# 2024 SVS VQI ANNUAL REPORT



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



# What's on the Horizon for VQI and the Future of Vascular Care?

The past few years have been marred by significant upheavals, from global conflicts and health crises to controversies within the vascular field. As we navigate through these turbulent times, one question emerges - what's next? Artificial Intelligence (AI) has emerged as a powerful force, revolutionizing various industries and offering new possibilities for data analysis and decision-

making. The VQI database, with its wealth of data and potential for guiding action, is well poised to harness the capabilities of AI in driving quality improvement initiatives and shaping the future of vascular care.

While traditional statistical methods have been the cornerstone of data analysis within the VQI registry, the exploration of AI as a complementary tool holds promise for uncovering insights and optimizing patient outcomes. Learning from our data remains paramount, with a focus on identifying strategies that enhance care delivery and improve patient safety. As we embark on this journey of discovery, the utilization of AI alongside established methodologies will enable us to unlock new perspectives and drive transformative change in vascular healthcare.

The impact of VQI data on clinical practice and patient outcomes cannot be overstated, as evidenced by the numerous scientific publications and real-world improvements in care delivery. The collaborative efforts of VQI members and partners have not only advanced the field of vascular diseases but have also paved the way for global initiatives and collaborations through platforms like the International Consortium of Vascular Registries (ICVR).

Looking ahead, the VQI registries are poised for continued growth and impact, with a steadfast commitment to promoting excellence in care and driving innovation through data-driven insights. With over 1,000 centers contributing to the registry and an ever-expanding dataset with over 1,200,000 procedures, VQI remains at the forefront of quality improvement, research, and collaborative efforts aimed at enhancing vascular care on a national and international scale.

As we embrace the challenges and opportunities that lie ahead, we are confident that the VQI clinical registry will continue to serve as a vital tool for shaping the future of vascular care. Through ongoing collaboration, innovation, and a steadfast commitment to excellence, we stand ready to navigate the evolving landscape of healthcare and redefine the standards of care for vascular patients worldwide. Thank you for your continued support and dedication to our shared mission of improving patient outcomes and advancing the field of vascular healthcare.

Dr. Jens Eldrup-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.

#### SVS PATIENT SAFETY ORGANIZATION **VQI PROCEDURE VOLUME GROWTH** 1,300,000 1,200,000 1,100,000 1,000,000 900,000 800.000 700,000 600,000 500.000 400,000 300.000 200,000 100,000 0 0dt-15 Apr-16 Oct-16 Apr-17 Oct-17 Apr-18 Oct-18 Apr-19 0dt-19 Apr-20 Oct-20 Oct-14 Apr-22 Oct-22 Apr-23 Apr-21 0d:-21 ģ

### THE SVS VQI REGISTRIES

As of May 1, 2024, 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 5/1/20241,2	233,467
Peripheral Vascular Intervention	428,682
Carotid Endarterectomy	214,378
Carotid Artery Stent	127,659
Endovascular AAA Repair	89,163
Infra-Inguinal Bypass	88,754
Hemodialysis Access	82,677
Varicose Vein	66,572
Thoracic and Complex EVAR	34,131
Lower Extremity Amputations	32,672
Supra-Inguinal Bypass	28,044
IVC Filter	19,324
Open AAA Repair	19,213
Vascular Medicine Consult	1,923
Venous Stent	275



### 3. SVS VQI - TAKING STEPS Forward for Vascular Care

It's been another exciting year for the SVS VQI. forging new pathways for improved quality and patient safety in vascular medicine. Here's a look at the SVS VQI by numbers.

### 1,230,000+

procedures

**1,000+** participating centers

**6,000+** contributing physicians

### **100+** annual quality charters

\_\_\_\_\_

18

regional quality groups

SVS VQ

### 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 guidelines •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. 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 May 2024 (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 – 42% vascular surgeons, 18% interventional cardiology, 14% interventional radiology, 5% general surgery, 5% cardiothoracic surgery, 4% neurosurgery, 3% podiatry, 2% orthopedic surgery and 2% Neurology (Figure 4.3).

Canadian Vascular Quality Initiative | 7 Centers Carolinas Vascular Quality Group | 41 Centers Great Lakes Vascular Study Group | 63 Centers Michigan Vascular Study Group | 37 Centers Mid-America Vascular Study Group | 81 Centers Mid-Atlantic Vascular Study Group | 94 Centers MidSouth Vascular Study Group | 26 Centers Midwest Vascular Collaborative | 50 Centers Northern California Vascular Study Group | 26 Centers Pacific NW Vascular Study Group | 38 Centers Rocky Mountain Vascular Quality Initiative | 55 Centers Southeastern Vascular Study Group | 137 Centers Southern California VOICE | 42 Centers Southern Vascular Outcomes Network | 116 Centers Upper Midwest Vascular Network | 65 Centers Vascular Study Group of Greater New York | 45 Centers Vascular Study Group of New England | 48 Centers Virginias Vascular Study Group | 45 Centers Singapore | 1 Center TOTAL CENTERS | 1,019 Centers

Figure 4.1: Growth of SVS VQI Centers (as of May 1, 2024) Source: Fivos PATHWAYS data, May 2024









## **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 work closely with their VQI mentor on participation in regional biannual meetings and reviewed comparative data including center level quality improvement processes. Opportunities include engagement in guality 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 provides 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. Monthly FIT Program Zoom meetings were added over the past year to build a FIT community and provide guidance of ongoing research activities and quality improvement projects.

The first class of FIT Scholars that were selected included Ben Li, Hanaa Dakour Aridi, Caronae Howell, Brianna Krafcik, and Christine Kariya. Over the past year, they have been instrumental in engaging with RAC Committees, VQI Statistical support, VQI@VAM program development and review, as well as other PSO Committee involvement while continuing their quality and/or research FIT Program project.



Five of the Eleven 2023-2024 FIT Fellows 2nd class were selected in either Quality Improvement or Research to receive the Jack L. Cronenwett Scholarship. Those selected included:

### 2023-2024 Jack L. Cronenwett Scholarship Award Recipients

### Saranya Sundaram, PGY-3

Medical University of South Carolina Mentor: Dr. Thomas Brothers

### Mikayla Lowenkamp, PGY-4

University of Pittsburgh Medical Center Mentor: Michael Madigan Co Mentor: Mohammad Eslami

### Mitri Khoury, PGY-9

Massachusetts General Hospital Mentor: Nikolaos Zacharias

### **Christopher Chow, PGY-2**

University of Miami Mentor: Arash Bornak

### Amanda Filiberto, PGY-8

University of Alabama at Birmingham, Mentor: Adam Beck, MD



### **5. SVS VQI TRAINEE PROGRAM (CONTINUED)**





Figure 5.1: Back Row L-R Dr. Gary Lemmon, Co-Founder of FIT Program; Dr. Jack Cronenwett, Scholarship Honoree; Dr. Adam Johnson, Chair of FIT Program. Bottom Row L-R JC Scholars Dr. Ben Li, Dr. Hanaa Dakour Aridi, Dr. Christine Kariya, Dr. Brianna Krafcik and Dr. Caronae Howell

A rigorous selection process was employed to review over twenty applicants with stellar resumes for the third class, 2024 -2025, FIT Fellow application process. 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!

### 2024-2025 SVS VQI FIT FELLOWS

**Lisa Vi** Mentor: Dr. Miranda Witheford University Health Network, Toronto, ON

> **Chinmayee Potti** Mentor: Dr. Mounir Haurani The Ohio State University

**Lindsey A. Olivere** Mentor: Dr. Michael Madigan UPP Vascular Surgery

**Gabrielle Rieth** Mentor: Matthew Corrierre Wexner

**Guillermo Polanco Serra** Mentor: Dr. Pouya Entezami Henry Ford Health

**Michael Chaney** Mentor: Dr. Jason Ryan Western Michigan University

**Vinay Bhushan Lakki** Mentor: Dr. Abhishek Singh Creighton University Med Center

**Lara Lopes** Mentor: Dr. Ashley Vavra Northwestern Memorial Hospital

**Karan Chawla** Mentor: Dr. Matthew Blecha Integrated Vascular Surgery Loyola Medical Center Lorela Weise Mentor: Dr. Matthew Blecha Loyola University Medical Center, Integrated Vascular Surgery Residency

> **Ioannis Tsouknidas** Mentor: Dr. Robert Meisner Lankenau Medical Center

Angela Danielle Sickels Mentor: Dr. Adam Beck University Of Alabama Medical Center

> **Menna Hegazi** Mentor: Dr. Nii-Kabu Kabutey University of California, Irvine

**Isaac Naazie** Mentor: Dr. Linda Harris Buffalo General Medical Center

**Irina Kanzafarova** Mentor: Dr. Michael Stoner University of Rochester, Rochester, NY

**Falen Demsas** Mentor: Dr. Nikolaos Zacharias Massachusetts General Hospital

**Justin Jay Bader** Mentor: Dr. Cassius Chaar Yale New Haven Hospital

**Camila Guetter** Mentor: Dr. Marc L. Schermerhorn Beth Israel Deaconess Medical Center

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## 6. VQI INTERACTIVE DASHBOARDS

The SVS PSO's new VQI Interactive Dashboards are an enhanced version of the current VQI Best Practices Dashboards. These interactive dashboards will allow centers to access more up-to-date information in an actionoriented manner when compared to the static quarterly dashboards. Following a pilot launch, the VQI Interactive Dashboard for the Carotid Artery Stent (CAS) registry was released on April 4th 2024 and can be accessed through PATHWAYS under the "Reporting" tab. These new online reports will be rolled out for rest of the VQI registries over the course of 2024.

Detailed below are some of the updated features (see accompanying Screenshots 6.1, 6.2, 6.3, and 6.4):

1. Access the most recent (refreshed nightly), up to date data       Instantly identify current gaps to operations in a timely manner         2. Select a custom date range to view your center's data       Readily track and compare performance trends         3. Choose different procedural and clinical filter combinations       Track procedure performance acro categories         4. Download your center's data       Perform further internal analysis         4. Download your center's data       Perform further internal analysis         4. Most Type Columnation       20060701 - 20200600         2. Select fue theread       Most Type Columnation         2. Select a custom date range to view your center's data       Perform further internal analysis         4. Download your center's data       Perform further internal analysis         4. Most Type Columnation       2.3 4 3 5 7 5         3. Weak there if the they is a 2.3 2 7 5       3 4 3 5 7 5         4. Most Type Columnation       Most Type Columnation         3. Weak there if the they is a 2.3 2 7 5       3 4 4 3 5 7 5         4. Most Type Columnation       Most Type Columnation         3. State they is a 2.3 2 7 2 7 5       Mean type is a 2.3 2 7 2 7 5         4. Most Type Columnation       Material Columnation         3. State they is a 2.3 2 7 2 7 5       Mean type is a 2.3 2 7 2 7 5         4. Most Type Columnation       Materia 2.4 (Colum		MENTS	BEN	NEFITS
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Figure 6.1: VQI Interactive Dashboards enable centers to select custom date range.

## 6. VQI INTERACTIVE DASHBOARDS (CONTINUED)

		is Asymptomatic	2006/07/01 - 2023/06/30			
		Symptomatic		Case Data		
0	Case Data	weither	Your Center	Your Region	VQI Overall	
1	Number of Cases	00 (0)		21	NA (<3 Centers)	40
	Median Postop L	US (Days)		1.0	NA (<3 Centers)	0.0[0.0]0.0]0.0]1.0]1.0]
	movier rotel DA			Neurological Events (at discharge)		
	Neurological Eve	nts (at discharge)	Your Center	Neurological Events (at discharge) Your Region	VQI Overal	
N	Neurological Eve	nts (at discharge)	Your Center	Neurological Events (at discharge) Your Region 4.8% (1/21)	VQI Overall NA (<3 Centers)	2.5%
M II	Neurological Eve Ipsilateral TIA Ipsilateral Stroke	nts (at discharge)	Your Center	Neurological Events (at discharge) Your Region 4.8% (1/21) 4.8% (1/21)	VQI Overal NA (<3 Centers) NA (<3 Centers)	2.5% 2.5%
M II I	Neurological Eve Ipsilateral TIA Ipsilateral TIA	nts (at discharge)	Your Center	Neurological Events (at discharge) Your Region 4.8% (1/21) 4.8% (1/21) 47.6% (10/21)	VQI Overal NA (-3 Centers) NA (-3 Centers) NA (-3 Centers)	2.5% 2.5% 25.0%
N II II C	Neurological Eve Ipsilateral TIA Ipsilateral Stroke Contralateral Stro	nts (at discharge)	Your Center	Your Region           4.8% (1/21)           4.8% (1/21)           4.7% (1/21)           4.7% (1/0/21)	VQI Overall           NA (<3 Centers)	2.5% 2.5% 2.50 2.50%
M N N C C	Neurological Eve Ipsilateral TIA Ipsilateral Stroke Contralateral Stro Vertebrobasilar 1	nts (at discharge) Ne 1A	Your Center	Your Region           48% (1/21)           48% (1/21)           48% (1/21)           47.6% (10/21)           47.6% (10/21)           48% (1/21)	VQI Overall           NA (<3 Centers)	2.5% 2.5% 250% 250% 250%

Figure 6.2: VQI Interactive Dashboards enable centers to select different procedural and clinical filter combinations.

Neu	rological Events (at discharge)	Download	×
CAS	REPORTING DATA (6 Filters) 🗸		
	PRIMPROCID		
1	2559461		
2	2551047		
3	2561067		
4	2551079		
5	2531119		
6	2551235		
7	2551252		
8	2551255		
9	2561371		
10	2658723		

|--|

1	2550,851	CSV			
2	2551047			-	
- 3	2551067	<ul> <li>Advanced data options</li> </ul>			
4	2551079				
5	2561110				
6	2561235	Open in Browser	Cancel Download		
7	2551252				
8	2551255				
0	2561271				
	2652720				
10	ACCULAL CONTRACT				

Figure 6.4: VQI Interactive Dashboards enabling centers to access PRIMPROCIDs associated with a particular event.

## 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.

SVS VQI centers diligently work on and submit quality improvement charters throughout the year. In 2023, there were 116 charters submitted by the identified 18 VQI regions. Of these 116 charters, 2% were Hashtag, 40% were Regional, and 58% were Center charters.

### **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
- Toolkits
- Educational Videos/Audio
- Sample Charters
- Case Studies
- 1:1 Mentoring



Figure 8.1 – Quality Improvement Projects Submitted in 2023

- SVS VQI Annual Summary Report
- QI Annual Abstract Guide
- Annual Rapid Fire Abstract Guide

\*Some tools are within members only section

#### **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 VQI 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)





### 9. NATIONAL QUALITY IMPROVEMENT INITIATIVES: OPTIMAL DISCHARGE MEDICATIONS, EVAR LONG-TERM FOLLOW-UP IMAGING, AND SMOKING CESSATION

The SVS PSO chose to focus on Discharge Medications, EVAR Follow-up Imaging, and Smoking Cessation because these quality measures have been shown to increase longterm 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. Studies show that patients who quit or don't smoke have better outcomes and better survival rates.

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, EVAR LTFU Imaging, & Smoking Cessation and are in the process of implementing your processes. These initiatives are discussed in detail at regional meetings.

The VQI overall DC medication rate was 88% in 2023. 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'.





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 2020 was at 79%, and VQI overall LTFU for 2021 was at 76%. We still have room for improvement to reach our goal.



Figure 9.2 - Long-Term Follow-Up by Region

As of June 2023, we added a new National Quality Initiative of Smoking Cessation. Two additional quality measures were incorporated into 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 2023, the VQI overall preoperative smoking rate was 29%.





### 9. NATIONAL QUALITY IMPROVEMENT INITIATIVES: OPTIMAL DISCHARGE MEDICATIONS, EVAR LONG-TERM FOLLOW-UP IMAGING, AND SMOKING CESSATION

Smoking Cessation at 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. This measure includes all elective, urgent, and emergent 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 followup record where the patient's follow-up smoking status was recorded. For 2021, the VQI overall smoking cessation rate was 32%.



Figure 9.4 – Smoking Cessation by Region

Since adding the new National Quality Initiative Smoking Cessation in June 2023, there have been additional webinars, toolkits, and education provided over the past year. SVS and VQI in collaboration have aligned their websites to offer smoking cessation education for clinicians and patients. Please visit www.vqi.org or https:// vascular.org/ for more information and multiple resources.

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**

In 2019 the PSO started the first phase of the source data audits. Source data audits play a crucial role in ensuring accuracy, consistency, and reliability of data. These audits help identify and rectify areas in need of improvement with data element or help text, ultimately improving operational efficiency, enhancing decision-making processes. Moreover, by demonstrating a commitment to data integrity through independent audits, the PSO can build trust and transparency among stakeholders. This assurance of accurate, secure, and trustworthy data can lead to improved relationships and increased confidence in the data.

The journey of the source data audits underscores their importance. In the initial phases (2019 and 2020), a thirdparty vendor was employed to review completed data forms for abstracted variable matches across multiple centers and registries. Although these centers did not receive center-level reports, the information gathered was instrumental in the discovery process and for deriving lessons learned. As the program progressed to its current phase, we again utilized a third party vendor, we now have included a more extensive sample size of 100 randomly selected centers with approximately 10 records each. This phase focused on a specific registry, CAS, limiting procedures to those performed in 2022. Notably, centers previously involved in Phases I and II were excluded from Phase III, as were those selected for full claims validation in 2022.

We were thrilled with the results. Out of the 76,358 total analytically appropriate data elements re-abstracted for the 2023 audit of 2022 CAS procedures, 67,396 elements matched between the participant and auditor, resulting in an 88% raw match rate at the data element level. Once the data was reviewed, the overall data match rate was 90.63%. This progression illustrates the evolution and significance of source data audits in maintaining highquality, reliable data within our registries.

## **11. SVS VQI SYSTEM QUALITY REPORT**

In Fall 2024, the SVS PSO will be introducing a new benchmark report at the hospital system level, produced semiannually (Spring and Fall). This report will follow a similar structure to the semi-annual VQI Regional Quality report, including the same 30+ peri-operative and long-term outcomes selected by SVS PSO registry committees. This report will provide targeted, comparative results and benchmarks to VQI overall for these procedures, process measures, and complications (Figure 1). The report will be shared only with system level executives and include identified center information (Figure 2). Additionally, there will be an appendix at the end of each report showcasing the system's case volumes for each individual report as well as the number of centers contributing data.

Dashboard Procedure Volume	The dashboard provides for comparison. The "Yo well as the 10th, 25th, 50 (110th)25th)50th)25th)60	a high-level summarization of your system ur System" and "VQI Overall" columns give t Oth (median), 75th, and 90th percentiles for (http://www.system.org)	s results for each of 34 reports, an he aggregate percentage of cases centers in Your System and VQI, re	d gives VQI-wide benchmarks with the noted outcome, as spectively
rocedure Volume, All Years	The dashbaard summer	ning. A can be developed at an Event file or price	ted using the butters below Mate	that aciatian allows you to
ysician Specialties	save as PDF with the "Pi	rint to PDF" feature in your browser. For deta	ils on a particular report, click on	the report name in the table of
gistry Subscriptions	contents on the tert.			
ng-Term Follow-up	Download Print			
scharge Medications				
op Smoking	Procedure Group	Outcome	Your System	VQI Overal
oking Cessation at Follow-up	All	Procedure Volume	N=2219 (14 Centers)	[7   22   74   223   40
		Procedure Volume, All Years	N=24530 (16 Centers)	[17   68   278   1263   337
M CAS ASYMP: Stroke/Death	Multiple	Long-Term Follow-up	53.5% (1563/2922)	75.7% [0   53   79   90   9
M CAS SYMP: Stroke/Death		Discharge Medications	91.9% (1918/2088)	87.7% [77   84   91   98   10
		Preop Smoking	30.4% (479/1574)	28.896 [6   17   25   33   4
RASYMP: Stroke/Death		Smoking Cessation at Follow-up	3196 (146/471)	3296 [0   19   32   43   6
SYMP: Stroke/Death	TFEM CAS ASYMP	Stroke/Death	7.3% (3/41)	1.9% [0 0 0 0
SVMD Stroke/Death	TFEM CAS SYMP	Stroke/Death	0% (0/63)	496 [0   0   0   0   1
TMP: Stroke/Death	TCAR ASYMP	Stroke/Death	0% (0/137)	196 [0   0   0   0
MP: Postop LOS>1 Day	TCAR SYMP	Stroke/Death	2.8% (2/71)	2.296 [0   0   0   0
IP: Stroke/Death	CEA ASYMP	Stroke/Death	0% (0/193)	0.896 [0   0   0   0
MP. Stroke/Death		Postop LOS>1 Day	30.7% (59/192)	22.296 [0   12   21   33   50
MP: Postop LOS>1 Day	CEA SYMP	Stroke/Death	096 (0/78)	1.896 [0   0   0   0
Poston LOS>2 Days		Postop LOS>1 Day	47.4% (37/78)	4196 [0   25   42   58   8
rostop cos-z bays	EVAR	Postop LOS>2 Days	14.1% (18/128)	12.296 [0   4   10   18   2
I: Sac Diameter Reporting		Sac Diameter Reporting	53.5% (84/157)	61.896 [0   41   67   81   9
R: SVS AAA Diameter Guideline		SVS AAA Diameter Guideline	78.3% (101/129)	76.3% [55   67   76   87   9
	TEVAR	Sac Diameter Reporting	55.8% (24/43)	63.7% [0   44   67   88   10
R: Sac Diameter Reporting	OAAA	In-Hospital Mortality	1296 (3/25)	496 [0   0   8   1
: In-Hospital Mortality		SVS Cell-Saver Guideline	8196 (17/21)	93.2% [77   90   98   100   10
	PVI CLAUD	ABI/Toe Pressure	64.1% (252/393)	66.8% [17   50   75   88   9
: SVS Cell-Saver Guideline	INFRA	ABI/Toe Pressure	No cases	69.996 [33   53   74   87   9
AUD: ABI/Toe Pressure	INFRA CLAUD	RTOR	No cases	3.296 [0   0   0   0   1
01/7 - 0	INFRA CLTI	RTOR	No cases	5.696 [0   0   3   7   1
ABI/ Ioe Pressure	INFRA CLTI	WIII	No cases	71.196 [15   50   77   100   10
CLAUD: RTOR	SUPRA	ABI/Toe Pressure	No cases	69.5% [35   50   74   89   10
	SUPRA CLAUD	RIOR	No cases	2.996 [0   0   0   0   1
LIL RIVE	SUPRA CLTI	RIOR	No cases	3.796[0 0 0 1
CLTI: WIFI	SUPRA CLTI	With Restor Complianting	No cases	56.1% [0   0   75   100   10
ABI/Toe Pressure	LEAMP	Postop Complications	No cases	10.9% [0   4   8   13   1
	HDA	Primary AVE VS. Graft	No cases	82.8% [65   73   84   90   9
		Ottrasound Vein Mapping	No cases	87.7% [67   80   89   98   10
		Postop Complications	No cases	1.396[0 0 2]

Figure 11.1: Dashboard Summary of System Reports

### **11. VQI SYSTEM QUALITY REPORT (CONTINUED)**



Figure 11.2: Dashboard Summary of System Reports

## **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 <u>https://www.vqi.org/data-analysis/</u> 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.

## **14. VQI.ORG EXPERIENCE**

### **VQI** Website

The <u>VQI Website</u> offers a clean and intuitive layout, designed for effortless navigation. With its wealth of resources, from articles to multimedia content, this website seeks to provide an enriching user experience.

#### IMPORTANCE OF REGIONAL GROUPS

Through regional quality group meetings, participants share and analyze collected data to initiate quality improvement projects to reduce complications, readmissions, and length of stay. Quality improvements projects can translate directly to hospital cost reduction. With continued expansion of the SVS VQI and regional quality groups, data will more rapidly accumulate and can be leveraged for benchmarking and quality improvement initiatives.

Benefits of regional quality group participation include:

- Anonymous, benchmarked reports for comparison
  Increasing power and ability to detect root causes of outcomes
- Facilitating & initiating quality improvement projects
   Access to blinded datasets for data analysis at regional and national level

Improving long-term patient surveillance

FIND YOUR REGIONAL GROUP  $\rightarrow$ 

### **Website Features**

Some of our favorite aspects of the VQI website include: 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, information about our Quality Initiatives, FIT Trainee Program and much more!



#### **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 on <u>LinkedIn</u>. 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: <u>https://www. vqi.org/resources/fda-communication/</u>

### **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 meeting invitations, details about meeting location, links to minutes and presenations, etc...Additionally, we are sending emails via Mailchimp with invitation information.

### **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 <u>VQI website</u>.

### **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 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.



#### SOCIETY FOR VASCULAR MEDICINE

The SVS VQI and the Society for Vascular Medicine (SVM) collaborated on the Vascular Medicine Consult (VMC) Registry, which launched in 2020. 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.

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.





Vascular Medicine



# American Venous Forum

### 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.

# INTERNATIONAL CONSORTIUM OF VASCULAR REGISTRIES (ICVR)

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.

# **17. SYMMETRIC SOLUTIONS**

In July 2022, SVS VQI launched a partnership with Symmetric Health Solutions–a medical device software company that works with more than 750 US and OUS hospitals, with over 15 million devices/products, and over 400 attributes–to more accurately identify healthcare supply chain and medical device data. Ultimately, this partnership afforded SVS VQI access to reliable, accurate UDI (Unique Device Identification) -based device information when it is needed most for patient safety and clinical care.

Symmetric offers a device data platform to improve the completeness and accuracy of existing Access Global Medical Device Nomenclature (GMDN) data and offer data on products that are not currently available in AccessGUDID. Symmetric leverages machine learning, natural language processing, and optical character recognition technology to create a single source of truth for medical device data, including vascular devices. The Fivos redesigned PATHWAYS platform "Device Assist" integrates the Symmetric device data feed into Device Assist, providing users with access to near real-time device data and increasing the accuracy of the details captured in the registry.

The partnership with Symmetric eliminates manual maintenance by SVS VQI and registry providers to add new devices to the clinical registry and maintain and update existing records. It also increases the number of device attributes that can be captured, enhancing patient safety, and expanding opportunities for research. Some customer feedback includes "Genius", "Kudos on a great update", and "Brillant".

"A useful retrospective return on data can only be realized with factual data. Data abstractors left to make judgment calls on device characteristics open a data registry to the entry of non-factual data. PVI Device Assist enables data abstractors to enter factual data. Research driving quality, based on facts, holds manufacturers to continual quality improvement, which benefits patients. PVI Device Assist bolsters the abstractor's desire to enter factual data and quickly at that—with entry of a few manufacturer numbers, device characteristics are returned in full." - Springfield Memorial Hospital

# 18. USING SVS VQI DATA FOR COLLABORATIVE PROJECTS WITH FDA AND INDUSTRY

Medical devices are an integral component of vascular healthcare. VQI clinical data can help better understand device performance. Real world 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 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**

The VQI TEVAR for Type B Aortic Dissection project began in 2014 with retrospective collection of data to include the date of FDA approval for the Medtronic and Cook devices in 2013. Patient enrollment was rapid and all planned patients have been enrolled for each device and are now greater than 5 years out from their procedures. 5-year data for these patients will be presented to the Steering Committee of the project at the SVS VAM with a planned publication shortly afterwards.

Cook Medical received market approval for their dissection devices in 2019 and have enrolled all patients in the chronic dissection arm of the project. The acute dissection arm is still enrolling with a requirement for use of both components of the Cook Dissection system. Once data are collected for these patients, an aggregate analysis of all patients will be performed. There are a number of ongoing sub-studies within the project, including an assessment of TEVAR performance in patients with "high-risk" anatomic/clinical features based on the SVS/ STS reporting guidelines, an assessment of patient characteristics in the post-approval project versus similar patients within the MDT/Gore Pivotal studies, and the five-year outcomes of patients from the original study cohort.

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

### Transcarotid Artery Revascularization (TCAR) Surveillance Project

The TCAR Surveillance Project (TSP) was designed to

study the efficacy of TCAR in comparison with the standard of care, CEA. Reimbursement for TCAR procedures on high risk patients in the TSP was approved in 2016, by the Centers for Medicare and Medicaid Services (CMS) under the current National Coverage Determination.

In 2022, 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. Last year, CMS expanded coverage for carotid stenting on select patients requiring a formal shared decision making interaction and independent neurologic assessment. These requirements can be obviated by participation in the TSP.

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 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 guidance.

**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. Since the panel, VQI, VISION, FDA, Kaiser Permanente, and industry partners have been working together to develop a real world EVAR surveillance mechanism to identify outcomes of interest. Working together, this collaborative group developed the LEAF (Long term EVAR surveillance and Follow up) proposal which harnesses the clinical details of VQI data with the long term follow up of VISION to measure real world device performance with appropriate comparators.

#### **VASCULAR RESEARCH COLLABORATIVE (VRC) -**

The BEST-CLI trial has shown the value of a randomized clinical trial (RCT) to generate high quality evidence. A registry-based RCT leverages the preexisting infrastructure of a registry to efficiently collect data and provide real world evidence. 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, could provide annual follow up for 5-10 years. A task force is being organized to explore the feasibility of a registry-based RCT and to encourage further trials.

**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. 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.

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 infrastructure to provide high quality evidence to guide patient care.

### **19. THE SVS VQI AND MEDICAL DEVICE EVALUATION**

Increasing attention is being focused on the safety and effectiveness of medical devices after they have been approved and are in general use. In most cases, devices are approved based on their performance in a narrow cohort of patients treated at centers of excellence according to strict inclusion criteria. In practice, however, a broader group of patients is often treated with an approved device, not always according to the exact instructions for use. For this reason, real-world evidence from registries is increasingly sought by device manufacturers and regulators to evaluate devices.

As an example, the European Union Medical Device Regulation (EU MDR) now requires total life-cycle reporting for CE marked medical devices. The Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) recognizes the importance of supporting manufacturers and regulators, both domestic and international, to evaluate vascular devices currently being used in daily practice. SVS VQI collects much relevant data to provide the real-world evidence needed, including blinded comparison with similar device types.

SVS VQI and Fivos have successfully worked together on a variety of projects to provide registry data to device manufacturers to help meet regulatory requirements, including:

- Embedding post-approval device trials in the registry to allow more rapid recruitment of optimally selected centers with overall lower cost
- Expanding indications for use of current devices using RWD about off-label use in VQI
- Providing propensity-score matched control groups as an accurate comparator for new devices that may be disadvantaged by historical control studies treating less severe disease
- Providing data to meet EU MDR requirements for devices used in Europe
- Providing general data for new device development

One of the challenges of device evaluation is longterm follow-up. SVS VQI has been uniquely successful in recording one-year follow-up, but more extended follow-up is needed. To meet this challenge, the SVS VQI has developed the Vascular Implant Surveillance and Interventional Outcomes Network (VISION). VISION matches Medicare claims data with VQI registry data to allow capture of outcome events that are reported in Medicare patients for 5, 10, or more years after initial treatment. This methodology provides an efficient mechanism to capture key long-term outcomes and is now being used by several device manufacturers to evaluate device performance.

# **20. TECHNOLOGY & REGISTRY DEVELOPMENTS**

### **Upcoming Registry Highlights:**

- Supra-inguinal Bypass Follow-up Outcomes Report
- VQI Interactive Dashboard for Carotid
   Endarterectomy
- Open AAA Major Revision
- PVI minor revision (bailout stent/stent graft)
- CEA Revision (shared decision making)
- Cross Registry Revision (height, race, ethnicity)

### **PATHWAYS** Technology Highlights:

- Collection of delete reason for previously submitted records
- Center Characteristics added Contract Entity
   Name
- PATHWAYS Messages
- Resources moved to Support with additional attributes for searching

### **Registry Highlights:**

### **New Reporting**

- Physician Snapshot Reports Carotid Artery Stent
- Infra-inquinal Bypass Follow-up Outcomes Report
- Missing Aortic Diameter Report (EVAR & TEVAR)
- VQI Interactive Dashboard Carotid Artery Stent

### **Across-Registry Revisions**

- Smoking Cessation
- Retired COVID & Opioid fields
- CAD Harmonization
- Exercise Program Variables (Infra & Supra-inguinal Bypass, PVI, VMC)
- Anticoagulant Harmonization

### **CAS Registry**

Shared Decision Making

#### **Open AAA Repair**

ERAS (Enhance Recovery After Surgery)

### **Minor Revisions**

- Infra/Supra-inguinal Bypass minor revision to update dependencies
- PVI redesigned collection of Mechanical thrombolysis/thrombectomy data, capture reused balloons
- TEVAR Aberrant Anatomy revision

## **21. FUTURE DEVELOPMENTS**

In 2024-2025, the SVS VQI plans to support improved care and promote patient safety in the following areas:

- Interactive Dashboards for all VQI Registries
- Release of Hospital System Reporting
- Enhanced Physician Reporting
- Revisions to Lower Extremity Amputation Registry
- Addition of New Outcome Reporting Measures to all Registries
- Data Automation Integration

# SVS VQ In collaboration with NCDR®

# **APPENDIX**

### APPENDIX A— VQI SITES LISTED IN ALPHABETICAL ORDER (AS OF 5/1/2024)

Abbott Northwestern Hospital (Alina) MN Abington Memorial Hospital PA Abrazo Arrowhead Campus AZ AdventHealth Despital PA AdventHealth Celebration FL AdventHealth Qcala FL AdventHealth Qcala FL AdventHealth Ocala FL AdventHealth Ocala FL AdventHealth Vaterman FL AdventHealth Zephyrhills FL AdventHealth Zephyrhills FL AdventHealth Zephyrhills FL Adventis Healthcare Shady Grove Medical Center MD Adventist Healthcare White Oak Medical Center IL Advocate Good Shamaritan Hospital IL Advocate Good Shepherd Hospital IL Advocate Trinity Hospital IL Advocate Sherman Hospital IL Advocate Trinity Hospital IL Advocate Sherman Hospital IL Ad Ascension Borgess Hospital MI Ascension Columbia St. Mary's Hospital Ozaukee, Inc. WI Ascension Dell Seton Medical Center at the University of Texas TX Ascension Embrook WI Ascension Franklin Hospital WI Ascension Our Lady of Lourdes Memorial NY Ascension Our Lady of Lourdes Memorial NY Ascension Our Lady of Lourdes Memorial NY Ascension Providence Hospital - Rochester MI Ascension Providence Hospital (TX) TX Ascension Providence Hospital (TX) TX Ascension Providence Hospital S, Southfield Campus MI Ascension Providence Hospital S, Southfield Campus MI Ascension Providence Hospital S, Southfield Campus MI Ascension Resurrection Medical Center IL Ascension Sacred Heart Emerald Coast FL Ascension Sacred Heart Hospital Bay FL Ascension Saint Joseph - Elgin IL Ascension Saint Joseph - Elgin IL Ascension Saint Joseph - Elgin IL Ascension Saint Joseph Hospital - Chicago IL Ascension Saint Joseph Hospital - Chicago IL Ascension Saint Joseph Hospital - Joliet IL Ascension Saint Mary - Chicago IL Ascension Saint Thomas Midtown Hospital TN Ascension Saint Thomas Mutherford Hospital TN Ascension Saint Thomas West Hospital TN Ascension Seton Medical Center Austin TX Ascension Seton Medical Center Austin TX Ascension Seton Medical Center Austin TX Ascension St. Agnes Hospital MD Ascension St. Agnes Hospital MD Ascension St. Mary's Hospital MI Ascension St. John Macomb Oakland MI Ascension St. Vincent Hospital MI Ascension St. Vincent Heart Center of Indiana, LLC IN Ascension St. Vincent Heart Center of Indiana, LLC IN Ascension St. Vincent Heart Center of Indiana, LLC IN Ascension St. Vincent Heart Center of Marking KS Ascension St. Vincent S Medical Center - Clay County FL Ascension St. Vincent S Medical Center - Clay County FL Ascension St. Vincent's Medical Center NJ Atrium Health Pineville NC Artium Health Pineville NC Audras Medical Center Kinaki Wichita KS Ashland Hospital Orporation d/b/a UK King's Daughters Me

Bakersfield - Bakersfield Memorial Hospital CA Baltimore Washington Medical Center MD Banner Desert Medical Center AZ Banner Desert Medical Center AZ Banner North Colorado Medical Center CO Banner-University Medical Center Phoenix AZ Banner-University Medical Center Tucson AZ Baptist Health Deaconess Madisonville, Inc. KY Baptist Health Leuisylle KY Baptist Health Leuisylle KY Baptist Health Leuisylle KY Baptist Health Medical Center - Little Rock AR Baptist Health Medical Center - North Little Rock AR Baptist Health Medical Center FL Baptist Health Medical Center FL Baptist Health Medical Center FL Baptist Menorial Hospital TN Barnes Jewish Hospital MO Bartow Regional Medical Center FL Baster Regional Medical Center AR Bayter Regional Medical Center AR Bayter Agional Medical Center TX Baytor All Saints Medical Center TX Baytor All Saints Medical Center TX Baytor All Saints Medical Center TX Baytor Als Anter Medical Center TX Baytor Scott & White Medical Center - Irving TX TX Baylor Scott & White Medical Center - Inving TX Baylor Scott & White Medical Center - Morkinney TX Baylor Scott & White Medical Center - Round Rock TX Baylor Scott & White Medical Center - Round Rock TX Baylor Medical Center NJ Baystate Medical Center NJ Baystate Medical Center NJ Beaufort Memorial Hospital SC Beebe Medical Center WV Berkeley Medical Center MA Bethesd Hospital West FL Bethesd Hospital West FL Bethesd North Hospital OH Billin Memorial Hospital OH Billings Clinic MT Birmingham St. Vincent's East Hospital AL Bismark - CHI St. Alexius Health ND Blake Medical Center FL Boon Secours Maryview Medical Center VA Bon Secours Maryview Medical Center VA Bon Secours St. Francis Medical Center VA Boston Medical Center MA Bridgeport Hospital CT Brigham and Women's Hospital MA Brookton Hospital MA Bronson Battecreek Hospital MI Bronson Methodist Hospital MI Bronson Methodist Hospital MA Brockton Hospital PA California Pacific Medical Center AL Bryan Medical Center NY Butfler Memorial Hospital PA California Pacific Medical Center NA California Pacific Medical Center NA Cape Cod Hospital MA Cape Coral Hospital PA California Pacific Medical Center NJ Capital Health Medical Center NC Caratial Regional Medical Center NC Caratial Medical Center NC Caratia Medical Center NC Caratia Makeman Medical Center NC Caratia Makeman Medical Center NC Caratia Medical Center NC Caratia Makeman Medical Center NC Caratia Makeman Medical

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### APPENDIX A— VQI SITES LISTED IN ALPHABETICAL ORDER (AS OF 5/1/2024)

HCA Florida South Tampa Hospital FL HCA Houston Healthcare Contor TX HCA Houston Healthcare Kingwood TM HCA Houston Healthcare North Cypress TX HCA Houston Healthcare Southeast TX HCA Houston Healthcare West TX Henry Ford Medical Draw Heart Hospital of Austin TX Henry Ford Hospital J Detroit MI MI Henry Ford Hospital J Detroit MI MI Henry Ford Hospital J Detroit MI MI Henry Ford Macomb Hospital MI Henry Ford Macomb Hospital TX Hillicest Hospital South OK Hilo Medical Center HI Hospital South OK Hilo Medical Center NJ Hoondrelath Scottsdale Osborn Medical Center AZ Hoondrelath Scottsdale Osborn Medical Center AZ Hoondrelath Scottsdale Coster IN Houston Methodist Baytown Hospital TX Houston Methodist Clear Lake Hospital TX Houston Methodist Clear Lake Hospital TX Houston Methodist Sugar Land Hospital TX Houston Methodist Sugar Land Hospital TX Houston Methodist Sugar Land Hospital TX Houston Methodist Clear Lake Hospital TX Houston Methodist Sugar Land Hospital TX Houston Methodist Baytown Hospital TX Houston Methodist Center PA Houston Heath Hospital NA Houston Methodist Center PA Houston Heath Hospital NA Houston Heath Hospita

Manatee Memorial Hospital FL Mansfield Hospital OH Margaret R. Pardee Memorial Hospital NC Margaret R. Pardee Nemorial Hospital NC Margaret R. Pardee Nemorial Hospital NC Marshall Medical South AL Marshall Medical Conter IN May O Elinic Florida FL Mayo Clinic Health System - Franciscan Healthcare, Inc. (in La Crosse) WI Mayo Clinic Health System - Franciscan Healthcare, Inc. (in La Crosse) WI Mayo Clinic Hospital - Rochester NN Mayo Clinic Hospital TL McLaren Darchtem Michigan MI McLaren Nather Michigan MI McLaren Nather Michigan MI McLaren Nather Michigan MI McLaren Charther Michigan MI McLaren Charther Michigan MI McLaren Chart Hospital TL Medical City Denton TX Medical City Denton TX Medical City Port Worth X Medical City Denton TX Medical City Port Worth X Memorial Hospital Michigal City City Medical City Port Worth X Memorial Hospital Port Michigal City City Memorial Hospital Port Michigal City Modical City

Morristown-Hamblen Healthcare System TN Morton Plant Hospital FL Morton Plant North Bay Hospital FL Mosaic Life Care MO Mount Auburn Hospital MA Mount Carmel East Hospital OH Mount Carmel Grove City Hospital OH Mount Carmel Grove City Hospital OH Mount Sinai Hodical Center PA Mount Sinai Medical Center FL Mount Sinai Medical Center FL Mount Sinai Mola Center FL Mount Sinai South Nassau Hospital NY MultiCare Deaconess Hospital WA MultiCare Deaconess Hospital WA MultiCare Cood Samaritan Hospital WA MultiCare Cood Samaritan Hospital WA MultiCare Carena General Hospital WA MultiCare Carena General Hospital WA MultiCare Hold Center MI Murray Calloway County Hospital KY MUSC Health Florence Medical Center SC MyMichigan Health - Midland MI Naples Community Hospital FL Nazareth Hospital Hospital AK NEA Baptist Memorial Hospital AK Nebraska Methodist Hospital NE New Hanover Regional Medical Center NJ Newtork-Presbyterian Gucens NY NewYork-Presbyterian Queens NY NewYork-Presbyterian Queens NY New Art Response of the second second

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Piedmont Augusta Hospital GA Piedmont Augusta Hospital GA Pikeville Medical Center KY Pima Vascular AZ PineHurst Surgical NC Pacentia-Linda Hospital CA Portneuf Medical Center ID Portsmouth Regional Hospital NH Presbyterian Hospital NM Presbyterian YSL Luke's Medical Center CO Prescott - Yavapai Regional Medical Center AZ Princeton Baptist Medical Center AL Prisma Health Richland SC Providence Holy Cross Medical Center CA Providence Holy Cross Medical Center CA Providence Medford Medical Center CA Providence Regional Medical Center CA Providence Regional Medical Center CA Providence St. Joseph Medical Center WA Providence St. Joseph Medical Center WA Providence St. Jude Fullerton CA Providence St. Jude Fullerton CA Providence St. Vincent Medical Center OR Radiology Associates-Fox Valley WI Raleigh General Hospital WW Rapides Regional Medical Center LA Redwaod City - Sequia Hospital CA Redwood City - Sequia Hospital CA Redwood City - Sequia Hospital CA Redwood City - Sequia Hospital CA Rediand Sommunity Hospital CA Rediand Sommunity Hospital CA Rediand Hospital RI Riverside Medical Center VA Rex Hospital, Inc. NC Rhode Island Hospital RI Riverside Medical Center IL Riverside Saint Francis Hospital and Medical Center CT Saint Joseph Hospital CO Saint Joseph Regional Medical Center-South Bend Campus IN Saint Joseph's Hospital GA Saint Luke's Episcopal Presbyterian Hospital MO Saint Luke's Episcopal Presbyterian Hospital MO Saint Luke's Memorial Hospital PR Saint Mary's Regional Medical Center NV Salem Health OR 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 Center CA San Luis Obispo - French Hospital Medical Center CA Sanford Clinic Vascular Associates SD Sanford Clinic Vascular Institute NC Santa Cruz - Dominican Hospital CA Santa Cruz - Dominican Hospital CA Santa Cruz - Dominican Hospital CA Sarasota Memorial Hospital - Venice Campus FL Sarasota Memorial Hospital TX Scripps Green Hospital Encinitas CA Scripps Memorial Hospital La Jolla CA Seattle - Virginia Mason Medical Center WA Seattle Vascular Surgery WA Self Regional Health SC Sentara Albemarle Medical Center NC Sentara Albemarle Medical Center NC Sentara Albemarle Medical Center NA Seattle Vascular Surgery WA Self Regional Health SC Sentara Albemarle Medical Center NA Sentara Norfolk General Hospital VA Sentara Norfolk General Hospital VA Sentara Norfolk General Hospital VA Sentara Rim Hospital CA Sentara Careplex Hospital VA Sentara Rim Hospital CA Sentara Williamsburg Regional Medical Center VA Sentara Rim Hospital CA Shanp Meroiral Hospital LA South Miam Hospital LA South Bay Hospital FL South Forida Baptist FL South Forida Baptist FL South Forida Baptist FL South Forida GA Southern Hills Hospital and Medical Center NV Southern Ocean Medical Center NJ Southvide Hospital NY Southwest Healthcare System CA Sparrow Hospital MI Spartanburg Regional SC Spotsylvania Regional Medical Center VA Springfield Memorial Hospital IL

Springfield Regional Medical Center OH Springfield Regional Medical Center OH SMM Health Secto Gamaritan - Mount Vernon IL IL SSM Health St. Apper Hospital - Fonton MO SSM Health St. Joseph Hospital - St. Louis MO SSM Health St. Joseph Hospital - Konfes MO SSM Health St. Joseph Hospital - Konfes MO SSM Health St. Joseph Hospital - Konfes MO SSM St. Anthony Hospital - KL. Icharles MO St. Charles Hospital NY St. Clair Hospital PM St. David's North Austin Medical Center TX St. David's North Austin Medical Center TX St. David's North Austin Medical Center TX St. David's Sourth Austin Medical Center TX St. Francis Hospital Downtown SC St. Francis Hospital Downtown SC St. Francis Hospital Of NH NH St. Joseph Hospital - KL. If St. Joseph Hospital - KL. If St. Joseph Hospital - Allentown Campus PA St. Luke's Hospital - NU MN St. Luke's Hospital - NU MN St. Luke's Hospital - NU MN St. Luke's Hospital - MI MN St. Luke's Hospital MI St. Luke's Hospital - MI MN St. Luke's Hospital -

Turkey Creek Medical Center TN Tyler Regional Hospital TX U of Texis Health System CA UCLA Ronald Reagan Medical Center OH UK Health Ownerial Medical Center OH UK Health Johnston NC United Health Johnston NC United Health Services Hospitals, Inc. NY United Health Johnston NC United Health Services Hospitals, Inc. NY United Hospital (Alina) MN University of Colorado, North Vascular Services CO University of Colorado, North Vascular Services CO University of Hospital And Clinics IA University of Miami Hospital and Clinics IA University of Missour Medical Center (MMC) MN University of Missour Medical Center MN University of Versital And Clinics IA University of Versital AND University of Versit

### 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—PATHWAYS FIVOS CLINICAL PLATFORM

The SVS Vascular Quality Initiative is built on the Fivos PATHWAYS® clinical registry platform. The secure, cloud-based solution allows users—physicians, clinical data managers, researchers, and more—to track, measure, and analyze clinical information, promote collaboration, objectively drive decisions, and optimize performance.

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 modified.

### **About Fivos**

Fivos connects healthcare professionals with real world data, providing the insight necessary to elevate patient care, advance innovation, and achieve regulatory goals. Fivos' solutions include registry development and support for medical societies, along with custom data services for device manufacturers.

Combining decades of industry experience, a thorough understanding of data science, and a large dose of curiosity, Fivos is committed to empowering healthcare organizations to leverage data to create efficiencies, manage costs, and improve outcomes. For more information, visit www. fivoshealth.com.

fivos

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