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1. EXECUTIVE SUMMARY - THE VALUE OF PARTICIPATION IN THE SOCIETY FOR VASCULAR SURGERY (SVS) VASCULAR QUALITY INITIATIVE (VQI)

BIGDATA

According to Oxford languages, "big data are extremely large data sets that may be analyzed computationally to reveal patterns, trends, and associations, especially relating to human behavior and interactions."

The VQI database clearly meets this definition. The VQI registry contains over 1,000,000 procedures that have been entered with over 100 million exposure variables and greater than 50 million outcome variables for analysis. That is indeed a robust source of high quality data for analysis. VQI data has been the source of > 600 peer reviewed scientific publications. VQI data analysis has led to changes in clinical practice that has improved the care of vascular patients - appropriate prescription of preoperative and postoperative medications, patching for carotid endarterectomy, protamine reversal of heparin, and others. Compliance with these measures has led to thousands of lives saved, strokes prevented, and limbs preserved. These findings would not have been possible in a smaller data set and required the large volume and sophisticated analytic methodology to become identifiable. VQI data has helped us understand and resolve the Paclitaxel issue affirming the safety of drug-coated balloons and drug-eluting stents. VQI data has helped us understand the impact of COVID-19. In 2021, the FDA convened a 2 day panel on endovascular AAA graft surveillance and type III endoleaks. Again, VQI data made a significant contribution to the discussion which is still ongoing. Tip O'Neill once said "all politics is local". At VQI, we feel that all patient care improvement is local. Every provider and center that participates in VQI receives quarterly dashboards and regular performance reports to facilitate meaningful quality assessment and focus 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.

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 1,000 centers that have entered more than 1,000,000 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 14,000 new procedures are added monthly. The wealth of data in the registry allows centers and providers to measure their own performance and compare it to regional and national benchmarks.

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 600 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 College of Cardiology (ACC), 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.



Dr. Jens Jorgensen SVS PSO Medical Director

2. INTRODUCTION TO THE SVS VQI

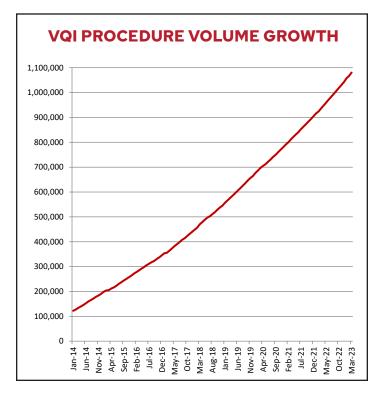
The SVS VQI is a collaboration of the SVS Patient Safety Organization (PSO), 18 regional quality improvement groups, and Fivos, its commercial technology partner. The mission of SVS VQI is to improve the quality, safety, effectiveness, and cost of vascular healthcare.

The SVS PSO is a wholly owned subsidiary of the Society for Vascular Surgery, with headquarters in Rosemont, IL. 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 the 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.





THE SVS VQI REGISTRIES

As of May 1, 2023, there are 14 SVS VQI registries that contain 1,092,096 vascular procedures. From April 1, 2022 through May 1, 2023, there were over 155,000 procedures added to the registries.

Total Procedures Captured as of 5/1/2023 1,092,096

Peripheral Vascular Intervention	377,562	
Carotid Endarterectomy	193,672	
Carotid Artery Stent	98,364	
Infra-Inguinal Bypass	81,662	
Endovascular AAA Repair	80,821	
Hemodialysis Access	79,936	
Varicose Vein	61,706	
Thoracic and Complex EVAR	29,084	
Lower Extremity Amputations	28,598	
Supra-Inguinal Bypass	26,070	
IVC Filter	18,357	
Open AAA Repair	17,850	
Vascular Medicine Consult	1,236	
Venous Stent	178	



3. A YEAR OF MILESTONES

It has been a year of numbers! As we celebrate our 12th Anniversary, SVS VQI has a lot to be proud of. In the past year, the VQI reached 1,000,000 procedures and 1,000 centers, surpassed the 1,000 mark for Data Analysis Projects. We also had over 100 Quality Charters submitted since last year. We applaud each of the VQI participating centers and individuals and their part of helping the registry achieve these milestones.





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 and compliance with quidelines
- •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
- •Work collaboratively with the SVS to develop quality measures

For Payers

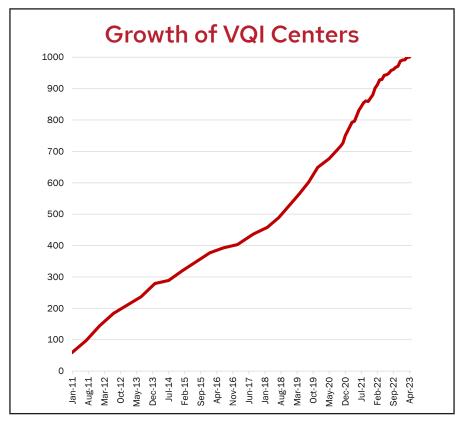
- •Adopt best practices to provide better care and reduce complications and expenses
- •Inform population health approaches through use of comparative data
- •Reduce expenses due to decreased length of stay and resource utilization

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

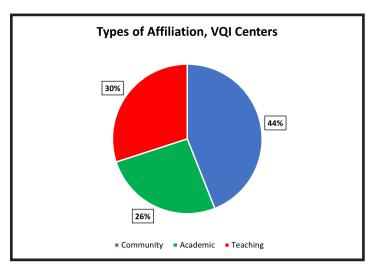
4. SVS VQI MEMBERS PROFILE

Participation in SVS VQI continues with steady growth reaching over 1,000 centers including office-based laboratories by the end of March 2023 (Figure 4.1). There is a broad distribution of different practice types – 26% academic institutions, 30% teaching hospitals and 44% community hospitals (Figure 4.2). There is also broad distribution of physician specialties – 43% vascular surgeons, 18% interventional cardiology, 14% interventional radiology, 5% general surgery, 5% cardiothoracic surgery, 4% neurosurgery, 3% podiatry, 2% orthopedic surgery and 1% Neurology (Figure 4.3).



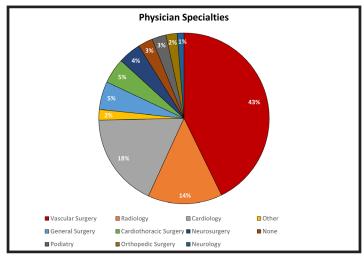
Source: Fivos PATHWAYS Data, April 2023

Figure 4.1: Growth of SVS VQI Centers (as of April 1, 2023)



Source: Fivos PATHWAYS data, Feb 2023

Figure 4.2: SVS VQI Participating Hospital Types



Source: Fivos PATHWAYS Data, Jan 2023

Figure 4.3: Distribution of SVS VQI Physician Specialties

5. SVS VQI TRAINEE PROGRAM

The SVS PSO rolled out the Quality Fellowship in Training (FIT) pilot program for residents and fellows in vascular surgery and medicine in collaboration with APDVS in 2022. The Fellowship in Training (FIT) program was designed to introduce residents and fellows in vascular programs to quality improvement through the mechanism of our patient safety organization (VQI/PSO). Using a mentordirected approach, these FIT applicants worked closely with their VQI mentor on participation in regional biannual meetings and reviewed comparative data including center level quality improvement processes. Opportunities included engagement in quality charter development, center level QI process and research initiatives using VQI data reviewed by the VQI research advisory committee (RAC). Advancement through the 12–18-month program provided the FIT applicants opportunities to present their work during VQI@VAM with potential selection for a highly coveted Jack L Cronenwett Scholarship to continue research and/or work more closely with VQI/PSO staff and committees.

Five of the Sixteen FIT Fellows were selected in either Quality Improvement or Research to receive the Jack L Cronenwett Scholarship worth up to \$5,000 each. Those selected included:

2023 Jack L. Cronenwett Scholarship Award Recipients

Ben Li (Research)

Mentor: Dr. Graham Roche-Nagle Toronto General Hospital

Christine Kariya (QI)

Mentor: Danny Bertges University of Vermont Medical Center

Brianna Krafcik (Research)

Mentor: Phil Goodney Dartmouth Hitchcock Medical Center

Hanaa Dakour Aridi - (QI)

Mentor: Michael Murphy IU Health - Methodist

Caronae Howell - (Research)

Mentor: Ben Brooke University of Utah Hospital and Clinics



A rigorous selection process was employed to review the next many strong applications for the 2023 -2024 FIT Fellow application process that we received for the program. We are inspired by the genuine interest in and commitment to quality improvement. We are confident that the VQI FIT Program will further enhance their knowledge and skills to be able to lead and improve the quality of vascular care throughout their careers. Please join us in congratulating this next outstanding group of young physicians committed to vascular care!

2023-2024 FIT Trainees

Deena Chihade

Mentor: Dr. Michael Costanza University Hospital

Paul Rothenberg

Mentor: Dr. Samantha Minc West Virginia University

Mitri Khoury Mentor: Dr. Nikoloas Zacharias Massachusetts General Hospital

Tiffany Bellomo

Mentor: Dr. Nikoloas Zacharias Massachusetts General Hospital

Christopher Chow

Mentor: Dr. Arash Bornack University of Miami

Mikayla Lowenkamp

Mentor: Dr. Mohammed Eslami

Sarayana Sundaram Mentor: Dr. Thomas Brothers Medical University in South Carolina

Michael Fassler

Mentor: Dr. Sal Scali University of Florida

Amanda Filiberto

Mentor: Dr. Adam Beck University of Alabama Medical Center

Syeda Ayesha Farooq

Mentor: Dr. Dan Newton VCU

Nakia Sarad

Mentor: Dr. Brian DeReburtis Weill Cornell Medical Center



6. DATA QUALITY DASHBOARDS & REGIONAL REPORTS

The SVS PSO Best Practice Dashboards allow centers to review their performance and compare it 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

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

Includes Peripheral Vascular Intervention (PVI) procedures for mild, moderate, or severe claudication.

Legend: Blue = "Top" 25th percentile Coral = "Bottom" 25th percentile

Category	Outcome/Complication	Your Center	Your Region	VQI Overall
Case Data				
	Number of Cases Reviewed	117	1935	12419
	Median Postop LOS (days)	0	0	0 [0 0 0 0 1]
	Median Total LOS (days)	0	0	0 [0 0 0 0 1]
Smoking				
	Never	10.3%	20.4%	14.8% [0 4 9.2 15.1 25.9]
	Prior	62.4%	49%	48.6% [31 40.8 50 60.4 71.4]
	Current	27.4%	30.6%	36.6% [14.4 25 36.3 48.1 57.8]
Preop ABI				
	Preop ABI/Toe Pressure Reported	81.2%	64%	75% [31.9 63.9 81.8 93.8 100]
Postop Events				
	MI	2.6%	0.3%	0.2% [0 0 0 0 0]
	Change in Renal Status	0%	0.4%	0.3% [0 0 0 0 0.6]
	Thrombosis	2.6%	0.4%	0.5% [0 0 0 0 2]
	Embolization	0.9%	0.3%	0.4% [0 0 0 0 1.4]
	Target Lesion Dissection	2.6%	1.7%	3.3% [0 0 0 3.8 10.2]
	Artery Perforation	2.6%	0.7%	0.6% [0 0 0 0 2.2]
	Access Site Hematoma	0%	1.9%	1.6% [0 0 0 2 5]
	Access Site Infection	0%	0.1%	0% [0 0 0 0 0]
	Unplanned Amputation	0%	0.3%	0.3% [0 0 0 0 0]
Discharge Medication	ns			
	Antiplatelet+Statin	92.9%	92.9%	85.8% [66.8 81.1 89.9 97 100]
Discharge Destinatio	n			
	Home	96.6%	96.6%	97.8% [93.8 97.1 100 100 100]
	Rehab Unit	1.7%	1%	0.9% [0 0 0 0 2.3]
	Nursing Home	0%	1.1%	0.7% [0 0 0 0 2.6]
	Other Hospital	0%	0.1%	0.2% [0 0 0 0 0]
	Homeless	0.9%	0.2%	0.1% [0 0 0 0 0]
	Dead	0.9%	1%	0.4% [0 0 0 0 0.5]

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.

Legend: Blue = "Top" 25th percentile Coral = "Bottom" 25th percentile

Category	Outcome/Complication	Your Center	Your Region	VQI Overall
Case Data				
	Number of Cases Reviewed	337	3894	23642
	Median Postop LOS (days)	2	1	1 [0 0 1 2 4
	Median Total LOS (days)	3	3	3 [0 0 2 4.5 7]
Smoking				
	Never	19.9%	30.3%	28.8% [13.5 21 27.6 34.5 43.8]
	Prior	51.6%	43.9%	41.4% [26.6 34.7 41.7 47.6 53.4
	Current	28.5%	25.8%	29.7% [15.4 22.2 29.5 39.3 46.4]
Preop ABI				
	Preop ABI/Toe Pressure	700/	07.70/	CF 00/ F07 0140 4170 CID4 4104 0
	Reported	73%	67.7%	65.9% [27.9 48.1 70.6 84.1 91.9]
Postop Events				
	MI	0.6%	0.8%	0.8% [0 0 0 1 2.6
	Change in Renal Status	2.1%	2.3%	1.9% [0 0 0 3.2 5.2
	Thrombosis	1.8%	0.9%	1.2% [0 0 0 1.7 3.8
	Embolization	0.3%	0.5%	0.8% [0 0 0 0.8 2
	Target Lesion Dissection	6.2%	2.3%	4% [0 0 0.9 5.1 10.1
	Artery Perforation	0.6%	0.4%	0.9% [0 0 0 0.7 2.4]
	Access Site Hematoma	3%	2.3%	2.2% [0 0 1.2 3.2 5.5
	Access Site Infection	0%	0.2%	0.1% [0 0 0 0 0
	Unplanned Amputation	3.3%	2.5%	3.1% [0 0 1 3.9 8.5]
Discharge Medications				
	Antiplatelet+Statin	92.3%	87.2%	81.8% [62.5 71.9 83.3 89.1 95.1]
Discharge Destination				
	Home	81.1%	79.9%	81.7% [69.2 76.7 82.8 88 94.8]
	Rehab Unit	13.2%	11.4%	7.9% [0 1.7 5.4 11.3 17.7
	Nursing Home	4.2%	6.3%	7.3% [0 1.7 5.8 11 17.1]
	Other Hospital	0.6%	0.6%	1.4% [0 0 0 1.8 4
	Homeless	096	0.1%	0.1% [0 0 0 0 0
	Dead	0.9%	1.6%	1.6% [0 0 0.8 2.4 3.6

7. REGIONAL QUALITY GROUPS

SVS VQI has 18 regional quality groups based on geographic proximity (Figure 7.1). 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.

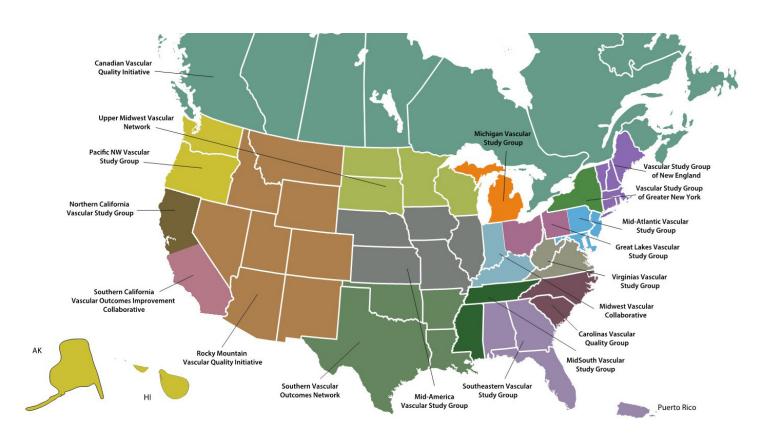


Figure 7.1: SVS VQI Regional Group Map

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

8. QUALITY IMPROVEMENT PROJECTS: LEARNING FROM THE DATA

The SVS PSO encourages centers to submit quality improvement (QI) charters that are based on projects using SVS VQI data. This process has helped the SVS PSO identify groups working on similar initiatives and facilitate networking opportunities. As projects reach completion, the SVS PSO encourages centers to share best practices with the full VQI membership through the several QI resources and tools that are currently offered.

Quality Improvement Projects

SVS VQI centers work on QI projects which may be selected for presentation at the VQI Annual Meeting. These projects are often related to the National QI Initiatives; however, they can address any vascular topic supported by VQI data. We encourage centers to use their Pathways Dashboards when considering QI projects as well. The SVS PSO provides resources to assist SVS VQI centers with their QI projects.

Quality Improvement Tools

The SVS PSO, together with FIVOS, develops QI tools to assist VQI members, data managers, vascular nurses, quality improvement staff, and hospital administrators with their own vascular quality programs. These tools include:

- Presentations
- Webinars/Events
- VQI Annual Meeting
- QI Supplemental Guide
- Educational Videos/Audio
- Sample Charters
- Case Studies
- 1:1 Mentoring
- SVS VQI Annual Summary Report
- QI Annual Abstract Guide
- Annual Rapid Fire Abstract Guide

Participation Awards

The SVS PSO encourages provider and center engagement through a program of annual Participation Awards. Participation Awards are given based on four domains that include: long-term follow-up rates, regional meeting participation, quality improvement initiatives, and registry participation. Certificates are distributed to centers receiving the maximum award level at the national meeting. All award levels are acknowledged during regional meetings. Marketing guidelines for displaying Participation Awards can be found on the VQI website. Participating centers can earn up to three stars based on the following criteria of the four domains:

- 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 VOI data
- The number of vascular registries in which the center participates

SVS VQI centers diligently work on and submit quality improvement charters throughout the year. In 2022, there were 113 charters submitted by the identified 18 VQI regions (Figure 8.1). Of these 113 charters, 3% were Hashtag, 22% were Regional, and 75% were Center charters. (Figure 8.2)

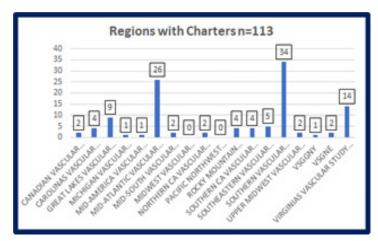


Figure 8.1 – Quality Improvement Projects Submitted in 2022

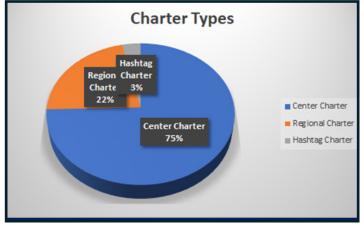


Figure 8.2 - Quality Improvement Charter Types

^{*}Some tools are within members only section

9. NATIONAL QUALITY IMPROVEMENT INITIATIVES OPTIMAL DISCHARGE MEDICATIONS AND EVAR LONG-TERM FOLLOW-UP IMAGING

The SVS PSO chose to focus on discharge medications and EVAR follow-up imaging because these two quality measures have been shown to increase long-term survival rates for vascular patients. Previous work by De Martino et al (J Vasc Surg, 2014 Jun;59(6):1615-21) demonstrated that patients undergoing major arterial procedures have a 25% improvement in 5-year survival if they are discharged on an anti-platelet agent and a statin. Long-term follow-up imaging is essential after EVAR to determine the success of the procedure, defined by exclusion of the aneurysm without significant endoleak or continued sac enlargement.

Tracking the performance of individual medical centers on these measures allows our members to use their data for successful QI initiatives.

To support these initiatives, the SVS PSO continues to provide quality improvement (QI) webinars, focused charter webinars, newsletters, regional meetings, and reports to assist you, our members, in analyzing your data, defining the problem, developing a plan (charter), implementing a process, and evaluating your outcomes. Many of you have created charters on D/C Medications and EVAR LTFU Imaging and are in the process of implementing your processes. Both initiatives are discussed in detail at regional meetings.

The VQI overall DC medication rate was 87% in 2022. In fact, most of the identified 18 VQI Regions have stabilized and the SVS PSO have decided that this NQI, although still important, will be termed as in 'maintenance mode'. (Figure 9.1)

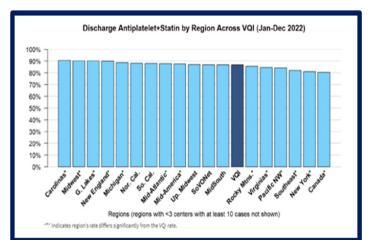


Figure 9.1 – Discharge Medications and Statin Rate for 121 SVS VQI Hospitals (2012 to Date).

Since EVAR imaging is a long-term follow-up measure, rates are not calculated until two years after the date of operation to allow centers adequate time to capture and enter LTFU. The goal is for 100% of EVAR patients to have imaging at one year. VQI overall LTFU for 2019 was at 71%, and VQI overall LTFU for 2020 was at 75%. We still have room for improvement to reach our goal (Figure 9.2).

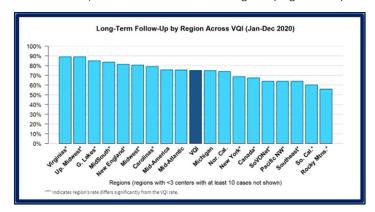


Figure 9.2 - Long-Term Follow-Up by Region

As of June 2023, we are adding a new National Quality Initiative of Smoking Cessation. Two quality measures were added in the 2023 Spring Reports. Those included Preoperative Smoking and Smoking Cessation.

Preoperative Smoking includes all elective procedures for arterial registries. Inclusion criteria is the percentage of those procedures where the patient was still smoking within one month of the procedure. For 2022, the VQI overall preoperative smoking rate is 30% (Figure 9.3).

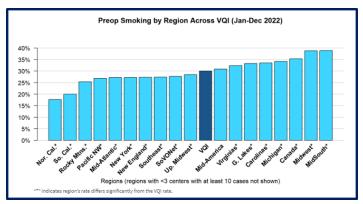


Figure 9.3 - Preop Smoking by Region

Smoking Cessation is a long-term follow-up measure. Rates are not calculated until two years after the date of operation to allow centers adequate time to capture

9. NATIONAL QUALITY IMPROVEMENT INITIATIVES OPTIMAL DISCHARGE MEDICATIONS AND EVAR LONG-TERM FOLLOW-UP IMAGING (CONT.)

and enter LTFU. This measure includes all elective procedures for arterial registries performed on patients still smoking within one month of the procedure. It excludes procedures that do not have at least one long-term follow-up record where the patient's follow-up smoking status was recorded. For 2020, the VQI overall smoking cessation rate was 26% where the patient was not smoking within one month on follow-up for *all* LTFU records. (Figure 9.4)

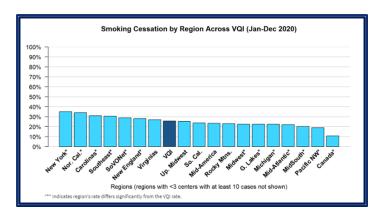


Figure 9.4 – Smoking Cessation by Region

Given this new National Quality Initiative, there will be many webinars, toolkits, and education provided. Please visit www.vqi.org for more information and to register for various educational offerings.

With the various resources and support provided to you, our members, together, we can reach our goal for each of these initiatives.

10. SVS PSO DATA INTEGRITY AUDITS

The SVS PSO is excited to announce the next phase of our data integrity audits. Historically, the SVS PSO have performed both claims validation audits and data outlier audits. We have rolled out the new data integrity audit in May 2023 for centers participating in the carotid artery stent registry. Over time, the SVS PSO intends to roll out data integrity audits to all our registries.

There have been over 600 published articles and 1000+ total data analysis projects using VQI data. These published articles have assisted in developing practice guidelines and standards. It is imperative for the SVS PSO to support the validity of the data captured on our registry. Gaps in a centers' data integrity can lead to poor decision-making that can impact the data analysis, benchmarking, and quality of patient care. Without a tool to objectively measure the accurateness of the data entered, areas of opportunities for improvement are missed. The overall purpose of this program is to ensure that data submitted to the VQI registries is complete, valid, and accurately interpreted and collected, to improve the quality of VQI registries.

The SVS PSO has contracted with an independent firm to perform the data integrity audits. Telligen will blindly abstract the selected cases. Then the Telligen results will be compared to the originally abstracted information to determine an accuracy rate.

Centers who are not currently selected for claims validation audits and are participating in the carotid stent registry could be randomly selected to included in the 2023 data integrity audits. Over time, all VQI participating sites will be audited on a rotating basis over a three-year period.

11. SVS VQI CARDIAC RISK INDEX (VQI CRI)

The VQI Cardiac Risk Index (VQI-CRI) estimates the chance that a patient will have an in-hospital postoperative myocardial infarction based on preoperative patient and procedure information that is entered into an online calculator (Figure 11-1). These estimates are calculated using VQI data collected from a large number of patients who had a procedure similar to the one for which the patient may be a candidate. The VQI-CRI was designed to provide accurate, patient-specific risk estimates to guide decision-making and informed consent. The VQI-CRI is available for the following five vascular surgery procedures: Carotid Endarterectomy, Endovascular AAA Repair, Infrainguinal Bypass, Open AAA Repair, and Suprainguinal Bypass.

Once the patient characteristics have been entered, the VQI-CRI calculator outputs the resulting risk value along with a figure to display comparative risk. The user then has the option to save this output via the "Generate report" feature, which will create an HTML document (Figure 11:2).

This calculator will be available through the VQI website and QxMD in both a desktop and mobile friendly format.

The VQI CRI can be accessed from the VQI website. Click here to learn more:

https://www.vqi.org/risk-calculators/

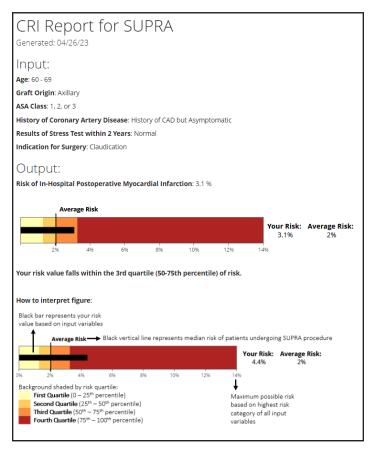


Figure 11.2: CRI Report

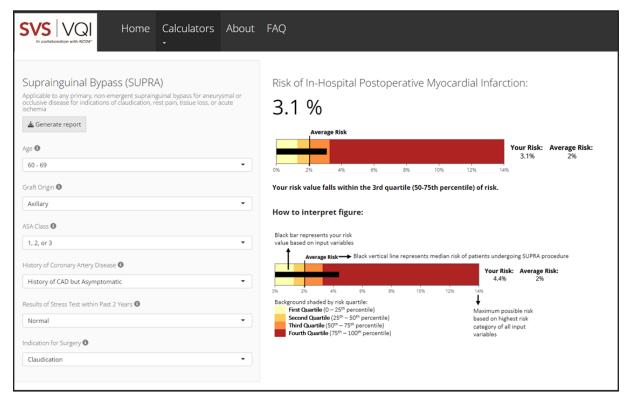


Figure 11.1: CRI Online Calculator

12. 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 April 2023, the RAC has approved over 1,000 projects, and of those, 695 have been published in peer-reviewed journals.

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.

13. SVS CLINICAL PRACTICE GUIDELINES AND THE SVS VQI

Professional societies write clinical practice guidelines to improve care and reduce practice variation. A few years ago, the SVS Document Oversight Committee asked VQI to assess practitioner compliance with guidelines and adoption over time. VQI was able to measure adherence to guidelines as well as correlating guideline compliance with outcomes. Subsequently two analyses of guideline compliance have been done on AAA and carotid disease. 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 (VASCULAR QUALITY INITIATIVE ASSESSMENT OF COMPLIANCE WITH SOCIETY FOR VASCULAR SURGERY CLINICAL PRACTICE GUIDELINES ON THE CARE OF PATIENTS WITH ABDOMINAL AORTIC ANEURYSM. Eldrup-Jorgensen J, Kraiss LW, Chaikof EL, Neal D, Forbes TL. J Vasc Surg. 2020 Jan 20). Participation in the VQI registry was shown to provide an objective assessment of performance and compliance with guidelines. Compliance with recommendations was associated with improved outcomes and was encouraged for providers. VQI provider and center reports may be used as a focus for quality improvement efforts.

During the past year, another analysis has been done on compliance with treatment for extracranial cerebrovascular disease CPG, (VASCULAR QUALITY INITIATIVE ASSESSMENT OF COMPLIANCE WITH SOCIETY FOR VASCULAR SURGERY CLINICAL PRACTICE GUIDELINES ON THE MANAGEMENT OF EXTRACRANIAL CEREBROVASCULAR DISEASE. Marcaccio CL, AbuRahma AF, Eldrup-Jorgensen J, Brooke, BS, Schermerhorn ML. J Vasc Surg. 2023 Mar 20;S0741-5214(23)00471-8. doi: 10.1016/j.jvs.2023.03.026.). Compliance with these recommendations was associated with improved outcomes after carotid revascularization. This finding confirmed the value of guideline compliance. Optimization of VQI data to promote evaluation of quideline compliance and distribution of these findings to VQI centers and providers will help facilitate quality improvement efforts in the care of vascular patients. VQI continues to collaborate with the SVS Document Oversight Committee to analyze compliance with SVS clinical practice guidelines.

www.VQI.org

14. NEW VQI.ORG EXPERIENCE

New VQI Website!

We started the process of getting a newly designed VQI website over a year ago, and worked to develop what we hope users find to be an easier site to navigate. We have also added some visual pieces and videos that provide the benefits of the VQI in the words of our members. Earlier this year, we launched, the new and improved VQI Website.



Exciting New Features

The new site features a clean and easy to navigate interface, webpages dedicated to each of the 14 different VQI Registries, consistency among the Regional Group pages, more robust search capabilites, a streamlined Members Only area, a calendar of upcoming webinars and events, and much more!



VQI Website - Members Only Area

The Members Only area of the VQI Website has also been redesigned. If you do not have have a login, please reach out to Jen Correa, jcorrea@svspso.org (please note you will need different credentials than your PATHWAYS login). With Members Only, users have access to resources such as VQI@VAM recordings, certain webinar recordings, and much more. Please note that this login is different than your PATHWAYS user account.

15. SVS VQI COMMUNICATIONS

In addition to the new website, the SVS VQI has made many efforts to improve on the methods to disseminate information to VQI participants and other stakeholders. Here are just some of the ways, we are helping to get information into your hands.

Monthly VQI News

The monthly VQI Newsletter is your source for all things VQI. The newsletter contains information about upcoming events, PATHWAYS announcements, VQI@VAM information, where to access webinars and recordings, and many other important details.

Follow Us On LinkedIn

The SVS Vascular Quality Initiative (VQI) is now on LinkedIn. Follow our page for the latest news and events!

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/

Regional Group Meetings

Regional Group Meetings are a great source of information for VQI members. Information about each Regional Group meeting can be found on the individual Regional Group pages. On each page, you will find the location, links to minutes and presenations, etc...

Quality Improvement Calls/Webinars

Betsy Wymer, SVS VQI Director of Quality, hosts quarterly Quality Improvement Calls and Quality Improvement Webinars. Registration links for these events can be found on the VQI website.

Email Communications

We know email fatigue is real. We try not overloading you with emails, but sometimes, that is simply the most direct and efficient way of getting you the information you need. Once you signup for the VQI and have access to PATHWAYS, you will automatically receive emails. If you are not receiving emails from us, there is a chance that your facility may have a firewall preventing messages from getting through. Emails we send come from either Vascular Quality Initiative or PATHWAYS Support.

16. 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 thank 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



AMERICAN COLLEGE OF CARDIOLOGY (ACC)/NCDR

The American College of Cardiology and Society for Vascular Surgery have moved to a single vascular registry to harness the strengths of both organizations in improving care and outcomes of patients with vascular disease.

The ACC NCDR Peripheral Vascular Intervention (PVI) registry has been operated by SVS since January 1, 2021, creating a co-branded VQI program that is a unique and comprehensive resource for measuring and improving the care provided to a growing population of patients with vascular diseases.

The new registry collaboration provides greater opportunities to evaluate new and emerging technologies, pharmacologic therapies, and medical and lifestyle management. It also provides a rich source of data for academicians, the FDA and industry looking to answer scientific questions about patient characteristics and outcomes and the use and effectiveness of different treatments.

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@fivoshealth.com, or by calling 603-298-0263, 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 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.

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AMERICAN VENOUS FORUM

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, mechanochemical 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.

17. 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









Quality Partner



Quality Associate















18. 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 using real world evidence and 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.

Last year the Cook Zenith Dissection Endovascular System® joined the TEVAR Dissection Surveillance Project. 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 postmarket surveillance, as is done through VQI for the W. L. Gore and Medtronic devices after their approval.

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

Transcarotid Artery Revascularization (TCAR) Surveillance Project

The TCAR Surveillance Project is designed to study the efficacy of TCAR in comparison with the standard of care, CEA, on patients requiring intervention for carotid stenosis 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 on high risk patients 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. 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. Last year the FDA issued an Approval For The Expansion Of The Indications For Use To Include Treatment Of Patients At Standard Risk For Adverse Events From Carotid Endartectomy. For centers or providers to be reimbursed for performance of TCAR, they must participate and enter data in the VQI Carotid Artery Stent Registry.

For more information on the TCAR Surveillance Project, please see Clinical Trials.gov: https://clinicaltrials.gov/ct2/show/NCT02850588

FDA PANEL ON TYPE III ENDOLEAKS AND REAL WORLD EVIDENCE - The US Food and Drug Administration (FDA) convened a two-day panel in November, 2021 to review the performance of endovascular aortic stent grafts and real-world evidence. The FDA panel expressed concern about the real world data that is available for evaluation and surveillance of endovascular aneurysm repair (EVAR) devices. The panelists recommended strengthening EVAR surveillance and data collection recognizing that it would require a change in culture and additional support.

IMPROVING PATIENT CARE – The IFU for all EVAR devices and SVS clinical practice guidelines recommend annual scans following EVAR. Current compliance in clinical practice with annual follow up is poor. Numerous reports have shown that less than half of patients undergo recommended imaging post–EVAR putting patients at risk for undetected endoleaks, aneurysm rupture and aneurysm-related mortality. Clearly providers and patients need more motivation to comply with the guidelines regarding follow up. Lack of compliance with scanning results in poor patient care and lack of evidence for evaluation of device performance and regulatory quidance.

IMPROVING DATA COLLECTION - The primary message from the FDA panel is the increased risk of type III endoleaks from certain devices and the lack of adequate data for analysis. Data sources including the SVS VQI registry and Medicare claims were mentioned as potential sources/solutions for data collection. At present, 189 sites participate in the VQI EVAR registry. In order for VQI centers to ensure adequate follow up and data collection annually for 5+ years would require additional personnel and resources. VQI has the appropriate infrastructure in place - registry forms and data collection personnel are present at all sites. In order to obtain adequate data for analysis, it is not necessary to require all centers to participate in prolonged post-EVAR data collection. A subset of centers could record annual long term follow up providing adequate data for device evaluation.

1/01

VASCULAR RESEARCH COLLABORATIVE (VRC) -

A subset of VQI centers (40–50) could be selected based on volume, quality of data entry, site variety (academic, teaching, community, urban, rural, etc) and patient diversity (Under Represented In Medicine) to ensure appropriate representation. These sites, a tiered subset of VQI centers, would require additional financial support to ensure annual follow up for 5–10 years. As many centers are performing 50–100 EVARs annually, this tiered approach would provide a large sample (>3000 annually) for developing an evidence-based analysis of device performance.

VQI-VISION - An existing program called the VQI Vascular Implant Surveillance and Interventional Outcomes Network, or VQI-VISION, has linked Medicare patients in the VQI registry to their Medicare claims, and may be a feasible next step forward to improve data collection after EVAR.² This partnership, in collaboration with the FDA-funded Medical Device Epidemiology Network (MDEpiNet), allows the coordinated registry network (CRN) formed by linking VQI patients to their own Medicare claims to measure long-term outcomes after EVAR. Data from VQI-VISION has been used to examine five and ten-year outcomes after EVAR, including survival, the need for reintervention, and device surveillance. During the panel discussion, the group discussed using data from VQI-VISION to create long-term, device-specific Device Dashboards, which would provide surgeons, regulators, and industry stakeholders long-term outcomes data for device evaluation and surveillance.

In conclusion, FDA needs better data to evaluate safety and efficacy. Industry needs better data for device evaluation and improvement. Our patients need the best devices and the best care. Via VQI, VRC or VISION, VQI can provide the data to guide device evaluation and assess compliance with SVS clinical guidelines. EVAR manufacturers have submitted a proposal to the FDA using VQI and VISION methodology for enhanced device data collection and surveillance.

19. REGISTRY ASSESSMENT OF PERIPHERAL INTERVENTIONAL DEVICES (RAPID) UPDATE

RAPID is a public private partnership of 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 Coordinated Registry Networks (CRNs) to generate real-world evidence on medical device performance. The goal of RAPID is to promote the evaluation of peripheral vascular devices throughout the total product lifecycle using registry based data.

Randomized controlled trials nested in registries

Over the past year, RAPID has focused on promoting the use of registries for randomized clinical trials. VQI has participated in and presented at two virtual think tanks sponsored by MDEpiNet RAPID. There are two work groups in RAPID focused on peripheral vascular disease, Peripheral Arterial Disease and Aortic Interventions. There is significant interest in using clinical registries, e.g. VQI, to nest clinical trials. The Aortic Interventions work group has written a Registry-Based Randomized Clinical Trial (RBRCT) aimed at enhancing and collecting long term follow up after EVAR.

VQI is one of the few cardiovascular registries that collects device identification details using the Global Unique Identification Database (GUDID). GUDID is an FDA administered database that is a reference catalog for all medical devices. By collecting GUDID on devices, VQI is able to identify a device in conjunction with patient level clinical, anatomic and procedural details and correlate it with outcomes. Specific device identification has been critically important in analyzing the Paclitaxel controversy and EVAR endograft performance. VQI has engaged Symmetrics® in an effort to enhance the value of GUDID. Symmetrics has standardized device names, amended device information and modified Global Medical Device Nomenclature (GMDN).

¹. USDA: US Food & Drug Administration. November 2–3, 2021: Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting Announcement. 2021 [cited 2022 Jan]; Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-2-3-2021-circulatory-system-devices-panel-medical-devices-advisory-committee-meeting.

² Tsougranis G, Eldrup-Jorgensen J, Bertges D, Schermerhorn M, Morales P, Williams S, Bloss R, Simons J, Deery SE, Scali S, Roche-Nagle G, Mureebe L, Mell M, Malas M, Pullin B, Stone DH, Malone M, Beck AW, Wang G, Marinac-Dabic D, Sedrakyan A, Goodney PP. The vascular implant surveillance and interventional outcomes (VISION) coordinated registry network: An effort to advance evidence evaluation for vascular devices. Journal of vascular surgery. 2020;72:2153-2160

20. 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 2022 it will complete 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 included collection of data from 13 different countries participating in ICVR.

The central purpose of this project was 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.



21. 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 preapproval 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. Fivos 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 Fivos. "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 the SVS VQI registry will be a primary data source to address current and future regulatory challenges faced by device manufacturers world-wide."

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22. TECHNOLOGY & REGISTRY DEVELOPMENTS

Upcoming Registry Highlights:

- Video training library on the Support Tab
- Help Text version difference in PATHWAYS
- Smoking Cessation
- Harmonization of anticoagulants across registries
- Harmonization of CAD across registries
- Infra & Supra Follow-up Outcomes Reports
- Open AAA Major Revision

PATHWAYS Technology Highlights:

Recent Records

Added procedure status column

Registry Highlights:

New Reporting

HDA Follow-up Outcomes Report TEVAR Follow-up Outcomes Report IVC Filter Follow-up Outcomes Report VVR Follow-up Outcomes Report

PVI

Implemented Device Assistant with Symmetric integration

Infra-inguinal & Supra-inguinal Bypass registry

Major revision to both the Infra and Supra-inguinal bypass registries Cloning feature for LEB procedures

Across-Registry Revisions

Added Bleeding Complication fields COVID update to capture past history

Minor Revisions

Peripheral Vascular Intervention - minor revision to align with Infra/Supra changes Carotid Artery Stent - expanded pre-dilate options, flow reversal

23. FUTURE DEVELOPMENTS

In 2023-2024, the SVS VQI plans to support improved care and promote patient safety in the following areas:

- Data Integration from EMRs directly into the SVS VQI to reduce data burden and enhance data integrity
- Planned Revisions to the OAAA and Amputation Registries
- The addition of the National Quality Initiative on Smoking Cessation
- Improvements to On-line Reporting and Analytics



APPENDIX

APPENDIX A-VQI SITES LISTED IN ALPHABETICAL ORDER (AS 0F 5/1/2023)

Abbott Northwestern Hospital (Allina) MN
Abington Memorial Hospital PA
Abrazo Arrowhead Campus AZ
AdventHealth Celebration FL
AdventHealth Daytona Beach FL
AdventHealth Daytona Beach FL
AdventHealth Stall FL
Adventist Health St. Helena CA
Adventist Health St. Helena CA
Adventist Health St. Helena CA
Adventist Health Care Shady Grove Medical Center MD
Adventist Medical Center La Grange IL
Advocate Condell Medical Center IL
Advocate Condell Medical Center IL
Advocate Condell Medical Center IL
Advocate Good Samaritan Hospital IL
Advocate Sherman Hospital IV
Advocate Sherman Hospital IV
Advocate Sherman Hospital IV
Albany Medical Center NC
Alaska Regional Hospital AV
Albany Medical Center NC
Alaska Regional Hospital AV
Albany Medical Center GA
All Saints Hospital IV
Albany Vascular Specialist Center GA
All Saints Hospital IV
All Bares Summit Medical Center CA
Alyeska Vascular Surgery AV
Anned Health SC
Arizona Endovascular Center AZ
Arizona Vascular Specialists, LLC AZ
Arkansas Heart Hospital Facore AR
Arnot Health NY
Artery and Vein Institute PA
Asante Roque Regional Medical Center IL
Ascension Genesys Hospital MI
Ascension Mercy Hospital Funder II
Ascension Saint Thomas Medical Center IL
Ascension Saint Sherial Sherial Aurora IL
Ascension Saint Homas Medical Center II
Ascension Saint Homas Medical Center NJ
Attinum Health Union NC
Autoria Medical Center WI
Aurora Medical Center IX Baylor Scott & White Medical Center - Irving TX Baylor Scott & White Medical Center - McKinney TX Baylor Scott & White Medical Center - Round Rock TX Bayshore Medical Center NJ

Baystate Medical Center MA
Beaufort Memorial Hospital SC
Beebe Medical Center DE
Bellin Memorial Hospital, Inc. WI
Bekelper Medical Center MA
Beth Israel Deaconess Medical Center MA
Beth Israel Medical Center NY
Bethesda Hospital Bast FL
Bethesda Hospital Bast FL
Bethesda Hospital West FL
Bethesda North Hospital FL
Bethesda North Hospital FL
Bethesda North Hospital FL
Boca Raton Regional Hospital FL
Boca Secours St. Hary's Hospital WA
Boston Secours St. Mary's Hospital WA
Boston Medical Center MA
Born Secours St. Mary's Hospital WA
Boston Medical Center MA
Born Secours St. Mary's Hospital WA
Boston Medical Center MA
Bronson Battlecreek Hospital MI
Brosolym Methodist Mospital MI
Brosolym Methodist Mospi

DCH Regional Medical Center AL
Deaconess Mictrown Hospital IIN
Deborah Heart and Lung Center NJ
Decatur Morgan Hospital IIL
Dell Secton Medical Center at the University of Texas TX
Deseat Regional Medical Center CA
DLP Conemaugh Memorial Medical Center, LLC PA
Doctors Hospital OH
Doctors Hospital of Augusta GA
Doctors Hospital of Center NC
East Alabama Medical Center NC
East Alabama Medical Center NC
East Jefferson General Hospital LA
East Iremont Vaccular Health Care, PLLC NY
Edward Hospital IIL
Einstein Medical Center Montgomery PA
Eisenhower Medical Center CA
El Camino Health CA
Elkhart General Hospital IIN
Elliot Health System NH
Ellis Hospital INY
Ellibriotok Memorial WI
Ellmotok Memorial WI
Ellmotok Memorial WI
Ellmotok Memorial WI
Elmhors Memorial Hospital IIA
Emanate Health Inter-Community Hospital CA
Emanate Health Hiter-Community Hospital CA
Emanate Health Hiter-Community Hospital CA
Emony St. Joseph's Hospital GA
Englewood Hospital and Medical Center NJ
Essentia Health - Fargo ND
Essentia Health - St. Mary's Medical Center NA
Essentia Health - St. Mary's Medical Center ND
Essentia He

APPENDIX A-VOI SITES LISTED IN ALPHABETICAL ORDER (AS 0F 5/1/2023)

Holmes Regional Medical Center FL
Holston Valley Medical Center TN
Holy Cross Hospital FL
Holy Warme Medical Center NJ
Holy Cross Hospital FL
Holy Warme Medical Center AZ
HonorHealth Scottsdale Gosborn Medical Center AZ
HonorHealth Scottsdale Thompson Peak Medical Center AZ
Houston Haplor St. Luke's Medical Center TX
Houston Methodist Baytown Hospital TX
Houston Methodist Baytown Hospital TX
Houston Methodist Hospital TX
Houston Methodist West Hospital IX
Hos

McLeod Health SC
Mease Countryside Hospital FL
Medical Center Newtwent Healthcare GA
Medical Center Newtwent Healthcare GA
Medical City Dallsa TX
Medical City Denton TX
Medical City Fort Worth TX
Medical City Plano TX
Medical City Plano TX
Medical City Plano TX
Medical City Plano TX
Medical University Hospital Authority SC
Medistar Cardiology Associates DC
Medistar Frankiin Square Medical Center MD
Medistar Frankiin Square Medical Center MD
Medistar Frankiin Square Medical Center MD
Medistar Harbor Hospital MD
Medistar Harbor Hospital MD
Medistar Harbor Hospital MD
Medistar Washington Hospital Center DC
Medistar Washington Hospital Center DC
Memorial Hermann Cypress Hospital TX
Memorial Hermann Square Medical Center GA
Memorial Hermann Memorial City Medical Center TX
Memorial Hermann Memorial City Medical Center TX
Memorial Hermann Southeast Hospital TX
Memorial Hospital Central CO
Memorial Hospital Central CO
Memorial Hospital Central CO
Memorial Hospital Central CO
Memorial Hospital Gentral CO
Memorial Hospital Gentral CO
Memorial Hospital Hospital Center CA
Memorial Hospital FI
Memorial Hospital Hospital Center CA
Memorial Hospital FI
Memorial Hospit

North Fulton Hospital, Inc. GA
North Memorial Health Hospital MN
North Mississippi Medical Center MS
North Okaloosa Medical Center FL
North Shore University Hospital NY
NorthBay Medical Center CA
Northeast Georgia Medical Center Gainesville GA
Northside Hospital IL
Northside Hospital Cherokee GA
Northside Hospital Forsyth GA
Northside Hospital Forsyth GA
Northside Hospital Gwinnett GA
Northside Hospital Gwinnett GA
Northwest Community Hospital IL
Northwestern Medicine Central DuPage Hospital IL
Northwestern Medicine Lake Forest Hospital IL
Northwestern Memorial Hospital IL
Nortn-Audubon KY
Norton-Brownsboro Hospital KY Norton-Brownsborn Hospital KY
Norton-Downtown KY
Norton-Downtown KY
Norwalk Hospital CT
Novant Health Matthews Medical Center NC
Novant Health Matthews Medical Center NC
Novant Health Matthews Medical Center NC
NVU Langone Hospital – Brooklyn NY
NVU Langone Hospital – Brooklyn NY
NVU Langone Hospital – Long Island NY
NYU Langone Medical Center NY
Oaklawn Hospital MI
Ocala Regional Medical Center PU
Ocala Regional Medical Center LA
Ochsner Lafayette General Medical Center LA
Ochsner Medical Center LA
Ogene Regional Medical Center UT
Oklahoma Heart Hospital South, LLC OK
Oklahoma Heart Hospital LLC OK
Omaha – CHI Health Creighton University Medical Center –
Bergan Mercy NE
Omaha – CHI Health Creighton University Medical Center –
Bergan Mercy NE
Oragon Vascular Specialists, LLC OR
Oragon Vascular Noragon Medical Center FL
Orlando Health, Inc. South Eake Hospital FL
Orlando Health, Inc. South Eake Hospital FL
Orlando Health, Inc. South Seminole Hospital FL
OSF St. Joseph Medical Center IL
OSF Saint Francis Medical Center IL
OSF Saint Francis Medical Center IL
OSF Saint Francis Medical Center IL
OSF St. Joseph Medical Center IL
OSF Saint Francis Medical Center IL
OSF Saint Francis Medical Center IN
Overlace Medical Center IN
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APPENDIX A-VQI SITES LISTED IN ALPHABETICAL ORDER (AS 0F 5/1/2023)

UCSF Medical Center CA
UH Elyria Medical Center OH
UH St. John Medical Center OH
UK Health Care KY
UMass Memorial Medical Center, Inc. MA
UMC El Pass Delathcare, Inc. TX
United Hospital (Allina) MN
UnityPoint Health - Meriter Hospital WI
UnityPoint Health - Meriter Hospital WI
UnityPoint Health Des Moines IA
University Hospitals Ahuja Medical Center OH
University of Alabama Medical Center AL
University of Alabama Medical Center IL
University of Chicago Medical Sciences AR
University of Chicago Medical Center IL
University of Colorado, Denver CO
University of Colorado, Denver CO
University of Connecticut Health Center CT
University of Florida, Gainesville FL
University of Iowa Hospitals and Clinics IA
University of Mana Hospitals and Clinics IA
University of Miami Hospital and Clinics FL
University of Mismi Hospital and Clinics FL
University of Mississippi Medical Center MD
University of Mississippi Medical Center MO
University of Mississippi Medical Center MO
University of New Mexico NM
University of New Mexico NM
University of New Mexico NM
University of Oklahoma School of Community Medicine OK
University of Tennessee Medical Center TN
University of Tennessee Medical Center TN
University of Virginia Health System VA
University of Virginia Health System VA
University of Washington Medical Center (Montlake Campus)
WA
University of Washington Medical Center (Northwest Campus)
WA
University of Washington Medical Center (Northwest Campus)
WA
University of Washington Medical Center (Montlake Campus)
WA
University of Washington Medical Center (Northwest Campus)
WA St. Francis Hospital Downtown SC
St. George Regional Hospital UT
St. John Maccomb Oakland MI
St. John Maccomb Oakland MI
St. Joseph - Grange CA
St. Joseph - Orange CA
St. Joseph Hospital (Eureka) CA
St. Joseph Hospital St. St. Joseph Hospital St. Joseph Hospital North FL
St. Joseph's Hospital North FL
St. Luke's Hospital North FL
St. Mary Medical Center PA
St. Mary Hospital North FL
St. Mary St. Hospital North FL
St. Vincent St. Parick Hospital North FL
St. Vincent St. Parick North FL
St. Vincent St. Medical Center CA
St. Vincent St. Medical Center CA
St. Vincent St. Medical Center North FL
St. Vincent St. Medical Center North FL
St. Vincent St. Medical Center North Medical Center North Medical Center North Medical Center N Redwood City - Sequoia Hospital CA Regional Medical Centers of Orangeburg and Calhoun Counties SC Reid Health IN Reston Hospital Center VA Rex Hospital, Inc. NC Rhode Island Hospital RI Rex Hospital, Inc. NC
Rhode Island Hospital RI
Riverside Community Hospital CA
Riverside Medical Center IL
Riverside Methodist Hospital OH
Riverside Regional Medical Center VA
Riverview Medical Center NJ
Rockledge Regional Medical Center FL
Roper St. Francis SC
Roseburg - CHI Mercy Health Medical Center OR
Rush University Medical Center IL
Rutgers, The State University of New Jersey for Robert Wood
Johnson Medical School NJ
Sacred Heart Emerald Coast FL
Sacred Heart Hospital of the Hospital Sisters of the Third
Order of St. Francis WI
Sacred Heart Pensacola FL
Saint Alphonsus Regional Medical Center ID
Saint Barnabas Medical Center NJ
Saint Francis Hospital and Medical Center CT
Saint Francis Hospital Memphis TN
Saint Joseph Hospital CO
Saint Joseph Regional Medical Center-South Bend Campus
IN
Saint Joseph's Hospital GA
Saint Joseph's Hospital Bases Andread Saint Joseph's Hospital Bases Descriptions Andread Saint Joseph's Hospital Bases Descriptions Andread Saint Joseph's Hospital Bases Descriptions Andread Saint Joseph's Hospital GA
Saint Joseph's Hospital Bases Descriptions Andread Saint Joseph's Hospital Bases Descriptions Andread Saint Joseph's Hospital Bases Descriptions Andread Saint Joseph's Hospital GA
Saint Joseph's Hospital Bases Descriptions Andread Saint Joseph's Hospital Bases Descriptions Andread Saint Joseph Research Descriptions Andread Saint Joseph Hospital GA
Saint Joseph's Hospital GA IN
Saint Joseph's Hospital GA
Saint Luke's Episcopal Presbyterian Hospital MO
Saint Luke's Hospital of Kansas City MO
Saint Luke's Memorial Hospital PR
Saint Mary's Regional Medical Center NV
Salem Health OR Saint Luke's Memorial Hospital PR
Saint Mary's Regional Medical Center NV
Salem Health OR
Salem Hospital MA
San Antonio Vascular and Endovascular Clinic TX
San Bernardino - St. Bernardine Medical Center CA
San Diego Vascular and Endovascular Clinic TX
San Bernardino - St. Bernardine Medical Center CA
San Diego Vascular Clinic Macular Associates SD
Sanford Bemidji Medical Center MN
Sanford Glinic Vascular Associates SD
Sanford Medical Center Fargo ND
Sanger Heart and Vascular Institute NC
Santa Clara Valley Medical Center CA
Santa Cruz - Dominican Hospital CA
Santa Ross Memorial Hospital FL
Sarasota Memorial Hospital FL
Sarasota Memorial Hospital FL
Sarasota Memorial Hospital FL
Sarasota Memorial Hospital TX
Scripps Green Hospital CA
Scripps Memorial Hospital La Jolla CA
Scripps Memorial Hospital La Jolla CA
Scattle - Virginia Mason Medical Center WA
Seattle Vascular Surgery WA
Self Regional Health SC
Sentara Careplex Hospital VA
Sentara Martha Jefferson VA
Sentara Martha Jefferson VA
Sentara Morthem Virginia Medical Center VA
Sentara Princess Anne Hospital VA
Sentara Princess Anne Hospital VA
Sentara RMH Medical Center VA
Sentara Williamsburg Regional Medical Center VA
Sentara Williamsburg Regional Medical Center VA
Shanp Memorial Hospital CA
Sharp Memorial Hospital CA
Sharp Memorial Hospital LA
Suthar Saptist Medical Center VA
Sinap Grossmont Hospital ICA
Sharp Memorial Hospital LA
South Bay Hospital FL
South Georgia Medical Center GA
South Bay Hospital FL
South Florida Baptist FL
South Georgia Hedical Center GA
South Miami Hospital FL
South Georgia Hedical Center GA
South Hills Hospital and Medical Center NV
Southern Ocean Medical Center NJ South Miami Hospital FL
Southeast Georgia Health System, Inc. - Brunswick Campus
GA
Southern Hills Hospital and Medical Center NV
Southern Ocean Medical Center NJ
Southside Hospital NY
Southside Hospital NY
Southside Hospital NI
Spartanburg Regional SC
Spectrum Health Hospital MI
Spartanburg Regional SC
Spectrum Health Hospital MI
Spotsylvania Regional Medical Center VA
Springhill Medical Center AL
SSM Health Deal Hospital - St. Louis MO
SSM Health Good Samaritan - Mount Vernon, IL IL
SSM Health Good Samaritan - Mount Vernon, IL IL
SSM Health St. Clare Hospital - Fond du Lac, WI WI
SSM Health St. Clare Hospital - Fenton MO
SSM Health St. Joseph Hospital - Fenton MO
SSM Health St. Joseph Hospital - Madison WI
SSM St. Anthony Hospital OK
St. Anthony Hospital OK
St. Anthony Hospital NY
St. Anthony Community Hospital NY
St. Anthony St. Anthony Hospital FL FL
St. Bernards Medical Center AR
St. Charles Health System, Inc. OR
St. Charles Hospital PA
St. David's Round Rock Medical Center TX
St. David's South Austin Medical Center TX
St. David's Round Rock Medical Center TX
St. David's South Austin Medical Center WI
St. Francis Hospital INY

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 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 ensures 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 offers specialty-based workflow reporting applications for providers, registry solutions and support for medical societies, and custom data sets for device manufacturers that provide real world evidence to advance innovation and regulatory goals.

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



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