI would like to recognize and thanks the following Societies for their ongoing involvement with the SVS VQI. The expertise and guidance provided by our colleagues has been instrumental to the success of VQI:

- American College of Cardiology
- American Heart Association
- American Venous Forum
- Society for Vascular Medicine
- Society for Vascular Nursing
- Society for Vascular Ultrasound
- Vascular Access Society of the Americas

The ACC holds seats on SVS PSO committees and councils, and collaborates with the PSO on Quality Improvement education.

Over 60 former NCDR PVI sites now participate in VQI. Participants who have not yet joined the SVS VQI, may contact the SVS VQI account team by emailing vqi@m2s.com, or by calling 603-298-6717, to begin enrollment.

AMERICAN HEART ASSOCIATION and SOCIETY FOR VASCULAR MEDICINE

The SVS VQI and the Society for Vascular Medicine (SVM), in collaboration with the American Heart Association® (AHA) created and released the Vascular Medicine Consult Registry (VMC) in early 2020. Dr. Josh Beckman, Dr. Marc Bonaca, and former Association president Dr. Mark Creager are among those members serving on the VMC Steering Committee to provide scientific expertise and oversight. Dr. Randall DeMartino, MD and Dr. Michael R. Jaff, from the SVS serve as co-chairs of the VMC Steering Committee. The Registry targets new patients who are being treated medically for Atherosclerotic Carotid Artery Occlusive Disease, Abdominal Aortic Aneurysm, and Peripheral Lower Extremity Arterial Disease due to atherosclerosis. Medication details and dosages, risk factor and lifestyle modifications, non-operative treatments and counseling will be the emphasis of the VMC. The Registry also helps define the natural history of disease and the impact of medical management. Features include a web-based platform with real-time reporting.

The American Heart Association, a global force for longer, healthier lives, has a longstanding commitment to improving systems of care through its quality improvement programs such as its flagship Get With The Guidelines® (GWTG) program, promoting consistent adherence to evidence-based guidelines in hospital and healthcare settings across the U.S. This team effort represents an opportunity to leverage the strengths of both organizations to improve care delivered to patients with vascular disease in the outpatient populations as well.

www.VQI.org
The Society for Vascular Surgery® Vascular Quality Initiative® (SVS VQI) and the American Venous Forum (AVF) are pleased to collaborate in the treatment of venous disease.

With more than 20 percent of the adult population suffering from chronic venous diseases, AVF is committed to expanding its efforts through the VQI to assess the efficacy of various treatments for patients with venous disease. AVF and SVS have positioned themselves as leaders in vascular quality improvement by providing a platform for their members to analyze outcomes, determine best practices, and collaborate on quality improvement efforts across regions.

The VQI and AVF worked together to launch the Varicose Vein Registry in 2014 and the Venous Stent Registry in late 2019. As part their collaboration with VQI, AVF thought leaders serve as volunteers on the committee that worked on creating and enhancing both registries, including participation on the Venous Research Advisory Committee (RAC). Additionally, the VQI participates in registry education sessions at the AVF annual meeting.

The Varicose Vein Registry captures procedures performed in vein centers, office-based practices, and ambulatory or inpatient settings and includes therapies such as thermal radiofrequency ablation, thermal laser ablation, mehanochemical ablation, chemical ablation, embolic adhesive ablation, and surgical ablation (including high ligation, stripping, and phlebectomy). The Venous Stent Registry treats patients with symptomatic venous obstructions due to chronic thrombosis and/or some venous compression disorders.

14. MYPAD PILOT FOR PATIENT REPORTED OUTCOMES

The SVS VQI has created My PAD, a pilot program for the collection of patient-reported outcomes (PRO) on patients undergoing endovascular treatment for peripheral arterial disease (PAD).

Traditional clinical outcomes such as patency and reintervention may not fully capture the quality of care or the experience of PAD patients. It is important to learn and measure from the patient’s perspective.

VQI launched the My PAD pilot in April. It includes several SVS VQI centers that participate in the Peripheral Vascular Intervention (PVI) Registry. The pilot will collect center workflow data and seeks to optimize PRO collection in the least burdensome and patient-centered manner by leveraging technology, such as smart phones and tablets.

The SVS VQI will enroll a variety of practice types ranging from university to community-based practices in rural and urban settings. MyPAD will serve as a foundation for future SVS VQI patient-reported outcome programs.

The data will be collected from patients undergoing peripheral vascular interventions for claudication or chronic limb-threatening ischemia. Centers will use the VascuQoL-6 and EuroQol 5D-5L questionnaires (estimated completion time is less than 10 to 15 minutes) to collect data at three time points, pre-procedure and at one month and one-year post-procedure.

VQI is exploring the introduction of Patient Advisor groups this fall to further understand the patient’s perspective on their PAD treatment.
15. USING SVS VQI DATA FOR COLLABORATIVE PROJECTS WITH FDA AND INDUSTRY

Medical devices are an integral component of vascular healthcare. SVS VQI collects clinical data to help better understand device performance. Data may be used to meet regulatory requirements, support post-approval surveillance or expand existing indications for use (IFU).

Post-Approval Surveillance Projects
The use of SVS VQI data for post-approval surveillance is consistent with the FDA vision of registry-based evaluation throughout the total product lifecycle. Initial projects have leveraged existing SVS VQI infrastructure and reduced recruitment time and expenses. For example, the recruitment for the Thoracic EndoVascular Aortic Dissection (TEVAR) project (see below) was completed in half the time initially estimated by industry sponsors, Medtronic and Gore.

SVS VQI has partnered with several device manufacturers to provide aggregate data for product development, creation of performance standards, and expansion of device indications:

TEVAR Post-Approval Surveillance Projects - Initiated in October 2014, this project has demonstrated the value of expanding surveillance to real-world device evidence with faster than expected enrollment while meeting FDA requirements. In partnership with Gore and Medtronic, the SVS PSO and M2S has completed enrollment of the one-year and five-year cohorts.

The SVS PSO is excited to announce the continuation of the TEVAR Dissection Surveillance Project to evaluate the Cook Zenith Dissection Endovascular System. FDA approval was granted for this device after safety and effectiveness were demonstrated in pre-market studies of complicated dissection with the proviso that the efficacy of TEVAR treatment of descending aortic dissection would be more fully analyzed through post-market surveillance, as is done through VQI for the W. L. Gore and Medtronic devices after their approval.

For more information, please contact: tevarproject@m2s.com

Transcarotid Artery Revascularization (TCAR) Surveillance Project
The TCAR Surveillance Project is designed to obtain more data about real-world outcomes of TCAR in comparison with CEA as performed by centers participating in the Vascular Quality Initiative (VQI). The TCAR Surveillance Project was evaluated by the US Food and Drug Administration (FDA) and found to be scientifically valid and clinically relevant. Based on this, reimbursement for TCAR procedures performed by centers participating in the VQI TCAR Surveillance Project was approved on Sept. 1, 2016, by the Centers for Medicare and Medicaid Services (CMS) under the current National Coverage Determination. For centers or providers to be reimbursed for performance of TCAR, they must participate and enter data in the VQI Carotid Artery Stent Registry. The TCAR Surveillance Project is directed by an SVS PSO Steering Committee that will make periodic analyses of outcomes collected in the VQI CAS and CEA Registries.

For more information on the TCAR Surveillance Project, please see Clinical Trials.gov:

SVS VQI TransCarotid Revascularization Surveillance Project
https://clinicaltrials.gov/ct2/show/NCT02850588

16. CORPORATE SUPPORT

The operations of the SVS PSO are financed by fees paid by participating sites. New project development, including addition of new registries, quality reports, and improved functionality in SVS VQI has been made possible through generous unrestricted contributions by Quality Champion, Quality Partner and Quality Associate-level corporations. Corporate sponsors of the SVS PSO are listed below:

Quality Champions

BD
BARD
Gore
Boston Scientific

Quality Partners

3M
KCI

www.VQI.org
17. REGISTRY ASSESSMENT OF PERIPHERAL INTERVENTIONAL DEVICES (RAPID) UPDATE

RAPID is a public-private partnership between professional society registries (Society for Vascular Surgery, American College of Cardiology and Society for Interventional Radiology), academia, industry and federal regulators including CMS and FDA. The FDA, through the Medical Device Epidemiology Network (MDEpiNet), has promoted the concept of CRNs to generate real-world evidence about medical device performance. The goal of RAPID is to promote the evaluation of peripheral vascular devices throughout the total product lifecycle.

Updates on RAPID related VQI activities

1. Objective performance goals (OPG)
   Objective performance goals for femoral-popliteal peripheral vascular interventions were published in the Journal for Vascular Surgery in the fall of 2020. The Superficial Femoral Artery-Popliteal Evidence Development (SPEED) OPGs were derived from VQI PVI data. The publication generated discussion about the future of objective performance goals. Two commentaries will be published in the JVS in 2021. The first is titled, “A critical appraisal of registry-based objective performance goals in peripheral arterial disease.” A counter is titled, “Toward a better system for the sustainable development of objective performance goals for peripheral vascular interventions.” Both viewpoints illustrate a pathway forward for OPG development.

2. Lean Case Report Form for PVI
   The RAPID LEAN working group led by James Black, MD and Donna Buckley, MD has developed a “lean” case report form (CRF) for peripheral vascular interventions. The form was developed after considering the lessons learned from the paclitaxel experience. The lean CRF released for comment by the RAPID community and submitted for peer review. In the future, the CRF may be used as a template for peripheral device trials.

3. Paclitaxel (PTX) studies
   Two VQI projects on the safety of paclitaxel devices in the treatment of femoral-popliteal disease have progressed over the past year. First, VQI has continued surveillance of mortality in the after PTX treatment through DELTA (Data Extraction and Longitudinal Trend Analysis). In this analysis performed in collaboration with Dr. Fred Resnic and the Lahey Hospital and Medical Center, treatment with any PTX vs. non-PTX devices was associated with increased two-year survival (89.5% vs. 86.7%; hazard ratio (HR)= 0.79, 95% confidence interval (CI) 0.72-0.87, P= 0.004). The manuscript “Vascular Quality Initiative Surveillance of Femoral-popliteal Artery Paclitaxel Devices Shows Improved Two-year Survival” was accepted for publication in Journal of the American College of Cardiology Cardiovascular Interventions. Second, a VQI analysis linked to Medicare claims was performed by the VISION team at Weill Cornell Medical Center led by Dr. Art Sedrakyan and Dr. Philip Goodney of Dartmouth Medical Center. In this large, claims-linked, VQI based analysis, there was no increase in patient mortality or major amputation after PVI with paclitaxel vs non-paclitaxel devices. The study is being submitted for peer review.

4. Randomized controlled trials nested in registries
   Over the next year, RAPID will focus on promoting the use of registries for randomized trials. A virtual think tank “Registry-supported Prospective Trials: What Are We Missing?” is scheduled for Friday, September 9th from 12-5pm. The five-hour session will bring together the major stakeholders to discuss why the concept has not been successfully adopted and consider strategies to promote clinical trials within registries. The meeting will include discussion of past and current proposals and a brainstorming session with industry and federal regulators on new use cases. Those interested in participating may contact Rebecca Wilgus at rebecca.warlick@duke.edu.

Reference

FDA Notifications
As a Patient Safety Organization, we share Safety Notifications with VQI Members:
- FDA will contact the SVS PSO with Safety Notifications it wants us to communicate
- Safety Notifications will appear in both the PSO and SVS newsletters
- All Safety Notifications are posted to the VQI and SVS Websites
- https://www.vqi.org/resources/fda-communication/
18. INTERNATIONAL CONSORTIUM OF VASCULAR REGISTRIES (ICVR) UPDATE

The ICVR was launched in November 2014 at Cornell University as a partnership of VQI, VASCUNET and other registries that include over 12 national registries, the FDA, manufacturers, and other stakeholders. The mission of the International Consortium of Vascular Registries (ICVR) is to provide a collaborative platform through which registries and other stakeholders around the world can share data to improve vascular health care. In order to create this collaborative platform, the ICVR is leveraging existing national registries, including the Society for Vascular Surgery Vascular Quality Initiative (VQI) and Vascunet, a vascular registry collaboration within the European Society of Vascular Surgery which involves national and regional vascular registries from Europe, Australia and New Zealand.

The ICVR is proud to announce that in 2021 it formally launched a project entitled “ICVR Evaluation of EVAR Treatment of Ruptured AAA”. The aim of this project is to evaluate the safety and effectiveness of EVAR devices used to treat rAAA (compared to open rAAA repair) in the ICVR registries, and to provide manufacturers of current EVAR devices with individual data about their device. The design of the study will include collection of data from 13 different countries participating in ICVR.

The central purpose of this project is to evaluate in-hospital mortality after EVAR for ruptured AAA in a multinational registry collaboration using mortality associated with standard open repair to establish a benchmark. The hypothesis is that EVAR for rAAA is associated with in-hospital survival that meets a performance goal derived from open rAAA repair. Given that untreated rAAA carries a mortality approaching 100%, the intent of this project is to focus specifically on survival to discharge. Further, the long term safety and effectiveness of these EVAR devices has been extensively studied and established for elective AAA repair. The key to improving outcome after rAAA repair is improving initial survival, which is the major endpoint for this project.

19. THE SVS VQI AND COMPLIANCE WITH THE EUMDR

The European Medical Device Regulation (EU MDR) was introduced in 2017 to ensure high standards of quality and safety for medical devices being used in Europe. It establishes a framework for medical device monitoring to ensure a high level of health and safety while supporting innovation. While the new European MDR includes pre-approval evaluation for medical device manufacturing, it adds a new total life-cycle reporting requirement to medical device regulation.

One of the most important but most challenging requirements of EU MDR is the active Post-Market Clinical Follow-up required to establish safety and performance during the total lifecycle of a device. Manufacturers must report such data to maintain their CE mark for each device by May 2020. Medstreaming/M2S and the Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) recognize the importance of supporting manufacturers and regulators, both domestic and international, to evaluate the safety and performance of vascular devices currently being used in daily practice. SVS VQI collects much relevant data to provide the real-world evidence needed to meet the new EU MDR. “Manufacturers face significant challenges in collecting real-world clinical follow-up data about ALL their devices,” said Jack Cronenwett, MD, CMO Medstreaming/M2S. “In fact, some companies are now considering the need to remove some currently CE-marked devices from the European market if they cannot obtain needed data. We are pleased to have supplied data from the SVS VQI to several manufacturers to help them successfully meet EU MDR requirements. Going forward, we believe that the SVS VQI registry will be a primary data source to address current and future regulatory challenges faced by device manufacturers world-wide.”
20. TECHNOLOGY & REGISTRY DEVELOPMENTS

Technology Highlights:

**Move Record** – Move procedure data to the correct patient when duplicate/miskeyed patient records have been identified.

**Audit Info** – View record details including creator and created date, last user to update and date updated, and form validation submission status.

**Recent Records** – Quickly return to your recently accessed procedure and follow up records.

**Release Notes** – Go to the Support Tab to access historical release announcements to review recent updates.

**Reporting Tab** – This new tab will be home to future new data analysis reporting including the current analytics engine.

Registry Highlights:

- Across-registry revision to add COVID-19 variables
- TEVAR Revision to align with SVS/STS guidelines
- Vascular Ultrasound Registry (VUR) major revision
- Varicose Vein Registry (VVR) revision for New CEAP Clinical Classification
- Venous Stent Registry (VSR) revision for New CEAP Clinical Classification
- Vascular Medicine Consult (VMC) registry revision to add new drug category and update CAD
- VQI PRO collection for PVI

Upcoming Registry Highlights:

- Minor revision to CEA, CAS, and VMC to add stenosis and contralateral events
- Add Opioid variables to INFRA
- Follow-up Outcomes reports for CAS, CEA and EVAR using new reporting technology
- New Device Assistant feature to streamline device search and selection
- Minor revision to TEVAR to update dependencies for Entry Flow and Dissection Date/Type
- Minor revision across registries to change Gender to Sex, add COVID Vaccination variables, and add medical resident variables
- Minor revision to IVC Filter manufacturer options

21. FUTURE DEVELOPMENTS

In 2021-2022, the SVS VQI plans to support improved care and promote patient safety in the following areas:

- Infra-Inguinal and Supra-Inguinal registries will be revised in late 2021
- Open AAA Registry and Lower Extremity Amputation Registry will be revised in 2022
- Addition of Vaccination details to all Registries to continue to analyze the affect of COVID-19
- Enhanced Long Term follow up reporting capabilities for all registries will be released over time, beginning with EVAR, CAS, CEA and PVI in 2021
- Infra-Inguinal Bypass pilot of variables to help better manage the usage of Opioids in Vascular procedures
- Expand Patient Reported Outcomes to all PVI users Fall 2021 and other registries in 2022
- Collection of details about level of residency will be added to the registries

137 new centers
814 total centers
831,524 procedures

810 total data analysis projects
439 total published journal articles

38 new quality improvement abstracts and posters
APPENDIX A — VQI SITES LISTED IN ALPHABETICAL ORDER (AS OF 6/1/2021)

Roper St. Francis Hospital (SC)
Roper Medical Center (SC)
Royal Oak (William Beaumont Hospital) (MI)
Russell Foundation (CA)
Rutland Robert Wood Johnson Medical School (NJ)
Sacred Heart - Hospital Sisters of the Third Order of St. Francis (WI)
St. Alphonsus Regional Medical Center (ID)
St. Bonaventure Medical Center (NY)
St. Francis Hospital and Medical Center (CT)
St. Joseph Health System, Inc d/b/a Chi St. Joseph Health (IL)
St. Joseph's Hospital South (FL)
St. Joseph's Hospital North (FL)
St. Joseph's Hospital (FL)
St. Joseph Medical Center (CHI Franciscan Health) (WA)
St. Joseph Medical Center (MO)
St. John's Hospital (IL)
St. Francis Medical Center (CHI Franciscan Health) (WA)
St. Mary Convin Medical Center (Centura Health Corporation) (CO)
St. Mary Medical Center (CA)
St. Mary's Hospital (MO)
St. Mary's Hospital (CO)
St. Mary's Medical Center (WI)
St. Patrick Hospital (Providance) (MT)
St. Vincent Healthcare (MT)
St. Vincent Heart Center of Indiana, LLC (IN)
St. Vincent Health Care Center, Inc. (IN)
St. Vincent Hospital of the Hospital Sisters of the Third Order of St. Francis (WI)
St. Vincent's Medical Center (CT)
Stamford Hospital (CT)
Stanford Hospital and Clinics (CA)
Steward Goodwin Medical Center, Inc. (MA)
Steward St. Anne's Hospital Corporation (MA)
Steward Tuvalu Memorial Hospital, Inc. (OH)
Stockton Cardiovascular Surgical Medical Group (CA)
Stony Brook University Medical Center (NY)
Strahm Medical Center (NJ)
Strong Memorial Hospital, University of Rochester Medical Center (NY)
Suburban Hospital (MD)
Sunna Health System (NH)
Sunnybrook Health Sciences Centre (Canada)
SUNY Upstate-University Hospital Medical Center (NY)
Superior Vascular Associates, Inc. (CA)
Surgical Specialists of Central Florida (FL)
SwedishAmerican Hospital (IL)
Swedish Cherry Hill (Providance) (WA)
Swedish Edmonds (Providance) (WA)
Swedish First Hill (Providance) (WA)
Tallahassee Memorial Healthcare, Inc. (FL)
Tampa General Hospital (FL)
Tenet Florida Physicians Services, LLC (FL)
Texas Heart Hospital (TX)
Texas Heart Presbyterian Hospital (TX)
The Christ Hospital (OH)
The Hospital Authority of Valdosta and Lowndes County Georgia (GA)
The Johns Hopkins Hospital (MD)
The Medical Center of Aurora (CO)
The Medical Center, Navicent Health (The Medical Center Authority of Central Georgia, Inc.) (GA)
The Methodist Hospital (TX)
The Methodist Medical Center of Dallas (TX)
The Methodist Medical Center of Illinois (IL)
The Methodist Health System (OH)
The Ohio State University, Wexner Medical Center (OH)
The Practice of John F. Lucas III, M.D. (MS)
The Proctor and Gamble Medical Center (PA)
The University of Arizona Medical Center-University Campus (AZ)
The University of California Irvine Medical Center (CA)
The University of Southern California on behalf of its Keck Medicine of USC (CA)
The University of Texas M.D. Anderson Cancer Center (TX)
The University of Texas Southwest Medical Center (TX)
The Valley Hospital (NJ)
The Vencor and Vascular Institute of Tampa Bay (FL)
Thomas Jefferson University Hospitals, Inc. (PA)
Thunder Bay Regional Health Sciences Centre (Canada)
TID Regional Medical Center (GA)
Toronto General Hospital (Canada)
Tradition Medical Center (CA)
Trinity Medical Center (CA)
Tristar Centennial Medical Center (TN)
Tristar Summit Medical Center (TN)
Tucson Medical Center (AZ)
Tufts Medical Center (MA)
Turkey Creek Medical Center (TN)
UC Davis Health System (CA)
UCHA- Medical Center Hospital, Inc. (CO)
UCAL- Ronald Reagan Medical Center (CA)
UCSD Medical Center (CA)
UCSF Medical Center (CA)
UF Health- Shands Hospital (FL)
UNC Hospitals (NC)
United Health Services Hospitals, Inc. (NY)
United Hospital Center (WV)
UnityPoint Health- Des Moines (IA)
UnityPoint Health- Meriter Hospital (WI)
University of Washington Medical Center (Moffitt Cancer) (WA)
University Hospitals Cleveland Medical Center (OH)
University Hospitals Health System (OH)
University of Iowa (IA)
University of Kansas Medical Center (KS)
University of Kentucky (KY)
University of Maryland Medical Center (MD)
University of Massachusetts Memorial Hospital (MA)
University of Missouri Kansas City (MO)
University of Missouri (MO)
University of Oklahoma School of Community Medicine (OK)
University of Pennsylvania Medical Center (PA)
University of Texas Health Science Center, San Antonio (TX)
University of Utah Hospital and Clinics (UT)
University of Vermont Medical Center (VT)
University of Washington Medical Center (WA)
University of Wisconsin Hospitals and Clinics Authority (WI)
Upstate Surgical Associates (TN)
UPMC Altoona (PA)
UPMC/UP Vascular Surgery (PA)
UPMC/Hamilton General Hospital (PA)
UPMC Pinnacle Hanover (PA)
UPMC Pinnacle Hazleton (PA)
UPMC Pinnacle Memorial (PA)
UPMC Pinnacle West Shore (PA)
UPMC Shadyside Hospital (PA)
UPMC Williamsville (PA)
UPMC Western Maryland (MD)
Utah Valley Hospital (UT)
UVA Medical Center (UVA Health System) (VA)
ValleyCare (CA)
Vanderbilt University Medical Center (TN)
Vascular & Vascular Surgical Specialists of SWFL (FL)
Vascular Institute of Chattanooga (TN)
Vascular Institute of Michigan (MI)
Vascular Surgery Associates (FL)
Venice Regional Bayfront Hospital (FL)
Vereen Valley Medical Center (AZ)
Vidant Medical Center (NC)
Virginia Commonwealth University Hospital (VA)
Virginia Mason (WA)
Wadley Regional Medical Center (TX)
Wake Forest Baptist Health (NC)
WakeMed Health & Hospitals – Cary Campus (NC)
WakeMed Health & Hospitals – Raleigh Campus (NC)
Washington Hospital Health System (CA)
Wayne UNC Health Care (NC)
Well Cornwall Medical College (NY)
Weiss Memorial Hospital (IL)
Well Spur Surgery Center (Good Samarran) (PA)
WellSpan York Hospital (PA)
West Hospital (TX)
West Jefferson Medical Center (LA)
West Tennessee Heart and Vascular Center (TN)
West Virginia University Hospitals, Inc. (WV)
Westchester Medical Center (NY)
White Plains Hospital (NY)
White Square Vascular Surgery (MD)
Wills-Knighton North (LA)
Winchester Medical Center (VA)
Winter Haven Hospital (FL)
Yale New Haven Hospital (CT)
Yavapai Regional Medical Center (AZ)
Yuma Regional Medical Center (AZ)
APPENDIX B— SOCIETY FOR VASCULAR SOCIETY PATIENT SAFETY ORGANIZATION (SVS PSO)

The Patient Safety and Quality Improvement Act of 2005 authorized the creation of Patient Safety Organizations (PSO) to improve the quality and safety of health care by the collection and analysis of patient data. It protects any comparative outcome analyses or other aggregated reports that is generated by a PSO from discovery in state and federal court. These analyses and reports, called Patient Safety Work Products (PSWP) can be used for quality improvement but not for disciplinary action against a provider. It allows patient identifiers to be collected, without specific IRB or patient approval. This permits a PSO to match patients with other data sources, such as the Social Security Death Index or Medicare claims data to evaluate long-term effectiveness of procedures in terms of mortality or complications. The identity of patients, hospitals, providers and other protected health information cannot be disclosed by a PSO, although non-identifiable data can be published for quality improvement research, adhering to both PSO and HIPAA requirements. SVS VQI embraced the use of a PSO to house its activities, because it provides substantially more security and protection than most registries.

VQI SUPPORTING SOCIETIES
American College of Cardiology*
American Venous Forum*
Canadian Society for Vascular Surgery
Eastern Vascular Society
Florida Vascular Society
Georgia Vascular Society
Michigan Vascular Society
Midwestern Vascular Surgical Society
New England Society for Vascular Surgery
New York Society for Vascular Surgery
Peripheral Vascular Surgery Society
Rocky Mountain Vascular Society
Society for Clinical Vascular Surgery
Society for Vascular Medicine*
Society for Vascular Ultrasound*
Southern Association for Vascular Surgery
Southern California Vascular Surgical Society
The American Heart Association*
Vascular Access Society of America*
Western Vascular Society

*Members of SVS PSO Governing Council

APPENDIX C—FIVOS (FORMERLY MEDSTREAMING/M2S) CLINICAL PLATFORM

The SVS Vascular Quality Initiative is built on Fivos PATHWAYS® clinical registry platform, allowing users to track, measure, and analyze clinical information, promote collaboration, objectively drive decisions, and optimize performance.

PATHWAYS is a secure, cloud-based solution that enables physicians, institutions, clinical data managers, and researchers to collect, manage, analyze, and disseminate their clinical data to achieve optimal outcomes. Accessible by any computer with a compatible browser, PATHWAYS is designed to easily integrate into a variety of workflows by allowing multiple users to access and enter data on a single procedure form, and to spread the responsibilities of data entry to more than one individual. Authentication identifies users’ roles and permissions to ensure appropriate access to content within PATHWAYS. Real-time data validation through error-trapping and alerts ensure that only high-quality data is populated into the system. PATHWAYS has been designed to support large-scale quality improvement and research projects as dynamic content within registries can easily be added and/or modified.

About Fivos
Fivos was formed in 2021 by the planned combination of two highly complementary businesses, Medstreaming and M2S. Fivos offers specialty-based workflow reporting applications for providers, registry solutions and support for medical societies, and custom data sets for device manufacturers that advance innovation.

At Fivos, we believe in healthcare IT innovation that enables proactive patient care and improves the quality of healthcare. Combining decades of industry experience, a thorough understanding of data science, and a large dose of curiosity, we are committed to empowering healthcare organizations to leverage data to create efficiencies, manage costs, and improve outcomes. For more information, visit www.fivoshealth.com.