

2022 ANNUAL REPORT

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

"If you can't measure it, you can't improve it."

This famous business aphorism is attributed to Peter Drucker, management guru, and VQI is all about measuring and improving (vascular care). The mission of VQI is to improve the quality of vascular care by providing clinicians the data and the tools to facilitate guality improvement. In 2019, the Paclitaxel controversy erupted and interrupted our usual clinical algorithms. In 2020, COVID-19 came into our world and didn't go away. VQI data has played a significant role in analyzing, understanding, and treating patients with regards to both the Paclitaxel issue and COVID-19. VQI provided real world evidence that informed clinicians about how their patients could be impacted by Paclitaxel devices^{1,2} and/or COVID-19 illness.^{3,4} In November, 2021, the FDA convened a panel to look at the risk-benefit of Endologix endovascular grafts and the role of real world surveillance⁵. Again, VQI data was highlighted as playing a significant role in device evaluation and providing real world evidence (more details in section Using SVS VQI Data for Collaborative Projects).

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

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 900,000 vascular procedures performed nationwide and in Canada, Puerto Rico and Singapore. Each record includes information from the patient's initial treatment and oneyear follow-up. Over 10,000 new procedures are added monthly. The wealth of data in the registry allows centers and providers to be aware of their performance and comparison to regional and national benchmarks.

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 500 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.

So in response to Peter Drucker, VQI will continue to measure "it", so we can all continue to improve the quality of vascular care.

^{1.} MORTALITY AFTER PACLITAXEL COATED BALLOON ANGIOPLASTY AND STENTING OF SUPERFICIAL FEMORAL AND POPLITEAL ARTERY IN THE VASCULAR QUALITY INITIATIVE. Bertges DJ, Sedrakyan A, Sun T, Eslami MH, Schermerhorn M, Goodney PP, Beck AW, Cronenwett JL, Eldrup-Jorgensen J. Circ Cardiovasc Interv. 2020 Feb;13(2):e008528. doi: 10.1161/ CIRCINTERVENTIONS.119.008528. Epub 2020 Feb 7. PMID: 32069110

^{2.} Vascular Quality Initiative Surveillance of Femoropopliteal Artery Paclitaxel Devices.

Bertges DJ, Eldrup-Jorgensen J, Robbins S, Ssemaganda H, Malone M, Marinac-Dabic D, Smale J, Lottes AE, Majithia A, Resnic FS; Society for Vascular Surgery Vascular Quality Initiative.JACC Cardiovasc Interv. 2021 Dec 13;14(23):2598-2609. doi: 10.1016/j.jcin.2021.08.058

^{3.} The impact of COVID-19 pandemic on vascular registries and clinical trials. Aziz F, Behrendt CA, Sullivan K, Beck AW, Beiles CB, Boyle JR, Mani K, Benson RA, Wohlauer MV, Khashram M, Jorgensen JE, Lemmon GW.Semin Vasc Surg. 2021 Jun;34(2):28-36. doi: 10.1053/j. semvascsurg.2021.04.001. Epub 2021 May 21

^{4.} EFFECTS OF CORONAVIRUS 2019 ON THE SOCIETY FOR VASCULAR SURGERY VASCULAR QUALITY INITIATIVE ARTERIAL PROCEDURE REGISTRY. Natarajan JP, Mahenthiran AK, Bertges DJ, Huffman KM, Eldrup-Jorgensen J, Lemmon GWJ Vasc Surg. 2021 Feb 4:S0741-5214(21)00138-5. doi: 10.1016/j.jvs.2020.12.087

^{5.} https://www.fda.gov/advisory-committees/advisory-committeecalendar/November-2-3-2021-circulatory-system-devices-panelmedical-devices-advisory-committee-meeting

2. INTRODUCTION TO THE SVS VASCULAR QUALITY INITIATIVE

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

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

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

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





VQI Procedure Volume Growth

THE SVS VQI REGISTRIES

As of April 1, 2022, there are 14 SVS VQI registries that contain 936,887 vascular procedures. From May 1, 2021 through April 1, 2022, there were over 105,000 procedures added to the registries.

Total Procedures Captured as of 4/1/2022	936,887	
Peripheral Vascular Intervention	317,955	
Carotid Endarterectomy	172,414	
Infra-Inguinal Bypass	73,346	
Carotid Artery Stent	72,267	
Endovascular AAA Repair	71,506	
Hemodialysis Access	69,705	
Varicose Vein	53,246	
Lower Extremity Amputations	24,459	
Thoracic & Complex EVAR	24,435	
Supra-Inguinal Bypass	23,646	
IVC Filter	17,117	
Open AAA Repair	16,188	
Vascular Medicine Consult	527	
Venous Stent	76	



POTENTIAL BENEFITS OF VQI FOR KEY STAKEHOLDERS

For Patients

• Improve care based on SVS VQI data and quality initiatives

•Use best practices to reduce length of stay

• Improve long-term outcomes through emphasis on follow-up and secondary prevention

For Physicians/Providers

• Adopt best practices through SVS VQI data analysis

• Improve care through quality initiatives and charters

• Monitor performance by comparison with regional and national benchmarks

• Improve patient selection using SVS VQI risk assessment calculators

For Hospitals and Quality Officers

• Improve care by quality initiatives and projects

• Regional and national benchmarks for QA and QI efforts

• Reduce expenses by addressing resource utilization and length of stay

For Policymakers

•Better data to inform decision making on policy development

• Monitor safety and efficacy using real world evidence

• Work collaboratively with the SVS to develop quality measures

For Payers

Adopt best practices to provide better care and reduce complications and expenses
Inform population health approaches through use of comparative data

 Reduce expenses due to decreased length of stay and resource utilization

For Industry

Enhance efficiency for label expansion using registry data

• Utilize registry-based trials for pre-market approval and post-market surveillance

• High quality, large scale, real-world data for evaluation of device performance

3. MYPAD PILOT FOR PATIENT REPORTED OUTCOMES

In April of 2021, the SVS VQI launched My PAD, a pilot program for the collection of patientreported outcomes (PRO) on patients undergoing endovascular treatment for peripheral arterial disease (PAD) in the Peripheral Vascular Intervention (PVI) Registry.



Ten centers that participate in the PVI Registry, volunteered to collect health related quality of life surveys before and after PVI for claudication and chronic limb threatening ischemia (CLTI). Vascu-Qol-6 (VQ-6) and Euro-QoL 5D-5L were collected preoperatively and at 30-days. Multiple workflows for PRO entry including paper forms and webbased entry with email prompts were provided and implemented at the centers' discretion.

Early analysis of preoperative and 30-day PRO demonstrates the feasibility of PRO collection in multiple clinical settings within the VQI PVI registry. Objective assessment of the patient perspective is an important clinical reference. Early postoperative improvement was recorded for patients with claudication and CLTI. Future work will focus on one-year outcomes, improving data capture and expanding PRO collection to additional centers. We are working towards a future in which patient reported outcomes are available at the bedside and become an important part of vascular practice.

The SVS VQI is extending the pilot of the My PAD project to continue to gather information. My PAD will serve as a foundation for future SVS VQI patient-reported outcome programs.

If you are interested in joining our effort please contact PathwaysSupport@fivoshealth.com

4. SVS VQI MEMBERS PROFILE

Participation in SVS VQI continues with steady growth reaching over 900 centers including office-based laboratories by the end of March 2022 (Figure 5.1). There is a broad distribution of different practice types – 28% academic institutions, 30% teaching hospitals and 42% community hospitals (Figure 5.2). There is also broad distribution of physician specialties – less than half vascular surgeons, 16% interventional cardiology, 14% interventional radiology, 6% general surgery, 5% cardiothoracic surgery, 4% neurosurgery, 3% podiatry, 2% orthopedic surgery and 1% Neurology (Figure 5.3).



Source: Fivos PATHWAYS Data, April 2022

Figure 4.1: Growth of SVS VQI Centers (as of April 1, 2022)



Source: Fivos PATHWAYS data, Jan 2022





Source: Fivos PATHWAYS Data, Jan 2022

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. The program began in 2022. This program is open to interested residents and fellows in General Surgery, both tracks of Vascular Surgery programs, Interventional Cardiology and Vascular Medicine.

The Fellowship in Training (FIT) program is designed to introduce residents and fellows in vascular programs to quality improvement through the mechanism of our patient safety organization (VQI/PSO). Using a mentor-directed approach, FIT applicants work closely with their VQI mentor on participation in regional biannual meetings and review of comparative data including center level quality improvement processes. Opportunities include engagement in quality charter development, center level QI process and research initiatives using VQI data reviewed by VQI research advisory committee (RAC). Advancement through the 12-18 month program provides the FIT applicant opportunity to present their work during VQI@VAM with potential selection for a highly coveted Jack L Cronenwett Scholarship (five scholarships to be awarded for up to \$10,000) to continue research and/or work more closely with VQI/PSO staff and committees.

A rigorous selection process was employed to review the many strong applications 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 outstanding group of young physicians committed to vascular care!

Inaugural FIT Trainees

Aarathi Minisandram Mentor: Sarah Deery Maine Medical Center

Ben Li Mentor: Graham Roche-Nagle Toronto General Hospital

Blake Murphy Mentor: Sara Zettervall University of Washington Medical Center

Brianna Krafcik Mentor: Phil Goodney Dartmouth Hitchcock Medical Center

Caronae Howell Mentor: Benjamin Brooke The Univ. of Arizona/University of Utah Hospital & Clinics

> Channa Blakely Mentor: Shihuan K Wang UTMB Health/Memorial

Hermann Texas Medical Center
Christine Kariya

Mentor: Danny Bertges University of Vermont Medical Center

Claire Motyl Mentor: Adam Beck University of Alabama Medical Center

> Hanaa Dakour Aridi Mentor: Michael Murphy IU Health – Methodist

Laura Healy Mentor: Edward Gifford Hartford Hospital University of Connecticut

> Lauren Grimsley Mentor: Eleftherios Xenos UK Healthcare

Leah Gober Mentor: Kyla Bennett University of Wisconsin Hospitals & Clinics Authority

> **Rae Rokosh** Mentor: Karan Garg NYU Langone Health

Razan Elsayed Mentor: Beau Hawkins OU Medical Center

Roberto Loanzon Mentor: Mitchell Cox Duke University Health System

Srihari Kumar Lella Mentor: Nikoloas Zacharias Massachusetts General Hospital

6. DATA QUALITY DASHBOARDS & REGIONAL REPORTS

The SVS PSO Best Practice Dashboards allow centers to review their performance and compare to regional and national benchmarks. The SVS PSO registry committees select outcome measures to be reported in the dashboards, which are distributed quarterly to SVS VQI members. The dashboards provide each center their individual performance, along with results for their region and SVS VQI overall (including the threshold for the 25th and 75th percentile). 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.

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 1]
	Median Total LOS (days)	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]
	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 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 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]
	Unplanned Amputation	0%	0.3%	0.3% [0 0 0 0]
Discharge Medicatio	ons			
	Antiplatelet+Statin	92.9%	92.9%	85.8% [66.8 81.1 89.9 97 100]
Discharge Destination	on			
	Home	96.6%	96.6%	97.8% [93.8 97.1 100 100 100]
	Rehab Unit	1.7%	1%	0.9% [0 0 0 2.3]
	Nursing Home	0%	1.1%	0.7% [0 0 0 2.6]
	Other Hospital	0%	0.1%	0.2% [0 0 0 0]
	Homeless	0.9%	0.2%	0.1% [0 0 0 0]
	Dead	0.9%	1%	0.4% [0 0 0 0 0.5]

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

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 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]
	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]
	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 in 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 collaboration on quality improvement projects.



Figure 7.1: SVS VQI Regional Group Map

During each region's bi-annual meeting, data are reviewed and discussed by the membership. Many groups identify an area for improvement and launch region-wide efforts to improve care. Previous quality improvement projects 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 on projects using SVS VQI data. This process has helped the SVS PSO identify groups working on similar initiatives and facilitate networking opportunities. The SVS PSO provides various resources to assist SVS VQI centers with their QI projects.

Quality Improvement Projects

SVS VQI centers work on quality improvement projects which may be selected for presentation at the VQI Annual Meeting. These projects are often related to the National QI Initiatives, currently Endovascular AAA Longer Term Follow-Up Imaging and Discharge Medication; however, they can address any vascular topic supported by VQI data. The SVS PSO provides resources to assist SVS VQI centers with their QI projects.

Quality Improvement Tools

The SVS PSO, together with FIVOS, develops quality improvement 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 (presentations and videos available for attendees only)
- QI Supplemental Guide (for VQI members only)
- Educational Videos/Audio
- Sample Charters
- Case Studies
- 1:1 Mentoring

Participation Awards

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

Participating centers can earn up to three stars based on the following criteria:

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

SVS VQI centers work on quality improvement charters throughout the year. These projects are often related to the National QI Initiatives, currently Endovascular AAA Longer Term Follow-Up Imaging and Discharge Medication; however, they can address any vascular topic supported by VQI data. The following graphs are a historical review of QI charters 2018-2021 and their topics. *Other represents either a blend of topics (ex: LTFU and Documentation) or a different topic than labeled.



Figure 8.1 – Quality Improvement Projects to Date



Figure 8.2 - Quality Improvement Projects to Date

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

The VQI 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 VQI 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.

De Martino et al (J Vasc Surg), along with a growing body of literature demonstrating similar results, prompted the national VQI quality initiative to increase the appropriate use of statin and antiplatelet agents in vascular patients. Our goal is to have 100% of all eligible patients (i.e. those without contraindications to these medications) discharged on these medications after their vascular procedure. Overall VQI rates for discharge medications have been steadily tracking upward — VQI overall DC medication rate was 86% in 2021.

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 2018 was at 73% and VQI overall LTFU for 2019 was at 71%. We still have room for improvement to reach our goal.



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

Given COVID-19 challenges, a VQI PSO National LTFU Survey was sent to all VQI data managers to determine challenges and barriers for LTFU. The following three graphs depict questions and responses of the survey. Please note that *Other was a free text option that allowed data managers to type in any response that wasn't available. For additional information on the LTFU survey, please contact bwymer@svspso.org.









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



Another excellent avenue of networking and communicating is the VQI Annual Meeting at the Vascular Annual Meeting (VQI@VAM). There are many opportunities to meet other VQI members and participants to discuss areas for improving quality care. The poster networking reception is just one example. Participants can share their QI projects, charters that have become posters, or other quality work from their center. It is an opportunity to learn from others including implementation strategies, challenges, and other ideas.

Figure 9.4 – LTFU Survey Results

Two excellent posters on LTFU were presented at the 2021 VQI@VAM poster session.

The University of Alabama School of Medicine, Birmingham, AL presented 'Implementation of a LIFU Performance Improvement Project for the VQI TEVAR and Complex EVAR Registry'. They were able to improve their LTFU rates from 26% to 69%.

Stanford Health Care Stanford, CA presented **'Sustaining High Performance in LTFU Care'**. They were able to improve their LTFU rates from 69% to 92%.

Experienced SVS VQI centers have applied registry data and implemented innovative approaches to improve success rates for the current national quality initiatives on Use of Discharge Medications and Endovascular AAA Long-term Follow-Up with Imaging. Given the various resources and support provided to you, our members, together, we can reach our goal for each of these initiatives.



Figure 9.5 - The University of Alabama School of Medicine, Birmingham, AL



Figure 9.6 - Stanford Health Care, Stanford, CA

10. SVS VQI DATA ANALYSIS

SVS VQI physicians may request de-identified datasets from each registry that they participate in for analysis. The SVS PSO Research Advisory Council (RAC) reviews, evaluates, and approves requests for datasets by investigators based on their application to the RAC. As of the end of April 2022, the RAC has approved over 900 projects, and of those, 495 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 longterm 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, RAC applications, previously approved projects, and more.

11. SVS CLINICAL PRACTICE GUIDELINES AND THE SVS VQI

SVS VQI data has been used to document compliance with SVS AAA Clinical Practice Guidelines (CPG) and to assess impact on outcomes. VQI data demonstrated that compliance with SVS CPG recommendations was associated with improved outcomes and should be encouraged for providers. Participation in the SVS VQI registries provides an objective assessment of performance and compliance with the SVS guidelines. SVS VQI provider and center reports may be used as a focus for quality improvement efforts (see Figure). Vascular Quality Initiative assessment of compliance with Society for Vascular Surgery CPG on the care of patients with abdominal aortic aneurysm was published in the September 2020 issue of the JVS.¹

During the past year, another analysis has been done on compliance with treatment for extracranial cerebrovascular disease CPG. Compliance with carotid guidelines was found to be associated with a lower risk of inhospital stroke/death emphasizing the value of compliance. However, compliance with the guidelines was again found to be extremely variable highlighting an opportunity for improvement at select centers. VQI continues to plan to collaborate with the SVS Document Oversight Committee to analyze compliance with SVS CPG.

Enhanced Recover After Surgery (ERAS) has gained increased recognition throughout all the surgical specialties and has been embraced by vascular surgeons. In an effort to document and collect data on the impact of ERAS in vascular surgery, VQI has begun to revise our registries to include ERAS focused variables. Compliance with ERAS should improve care, enhance the patient experience and reduce resource utilization.



Figure 11.1 Center Compliance with SVS CPG on Cell Saver use with Open AAA Repair

12. COLLABORATION WITH SOCIETIES

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

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



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.

Effective January 1, 2021, the ACC NCDR Peripheral Vascular Intervention (PVI) registry is now operated by SVS, 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 107 former NCDR PVI sites now participate in VQI. NCDR participants who have not yet joined the SVS VQI, may contact the SVS VQI account team by emailing vqi@fivoshealth.com, or by calling 603-298-6717, to discuss participation.



AMERICAN HEART ASSOCIATION and SOCIETY FOR VASCULAR MEDICINE

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

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



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.



13. 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 Partners



14. IMPROVED STAKEHOLDER COMMUNICATIONS

New and Improved VQI.org

A new VQI.org experience is coming! The new and improved website will have a new look and feel, fresh content, and improved navigation.

Follow Us On LinkedIn

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

SVS VQI Mobile App

The SVS PSO is pursuing the creation of a brand new VQI Mobile App that could be used on your personal device. We hope this will allow us to get information to you more effectively and efficiently. The VQI Mobile App will start out as a communication tool, and hopefully grow from there.

VQI Risk Calculator

The VQI is actively working to update and add more Risk Calculators. We plan to give these valuable resources more prominence on the VQI website in the coming months.

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

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

Post-Approval Surveillance Projects

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

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

TEVAR Post-Approval Surveillance Projects

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

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

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

Transcarotid Artery Revascularization (TCAR) Surveillance Project

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

https://www.accessdata.fda.gov/scripts/cdrh/ cfdocs/cfpma/pma.cfm?id=P140026S016

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

SVS VQI TransCarotid Revascularization Surveillance Project <u>https://clinicaltrials.gov/ct2/show/</u> 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 to review the performance of endovascular aortic stent grafts and real-world evidence.¹ 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 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. Data sources including the SVS VQI registry and Medicare claims were mentioned as potential sources/solutions for data collection. At present, 302 sites participate in the VQI EVAR registry. It would require additional personnel and resources for VQI centers to ensure adequate follow up and data collection annually for 5+ years. 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 302 centers to participate in prolonged post-EVAR data collection.

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. SVS VQI looks forward to working with the FDA and industry partners to ensure that our patients receive the best treatment and the highest quality care.

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

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

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

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 is significant interest in using clinical registries, e.g. VQI, to nest clinical trials. By leveraging the existing infrastructure of case report forms and data collection methodology, there is marked increased efficiency by avoiding starting from a blank slate. In addition, current participation in the registry allows selection of appropriate sites - low and high volume centers, academic and rural, experienced trialists and a diverse patient population (including traditionally UnderRepresented In Medicine). The next think tank will explore specific use cases for peripheral vascular and aortic interventions.

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 accurately identify a device in conjunction with patient level clinical, anatomic and procedural details and correlate it with outcomes. This allows assessment of device performance. Specific device identification has been critically important in analyzing the Paclitaxel controversy and EVAR endograft performance. Unfortunately, the GUDID database is rife with missing and inaccurate data. In addition, if a company changes ownership the device usually remains under the name of original manufacturer and will be hard to identify. VQI has engaged Symmetrics® in an effort to improve the accuracy of device data in GUDID. Symmetrics has standardized device names, amended many inaccuracies in device data and corrected multiple 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-panelmedical-devices-advisory-committee-meeting.

17. 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 of the 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.



18. THE SVS VQI AND COMPLIANCE WITH THE EUMDR

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

One of the most important but most challenging requirements of EU MDR is the active Post-Market Clinical Follow-up required to establish safety and performance during the total lifecycle of a device. Manufacturers must report such data to maintain their CE mark for each device by May 2020. 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."

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/fdacommunication/</u>

19. TECHNOLOGY & REGISTRY DEVELOPMENTS

PATHWAYS Technology Highlights:

Procedure Record Comments - Comments may now be updated on submitted forms without having to revert the forms to incomplete.

Auto-Save before Timeout - PATHWAYS will save incomplete records in progress should PATHWAYS timeout due to inactivity.

Support Tab Enhancements

- Training Schedule Register for upcoming PATHWAYS training webinars!
- Documents Access critical registry documents quickly and easily!
 Code list - List of registry eligible CPT and

ICD-10 codes

- Inclusion/Exclusion Criteria - Describes procedures to be included in each procedure registry as well as follow-up requirements

- Data Dictionary - Complete list of all fields collected in the registry (active and retired) with dependencies and help text - Paper Form - Registry data forms that may be printed and used to manually capture registry data on paper

Data Download - Expanded functionality now provides the ability to filter by different types of date ranges and submission status (incomplete vs. submitted), change the column header format, and generate custom download files limited to selected fields of interest.

Registry Highlights:

New Reporting

- CAS Follow-up Outcomes Report
- EVAR Follow-up Outcomes Report (updated)
- CEA Follow-up Outcomes Report
- PVI Occlusive Disease Follow-up Outcomes
 Report

Across-Registry Revisions

- New Trainee & Other Assistant fields
- Revised Gender to Birth Sex
- Added COVID Vaccine fields

Hemodialysis Access registry

Expanded endovascular data collection

Infra-inguinal Bypass registry

 Opioid data collection fields add to procedure and follow-up forms

Minor Revisions

- Endovascular AAA Repair Access sheath size updates
- Thoracic and Complex EVAR Update dependencies for Entry Flow and Dissection Date/Type, Access sheath size
- Carotid Endarterectomy Stenosis and contralateral events
- Carotid Artery Stent Stenosis and contralateral events
- Vascular Medicine Consult Stenosis and contralateral events
- IVC Filter Update `other' device collection

Upcoming Registry Highlights:

- Major revisions to Infra and Supra-inguinal Bypass registries
- Major revision to Open AAA registry
- Follow-up Outcomes Reports for additional registries

20. FUTURE DEVELOPMENTS

In 2022-2023, the SVS VQI plans to support improved care and promote patient safety in the following areas:

- Infra-Inguinal and Supra-Inguinal registries revisions will be completed in 2022
- Open AAA Registry and Lower Extremity Amputation Registry will be revised in 2022
- Enhanced Long Term follow up reporting capabilities for all registries in 2022
- The VQI has engaged Symmetric Health Solutions to provide additional information to cleanse and augment device data pulled into the VQI, through an integration with the Global Unique Device Identification Database (GUDID)
- As Enhanced Recovery Protocols gain traction in Vascular, the VQI will add variables to track the efficacy of these pathways in several of the VQI modules
- The VQI will begin exploring adding formal Frailty variables to registries in 2022, with a goal of implementation in 2023

APPENDICES

APPENDIX A- VQI SITES LISTED IN ALPHABETICAL ORDER (AS OF

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Bayshore Medical Center NJ Baystate Medical Center MA Beaufort Memorial Hospital SC Beaumont Royal Oak MI Beebe Medical Center DE Beebe Medical Center DE Beilin Memorial Hospital, Inc. WI Berkeley Medical Center WV Berkeley Medical Center WV Berkshire Medical Center MA Beth Israel Deaconess Medical Center MA Beth Israel Medical Center NY Bethesda Hospital Center NY Bethesda Hospital Gast FL Bethesda North Hospital OH Birmingham St. Vincent's East Hospital AL Boca Raton Regional Hospital FL Boon Secours Maryview Medical Center VA Bon Secours Maryview Medical Center VA Bon Secours St. Francis Medical Center VA Bon Secours St. Mary's Hospital VA Boston Medical Center MA Bridgeport Hospital CT Bon Secours St. Francis Medical Center VA Bons Secours St. Mary's Hospital VA Boston Medical Center MA Bridgeport Hospital CT Brigham and Women's Hospital MA Bronson Battlecreek Hospital MI Bronson Methodist Hospital NY Brookwood Baptist Medical Center AL Bryan Medical Center NE BSA Hospital, LLC TX Buffalo General Medical Center NY Buffalo General Medical Center NY Buffalo General Medical Center WV Cape Canaveral Hospital FL Cape Coad Hospital MA Cape Fear Valley Health NC Cape Canaveral Hospital FL Cape Cod Hospital MA Cape Fear Valley Health NC Capital Health Medical Center HU Capital Health Medical Center FL Cardiothoracic and Vascular Surgical Associates FL Cardion New River Valley Medical Center NU Capital Regional Medical Center NC Carlinon Roanoke Memorial Hospital VA Carle BroMenn Medical Center NC Cardiothoracic and Vascular Surgical Associates FL Cardion New River Valley Medical Center NC Carbolic Health Ster of Charty Hospital NY Catholic Health Ster of Charty Hospital NY Catholic Health Mercy Hospital Of Buffalo NY Catholic Health Mercy Hospital Of Buffalo NY Catholic Health Mercy Hospital FL Centrol Medical Center NC Catholic Health Mercy Hospital NY Catholic Medical Center MO CentraCare Health MN Central Florida Regional Medical Center NC Catholic Medical Center MO CentraCare Health MN Central Florida Regional Medical Center WC Catholic Medical Center ME Central Maine Medical Center ME Central Maine Medical Center ME Central Maine Medical Center WC Charleston Area Medical Center K2 Charleston Area Medical Center WC Charleston Area Medical Center K2 Charleston Area Medical Center K4 Chesapeake Regional Medical Center K4 Chesapeake Regional Medical Center K4 Chesapeake Regional Medical Center K4 Chistus St. Michael Hospital FA Chistus St. Michael Hospital TA Christus St. Michael Hospital TA Christus St. Michael Hospital TX Christus St. Michael Hospital TX Christus Christus St. Michael Hospital IX Christus Trinity Mother Frances Hospital TX CHUM QC ClSSSO Outaouais QC Cleveland Clinic Martin North Hospital FL Cleveland Clinic Tradition Hospital FL Cleveland Clinic Tradition Hospital FL Cleveland Clinic Tradition Hospital FL Cleveland Clinic At the tradition Hospital FL Coastal Vascular & Interventional, PLLC FL Coastal Vascular & Interventional, PLLC FL Coastal Vascular & Interventional FL Columbia St. Mary's Hospital Milwaukee, Inc. WI Columbia St. Mary's Hospital Milwaukee, Inc. WI Columbia University Irving Medical Center NY Columbus Regional Hospital IN Community Heapt and Vascular Hospital IN Community Hospital South IN Community Regional Medical Center CA Concer Health NC Cookeville Regional Medical Center TN Coonserve the Intervent U Concora Hospital NH Cone Health NC Cookeville Regional Medical Center TN Cooper University Hospital NJ Coral Gables Hospital FL Corpus Christi Medical Center TX Covenant Health-Grey Nuns Hospital AB Covenant Health-Grey Nuns Hospital AB Covenant Medical Center TX Cox Medical Center South MO Crouse Hospital NY Danbury Hospital CT Dartmouth Hitchcock Medical Center NH Deaconess Midtown Hospital IN Deborah Heart and Lung Center NJ Decatur Memorial Hospital IN Dell Seton Medical Center at the University of Texas TX Delray Medical Center FL Desert Regional Medical Center CA Diagnostic Imaging of Milford CT

DLP Conemaugh Memorial Medical Center, LLC PA DMC Harper University Hospital MI Doctors Hospital at Renaissance TX Doctors Hospital OH Dominican Hospital CA Dominican Hospital CA Doylestown Hospital PA Dr. Ricardo Vasquez, MD IN Duke Raleigh Hospital NC Duke University Medical Center NC East Alabama Medical Center AL East Jefferson General Hospital LA East Tremont Vascular Health Care, PLLC NY Edward Hospital IL Eisenhower Medical Center Montgomery PA Eisenhower Medical Center CA El Camino Health CA Elkhart General Hospital IN Elliot Health System NH Eisenhower Medical Center CA El Camino Health CA Elkhart General Hospital IN Elliot Health System NH Elmbrook Memorial WI Emhurst Memorial Hospital IL Emanate Health Inter-Community Hospital CA Emanate Health Queen of the Valley Hospital CA Emanuel Medical Center OH Evangelical Community Hospital PA Evansville Surgical Associates IN Exeter Hospital NH Fairfield Medical Center OH Fairview Southdale Hospital MN Faith Regional Medical Center OH Fairview Southdale Hospital MN Faith Regional Medical Center OH Flagler Hospital IL Flagtsff Medical Center AZ Flint Hills Heart, Vascular, Vein Clinic, LLC Ks Florida Hospital Zephyrhills FL Florda Hospital Zephyrhills FL Florda Hospital Vascular Services MS Fort Sanders Regional Medical Center TN Fox Valley Surgical Associates Ltd. WI Franciscan Health Indianapolis IN Franklin Hospital WI Fresno Heart & Surgical Hospital CA Froedtert Health WI Galion Hospital OH Geisinger Community Medical Center PA Geisinger Wyoming Valley Medical Center PA Geisinger Medical Center N Genesis Hospital N Genesis Medical Center, Davenport IA Gilvydis Vein Clinic IL Glens Falls Hospital NY Global Neuroscience Institute at Crozer PA Good Samaritan Hospital Medical Center NY Good Samaritan Hospital OH Gosthieb Memorial Hospital IL Grady Memorial Hospital IL Grady Memorial Hospital OH Grady Memorial Hospital OH Grady Memorial Hospital OH Grady Memorial Hospital OH Grady Memorial Center IA Griffin Hospital CT Gulf Coast Medical Center RL Gulf Coast Medical Center FL Guthie Clinic PA Hackensack University Medical Center NJ Halifax Infirmary Robie Street Entrance - QEII NS Harborview Medical Center TX Harison Medical Center TX Harison Medical Center WA Hartingen Medical Center TX Harison Medical Center TX Harison Medical Center TX Harison Healthcare Clear Lake TX HCA Houston Healthcare Conroe TX HCA Houston Healthcare North Cypress IX HCA Houston Healthcare Routheast IX HEA Henric Doctors' Hospital VA Henry Ford Allegiance Health MI Henry Ford Allegiance Health MI Henry Ford Hospital South OK Holmose Regional Medica Center AZ Horizon Vascular Specialists MD Houston Methodist Baytown Hospital TX Houston Methodist Clear Lake Hospital TX

APPENDIX A- VQI SITES LISTED IN ALPHABETICAL ORDER (AS OF 6/1/2021)

Houston Methodist Hospital TX Houston Methodist Sugar Land Hospital TX Houston Methodist The Woodlands Hospital TX Houston Methodist West Hospital TX Houston Methodist Wildowbrook Hospital TX Houston Methodist Willowbrook Hospital T Huntington Hospital CA Inova Alexandria Hospital VA Inova Fair Oaks Hospital VA Inova Fairfax Hospital VA Inova Loudoun Hospital VA Inova Mount Vernon Hospital VA INTEGRIS Baptist Medical Center, Inc. OK Intermountain Medical Center, Inc. OK Intermountain Medical Center UT IU Health - Arnett Hospital IN IU Health - Ball Memorial Hospital IN IU Health - Bloomington Hospital IN IU Health - Methodist IN IU Health - Saxony Hospital IN IU Health - Bloomington Hospital IN IU Health - Methodist IN IU Health - Methodist IN IU Health - Saxony Hospital IN IU Health - West Hospital IN Jackson Memorial Hospital IN Jackson Memorial Hospital FL Jane Phillips Medical Center OK Javon Bea Hospital - Riverside Campus IL Jersey Shore University Medical Center NJ JFK Medical Center NJ Jobst Vascular Institute OH Johns Hopkins Bayview Medical Center MD Johns Hopkins Bayview Medical Center MD Johnston-Willis Hospital VA Kaalec Regional Medical Center TN Johnston-Willis Hospital VA Kaansas Heart Hospital KS Kaweah Delta Medical Center CA Kennedy University Hospital NJ Kennestone Hospital GA Kent Hospital RI Kettering Health Dayton OH Kettering Health Hamilton OH Kettering Health Hamilton OH Kettering Health Hamilton OH Kettering Health ID Lakeland Regional Medical Center FL Lakeview Regional Medical Center LA Lancaster General Hospital PA Lancaster General Hospital PA Lawrence + Memorial Hospital CT Legacy Health OR Lehigh Valley Hospital PA Lenox Hill Hospital NY Lexington Medical Center SC Loma Linda University Medical Center CA Long Island Jewish Medical Center NY Los Angeles County Harbor - UCLA Medical Center CA Los Angeles County Harbor - UCLA Medical Center CA Los Robles Medical Center NM Loyola University Medical Center IL Lutheran Medical Center NM Loyola University Medical Center IL Lutheran Medical Center CO Lyerly Baptist Neurosurgery FL Lynchburg General Hospital VA M Health Fairview Clinic - Woodwinds MN MacNeal Hospital IL Maimonides Medical Center NY Main Line Health's subsidiary - Riddle Hospital PA Main Line Health's subsidiary. Main Line Hospitals, Inc. -Bryn Mawr Hospital PA Maimonides Medical Center NY Main Line Health's subsidiary - Riddle Hospital PA Main Line Health's subsidiary, Main Line Hospitals, Inc. -Bryn Mawr Hospital PA Main Line Health's subsidiary, Main Line Hospitals, Inc. -Lankenau Medical Center PA Maine Mealth's subsidiary, Main Line Hospitals, Inc. - Paoli Hospital PA Maine Mealth's subsidiary, Main Line Hospitals, Inc. - Paoli Hospital PA Maine Mealth's subsidiary, Main Line Hospitals, Inc. - Paoli Hospital PA Maine Mealth's subsidiary, Main Line Hospitals, Inc. - Paoli Hospital OH Marine General Medical Center ME Manafield Hospital OH Marine General Hospital OH Marine General Hospital OH Marishall Medical North AL Marshall Medical South AL Marshall Medical North AL Marshall Medical South AL Mary Clinic Arizona AZ Mayo Clinic Florida FL Mayo Clinic Hospital - Rochester TN Mayo Clinic Hospital - Rochester MN Mayo Clinic Hospital - Rochester MN Mayo Clinic Northwest Wisconsin WI McKay-Dee Hospital UT McKarzie-Willamette Medical Center OR McLaren Bay Region MI McLaren Macomb MI McLaren Northern Michigan MI McLaren Northern Michigan MI McLaren Port Huron MI McLaren City Delita TX Medical City Delita TX Medical City Port Worth TX Medical City Port Worth

Medstar Good Samaritan Hospital MD Medstar Harbor Hospital MD Medstar Montgomery Medical Center MD Medstar Southern Maryland Hospital Center MD Medstar Union Memorial Hospital MD Medstar Union Memorial Center DC Memorial Heatth University Medical Center GA Memorial Hermann Katy Hospital TX Memorial Hermann Memorial City Medical Center TX Memorial Hermann Northeast Hospital TX Memorial Hermann Southeast Hospital TX Memorial Hermann Sugar Land TX Memorial Hermann Texas Medical Center TX Memorial Hermann Texas Medical Center TX Memorial Hospital at Gulfport MS Memorial Hospital Belleville IL Memorial Hospital Jacksonville FL Memorial Hospital Jacksonville FL Memorial Hospital Jacksonville FL Memorial Hospital Jacksonville FL Memorial Hospital Central CO Memorial Hospital Central CO Memorial Hospital of Carbondale IL Memorial Hospital of Carbondale IL Memorial Hospital of Carbondale IL Memorial Hospital of South Bend IN Memorial Hospital Of South Bend IN Memorial Hospital Pembroke FL Memorial Hospital Vest FL Memorial Regional Hospital FL Memorial Regional Hospital FL Memorial Care Long Beach Medical Center CA Memorialcare Corange Coast Medical Center CA Memorialcare Corange Coast Medical Center CA Memorial Center KS Mercy Health - Anderson Hospital OH Mercy Health - Anderson Hospital OH Mercy Health - St. Elizabeth Youngstown Hospital OH Mercy Health - St. Elizabeth Youngstown Hospital OH Mercy Health - St. Elizabeth Youngstown Hospital OH Mercy Health - St. Elizabeth Mongstown Hospital OH Mercy Health Spingfield MO Mercy Hospital Springfield MO Mercy Medical Center - Oshkosh WI Mercy Medical Center A MercyOne Des Moines Medical Center IA MercyOne Des Moines Medical Center IA MercyOne Siouxland Medical Center IA Merty Medical Center MD MercyOne Des Moines Medical Center IA MercyOne Siouxland Medical Center IA Meritus Medical Center MD Methodist Dallas Medical Center TX Methodist Germantown Hospital TN Methodist Richardson Medical Center TX Methodist Richardson Medical Center TX Methodist University Hospital TN MetroHealth Medical Center OH Miami Vein Center FL Michigan Vascular Center MI Middlesex Hospital CT MidHudson Regional Hospital NY Midland Memorial Hospital NY Midland Memorial Center CT Midwest Aortic & Vascular Institute, P.C. MO Midwest Aortic & Vascular Institute, P.C. MO Midwest Institute Minimally Invasive Therapies IL Mission Hospital NC Middia Medical Center Cf Middeat Aortic & Vascular Institute, P.C. MO Midwest Institute Minimally Invasive Therapies IL Mission Hospital NC Mission Hospital MC Mission Hospital Magina Center MS Mongalia County General Hospital Company d/b/a Media Medical Center WV Mone Medical Center WV Mone Medical Center WI Mone Medical Center MY Mone Medical Center MS Mone Carmel East Hospital OH Mone Carmel East Hospital OH Mone Carmel East Hospital MA Mone Carme Medical Center RI MidGrae Deaconess Hospital MA MidGrae Deaconess Hospital MA MidGrae Good Samaritan Hospital MA MidGrae Good Samaritan Hospital MA MidGrae Good Samaritan Hospital MA MidGrae Medical Center MI MidGrae Medical Center MS MidGrae Medical Center MS MidGrae Medical Center MI MidGrae Medical Cent

Northwestern Medicine Central DuPage Hospital IL Northwestern Medicine Lake Forest Hospital IL Northwestern Memorial Hospital IL Norton-Brownsboro Hospital KY Norton-Brownsboro Hospital KY Norton-Downtown KY Norwalk Hospital CT Novant Heatth Forsyth Medical Center NC Novant Heatth Matthews Medical Center NC Novant Heatth Presbyterian Medical Center NC NVU Langone Medical Center NY NYU Winthrop Hospital NY Ocala Regional Medical Center FL Ocean Medical Center KJ Ocala Regional Medical Center UT Oklahoma Heart Hospital South, LLC OK Oklahoma Heart Hospital, LLC OK Oklahoma Heart Institute at Hillcrest Medical Center OK Oklahoma Hearr Institute at Hillcrest iviedical Ce OK Orange Regional Medical Center NY Oregon Health & Science University OR Orando Health, Inc. Dr. P. Phillips Hospital FL Orlando Health, Inc. Health Central Hospital FL Orlando Health, Inc. Orlando Regional Medical Contar El Oregon Vascular Specialists, LLC OR Ordando Health, Inc. Dr. P. Phillips Hospital FL Ordando Health, Inc. Chando Regional Medical Center FL Ordando Health, Inc. South Lake Hospital FL Ordando Health, Inc. South Seminole Hospital FL OSF Saint Francis Medical Center IL OV Medical Center OK Our Lady of Lourdes Heart Hospital LA Our Lady of Lourdes Memorial NV Our Lady of Lourdes Medical Center IL Overlack Medical Center NJ Owensboro Health Regional Medical Center LA Overlack Medical Center NJ Owensboro Health Regional Hospital KY Palm Beach Gardens Medical Center IN Parkwew Regional Medical Center IN Parkwew Medical Center CO Parkview Statis Medical Center PA Penn State Health Niton S. Hershey Medical Center PA Penn State Health Niton S. Hershey Medical Center PA Penn State Health Niton S. Hershey Medical Center PA Penn State Health Niton S. Hershey Medical Center PA Penn State Health Niton S. Hershey Medical Center PA Penn State Health Niton S. Hershey Medical Center PA Penn State Health Niton S. Hershey Medical Center PA Penn State Health Niton S. Hershey Medical Center PA Penn State Health Niton S. Hershey Medical Center PA Penn State Health Niton S. Hershey Medical Center PA Penn State Health Niton S. Hershey Medical Center PA Pennsylvania Hospital PA Peripheral Vascular Az Piedmont Athens Regional Medical Center CA Providence Actific Medical Center CA Providence Medical Center CA Providence Hospital NM Presbyterian Medical Center CA Providence Sacred Head Medical Center CA Providence Sacred Head Medical Center CA Providence Sacred Head Medical Center CA Providence St. Vincent Medical Center CA Providence St. Vincent Medical Center CA Providence St. Nice Medical Cen

APPENDIX A- VQI SITES LISTED IN ALPHABETICAL ORDER (AS OF 6/1/2021)

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 Joseph Hospital CO Saint Joseph Regional Medical Center-South Bend Campus IN Saint Joseph's Hospital GA 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 Memorial Hospital PR Saint Mary's Regional Medical Center NV Salem Heatth OR San Antonio Vascular and Endovascular Clinic TX San Diego Vascular Center CA Sanford Bemidij Medical Center MN Sanford Clinic Vascular Center CA Sanford Bemidij Medical Center MN Sanford Clinic Vascular Associates SD Sanford Medical Center Fargo ND Sanger Heart and Vascular Institute NC Santa Rosa Memorial CA Sarasota Memorial Hospital - Venice Campus FL Sarasota Memorial Hospital - Venice Campus FL Sarasota Memorial Hospital FL Scott & White Memorial Hospital TX Scripps Memorial Hospital Encinitas CA Seripps Memorial Hospital Encinitas CA Seripps Memorial Hospital Encinitas CA Seripps Memorial Hospital CA Seripts Memorial Hospital IX Seripts Memorial Hospital VA Sentara Norfolk General Hospital VA Sentara Virginia Beach General Hospital VA Sentara Sulti Medical Center VA Sequoia Hospital CA Sharp Memorial Hospital CA Sharp Memorial Hospital CA Sharp Memorial Hospital CA Sharp Memorial Hospital NA Sidell Mem St. Clair Hospital PA
St. Clair Hospital PA
St. Dominic's Memorial Hospital and Medical . ates MS
St. Elizabeth Medical Center MA
St. Elizabeth's Medical Center MI
St. Francis Hospital - Milwaukee WI
St. Francis Medical Center-WA WA
St. George Regional Hospital UT
St. John's Heath Center CA
John's Hospital NI
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St. John's Regional Medical Center CA
John's Regional Medical Center CA
Joseph Hospital (Eureka) CA
St. Joseph Hospital (Eureka) CA
St. Joseph Medical Center MO
St. Joseph Stapital and Medical Center AZ
St. Joseph's Hospital North FL
St. Joseph's Hospital South FL
St. Joseph's Medical Center of Stockton CA
St. Joseph's Medical Center MO
Joseph's Medical Center of Stockton CA
St. Joseph's Medical Center of Stockton CA
St. Joseph's Medical Center WA
St. Joseph's Hospital North FL
St. Joseph's Medical Center of Stockton CA
St. Joseph's Hospital All Morth PL
St. Joseph's Medical Center MO
St. Joseph's Medical Center of Stockton CA
St. Joseph's Medical Center WA
Luke's Campus NY
St. Luke's Hospital - Allentown Campus PA
St. Luke's Hospital - Allentown Campus PA

St. Luke's Hospital - Bethlehem Campus PA St. Luke's Hospital - MIN MN St. Luke's Hospital - Wonroe Campus PA St. Luke's Hospital - Wonroe Campus NJ St. Luke's Hospital - Waren Campus NJ St. Luke's Hospital Waren Campus NJ St. Luke's Methodist Hospital Center NV St. Mary Corwin Medical Center CO St. Mary Medical Center (CA) CA St. Mary Science Campus NJ St. Luke's Methodist Hospital Center NV St. Mary Corwin Medical Center CO St. Mary Medical Center PA St. Mary Science Campus NJ St. Mary Medical Center (CA) CA St. Mary Medical Center (CA) CA St. Mary's Hospital - XZ AZ St. Mary's Hospital - Waterbury CT St. Mary's Hospital - Waterbury CT St. Mary's Hospital - Waterbury CT St. Mary's Hospital NJ St. Vincent Anderson IN St. Vincent Anderson IN St. Vincent HeadthCare MT St. Vincent Hospital of the Hospital Sisters of the Third Order of St. Francis W St. Vincent's Medical Center Cay County FL St. Vincent's Medical Center CA Stafen Island University Hospital - North Site NY Steward Good Samaritan Medical Center, Inc. MA Steward Good Samaritan Medical Center, NA Steward St. Anne's Hospital - North Site NY Steward Good Samaritan Medical Center NY Strauford Health Care CA Stafen Island University Hospital - North Site NY Steward Good Samaritan Medical Center NY Straub Medical Center HI Suburban Hospital IM Steward St. Anne's Hospital - North Site NY Steward Groud Samaritan Medical Center NY Straub Medical Center HI Suburban Hospital IM Steward St. Anne's Hospital I Corporation MA Steward St. Anne's Hospital I Allohassee Memorial HealthCare, Inc FL Impedent Postorent HI Suburban Hospital IM Straub Medical Center HI Suburban Hospital IM Berebanne General Medical Center NY Straub Medical Center HI Suburban Hospital IM Berebanne General Medical Center NT Terebanne General Medical Center NT Ine keading Hospital and Medical Center PA The University of California Irvine CA The University of Southern California on behalf of its Keck Medicine of USC CA The University of Texas Southwestern Medical Center -Cerebrovascular Group TX The University of Texas Southwestern Medical Center TX The University of Texas Southwestern Medical Center TX The Valuey Hospital NJ The Vascular Care Group MA The Vein and Vascular Institute of Tampa Bay FL Thomas Jefferson University Hospital PA Thunder Bay Regional Health Science Center ON Tidallealth Guerrieri Heart and Vascular Institute MD Tif Regional Medical Center GA Toronto General Hospital ON Toronto General Hospital ON Toronto General Medical Center TN Tifstar Summit Medical Center TN Tifstar Summit Medical Center TN Turkey Creek Medical Center TN Typer Regional Hospital TX U of Texas Health Science Center, San Antonio TX UC Davis Health Science Center CA ULAR Ronald Regan Medical Center CA ULAR Ronald Regan Medical Center CA ULAR Ronald Regan Medical Center CA ULAR String Medical Center OH UH St. John Medical Center OH UH Haith Care KY UMass Memorial Medical Center, Inc. MA United Hospital (Allino) MN United Hospital (Allino) MN United Hospital (Allino) MN UnityPoint Health - Meriter Hospital Wi

UnityPoint Health Des Moines IA University Hospital NY University Hospitals Ahuja Medical Center OH University Hospitals Cleveland Medical Center OH University of Alabama Medical Center AL University of Arkansas for Medical Center AZ University of Arkansas for Medical Center AZ University of Chicago Medical Center IL University of Colorado, Denver CO University of Colorado, Denver CO University of Colorado, North Vascular Services CO University of Colorado, North Vascular Services CO University of Colorado, North Vascular Services CO University of Florida, Gainesville FL University of Kansas Hospitals and Clinics IA University of Maryland Medical Center MD University of Maryland Medical Center MD University of Minnesota Medical Center MS University of Minnesota Medical Center MS University of Missouri Medical Center MS University of Mesyata Medical Center MS University of Meson Medical NC University of Meson Medical Center MO University of Meson Medical Center MO University of Meson Medical Center MS University of Meson Medical NC University of Oklahoma School of Community Medi-cine OK University of Pennsylvania PA cine OK University of Pennsylvania PA University of Rochester Medical Center NY University of Tennessee Medical Center NY University of Utah Hospital and Clinics UT University of Vermont Medical Center VT University of Viginia Health System VA University of Viginia 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 Wisconsin Hospitals and Clinics Authority WI cine OK University of Wisconsin Hospitals and Clinics Aut Wi University Surgical Associates TN UofL Health - Jewish Hospital KY UofL Health - Mary & Elizabeth Hospital KY UofL Health - Mary & Elizabeth Hospital KY UofL Health - University of Louisville Hospital KY UPMC Altoona PA UPMC Pinnacle Hanover PA UPMC Pinnacle Hamover PA UPMC Pinnacle Hamover PA UPMC Pinnacle Hamover PA UPMC Pinnacle Hamover PA UPMC Visital PA UPMC Visital PA UPMC Western Maryland MD UPMC Williamsport PA UPMC/Hamot Hospital VT Valley Asscular Surgery PA Utah Valley Hospital UT Valley Vascular Consultants, P.C. AL Vanderbilt University Medical Center TX Vascular Institute of Michigan MI Vascular Surgery Associates FL Vence Yalley Medical Center NY VCU Health System Authority VA Venice Regional Bayfront Hospital FL Verde Valley Medical Center AZ VHS of Arrowhead, Inc. d/b/a Abrazo Arizona H Hospital AZ Verde Valley Medical Center AZ VHS of Arrowhead, Inc. d/b/a Abrazo Arizona Heart Hospital AZ Via Christi Hospital Pittsburg KS Vidant Medical Center NC Virginia Mason WA VVAS - Varicose Vein and Aesthetic Solutions AZ Wadley Regional Medical Center TX Wadke Forest University Baptist Health Medical Center NC Wake Forest University Baptist Health Medical Center NC WakeMed Health & Hospitals-Cary Campus NC WakeMed Health & Hospitals-Raleigh Campus NC Washington Regional Medical Center AR Waukesha Memorial Hospital WI Wayne UNC Healthcare NC Weill Cornell University Medical Center NY WeilSpan Surgery Center PA WeilSpan Surgery Center PA West Jefferson Medical Center LA West Medical Center OH West Medical Center OH West Verginia University Hospital WV Westchester Medical Center NY Westchester Medical Center NY Withe Plains Hospital NA Wexner Medical Center OH White Plains Hospital NY White Square Vascular Surgery MD Williamson Medical Center NA Williamson Medical Center VA Winchester Medical Center VA Winter Haven Hospital FL Yale New Haven Hospital CT Yavapai Regional Medical Center AZ Yuma Regional Medical Center AZ

APPENDIX B— SOCIETY FOR VASCULAR SOCIETY PATIENT SAFETY ORGANIZATION (SVS PSO)

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

VQI SUPPORTING SOCIETIES

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

*Members of SVS PSO Governing Council

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

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

PATHWAYS is a secure, cloud-based solution that enables physicians, institutions, clinical data managers, and researchers to collect, manage, analyze, and disseminate their clinical data to achieve optimal outcomes. Accessible by any computer with a compatible browser, PATHWAYS is designed to easily integrate into a variety of workflows by allowing multiple users to access and enter data on a single procedure form, and to spread the responsibilities of data entry to more than one individual. Authentication identifies users' roles and permissions to ensure appropriate access to content within PATHWAYS. Real-time data validation through error-trapping and alerts 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 was formed in 2021 by the planned combination of two highly complementary businesses, Medstreaming and M2S. Fivos offers specialty-based workflow reporting applications for providers, registry solutions and support for medical societies, and custom data sets for device manufacturers that advance innovation.

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



SVS PSO